ECDEU MANUAL

ON DOCUMENTATION AND ASSESSMENT PROCEDURES

FOR

CLINICAL TRIALS IN NEUROPSYCHOPHARMACOLOGY

Second Revision

1983

Edited by

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DEVELOPED FROM:

W. Guy: ECDEU Assessment Manual for Psychopharmacology. Revised. 1976. U.S. Department of Health, Education and Welfare. DHEW Publication No. (ADM) 76-338, printed 1976.

W. Guy and R.R. Bonato: Manual for the ECDEU Assessment Battery. National Institute of Mental Health, DHEW, July 1970.

ACKNOWLEDGEMENTS

This revision of the ECDEU Manual represents the cooperative effort of many individuals whose comments and criticism have served to sustain the NCDEU (formerly ECDEU) program as an evolving entity. The elements of the NCDEU Assessment Battery have modified, expanded and transformed over the period of the last 13 years as a consequence of the interaction among those investigators employing the Battery in clinical drug trials, the pharmaceutical industry, drug regulatory agencies, the Pharmacologic and Somatic Treatment Branch of the National Institute of Mental Health of the United State and the Center for Clinical Psychopharmacology Documentation of the Psychiatric Clinic II of the University of Pisa, in Pisa, Italy (Professor Giovanni Cassano). The size of tis group makes it difficult to acknowledge every individual by name, therefore appreciation for their contributions are extended collectively, but no less warmly.

The emergence of the Present Assessment Battery has been accompanied by the transformation of the data processing system, called the Biometric Laboratory Information Processing System (BLIPS), into the BLIPS/BDP System (in which BDP stands for Data Bank for Psychopharmacology in Italian).

To the entre staff of the Center for Clinical Psychopharmacology Documentation, developers of the BLIPS/BDP System, I wish to extend special thanks for their continuous effort in improving the system.

In the preparation of the material I have used freely material from the following sources:

Guy,W. and Bonato, D.D.: Manual for the ECDEU Assessment Battery. National Institute of Mental Health. DHEW, July 1970.

Guy, W.: ECDEU Assessment Manual for Psychopharmacology. Revised. 1974. U.S. Department of Health and Welfare. DHEW Publication No. (ADM) 76-338, printed 1976.

McGlashan, T. The Documentation of Clinical Psychotropic Drug Trials. National Institute of Mental Health. DHEW Publication No. (HSM) 73-9038, printed 1973.

Last, but not least, I am grateful to the authors of the numerous assessment instruments described in this volume. It is their contribution which has made this manual possible.

Without Jerome Levine's encouragement this second revision of the Manual for the ECDEU Assessment Battery would not have been completed. .

C O N T E N T S

P A R T O N E

INTRODUCTION : HISTORICAL DEVELOPMENT

Psychopharmacotherapy began with the serendipitous discovery of the antipsychotic properties of chlorpromazine in the early 1950's. In subsequent years, a very large number of drugs with psychotropic properties have been synthesized. By the early 1980's, psychopharmacotherapy, with the use of antipsychotic, antidepressant and antianxiety substances, became the prevailing treatment modality in the majority of psychiatric disorders.

In spite of the successful course of events, within a relatively short period of 30 years, progress in psychopharmacotherapy has encountered great difficulties. One of the major sources of these difficulties was in the reluctance of psychiatrists to accept the introduction of new drugs.

Recognizing potentially that psychopharmacotherapy could provide care to psychiatric patients on a large scale, the Psychopharmacology Service Center (PSC) was created by the National Institute of Mental Health (NIMH) of the United States. It was the PSC, directed by Dr. Jonathan Cole, which, during the first period of its existence, developed the necessary machinery, in the form of Early Clinical Drug Evaluation Units (ECDEU), to render the new drugs acceptable for clinical use.

ECDEU investigators, in close collaboration with industry and academia, and with the assistance of the Psychopharmacology Research Branch (PRB), which, under the leadership of Jerome Levine, replaced the PSC in due course, created the necessary methodology for the clinical development and evaluation of psychotropic drugs. This methodology, which was developed during the second period, after the establishment of the Biometric Laboratory Information Processing System (BLIPS), was first tested by a limited number of ECDEU investigators. Subsequently, during the third period, it was verified on a national scale, with the participation of a large number of investigators.

After accomplishing its task, the PRB was replaced by the Pharmacologic and Somatic Treatment Research Branch; the ECDEU network by the NCDEU, New Clinical Drug Evaluation Units, a group of loosely connected investigators; and the

ECDEU/BLIPS system by the BLIPS/BDP system. The merging of the American BLIPS with the Italian BDP, primarily aimed as a Data Bank for Psychopharmacology, and transferring the laboratory from Washington to Pisa, heralded the beginning of the fourth period. Characteristic of the fourth period is the shift in emphasis from the concept of an assessment battery to the concept of systematic documentation; and the supplementation of the evaluation of drug effects with the evaluation of the quality of the clinical trial. Probably even more important are the gradual replacement of single center clinical trials by multi-centre or even multi-national clinical investigations; and the utilization of the data bank, beyond the conventional function of storage and memory, as an integral part of research that can provide the necessary data for comparisons and historical control. As a result of these changes, the necessary information about a psychotropic drug should be attainable with a considerably lower number of experimental subjects than before, while the information should be applicable to the use of the drug in all the countries of the world.

In the following, some of the details of this historical development are given :

> This new Manual on Documentation and Assessment Procedures for Clinical Trials in Psychopharmacology was prepared to replace the Revised ECDEU Assessment Manual. The title reflects the shift in emphasis from assessment procedures to comprehensive documentation.
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> The origin of the Manual rests with the history and evolution of Early Clinical Drug Evaluation program, usually referred to as ECDEU and the Biometric Laboratory Information Processing System (BLIPS). They were the results of the discovery of chlorpromazine in 1951 and the subsequent development of a new discipline within psychiatry, which has become known as psychopharmacology. Progress in psychopharmacology introduced a great number of new psychoactive drugs and precipitated a vast amount of investigation in the use of new and old chemicals for psychiatric populations. During the 1950's this field of investigation and research mushroomed. Many of the drugs discovered earlier in the decade proved to be consistently efficacious, and new compounds were being developed that had potential utility.
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> In the midst of increasing investment of research time and energy in psychopharmacology, problems inevitably developed. Many of these were scientific in nature. For example, drug-related efficacy had to be differentiated from other, often powerful, non-specific therapeutic

effects. This led to the development of placebo assessment. Investigators discovered that attitude, setting, and other variables could influence results. Thus, the double-blind study was engineered to buffer investigational bias. Questions arose as to what constituted a valid and reliable measure of change, leading to the development of scales which were sensitive and which could be used in a standard way. Because of these and other more practical problems, investigators began searching for new methods of measurement and documentation which would assist them to test their hypotheses with clarity, validity and reliability.

First Period

To help investigators deal with some of these difficulties, the Psychopharmacology Service Center (PSC) (part of the National Institute of Mental Health, United States) was created in 1956. Its stated purposes at the time were to support clinical and preclinical research, act as an information and communications center, and extend technical consultation to people in the field. Though highly effective in ameliorating some of the problems involved in psychopharmacologic research, there was an increasing feeling at the PSC and in the pharmaceutical industry that clinical trials of new drugs needed federal support. Very few potentially useful compounds were reaching the market; and there was concern that drugs were being overlooked or screened out because of poor methodology. As the director, Dr. J. Cole, stated : "A great majority of the clinical research on new psychiatric drugs has been carried out by investigators at public mental hospitals receiving small amounts of support from the pharmaceutical industry... This work in general has not been extensive and has resulted in most drugs being released by the United States Food and Drug Administration (FDA) for general clinical use with only a small number of uncontrolled studies of variable quality being available in print. The absence of well organized and well supported units carrying out early clinical drug studies may have contributed to the slowness with which really new and different drugs have been developed in recent years."

These concerns resulted in the development of a system for subsidizing early clinical trials. The focus was on drugs not yet approved by the FDA, but for which there existed some evidence of clinical efficacy and safety through prior, more basic research. The program involved government funding of research units around the country to do Phase II and Phase III clinical trials of new compounds. These units were not regulatory in any sense and had essentially two functions : 1) service, i.e., to investigate new drugs; and 2) methodology advance, i.e., to devise improved and more efficient ways of evaluating psychoactive agents. Federal research grants were given on a five-year renewal basis with considerable latitude afforded to the investigator as to the use of his funds and the compounds he wished to investigate.

Within one year of the announcement (1960), there were 12 investigational units which had begun functioning. By the second annual meeting of investigational units in January of 1962, there were 15 units. In total, they were investigating 48 new compounds. By 1963 the program had become fairly well consolidated. Investigators were actively engaged in research, methodologic refinement, and mutual communication with one another concerning problems, difficulties and results. In addition, at the inception of the ECDEU program, Dr. Jonathan Cole introduced the Biometric Laboratory of George Washington University to consult with the units on data handling and statistical analysis. The Laboratory had a particular interest in the use of standard and sensitive rating scales.

Second Period

During the mid-1960's, there was a growing interest in the methodology of clinical research. It started with an increasing concern and frustration with the heterogeneity of descriptions of clinical phenomena; and culminated in systematic efforts to develop sensitive and uniform assessment devices to measure clinical changes. As an outgrowth of this, the ECDEU Standard Reporting System evolved. The rationale behind this effort was two-fold : first, it was felt that such a system would enhance both quality of drug research and allow greater generalizability of results across studies and investigating units. Second, data collected on common forms could be stored in a data bank for future study and research.

The ECDEU Standard Reporting System consisted of a standard package of rating scales and forms which were used by ECDEU investigators in their clinical trials where appropriate. In addition, descriptive and inferential statistical analyses of data obtained from these scales were performed by the Biometric Laboratory. This data processing operation was a service to investigators and a method for accumulating data from the investigations.

By 1967 the system had achieved a fair degree of sophistication. Rating scales were put into optical scan format so they could be processed much easier and faster in the computer. The analysis was produced in a standard format known as the Output Package, and contained such descriptive statistics as data arrangements, frequency distributions, cross tabulations, factor scores, and means and standard deviations. Inferential analyses such as analysis of variance and covariance were routinely performed.

Third Period

In 1968 the scales of the Standard Reporting System became available also to others than ECDEU investigators. The Biometric Laboratory opened its doors to provide data analysis for investigators who were willing to :

1) submit a Research Plan Report and agree to send the study data to the Biometric Laboratory;

2) collect sufficient information about the subjects in his study so that the data can be entered into the ECDEU data bank. This means, essentially, that a core of data must be collected for each patient. Such a core of data includes :

   a) demographic information, e.g., the Adult Personal Data Inventory,

   b) at least one major rating scale of efficacy or psychopathology, e.g. the Brief Psychiatric Rating Scale,

   c) information on dosage and toxicity, e.g., the Dosage Record and Treatment Emergent Symptom Scale.

In return, investigators received a sufficient number of assessment scales to conduct their research. Once the trial was completed, the forms were returned to the Biometric Laboratory for processing and data analyses. Results of the analysis were sent to the investigator in the form of a standard data package. The rating scales and data processing services were provided at no charge. It should be stressed that an investigator's data and/or results were never published or disseminated to others without his permission.

To facilitate participation and improve the quality of research, the first ECDEU Assessment Manual was prepared by Drs. W. Guy and R.R. Bonato and published in 1970. It was followed by a Workbook on the Documentation of Clinical Psychotropic Drug Trials, prepared by Dr. T. McGlashan in 1973.

ECDEU Assessment Manual

The first ECDEU Assessment Manual delineated the various assessment forms and scales contained in the ECDEU Standard Reporting System. It was revised in 1976. The need for the revision was created by the changes in the System during a decade. These were to the effect that the adult elements of the Battery had been modified and expanded over the period, and a new pediatric section was created as a culmination of several years of effort. The most prominent feature of the new Battery, or revised Manual (expansion aside) was the redesigned format of the scales. In the original Battery, the scales were self-contained with both items and their response positions preprinted on the form. While this format provided maximal rater legibility, the amount of data retrievable per page was low; and, since it was necessary to record identifying information on each page, the rater was faced with a great deal of redundant encoding. To offset these problems, items and response positions were separated. A universal answer sheet called the General Scoring Sheet was designed to serve as a means of encoding not only responses to the scales included in the Battery, but any type of data which an investigator might wish to encode.

Coupled with the General Scoring Sheet, five packets were developed :

1) Demographic - containing 3 instruments for both pediatric and adult populations.

2) Pediatric - containing 6 instruments for rating psychopathology, diagnosis, adverse reactions and termination status.

3) Adult - containing 9 instruments (3 of which were also contained in the pediatric packet) for adult populations.

4) Nurse - containing 4 pediatric and adult behavior scales for rating by ward or paraprofessional personnel.

5) Psychologist - containing 9 pediatric and adult psychometric scales.

In addition to the 28 scales contained within 5 packets, there were 15 independent instruments classified by applicability, format, content and rater. Applicability referred to the populations for which a scale was appropriate. Format indicated whether a scale was designed for opscan or not and whether it was contained within a packet or was independent. The content areas were : demographic, efficacy, toxicity, medical, psychometric and administrative. Finally, the rater was designated. Fourteen of the 43 instruments were "universal" - reflecting the integration and compatibility of the Battery across diverse research populations.

The various instruments in the ECDEU Assessment Battery were employed in the following sequence during the three major phases of a research study, i.e., planning, data collection and analyses :

1) Planning Phase - Having developed an hypothesis and a research design to test, the investigator had to decide whether he would utilize the assessment instruments and services of the ECDEU program. Generally, the investigator had to prepare his own protocol from which he could extract information required on the Research Plan Report (RPR).

   The RPR served to notify the Biometric Laboratory and Psychopharmacology Research Branch that a study was contemplated and that it was expected to take a certain length of time for completion. Along with its intrinsic value as a description of ongoing research, the RPR served to alert the Laboratory to its future work load and, upon receipt of the data, to the nature of the study and the procedures employed. Along with the RPR, an ECDEU Order Form requesting the quantities of forms necessary to carry out the study was completed and mailed to the Biometric Laboratory. In case of problems encountered in completing the RPR or ECDEU Order Form, assistance could be obtained from the Biometric Laboratory.

2) Data Collection Phase - With the availability of the General Scoring Sheet, the choice of assessment instruments was not limited to the standard ECDEU scales. The investigator was able to select those devices which he felt would best serve his needs - provided that he had supplied the core information required for ECDEU services.

   For new investigators unfamiliar with the instruments, the following scales were recommended :

   . Neuroleptic Studies with Schizophrenic Populations

   a) Brief Psychiatric Rating Scale (BPRS)

   b) Clinical Global Impressions (CGI)

   c) Nurses Observation Scale for Inpatient Evaluation (NOSIE)

   . Antidepressant Studies

   a) Hamilton Psychiatric Rating Scale for Depression (HAMD)

   b) Clinical Global Impressions (CGI)

   c) Depression Status Inventory (DSI)

   d) Self-rating Depression Scale (SDS)

   . Anxiolytic Studies

   a) Hamilton Anxiety Scale (HAMA)

   b) Clinical Global Impressions (CGI)

   c) Anxiety Status Inventory (ASI)

   d) Self-rating Anxiety Scale (SAS)

   e) Self Report Symptom Inventory (SCL-90)

   It was suggested that along with appropriate demographic information, the assessment of side effects and the recording of dosages through the use of an instrument such as the Dosage Record and Treatment Emergent Symptom Scale (DOTES) should be considered. Finally, it was also recommended that information concerning the disposition of subjects should be gathered, e.g. Patient Termination Record (PTR).

3) Analytic Phase - Two administrative forms were completed at this phase. The Data Shipment (DS) form served such a vital function in BLIPS II that processing of a study simply could not proceed without an accompanying DS. The Research Completion Report (RCR) completed the transaction by documenting the investigator's overall conclusions and future plans as based on the results of his study.

Documentation of Psychotropic Drug Trials

While the purpose of the ECDEU Assessment Manual was to provide the clinical investigator with the necessary tools for data collection, assessment of change and communication between the various phases of the study, the purpose of the Workbook (the Documentation of Clinical Psychotropic Drug Trials) was to aid the clinical investigator in understanding and interpreting the package of processed data known as the "BLIPS Output Package". This was the computer-generated output developed by the Biometric Laboratory of George Washington University in collaboration with the Early Clinical Drug Evaluation Unit of the Psychopharmacology Research Branch (which replaced the Psychopharmacology Service Center). The purpose of the Output Package was to provide documentation of clinical drug trials that typically involved evaluation of new psychotropic compounds. It was predicated on the single principle that the more in depth and well organized the information which was available to an investigator, the more confident and accurate will be his judgements and decisions concerning any particular clinical trial.

Substantively, the Workbook covered the following general areas :

a) principles of documentation of research studies;

b) review of the content and use of standard reporting forms to record demographic information, clinical symptomatology, laboratory values, and drugs given with therapeutic and toxic effects;

c) explanation of the various statistical methods involved in processing data from clinical trials; and

d) intensive study of a sample BLIPS Output Package focusing on various ways of displaying data for quick and reliable interpretation.

Though many topics pertinent to clinical research were covered, the principal focus of the Workbook was the Output Package. In this way, the Workbook was complementary to the ECDEU Assessment Manual.

There were two main parts to the Workbook : a sample Output Package and a narrative description designed to facilitate understanding and interpretation of the package. The package contained study data (from a study to be described) in much the same form as it appeared when sent to the investigator following processing. The Output Package was organized by form and paginated for convenience. Such niceties were not usually provided in an "ordinary" package. The format of the output data, however, was exactly that which was routinely generated by the Biometric Laboratory in their processing of some 70 to 80 studies per year for various investigators. The teaching narrative was self-explanatory. It was organized roughly according to the steps taken in a clinical trial, i.e., design, assessment, reading of output, and general strategy for interpretation of statistical results.

The Workbook was designed for utilization by anyone interested in or involved with clinical assessment and research. The areas covered in the Workbook concerned psychotropic drugs in psychiatric populations. Indeed, most of the material contained came from an actual early clinical psychotropic drug trial. However, BLIPS as a system of documentation has wider potential for application than simply psychotropic drug research. The principles of BLIPS can be utilized in a number of different research settings. Consequently, the Workbook was designed for the psychiatric researcher and any other investigator who was interested in the documentation of his clinical research.

Fourth Period

During the third period and especially following the publication of the Revised Assessment Manual in 1976, there was a rapid expansion in the use of the System from a limited number of clinical investigators within the United States and Canada to an international scale. The name ECDEU with its connotation to a small group of pioneers did not apply any longer and it was replaced by the name NCDEU, i.e., New Clinical Drug Evaluation Units, referring to all clinical investigators interested in using the System, regardless of their affiliation, located and support. The Biometric Laboratory was unable to cope with the increased demand in providing services freely, and having fulfilled its purpose by developing a comprehensive system in collaboration with the Psychopharmacology Research Branch and ECDEU investigators ceased to exist. Replacing it were primarily university-based laboratories which adapted the System (but of course could not offer free services). One of the two laboratories which adapted the entire System was with the Clinical Research Service of the Tennessee Neuropsychiatric Institute, Vanderbilt University in Nashville, Tennessee (United States), and the other with the Psychiatric Clinic II of the Institute of Psychiatry University of Pisa, in Pisa, Italy. The laboratory in Pisa, with the assistance of the National Institute of Mental Health (United States) and in collaboration with Dr. Jerome Levine, Chief of Pharmacologic and Somatic Treatment Research Branch, developed into a Center for Clinical Psychopharmacology Documentation (CCPD) with a capability to provide assistance and collaboration to clinical investigators interested in using the System around the world. With these developments the ECDEU/BLIPS System was replaced by the BLIPS/BDP System.

Under the changed circumstances the constraints of the optical scan (op-scan) format became forbidding. The op-scan reader is a sensitive machine which compulsively records intended as well as unintended marks. The op-scan page is covered with a field of response positions which are "read" by the op-scan machine. With appropriate programming, many but not all of these extraneous positions can be suppressed. Consequently, some will be triggered by superfluous or incorrectly entered marks. Therefore for the use of op-scan scales, users had to be instructed to observe several rules.

Since observing these rules became a practical impossibility with the expansion of the System into an international scale, the op-scan format was abandoned and with it the General Scoring Sheet. The System returned to the use of self-contained scales with both items and their response positions preprinted on the form.

Simultaneously with these developments, two prospective users of the System appeared : the pharmaceutical industry and drug regulatory agencies. To comply with their needs, it was not sufficient to obtain data displays on individual patients and on projects per se, but it was also desirable to obtain information on the basis of which a judgement about the quality of the clinical trial could be made. Therefore assessment forms relevant to the assessment of individual patients (i.e., from the Adult Personal Data Inventory to the Patient Termination Record) and assessment forms relevant to the study per se (i.e., from the Research Plan Report to the Research Completion Form) were supplemented with a new form, referred to as Trial Assessment Procedure Scale (TAPS).

Description of the Assessment Battery

Clinical trials initiated by industry with a new psychotropic drug are not restricted to one or another country, but may embrace several countries or the whole world. Different countries may have different orientations in psychiatry and consequently use different instruments in the assessment of change. At least two of these scales have gained wide acceptability in recent years, the Psychopathological Symptoms form of the AMDP System, used primarily in German-speaking countries, and the CPRS (Comprehensive Psychiatric Rating Scale) used primarily in Scandinavian countries. To facilitate international acceptability of the System, these two scales were added to the Standard Battery.

During recent years, geriatric psychopharmacology has gained increasing importance and therefore it was thought to be desirable to include in the new Manual a psychogeriatric section.

As a result of these changes, the new standard Battery includes the following assessment instruments :

I. Documentation of the Clinical Trial

1. Research Plan Report
2. Data Shipment
3. Research Completion Report

II. Documentation of the Individual Patient A) Background Information

4. Children's Personal Data Inventory
5. Adult Personal Data Inventory
6. Prior Medication Record
7. Social Adjustment Scale

B) Assessment of Change

I. All Populations

8. Clinical Global Impressions
9. Nurses Global Impressions
10. Dosage Record and Treatment Emergent Symptoms Scale
11. TESS Write - In Scale
12. Laboratory Data

II. Children's Scales

13. Children's Psychiatric Rating Scale
14. Children's Behavior Inventory

III. Adults and Aged

IIIa. Psychiatrists' Scales

15. Brief Psychiatric Rating Scale
16. Hamilton Depression Scale
17. Hamilton Anxiety Scale
18. Comprehensive Psychopathological Rating Scale
19. AMDP-Psychopathological Symptoms

IIIb. Nurses' Scales

20. Nurses Observation Scale for Inpatient Evaluation

IIIc. Patients' Scales

21. Self-report Symptom Inventory
22. Self-assessment Depression Scale

IV. Scales for the Aged

23. Sandoz Clinical Assessment Geriatric
24. Plutchik Geriatric Rating Scale

V. Final Documentation

25. Patient Termination Record

III. Evaluation of Documentation

26. Trial Assessment Procedure Scale

In addition to the assessment instruments included in the Battery, the BLIPS/BDP System has the necessary programs to produce a regular output package on several other assessment instruments and the capability of developing a regular output package on any other assessment instrument.

Description of the Output Package

After editing and error corrections, all the collected data are processed. Results of the analyses are presented in the regular data package. The usual order of presentation in the data package is as follows :

1) Table of Contents
2) Narrative Summary
3) Patient Listing
4) Data Inventory
5) Demographic Data
6) Efficacy Data
   a. Psychiatric Rating Scales
   b. Nurses Rating Scales
   c. Self-rating Scales
7) Adverse Reaction Data
   a. Dosage Record and Treatment Emergent Symptoms
   b. Laboratory Data
8) Medical Data (optional)
9) Non-standard Data (optional)
10) Multi-instrument Displays
11) Error Diagnostics

Within the data package the usual order of presentation of rating scale output is as follows :

1) Legend
2) Raw Score Printout
3) Computed Score Printout
4) Means and Standard Deviations
5) Frequency Tables
6) Cross-tabulations
7) Graphic Displays
8) Variance or Covariance Analysis
9) Correlational Analyses (Across Instruments).

To comply with the increasing need for historical comparisons, the data bank has gained increasing importance and with it a shift in

emphasis from assessment instruments to documentation. In other words, the BLIPS/BDP System is not just a carefully selected collection of scales, but also a particular software. It memorizes data in a data bank and communicates data in an output package. Through its comprehensiveness and systematic dealing with the collected data, it should facilitate the decision-making process. However, it must be emphasized that although the BLIPS/BDP provides a system for documenting clinical trials, it is but one of several possible sources of information available to the investigator, i.e., it is not a substitute for clinical expertise and experience; since the investigator must provide the criteria against which all information is evaluated, BLIPS/BDP documentation is not evaluative in nature. It is oriented toward providing clear, organized and accurate output that may enter into the investigator's decision-making activities; and the system documents what occurred during a clinical trial, not how research should be conducted.

Considering the shift in emphasis the ECDEU Assessment Manual (original and revised) the new manual is called Manual of Documentation and Assessment Procedures for Clinical Trials in Psychopharmacology and is subdivided into nine sections :

I. Introduction : Historical Development (see above)

II. Documentation as a Methodology

III. A Documentation System in Operation

A) Documentation of the Clinical Trial

IV. A Documentation System in Operation

B) Documentation of the Individual Patient (Input Package)

a. Background Information
b. Assessment of Change
c. Final Documentation

V. A Documentation System in Operation

C) Data Processing

VI. A Documentation System in Operation

D) Analyses of Data (Output Package)

VII. A Documentation System in Operation

E) Evaluation of Documentation

VIII. Additional Assessment Instruments

IX. Data Bank in Use.

P A R T T W O

DOCUMENTATION AS A METHODOLOGY

The developmental phases of clinical drug evaluation of psychotropic drugs have been fairly well standardized and accepted by both clinical investigators and regulatory authorities. What is not generally agreed upon is the technique for documenting and presenting the information acquired during individual clinical trials in a detailed, logical and comprehensive manner.

The difficulties created by this are acutely felt in the considerable loss of information and especially in the inability to utilize data and compare results of different clinical trials with the same drug. It results in a situation in which a great number of clinical trials need to be conducted with a great number of patients at risk, with great time delays and excessive costs before a new therapeutic agent becomes available for general clinical use.

To overcome these difficulties the ECDEU/BLIPS documentation system was created. The merging of the BLIPS and the BDP has lead to a unique and powerful analytic tool in which the formal data documentation techniques of BLIPS are utilized to create a data bank of clinical trials which is readily analysable through the use of a general selection program and access to a variety of statistical programs.

The BLIPS/BDP data documentation system consists of three different sets of forms. One set of forms deals with documentation of the clinical trial, another with the documentation of individual patients included in the clinical trial, and the third with the documentation of the evaluative process of the completed clinical trials. The system is based on tabulations of data from these three sets of forms. The various types of tabulations and displays are organized in a systematic and logical fashion. Hence the widespread use of the BLIPS/BDP data presentation formats would greatly simplify the work of investigators, drug companies and regulatory agencies, since each would not have to develop and interpret different data presentation formats. By employing the system, some of the problems, such as language and cultural differences in multi-national collaborative studies could also be overcome; the number of patients included in clinical trials, and the related risks, consequently could be reduced.

The CLIPS/BDP is not the only system of documentation of clinical trials with psychotropic drugs. It is, however, probably the most flexible and open system since it continuously evolves and has the capability to utilize new data collection forms and assessment instruments. While originally it was developed for adult populations, today it can accommodate studies carried out in children, adults and in aged psychiatric patients.

Every clinical trial with psychotropic drugs entail three distinct phases : planning or designing, data collection and data analysis. Insofar as planning is concerned, completion of the Research Plan Report (RPR) ascertains that all the relevant aspects of a proper research design are considered. As such, this aspect of the documentation is likely to improve the quality of the research in general and should have a determinant effect on the validity of the results. While the RPR predetermines the data that will be collected, it has no effect on the quality of the data collection phase and on the coordination and monitoring of the clinical study. These particular aspects of the clinical study are evaluated in the TAPS. By completing the TAPS, shortcomings of this phase can be brought to attention, opening the possibility of correction in future research. Employment of suitable rating scales in the assessment of change provides for the quantification of psychopathological concepts, improving the possibility for an equivocal interpretation of the results and an improved communication of the findings. This aspect of documentation may also have an important role in education and training.

Finally, documentation as a methodology implies that analysis of data, like any other aspects of the study, is planned in advance; restricting the collection of data to relevant material, i.e. material to be used in the analysis of data.

P A R T T H R E E

A DOCUMENTATION SYSTEM IN OPERATION

A. DOCUMENTATION OF THE CLINICAL TRIAL

Every clinical trial consists of three distinct stages: development of research design, data collection and analyses. While documentation in the data collection stage is based on the completion of assessment instruments used in the evaluation of the clinical state of individual patients, documentation of the entire clinical trial is based on the completion of three essential forms :

Research Plan Report
Data Shipment
Research Completion Form.

Documentation as a concept is used in its broadest sense; proper documentation of a clinical trial enables one who uses that documentation to recreate through symbols what transpired during the actual trial. It includes the objectives of the trial, the procedures used in conducting the trial, the observations and measurements made during the trial and, finally, the organization and statistical analyses of the data resulting from the observations. These should be presented in such a fashion that conclusions about the trial, and not just the drug involved in the trial, can be reached.

Proper documentation can lead to the conclusion that a faulty trial has been conducted and thus the observations and measurements may not be susceptible to analysis leading to valid conclusions. A badly designed trial, for example, may generate data leading to the judgement that a drug is ineffective, when in fact it might be effective. Thus, proper documentation allows for the observations and measurements made during the trial as well as for the evaluation of the trial itself.

RESEARCH PLAN REPORT (RPR)

RPR Form

The first step in clinical research involves designing an experimental trial which will adequately test the investigator's hypothesis. This task may be simple or complex, depending on the question under investigation.

The Research Plan Report (RPR) is a form on which pertinent information is gathered about the study design. It does not state what design should be used, but merely records what methods have been decided upon by the investigator.

The RPR is utilized before actually commencing research. It is a way of"documenting" what is to transpire in the clinical trial.

The form within the standard battery of the BLIPS/BDP System used to document or describe the trial itself is the RPR.

National Institute of Mental Health (USA) - University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) RESEARCH PLAN REPORT (RPR)	Do not write in this box Unit No Study No RPR No

General Instructions

The Research Plan Report is designed to collect data concerning psychopharmacological research procedures in a format suitable for computer processing. The restrictions of such a format plus the great variety in research designs may create some difficulties in choosing a response. The investigator is asked, however, to make every effort to complete the form according to the instructions. If aspects of your study cannot be described appropriately under a given item or if the space provided is inadequate for your response, please describe the details on page or on a separate sheet and attach to the form. Submission of the investigator's complete protocol would also be appreciated so that errors of interpretation can be avoided.

Specific instructions for this form (RPR) are given on page - and should be read PRIOR TO COMPLETING THE FORM.

I. IDENTIFICATION

Name/s of the Investigator/s . . . . . Address . . . . . .

Title of Study . . . . . .

Starting Date
Month . . . . . Year . . . . . .

Anticipated Completion Date
Month . . . . . Year . . . . . .

Purpose/s - Briefly state purpose/s and any specific hypotheses of the study.

If you concur, the Research Plan Report which you submit can be released to the scientific community in the form of a short narrative description of the study. Chemical formulae may be held confidential even if other information is released.

Is this RPR a revision or modification of a previously submitted one ? _____ Yes _____ No

If YES, give Unit and Study numbers assigned to original RPR : _____

May data on this form be given to the scientific community ? _____ Yes _____ No

Should chemical formulae be held confidential ? _____ Yes _____ No

Will BLIPS/BDP forms be used and data be sent to the CCPDD ? _____ Yes _____ No

Mail this completed form to : Center for Clinical Psychopharmacology Data Documentation
Institute of Clinical Psychiatry
University of Pisa
Via Roma 67
56100 PISA (Italy)

ALL CARDS	Do not write here - for CCPDD use only							
	Unit No.	Study No.	Year completed	Revision	Form	Receipt Mo/Yr	RPR No.	Status
	(2-4) - - -	(5-7) - - -	(8-9) - - - - -	(10) - - -	(11-12) 2 1	(13-16) - - - -	(75-78) - - - -	(79-80) - - -

II. DESCRIPTION OF DRUG/S EMPLOYED

Do not write here

(17-18) 0 1

A. TEST DRUGS

1. Test Drug No 1

a. Name — Single drug ___1 Combination drug ___2 — (19-23) - - - - -

b. Synonyms

c. Manufacturer — (24-26) - - -

d. 1. Approved for prescribing or sale and for the present indication or use ___1
2. Approved for prescribing or sale but NOT for the present indication or use ___2
3. Not approved for any use ___3 — (27) -

2. Test Drug No 2

a. Name — (28-32) - - - - -

b. Synonyms

c. Manufacturer — (33-35) - - -

d. 1. Approved for prescribing or sale and for the present indication or use ___1
2. Approved for prescribing or sale but NOT for the present indication or use ___2
3. Not approved for any use ___3 — (36) -

Do not write here

3. Presumed Clinical Action/s	Test Drug No 1 01 __ neuroleptic 02 __ anxiolytic/sedative 03 __ antidepressant 04 __ stimulant 05 __ psychotomimetic 06 __ hypnotic 99 __ unknown	Test Drug No 2 01 __ neuroleptic 02 __ anxiolytic/sedative 03 __ antidepressant 04 __ stimulant 05 __ psychotomimetic 06 __ hypnotic 99 __ unknown	Test Drug No 1 (37-38) - - Test Drug No 2 (39-40) - -
	Other action (test drug No 1)		(41-42) - -
	Other action (test drug No 2)		(43-44) - -
4. For Investigations of New Uses for Established Drugs			
Test Drug No 1	The generally accepted action is :		(45-46) - -
	The action to be tested in this study is :		(47-48) - -
Test Drug No 2	The generally accepted action is :		(49-50) - -
	The action to be tested in this study is :		(51-52) - -

5. Chemical Class/es (if known)				Do not write here
Test Drug No 1	Test Drug No 2	Chemical classes	Test Drug No 1	Test Drug No 2	Chemical classes	(53-55)
101		Phenothiazines	401		Phenylethylamine derivatives	
102		Phenothiazine analogues & isosteres	402		Phenylacetic acid derivatives	- - -
201		Lysergic acid derivatives	403		Diphenylmethane derivatives	(56-58)
202		Reserpine & derivatives	404		Benzoic acid derivatives	
203		Harmine & derivatives	405		Other aromatic compounds	
204		Other indole derivatives	501		Glycols	- - -
301		Cannabis derivatives	502		Carbamates	(59-61)
302		Chromone derivatives	503		Carbinols	
303		Benzodiazepines	504		Amides & hydrazides	
305		Barbiturates	505		Amines & hydrazines	- - -
306		Heterocyclic butyrophenones	506		Other aliphatic compounds	(62-64)
307		Other nitrogen heterocycles	507		Other	
308		Benzodioxane derivatives	999		Unknown	
309		Other non nitrogen heterocycles				- - -

6. For NEW DRUGS, draw chemical structure

Formulae	(65) Yes = 1 No = 2
Public	(66) Yes = 1 No = 2
Scales	(67) Yes = 1 No = 2
Purposes	(68-69) - -
	(70-71) - -

B. COMPARISON DRUGS			Do not write here
1. Does the study employ comparison drugs ? ___ yes If yes, which ? Standards ___ 1 ___ no (0) Active placebo ___ 2 Inert placebo ___ 3 Both standard/s and placebo/s ___ 4			(17-18) 0 2 (19) -
2. Comparison Drug No 1	a. Name	Single drug ___ 1 Combination drug ___ 2	(20-24) - - - - -
	b. Manufacturer		(25-27) - - -
3. Comparison Drug No 2	a. Name	Single drug ___ 1 Combination drug ___ 2	(28-32) - - - - -
	b. Manufacturer		(33-35) - - -
4. Placebo	a. Composition		(36-40) - - - - -
	b. Manufacturer		(41-43) - - -
III. POPULATION			
A. Demo-graphy	1. Total number of subjects in study : _____		1 - (44-46) - - -
	2. Sex : males only ___ 1 females only ___ 2 both sexes ___ 3	3. Maturity : children ___ 1 adolescents ___ 2 adults ___ 3 geriatric ___ 4	2 - (47) - 3 - (48) - 4 - (49-50 - -
	4. Age range : from _____ to _____		(51-52) - -

B. Subject Status	1. (check one) Inpatient ___ 1 Outpatient ___ 2 Both ___ 3 Not applicable ___ 9	2. (check one) Acute ___ 1 Chronic ___ 2 Both ___ 3 Not applicable ___ 9	Do not write here (53) 1 (54) 2
C. Principal Diagnostic Categories	1. Adult - Check all applicable (omit if study involves children only) Organic brain disorders ___10 Geriatric disorders ___11 Alcoholism ___13 Psychotic depressions ___20 Schizophrenia ___22 Personality disorders ___50 Mental deficiency ___60 Psychophysiological disorders ___70 Varied psychiatric disorders ___80 Non psychiatric populations ___88		(55-56) 1 or 2
	A. Other Categories (DSM-III or ICD.9-CM)		(57-58) (59-60)
	2. Children Childhood schizophrenia ___71 Overanxious reaction ___72 Unsocialized Aggresive React ___73 Hyperactive reaction ___74 Withdrawing reaction ___75 Speech disturbance* ___76 Learning disturbance* ___77 Tic* ___78 Sleep disorder* ___79 Feeding disturbance* ___81 Enuresis* ___82 Encopresis* ___83 Varied psychiatric disorders ___84 Non psychiatric population ___85 * special symptom disturbances		(61-62) (63-66) A or B (67-70)
	B. Other Categories (DSM-III or ICD.9-CM)		(71-74)

D. Basis for Diagnosis

Check method/s for determining diagnoses of research sample :

Psychiatric case record	___01	Clinical target symptoms	___04
Investigator's clinical judgment	___02	Psychometric (cutoff) score/s*	___05
Independent clinical judgment	___03	Biological markers	___06

If "psychometric score/s" checked, describe method :

Other methods (specify) :

E. Exclusion Criteria

Check all conditions which would lead you to exclude (or remove) an individual from the study :

Acute or chronic brain syndrome	___27	Electroconvulsive therapy	___32
History of convulsive disorder	___28	Alcoholism	___33
History of CNS disease	___29	Drug addiction	___34
Mental deficiency	___30	Pregnancy	___35
Psychosurgery	___31	Females of childbearing age	___36

Medical illnesses/conditions :

Allergic	___37	Hepatic	___39	Pulmonary	___41
Cardiac	___38	Hematologic	___40	Renal	___42

Other medical illness or condition (specify) :

Any other exclusion criteria (specify) :

Do not write here	
(17-18)	0 3
(19-20)	- -
(21-22)	- -
(23-24)	- -
(25-26)	- -
(27)	-
(28)	-
(29)	-
(30)	-
(31)	-
(32)	-
(33)	-
(34)	-
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(37)	-
(38)	-
(39)	-
(40)	-
(41)	-
(42)	-
(43-44)	- -
(45-46)	- -
(47-48)	- -
(49-50)	- -

F. Research Setting

	do not write here
1. For inpatient studies - During the study, the population will reside : (check all applicable) a) on 1 ___ one research ward at 3 ___ one institution (hospital) 2 ___ more than one research ward 4 ___ more than one institution (hospital) 5 ___ under administrative control of principal investigator 6 ___ not under administrative control of principal investigator	(51-53) - - -
b) on 1 ___ one clinical ward at 3 ___ one institution (hospital) 2 ___ more than one clinical ward 4 ___ more than one institution (hospital) 5 ___ under administrative control of principal investigator 6 ___ not under administrative control of principal investigator	(54-56) - - -
c) Describe in detail research settings which do not fit in the above categories	(57-58) - -
	(59-60) - -
2. For outpatient studies - During the study the population will be admitted : (check all applicable) a) from 1 ___ one catchment area 2 ___ more than one catchment area to 3 ___ one 5 ___ community mental health center 4 ___ more than one 6 ___ other psychiatric clinic 7 ___ child guidance center 8 ___ psychiatric section (OPD) of a general hospital 9 ___ office of private practitioner	(61-67) - - - - - - -

	b) Describe in detail research setting which do not fit the above categories			do not write here (68-69) - - (70-71) - -
	IV. PROTOCOL			
A. CLASS OF STUDY				(17-18) 0 4
1. Clinical Pharmacology :	phase I	(activity, toxicity, dose tolerance)	___ 1	(19)
	early phase II	(efficacy, dose range, small sample, non-blind)	___ 2	
2. Clinical Trial :	late phase II	(blind, efficacy, comparative agent)	___ 3	
	phase III	(definitive efficacy trial, large sample size)	___ 4	
3. Special Drug Study		(EEG, metabolism, dose response, etc.)	___ 5	
4. Special Non Drug Focused Study		(demographic, methodological, etc.)	___ 6	-
B. EXPERIMENTAL DESIGN				
1. Type	a) Drug alone or compared with another drug/s :	test drug/s only	___01	(20-21)
		test vs. placebo	___02	
		test vs. comparison drug	___03	
		test vs. comparison vs. placebo	___04	
	b) 2 or more test conditions in the same drug :	2 or more dose levels	___05	
		2 or more "brands"	___06	- -
		2 or more dosage forms	___07	

			do not write here
1. Type (contd)	c. Drug in combination with or compared to non drug treatment :	drug vs. individual psychotherapy ___08 drug vs. behavior modification ___09 drug vs. group psychotherapy ___10	(20-21) _ _
	d. Other type (specify) :		
2. Duration	a. "Drying-out" period? ___ yes ___ no If yes, length will be : (Insert Number) Length of Period / Time Unit _____ days 1 _____ weeks 2 Drying-out period will employ : no treatment _____ 1 placebo _____ 2		(22-24) _ _ _ (25) _
	b. Drug administration period will be :	_____hours 1 _____days 2 _____weeks 3 _____months 4	(26-27) _ _ (28) _
	c. Post treatment (follow-up) period will be :	_____hours 1 _____days 2 _____weeks 3 _____months 4 none _____	(29-30) _ _ (31) _

3. For Cross-over Designs Only

Describe duration and drug sequences to be employed. Duration should apply to the first sequence and will be adjusted for other sequences. Code drugs as follows:

Test drug No. 1 = T1 Comparison drug no. 1 = C1 Placebo = PBO
Test drug No. 2 = T2 Comparison drug No. 2 = C2

Duration coded in: 1___ hours 2___ days 3___ weeks 4___ months

Treatment

Duration	Sequence No 1	No 2	No 3	No 4

do not write here

(17-18) 0 5

(19) _

(20-25) _ _ _ _ _ _

(26-31) _ _ _ _ _ _

(32-37) _ _ _ _ _ _

(38-43) _ _ _ _ _ _

(44-49) _ _ _ _ _ _

(50-55) _ _ _ _ _ _

C. DOSAGE ADMINISTRATION

	Test Drug No 1		Test Drug No 2	Comparison Drug No 1		Comparison Drug No 2	Placebo	
1. Form	1 ___	tablet	___ 1	1 ___	tablet	___ 1	tablet	___ 1
	2 ___	capsule	___ 2	2 ___	capsule	___ 2	capsule	___ 2
	3 ___	"spansule"	___ 3	3 ___	"spansule"	___ 3	"spansule"	___ 3
	4 ___	liquid	___ 4	4 ___	liquid	___ 4	liquid	___ 4
	5 ___	I.V.	___ 5	5 ___	I.V.	___ 5	I.V.	___ 5
	6 ___	S.Q.	___ 6	6 ___	S.Q.	___ 6	S.Q.	___ 6
	7 ___	I.M.	___ 7	7 ___	I.M.	___ 7	I.M.	___ 7
	8 ___	depot	___ 8	8 ___	depot	___ 8	depot	___ 8
	other			other			other	

Card 04 (continuation)

(32-33) _ _

(34-35) _ _

(36-37) _ _

(38-39) _ _

(40-41) _ _

2. Dosage Schedule

	do not write here
a. Fixed/unchanging - dosage fixed in protocol prior to study at single level, e.g., 5 mg/day for 10 days _____ 1	(42)
b. Fixed/changing - dosage fixed in protocol prior to study with increasing or decreasing levels, e.g. 100 mg for 1st week, 200 for 2nd, 300 for 3rd, etc. _____ 2	
c. Flexible - dosage changed according to needs of subject _____ 3	
d. Fixed/flexible - dosage fixed in protocol for earlier dosages with option to "individualize" dosage according to needs of subject later on _____ 4	-

3. Dosage Protocol

a. Record dosage schedules below.

If flexible dosage schedule, give initial and maximum dosage. Enter TOTAL DAILY DOSE at each appropriate time period. For combination drugs, use test No 1 for component A and test No 2 for component B.

Test 1 card 06
Test 2 card 07
Comp 1 card 08
Comp 2 card 09

Dosage Levels

Test Drug				Comparison Drug				
No 1		No 2		No 1		No 2		
Time period	Dosage	Time period	Dosage	Time period	Dosage	Time period	Dosage	
								(19-24) - - - - - -
								(25-30) - - - - - -
								(31-36) - - - - - -
								(37-42) - - - - - -
								(43-48) - - - - - -
								(49-54) - - - - - -
								(55-60) - - - - - -
								(61-66) - - - - - -

3. Dosage Protocol (cont'd)	b. Dosages are recorded in (check appropriate unit for dosage) :	mcg	_____ 1	do not write here (67)
		mg	_____ 2	
		gm	_____ 3	
		mg/kg	_____ 4	
	Other (specify) :			-
	c. Time periods are recorded in : (check appropriate unit for time)	hours	_____ 1	(68)
		days	_____ 2	
		weeks	_____ 3	
		months	_____ 4	
	Other (specify) :			-
D. CONTROL PROCEDURE				(17-18) 1 0
	1. Procedure will be :	nonblind	_____ 1	(19)
		double blind	_____ 2	-
	2. Subjects will be assigned to treatment by :	strict random number	_____ 1	(20)
		sequential assignment	_____ 2	
		matching	_____ 3	
		stratified-random (describe under"other")	_____ 4	
	Other :			-
	3. Will other concomitant non drug therapies be permitted for the research population ?			(21)
	Yes ___ If Yes, which therapies?	individual psychotherapy	_____ 1	
	No _____	group psychotherapy	_____ 2	
		behavior modification	_____ 3	
		varied psychological therapies	_____ 4	
		other therapies	_____ 5	
	Other (specify):			-
	4. Will other drug therapies be permitted ? (check all applicable)			(22-23)
	No other drug therapies for any reason		_____ 1	- -
	Only remedial medications, i.e., medications for the amelioration of adverse reactions		_____ 2	

		do not write here
4. (cont'd.)	Antiparkinson medication will be given prophylactically to all subjects _____ 3 Medication/s for medical conditions prescribed for subject prior to study will be permitted _____ 4 Non-study psychotropic medication may be administered in emergency (crisis) situation _____ 5 No restriction of use of other drug therapies _____ 6	(22-23) _ _
	Describe in detail other procedures which do not fit the above categories :	(70-71) _ _
E. ASSESSMENT INSTRUMENTS (check all applicable instruments)		
1. Demographic	Others : APDI _____ 24 CPDI _____ 25	(24) _ (25) _
2. Diagnostic	_____ 26 _____ 27 _____ 28 Specify : _____ 29 _____ 30	(26) _ (27) _ (28) _ (29) _ (30) _

3. Efficacy

Adult and Geriatric Behavioral Rating Scales

31 _____ CGI
32 _____ BPRS
33 _____ HAM Depression
34 _____ HAM Anxiety
35 _____ SCAG
36 _____ CPRS
37 _____ AMDP (Psychopathological symptoms)
38 _____ NOSIE
39 _____ NGI
40 _____ PLUT
41 _____ SCL-90
42 _____ SAD
43 _____
44 _____
45 _____
46 _____

Others :

Children's Behavioral Rating Scales

47 _____ CGI
48 _____ CPRS
49 _____ CBI
50 _____
51 _____
52 _____
53 _____
54 _____

Others :

do not write here
(31) _
(32) _
(33) _
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(54) _

					do not write here
4. General	55 _____ PMR 56 _____ PTR 57 _____ SAS II Others :		58 _____ 59 _____ 60 _____		(55) _ (56) _ (57) _ (58) _ (59) _ (60) _
5. Adverse Reactions	61 _____ 62 _____ DOTES Others :	63 _____ TWIS 64 _____ LAB		65 _____ 66 _____	(61) _ (62) _ (63) _ (64) _ (65) _ (66) _
6. Lab. Tests	Hematology 19 _____ Hgb 20 _____ Hct 21 _____ RBC 22 _____ WBC 23 _____ Differential Other :		24 _____ Sed. Rate 25 _____ Platelet 26 _____ Prothrombin time 27 _____ 28 _____		(17-18) 1 1 (19) _ (20) _ (21) _ (22) _ (23) _ (24) _ (25) _ (26) _ (27) _ (28) _

		do not write here
6. Lab. Tests (cont'd)	**Serum Chemistry** 29 _____ Electrolytes 30 _____ Liver function tests 31 _____ Kidney function tests 32 _____ Sugar metabolism 33 _____ Blood work 34 _____ Thyroid function tests 35 _____ 36 _____ Other :	(29) _ (30) _ (31) _ (32) _ (33) _ (34) _ (35) _ (36) _
	Urine 37 _____ Sp.Gr. 38 _____ pH 39 _____ Albumin 40 _____ Sugar 41 _____ Microscopic 42 _____ Electrolytes 43 _____ 44 _____ Other :	(37) _ (38) _ (39) _ (40) _ (41) _ (42) _ (43) _ (44) _
	Tests on Other Biological Specimens 45 _____ Saliva 46 _____ Feces 47 _____ Cerebrospinal fluid 48 _____ 49 _____ Other :	(45) _ (46) _ (47) _ (48) _ (49) _

		do not write here
7. Medical Assessment Procedures	50 _____ Physical examination 51 _____ Neurological examination 52 _____ PANESS 53 _____ EKG 54 _____ EEG 55 _____ Slit-lamp 56 _____ 57 _____ Other :	(50) _ (51) _ (52) _ (53) _ (54) _ (55) _ (56) _
8. Any Other Procedures	58 _____ 59 _____ 60 _____	(57) _ (58) _ (59) _ (60) _
F. RATERS		
1. How many different individuals (e.g., psychiatrists/psychologists) will perform the major behavioral ratings ? No _____		(61-62) _ _
2. Will "multiple raters" be used, i.e., 2 or more individuals performing simultaneous or concurrent ratings of the same subject ? (check one)	No _____ 0 Yes _____ 1	(63) _
G. ASSESSMENT SCHEDULE		
For time periods, check appropriate time units (days, weeks, etc.) and write in the assessment periods to be employed. In the 4 other columns, mark (X) in all rows where ratings will be made.		(64) _
Circle the periods where drug treatment begins and ends. Designate initial (first) rating as "00".		(65-66) _ _
For adverse reaction only		(67-68) _ _
a. If symptoms are to be rated only if and when they occur : check here _____ 1		(69-70) _ _
b. If symptoms are to be rated at each dosage change : check here _____ 2		
c. If symptoms are to be rated on a fixed schedule, complete in manner described above. Check whether time periods refer to : 1 ___ hours; 2 ____ days; 3 ____ weeks; 4 ___ months		17-18 1 2

G. ASSESSMENT SCHEDULE (cont'd)

Time Period	Major Behavioral Scale	Major Psychometric/ Performance	Adverse Reaction	Laboratory Tests		do not write here
						(19-24) - - - - - -
						(25-30) - - - - - -
						(31-36) - - - - - -
						(37-42) - - - - - -
						(43-48) - - - - - -
						(49-54) - - - - - -
						(55-60) - - - - - -
						(61-64) - - - -
						(65) -

H. TYPE OF DATA ANALYSIS

1. Pre (Middle) Post - one way analyses of rating periods _____ 1

2. Treatment (Groups) Comparison - e.g., drugs x periods _____ 2

3. Factorial - more than 2 factors, e.g., drugs x periods x diagnosis _____ 3

   Describe factorial design :

4. Crossover - 2 or more treatments in same subjects _____ 4

5. Other :

(66) -

REMARKS:

SPECIAL INSTRUCTIONS

I. IDENTIFICATION

All items are self-explanatory.

II. DESCRIPTION OF DRUG/S EMPLOYED

The term "test drug" refers to the investigational drug, while "comparison drug" refers to the control drug. As used here, these terms are not necessarily synonymous with the ones used by regulatory agencies. Space limitations allow a maximum of four drugs to be encoded - two test drugs under A and two comparison drugs under B of this section. In some instances, these space limitations may force arbitrary assignment of drugs to test or comparison categories, e.g., one test vs. three control drugs. Space is provided to encode a PLACEBO in addition to the maximum of four drugs.

The terms "test" and "comparison" may be used in various ways; not only as test vs. control drugs but also to describe any test vs. control situation (different brands of the same drug, different populations or age groups, high vs. low doses, liquid vs. tablet , etc.). In such cases, record the usual or standard medication as comparison and the new or unusual form as test.

A. Test Drugs

1a. Name - Give the generic name for the drug or, if none yet exists, give the code number.

Single/Combination - "Single drug" means a drug consisting of one compound. "Combination drug" refers to two or more compounds given as a single treatment, even if the components are not enclosed within a single "capsule" or "tablet". The drug "Triavil", for example, is a combination of amitriptyline (Elavil) plus perphenazine (Trilafon). To record this drug, write in one space the generic name of each component - amitriptyline and perphen-

azine. Do not record the two components as test drug No 1 and test drug No 2.

b. Synonyms - Give only the more frequently used synonyms, trade names and/or code numbers.

c. Answer on the basis of the drug's status for general use and for the use/indication being tested in the study. Example : a drug approved for use in general adult populations is to be tested for use in children. It is not approved for such a population by the appropriate regulatory agency. Check 2 - "Yes, approved for prescribing or sale but not the present indication or use in this case."

3. Presumed Clinical Action - Two columns are provided for studies which involve two test drugs. In these studies, be sure to mark the action for each drug in the correct column. For example, if thiothixene is test drug No 1 and imipramine is test drug No 2, check "neuroleptic" in column No 1 and "anti-depressant" in column No 2. When combination drugs are present, mark the action of each component of the combination in the column. For example, if the combination drug, Triavil (amitriptyline + perphenazine) is test drug No 1 check both "anti-depressant" and "neuroleptic" in column 1.

4. New Uses for Established Drugs - To be completed when a drug has an established psychotropic action, e.g., neuroleptic; and is being studied for some other presumed action, e.g., anti-depressant; or when a non psychotropic drug, e.g., an analgesic is tested for psychotropic action, e.g., anxiolytic.

5. Chemical Classes - The classification is based on that of Usdin and Efron in their book "Psychotropic Drugs and Related Compounds" (second edition, DHEW publication No 72-9074, printed 1972). From the code numbers (101-506) choose the lowest number which is applicable to your test drug. If the drug, for instance, is both a heterocycle (307) and a carbamate (502), check only (307). For those drugs which belong to a chemical class that is not listed, check 507 and where chemical class is yet unknown, check 999. For studies involving two test drugs and/or combination drugs, follow the procedure described under A3, "Presumed Clinical Action."

III. POPULATION

C. Principal Diagnostic Categories

Complete either subsection 1 - Adult (incl. geriatric) or 2 - Children. You may record a maximum of four categories. If the population is so heterogeneous that four of the categories cannot account for the bulk of the sample, check "Varied Psychiatric Disorders". DSM-III and/or ICD9-CM diagnostic entities may be recorded under "Other Categories" if the investigator chooses.

D. Basis for Diagnosis

- Psychiatric Case Record - Refers to use of diagnosis contained in the subject's case (hospital) record as the determinant.

- Investigator's Clinical Judgment - Refers to the determination of diagnosis by the principal investigator or member of the research team.

- Independent Clinical Judgment - Indicates determination by an individual not directly involded in the study, e.g., a consultant - not a member of the research team - whose function is to ascertain or verify the appropriateness of the diagnosis.

- Clinical Target Symptoms - Refers to the clinical judgment of the presence or absence of specific symptoms or characteristics.

- Psychometric Scores - Refers to determination by the use of specific score/s on a psychometric assessment instrument/s, e.g., subjects rated below a specified severity (score) on a scale are ineligible (cutoff) for acceptance into the study sample.

- Biological Markers - Refers to a qualitative or quantitative biochemical and/or psychophysiological measure suitable for the identification of a homogeneous patient population.

F. Research Setting

Research ward refers to a unit specifically organized for research purposes. Residents on a research ward are selected primarily on the basis of research requirements.

IV. PROTOCOL

A. Class of Study

Check ONE of the six alternatives.

B. Experimental Design

1. Type - Check ONE of the ten alternatives listed under a, b and c or write in a more appropriate description under d.

   Type of drying-out - If a placebo is used only during drying-out period and the design is not conceptualized as a crossover, DO NOT designate the study as test vs. placebo.

2. Duration - For each of the subheadings a, b and c, insert numerals on the line before the appropriate time unit to indicate the length of the period. For example, an investigator plans to have a 2-week, no treatment drying-out period followed by 6 weeks of drug administration and no follow-up, item 2a, 2b and 2c would be completed as follows :

   a. Drying-out period ? ✓ yes / ____ no

      ____ days
      2 weeks

      Drying-out period will employ : no treatment ✓
      placebo ____

   b. Drug administration period will be :

      ____ hours
      ____ days
      6 weeks
      ____ months

   c. Post treatment (follow-up) period will be :

      ____ hours
      ____ days
      ____ weeks
      ____ months
      none ✓

3. Crossover - Example : In a study involving a test drug (T1), comparison drug (C1) and placebo (PBO), the investigator plans to vary the order in which the treatments are given. He plans to administer each of the drugs for 4 weeks and the placebo for 2 weeks. One half of the research sample will be placed on one sequence or the other. Coding is as follows :

Duration is recorded in : _____ days ___✓___ weeks _____ months

Treatment		
Duration*	Sequence No 1	Sequence No 2
2	PBO	C1
4	T1	PBO
2	PBO	T1
4	C1	PBO

*Duration applies to Sequence No 1. It is assumed that the durations for Sequence No 2 would be shifted along with the treatments, e.g., 4, 2, 4, 2.

A Latin square design involving test drug No 1 (T1), comparison drug No 1 (C1), comparison drug No 2 (C2) and placebo (PBO) would be completed as follows :

Treatment Duration	Treatment Sequences			
	1	2	3	4
2	T1	C1	C2	PBO
2	C1	C2	PBO	T1
2	C2	PBO	T1	C1
2	PBO	T1	C1	C2

C. Dosage Administration

1. Form - Check ONE of the dosage forms for each group in the study. For example, in a study consisting of 2 drug groups - Test and Comparison - in which both groups receive their medication in tablet form, check "tablet" under both test and comparison columns. "Spansule" refers to a sustained release form. Depot refers to a drug contained in a vehicle for I.M. injection which allows for slow release and long action.

2. Dosage Schedule - Dose ranges rather than specific doses are often fixed in the protocol prior to the study and should be coded according to level, e.g., 3 to 7 mg/day for 10 days would be coded as fixed/unchanging; 75 to 125 mg/day for the 1st week, 172-225 mg/day for the 2nd week, etc. would be coded as fixed/changing.

3. Dosage Protocol

Example 1 - Test and comparison drugs with a fixed/changing schedule. The total daily dose for the test drug will be 50 mg for 1 week, 100 mg for 1 week, 200 mg for 1 week, etc. For the comparison drug, the total daily dose will be 25 mg for 1 week, 50 mg for 1 week, 75 mg for 1 week, etc. Code as follows :

a.

Time Period	Test Drug No 1	Time Period	Comparison Drug No 1
1	50	1	25
1	100	1	50
1	200	1	75

b. Dosages are recorded in : 1 ✓ mg 2 ___ mcg 3 ___ gm 4 ___ mg/kg

c. Time periods are recorded in : 1 ___ hours 2 ___ days 3 ✓ weeks 4 ___ months

Example 2 - Test and comparison drugs with a flexible schedule. Over a 4-week period a range of 10-100 mg of test drug is to be administered; 100-500 mg for the comparison drug.

Code as follows :

Time Period	Test Drug No 1	Time Period	Comparison Drug No 1
4	10-100	4	100-500

(Units of dosage and time omitted for brevity)

Example 3 - Combination test drug and 2 comparison drugs with a fixed/changing schedule. Component A of combination is coded under Test No 1 and Component B under Test No 2. Dosage is changed as indicated.

Time Period	Test Drug No 1	Time Period	Test Drug No 2	Time Period	Comparison Drug No 1	Time Period	Comparison Drug No 2
1	50	1	5	1	50	1	5
2	100	2	10	2	100	2	10
2	150	2	15	2	150	2	15

Example 4 - Test drug in depot form and comparison drug in tablet form. Depot form (200 mg) is presumed to be effective for 4 weeks. Initial dose of comparison drug is 50 mg and is increased 50 mg each week to maximum of 200 mg.

Time Period	Test Drug No 1	Time Period	Comparison Drug No 1
4	200	1	50
		1	100
		1	150
		1	200

Example 5 - Test and comparison drug with a fixed/flexible schedule. Dosages for both test and comparison drugs are raised 100 mg each week for first 3 weeks of 6-week study. Dosages can then be "individualized" according to needs of subject. (Write in "open" to indicate "individualizing")

Time Period	Test Drug No 1	Time Period	Comparison Drug No 1
1	100	1	100
1	200	1	200
1	300	1	300
3	open	3	open

D. Control Procedure

1. Blindness - Single blind studies should be checked nonblind.

2. Treatment Assignment - Strict random number refers to the use of a table of random numbers for assignment of subjects.

   Matching refers to any attempt at specific matching of individuals.

   Sequential assignment refers to selection and/or assignment by order or

sequence, i.e., alternating treatments to subjects as they are admitted; choosing every nth subject, etc. Stratified random - a variant of "matching" in which groups rather than individuals are selected on basis of a set of characteristics, e.g., sex, age, etc.

3. Concomitant Therapies - Refers to therapies which may be given to patients as part of their treatment but which are not part of of the research design.

G. Assessment Schedule

Example 1 - Using the BPRS as his major behavioral rating scale, an investigator plans to make an assessment at pre-treatment, 2, 4, 6 and 8 weeks. Drug treatment will begin immediately following the initial rating and cease following the final rating. Ratings of adverse reactions and laboratory tests will be made at pre-treatment, 4 and 8 weeks. No psychometric/performance scales will be employed.

Time Period	Major Behavioral Scale	Major Psychometric Performance	Adverse Reaction	Basic Laboratory
(00)	X		X	X
02	X		...	...
04	X		X	X
06	X		...	...
(08)	X		X	X

Example 2 - On the major behavioral rating scale, the investigator plans to make assessments at the beginning and end of a 2-week drying-out period: the 1st, 3rd and 5th weeks of drug administration and 2 weeks after cessation of treatment. (Psychometric/performance tests, adverse reaction and laboratory tests are to be rated as marked.)
Code as follows :

Note that the time periods are numbered in sequence regardless of initiation/cessation of drug administration.

Time Period	Major Behavioral Scale	Major Psychometric Performance	Adverse Reaction	Basic Laboratory
00	X	X		
02	X	X	X	X
03	X	X		
05	X	X		
07	X	X	X	X
09	X	X		

H. Type of Data Analysis

All items self-explanatory.

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU program, the RPR is a self-contained scale for the recording of research procedures. It is, in essence, a summary protocol in which the purposes of the study are recorded, the size and nature of the population delineated, the investigational and comparative agents described, the duration and dosage set forth, the experimental conditions to be observed and the assessment procedures recorded. The value of the instrument extends beyond its usefulness for describing the design of a given study. As a data file, it can serve to describe the current status of research activities among a large group of investigators as well as provide an historical record of past activities.

APPLICABILITY - For all research populations.

UTILIZATION - Once per study. Completed prior to the initiation of the study.

SPECIAL INSTRUCTIONS - The investigator should be familiar with the instructions printed on the form itself as well as those contained below. Since no one form or the items contained therein can possibly cover all eventualities, investigators are asked to include a copy of their research protocol along with the RPR. An extensive coding system has been developed for the RPR which contains many more categories for each item than those printed on the RPR itself. With the investigator's personal protocol at hand, it has been possible to categorize almost all research procedures within the general framework of the RPR.

I. Identification

Unit and Study Numbers - These numbers are assigned by the CCPDD. When a RRN is received, a notice will be sent to the investigator acknowledging receipt and will give the unit and study number assigned to that RPR. This 6-digit identification number should be referred to in all subsequent correspondence regarding that particular study, so that misinterpretations can be minimized.

RPR Revision or Modification - If the investigator makes substantive changes in his study, a new RPR should be submitted. The original RPR can then be updated in the CCPDD data bank.

Confidentiality - Investigators may request that all or part of the information on a RPR be held confidential. For many reasons, new chemical formulae may need to be confidential and data pertaining to this area can be withheld while disseminating the other RPR information to the scientific community.

BLIPS/BDP Forms- Indicates that BLIPS/BDP forms will be employed either wholly or in part.

II. Drug/s Employed - This section focuses on a description of the agents or conditions to be studied.

"Test drugs" refers to any test condition; "comparison drug" to any comparison condition. Examples:

a. An atypical dosage of drug A (test condition) vs. a typical dosage of drug A (comparison condition) using the same drug in both instances.

b. "Brand X" (test) vs. "standard brand" (comparison).

c. Drug A given once a day (test) vs. drug A given 3 times a day (comparison).

d. Drug A given in "depot" form (test) vs. drug A given in tablet form (comparison).

e. Drug A given with a smile (test) vs. drug A given without a smile (comparison).

f. Withdrawal of drug A with PBO substitution (test) vs. withdrawal of drug A without PBO (comparison).

Space limitations allow recording of 2 "tests", 2 "comparisons" and a placebo. Which drugs or conditions are designated as "test" or "comparison" is left to the investigator and this decision may often be an arbitrary one.

Combination Drugs (A/1a) - The intent here is to describe the condition in which 2 or more drugs are given simultaneously as ONE treatment; i.e., the investigator presumes that the combination has a different effect than either of the components used singly. Combination treatments may also consist of drug and non-drug components; e.g. drug and ECT, drug and psychotherapy, drug and conditioning, etc.

Manufacturer (A/I/C) - Should be interpreted as the SUPPLIER of the drug/s employed in the study. The supplier is not necessarily the actual manufacturer of the drug/s.

Presumed Clinical Action/s (A/3) - The categories contained in this section are based on the classification developed by the International Reference Center for Information on Psychotropic Drugs (see table).

Chemical Class (A/5) - Investigators may leave this section blank if they are uncertain of the classification of a drug. With very new drugs, a drawing of the chemical structure is most helpful in arriving at correct classification. When classifying a combination drug, check a class for each component - both in the appropriate column.

Example 1 - Test drug No 1 is a combination of amitriptyline (class - phenothiazine analogue and isosteres) and perphenazine (class - phenothiazines). This combination of drugs will be administered as a single test condition. Code by checking both 1.01 and 1.02 under the column "test drug No 1".

5. Chemical Class/es (if known)

Test Drug No 1	Test Drug No 2	Chemical Classes
X	101	Phenothiazines
X	102	Phenothiazine analogues & isosteres
	201	Lysergic acid derivatives

Example 2 - Test drug No 1 is a single drug, amitriptyline, and test drug No 2 is a single drug, perphenazine. Each is to be administered to one of two independent groups. Code test drug No 1 in its appropriate column; test drug No 2 in its appropriate column.

5. Chemical Class/es (if known)

Test Drug No 1	Test Drug No 2	Chemical Classes
	101 X	Phenothiazines
X	102	Phenothiazine analogues & isosteres

Comparison Drug/s (B) - Refers to any control or standard condition against which the test condition is to be compared. A frequent misinterpretation in completing the RPR occurs in studies where two drugs (conditions) are employed and, although the investigator is actually going to compare these conditions, he encodes both of them as "test drugs". For uniformity in the Data Bank, categorizing one drug as "test" and one as "comparison" is preferred - even though this may be arbitrary from the investigator's point of view.

III. Population - Total Number of Subjects in Study (A) - Give an estimate of the sample size you plan to achieve, even though it may be a tentative one.

Principal Diagnostic Categories (C) - Up to 4 categories of diagnoses have been allotted in the coding system. Populations which exceed this limitation should be coded "varied psychiatric disorders". The spaces labeled "other categories" may be used to record any additional diagnoses or to record the DSM-III and/or ICD9-CM diagnoses.

Basis for Diagnosis (D) - When the response "psychometric (cutoff) score/s" is checked, specify the nature of the "cutoff score".

Examples :

BPRS total score of 30 or more.
HAMA total score of 25 or more
BPRS thought disorder factor score of 4 or more

Research Setting (F) - For items F,I,a and F,i,b, 3 MARKS are required.

Example : the population will reside on one clinical ward in one hospital. The ward is not under the investigator's administrative control.

---

b. on : 1 X one CLINICAL ward
2 ___ more than one CLINICAL ward

at : 3 X one institution (hospital)
4 ___ more than one institution (hospital)
5 ___ under administrative control of principal investigator
6 X not under administrative control of principal investigator

---

For mixed inpatient/outpatient studies, fill in both sections of this item. The distinction between a research and clinical ward may be confusing. A clinical ward is one organized for treatment purposes. Patients residing on such a ward may be selected as research subjects but the ward itself is not organized as a research ward. Catchment area refers to a geographical subdivision of a larger area (metropolitan area, ward, city, county, state, province, etc.) from which a given agency receives its clients.

IV. Protocol

"Drying-out" Period (B/2a) - In addition to checking the presence and length of a drying-out period, the investigator should indicate whether "no treatment" or PBO will be employed during this period. Should some other condition be maintained during the drying-out period, describe the nature of the condition.

Posttreatment (follow-up) Period (B/2c) - Refers to the period immediately following the cessation of drug administration and during which assessment procedures will be conducted.

Dosage Schedule (C/2a-d) - A single dose ("one-shot") would be coded as "fixed/unchanging". When recording "dosage protocol" for a single dose, give the time period over which the dose is presumed effective and the amount of the dose. Single dose is coded the same way as "depot" althought its length of action may be considerably shorter.

Assessment Instruments (E) - When recording assessment instruments not printed on the RPR, give the FULL NAME of the instrument since there can be confusion in the interpretation of initials or partial titles. This is particularly important in describing laboratory tests or medical procedures.

Raters (F) - Question 1 refers to the number of individuals performing the major behavioral ratings; e.g., the Children's Psychiatric Rating Scale and Clinical Global Impressions are selected by the investigator as his major instruments and he and 2 other colleagues will perform all of these ratings; enter "3" for the item.

Documentation - Documentation for the RPR is both study-specific and general. For the study itself, the RPR provides the information for the "Description" paragraph contained in the Narrative Summary which accompanies each standard data analyses package and which is stored in the data bank. For general documentation, the form is on some selected RPR's or RPR items contained inthe CCPDD Data Bank.

Sample Output/s

1. Description from Narrative Summary sent to Investigators

The purpose of this study, involving 80 inpatient, acute adults with diagnoses of manic-depressive-depressive phase and psychotic depressions, was to determine efficacy. The subjects were male and female and their ages ranged from 21 to 65 years. The study was classified as late phase II. The experimental design involved test vs. comparison drug. Subjects were assigned to treatment on stratified number basis. The study was conducted under double-blind conditions, no drying-out period was utilized. The duration of drug administration was 28 days with no follow-up. The test drug, Normaline, was FDA-approved and was supplied by Company. Its presumed clinical action is antidepressant. Its chemical class is other non nitrogen heterocycles. It was administered in capsule form on a flexible dosage schedule. The minimum and maximum daily doses were 50 mg and 200 mg. The comparison drug, amitriptyline, was supplied by Merck. It was administered in capsule form on a flexible dosage schedule. The minimum and maximum daily doses were 50 mg and 200 mg. No concomitant therapies were permitted for the research population. The assessment schedule consisted of one pretreatment rating and four ratings at 7-day intervals during the course of the study.

2. Description from Material Stored in Data Bank

This (Unit 033 Study 032 RPR No 0998) is an early phase 2 study of the psychotropic activity of non FDA-approved single drug 19900 manufactured by 887 and having a presumed neuroleptic action. The drug's chemical class is phenothiazine analogue or isostere. The investigation involved 010 chronic inpatient adult subjects who were both sexes and their diagnoses were reported as being schizophrenia. Their ages ranged from 18 to 55 years. The design consisted of test drug only and no comparison drug was used in this study. The investigational drug was administered in capsule form and 0020. and 0100. mg were the minimum and maximum daily doses. The study was nonblind and treatment duration was 12 weeks using a fixed/changing dosage schedule.

There was a 02 week drying out period. The assessment schedule consisted of 01 ratings at pretreatment, 02 ratings at 06 week intervals during treatment and no follow-up ratings. This study, which has a completion date of 1970, is listed as being complete and in the data bank.

GLOSSARY of ASSESSMENT INSTRUMENTS

1. Demographic	CPDI	Children's Personal Data Inventory
	APDI	Adult Personal Data Inventory
2. Diagnostic	CDS	Children's Diagnostic Scale
	HIS	Hachinski's Ischemia Score
3. Efficacy		
a. Children	CPRS	Children's Psychiatric Rating Scale
	CBI	Children's Behavior Inventory
b. Adults	CGI	Clinical Global Impressions
	BPRS	Brief Psychiatric Rating Scale
	HAMD	Hamilton Depression Scale
	HAMA	Hamilton Anxiety Scale
	SAD	Self-Assessment Depression Scale
	SCL90	Self-Report Symptoms Inventory
	CPRS	Comprehensive Psychiatric Rating Scale
	AMDP	AMDP Psychopathological Symptom Form
	NOSIE	Nurses Observation Scale for Inpatient Evaluation
	NGI	Nurses Global Impressions
c. Geriatric	SCAG	Sandoz Clinical Assessment Geriatrics
	PLUT	Plutchik Geriatric Rating Scale
4. Social	SASII	Hogarty's Social Adjustment Scale
5. Medication	PMR	Prior Medication Record
6. Adverse Reaction	DOTES	Dosage Record and Treatment Emergent Symptom Scale
	TWIS	TESS Write-in Scale
7. Laboratory Tests	LAB	Laboratory Data
8. Administrative	RPR	Research Plan Report
	DS	Data Shipment
	PTR	Patient Termination Record
	RCR	Research Completion Report
	TAPS	Trial Assessment Procedure Scale

PSYCHOTROPIC DRUG CLASSIFICATION - INTERNATIONAL REFERENCE CENTER NETWORK

Drug Groups	Synonyms	Working Definition	Sub-Groups	Examples
NEUROLEPTICS	Major tranquilizers Neuroplegics Psychoplegics Psycholeptics Antipsychotics	Non-hypnotic drugs with antipsychotic effects	Phenothiazine derivatives . . . . . Benzoquinolizine derivatives . . . Thioxanthene derivatives . . . . . Butyrophenone derivatives . . . . Rauwolfia alkaloids . . . . . . Other :	Chlorpromazine Thioridazine Fluphenazine Tetrabenazine Chlorprothixene Haloperidol Reserpine
ANXIOLYTICS	Antianxiety drugs Minor tranquilizers Sedatives	Non-hypnotic drugs with antianxiety effects but without antipsychotic effects	Benzodiazepine derivatives. . . . Glycol derivatives . . . . . . Carbinols . . . . . . Diphenylmethane derivatives . . . Barbiturates . . . . . . Other :	Chlordiazepoxide Oxazepam Meprobamate Phenaglycodol Phenprobamate Methaqualone Hydroxazine Phenobarbital Amobarbital
ANTI-DEPRESSANTS	Thymoleptics Thymoanaleptics Psychoanaleptics Psychic energizers	Drugs which elevate mood and relieve depression	MAO-Inhibitors . . . . . . Tricyclics . . . . . . Other :	Isocarboxazid Nialamide Phenelzine Tranylcypromine Imipramine Desipramine Amitriptyline Protriptyline

Drug Groups	Synonyms	Working Definitions	Sub-Groups	Examples
STIMULANTS	Psychoanaleptics Psychotonics Analeptics Psychomotor stimulants	Drugs which accelerate psychomotor function and activity and improve performance under conditions of fatigue	Phenylethylamine derivatives... Other	Amphetamine Methamphetamine Phenmetrazine Methylphenidate Pipradol
PSYCHOTOMIMETICS	Psycholytics Psychodysleptics Hallucinogenics Psychedelics Eidetics	Drugs producing alteration in consciousness, characterized by perceptual and emotional changes without disorientation	Phenylethylamine derivatives Indole-alkaloids . . . . . . Piperidine derivatives . . . . Other :	Mescaline LSD Psilocybin Tryptamine-derivatives Ditran Phencyclidine
HYPNOTICS	Soporifics Somnifacients	Psycholeptics with sleep-inducing and sleep-sustaining effects	Barbiturates . . . . . . Non-barbiturates . . . . . . Other :	Secobarbital Pentobarbital Glutethimide Ethchlorvynol Ethinamate

DATA SHIPMENT (DS)

DS Form

Perhaps the least exhilarating aspect of research is the data collection phase since it demands close and constant attention to a myriad of details. However, the care expended here is subsequently justified in the analytic phase. Since the greatest amount of processing time is spent in creating an error-free data set, it is as much in the interest of the CCPDD to campaign for strict data control as it is in the investigator's interest.

Experience has shown that processing time is reduced substantially when an investigator establishes his own control procedures prior to sending data for computer processing. This is best accomplished when the responsibilities for data control and coordination are assigned to some member of his research staff. The data coordinator has the task of seeing that the requirements of the protocol - particularly the data collection aspects - are carried out. By constructing an overall assessment table showing rater assignment and required rating instruments, the coordinator can drastically reduce subsequent "missing data" problems. By monitoring each set of ratings as they are obtained, the coordinator can ensure the completeness and correctness of the encoding. To accomplish this, the coordinator must be thoroughly familiar with the proper encoding procedures for all the instruments used in a study.

Assembling Data for Shipment

Predominantly, input data has been received at the CCPDD in the form of completed sheets which represent the data collection for an entire study. In preparing a data set for shipment, the following instructions should be noted :

1. Check all forms for completeness both in the ID blockand in the data matrix. Erase extraneous marks or writing.
2. Only the original copy should be sent. Another copy should be retained by the investigator.
3. Sorting data in a uniform manner serves to alert the unit coordinator to missing ratings or other errors and, later, aids CCPDD editors to locate a specific form during their editing procedures. Two of the most frequently used sorting arrangements are :

a. Subjects and periods ordered within Sheet and/or Form as follows :

Treatment Group A

Sheet or Form Number (in numeric order)

Subject 001	Period 00
Subject 001	Period 01
Subject 001	Period 02
Subject 001	Period k
Subject 002	Period 00
Subject 002	Period 01
Subject 002	Period 02
Subject 002	Period k
Subject n	Period 00

Sheet or Form Number

(as above)

Treatment Group B (repeat as in "A")

b. Sheets, forms and periods ordered by subject as follows :

Treatment Group A

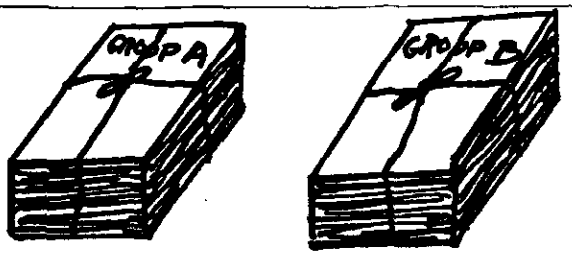
Subject 001

Sheet 01	Period 00
Sheet 01	Period 01
Sheet 01	Period 02
Sheet 01	Period k
Sheet 03	Period 00
Sheet 03	Period 01
Form n	Period 00

Treatment Group B (repeat as in "A")

4. Note in the above sorting examples (3a and 3b) that data is always separated into treatment groups. Identify each treatment group by writing its name on a sheet of paper and placing it on top of the data and tie the data together to make a bundle of each group's data.

Example :



5. Make sure that you have enclosed the completed DS. If you have additional special requests or comments, state them in a letter even though you may have discussed them previously by telephone.

6. Place all the data into a stout box and wrap securely. Please enclose ONLY ONE STUDY TO A BOX. More than one box may, of course, be used for large studies. To avoid mistakes, however, we urge that you do not enclose two or more different studies in a single box.

7. Mail to : Center for Clinical Psychopharmacology Data Documentation
   Institute for Clinical Psychiatry
   University of Pisa
   Via Roma 67
   56100 PISA (Italy)

When data is received at the CCPDD, a notice will be sent acknowledging its receipt and giving an estimate of turnaround time. If, after a reasonable time, you do not receive this notice, notify the CCPDD so that tracing can begin.

ALTERNATIVE TYPES OF DATA SUBMISSION

In the majority of cases, submission of "complete study" data is logistically preferred. However, the following alternative types of data submissions are acceptable :

1. Partial Submission - Often, there is a need to examine data before a study is completed; e.g., multi-phase studies where one phase of the design is dependent upon the results of a preceding one.

2. Card input - Data submitted in this manner is acceptable as long as it conforms to the standard BLIPS/BDP card format. Investigators should recognize the need to undertake their own editing of the source documents; since CCPDD editing will necessarily be limited to the cards themselves.

3. Tape-input - Tapes may be submitted, provided the following specifications are met :

   Tape restrictions :

   a. 9 track

   b. 1600 bits per inch

   c. Maximum block size = 32,000

   d. IBM mode

   Information required :

   a. blocking factor

   b. number of records

   c. label information.

   As noted with card formats, BLIPS/BDP editing is limited to the tape.

DATA SHIPMENT (DS)

National Institute of Mental Health (USA) - University of Pisa (Italy)

Institute of Clinical Psychiatry of Pisa

Center for Clinical Psychopharmacology Data Documentation (CCPDD)

DATA SHIPMENT (DS)

For Biometric CCPDD Use

BLIPS/BDP No.

Date Received

Principal Investigator/s

Title of Study

1. Have you previously submitted a Research Plan Report (RPR) for this study ?

_____ yes

_____ No (if No, please complete an RPR and enclose along with data. Studies cannot be processed without an RPR.)

2. Were there any revisions from the original protocol as described on the RPR which you have submitted ?

_____ Yes (if yes, please submit revised RPR)

_____ No

Instructions

The Data Shipment form has been designed to facilitate processing of studies and to involve the investigator in the decision process regarding analyses to a greater extent than heretofore possible. In completing the form, the investigator can select or delete ratings and/or raters for analyses; construct a factorial design and request special analyses. For the CCPDD, the Data Shipment will serve as a "master control form", selecting the appropriate programs for use in processing and analyses. Errors of patient assignment and/or period (rating) utilization can be minimized. Further, output displays can be labeled by drug name and/or other factor names. Since the form serves such a crucial role, A DATA SHIPMENT FORM MUST ACCOMPANY THE DATA WHEN IT IS MAILED TO THE CCPDD. Answer all items as completely as possible. Should the form be inappropriate for your data or should you be uncertain about its completion, please contact the CCPDD.

ITEM I - Inventory of Forms

1. Sheet Number

Sheet numbers routinely assigned to the standard scales are preprinted on the DS. When non-standard scales are employed, the investigator must assign the same sheet number to a given data set throughout the study. Any 2-digit number not already assigned may be used.

2. Time Unit

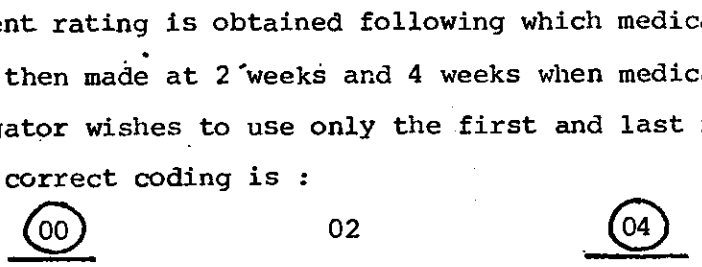
Indicate whether the time units are hours = H, days = D, weeks = W, or months = M.

3. Periods

For each scale, record all time periods (ratings) which were made during the study. The initial (first) rating should be designated "00"; others by the week (or other time unit) when they were made. CIRCLE the ratings where drug medication began and ended. UNDERLINE those periods (ratings) you wish to employ in subsequent analyses.

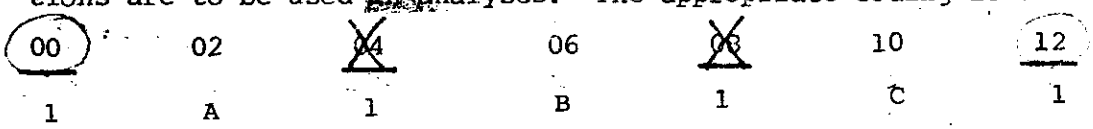
Examples :

a. A pretreatment rating is obtained following which medication is begun. Ratings are then made at 2 weeks and 4 weeks when medication is stopped. The investigator wishes to use only the first and last ratings in analyses. The correct coding is :



b. Ratings are made at the beginning and end of a 2-week drying-out period, following which medication begins. Ratings are also made at 4 and 6 weeks, when medication is stopped. A final rating is made 2 weeks later. The investigator wishes to use all ratings in analyses. The appropriate coding is :

c. For CROSSOVER designs, designate the medication changeover points by x's. For example, three drugs A, B and C are alternated every 4 weeks and ratings are made every 2 weeks. Only ratings at the beginning and end of medications are to be used in analyses. The appropriate coding is :



4. Last Available Rating

A check in this box signifies that there was an uneven and point in the study, i.e., patients were terminated after different durations of treatment. For example : in a 4-week study with weekly ratings, the investigator found that all subjects completed at least 2 weeks of treatment and were rated at weeks 00, 01 and 02. However, some subjects were so improved that they could be terminated prior to the 4th week. He wishes to use all subjects in a repeated model design. He wishes to use the first 3 ratings (00,01, 02) and the final rating for each subject whether it is the 03 or 04 week rating. The appropriate coding is :

(00)	01	02	✓ in the appropriate column

5. Rater

For each scale, give the number/s of the rater/s. Circle those rater numbers which you wish used in analyses.

ITEM II - Non BLIPS/BDP Forms

This item is to be completed in the same manner as Item I with the exceptions of the column named "Form". Under "Form", give the title of the scale or data set. For Sheet Number, use any number not already assigned. Use the same Sheet Number for the same data set for all assessment periods.

ITEM III - Rater Identification

This item becomes crucial if investigators contemplate conducting reliability studies across a number of trials. It is suggested that investigators try to use the same number for a rater who participates in a series of trials as this will simplify identification for both the investigator and the Biometric Laboratory. Do NOT use duplicate numbers in a single study.

ITEM IV - Variance Analyses

The present analyses of variance/covariance (AVACOV) program used in BLIPS/BDP allows for a 4-factor design. RESERVING ONE FACTOR FOR PERIOD EFFECT, the investigator may designate the number of additional factors (maximum of 3) he wishes to employ in his statistical design. In the usual clinical trial, Factor 1 would be named "DRUG" and the drug/s employed in the study labeled as Group A, B,C, etc. Factors 2 and 3 can be any designated effect that the investigator wishes to study, e.g., age, diagnosis, hospital, chronicity, dosage, experimental

manipulation, etc. A maximum of 10 groups may be categorized under any one factor. Part 2 of Item 4 asks for a choice of the standard variance models; while Part 3 provides for requests for special analyses.

a. For a study in which only one drug (UGH) was employed the coding is :

Factor 1	Name	drug
Group A		Ugh

This, in essence, would indicate a one-way analyses of periods.

b. Two drugs - WOW and GEE - were employed in the study, in addition, and the investigator wishes to test the effect of diagnosis - schizophrenic vs. non-schizophrenic. The coding is :

Factor 1	Name	drug
Group A		Wow
Group B		Gee
Factor 2	Name	Diagnosis
Group A		schizophrenic
Group B		non-schizophrenic

ITEM V - Patient Identification

This listing will be used for editing and processing procedures. In addition to the patient's number, sex and initials, the investigator is asked to categorize the factorial assignment of the patient. By specifically categorizing each subject, subsequent analyses can be checked for misassignment. Males are numbered 001 to 499; females 500 to 998.

Example - patient 507, a female whose initials are ZZ, received the drug WOW during the study and she is non-schizophrenic (see Item IV, example b. above). The coding is :

Patient No.	Sex	Initials	Factor Assignment 1	2	3
507	F	ZZ	A	B	

ITEM VI - Output

Check whether one or two copies of the data package and one or two decks of cards are desired.

ITEM VII - Dosage Data

This information is requested ONCE on this form rather than asking raters to complete it at every dosage change.

I. INVENTORY OF FORMS

Scales	Check	Sheet No	Time Unit	P e r i o d s	Check if last available rating to be used	Give rater No/s to be used in analyses
27-CPRS		01				
28-CGI		01				
29-DOTES		02				
30-CDS		03				
31-PTR		04	/////	//////////////////////	//////////	
32-TWIS		//////	/////	//////////////////////	//////////	
33-CBI		20				
34-NOSIE		20				
35-PLUT		20				
36-NGI		20				
37-CPDI		10	//////	//////////////////////	//////////	
38-APDI		12	/////			
38-TRAITS		13	//////	//////////////////////	//////////	
39-PMR		/////				
40-BPRS		01				
41-HAMA		01				
42-HAMD		01				
43-SCL90		//////				
44-LAB		//////				
45-SAD		//////				
46-SASII		//////				
47-AMDP		//////				
48-CPRS		//////				
49-HIS		//////				
50-SCAG		//////				

II. NON-BLIPS/BDP FORMS

Complete this section only if you are submitting data from scales which are not part of the BLIPS/BDP Assessment Battery. Copies of the scales and any relevant material would be appreciated and would aid in processing.

Title of Form	Sheet No	Time Unit	P e r i o d s	Check if last available rating to be used	Rater No/s to be used in analyses

III. RATER IDENTIFICATION

Complete items for all raters utilized in the study.

Rater No	Rater's Name (first initial and last name)	Rater No	Rater's Name (first initial and last name)

Note : When "multiple raters" are used, i.e., 2 or more individuals performing simultaneous or concurrent ratings of the same subject, and the investigator wishes to include this dimension in analyses, the raters should be identified under a factor entitled "Rater" (Item IV).

IV. VARIANCE ANALYSES

1. Factor Identification	Factor 1	Give Name _____ Group A _____ Group B _____ Group C _____ Group D _____ Group E _____ Group F _____
1. Factor Identification (cont'd)	Factor 2	Give Name _____ Group A _____ Group B _____ Group C _____ Group D _____ Group E _____ Group F _____
	Factor 3	Give Name _____ Group A _____ Group B _____ Group C _____ Group D _____ Group E _____ Group F _____
2. Variance Model Desired		Analyses of Variance - Regular Model _____ Analyses of Variance - Repeated Model _____ Analyses of Covariance - Regular Model _____ Analyses of Covariance - Repeated Model _____
3. Special Analyses (describe)		

V. PATIENT IDENTIFICATION

Please complete all items. Use additional sheets if necessary.
Males are numbered 001 to 499; females 500 to 998.

Patient Number	Initials (1st-last)	Sex (M or F)	Factor Assignment		
			1	2	3

VI. OUTPUT

A. Number of data packages requested : 1 _____ 2 _____

B. Number of card decks requested : 1 _____ 2 _____

C. If 2 data packages/card decks are requested, should both be sent to you ? Yes _____ No _____

If NO, give name and address of other recipient :

D. Do you want the original data forms returned to you ? Yes _____ No _____

To another address ? Yes _____ No _____

If YES, give name and address of other recipient :

VII. DOSAGE DATA

Check appropriate units for dosages coded on Dosage Record and Treatment Emergent Symptoms (DOTES) for each treatment group.

Drug Group	Units (check)				Other (specify)
	mg	mcg	gm	mg/kg	
A					
B					
C					
D					
E					
F					

	For CCPDD use only		
Code	Start	Finish	Comments
Keypunch			
Edit			
Analyses			

Date mailed :

Editor :

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU program, the DS contains 7 items and is designed to supply information necessary for BLIPS/BDP processing. The data from DS are key-punched and serve as control cards to select the appropriate programs for processing.

APPLICABILITY - For all research populations.

UTILIZATION - Once per study - when shipping data to the CCPDD.

SPECIAL INSTRUCTIONS - Instructions are printed directly on the form. Since DS information is essential to BLIPS/BDP processing, this form is MANDATORY and must be submitted with shipment of data. If uncertain about completing the DS or any of its items, the investigator is urged to contact the CCPDD.

Item I. Inventory of Forms - The shaded areas within the item indicate that no entries are required. These data are used to :

a) identify and locate each scale used in a study.

b) record the total number of assessment periods as well as those to be used in subsequent analyses.

c) call forth the appropriate programs for the editing and routine displaying of the data.

Item II. Non ECDEU Forms - This item serves the same purpose as Item I, but requires an alternative set of programs for processing. To insure precise labeling and correct interpretation of data displays, it is strongly suggested that a copy of the instrument - showing items and scale points - be sent to the CCPDD. If the data is composed of factor or cluster scores, their names, and information on their nature should be given. Should the investigator wish to have the CCPDD "factor score" the items on the basis of his own factor analysis, inclusion of the item composition of each factor is required. The more information an investigator can supply about a non-standard data set, the less likely it will be that BLIPS/BDP makes an error.

Item IV.3. Special Analyses - The investigator can describe additional analyses here.

Item V. Patient Identification - This item provides both a clerical and a computer check of patient identity and treatment assignment. The item conveys the necessary information for the identification of data while maintaining the anonymity of the subject. Only the principal investigator will know the identity of the subject and this identity cannot be ascertained from the data package or, later, when the data are entered into the data bank. By asking for treatment assignment once, the rater's task will be reduced, i.e., he need not encode treatment assignment for each subject on several scales.

Item VI. Output - Here the investigator can specify how many copies of the data package and card decks he desires as well as to whom they should be sent. It is necessary to state the number at this time, since a later request for an additional package would require a complete "rerun" of the study. By requesting here that a copy of the data package be sent to another part, e.g., a drug firm, the investigator is assumed to be giving his formal consent for such transmission of data.

Item VII. Dosage Data - By asking for this information here and only once, raters will be spared the task of marking "units" ad nauseum throughout a study. Computer programming will insert "units" in the appropriate data displays.

RESEARCH COMPLETION REPORT (RCR)

RCR Form

The last step in an experimental trial involves the preparation of a summary of the clinical study with a review of its various stages and presentation of the results. From the research findings, it is the responsibility of the investigator to derive his/her conclusions and develop future plans.

The Research Completion Report (RCR) is a form on which pertinent information is gathered about the entire study from planning to execution and results, including investigator's interpretation.

The RCR is utilized after the completion of the clinical trial with the results of data analyses in hand. As such, it should contain the answers (results and interpretations) to the questions asked in the RPR.

If the RPR is a way of "documenting" what is to transpire in the clinical trial, the RCR is a way of "documenting" what had transpired in the clinical trial. It includes information beyond the Narrative Summary, the printout generated through BLIPS/BDP data processing and analyses.

Narrative Summary

The narrative summary provides the investigator with an overview of the study. Though brief, it contains sufficient detail to enable the reader to grasp the essential nature of the study and its results. As with all other segments of the standard package, the narrative summary is non-judgmental and contains only statements based directly on the data received and the analyses performed. Final judgment as to the clinical meaningfulness of the data or the efficacy of the drugs involved remains entirely with the investigator. Narrative summaries consist of 4 paragraphs:

1. Description - Data are derived from the Research Plan Report and consist of details of the research design, the drugs and dosages employed and the research procedures.
2. Efficacy - Derived primarily from variance analyses. All statistically significant findings - or their absence - are cited for each of the psychopathological rating scales employed.
3. Toxicity - Derived primarily from Dosage Record and Treatment Emergent Symptom Scales. Toxicity is described in terms of the number and kinds of symptoms evolving under each treatment condition, as well as the clinical

actions necessitated by the emergence of such symptoms.

4. Demography - Derived primarily from the Adult or Children's Personal Data Inventory. Distribution for a number of pertinent demographic variables are given for each treatment group.

Sample Output

33032 - Welby and Kildare, Normaline, Nirvana State Hospital, Forest Lawn, Calif. 05/22/72.

Description

The purposes of this study involving 10 inpatient, chronic adults with diagnoses of schizophrenia were to determine psychotropic activity and toxicity. The subjects were male and female and their ages ranged from 23 to 51 years. The study was classified as early phase II and the experimental design involved test drug only. The study was conducted under nonblind conditions. A no treatment drying-out period of 2 weeks was utilized. The duration of drug administration was 12 weeks. The test drug, Normaline, was non FDA-approved and was supplied by Creative Drugs. Its presumed clinical action is neuroleptic. Its chemical class is phenothiazine analogues & isosteres. It was administered in capsule form on a fixed/changing schedule. The minimum and maximum daily doses were 20.0 mg and 100.0 mg. No concomitant therapies were permitted for the research population. The assessment schedule consisted of 1 pretreatment rating and 2 ratings at 6 weeks intervals during the course of the study.

Efficacy

All statistical significances cited are at the .05 level or greater. 10 subjects were available for analyses of variance-repeated measures model. On clinical global impressions, significant differences were obtained on the following items : severity of illness, global improvement - all reflecting greater improvement at termination. On the Brief Psychiatric Rating Scale, significant differences were obtained on the following symptoms : emotional, withdrawal, conceptual disorganization, tension, hallucinatory behavior,

unusual thought content and blunted affect and the factors of thinking disorder and anergia - all reflecting improvement at termination; anxiety and the factor of depression - reflecting improvement at week 6 with some dissipation at termination.

Toxicity

Under Normaline conditions, 22 symptoms were reported as occurring 37 times in 7 subjects across 4 rating periods. Efficacy indices (therapeutic effects divided by toxic effects) were : 06 = 1.65; 12 = 2.05. No static symptoms were reported, 3 subjects were asymptomatic throughput the study. Occurrences by symptom clusters were 2.7 percent in adverse behavioral effects, 45.9 percent in central nervous system, 29.7 percent in autonomic nervous system, 21.7 percent in miscellaneous. The most cited symptoms were : rigidity and tremor. Anti-parkinson or other remedial medication was required by 3 subjects. Premature termination of treatment was not required by any subjects.

Demography

All numbers are expressed in percent; NA = not ascertained. Under Normaline conditions, males = 30.0; females = 70.0 : caucasoid = 80.0; race NA = 20.0 : subjects ever married = 30.0; never married = 70.0 : subjects from home situations, conjugal = 20.0; non conjugal = 80.0 : social class distribution was class 3 = 10.0; 4 = 20.0; 5 = 40.0; NA = 30.0 : age distribution by decades was : 3rd = 10.0; 4th = 30.0; 5th = 40.0; 6th = 20.0 : subjects with rapid onset = 10.0; gradual onset = 90.0 : subjects with previous treatment = 100. : subjects with previous hospitalization = 100. : subjects whose age at first hospitalization was less than 20 = 40.0; more than 20 = 60.0 : subjects with history of family mental illness = 30.0; no history of family mental illness = 30.0; history of family mental illness NA = 40.0; schizoid style of life definite = 30.0; questionable = 40.0; NA = 30.0 : symptoms of an affective nature were present = 100. :

subjects whose occupational adjustment was considered marginal = 70.0; inadequate = 20.0; NA = 10.0 : subjects with possible stress = 60.0; precipitating stress NA = 40.0; subjects who entered treatment on initiative of others = 60.0; NA initiative = 40.0; upon admission subjects were cooperative = 40.0; indifferent = 40.0; uncooperative = 20.0; subjects currently hospitalized more than one year = 100; subjects with no concurrent medical conditions = 100. : hospital adjustment prior to study was : withdrawn and vegetative = 60.0; partial ward participation = 40.0 : distribution of diagnoses was schizophrenia = 100.

National Institute of Mental Health (USA) - University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) RESEARCH COMPLETION REPORT (RCR)	Do not write in this box Unit/Study No RPR No RCR No

General Instructions

The Research Completion Report (RCR) is a companion form of the Research Plan Report (RPR). In contrast to the RPR's emphasis on the planning phase of research, the RCR is designed to collect data on the results of the study and the investigator's interpretations and conclusions in a format suitable for computer processing. The two forms - in concert - will provide a better understanding of the research process as well as document the specific study. The investigator is asked to make every effort to complete the form according to the instructions. If aspects of the study cannot be described appropriately under a given item or if the space provided is inadequate for your response, please describe the details on a separate sheet and attach to the form. Specific instructions for this form (RCR) are given on pages , and and should be read PRIOR TO COMPLETING THE FORM.

I. IDENTIFICATION

Name of Investigator/s Address

Title of Study

Planning Phase				Data Collection Phase				Analytic Phase			
Initiated		Completed		Initiated		Completed		Initiated		Completed	
Mo.	Yr.	Mo.	Yr.	Mo.	Yr.	Mo.	Yr.	Mo.	Yr.	Mo.	Yr.

1. Has a Research Plan Report (RPR) for this study been submitted ? 1 _____ yes 2 _____ no

2. If YES, give Unit and Study numbers assigned : _____

   If NO, please complete an RPR for the study.

3. Is this RCR a revision or modification of a previously submitted one ? 1 _____ yes 2 _____ no

   If you concur, the RCR which you submit - in conjunction with the RPR - may be released to the scientific community in the form of a short narrative description of the study. Chemical formulae may be held confidential even if other information is released.

4. May data on this form be given to the scientific community ? 1 _____ yes 2 _____ no

5. Should chemical formulae be held confidential ? 1 _____ yes 2 _____ no

6. Have data from this study been sent to the CCPDD ? 1 _____ yes 2 _____ no

7. If NO, will data be sent ?

Mail this completed form to : Center for Clinical Psychopharmacology Data Documentation
Institute of Clinical Psychiatry
University of Pisa
67, Via Roma
56100 PISA (Italy)

All cards	Do not write here - for CCPDD use only								do not write here
	Unit No	Study No		Revision	Form	Receipt Mo/Year	RPR No	Status	(17-18)
	(2-4)	(5-7)	(8-9)	(10)	(11-12)	(13-16)	(75-78)	(79-80)	0 1
	---	---	--	-	5 9	----	----	--	

II. DISPOSITION OF STUDY

1. Was the study (as a whole) discontinued before its planned completion ? 1 ___ yes 2 ___ no — (19) _

2. Abbreviated ? 1 ___ yes 2 ___ no — (20) _

3. Significantly modified from original protocol (other than by abbreviation) ? 1 ___ yes 2 ___ no — (21) _

   If answers to 1, 2 and 3 are all NO, go to Item 7.

4. If YES to any of the above, was the decision to discontinue/abbreviate/modify made by : (check all applicable) — (22-23) - - / (24-25) - - / (26-27) - -

   01 ___ Investigator
   02 ___ Pharmaceutical firm
   03 ___ Government regulatory agency
   04 ___ Other (specify) _____

5. What was/were the reasons/s for the disposition ? (check most important. Maximum of 3) — (28-29) - - / (30-31) - - / (32-33) - -

   01 ___ Ineffectiveness of drug/s
   02 ___ Occurrence of adverse reactions
   03 ___ Withdrawal or reduction of financial support
   04 ___ Loss of key personnel
   05 ___ Problems in obtaining population
   06 ___ Other (specify) _____

6. If the study was abbreviated or modified, what was/were the procedure/s ? (check most important. Maximum of 3) (34-35)

01 ___	increase	or	07 ___	decrease in sample size
02 ___	increase		08 ___	decrease in dosage
03 ___	extension		09 ___	reduction of duration of treatment
04 ___	addition		10 ___	reduction of frequency of assessment
05 ___	addition		11 ___	deletion of assessment instruments
06 ___	expansion		12 ___	constriction of population (by diagnosis, age, symptoms, etc.)

13 ___ other (specify) _____ (36-37) (38-39)

III. RESEARCH PLAN

	Not applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	
7. Was the research plan satisfactory to test the study hypothesis/es ?	0	1	2	3	4	5	(40)
Duration 8. Was the duration of the drying-out period satisfactory ?	0	1	2	3	4	5	(41)
9. If NO drying-out period was employed in the study, do you, in retrospect, believe one should have been employed ?	0	1	2	3	4	5	(42)

	Not applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	do not write here
10. Was the duration of the drug administration period sufficient ?	0	1	2	3	4	5	(43) -
11. Was the duration of the follow-up period sufficient ?	0	1	2	3	4	5	(44) -
12. If NO follow-up period was employed, do you, in retrospect, believe one should have been employed ?	0	1	2	3	4	5	(45) -
13. For crossover designs, were any of the treatment sequences of insufficient duration ?	0	1	2	3	4	5	(46) -
14. For crossover designs, were there significant "carry-over effects" i.e. one treatment affecting the subsequent treatment ?	0	1	2	3	4	5	(47) -
Dosage Do you feel that optimal dose levels for the test drug/s were attained in this study ?							
15. Test drug No 1	0	1	2	3	4	5	(48) -
16. Test drug No 2	0	1	2	3	4	5	(49) -
If the answer to Item 15 or 16 is box 1, 2 or 3, check reason/s for your judgment. (check most important. Maximum of 3)						17	(50-51) - -
17. Test drug No 1 01 ___ initial dosage too low 02 ___ dosage increased too slowly 03 ___ effective level never reached							(52-53) - -
18. Test drug No 2 01 ___ initial dosage too low 02 ___ dosage increased too slowly 03 ___ effective level never reached							(54-55) - -

17. Test drug No 1 (cont'd)	18. Test drug No 2 (cont'd)	18	do not write here
04 ___ dosage increased too rapidly	04 ___ dosage increased too rapidly		(56-57) - -
05 ___ initial dosage too high	05 ___ initial dosage too high		(58-59) - -
06 ___ effective level exceeded	06 ___ effective level exceeded		(60-61) - -
07 ___ other (specify below)	07 ___ other (specify below)		
_____	_____		

For test vs. comparison drug studies	Not applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	
Was the comparison drug/s utilized in the study aptly chosen, i.e. did it closely resemble the test drug in clinical action ?	0	1	2	3	4	5	(62) -
19. Comparison drug No 1							
20. Comparison drug No 2	0	1	2	3	4	5	(63) -
21. For test vs. comparison drug/s : was dosage equivalence among the drugs achieved ?	0	1	2	3	4	5	(64) -

22. If the answers to items 19, 20 or 21 were box 1, 2 or 3, please describe difficulties.	(65-66) - -
	(67-68) - -
	(69-70) - -

IV. RESEARCH EXECUTION

	Not applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	do not write here (17-18) 0 2
23. Were there problems in the execution of the study, i.e. in the conduct of the trial and collection of the data ?	0	1	2	3	4	5	(19) -
Dosage Administration	0	1	2	3	4	5	(20)
24. As a consequence of its form, i.e. tablet, capsule, etc. were there significant problems in dispensing the test drug medication ?							-
25. Were there significant dosage violations by the subjects or their families, i.e. not taking specified amounts, taking prohibited medications, lapses in medication, etc. ?	0	1	2	3	4	5	(21) -
26. Were there significant dosage deviations by staff in violation of the protocol ?	0	1	2	3	4	5	(22) -
Control Procedures	0	1	2	3	4	5	(23)
27. Were there significant violations of blind conditions by the subjects/families ?							-
28. By the staff ?	0	1	2	3	4	5	(24) -
29. Was there significant introduction by staff of other drug therapies in violation of the protocol ?	0	1	2	3	4	5	(25) -
30. Non-drug therapies ?	0	1	2	3	4	5	(26) -

Assessment Procedures	Adequate ?						do not write here
For the assessment areas listed, rate whether the frequency of assessment and/or sensitivity of the instruments were sufficient to provide an adequate test of your hypotheses.	Not applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	
31. Demographic	0	1	2	3	4	5	(27) _
32. Diagnostic	0	1	2	3	4	5	(28) _
33. Therapeutic efficacy	0	1	2	3	4	5	(29) _
34. Psychometric/performance	0	1	2	3	4	5	(30) _
35. Adverse reactions	0	1	2	3	4	5	(31) _
36. Laboratory tests	0	1	2	3	4	5	(32) _
37. Medical assessment procedures	0	1	2	3	4	5	(33) _
38. Other (specify)	0	1	2	3	4	5	(34-36) _ _ _
39.	0	1	2	3	4	5	(37-39) _ _ _
40. If the answers to any of the above (items 31-39) were box 1, 2 or 3, please describe difficulties :							(40-41) _ _
							(42-43) _ _
							(44-45) _ _

Statistics	Not applicable	Definitely NO	Inclined to say NO	Undecided	Inclined to say YES	Definitely YES	do not write here
41. In multidrug studies, were there significant demographic differences among the groups (treatments) ?	0	1	2	3	4	5	(46) _
42. Were there significant pretreatment differences in severity and/or type of psychopathology among the groups (treatments) ?	**0**	**1**	**2**	**3**	4	5	(47) _
43. Was there differential utilization of permissible concurrent drug therapies, i.e. significantly greater use in one group than another ?	0	1	2	3	4	5	(48) _
44. Differential utilization of permissible non-drug therapies ?	0	1	2	3	4	5	(49) _
45. If CCPDD analyses were performed, were the routine BLIPS/BDP analyses complete and free from significant error ?	0	1	2	3	4	5	(50) _

V. RESEARCH RESULTS

(51-53)

46. How many subjects were screened (evaluated) for the study ? total number _____ _ _ _

(54-56)

47. How many subjects were accepted into the study ? total number _____ _ _ _

What was/were the reason/s for rejection ?

(57-59)

48. _____ (No of subjects) subject refusal _ _ _

(60-62)

49. _____ (No of subjects) family member (guardian) refusal _ _ _

What was/were the reason/s for rejection ? (cont'd)			do not write here
	No of subjects		
50.	_____	psychiatric exclusion criteria	(63-65) - - -
51.	_____	medical exclusion criteria	(66-68) - - -
52.	_____	failure to meet target symptom/diagnostic criteria	(69-71) - - -
53.	_____	other (specify) _____	(72-76) - - - - -
54.	Of the subjects accepted into the study, how many completed the protocol requirements, i.e. completed the planned treatment regime ? total number ____		(17-18) 0 3
			(19-21) - - -
	What was/were the reason/s for premature termination, i.e. failure to complete the protocol ?		
	No of subjects		
55.	_____	subject withdrawal from treatment, i.e. refused continued participation	(22-24) - - -
56.	_____	family (guardian) withdrawal from treatment	(25-27) - - -
57.	_____	protocol violation by subject/family	(28-30) - - -
58.	_____	protocol violation by staff	(31-33) - - -
59.	_____	ineffectiveness of treatment, i.e. deterioration of clinical course	(34-36) - - -
60.	_____	occurence of adverse reaction	(37-39) - - -
61.	_____	intercurrent medical illness	(40-42) - - -
62.	_____	other (specify) _____	(43-47) - - - - -
63.	Of the protocol completers,how many were utilized in major statistical analyses ? total number _____		(48-50) - - -

What was/were the reason/s for exclusion from analyses ?	do not write here
No of subjects	(51-53)
64. _____ missed assessments (due to subject)	- - -
65. _____ missed assessments (due to staff)	(54-56) - - -
66. _____ missing data on assessment instrument/s	(57-59) - - -
67. _____ incorrect rating procedures	(60-62) - - -
68. _____ other (specify)	(63-67) - - - - -
69. Do you consider the rate of attrition : 1 ___ unusually low 2 ___ usual or expected 3 ___ excessive 4 ___ uncertain	(68) -
70. Did the pattern of attrition seem to be (check one) : 1 ___ random 2 ___ systematic 3 ___ uncertain	(69) -
If bias is suspected, in which subset/s (group) of the sample did it occur ? (check all applicable and designate subset by name)	(17-18) 0 4
71. Specific drug (treatment) group test: No 1 = 01, No 2 = 02; comparison: No 1 = 03, No 2 = 04; placebo = 05 Other treatment group (specify)	(19-22) - - - -
72. Specific sex ___ male ___ female	(23-24) - -
73. Specific age group (specify)	(25-28) - - - -
74. Specific diagnostic group (specify)	(29-32) - - - -

	do not write here
75. Specific treatment period - including pretreatment (specify)	(33-36) - - - -
76. Specific treatment agency (ward, hospital, clinic, school, etc.) (Specify): _____	(37-40) - - - -
77. Other subset/s (Specify) _____	(41-46) - - - - - -

Adverse Reactions

What were the clinically important DRUG-RELATED adverse reactions which emerged under the test drug and comparison drug conditions and what was the MOST STRINGENT ACTION required as a consequence of their emergence ? Under column labeled "Drug", indicate under which drug condition/s the symptom emerged (T1, T2, C1, C2, PBO) and then check the most stringent action.

Name of adverse reaction	Action Taken								do not write here
	DRUG	none	increased surveil-lance	contra-active Rx	change dose	change dose plus contra-active RX	suspend RX	dis-continue RX	
		0	1	2	3	4	5	6	(17-18) 0 5
78.									(19-28) _ _ _ _ _ _ _ _ _ _
79.									(29-38) _ _ _ _ _ _ _ _ _ _
80.									(39-48) _ _ _ _ _ _ _ _ _ _
81.									(49-58) _ _ _ _ _ _ _ _ _ _
82.									(59-68) _ _ _ _ _ _ _ _ _ _
83.									(17-18) 0 6 (19-28) _ _ _ _ _ _ _ _ _ _
84.									(29-38) _ _ _ _ _ _ _ _ _ _
85.									(39-48) _ _ _ _ _ _ _ _ _ _
86.									(49-58) _ _ _ _ _ _ _ _ _ _
87.									(59-68) _ _ _ _ _ _ _ _ _ _

VI. STATISTICAL RESULTS

Report all assessment instruments employed - whether or not statistically significant results were obtained on the instrument.

In this latter case, give the name of the scale and write "N.S." under Interpretation of Results.

If CCPDD ANALYSES have been performed :

Do you wish all BLIPS/BDP results incorporated in this section ? 1 ___ yes 2 ___ No

(If YES, you need not enter those results here. They will be entered automatically by CCPDD.)

Name of scale	Name of variable	Type of variable	Type of statistic	Significance level	Type of effect	Interpretation of results

VI. STATISTICAL RESULTS (Cont'd)

Name of scale	Name of variable	Type of variable	Type of statistic	Significance level	Type of effect	Interpretation of results

VII. RESEARCH CONCLUSIONS

Do not write here

card 04 (cont'd)

88. What was/were the hypothesis/es of this study ?

(47-52)

	not applicable	definitely NO	inclined to say NO	undecided	inclined to say YES	definitely YES	
89. Do you feel that the study provided a valid test of the hypothesis/es ?	0	1	2	3	4	5	(53)
90. On balance, do the results support the major hypothesis/es of the study ?	0	1	2	3	4	5	(54)

91. Please describe your conclusions regarding the hypothesis/es

(55-60)

CLINICAL ACTION	do not write here
92. For single test drug/s - was the clinical action of the test drug/s as presumed; i.e., as anticipated or hypothesized ? (check one) 1 ___ Clinical action as presumed with NO unexpected or secondary therapeutic action 2 ___ Clinical action as presumed WITH unexpected or secondary therapeutic action Specify secondary action : _____ 3 ___ Presumed clinical action NOT apparent BUT unexpected secondary action noted Specify secondary action: _____ 4 ___ Presumed clinicalaction NOT apparent and NO unexpected or secondary action noted 5 ___ Other - for responses which cannot be categorized above - please specify: _____	(61-65) - - - - -
93. For combination test drug/s - were the clinical actions of ALL the components as anticipated ? 1 ___ Yes 2 ___ No 3 ___ Undecided	(66) -
94. Comments _____ _____ _____	(67-72) - - - - - - -

CLINICAL COMPARISONS

do not write here

(17-18) 0 7

95. For Test Drug Only studies, i.e. studies in which no comparison (control) drug is employed, which standard drug/s do you feel it most resembles in clinical action ?

_____

_____

(19-28) - - -
- - -

96. In your judgment, what is the dose equivalent of the test drug to the standard/s given in the item above ?

(29-33) - - - - -

97. Comparative index - This item is analogous to the efficacy index which appears on the BLIPS/BDP scale, Clinical Global Impressions. The investigator is asked to judge the overall efficacy and toxicity of the test drug in comparison to the standard drug. Check the ONE single box which best reflects your clinical judgment. (For Test Drug Only studies, compare test drug with standard named in item 95)

Efficacy	Toxicity			
	less toxic	equally toxic	more toxic	much more toxic
	1	2	3	4
4 Greatly superior				
3 Superior				
2 Equivalent				
1 Inferior				

(34-35) - -

CLINICAL INFERENCE	do not write here
98. How do the statistical results compare with clinical judgments ? (check one) 01 ___ no statistical analyses performed 02 ___ statistical results strongly confirm and coincide with clinical judgment 03 ___ statistically, results generally confirm with some exceptions 04 ___ positive statistical findings are not clinically meaningful 05 ___ negative or equivocal statistical findings do not confirm clinical judgment 06 ___ not possible to answer 07 ___ other (specify): _____	(36-37) - -
99. Comments	(38-43) - - - - - -
VIII. FUTURE PLANS	
100. What priority would you assign to any further investigation of this test drug (or hypothesis) ? (check one) highest high moderate low lowest 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ high priority ◄----------► low priority	(44) _

101. What recommendation/s would you make for further research ?
Rank your recommendations (maximum of 3) on the basis of priority :

___ replication of study/hypothesis
___ comparison trial against PBO
___ comparison trial against standard
___ comparison trial against both
___ crossover design
___ larger sample
___ other (specify) _____
___ other (specify _____
___ other (specify) _____
___ dosage alteration
___ different dosage regime
___ duration alteration
___ different population
___ no further investigation

do not write here

(44-50) _ _ _ _ _ _ _

102. Do you plan to conduct further studies of this drug (or hypothesis) at your research unit ?

1 ___ yes 2 ___ no 3 ___ undecided

(51) _

103. What are your plans to publish (disseminate) the results of this study ? (check all applicable)

01 ___ no plans to publish
02 ___ article to be submitted for publication but no decision as to specific journal
03 ___ article submitted to specific journal or book
name of journal or book _____
04 ___ oral presentation of results at professional meeting
specify meeting _____
05 ___ other (specify) _____

(52-55) _ _ _ _

SPECIAL INSTRUCTIONS

The primary purpose of the Research Completion Report (RCR) is to obtain from the investigator a summary of his study and its results. As such, the RCR attempts to document conclusions pertinent to a single drug trial and, simultaneously, assemble a data base for the methodological examination of psychotropic drug trials as a generic process. Investigators are encouraged to amplify any of their responses by the insertion of additional pages. When there are several such "insertions", please label each separate comment with the appropriate item number. To facilitate reference, items are numbered consecutively regardless of headings and subheadings.

I. IDENTIFICATION

Phases of Study - The separation into three phases may be artificial for some studies; e.g., aspects of the analytic phase may be carried out concurrent with data collection. Since the purpose of the item is to obtain estimates of the times required to complete various aspects of clinical trials, investigators are asked to make the best estimates possible within the context of these categories.

Research Plan Report (RPR) - Together, the RPR and RCR constitute a detailed description of a given trial. It is necessary, therefore, to request that investigators complete both of these forms - whether or not they submit the actual data of the trial to the CCPDD.

II. DISPOSITION OF STUDY

Disposition refers to the abandonment, abbreviation or significant modification of the entire study rather than the disposition of individual subjects. Abbreviation refers to reduction in data collection phase from that planned in the original protocol.

III. RESEARCH PLAN and

IV. RESEARCH EXECUTION

These sections contain items to be rated on a five-point scale. A sixth response position, "not applicable", is provided for those items which are not relevant to a given study. For some items, space is provided for 2 test drugs and/or 2 comparison drugs. Be sure to encode your responses in the appropriate boxes.

V. RESEARCH RESULTS

Items in this section describe the course of events from the initial screening pool to the final analytic cohort.

Items 46 through 69 - The investigator is asked to record the numbers of subjects and their dispositions at each step.

Example :

Item	Response
46. Number screened	25
47. Number accepted	20
48. Subject refusal	1
50 Psychiatric exclusion	2
51. Medical exclusion	2
54. Number completers	18
56. Family withdrawal	1
61. Intercurrent illness	1
63. Number used in analysis	16
66. Missing data	2

Note that the investigator omits those items (reasons) which are not pertinent.

Items 71 through 77 - Bias here refers to systematic differences among the treatment groups or other subsets of the sample which tend to distort, restrict or confound the interpretation of the results.

Examples :

72. Specific Sex - A trial in which only males are prematurely terminated.
73. Specific Age Group - Only older subjects show response to treatment.
74. Specific Diagnostic Group - In a trial utilizing subjects with heterogeneous depressive diagnoses, only involutional melancholics show positive change.

75. Specific Treatment Period - Significant pretreatment differences exist among the groups.
76. Specific Treatment Agency - Subjects residing on one of the three wards utilized in a trial show a set of adverse reactions not observed on the other wards.

Items 78 through 87 - Adverse Reactions - Complete this item for all appropriate studies, i.e., Test Drug Only or Test vs. Comparison Drug. Clinically important adverse reactions should include those judged to be drug-related and clinically important on the basis of the stringency of the action undertaken as a consequence of their emergence. "Actions" are aligned in order of stringency, i.e., from "none" to "discontinue RX".

VI. STATISTICAL RESULTS

This section permits the investigator to record all statistical results - BLIPS/BDP and/or his own - that he wishes. The interpretation of all results - including BLIPS/BDP - is the prerogative of the investigator.

Non-significant Results - For those assessment instruments used in the study which do not yield any statistically significant results, record the name of the instrument and write "n.s." or "no significance" under the column "interpretation of results".

Type of Variable - Refers to composition of the variable; e.g.,

I = item	C = cluster
F = factor	T = total score.

Type of Statistic - Refers to statistical operation performed; e.g.,

VAR = analyses of variance - regular model
VAR-R = analyses of variance - repeated measures
COV = analyses of covariance - regular
COV-R = analyses of covariance - repeated measures
T = "t" test
X^2 = chi square

Significance Level - Refers to the probability level to be exceeded if support of the hypothesis being tested is warranted. While the p = .05 level is the "establishment level", investigators may select the level which is considered best to reflect their conclusions.

Type of Effect - Refers to effect in the statistical sense; e.g.,

G = group (treatment) effect

P = period (time) effect

GxP = interaction (group x period)

Interpretation of Effect - Refers to the direction of change, magnitude of effect, differential change, etc.

BLIPS/BDP Results - If the investigator checks "yes", all significant BLIPS/BDP results will be encoded automatically for him. If he wishes to select only part of the BLIPS/BDP interpretation, the investigator should record the appropriate results and check "No" to the question. The investigator may, of course, enter other statistical results in addition to "automatic" BLIPS/BDP results. Examples of encoding are given in Table 1.

VII. RESEARCH CONCLUSIONS

Items 88 through 91 - Hypotheses, in many cases, may correspond to the "purpose/s" recorded on the RPR. Item 90 refers to the clinical hypothesis rather than the statistical one. Example : the null hypothesis states that there is no significant difference between the two treatments; while the clinical hypothesis states that the test drug is more efficacious than the placebo.

Items 92 through 94 - Clinical Action - Complete only the pertinent section/s. Presumed clinical action refers to the verification of the presumed or anticipated main therapeutic action of the drug; i.e., if the drug was presumed to be a neuroleptic, did it indeed exhibit this action during the study. Secondary clinical action refers to the observation of a clinical action other than the presumed one; e.g., a drug which is presumed a neuroleptic exhibits an antidepressant action. A drug may exhibit both its main presumed action and a secondary one or it may not exhibit the presumed action but demonstrate an unexpected one.

Item 95 - Clinical Comparisons - Test Drug Only - If the test drug is unique and does not closely resemble any standard drugs in its clinical action, state this fact.

Item 96 - Dose Equivalent - Make the best estimate of equivalence.
Example : the test drug most resembles chlorpromazine. The investigator might state the equivalence as : 200 mg of test drug = 100 mg of CPZ or: Test drug to CPZ = 2:1.

Item 97 - Comparative Index - Only ONE box should be checked.

Example : the test drug is judged to be equally efficacious to the comparison drug but more toxic. Code as follows :

	Toxicity			
	less toxic	equally toxic	more toxic	much more toxic
4. greatly superior				
3. superior				
2. equivalent			X	
1. inferior				

For Test Drug Only studies, compare the test drug to the standard drug you feel it most resembles; i.e., the one given in Item 95.

Item 98 - Clinical Inference - The purpose of this section is to obtain from the investigator a judgment relating the statistical results to clinically meaningful changes. Essentially, the investigator is asked to judge whether the magnitude and/or direction of the changes obtained by statistical methods - be they significant or not - have clinical relevance.

VIII. FUTURE PLANS

Item 100 - Priority - Refers to the general priority you would set for your own research unit taking into consideration the merits of the study itself in the context of your other research activities. "1" = highest priority; "5" = lowest.

Item 101 - Recommendations- This item requires the ranking rather than mere checking of items. The rankings should reflect the order in which you feel further research might proceed - whether or not you intend to carry out the recommendations at your research unit.

Example : based on the results of a small Test Drug Only study, the investigator recommends that a trial using a standard drug should be undertaken as the next step. He also has a hunch that the drug, a neuroleptic, might have antidepressant effects. He marks a "1" beside "comparison trial against standard" and a "2" beside one of the "others" and specifies that he wishes to examine "antidepressant action".

TABLE I

EXAMPLES of ENCODING STATISTICAL RESULTS

Name of scale	Name of variable	Type of variable	Type of statistic	Significance level	Type of effect	Interpretation of results
BPRS	Anxiety	I	VAR-R	.01	P	test drug - greater improvement across time
	Anergia	F	VAR-R	.05	GxP	test drug - improved at 4th week PBO - worse at 4th week
NOSIE	Total Assets	T	COV	.05	G	comparison drug - greater improvement at termination
Children's Psychiatric Rating scale	Hyper-active	C	VAR-R	.01	POP	population A - greater improvement than pop B
Self-esteem scale	Down-trodden	I	T	.05	G	psychologists - more downtrodden than psychiatrists
CGI	Global Improvement	I	X^2	.05	AGE	younger subjects - greater improvement than older subjects
Attila hostility Scale	Total Score	T	Wilcoxon Sign test	.01	SEX	females - greater increase in hostility than males
O'Reilly sobriety Scale	Total Score	T	VAR-R			n.s.

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU program, the RCR is an instrument designed to collect information on the execution, results and conclusions of a clinical trial in computer-compatible form. Together with the Research Plan Report, the RCR permits a detailed historical reconstruction of the individual trial as well as providing data for subsequent collation with other trials.

APPLICABILITY - For all research populations.

UTILIZATION - Once per study. To be completed after the completion of the trial and the analyses of the data.

SPECIAL INSTRUCTIONS - Investigators should be thoroughly familiar with the instructions printed on the form itself. Since it is impossible to construct a form which will be adequate in all circumstances, investigators are urged to augment their responses - through the use of additional sheets - whenever the constraints of the RCR format make explanations difficult.

At first glance, the RCR looks long and formidable. Investigators should keep in mind, however, that the majority of items require only a checkmark and, in any given trial, not all items are relevant - hence can be omitted. The potential usefulness of this type of data is such that we feel the time and effort involved will be justified.

USE OF THE RCR - When data analyses are performed by the CCPDD, an RCR will be sent to the investigator along with his data package. After reviewing the BLIPS/BDP analyses and any additional analyses that he may have performed, the investigator completes the RCR and returns it to the CCPDD. The form will then be coded and a computer printout of the data will be mailed to the investigator.

NOTE - Investigators are urged, however, to complete an RCR - along with a Research Plan Report - whether or not data are sent to the CCPDD.

DOCUMENTATION - Like its counterpart - the RPR - documentation for the Research Completion Report is two-fold. For the individual study, printouts will be generated - utilizing both RPR and RCR data - to provide an historical narrative. For general documentation, RPR and RCR data will be assembled in a data file for methodological research.

P A R T F O U R

A DOCUMENTATION SYSTEM IN OPERATION

B. DOCUMENTATION OF THE INDIVIDUAL PATIENT

Data collection is the most time-consuming and least appreciated of the three stages of the clinical trial. While everyone would agree that with unreliable data, results, even of the most properly designed clinical study, are of questionable value, little effort is made to ascertain that the collected data are reliable. It is an unfortunate fact that even today, designing is usually done by the "generals" and analysis by their "lieutenants", while data collection is left for the "soldiers". Both designing and data analyses deal with a clinical trial, which essentially is an abstraction. On the other hand, data collection deals with the factual-concrete element of the study and is centred around the individual patient.

Documentation of individual patients is based on the completion of a number of different forms which provide for a record of patients clinical state from admission to discharge in the clinical trial, with adequate information in the contingents, with a possible effect on the experimental subjects. Therefore, data collection in the BLIPS/BDP System include:

- background information - initial evaluation
- assessment of change - evaluation in the course of treatment
- study record - final evaluation.

GENERAL INSTRUCTIONS

To fulfill their purpose, it is absolutely necessary to have all the forms completed in a uniform manner. Completion of a form requires substantive judgement from the assessor (rater). While it is inevitable that different raters may arrive at different judgments from the same observations, the following instructions should increase (improve) consensus among raters participating in the same and/or different clinical studies :

1. Generally, assessment instruments (rating scales) require the rater to assess effects which are directly observable either in word or deed. Inferences should be minimized. While this restricts the rater, variability related to rater experience and theoretical orientation is reduced.

2. With some exceptions, rating scales require a time-limited evaluation, i.e., the presence, absence and/or intensity of symptom at the time of the rating or within a specified time span prior to the rating. For example, on the Children's Psychiatric Rating Scale (CPRS) the subject reports feeling depressed "a couple of months ago, but not now". Since the time span for this item (35) is "now or within the past 7 days", the rater marks the item "not present". At the discretion of the principal investigator and with appropriate communication to the CCPDD, alternative time spans may be specified for a particular study objective. Suggested rating spans, where applicable, are given with each scale.

3. Raters often exhibit a tendency to remain in the conservative center of a scale. When undecided about two alternatives, the rater should choose the response nearer the extreme end of the scale. For example, if undecided whether to rate "mild" or "moderate" on an item in which there has been a positive change from "severe", the rater should choose "mild" - the alternative nearer the positive end of the scale. Similarly, the rater should choose the alternative representing the higher degree of pathology when he is undecided about the severity of illness. In essence, raters should choose the more "radical" response in either the direction of improvement or deterioration.

4. The style of interview is left to the discretion of the rater. Most raters quickly establish a method from which the material necessary for rating can

be extracted. Generally, the method takes the form of a semi-structured interview in which target areas are explored in a more or less consistent sequential fashion. It is suggested, however, that raters not change interviewing techniques during the course of a study.

5. It is strongly urged that every effort be made to maintain the same rater for all assessments of a given subject on a given scale.

6. The processing system has been programmed to expect a response for all items. Raters are, therefore, urged to complete all items on all forms they use. When this is not possible, the rater should utilize the "not ascertained" or "not assessed" response positions. "Not ascertained" should be interpreted as not available, not applicable, no answer , or in situations where the information is considered specious or improbable. "Not assessed" indicates that the rater made no effort to elicit the information.

7. While the investigator has complete freedom to employ any additional assessment techniques he wishes, the standard scales, their formats and items must not be modified or altered. It is imperative that data sent to the CCPDD be constituted under the contexts provided in this manual.

IDENTIFICATION BLOCK (ID)

All data collection forms of the BLIPD/BDP System has the same basic information, referred to as the Identification Block (ID) printed at the top of each page. Accurate encoding of the ID block is of paramount importance. Since experience has shown that errors of omission and commission with in the ID block are a major problem in data editing, raters are urged to be particularly conscientious in completing this block correctly.

Items comprising the ID block consist of non-computerized and computerized data. The non-computerized data include the surname, the first name and the hospital number of the patient; date of completion of the form, and the name of the rater.

The computerized component of the ID block includes eight items :

1) Unit Number (columns 1-3) : the number (given by the CCPDD) of the clinic,

hospital or other facility conducting the study.

2) Study Number (columns 4-6) : the number (given by the CCPDD) of the study, trial or investigation in which the patient is a participant.

3) Subject Number (columns 7-9) : a number assigned to a given patient throughout a given study and employed later in data processing as an anonymous designator. This number is uniformly encoded on all BLIPS/BDP forms for all evaluations. It is customary to have numbers between 001 and 499 to designate males, and numbers between 500 and 999 to designate females. Any three digit number, within the stricture on sex, may be used, although it is the usual practice of investigators to assign numbers sequentially as subjects enter the study. In double-blind studies, care should be taken that the assigned patient numbers do not form a pattern which might reveal treatment assignment. All three digits must always be encoded, including leading and following zeros.

4) Form Number (columns 10-12) : a number assigned to a given rating scale which identifies for the computer the specific assessment instrument. Unlike assessment period numbers which correspond to the time when a particular rating is performed, rating scale numbers remain constant throughout the study. Thus, if a rating scale, e.g., Social Adaptation Scale, is assigned the rating scale number "247" at the initial rating, this number "247" must be assigned to all subsequent rating of the Social Adjustment Scale.

5) Assessment Period (columns 13-15) : a three-digit code which designates the time when a specific rating is made. Two digits are required for the numeric and one digit for the units of time, i.e., hours, days, weeks or months. Time units should be consistent on all scales throughout the study, i.e., one should code week 01, week 02, week 04 or day 01, day 14, day 28 and not week 01, day 14, month 01. While uniform use of any of the time units is acceptable, it is recommended that days be used whenever possible.

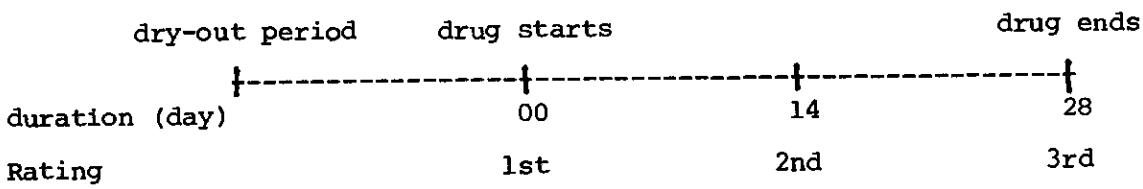
In most studies, assessments are planned at regular intervals (week 00, 02, 04, etc.) although the actual assessment may not be completed on the precise schedule. For uniformity, raters should encode PERIOD according to the study protocol. Example : assessment is scheduled for day 14 but the rater is unable to accomplish it until day 15. Encode day 14 - not 15 - as 15

would appear as an aberrant assessment in subsequent analyses and be deleted. Should a subject be prematurely terminated, however, and an assessment made at the time, encode the real time of the assessment even though it is "off schedule".

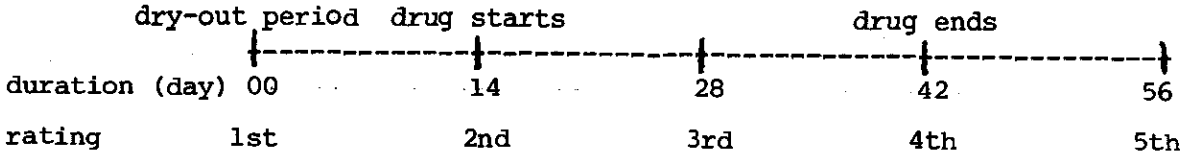
Coding Duration of Study - In order to achieve uniformity within a given study and across different studies, duration of study should - in all cases - be coded in the following manner. The initial rating should be encoded "000". Duration in the study for any subject is counted from the initial rating to the final rating whether or not this time period corresponds to the actual period of drug (treatment) administration. This method of counting is necessary to encompass those studies, in which more than one pretreatment (pre-drug) assessments are made. Similarly, the cessation of treatment may or may not coincide with the final rating. Many studies employ more than one follow-up rating after the treatment (drug) has been stopped. In this coding system, both pretreatment and follow-up phases are included in determining total duration of the study IF assessments are made which span these pretreatment and follow-up phases.

Examples :

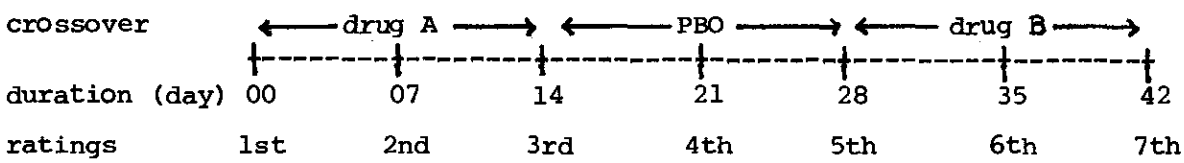
1. The investigator plans to have a 2-week drying-out period following which the first ratings will be made. He then will administer his test drug for 4 weeks. He plans to make additional ratings 2 weeks and 4 weeks after the initiation of treatment. There will be no follow-up assessments. Duration of this study would be calculated and coded as follows :



2. The investigator plans a study exactly as before (1) but adds a rating at the beginning of the drying-out period and 2 weeks following the cessation of drug treatment. Duration in this study would now be calculated and coded as follows :



3. A crossover study is planned in which the sequence, drug A - PBO - drug B will be employed. Each treatment will be of 2-week duration with assessments every week. Duration would be calculated and coded as follows :

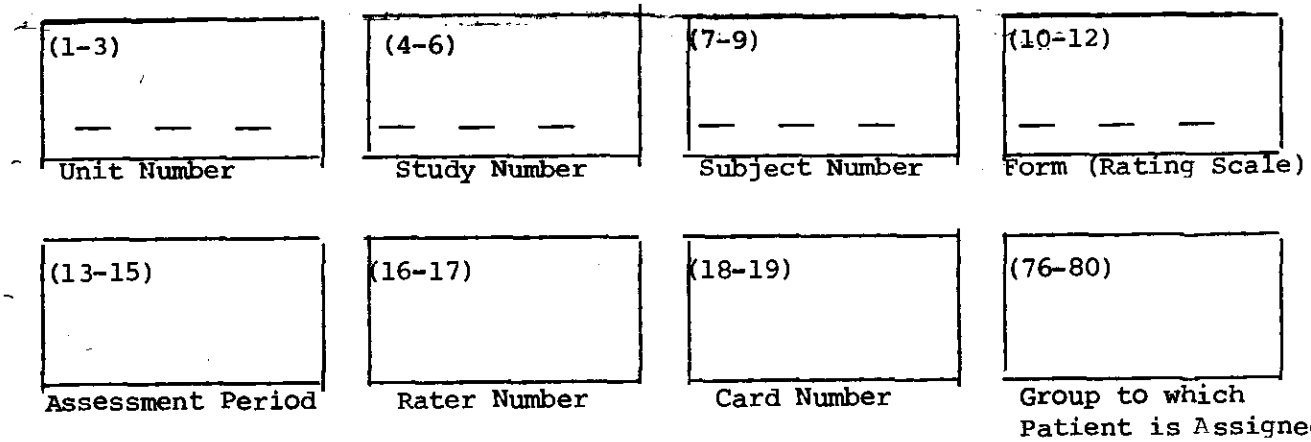


6. Rater Number (columns 16-17) : a two-digit number. Whenever possible, it is advisable that investigators maintain the same numbers for their "permanent" raters, i.e., those who rate in a series of studies. Sections of some of the scales may be completed by different individuals. In these cases, it is recommended to assign the number of that rater who completed the greater portion of the scale.

7. Card Number (columns 18-19) : a two-digit code which identifies the computer card to be used in the data processing. It is standard for all BLIPS/BDP forms.

8. Group to which Patient is Assigned (columns 76-80) : a five-digit code which designates the assignment for each individual subject to specific groups.

The Identification Block has a universal format for all BLIPS/BDP forms :



1. Background Information - Initial Evaluation

Background information is collected on the demographic forms. There are two demographic forms included in the standard BLIPS/BDP Battery : the Children's Personal Data Inventory (CPDI) and the Adult Personal Data Inventory (APDI). Complementing the personal data inventories in the collection of background data are the Social Adjustment Scale (SASII) of Schooler and Hogarty (1978) and the Prior Medication Record (PMR). All these forms are to be completed once only; at the time of admission to the clinical trial.

The demographic forms contain items which require varying degreees of professional "expertise" - from a clinical recording of a well-documented event to subtle judgements of development, motivation and veracity. What is paramount is the rater's ingenuity and persistence in acquiring complete and reliable information.

The manner in which demographic data should be collected is succintly described by Boothe and Schooler (1972) in their Instruction Manual for Brief Social History for Studies in Schizophrenia*:

> "Ideally, the interviewer is so familiar with the content of the instrument that he can lead the discussion to each item in whatever way is most comfortable to the person interviewed, rather than by a rigid adherence to the word order of items in the form. He may not even want to have the form in sight, but may want to rely on his notes to complete the recording after the interview is finished. In any event, it is good practice to check through the form before the informant leaves, to make sure that no items have been overlooked.
>
> The number and length of interviews needed to complete the form depend on a variety of factors, such as the personalities of the informants, their availability for interviews, the style of the interviewer, etc. Whenever possible, the interviewer should obtain a sufficient number of informants to cover the included items in the patient's life span adequately. For a married adult, this ideally means a minimum of two people, a spouse and a parent. Available hospital records as well as additional knowledgeable informants are desirable. In fact, in dealing with schizophrenic patients who may be disconnected from any familial setting, an informant such as the landlady of the rooming-house, a neighbour, or such significant other person may be preferable as a source of

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* Psychopharmacology Bulletin 8 : 23-24, 1972

reliable information about the patient's present circumstances to a relative who has had no real and recent contact with the patient. In each case, the objective is to acquire pertinent, reliable information, whatever the source.

Some of the information requested concerns straightforward, factual matters such as those specified by the first few items in the form. On the other hand, a much larger body of material is not strictly "factual" but is subject to interpretation and the interviewer must often probe for additional illuminating information. For example, the discussion about the patient's past may lead the interviewer to suspect that the patient had been psychiatrically sick before, despite the informant's earlier statement that the present illness was the first. By a skillful question, however, the interviewer may elicit information that confirms or eliminates his hunch.

Every interviewer has to contend with the empirical fact that there is no "one truth" about a mental illness. To reconcile fragments of historical data and to arrive at an interpretation which most closely resembles the "objective truth" is one of the interviewer's most challenging tasks. It requires knowledge, ingenuity, skill and time. There are circumstances, however, which make it impossible to obtain reliable information. In these rare instances, the interviewer is asked to mark "not ascertained" rather than to provide answers which are mainly guesses".

For the determination of occupational attainment in the demographic forms, Hollingshead's (1957) occupational categories* and for the determination of diagnosis the DSM-III and the ICD9-CM are used.

---

* Two Factor Index of Social Positions, 1965, Yale Station, New Haven, Connecticut 1957

Occupational Categories

Code 1. Higher executives, proprietors, of large concerns or major professionals

a. Higher executives
bank presidents; vice-presidents
judges (superior courts)
large businesses, e.g., director, presidents, vice-presidents, assistant vice-presidents, executive secretary, treasurer.
Military, comm. officers, majors & above, officials of the executive branch of Government, federal state, local, e.g., mayor; city manager, city plan director, internal revenue directors.
Research directors, large firms

b. Proprietors of large concerns
brokers
contractors
dairy owners
lumber dealers

b. Major professionals
accountants (CPA)
actuaries
agronomists
architects
artists, portrait
astronomers
auditors
bacteriologists
chemical engineers
chemists
clergymen (professionally trained)
dentists
economists
engineers (college grad.)
foresters
geologists
lawyers
metallurgists
physicians
physicists, research
psychologists, practicing
symphony conductor
teachers, university, college
veterinarians (veterinary surgeons)

Code 2. Business managers in large concerns, proprietors of medium-sized businesses, and lesser professionals

a. Business managers in large concerns
advertising directors
branch managers
brokerage salesmen
district managers
executive assistants
export managers, int. concern
Govt officials, minor, e.g., internal revenue agents
farm managers
office managers
personnel managers
police chief; sheriff
postmaster
production managers
sales engineers
sales managers, national concerns
store managers

b. Proprietors of medium-sized businesses
advertising owners
clothing store owners
manufacturer's representatives
poultry business
contractors
express company owners
fruits, wholesale
furniture business
jewelers
labor relations consultants
purchasing managers
real estate brokers
rug business
store owners
theater owners

c. Lesser professionals
accountants (not CPA)
chiropodists
chiropractors
correction officers
director of community house
engineers (not college grad.)
finance writers
health educators

librarians
military, comm. officers, lts, captains
musicians (symphony orcherstra)
nurses
opticians
pharmacists
public health officers (MPH)
research assistants, university (full-time)
social workers
teachers, elementary and high

Code 3. Administrative personnel, owners of small independent businesses, minor professionals and farmers

a. Administrative personnel
advertising agents
chief clerks
credit managers
insurance agents
managers, dept stores
passenger agents--RR
private secretaries
sales representatives
purchasing agents
section heads, federal, state, and local govt offices
section heads, large businesses and industries
service managers
shop managers
store managers (chain)
traffic managers

b. Owners of small independent businesses
art gallery
auto accessories
awnings
bakery
beauty shop
boatyard
brokerage, insurance
car dealers
cattle dealers
cigarette machines
cleaning shops
5 & 10 cents stores
florist
food equipment
food products
foundry
funeral directors
furniture
garage
gas station
glassware
clothing
coal businesses
contracting businesses
convalescent homes
decorating
dog supplies
dry goods
engraving business
feed
finance co., local
fire extinguishers
painting contracting
plumbing
poultry producers
publicity & public relations
real estate
records and radio
restaurant
roofing contractor
shoe
signs
grocery-general
hotel proprietors
inst. of music
jewelry
machinery brokers
manufacturing
monuments
package store (liquor)
tavern
taxi company
tyre shop
trucking
trucks and tractors
upholstery
wholesale outlets
window shades

c. Minor professionals
actors and showmen
army M/sgt; navy, CPO
artists, commercial
appraisers (estimators)
clergymen (not prof. trained)
concern managers
deputy sheriffs
dispatchers, train
interior decorators

interpreters, Court
laboratory assistants
landscape planners
morticians
oral hygienists
photographers
physiotherapist
piano teachers
radio, TV announcers
reporters, Court
reporters, newspapers
surveyors
title searchers
tool designers
travel agents
yard masters

d. Farmers
owners of large farms

Code 4. Clerical and sales workers, technicians, owners of small businesses, and farmers

a. Clerical and sales workers
bank clerks and tellers
bill collectors
bookkeepers
business machine operators, office
claims examiners
clerical or stenographic
conductors, railroad
employment interviewers
factory storekeeper
factory supervisor
post office clerks
route managers
sales clerks
shipping clerks
supervisors, utilities, factories
toll station supervisors
warehouse clerks

b. Technicians
dental technicians
draftsmen
driving teachers
expeditor, factory
experimental tester
instructors, telephone co., factory
inspectors, weights, sanitary inspectors, etc. factory
investigators
laboratory technicians
locomotive engineers
operators, PBX
proofreaders
safety supervisors
supervisors of maintenance
technical assistants
telephone company supervisors
timekeepers
tower operators, railroad
truck dispatchers
window trimmers (store)

c. Owners of small businesses
flower stand
newsstand
tailor shop

d. Farmers
owners of medium-sized farms

Code 5. Skilled manual employees and farmers

a. Skilled manual employees
auto body repairers
bakers
barbers
blacksmiths
bookbinders
boilermakers
brakeman, railroad
brewers
bulldozer operators
butchers
cabinet makers
cable splicers
carpenters
casters (founders)
cement finishers
cheese makers
chefs
compositors
diemakers
diesel engine repair & maintenance (trained)
diesel shovel operators
machinists (trained)
maintenance foremen
installers, electrical appliances
masons
masseurs
mechanics (trained)

millwrights
moulders (trained)
painters
paperhangers
patrolmen
pattern and model makers
piano builders
piano tuners
plumbers
policemen, city
postmen
printers
radio TV, maintenance
electricians
electrotypers
exterminators
engravers
fitters, gas, steam
firemen, city
firemen, RR
foremen, construction, dairy
gardeners, landscape (trained)
glassblowers
glaziers
gunsmiths
gauge makers
hair stylists
heat treaters
horticulturists
lineman, utility
linoleum layers (trained)
linotype operators
lithographers
locksmiths
loom fixers
repairmen, home appliances
rope splicers
sheetmetal workers (trained)
shipsmiths
shoe repairmen (trained)
stationary engineers (licensed)
stewards, club
switchmen, railroad
tailors (trained)
teletype operators
toolmakers
track supervisors, RR
tractor-trailer trans.
typographers
upholsterers (trained)
watchmakers
weavers
welders
yard supervisors, RR

b. Farmers
owners of little farms
tenant farmers who own farm equipment

Code 6. Machine operators, semi-skilled employees and farmers

a. Machine operators
aides, hospital
apprentices, electricians, printers, steamfitters, toolmakers
assembly line workers
bartenders
bingo tenders
bridge tenders
building superintendents (cust.)
bus drivers
checkers
coin machine fillers
cooks, short order
delivery men
dressmakers, machine
elevator operators
enlisted men, military services
filers, benders, buffers
foundry workers
garage and gas station assistants
greenhouse workers
guards, doorkeepers, watchmen
timers
tyre moulders
trainmen, railroad
truck drivers, general
waiters - waitresses
weighers

b. Semi-skilled employees
hairdressers
housekeepers
meat cutters and packers
meter readers
operators, factory machines
oilers, RR
practical nurses
pressers, clothing
pump operators
receivers and checkers
roofers
set-up men, factories
shapers
signalmen, railroad
solderers, factory
sprayers, paint
steelworkers (not skilled)

stranders, wire machines
strippers, rubber factory
taxi drivers
testers
welders, spot
winders, machine
wiredrawers, machine
wine bottlers
wood workers, machine
wrappers, stores and factories

c. Farmers
tenant farmers who own little equipment

Code 7. Unskilled employees and farmers

a. Unskilled employees
amusement park workers (bowling alleys, pool rooms)
ash removers
attendants, parking lots
cafeteria workers
car cleaners, RR
car helpers, RR
carriers, coal
countermen
dairy workers
deck hands
domestics
farm helpers
fishermen (clam diggers)
freight handlers
garbage collectors
grave diggers
hod carriers
hog killers
hospital workers, unspecified
hostlers, railroad
janitors (sweepers)
laborers, construction
laborers, unspecified
laundry workers
messengers
platform men, railroad
peddlers
porters
roofer's helpers
shirt folders
shoe shiners
sorters, rag & salvage
stagehands
stevedores
stock handlers
street cleaners
unskilled factory workers
truckmen, railroad
waitress
washers, cars
window cleaners

b. Farmers
share croppers

DSM-III *

All official DSM-III codes and terms are included in ICD-9-CM. However, in order to differentiate those DSM-III categories that use the same ICD-9-CM codes, unofficial non-ICD-9-CM codes are provided in parentheses for use when greater specificity is necessary.

The long dashes indicate the need for a fifth-digit subtype or other qualifying term.

DISORDERS USUALLY FIRST EVIDENT IN INFANCY, CHILDHOOD OR ADOLESCENCE

Mental retardation

[Code in fifth digit : 1 = with other behavioral symptoms (requiring attention or treatment and that are not part of another disorder), 0 = without other behavioral symptoms.]

317.0(x) Mild mental retardation, ------
318.0(x) Moderate mental retardation ------
318.1(x) Severe mental retardation ------
318.2(x) Profound mental retardation ------
319.0(x) Unspecified mental retardation ------

Attention deficit disorder

314.01 With hyperactivity
314.00 Without hyperactivity
314.80 Residual type

Conduct disorder

312.00 Undersocialized, aggressive
312.10 Undersocialized, non agressive
312.23 Socialized, aggressive
312.21 Socialized, non aggressive
312.90 Atypical

Anxiety disorders of childhood or adolescence

309.21 Separation anxiety disorder
313.21 Avoidant disorder of childhood or adolescence
313.00 Overanxious disorder

Other disorders of infancy, childhood or adolescence

313.89 Reactive attachment disorder of infancy
313.22 Schizoid disorder of childhood or adolescence
313.23 Elective mutism
313.81 Oppositional disorder
313.82 Identity disorder

Eating disorders

307.10 Anorexia nervosa
307.51 Bulimia

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* Adapted from the Diagnostic and Statistical Manual of Mental Disorders (third edition) of the Americas Psychiatric Association (pages 15-19)

(Eating disorders, cont'd)

307.52 Pica
307.53 Rumination disorder of infancy
307.50 Atypical eating disorder

Stereotyped movement disorders

307.21 Transient tic disorder
307.22 Chronic motor tic disorder
307.23 Tourette's disorder
307.20 Atypical tic disorder
307.30 Atypical stereotyped movement disorder

Other disorders with physical manifestations

307.00 Stuttering
307.60 Functional enuresis
307.70 Functional encopresis
307.46 Sleepwalking disorder
307.46 Sleep terror disorder (307.49)

Pervasive developmental disorders

Code in fifth digit : 0 = full syndrome present, 1 = residual state.

299.0x Infantile autism ------
299.9x Childhood onset pervasive developmental disorder ------
299.8x Atypical ------

Specific developmental disorders

Note : These are coded on Axis II

315.00 Developmental disorder
315.10 Developmental arithmetic disorder
315.31 Developmental language disorder
315.39 Developmental articulation disorder
315.50 Mixed specific developmental disorder
315.90 Atypical specific developmental disorder

ORGANIC MENTAL DISORDERS

Section 1. Organic mental disorders whose etiology or pathophysiological process is listed below (taken from the mental disorders section of the ICD-9-CM).

Dementias arising in the senium and presenium

Primary degenerative dementia, senile onset
290.30 With delirium
290.20 With delusions
290.21 With depression
290.00 Uncomplicated

Code in fifth digit : 1 = with delirium, 2 = with delusions, 3 = with depression, 0 = uncomplicated

290.1x Primary degenerative dementia, presenile onset ------
290.4x Multi-infarct dementia ------

Substance-induced

Alcohol
303.00 Intoxication
291.40 Idiosyncratic intoxication

(Substance-induced, alcohol, cont'd)

291.80 Withdrawal
291.00 Withdrawal delirium
291.30 Hallucinosis
291.10 Amnestic disorder

Code severity of dementia in fifth digit : 1 = mild, 2 = moderate, 3 = severe, 0 = unspecified.

291.2x Dementia associated with alcoholism ------

Barbiturate or similarly acting sedative or hypnotic
305.40 Intoxication (327.00)
292.00 Withdrawal (327.0)
292.00 Withdrawal delirium (327.02)
292.83 Amnestic disorder (327.04)

Opioid
305.50 Intoxication (327.10)
292.00 Withdrawal (327.11)

Cocaine
305.60 Intoxication (327.20)

Amphetamine or similarly acting sympathomimetic
305.70 Intoxication (327.30)
292.81 Delirium (327.32)
292.11 Delusional disorder (327.35)
292.00 Withdrawal (327.31)

Phencyclidine (PCP) or similarly acting arylcyclohexylamine
305.90 Intoxication (327.40
292.81 Delirium (327.42)
292.90 Mixed organic mental disorder (327.49)

Hallucinogen
305.30 Hallucinosis (327.56)
292.11 Delusional disorder (327.55)
292.84 Affective disorder (327.57)

Cannabis
305.20 Intoxication (327.60)
292.11 Delusional disorder (327.65)

Tobacco
292.00 Withdrawal (327.71)

Caffeine
305.90 Intoxication (327.80)

Other or unspecified substance
305.90 Intoxication (327.90)
292.00 Withdrawal (327.91)
292.81 Delirium (327.92)
292.82 Dementia (327.93)
292.83 Amnestic disorder (327.94)
292.11 Delusional disorder (327.95)
292.12 Hallucinosis (327.96)
292.84 Affective disorder (327.97)

(Substance-induced - other or unspecified substance, cont'd)

292.89 Personality disorder (327.98)
292.90 Atypical or mixed organic mental disorder (327.99)

Section 2. Organic brain syndromes whose etiology or pathophysiological process is either noted as an additional diagnosis from outside the mental disorders section of ICD-9-CM or is unknown

293.00 Delirium
294.10 Dementia
294.00 Amnestic syndrome
293.81 Organic delusional syndrome
293.82 Organic hallucinosis
293.83 Organic affective syndrome
310.10 Organic personality syndrome
294.80 Atypical or mixed organic brain syndrome

SUBSTANCE USE DISORDERS

Code in fifth digit : 1 = continuous, 2 = episodic, 3 = in remission, 0 = unspecified.

305.0x Alcohol abuse ------
303.9x Alcohol dependence (alcoholism) ------
305.4x Barbiturate or similarly acting sedative or hypnotic abuse
304.1x Barbiturate or similarly acting sedative or hypnotic dependence ------
305.5x Opioid abuse ------
304.0x Opioid dependence ------
305.6x Cocain abuse ------
305.7x Amphetamine or similarly acting sympathomimetic abuse ------
304.4x Amphetamine or similarly acting sympathomimetic dependence ------
305.9x Phencyclidine (PCP) or similarly acting arylcyclohexylamine abuse ------ (328.4x)
305.3x Hallucinogen abuse ------
305.2x Cannabis abuse ------
304.3x Cannabis dependence ------
305.1x Tobacco dependence ------
305.9x Other, mixed or unspecified substance abuse ------
304.6x Other specified substance dependence ------
304.9x Unspecified substance dependence ------
304.7x Dependence on combination of opioid and other non-alcoholic substance ------
304.8x Dependence on combination of substances, excluding opioids and alcohol ------

SCHIZOPHRENIC DISORDERS

Code in fifth digit : 1 = subchronic, 2 = chronic, 3 = subchronic with acute exacerbation, 4 = chronic with acute exacerbation, 5 = in remission, 0 = unspecified

Schizophrenia
295.1x Disorganized ------
295.2x Catatonic ------
295.3x Paranoid ------
295.9x Undifferentiated ------
295.6x Residual ------

PARANOID DISORDERS

297.10 Paranoia
297.30 Shared paranoid disorder
298.30 Acute paranoid disorder
297.90 Atypical paranoid disorder

PSYCHOTIC DISORDERS NOT ELSEWHERE CLASSIFIED

295.40 Schizophreniform disorder
298.90 Brief reactive psychosis
295.70 Schizoaffective disorder
298.90 Atypical psychosis

NEUROTIC DISORDERS

These are included in affective, anxiety, somatoform, dissociative, and psychosexual disorders. In order to facilitate the identification of the categories that in DSM-II were grouped together in the class of neuroses, the DSM-II terms are included separately in parentheses after the corresponding categories. These DSM-II terms are included in ICD-9-CM and therefore acceptable as alternatives to the recommended DSM-III terms that precede them.

AFFECTIVE DISORDERS

Major affective disorders

Code major depressive episode in fifth digit : 6 = in remission, 4 = with psychotic features (the unofficial non-ICD-9-CM fifth digit 7 may be used instead to indicate that the psychotic features are mood-incongruent), 3 = with melancholia, 2 = without melancholia, 0 = unspecified.

Code manic episode in fifth digit : 6 = in remission, 4 = with psychotic features (the unofficial non-ICD-9-CM fifth digit 7 may be used instead to indicate that the psychotic features are mood-incongruent), 2 = without psychotic features, 0 = unspecified.

Bipolar disorder
296.6x Mixed ------
296.4x Manic ------
296.5x Depressed ------

Major depression
296.2x Single episode ------
296.3x Recurrent ------

Other specific affective disorders

301.13 Cyclothymic disorder
300.40 Dysthymic disorder (or depressive neurosis)

Atypical affective disorders

296.70 Atypical bipolar disorder
296.82 Atypical depression

ANXIETY DISORDERS

Phobic disorders (or phobic neuroses)
300.21 Agoraphobia with panic attacks

300.22 Agoraphobia without panic attacks
300.23 Social phobia
300.29 Simple phobia

Anxiety states (or anxiety neuroses)
300.01 Manic disorder
300.02 Generalized anxiety disorder
300.30 Obsessive compulsive disorder (or obsessive compulsive neurosis)

Post-traumatic stress disorder
308.30 Acute
309.81 Chronic or delayed
300.00 Atypical anxiety disorder

SOMATOFORM DISORDERS

300.81 Somatization disorder
300.11 Conversion disorder (or hysterical neurosis, conversion type)
307.80 Psychogenic pain disorder
300.70 Hypochondriasis (or hypochondriacal neurosis)
300.70 Atypical somatoform disorder (300.71)

DISSOCIATIVE DISORDERS (or HYSTERICAL NEUROSES, DISSOCIATIVE TYPE)

300.12 Psychogenic amnesia
300.13 Psychogenic fugue
300.14 Multiple personality
300.60 Depersonalization disorder (or depersonalization neurosis)
300.15 Atypical dissociative disorder

PSYCHOSEXUAL DISORDERS

Gender identity disorders

Indicate sexual history in the fifth digit of transsexualism code : 1 = asexual, 2 = homosexual, 3 = heterosexual, 0 = unspecified

302.5x Transsexualism ------
302.60 Gender identity disorder of childhood
302.85 Atypical gender identity disorder

Paraphilias

302.81 Fetishism
302.30 Transvestism
302.10 Zoophilia
302.20 Pedophilia
302.40 Exhibitionism
302.82 Voyeurism
302.83 Sexual masochism
302.84 Sexual sadism
302.90 Atypical paraphilia

Psychosexual dysfunctions

302.71 Inhibited sexual desire
302.72 Inhibited sexual excitment
302.73 Inhibited female orgasm
302.74 Inhibited male orgasm

(psychosexual dysfunctions, cont'd)

302.75 Premature ejaculation
302.76 Functional dyspareunia
306.51 Functional vaginismus
302.70 Atypical psychosexual dysfunction

Other psychosexual disorders

302.00 Ego-dystonic homosexuality
302.89 Psychosexual disorder not elsewhere classified

FACTITIOUS DISORDERS

300.16 Factitious disorder with psychological symptoms
301.51 Chronic factitious disorder with physical symptoms
300.19 Atypical factitious disorder with physical symptoms

DISORDERS OF IMPULSE CONTROL NOT ELSEWHERE CLASSIFIED

312.31 Pathological gambling
312.32 Kleptomania
312.33 Pyromania
312.34 Intermittent explosive disorder
312.35 Isolated explosive disorder
312.39 Atypical impulse control disorder

ADJUSTMENT DISORDER

309.00 With depressed mood
309.24 With anxious mood
309.28 With mixed emotional features
309.30 With disturbance of conduct
309.40 With mixed disturbance of emotions and conduct
309.23 With work (or academic) inhibition
309.83 With withdrawal
309.90 With atypical features

PSYCHOLOGICAL FACTORS AFFECTING PHYSICAL CONDITION

Specify physical condition on Axis III.

316.00 Psychological factors affecting physical condition

PERSONALITY DISORDERS

Note : These are coded on Axis II

301.00 Paranoid
301.20 Schizoid
301.22 Schizotypal
301.50 Histrionic
301.81 Narcissistic
301.70 Antisocial
301.83 Borderline
301.82 Avoidant
301.60 Dependent
301.40 Compulsive
301.84 Passive-aggressive
301.89 Atypical, mixed or other personality disorder

V. CODES FOR CONDITIONS NOT ATTRIBUTABLE TO A MENTAL DISORDER THAT ARE A FOCUS OF ATTENTION OR TREATMENT

V65.20	Malingering
V62.89	Borderline intellectual functioning (V62.88)
V71.01	Adult antisocial behavior
V71.02	Childhood or adolescent antisocial behavior
V62.30	Academic problem
V62.20	Occupational problem
V62.82	Uncomplicated bereavement
V15.81	Noncompliance with medical treatment
V62.	Phase of life problem or other life circumstance problem
V61.10	Marital problem
V61.20	Parent-child problem
V61.80	Other specified family circumstances
V62.81	Other interpersonal problem

ADDITIONAL CODES

300.90	Unspecified mental disorder (non-psychotic)
V71.09	No diagnosis or condition on Axis I
799.90	Diagnosis or condition deferred on Axis I

V7109	No diagnosis on Axis II
799.90	Diagnosis deferred on Axis II

ICD-9-CM *

Underlined (dotted) indicates specific ICD-9-CM codes and the categories not included in DSM-III.

The lozenge symbol (□) printed in the left margin preceding the disease code denotes a four-digit rubric unique to ICD-9-CM. The contents of these rubrics in ICD-9-CM are not the same as those in ICD-9.

PSYCHOSES (290-299)

Organic Psychotic Conditions (290-294)

290 Senile and presenile organic psychotic conditions

- 290.0 Senile dementia, uncomplicated
- 290.1 Presenile dementia
  - 290.10 Presenile dementia, uncomplicated
  - 290.11 Presenile dementia with delirium
  - 290.12 Presenile dementia with delusional features
  - 290.13 Presenile dementia with depressive features
- 290.2 Senile dementia with delusional or depressive features
  - 290.20 Senile dementia with delusional features
  - 290.21 Senile dementia with depressive features
- 290.3 Senile dementia with delirium
- 290.4 Arteriosclerotic dementia
  - 290.40 Arteriosclerotic dementia, uncomplicated
  - 290.41 Arteriosclerotic dementia with delirium
  - 290.42 Arteriosclerotic dementia with delusional features
  - 290.43 Arteriosclerotic dementia with depressive features
- 290.8 Other specified senile psychotic conditions
- 290.9 Unspecified senile psychotic condition

291 Alcoholic psychoses

- 291.0 Alcohol withdrawal delirium
- 291.1 Alcohol amnestic syndrome
- 291.2 Other alcoholic dementia
- 291.3 Alcohol withdrawal hallucinosis
- 291.4 Idiosyncratic alcohol intoxication

*Adapted from the International Classification of Diseases, Clinical Modification, Ninth Revision, Commission on Professional and Hospital Activities.

291.5 Alcoholic jealousy

291.8 Other specified alcoholic psychosis

291.9 Unspecified alcoholic psychosis

292 Drug psychoses

292.0 Drug withdrawal syndrome

292.1 Paranoid and/or hallucinatory states induced by drugs

292.11 Drug-induced organic delusional syndrome

292.12 Drug-induced hallucinosis

292.2 Pathological drug intoxication

292.8 Other specified drug-induced mental disorders

292.81 Drug-induced delirium

292.82 Drug-induced dementia

292.83 Drug-induced amnestic syndrome

292.84 Drug-induced organic affective syndrome

292.89 Other

292.9 Unspecified drug-induced mental disorder

293 Transient organic psychotic conditions

293.0 Acute delirium

293.1 Subacute delirium

293.8 Other specified transient organic mental disorders

293.81 Organic delusional syndrome

293.82 Organic hallucinosis syndrome

293.83 Organic affective syndrome

293.89 Other

293.9 Unspecified transient organic mental disorder

294 Other organic psychotic conditions (chronic)

294.0 Amnestic syndrome

294.1 Dementia in conditions classified elsewhere

294.8 Other specified organic brain syndromes (chronic)

294.9 Unspecified organic brain syndrome (chronic)

OTHER PSYCHOSES (295-299)

295 Schizophrenic disorders

295.0 Simple type

295.1 Disorganized type

295.2 Catatonic type

295.3 Paranoid type

295.4 Acute schizophrenic episode

295.5 Latent schizophrenia

295.6 Residual schizophrenia

295.7 Schizo-affective type

295.8 Other specified types of schizophrenia

295.9 Unspecified schizophrenia

296 Affective psychoses

☐ 296.0 Manic disorder, single episode

☐ 296.1 Manic disorder, recurrent episode

☐ 296.2 Major depressive disorder, single episode

☐ 296.3 Major depressive disorder, recurrent episode

☐ 296.4 Bipolar affective disorder, manic

☐ 296.5 Bipolar affective disorder, depressed

☐ 296.6 Bipolar affective disorder, mixed

☐ 296.7 Bipolar affective disorder, unspecified

☐ 296.8 Manic-depressive psychosis, other and unspecified

296.80 Manic-depressive psychosis, unspecified

296.81 Atypical manic disorder

296.82 Atypical depressive disorder

296.89 Other

☐ 296.9 Other and unspecified affective psychoses

296.90 Unspecified affective psychosis

296.99 Other specified affective psychoses

297 Paranoid states

297.0 Paranoid state, simple

297.1 Paranoia

297.2 Paraphrenia

297.3 Shared paranoid disorder

297.8 Other specified paranoid states

297.9 Unspecified paranoid state

298 Other nonorganic psychoses

298.0 Depressive type psychosis

298.1 Excitative type psychosis

298.2 Reactive confusion

298.3 Acute paranoid reaction

298.4 Psychogenic paranoid psychosis

298.8 Other and unspecified reactive psychosis

298.9 Unspecified psychosis

299 Psychoses with origin specific to childhood

299.0 Infantile autism

299.1 Disintegrative psychosis

299.8 Other specified early childhood psychoses

299.9 Unspecified

NEUROTIC DISORDERS, PERSONALITY DISORDERS, AND OTHER NONPSYCHOTIC MENTAL DISORDERS (300-316)

300 Neurotic disorders

300.0 Anxiety states

300.00 Anxiety state, unspecified

300.01 Panic disorder

300.02 Generalized anxiety disorder

300.09 Other

300.1 Hysteria

300.10 Hysteria, unspecified

300.11 Conversion disorder

300.12 Psychogenic amnesia

300.13 Psychogenic fugue

300.14 Multiple personality

300.15 Dissociative disorder or reaction, unspecified

300.16 Factitious illness with psychological symptoms

300.19 Other and unspecified factitious illness

300.2 Phobic disorders

300.20 Phobia, unspecified

300.21 Agoraphobia with panic attacks

300.22 Agoraphobia without mention of panic attacks

300.23 Social phobia

300.29 Other isolated or simple phobias

300.3 Obsessive-compulsive disorders

300.4 Neurotic depression

300.5 Neurasthenia

300.6 Depersonalization syndrome

300.7 Hypochondriasis

300.8 Other neurotic disorders

300.81 Somatization disorder

300.89 Other

300.9 Unspecified neurotic disorder

301 Personality disorders

301.0 Paranoid personality disorder

301.1 Affective personality disorder

301.10 Affective personality disorder, unspecified

301.11 Chronic hypomanic personality disorder

301.12 Chronic depressive personality disorder

301.13 Cyclothymic disorder

301.2 Schizoid personality disorder

301.20 Schizoid personality disorder, unspecified

301.21 Introverted personality

301.22 Schizotypal personality

301.3 Explosive personality disorder

301.4 Compulsive personality disorder

301.5 Histrionic personality disorder

301.50 Histrionic personality disorder, unspecified

301.51 Chronic factitious illness with physical symptoms

301.59 Other histrionic personality disorder

301.6 Dependent personality disorder

301.7 Antisocial personality disorder

301.8 Other personality disorders

301.81 Narcissistic personality

301.82 Avoidant personality

301.83 Borderline personality

301.84 Passive-aggressive personality

301.89 Other

301.9 Unspecified personality disorder

302 Sexual deviations and disorders

302.0 Homosexuality

302.1 Zoophilia

302.2 Pedophilia

302.3 Tranvestism

302.4 Exhibitionism

302.5 Trans-sexualism

302.6 Disorders of psychosexual identity

302.7 Psychosexual dysfunction

302.70 Psychosexual dysfunction, unspecified

302.71 With inhibited sexual desire

302.72 With inhibited sexual excitement

302.73 With inhibited female orgasm

302.74 With inhibited male orgasm

302.75 With premature ejaculation

302.76 With functional dyspareunia

302.79 With other specified psychosexual dysfunctions

302.8 Other specified psychosexual disorders

302.81 Fetishism

302.82 Voyeurism

302.83 Sexual masochism

302.84 Sexual sadism

302.85 Gender identity disorder of adolescent or adult life

302.89 Other

302.9 Unspecified psychosexual disorder

303 Alcohol dependence syndrome

303.0 Acute alcoholic intoxication

303.9 Other and unspecified alcohol dependence

304 Drug dependence

304.0 Opioid type dependence

304.1 Barbiturate and similarly acting sedative or hypnotic dependence

304.2 Cocaine dependence

304.3 Cannabis dependence

304.4 Amphetamine and other psychostimulant dependence

304.5 Hallucinogen dependence

304.6 Other specified drug dependence

304.7 Combinations of opioid type drug with any other

304.8 Combinations of drug dependence excluding opioid type drug

304.9 Unspecified drug dependence

305 Nondependent abuse of drugs

305.0 Alcohol abuse

305.1 Tobacco use disorder

305.2 Cannabis abuse

305.3 Hallucinogen abuse

305.4 Barbiturate and similarly acting sedative or hypnotic abuse

305.5 Opioid abuse

305.6 Cocaine abuse

305.7 Amphetamine or related acting sympathomimetic abuse

305.8 Antidepressant type abuse

305.9 Other, mixed, or unspecified drug abuse

306 Physiological malfunction arising from mental factors

306.0 Musculoskeletal

306.1 Respiratory

306.2 Cardiovascular

306.3 Skin

306.4 Gastrointestinal

306.5 Genitourinary

306.50 Psychogenic genitourinary malfunction, unspecified

306.51 Psychogenic vaginismus

306.52 Psychogenic dysmenorrhea

306.53 Psychogenic dysuria

306.59 Other

306.6 Endocrine

306.7 Organs of special sense

306.8 Other specified psychophysiological malfunction

306.9 Unspecified psychophysiological malfunction

307 Special symptoms or syndromes, not elsewhere classified

307.0 Stammering and stuttering

307.1 Anorexia nervosa

307.2 Tics

307.20 Tic disorder, unspecified

307.21 Transient tic disorder of childhood

307.22 Chronic motor tic disorder

307.23 Gilles de la Tourette's disorder

307.3 Stereotyped repetitive movements

307.4 Specific disorders of sleep of nonorganic origin

307.40 Nonorganic sleep disorder, unspecified

307.41 Transient disorder of initiating or maintaining sleep

307.42 Persistent disorder of initiating or maintaining sleep

307.43 Transient disorder of initiating or maintaining wakefulness

307.44 Persistent disorder of initiating or maintaining wakefulness

307.45 Phase-shift disruption of 24-hour sleep-wake cycle

307.46 Somnambulism or night terrors

307.47 Other dysfunctions of sleep stages or arousal from sleep

307.48 Repetitive intrusions of sleep

307.49 Other

307.5 Other and unspecified disorders of eating

307.50 Eating disorder, unspecified

307.51 Bulimia

307.52 Pica

307.53 Psychogenic rumination

307.54 Psychogenic vomiting

307.59 Other

307.6 Enuresis

307.7 Encopresis

307.8 Psychalgia

307.80 Psychogenic pain, site unspecified

307.81 Tension headache

307.89 Other

307.9 Other and unspecified special symptoms or syndromes, not elsewhere classified

308 Acute reaction to stress

308.0 Predominant disturbance of emotions

308.1 Predominant disturbance of consciousness

308.2 Predominant psychomotor disturbance

308.3 Other acute reactions to stress

308.4 Mixed disorders as reaction to stress

308.9 Unspecified acute reaction to stress

309 Adjustment reaction

309.0 Brief depressive reaction

309.1 Prolonged depressive reaction

309.2 With predominant disturbance of other emotions

309.21 Separation anxiety disorder

309.22 Emancipation disorder of adolescence and early adult life

309.23 Specific academic or work inhibition

309.24 Adjustment reaction with anxious mood

309.28 Adjustment reaction with mixed emotional features

309.29 Other

309.3 With predominant disturbance of conduct

309.4 With mixed disturbance of emotions and conduct

309.8 Other specified adjustment reactions

309.81 Prolonged posttraumatic stress disorder

309.82 Adjustment reaction with physical symptoms

309.83 Adjustment reaction with withdrawal

309.89 Other

309.9 Unspecified adjustment reaction

310 Specific nonpsychic mental disorders due to organic brain damage

310.0 Frontal lobe syndrome

310.1 Organic personality syndrome

310.2 Postconcussion syndrome

310.8 Other specified nonpsychotic mental disorders following organic brain damage

310.9 Unspecified nonpsychotic mental disorder following organic brain damage

311 Depressive disorder, not elsewhere classified

312 Disturbance of conduct, not elsewhere classified

☐ 312.0 Undersocialized conduct disorder, aggressive type

☐ 312.1 Undersocialized conduct disorder, unaggressive type

☐ 312.2 Socialized conduct disorder

☐ 312.3 Disorders of impulse control, not elsewhere classified

312.30 Impulse control disorder, unspecified

312.31 Pathological gambling

312.32 Kleptomania

312.33 Pyromania

312.34 Intermittent explosive disorder

312.35 Isolated explosive disorder

312.39 Other

☐ 312.4 Mixed disturbance of conduct and emotions

312.8 Other specified disturbances of conduct, not elsewhere classified

312.9 Unspecified disturbance of conduct

313 Disturbance of emotions specific to childhood and adolescence

313.0 Overanxious disorder

313.1 Misery and unhappiness disorder

313.2 Sensitivity, shyness and social withdrawal disorder

313.21 Shyness disorder of childhood

313.22 Introverted disorder of childhood

313.23 Elective mutism

313.3 Relationship problems

313.8 Other or mixed emotional disturbances of childhood or adolescence

313.81 Oppositional disorder

313.82 Identity disorder

313.83 Academic underachievement disorder

313.89 Other

313.9 Unspecified emotional disturbance of childhood or adolescence

314 Hyperkinetic syndrome of childhood

314.0 Attention deficit disorder

314.00 Without mention of hyperactivity

314.01 With hyperactivity

314.1 Hyperkinesis with developmental delay

314.2 Hyperkinetic conduct disorder

314.8 Other specified manifestations of hyperkinetic syndrome

314.9 Unspecified hyperkinetic syndrome

315 Specific delays in development

315.0 Specific reading disorder

315.00 Reading disorder, unspecified

315.01 Alexia

315.02 Developmental dyslexia

315.09 Other

315.1 Specific arithmetical disorder

315.2 Other specific learning difficulties

315.3 Developmental speech or language disorder

315.31 Developmental language disorder

315.39 Other

315.4 Coordination disorder

315.5 Mixed development disorder

315.8 Other specified delays in development

315.9 Unspecified delay in development

316 Psychic factors associated with diseases classified elsewhere

MENTAL RETARDATION (317-319)

317 Mild mental retardation

318 Other specified mental retardation

318.0 Moderate mental retardation

318.1 Severe mental retardation

318.2 Profound mental retardation

319 Unspecified mental retardation

CHILDREN'S PERSONAL DATA INVENTORY (CPDI)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
CHILDREN'S PERSONAL DATA INVENTORY (CPDI)

Surname
First Name
Additional Patient ID No
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 4 3
Form Number

(13-15) _ _ _
Assessment Period *

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first two digits are provided for the numeric and the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3, months = 4
Example : 20 days = 202; 3 weeks = 033, pretreatment = 000

Instructions : follow the coding instructions carefully. Complete once for each subject. Please answer all items. If information is not ascertained. mark a field of "9"s, e.g., 9, 99, 999, etc.

1. Identification a. Subject's sex : 1 = male, 2 = female	(20) _
b. Subject's age : mark time units - 1 = months, 2 = years (col. 21) and give numeric (2 digits) (col. 22-23)	(21) _ (22-23) _ _
c. Subject's race is : 0 = caucasoid, 1 = negroid, 2 = mongoloid, 3 = other	(24) _
d. Has subject's residence been : 5 = primarily urban 6 = primarily suburban 7 = primarily rural	(25) _
e. Sibling sequence : subject is the (enter number) (2 digits) child (col. 26-27) of (enter number) (2 digits) children (col. 28-29) Only child is coded "the 01 child of 01 children"	(26-27) _ _ (28-29) _ _
f. Is subject one of twins, triplets, etc. ? 0 = no 1 = yes, homozygous 2 = yes, heterozygous 3 = yes, unknown zygosity	(30) _
g. The subject's present family constellation consists of : (mark all applicable in the corresponding box) 1 = Yes 2 = No 0 = natural mother 1 = natural father 2 = step-parent 3 = adoptive parent/s 4 = paid foster parents 5 = adult relative/s (grandparents. uncles, aunts, etc.) 6 = siblings. step-siblings and/or other children 7 = subject not living with family, is in a non-psychiatric institution 8 = subject not living with family, is in psychiatric institution/unit	(31) 0 _ (32) 1 _ (33) 2 _ (34) 3 _ (35) 4 _ (36) 5 _ (37) 6 _ (38) 7 _ (39) _ 8
2. Parents' Demography a. Is either natural parent : (code both a and b on row 11) dead ? 0 = no 1 = yes, mother 2 = yes, father 3 = yes, both	(41) _

b. divorced or out of home ? 5 = no 6 = yes, mother 7 = yes, father 8 = yes, both	(42) -
c. Mother's age : mother or mother surrogate in the home presently (2 digits) 00 = not applicable	(43-44) - -
d. Father's age : father or father surrogate presently in the home (2 digits) 00 = not applicable	(45-46) - -
Parent's Education e. Mother or present surrogate (code highest level attained for mother) f. Father or present surrogate (code highest level attained for father) 0 = not applicable 5 = some high school (10-11) 1 = graduate professional training 6 = junior high school (7,8,9) 2 = college graduate 7 = less than 7 years of school 3 = some college or technical school 9 = not ascertained 4 = high school graduate	(47) a - (48) b -
Parent's Occupation g. Mother's or female surrogate's present occupational status is : h. Father or male surrogate's present occupational status is : Use this code for g and h : 0 = not applicable 1 = full time gainful employment 2 = part-time gainful employment 3 = unemployed 4 = dependent spouse or student 5 = recipient of public or private assistance	(49) a - (50) b -

i. Mother's or female surrogate's highest occupational attainment is : j. Father or male surrogate's highest occupational attainment is : Use this code for i and j : (see manual for detailed list of occupations) 1 = higher executive, proprietor of large concern, major professional 2 = business manager of large concern, proprietor of medium-sized business, lesser professional 3 = administrative personnel, owner of small independent business, minor professional 4 = clerical or sales worker, technician, owner of little business 5 = skilled manual employee 6 = machine operator, semi-skilled employee 7 = unskilled employee 8 = never worked in paid employment 9 = not ascertained	a b	(51) - (52) -
Has either parent or present surrogate been : (mark one response for each item using this code :) 0 = neither parent 2 = father 1 = mother 3 = both parents k. out of home (3 months or longer) due to physical or mental illness l. separated (3 months or longer) due to marital difficulties m. cruel or abusive (to patient, spouse, siblings, etc.) n. not a steady worker or competent housewife	k l m n	(53) - (54) - (55) - (56) -

3. **Family History of Psychiatric Illness**

Has there been a history of psychiatric illness in family member/s ?

(mark all applicable for each item)

1 = Yes

2 = No

	none of the members	natural mother	natural father	siblings	present mother surrogate	present father surrogate	not ascer-tained
a. Non-psychotic psychiatric disturbance	(57) Yes No	(58) Yes No	(59) Yes No	(60) Yes No	(61) Yes No	(62) Yes No	(63) Yes No
b. Manic-depressive disturbance	(64) Yes No	(65) Yes No	(66) Yes No	(67) Yes No	(68) Yes No	(69) Yes No	(70) Yes No
c. Other major affective disturbance	(71) Yes No	(72) Yes No	(73) Yes No	(74) Yes No	(75) Yes No	(20)* Yes No	(21) Yes No
d. Schizophrenia	(22) Yes No	(23) Yes No	(24) Yes No	(25) Yes No	(26) Yes No	(27) Yes No	(28) Yes No
e. Other psychotic disturbance	(29) Yes No	(30) Yes No	(31) Yes No	(32) Yes No	(33) Yes No	(34) Yes No	(35) Yes No
f. Hospitalized for any psychiatric illness	(36) Yes No	(37) Yes No	(38) Yes No	(39) Yes No	(40) Yes No	(41) Yes No	(42) Yes No
g. Mental deficiency	(43) Yes No	(44) Yes No	(45) Yes No	(46) Yes No	(47) Yes No	(48) Yes No	(49) Yes No
h. Excessive use of alcohol	(50) Yes No	(51) Yes No	(52) Yes No	(53) Yes No	(54) Yes No	(55) Yes No	(56) Yes No
i. Excessive use of drugs	(57) Yes No	(58) Yes No	(59) Yes No	(60) Yes No	(61) Yes No	(62) Yes No	(63) Yes No
j. Imprisonment	(64) Yes No	(65) Yes No	(66) Yes No	(67) Yes No	(68) Yes No	(69) Yes No	(70) Yes No

* Card No. 02

4. Subject's History of Psychiatric Illness

Treatment Status

a. Subject is presently : 1 = not in any type of psychiatric treatment
2 = in psychiatric treatment as an outpatient
(mark one) 3 = in partial hospitalization, e.g., day or night hospital halfway house, etc.
4 = hospitalized (24 hours)

(71) _

b. Prior to this episode, subject:

(mark all applicable in the corresponding box - 1 = Yes, 2 = No)

5 = never had any type of psychiatric treatment
6 = received psychiatric outpatient treatment
7 = received treatment in partial hospitalization setting
8 = received treatment in 24-hour hospital
9 = not ascertained

(72) 5 _

(73) 6 _ (74) 7 _

(75) 8 _ (20)** 9 _

Psychiatric treatment should be interpreted broadly to include all forms of therapy whose basic function is the alleviation of emotional, behavioral or mental disturbance: "Partial hospitalization" and 24-hour hospitalization include all forms of treatment environments in which the subject spends a substantial part of the day or, in the latter case, the full day.

c. Age (years) when first received treatment for psychiatric illness (21-22) _ _

d. Estimate total duration of ALL outpatient psychiatric treatment - exclusive of present episode . . . . . .

(give time units - 0 = days, 1 = weeks, 2 = months, 3 = years, col. 23; and duration - 2 digits - col. 24-25)

Example : subject's total treatment amounts to 10 months.
Code 210. 000 = no outpatient treatment

(23) _

(24-25) _ _

** Card No. 03

e. Estimate total duration of ALL partial hospitalization - exclusive of present episode	(26) _
(give time units : 0 = days. 1 = weeks. 2 = months. 3 = years, col. 26; and duration - 2 digits - col. 27-28) 000 = no partial hospitalization	(27-28) _ _
f. Estimate total duration of ALL hospitalization (24-hour) exclusive of present episode.	(29) _
(give time units · 0 = days, 1 = weeks 2 = months. 3 = years - col. 29; and duration - 2 digits - col. 30-31) 000 = no hospitalization Example : subject's total hospitalization amounts to 4 years. Code 304.	(30-31) _ _
g. Duration of present episode	(32) _
Mark whether coded in 0 = days, 1 = weeks, 2 = months, 3 = years, col. 32; and give duration (2 digits) - col. 33-34. 000 = not applicable.	(33-34) _ _
5. Subject's Developmental History	(35)
a. Pregnancy and neonatal course were : 0 = normal 1 = suspected abnormalities 2 = definite abnormalities 3 = not ascertained	_
b. Were there infant feeding problems ? 4 = yes 5 = no 6 = not ascertained	(36) _
c. Colic ? 7 = yes 8 = no 9 = not ascertained	(37) _
For each of the following items, d through k. record months in 2 digits and judge rate of development on next row :	

d. Age (months) first ate solids - not pureed or strained food	(38-39) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(40) _
e. Age (months) first fed self with a spoon	(41-42) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(43) _
f. Age (months) sat unsupported	(44-45) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(46) _
g. Age (months) first walked by self without holding on	(47-48) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(49) _
h. Age (months) first words other than Mama and Dadda	(50-51) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(52) _
i. Age (months) of speaking 3-word sentences	(53-54) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(55) _
j. Age (months) trained bladder during day	(56-57) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(58) _
k. Age (months) trained bowels	(59-60) _ _
Consider 0 = slow, 1 = normal, 2 = fast	(61) _
l. Age (year) began menstruating (2 digits) - 00 = not applicable	(62-63) _ _
Mark m, n and o all on row 37	(64)
m. Masturbates ? 0 = No 1 = Yes 2 = Not ascertained	_
n. Does he/she dress in clothes or play with toys of opposite sex ? 0 = No 1 = Yes 2 = Not ascertained	(65) _

o. Does he/she express a desire to grow up to be a member of opposite sex ?

6 = No 7 = Yes 9 = Not ascertained

(66) -

6. Subject's School History

a. Current grade placement (2 digits)

Number grades 01-12
20 = preschool 21 = nursery 22 = kindergarten
23 = special or ungraded 24 = not in school

(67-68) - -

Mark both b and c on row 20

b. Child's school history is best characterized by :

0 = not applicable
1 = no significant problems at any time
2 = minor problems or occasional difficulties
3 = major problems seen only in current year
4 = major problems throughout school history with periods of quiescence, "up and down"
5 = major problems almost continually since entrance into school

(69) -

c. In general, academic achievement has been :

6 = above average 7 = average 8 = below average

(70) -

7. Attitude Toward Present Treatment

At pretreatment, the attitudes of the child and his parent/s were ·

(make 2 marks · one for child· one for family - both on row 41)

a. 0 = child positive
1 = child indifferent
2 = child ambivalent
3 = child negative
4 = child's attitude not ascertained

b. 5 = family positive
6 = family indifferent
7 = family ambivalent
8 = family negative
9 = family's attitude not ascertained

(71) a -

(72) b -

*Card No. 04

Date

(70-79)* - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Developed by members of a Pediatric Psychopharmacology Workshop, organized under the auspices of the Psychopharmacology Research Branch of the NIMH (USA) in 1973, the CPDI is a 55-item scale. Its purpose is to gather social and demographic data concerning the child and his family. Wherever possible, items were made compatible with similar items contained in the Adult Personal Data Inventory.

APPLICABILITY - Children to age 15.

UTILIZATION - Once per subject at the time of initial evaluation.

SPECIAL INSTRUCTIONS

Item 1. Identification

Age (b) - Three marks are required : a designation of the time unit in terms of months or years (21) and the number for age (22 and 23).

Race (c) - Subjects of mixed racial heritage should be marked "other".

Residence (d) - Where there is difficulty in deciding primacy of residence, mark the most recent residence.

Siblings sequence (e) - Consider only maternal siblings. Mark the child's position in the sibling sequence first (26-27) and then the total number of siblings (28-29).

Present family constellation (f) - The rater should mark all individuals living together as a family at the start of the study.

Item 2. Parent's Demography

Items 2a and 2b refer to natural parents. Subsequent items (2c through 2n) refer to natural parents or their surrogates - whichever are presently part of the family constellation, i.e., at the beginning of the study. When information about the natural parents is not available, response position "4" may be used to indicate lack of information about death; position "9" to indicate lack of information about divorce.

Parent's occupational states (g and h) - The parent's present occupational states are marked for the mother (49) and the father (50) separately, using the 5 categories given. To the original 5, 3 other categories have been added, i.e.,

6 = part-time employment end recipient of assistance

7 = unemployed and recipient of assistance

8 = dependent student/spouse or recipient of assistance.

It is optional whether to use these additional categories.

The parent's highest occupational status (i and j) - The parent's highest occupational status are marked for the mother (51) and the father (52) separately, using the 8 categories given. The list of occupations adapted from Hollingshead (1957) should be used in classifying specific occupations.

Computation of Social Class

Social class for each parent is computed from their highest educational level and highest occupational level, using the Hollingshead (1957) method. The calculation of computed score for social class is as follows :

			Factor weight		
Occupation score	(1-7)	x	7	=	weighted score
Education score	(1-7)	x	4	=	weighted score
Sum of weighted scores				=	computed score.

Social class is assigned on basis of computed score as follows :

Class	Computed score
I	11 - 17
II	18 - 27
III	28 - 43
IV	44 - 60
V	61 - 77

Example : a graduate of a college nursing program is currently employed as an OR (operating room) supervisor. Her social class is calculated as follows :

Occupation = 2 x 7 = 14

Education = 2 x 4 = 8

22

computed score = 22, social class = 2

Social class for each parent is calculated via programming and documented in the output.

"k" through "n" - Each of these four items requires a single response using the code provided :

0 = item applies to neither parent

1 = item applies to mother only

2 = item applies to father only

3 = item applies to both parents.

Item 3. Family History of Psychiatric Illness

For each of the ten items (a to j), one to five positions may be marked, depending on the number of family members exhibiting the condition.

Item 4. Subject's History of Psychiatric Illness

Present treatment (a) : only one treatment status may be marked.

Prior treatment (b) : as many marks as necessary (maximum of 5) may be used for prior history.

"Psychiatric treatment" should be interpreted broadly to include all forms of generally accepted therapies, i.e., chemotherapy, individual and group psychotherapies, behavior modification, counseling for behavioral or emotional problems, etc., provided by any of the professionally recognized disciplines; e.g., psychiatrist, pediatrician, physician, psychologist, social worker, superviser paraprofessionals, etc.

The code for prior treatment is as follows :

0 = not ascertained
1 = 24-hour hospitalization
2 = partial hospitalization
3 = partial, 24-hour
4 = outpatient
5 = outpatient, 24-hour
6 = outpatient, partial hospitalization
7 = outpatient, partial, 24-hour
8 = never had treatment.

Age when first treated (e) - Mark the age at which the subject first received any psychiatric treatment. To record the fact that the subject has never been "treated", the rater must mark "00" - leaving the item blank will be interpreted as missing data. The code "99" indicates "not ascertained".

Duration of treatments (d to g) - Each of these four items requires a three-digit entry, one digit indicating the time unit and two digits indicating the the numerics for duration. Whichever time unit is employed, mark to the nearest whole unit.

"Outpatient psychiatric treatment" is to be interpreted broadly to include all forms of accepted therapy for behavioral or emotional disorders for which there are no "in-residence" requirements; e.g., outpatient hospital clinics, office visits to private practitioner, "the 50-minute hour", child guidance clinics, etc. "Partial hospitalization" refers to all therapies in which there is a "residency" requirement - either in terms of a certain portion of the day or in terms of a specific living situation; e.g., day hospitals, night hospitals, half-way houses, etc. "24-hour hospitalization" refers to therapies in which full time residency is a requirement; e.g., public or private psychiatric hospitals, psychiatric wards of general hospitals, schools for the emotionally disturbed, etc.

Item 5. Subject's Developmental History

"a"through "c" - Response positions 3 and 6as well as 9 serve as "not ascertained".

"d" through "k" - Each of these items requires the recording of age in months and a judgment of developmental normality. If the information for one of the items is not available, code "999".

The following table - supplied by Dr. Rachel Gittelman-Klein - provides developmental norms for each of the eight items :

	Months		
item	slow	normal	fast
d. First ate solids	13 or more	8-12	7 or less
e. First fed self	24 or more	12-23	11 or less
f. First sat alone	8 or more	5-7	4 or less
g. First walked	14 or more	11-13	10 or less
h. First words	21 or more	12-20	11 or less
i. Speaking sentences	43 or more	24-42	23 or less
j. Trained bladder	29 or more	18-28	17 or less
k. Trained bowels	25 or more	15-24	14 or less

Developmental History Score - Items 5d through 5k are used to calculate a developmental score. Using the 3-point scale, the 8 items are added together and the sum is divided by the number of items minus "not ascertained". Five of the 8 items must be present, however, for a score to be computed. Developmental scores below one reflect slower development; those above one reflect accelerated development.

Other developmental inventories which may be of interest are :

1. Frankenburg, W.K. and Dodds, J.B., The Denver Developmental Screening Test, J. Pediatrics, 71, 2, 181-191, August 1967.

2. Ireton, H.R. and Thwing, E.J., Minnesota Child Development Inventory, published by Interpretive Scoring Systems, 4401 W. 76th St., Minneapolis, Minnesota, 1972.

Age of menstruation (1) - This item requires the marking of the year of menarche. The code "00" - not two blanks - indicates "not applicable"; the code "99" indicates "not ascertained". No judgement of developmental normality is required.

"m" through "o" - Response positions 2 and 5 as well as 9 serve to indicate "not ascertained".

Item 6. Subject's School History

Current grade placement (a) - give 2-digit numeric code for grades 01 through 12 or use the following special codes :

20 - preschool
21 - nursery
22 - kindergarten
23 special or ungraded
24 not in school
99 - not ascertained.

When child is in-between grades, e.g., has finished the fourth grade and is about to enter (promoted to) the fifth, encode the higher grade (05).

"b" through "c" - Both require a "global judgement", i.e., an overall characterisation of the child's behavior and academic achievement.

Item 7. Attitude Toward Present Treatment

Judgements of both the child's (a) and the family's (b) attitudes are required. Note that response positions 4 as well as 9 are used to indicate "not ascertained".

DOCUMENTATION

a. Raw score printout
b. Frequency tables
c. Cross-tabulations

ADULT PERSONAL DATA INVENTORY (APDI)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
ADULT PERSONAL DATA INVENTORY (APDI)

Surname
First Name
Additional Patient ID Number
Date
Name of Rater

(1-3)
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 4 5
Form Number

(13-15) _ _ | _
Assessment period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first two digits are provided for the numeric and the third for the unit of time.

Time units : pretreatment = 0, hours = 1, days = 2, weeks = 3, months = 4
Example : 20 days = 202, 3 weeks = 033, pretreatment = 000

1. Subject's age (two digits) :	(20-21)
2. Subject's sex : 1 = male 2 = female	(22)
3. Subject's race : 0 = caucasoid 1 = negroid (mark one) 2 = mongoloid 3 = other	(23)
4. Marital status : 0 = never married 1 = presently married for first time (mark one) 2 = presently married with previous marriage/s 3 = previously but not presently married (separated or divorced) 4 = previously but not presently married (widowed)	(24)
5. Socioeconomic status a. Occupation - Use scale given below for 1 and 2. See Manual for detailed list of occupations. 1. Subject's highest occupational attainment is	(25)
2. Head of Household's highest occupational attainment is If subject is Head of Household, code "0" here	(26)
1 = higher executive, proprietor of large concern, major professional 2 = business manager of large concern, proprietor of medium-sized business, lesser professional 3 = administrative personnel, owner of small independent business, minor professional 4 = clerical or sales worker, technician, owner of little business 5 = skilled manual employee 6 = machine operator, semi-skilled employee 7 = unskilled employee 8 = never worked in paid employment 9 = not ascertained	

b. Education

1. Using scale provided, code highest level attained by the SUBJECT. (27) -

2. Code highest level attained by HEAD of HOUSEHOLD.
If subject is head of household, code "0" here. (28) -

1 = graduate or professional training (individuals who have completed or who have attended one year of a recognized professional course)
2 = college or university graduate (individuals who have completed a four-year college or university course leading to a recognized college or university degree)
3 = partial college training (individuals who have completed at least one year but not a full college course; individuals who have attended at least one year of, or who have completed a recognized junior college, technical school, nursing school, etc.)
4 = high school graduate (private preparatory, public, parachial or trade school)
5 = partial high school (individuals who completed grades 10 or 11 but did not complete high school)
6 = junior high school (individuals who completed grades 7, 8 and 9)
7 = less than 7 years of school
9 = information not available

6. Treatment Status (29) -

a. Subject is presently : (mark one)

1 = not in any type of psychiatric treatment
2 = in psychiatric treatment as an outpatient
3 = in partial hospitalization, e.g., day or night hospital, halfway house, etc.
4 = hospitalized (24-hour)

b. Prior to this episode, subject has : (30) -

(mark all applicable in corresponding box; 1 = no, 2 = yes)

1 = never had any type of psychiatric treatment (30)
2 = received psychiatric outpatient treatment (31) (31) -

(b. Prior to this episode, subject has - cont'd) 3 = received treatment in partial hospitalization setting (32) 4 = received treatment in 24-hour hospital (33) 5 = not ascertained (34)	(33) —	(32) - (33) - (34) -
"Psychiatric treatment" should be interpreted broadly to include all forms of therapy whose basic function is the alleviation of emotional, behavioral or mental disturbance. "Partial hospitalization" and "24-hour hospitalization" include all forms of treatment environments in which the subject spends a substantial part of the day or, in the latter case, the full day.		
7. Duration of Present Episode Code whether in : 0 = days, 1 = weeks, 2 = months, 3 = years, and give length. Examples : present episode = 11 weeks - code 111 " " = 3 months - code 203 " " = 4 years - code 304		(35) - (36-37) - -
8. Primary Psychiatric Diagnosis a. Indicate nosological system used - 1 = DSMIII; 2 = ICD-9-CM		(38) -
b. Code diagnosis from those listed in ECDEU Manual using 4 digits for DSMIII or 3 digits for ICD-9-CM		(39-42) - - - -
c. Secondary psychiatric diagnosis Use same nosological system as 8a. If no secondary diagnosis, code field 0000		(43-46) - - - -

9a. Significant Current Medical Conditions ? If "no", 9b and 9c may be left blank.	1 = yes 2 = no	(47) _
b. If YES, give ICD-9 code for illness (3 digits) See Manual for ICD-9 list of diseases. Maximum of 2 conditions may be entered at 9b and 9c.		(48-50) _ _ _
c. Second medical condition (3 digits) Code 000 if no second condition.		(51-53) _ _ _
10. Are the following items (11-15) to be completed for this Subject ? If YES, continue with item 11 on L-10	1 = yes 2 = no	(54) _
11. Current Condition (present episode) a. The current condition (present episode) is best characterized as : 1 = indistinguishable from the past; continuation of long-standing condition 2 = exacerbation of chronic condition 3 = recurrence of similar previous condition 4 = significantly different from any previous condition 5 = first occurrence with no previous psychiatric illness		(55) _
b. Onset of current condition was : 1 = sudden - less than 4 weeks 2 = gradual - one to several months 3 = very gradual - one to several years		(56) _
c. Precipitating external stress was : 0 = absent 1 = probably present 2 = definitely present		(57) _

12. Subject's Psychiatric History a. Age when first received any treatment for psychiatric illness (2 digits) 00 = never treated	(58-59) - -
b. Age when first hospitalized for psychiatric illness (2 digits) 00 = never hospitalized	(60-61) - -
c. Estimate total duration of ALL outpatient psychiatric treatment - exclusive of present episode Give time unit : 0 = days, 1 = weeks, 2 = months, 3 = years, and duration (2 digits) Example : subject's total treatment amounts to 10 months : code 210. 9-99 = not ascertained, 000 = no outpatient treatment	(62) - (63-64) - -
d. Estimate total duration of ALL partial hospitalization - exclusive of present episode Give time units : 0 = days, 1 = weeks, 2 = months, 3 = years; and duration 9-99 = not ascertained, 000 = no partial hospitalization	(65) - (66-67) - -
e. Estimate total duration of ALL hospitalizations (24-hour) - exclusive of present episode Give time units : 0 = days, 1 = weeks, 2 = months, 3 = years; and duration Example : subject's total hospitalization amounts to 4 years : code 304 9-99 = not ascertained, 000 = no hospitalization	(68) - (69-70) - -
f. Number of hospitalizations 0 = none; 1, 2, 3, 4, 5, 6, 7; 8 = 8 or more; 9 = not ascertained	(71) -

(12. Subject's Psychiatric History - cont'd)

g. Does subject have a history or:

1. excessive use of alcohol (72)
2. excessive use of tobacco (73)
3. excessive use of opiates (74)
4. excessive use of marijuana (75)
5. excessive use of sleeping pills or sedatives (20)
6. excessive use of amphetamines/stimulants (21)
7. excessive use of hallucinogens (22)
8. excessive use of other drugs (23)
9. imprisonment (24)
10. sexual deviation (25)
11. suicidal attempts (26)
12. contributory physical illness or injury (27)

0 = no, 1 = yes but not within last year, 2 = yes, only within last year.
3 = yes, both in past and last years, 9 = not ascertained

(72)	-
(73)	-
(74)	-
(75)*	-
(20)	-
(21)	-
(22)	-
(23)	-
(24)	-
(25)	-
(26)	-
(27	-

*Card No. 02

13. Family Psychiatric History

Among family members (lineal and conjugal), has there been a history of :

(mark all applicable in the appropriate rows; 1 = yes, 2 = no)

	no history in lineal & conjug. family members	no history in parents or siblings	mother	father	siblings	no history in spouse or children	spouse	children	Not ascert-ained
a. Non psychotic-psychiatric disturbance	(28)	(29)	(30)	(31)	(32)	(33)	(34)	(35)	(36)
b. Manic depressive disturbance	(37)	(38)	(39)	(40)	(41)	(42)	(43)	(44)	(45)
c. Other major affective disturbance	(46)	(47)	(48)	(49)	(50)	(51)	(52)	(53)	(54)
d. Schizophrenia	(55)	(56)	(57)	(58)	(59)	(60)	(61)	(62)	(63)
e. Other psychotic disturbance	(64)	(65)	(66)	(67)	(68)	(69)	(70)	(71)	(72)
f. Suicide	(73)	(74)	(75)	(20)*	(21)	(22)	(23)	(24)	(25)
g. Hospitalization for any psychiatric illness	(26)	(27)	(28)	(29)	(30)	(31)	(32)	(33)	(34)
h. mental deficiency	(35)	(36)	(37)	(38)	(39)	(40)	(41)	(42)	(43)
i. Excessive use of alcohol	(44)	(45)	(46)	(47)	(48)	(49)	(50)	(51)	(52)
j. Excessive use of drugs	(53)	(54)	(55)	(56)	(57)	(58)	(59)	(60)	(61)
k. Imprisonment	(62)	(63)	(64)	(65)	(66)	(67)	(68)	(69)	(70)

*Card No. 03.

14. Living Situation (71)

a. In the 3 years preceding the present episode, the subject's residence has been :

1 = primarily urban
2 = primarily suburban
3 = primarily rural

b. Family type during this period has been : (72)

1 = parental or lineal - patient does not carry major responsibility for the home; it is either the home of his family of origin or of his children. Code foster home here.

2 = conjugal - the patient or his spouse carries major responsibility for the home; the household may include his parents and/or any children.

3 = collateral - home is not the responsibility of the patient, his parents or children, but of a sibling, aunt or some other non-linear relative.

4 = alone - patient maintains - wholly or in part - his own quarters. Home may be shared with others not related to the patient, or he may live in a rooming house, dormitory, etc.

15. Role Performance (73)

a. Subject's present occupational status is :

0 = not applicable
1 = full time gainful employment
2 = part-time gainful employment
3 = unemployed
4 = dependent spouse or student
5 = recipient of public or private assistance
6 = 2 + 5
7 = 3 + 5
8 = 4 + 5
9 = not ascertained

(15. Role Performance, cont'd) b. In the past 3 years, subject has been gainfully employed : 1 = briefly or not at all 2 = less than half of the time 3 = half of the time 4 = most of the time 5 = virtually all of the time 9 = not ascertained	(74) –
c. His/her employment has been limited primarily by : (max. 2 responses - 1 = yes, 2 = no) 0 = not limited (75)	(75) –
1 = going to school (20)	(20)* –
2 = household responsibilities (21)	(21) –
3 = job market(22)	(22) –
4 = retirement (23)	(23) –
5 = physical illness (24)	(24) –
6 = psychopathology (25)	(25) –
7 = institutionalization (26)	(26) –
9 = not ascertained (27)	(27) –
d. The subject's work performance (whether in job, household or as student) during the past 3 years is best characterized as : 0 = not applicable 1 = marked decline in effectiveness 2 = some decline in effectiveness 3 = adequate with no change in effectiveness, static 4 = some increase in effectiveness 5 = variable, fluctuating in degree of effectiveness	(28) –

*Card No. 04.

(15. Role Performance, cont'd)

e. The subject's social functioning during the past 3 years is best characterized as :

. 1 = marked decline in competence
2 = some decline in competence
3 = adequate with no change in competence, static
4 = some increase in competence
5 = marked increase in competence
6 = variable, fluctuating in degree of competence

(29) -

	(70-75)		
Date:	- -	- -	- -

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU-program, the APDI is a 55-item scale. Its purpose is to describe the social and demographic background of the subject. Evolving from the now obsolete Patient Personal Data Inventory, the APDI has beedesigned to cover a greater diversity of subject types than its forbear. Most of the items from the original inventory have been retained, although the majority have been modified to increase their universality. Items numbered 1 through 10 constitute the basis minimum of necessary demographic information. Items numbered 11 through 15 are considered supplemental, although they represent the types of information most investigators commonly collect.

APPLICABILITY - All adult populations.

UTILIZATION - Once per subject at the time of initial evaluation.

SPECIAL INSTRUCTIONS - Items numbered 1 through 10 must be completed. No data will be processed by CCPDD without completion of these 10 items for each subject.

Item 1. Age - Mark the subject's age to the nearest whole year. Since "99" is employed as a "missing" or "not ascertained" code, no subject can be 99 years of age - or, for that matter, any older - in this system. Any bias introduced by halting time at 98, however, would appear acceptable.

Item 2. Race - Subjects whose racial heritage is melanesoid, australoid or mixed should be marked as "other" (3). In geographical areas where these racial types are prevalent, rater may encode melanesoid as 4; australoid as 5, and mixed as 6. "Unknown" racial heritage should be marked as 9.

Item 4. Maritas Status - The choice of categories is almost always straightforward. In the event that the subject could be classified as both "3" and "4", mark the most recent status, e.g., the subject's first marriage ended in divorce, the second in the death of the spouse. Mark as 4 (widowed). Code "5" may be used to designate common law relationships, i.e., living in a conjugal situation without legal status.

Item 5. Socioeconomic Status - Occupation (a) and education (b) require ratings of the subject and/or the head of household. If the subject is also the head of

household, only one actual rating is required - "0" being marked for both head of household's occupation (a/2) and education (b/2).

The list of occupation adapted from Hollingshead (1957) should be used in classifying specific occupations.

Computation of Social Class

Social class is computed from the highest educational level and highest occupational level, using the Hollingshead (1957) method.

Item 6. Treatment Status - While only one response is marked for present treatment (a), a maximum or 3 responses may be marked for prior treatments (b). The items "psychiatric treatment", "outpatient", "partial hospitalization","24-hour hospitalization", should be interpreted broadly.

Item 7. Duration of Present Episode - A 3-digit entry is required : one digit to indicate the time unit; 2 digits for the numeric for duration. Whichever time unit is employed, mark the nearest whole unit.

Item 8. Nosological System - The rater may use one of two nosological systems (a), i.e., DSM-III or ICD-9-CM. For psychiatric diagnosis (b), mark diagnosis on the basis of chosen system. The same applies to secondary psychiatric diagnosis (c).

Item 9. Significant Current Medical Condition - If no significant current medical conditions are present, items 9b and 9c may be left blank. No error citations will occur since the "no" response to item 9a is a programming signal. A "yes" response to the item requires that the rater then must encode responses for items a and/or b.

Medical Condition Number 1 (b) - The rater selects the 3-digit code appropriate to his diagnosis from the ICD-9 and marks it.

Medical Condition Number 2 (c) - Rater identifies and marks second significant medical condition.

Item 10. This is a mandatory item. It is a programming signal as well as a statement of fact. In responding "yes", the rater commits himself to respond to all of the remaining items (11-15).

Item 11. Current condition (a) - Only one response is permitted. Select the category which best describes the subject's current condition.

1) Indistinguishable from the past - refers to those conditions which have exhibited little, if any, variation in intensity or floridity from the previous status.

2) Exacerbation of chronic condition - refers to an intensification (flare-up) of a previously stable (static) condition.

3) Recurrence of similar previous condition - refers to recurrent episodes of illness. Differs from 2 in that there are symptom-free periods between episodes.

4) Significantly different from previous condition - refers to a present condition which can be clearly distinguished from any in the subject's past.

5) First occurence - refers to the initial recognized episode of psychopathology. Differs from 4 in that there is no prior history of illness.

Item 12. Subject's Psychiatric History - The several parts of this item (a-f) ask for the temporal aspects of some of the events in the subject's history. The information necessary to answer the items is not always complete or precise and the rater is urged to make the best estimates possible.

"a" and "b" - These 2 items require a 2-digit code for age in years. Mark age in the nearest whole year. Mark "99" if the subject is known to have been treated and/or hospitalized, but the age is "not ascertained".

"c" through "e" - Each of these items requires a 3-digit code : one digit to indicate the time unit and 2 digits to indicate the numeric for duration. To indicate that the subject has not received one or more of the treatments, the rater must mark "000". Do not leave blank; rather mark "999" when data is "not ascertained".

Each of the items (g/1-12) ask whether the event has been present in the subject's recent (within the last year) and/or past (beyond the last year) history. Do not leave blanks. Mark 9 for "not ascertained".

Item 13. Family Psychiatric History - This item gathers information on the presence of a variety of psychiatric illnesses within both the subject's lineal and conjugal families. For each of the items (a through k), record the presence or absence of the characteristics among family members by marking all appropriate response positions. The code "0" indicates the absence of the characteristic in both lineal and conjugal family members. The code "1" indi-

cates the absence of the characteristic among the subject's lineal family members only, i.e., the subject's parents and/or his siblings. The code "5" indicates absence among the subject's conjugal family members only, i.e., the subject's spouse and/or his children.

Item 14. Living Situation - Subject's residence (a) - If the subject's residence has been split approximately 50 percent between 2 of the categories, mark the most recent residence.

Family type (b) - In circumstances analogue to those cited in item (a), mark the most recent family type.

Item 15. Role Performance - "a" and "b" - Only one response is marked for each.

His/her employment has been limited primarily by (c) - A maximum of 2 responses may be marked.

"d" and "e" - These items attempt to characterize the course of work performance (d) and social functioning (e) during the past 3 years by a "global judgment".

"Work performance" should be interpreted in a general way to include effectiveness as a housekeeper or student as well as effectiveness in gainful employment. For subjects who have been hospitalized for the 3-year period, rate their performance in industrial therapy, ward assignements, etc. Similarly, the social functioning of inpatients should be rated in the context of the hospital setting.

DOCUMENTATION - a) Raw score printout
b) Frequency tables
c) Cross - tabulations

SOCIAL ADJUSTMENT SCALE (SASII)

GENERAL INSTRUCTIONS

FORMAT : TEXT IN UPPER CASE REPRESENTS INSTRUCTIONS TO THE INTERVIEWER. TEXT IN BOTH UPPER AND LOWER CASE IS TO BE READ TO THE SUBJECT. PHRASES IN PARENTHESES SHOULD BE REPLACED BY TERM APPROPRIATE TO PERSON BEING INTERVIEWED. FOR EXAMPLE -- (date) "the first of the year", (he) "your husband", "your cousin", "her". TEXT IN DOUBLE PARENTHESES ((Has anyone had to talk to you about your work ?)) ARE PROBE QUESTIONS WHICH ONLY NEED TO BE ASKED IF INSUFFICIENT INFORMATION IS PROVIDED BY THE LEAD QUESTIONS. LEAD QUESTIONS MUST ALWAYS BE ASKED. NON-SPECIFIC PROBES SUCH AS -- Could you tell me more about that ? Could you give me an example ? Anything else ? -- ARE ALWAYS IN ORDER. IT IS ALSO PERMISSIBLE TO REPEAT WHAT THE SUBJECT HAS SAID AS A QUESTION TO ELICIT FURTHER INFORMATION. OTHER THAN THESE NON-SPECIFIC PROBES, OTHER QUESTIONS SHOULD BE MINIMIZED. DEFINED ANCHOR POINTS FOR EACH ITEM ARE SET OFF BETWEEN LINES AND NUMBERED. ONLY THE NUMBERS ARE TO BE ENTERED ON THE RECORDING SHEET.

IF NECESSARY, PHRASES FROM CATEGORIES MAY BE READ TO SUBJECT. ALWAYS READ AT LEAST TWO CATEGORIES AND ALTERNATE ORDER, i.e. HIGHER OR LOWER FIRST.

INTRODUCING INTERVIEW TO SUBJECT

THE INTRODUCTION HAS TWO MAJOR PURPOSES :

1. TO LEGITIMIZE THE INTERVIEWER AND
2. TO ESTABLISH THE TIME PERIOD IN QUESTION BY GIVING ANCHOR POINTS.

(Doctor or other authority) is interested in finding out how you have been doing in the last 2 months. That would be from (date) to now. I'll be asking you some questions about your work, your family life and your free time; reading some of the questions just to be sure I get them right and making a note of your answers. Try to answer all the questions for the last 2 months. Have you been on a vacation, living away from home, or any other change like that ? If any question does not make sense to you, let me know. Do you have any question before we start ?

Are you married ? IF YES : do you live with your (spouse) ? Anyone else in the household ? IF NO : who lives with you ? Anyone else ?

AREA I - WORK

ASK ALL SUBJECTS : how old are you ? How far did you go in school ? Are you still in school ?

WOMEN - Do you usually have a full or part-time job outside your home ? IF YES : what is your usual job ? Have you been working at all since (date) ?

MEN - What is your usual job ? Have you been working at all since (date) ?

1. WORK ROLE (20)

FOR THE PURPOSES OF THIS SCALE, A PERSON IS CLASSIFIED AS A "WORKER" UNLESS ONE OF THE FOLLOWING CONDITIONS EXIST :

1) HE IS IN SCHOOL FULL TIME, IN WHICH CASE HE IS CLASSIFIED AS A "STUDENT".
2) A WOMAN, MARRIED, DIVORCED OR SEPARATED, HAS MAJOR RESPONSIBILITY FOR A HOUSEHOLD WHICH GIVES HER THE CLASSIFICATION "HOMEMAKER".

NOTE THAT THE WORK ROLE CLASSIFICATION DOES NOT REFLECT THE CURRENT PERFORMANCE.

A. WORKER

IF SUBJECT IS DEFINED AS A WORKER BUT HAS NOT WORKED DURING RATING PERIOD, MARK (20) AND (21) AS "5", (22) AS "9" AND SKIP TO (23) -- FRICTION.

IF OTHER THAN FULL TIME WORK : why is that ?

2. TIME LOST (21) (WORKER)

Have you missed any time from work in the last two months ? How many days did you miss ? Was that a vacation ?

INCLUDE TIME LOST DUE TO : PHYSICAL ILLNESS, MENTAL ILLNESS, DAYS LAID OFF, DAYS UNEMPLOYED. DO NOT INCLUDE PAID VACATION UNLESS TAKEN BECAUSE OF ILLNESS.

3. PERFORMANCE ADEQUACY (22) (WORKER)

Have you been doing your job well during the last two months ? Have you had trouble keeping up with your work ? ((Has anyone had to speak to you about your work?)) IF NO IMPAIRMENT : do you find your work too easy ?

RATE DESCRIBED IMPAIRMENT, NOT FEELINGS. PART-TIME WORK, IF NOT ALSO HOUSEWIFE OR STUDENT, CANNOT SCORE ABOVE "3".

B. HOMEMAKER

2. TIME LOST (CONSISTENCY) (21)

3. PERFORMANCE ADEQUACY (EFFECTIVENESS) (22)

How have you been doing your work at home ? Were there days in the last two months when you had serious trouble doing your housework ? Could you tell me what those days were like ?

RATE EACH ITEM AND AVERAGE. MEALS : have you been making all the meals in the last two months ? ((Have you had problems getting meals ? What do you cook on an average day ? Have you been taking short cuts or using more frozen dinners ? Is this different from usual ? Have you had to eat out because you could not get dinner together ? About how often ?))

CLEANING : Have you been keeping up with the housecleaning ? ((Have you had to let things slide ?))

WASHING : Have you been keeping up with the laundry since (date) ? ((Has anyone run out of clean clothes ?))

GROCERIES : About how often have you been grocery shopping in the last two months ? Is that more or less -- different from usual ? ((Do you have to make extra trips?))

ERRANDS : Have you had problems keeping up with other shopping, errands and the things you have to do to run the house, like buying clothes, going to the drug-store, paying bills ?

C. STUDENT

2. TIME LOST (21) (STUDENT)

How many hours a week are you scheduled for classes ? Have you had to miss any classes during the past two months ? ((How many ? Why was that ?))

3. PERFORMANCE ADEQUACY (22) (STUDENT)

How have you been doing in your schoolwork ? ((Have you been able to keep up with assignments ?)) Have you had any tests ? ((How did you do ?))

FOR ALL SUBJECTS

4. FEELINGS OF ADEQUACY (23)

Have you been doing your (work) as well as possible or do you feel you could do better ?((Have you felt that you might have done a poor job at any time in the last two months ?))

RATE SUBJECT'S FEELINGS.

5. FRICTION (24)

How have you and (people at work) been getting along in the last two months ? Are there things they do which annoy you or make you angry ? IF YES : did you hold your feelings in ? Did the other person know you were upset ?

Are there things you do which annoy them or make them angry ? Do you argue much ? ((Have there been any open disagreements ? How often ? How serious have those arguments been ?))

Is there anyone you avoid because you know you'll get into an argument ?

RATE OVERT BEHAVIOR INCLUDING ARGUMENTS, OVERT ANNOYANCE, WITHDRAWAL.
CONSIDER :
FOR WORKER - SUPERVISOR, CO-WORKERS, CUSTOMERS
FOR HOMEMAKER - SALESPEOPLE, REPAIRMEN, NEIGHBORS (EXCLUDE CLOSE FRIENDS AND FAMILY)
FOR STUDENT - TEACHERS, ADMINISTRATORS, OTHER STUDENTS
FOR UNEMPLOYED WHO ARE IN DAY TREATMENT SETTINGS - OTHER PATIENTS, STAFF.

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6. DISTRESS (25)

ASK ONLY IF NEEDED TO RATE.

(Have you felt upset or worried for any reason while doing your work these last 2 months ?
Do you ever have to stop doing your work because you are too upset to continue ?)

RATE SUBJECT'S FEELINGS.

BASE RATINGS ON BOTH FREQUENCY AND INTENSITY. DISTRESS INCLUDES BEING BLUE OR CRYING, BEING TENSE OR JITTERY, HEART POUNDING, BUTTERFLIES INSIDE, TIREDNESS, ETC.

WORK AFFECT

7. LIKES (26)
8. INTEREST (27)

What do you like about your (work) ? Anything you dislike ? (What do you like most ... least ?) Have you found your (work) interesting these last 2 months ? (Are you satisfied when your (work) is done ?)

9. SOURCES OF FINANCIAL SUPPORT (28)

What was your main source of income during the past 2 months ?

10. ECONOMIC ADEQUACY (29)

In the last 2 months, have you had enough money for basic expenses?: paying the rent, food, and paying your bills ? Is there money left over for other things ? IF NO, can you borrow or do you get money some other way ? (Have you had to use savings ? Have you had to put off important things, such as doctor visits ? Have you had trouble with bill collectors ? Are you receiving welfare ?)

AREA II - HOUSEHOLD

A. PRINCIPAL HOUSEHOLD MEMBER

11. PRINCIPAL HOUSEHOLD MEMBER (30)

Now we would like to talk about the people who live with you at home. That would be (household member).

IF LIVING WITH SPOUSE OR UNMARRIED CONJUGAL PARTNER, OR SEPARATED BUT STILL HAS REGULAR CONTACT AND A CONSISTENT RELATIONSHIP WITH SPOUSE, ASK ABOUT SPOUSE. IF ONLY ONE OTHER PERSON IN HOUSEHOLD, ASK ABOUT THAT PERSON. IF NO CONJUGAL PARTNER AND MORE THAN ONE ADULT PERSON IN HOUSEHOLD, IDENTIFY HOUSEHOLD MEMBER WITH WHOM SUBJECT HAS MOST IMPORTANT RELATIONSHIP -- LEAST DISTANCE. DO NOT CHOOSE MINOR CHILDREN OR PETS.

IF NECESSARY, ASK : (When you are at home, generally who else is home ? Who spends the most time with you ?)

12. FRICTION (31)

How have you and (principal household member) been getting along in the last 2 months ? Are there things (he) does which annoy you or make you angry ? IF YES : did you hold your feelings in ? Did (he) know you were upset ? Are there things you do which annoy (him) or make (him) angry ? Do you argue much ? (Have there been any open disagreements ? How often ? How serious have those arguments been ?) Do you ever avoid (him) because you know you'll get into an argument ?

RATE OVERT BEHAVIOR INCLUDING ARGUMENTS, OVERT ANNOYANCE, WITHDRAWAL.

13. ADAPTABILITY (32)

If you and (principal household member) have a disagreement, who usually gives in ? Who gets their way ? (Could you give me an example ?) Even when you disagree, can you see (his) side of it ? What kinds of things make (him) happy ? Are there things you do to help you get along ? (Could you give me an example?)

14. COMMUNICATION (33)

During the last 2 months, have you been able to talk easily with (principal household member) ? What types of things do you talk about ? When was the last time you talked about your feelings and problems ? (What did you talk about ? Can you give me an example? Are there some things you find it hard to talk about? Is this different than usual? Are there things you feel you should talk about but don't?)

15. INDEPENDENCE (34)

During the last 2 months, since (date), has (principal household member) turned to you for help or advice ? ((What kind of things has (he) needed help with ?)) Have you turned to (him) for help or advice ? ((What kind of things have you needed help with ?)

ASK ABOUT SPECIFIC TYPES AND INSTANCES OF ASSISTANCE.
FOR WOMEN : DRIVING, SHOPPING, MONEY, CHILDREN, HOUSEWORK, MINOR REPAIRS.
FOR MEN : MONEY, DRIVING, UPKEEP OF HOUSE.

How much have you leaned on (him) when things went wrong or you were upset these last 2 months ?

RATE DESCRIBED BEHAVIOR, NOT FEELINGS.

16. EXPRESSED FEELINGS (35)

What have your feelings been toward (principal household member) during the last 2 months ? ((Do you feel friendly ? Do you dislike (him) ? Do you care for (him) even if you are not getting along ?))

DO NOT RATE FRICTION. RATE SUBJECT's FEELINGS.

B. SEXUAL ADJUSTMENT - CONJUGAL

IF PRINCIPAL HOUSEHOLD MEMBER IS NOT A CONJUGAL PARTNER, SKIP TO p. "PARENTAL".

THE FLOW OF QUESTIONS IS DESIGNED TO MOVE FROM 1-INTEREST TO 2-PROBLEMS TO 3-FREQUENCY.

17. BIRTH CONTROL (36)

Have you and (name) been using any form of birth control or rhythm in the last 2 months ?
IF YES : what have you been using ?

Have you been interested in having sex during the last 2 months ?
IF YES : has it been satisfying to you ? Any problems ? (How serious would you say these are ?) About how often have you had (sexual intercourse) in the past 2 months ? (Is that a change for you ? Has it been less often when you have been upset or not feeling well ?)
IF NO : what seems to be the problem ? [Any problems in starting things going being interested, or getting your (husband) interested ?] Has there been any change in how often you have sexual intercourse during the last 2 months ?

18. INTERESTS (37)

RATE SUBJECT'S FEELINGS.

FOR SUBJECTS COMPLETELY INACTIVE DURING THE TIME PERIOD, SCORE ON BASIS OF INTEREST ALONE.

19. PROBLEMS (38)

20. FREQUENCY (39)

C. PARENTAL

Do you have any children ? Foster children ? What are their names and ages ? Are they living at home with you now ?

THESE QUESTIONS APPLY TO ALL CHILDREN LIVING IN THE HOME AND TO DEPENDENT, MINOR CHILDREN (UNDER AGE 18) EVEN IF IN FOSTER PLACEMENT OUTSIDE THE HOME. ASK ABOUT EACH CHILD BY NAME AND AVERAGE FOR RATINGS. DO NOT RATE A CHILD WHO IS RATED AS PRINCIPAL HOUSEHOLD MEMBER.

IF NO RATABLE CHILDREN, SKIP TO "FAMILY CONCERNS".

21. INVOLVEMENT (40)

What kinds of things have you been doing with the children these last 2 months ? Let's start with (name).

FOR PRE-SCHOOL CHILDREN - ASK ABOUT CHILD'S PLAY ACTIVITIES, PRE-SCHOOL LEARNING, APPEARANCE AND PHYSICAL CARE.FOR OLDER CHILDREN - ASK ABOUT CHILD'S SCHOOL PROGRESS, INTERESTS, FRIENDS, WORK.

RATE EXPRESSED CONCERN AND EMOTIONAL INVOLVEMENT, KNOWLEDGE AND BEHAVIOR BEYOND MINIMAL CARE.

22. FRICTION (41)

How have you been getting on with (names) these past 2 months ? ((Have they been giving you trouble ? Have you had to correct them much ? Have you lost your patience ? Could you give me an example ?))

RATE IN TERMS OF NUMBER OF ACTUAL INCIDENTS, AMOUNT OF FRICTION, AND FREQUENCY AND SEVERITY OF IMPOSED SANCTIONS. INCLUDE COOLNESS, DISTANCE AND TENSION.

23. COMMUNICATION (42)

During the last 2 months, have you been able to talk easily with (names) ? How do you tell when something important or upsetting has happened to one of the children ? Does (he) come to you with problems ? ((Could you give me an example since (date) ?))

RATE EACH CHILD SEPARATELY AND AVERAGE. CONSIDER APPROPRIATE COMMUNICATION FOR CHILD'S AGE, INCLUDING BOTH VERBAL AND NON-VERBAL BEHAVIOR.

VERBAL COMMUNICATION - DISCUSSION OF FEELINGS, PROBLEMS ETC., NOT JUST RECOUNTING DAILY ACTIVITIES.

NON-VERBAL COMMUNICATION - EXPRESSED AWARENESS OF CHILD'S MOODS AND NEEDS

24. EXPRESSED FEELINGS (43)

Most parents sometimes get angry at their children so that their feelings change. Considering what you have been telling me about the children, what have your feelings been toward them the last 2 months ? (Have you sometimes wished they were not around or did not live with you ?)

IF CHILD IS NOT LIVING IN HOUSEHOLD : (Have you wished you did not have to be involved with them ?)

RATE SUBJECT'S FEELINGS.

D. CONCERNS ABOUT HOUSEHOLD MEMBERS

RATE THE NEXT 3 ITEMS FOR ALL HOUSEHOLD MEMBERS. IF SPOUSE AND/OR DEPENDENT CHILDREN ARE LIVING OUTSIDE THE HOUSEHOLD, INCLUDE THEM ALSO. RATING ANCHOR POINTS FOR ALL 3 ITEMS IN THIS SECTION INCLUDE BOTH INTENSITY AND FREQUENCY. RATE ON THE BASIS OF THE GREATEST DISABILITY. E.G. MILD WORRY ALL THE TIME OR SEVERE WORRY SOME OF THE TIME ARE BOTH RATED "5".

25. WORRY (44)

Have you worried about things happening to (household members) during the last 2 months ? (Has anyone caused you to worry much ? What kinds of things have you been worried about ?)

RATE SUBJECT'S FEELINGS.

26. GUILT (45)

In the last 2 months, have you been feeling that you let (household members) down ? ((How did you let them down ? Have you felt badly about it ?))

RATE SUBJECT'S FEELINGS.

27. WRONGED (46)

In the last 2 months, have you been feeling that (household members) have let you down ? ((Have they treated you unfairly or unjustly ? How did they let you down ? Have you felt bitter ?))

AREA III - EXTERNAL FAMILY

We have talked about your (family) at home. Do you have (other) relatives who do not live with you but live in the area ? Anybody outside the area with whom you are in touch ?

FOR EACH ITEM ASK SPECIFICALLY ABOUT ALL OF THE FOLLOWING WHO DO NOT LIVE IN THE HOME BUT IN THE AREA OR WITH WHOM SUBJECT HAS BEEN IN TOUCH :

How about : parents
brothers and sisters
in-laws
adult children
other relatives ?

Have you seen or heard from your (relative) in the last 2 months ?

Have you made the effort to keep in touch with (relative) or have you waited for (relative) to contact you ? ((Who usually arranges getting together ? Is there anyone you have avoided seeing ?))

Now, how about your (next relative) ?

ASK ABOUT EACH RELATIVE IDENTIFIED.

RATE OVERT BEHAVIOR INCLUDING ARGUMENTS, OVERT ANNOYANCE, WITHDRAWAL.

28. FRICTION (47)

How have you been getting along with (relative) ? Are there things (he) does which annoy you or make you angry ?
IF YES : Did you hold your feelings in ? Did (he) know you were upset ? Are there things you do which annoy (him) or make (him) angry ? Do you argue much ? ((Have there been any open disagreements ? How often ? How serious have those arguments been ?)) Is there anyone you avoid because you know you will get into an argument ?

29. INDEPENDENCE (48)

Do your relatives turn to you for help or advice ? ((What kinds of things have they needed help with : baby-sitting, helping out around the house, other things ? Emotional support ?)) Do you depend on them for help or advice ? ((What kinds of things have you needed help with : baby-sitting, transportation, getting a job, financial help ?))

CONCERNS

RATING ANCHOR POINTS FOR ALL 3 ITEMS IN THIS SECTION INCLUDE BOTH INTENSITY AND FREQUENCY. RATE ON THE BASIS OF THE GREATEST DISABILITY , E.G. MILD WORRY ALL THE TIME OR SEVERE WORRY SOME OF THE TIME ARE BOTH RATED "5".

30. WORRY (49)

Have you worried about things happening to (relative) during the last 2 months ? ((Has anyone caused you to worry much ? What kinds of things have you been worried about ?))

RATE SUBJECT'S FEELINGS.

31. GUILT (50)

In the last 2 months, have you had the feeling that you let (relative) down ? ((How did you let them down ? Have you felt badly about it ?))

RATE SUBJECT'S FEELING.

32. WRONGED (51)

In the last 2 months, have you had the feeling that (relative) have let you down? ((Have they treated you unfairly or unjustly ? How did they let you down ? Have you felt bitter ?))

RATE SUBJECT'S FEELINGS.

AREA IV - SOCIAL / LEISURE

A. ACTIVITIES

33. LEISURE ACTIVITIES (52)

What kinds of things do you do in your free time ? ((Do you have any hobbies or things you specially enjoy like sports, political activities, gardening, special cooking, favorite TV program, magazine column ? Could you tell me about these ?)) What have you been doing about them the last 2 months ?

B. SOCIAL CONTACTS

34. FREQUENCY (53)

35. DEGREE OF ACTIVITY (54)

Have you had a chance to do anything socially with your friends or family ? ((Like going out to a movie or a restaurant or some place you saw people you know, like at church or a club meeting ...? Have you had people over to the house ?)) How many times in the last 2 months have you (activities mentioned) ? Who have you been doing these things with ? Do you generally make the plans or does someone usually ask you to go along ? Do you tend to join in conversations or do you tend to be quiet ?

INCLUDE ENTERTAINING OR VISITING FRIENDS, GOING OUT IN COMPANY OF OTHERS, INCLUDING MOVIES, SPORTS EVENTS, RESTAURANTS, BARS, SHOPPING WITH FRIENDS, PLAYING CARDS, PARTIES, CLUB MEETINGS. INCLUDE CHURCH ATTENDANCE ONLY IF SUBJECT SOCIALIZES.

36. OBSTACLES (55)

ASK ONLY IF NEEDED TO RATE :

Considering what you have been telling me about what you have been (doing/not doing), are there any problems in getting out or meeting people ? Would you get out and do more if you had a ride, if money was not a problem, if you had someone to go with, if you were not working so hard ?

RATE SUBJECT'S FEELINGS. INCLUDE ECONOMIC, ENVIRONMENTAL AND SOCIAL FACTORS, E.G., NO MONEY, NO TRANSPORTATION, NO FRIENDS OR FAMILY, WORK-RELATED REASONS.

37. SOCIAL COMFORT (56)

Do you enjoy being with people ?
IF NO CONTACT, ASK : if you have to be with people, do you enjoy it ? (Do you sometimes feel ill at ease or uncomfortable ? What do you like most about being with people ? What do you like least ? Did you feel anxious to get away or to be alone when with people ?)

RATE FOR ALL SUBJECTS WHETHER OR NOT THERE ARE CONTACTS.

C. INTERPERSONAL CONTACTS

We have talked about your family and what you do in spare time. Now could you tell me about your friends ? Not your family (or your romantic interests, like a boy-friend or girl-friend) but any friends who you are interested in or care about.

IF SUBJECT ASKS FOR DEFINITION OF "FRIEND" : someone who you consider a friend.

38. FREQUENCY (57)

Have you seen any of your friends or been in touch with them by phone or letter in the last 2 months? Who?

39. COMMUNICATION (58)

During the last 2 months, have you been able to talk easily with (one friend) ? What types of things do you talk about ? ((Can you talk about your feelings and problems ? Are there some things you find it hard to talk about ? Is this different than usual ? Are there things you feel you should talk about but do not ?))

40. FRICTION (59)

How have you and (friends) been getting along in the last 2 months ? Are there things (they) do which annoy you or make you angry ?
IF YES : did you hold your feelings in ? Did the other person know you were upset ? Are there things you do which annoy (them) or make (them) angry ? Do you argue much ? ((Have there been any open disagreements ? How often ? How serious have those arguments been ?)) Is there anyone you avoid because you know you will get into an argument ?

RATE OVERT BEHAVIOR INCLUDING ARGUMENTS, OVERT ANNOYANCE, WITHDRAWAL.

IF NO CONTACTS, RATE AS "5".

41. SENSITIVITY (60)

Have any of your friends offended you or hurt your feelings in the past 2 months ? ((Tell me what happened.))
IF YES : have you been able to get over this ?
ASK ALL SUBJECTS : is there anything that happened in the past that you still have not been able to get over ?

D. ROMANTIC INVOLVEMENT

FOR THOSE WITH CONJUGAL PARTNER, SKIP TO "PHYSICAL HEALTH AND CARE".

FOR SINGLE, DIVORCED, WIDOWED AND SEPARATED FOR WHOM SEXUAL ADJUSTMENT CONJUGAL QUESTIONS HAVE NOT BEEN ASKED.

INTERACTION

42. FREQUENCY (61)
43. INTEREST (62)
44. PROBLEMS (63)

Have you had any romantic interests the last 2 months, you know a(boy-friend/girl-friend/companion) or someone you just met ?
IF YES, ASK : how often have you seen (him) ? (Is there anyone else you have seen ? How often ?)
Have you enjoyed your time together ? Any problems ? (Is breaking up a problem ? How serious would you say these are ?)
IF NO, ASK : would you like to meet someone ? Is there a problem meeting someone ? (Is breaking up a problem ?)

E. SEXUAL ADJUSTMENT - NON CONJUGAL

Have you been interested in having sex during the last 2 months ?
FOR ALL SUBJECTS : have you had sexual intercourse during the last 2 months ?
IF YES : how often ? ((Is that a change for you ? Has it been less often when you have been upset or not feeling well ?)) Has it been satisfying to you ? Any problems ? ((How serious would you say these are ?))
Have you been using any form of birth control or rhythm these last 2 months ?
IF NO : is there any problem ? Has there been a change in how often you have sex in the last 2 months ?

45. INTEREST (64)

RATE SUBJECT'S FEELINGS.

FOR SUBJECTS COMPLETELY INACTIVE DURING THE TIME PERIOD, SCORE ON BASIS OF INTEREST ALONE.

46. PROBLEMS (65)

47. FREQUENCY (66)

48. BIRTH CONTROL (67)

AREA V - PERSONAL WELL BEING

49. PHYSICAL HEALTH AND CARE (68)

How has your physical health been since (date) ? Have you been taking care of yourself ? ((Like eating regularly, getting enough sleep, exercise, physical and dental checkups ?)) Any problems with (chronic medical condition

50. PERSONAL APPEARANCE AND GROOMING (69)

RATE ON BASIS OF APPEARANCE AND APPARENT CONCERN.

IF NECESSARY TO RATE, ASK : does anyone help you choose your clothes ? ((Who sees to it that you have clean clothes ? Does (someone) lay out your clothes in the morning ?))

51. LONELINESS (70)

Have you felt lonely these last 2 months? ((Have you felt cut off or left out by your family or friends? Have there been times when you wished you could be closer to a certain friend or someone in the family? Do you feel this way even when there are people around ?))

RATE SUBJECT'S FEELINGS.

52. SELF APPRAISAL (71)

In looking over the way things have been going the last 2 months, in general, how satisfied, content, or happy have you been ?

RATE SUBJECT'S FEELINGS.

Thank you very much for your cooperation. Is there anything else you want to tell me ? Do you want to ask me any questions ?

GLOBALS

RATE GLOBAL ITEMS IMMEDIATELY AFTER THE INTERVIEW. USE ALL AVAILABLE INFORMATION SUPPLIED BY SUBJECT AS WELL AS INFORMATION WHICH MAY NOT HAVE BEEN SPECIFICALLY RELEVANT TO THE INDIVIDUAL ITEMS. RATE RAPIDLY ON GENERAL IMPRESSIONS. INCLUDE NON-SPECIFIC ASPECTS OF THE SUBJECT'S BEHAVIOR IN THE INTERVIEW SITUATION -- NON VERBAL CUES, SUSPECTED DENIAL, INSIGHT DEFICIENCY, ETC. IN MAKING JUDGMENTS, COMPARE SUBJECT TO COMMUNITY NORMS AND STANDARDS, NOT TO WHAT YOU MAY KNOW OF HIS EARLIER ADJUSTMENT OR TO OTHER FORMER PATIENTS.

SCALE POINTS FOR ALL GLOBALS

1 = excellent adjustment
2 = very good adjustment
3 = good adjustment
4 = fair adjustment
5 = poor adjustment
6 = very poor adjustment
7 = severe maladjustment
9 = category not ratable

AREA I - WORK (20)

CONSIDER CONSISTENCY AND EFFECTIVENESS OF WORK PERFORMANCE IN VIEW OF EDUCATION, PRIOR TRAINING AND EXPERIENCE.

AREA II - HOUSEHOLD (21)

CONSIDER DEGREE OF INTEGRATION IN HOUSEHOLD IN TERMS OF MUTUAL SUPPORT, AFFECTION AND PARTICIPATION.

AREA III - EXTERNAL FAMILY (22)

CONSIDER DEGREE OF RELATIONSHIP WITH RELATIVES IN TERMS OF MUTUAL SUPPORT, AFFECTION AND PARTICIPATION.

AREA IV - SOCIAL LEISURE (23)

CONSIDER BOTH LEVEL OF AND QUALITY OF ACTIVITIES AND MEANINGFULNESS OF INTERPERSONAL RELATIONSHIPS

GENERAL ADJUSTMENT (24)

CONSIDER PERFORMANCE IN ALL ROLES (WORK, PARENTAL, MARITAL, ETC), INTERPERSONAL RELATIONSHIPS IN AND OUT OF THE HOME, AND PERSONAL COMFORT.

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) SOCIAL ADJUSTMENT SCALE (SASII)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) _ _ _
Form Number

(13-15) _ _ | _
Assessment Period

(16-17) _ _
Rater Number

(18-19) _ _
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

AREA I - WORK

1. WORK ROLE (20)

1 = WORKER

2 = HOMEMAKER

3 = STUDENT

2. TIME LOST (21)

1. WORKER

1 = less than half a week

2 = up to one week

3 = at least one but less than two weeks (25%)

4 = at least 2 but less than 4 weeks (less than 50%)

5 = over 4 weeks (more than 50%)

9 = homemaker or student

2. HOMEMAKER

1 = carries out all household tasks most of the time

2 = usually carries out most tasks

3 = carries out some but not others

4 = usually does not carry out most tasks

5 = almost always fails to carry out any tasks

9 = worker or student

3. STUDENT

1 = less than half a week

2 = up to one week

3 = at least one but less than 2 weeks (25%)

4 = at least 2 but less than 4 weeks (less than 50%)

5 = over 4 weeks (more than 50%)

9 = worker or homemaker

3. PERFORMANCE ADEQUACY (22)

1. WORKER

1 = no impairment

2 = adequate but some impairment

3 = moderate impairment or partially employed or underemployed but doing adequately

4 = marked impairment or underemployed and not doing adequately

5 = extreme impairment or not working at all

9 = homemaker or student

2. HOMEMAKER

RATE DESCRIBED IMPAIRMENT, NOT FEELINGS.

1 = no impairment

2 = adequate but some impairment

3 = moderate impairment or needed (received) help

4 = marked impairment or needed (received) substantial help

5 = extreme impairment or not functioning at all

9 = worker or student

3. STUDENT

1 = no impairment

2 = adequate but some impairment

3 = moderate impairment

4 = marked impairment

5 = extreme impairment or not performing at all

9 = worker or homemaker

FOR ALL STUDENTS

4. FEELINGS OF ADEQUACY (23)

1 = almost always feels adequate or able to handle things

2 = usually or often feels adequate or able to handle things

3 = sometimes feels adequate or able to handle things

4 = rarely feels adequate or able to handle things

5 = almost never feels adequate or able to handle things

9 = not working or not ratable as homemaker or student

5. FRICTION (24)

1 = no friction and smooth relationships

2 = some mild friction but no avoidance

3 = some friction and/or minimizes some contacts

4 = moderate friction and/or minimizes many contacts

5 = extreme friction and/or avoids/avoided by others

9 = not ratable as worker, homemaker, student or in day care

6. DISTRESS (25)

1 = not at all distressed

2 = a little distressed

3 = moderately distressed

4 = very distressed

5 = extremely distressed

9 = not ratable

7. LIKES (26)

1 = likes many aspects of the work

2 = likes some aspects of the work with some minor dislikes

3 = likes some, dislike others equally

4 = dislikes some, but not entirely

5 = dislikes many aspects of work

9 = not ratable

8. INTEREST (27)

1 = very interested

2 = somewhat interested

3 = neutral

4 = somewhat uninterested

5 = very uninterested

9 = not ratable

9. SOURCES OF FINANCIAL SUPPORT (28)

1 =patient's own earnings

2 = spouse's earnings

3 = pension, loan, savings interest or dividends, unemployment insurance

4 = earnings of others except spouse

5 = public assistance, welfare

10. ECONOMIC ADEQUACY (29)

1 = available funds and reserves adequate for incurred obligations and some money or purchasing power remains

2 = available funds and reserves adequate for incurred obligations but only restricted purchasing power remains

3 = available funds and reserves adequate only for incurred obligations

4 = available funds and reserves somewhat inadequate for incurred obligations

5 = available funds and reserves very inadequate for incurred obligations

AREA II - HOUSEHOLD

A. PRINCIPAL HOUSEHOLD MEMBER

II. PRINCIPAL HOUSEHOLD MEMBER (30)

1 = spouse or conjugal partner

2 = mother

3 = father

4 = brother or sister

5 = brother-in-law or sister-in-law

6 = other relative

7 = child - non minor

8 = non relative

9 = no principal household member

12. FRICTION (31)

1 = no friction and smooth relationships

2 = some mild friction but no avoidance

3 = some friction and/or minimizes some contacts

4 = moderate friction and/or minimizes many contacts

5 = extreme friction or avoids/avoided by others

9 = no principal household member

13. ADAPTABILITY (32)

1 = aware of and is able to empathize with other's needs and desires

2 = aware of other's needs and desires but limited empathy with other

3 = shows only limited awareness of other's needs and desires and limited empathy

4 = shows only limited awareness of other's needs and desires but no empathy

5 = unaware of other's needs and desires and no empathy for other

9 = no principal household member

14. COMMUNICATION (33)
COL 26

1 = almost always can talk about feelings and problems when appropriate

2 = usually can talk about feelings and problems when appropriate

3 = sometimes can and sometimes cannot talk about feelings and problems when appropriate

4 = usually cannot talk about feelings and problems when appropriate

5 = almost never can talk about feelings and problems when appropriate

9 = no principal household member

15. INDEPENDENCE (34)

1 = independent - receives no help

2 = independent and receives help

3 = dependent and receives a lot of help

4 = dependent and receives some help

5 = dependent but receives no help

9 = no principal household member

16. EXPRESSED FEELINGS (35)

1 = likes most of the time

2 = likes and dislikes about equally

3 = indifferent

4 = dislikes more of the time

5 = dislikes most of the time

9 = no principal household member

B. SEXUAL ADJUSTMENT CONJUGAL

17. BIRTH CONTROL (36)

1 = tubal ligation, vasectomy, IUD

2 = the pill

3 = diaphragm, condom, contraceptive foam or jelly

4 = rhythm, other less reliable methods, anything respondent considered as a method

5 = nothing

6 = beyond age of fertility, surgical sterilization, hysterectomy

9 = does not apply : principal household member is not a conjugal partner or no principal household member

18. INTEREST (37)

1 = pleasant and/or actively interested

2 = often pleasant and/or often interested

3 = tolerable and/or uninterested - indifferent

4 = often unpleasant and/or generally uninterested

5 = unpleasant and/or no interest

9 = principal household member not conjugal partner or no principal household member

19. PROBLEMS (38)

1 = almost never has problems

2 = sometimes has problems and/or experiences difficulties

3 = often has problems and/or experiences difficulties

4 = very often has problems and/or experiences difficulties

5 = almost always has problems and/or experiences difficulties

9 = principal household member not conjugal partner or no principal household member

20. FREQUENCY (39)

1 = more than once a week on the average

2 = once a week on the average

3 = about twice a month on the average

4 = no more than once a month on the average

5 = not at all

9 = principal household member not conjugal partner or no principal household member

C. PARENTAL

21. INVOLVEMENT (40)

1 = active involvement and participation in children's lives

2 = some active involvement and participation in children's lives

3 = little active participation but reasonable knowledge and concern about children

4 = no participation but some knowledge and concern

5 = no participation and only minimal knowledge and concern

9 = no children

22. FRICTION (41)

1 = smooth and close relationships

2 = a little friction and/or distance

3 = moderate friction and/or distance

4 =marked friction and/or distance

5 = constant state of friction and/or children avoid parent totally

9 = no children

24. EXPRESSED FEELINGS (43)

1 = likes children almost all the time

2 = likes children much of the time

3 = likes and dislikes children about equally or ambivalent

4 = dislikes children much of the time

5 = dislikes children almost all the time

9 = no children

D. CONCERNS ABOUT HOUSEHOLD MEMBERS

25. WORRY (44)

1 = almost never feels worried

2 = sometimes (mildly) feels worried

3 = often (moderately) feels worried

4 = usually (markedly) feels worried

5 = almost always (severely) feels worried

9 = no household members

26. GUILT (45)

1 = almost never feels guilty

2 = sometimes (mildly) feels guilty

3 = often (moderately) feels guilty

4 = usually (markedly) feels guilty

5 = almost always (severely) feels guilty

9 = no household members

23. COMMUNICATION (42)

1 = almost always able to identify and respond to children's needs and moods and/or talk easily with them

2 = usually able to identify and respond to children's needs and moods and/or to talk easily with them

3 = sometimes able to identify and respond to children's needs and moods and/or to talk easily with them

4 = rarely able to identify and respond to children's needs and moods and/or to talk easily with them

5 = almost never able to identify and respond to children's needs and moods and/or talk easily with them

9 = no children

27. WRONGED (46)

1 = almost never feels let down or treated unfairly

2 = sometimes (mildly) feels let down or treated unfairly

3 = often (moderately) feels let down or treated unfairly

4 = usually (markedly) feels let down or treated unfairly

5 = almost always (severely) feels let down or treated unfairly

9 = no household members

28. FRICTION (47)

1 = no friction and smooth relationships

2 = some mild friction but no avoidance

3 = some friction and/or minimizes some contacts

4 = moderate friction and/or minimizes many contacts

5 = extreme friction or avoids/avoided by others

9 = no ratable relatives

29. INDEPENDENCE (48)

1 = independent - receives no help

2 = independent and receives help

3 = dependent and receives a lot of help

4 = dependent and receives some help

5 = dependent but receives no help

9 = no ratable relatives

CONCERNS

30. WORRY (49)

1 = almost never feels worried

2 = sometimes (mildly) feels worried

3 = often (moderately) feels worried

4 = usually (markedly) feels worried

5 = almost always (severely) feels worried

9 = no ratable relatives

31. GUILT (50)

1 = almost never feels guilty

2= sometimes (mildly) feels guilty

3 = often (moderately) feels guilty

4 = usually (markedly) feels guilty

5 = almost always (severely) feels guilty

9 = no ratable relatives

32 WRONGED (51)

1 = almost never feels let down or treated unfairly

2 = sometimes (mildly) feels let down or treated unfairly

3 = often (moderately) feels let down or treated unfairly

4 = usually (markedly) feels let down or treated unfairly

5 = almost always (severely) feels let down or treated unfairly

9 = no ratable relatives

AREA IV - SOCIAL / LEISURE

A. ACTIVITIES

33. LEISURE ACTIVITIES (52)

1 = well developed, specific interests or activities - participates more than once a week

2 = definite interests or activities - devotes regular but less frequent time

3 = some specific interests, but activity is irregular

4 = some superficial interests, favorite TV program or magazine, follows a team, or comic, etc.

5 = absence of any specific interests or activities, e.g., non-discriminating TV viewing

B. SOCIAL CONTACTS

34. FREQUENCY (53)

1 = more than once a week on the average

2 = once a week on the average

3 = about twice a month on the average

4 = no more than once a month on the average

5 = never or only once during 2 months

35. DEGREE OF ACTIVITY (54)

1 = actively participates with others and/or initiates contacts

2 = sometimes participates with others and/or initiates contacts

3 = responds to contacts initiated by others

4 = sometimes responds to contacts initiated by others

5 = completely passive - does not interact with others, even if in group situation

9 = completely inactive

36. OBSTACLES (55)

1 = numerous realistic external obstacles to social contact

2 = quite a few realistic external obstacles to social contact

3 = some realistic external obstacles to social contact

4 = very few realistic external obstacles to social contact

5 = no realistic external obstacles to social contact

37. SOCIAL COMFORT (56)

1 = has contacts and is rarely ill at ease

2 = has contacts and is sometimes ill at ease

3 = has contacts and is often ill at ease or has no contacts but does not anticipate discomfort

4 = has no contacts and anticipates some discomfort

5 = has no contacts and anticipates severe discomfort

38. FREQUENCY (57)

1 = more than once a week on the average

2 = once a week on the average

3 = about twice a month on the average

4 = no more than once a month on the average

5 = never or only once during 2 months

39. COMMUNICATION (58)

1 = almost always talks easily with at least one person

2 = usually talks easily with at least one person

3 = sometimes does and sometimes does not talk easily

4 = usually does not talk easily

5 = almost never talks easily

9 = no interpersonal contacts

40. FRICTION (59)

1 = no friction and smooth relationships

2 = some mild friction but no avoidance

3 = some friction and/or minimizes some contacts

4 = moderate friction and/or minimizes many contacts

5 = extreme friction or avoids/avoided by others

41. SENSITIVITY (60)

1 = has not felt hurt or offended

2 = has felt hurt or offended once or twice but recovered quickly

3 = has felt hurt or offended once or twice and recovered with difficulty

4 = frequently felt hurt or offended - or hurt and may or may not have recovered

5 = typically has felt hurt or offended over the last 2 months

42. FREQUENCY (61)

1 = more than once a week on the average

2 = once a week on the average

3 = about twice a month on the average

4 = no more than once a month on the average

5 = never or only once during 2 months

9 = does not apply; has conjugal partner

43. INTEREST (62)

1 = contacts are almost always pleasant and/or actively interested in contacts

2 = contacts are often pleasant and/or often interested

3 = tolerable and/or indifferent

4 = often unpleasant and/or generally uninterested

5 = contacts are almost always unpleasant and/or no interest in contacts

9 = does not apply; has conjugal partner

44. PROBLEMS (63)

1 = almost never has problems in meeting or sustaining contacts

2 = sometimes has problems

3 = often has problems

4 = very often has problems

5 = almost always has problems in meeting or sustaining contacts

6 = no contacts

9 = does not apply : has conjugal partner

E. SEXUAL ADJUSTMENT - NON CONJUGAL

45. INTERESTS (64)

1 = pleasant and /or actively interested
2 = often pleasant and/or often interested
3 = tolerable and/or uninterested - indifferent
4 = often unpleasant and/or generally uninterested
5 = unpleasant and/or no interest
9 = does not apply : sexual adjustment rated with conjugal partner

46. PROBLEMS (65)

1 = almost never has problems
2 = sometimes has problems and or experiences difficulties
3 = often has problems and or experiences difficulties
4 = very often has problems and or experiences difficulties
5 = almost always has problems and or experiences difficulties
6 = no contacts
9 = does not apply - sexual adjustment rated with conjugal partner

47. FREQUENCY (66)

1 = more than once a week on the average
2 = once a week on the average
3 = about twice a month on the average
4 = no more than once a month on the average
5 = not at all
9 = does not apply; sexual adjustment rated with conjugal partner

48. BIRTH CONTROL (67)

1 = tubal ligation, vasectomy, IUD
2 = the pill
3 = diaphragm, condom, contraceptive foam or jelly
4 = rhythm, or less reliable methods; anything respondent considers as a method
5 = nothing
6 = beyond age of fertility, surgical sterilization, hysterectomy, or no contacts
9 = does not apply : sexual adjustment rated with conjugal partner

AREA V. PERSONAL WELL BEING

49. PHYSICAL HEALTH AND CARE (68)

1 = attempts to maintain optimal health

2 = moderate concern for health but not doing everything possible

3 = no apparent neglect but no active concern about health

4 = some signs or reports of neglected health

5 = many signs or reports of neglected health

50. PERSONAL APPEARANCE AND GROOMING (69)

1 = particularly well groomed

2 = reasonably neat, clean and appropriate

3 = reasonable appearance, but responsibility borne by someone else

4 = some signs of neglect or bizarre or inappropriate appearance

5 = unkempt, dirty, signs of extreme neglect

51. LONELINESS (70)

1 = has not felt lonely

2 = has felt a little lonely sometimes

3 = has felt a little lonely frequently

4 = has felt very lonely occasionally or frequently

5 = feels totally alone (even in the presence of others)

52. SELF-APPRAISAL (71)

1 = extremely happy, satisfied, content

2 = moderately happy, satisfied, content

3 = indifferent or bored or unable to express or verbalize feelings or fluctuating feelings

4 = moderately unhappy, dissatisfied, discontent

5 = extremely unhappy, dissatisfied, discontent

GLOBAL EVALUATION

	Work I	Household II	External Family III	Social/ Leisure IV	General Adjustment
	(20)	(21)	(22)	(23)	(24)
Excellent adjustment	1	1	1	1	1
Very good adjustment	2	2	2	2	2
Good adjustment	3	3	3	3	3
Fair adjustment	4	4	4	4	4
Poor adjustment	5	5	5	5	5
Very poor adjustment	6	6	6	6	6
Severe maladjustment	7	7	7	7	7
Category not ratable	9	9	9	9	9

INFORMATION for USERS

DEVELOPMENT - Developed by Mrs. Nina Schooler and G.E. Hogarty, the SASII is a 71-item scale. Its purpose is to gather information on four essential areas of social functioning, i.e., work, household, external family and leisure.

APPLICABILITY - All adult populations.

UTILIZATION - Once per subject at the time of initial evaluation.

PRIOR MEDICATION RECORD (PMR)

PRIOR MEDICATION RECORD (PMR)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) PRIOR MEDICATION RECORD (PMR)	Surname First Name Additional Patient ID Number Date Name of Rater

(1-3) _ _ _ Unit Number

(4-6) _ _ _ Study Number

(7-9) _ _ _ Subject Number
Male 001-499
Female 500-999

(10-12) _ _ _ Form Number

(13-15) _ _ _ Assessment Period*

(16-17) _ _ Rater Number

(18-19) _ _ Card Number

(76-80) _ _ _ _ _ Group to which Patient is Assigned

* The first two digits are provided for the numeric and the third one for the unit of time.

Time units :

pretreatment	= 0
hours	= 1
days	= 2
weeks	= 3
months	= 4

Example = 20 days = 202; 3 weeks = 033; pretreatment = 000

1. PRIOR PSYCHOTROPIC MEDICATION

A. Record the name/s and maximum total daily dose/s of the drug/s which the subject received during the MONTH PRECEDING THE STUDY (prior to any drying-out period). If no drugs received, write "none".

1. Drug Name						
Drug Code						
(20-24)				(25-27)		(28)

2. Drug Name						
Drug Code						
(29-33)				(34-36)		(37)

B. Estimate length of time subject has been receiving psychotropic medications. Mark appropriate time units and enter number.

Time units : 4 = never; 5 = week; 6 = month; 7 = year; 9 = not ascertained.

Neuroleptic	(38)	(39-40)
Antidepressant	(41)	(42-43)
Anxiolytic	(44)	(45-46)
Other psychotropic	(47)	(48-49)

2. OTHER TREATMENTS RECEIVED PRIOR TO STUDY

Mark "yes" for all treatments which subject received in MONTH PRECEDING THE STUDY (prior to any drying-out period). Mark "NO" for those not received.

a. Drug		NO	YES
Analgesic-narcotic	(50)	0	1
Analgesic non-narcotic	(51)	0	1
Anesthetic - general	(52)	0	1
Anesthetic - local	(53)	0	1

		No	Yes
Antiallergenic	(54)	0	1
Anticoagulant	(55)	0	1
Anticonvulsant	(56)	0	1
Antifertility	(57)	0	1
Antihypertensive	(58)	0	1
Antimicrobial	(59)	0	1
Antiparkinson	(60)	0	1
Antitumor	(61)	0	1
Blood tonic	(62)	0	1
Broncho dilator	(63)	0	1
Cardiac medication	(64)	0	1
Cough and cold preparation	(65)	0	1
Dermatological preparation	(66)	0	1
Diabetic medication	(67)	0	1
Diet medication	(68)	0	1
Diuretic	(69)	0	1
Gastrointestinal preparation	(70)	0	1
Hormonal medication	(71)	0	1
Muscle relaxant	(72)	0	1
Sedative/hypnotic	(73)	0	1
Stimulant	(74)	0	1
Thyroid medication	(75)	0	1
Vitamin	(20)*	0	1
b. NonDrug			
Behavior modification	(21)	0	1
Electroconvulsive therapy	(22)	0	1
Milieu therapy	(23)	0	1
Physical therapy	(24)	0	1
Psychotherapy - group	(25)	0	1
Psychotherapy - individual	(26)	0	1
Rehabilitation/occupational therapy	(27)	0	1
Remedial educational therapy	(28)	0	1

Date: (70-75) _ _ _ _ _ _

*Card No. 02

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU program, the PMR is a single-page, 8-item form designed to capture information concerning the subject's medication history prior to his entrance into the study.

APPLICABILITY - All research populations.

UTILIZATION - Once per subject at the time of initial evaluation.

TIME SPAN RATED - For items 1a, 2a and 2b, one month. For item 1b, time span is dependent on subject's psychotropic history.

SPECIAL INSTRUCTIONS -
Item 1. Prior Psychotropic Medication. a. "Month preceding study" means prior to any drying-out period.

Codes for drugs are assigned by the CCPDD.

b. This item is not limited in time to the month prior to the study, but encompasses the subject's entire prior drug history. Estimate duration as an aggregate total in those instances where intake may be intermittent.

To fill in this 4-part item, the rater must designate the time unit and then mark in the numeric for duration.

DOCUMENTATION - a. Raw score printout
b. Frequency tables.

2. Assessment of Change in the Course of Treatment (Input Package)

Input Package

Documentation which describes what happened during the clinical trial is based on rating scales. Many kinds of judgments depend upon these documents. It is vital, therefore, that the documentation depict the events of the trial as accurately and comprehensibly as possible, for they are ultimately the only evidence admissible in a scientific court. All too frequently, failure to document a trial properly has led to incomplete or ambiguous findings. This makes it impossible to arrive at a substantive judgement of the trial itself, or to compare its results with other similar trials. The effects of the drug cannot be assessed under these conditions and its true merits may be obscured. Since much time, effort, and expense go into a trial, the completeness of the documentation should reflect this undertaking.

In clinical psychotropic drug trials, the major criterion measure is usually the reduction of symptoms. This criterion can be assessed in a global fashion by items which state simply that the patient is less mentally ill now than he was at some previous time or that he has improved generally from some previous time. Such judgements, when made by a trained professional, are certainly valid, but provide only a minimum of information. Usually, the investigator is interested in a more detailed description of the drug's effect upon certain kinds of symptoms, or in effects which differentiate the drug's actions from other agents. A global rating will not suffice; separate judgements of a variety of symptoms or behaviors are required.

A behavioral scale is created by assigning numbers by some set of rules to some aspect of an event or, to be precise, to a judgement of some aspect of an event. The judgement of the presence of a psychiatric symptom is usually the event and its magnitude is the aspect to which the scale numbers refer. The rules or operation used determine the types of scales achieved.

If the number assigned simply identifies an event or category of events, no magnitude is attached to the event. It has only been named and we have a nominal scale. The RPR is a good example of this in that it classifies a number of events or variables pertaining to the conduct of a clinical trial. The APDI is another example. Assigning number 1 to male and number 2 to female does not imply that "female" is twice "male", but rather that two categories of the trait, sex, are involved. At this point, we still have a nominal scale. However, if we characterize certain behaviors as masculine and others as feminine, observe them in subjects, and on the basis of the number of characteristics possessed by a subject, judge him to be a little bit male, moderately male, or much male,

we begin to create an ordinal scale, that is, one in which the categories are ranked. Most psychological scales are ordinal. Some event, such as a psychiatric symptom, is judged to be present in a given individual to a greater or lesser degree than at some previous time. Usually the judgement points along such a scale are set arbitrarily, such as mild, moderate, or severe and the magnitude between these points is unknown; that is, "moderate" is not known to be twice "mild", or one-half "severe".

When, through psychometric techniques, equal scale points are approximated, an interval scale is created. Standard scores on some achievement tests are a good example of this. However, rarely is the zero or anchor point of such scales known. Intelligence can be usefully assessed on an ordinal scale which approximates an interval scale, but zero intelligence is neither defined nor known to exist. When a zero point and equal intervals are defined, a ratio scale is created. Such scales occur in physics, for example, with length, weight, etc. Ratio scales can be transformed by multiplying each value by a constant, say, in the case of inches to feet, etc. In the very strictest sense, only with ratio scales can all types of statistical measures be applied. However, because it has been found pragmatically useful and has led to meaningful results, most psychological scales are treated statistically as though they were interval or, indeed, even ratic scales. It is assumed, albeit without evidence, that the scale points are equal, and it is further assumed that we know the zero point. That is, we define the zero point as "no presence of the symptom".

Brushing statistical impurity under the rug, for the moment most investigators concern themselves with two other aspects of a scale : is it reliable and is it valid ? Reliability measures the extent to which the results of a scale are verifiable. For most rating scales, the usual way of measuring reliability is to have multiple raters judge the same psychiatric condition in the same subject. In general, the length of a scale, the time necessary to complete it, the objectivity and homogeneity of the items, all affect reliability, as will the professional experience of the raters, their set at the time of rating, and their enthusiasm for the task. A long period of time between ratings tends to decrease reliability, as does the interdependence of items. That is, if the judgement of one item is related to the judgment given on several other items, reliability between raters tends to decrease. Most widely used psychiatric rating scales have undergone reliability studies and the results of these studies are published by the authors.

Validity refers to the extent to which a scale measures what it purports to measure. A valid scale for psychotropic drug trials should measure accurately the degree to which certain symptoms are present at a given time and also reflect changes of those symptoms under drug treatment. Usually a scale is shown to be valid if it correlates highly with some other independent acceptable criterion. This may be the expert opinions of professionals or high correlation with established rating scales or measures such as release from the hospital, better work, and /or social performance, etc.

In reviewing the documentation for a study, a monitor should first be familiar with the scales chosen. In those cases where the scale is well known, the monitor will be familiar with the items of the scale and its relevance to the study at hand. For example, if a drug is considered to be a neuroleptic, and the major rating scale is a measure of anxiety, even one which validly and reliably measures anxiety, there can be little proof of the drug's potential antipsychotic action. When faced with unfamiliar scales, the monitor should ask for further information about the scale and thereby determine its psychometric characteristics and its relevance to the study. Even with a well-established scale, the monitor should be careful to note whether the scale has been used in its accepted form. Changing items, omitting items, or adding interpretations to items of an established scale can invalidate that scale, and it is up to the investigator to demonstrate that he is still measuring behavior in a reliable and valid fashion.

The scales for the BLIPS/BDP System were chosen through a consensus of experts in the field. These scales should not be regarded as the only measures available or, for that matter, the best measures that might have been chosen. They are all widely-used scales and all have reliability and validity data reported upon them.

The present BLIPS/BDP Battery consists of 26 scales. Of them, 14 are employed in the assessment of change in the course of treatment. In 2 of the 14 rating scales, change is assessed in a global fashion, based on the judgment of the assessing psychiatrist, in case of Clinical Global Impressions, or on the judgement of the assessing nurse, in case of Nurses' Global Impressions. Both scales may be employed in studies conducted in children, adults and/or aged patients.

The remaining 12 instruments are behavioral rating scales which provide a detailed description of the drug's effect on certain kinds of syptoms. Two of

the 12 scales are exclusively for the assessment of change in children, one the Children's Psychiatric Rating Scale, completed by a psychiatrist, and the other the Children's Behavior Inventory, completed by a nurse; and 2 are exclusively for the assessment of change in the aged, one the Sandoz Clinical Assessment Geriatric, completed by a psychiatrist, and the other the Plutchik Geriatric Rating Scale, completed by a nurse. Of the 8 scales primarily for adult (also for elderly adult) populations, 5 are completed by the psychiatrist, i.e., Brief Psychiatric Rating Scale, Hamilton Depression Scale, Hamilton Anxiety Scale, Comprehensive Psychopathological Rating Scale and the AMDP Psychopathological Symptoms Form ; one, the Nurses' Observation Scale, is completed by the nurse, and 2 scales, the Self-Assessment Depression Scale and the Self-Report Symptom Inventory, are completed by the patient.

a) ALL POPULATIONS

Dosage Record and Treatment Emergent Symptom Scale

(DOTES)

DOSAGE RECORD AND TREATMENT EMERGENT SYMPTOM SCALE (DOTES)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Dosage Record and Treatment Emergent Symptom Scale (DOTES)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) - - -
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-999

(10-12) - - -
Form Number

(13-15) - - -
Assessment Period

(16-17) 0 2 9
Rater Number

(18-19) 0 1
Card Number

(76-80) - - - - -
Group to which
Patient is Assigned

INSTRUCTIONS

CATALOGUE OF SYMPTOMS - For each symptom cited (present), 3 judgments are required - intensity of the symptom, its relationship to the drug and the action undertaken as a consequence of its presence.

a. Intensity - Generally, the levels of intensity are defined as follows :

0 = not assessed - Mark this category when NO assessment (rating) of a specifuc symptom is made. Leave Relationship and Action sections blank.

1 = not present - Mark this category if symptom is assessed and is found absent.

2 = mild - The symptom does not hinder the subject's normal functioning level, i.e., his level at pretreatment. An annoyance to the subject.

3 = moderate - The symptom produces some degree of impairment to functioning but is not hazardous to health. Uncomfortable and/or embarrassing to the subject.

4 = severe - The symptom is a definite hazard to well being. Significant impairment of functioning or incapacitation.

b. Relationship - A judgment of the degree of relationship between the occurrence of the symptom and the drug rated on a 5-point scale.

5 = none - No relationship between symptom and drug.

6 = remote - Less than a 10% probability that symptom occurence is related to drug employed.

7 = possible - Probability between 10% and 50%.

8 = probable - Probability between 50% and 90%.

9 = defined - Greater than 90% probability that symptom is related to drug employed.

c. Action taken - Refers to action taken as a consequence of the symptom's appearance. Actions are arranged in order of increasing stringency. Only ONE action - the most stringent - should be recorded as it is assumed that less stringent actions may also be employed.

ACTION CODE : 0 = none
1 = increased surveillance
2 = contraactive Rx
3 = change dose
4 = change dose plus contraactive Rx
5 = suspend Rx
6 = discontinue Rx

DOSAGE RECORD and TREATMENT EMERGENT SYMPTOM SCALE

1. Reason for Completing Scale

On the DAY recorded under PERIOD, dosage was : (mark ONE only)

0 = initiated (first dose)
1 = changed per protocol
2 = changed due to ineffectiveness
3 = changed due to toxicity
4 = changed for titration (test dose)
5 = discontinued/suspended
6 = reinitiated following suspension
7 = changeover point of crossover design
8 = not changed but treatment emergent symptom/s occured
9 = regular (fixed) TESS assessment

(20)

2. Total Daily Dose

a. Component (use for all single component drugs) (21-23) (24)

b. Component (for combination drugs only) (25-27) (28)

c. FOR STUDIES IN WHICH RECORDING "TOTAL DAILY DOSE" IS INAPPROPRIATE, E.G. LONG-ACTING DRUGS, DEPOT DRUGS, VERY SHORT-ACTING DRUGS, etc., enter amount of drug in 2 a (b) and mark the length of time and time units over which the drug is presumed to be effective.

Drug is presumed to be effective for :

time unit : 1 = hours 3 = weeks
2 = days 4 = months

(25-30) (31)

3. Prescription

Mark 2 responses : one for prescription (No 0 through 6) and one for proportions (No 7 or 8).

Dosage is to be given : 0 = hs 5 = prn
1 = qd 6 = depot
2 = bid 7 = equal
3 = tid 8 = unequal proportions
4 = qid

a (32)

b (33)

4. Treatment Emergent Symptoms

At the previous dosage level (or since the last assessment), were any significant physical signs, laboratory findings or symptoms present ? (For initial assessment, record presence or absence of symptoms for that day only.)

Mark one :

0 = NO (If NO and ALL SYMPTOMS WERE ASSESSED, no further response necessary)

1 = YES printed symptoms present but no "write-ins"

2 = YES both printed and "write-in" symptoms present

3 = YES only "write-ins" present. (Do not forget to complete Item 6 before proceeding to TWIS, TESS Write-In Scale.)

(34)

5. Catalogue of Symptoms		a	b	c
Behavioral Toxicity :	toxic confusional state	(35-37)		
	excitment/agitation	(38-40)		
	depressive affect	(41-43)		
	increased motor activity	(44-46)		
	decreased motor activity	(47-49)		
	insomnia	(50-52)		
	drowsiness	(53-55)		
Abnormal laboratory findings :	abnormal hematologic	(56-58)		
	abnormal liver	(59-61)		
	abnormal urine	(62-64)		
Neurologic :	rigidity	(65-67)		
	tremor	(68-70)		
	dystonic symptoms	(71-73)		
	akathisia	(74-75-20)*		
Autonomic	dry mouth	(21-23)		
	nasal congestion	(24-26)		
	blurred vision	(27-29)		
	constipation	(30-32)		
	increased salivation	(33-35)		

*Card No. 02

(5. Catalogue of Symptoms, cont'd)

		a	b	c
(Autonomic, cont'd)	sweating	(36-38)		
	nausea/vomiting	(39-41)		
	diarrhea	(42-44)		
Cardiovascular :	hypotension	(45-47)		
	syncope/dizziness	(48-50)		
	tachycardia	(51-53)		
	hypertension	(54-56)		
	EKG abnormality	(57-59)		
Other :	dermatologic	(60-62)		
	weight gain	(63-65)		
	weight loss	(66-68)		
	anorexia/decreased appetite	(69-71)		
	headache	(72-74)		
	tardive dyskinesia	(75-20-21)*		

6. Global Judgements (omit at pretreatment)

a. Compared to other subjects in this study, how serious have his/her treatment emergent symptoms been ?

(22)

0 = not at all
1 = minimal
2 = moderate
3 = marked
4 = not ascertained

b. Compared to other subjects in this study, how much distress has this subject expressed or attributed to his symptoms ?

(23)

5 = not at all
6 = minimal
7 = moderate
8 = marked
9 = not ascertained

*Card No. 03

Date (70-75) ___ ___ ___

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU Programm, the DOTES is a 41-item scale in which treatment emergent symptoms are recorded and related to a specific dosage. It is designed to capture judgments on the relationship of symptoms to the drug and the action undertaken as well as the intensity of that. These three judgments - linked to a specific dosage - allow for a precise documentation of the adverse event.

APPLICABILITY - All populations.

UTILIZATION - Completed for every dosage change. A pretreatment and terminal DOTES should always be completed.

SPECIAL INSTRUCTIONS

DOTES is the most difficult form : the data are not as "fixed in time" as are efficacy measures. The advent of side effects and the need for dosage manipulations are much more idiosyncratic and not readily scheduled in a pre-determined protocol. Raters should, therefore, pay particular attention to the following instructions.

Item 1. Reason for completing scale - Preferably DOTES should be completed for each dosage change and/or occurrence of treatment emergent symptoms. Only one response is permitted for each DOTES.

1. "Per protocol" refers to all planned dosage changes established prior to the study.
2. Ineffectiveness - Includes instances of increased psychopathology (worsening) as well as instances where psychopathological condition is unchanged, unimproved or static.
3. Toxicity - Refers to changes which in the judgement of the clinician are the result of an untoward effect of the medication, i.e., to be distinguished from ineffectiveness (2).
4. Titration - Refers to changes which are made to enhance therapeutic response in the individual subject, i.e., "test doses".
5. Discontinued/suspended - Refers to unplanned interruptions in dosage schedule.

6. Reinitiated - Use this category when restarting medication following suspensions (5).

7. "Changeover point" - Refers to planned switches of medication and is for use only in crossover designs. Mark the dosage of the new medication as usual.

8. "Not changed but treatment emergent symptom/s occurrence- Although the dosage is unchanged from previous one, it should nevertheless be marked again rather than left blank.

9. "Regular TESS assessment" - Enter dosage whether or not the regular TESS assessment coincides with an actual dosage change. "Regular TESS assessment" refers to the use of the scale independent of dosage change, i.e., using the DOTES in the manner of the original TESS, e.g., fixed periods of assessment which are scheduled prior to the start of the study.

Item 2. Total Daily Dose - DOTES' time perspective requires the rater to be like Janus - looking simultaneously in two directions, forward for dosage; backward for symptoms. The dosage which he marks is the dosage which he is going to give - not the dosage which has been given. Conversely, the symptoms which he cites have occurred under the previous dosage - not the one actually encoded on the form.

For single drugs, i.e., drugs with one chemical component, complete Item 2a only. For combination drugs, mark Component a in 2a and Component b in 2b. Even if the dosage for only one component of the combination is being changed, mark BOTH the "changed" and "unchanged" components. In a given study, always mark the components in a consistent fashion, i.e., a in 2a and b in 2b.

Item 2c. The sole purpose of this item is to record dosage regimes which cannot be adequately described by Total Daily Dose. In all other circumstances, it should be left blank.

NOTE : for double-blind studies in which the rater is unaware of the actual dosage administered, the number of capsules or other units may be marked rather than dosage. Later, when the data are processed, actual dosages can be calculated via computer.

Item 3. Prescription - The item requires 2 responses, one for prescription (0-6) and one for proportions (7 and 8). "Depot", which refers to a drug contained in a vehicle allowing for slow release and long action, should

always be marked as equal proportions.

Similarly, QD, HS and PRN are marked as equal proportions.

Item 4. Presence/Absence of Symptoms - Since symptoms other than those printed on the scale can occur and should be recorded, a separate "write-in" form has been provided (TWIS). In case where only write-in symptoms are present, mark response 3 - leave all the catalogue of symptoms blank (Item 5) - but be sure to answer Item 6, Global Judgment.

Item 5. Catalogue of Symptoms - Raters need to mark only those symptoms "present" or "not assessed". Leave the rest of the catalogue blank.

The rater should endeavor to make an assessment of all symptoms printed on the scale as well as an inquiry into the occurrence of any other "non-printed" symptoms. The extent to which symptoms may be monitored is - in part .- dependent upon the setting of the study, the sources of observation and the capacity of the subject to report their occurrence. In making judgements, it is suggested that the rater make use of all available sources of information (nurses' observations, family comments, subject's complaints, etc.). Whenever possible, objective verification of the symptom should be attempted. General questions such as "How have you been feeling physically ?"; "How does the drug make you feel ?" may be utilized to elicit the occurrence of symptoms which are not directly observerable or which have not been brought to light from other sources.

For each symptom cited (present), 3 judgments are required : intensity of the symptom, its relationship to the drug and the action undertaken as a consequence of its presence.

a. Intensity - Precise definition of the levels of intensity is complicated. Many symptoms are subjective, i.e., not directly observable; and, further, no established standards exist for rating intensity. (see note below). Generally, however, the 3 levels may be defined as :

2 = mild — The symptom does not hinder the subject's normal functioning level, i.e., his level at pretreatment. An annoyance to the subject. Evidence for the presence of the symptom may be equivocal or based entirely on subjective report.

3 = moderate — The symptom produces some degree of impairment to functioning but is not a hazard to life. Uncomfortable and/or embarrassing to the subject. Evidence for the pre-

sence of the symptom is clear-cut, i.e., directly observale and/or deduced from the subject's behavior.

4 = severe — Symptom is a definite hazard to well being. Significant impairment of functioning or incapacitation. Again, evidence is clear-cut.

Intensity should be rated independently without regard to its relationship to drug. Since there is a high degree of correlation between intensity and the action undertaken as a consequence of a symptom, however, raters may find that they differentiate intensity levels partially on the basis of action.

b. Relationship - A judgment of the degree of relationship between the occurrence of the symptom and the drug rated on a 5-point scale.

5 = none - no relationship

6 = remote - less than a 10% probability that symptom occurrence is related to drug employed

7 = possible - probability between 10% and 50%.

8 = probable - probability between 50% and 90%

9 = defined - greater than 90% probability that symptom occurrence is related to drug employed.

c. Action taken - Refers to action taken as a consequence of the symptom's appearance. Actions are arranged in order of increasing stringency. Only ONE action - the most stringent - should be recorded as it is assumed that less stringent actions may also be employed.

0 = none - No action is taken; the symptom is simply cited as present by the investigator.

1 = increased surveillance - Increased alertness over and above routine observation is required by the professional staff, the subject's relatives and/or the subject himself.

2 = contraactive Rx - Remedial medication or treatment is prescribed. Include all medications and treatments which, in the opinion of the physician, are administered in response to the presence of an adverse reaction/s.

3 = change dose - Any non-protocol change (increase or decrease) ordered as a consequence of adverse reaction/s.

4 = change plus contraactive Rx - A combination of actions 2 and 3 undertaken simultaneously.

5 = suspend Rx - Cessation of treatment for a period of time as a consequence of an adverse reaction. Be sure to mark response 6 (Item 1) when reinitiating medication.

6 = discontinue Rx - A decision to stop medication completely as a consequence of adverse reaction/s. Do not rate the termination of treatment as planned in the protocol here. Such "planned" termination is considered "per protocol".

Item 6a. Global Severity - An overall judgment - similar to the widely used efficacy - of the extent to which treatment emergent symptoms have affected the subject in comparison to all other subjects in the study. Omit the item at the pretreatment rating.

b. Degree of distress.- An overall judgment of the subject's degree of distress attributed by him to "adverse reactions" in comparison to all other subjects in the study. The subject's degree of distress is judged here - not the accuracy of his attributions. Omit the item at pretreatment.

NOTE ON DEFINING INTENSITY

The following list of definitions is presented as guidelines for rating the intensity of symptoms in adults. The sources for these definitions are :

1. Vinar, O., Scale for Rating Side Effects during Psychiatric Psychopharmacology, Activ. Nerv. Super. 8, 4, 411-412, 1966.
2. Schiele, B., Parkinson's Disease Rating Scale
3. McGlashan, T., Personal Communication

CATALOGUE of SYMPTOMS

1. Toxic Confusional State (Vinar)

   Moderate - Transitory toxic confusion during night.
   Severe - Toxic confusion lasting during daytime.

2. Excitment/Agitation (McGlashan)

   Mild - Expressed fear and anxiety.
   Moderate - Expressed fear and anxiety and frequent - but not constant - agitated motor movements.
   Severe - Expressed fear and anxiety with constant agitated motor movements, e.g., pacing, wringing of hands, etc.

3. Depressive Affect (McGlashan)

   Mild - Complains of depressed mood when questioned.

   Moderate - Volunteers feelings of depression and hopelessness. Cries easily.

   Severe - Mimics full blown depressive episode with psychomotor retardation.

4. Increased Motor Activity (McGlashan)

   Mild - Increased, but not constant, activity which can be self-controlled.

   Moderate - Constant activity but no external controls needed.

   Severe - Constant activity; external controls needed.

5. Insomnia (McGlashan)

   Mild - Loss of 2 hours from regular sleep pattern.

   Moderate - Loss of 3-6 hours.

   Severe - Loss of more than 6 hours.

6. Drowsiness (McGlashan)

   Mild - Dozing or sleeping the equivalent of 2 hours during daytime.

   Moderate - The equivalent of 2-8 hours/day.

   Severe - More than 8 hours; asleep most of the time but not comatose.

7. Liver Functions (Vinar)

   Moderate - Changes in the liver tests.

   Severe - Jaundice.

8. Rigidity (Schäele)

   Mild - Detectable rigidity in neck and shoulders. Activation phenomenon is present. One or both arms show mild, negative, resting rigidity.

   Moderate - Moderate rigidity in neck and shoulders. Resting rigidity is positive when patient not on medication.

   Severe - Severe rigidity in neck and shoulders. Resting rigidity cannot be reversed by medication.

9a. Tremor (Schiele)

Mild - Less than one inch of peak-to-peak tremor movement observed in limbs or head at rest or in either hand while walking or during finger to nose testing.

Moderate - Maximum tremor envelope fails to exceed 4 inches. Tremor is severe but not constant and patient retains some control of hands.

Severe - Tremor envelope exceeds 4 inches. Tremor is constant and severe. Patient cannot get free of tremor while awake unless it is a pure cerebellar type. Writing and feeding himself are impossible.

9b. Tremor (Vinar)

Mild - A feeling of inner tremble or tremor, which is not objectively visible unless a little when the arms are stretched in front of the body and the eyes are closed.

Moderate - Clear, objectively visible tremor, not preventing the patient from work (not even fine work or writing).

Severe - Greater tremor, preventing the patient from precise manual work. Big tremor, the patient cannot even eat.

10. Dystonic Symptoms (McGlashan)

Mild - Rigidity without impaired mobility.

Moderate - Interferes with mobility but not incapacitating.

Severe - Incapacitated (motoric mobility).

11. Akathisia (Vinar)

Mild - Subjectively felt "inner agitation", lack of patience; the patient resists it.

Moderate - Lack of patience makes the patient stand up during conversation; when working, he stands up now and then and walks a little. The conversation, however, is not interrupted and the work is finished in due time.

Severe - The patient cannot keep sitting even when consulting the doctor, must walk along the room; his rate of work is substantially reduced, cannot even read one page of a book without break. Impatience and agitation prevent the patient completely from any useful activity; he must be walking continuously, cannot master himself.

12. Dry Mouth (Vinar)

Mild - Mucuous membranes are dry; the patient complains of it.

Moderate or Severe - Mucuous membranes are so dry that it can be seen by the observer clearly.

13. Nasal Congestion (Vinar)

Mild - Feeling of stopped-up nose - or a very disagreeable feeling of completely dry membrane in the nose.

Moderate or Severe - A stopped-up nose - it may be observed and proved (as the patient speaks, etc.).

14. Blurred Vision (McGlashan)

Mild - Complaints of blurriness but little if any sensory impairment

Moderate - Interferes with acuity

Severe - Interferes with acuity and motor movements, e.g., bumps into things.

15. Constipation (Vinar)

Mild - Constipation for more than 36 hours.

Moderate - Constipation for more than 4 days

Severe - The patient need to be given clysma.

16. Increased Salivation (Vinar)

Moderate - More saliva, the patient manages to swallow it.

Severe - Saliva flows out of the mouth.

17. Sweating (Vinar)

Mild or Moderate - He sweats more than usually or in fits.

Severe - Facies oleosa.

18. Nausea/Vomiting (Vinar)

Moderate - Nausea.

Severe - Vomiting.

19. Diarrhea (McGlashan)

Mild - Two loose bowel movements per day.

Moderate - 5 loose bowel movements per day.

Severe - Over 5 a day.

20. Hypotension (Vinar)

Mild - Blood pressure one-tenth lower than before treatment.

Moderate - Blood pressure two-tenths lower.

Severe - Blood pressure scarcely measurable.

Note : this evaluation does not refer to subjective troubles that may be in connection with hypotension. There is only the question of objectively measured values of blood pressure with mobile patients sitting and immobile patients lying.

21. Syncope/Dizziness (McGlashan)

Mild - Transient feelings of dizziness either standing or sitting with no interference with equilibrium.

Moderate - Dizziness with disequilibrium. No unconsciousness.

Severe - Unconsciousness.

22. Tachycardia (Vinar)

Mild - The heart rate is between 90 and 100/min. in subjects where it was under 80/min. before treatment.

Moderate - The heart rate is between 100 and 120/min.

Severe - The heart rate is over 120/min.

Note : the heart rate is recorded in the morning, before the patient leaves his bed.

23. Hypertension (McGlashan)

Mild - Blood pressure 140/190.

Moderate - 160/100

Severe - 200/120.

24. Dermatologic (Vinar)

Mild - Photosensitivity (the patient complains and/or is more sunburnt than usual).

Moderate - Itch, rash, transitory.

Severe - Dermatitis.

25. Weight Gain (McGlashan)

    Mild - Gain of 5 pounds in 1 month.

    Moderate - Gain of 6-10 pounds/month.

    Severe - Over 10 pounds gain in one month.

26. Weight Loss (McGlashan)

    Mild - Loss of 5 pounds in 1 month.

    Moderate - Loss of 6-10 pounds/month.

    Severe - Over 10 pounds/month.

27. Anorexia/Decreased Appetite (McGlashan)

    Mild - Subject consumes the equivalent of 2 meals/day.

    Moderate - The equivalent of 1 meal/day.

    Severe - Does not eat.

28. Headache (McGlashan)

    Mild - Subjective complaint with no impairment.

    Moderate - Sensory input painful but not incapacitating.

    Severe - Incapacitating.

FACTOR COMPOSITION

Six factors have been derived from a 1974 BLIPS analysis of 1963 pretreatment TESS records. (See table II). A seventh "factor" - actually an empirical cluster - is composed of the 3 Abnormal Laboratory Findings.

I. Anti-cholinergic (ANT)
   - Drowsiness
   - Nasal Congestion
   - Dry mouth
   - Blurred vision

II. Central Nervous System (CNS)
   - Rigidity
   - Tremor
   - Dystonic
   - Akathisia
   - Increased salivation

III. Neurotic (NEU)
   - Insomnia
   - Depression
   - Constipation
   - Headache
   - Height loss

IV. Autonomic Nervous System (ANS)
   - Hypotension
   - Syncope/dizziness*
   - Tachycardia
   - Nausea/vomiting
   - Diarrhea

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* dizziness combined with syncope

V. Misçeallenous (MIS)
Dermatologic
Weight gain

VI. Delirium (DEL)
Excitement
Toxic confusion

VII. Abnormal Laboratory Findings (LAB)
Abnormal hematologic
Abnormal liver
Abnormal urine

Symptoms not included in any factor
Increased motor activity
Decreased motor activity
Sweating
EKG abnormality
Anorexia/decreased appetite
Tardive dyskinesia.

T A B L E II

6-FACTOR VARIMAX SOLUTION OF PRETREATMENT TESS

SCORES OF 1963 SCHIZOPHRENIC SUBJECTS (Guy and Cleary)

Item	I	II	III	IV	V	VI	Communalities
Insomnia	-011	032	-685	-094	106	242	549
Drowsiness	-482	018	-031	-025	-092	171	272
Excitment	-134	045	-040	-100	-100	528	320
Depression	007	-040	-733	-201	073	123	600
Toxic confusion	038	059	-107	036	-007	612	392
Rigidity	-062	660	059	143	-039	033	466
Tremor	-171	574	-121	049	-075	118	395
Dystonia	162	578	073	-191	124	002	418
Akathisia	-019	708	-030	-003	-035	-099	514
Hypotension	059	187	098	-556	-050	-304	452
Syncope	-021	005	-029	-653	-015	041	430
Tachycardia	-234	005	-220	-530	-076	040	391
Nasal congestion	-713	014	083	-072	081	055	530
Dry mouth	-629	196	-251	-073	007	-123	517
Increased salivation	-217	328	128	-109	182	206	259
Blurred vision	-612	089	-105	-199	-012	-008	434
Nausea	-261	-102	-095	-358	164	092	251
Diarrhea	-129	-059	-145	-470	-059	189	301
Constipation	-307	172	-517	060	090	-301	493
Dermatitis	-060	-078	047	054	743	-058	570
Headache	-187	-116	-467	-295	178	327	493
Dizziness	-282	-022	-454	-278	-018	279	442
Weight gain	065	070	-138	035	521	-036	302
Weight loss	010	-088	-498	100	-216	-301	402
VP	1.99	1.88	2.19	1.73	1.05	1.35	10.19
% total variance	19.5	18.4	21.5	16.9	10.3	13.2	42.5
% common variance	8.3	7.8	9.1	7.2	4.4	5.6	

DOCUMENTATION

Since DOTES is a crucial element in the documentation, the data displays provided for it are extensive and, to a large extent, unique - requiring discussion in detail.

a. Raw score printout.

b. Cumulative factor scores - Factor scores along with total score are the variables employed in the quantitative analysis of DOTES. Unlike most efficacy measures, however, DOTES is not necessarily completed on a fixed schedule since differences in treatment response and/or the emergence of adverse reactions among subjects are to be expected. These individual differences produce variations in temporal order which make nomethetic analyses extremely difficult. By restructuring the DOTES data set, however, a temporal uniformity - necessary for analysis - can be achieved. The method chosen involves accumulating individual DOTES by time spans which correspond to those designated in the protocol for the major efficacy measure/s. Factor scores along with total score are first computed for each DOTES and then all DOTES within the specified time span are added together to produce cumulative scores.

c. Individual summary - Provides a detailed record of events on an idiographic level. Emergent symptoms and their attributes are linked directly to a given dosage level (total daily dose and cumulative dose) so that the investigator can follow the treatment course within the individual subject.

d. Dosage by groups - Summarizes dosage events by group and is organized by uniform time spans. Treatment groups are juxtaposed so that the investigator can make direct comparisons.

e. All symptoms by group - A group summary of symptoms events by uniform time spans.

f. Drug-related emergent symptoms - This group display enumerates ONLY those symptoms which meet the following criteria :
   1. The symptom is not present in a subject at pretreatment.
   2. Relationship is judged to be either "Probable" or "Defined".
   3. Some action - excluding "None" - is recorded.

g. Variance analyses.

TESS Write-In Scale

(TWIS)

TESS WRITE-IN SCALE (TWIS)

National Institute of Mental Health (USA)	Surname
University of Pisa	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient-ID Number
Center for Clinical Psychopharmacology Data Documentation	Date
TESS Write-In Scale (TWIS)	Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-999

(10-12) 0 3 3
Form Number

(13-15) - - -
Assessment Period

(16-17) - - -
Rater Number

(18-19) 0 1
Card Number

(76-80) - - - - -
Group to which
Patient is Assigned

INSTRUCTIONS : this scale MUST be used in conjunction with the DOTES. Make 3 judgements for each symptom.

A. Intensity
1 = mild
2 = moderate
3 = severe

B. Relationship
0 = none
1 = remote
2 = possible
3 = probable
4 = defined

C. Action Taken
0 = none
1 = increased surveillance
2 = contraactive Rx
3 = change dose
4 = change dose + contraactive Rx
5 = suspend Rx
6 = discontinue Rx

1. Other Symptoms					(20-22)
A. Intensity	(23)	B. Relationship	(24)	C. Action taken	(25)
2. Other Symptoms					(26-28)
A. Itensity	(29)	B. Relationship	(30)	C. Action taken	(31)
3. Other Symptoms					(32-34)
A. Intensity	(35)	B. Relationship	(36)	C. Action taken	(37)
4. Other Symptoms					(38-40)
A. Intensity	(41)	B. Relationship	(42)	C. Action taken	(43)
5. Other Symptoms					(44-46)
A. Intensity	(47)	B. Relationship	(48)	C. Action taken	(49)
6. Other Symptoms					(50-52)
A. Intensity	(53)	B. Relationship	(54)	C. Action taken	(55)

INSTRUCTIONS for USERS

DEVELOPMENT - Developed within the ECDEU program, the TESS Write-In Scale (TWIS) is an independently formatted 6-item scale to be used in conjunction with the Dosage Record and Treatment Emergent Symptoms (DOTES).

APPLICABILITY - For all research populations.

UTILIZATION - Used in conjunction with DOTES whenever it is necessary to record the presence of a symptom not printed on DOTES.

TIME SPAN RATED - Same as the referent DOTES.

SPECIAL INSTRUCTIONS

Identification Block (ID) - It is essential that the ENTIRE ID BLOCK CODED ON TWIS MATCH EXACTLY the ID block of the corresponding DOTES. Example : while rating the DOTES at Day 24, the rater observes that, in addition to tremor and increased salivation (printed symptoms), the subject is grinding his teeth. On Item 4 of DOTES, he marks "2 = yes, both printed and write-ins present" and then proceeds to mark his judgements of "tremor" and "increased salivation". He next fills out the TWIS by completing the ID block exactly as it appears on DOTES. Finally, he writes in "grinding teeth" and marks his 3 judgments of the symptom.

Item 1-6 - Other Symptoms - When writing in a symptom, the rater must make judgements of intensity, relationship and action undertaken exactly as he does for DOTES.

Intensity, Relationship, Action - These 3 judgments are rated in the same manner as described in DOTES.

DOCUMENTATION - a. Raw score printout.

b. "Write-ins" will be incorporated within the documentation provided for DOTES.

Laboratory Data (LAB)

INSTRUCTIONS

LABORATORY STANDARDS - If laboratory standards (normal limits) are not already established for your unit, i.e., in the BLIPS/BDP data file, or if you wish to employ different standards for analyses, please include such standards with data

PERIOD - Laboratory tests must be encoded period by period, i.e., do not encode laboratory data from different assessment periods on the same form.

Record period in days from initial (first) rating regardless of initiation of medication.

While a set of laboratory tests may actually be collected in 2 days, code the entire set under one period if they were meant to constitute a single assessment. When a test requires verification, i.e., repeated to check results, only the verified value should be encoded.

For each laboratory test encoded, the rater must make 4 entries :

1. the numeric value,
2. a clinical judgment of abnormality,
3. a clinical judgment of relationship to drug,
4. the action undertaken as a consequence of the finding.

VALUE - Refers to the numeric value obtained from the test.

CLINICAL JUDGEMENTS - For each laboratory test, 3 clinical judgements are made : abnormality (ABN), relationship (REL) and ACTION.

a. Abnormal - Abnormal refers to a clinical judgment of abnormality - regardless of numerical value.
   N = no, not abnormal
   ? = questionably abnormal
   Y = yes, clinically abnormal
   A = alert, an extreme abnormality.

b. Relationship - A judgment of the degree of relationship between the test abnormality and the drug rated on a 5-point scale.

(b. Relationship, cont'd)

N = none - no relationship

R = remote - less than a 10% probability that symptom occurence is related to drug employed

PO = possible - probability between 10% and 50%

PR = probable - probability between 50% and 90%

D = defined - greater than 90% probability that symptom occurence is related to drug employed.

c. Action Taken - Refers to action taken as a consequence of the symptom's appearance.

Actions are arranged in order of increasing stringency. Only one action - the most stringent - should be recorded as it is assumed that less stringent actions may also be employed.

Action Code :

NO = none	CH+ = change + contraactive Rx
SR = increased surveillance	SU = suspend Rx
CO = contraactive Rx	DI = discontinue Rx
CH = change dose	

If you obtain data from laboratory test using units other than those printed on the form, do not record the data on the preprinted section. Record the data in one of the sections under "Additional Laboratory Tests".

National Institute of Mental Health (USA) University of Pisa Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data DOCUMENTATION (CCPDD) Laboratory Data (LAB)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 5 5
Form Number

(13-15) _ _ _
Assessment Period

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

Laboratory Tests	Value	Abnormal	Action Taken	Relationship
HGB xx.x gm/100ml	(20-22)	(23) 0 2 4 6	(24) 0 1 2 3 4 5 6	(25) 0 2 4 6 7
HCT xx%	(26-27)	(28) 0 2 4 6	(29) 0 1 2 3 4 5 6	(30) 0 2 4 6 7
RBC millions/mm3	(31-32)	(33) 0 2 4 6	(34) 0 1 2 3 4 5 6	(35) 0 2 4 6 7
WBC thousands/mm3	(36-38)	(39) 0 2 4 6	(40) 0 1 2 3 4 5 6	(41) 0 2 4 6 7
Neutrophiles xx%	(42-43)	(44) 0 2 4 6	(45) 0 1 2 3 4 5 6	(46) 0 2 4 6 7
Lymphocytes xx%	(47-48)	(49) 0 2 4 6	(50) 0 1 2 3 4 5 6	(51) 0 2 4 6 7
Eosinophiles xx%	(52-53)	(54) 0 2 4 6	(55) 0 1 2 3 4 5 6	(56) 0 2 4 6 7
Monocytes xx%	(57-58)	(59) 0 2 4 6	(60) 0 1 2 3 4 5 6	(61) 0 2 4 6 7
Basophiles xx%	(62-63)	(64) 0 2 4 6	(65) 0 1 2 3 4 5 6	(66) 0 2 4 6 7
Sedimentation Rate xx mm/hr	(67-68)	(69) 0 2 4 6	(70) 0 1 2 3 4 5 6	(71) 0 2 4 6 7
NA+ xxx meq/l	(72-74)	(75) 0 2 4 6	(20)* 0 1 2 3 4 5 6	(21) 0 2 4 6 7
K+ x.x meq/l	(22-23)	(24) 0 2 4 6	(25) 0 1 2 3 4 5 6	(26) 0 2 4 6 7
CL- xxx meq/l	(27-29)	(30) 0 2 4 6	(31) 0 1 2 3 4 5 6	(32) 0 2 4 6 7
CA++ xx mg/100ml	(33-34)	(35) 0 2 4 6	(36) 0 1 2 3 4 5 6	(37) 0 2 4 6 7
PO4 x.x mg/100ml	(38-39)	(40) 0 2 4 6	(41) 0 1 2 3 4 5 6	(42) 0 2 4 6 7
MG++ x.x meq/l	(43-44)	(45) 0 2 4 6	(46) 0 1 2 3 4 5 6	(47) 0 2 4 6 7
LI+ x.x meq/l	(48-49)	(50) 0 2 4 6	(51) 0 1 2 3 4 5 6	(52) 0 2 4 6 7
SGOT xx U Karmen/100 ml	(53-54)	(55) 0 2 4 6	(56) 0 1 2 3 4 5 6	(57) 0 2 4 6 7

*Card No. 02

Laboratory Tests	Value	Abnormal				Action Taken							Relationshop				
SGPT xx U/100ml	(20-21)*	(22) 0	2	4	6	(23) 0	1	2	3	4	5	6	(24) 0	2	4	6	7
LDH xxx U/100ml	(25-27)	(28) 0	2	4	6	(29) 0	1	2	3	4	5	6	(30) 0	2	4	6	7
A ylase xxx Somogyi units 100ml	(31-33)	(34) 0	2	4	6	(35) 0	1	2	3	4	5	6	(36) 0	2	4	6	7
Alcaline Phosphastase King Armstrong U/100ml	(37-39)	(40) 0	2	4	6	(41) 0	1	2	3	4	5	6	(42) 0	2	4	6	7
BUN xx mg/100ml	(43-44)	(45) 0	2	4	6	(46) 0	1	2	3	4	5	6	(47) 0	2	4	6	7
CREATININE x.xmg/100ml	(48-49)	(50) 0	2	4	6	(51) 0	1	2	3	4	5	6	(52) 0	2	4	6	7
Uric Acid x.xmg/100ml	(53-54)	(55) 0	2	4	6	(56) 0	1	2	3	4	5	6	(57) 0	2	4	6	7
Total Bilirubin x.xmg/100ml	(58-59)	(60) 0	2	4	6	(61) 0	1	2	3	4	5	6	(62) 0	2	4	6	7
Direct Bilirubin x.xxmg/100ml	(63-65)	(66) 0	2	4	6	(67) 0	1	2	3	4	5	6	(68) 0	2	4	6	7
Total Protein x.xgm/100ml	(69-70)	(71) 0	2	4	6	(72) 0	1	2	3	4	5	6	(73) 0	2	4	6	7
Blood Albumin x.xgm/100ml	(74-75)	(20)** 0	2	4	6	(21) 0	1	2	3	4	5	6	(22) 0	2	4	6	7
FBC xxxmg/100ml	(23-25)	(26) 0	2	4	6	(27) 0	1	2	3	4	5	6	(28) 0	2	4	6	7
Cholesterol xxxmg/100ml	(29-31)	(32) 0	2	4	6	(33) 0	1	2	3	4	5	6	(34) 0	2	4	6	7
PBI x.xmcg/100ml	(35-36)	(37) 0	2	4	6	(38) 0	1	2	3	4	5	6	(39) 0	2	4	6	7
Triglycerides xxxmg/100ml	(40-42)	(43) 0	2	4	6	(44) 0	1	2	3	4	5	6	(45) 0	2	4	6	7

*Card No. 03
**Card No. 04

Laboratory Tests	Value	Abnormal	Action Taken	Relationship
Specific Gravity (Urine) 1.xxx	(46-48)	(49) 0 2 4 6	(50) 0 1 2 3 4 5 6	(51) 0 2 4 6 7
Albumin (Urine)	(20)* none or trace 1 2 4 40+	(21) 0 2 4 6	(22) 0 1 2 3 4 5 6	(23) 0 2 4 6 7
Sugar (Urine)	(24) none or trace 1 2 4 40+	(25) 0 2 4 6	(26) 0 1 2 3 4 5 6	(27) 0 2 4 6 7
RBC (Urine) xxx/HPF	(28-29)	(30) 0 2 4 6	(31) 0 1 2 3 4 5 6	(32) 0 2 4 6 7
WBC (none) xxx/HPF	(33-35)	(36) 0 2 4 6	(37) 0 1 2 3 4 5 6	(38) 0 2 4 6 7

Additional Laboratory Tests

Spaces are provided below for the recording and rating of laboratory tests not printed above. Write in the name of test in the space provided and then record value and make the clinical judgements as usual. Always be sure to answer the following 2 questions :

. Have you recorded non-listed tests on page 3 ?

. Have you recorded non-listed tests on page 4 ?

	No	Yes
(39)	0	1
(40)	0	1

*Card No. 05

	Units	Value	Abnormal	Action Taken	Relationship
Name of Test and Units :					
	(41-43)	(44-46)	(47) 0 2 4 6	(48) 0 1 2 3 4 5 6	(49) 0 2 4 6 7
Name of Test and Units :					
	(50-52)	(53-55)	(56) 0 2 4 6	(57) 0 1 2 3 4 5 6	(58) 0 2 4 6 7

Name of Test and Units	(59-61)	(62-64)	(65)	(66)	(67)
			0 2 4 6	0 1 2 3 4 5 6	0 2 4 6 7

Name of Test and Units :	(68-70)	(71-73)	(74)	(75)	(20)*
			0 2 4 6	0 1 2 3 4 5 6	0 2 4 6 7

Date:	(70-75)
	- - - - - -

*Card No. 06

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Laboratory Data (LAB)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-999

(10-12) 0 5 5
Form Number

(13-15) - - -
Assessment Period

(16-17) - -
Rater Number

(18-19) 0 7
Card Number

(76-80) - - - - -
Group to which Patient is Assigned

If the laboratory data you wish to record consists ONLY OF TESTS NOT PRINTED ON PAGES 1-3, this page (6) may be used independently, i.e., by itself.

	Units	Value	Abnormal	Action Taken	Relationship
Name of Test and Units :	(21-23)	(24-26)	(27) 0 2 4 6	(28) 0 1 2 3 4 5 6	(29) 0 2 4 6 7
Name of Test and Units :	(30-32)	(33-35)	(36) 0 2 4 6	(37) 0 1 2 3 4 5 6	(38) 0 2 4 6 7
Name of Test and Units :	(39-41)	(42-44)	(45) 0 2 4 6	(46) 0 1 2 3 4 5 6	(47) 0 2 4 6 7
Name of Test and Units :	(48-50	(51-53)	(54) 0 2 4 6	(55) 0 1 2 3 4 5 6	(56) 0 2 4 6 7

Note that 4 rows are provided for value in the next 2 blocks.

Name of Test and Units :	(57-59)	(60-63)	(64) 0 2 4 6	(65) 0 1 2 3 4 5 6	(66) 0 2 4 6 7
Name of Test and Units :	(67-69)	(70-73)	(74) 0 2 4 6	(75) 0 1 2 3 4 5 6	(20) 0 2 4 6 7

*Card No. 02

Date: (70-75) _ _ _ _ _ _

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU Program, LAB is a 52-item form for the recording of results from clinical laboratory tests.

APPLICABILITY - All populations.

UTILIZATION - Once at pretreatment; at least once at post-treatment. Additional assessments are at the discretion of the investigator.

TIME SPAN RATED - By their nature, laboratory tests are "point in time" assessments.

SPECIAL INSTRUCTIONS - Detailed instructions are printed directly on the form and should be read carefully by the rater.

1. Standards refer to the limits of normality set by the investigator for his laboratory data. These standards MUST be sent to the Center for Clinical Psychopharmacology Documentation otherwise processing cannot proceed. In subsequent BLIPS/BDP processing each investigator's standards will be used as the basis of analyses for his data. Investigators may utilize more than one set of standards if they desire. For a given study, however, the investigator must specify which set of standards is to be used in the analyses.
2. ONLY DATA FROM A SINGLE PERIOD CAN BE ENCODED ON A SINGLE FORM.
3. In assigning PERIOD to a set of LAB tests, ALWAYS mark the day on which the set of tests was actually obtained - not the day the report of results was obtained. Since the LAB usually requires transcription from hospital laboratory slips, this post-dating should not be any great problem.
4. When a given test value requires verification (repeating the test), RECORD THE "VERIFIED" VALUE ONLY, i.e., the value the investigator considers correct.
5. If one of the LAB tests printed on the form employs UNITS OTHER THAN THOSE INDICATED, the test must be recorded as a write-in and the units indicated; e.g., SGOT values are obtained in Frankel units - not Karmen units. The investigator codes SGOT in one of the "write-in" blocks - not in the SGOT block printed on the form.

6. In instances where the obtained value of a test exceeds the number of rows provided for that test, use one of the "write-in" blocks; e.g., a BUN value of 100 is obtained and, as this exceeds the 2 rows provided, the investigator uses one of the "write-in" blocks.

Recording Tests Not Listed on the Scale

1. Recording non-listed tests in conjunction with listed tests - When the investigator wishes to record both listed and unlisted tests at a given assessment period, he MUST so indicate by answering the 2 questions on page . He then may encode a maximum of 10 additional tests on pages and .

2. Recording non-listed tests only - When the investigator's data consist ONLY of unlisted tests, he MUST use page and NOT page . In this case, page becomes an "independent" scale - the first pages can be discarded. When using page as an independent scale, the investigator MUST COMPLETE THE ENTIRE IDENTIFICATION BLOCK ON PAGE .

3. Note that the last 2 sections of page contain 4 rows of digits under VALUE rather than 3 rows. This provides for the recording of test values which may require the extra digit.

DOCUMENTATION

a. Standards printouts - It is the investigator's prerogative as to the set of standards employed.

b. Intra-subject display of test values and judgements.

c. Group summaries by test.

d. Cross-tabulation of tests/actions.

e. Variance analyses.

For each subject, the events occuring throughout the study are described test by test. The daily and cumulative dosages, the actual value and its position in regard to limits and judgements of abnormality and drug-relatedness are given.

Similar data are summarized by treatment group. Finally, a cross-tabulation of actions undertaken by test are displayed for each treatment group.

Clinical Global Impressions
(CGI)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Clinical Global Impressions (CGI)

Surname
First Name
Additional Patient-ID Number
Date
Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-599

(10-12) 0 2 8
Form Number

(13-15) - - -
Assessment Period

(16-17) - -
Rater Number

(18-19) 0 1
Card Number

(76-80) - - - - -
Group to which
Patient is Assigned

INSTRUCTIONS

Complete Item 1 - Severity of Illness - at the initial and subsequent assessments. Items 2 and 3 may be omitted at the initial assessment.

Clinical Global Impressions

1. Severity of Illness

Considering your total clinical experience with this particular population, how mentally ill is the patient at this time ?

0 = not assessed	5 = markedly ill
1 = normal, not at all ill	6 = severely ill
2 = borderline mentally ill	7 = among the most extremely ill patients
3 = mildly ill	
4 = moderately ill	

(20) -

The next 2 items may be omitted at the initial assessment by marking "not assessed" for both items.

2. Global Improvement

Rate total improvement whether or not, in your judgement, it is due entirely to drug treatment.

Compared to his condition at admission to the project, how much has he changed ?

0 = not assessed	4 = no change
1 = very much improved	5 = minimally worse
2 = much improved	6 = much worse
3 = minimally improved	7 = very much worse

(21) -

3. Efficacy Index

Rate this item on the basis of DRUG EFFECT ONLY.

Select the terms which best describe the degrees of therapeutic effect and side effects and record the number in the box where the 2 items intersect.

(22-23) - -

Therapeutic Effect	Side Effects			
	None	Do not significantly interfere with patient's functioning	Significantly interferes with patient's functioning	Outweighs therapeutic effect
Marked - Vast improvement. Complete or nearly complete remission of all symptoms	01	02	03	04
Moderate - Decided improvement. Partial remission of symptoms	05	06	07	08
Minimal - Slight improvement which does not alter status of care of patient	09	10	11	12
Unchanged or Worse Not assessed = 00	13	14	15	16

Date: __ __ __ __ __ __

INFORMATION for USERS

DEVELOPMENT - The CGI developed during the Psychopharmacology Research Branch collaborative schizophrenia studies. It consists of 3 global scales (items). Two of the items, Severity of Illness and Global Improvement, are rated on a 7-point scale; while the third, Efficacy Index, requires a rating of the interaction of therapeutic effectiveness and adverse reactions.

APPLICABILITY - For all research populations.

UTILIZATION - For Severity of Illness : once at pretreatment and at least one post-treatment assessment. Additional ratings are at the discretion of the investigator. For Global Improvement and Efficacy Index : no pretreatment (baseline) assessment is required. At least one post-treatment assessment should be made. Additional post-treatment ratings are at the discretion of the investigator.

TIME SPAN RATED - For Severity of Illness : now or within the last week. For Global Improvement : since admission to the study. For Efficacy Index : now or within the last week.

SPECIAL INSTRUCTIONS

Item 2 - Global Improvement. Raters are cautioned to observe the unique time span rated for Global Improvement.

For most other items, the time span to be rated is either a specified number of days or since the last rating. The time span for Global Improvement - at each and every rating - is "since admission to the project (study)" - NOT from the last rating period.

Item 3 - Efficacy Index. Efficacy Index is an attempt to relate therapeutic effects and side effects. Therapeutic effect is regarded as gross profit, side effects as cost. The Index, then, is analogous to net profit. The Index is derived by dividing therapeutic effect score by side effect score as follows :

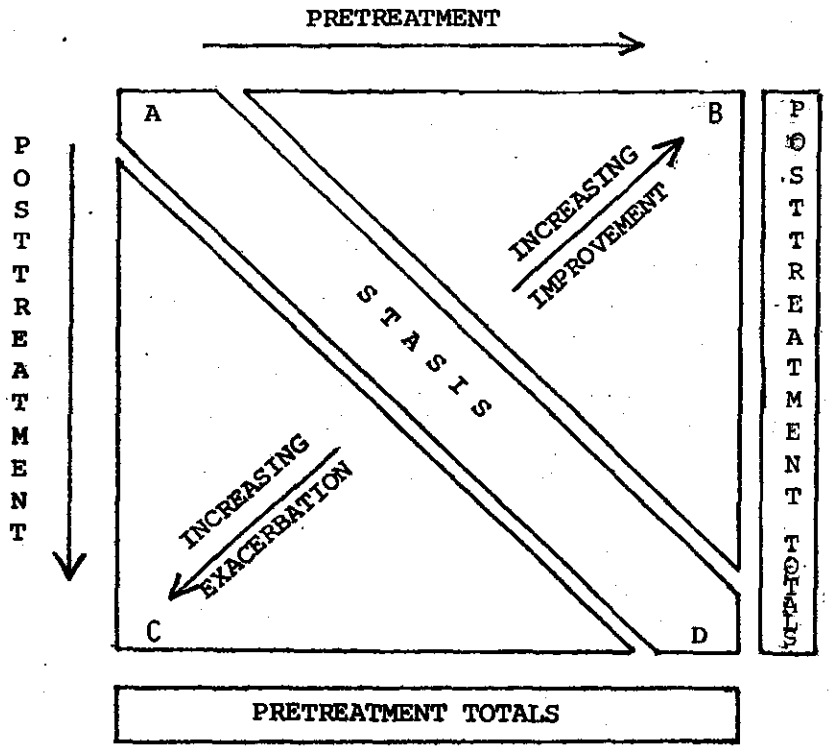
Therapeutic effect	Side Effects: None 1	No Significant Interference 2	Significant Interference 3	Outweighs 4
4 Marked	4.00*	2.00	1.33	1.00
3 Moderate	3.00	1.50	1.00	0.75
2 Minimal	2.00	1.00	0.67	0.50
1 Unchanged or Worse	1.00	0.50	0.33	0.25

* Example : $\frac{\text{therapeutic score (4)}}{\text{side effect score (1)}}$ = Efficacy Index (4.00)

The transformation procedure for Efficacy Index (EI) is :

Number Encoded	= Transformed Score	= EI
01	41	4.00
02	42	2.00
03	43	1.33
04	44	1.00
05	31	3.00
06	32	1.50
07	33	1.00
08	34	0.75
09	21	2.00
10	22	1.00
11	23	0.67
12	24	0.50
13	11	1.00
14	12	0.50
15	13	0.33
16	14	0.25
00	00	0.00

Employing the cross tabulation scheme below to interpret EI, indices falling on the diagonal CB would indicate that the therapeutic and toxic effects of a treatment are equivalent. Those in the upper left quadrant would indicate some degree of "profit" - the profit increasing as pole A is approached. The converse is true of indices falling in the lower right quadrant and, in fact, in all of the last column. The treatment with the greatest efficacy fills the cell at pole A; the worst at pole D. The cell at pole C contains the "inert" treatment. Pole B represents a paradoxical and "theoretical" cell - not one likely to be encountered in the real world.



DOCUMENTATION

a. Raw score printout

b. Means and standard deviations

c. Frequencies and crosstabulations

d. Variance analyses

Nurses Global Impressions

(NGI)

NURSES GLOBAL IMPRESSIONS (NGI)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Nurses Global Impressions (NGI)

Surname
First Name
Additional Patient-ID Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 4 2
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the numeric and the third for the unit of time.
Time unit : pretreatment : 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS - Choose one response for each item.

1. Severity of Illness

Considering your total clinical experience with this particular population, how mentally ill is the patient at this time ?

0 = not assessed
1 = normal, not at all
2 = borderline mentally ill
3 = mildly ill
4 = moderately ill
5 = markedly ill
6 = severely ill
7 = among the most extremely ill patients

(20) -

2. Global Improvement

Compared to his condition at admission to the study, how much has he changed ?

(This item may be omitted at the initial evaluation by marking "0" - not assessed.)

0 = not assessed
1 = very much improved
2 = much improved
3 = minimally improved
4 = no change
5 = minimally worse
6 = much worse
7 = very much worse

(21) -

(70-75)

DATE : - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The NGI developed during the Psychopharmacology Research Branch collaborative schizophrenia studies and is a 2-item scale for the assessment of global clinical judgements.

APPLICABILITY - All populations.

UTILIZATION - Generally rated simultaneously with other nurses' scales. If used alone, the NGI should be rated once at pretreatment and at least once at post-treatment. Additional ratings of the NGI are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS

Severity of Illness - It should be noted that this item is rated in the context of the particular population under study, e.g., in a study involving schizophrenic subjects, the degree of illness should be assessed against the rater's clinical experience with this type of subject. This represents a contextual change from the original item in which the rater was asked to judge severity in the context of total clinical experience with ALL populations (see page).

Global Improvement - Change at any given rating should be compared to the subject's condition at pretreatment - NOT to his condition at the preceding rating. This item should be rated in the same context as CGI Global Improvement, i.e., "Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment".

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Frequencies
d. Cross tabulations
e. Variance analysis .

b. Children's Scales

Children's Psychiatric Rating Scale

(CPRS)

CHILDREN'S PSYCHIATRIC RATING SCALE (CPRS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Children's Psychiatric Rating Scale (CPRS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _ Unit Number

(4-6) _ _ _ Study Number

(7-9) _ _ _ Subject Number
Male 001-499
Female 500-999

(10-12) 0 2 7 Form Number

(13-15) _ _ _ | _ Assessment Period*

(16-17) _ _ Rater Number

(18-19) 0 1 Card Number

(76-80) _ _ _ _ _ Group to which Patient is Assigned

* The first 2 digits are provided for the numeric and the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2, weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS : rate the first 28 items exclusively on the basis of direct observation during the interview. Rate the last 34 items (29-63) on the basis of the child's verbal report of occurence at the time of the interview or during the past 7 days. Do not use any other data but that obtained in the interview with the child.

0	1	2	3	4	5	6	7
not assessed	not present	very mild	mild	moderate	moderately severe	severe	extremely severe

1. Tension (do not include fidgetiness) Musculature appears taut, strained or tense. Fingers clothing, clenches jaws, grips arms of chair, hands tremulous.	(20) _
2. Underproductive Speech (Rate amount of speech only, not rate or relevance.) Fails to answer questions, monosyllabic; has to be pushed to get an answer, does not elaborate, blocked.	(21) _
3. Fidgetiness (Do not include tics.) Wriggles, squirms, moves or shifts restlessly in chair.	(22) _
4. Hyperactivity Has difficulty sitting in chair, gets up; moves fast, vigorously, impulsive bursts of locomotion. Exclude slow ambling even if constant. In rating degree of overactivity, consider the ease with which the hyperactivity can be controlled.	(23) _
5. Hypoactivity Few or no spontaneous movements. Sluggish. Movements are slowed, feeble or labored. Requires prompting for initiation of motor movements. Long latencies of appropriate motor behavior.	(24) _
6. Distractibility Distracted by usually minor, irrelevant stimuli. Shifts from one topic to another. Interrupts thought or action abruptly.	(25) _
7. Abnormal Object Relationships Autistic use of objects with disregard for usual function. Stereotyped and repetitive sequences or fragments of play. Aimless behavior without organizing goal idea.	(26) _
8. Withdrawal Oblivious of examiner, preoccupied. Facial expression and behavior do not respond directly to examiner. Attention focus is oblique and vague in direction, with avoidance of eye contact. Responses are very delayed and require forceful stimuli. (The fact that the child may have peculiar interest in examiner, such as obsessive interest in parts of body or clothing, does not preclude a rating of withdrawal.)	(27) _

9. Overcompliant Goes along with whatever examiner says in a passive fashion, even contradicting self. Does not assert self in a reasonable manner.	(28) -
10. Negative, uncooperative Active opposition and resistance to examiner's initiative (differs from withdrawal and oblique avoidance). Guarded, evasive replies, teasing, manipulative or hostile refusal to cooperate. Child may remain silent in passive-aggressive manner.	(29) -
11. Angry affect Irritable, touchy, erupts easily - shouts angrily, screams at examiner, overtly and directly hostile.	(30) -
12. Silly affect Clowning, inappropriately giddy, playful, silly behavior.	(31) -
13. Confusion Confused, bewildered, perplexed in behavior or verbal expression.	(32) -
14. Disorientation Child is unaware of identity of surroundings after being told where he is. Not aware of time discriminations. Does not know age or surname.	(33) -
15. Clinging Behavior Clinging, in physical and verbal behavior, with the examiner. Seeks physical contact; demands constant direction.	(34) -
16. Unspontaneous Relation to Examiner Responds to examiner, but does not initiate social or verbal overtures, nor sustain conversation once begun. Lacks spontaneity. Restricted.	(35) -
17. Suspicious Affect Expresses concern about the intent of the examination. Questions instructions and good will of interviewer.	(36) -
18. Depressed demeanor Exhibits a dejection, depression in mood. Looks sad. Seems to be in a state of painful dejection.	(37) -
19. Blunted affect Restricted range and intensity of emotional expressions; blank or fixed facial expression, monotonous voice.	(38) -

20. Lability of affect Can suddenly vary from calm or silly to sullen mood, to screaming, crying, loud complaining.	(39) _
21. Pressure of speech Speech is hurried, accelerated, pushed, difficult to interrupt.	(40) _
22. Level of speech development (Do not include diction, rate of speech, or relevance of speech.) From age-appropriate (1) to severely retarded (7) speech development. Using your clinical judgement of verbal I.Q., estimate the level of speech development (in%) in relation to verbal IQ. 1 = over 90% 2 = 76-90% 3 = 61-75% 4 = 46-60% 5 = 31-45% 6 = 15-30% 7 = less than 15%	(41) _
23. Stuttering	(42) _
24. Low voice Voice weak, mumbling, whispering, almost inaudible.	(43) _
25. Loud voice Voice loud, boisterous, shouting.	(44) _
26. Mispronunciations Lisping, mispronounces letters such as r, s, l, etc. Unclear speech.	(45) _
27. Other speech deviance Echolalia; question-like melody; neologisms; sentences fragmented, unusual syntax	(46) _
28. Rhythmic motions (stereotype) Rocking, whirling, head banging, rolling, repetitive jumping; hand movements, athetoid, twiddling arm flapping.	(47) _

Rate the following 34 items on the basis of the child's verbal report of occurence at the time of the interview or during the past 7 days. Do not use any other data but that obtained in interview with the child.

29. Expressed feelings of inferiority Describes feelings of inadequacy, inferiority, self-depreciating, self-belittling.	(48)
30. Expressed feelings of grandiosity Exaggerates own value, boasting. Unduly pleased with own achievement. Says he is much better than others. Distorted sense of own capacity.	(49)
31. Physical complaints Somatic complaints of headaches, stomach aches, dizziness, not feeling well, etc. (do not include fatigue).	(50)
32. Obesity Judge from child's appearance from normal physical appearance to severe obesity.	(51)
33. Other eating problems Picky, fussy, many dislikes, extremely restricted diet, peculiar food tastes.	(52)
34. Separation anxiety Ease with which child separates from mother or other significant people. Extent of observed or reported anxiety (by child) experienced by child when separated from mother or other significant people.	(53)
35. Depression Admits feeling sad, lonely, feels like crying, expresses a despondent or despairing attitude. Difficulty in anticipating success and enjoyment.	(54)
36. Euphoria - elation States he feels terrific, great, elevation of mood, hypomanic state. "This is the best of all possible worlds". Feels elated and wonderful. Nothing is impossible.	(55)
37. Lack of energy States he feels sluggish, fatigued. Everything is too much. Weary and feels unable to make slightest effort. (Do not infer from motor retardation or expressed indifference.)	(56)
38. Preoccupation with topics of anxiety Says he has nervous or scary feelings, concerns, apprehension, fears. Says he worries about failure or other mishaps, thinks about something happining to self or parents--illness, injury, death, loss or separation	(57)

39. Preoccupation with depressive topics Preoccupied with feelings of inadequacy and inferiority. Expresses feeling that nothing can turn out all right. Preoccupied with feelings of uselessness, futility, and possibly guilt. Suicidal preoccupation.	(58) –
40. Suicidal attempts 0 = not assessed 1 = none 2 = suicidal threat 3 = one minor gesture without danger 4 = a couple or several minor gestures without danger 5 = dangerous gesture 6 = infliction of life-threatening damage to self 7 = several life-threatening attempts	(59) –
41. Fears and phobias Irrational morbid fears of specific objects, persons or situations, which, if extreme, lead to avoidance behavior. Rate 6 or 7 only when fear is so severe it leads to phobic avoidance.	(60) –
42. Compulsive acts Acts or "habits" which are regarded as unreasonable by the child, such as counting, checking, rituals, excessive orderliness and cleanliness.	(20)* –
43. Nervous habits and mannerisms Stereotyped movements; rituals which are not perceived as irrational. Facial tics or mannerisms. Biting nails, finger cuticles. Sucking of objects or body parts (thumb, finger, hair, etc.). Picking on skin, scabs, nose, twisting hair.	(21) –
44. Obsessive thinking Inability to "turn off" repetitive thought. Preoccupation, ruminations about abstract problems or personal matters.	(22) –
45. Solitary interests Interested in activities which require little, if any, peer interaction, such as stamp collecting, movie going, reading, school work, solitary activities.	(23) –
46. Lack of peer interaction Isolated from other children. Has no friends or cannot name current close friend nor describe participation in play with peers. Lacks interest in peers.	(24) –
47. Gang activity Joins in antisocial activities along with a group of children (fighting, trouble-making, stealing) as a cooperating group against others.	(25) –

* Card No. 02

48. Fighting with peers Says he frequently gets into fights - beats up other kids or gets beaten up. Says he has a bad temper.	(26) _
49. Bully Says he is always the leader, winner; or says he teases, bullies children; pushes children around, threatens them.	(27) _
50. Temper outbursts Admits to feeling angry, irritable, touchy, admits he has a temper.	(28) _
51. Scapegoat Says he is picked on, teased, left out or pushed around and bullied by other children. May be called "sissy" or "baby".	(29) _
52. Lying Contradicts self in ways indicative of effort to hide the truth. Reports telling tall stories, fibs or admits he is accused of telling lies.	(30) _
53. Exploitative relationship Interested in other people insofar as he can get something out of it. Callous and calculating in interpersonal activities.	(31) _
54. Inability to fall asleep Child reports a long time to fall asleep after going to bed. 1 = not present 2 = 10 to 15 mn. 3 = 16 to 30 mn. 4 = 31 to 45 mn. 5 = 46 to 60 mn. 6 = 60 to 90 mn. 7 = over 9o mn.	(32) _
55. Other sleep difficulties Nightmares, early morning awakening, sleep walking,interrupted sleep.	(33) _
56. Bedwetting Rating is for frequency of bedwetting for past 7 nights. 1 = none 2 = one time 3 = 2 times 4 = 3 times 5 = 4 times 6 = 5 times 7 = 6 to 7 times	(34) _
57. Ideas of reference People are looking at him, following him, staring, etc. Malevolent intent is not necessary, but may occur.	(35) _

58. Persecutory Feels people have it in for him, try to hurt him. In the extreme rating, the thinking has a delusional quality in that the belief is impervious to change, rational arguments, or corrective experiences.	(36) –
59. Other thinking disorders Irrelevant speech; or incoherent speech; or loose associations.	(37) –
60. Delusions Delusional beliefs or convictions besides paranoia (58), i.e., believes has introjected persons or objects in his body, has a mission; is some other person or character, has unusual powers; is guilty of some event.	(38) –
61. Hallucinations The overall rating is a frequency rating reflecting the constancy of the experience. 1 = not present 2 = once 3 = 2 times 4 = 3 times 5 = 4 to 5 times 6 = 5 to 6 times 7 = daily recurrent phenomenon	(39) –
62. Peculiar fantasies Morbid or bizarre fantasies and pre-occupations, peculiar body sensations, disturbances of body image experiences, (not figure drawings); preoccupation with flying, super-natural influences, sadism, masochism.	(40)
63. Lack of insight Is convinced of the reality of hallucinations or fantasies.	(41) –
Date :	(70-75) – – – – – –

INFORMATION for USERS

DEVELOPMENT - The CPRS is a 63-item, 7-point original scale constructed by the participants of the Pediatric Psychopharmacology Workshop. It is a comprehensive scale scored by a psychiatrist, which endeavors to assess the broad spectrum of psychopathology within this age group. As a consequence, items of the CPRS will have varying degreesof relevance when assessing a circumscribed diagnostic group.

APPLICABILITY - For children to age 15.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - The first 28 items are rated on the basis of direct observation of behavior during the interview. The last 34 items are rated on the basis of the child's report of occurrence during the interview or within the past week.

SPECIAL INSTRUCTIONS - Cues for rating as well as specific instructions for each item are printed on the scale. Strict adherence to these instructions is required of all raters.

Item 22 - Level of Speech Development. This item may be confusing. The rater is asked to judge whether the level of speech development is appropriate to the child's verbal IQ. For example, response position 4 is read as level of speech development is only 46-60% of verbal IQ; position 2 as level of speech development is 76 to 90% of verbal IQ.

Item 56 - Bedwetting, and Item 61 - Hallucinations. Remember that these items (as with all items from 29 to 63) refer to the past 7 days.

CLUSTER COMPOSITION - As a means of data reduction, the clusters have been empirically derived for use in statistical analyses. It is planned to undertake psychometric analyses of the CPRS when sufficient data are accumulated.

I. Psychotic

2. Underproductive speech
7. Abnormal object relationship
19. Blunted affect
27. Other speech deviance
28. Rhythmic motions (stereotypic)
57. Ideas of reference

II. Hostile/Uncooperative

10. Negative, uncooperative
11. Angry affect
17. Suspicious affect
50. Temper outbursts

III. Hyperactive

3. Fidgetiness
4. Hyperactivity
6. Distractibility
20. Lability of affect

IV. Anxiety

1. Tension
15. Clinging behavior
34. Separation anxiety
38. Preoccupation - anxiety
41. Fears and phobias

V. Thought disturbance

58. Persecutory ideation
59. Other thinking disturbances
60. Delusions
62. Peculiar fantasies
63. Lack of insight

VI. Neurotic

31. Physical complaints
42. Compulsive acts
43. Nervous habits
44. Obsessive thinking

VII. Depression

5. Hypoactivity
18. Depressed demeanor
24. Low voice
29. Expressed feelings of inferiority
35. Depression

(VII. Depression, cont'd)

37. Lack of energy
39. Preoccupation with depressive topics
40. Suicidal attempts

VIII. Excited mood

12. Silly affect
21. Pressure of speech
25. Loud voice
30. Expressed feelings of grandiosity
36. Euphoria - elation

IX. Withdrawal

8. Withdrawal
9. Overcompliant
16. Unspontaneous relation to examiner
45. Solitary interests
46. Lack of peer interaction
51. Scapegoat

X. Antisocial

47. Gang activity
48. Fighting with peers
49. Bully
52. Lying
53. Exploitative relationships

XI. Organic

13. Confusion
14. Disorientation

XII. Speech disturbance

22. Level of speech development
23. Stuttering
26. Mispronunciations

XIII. Sleep disturbance

54. Inability to fall asleep
55. Other sleep difficulties

XIV. Eating disturbances

32. Obesity
33. Other eating problem

XV. Enuresis

56. Bedwetting

Cluster score = $\frac{\text{sum of composite items}}{\text{number of composite items}}$ Cluster score range = 1-7

Total score = sum of all items Total score range = 63-441.

DOCUMENTATION

a. Raw score printout

b. Cluster score printout

c. Means and standard deviations for cluster scores

d. Cross tabulations

e. Variance analyses.

Children's Behavior Inventory

(CBI)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Children's Behavior Inventory (CBI). (E.I. Burdock & A.S. Hardesty)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 3 4
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the numeric and the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

This inventory is applicable to children from 1 to 15 years of age. The items have been grouped according to the ages at which the corresponding behaviors first become significant of departure from developmental norms. The behavior recorded should have occurred during a specified interval of the observation day. Always start at the beginning of the inventory and proceed through the level corresponding to the child's last birthday. A STOP signal is given at the end of each age grouping. Mark "Yes" when you reach the level corresponding to the child's last birthday; "No" if you are continuing to the next level.

For each item record your judgement by marking "Yes" or "No". All items within appropriate age-grouping should be answered.

	1	0
Ages one to three		
1. Responds to social stimulation (by talking, smiling, or reaching, etc.)	(20) yes	no
2. Is slow in his movements	(21) yes	no
3. Maintains a rigid posture when standing, sitting, lying or being held	(22) yes	no
4. Grinds teeth	(23) yes	no
5. Voice is flat and monotonous	(24) yes	no
6. Ignores toys or other objects around him	(25) yes	no
7. Repeatedly falls asleep	(26) yes	no
8. Bangs head on wall or other hard surfaces	(27) yes	no
9. Holds breath until face changes colour	(28) yes	no
10. Responds to physical contact with limpness	(29) yes	no
11. Utters no sound	(30) yes	no
STOP (mark YES or NO)	(31) yes	no

Ages three to five	I	C
12. Soils bed or clothing with excrement	(32) yes	no
13. Acts apprehensive and afraid	(33) yes	no
14. Engages in rhythmic motions (swaying, head rolling, etc.)	(34) yes	no
15. Says that he had a bad dream	(35) yes	no
16. Eats or drinks strange substances (plaster, ink, etc.) . .	(36) yes	no
17. Has attack of panic	(37) yes	no
18. Remains in one place unless directed into some activity	(38) yes	no
19. Has momentary lapse of consciousness	(39) yes	no
20. Complains of aches and pains of physical distress	(40) yes	no
21. Picks at self (pulls out hair, picks at skin, face, buttocks, genitals, etc.)	(41) yes	no
22. Talks and talks or babbles and babbles (pressure of speech)	(42) yes	no
23. Refuses to eat	(43) yes	no
24. Lisps	(44) yes	no
25. Has tic or twitch (distorts face, turns neck, blinks, etc.)	(45) yes	no
26. Gets angry or annoyed when addressed by adult	(46) yes	no
27. Has recurrent spells of nausea or vomiting	(47) yes	no
28. Appears listless and apathetic	(48) yes	no
29. Responds to own antisocial act with no sign of sorrow or remorse	(49) yes	no
30. Shows incongruous emotional response	(50) yes	no
31. Smears self and surroundings with food or feces	(51) yes	no
32. Acts perplexed or confused	(52) yes	no
33. Repeatedly gets irritated	(53) yes	no
34. Repeats some act over and over again as though driven	(54) yes	no
35. Wets bed or clothing (incontinent)	(55) yes	no
36. Is tense and anxious	(56) yes	no

(Ages three to five, cont'd)	1	2
37. Has a fixed grin	(57) yes	no
38. Speech is inarticulate	(58) yes	no
STOP (mark YES or NO)	(59) yes	no
Ages five to seven	(60)	
39. Clings to adult	yes	no
40. Keeps drooling	(61) yes	no
41. Has temper tantrum	(62) yes	no
42. Slurs his speech	(63) yes	no
43. Uses baby talk	(64) yes	no
44. Keeps feeling contour of objects within reach	(65) yes	no
45. Shifts attention in a restless manner	(66) yes	no
46. Becomes anxious when he cannot make things neat and orderly	(67) yes	no
47. Has a dull expression	(68) yes	no
48. Maltreats younger child with deliberate cruelty	(69) yes	no
49. Complains of insomnia	(70) yes	no
50. Gets angry when interrupted at play by adult	(71) yes	no
51. Displays excessive self-control and composure	(72) yes	no
52. Cries or looks hurt when criticized	(73) yes	no
53. Takes part in ongoing activity without being urged	(74) yes	no
54. Does not play with other children	(75) yes	no
55. Protests or resists directions of adult	(20)* yes	no
56. Keeps asking for help in whatever he is doing	(21) yes	no
57. Utterances consist of monosyllables or single words	(22) yes	no
58. Says he is going to kill himself	(23) yes	no
59. Shows understanding when given directions	(24) yes	no
60. Sucks thumb	(25) yes	no
61. Acts nervous or agitated	(26) yes	no

Card No. 02

(Ages five to seven, cont'd)	1	0
62. Uses no gestures	(27) yes	no
63. Plays with genitals or masturbates	(28) yes	no
64. Has a tight-lipped expression	(29) yes	no
65. Swears or uses bad language	(30) yes	no
66. Speaks in a faint voice	(31) yes	no
67. Bites lip	(32) yes	no
68. Keeps slopping food on self or table	(33) yes	no
69. Twists mouth	(34) yes	no
70. Has a mournful and downcast expression	(35) yes	no
71. Bites nails	(36) yes	no
72. Walks on tiptoe	(37) yes	no
73. Stays by himself	(38) yes	no
74. Speech is slow and full of pauses	(39) yes	no
75. Is hesitant and uncertain in making up his mind	(40) yes	no
76. Gives excuses for breaking the rules	(41) yes	no
77. Spills something or bumps into something	(42) yes	no
78. Talks about death and killing	(43) yes	no
79. Whines or whimpers	(44) yes	no
80. Deliberately hurts himself	(45) yes	no
STOP (mark YES or NO)	(46) yes	no
Ages seven to nine		
81. Snatches food from others	(47) yes	no
82. Pinches, slaps or spits at others	(48) yes	no
83. Does not play at all	(49) yes	no
84. Joins in competitive game	(50) yes	no
85. Forgets detail, task or event	(51) yes	no
86. Twists or turns hands	(52) yes	no
87. Speech is sensible and connected	(53) yes	no

(Ages seven to nine, cont'd)	1	0
88. Starts talking about sex	(54) yes	no
89. Keeps moving about	(55) yes	no
90. Eggs on other child to complain or rebel	(56) yes	no
91. Says that he is bad, that he is in the wrong, or that he is ashamed of himself	(57) yes	no
92. Looks obese	(58) yes	no
93. Does the opposite of what he is asked to do	(59) yes	no
94. Eyes keep shifting	(60) yes	no
95. Acts as if he has a vision or talks about his vision .	(61) yes	no
96. Pouts	(62) yes	no
97. Talks to his voices or acts as if he hears voices	(63) yes	no
98. Says there are many people he hates	(64) yes	no
99. Is impatient (will not wait for something to be given to him or to be done for him)	(65) yes	no
100. Is overcome by frenzied excitement	(66) yes	no
101. Runs away or plays truant	(67) yes	no
102. Keeps eyes closed or averted or head bowed down	(68) yes	no
103. Has an angry expression	(69) yes	no
104. Walks with a cautious tread (as if stepping on eggs)	(70) yes	no
105. Shows suspicion or complains of unfair treatment	(71) yes	no
106. Deliberately tears or breaks something	(72) yes	no
107. Tries to kill himself	(73) yes	no
108. Screams again and again	(74) yes	no
109. Squirms or moves limbs restlessly	(75) yes	no
110. Curses or sneers at other children	(20)* yes	no
111. Attacks adult	(21) yes	no
112. Sets a fire	(22) yes	no
113. Jumps up and walks about restlessly	(23) yes	no

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* Card No. 03

(Ages seven to nine, cont'd)	1	0
114. Keeps smiling	(24) yes	no
115. Shows cringing submissiveness	(25) yes	no
STOP (mark YES or NO)	(26) yes	no
Ages nine to eleven		
116. Assumes clownish posture and expression	(27) yes	no
117. Talks, mutters, or mumbles to himself	(28) yes	no
118. Giggles inappropriately	(29) yes	no
119. Weeps under slight provocation	(30) yes	no
120. Keeps demanding to be the leader	(31) yes	no
121. Says he feels sad	(32) yes	no
122. Has a scornful expression	(33) yes	no
123. Attention wanders	(34) yes	no
124. Gets angry when something does not suit him	(35) yes	no
125. Hits or attacks other child	(36) yes	no
126. Takes part in conversation	(37) yes	no
127. Runs around or throws himself about in a wild and uncontrolled manner	(38) yes	no
128. Grimaces or gestures grotesquely	(39) yes	no
STOP (mark YES or NO)	(40) yes	no
Ages eleven to thirteen		
129. Bullies younger child	(41) yes	no
130. Has a dirty appearance	(42) yes	no
131. Speaks in a jerky, uneven fashion	(43) yes	no
132. Acts friendly with another child	(44) yes	no
133. Shows pleasure in being talked to	(45) yes	no
134. Behaves in a sullen or argumentative manner	(46) yes	no
STOP (mark YES or NO)	(47) yes	no

Ages thirteen to fifteen	1	0
135. Shows difficulty in concentrating	(48) yes	no
136. Shows interest in the opposite sex (positive or negative feeling)	(49) yes	no
137. Expresses feelings of inferiority	(50) yes	no
138. Expresses a pesimistic outlook toward his future accomplishments	(51) yes	no
139. Complains that an adult wants to kill him	(52) yes	no

	(70-75)
Date	- - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Burdock and Hardesty's CBI is a 139-item, 2-point scale for recording maladaptive behavior of children. The absence of professional or technical jargon makes it possible for members of different professions to carry out and record the relevant observations after brief training. Experience with the method to date has demonstrated that with proper selection and adequate training, the CBI is equally reliable in the hands of nurses, teachers, psychologists, psychiatrists and graduate students in psychology or special education.

REFERENCES - 1. Burdock, E.i. and Hardesty, A.S., A Children's Behavior Diagnostic Inventory, Ann. New York Academy of Sciences, 105 : 890-896, 1964.

2. Burdock, E.I. and Hardesty, A.S., Contrasting Behavior Patterns of Mentally Retarded Children and Emotionally Disturbed Children, in Psychopathology of Mental Development. p. 370-386, Grune and Stratton, New York, 1967.

APPLICABILITY - Children aged 1 to 15.

UTILIZATION - Once at pretreatment, at least one posttreatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Restricted to the period of observation.

SPECIAL INSTRUCTIONS -

1. Conduct of Observers - Whenever a study is to be undertaken in a new setting , the observer should arrange to let himself be seen in the situation and by the subjects before the beginning of the formal observations in order that his presence lose its novelty. It is best when the child who is the focus of interest does not perceive himself as such. The observer should give an impression of being interested in the activities of the whole group. If a child inquires about the observer's role or purpose, the observer may tell him, "I am watching because I am interested in what children do here." There are 2 requirements which are essential if quantitative or even only qualitative use is to be made of the instrument :
   a. The observer must be able to maintain a friendly detachment from the situation so that he neither manipulates nor purposely evokes behavior that would not have occurred in his absence.

b. The observer must be closely attentive to the appearance, verbalizations, movements and gestures of the child.

2. Recording Observations - The CBI has 139 dichotomous items. The observer should always start with the first item and proceed through all the items listed for the age group of the child under observation. When the child's age "overlaps" 2 age groupings, answer all items of the OLDER groupings and stop. (Example : if a child is 5, complete age group "Five to seven". If child is 7, complete group "Seven to nine".) The observer should mark YES when the child has displayed the behavior noted and NO if he has not seen the relevant behaviors. The observer must be able to set aside what he remembers or has heard from others about the child. His judgements must be based solely on what he sees or hears from the child during the observation period. He must be sure to read every item carefully. Some items call for a judgment of the presence of a behavior; other items require judgment, that a particular behavior is absent. Certain items describe behaviors which can be judged unequivocally from a single event; others describe complex qualities whose presence may only be inferred toward the end of the observational interval.

3. Time Interval - The most effective use of the CBI is achieved when it is possible to observe an individual child in his normal activities over several behavioral settings. When the observer can give his undivided attention to the actions and reactions of a single child, a period of 2 hours has been found to produce enough behavioral diversity to be of discriminative significance. On the other hand, should service obligations preclude such highly focussed observation, the behavior displayed over the usual working shift of approximately 8 hours will offer a reliable basis for judgment, provided observations are carried out consistently.

SUBTEST COMPOSITION -

1. Anger / Hostility - Contains items describing verbal behavior, attitudes and actions of an angry or hostile nature.

26	50	90	103	120
29	55	93	106	122
33	65	96	110	124
41	76	98	111	125
48	82	99	112	129
				134

II. Conceptual Dysfunctioning - Contains items reflecting disturbances of speech, memory, or orientation.

11	42	85
19	43	87*
22	45	117
24	56	123
32	59*	131
38	75	135

* = items reflected in scoring

III. Fear and Worry - Contains items describing verbal behavior or actions reflecting fear and worry.

13	52
15	61
17	79
36	119
46	121

IV. Incongruous Behavior - Indicates modes of behavior which are either inconsistent with one another or with age norms, or which are anomalous and unusual ways of doing things : head banging, incontinence, walking on tiptoe, etc. The more visual characteristics of psychological deviance are grouped here.

4	35	69	104
8	37	71	108
9	39	72	109
12	40	77	113
14	44	81	114
16	60	86	115
21	63	89	116
25	64	94	118
31	67	100	127
34	68	101	128
			130

V. Incongruous Ideation - Contains items indicative of bizarre emotional and cognitive behaviors.

30	105
78	139
88	

VI. Lethargy - Dejection - Is reflected in both physical and emotional behavior. A child may be reported to be slow in his movements, to fall asleep repeatedly or to have a voice that is flat or monotonous; on the other hand, he may detach himself from his environment by staying by himself, or by ignoring toys or other objects around him.

1*	28	62	84*
2	47	66	102
5	51	70	126*
6	53*	73	132*
7	54	74	133*
18	57	83	136*

* = items reflected in scoring

VII. Perceptual Dysfunctioning - Items related to hallucinatory experiences.

95 97

VIII. Physical Complaints - Is concerned with such indicators as refusal to eat, recurrent spells of vomiting, or responding to physical contact with limpness.

3	27
10	49
20	92
23	

IX. Self-Depreciation - Is more dependent on verbal report than the other subareas. However, deliberately hurting himself and trying to kill himself are behavioral items included here in addition to expressions of feeling of inferiority.

58	107
80	137
91	138

Subtest score = sum of composite items

Total score = sum of all items

Total score range = 0-139.

DOCUMENTATION - a. Raw score printout - item listings will end at each individual subject's appropriate age group.

b. Subtest scores.

c. Means and standard deviations for subtests.

d. Cross-tabulations of subtest scores.

e. Variance analyses.

c. Scales for Adults and the Aged

Brief Psychiatric Rating Scale

(BPRS)

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Brief Psychiatric Rating Scale (BPRS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) 1 8 3 Unit Number	(4-6) - - - Study Number	(7-9) - - - Subject Number Male 001-499 Female 500-999	(10-12) 0 4 7 Form Number
(13-15) - - - Assessment Period*	(16-17) - - Rater Number	(18-19) 0 1 Card Number	(76-80) - - - - - Group to which Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example = 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

This form consists of 18 symptom constructs, each to be rated on a 7-point scale of severity, ranging from "not present" to "extremely severe". If a specific symptom is not rated, mark "0" = not assessed.

Mark the column headed by the term which best describes the patient's present condition.

not assessed	not present	very mild	mild	moderate	moderately severe	severe	extremely severe
0	1	2	3	4	5	6	7

1. Somatic Concern	Degree of concern over present bodily health. Rate the degree to which physical health is perceived as a problem by patient, whether complaints have a realistic basis or not.	(20) _
2. Anxiety	Worry, fear, or over-concern for present or future. Rate solely on basis of verbal report of patient's own subjective experiences. Do not infer anxiety from physical signs or from neurotic defense mechanisms.	(21) _
3. Emotional Withdrawal	Deficiency in relating to the interviewer and to the interviewer situation. Rate only the degree to which the patient gives the impression of failing to be in emotional contact with other people in the interview situation.	(22) _
4. Conceptual Disorganization	Degree to which the thought processes are confused, disconnected or disorganized. Rate on the basis of integration of the verbal products of the patient; do not rate on the basis of the patient's subjective impression of his own level of functioning.	(23) _
5. Guilt Feelings	Over-concern or remorse for past behavior. Rate on the basis of the patient's subjective experiences of guilt as evidenced by verbal report with appropriate affect; do not infer guilt feelings from depression, anxiety or neurotic defenses.	(24) _
6. Tension	Physical and motor manifestations of tension, "nervousness", and heightened activation level. Tension should be rated solely on the basis of physical signs and motor behavior and not on the basis of subjective experiences of tension reported by the patient.	(25) _

7. Mannerisms and Posturing	Unusual and unnatural motor behavior; the type of motor behavior which causes certain mental patients to stand out in a crowd of normal people. Rate only abnormality of movements; do not rate simple heightened motor activity here.	(26) -
8. Grandiosity	Exaggerated self-opinion, conviction of unusual ability or powers. Rate only on the basis of patient's statement about himself or self-in-relation-to-others, not on the basis of his demeanor in the interview situation.	(27) -
9. Depressive Mood	Despondency in mood, sadness. Rate only degree of despondency; do not rate on the basis of inferences concerning depression based upon general retardation and somatic complaints.	(28) -
10. Hostility	Animosity, contempt, belligerence, disdain for other people outside the interview situation. Rate solely on the basis of the verbal report of feelings and actions of the patient toward others; do not infer hostility from neurotic defenses, anxiety, nor somatic complaints (rate attitude toward interviewer under "cooperativeness").	(29) -
11. Suspiciousness	Belief (delusional or otherwise) that others have now, or have had in the past, malicious or discriminatory intent toward the patient. On the basis of verbal report, rate only those suspicions which are currently held, whether they concern past or present circumstances.	(30) -
12. Hallucinatory Behavior	Perceptions without normal external stimulus correspondence. Rate only those experiences which are reported to have occurred within the last week and which are described as distinctly different from the thought and imagery process of normal people.	(31) -
13. Motor Retardation	Reduction in energy level evidenced in slowed movements. Rate on the basis of observed behavior of the patient only; do not rate on ba of patient's subjective impression of own energy level.	(32) -
14. Uncooperativeness	Evidence of resistance, unfriendliness, resentment, and lack of readiness to cooperate with interviewer. Rate only on the basis of the patient's attitude and responses to the interviewer and the interview situation; do not rate on basis of reported resentment or uncooperativeness outside the interview situation.	(33) -

15. Unusual Thought Content	Unusual, odd, strange, or bizarre thought content. Rate here the degree of unusualness, not the degree of disorganization of thought processes.	(34) -
16. Blunted Affect	Reduced emotional tone, apparent lack of normal feeling or involvement.	(35) -
17. Excitment	Heightened emotional tone, agitation, increased reactivity.	(36) -
18. Disorientation	Confusion or lack of proper association for person, place or time.	(37) -

(70-75) Date	--	--	--

INFORMATION for USERS

DEVELOPMENT - Developed by Overall and Gorham, the BRPS is an 18-item, 7-point scale. Developed from the longer Lorr Multidimensional Scale for Rating Psychiatric Patients (MSRPP) and Lorr Inpatient Multidimensional Psychiatric Scale (IMPS), the BPRS provides a rapid and efficient evaluation of treatment response in both clinical drug trials and routine clinical settings. Its focus is primarily inpatient psychopathology. It has been employed in outpatient settings to assess levels of anxiety and depression and to distinguish neurotic from more severely disturbed patients; but the authors caution that the BPRS was not designed to represent the fine distinctions between types of neurotic patients.

REFERENCES - 1. Overall, J.E. and Gorham, D.R., The Brief Psychiatric Rating Scale, Psychol. Rep., 10:799-812, 1962.

2. Overall, J.E., The Brief Psychiatric Rating Scale in Psychopharmacology Research, Psychometric Laboratory Reports, No 29, University of Texas, Galveston, June, 1972.

APPLICABILITY - Primarily for adult inpatient populations.

UTILIZATION - Once at pretreatment; at least one posttreatment assessment. The number and spacing of post-treatment assessments are at the discretion of the investigator.

TIME SPAN RATED - At a maximum, the interval since the last assessment. At pretreatment, a span of one week is suggested.

SPECIAL INSTRUCTIONS

Brief instructions for rating each item are printed on the scale itself. To increase the degree of communality in interpretation, the items are defined below in greater detail by Overall and Gorham, and the rater is urged to confine his responses within these contexts.

A. Ratings Based upon Observation of Patient

3. Emotional Withdrawal - This construct is defined solely in terms of the ability of the patient to relate in the interpersonal interview situation. Thus, an attempt is made to distinguish between motor aspects of general retardation, which are rated as "motor retardation" and the more mental-emotional aspects of withdrawal, even though ratings in the 2 areas may be expected to covary to

some extent. In the factor analyses of change in psychiatric ratings, a "general retardation" factor has emerged in several different analyses, and this general retardation factor has included both emotional and motor retardation items. It is difficult to identify the basis for rating of "ability to relate"; however, initial work has indicated that raters achieve reasonably high agreement in rating this quality. Emotional withdrawal is represented by the feeling on the part of the rater that an invisible barrier exists between the patient and other persons in the interview situation. It is suspected that eyes, facial expression, voice quality and variability, and expressive movements all enter into the evaluation of this important, but nebulous, quality of the patients.

6. Tension - It should be noted that the construct "tension" is restricted in the Brief Scale to physical and motor signs commonly associated with anxiety. Tension does not involve the subjective experience or mental state of the patient. Although research psychologists, in an effort to attain a high degree of objectivity, frequently define anxiety in terms of physical signs, in the Brief Scale observable physical signs of tension and subjective experiences of anxiety are rated separately. Although anxiety and tension tend to vary together, developmental research with an earlier form of the Brief Scale indicated that the degree of pathology in the 2 areas may be quite different in specific patients. A patient, especially when under the influence of a drug, may report extreme apprehension but give no external evidence of tension whatsoever, or vice-versa. In rating the degree of tension, the rater should attend to the number and nature of signs of abnormally heightened activation levels such as nervousness, fidgeting, tremors, twitches, sweating, frequent changing of posture, hypertonicity of movements, and heightened muscle tone.

7. Mannerisms and Posturing - This symptom area includes the unusual and bizarre motor behavior by which a mentally ill person can often be identified in a crowd of normal persons. The severity of manneristic behavior depends both upon the nature and number of unusual motor responses. However, it is the "unusualness", and not simply the amount of movement, which is to be rated. Odd, indirect, repetitive movements, or movements lacking normal coordination and integration, are rated on this scale. Strained, distorted, abnormal postures which are maintained for extended periods are rated. Grimaces and unusual movements of lips, tongue, or eyes are considered here also. Tics and twitches which are rated as signs of tension are not rated as manneristic behavior.

13. Motor Retardation - Motor retardation involves the general slowing down and weakening of voluntary motor responses. Symptomatology in this area is represented by behavior which might be attributed to the loss of energy and vigor necessary to perform voluntary acts in a normal manner. Voluntary acts which are especially affected by reduced energy level include those related to speech as well as gross muscular behavior. With increased "motor retardation" speech is slowed, weakened in volume, and reduced in amount. Voluntary movements are slowed, weakened, and less frequent.

14. Uncooperativeness - This is the term adopted to represent signs of hostility and resistance to the interviewer and interview situation. It should be noted that "uncooperativeness" is judged on the basis of response of the patient to the interview situation while "hostility" is rated on the basis of verbal reports of hostile feelings or behavior toward others outside the interview situation. It was found necessary to separate the 2 areas because of an occasional patient who refrained from any reference to hostile feelings and who even denies them, while evidencing strong hostility toward the interviewer.

B. Ratings Based Primarily upon Verbal Report

1. Somatic Concern - The severity of physical complaints should be rated solely on the number and nature of complaints of bodily illness or malfunction, or suspiciousness of same, alleged during the interview period. The evaluation is of the degree to which the patient perceives or suspects physical ailments to play an important part in his total lack of well being. No consideration of the probability of true organic basis for the complaints is required. Only the frequency and severity of complaints are rated.

2. Anxiety - Anxiety is a term restricted to the subjective experience of worry, overconcern, apprehension or fear. Rating of degree of anxiety should be based upon verbal responses reporting such subjective experiences on the part of the patient. Care should be taken to exclude from consideration in rating anxiety the physical signs which are included in the concept of tension, as defined in the scale. The sincerity of the report and the strength of the experience as indicated by the involvement of the patient may be important in evaluating the degree of anxiety.

4. Conceptual Disorganization - Conceptual disorganization involves the disruption of normal thought processes and is evidenced in confusion, irrelevance, inconsistency, disconnectedness, disjointedness, blocking, confabulation, autism, and unusual chain of associating. Ratings should be based upon the

patient's spontaneous verbal products, especially those longer, spontaneous response sequences which are likely to be elicited during the initial, non-directive portion of the interview. Attention to the facial expression of the patient during the verbal response may be helpful in evaluating the degree of confusion or blocking.

5. Guilt Feelings - The strength of guilt feelings should be judged from the frequency and intensity of reported experiences of remorse for past behavior. The strength of the guilt feelings must be judged in part from the involvement evidenced by the patient in reporting such experiences. Care should be exercised not to infer guilt feelings from signs of depression or generalized anxiety. Guilt feelings relate to specific past behavior which the patient now believes to have been wrong and the memory of which is a source of conscious concern.

8. Grandiosity - Grandiosity involves the reported feeling of unusual ability, power, wealth, importance, or superiority. The degree of pathology should be rated relative to the discrepancy between self-appraisal and reality. The verbal report of the patient and not his demeanor in the interview situation could provide the basis for evaluation of grandiosity. Care should be taken not to infer grandiosity from suspicions of persecution or other unfounded beliefs where no explicit reference to personal superiority as the basis for persecution has been elicited. Ratings should be based upon opinions currently held by the patient, even though the unfounded superiority may be claimed to have existed in the past.

9. Depressive Mood - Depressive mood includes only the affective component of depression. It should be rated on the basis of expressions of discouragement, pessimism, sadness, hopelessness, helplessness, and gloomy thema. Facial expression, weeping, moaning and other modes of communicating mood should be considered, but motor retardation, guilt, and somatic complaints, which are commonly associated with the psychiatric syndrome of depression, should not be considered in rating depressive mood.

10. Hostility - Hostility is a term reserved for reported feelings of animosity, belligerence, contempt, or hatred toward other people outside the interview situation. The rater may attend to the sincerity and affect present in

reporting of such experiences when he attempts to evaluate the severity of pathology in the symptom area. It should be noted that evidences of hostility toward the interviewer in the interview situation should be rated on the "Uncooperativeness" item and should not be considered in rating hostility as defined here.

11. Suspiciousness - Suspiciousness is a term which is used to designate a wide range of mental experience in which the patient believes himself to have been wronged by another person or believes that another person has, or has had, intent to wrong. Since no information is usually available as a basis for evaluating the objectivity of the more plausible suspicions, the term "accusations" might be a more appropriate characterization of this area. The rating should reflect the degree to which the patient tends to project blame and to accuse other people of forces of malicious or discriminatory intent. The pathology in this symptom area may range from mild suspiciousness through delusions of persecution or ideas of reference.

12. Hallucinatory Behavior - The evaluation of hallucinatory experiences frequently requires judgement on the part of the rater as to whether the reported experience represents hallucination or merely vivid mental imagery. In general, unless the rater is quite convinced that the experiences reported represent true deviations from normal thought and imagery processes, hallucinatory behavior should be rated as "not present".

15. Unusual Thought Content - This symptom area is concerned solely with the CONTENT of the patient's verbalization; the extent to which it is unusual, odd, strange, or bizarre. Notice that a delusional or paranoid patient may present bizarre or unbelievable ideas in a perfectly straightforward, clear and organized fashion. Rate only unusualness of content for this item, not degree of organization or disorganization.

16. Blunted Affect - This symptom area is recognized by reduced emotional tone and apparent lack of normal feeling or involvement. Emotional expressions are not to be absent or of marked indifference and apathy. Attempted expressions of feeling may appear to be mimetic and without sincerity.

FACTOR COMPOSITION - This factor structure is based on a 1974 analysis of the pretreatment scores of 3,596 subjects with diagnoses of schizophrenia (see Table III).

I. Anxiety-Depression (ANDP)

1. Somatic concern
2. Anxiety
5. Guilt feelings
9. Depressive mood

II. Anergia (ANER)

3. Emotional withdrawal
13. Motor retardation
16. Blunted affect
18. Disorientation

III. Thought Disturbance (THOT)

4. Conceptual disorganization
8. Grandiosity
12. Hallucinatory behavior
15. Unusual thought content

IV. Activation (ACTV)

6. Tension
7. Mannerisms and posturing
17. Excitement

V. Hostile-Suspiciousness (HOST)

10. Hostility
11. Suspiciousness
14. Uncooperativeness

Factor score = $\frac{\text{Sum of composite items}}{\text{No. of composite items}}$ Factor score range = 1-7

Total score = Sum of all items Total score range = 18-126

DOCUMENTATION - a. Raw score printout
b. Factor score printout
c. Means and standard deviations
d. Cross tabulations
e. Variance analyses

T A B L E III

5-Factor Varimax Solution of 18-Item Brief Psychiatric Rating Scale

P. W. Cleary, and R. R. Bonato: Methodological Implications of a Large Central Data System, published in Proceedings of IXth Congress, CINP, Excerpta Medica, Amsterdam, 1975.

Item	I	II	III	IV	V	Communalities
Somatic concern	-627	066	-164	030	014	425
Anxiety	-746	115	-073	293	127	677
Emotional withdrawal	156	-808	-139	157	073	726
Conceptual disorganization	019	-344	-640	280	052	610
Guilt feelings	-694	014	-055	013	074	491
Tensions	-381	-040	-064	732	161	712
Mannerisms	023	-463	-216	568	-082	591
Grandiosity	004	208	-536	-027	441	526
Depressive mood	-784	-116	099	-008	124	653
Hostility	-208	036	-156	195	778	712
Suspiciousness	-346	078	-376	-020	650	689
Hallucinatory behavior	-081	-147	-711	156	003	558
Motor retardation	-337	-635	125	-198	039	573
Uncooperativeness	078	-451	044	301	641	713
Unusual thought content	159	-027	-797	049	286	745
Blunted affect	015	-793	-094	-077	-032	645
Excitement	-030	172	-210	744	319	729
Disorientation	227	-475	-330	300	-208	519
Contribution of factor (V_p)	2.58	2.48	2.30	1.89	1.94	11.29
% Total Variance	14.3	13.8	12.8	10.5	10.8	62.7
% Common Variance	22.8	21.1	20.3	16.7	17.1	

Drug Evaluation Unit of the Psychopharmacology Research Branch NIMH. It is based on a fictional study (No. 33032) with a fictional substance (Normaline) carried out by fictional investigators (Welby and Kildare).

Hamilton Depression Scale

(HAMD)

HAMILTON DEPRESSION SCALE (HAMD)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Hamilton Depression Scale (HAMD)	Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 4 8
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example = 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

For each item select the one "cue" which best characterizes the patient.

1. Depressed mood (sadness, hopeless, helpless, worthless)

   0 = absent

   1 = these feeling states indicated only on questioning

   2 = these feeling states spontaneously reported verbally

   3 = communicates feeling states non-verbally, i.e., through facial expression, posture, voice, and tendency to weep

   4 = patient reports virtually only these feeling states in his spontaneous verbal and non-verbal communication

(20) ___

2. Feelings of guilt

   0 = absent

   1 = self reproach, feels he has let people down

   2 = ideas of guilt or rumination over past errors or sinful deeds

   3 = present illness is a punishment. Delusions of guilt

   4 = hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

(21) ___

3. Suicide

   0 = absent

   1 = feels life is not worth living

   2 = wishes he were dead or any thoughts of possible death to self

   3 = suicidal ideas or gesture

   4 = attempts at suicide (any serious attempt rates 4)

(22) ___

4. Insomnia early

   0 = no difficulty in falling asleep

   1 = complains of occasional difficulty falling asleep, i.e., more than ½ hour

   2 = complains of nightly difficulty falling asleep

(23) ___

5. Insomnia middle

   0 = no difficulty

   1 = patient complains of being restless and disturbed during the night

   2 = waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

(24) ___

6. Insomnia late

0 = no difficulty

1 = walking in early hours of the morning but goes back to sleep

2 = unable to fall asleep again if he gets out of bed (25) ___

7. Work and activities

0 = no difficulty

1 = thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

2 = loss of interest in activity; hobbies or work - either directly reported by patient or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

3 = Decrease in actual time spent in activities or decrease in productivity. In hospital, rate 3 if patient does not spend at least 3 hours a day in activities (hospital job or hobbies) exclusive of ward chores.

4 = Stopped working because of present illness. In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted. (26) ___

8. Retardation (slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

0 = normal speech and thought

1 = slight retardation at interview

2 = obvious retardation at interview

3 = interview difficult

4 = complete stupor (27) ___

9. Agitation

0 = none

1 = fidgetiness

2 = playing with hands, hair, etc.

3 = moving about, cannot sit still

4 = hand-wringing, nail-biting, hair-pulling, biting of lips (28) ___

10. Anxiety psychic

0 = no difficulty

1 = subjective tension and irritability

2 = worrying about minor matters

3 = apprehensive attitude apparent in face or speech

4 = fears expressed without questioning (29) ___

11. Anxiety somatic

Physiological concomitants of anxiety, such as :

gastro-intestinal - dry mouth, wind, indigestion, diarrhea, cramps, belching

cardio-vascular - palpitations, headaches

respiratory - hyperventilation, sighing

urinary frequency

sweating

11. Anxiety somatic, cont'sd

0 = absent

1 = mild

2 = moderate

3 = severe

4 = incapacitating (30) ___

12. Somatic symptoms, gastro-intestinal

0 = none

1 = loss of appetite but eating without staff encouragement. Heavy feelings in abdomen

2 = difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms (31) ___

13. Somatic symptoms, general

0 = none

1 = heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability

2 = any clear-cut symptom rates 2 (32) ___

14. Genital symptoms

Symptoms such as : loss of libido, menstrual disturbances

0 = absent

1 = mild

2 = severe (33) ___

15. Hypochondriasis

0 = not present

1 = self-absorption (bodily)

2 = preoccupation with health

3 = frequent complaints, requests for help, etc.

4 = hypochondriacal delusions (34) ___

16. Loss of weight - rate either A or B

A. When rating by history :

0 = no weight loss

1 = probable weight loss associated with present illness

2 = definite (according to patient) weight loss

3 = not assessed (35) ___

B. On weekly ratings by ward psychiatrist, when actual weight changes are measured :

0 = less than 1 lb. weight loss in week

1 = greater than 1 lb. weight loss in week

2 = greater than 2 lb. weight loss in week

3 = not assessed

(36) ___

17. Insight

0 = acknowledges being depressed and ill

1 = acknowledges illness but attributes causes to bad food, climate, overwork, virus, need for rest, etc.

2 = denies being ill at all

(37) ___

18. Diurnal variation

A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none.

0 = no variation

1 = worse in a.m.

2 = worse in p.m.

(38) ___

B. When present, mark the severity of the variation. Mark "none" if NO variation

0 = none

1 = mild

2 = severe

(39) ___

19. Depersonalization and derealization

such as : feelings of unreality, nihilistic ideas

0 = absent

1 = mild

2 = moderate

3 = severe

4 = incapacitating

(40) ___

20. Paranoid symptoms

0 = none

1 = suspicious

2 = ideas of reference

3 = delusions of reference and persecution

(41) ___

21. Obsessional and compulsive symptoms

0 = absent
1 = mild
2 = severe

(42) ___

Date: ___ ___ | ___ ___ | ___ ___

INFORMATION for USERS

DEVELOPMENT - The HAMD is a 23-item scale with scale points varying from 3 to 5. The HAMD is one of the most widely used instruments for the clinical assessment of depressive states. Unfortunately, the scale has been employed in a number of different versions - creating considerable difficulty when attempting to compare published findings.

REFERENCE - Hamilton, M., Development of a Rating Scale for Primary Depressive Illness, Brit. J. Soc. Clin. Psychol., 1967, 6, 278-296.

APPLICABILITY - Adults with depressive symptomatology.

UTILIZATION - Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the last week.

SPECIAL INSTRUCTIONS -

Item 7 - Work and Activities. Rater may seek information from relatives or ward personnel.

Item 16 - Loss of Weight. This is an "either/or" item requiring a response to only part of the item, i.e., 16A or 16B. Actual Weight Changes (16B) is the preferred choice - particularly during the course of a study. It is suggested that Weight by History (16A) be used only at the pretreatment rating.

Item 18 - Diurnal Variation. When no variation is present, mark "0" for Item A and leave 18B blank.

When diurnal variation is present, mark the time of day when the symptoms are worse in 18A and indicate the severity of variation; i.e., the degree or amount of variation, in 18B. "Mild" should be interpreted as doubtful or slight variation; "severe"as clear or marked variation.

FACTOR COMPOSITION - This factor structure is based on a 1975 analysis of the pre-treatment ratings of 480 subjects with diagnoses of neurotic depression (see Table IV).

Factor I - Anxiety/Somatization

10. Anxiety, psychic
11. Anxiety, somatic
12. Somatic symptoms, gastro-intestinal
13. Somatic symptoms, general
15. Hypochondriasis
17. Insight

Factor II - Weight

16A. Loss of weight (history)
16B. Loss of weight (actual)

Factor III - Cognitive Disturbance

2. Feelings of guilt
3. Suicide
9. Agitation
19. Depersonalization and derealization
20. Paranoid symptoms
21. Obsessional and compulsive symptoms

Factor IV - Diurnal Variation

18A. Diurnal variation (time)
B. Diurnal variation (severity)

Factor V - Retardation

1. Depressed mood
7. Work and activities
8. Retardation
14. Genital symptoms

Factor VI - Sleep Disturbance

4. Insomnia, early
5. Insomnia, middle
6. Insomnia, late

Factor score = $\frac{\text{Sum of composite items}}{\text{No of composite items}}$ Factor score range = 0-4

Total score = Sum of all items* Total score range = 0-62.

*In calculating total score, only Item 18B - not 18A - is included.

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Means and standard deviations of factor scores
d. Cross tabulations
e. Variance analyses.

T A B L E IV

6 - Factor Varimax Solution of 23-Item Hamilton Depression Scale

Cleary, P. and Guy, W., Factor Analyses of the Hamilton Depression Scale, presented at the International Symposium on the Evaluation of New Drugs in Clinical Psychopharmacology, Pisa, September, 1975.

		F1	F2	F3	F4	F5	F6	Communalities
Depressed mood	1	077	052	-213	043	709	100	57
Feelings of guilt	2	012	006	-678	-068	152	090	50
Suicide	3	009	237	-429	163	366	157	43
Insomnia (early)	4	091	367	-065	052	105	585	50
Insomnia (middle)	5	058	109	-194	104	223	709	62
Insomnia (late)	6	105	084	-102	119	244	708	60
Work & activities	7	184	103	-167	-032	602	261	50
Retardation	8	167	000	-065	074	645	222	50
Agitation	9	420	144	-465	-196	-021	295	54
Anxiety psychic	10	448	233	-393	117	201	030	46
Anxiety somatic	11	720	155	-158	-030	156	109	60
Somatic symptoms GI	12	462	293	-139	048	224	326	48
Somatic symptoms, general	13	601	002	-211	116	338	284	61
Genital symptoms	14	340	083	-117	325	531	004	52
Hypochondriasis	15	731	076	-070	048	167	-097	58
Loss of weight A	16	086	746	025	167	136	269	68
Loss of weight B	17	262	898	-101	054	-040	174	92
Insight	18	513	-417	054	094	-252	323	62
Diurnal a.m.	19	-015	109	-121	731	229	078	62
Diurnal p.m.	20	084	064	-082	814	-030	134	70
Depersonalization & dualization	21	119	235	-556	140	223	146	47
Paranoid	22	173	-139	-678	229	-083	163	59
Obsessional-compulsive symptoms	23	162	-022	-626	076	205	-051	47
Contribution of factor (V_p)		2.63	2.05	2.45	1.56	2.33	2.09	13.11
% of total variance		11.43	8.91	10.65	6.78	10.13	9.08	56.9
% of common variance		20.06	15.63	18.68	11.89	17.77	15.94	

Hamilton Anxiety Scale

(HAMA)

HAMILTON ANXIETY SCALE (HAMA)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Hamilton Anxiety Scale (HAMA)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) . _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) _ _ _
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) _ _
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.
Time units : pretreatment = 0, hours = 1, days = 2, weeks = 3, months = 4.
Example = 20 days = 202, 3 weeks = 033, pretreatment = 000.

not present	mild	moderate	severe	very severe
0	1	2	3	4

1. Anxious mood	Worries, anticipation of the worst, fearful anticipation, irritability	(20) ___
2. Tension	Feelings of tension, fatigability, startle response, moved to tears easily, trembling feelings of restlessness, inability to relax	(21) ___
3. Fears	Of dark, of strangers, of being left alone, of animals, of traffic, of crowds	(22) ___
4. Insomnia	Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors	(23) ___
5. Intellectual	Difficulty in concentration, poor memory	(24) ___
6. Depressed mood	Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing	(25) ___
7. Somatic (muscular)	Pains and aches, twitchings, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone	(26) ___
8. Somatic (sensory)	Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation	(27) ___
9. Cardiovascular symptoms	Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, sighing, dyspnea	(28) ___
10. Respiratory Symptoms	Pressure or constriction in chest, choking feelings, sighing, dyspnea	(29) ___
11. Gastrointestinal symptoms	Difficulty in swallowing, wind, abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation	(30) ___
12. Genitourinary symptoms	Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence	(31) ___
13. Autonomic symptoms	Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair	(32) ___
14. Behavior at Interview	Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.	(33) ___

Date: | _ _ | _ _ | _ _ |

INFORMATION for USERS

DEVELOPMENT - The HAMA is a 14-item, 4-point scale. It was designed by Hamilton and intended for use with patients already diagnosed as suffering from neurotic anxiety states - not for assessing anxiety in patients suffering from other disorders. Until the contrary is proved, it must be regarded as invalid for the rating of anxiety in any other setting. This limits the range of usefulness of the scale but, within these limits, patients can be compared meaningfully. The scale places great emphasis on the patient's subjective state. In treatment, the patient's subjective state takes first place, both as a criterion of illness, which brings the patient for treatment and as a criterion of improvement.

REFERENCES

1. Hamilton, M., The Assessment of Anxiety States by Rating, Brit. J. Med. Psychol., 32, 50-55, 1959.
2. Hamilton, M., Diagnosis and Rating of Anxiety, in : Studies of Anxiety, Lader, M.H., Brit. J. Psychiat., Spec. Pub. 3, 76-79, 1969.

APPLICABILITY - Adults with diagnosis of anxiety neurosis.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or during the past week.

SPECIAL INSTRUCTIONS

1. Assessments are made on a 5-point scale. In practice, however, the last scale point (very severe, grossly disabling) is very rarely used for out-patients and serves more as a marker, a method of delimiting the range, rather than as a grade of practical use.

2. Each of the 14 items represents a set of symptoms grouped together according to their nature or where clinical experience indicates that they were associated. The symptom groups which serve as cues for the rater are :

1. Anxious mood
   - Worries
   - Anticipation of the worst
   - Apprehension (fearful anticipation)
   - Irritability

2. Tension
   - Feelings of tension
   - Fatiguability
   - Inability to relax
   - Startle response
   - Moved to tears easily
   - Trembling
   - Feelings of restlessness

3. Fears of
   - Dark
   - Strangers
   - Being left alone
   - Large animals, etc.
   - Traffic
   - Crowds

4. Insomnia
   - Difficulty in falling asleep
   - Broken sleep
   - Unsatisfying sleep and fatigue on waking
   - Dreams
   - Nightmares
   - Night terrors

5. Intellectual (cognitive)
   - Difficulty in concentration
   - Poor memory

6. Depressed mood
   - Loss of interest
   - Lack of pleasure in hobbies
   - Depression
   - Early waking
   - Diurnal swing

7. General somatic (muscular)
   - Muscular pains and aches
   - Muscular stiffness
   - Muscular twitchings
   - Clonic jerks
   - Grinding of teeth
   - Unsteady voice

8. General somatic (sensory)
   - Tinnitus
   - Blurring of vision
   - Hot and cold flushes
   - Feelings of weakness
   - Prickling

9. Cardiovascular symptoms
   - Tachycardia
   - Palpitations
   - Pain in chest
   - Throbbing of vessels
   - Fainting feelings
   - Missing beat

10. Respiratory symptoms
    - Pressure or constriction in chest
    - Choking feelings
    - Sighings
    - Dyspnoea

11. Gastro-intestinal symptoms
    - Difficulty in swallowing
    - Wind
    - Dyspepsia :
      - pain before and after meals
      - burning sensations
      - fullness
      - waterbrash
      - nausea
      - vomiting
      - sinking feelings
    - "Working" in abdomen
    - Borborygmi
    - Looseness of bowels
    - Loss of weight
    - Constipation

12. Genito-urinary symptoms

Frequency of micturition
Urgency of micturition
Amenorrhea
Menorrhagia
Development of frigidity
Ejaculation praecox
Loss of erection
Impotence

13. Autonomic symptoms

Dry mouth
Flushing
Pallor
Tendency to sweat
Giddiness
Tension headache
Raising of hair

14. Behavior at interview

a) General

Tense, not relaxed
Fidgeting : hands
picking fingers
clenching, tics,
handkerchief
Restlessness : pacing
Tremor of hands
Furrowed brows
Strained face
Increased muscular tone
Sighing respirations
Facial pallor

b) Physiological

Swallowing
Belching
High resting pulse rate
Respiration rate over 20/min
Brisk tendon jerks
Tremor
Dilated pupils
Exophtalmos
Sweating
Eye-lid twitching

FACTOR COMPOSITION

Hamilton has presented both centroid and orthogonal factor structures in his 1959 article. Since other ECDEU factors are orthogonal and unipolar, this structure - rather than the centroid one - will be employed for analyses. When a sufficient sample is accumulated, factor analysis will be performed on ECDEU data.

I. Somatic anxiety

7. Somatic, muscular
8. Somatic, sensory
9. Cardiovascular symptoms
10. Respiratory symptoms
11. Gastro-intestinal symptoms
12. Genito-urinary symptoms
13. Autonomic symptoms

II. Psychic anxiety

1. Anxious mood
2. Tension
3. Fears
4. Insomnia
5. Intellectual
6. Depressed mood
14. Behavior at interview.

$$\text{Factor score} = \frac{\text{Sum of composite items}}{\text{No. of composite items}}$$

Factor score range = 0-5

Total score = Sum of all items

Total score range = 0-70

DOCUMENTATION

a. Raw score printout

b. Factor score printout

c. Means and standard deviations of factor scores

d. Variance analyses.

Comprehensive Psychopathological Rating Scale

(CPRS)

COMPREHENSIVE PSYCHOPATHOLOGICAL RATING SCALE (CPRS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Comprehensive Psychopathological Rating Scale (CPRS) - Scoring Sheet

Surname
First Name
Additional Patient ID-No.
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 4 4
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the numeric and the third for the unit of time.
Time units : pretreatment = 0, hours = 1, days = 2, weeks = 3, months = 4
Example = 20 days = 202, 3 weeks = 033, pretreatment = 000

Reported Psychopathology		
1. Sadness	(20)	0 1 2 3
2. Elation	(21)	0 1 2 3
3. Inner tension	(22)	0 1 2 3
4. Hostile feelings	(23)	0 1 2 3
5. Inability to feel	(24)	0 1 2 3
5. Pessimistic thoughts	(25)	0 1 2 3
7. Suicidal thoughts	(26)	0 1 2 3
8. Hypochondriasis	(27)	0 1 2 3
9. Worrying over trifles	(28)	0 1 2 3
10. Compulsive thoughts	(29)	0 1 2 3
11. Phobias	(30)	0 1 2 3
12. Rituals	(31)	0 1 2 3
13. Indecision	(32)	0 1 2 3
14. Lassitude	(33)	0 1 2 3
15. Fatiguability	(34)	0 1 2 3
16. Concentration difficulties	(35)	0 1 2 3
17. Failing memory	(36)	0 1 2 3
18. Reduced appetite	(37)	0 1 2 3
19. Reduced sleep	(38)	0 1 2 3
20. Increased sleep	(39)	0 1 2 3
21. Reduced sexual interest	(40)	0 1 2 3
22. Increased sexual interest	(41)	0 1 2 3
23. Autonomic disturbances	(42)	0 1 2 3
24. Aches and pains	(43)	0 1 2 3
25. Muscular tension	(44)	0 1 2 3
26. Loss of sensation or movements	(45)	0 1 2 3
27. Derealization	(46)	0 1 2 3
28. Depersonalization	(47)	0 1 2 3
29. Feeling controlled	(48)	0 1 2 3
30. Disrupted thoughts	(49)	0 1 2 3
31. Ideas of persecution	(50)	0 1 2 3
32. Ideas of grandeur	(51)	0 1 2 3
33. Delusional mood	(52)	0 1 2 3
34. Ecstatic experiences	(53)	0 1 2 3
35. Morbid jealousy	(54)	0 1 2 3
36. Other delusions	(55)	0 1 2 3
37. Commenting voices	(56)	0 1 2 3
38. Other auditory hallucinations	(57)	0 1 2 3
39. Visual hallucinations	(58)	0 1 2 3
40. Other hallucinations	(59)	0 1 2 3
Observed Psychopathology		
41. Apparent sadness	(60)	0 1 2 3
42. Elated mood	(61)	0 1 2 3
43. Hostility	(62)	0 1 2 3
44. Labile emotional responses	(63)	0 1 2 3
45. Lack of appropriate emotion	(64)	0 1 2 3
46. Autonomic disturbances	(65)	0 1 2 3

47. Sleepiness	(66)	0 1 2 3
48. Distractability	(67)	0 1 2 3
49. Withdrawal	(68)	0 1 2 3
50. Perplexity	(69)	0 1 2 3
51. Blank spells	(70)	0 1 2 3
52. Disorientation	(71)	0 1 2 3
53. Pressure of speech	(72)	0 1 2 3
54. Reduced speech	(73)	0 1 2 3
55. Specific speech defects	(74)	0 1 2 3
56. Flight of ideas	(75)	0 1 2 3
57. Incoherent speech	(20)*	0 1 2 3

58. Perseveration	(21)	0 1 2 3
59. Overactivity	(22)	0 1 2 3
60. Slowness of movement	(23)	0 1 2 3
61. Agitation	(24)	0 1 2 3
62. Involuntary movements	(25)	0 1 2 3
63. Muscular tension	(26)	0 1 2 3
64. Mannerisms and postures	(27)	0 1 2 3
65. Hallucinatory behavior	(28)	0 1 2 3
66. Global rating of illness	(29)	0 1 2 3
67. Assumed reliability of the rating	(30)	0 1 2 3
Date	(70-75)	- - | - - | - -

*Card No. 02

INFORMATION for USERS

DEVELOPMENT - Developed by Asberg,Montgomery, Perris, Schalling and Sedvall, the CPRS consists of 67 items, 40 reported and 27 observed, scored on a 2-point scale.

REFERENCE - Asberg, Marie, Perris, C., Schalling, Daisy and Sedvall, G. : The CPRS - Development and Applications of a Psychiatric Rating Scale. Acta Psychiatrice Scandinavica Supplementum 271, 1978.

APPLICABILITY - Primarily for adult populations.

UTILIZATION - Once at pretreatment and at least one post-treatment assessment. The number and spacing of post-treatment assessments are at the discretion of the investigator.

TIME SPAN RATED - At a maximum, the interval since the last assessment. At pretreatment, a span of one week is suggested.

SPECIAL INSTRUCTIONS

The rating should be based on a flexible clinical interview where the subject is initially encouraged to describe in his own words, and in as much detail as possible, the symptoms that are relevant to him. The interviewer should then decide which items in the scale have not been fully covered and phrase questions in as broad and neutral manner as possible to allow the subject to elaborate these areas. If this is not sufficient for the rating, more specific questions may be needed. The first interview in a series intended to measure change is to some extent a training session for both the rater and the subject. It may therefore be useful to let the interview cover a much longer time span than will eventually be rated, to make sure that the subject fully understands the questions and to let the rater familiarize himself with the subject's history. This will make it easier for the rater to phrase the pertinent questions in later interviews. We have found it useful and would recommend that a separate sheet is used for each new rating.

Reported Psychopathology

1. Sadness

Representing subjectively experienced mood, regardless of whether it is reflected in appearance or not. Includes depressed mood, low spirits, despondency, and the feeling of being beyond help and without hope.

Rate according to intensity, duration and the extent to which the mood is influenced by events.

Elated mood is scored zero on this item.

0 Occasional sadness may occur in the circumstances.
1 Predominant feelings of sadness, but brighter moments occur.
2 Pervasive feelings of sadness or gloominess. The mood is hardly influenced by external circumstances.
3 Continuous experiences of misery or extreme despondency.

2. Elation

Representing subjectively experienced mood - regardless of whether it is reflected in demeanor or not. Includes reports of well-being, high spirits and unvarying exuberance. Rate according to intensity, duration and the extent to which the mood is influenced by external circumstances.

Distinguish from ecstatic experiences (34).

Depressed mood is scored zero.

0 Occasional cheerfulness may occur in the circumstances.
1 Predominating feelings of well-being and high spirits but lower moods occur.
2 Pervasive feeling of well-being and high spirits. The mood is hardly influenced by the circumstances. Longer periods of abundant good humour.
3 Unvarying exuberance, supreme well-being, intense exhilaration.

3. Inner tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to panic, dread and anguish.

Rate according to intensity, frequency, duration and the extent of reassurance called for. Distinguish from sadness (1), worrying (9) and muscular tension (25).

(3. Inner tension, cont'd)

0 Placid. Only fleeting inner tension.

1 Occasional feelings of edginess and ill-defined discomfort.

2 Continuous feelings of inner tension, or intermittent panic which the patient can only master with some difficulty.

3 Unrelenting dread or anguish. Overwhelming panic.

4. Hostile feelings

Representing anger, hostility and aggressive feelings regardless of whether they are acted on or not.

Rate according to intensity, frequency and the amount of provocation tolerated. Inability to feel angry is scored zero on this item (Cf. inability to feel, 5).

0 Not easily angered.

1 Easily angered. Reports hostile feelings, which are easily dissipated.

2 Reacts to provocation with excessive anger or hostility.

3 Persistent anger, rage or intense hatred which is difficult or impossible to control.

5. Inability to feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

Distinguish from lassitude (14).

0 Normal interest in the surroundings and in other people.

1 Reduced ability to enjoy usual interests. Reduced ability to feel anger.

2 Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.

3 The experience of being emotionally paralyzed, inability to feel anger or grief, and a complete or even painful failure to feel for close relatives and friends.

6. Pessimistic thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

0 No pessimistic thoughts.

1 Fluctuating ideas of failure, self-reproach or self-depreciation.

2 Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.

(6. Pessimistic thoughts, cont'd)

3 Delusions of ruin, remorse and unredeemable sin. Absurd self-accusations.

7. Suicidal thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide.

Suicidal attempts should not in themselves influence the rating.

0 Enjoys life or takes it as it comes.
1 Weary of life. Only fleeting suicidal thoughts.
2 Much better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.
3 Explicit plans for suicide when there is an opportunity. Active preparations for suicide.

8 Hypochondriasis

Representing exaggerated preoccupation or unrealistic worrying about ill health or disease. Distinguish from worrying over trifles (9), aches and pains (24) and loss of sensation or movement (26).

0 No particular preoccupation with ill health.
1 Reacting to minor bodily dysfunction with foreboding. Exaggerated fear of disease.
2 Convinced that there is some disease but can be reassured, if only briefly.
3 Incapacitating or absurd hypochondrical convictions (body rotting away, bodily have not worked for months).

9. Worrying over trifles

Representing apprehension and undue concern over trifles, which is difficult to stop and out of proportion to the circumstances.

Distinguish from inner tension (3), pessimistic thoughts (6), hypochondriasis (8), compulsive thoughts (10), phobias (11) and indecision (13).

0 No particular worries.
1 Undue concern, worrying that can be shaken off.
2 Apprehensive and bothered about trifles or minor daily routines.
3 Unrelenting and often painful worrying. Reassurance is ineffective.

10. Compulsive thoughts

Representing disturbing or frightening thoughts or doubts which are experienced

(10. Compulsive thoughts, cont'd)
as silly or irrational, but keep coming back against one's will.

Distinguish from hypochondriasis (8), worrying over trifles (9), and disrupted thoughts (30).

0 No repetitive thoughts.
1 Occasional compulsive thoughts which are not disturbing.
2 Frequent disturbing compulsive thoughts.
3 Incapacitating or obnoxious obsessions occupying one's entire mind.

11. Phobias

Representing feelings of unreasonable fear in specific situations (such as buses supermarkets, crowds, feeling enclosed, being alone) which are avoided if possible.

0 No phobias.
1 Feelings of vague discomfort in particular situations which can be mastered without help or by taking simple precautions, like avoiding rush hours when possible.
2 Certain situations consistently provoke marked discomfort, and are avoided without impairing social performance.
3 Incapacitating phobias which severely restrict activities, for example completely unable to leave home.

12. Rituals

Representing a compulsive repeating of particular acts or rituals which are regarded as unnecessary or absurd and resisted initially but cannot be suppressed without discomfort. The rating is based on the time spent on rituals and the degree of social incapacity.

0 No compulsive behavior.
1 Slight or occasional compulsive checking.
2 Clearcut compulsive rituals which do not interfere with social performance.
3 Extensive rituals or checking habits that are timeconsuming and incapacitating.

13. Indecision

Representing vacillation and difficulty in choosing between simple alternatives. Distinguish from worrying over trifles (9) and compulsive thoughts (10).

(13. Indecision, cont'd)

0 No indecisiveness.

1 Some vacillation but can still make a decision when necessary.

2 Indecisiveness or vacillation which restricts or prevents action, makes it difficult to answer simple questions or make simple choices.

3 Extreme indecisiveness even in situations where conscious deliberation is not normally required, such as whether to sit or stand, enter or stay outside.

14. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

Distinguish from indecision (13) and fatiguability (15).

0 Hardly any difficulty in getting started. No sluggishness.

1 Difficulties in starting activities.

2 Difficulties in starting simple routine activities which are carried out only with effort.

3 Complete inertia. Unable to start activity without help.

15. Fatiguability

Representing the experience of tiring more easily than usual. When lassitude (14) is extreme, this item is difficult to evaluate. If impossible, do not rate.

Distinguish from lassitude (14).

0 Ordinary staying power. Not easily fatigued.

1 Tires easily but does not have to take a break more often than usual.

2 Easily wearied. Frequently forced to pause and rest.

3 Exhaustion interrupts almost all activities or even makes them impossible.

16. Concentration difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.

Rate according to intensity, frequency, and degree of incapacity produced.

Distinguish from failing memory (17) and disrupted thoughts (30).

0 No difficulties in concentrating.

1 Occasional difficulties in collecting one's thoughts.

2 Difficulties in concentrating and sustaining thought which interfere with reading or conversation.

3 Incapacitating lack of concentration.

17. Failing memory

Representing subjective disturbances of recall compared with previous ability. Distinguish from concentration difficulties (16).

0 Memory as usual.

1 Occasional increased lapses of memory.

2 Reports of socially inconvenient or disturbing loss of memory.

3 Complaints of complete inability to remember.

18. Reduced appetite

Representing the feeling of a loss of appetite compared with when well.

0 Normal or increased appetite.

1 Slightly reduced appetite.

2 No appetite. Food is tasteless. Need to force oneself to eat.

3 Must be forced to eat. Food refused.

19. Reduced sleep

Representing a subjective experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

0 Sleeps as usual.

1 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep.

2 Sleep reduced or broken by at least 2 hours.

3 Less than 2 or 3 hours' sleep.

20. Increased sleep

Representing a subjective experience of increased duration or depth of sleep, compared to the subject's own normal pattern when well.

0 No extra sleep

1 Sleeps deeper or longer than usual

2 Several hours extra sleep

3 Spends a great part of day asleep in spite of normal or increased sleep at night.

21. Reduced sexual interest

Representing descriptions of a reduced sexual interest or a reduction of sexual activity (this should always be judged against the subject's usual sexual habits when well). Habitual impotence or frigidity should be ignored when assessing interest.

(21. Reduced sexual interest, cont'd)

Distinguish from inability to feel (5).

Increased sexual interest is rated 0.

0 No reduction of sexual interest.

1 Sexual interest is admitted to be reduced, but activity is unimpaired.

2 Definite reduction of sexual interest. Ordinary sexual activities are reduced or non-existent.

3 Complete sexual indifference.

22. Increased sexual interest

Representing descriptions of a stronger sexual interest than usual, which may be reflected in an increase in sexual activities or phantasies (this should always be judged against the subject's usual sexual habits when well).

0 No increase in sexual interest.

1 Increase in sexual interest or phantasies not reflected in activities.

2 Definite increase in sexual interest or activities or intrusive sexual phantasies.

3 Totally preoccupied with sexual phantasies. Very marked increase in sexual activities.

23. Autonomic disturbances

Representing descriptions of palpitations, breathing difficulties, dizziness, increased sweating, cold hands and feet, dry mouth, indigestion, diarrhoea, frequent micturition. Distinguish from inner tension (3), aches and pains (24), and loss of sensation or movement (26).

0 No autonomic disturbances.

1 Occasional autonomic symptoms which occur under emotional stress.

2 Frequent or intense autonomic disturbances which are experienced as discomforting or socially inconvenient.

3 Very frequent autonomic disturbances which interrupt other activities or are incapacitating.

24. Aches and pains

Representing reports of bodily discomfort, aches, and pains.

Rate according to intensity, frequency and duration, and also request for relief. Disregard any opinion of organic cause.

(24. Aches and pains, cont'd)

Distinguish from hypochondriasis (8), autonomic distrubances (23), and muscular tension (25).

0 Absent or transient aches.

1 Occasional definite aches and pains.

2 Prolonged and inconvenient aches and pains. Requests for effective analgesics.

3 Severely interfering or crippling pains.

25. Muscular tension

Representing the description of increased tension in the muscles and a difficulty in relaxing physically.

Distinguish from aches and pains (24).

0 No increase in muscular tension.

1 Some occasional increase in muscular tension, more evident in demanding situations.

2 Considerable difficulty in finding a comfortable position when sitting or laying. Disturbing muscular tension.

3 Painful muscular tension. Completely incapable of relaxing physically.

26. Loss of sensation or movement

Representing impairment or loss of particular motor or sensory functions. Disregard any organic basis.

Distinguish from hypochondriasis (8), autonomic disturbances (23), and aches and pains (24).

0 No impairment of sensory or motor functions.

1 Slight and transient impairment which does not disturb ordinary activities.

2 Clearcut impairment or loss of some function, but manages daily activities without help.

3 Severely incapacitating and persistent sensorimotor löss which necessitates help, such as blindness, inability to walk or speak.

27. Derealization

Representing a change in the quality of awareness of the surroundings, which may appear artificial. Also includes déjà vu, déjà vécu, and changed intensity of perceptions.

Distinguish from depersonalization (28).

(27. Derealization, cont'd)

0 No change in awareness.

1 Occasional episodes of déjà vu phenomena or derealization.

2 Frequent episodes of derealization.

3 Very frequent or persistent derealization.

28. Depersonalization

Representing a change in the quality of awareness of oneself combined with feelings of unreality, bodily change, detachment, or radical change of person.

Distinguish from inability to feel (5), derealization (27), feeling controlled (29).

0 No experience of change.

1 Occasional or vague feeling of change in oneself.

2 Feelings of change of person which are intrusive.

3 Continuous experience of a radical change of one's person.

29. Feeling controlled

Representing the experience of being in the literal sense influenced or controlled from without, and the experience that feelings, impulses or volitions are imposed from without.

Also rated under this heading is the experience of being able to control others in a similar manner.

Distinguish from disrupted thoughts (30), and ideas of persecution (31).

0 Ordinary influence from social forces.

1 Vague or unconvincing report of being unnaturally influenced from without.

2 Occasional but clear experiences of being controlled from without, e.g., by means of hypnosis.

3 Continuous experiences that feelings or impulses do not derive from oneself but are forced into one, say by means of rays.

30. Disrupted thoughts

Representing the experience of a sudden stoppage of thoughts (thought blocking), or thoughts being put into one's head (insertion), or being taken out (withdrawal), or listened to or broadcast.

Distinguish from compulsive thoughts (10), and concentration difficulties (16).

(30. Disrupted thoughts, cont'd)

0 No thought interruptions.

1 Vague or unconvincing reports of episodes of interruptions to thoughts.

2 Occasional but clear thought blocking or occasional episodes of thought insertion or withdrawal. Feeling that thoughts are being read.

3 Disturbing or disabling thought interruptions. Thought broadcasting.

31. Ideas of persecution

Representing suspiciousness, exaggerated self-consciousness, the conviction of being talked about or watched or persecuted with malicious intent.

0 No undue suspiciousness or self-consciousness.

1 Vague feelings of being observed. Occasional suspicions of malice.

2 Pervasive feelings of being talked about, threatened or persecuted.

3 Unalterable conviction of being the victim of systematic persecution. Delusional misinterpretation of ordinary events or "cues". Conviction of being referred to beyond the realm of likelihood (for example on television or in newspapers).

32. Ideas of grandeur

Representing exaggerated opinion of self-importance, capabilities or good health.

Distinguish from elation (2) and ecstatic experiences (34).

0 No ideas of grandeur.

1 Self assured, with an inflated senseof one's own importance.

2 Clearly exaggerated opinion of self-importance and capabilities. Grandiose, facile, and unrealistic plans for the future.

3 Absurd, delusional ideas of grandeur.

33 Delusional mood

Representing strong, unreasonable premonitions, the feeling or sudden conviction that trivial events or things have a profound and bizarre significance.

Distinguish from derealization (27) and ecstatic experiences (34).

0 Only ordinary superstitions. No delusional mood.

1 Vague premonitions that something personal and unknown is about to happen.

2 A strong feeling that generally trivial events have a special significance (delusional mood).

3 The sudden unshakable conviction, appearing out of the blue, that a particular set of events has a profound and often bizarre meaning (autochtonous delusions).

34. Ecstatic experiences

Representing experiences of mystic rapture, bliss or ecstatic happiness which may involve sudden illumination, insight into religious matters or union with God.

Distinguish from elation (2), and ideas of grandeur (32).

0 No ecstatic experiences.

1 Occasional inexplicable feelings of happiness with metaphysical overtones.

2 Frequent experiences of bliss rapture connected with feelings of sudden insight into metaphysical matters.

3 Marked, or continuous feelings of bliss or mystic rapture, "oceanic feelings", mystical union with God.

35. Morbid jealousy

Representing an absorbing preoccupation with the possible unfaithfulness of a sexual partner.

0 No undue suspicions towards the partner.

1 Vague feelings of insecurity and suspicions about the partner's faithfulness.

2 Searches for and misinterprets "evidence" of unfaithfulness.

3 Morbid ideas of jealousy dominate life and actions. Threatens the partner and tries to extract"confessions".

36. Other delusions

Representing any other delusions than those above (pessimistic thoughts (6), hypochondriasis (8), feeling controlled (29), ideas of persecution (31), ideas of grandeur (32), delusional mood (33) and morbid jealousy (35)).

0 No other delusions.

1 Vague and unconvincing descriptions.

2 Definitely pathological ideas, approaching delusional strength.

3 Absurd delusions which may be reflected in behavior.

37. Commenting voices

Representing the experience of hearing one's own thoughts spoken or repeated aloud, or hearing voices commenting or arguing about one in the third person.

Distinguish from other auditory hallucinations (38).

0 No hallucinated commenting voices.

1 Vague, or unconvincing reports of commenting voices.

2 Definite, but not disabling hallucinated voices.

3 Frequent, disabling hallucinated voices.

38. Other auditory hallucinations

Representing all hallucinated sounds or voices except commenting voices (37). Also includes auditory hallucinations in keeping with the predominant mood such as depression or elation.

0 No auditory hallucinations, except for hypnagogic phenomena (on going to sleep).

1 Misinterpretation of auditory stimuli. Vague or unconvincing reports of auditory hallucinations.

2 Definite hallucinations which may be persistent but not intrusive.

3 Loud, or unpleasant hallucinations. Forceful commands.

39. Visual hallucinations

Representing a misinterpretation of a visual stimulus (illusion) or a false visual perception without any actual outside stimulus (hallucination).

0 No false visual experiences, except for possible hypnagogic phenomena.

1 Occasional illusions.

2 Frequent illusions or occasional visual hallucinations.

3 Clear, frequent or persistent hallucinations.

40. Other hallucinations

Representing hallucinations of taste, smell or bodily sensation. Specify the senses, and base the rating on the most severe.

0 No hallucinations.

1 Vague or unconvincing reports of hallucinations.

2 Occasional but definite hallucinations.

3 Clear, frequent or persistent hallucinations.

Observed Psychopathology

41. Apparent sadness

Representing despondency, gloom and despair (more than just ordinary transient low spirits), reflected in speech, facial expression and posture. Rate by depth and inability to brighten up.

0 No sadness.

1 Looks dispirited but brightens up occasionally.

2 Appears sad and unhappy all of the time.

3 Extreme and continuous gloom and despondency.

42. Elated mood

Representing an elated and exuberant state (excludes ordinary transient high spirits). Includes evident increased well-being, self-confidence, elation and hilarity shown in speech, choice of subject, facial expression, posture and activity. Rate according to intensity and inability to respond seriously when demanded.

0 Normal cheerfulness.

1 Self-confident and somewhat expansive but can change to seriousness when demanded.

2 Expansive hilarity with exaggerated self-confidence and mirth that is out of tune. Unable to respond seriously.

3 Displays persistent extreme exuberance, exhilaration, and absurd hilarity.

43. Hostility

Representing irritability, angry looks, words or actions. Rate by intensity and frequency, and the small amount of provocation that elicits the response and the time taken to quieten.

0 No evident hostility.

1 Querulous, touchy and irritable on provocation. Occasional angry glances.

2 Pugnacious, quarrelsome, very aggressive gestures, but can be calmed down.

3 Threatening behavior or actual physical violence.

44. Labile emotional responses

Representing rapidly changing moods say to sudden elation or sadness with a tendency to display intense emotional responses. Should not be confused with the preponderant mood.

Rate by speed, and frequency of change.

0 No sudden mood changes.

1 Occasional and understandable rapid mood changes.

2 Frequent sudden or exaggerated mood changes.

3 Very rapid changes between intense opposite moods.

45. Lack of appropriate emotion

Representing blunting of affects as shown by lack of emotional expression, or the occurrence of incongruous emotional displays which are clearly out of keeping with the situation.

Distinguish from apparent sadness (41), and elated mood (42).

(45. Lack of appropriate emotions, cont'd)

0 Appropriate affect in keeping with mood.

1 Apparent lack of concern, slightly odd displays of emotions.

2 Responds in a clearly inappropriate way on sensitive issues, or appears not to respond at all.

3 Only clearly bizarre emotional response, or total emotional indifference.

46. Autonomic disturbances

Representing signs of autonomic dysfunction, hyperventilation or frequent sighting, blushing, sweating, cold hands, enlarged pupils and dry mouth, fainting.

0 No observed autonomic disturbances.

1 Occasional or slight autonomic disturbances such as blushing or blanching, or sweating under stress.

2 Obvious autonomic disturbance on several occasions even when not under stress.

3 Autonomic disturbances which disrupt the interview.

47. Sleepiness

Representing evident diminished ability to stay awake as seen in facial expression, speech or posture.

Distinguish from withdrawal (49), perplexity (50), and slowness ov movement (60).

0 Fully awake.

1 Looks sleepy. Yawns occasionally.

2 Tends to fall asleep when left in peace.

3 Falls asleep during interview or is difficult to wake.

48. Distractability

Representing attention easily diverted by irrelevant external stimuli.

Distinguish from withdrawal (49), perplexity (50), blank spells (51), flight of ideas (56), and hallucinatory behavior (65).

0 Adequately sustained attention.

1 Attention occasionally distracted by irrelevant stimuli (such as background noises).

2 Easily distracted.

3 Continually distracted by incidental events and objects which makes interviewing difficult or impossible.

49. Withdrawal

Representing grossly restricted attention and apparent unawareness of people or surroundings.

Distinguish from sleepiness (47), perplexity (50), blank spells (51), and reduced speech (34).

0 Apparently well aware of the surroundings.

1 Occasional withdrawal, but attention can be brought back without difficulty.

2 Appears absent and withdrawn and is only brought back to interview with difficulty.

3 Completely withdrawn. Appears not to react to words or touch.

50. Perplexity

Representing bewilderment, a difficulty in comprehending any situation and interpreting the context.

Distinguish from sleepiness (47), distractability (48), and withdrawal (49).

0 No perplexity

1 Puzzled. Occasional difficulty understanding what should be simple questions.

2 Appears bewildered. Simple questions must be repeated to be understood. Occasional answers unrelated to the question.

3 Obviously perplexed and bewildered. Speech and behyvior clearly inappropriate, as if in a dream.

51. Blank spells

Representing sudden stoppages and inattention while speaking, which last for a few seconds or longer. It is often accompanied by immobility and apparent thought blocking.

Distinguish from reduced speech (54), specific speech defects (55), incoherent speech (57).

0 No blank spells.

1 Occasional lapses which could be interpreted as wandering of the mind.

2 Obvious blank spells even when not under particular stress.

3 Frequent or long blank spells which interfere with conversation.

52. Disorientation

Representing failure of orientation in time and place.

0 Fully oriented.

1 Minimal disorientation as to day or date.

2 Marked disorientation for date or some disorientation in time.

3 Markedly disoriented for time and place.

53. Pressure of speech

Representing pressure to talk, increased flow of speech, and undue loquaciousness. Reduced speech is scored zero on this item.

Distinguish from flight of ideas (56), and incoherent speech (57).

0 Ordinary speech without undue loquaciousness.

1 Rapid verbose speech. Gives detailed answers.

2 Garrulous and very difficult to interrupt.

3 Leads the interview. Words come tumbling out. Cannot be interrupted.

54. Reduced speech

Representing reticent or slowed speech with long delays or pauses. Pressure of speech is scored zero on this item.

Distinguish from withdrawal (49), perplexity (50), blank spells (51), specific speech defects (55).

0 Ordinary speech without undue pauses.

1 Takes time to produce brief answers.

2 Extremely brief monosyllabic answers with long delays. Hardly any spontaneous comments and when they occur they are slow.

3 Monosyllabic answers are only produced with great effort. Almost or completely mute.

55. Specific speech defects

Representing for example stuttering, dysarthria, and aphasia - specify the type, and any obvious reason.

0 No specific difficulties with speech.

1 Occasional speech defects, especially when upset.

2 Very evident speech defects which are intrusive but do not interfere with communication.

3 Persistent and disturbing speech defects which markedly interfere wich communication.

56. Flight of ideas

Representing a rapid flow of ideas shown in speech. There is a continuity of thought, even if it is difficult or even impossible to catch up, in contrast to incoherent speech (57).

0 Ordinary flow of ideas.

1 Free and lively associations with tendency to drift in the discussion.

2 Rapid flow of ideas which can be followed. Frequent changes of subject which interfere with conversation.

3 The rapid changes of subject, and the richness and speed of associations make conversation extremely difficult or impossible.

57. Incoherent speech

Representing circumlocutory disorganized or apparently illogical speech with inexplicitable shifts from topic to topic, distortion and fragmenting of syntax and words.

Distinguish from flight of ideas (56).

0 Coherent and understandable speech.

1 Pedantic and slightly circumlocutory speech. Some idiosyncratic but comprehensible use of words or phrases, especially under stress.

2 Illogical association between words or phrases even when not under stress. "Knight's move" shifts.

3 Obviously disjointed and illogical speech. Fragmentation of phrases or words or bizarre neologisms, which seriously interfere with communication.

58. Perseveration

Representing a tendency to get stuck, to repeat sentences or actions such as repeating the answer to a previous question to subsequent questions and to constantly return to the same topic, or being unable to interrupt a thought of action.

0 No perseveration.

1 The same phrase is occasionally repeated. Returns to the same question several times.

2 Repeats the same phrase, but can be persuaded to give more adequate answers. Difficulties in interrupting a line of thought or an action once started.

3 Perseverating phrases or behavior makes communication difficult or impossible.

59. Overactivity

Representing an increase in frequency and extent of voluntary movement (facial movement, gait, accompanying movements and gestures) and an increased speed in their initiation and completion.

(59. Overactivity, cont'd)

Distinguish from agitation (61), and involuntary movements (62).

0 Ordinary change between activity and rest.

1 Lively gestures and hurried gait but can rest.

2 Obviously expansive and rapid movements and gestures. Abrupt reactions. Leaves the chair occasionally during interview.

3 Continuous wildly exaggerated motor activity. Cannot be persuaded to sit or lie down.

60. Slowness of movement

Representing a decrease in frequency and extent of voluntary movements. Facial movements, gait, accompanying movements and gestures retarded and sluggish.

0 Ordinary change between rest and activity.

1 Minimal gestures and facial movements.

2 Almost no spontaneous motor activity. Slow and laboured movement.

3 Has to be led to the interview. No spontaneous movements. Immobile face. Stupor.

61. Agitation

Representing "purposeless" motor activity such as hand-wringing, picking at objects and clothes, inability to sit still.

Distinguish from overactivity (59), involuntary movements (62) and mannerisms (64).

0 No agitation.

1 Difficulty to keep hands still. Changes position several times during the interview. Fiddles with objects.

2 Obviously restless. Vacant and obtrusive picking at objects. Half rises occasionally.

3 Cannot be persuaded to sit except for brief periods. Incessant purposeless wandering.

62. Involuntary movements

Representing the following involuntary movements : tics, tremor, choreoathetotic movements, dyskinesias, dystonias, and torticollis. Specify the type.

Distinguish from overactivity (59), agitation (61) and mannerisms (64).

0 No involuntary movements.

1 Occasional involuntary movements when under stress.

2 Obvious and frequent involuntary movements, accentuated when under stress. Manages not to let them interfere with ordinary motor activity.

3 Continuous involuntary movements which seriously interfere with ordinary activities.

63. Muscular tension

Representing observed muscular tension as shown in facial expression, posture and movements.

0 Appears relaxed.

1 Slightly tense face and posture.

2. Moderately tense posture and face (easily seen in jaw and neck muscles). Does not seem to find a relaxed position when sitting. Stiff and awkard movements.

3 Strikingly tense. Often sits hunched and crouched, or tense and rigidly upright at the edge of the chair.

64. Mannerisms and postures

Representing repeated or stereotypic complex movements or postures, such as grimmacing, stylized movements, odd postures, catalepsy. The rating is based on frequency, and degree of interference with other activities.

Distinguish from perseveration (58), agitation (61), and involuntary movements (62), especially tics.

0 No mannerisms.

1 Occasional or doubtful grimaces or stylized movement.

2 Mannerisms, grimaces or postures which are obvious but do not interfere.

3 Pronounced mannerisms or postures which take over from ordinary motor activity.

65. Hallucinatory behavior

Representing odd behavior, suggestive of hallucinations, for example turning around suddenly, shouting, or apparently answering voices, retreating from presumed visual hallucinations. Should be rated regardless or whether hallucinations are admitted or not.

Distinguish from involuntary movements (62) and mannerisms and posturing (64).

0 No hallucinatory behavior.

1 Odd behavior, like talking to oneself which migh represent hallucinatory behavior but is thought not to be.

2 Convincing hallucinatory behavior.

3 Bizarre or frequent hallucinatory behavior which interferes with the interview.

66. Global rating of illness

0 None. Absence of illness.

1 Minimal or doubtful illness which does not interfere.

2 Moderate and definite illness.

3 Severe or incapacitating illness.

67. Assumed reliability of the rating

0 Very poor.

1 Fair.

2 Good.

3 Very good.

The CPRS is at present available in the following languages : Swedish, German, Danish, Italian and Finnish.

AMDP-Psychopathological Symptoms

(AMDP-PS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
AMDP-Psychopathological Symptoms (AMDP-PS)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 4 6
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the numeric and the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

	absent	mild	moderate	severe	extremely severe	not assessed
Disorders of consciousness (20)	0					
1. Lowered vigilance (21)	0	1	2	3	4	9
2. Clouded consciousness (22)	0	1	2	3	4	9
3. Narrowed consciousness (23)	0	1	2	3	4	9
4. Expanded consciousness (24)	0	1	2	3	4	9
Disorders of orientation (25)	0					
5. Time (26)	0	1	2	3	4	9
6. Place (27)	0	1	2	3	4	9
7. Situation (28)	0	1	2	3	4	9
8. Self (29)	0	1	2	3	4	9
Disturbances of attention & memory (30)	0					
9. Apperception (31)	0	1	2	3	4	9
10. Concentration (32)	0	1	2	3	4	9
11. Memorization (33)	0	1	2	3	4	9
12. Retention (34)	0	1	2	3	4	9
13. Confabulation (35)	0	1	2	3	4	9
14. Paramnesias (36)	0	1	2	3	4	9
Formal disorders of thought (37)	0					
15. Inhibited thinking (38)	0	1	2	3	4	9
16. Retarded thinking (39)	0	1	2	3	4	9
17. Circumstantial thinking (40)	0	1	2	3	4	9
18. Restricted thinking (41)	0	1	2	3	4	9
19. Perseveration (42)	0	1	2	3	4	9
20. Rumination (43)	0	1	2	3	4	9
21. Pressured thinking (44)	0	1	2	3	4	9

	absent	mild	moderate	severe	extremely severe	not assessed
22. Flight of ideas (45)	0	1	2	3	4	9
23. Tangential thinking (46)	0	1	2	3	4	9
24. Blocking (47)	0	1	2	3	4	9
25. Incoherence (48)	0	1	2	3	4	9
26. Neologisms (49)	0	1	2	3	4	9
Phobias & compulsions (50)	0					
27. Suscpiciousness (51)	0	1	2	3	4	9
28. Hypochondriasis (52)	0	1	2	3	4	9
29. Phobias (53)	0	1	2	3	4	9
30. Obsessive thoughts (54)	0	1	2	3	4	9
31. Compulsive impulses (55)	0	1	2	3	4	9
32. Compulsive actions (56)	0	1	2	3	4	9
Delusions (57)	0					
33. Delusional mood (58)	0	1	2	3	4	9
34. Delusional perception (59)	0	1	2	3	4	9
35. Sudden delusional (60)	0	1	2	3	4	9
36. Delusional ideas (61)	0	1	2	3	4	9
37. Systematized delusions (62)	0	1	2	3	4	9
38. Delusional dynamics (63)	0	1	2	3	4	9
39. Delusions of reference (64)	0	1	2	3	4	9
40. Delusions of persecution (65)	0	1	2	3	4	9
41. Delusions of jealousy (66)	0	1	2	3	4	9
42. Delusions of guilt (67)	0	1	2	3	4	9
43. Delusions of impoverishment (68)	0	1	2	3	4	9

	absent	mild	moderate	severe	extremely severe	not assessed
44. Hypochondriacal delusions (69)	0	1	2	3	4	9
45. Delusions of grandeur (70)	0	1	2	3	4	9
46. Other delusions (71)	0	1	2	3	4	9
Disorders of perception (72)	0					
47. Illusions (73)	0	1	2	3	4	9
48. Verbal hallucinations (74)	0	1	2	3	4	9
49. Other auditory hallucinations (75)	0	1	2	3	4	9
50. Visual hallucinations (20)*	0	1	2	3	4	9
51. Bodily hallucinations (21)	0	1	2	3	4	9
52. Olfactory/gustatory hallucinations (22)	0	1	2	3	4	9
Disorders of ego (23)	0					
53. Derealization (24)	0	1	2	3	4	9
54. Depersonalization (25)	0	1	2	3	4	9
55. Thought broadcasting (26)	0	1	2	3	4	9
56. Thought withdrawal (27)	0	1	2	3	4	9
57. Thought insertion (28)	0	1	2	3	4	9
58. Other feelings of alien influence (29)	0	1	2	3	4	9
Disorders of affect (30)	0					
59. Perplexity (31)	0	1	2	3	4	9
60. Feeling of loss of feeling (32)	0	1	2	3	4	9
61. Blunted affect (33)	0	1	2	3	4	9
62. Loss of vitality (34)	0	1	2	3	4	9
63. Depressed mood (35)	0	1	2	3	4	9
64. Hopelessness (36)	0	1	2	3	4	9
65. Anxiety (37)	0	1	2	3	4	9
66. Euphoria (38)	0	1	2	3	4	9

* Card No 02

67. Dysphoria	(39)	0	1	2	3	4	9
68. Irritability	(40)	0	1	2	3	4	9
69. Inner restlessness	(41)	0	1	2	3	4	9
70. Complaintive	(42)	0	1	2	3	4	9
71. Feeling of inadequacy	(43)	0	1	2	3	4	9
72. Exaggerated self-confidence	(44)	0	1	2	3	4	9
73. Feelings of guilt	(45)	0	1	2	3	4	9
74. Feelings of impoverishment	(46)	0	1	2	3	4	9
75. Ambivalence	(47)	0	1	2	3	4	9
76. Parathymia	(48)	0	1	2	3	4	9
77. Affective lability	(49)	0	1	2	3	4	9
78. Affective incontinence	(50)	0	1	2	3	4	9
79. Affective rigidity	(51)	0	1	2	3	4	9
Disorders of drive and psychomotility	(52)	0					
80. Lack of drive	(53)	0	1	2	3	4	9
81. Inhibition of drive	(54)	0	1	2	3	4	9
82. Increased drive	(55)	0	1	2	3	4	9
83. Motor restlessness	(56)	0	1	2	3	4	9
84. Parakinesia	(57)	0	1	2	3	4	9
85. Mannerisms	(58)	0	1	2	3	4	9
86. Histrionic	(59)	0	1	2	3	4	9
87. Mutism	(60)	0	1	2	3	4	9
88. Logorrhea	(61)	0	1	2	3	4	9
Circadian disturbances	(62)	0					
89. Worse in AM	(63)	0	1	2	3	4	9
90. Worse in PM	(64)	0	1	2	3	4	9
91. Better in PM	(65)	0	1	2	3	4	9
Other Disturbances	(66)	0					

Other disturbances		absent	mild	moderate	severe	extremely severe	not assessed
92. Reduced social contact	(67)	0	1	2	3	4	9
93. Excessive social contact	(68)	0	1	2	3	4	9
94. Aggressiveness	(69)	0	1	2	3	4	9
95. Suicidal tendencies	(70)	0	1	2	3	4	9
96. Self-mutilation	(71)	0	1	2	3	4	9
97. Lack of feeling of illness	(72)	0	1	2	3	4	9
98. Lack of insight	(73)	0	1	2	3	4	9
99. Refusal of treatment	(74)	0	1	2	3	4	9
100. Lack of self-care	(75)	0	1	2	3	4	9
Supplementary items	(20)*	0					
P1 Mythomania	(21)	0	1	2	3	4	9
P2 Loss of desire to live	(22)	0	1	2	3	4	9
P3 Asthenia	(23)	0	1	2	3	4	9
P4 Accelerated thinking	(24)	0	1	2	3	4	9
P5 Tension	(25)	0	1	2	3	4	9
P6 Tendency to dramatize	(26)	0	1	2	3	4	9
P7 Anticipatory anxiety	(27)	0	1	2	3	4	9
P8 Social anxiety	(28)	0	1	2	3	4	9
P9 Objective anxiety	(29)	0	1	2	3	4	9
P10 Reduced sexual interest	(30)	0	1	2	3	4	9
P11 Increased sexual interest	(31)	0	1	2	3	4	9
P12 Sexual unsatisfactoriness	(32)	0	1	2	3	4	9
P13 Altered sexuality	(33)	0	1	2	3	4	9
P14 Pseudohallucination	(34)	0	1	2	3	4	9
P15 Social maladjustment	(35)	0	1	2	3	4	9
Reliability of information	(36)	0	1	2	3	4	9

(70-75) Date | - - | - - | - - |

*Card No. 03

INFORMATION for USERS

DEVELOPMENT - AMDP stands for Arbeitgemeinschaft für Methodik und Dokumentation in der Psychiatrie, or in English, Association for Methodology and Documentation of Psychiatry. It was founded in 1965 by a group of psychiatrists from Germany, Switzerland and Austria, to develop a uniform system for the documentation of information which would be useful in both clinical practice and psychopharmacological research.

The AMDP-PS is a 100-item, 4-point scale. The 100 items are organized under 11 headings.

REFERENCES - The AMDP System Manual for the Assessment and Documentation of Psychopathology, edited and translated from the German by William Guy and T. A. Ban, Springer Verlag, Berlin, Heidelberg, New York, 1982.

APPLICABILITY - Primarily for adult populations.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. The number and spacing of posttreatment assessments are at the discretion of the investigator.

TIME SPAN RATED - At a maximum, the interval since the last assessment.

SPECIAL INSTRUCTIONS - A thorough understanding of the AMDP-PS is necessary for its proper application and utilization. It is strongly recommended that examiners undergo training before attempting independent work. Assessors should be familiar with the following definitions of psychopathological symptoms :

Disorders of consciousness

In this category, degrees of disturbance in one's total experience and overall behavior are assessed including disturbances in activation, awareness of one's self and relationship to the environment, purposefulness of conduct, attentiveness, apperception, conversational interaction, reactivity, adaptiveness in thinking, will, and behavior and vigilance. Quantitative disturbances of consciousness such as distortions and qualitative disturbances such as changes in vigilance are frequently combined in the assessment of severity.

1. Lowered vigilance : A rise in the threshold for all incoming stimuli; decreased responsiveness to environmental contingencies or reduction of vigi-

lance. Lowered consciousness ranges from decreased clarity (Benommenheit) - scored "mild" - through somnolence (moderate), to sopor, precoma and coma (severe and extremely severe). The patient is apathetic, slowed down, and drowsy; easily awakened in somnolence but only with great difficulty in sopor.

2. Clouded consciousness : Dream-like state of consciousness characterized by the inability to distinguish between inner and outer experiences. These states can be constant or intermittent (fragmented consciousness).

3. Narrowed consciousness : Constriction of what enters into awareness. Seen with fixation or fascination with certain experiences. Characteristic of narrowed consciousness is the diminished reactivity to external events, i.e., shutting oneself off from stimuli.

4. Expanded consciousness : Heightened or intensified awareness of inner and outer events. An experience of expanded awareness as distinct from the usual level of consciousness. Distorted consciousness may occur spontaneously or in endogenous psychoses, e.g. in early schizophrenia and mania but can also be intentionally induced by drugs or meditation. States of ecstacy are included here.

Disturbances of orientation

Disorientation refers to the inability to differentiate or accurately evaluate the reality of temporal, spatial, and/or personal situations.

5. Time : Lack of awareness of day, month, year, or season. By convention, patients with memory disturbances who cannot order their past history in the correct chronological sequence are not included here. It is not uncommon for patients - or non-patients for that matter - to be imprecise in stating the numerical date, i.e., to be "off" one or two days from the actual date. Such deviations should be judged leniently.

6. Place : Lack of awareness of one's location. Patient does not know where he is, i.e., inability to identify one's present location.

7. Situation : Inability to assess correctly the surroundings and one's place in it, e.g., a patient being examined by the doctor.

8. Self : Lack of awareness of one's identity. Patient does not know his name and/or misconstrues his personal history.

   Ex. : An old man still knows his name but sees himself as a young boy who is just going shopping for his grandmother.

Disturbances of attention and memory

Attention and memory disturbances are to be rated as objectifiable manifestations - not subjective feelings - or impaired apperception, concentration, and memory. If the examiner is unable to find concrete evidence of impairment or obtain a credible report from the patient, only Item 71 ("Feelings of inadequacy") should be rated.

9. Apperception : The inability to grasp the meaning and significance of experience or to see the meaningful connections between them. In a wider sense, the inability to integrate new experiences with one's own past experience. Apperception may be inappropriate, slow or absent. One has to evaluate whether the behavior is congruent with the situation. Psychological testing through use of TAT, short stories, proverbs, etc., may be required. If the disturbance is the result of sensory aphasia, rate under "Neurological disturbances".

10. Concentration : The inability to focus on a topic and remain focused. Failure to keep one's attention on a pecific matter or objective for a reasonable period of time. In everyday language, the inability "to stick to a task".

11. Memorization : Disturbed immediate memory. The parial or total inability to retain freshly acquired material for more than 10 minutes. It may be tested by asking the patient to repeat a series of numbers, sentences, remember objects, etc., after a lapse of 10 minutes. Immediate memory impairment may vary from one sense modality to another and is dependent upon emotional state of the patient or the emotional loading of the material presented. Hence it is better to use neutral material when testing.

12. Retention : Reduction or loss of ability to retain or recall previously learned material for longer than 10 minutes, e.g., hypomnesia, amnesia. Amnesias are memory gaps, limited in content (systematized) or more often in time (localized). Amnesias are subdivided into lacunar or global on the basis of completeness into congrade (simple), retrograde, or anterograde on the basis of their relationship to time, and into transitory or persistent on the basis of their course.

13. Confabulation : The filling of memory gaps with reports of imagined or supposedly experienced events which the patient regards as real. The content of confabulation for the same memory gap can change continually. This last point is important for differentiation from pseudologia fantastica.

14. Paramnesias : 4 types of pathological recall are evaluated under this item; however, only one entry is required.

a) Delusional memories : Falsification of memories by delusional thinking. Also includes erreneous memories.

b) False recognitions : Never-experienced recognitions (déjà-vu) or unrecognized previous experiences (jamais-vu) are rated here. In déjà-vu, the patient reacts as though everything seen has been seen and experienced before in exactly the same way - down to the last detail. Conversely, jamais-vu consists of reacting to everything as though it is seen for the first time, everything is unfamiliar, fresh or incomprehensible.

c) Ecmnesia : Disturbance of time sense, i.e., temporal sequence in which the past is experienced as present, e.g., senile memory loss and certain emotionally loaded states.

d) Hypermnesia : Increased or heightened recall of the details of events; seen in hyperpyrexia, life-threatening disasters, mania and drug-induced states.

Formal disorders of thought

15. Inhibited thinking : Experienced by the patient as a slowing-down (braking), an irregularity, or cessation in the processing of ideas. The inhibition in tempo, content, or goal-directedness cannot be removed, however hard the patient tries. Inhibited thinking, in contrast to Item 16 (retarded thinking), is subjectively experienced.

16. Retarded thinking : Slow, laborious flow of thought processes. Continuous delays in expressing thoughts with almost no progress. The viscosity and torpidity in speech and reactions are observable to the rater. Retardation must be differentiated from Item 15 (inhibited thinking) and Item 19 (perseveration).

17. Circumstantial thinking : Inability to differentiate the essential from the unessential, getting lost in insignificant details without losing track of the question. Circumstantiality may be the result of loss of abstract ability or the result of an inability to omit insignificant details, e.g., pedantry. Rate only if the progress of the examination is hindered by the rambling of thoughts. Item 25 (incoherence) is not rated here.

18. Restricted thinking : Poverty of ideas. Characterized by shrinking of the thought content and the fixation on one or a few themes. Patient has difficulty in switching from one topic to another or returns to a given topic again and again. Constant repetition of a specific content (theme) is the most severe form of restricted thinking.

19. Perseveration : Persistent repetition of words, phrases, or sentences, to the point they become meaningless. Verbigeration, the senseless reiteration of words is a severe form of perseveration.

20. Rumination : Endless preoccupation or incessant concern with sometimes unpleasant thoughts not experienced as alien and usually related to the real situation in the patient's life. Do not rate obsessional thinking here.

21. Pressured thinking : Driven or kaleidoscopic thinking. Patient feels himself under great stress from disruptive or constantly recurring thoughts - sometimes sensible, sometimes senseless - which seem to tumble over one another.

22. Flight of ideas : Increased number of ideas with a loosening of internal direction or goal. Ideas flow so rapidly that sentences or thoughts are not completed because thinking is continuously interrupted by diverse associations - often clang associations. In contrast to Item 25 (incoherence), the examiner can usually follow the flight of ideas. The acceleration in the flight of ideas is sometimes subjectively perceived as pressured thinking and should be scored under Item 21. Accelerated thinking without a flight of ideas should be rated under Item P3 (accelerated thinking). In these latter conditions, the internal connections among ideas are retained.

23. Tangential thinking : Talking past or around the point. Although appearing to understand the question the patient does not answer directly but brings up another topic or something different in context. Do not rate deliberately misconstrued answers.

24. Blocking : Sudden blocks or interruptions in the flow of the thought process without obvious reason. The patient stops in the middle of a sentence, is silent, and then resumes conversation on another theme. Blocking occurs in states of clear consciousness and must not be confused with interruptions of thinking due to petit mal. The thought block is experienced by the patient who, however, is not aware of any motive(s) behind the breaks or blocks.

25. Incoherence : Thought and consequently speech no longer have understandable connections. What remain are fragmented, incomprehensible thoughts, phrases, and sentences arbitrarily thrown together. Thoughts jump from one topic to another. Differs from flight of ideas in that there are no connections whatsoever among the ideas. In the mild form, paralogia, the sentence structure can still remain intact, while in the severe form (paragrammatism), words and syllables are a senseless mixture as in schizophasia.

Other symptoms of formal thought disorder frequently resulting from looseness in association can be rated under Item 25 :

a) Contamination : Fusion of 2 or more unrelated items.

b) Condensation : Combination of more or less unrelated widely diverse ideas into one.

c) Substitution : Replacement of familiar concepts with unusual but nearly similar ones.

d) Derailment : Shifting or switching upon the main theme to a subsidiary one which intrudes disruptively.

e) Incomplete or desultory thoughts.

26. Neologisms : New word- or phrase-building in which the usual language conventions are not observed and which usually cannot be easily understood. Includes paralogisms, i.e., semantically unusual use of words. Manneristic speech is rated in Item 85.

Phobias and compulsions

27. Suspiciousness : Nondelusional propensity to view the world with anxious uncertainty and mistrust. Disinclination to engage in the usual positive social interactions. A special form is nondelusional jealousy.

28. Hypochondriasis : Anxious, fearful perception of one's body. Misgivings of a nondelusional type about the "reality" of the illness. Objectively unfounded fear of falling ill or being ill. Somatic sensations are perceived fearfully and are given undue attention. Delusional hypochondriasis is differentiated by the strength of the conviction of illness. There is some doubt in the nondelusional type despite the fear. Intermediate forms of hypochondriasis range from fear of cancer, syphilis, or heart disease to mortal dread, e.g., carcinophobia, syphilophobia, cardiophobia, in which a delusional conviction is present. Nondelusional hypochondriasis can become delusional over time.

29. Phobias : Overwhelming fear which repeatedly occurs in certain situations or in the presence of certain objects - more often than not resulting in the avoidance of the stimulus. Phobias differ from ordinary anxiety in that the compulsive inevitability of the fear is combined with intellectual insight (full, partial, or transient) of its unreasonableness and with the experience of inner resistance against the fear.

30. Obsessive thoughts : Preoccupation with thoughts which persist against one's will. While obsessive thoughts are not necessarily senseless, their persistence and penetrance must be regarded as senseless and meaningless. Include obsessive ideas, thoughts, questions, broodings, and fears under this category.

31. Compulsive impulses : Persistent drive (urge) to carry out actions against one's will, e.g., the urge to control something, to jump out the window, to attack somebody, to curse or utter obscene words, to count or calculate.

32. Compulsive actions : Actions persistently carried out against one's will - usually based on thoughts or impulses. Frequently a ritual or ceremony is carried out, e.g., handwashing in a precise, uniform and repetitive manner. When the ritual has been performed, there is often a "folie de doute", i.e., doubt that the ritual has been performed correctly - thus requiring repetition of the ritual. Repetitiveness, however, can also be seen without such doubt. Pathological laughing or weeping - as release phenomena of inborn expressive movements seen in cerebral disease processes - is not included here.

Delusions

There are 2 types of items under this heading : those concerned with the formal aspects of delusion (Items 34-38) and those concerned with content (Items 39-46).

One can define delusion as disease-induced failure in reality testing which is maintained on the basis of subjective belief and a priori evidence. A delusion is a contradiction of reality which is not supported by the collective beliefs and concepts of mankind. The patient feels no need to prove the reality of his delusion since, to him, its correctness (reality) is unequivocally certain. Delusions are present in a variety of psychoses and are not specific for schizophrenia.

33. Delusional mood : The affect which forms the background of the delusional experience. An atmosphere of perplexity and involvement in which the world or the self is experienced as strangely changed. The patient very often cannot give details of the content of the changes. The mood consists of unsubstantiated guesses, suppositions, and expectations which, to the healthy person have no meaning or relationship. There are a variety of moods, associated with the subjective belief in the delusional experience. Most often, it is a sense of awe or mistery about the changes in one's self or is the environment Other common moods are apprehension, terror, foreboding, fear,

suspiciousness, perplexity and, occasionally, elation and self-confidence.

Example :"something's in the air", "something's about to happen", or ordinary things in the surroundings take on special meaning.

34. Delusional perceptions : A normally perceived event (stimulus) is endowed with abnormal significance - usually related to the self - which it does not objectively possess. A delusional perception is actually a delusional misinterpretation of a real perception.

Example : "The tracks in the sky (jet trails) are the fingers of God", "The doctor nodded while shaking my hand which means I have cancer".

Delusional perception must be distinguished from Item 47 ("illusion"). Delusional memories should be coded under Item 14 ("paramnesia").

35. Sudden delusional idea : Sudden ("out of the blue") expression of a delusional notion; transient, delusional irruptions.

36. Delusional ideas : Isolated, irrational, or delusional thoughts which emerge singly or in combination; may be persistent but are unsystematized.

37. Systematized delusions : Organized system of delusional ideas. Delusions are assembled into a coherent - albeit irrational - interconnected construct. New delusional perceptions or ideas as well as secondary delusions (delusional elaborations) may be used to produce the system. There are systems in which only the first supposition is clearly delusional. In most cases, systematization is accomplished only after prolonged psychosis and is dependent upon the deterioration of the patient. There are chronically psychotic patients with well-preserved personalities where the systematized delusions appear to be the only recognizable symptoms. In paranoia, there are always well-elaborated systematized delusions. The criterion - a recognizable, definite structure with strong central connections - must be strictly met to be rated here. Unsystematized delusions are rated in Item 36.

38. Delusional dynamics : The force or intensity of the affective drive which accompanies the delusion. It is possible to estimate the dynamics by the way in which the delusion is reported. There are many variations ranging from vivid delusions forcefully narrated and intensely described to monotonous, stiff recitations of usually old delusions reported without affective resonance or productivity. The dynamics are strong when delusional experiences appear on a vivid or intense affective (sometimes parathymic) background with psychomotor activity and increased drive and when the delusional ideas are flowing rapidly and are marked by intense reactions. In long-term,

chronic schizophrenics, delusions are often reported in an emotionless, stereotyped way without any recognizable affect (residual delusion).

39. Delusions of reference : The conviction that environmental events or objects have a special meaning for the patient. The patient is convinced that events in the surroundings - which, in fact, have nothing to do with him - have a definite significance for him, e.g., conversation between others have some reference leading to him or a casual blink of the eye from a passerby conveys an important message. The patient feels himself to be the focus of observation and attention, and even the most insignificant events are sources of extremely important signals for him. Delusions of reference may occur in an isolated form or as the basis or background for other types of delusions, e.g., persecution, grandeur, etc. Delusions of love - a special form of delusions of reference in which there is a delusional conviction that a certain person loves the patient - are also rated here.

40. Delusions of persecution : Conviction that persons or organizations are attempting to do harm to the patient. He sees himself as the focus of animosity. He feels that he is threatened, offended, insulted, mocked, or derided by others who are striving to take his money, property, health or even his life. Querulous (litigious) delusions are a special type of persecutory delusion in which the patient struggles for justice because of some supposed judicial injury.

41. Delusions of jealousy : Conviction of being deceived or betrayed by a loved one. An unfounded conviction.

42. Delusions of guilt : Conviction of having failed in one's duty or having wronged others. The patient believes he has failed in his duty to God or to some higher moral code or has broken the law or a trust. It can be either an imagined guilt or an extreme exaggeration - due to pathological guilt - of actual errors or failures. The patient feels he is evil, inferior, rejected or unpardonably damned. The guilt may be related to acts of omission, e.g., not taking care of his children, not returning for the doctor's appointment. Frequently, self-accusations are seen, e.g., masturbation, perversion, abortion. In rare cases, it may be an existential guilt, e.g., mere existence as a human causes in itself feelings of guilt, failing one's task in life - one's individuation.

43. Delusions of impoverishment : Conviction of having lost one's fortune or livelihood. The themes of these delusions center around material loss, e.g.,

money, clothes, home, sustenance, job, etc.

44. Hypochondriac delusions : Conviction of improbable or impossible physical illness. The patient is convinced that his health is threatened, that he is chronically ill, or that he is about to die. The content can also be concerned with specific illnesses, e.g., cancer, syphilis, multiple sclerosis, brain tumor or injury, or mental illness. Nihilistic delusions are rated here.

    Example : "My bowels are completely blocked" (despite the fact that he defecates regularly), "My sex organs are dead and will not function again", "I am dead".

    Hypochondrical delusions may appear to be like coenesthetic hallucinations seen in schizophrenia. The abnormal bodily sensations of the depressive, however, do not have the character of "having been caused by outside forces". The bizarre character of the complaints reported and the parathymia as well as the general affective state and the appearance of associated disturbances of the ego usually make it possible to differentiate schizophrenic hypochondrical delusions from depressive ones. The bizarre character of hypochondrical delusions of the schizophrenic are exemplified by the following examples : "Every night they dry up my lungs", "Every time I eat, they turn my entrails to ashes", "My brain has been softened and in its place is a lake of pus".

45. Delusions of grandeur : Expansive or fantastic claims of one's abilities or position. The patient is convinced that he is superior to all other people by virtue of his talents, power, abilities, wealth, etc. He believes himself to be most powerful, the ruler of the world, God, or an envoy of God. There may be delusions of distinguished birth or having made great inventions. Religious delusions are rated here. The patient may believe he has been sent by or has some special relation with God or has been given a sacred mission to perform in the world.

46. Other delusions : Delusional themes not categorized above should be specified and scored here.

Disorders of perception

47. Illusions : Distortion or misinterpretation of a real perception. Falsified actual perceptions; the presence of a real object (percept) differentiates an illusion from a hallucination.

Example : At night, the frightened child perceived a poorly lit bush to be a threatening figure.

Hallucinations are perceptual experiences without a corresponding stimulus in the environment. One can hallucinate in all sense modalities and frequently in more than one. The judgment of reality is more or less narrowed or suspended.

48. Verbal (phonemic) hallucinations : Perception of human voices without external stimuli. Voices of humanoids are also included, e.g., God, Satan, spacemen, leprechauns. There are different degrees of clarity and substance to the voices. The voices may speak directly to the patient or may be experienced (overheard) as conversations between third persons. It is sometimes difficult to differentiate phonemes from Item 57 thought insertion

49. Other auditory hallucinations : Includes all nonverbal, non-human auditory hallucinations, e.g., animals, birds, trees, and inanimate objects.

50. Visual hallucinations : Visual perceptions without corresponding external stimuli. Range from simple optical phenomena (photomes) to elaborate scenes, e.g., "everything is brilliantly colored", "like in the movies", "like a big painting".

51. Bodily hallucinations (coenesthetic) : Unfounded tactile and somatic perceptions including touch, kinesthesic, pain, pressure, and thermic phenomena. Many such hallucinations have the character of being produced by external forces, e.g., the patient has the feeling of being abused sexually or by electricity or "rays". It is not always easy to differentiate bodily hallucinations from other delusional experiences, especially when perceptions of space and motion as well as of internal organs are involved.

52. Olfactory or gustatory hallucinations : Hallucinations in these sense modalities often occur together, alternate, or merge with one another.

Disorders of ego

According to Jaspers, ego disorders include disturbances in experiencing the self as "one" in a moment of time (ego-integrity), as the same in the course of time (ego-identity), and as distinct from the environment (ego-boundary). Item 54 ("depersonalization") is an impairment of ego-world boundaries. Item 55 ("thought broadcasting"), Item 56 ("thought withdrawal"), Item 57 ("thought insertion") and Item 58 ("other feelings of alien influence") are disturbances of ego integrity.

53. Derealization : The experience of one's environment being unreal, strange, or otherwise changed. To the patient, the world appears unfamiliar, peculiar, ghostly, somehow, changed. These feelings of estrangement can be part of a delusional mood. Changes in time perception are included here, as is the loss of vividness of sensory experiences, e.g., in depression.

54. Depersonalization Disturbances of the unity (oneness) of the self in the present or in one's identity in the present period of life. The experience of one's self being unreal, detached, strange, changed, or unidentifiable.

These ego disturbances can be fleeting or persistent. A disturbance of ego-identity over the course of time is present when the patient perceives himself as somebody different than he was at an earlier time and questions whether it was him or someone else. He does not know anymore who has experienced his past.

Example : patient proclaims himself Professor of Veterinary Medicine and Director of the Institution, and he is here to produce hebephrenia. Another male patient discovers he has become a woman (delusionsl sex transformation).

Transformation delusions, e.g., becoming an animal (lycantrophy) are also included here.

Delusionsl disturbances of ego-awareness should be differentiated from the so-called "Doppelgänger" experience or autoscopy - the phenomenon in which the person perceives his own form from outside. The nucleous of the ego remains intact when these phenomena occur, although through certain partial drives in the personality gaining autonomy, splitting and doubling experiences can occur. These disturbances of ego-awareness should be differentiated from the so-called multiple personality. In this unusual phenomenon, the patient, for a period of time, experiences and declares himself to be another person and has no memory of the earlier person. Thus, there is a succession of different personalities each of which, however, has a unified ego-consciousness; whereas in the true disturbance of ego-awareness, the different personalities are simultaneously experienced and act side by side. Misidentification of his own person - when there is preserved ego-consciousness - should be rated in Item 8 ("disturbances of self-orientation")

55. Thought broadcasting : The experience that one's thoughts are not exclusively one's own but are shared by others. The patient complains that "people know what I think. Everybody knows what goes on in my head". Audible thoughts, a kind of broadcasting in which it is believed that one's thoughts

are heard by others, are rated here.

56. Thought withdrawal : The experience that thoughts are being removed or pulled out of one's mind. Thought withdrawal should be differentiated from Item 24 ("blocking").

57. Thought insertion : Thoughts are externally introduced into one's mind and influence, direct or impel behavior.

    Example : "They've hypnotized thoughts into my head which aren't mine."

58. Other feelings of alien influence : Similar to the feeling that one's thoughts are directed by outside forces, the patient believes that other aspects of his being (feelings, strivings, will, behavior) are being influenced from outside. As a consequence, the patient must say something peculiar, scream, roar, behave in a peculiar way, attack someone, bluster, etc.

    Example : "It's not me screaming, it's somebody else. The rays are directing my mouth and speech muscles. The voices scream out of me. I myself do not roar". Just as in thought insertion, this is also a morbid change in one's action awareness (Jaspers).

Disturbances of affect

59. Perplexity : Good of uncertainty or puzzlement. The patient is no longer sure of himself, his situaiton, his surroundings,or his future. He cannot understand what is happening to him, what he is supposed to think, plan,or do. He is unable to come to grips with events or provide himself an overview of them. Objective manifestations of perplexity are a puzzled, strange or anxiously uncertain facial expression, sometimes restlessness or hesitant immobility, indecisiveness, searching behavior, and phrases like "what's the matter ? Where am I ? What's happening ? I don't know. I don't understand!" Perplexity can be found in various conditions, e.g., delusions and confusional states, "coming to" from states of disturbed consciousness such as anesthesia, and even in cases of severe memory disturbance.

60. Feeling of loss of feeling : Feeling that one has lost the ability for emotional resonance; loss or absence of feeling, feeling of emotional emptiness, feeling that one's emotions are "dead".

    Example : "I'm dead inside. I'm not able to feel anything at all. It's empty and dead within me. I don't feel pleasure or sadness or excitement - everything is without feeling".

61. Blunted affect : Observed decrease in emotional responsiveness, e.g., meager feelings, emotional indifference, lack of concern, loss of interest. If the patient complains about the indifference, Item 60 ("feelings of loss of feeling") must also be encoded.

62. Felt loss of vitality : Depression of general bodily feelings subjectively experienced by the patient. Disturbance in the underlying feeling of being alive. Loss or reduction in energy, liveliness, and vigor. Also included are the general feelings of fatigue, weakness, bodily discomfort, and lack of "pep" or animation.

    Example : "It's all so difficult. I have no bounce. I'm weighted down and am so tired".

    Strong localized disturbances, e.g., headache, feeling of fullness (bloat), pressure (tightness) in the chest, and muscle weakness in specific areas are not included here. They should be scored under the appropriate items of Part 5 ("somatic signs").

63. Depressed mood : Negatively tinged affective state characterized by lowered mood and experienced as sadness. It must be present during the evaluation or within the prescribed rating period. Depression covers a wide spectrum of feelings from sadness, uneasiness, being downcast, loss of pleasure, dullness, dejectedness, and loss of interest to feelings of grief, sorrow, despair, helplessness, and extreme, indescribable inner torment. The expressions of depressive symptomatology vary : crying, looking sad, downcast or in despair, and looking as though in pain or torment are all expressions of depression.

64. Hopelessness : Pessimistic mood with lack of positive expectations in the future.

65. Anxiety : Fearfulness or apprehensive feelings without specification or objective basis. The symptom should be explored explicitly with the patient and the rating should be based on the subjective experience of and expression by the patient.

66. Euphoria : Heightened mood or elevated sense of well-being. Excessive cheerfulness or serenity reaching to feelings of elation and ecstasy.

67. Dysphoria : A morose, sullen, dissatisfied mood. Ill-humored, crabby, discordant attitude.

68. Irritability : Undercurrent of anger or aggressiveness. The examiner can sense the imminence of aggressively tinged, affective outbursts even when the patient exhibits a seemingly calm exterior (tense calm).

69. Inner restlessness : Complaints or feelings of psychic unrest. The patient complains spontaneously - or in answer to questions - that he is stirred by and suffers from agitation and tension. Do not include Item 83 ("motor restlessness") here. Inner restlessness is frequently associated with depressive, fearful, hopeless, and despondent feelings and with manic states, delusional mood, and delusional states with various content.

70. Complaintiveness : Expressions of pain and grief through words, mimicry and gesture. Wailing, weeping, sighing, groaning, and other similar phenomena are seen. Lamentation - loud and repetitive complaints expressed in a morose way - is also rated here.

71. Feelings of inadequacy : Imagined lessened capacity. A delusional feeling that one is incompetent, incapable, clumsy, awkward, indecisive, dumb, ignorant, dowdy, etc. The feeling of pronounced loss of self-esteem should be scored "extremely severe".

72. Exaggerated self-esteem : Heightened self-confidence. High opinion of one's abilities. Although nondelusional, the patient believes himself to be very unusual, e.g., very smart, very strong, very competent, very talented, very powerful, very rich, etc.

73. Feelings of guilt : Exaggerated remorse for past behavior, thoughts or wishes which, in the patient's eyes, go against moral or religious tenets. Delusions of guilt are encoded under Item 42.

74. Feelings of impoverishment : Nondelusional feeling that one does not have the means to sustain one's livelihood. Delusional impoverishment is encoded in Item 43.

75. Ambivalence : Coexisting, contradictory conscious feelings which the patient experiences simultaneously and most often as harassing.

    Example : Love and hate at the same time.

    Avoid confusion with Item 59 ("perplexity.").

76. Parathymia : Paradoxical affect. Inappropriate emotional expression or response to a situation.

    Example : A patient describes how he was tormented the night before and, while doing so, is laughing. Another patient is delighted with a gift, yet he

is bewailing its receipt (paramimia).

77. Affective lability : Rapid changes in affect. Increases in affective variability in which an affect persists for only a very short period and shows many ups and downs. Take into consideration native temperament or cultural tradition.

78. Affective incontinence : Lack or loss of emotional control. Rash outbursts of affect which are uncontrolled and, often, of great intensity.

79. Affective rigidity : Reduction or loss of emotional modulation. The patient persists without modulation or oscillation, in certain moods or affects regardless of the external situation. If more than one affect suddenly emerges, rate this item "absent".

Disorders of drive and psychomotility

Drive is essentially independent of will. It is the animating (energizing) force that is the impetus behind the tempo, intensity and endurance of all psychological performance. Drive is recognized by the animation, verve, initiative, alertness, energy, or enterprise exhibited by the individual. Drive is primarily recognized in expressive, psychomotor behavior.

80. Lack of drive : Deficient energy or initiative. Subjectively reported by the patient or observed by the interviewer as sparse motor behavior and/or decreased initiation of conversation. Am example is the quiet, passive patient who cannot be prompted into conversation and who seems to be submerged within himself. In stupor, there is a loss of motoric activity with a maximum loss of drive.

81. Inhibition of drive : In contrast to lack of drive, inhibition does not refer to the diminution of energy and initiative of the patient but rather to a slowing down (braking) of drive. The patient's efforts to overcome the inhibition can be seen in psychomotor activity, perceptual experience, and thought processing. The patient tries to overcome the inhibition but cannot seem to brighten up; he stops trying, then tries to pull himself together again, etc.

82. Increased drive : Increase in activity and initiative as compared to the usual activity level. The behavior usually remains organized and purposeful.

83. Motor restlessness : Aimless and purposeless motor activity which can increase to frenzy. The patient is continually in motion, running around

(motor restlessness with locomotion) or moving his limbs while remaining in place. Restlessness can also be circumscribed, e.g., scratching, handwringing, tic-like movements, etc.

84. Parakinesia : ualitatively abnormal, complex movements which often affect gestures, facial expressions or speech. Motor stereotypy involves a tendency to repeat - in exactly the same form and often for a long time - speech or motoric expressions. In contrast to Item 19 ("perseveration"), the connection to words and /or gestures previously used in the conversation cannot be recognized. Score catalepsy, waxy flexibility, automatic behaviors, automatic obedience, and echo symptoms here. The patient carries out automatic acts which he does not perceive as intentional and automatically follows commands. When the stimulus for such behavior comes from the examiner and the movements of the patient consist of mimicry, it is called echopraxia. When there is an imitation of words or sentences, it is called echolalia.

85. Mannerisms : Natural movements and behavior (gestures, facial expressions, speech) become exaggerated, distorted, posed, and baroque - often in a pronounced playful fashion. Manneristic behavior also refers to unnatural, pompous, boastful (in the sense of bombastic), studied, affected, and artificial, cramped, stylistic, showy and bizarre behavior. A manneristic patient behaves in an extraordinary conspicuous fashion in speech, movement, or dress - compared with his group standards.

86. Histrionics : Theatricality. The patient gives the impression that he is exaggerating his situation, difficulties, and disturbances. His behavior often appears markedly demonstrative.

87. Mutism.: Parsimonious speech or the absence of speech on a psychological basis. The patient generally no longer speaks or, at the most, utters only very few words or syllables. Mutism can be the result of drive deficiency, inhibition, or blocking. It may also be an active, negativistic refusal to make verbal contact.

88. Logorrhea : Voluble speech. Speaking with unquenchable pressure and too excessively for understanding. Depending on its tempo, clarity, internal cohesiveness, logical, or meaningful connections, logorrhea can be quite comprehensible or not at all comprehensible to the interviewer.

Circadian disturbances

Oscillations in condition or behavior of the patient during a 24-hour period. Seasonal oscillations should not be included here.

89. Worse in the morning : Condition is worse between 12 midnight and 12 noon.

90. Worse in the evening : Condition is worse between 12 noon and 12 midnight.

91. Better in the evening : Distinct improvement of condition in the evening. Do not score if improvement is only relative when compared to morning low.

Other disturbances

92. Social withdrawal : ecreased social contact. Judge by the accessibility of the patient in conversation or by the ability to communicate on the ward and/or with people outside the clinic.

93. Excessive social contact : Markedly increased social contact in comparison with earlier behavior. The patient turns toward many people with an almost total loss of psychological distance, e.g., behavior which is sticky, clinging, superficial, machinating, stifling, querulous.

94. Aggressiveness : Agressive tendencies; refers to the inclination for violenee (verbal or physical) either in attacking others or in defending self. Aggressive acts refers to physical assault on persons or surroundings. Both tendency and behavior must be rated according to severity.

95. Suicidal tendencies : Suicidal intentions, plans, death wishes, preparations, or attempts. Each of these can be rated - from mild to extremely severe.

96. Self-mutilation : Non-life-threatening, self-inflicted damage, e.g., banging the head against the wall, scratching the skin, pricking with a needle, plucking out hair, etc.

97. Lack of feeling ill : The patient denies, spontaneously or upon questioning, that he feels ill. The differentiation between feeling ill psychologically or physically is not relevant.

98. Lack of insight : The patient is unable to recognize as morbid those experiences or behavior which his doctor has judged to be due to disease.

99. Uncooperativeness : Negative or oppositional behavior. Resistance against or refusal of various therapeutic measures and/or against admission to the hospital.

100. Lack of self-care : The patient is not able to eat or drink by himself, to attend to personal hygiene, or is bedridden. Incontinence of bowels and/or bladder is rated here.

P Symptoms

The symptom positions (P1-P15) in the German AMDP are left blank and can be used for "write-ins", i.e., additional symptomatology not included among the printed symptoms but deemed relevant by the examiner. In the French AMDP, these P positions are used for the routine assessment of 15 additional psychopathological items. The English adaptation has included 9 additional psychopathological symptoms for routine assessment (P1-P9) while leaving 6 positions for "write-ins" symptoms (P10-P15).

P1. Loss of desire to live : Expression of a desire to discontinue living but without suicidal intend. A positive desire for non-existence. "I don't want to live, but I don't want to kill myself". "I'm trapped in life, but I can't end it". If suicidal intention is also present in word or action, rate under Item 95 (suicidal tendencies).

P2. Asthenia : The experience of fatigue or debility. The physical draining which precedes the effort and tends to increase during the course of action. Asthenia is often more marked in the morning and tends to dissipate as the day progresses. The sleep pattern is either unchanged or aggravated. All these attributes distinguish asthenia from physiological fatigue.

P3. Accelerated thinking : Abnormally rapid flow of ideas and verbal output. Often but not necessarily associated with Item 22 ("flight of ideas") and Item 88 ("logorrhea").

P4. Tension : The tonic neuromuscular expression of affect or arousal which the patient seemingly cannot control, i.e., relax. Seen objectively by furrowed brow, clenched fists, taut musculature, and "uptight" appearance.

P5. Increased libido : The subjective state of sexual excitement as reported by the patient as well as observable genital excitement. Imagination may be the only outlet for gratification if actual consummation is impossible.

P6. Sexual dysfunction : Habitual dissatisfaction, impairment or absence of genital gratification as reported by the patient, e.g., ejaculatory or orgiastic dysfunction. Impotence and frigidity are rated under Item 109.

P7. Altered sexuality : Include all deviant sexual behavior, e.g., homosexuality, transvestitism, fetishism, zoophilia, etc. Rate actual behavior only, not thoughts or desires.

P8. Thought echo : Hearing one's own thoughts spoken aloud, i.e., as if an echo. Distinguish from Item 55 ("thought broadcasting") where one's thoughts are

"heard" as spoken by others.

P9. Pseudohallucination : A perception without external stimuli in which the patient maintains autocritical capacity, i.e., the patient is aware it is an hallucination and not a real perception.

P10-P15 : These positions may be used to encode any additional psychopathological symptoms. Entries must be legible and rated on the severity scale.

Unreliability of informations

After completing Part 4, the interviewer rates the unreliability of the information upon which the assessments are based, i.e., the degree of uncertainty concerning the validity of the information :

0 = not unreliable, i.e., reliable
1 = minor inconsistencies or contradictions
2 = some questionable information but essentially reliable
3 = significant amount of unreliable information
4 = unacceptable reliability.

NURSES OBSERVATION SCALE FOR INPATIENT EVALUATION

(NOSIE)

NURSES' OBSERVATION SCALE FOR INPATIENT EVALUATION (NOSIE)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Nurses' Observation Scale for Inpatient Evaluation (NOSIE)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 3 9
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

*The first 2 digits are provided for the number and the third for the unit of time.

Time unit : 0 = pretreatment, 1 = hours, 2 = days, 3 = weeks, 4 = months.

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

		never	sometimes	often	usually	always
1. Is sloppy	(20)	1	2	3	4	5
2. Is impatient	(21)	1	2	3	4	5
3. Cries	(22)	1	2	3	4	5
4. Shows interest in activities around him	(23)	1	2	3	4	5
5. Sits, unless directed into activity	(24)	1	2	3	4	5
6. Gets angry or annoyed easily	(25)	1	2	3	4	5
7. Hears things that are not there	(26)	1	2	3	4	5
8. Keeps his clothes neat	(27)	1	2	3	4	5
9. Tries to be friendly with others	(28)	1	2	3	4	5
10. Becomes easily upset if something does not suit him	(29)	1	2	3	4	5
11. Refuses to do the ordinary things expected of him	(30)	1	2	3	4	5
12. Is irritable and grouchy	(31)	1	2	3	4	5
13. Has trouble remembering	(32)	1	2	3	4	5
14. Refuses to speak	(33)	1	2	3	4	5
15. Laughs or smiles at funny comments or events	(34)	1	2	3	4	5
16. Is messy in his eating habits	(35)	1	2	3	4	5
17. Starts up a conversation with others	(36)	1	2	3	4	5
18. Says he feels sad or depressed	(37)	1	2	3	4	5
19. Talks about his interests	(38)	1	2	3	4	5
20. Sees things that are not there	(39)	1	2	3	4	5
21. Has to be reminded what to do	(40)	1	2	3	4	5
22. Sleeps, unless directed into activity	(41)	1	2	3	4	5
23. Says that he is no good	(42)	1	2	3	4	5
24. Has to be told to follow hospital routine	(43)	1	2	3	4	5
25. Has difficulty completing even simple tasks on his own	(44)	1	2	3	4	5

		never	sometimes	often	usually	always
26. Talks, mutters, or mumbles to himself	(45)	1	2	3	4	5
27. Is slow moving or sluggish	(46)	1	2	3	4	5
28. Giggles or smiles to himself without any apparent reason	(47)	1	2	3	4	5
29. Quick to fly off the handle	(48)	1	2	3	4	5
30. Keeps himself clean	(49)	1	2	3	4	5

INFORMATION for USERS

DEVELOPMENT - Developed by Honigfeld, Gillis and Klett, the NOSIE is a 30-item scale designed for the assessment of ward behavior by nursing personnel. It provides measures of the patient's strengths as well as pathology. Employing a 5-point scale, the items are written in simple language and ask for ratings based on the direct observation of behavior. Since its introduction in 1965, the scale has been widely used and has demonstrated its sensitivity to change.

REFERENCES

1. Honigfeld, G. and Klett, C., The Nurses Observation Scale for Inpatient Evaluation (NOSIE) : A New Scale for Measuring Improvement in Chronic Schizophrenia, J. Clin. Psychol., 1965, 21 : 65-71.

2. Honigfeld, G., NOSIE-30 : History and Current Status of its Use in Pharmacopsychiatric Research, published in Modern Problems in Pharmacopsychiatry : Psychological Measurement, P. Pichot (Ed), Karger, Basle, 1973.

3. Guy, W. and Cleary, P., Factor Analyses of the NOSIE, to be published.

APPLICABILITY - Adult and geriatric inpatients.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional rating periods are at the discretion of the investigator.

TIME SPAN RATED - The span has been established by the author as "the last 3 days only".

SPECIAL INSTRUCTIONS - Although most raters find it relatively easy to arrive at agreement on the meaning of the items, confusions and misinterpretations do occur. It would be prudent, therefore, to conduct training sessions for neophyte raters to reduce any confusion which may exist.

FACTOR COMPOSITION

This factor structure is based on a 1975 analysis of the pretreatment ratings of 2,415 subjects with diagnoses of schizophrenia. The factors derived are identical with the original Honigfeld factors except for addition of Factor VII - Depression (see Table V).

Positive Factors

I. Social competence

*13 - Has trouble remembering

*14 - Refuses to speak

*21 - Has to be reminded what to do

*24 - Has to be told to follow hospital routine

*25 - Has difficulty completing even simple tasks on his own

II. Social interests

4 - Shows interest in activities around him

9 - Tries to be friendly with others

15 - Laughs or smiles at funny comments or events

17 - Starts up conversation with others

19 - Talks about his interests

III. Personal neatness

*1 - Is sloppy

8 - Keeps his clothes neat

*16 - Is messy in his eating habits

30 - Keeps himself clean

Negative factors

IV. Irritability

2 - Is inpatient

6 - Gets angry or annoyed easily

10 - Becomes easily upset if something does not suit him

11 - Refuses to do ordinary things expected of him

12 - Is irritable and grouchy

29 - Quick to fly off the handle

V. Manifest psychosis

7 - Hears things that are not there

20 - Sees things that are not there

26 - Talks, mutters or mumbles to himself

28 - Giggles or smiles to himself without any apparent reason

VI. Retardation

5 - Sits, unless directed into activity

22 - Sleeps, unless directed into activity

27 - Is slow moving and sluggish

VII. Depression

3 - Cries

18 - Says he feels blue or depressed

23 - Says he is no god.

* = items reflected in scoring

Factor score = 2 x sum of composite items

Total assets = 150 + total POSITIVE (I, II, III) - total NEGATIVE factors (IV,V,VI,VII).

TABLE V

7-FACTOR VARIMAX SOLUTION OF THE NURSES OBSERVATION SCALE FOR INPATIENT EVALUATION

Item	I	II	III	IV	V	VI	VII	Communalities
1	-161	190	002	802	018	188	-257	807
2	052	780	-032	208	-087	140	-089	690
3	089	167	-059	-043	-612	032	-129	433
4	655	-116	-217	-273	-028	-160	160	616
5	-383	043	575	024	-047	-005	-255	547
6	-062	905	-045	076	-053	124	-096	858
7	-247	163	-150	135	-027	768	-155	743
8	230	-148	-023	-864	-024	-101	143	853
9	823	-115	-089	-116	-032	-087	137	739
10	004	893	-029	081	-120	091	-085	835
11	-087	567	128	226	-032	127	-441	608
12	-083	829	027	130	-090	124	-142	756
13	-106	024	115	259	008	251	-686	627
14	-312	167	013	029	010	035	-636	532
15	743	-025	201	-131	-037	110	189	660
16	-032	119	114	567	029	263	-324	525
17	849	047	-094	-075	-078	-107	149	777
18	154	067	147	-070	-797	-087	062	701
19	704	032	-175	-140	-222	-123	049	614
20	-234	192	-159	116	-042	725	-223	708
21	-195	256	185	400	011	192	-660	770
22	-014	024	862	076	-037	-027	020	752
23	032	036	084	050	-804	025	068	663
24	-141	342	153	381	010	161	-617	712
25	-205	241	060	366	-028	235	-654	721
26	-076	263	-014	238	-013	760	-111	722
27	-107	-141	562	092	-174	-158	-324	516
28	126	093	893	131	081	787	-094	685
29	-042	882	-011	058	-025	155	-098	817
30	245	-173	-073	816	025	-138	196	819
Contribution of factor (V_p)	3.57	4.61	1.73	3.27	1.79	2.83	2.99	20.80
% total variance	11.9	15.4	5.8	10.9	6.0	9.4	9.9	69.3
% common variance	17.1	22.2	8.3	15.7	8.6	13.6	14.3	

DOCUMENTATION

a. Raw score printout

b. Factor score printout

c. Means and standard deviations for factor scores

d. Cross-tabulations of factor scores

e. Variance analyses.

Self-Report Symptom Inventory

(SCL-90)

SELF-REPORT SYMPTOM INVENTORY (SCL-90)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Self-Report Symptom Inventory (SCL-90)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-999

(10-12) 0 5 3
Form Number

(13-15) - - | -
Assessment Period*

(16-17) - -
Rater Number

(18-19) 0 1
Card Number

(76-80) - - - - -
Group to which
Patient is Assigned

*The first 2 digits are for the number and the third one for the unit of time.

Time unit : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

Below is a list of problems and complaints that people sometimes have. Please read each one carefully. After you have done so, please fill in one of the numbered spaces to the right that best describes HOW MUCH THAT PROBLEM HAS BOTHERED OR DISTRESSED YOU DURING THE PAST WEEK INCLUDING TODAY. Mark only one numbered space for each problem and do not skip any item.

How much were you bothered by :	0 not at all	1 a little bit	2 moderately	3 quite a bit	4 extremely
1. Headaches (20)					
2. Nervousness or shakiness inside (21)					
3. Unwanted thoughts, words, or ideas that won't leave your mind (22)					
4. Faintness or dizziness (23)					
5. Loss of sexual interest or pleasure (24)					
6. Feeling critical of others (25)					
7. The idea that someone else can control your thoughts (26)					
8. Feeling others are to blame for most of your troubles (27)					
9. Trouble remembering things (28)					
10. Worried about slippiness or carelessness (29)					
11. Feeling easily annoyed or irritated (30)					
12. Pains in heart or chest (31)					
13. Feeling afraid in open spaces or on the streets (32)					
14. Feeling low in energy or slowed down (33)					
15. Thoughts of ending your life (34)					

	0 not at all	1 a little bit	2 moderately	3 quite a bit	4 extremely
16. Hearing voices that other people do not hear (35)					
17. Trembling (36)					
18. Feeling that most people cannot be trusted (37)					
19. Poor appetite (38)					
20. Crying easily (39)					
21. Feeling shy or uneasy with the opposite sex (40)					
22. Feeling of being trapped or caught (41)					
23. Suddenly scared for no reason (42)					
24. Temper outbursts that you could not control (43)					
25. Feeling afraid to go out of your house alone (44)					
26. Blaming yourself for things (45)					
27. Pains in lower back (46)					
28. Feeling blocked in getting things done (47)					
29. Feeling lonely (48)					
30. Feeling blue (49)					
31. Worrying too much about things (50)					
32. Feeling no interest in things (51)					
33. Feeling fearful (52)					
34. Your feelings being easily hurt (53)					
35. Other people being aware of your private thoughts (54)					

	0 not at all	1 a little bit	2 moderately	3 quite a bit	4 extremely
36. Feeling others do not understand you or are unsympathetic (55)					
37. Feeling that people are unfriendly or dislike you (56)					
38. Having to do things very slowly to ensure correctness (57)					
39. Heart pounding or racing (58)					
40. Nausea or upset stomach (59)					
41. Feeling inferior to others (60)					
42. Soreness of your muscles (61)					
43. Feeling that you are watched or talked about by others (62)					
44. Trouble falling asleep (63)					
45. Having to check and double-check what you do (64)					
46. Difficulty making decisions (65)					
47. Feeling afraid to travel on buses, subways or trains (66)					
48. Trouble getting your breath (67)					
49. Hot or cold spells (68)					
50. Having to avoid certain things, places, or activities because they frighten you (69)					
51. Your mind going blank (70)					
52. Numbness or tingling in parts of your body (71)					
53. A lump in your throat (72)					
54. Feeling hopeless about the future (73)					
55. Trouble concentrating (74)					
56. Feeling weak in parts of your body (75)					
57. Feeling tense or keyed up (20)*					

*Card No. 02

	0 not at all	1 a little bit	2 moderately	3 quite a bit	4 extremely
58. Heavy feelings in your arms or legs (21)					
59. Thoughts of death or dying (22)					
60. Overeating (23)					
61. Feeling uneasy when people are watching or talking about you (24)					
62. Having thoughts that are not your own (25)					
63. Having urges to beat, injure, or harm someone (26)					
64. Awakening in the early morning (27)					
65. Having to repeat the same actions such as touching, counting, washing (28)					
66. Sleep that is restless or disturbed (29)					
67. Having urges to break or smash things (30)					
68. Having ideas or beliefs that other people do not share (31)					
69. Feeling very self-conscious with others (32)					
70. Feeling uneasy in crowds, such as shopping or at a movie (33)					
71. Feeling everything is an effort (34)					
72. Spells of terror or panic (35)					
73. Feeling uncomfortable about eating or drinking in public (36)					
74. Getting into frequent arguments (37)					
75. Feeling nervous when you are left alone (38)					
76. Others not giving you proper credit for your achievement (39)					

	0 not at all	1 a little bit	2 moderately	3 quite a bit	4 extremely
77. Feeling lonely even when you are with people (40)					
78. Feeling so restless you could not sit still (41)					
79. Feelings of worthlessness (42)					
80. Feeling that familiar things are strange or unreal (43)					
81. Shouting or throwing things (44)					
82. Feeling afraid you will faint in public (45)					
83. Feeling that people will take advantage of you if you let them (46)					
84. Having thoughts about sex that bother you a lot (47)					
85. The idea that you should be punished for your sins (48)					
86. Feeling pushed to get things done (49)					
87. The idea that something serious is wrong with your body (50)					
88. Never feeling close to another person (51)					
89. Feelings of guilt (52)					
90. The idea that something is wrong with your mind (53)					

INFORMATION for USERS

DEVELOPMENT - Developed by Derogatis, Lipman and Covi, the SCL-90 is composed of 90 items - each rated on a 5-point scale of distress. Evolving from the earlier Hopkins Symptoms Checklist, the SCL-90 was designed primarily as a general measure of psychiatric outpatient symptomatology in both clinical and research situation.

REFERENCES - Derogatis, L.R., Lipman, R.S., Covi, L. and Rickels, K.:Dimensions of outpatient neurotic pathology : Comparison of a clinical vs. an empirical assessment. J. Consult and Clin. Psychol. 34 : 164-171, 1970.

Derogatis, L.R., Lipman, R.S., Covi, L. et al. : Neurotic symptoms,dimensions as perceived by psychiatrists and patients of various social classes. Arch. Gen. Psychiat. 24 : 454-565, 1971.

APPLICABILITY - Adults in psychiatric and non-psychiatric outpatient settings.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or in the last week.

SPECIAL INSTRUCTIONS - The SCL-90 is normally completed by the patient, with administration and monitoring being performed by a technician familiar with the procedure. Usually about 15 minutes of patient time and about 5 minutes of technician time are required. In instances where someone other than the patient is doing the rating (e.g., doctor, nurse, etc.), the technician's primary involvement is in verifying the accuracy for identifying information. The SCL-90 may be introduced to the patient as part of the facility's attempts to understand the problems of the patient, or it may be explained directly as part of a research project for which the patient's assistance is requested. Both methods have proven quite successful. Stress completion of ALL items as quickly as possible. The patient should also work independently without discussing the items with spouse, family members, etc. The instructions should be read and carefully explained to the patient by the technician/administrator.

Definition of scale points - To be explained to the subject and to be used by raters other than the subject.

0 - Not at all = Patient reports no distress associated with the particular symptom.

1 - A little bit = Patient is aware of some distress associated with the symptom, but it is infrequent and of low intensity.

2 - Moderately = Patient experiences distress associated with the symptom in a somewhat regular manner and it is of mild or moderate intensity.

3 - Quite a bit = Patient experiences distress associated with the symptom with regularity, and it is of moderate to high intensity.

4 - Extremely = Patient experiences extreme distress associated with the symptom, due to frequency, intensity, or a combination of both.

DIMENSION COMPOSITION - Dimensions (I-V) have been validated on samples involving over 2,500 patients. Dimensions VI-IX are presently assigned provisional status since validation studies for them are still in progress.

I. Somatization

1	48
4	49
12	52
27	53
40	56
42	58

II. Obsessive-Compulsive

3	45
9	46
10	51
28	55
38	64

III. Interpersonal Sensitivity

6	41
21	61
34	69
36	73
37	

IV. Depression

5	30
14	31
15	32
20	54
22	71
26	79
29	

V. Anxiety

2	57
17	72
23	78
33	80
39	86

VI. Anger-Hostility

11	67
24	74
63	81

VII. Phobic Anxiety

13	70
25	75
47	82
50	

VIII. Paranoid Ideation

8	68
18	76
43	83

IX. Psychoticism

7	84
16	85
35	87
62	88
77	90

Items Not Included in any Factor

19	64
44	66
59	89
60	

General Symptomatic Index (GSI) = $\frac{\text{Sum of all Items}}{\text{No. of Items}}$

Positive Symptom Total (PSI) = No of items rated positively, i.e., rated 1, 2, 3 or 4.

Positive Symptom Distress Index (PSDI) = $\frac{\text{Sum of all items}}{\text{PST}}$

DOCUMENTATION

a. Raw score printout

b. Dimension printout

c. Means and standard deviations of dimensions and global scores

d. Cross-tabulation of dimensions

e. Variance analyses.

Self-Assessment Depression Scale

(SAD)

SELF-ASSESSMENT DEPRESSION SCALE (SAD)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Self-Assessment Depression Scale (SAD)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 4 3
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the numeric and the third one for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

1. I am feeling blue, sad, depressed

not at all	a little bit	quite a bit	extremely	21
A	B	C	D	

2. I feel better in the evening, than in the morning

not at all	a little bit	quite a bit	extremely	22
A	B	C	D	

3. I feel like crying

not at all	a little bit	quite a bit	extremely	23
A	B	C	D	

4. During the night I sleep

normally	not so well	poorly	not at all	24
A	B	C	D	

5. My appetite is

normal	reduced	greatly reduced	absent	25
A	B	C	D	

6. I enjoy sex

as before	less than before	much less than before	not at all	26
A	B	C	D	

7. I lost weight

not at all	a little bit	quite a bit	extremely	27
A	B	C	D	

8. I have trouble with constipation or poor digestion

not at all	a little bit	quite a bit	extremely	28
A	B	C	D	

9. My heart beats faster than usual

never	sometimes	often	almost always	29
A	B	C	D	

10. I feel tired (heavy feelings in arms and legs)

never	sometimes	often	almost always	30
A	B	C	D	

11. My mind goes blank, I have trouble concentrating

never	sometimes	often	almost always	31
A	B	C	D	

12. In my work I get things done

as before	less than before	much less than before	not at all	
A	B	C	D	32

13. I feel restless, tense, anxious, fearful

not at all	a little bit	quite a bit	extremely	
A	B	B	D	33

14. I feel hopeful about the future

as usual	less than before	much less than usual	not at all	
A	B	C	D	34

15. I feel easily annoyed or irritated

not at all	a little bit	quite a bit	extremely	
A	B	C	D	35

16. I feel uncertain and insecure even for matters of little importance

not at all	a little bit	quite a bit	extremely	
A	B	C	D	36

17. I feel that my life has become useless and empty

never	sometimes	often	almost always	
A	B	C	D	37

18. I enjoy working and relaxing

as before	less than before	much less than before	not at all	
A	B	C	D	38

19. I feel pains or "stings" in my heart and chest

never	sometimes	often	almost always	
A	B	C	D	39

20. Seeing and talking with people bothers me

not at all	a little bit	quite a bit	extremely	
A	B	C	D	40

21. I am attached to life as before

yes	thoughts of death	talks of death	tempted suicides	
A	B	C	D	41

22. I feel breathless, and I feel as a "lump in my throat"

never	sometimes	often	almost always	
A	B	C	D	42

23. I feel guilty

never	sometimes	often	almost always	
A	B	C	D	43

24. I feel "the strings (nerves) in my neck" pulling

never	sometimes	often	almost always	
A	B	C	D	44

25. I feel that people are looking (watching) at me, or controlling me, or talking about me

never	sometimes	often	almost always	
A	B	C	D	45

26. I feel a nervousness in my stomach or a "shakiness inside"

not at all	mild	moderate	severe	
A	B	C	D	46

27. I am tormented by obsessive ideas or absurd fears that won't leave my mind

not at all	a little bit	quite a bit	extremely	
A	B	C	D	47

28. I feel like fainting or being dizzy

never	sometimes	often	almost always	
A	B	C	D	48

29. I would feel fine only lying in bed (during the day)

yes	not at all (no)	
D	A	49

30. I feel as if I were detached and could not love my relatives anymore

not at all	a little bit	quite a bit	extremely	
A	B	C	D	50

31. On the whole, my present disturbances are

irrelevant	mild	moderate	severe	
A	B	C	D	51

[ ] + [ ] + [ ] + [ ] = Total part [ ]

Note : A = 1
B = 2
C = 3
D = D

Total gen. [(52-54) - - -]

INFORMATION for USERS

DEVELOPMENT - Developed at the Center for Clinical Psychopharmacology Documentation, the SAD is composed of 31 items, of which 30 are rated on a 4-point scale (A, B, C, D).

APPLICABILITY - All adult and aged populations.

UTILIZATION - One at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or in the last week.

SPECIAL INSTRUCTIONS - One item (Item 29) i.e.,"I would feel fine only lying in bed during the day", is rated as A(no) or D (yes).

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses.

Scales for the Aged

Sandoz Clinical Assessment - Geriatric (SCAG)

SANDOZ CLINICAL ASSESSMENT - GERIATRIC (SCAG)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Psychopharmacology Data Documentation (CCPDD) Sandoz Clinical Assessment - Geriatric (SCAG)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-999

(10-12) 2 3 8
Form Number

(13-15) - - -
Assessment Period*

(16-17) - -
Rater Number

(18-19) 0 1
Card Number

(76-80) - - - - -
Group to which
Patient is Assigned

* The first 2 digits are provided for the numeric and the third one for the unit of time.
Time units : pretreatment = 0 hours = 1; days = 2; weeks = 3; months = 3.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

1	2	3	4	5	6	7
not present	very mild	mild	moderate	moderately severe	severe	extremely severe

1. MOOD DEPRESSION Dejected, despondent, helpless, hopeless, preoccupation with defeat or neglect by family or friends, hypochondriacal concern, functional somatic complaints, early waking. Rate on patient's statements, attitude and behavior.	(20) –
2. CONFUSION Lack of proper association for surroundings, persons and time - "not with it". Slowing of thought processes and impaired comprehension, recognition and performance; disorganization. Rate on patient response and behavior at interview and on reported episodes since last interview.	(21) –
3. MENTAL ALERTNESS Reduction of attentiveness, concentration, responsiveness, alacrity and clarity of thought, impairment of judgement and ability to make decisions. Rate on structured questions and responses at interview.	(22) –
4. MOTIVATION INITIATIVE Lack of spontaneous interest in initiating or completing tasks, routine duties and even attending to individual needs. Rate on observed behavior rather than patient's statements.	(23) –
5. IRRITABILITY (Cantakerousness) Edgy, testy, easily frustrated, low tolerance threshold to aggravation and stress or challenging situations. Rate on patient's response and general attitude at interview.	(24) –
6. HOSTILITY Verbal aggressiveness, animosity, contempt, quarrelsome, assaultive. Rate on impression at interview and patient's observed attitude and behavior towards others.	(25) –
7. BOTHERSOME Frequent unnecessary requests for advice or assistance, interference with others, restlessness. Rate on behavior at and outside the interview situation.	(26) –

8. INDIFFERENCE TO SURROUNDINGS
Lack of interest in everyday events, pastimes and environment where interest previously existed, e.g., news, TV, heat, cold, noise. Rate on patient's statements and observed behavior at and outside interview. (27) _

9. UNSOCIABILITY
Poor relationships with others, unfriendly, negative reaction to social and communal recreational activities, aloof. Rate on observed behavior and not on patient's own impressions. (28) _

10. UNCOOPERATIVENESS
Poor compliance with instructions or requests for participation. Performance with ill grace, resentment or lack of consideration for others. Rate on attitude and responses at interview and observed behavior outside interview situation. (29) _

11. EMOTIONAL LABILITY
Instability and inappropriateness of emotional response, e.g., laughing or crying or other undue positive or negative response to non-provoking situations as the interviewer sees them. (30) _

12. FATIGUE
Sluggish, listless, tired, weary, worn out, bushed. Rate on patient's statements and observed response to normal daily activities outside interview situation. (31) _

13. SELF-CARE
Impairment of ability to attend to personal hygiene, dressing, grooming, eating and getting about. Rate on observation of patient at and outside interview situation and not on statements of patient. (32) _

14. APPETITE (Anorexia)
Disinclination for food, inadequate intake, necessity for dietary supplements, loss of weight. Rate on observed attitude towards eating, food intake encouragement required and loss of weight. (33) _

15. DIZZINESS
In addition to true vertigo, dizziness in this context includes spells of uncertainty of movement and balance, subjective sensations in the head apart from pain, e.g., lightheadedness. Rate on physical examination as well as patient's subjective experience. (34) _

16. ANXIETY

Worry, apprehension, overconcern for present or future, fears, complaints of functional somatic symptoms, e.g., headache, dry mouth, etc. Rate on patient's own subjective experience and on physical signs, e.g., trembling, sighing, sweating, etc., if present. (35) _

17. IMPAIRMENT OF RECENT MEMORY

Reduction in ability to recall recent events and actions of importance to the patient, e.g., visits by members of family, content of meals, notable environmental changes, personal activities. Rate on structured pertinent questions and not on reported performance. (36) _

18. DISORIENTATION

Reduced awareness of place and time, identification of persons, including self. Rate on response to questions at interview only. (37) _

19. OVERALL IMPRESSION OF PATIENT

Considering your total clinical experience and knowledge of the patient, indicate the patient's status at this time, taking into account physical, psychic and mental functioning. (38) _

DATE (70-75) _ _ | _ _ | _ _

INFORMATION for USERS

DEVELOPMENT - The SCAG was recently developed by SANDOZ Pharmaceuticals for the rating of geriatric patients. The scale consists of 18 symptoms plus a global rating. The scale points (7) are similar to those employed on the Brief Psychiatric Rating Scale. The SCAG appears to differentiate among subjects of various degrees of impairment.

REFERENCE - Shader, R.I., Harmatz, J.S., and Salzman, C., A New Scale for Clinical Assessment in Geriatric Populations : Sandoz Clinical Assessment - Geriatric (SCAG), J. of Amer. Geriat. Soc., XXII, 3, 107-113, March 1974.

APPLICABILITY - Geriatric populations.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - The cues printed on the scale for each of the items indicate the context to be used by the rater.

SCORING - Total Score = Sum of items 1-18
Total Score Range = 19-126

DOCUMENTATION

a. Raw score printout
b. Means and standard deviations
c. Variance analyses.

Plutchik Geriatric Rating Scale

(PLUT)

PLUTCHIK GERIATRIC RATING SCALE (PLUT)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Plutchik Geriatric Rating Scale (PLUT)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 4 0
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the numeric and the third for the unit of time.
Time units : pretreatment = 0 hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202 ; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS - Choose one response for each item

1. When eating, the patient requires : 0 = no assistance (feeds himself) 1 = a little assistance (needs encouragement) 2 = considerable assistance (spoon feeding, etc.)	(20)
2. The patient is incontinent : 0 = never 1 = sometimes (once or twice per week) 2 = often (3 times per week or more)	(21)
3. When bathing or dressing, the patient needs : 0 = no assistance 1 = some assistance 2 = maximum assistance	(22)
4. The patient will fall from his bed or chair unless protected by side rail : 0 = never 1 = sometimes 2 = often	(23)
5. With regard to walking, the patient : 0 = has no difficulty 1 = needs assistance in walking 2 = does not walk	(24)
6. The patient's vision, with or without glasses, is : 0 = apparently normal 1 = somewhat impaired 2 = extremely poor	(25)
7. The patient's hearing is : 0 = apparently normal 1 = somewhat impaired 2 = extremely poor	(26)
8. With regard to sleep, the patient : 0 = sleeps most of the night 1 = is sometimes awake 2 = is often awake	(27)

9. During the day, the patient sleeps : (28)
   0 = sometimes
   1 = often
   2 = most of the day

10. With regard to restless behavior at night, the patient is : (29)
   0 = seldom restless
   1 = sometimes restless
   2 = often restless

11. The patient's behavior is worse at night than in the daytime : (30)
   0 = never
   1 = sometimes
   2 = often

12. When not helped by other people, the patient's appearance is : (31)
   0 = almost never sloppy
   1 = sometimes sloppy
   2 = almost always sloppy

13. The patient masturbates or exposes himself publicly : (32)
   0 = never
   1 = sometimes
   2 = often

14. The patient is confused (unable to find his way around the ward, looses his possessions, etc.) (33)
   0 = almost never
   1 = sometimes
   2 = often

15. The patient knows the names of : (34)
   0 = more than one member of the staff
   1 = only one member of the staff
   2 = none of the staff

16. The patient communicates in any manner (by speaking, writing, or gesturing) well enough to make himself easily understood : (35)
   0 = almost always
   1 = sometimes
   2 = almost never

17. The patient reacts to his own name : (36)
    0 = almost always
    1 = sometimes
    2 = almost never

18. The patient plays games, has hobbies, etc. : (37)
    0 = often
    1 = sometimes
    2 = almost never

19. The patient reads books or magazines on the ward : (38)
    0 = often
    1 = sometimes
    2 = almost never

20. The patient will begin conversations with others : (39)
    0 = often
    1 = sometimes
    2 = almost never

21. The patient is willing to do things asked of him : (40)
    0 = often
    1 = sometimes
    2 = almost never

22. The patient helps with chores on the ward : (41)
    0 = often
    1 = sometimes
    2 = almost never

23. Without being asked, the patient physically helps other patients : (42)
    0 = often
    1 = sometimes
    2 = almost never

24. With regard to friends on the ward, the patient : (43)
    0 = has several friends
    1 = has just one friend
    2 = has no friends

25. The patient talks with other people on the ward : (44)
    0 = often
    1 = sometimes
    2 = almost never

26. The patient has a regular work assignment : (45)
    0 = away from the ward
    1 = on the ward
    2 = no regular assignment

27. The patient is destructive of materials around him (breaks furniture, tears up magazines, etc.) : (46)
    0 = never
    1 = sometimes
    2 = often

28. The patient disturbs other patients or staff by shouting or yelling : (47)
    0 = never
    1 = sometimes
    2 = often

29. The patient steals from other patients or staff members (48)
    0 = never
    1 = sometimes
    2 = often

30. The patient verbally threatens to harm other patients or staff : (49)
    0 = never
    1 = sometimes
    2 = often

31. The patient physically tries to harm other patients or staff : (50)
    0 = never
    1 = sometimes
    2 = often

	(70-75)
DATE	- - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Developed by Plutchik, Conte, Lieverman, Bakur and Lehrman, the PLUT is a 31-item scale. It was designed to measure the degree to which geriatric patients are able to function, both physically and socially, in an intact, integrated manner. The items are rated on a 3-point scale and the ratings are based on the direct observation of the patient's behavior.

REFERENCE - 1. Plutchik, R., Conte, H., Lieverman, M., Bakur, M., Grossman, J., and Lehrman, N., Reliability and Validity of a Scale for the Assessing of Functioning of Geriatric Patients, J. Amer. Geriat. Soc., 18, 6, 491-500, June, 1970.

2. Guy, W., and Cleary, P., Factor Analysis of the Plutchik Geriatric Rating Scale, to be published.

APPLICABILITY - Geriatric inpatients.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - None specified by authors, but it is suggested that the time span be limited to now or within past week.

SPECIAL INSTRUCTIONS - Plutchik et al have also provided percentile scores for geriatric subjects. The following table "provides a frame of reference against which future patients may be evaluated for purposes of placement, selection, treatment, and research".

Percentile Distribution of Individual Plutchik Scores of Geriatric Patients

Score	Percentile	Score	Percentile
0-4	1	25	55
5-6	2	26	59
7	3	27	62
8	5	28	65
9	8	29	68
10	10	30	71
11	12	31	73
12	15	32	76
13	19	33	80
14	22	34	83
15	25	35	86
16	27	36	88
17	30	37	91
18	32	38	93
19	34	39	95
20	38	40	96
21	41	41	97
22	45	42-43	98
23	48	44-48	99
24	52	49-51	100

FACTOR COMPOSITION - This factor structure is based on a 1975 analysis of pre-treatment scores from 260 geriatric subjects (see Table VI).

I. Overall Dysfunction
- 1. Eating
- 2. Incontinent
- 3. Bathing and dressing
- 12. Appearance
- 14. Confusion
- 16. Communicates easily
- 17. Reacts to name
- 21. Willing to do things

II. Aggressive Behavior
- 27. Destructive
- 28. Disturbs others
- 29. Steals
- 30. Verbally threatens
- 31. Physically tries to harm

III. Sleep Disturbance
- 8. Sleeps at night
- 10. Restless at night
- 11. Behavior worse at night

IV. Social Isolation
- 20. Begins conversations
- 24. Friends
- 25. Talks with others

V. Sensory Impairment
- 6. Vision
- 7. Hearing

VI. Work and Activities
- 18. Games and hobbies
- 22. Helps with chores
- 23. Helps other patients
- 26. Regular work assignment

VII. Motor Impairment
- 4. Falls
- 5. Walking

Items not included in any factor
- 9. Sleep during day
- 13. Masturbates
- 15. Knows names of staff
- 19. Reads

$$\text{Factor Score} = \frac{\text{Sum of Composite Items}}{\text{No of Composite Items}}$$

Factor Score Range = 0-2

Total Score = Sum of all items

Total Score Range = 0-62

DOCUMENTATION

a. Raw score printout

b. Factor score printout

c. Means and standard deviations of factor scores

d. Variance analyses.

T A B L E VI

7-FACTOR Varimax Solution of Plutchik Geriatric Rating Scale

Items								Communalities
1	589	-069	-024	-151	-076	-163	-333	518
2	692	103	-077	-166	-051	-264	-246	655
3	683	071	-026	-103	026	-294	-245	631
4	269	-007	-008	-038	-144	-199	-640	544
5	305	-049	054	004	-150	-237	-654	604
6	-051	-026	-041	110	-547	-097	-245	387
7	-022	-031	023	-109	-768	018	-008	605
8	-103	010	-815	035	011	013	014	677
9	249	-010	-013	-044	-394	318	-025	321
10	-064	154	-809	091	031	-068	090	705
11	082	073	-770	003	-054	062	-073	618
12	706	130	-097	-140	134	-033	-133	581
13	033	289	-142	-371	-074	026	-104	260
14	702	-011	045	-042	-088	-320	006	607
15	234	033	-039	-301	-268	-413	246	451
16	690	-023	105	-269	-054	-103	066	578
17	604	-061	187	-245	029	-114	-068	482
18	260	058	014	-244	-127	-482	-032	380
19	273	044	042	-223	-108	-403	-064	306
20	331	-086	143	-719	014	-218	-042	703
21	460	044	085	-328	098	-416	-169	540
22	295	-021	-043	-153	085	-686	-269	663
23	170	-079	057	-477	047	-518	-181	570
24	225	025	-053	-653	-052	-219	135	549
25	242	-048	186	-790	049	-202	-056	767
26	222	044	-014	-054	073	-590	-174	439
27	187	555	086	-182	273	143	-196	517
28	137	513	194	-141	-037	-031	-174	372
29	144	503	-072	088	193	092	158	358
30	-144	780	-096	079	-086	-109	054	667
31	-116	755	022	066	-048	-119	126	621
Contribution of factor (V_p)								
	4.28	2.19	2.14	2.59	1.39	2.54	1.55	16.67
% Total Variance								
	13.8	7.1	6.9	8.4	4.5	8.2	5.0	53.8
% Common Variance								
	25.7	13.1	12.8	15.5	8.3	15.2	9.3	

3. Study Record - Final Evaluation

Patient Termination Record

(PTR)

PATIENT TERMINATION RECORD (PTR)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Patient Termination Record (PTR)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 3 2
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) _ _
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the numeric and the third one for the unit of time.
Time units : pretreatment = 0. hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202 ; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS: To be completed at the termination of the subject from the study.

1. REPEATER

a) Has the patient ever been a research subject before ?

0 = No
1 = Yes
2 = Not ascertained (20) _

b) If YES, was the patient a subject in a study in which the data was sent to the CCPDD Laboratory?

0 = No
1 = Yes
2 = Not ascertained (21) _

c) If YES, for the most recent previous study, give :

1. Study number (22-27) _ _ _ _ _ _

2. Patient's number in that study (28-30) _ _ _

2. DURATION (31-33)

a) Total number of days in that study _ _ _

b) Was patient prematurely terminated ? (Give major reason) :

0 = Not prematurely terminated
1 = Did not return for treatment or refused treatment
2 = Adverse reaction
3 = Ineffectiveness or deterioration
4 = Improvement
5 = Intercurrent illness
6 = Found not to meet study criteria
7 = Dosage/ Medication error or violation (34) _
8 = Administrative

3. INTERVAL HISTORY

During the course of the study, were there any significant events or changes - external to treatment situation - in the subject's life situation?

1) No significant events or changes	1	2	(35) _
2) Catastrophic event - fire, flood, financial disaster, accident, etc.	1	2	(36) _
3) Death of significant other	1	2	(37) _
4) Physical/mental illness or significant other	1	2	(38) _

(3. Interval history, cont'd)

5. Difficulties in relationships with relatives or peers (spouse, children, family, lover, friends, fellow employees, etc.)	1	2	(39) _
6. Decrease in status and/or responsibility - layoff, dismissal, demotion or retirement from employment, school failure, loss of hospital privileges, rejection or dissolution of family unit by divorce, separation or inability to perform household responsibilities	1	2	(40) _
7. Improvement in relationships with relatives or peers	1	2	(41) _
8. Increase in status and/or responsibility - promotion in school or employment, new employment, marriage or reuniting of family unit, increased hospital privileges	1	2	(42) _
9. Pregnancy of subject (spouse or parents) and/or birth of child/sibling	1	2	(43) _

4. NON-DRUG TREATMENT

a) Did the subject receive any non-drug treatments during the course of the study ? (44) _

0 = No 1 = Yes

b) If YES, rate the effectiveness of all treatments received.

	efficacy unknown 0	unsatisfactory 1	equivocal 2	satisfactory 3	
Behavior modification					(45)
Electroconvulsive therapy					(46)
Milieu therapy					(47)
Physical therapy					(48)
Psychotherapy - group					(49)
Psychotherapy - individual					(50)
Rehabilitation/occupational therapy					(51)
Remedial educational therapy					(52)

c) Did the subject's spouse/family receive therapy/counseling as part of the subject's overall treatment regime ? (53) _

0 = No 1 = Yes

d) If YES, rate the effectiveness of the therapy/counseling : (54) _

0 = Efficacy unknown 2 = Equivocal

1 = Unsatisfactory 3 = Satisfactory

5. DRUG INTAKE

How well did the patient follow his drug regime ?

0 = Not applicable, did not receive drugs

1 = Took study medication as prescribed

2 = Some irregularities but primarily took study medication as prescribed

3 = Suspected significant irregularities

4 = Confirmed significant irregularities

5 = Took additional medication in violation

9 = Not ascertained

(55) -

6. ANCILLARY MEDICATION (56) -

a) During the course of the study, did the subject receive any ancillary medication/s other than test/control drug/s ?

0 = No 1 = Yes

b) If YES, rate the effectiveness of all ancillary medication received.

Ancillary medication	efficacy unknown 0	unsatis-factory 1	equivocal 2	satis-factory 3	
Analgesic narcotic					(57)
Analgesic non-narcotic					(58)
Anesthesia - general					(59)
Anesthesia - local					(60)
Antiallergenic					(61)
Anticoagulant					(62)
Anticonvulsant					(63)
Antifertility					(64)
Antihypotensive					(65)
Antimicrobial					(66)
Antiparkinson					(67)
Antitumor					(68)
Blood tonic					(69)
Bronchodilator					(70)
Cardiac medication					(71)
Cough and cold preparation					(72)
Dermatological preparation					(73)
Diabetic medication					(74)
Diet medication					(75)

(6. Ancillary Medication, cont'd)

Ancillary medication	efficacy unknown 0	unsatis-factory 1	equvocal 2	satis-factory 3	
Diuretic					(20)
Gastrointestinal preparation					(21)
Hormonal preparation					(22)
Muscle relaxant					(23)
Psychotropic medication (other other test or control drug)					(24)
Sedative/hypnotic					(25)
Stimulant					(26)
Thyroid medication					(27)
Vitamin					(28)

7. GLOBAL ITEMS

a) Compared to other subjects, how well did this subject conform to study requirements ?

0 = Much below average

1 = Below average

2 = Average

3 = Above average

4 = Much above average

(29) _

b) Given the choice, would you continue this subject on his study medication ?

0 = Definitely no

1 = Inclined to say no

2 = Undecided

3 = Inclined to say yes

4 = Definitely yes

(30) _

8. DISPOSITION AT TERMINATION

Answer either (a) or (b)

a) Inpatients

0 = Elopement or discharge against medical advice

1 = Remains hospitalized and has lost privileges and/or work assignments previously held, e.g., loss or decrease in passes, or freedom of movement within hospital, loss or decrease in industrial therapy assignments, transfer to more closely supervised wards

(8. Disposition at Termination, cont'd)

2 = Remains hospitalized and status is unchanged from pretreatment

3 = Remains hospitalized and has earned greater privileges and/or work assignments, e.g., formal industrial therapy assignments, day or night passes, transfers to wards with less supervision

4 = Paroled or discharged to a supervised living situation in community, e.g., foster home, halfway house, day hospital, community mental health clinic, etc.

5 = Paroled or discharged to own custody or own family. Include patients discharged with recommendation to continue treatment with family physician; on OPD basis, etc.

6 = Transferred or discharged for reasons unrelated to present treatment, e.g., intercurrent illness or accident, administrative reasons, etc. (31)

b) Outpatients

0 = Discharged against medical advice, e.g., refused treatment, did not return for treatment, family uncooperative, etc.

1 = Hospitalized (transferred to inpatient status) because of exacerbation or deterioration of psychiatric condition

2 = Remains on outpatient status and treatment is intensified because of exacerbation or deterioration of psychiatric condition, e.g., greater psychiatric supervision, partial hospitalization, such as day or night hospital, etc.

3 = Remains on outpatient status and status is unchanged from pretreatment

4 = Remains on outpatient status and treatment is reduced because of improvement of psychiatric condition e.g., less supervision, more widely spaced visits, etc.

5 = Discharged to own custody or own family. Include patients discharged with recommendation to continue treatment with family physician or to seek treatment independently.

6 = Transferred or discharged for reasons unrelated to present treatment, e.g., intercurrent illness or accident, administrative reasons, geographical relocation, etc. (32)

(70-75) Date | - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Developed within the ECDEU program, the PTR consists of 8 items focusing on the historical events of the study itself, e.g., the course and length of treatment, ancillary treatments, disposition at termination, etc. The information elicited by the PTR is essential for the complete documentation and evaluation of a study.

APPLICABILITY - All research populations.

UTILIZATION - Once per subject. Completed at the time of the subject's termination from the study.

TIME SPAN RATED - The length of the study; from entrance to termination.

SPECIAL INSTRUCTIONS -

Item 1. Repeater - This item has been included on the PTR for technical reasons rather than for its pertinence to termination status. It enables BLIPS/BDP to identify those who have multiple data sets in the data bank. If the subject has participated in several previous studies, the rater should mark the identification data from the most recent study. If the subject has never been a repeater, leave items 1b and 1c blank. If the subject has been a repeater but does not have data in the data bank, leave item 1c blank.

Item 2a. Duration - Duration is defined as the number of days from a subject's entrance into a study to his termination. Entrance into a study is defined as the day of the initial assessment; termination as the day of the final assessment. Total number of days in the study may or may not coincide with total number of days under medication. Duration in studies in which a pretreatment drying-out period and/or a follow-up period are encompassed (bracketed) by assessments, for example, will exceed the actual duration of medication. Notice that duration MUST BE CODED IN DAYS.

Item 2b. Premature Termination - Only ONE reason should be given. Definitions for the categories are as follows :

1 = Did not return for treatment or refused treatment - includes elopement; unauthorized leaves; rescinding of treatment permission by parents, relatives or legal guardian; sporadic or insufficient attendance of treatment appointments; refusal to cooperate with assessment and/or other research procedures.

2 = Adverse reaction - Any reaction, side effect or treatment emergent symptom which, in the opinion of the investigator, requires termination of drug treatment.

3 = Ineffectiveness or deterioration - Refers to lack of change or exacerbation of psychiatric symptomatology which, in the opinion of the investigator, is ethically unacceptable and, therefore, requires termination.

4 = Improvement - Refers to a degree of positive change (improvement) in psychiatric symptomatology which, in the opinion of the inverstigator, ethically requires release from treatment situation, e.g., discharge or parole from hospital; discharge from clinic or other agency.

5 = Intercurrent illness - Refers to any non-treatment related illness or medical condition requiring termination of treatment. Pregnancy should be included here.

6 = Found not to meet study criteria - Refers to subjects erroneously admitted to study, e.g., lacks required target symptoms; does not fit age groups; has a history incompatible with inclusion criteria.

7 = Dosage/medication error or violation - Includes errors or violations by either the subject or the staff which necessitate termination, e.g., "over" or "under dosing" by subject himself or by his relatives; intake of medications prohibited by protocol; dispensing errors in dosage and/or medication.

8 = Administrative - Includes transfers to other wards or hospitals; subject moving from area; drug withdrawn by company; personnel defections; protocol violations such as accidental revelation of treatment assignment codes, improper assessment procedures, introduction of services or activities prohibited by protocol.

Item 3. Interval History - This item (and item 8) is written in general terms so that it might serve as wide a population as possible. Rather than specifying the exact nature of the event, the rater is asked to judge the effect of the event upon the subject. An external event or change is considered significant if, in the opinion of the investigator, it has had a substantial effect on the course of treatment.

1 = Catastrophic event - refers to any natural disaster, economic event, "act of God", etc.

4 = Difficulties in relationship with relatives or peers - refers to detrimental events or changes in the subject's emotional or social interactions which do not appear to be primarily related to treatment.

5 = Decrease in status and/or responsibility - includes any significant event or change which reflects a diminution in the subject's status or responsibility.

6 = Improvement in relationships with relatives or peers - non-treatment related events or changes which reflect facilitation of relationships.

7 = Increase in status and/or responsibility - any events or changes which enhance the subject's status or reflect increased responsibilities.

A maximum of 2 entries may be made for this item.

Item 4a and 4b. Non-drug treatments - If the answer to item 4a is "no", item 4b may be left blank. A "yes" response to 4a requires that each treatment received must be evaluated.

Item 5. Drug intake - Only one response is permitted.

Item 7a. This item requires a judgment of the behavior of the subject qua subject; i.e., how well did he follow the "rules" of the study; did he miss appointments, require surveillance, rebel against procedure, act as "guard-house lawyer", etc.

Item 7b. In double blind studies, it is crucial that this item be completed prior to breaking the blind, i.e., revealing the exact nature of the treatment to the rater.

Item 8. Disposition at termination. As in item 3, this item endeavors to be universal by stating the responses in general terms. The investigator must judge whether the subject's treatment regime - as it existed at the beginning of the study - has been reduced, intensified or altered substantially.

DOCUMENTATION

a. Raw score printout

b. Frequency tables

PART FIVE

A DOCUMENTATION SYSTEM IN OPERATION

C. Data Processing

The BLIPS/BDP is a fully operational, integrated series of computer programs that produce documentation for a variety of scientific data inputs. Based on a common assessment battery and standard documentation, BLIPS/BDP, nevertheless, attempts to minimize the constraints placed upon the investigator.

In its original version, in operation over a few years period as BLIPS, from 1967 to 1972, BLIPS consisted of numerous programs which were each designed to process a particular form. This created processing and analytic weaknesses whenever deviations from preprogrammed designs occured. In 1972, BLIPS was extensively motidified - and designated as BLIPS II - with the following objectives in mind :

1. Flexibility to process any scientific data which may be converted to computer readable form.
2. Exhaustive verification of data validity.
3. Simplification of external controls to a level at which non-technical personnel can manage routine system operations.
4. Capability to produce a final documentation report tailored to the investigator's needs.

In 1976, BLIPS was replaced by BLIPS/BDP with computer facilities transferred from Washington, USA, to Pisa, Italy. Acceptable input data for BLIPS/BDP processing and analyses may be of any type which can be converted into computer readable form.

The verification of data validity is executed by an error detection and correction subsystem which is called the preprocessor. The preprocessor consists of basic and specialized functions which detect missing information, duplicate identification fields, invalid entries and the logical consistency of interrelated items either within a single form or across several forms; e.g., the natural mother's age should not be less than or equal to her children's ages. When errors are detected, they are corrected via punched cards. These cards contain all the necessary information to locate the exact field within the data file where the correction is to be inserted and correspond in format to an error listing which is produced as a visual aid. The correction cards are resubmitted to the system. The preprocessor will then make the corrections and reprocess the data set. This process is repeated until no further errors are detected.

To maintain the external control at a level which non-technical personnel can manage, the transformation and analysis of the data is done via a semi-automated

subsystem called DATRAN. Fixed control information needed to process the data is stored permanently on disk, while the variable control information, e.g., the number of patients, the number of assessment periods, etc., is generated via a series of programs which examine the data as well as the Data Shipment form, completed by the investigator. In addition to self-generating complex control information, the subsystem will select the appropriate combination of procedures necessary to fully analyze the data. This selection is performed by testing criterion variables such as forms used in the drug trial, number of patients in the study, analysis desired, etc. The subsystem will run fully automated until new assessment instruments are introduced. Then additional control information must be generated to process the new entries.

To obtain a final documentation report tailored to meet most of the needs of the investigator, an output generator subsystem transforms the output obtained from existing analysis programs. This subsystem provides extensive labeling information merges several data sets, and combines the results to facilitate comparisons and make interpretation an easier task for the investigator. An indexed, paginated document is the final product.

Editing and Error Diagnostics

The editing of data has been, by far, the most time-consuming element in BLIPS/BDP. The procedure has been complicated by the fact that errors can enter the system by 3 avenues : the rater, editors and machine. While experience with the system has reduced errors from all sources, the preparation of data for analyses remains most vulnerable to delays. In dealing with the problem, the central premise has been to transfer human effort to computer operations insofar as possible. Thus, there has been a continuous development of editing programs especially designed to prepare diverse data sets for standard BLIPS/BDP analyses.

The frequency of errors attributable to the rater seems inversely proportional to the length of his experience with the forms. Neophyte raters tend to make a higher proportion of errors of commission in comparison to errors of omission. With experience, these commission errors diminish and errors of omission remain the primary problem.

The major portion of error detection is carried out by computer programs. An error is first specifically located, then defined and space provided for correction in an error diagnostics listing. Any and all errors are cited even though, in a specific study, certain items may have been purposely deleted by the investigator. Number and frequency of errors is summarized for each form and a table of this summary comprises part of the error diagnostics listing (see Table VII). Both the quality and quantity of errors serve as bases for the decision whether to proceed with analyses. A significant proportion of errors in any given study can be corrected by BLIPS/BDP personnel. However, BLIPS/BDP editors never assume what an ambiguous response should or might represent. In all cases, resolution of the ambiguity resides with the investigator.

The error citations employed in error diagnostics are defined as follows :

Citation	Definition
Missing	Item or part of item is missing.
Illegal	Item requiring only one entry contains 2 or more entries or the entry is out of range.
Logical	2 or more items are logically inconsistent; e.g., one cannot be the 5th child of a cohort of 3; diarrhea and constipation are present simultaneously.
Identification	Error occurs within the identification block.
Data	Error occurs within the data matrix.

T A B L E VII

SCHEMA for ERROR DIAGNOSTICS

STUDY NO. INVESTIGATOR NAME STUDY TITLE DATE PAGE NO.

SCALE NAME

PAT	PER	RAT	ITEM	ERROR	STATUS
XXX	XXX	XX	XX	-----	C
XXX	XXX	XX	XX	-----	(BLANK)

C = CORRECTED BY BLIPS/BDP

(BLANK) = NOT CORRECTED

LOGICAL = TWO OR MORE ITEMS ARE INCONSISTENT

MISSING = RESPONSE OR PART OF RESPONSE IS MISSING

ILLEGAL = RESPONSE IS UNACCEPTABLE, E.G., MULTIPLE ENTRIES, OUT OF RANGE

IDEN = IDENTIFICATION FIELD

DATA = DATA FIELD

ERROR SUMMARY

	ORIGINAL		TOTAL BEFORE EDIT	TOTAL AFTER EDIT
FORM	IDEN	DATA		
XXX	XX(%)	XX(%)	XX(%)	XX(%)
ALL	XX(%)	XX(%)	XX(%)	XX(%)

BEFORE EDIT = FREQUENCY AND PERCENT OF ERRORS IN ORIGINAL DATA SET

AFTER EDIT = FREQUENCY AND PERCENT OF RESIDUAL ERRORS FOLLOWING EDIT

Raw and Computed Score Listings

When the editing process is completed and retrieval of erroneous data accomplished, raw and computed scores are generated in tabular form. Descriptive headings, e.g., patient, period and rater numbers, are given along the top of the tables; data are displayed in columns (see Table VIII). When possible, items are labeled but for lengthy scales, item numbers are used. Spacing between sets of items, e.g., every 5, every 10, etc., aids in locating a specific item.

Computed scores are obtained by combining raw item scores according to some rule or set of operations. Most common are factor scores in which item scores are statistically combined on the basis of a factor analysis. Empirical clusters, i.e., combinations on the basis of logical decisions developed from clinical experience, are another example. Displays for computed scores follow the same format as raw scores.

T A B L E VIII

SCHEMA FOR RAW, FACTOR OR OTHER COMPUTED SCORES

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE DATE

			ITEMS						GP
RAT	PER	RAT	1	2	3	4	5 ———	N	GP
001	000	02	X	X	X	XX	XXX		1
001	012	02	X	X	X	XX	XXX		1
002	000	02	X			XX	XXX		
020	012	02							2
021	000	03							2
021	012	03							

PAT = PATIENT NUMBER

PER = PERIOD NUMBER : 3RD DIGIT REPRESENTS TIME UNIT

RAT = RATER NUMBER

ITEMS = ITEM NAMES (ABBREVIATED) WILL BE USED INSTEAD OF NUMBERS WHERE SPACE PERMITS

GP = GROUP ASSIGNMENT

1, 2 = TREATMENT GROUPS WILL FOLLOW ONE ANOTHER : TEST DRUG NO. 1; TEST NO. 2; COMPARISON NO. 1; ETC.

Means and Standard Deviations

These displays differ from raw and derived score printouts in that they present nomothetic (group) rather than idiographic (individual) data. Means, standard deviations and number of subjects involved in their calculations are displayed by period along the vertical; items by group(s) and total sample appear as headings along the horizontal (see Table IX). Grant item means and standard deviations for each group and the total sample are displayed following the last assessment period.

T A B L E IX

SCHEMA for MEANS and STANDARD DEVIATIONS

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE

SCALE NAME

PERIOD		GP 1	GP 2	GPn	SAMPLE
00	N	XXX	XXX	XXX	XXX
	MN	XXX	XXX	XXX	XXX
	5D	XXX	XXX	XXX	XXX
07	N	XXX	XXX	XXX	XXX
	MN	XXX	XXX	XXX	XXX
	SD	XXX	XXX	XXX	XXX
TOTAL	N	XXX	XXX	XXX	XXX
	MN	XXX	XXX	XXX	XXX
	SD	XXX	XXX	XXX	XXX

GROUP MEANS (MN) AND STANDARD DEVIATIONS (SD) ARE CALCULATED FOR RAW OR COMPUTED SCORES (WHICHEVER IS APPROPRIATE) FOR EACH RATING PERIOD. SAMPLE MEANS (ROW MEAN) PROVIDE DATA FOR THE ENTIRE POPULATION AT EACH PERIOD. GRAND MEANS (COLUMN MEAN) FOR ALL PERIODS ARE GIVEN FOR EACH GROUP AND FOR THE ENTIRE SAMPLE.

ITEM 2

Frequency Tables

This display is used primarily for categorical data such as demographic items, descriptive events, etc. Items and their response positions are listed vertically; frequency and percent of occurence by group and total sample along the horizontal (see Table X). Means and standard deviations are also supplied where relevant. Because of their complexity, some items, e.g., Family Psychiatric History, require special formatting or computation; e.g., Social Class.

T A B L E X

SCHEMA FOR FREQUENCY TABLES

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE

SCALE NAME

VARIABLE	GP 1	GP 2	GP_n	SAMPLE
NO SUBJECTS	XX	XX	XX	XX
VARIABLE 1				
RESPONSE 1	XX(XX)	XX(XX)	XX(XX)	XX(XX)
RESPONSE 2	XX(XX)	XX(XX)		
RESPONSE 3	XX(XX)			
MISSING	XX(XX)			
MEAN	XXX			
SD	XXX			
VARIABLE 2				

XX(XX) = FREQUENCY (PERCENT)

GP = GROUP

SAMPLE = FREQUENCY AND PERCENT FOR ENTIRE POPUALTION

MEANS AND SD ARE GIVEN ONLY WHEN APPROPRIATE.

Cross-Tabulations

The purpose of cross-tabulation is to condense and organize data so that directional changes can be readily detected. The usual comparison is between pre- and post treatment data although any 2 sets of data may be compared. The schema below illustrates some general principles of interpretation. The diagonal (AD) contains those cells in which patients exhibit no pre/post changes in rating. The upper triangle, ABD, contains cells in which some degree of improvement is rated. As cells approach pole B, greater degrees of improvement are implied. Conversely, the lower triangle, ACD, reflects degrees of exacerbation - greater degrees as pole C is approached. The cell at pole A contains patients who are asymptomatic; pole B, the zenith of treatment success; pole C, the nadir of treatment failure and pole D, the "untouchables" - sickest at pretreatment and sickest at posttreatment.

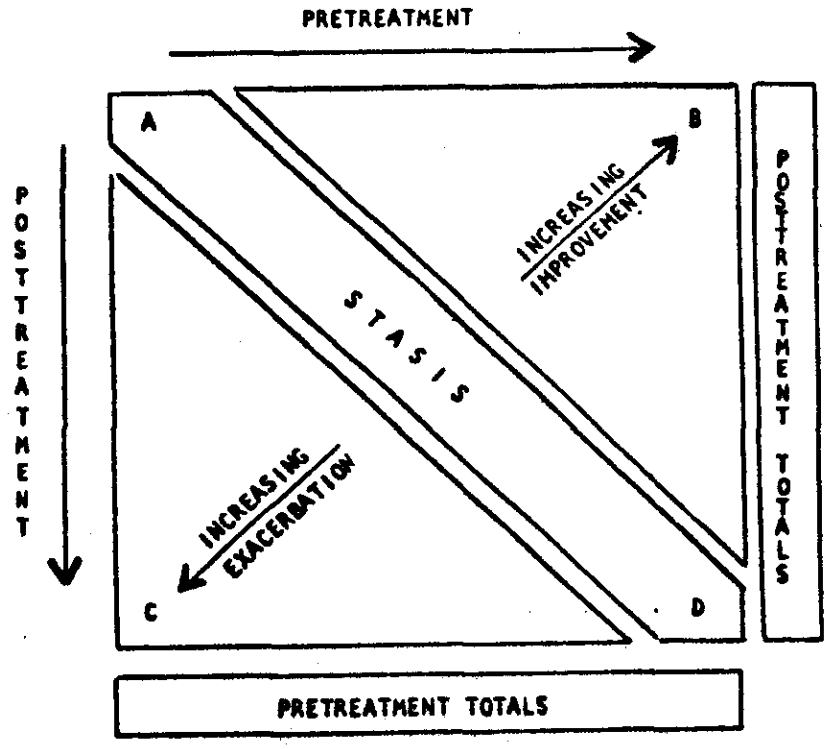


Table XI represents a cross-tabulation of the BPRS symptom, Somatic Concern. The distribution of 15 pre and posttreatment ratings on a 7-point scale ranging from NOT PRESENT to EXTREMELY SEVERE is shown. Pretreatment scores (presum) are read horizontally (7 = Not Present, 2 = Very Mild, 4 = Mild, etc.); posttreatment scores (postum) vertically (8 = Not Present, 4 = Very Mild, etc.). The diagonal of the matrix is emphasized by underlining. Scores which fall here reflect static scores, i.e., scores which remain at the same intensity level at both ratings. When both pre and posttreatment scores are "NOT PRESENT", this is

designated as asymptomatic. Asymptomatic is, of course, a variant of a static score and, in the example, there are 4 asymptomatic subjects. Any scores above the diagnoal represent improvement; any below represent worsening (increased severity). Three subjects, for example, changed from "Mild" at pretreatment to "Very Mild" at posttreatment. One subject changed from "Not Present" at pretreatment to "Moderately Severe" at posttreatment - a change of 4 points in a negative direction.

T A B L E XI

SCHEMA for CROSS TABULATIONS

STUDY NO. INVESTIGATOR'S NAME STUDY TITLE DATE

047-BPRS BRIEF PSYCHIATRIC RATING SCALE

GP 1 GP 2

SOMATIC CONCERN

		NP	VM	MI	MO	MS	SV	ES	NA	POST SUM
POST TREATMENT	NP	4	1	1	2	0	0	0	0	8
	VM	0	1	3	0	0	0	0	0	4
	MI	1	0	0	0	0	0	0	0	1
	MO	1	0	0	0	0	0	0	0	1
	MS	1	0	0	0	0	0	0	0	1
	SV	0	0	0	0	0	0	0	0	0
	ES	0	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0	0
PRESUM		7	2	4	2	0	0	0	0	

TOT N = TN-NA = ASYMPT = 4 (27)

STAT = 1 (7) + CHANGE = 7 (47); - CHANGE = 3 (20)

VARIABLE 2

4 CROSSTABS CAN BE PLACED ON A PAGE. IF MORE THAN 2 GROUPS, GROUP 3 AND 4 WILL BE PLACED IN LOWER LEFT AND RIGHT POSITIONS. WITH ONE OR TWO GROUPS, NEXT VARIABLE WILL APPEAR IN LOWER ROW.

NP	NOT PRESENT
VM	VERY MILD
MI	MILD
MO	MODERATE
MS	MODERATELY SEVERE
SV	SEVERE
ES	EXTREMELY SEVERE
NA	NOT ASCERTAINED AND/OR NOT ASSESSED

POSTSUM	POSTTREATMENT SUM
PRESUM	PRETREATMENT SUM
TOT N	TOTAL NO. OF SUBJECTS
TN-NA	TOTAL NUMBER - NOT ASCERTAINED
ASYMPT	NO (%) SUBJECTS RATED NP AT BOTH PERIODS
STATIC	NO (%) SUBJECTS RATED AT SAME INTENSITY AT BOTH PER. (NO CHANGE)
+ CHANGE	NO (%) SUBJECTS SHOWING POSITIVE CHANGE (IMPROVEMENT)
- CHANGE	NO (%) SUBJECTS SHOWING NEGATIVE CHANGE (WORSENING)

Cross-tabulation accomplishes data reduction and facilitates interpretation of group results without losing sight of the individual patient. The exact nature of changes between 2 ratings can be followed in detail irrespective of sample size or tests of significance. Cross-tabulations can be examined to ascertain whether the result is due to modest unidirectional changes in a large proportion of the sample or to dramatic changes in a few individuals. Noting bipolar changes, the investigator may find that specific subgroups are responding differentially under the same drug condition. It should be remembered, however, that cross-tabulation involves comparison between only 2 ratings. Investigators are cautioned that changes may have occurred at other points in the course of the study, e.g., pre- vs. posttreatment ratings will not reveal changes which occur at the midpoint of a study. Perusal of other data sets, e.g., means and SD, variance analyses, will alert the investigator to the possibility of change not revealed in the cross-tabulations.

Graphic Displays

These displays are of 2 types. The first presents data derived from a single assessment instrument in unaltered raw form. Only the format is changed to facilitate rapid assimilation of results. In Figure pre- and post-treatment factor means obtained from a hypothetical scale are shown and, further, data for 2 treatment groups are juxtaposed - greatly increasing the usefulness of the display.

The second type of graphic involves the conversion of data from several assessment instruments into standard scores and their presentation in one composite display. Conversion into standard scores, of course, does not alter the relative magnitude of data, while permitting instruments with differing scale points to be plotted together for rapid comparison (see Figure 1). Routinely, standard scores will be based on sample parameters. For each variable, the sample mean and standard deviation will be calculated and a standard score, for each treatment group derived on that basis. The formula for conversion is :

$$\text{Group Standard Score} = 50 + \frac{10\ (\text{Group Mn} - \text{Sample Mn})}{\text{Sample SD}}$$

F I G U R E 1

SCHEMA for GRAPHIC DISPLAY for SINGLE ASSESSMENT INSTRUMENT

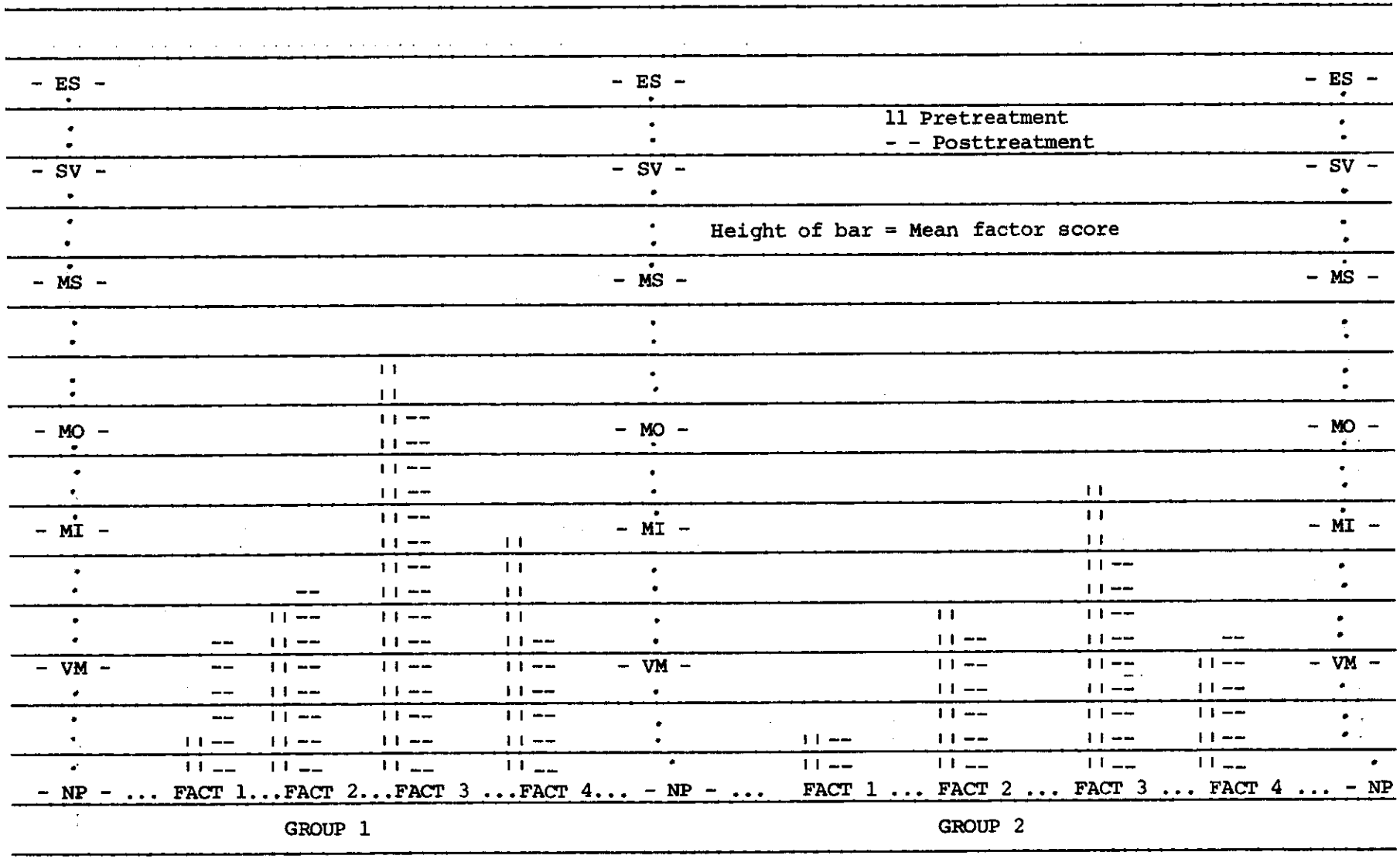
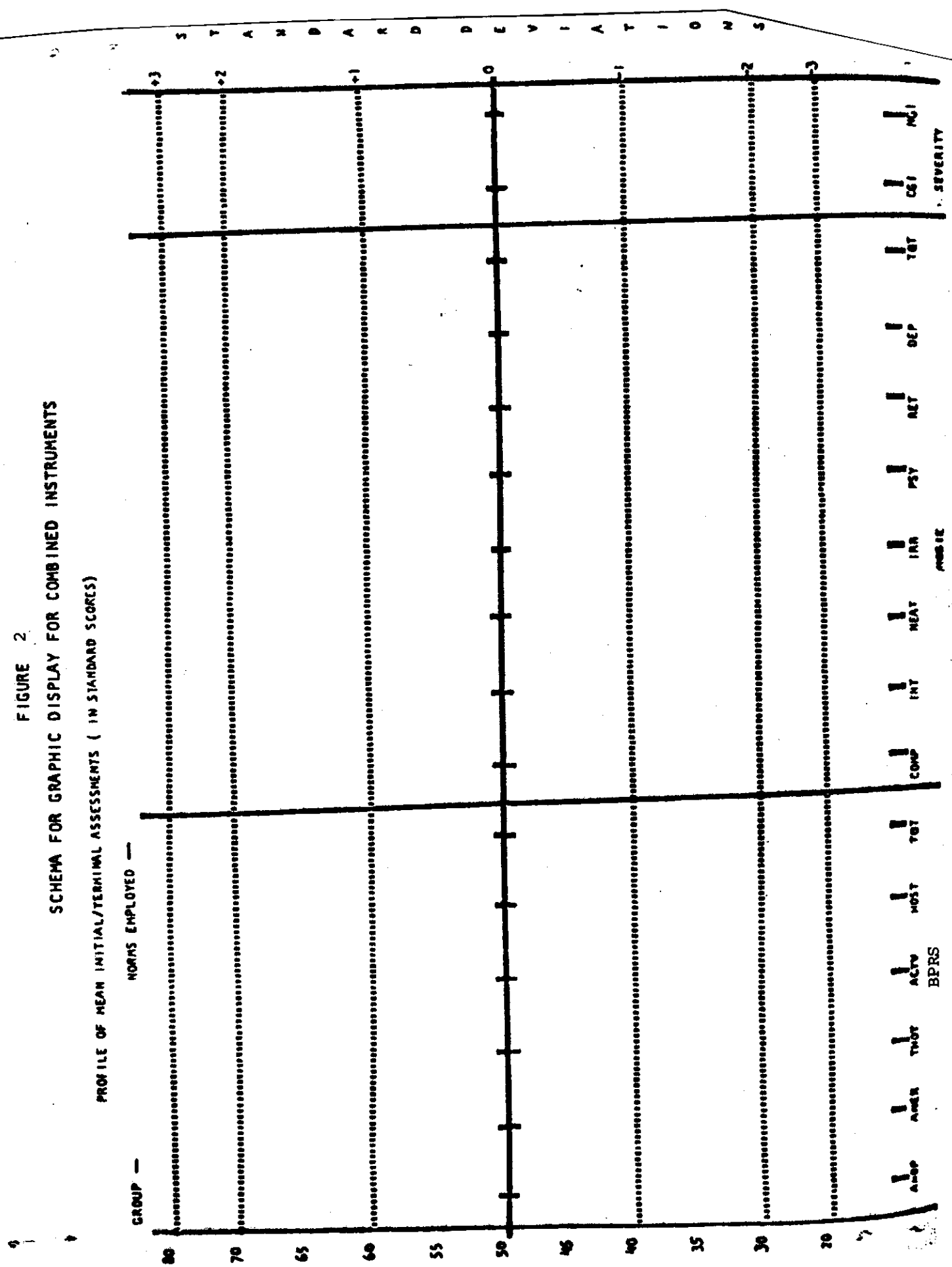


FIGURE 2

SCHEMA FOR GRAPHIC DISPLAY FOR COMBINED INSTRUMENTS

PROFILE OF MEAN INITIAL/TERMINAL ASSESSMENTS (IN STANDARD SCORES)



Data Inventory

The Data Inventory serves 2 purposes :

1. For an individual study, a subject by subject itemization of each form present in the data matrix.

2. Across studies, the source material for a cumulative inventory of the contents of the data bank.

Table XII illustrates the display provided for the individual study. The dots indicate "present" - the crosses "absent". Totals are provided for each form by subject, assessment period and grand sum. The inventory gives the investigator an accurate picture of the magnitude and distribution of his data matrix and provides a basis for decisions on further data transformations or analyses.

Cumulative inventories may be generated across all studies in the data bank. The number of forms, subjects, studies and items is summed for each rating scale as well as across all scales. They provide a general estimate of the amount of data available for any particular research purpose.

T A B L E XII

SCHEMA for DATA INVENTORY

STUDY NO. INVESTIGATOR NAME STUDY TITLE

FORM NAME

	PERIOD				
SUBJ	0	1	2	N	TOT
1	.	.	.	.	10
2	.	X	.	.	10
N					
TOT	10	10	10	10	100

THE INVENTORY TOTALS EACH FORM BY SUBJECT (ROW TOTAL) AND BY SAMPLE (COLUMN TOTAL).

. = FORM PRESENT FOR THAT PERIOD
X = FORM MISSING FOR THAT PERIOD

THE SUMMARY TABLES PRESENT THE TOTAL NUMBER OF FORMS FOR EACH PERIOD.

FORM NAME

	PERIOD		
SUBJ	0	2	TOT
1	.	.	10
2	.	X	10
N			

SUMMARY TABLES

	PERIOD			
FORM	0	1	2	N
27	20	20	20	20
28	20			
N	50	50	50	50

The Analytic Cohort

Preceding each statistical analysis, a listing of subjects excluded from that analysis along with the reason for exclusion is given (see Table XIII). The display continues with a listing of all subjects included in the analysis as well as the periods and raters used. Specification of the analytic cohort has proved to be highly desirable for interpreting the results of any statistical analyses performed.

T A B L E XIII

SCALE NAME

SCHEMA for ANALYTIC COHORT

STUDY NO. INVESTIGATOR NAME STUDY TITLE

SCALE NAME

SUBJECTS EXCLUDED FROM (FORM X) ANALYTIC COHORT

PAT	GROUP	REASON FOR EXCLUSION
XXX	1	MISSING PERIOD
XXX	1	MISSING PERIOD

IF NO SUBJECTS ARE EXCLUDED FROM AN ANALYSIS, THE DOCUMENTATION WILL SO STATE. THE LISTING OF EXCLUSIONS IS FOLLOWED BY A SEPARATE LISTING GIVING THE SUBJECTS INCLUDED IN THE ANALYSIS.

PAT	PER	RTR	CARD	GROUP
001	000	01	51	1
001	063	01	51	1
002	000	01	51	1
002	063	01	51	
017	000	01	51	2

Statistical Procedures

This discussion is divided into three areas. The first deals with the repeated measures analysis of variance and the use of stricter criteria in detecting significance for the within-subject variables. The second part concerns the multiple comparisons problem. By focusing on 2 methods it is expected that the decision to use a particular technique will be made clearer to our audience. The last section is an explanation of the displays of the statistical methods just discussed.

Repeated Measures Model

A popular research design in psychopharmacological research is the analysis of variance model in which a single dependent variable is measured on more than one occasion on the same subjects. This is often called a repeated measures analysis of variance. Several authors (1, 2, 3, 4) have discussed the problems which arise when this type of analysis is performed. One of the more serious problems is the distortions of p levels and confidence levels caused by the heterogeneity of covariance. The conclusions drawn are that multivariate tests are exact with repeated measurements but in many instances the n is too small. It is suggested that the Greenhouse-Geisser 3-step procedure might be most useful (5). However, even this approach is discouraged if p(population correlation) is not constant or relatively constant over treatments. That is, the assumption of homogeneity of covariances between repeated measurements must be met. When the design involves more than one factor the covariance assumptions are more stringent. For example, in a two-factor experiment in which factor A with levels a_1 and a_2 is not repeated but factor B with occasions b_1, b_2, b_3 and b_4 is repeated, two covariances assumptions must be made. First, the matrix of variances and covariances among the several repeated assessments (b_1 through b_4) must be the same within each level of the nonrepeated factor (the matrix must be the same within a_1 as within a_2). Second, the covariances pooled across levels of the independent factor must be homogeneous. Procedures for testing these assumptions are given by Winer (6). Figure outlines the Greenhouse-Geisser procedure when employing univariate analyses of repeated measures; (a) Use the regular degrees of freedom for the F tests on the repeated factors. If the result is not significant, the analysis is completed. Clearly, if the obtained F value using the conventional degrees of freedom is not significant, then there is no need to examine the effect further using the more conservative test. (b) If the result of (a) is significant, the most stringent test is employed. The degrees of freedom for the numerator and denominator of the obtained F are multiplied by the inverse of the degrees of freedom for the within-subjects variable. If the obtained F is still signif-

icant the analysis can stop at this point.

1. Gaito, John. Repeated Measurements Designs and Tests of Null Hypotheses. Educational and Psychological Measurement, 1973, 33, 69-75.

2. Gaito, John. Repeated Measurements Designs and Counterbalancing. Psychological Bulletin, 1961, 58, 46-54.

3. McCall, Robert B., and Appelbaum, Mark I. Bias in the Analysis of Repeated Measures Design : Some Alternative Approaches. Child Development, 1973, 44, 401-415.

4. Geisser, S., and Greenhouse, S.W. An Extension of Box's Results on the Use of the F Distribution in Multivariate Analysis. Annals of Mathematical Statistics, 1958, 29, 885-891.

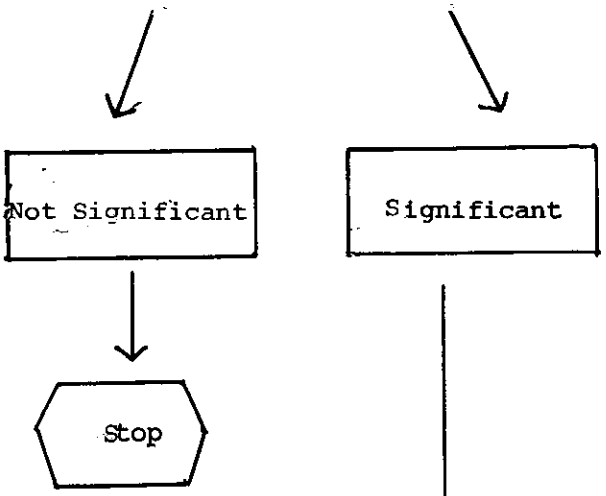
5. Greenhouse, S.W. and Geisser, S. On Methods in the Analysis of Profile Data. Psychometrika, 1959, 24, 95-112.

6. Winer, B.J. Statistical Principles in Experimental Design. (2nd ed.) New York : McGraw-Hill, 1971.

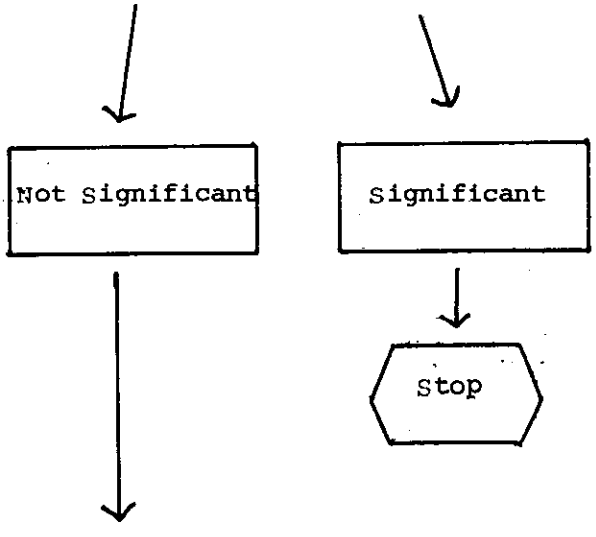
F I G U R E 3

GREENHOUSE-GEISSER PROCEDURE

a) Test main effects in repeated measures model



b) Conservative test with reduced df*



c) Use Univariate Approximate F test of Box

Need variance/covariance matrix to get ε.

(c) If step (b) indicates a lack of significance, the researcher may try the Box approximate F test in which ε a function of the heterogeneity of the variance and covariances, must be calculated. The degrees of freedom for the numerator and the denominator for the obtained F are then each multiplied by this function. These degrees of freedom will lie in the middle of the most liberal and the most conservative sets of degrees of freedom.

The Greenhouse-Geisser procedure is routinely applied in the analysis of Variance-covariance program (AVACOV) used in BLIPS/BDP analyses with the modification that the Box approximate test is not used. When an obtained F is significant at the .05 level, main effects and interactions using repeated measures are further tested using the reduced degrees of freedom. If they still indicate a significant result, a (*) is printed. A ( ) indicates significance was not reached using the conservative degrees of freedom. At this point the procedure stops.

When a two-factor experiment in which factor A with levels a_1 and a_2 is repeated as is factor B with occasions b_1, b_2, b_3 and b_4, AVACOV cannot be employed. In this type of design the Statistical Analysis System (SAS) procedure entitled Analysis of Variance and Covariance is employed. The model includes a subject by factor A interaction, as well as a subject by factor B interaction, and also a subject by factor A by factor B. These interactions are employed to test the main effects A and B and the AB interaction (8). In the last section the output from the AVACOV and the SAS procedure will be explained in more detail.

Multiple Comparison Techniques

When an analysis of variance indicates a significant difference among two of the means, paired comparisons aid the researcher in determining which differences contribute to the overall significance. It is generally agreed that the use of t-tests to carry out all possible ~~two-group~~ comparison produces a high rate of erroneous conclusions. Aside from this, there is no consensus among statisticians about the multiple comparisons methods most appropriate. Any single test of a comparison has probability of a type 1 error. However, as the number of comparison increases, the probability of at least one type 1 error increases. The usual level, the probability that a single comparison results in a type 1 error, is referred to as the error rate per comparison (EC). The probability that an entire set of comparisons contains at least one type 1 error is called the error rate experimentwise (EW). What is needed is a technique to adjust the EC down-

wards as the total number of comparisons increases and adjusting in such a way that the change in the number of comparisons does not alter EW. The literature is replete with proposals for dealing with the multiple comparison-error rate problem (9). However, only the Scheffé and the Tukey A or HSD (honestly significant difference) techniques hold the EW as for the entire possible set of contrasts. The Scheffé method is very conservative and it is possible that a signigicant test of main effects will not be followed by at least one significant contrast. The power of the Scheffé test is equal to that of the overall F test only when detection of the maximum possible contrast is at issue. Scheffé recommends use of Tukey's B method where sample sizes are equal and only paired comparisons are made. The Tukey B method fixes experimentwise error rates at conventional levels. This method is affected by those violations such as unequal sample size, unequal variances, non-normal populations to the degree that they also influence the obtained F value.

7. Bau, A.J., and Goodnight, J.H., Statistical Analyses System (SAS), North Carolina State University, 1971.

8. Myers, Jerome L. Fundamentals of Experimental Design. Boston : Allyn and Bacon, 1966.

9. Perrinovich, Lewis F. and Hardyck, Curtis D. Error Rates for Multiple Comparison Methods : Some Evidence Concerning the Frequency of Erroneous Conclusions. Psychological Bulletin, 1969, Vol. 71, No 1, 43-54.

Tukey B method is based on the distribution of Q, the studentized range statistic. It is a compromise between the Tukey A which, like the Scheffé, yields too few significances and the Newman-Keuls which can give too many erroneous results. Briefly, the procedure followed is :

$$\text{Critical Value} = \left[Q_{(K,df)} + Q_{(r,df)} \right] / 2$$

K = number of means in entire set

r = number of steps between the two means being compared

df= degrees of freedom for appropriate error term

$$Qr = M_i - M_j \Big/ \sqrt{MS_{error}} / n$$

If n_i are not equal use the harmonic means of the n_i's in the set.

Qr is the test statistic and is known to have a distribution known as the studentized range. Qr must be greater than the critical value for significance to be indicated

M_i and M_j are means for the two levels being compared

MS_{error} is the mean square for the error term used in testing the effect.

The treatment means are ordered from the lowest to the highest. In BLIPS/BDP output, these differences are given in the lower half of a matrix on the right in which the upper half is occupied by the Qr statistics. Table 40 of the sample output displays shows the treatment's means differences and the Qr statistics for the study effect. The number 4.05 is the ratio of

$$1.8333 - 1.3351 \ / \ \sqrt{\frac{1.1358}{\tilde{n}}}$$

where $\tilde{n}$ = harmonic mean = 75.0750

The critical value for means two steps apart is 3.31 which is the average of the critical values for means two steps apart and five means in a set

$$\text{Critical Value} = (2.77 + 3.86) \ / \ 2 = 3.31$$

These values are given in the lower half of the matrix on the left of page 485. The top half of matrix consists of * for those Qr's which are greater than the corresponding critical value. In our sample output on page 485, five studies with compared. The first comparison is treatment 1 versus treatment 4. Since the obtained Q of 5.96 is greater than the critical value of 3.86, an asterisk is placed in the upper portion of this matrix. In reading the significances we can discover that study 1 is significantly different from the other four but they are not different from one another.

Sample Output

AVACOV

AVACOV (Analysis of Variance-Covariance) is a modification of MANOVA. This program can perform analyses of variance on models consisting of four factors each with ten levels. It has the ability to analyze repeated measures on one factor only. Analysis of covariance can also be performed.

Additional features consist of :

1. Detection of F-Ratio's significant at the .05 probability level - with asterisks indicating significance.

2. Multiple Comparisons - Tukey B Method - run when main effects are significant at .05 level.

3. Means standard deviations and variances are output options for main effects and for interactions.

4. For the repeated measures designs when the main effects and/or interactions are significant, they are tested again against the Greenhouse-Geisser conservative criterion. If they are still significant, an (*) is assigned.

Tables XIV-XVI are sample outputs of AVACOV. The variable is the depression factor of the BPRS scale (the design is 5 studies by 2 drugs by 3 periods) - where the 3 periods represent repeated measures. The source table is displayed in Table XIV. Df represent degrees of freedom. The letters placed next to the appropriate df are there to illustrate which df are used to form which Mean Squares and which Mean Squares form which tests or F-Ratios. The * under Sig (.05) are significant using the table df. The (*) under the Sig (.05) - GG column where GG means Greenhouse-Geisser are indications that the effect is still significant using the stricter criteria of fewer degrees of freedom. We can see that two significant effects were obtained and that two of these three were still significant after testing with the stricter criteria. The df for this design are defined below the source table.

The significant main effects, that is, studies and periods, are reexamined via multiple comparisons in Table V. The mean and standard deviation are presented for each study - they represent the cumulation across both drug groups and all three periods in the first study. The matrices which contain the multiple comparison statistics were explained earlier. The means and standard deviations for the two drugs represent 213 different entries for the INV group and 210 for the Kontrol group; 213 represents the summing across the five studies and three rating periods; 210 represents the summing across the five studies and three rating periods for all the control subjects. The means and standard deviations for the period levels cumulate across drug and study. The multiple comparison for the significant period effects indicates that periods 2 and 3 are different from period 1 but not from each other.

Table XVI displays the last page of the AVACOV output which is the cell means and standard deviations. Cell III represents study 1, INV drug period 00; cell 523 represents study 5, Kontrol drug and period 02.

T A B L E XIV

THE CCPPD - AVACOV - UP TO 4 WAY CLASSIFICATION
BPRS REPEATED MEASURES
PROBLEM NO 1
VARIABLE 1 BPRS REPEATED MEASURES FIVE STUDY COMPARISON

		DF	SUM OF SQUARES	MEAN SQUARES	F-RATIO	SIG (.05)	SIG (.05) -GG
ANOVA ERROR 1 - BETWEEN		131 (A)	148.7892 (J)	1.1358 J/A=1			
ANOVA ERROR 2 - WITHIN		262 (B)	78.2368 (K)	0.2986 K/B=2			
STUDY DRUG	PERIODS	8 (C)	2.7663 (L)	0.3458 L/C=3	3/2=1.1580		
STUDY DRUG		4 (D)	3.2878 (M)	0.8219 M/D=4	4/1=0.7237		
STUDY	PERIODS	8 (E)	10.5166 (N)	1.3146 N/E=5	5/2=4,4023	*	(*)
DRUG	PERIODS	2 (F)	0.0653 (O)	0.0326 O/F=6	6/2=0.1093		
STUDY		4 (G)	35.7133 (P)	8.9283 P/G=7	7/1=7,8609	*	
DRUG		1 (H)	1.0273 (Q)	1.0273 Q/H=8	8/1=0.9044		
PERIODS		2 (I)	5.8043 (R)	2.9022 R/I=9	9/2=9.7188	*	(*)

$$A = \sum_{i=1}^{5} \sum_{j=1}^{2} (n_{ij} - 1)$$

D = H X G
E = I X G
F = H X I

G = ≠≠ of Studies - 1
H = ≠≠ of Drugs - 1
I = ≠≠ of Periods - 1

B = A X 1
C = I X H X G

T A B L E XV

VARIABLE 1 BPRS REPEATED MEASURES FIVE STUDY COMPARISON

LEVEL MEANS OF TREATMENT COMBINATION

	"N"	"MEAN"	"STD.DEV."
STUDY			
LEVEL 1	144	1.3351	0.65
LEVEL 2	78	1.8333	0.70
LEVEL 3	48	1.8594	0.62
LEVEL 4	75	2,0689	1.06
LEVEL 5	78	1.9231	0.81

MULTIPLE COMPARISONS ON RANK ORDERED MEANS (TUKEY-B METHOD)

LEVEL	1	2	3	5	4
1		*	*	*	*
2	3.31				
3	3.58	3.31			
5	3.74	3.58	3.31		
4	3.86	3.74	3.58	3.31	

SIGNIFICANCE (*) IN UPPER HALF MATRIX
CRITICAL VALUES IN LOWER HALF MATRIX

LEVEL	1	2	3	5	4
1		4.05	4.26	4.78	5.96
2	0.50				1.91
3	0.52	0.03			1.70
5	0.59	0.09	0.06		1.18
4	0.73	0.24	0.21	0.15	

Q-STATISTICS IN UPPER HALF MATRIX
DIFFERENCES IN LOWER HALF MATRIX

DRUG			
LEVEL 1	213	1.6761	0.80
LEVEL 2	210	1.7746	0.84
PERIODS			
LEVEL 1	141	1.8895	0.95
LEVEL 2	141	1.6596	0.76
LEVEL 3	141	1.6259	0.72

MULTIPLE COMPARISONS ON RANK ORDERED MEANS - (TUKEY-B METHOD)

LEVEL	3	2	1
3			*
2	3.04		*
1	3.31	3.04	

SIGNIFICANCE (*) IN UPPER HALF MATRIX
CRITICAL VALUES IN LOWER HALF MATRIX

LEVEL	3	2	1
3		0.73	5.73
2	0.03		5.00
1	0.26	0.23	

Q-STATISTICS IN UPPER HALF MATRIX
DIFFERENCES IN LOWER HALF MATRIX

T A B L E XVI

VARIABLE I BPRS REPEATED MEASURES FIVE STUDY COMPARISON

THE MEANS FOR EACH CELL CELL ID		"MEAN"	"STD.DEV."	THE MEANS FOR EACH CELL CELL ID		"MEAN"	"STD.DEV."
1 1 1	24 OBSERVATIONS	1.6979	1.01	3 2 1	8 OBSERVATIONS	1.7500	0.42
1 1 2	24 OBSERVATIONS	1.6667	0.24	3 2 2	8 OBSERVATIONS	1.9375	0.58
1 1 3	24 OBSERVATIONS	1.0729	0.17	3 2 3	8 OBSERVATIONS	2.0938	0.91
1 2 1	24 OBSERVATIONS	1.7500	0.88	4 1 1	13 OBSERVATIONS	2.1731	1.28
1 2 2	24 OBSERVATIONS	1.2396	0.48	4 1 2	13 OBSERVATIONS	1.8654	1.11
1 2 3	24 OBSERVATIONS	1.0833	0.19	4 1 3	13 OBSERVATIONS	1.6346	0.60
2 1 1	13 OBSERVATIONS	1.7692	0.77	4 2 1	12 OBSERVATIONS	2.0975	1.21
2 1 2	13 OBSERVATIONS	1.6923	0.56	4 2 2	12 OBSERVATIONS	2.3958	1.13
2 1 3	13 OBSERVATIONS	1.7115	0.64	4 2 3	12 OBSERVATIONS	2.2917	0.90
2 2 1	13 OBSERVATIONS	2.0962	0.87	5 1 1	13 OBSERVATIONS	2.1154	0.87
2 2 2	13 OBSERVATIONS	1.9615	0.65	5 1 2	13 OBSERVATIONS	1.9038	0.77
2 2 3	13 OBSERVATIONS	1.7692	0.73	5 1 3	13 OBSERVATIONS	2.0192	0.85
3 1 1	8 OBSERVATIONS	1.4063	0.55	5 2 1	13 OBSERVATIONS	2.0962	1.10
3 1 2	8 OBSERVATIONS	1.7813	0.39	5 2 2	13 OBSERVATIONS	1.6346	0.72
3 1 3	8 OBSERVATIONS	2.1875	0.56	5 2 3	13 OBSERVATIONS	1.7692	0.50

SAS Output

When the design of the study calls for a repeated measures across two factors - as in a rater by period design - then AVACOV cannot be used. A special analysis has to be performed and as an example of special analyses, the ANOVA procedure of the SAS, Statistical Analysis System will be given. The program allows the researcher to specify his own model and also the error terms he wishes to use to test various effects. In our example, a two-factor repeated measurements design - rater by period - we wish to use a subject by rater to test rater effect, a subject by period to test period effect and a subject by rater by period to test a rater by period interaction. Table XVII displays the source table for ANOVA. Again we are looking at BPRS factor, depression, whose mean is 1.81. The differences in this table from the source table of AVACOV are :

1. Corrected total is listed under source - its df and sum of squares are the sum of source items 1-7 df and sum of squares.
2. LSD .01 - least significant difference at .01 and LSD .05 - least significant difference at .05 level means whose difference exceeds this value are declared significantly different. This is another approach to the problem of regulating and apportioning the type 1 error rate.[6]
3. The tests of interest can be isolated in such a way that there is no confusion as to which error term was used. The probability associated with each F-Ratio is given. In our example we see that a significant rater effect is present with the probability of obtaining a F-value as large or larger of only .04.

This program expands the analytic facility of BLIPS/BDP.

T A B L E XVII

BPRS (FORM 047) ANOVA REP. MEASURES PERIOD X RATER (ITEMS)

ANALYSIS OF VARIANCE FOR VARIABLE DEPRESSION

SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	LSD.01	LSD.05	DIVISOR
1 SUB	8	24.8888889	3.1111111			
2 PERIOD	4	1.1777778	0.2944444			
3 RATER	1	10.6777778	10.6777778			
4 PERIOD*RATER	4	3.9333333	0.9833333			
5 SUB*PERIOD	32	21.2222222	0.6631944			
6 SUB*RATER	8	14.6222222	1.8277778			
7 SUB*PERIOD*RATER	32	17.2666667	0.5395833			
ERROR PERIOD	32	21.2222222	0.6631944	0.743380070	0.552933633	18
ERROR RATER	8	14.6222222	1.8277778	0.956328452	0.657255113	45
ERROR PERIOD X RATER	32	17.2666667	0.5395833	0.948275983	0.705337286	9
CORRECTED TOTAL	89	93.7888889	1.0538077			

TESTS	SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	F VALUE	PROB F
NUMERATOR:	PERIOD	4	1.7777778	0.2944444	0.44398	0.7780
DENOMINATOR:	ERROR PERIOD	32	21.2222222	0.6631944		
NUMERATOR	RATER	1	10.6777778	10.6777778	5.84195	0.0406
DENOMINATOR:	ERROR RATER	8	14.6222222	1.8277778		
NUMERATOR:	PERIOD* RATER	4	3.9333333	0.9833333	1.82239	0.1480
DENOMINATOR:	ERROR PERIOD X RATER	32	17.2666667	0.5395833		

Narrative Summary

The Narrative Summary provides the investigator or reviewer with an overview of the study. Though brief, it contains sufficient detail to enable the reader to grasp the essential nature of the study and its results. As with all other segments of the standard package, the Narrative Summary is non-judgmental and contains only statements based directly on the data received and the analyses performed. Final judgment as to the clinical meaningfulness of the data or the efficacy of the drugs involved remains entirely with the investigator. Narrative summaries consist of 4 paragraphs :

1. Description - Data are derived from the Research Plan Report and consist of details of the research design, the drugs and dosages employed and the research procedures.
2. Efficacy - Derived primarily from variance analyses. All statistically significant findings - or their absence - are cited for each of the psychopathological rating scales employed.
3. Toxicity - Derived primarily from Dosage Record and Treatment Emergent Symptom Scales. Toxicity is described in terms of the number and kinds of symptoms evolving under each treatment condition, as well as the clinical actions necessitated by the emergence of such symptoms.
4. Demography - Derived primarily from the Personal Data Inventory. Distributions for a number of pertinent demographic variables are given for each treatment group.

PART SIX

A DOCUMENTATION SYSTEM IN OPERATION

D. Data Analysis
(The Output Package)

Documentation refers to the presentation of data in a manner which describes what happened during a study and permits inferences to be drawn from it. It is vital, therefore, that the documentation depict the events of the trial as accurately and comprehensibly as possible. All too frequently, failure to document a trial properly has led to incomplete or ambiguous findings which make it impossible to arrive at a substantive judgment of the trial itself or to compare its results with other similar trials. The effects of the drug cannot be assessed under these conditions and its true merits may be obscured.

For many, the first exposure to computer output can be bewildering. The neophyte finds himself lost in the bulk of the package; and, even upon finding the location he desires, he is confused by the way in which the data is presented. He must learn to "decipher" the output before he can begin to interpret the findings of his study. Experience with the adult standard package has shown that there are almost as many inquiries relating to "deciphering" as there are regarding the interpretation of results. In the majority of these instances, more elaborate labeling - in English - would have avoided the need for "deciphering".

Since the late 1960's, the data package has undergone repeated changes in an attempt to increase its clarity and comprehensiveness. The concept of a standard data package, however, remains, since in concert with a standard assessment battery, it has proven advantageous as a method of documenting the single trial and for facilitating comparisons across several trials. In order that uniqueness of a trial is not lost, however, a greater degree of variation within the standard package has been introduced in the form of increased display and anaytical options.

The bulkiness of a data package necessarily varies from study to study depending upon the number of subjects, scales, and rating periods. The output for a given scale, however, is standardized regardless of the size of a study. For small studies, this may give the package the appearance of over elaborateness; while, for larger studies, the output may seem pedestrian. This lack of precise tailoring is inevitable, however, in a system which attempts to cover the diversity which exists among psychotropic drug trials. The usual order of presentation in the data package is as follows :

1. Table of Contents
2. Narrative Summary
3. Patient Listing
4. Data Inventory
5. Demographic Data
   a. Personal Data Inventory
   b. Prior Medication Record
   c. Patient Termination Record
6. Efficacy Data
   a. Psychiatric Rating Scales
   b. Nurses Rating Scales
   c. Self-Rating Scales
7. Adverse Reaction Data
   a. Dosage Record and Treatment Emergent Symptoms
   b. Laboratory Data
8. Medical Data (optional)
9. Non-standard Data (optional)
10. Multi-instrument Displays
11. Error Diagnostics.

Data displays for the individual assessment instrument are arranged as follows :

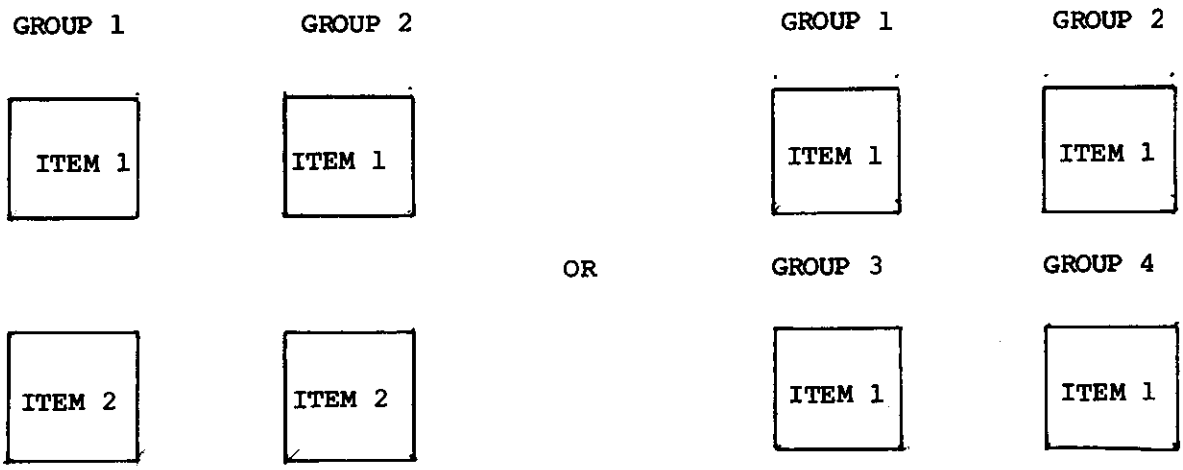
1. Legend
2. Raw score printout
3. Computed score printout
4. Means and standard deviations
5. Frequency tables
6. Cross tabulations
7. Graphic displays
8. Variance analyses
9. Correlational analyses (across instruments)

While not every display is present for each and every instrument, the order of the displays is maintained throughout. Data displays have been designed to provide maximal acuity and relevance to the clinician. Information regarding the individual subject as well as the various treatment groups has been provided in a variety of displays to increase the utility of the analyses and to provide meaningful clinical comparisons. In the design of the standard data package, a basic objective has been the utilization of all items in the assessment battery. Considering the great expenditure in time, effort and resources which goes into the collection of data, it is obligatory to generate an output which maximally utilizes the available material. Output has been therefore

universally generated on an idiographic and a nomothetic level - enabling the investigator to follow the progress of individual subjects as well as to compare various treatment groups.

There are a number of general features in the BLIPS/BDP package which should increase its utility.

1. Consistent with legibility, the bulkiness of the package has been reduced by conserving space whenever possible.
2. Preceding each data subset, i.e., all the data relating to one assessment instrument, a legend - defining all terms used in the subsequent displays - is provided.
3. For convenience in comparing treatment groups, equivalent data displays are juxtaposed on the same page :



Reviewing Output of Individual Case Record

By reading the Individual Case Record, a reviewer can obtain a detailed history of how each subject did in a study.

The following output* gives a narrative description (summary) of a patient (No 501) :

History

The subject was a separated/divorced 32-year-old female, race - NA -, from a nonconjugal home situation, whose level of education was partial college training, occupational class was unskilled worker and occupational adjustment described as adequate. Social class was V. There was previous treatment for mental illness for 1-3 months. First hospitalization occured at the age of 30 with one subsequent hospitalization. The duration of present hospitalization was less than 2 weeks. First signs of mental illness were manifested at the age of 30. The onset of symptoms of present episode was within 2 weeks of hospitalization/visit with a probably present precipitating stress. Admitted to the treatment on the patient's own initiative. The subject was described as cooperative. Concurrent significant medical conditions were not present. During the week prior to the study hospital adjustment was -NA-. There was not a history of family mental illness. Subject did not exhibit a schizoid style of life. Symptoms of an affective nature were not present. Diagnosis was schizophrenic-chronic undifferentiated.

Prior treatment

Prior to the study, the subject was receiving diazepam with maximum daily dose of 40.0 mg. After -NA- days of treatment response to this medication was rated equivocal. No other medications/treatments were received.

Research record

Dosage Data

The subject was assigned to the Normaline condition for a period of 18 days. It was administered in capsule form. The minimum and maximum

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* Output derived from BLIPS II

daily doses were 50.0 mg. and 100.0 mg. Total dose was 1600.0 mg. with a mean dose of 88.0. A total of 2 non-protocol dosage changes were required for the following reasons : 2 - toxicity. During the course of the study no adverse reactions were reported on FDA 1639.

Efficacy

Severity of illness was rated by the psychiatrist as mildly ill at pretreatment and borderline mentally ill at posttreatment. On psychiatrists Global Improvement the subject was rated as minimally improved. Efficacy index (therapeutic effects divided by toxic effects) was : 11 = 1.00. Therapeutic effect of the study was -NA-.

BPRS ;using two or more points of pre to posttreatment change as a criterion, the patient improved on the following : guilt feelings and hallucinatory behavior; worsened on the following : suspiciousness.

Toxicity

At pretreatment week the subject did not have any significant symptoms.

Under research medication the following actionable symptoms were recorded : drowsiness, hypotension and tachycardia. The most stringent action undertaken was, discontinue medication. Antiparkinson or other remedial medication was not required. Premature termination of treatment was required for the following reason : failure to return.

The first paragraph, labeled History, presents information obtained from the Personal Data Inventory (PDI). The paragraph labeled Prior Treatment comes from the Drug Study Resume (DSR). The paragraph labeled Dosage Data comes from the Dosage Record (DR). The Efficacy paragraph presents the data gathered on the CGI and BPRS. Finally, the paragraph Toxicity comes from the Treatment Emergent Symptom Scale (TESS).

Next is given the Individual Dosage Record.

Individual Dosage Record and Group Summary

Data definitions

Dose : 'O' = initial dose
'=' = no change in dosage in comparison with previous dose
'<' = decrease
'>' = increase.

Prescription : QD = once a day
BID = twice a day
TID = three times a day
QID = four times a day
HS = at bedtime
PRN = when necessary
OTH = other

Proportion : '-E' = equal
'-U' = unequal

Reason : PROT = per protocol
INEF = ineffective
TOX. = toxicity
TEST = test dose
OTHR = other
N.A. = not ascertained

** = in front of patient number indicate drug combination
*** = amount of days per change exceeds 750
***** = daily dose exceeds 8000.0 mg.

The dosage given is usually in mg (milligrams) unless otherwise specified.

Had 03 dosage changes over a period of 18 days
Total dose : 1600.0 mg with a mean dose of 88.9 and a range of 50.0 to 100.0.

Changes	00	01	02	03
Days	3	2	11	2
Dose/day	100.0	50.0 <	100.0 >	50.0 <
Presc.	BID-E	QD-E	BID-E	QD-E
Reason		TOX.	PROT.	TOX.

As can be seen, J.B. (No. 501) had three dosage changes over a period of 18 days. Change 01 at day 4 of the study was a reduction in dose from 100 mg. to 50 mg. because of toxicity. Her dose was kept at 50 mg. for 2 days. On day 6 it was changed a second time and increased back to 100 mg. per protocol. She was kept on this dose for 11 days until day 17 when it was reduced again to 50 mg. because of toxicity. The record ends at day 18 as the patient eloped from the hospital.

Some of these changes are reflected on the list of treatment emergent symptoms over the course of the study.

Total occur.	4			
Dose	0.0	50.0	100.0	50.0
RX day	0	5	11	18
Drowsiness	.	.	S+	M+
Hypotension	.	M+	.	.
Tachycardia	.	.	M+	.
Action		RD	RD	DR

The first TESS rating at treatment day 0 showed the presence of no side effects. The second rating was made at the fifth day of the study. During this period, she had developed mild hypertension which required a reduction in dose from 100 to 50 mg. per day. On the 16th treatment day at a dose of 100 mg. per day, she developed severe drowsiness and mild tachycardia, both of which necessitated a reduction in dose. Following her elopement from the hospital, a retrospective TESS was filled out for day 18. It was noted that her tachycardia had remitted but that the drowsiness continued, although mildly. Because the patient eloped and presumably discontinued her medication, the rater filled out DR or Discontinue Treatment under action.

The final displays in the Individual Case Record represent the laboratory data for this particular patient.

STANDARD TEST LIMIT TABLE USED IN THIS ANALYSES

UNIT	STD	SEX	LABORATORY TEST NAME	* * LIMITS * * UPPER	LOWER	* * SIGNIFICANT CHANGE * * UPPER	LOWER	DIFFERENCE
8	1	M	HEMOGLOBIN	17.000	14.000	99.900	11.000	NA
8	1	M	HEMATOCRIT	51.000	42.000	99.900	33.000	NA
8	1	M	RED BLOOD COUNT	5.500	4.500	9.990	3.500	NA
8	1	M	WHITE BLOOD COUNT	100.000	50.000	120.000	40.000	NA
8	1	M	NEUTROPHILES	67.000	51.000	99.900	40.000	NA
8	1	M	LYMPHOCYTES	35.000	21.000	60.000	0.0	NA
8	1	M	EOSINOPHILES	4.000	2.000	6.000	0.0	NA
8	1	M	MONOCYTES	8.000	4.000	12.000	0.0	NA
8	1	M	BASOPHILES	1.000	0.0	5.000	0.0	NA
8	1	M	SEDIMENTATION RATE	20.000	0.0	15.000	0.0	NA
8	1	M	PLATELETS	250.000	150.000	999.000	75.000	NA
8	1	M	PROTHROMBIN TIME	15.000	0.0	17.000	0.0	NA
8	1	M	BLOOD UREA NITROGEN	18.000	5.000	25.000	0.0	NA
8	1	M	TRANSAMINASE GLUTAMIC OXALACETIC (SGOT)	40.000	0.0	50.000	0.0	NA
8	1	M	NA +	146.000	140.000	999.000	120.000	NA
8	1	M	K +	5.400	4.000	9.990	3.500	NA
8	1	M	CREATININE	7.000	5.000	15.000	0.0	NA
8	1	M	TOTAL BILIRUBIN	1.000	0.300	2.000	0.0	NA
8	1	M	DIRECT BILIRUBIN	0.250	0.060	NA	NA	NA
8	1	M	TOTAL PROTEINS	8.000	6.000	8.500	0.0	NA
8	1	M	BLOOD ALBUMIN	5.000	3.500	5.500	3.000	NA
8	1	M	FASTING BLOOD SUGAR	120.000	80.000	140.000	0.0	NA
8	1	M	ALKALINE PHOSPHATASE	35.000	9.000	99.000	0.0	NA
8	1	M	CHOLESTROL	300.000	150.000	325.000	0.0	NA
8	1	M	LACTIC DEHYDROGENASE	120.000	30.000	150.000	0.0	NA
8	1	M	TRANSAMINASE GLUTAMIC PYRUVIC (SGPT)	30.000	0.0	40.000	0.0	NA
8	1	M	SPECIFIC GRAVITY (URINE)	1.025	1.015	NA	NA	NA
8	1	M	ALBUMIN (URINE)	0.0	0.0	1.000	0.0	NA
8	1	M	SUGAR (URINE)	0.0	0.0	NA	NA	NA
8	1	M	WHITE BLOOD COUNT (URINE)	0.0	0.0	NA	NA	NA
8	1	M	RED BLOOD COUNT (URINE)	0.0	0.0	NA	NA	NA
8	1	F	HEMOGLOBIN	16.000	13.000	99.900	10.500	NA
8	1	F	HEMATOCRIT	48.000	39.000	99.900	30.000	NA
8	1	F	RED BLOOD COUNT	5.500	4.500	9.990	3.500	NA
8	1	F	WHITE BLOOD COUNT	100.000	50.000	120.000	40.000	NA
8	1	F	NEUTROPHILES	67.000	51.000	99.900	40.000	NA
8	1	F	LYMPHOCYTES	35.000	21.000	60.000	0.0	NA
8	1	F	EOSINOPHILES	4.000	2.000	6.000	0.0	NA
8	1	F	MONOCYTES	8.000	4.000	12.000	0.0	NA
8	1	F	BASOPHILES	1.000	0.0	5.000	0.0	NA
8	1	F	SEDIMENTATION RATE	20.000	0.0	30.000	0.0	NA
8	1	F	PLATELETS	250.000	150.000	999.000	75.000	NA
8	1	F	PROTHROMBIN TIME	15.000	0.0	17.000	0.0	NA
8	1	F	BLOOD UREA NITROGEN	18.000	5.000	25.000	0.0	NA
8	1	F	TRANSAMINASE GLUTAMIC OXALACETIC (SGOT)	40.000	0.0	58.000	0.0	NA
8	1	F	NA +	146.000	140.000	999.000	120.000	NA
8	1	F	K +	5.400	4.000	9.990	3.500	NA
8	1	F	CREATININE	7.000	5.000	15.000	0.0	NA
8	1	F	TOTAL BILIRUBIN	1.000	0.300	2.000	0.0	NA
8	1	F	DIRECT BILIRUBIN	0.250	0.060	NA	NA	NA
8	1	F	TOTAL PROTEINS	8.000	6.000	8.500	0.0	NA
8	1	F	BLOOD ALBUMIN	5.000	3.500	5.500	3.000	NA
8	1	F	FASTING BLOOD SUGAR	120.000	80.000	140.000	2.300	NA
8	1	F	ALKALINE PHOSPHATASE	35.000	9.000	99.000	0.0	NA
8	1	F	CHOLESTROL	300.000	150.000	325.000	0.0	NA
8	1	F	LACTIC DEHYDROGENASE	120.000	30.000	150.000	0.0	NA
8	1	F	TRANSAMINASE GLUTAMIC PYRUVIC (SGPT)	30.000	0.0	40.000	0.0	NA
8	1	F	SPECIFIC GRAVITY (URINE)	1.025	1.015	NA	NA	NA
8	1	F	ALBUMIN (URINE)	0.8	0.0	1.000	0.0	NA
8	1	F	SUGAR (URINE)	0.0	0.0	NA	NA	NA
8	1	F	WHITE BLOOD COUNT (URINE)	0.0	0.0	NA	NA	NA
8	1	F	RED BLOOD COUNT (URINE)	0.0	0.0	NA	NA	NA

ACTIONS UNDERTAKEN BY TEST (ALL RATINGS)

TEST	NONE	SURV	CONT	RED	R<CON	SUS	DIS	VERI	NA	TOTAL*
HEMOGLOBIN	2	0	0	0	0	0	0	0	0	0
HEMATOCRIT	2	0	0	0	0	0	0	0	0	0
WHITE BLOOD COUNT	2	0	0	0	0	0	0	0	0	0
NEUTROPHILES	2	0	0	0	0	0	0	0	0	0
LYMPHOCYTES	2	0	0	0	0	0	0	0	0	0
EOSINOPHILES	2	0	0	0	0	0	0	0	0	0
MONOCYTES	2	0	0	0	0	0	0	0	0	0
BASOPHILES	2	0	0	0	0	0	0	0	0	0
BLOOD UREA NITROGEN	2	0	0	0	0	0	0	0	0	0
TRANSAMINASE GLUTAMIC OXALACETIC (SGOT)	2	0	0	0	0	0	0	0	0	0
TOTAL BILIRUBIN	2	0	0	0	0	0	0	0	0	0
DIRECT BILIRUBIN	2	0	0	0	0	0	0	0	0	0
FASTING BLOOD SUGAR	2	0	0	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	2	0	0	0	0	0	0	0	0	0
CHOLESTROL	1	0	0	0	0	0	0	0	0	0
SPECIFIC GRAVITY (URINE)	1	0	0	0	0	0	0	0	0	0
ALBUMIN (URINE)	1	0	0	0	0	0	0	0	0	0
SUGAR (URINE)	1	0	0	0	0	0	0	0	0	0
WHITE BLOOD COUNT (URINE)	1	0	0	0	0	0	0	0	0	0
RED BLOOD COUNT (URINE)	1	0	0	0	0	0	0	0	0	0
TOTAL	34	0	0	0	0	0	0	0	0	0

* TOTAL EXCLUDES 'NONE' 'VERIFY' AND 'NA'.

Reviewing Output of Data Package

There are, of course, many ways in which one might approach the data package. The strategy one chooses is dependent to a great degree on the specific interest area. That which would interest a clinician might be quite different from that which would arouse the statistician. The monitor of a pharmaceutical firm might be most interested in how this study compares to numerous other studies using the same protocol. Others might look at the data to see if proper scientific procedures had been adhered to and whether or not the conclusions are justified by the data.

The strategy presented is a general one which we think fits most of these particular viewpoints. It takes advantage of the computer by proceeding from the data in its most reduced form, i.e., the inferential statistics, back down to the raw data. One of the great advantages of the computer is its ability to crystallize mountains of data into conceptually comfortable chunks. The way in which the BLIPS/BPD documentation package is arranged reflects this strategy as well.

Opening the package first there is a Narrative Summary.

NARRATIVE SUMMARY

33033 - Welby and Kildare, Normaline, Nirvana State Hospital, Forest Lawn, Calif. 05/22/72.

Description

The purposes of this study involving 10 inpatient, chronic adults with diagnoses of schizophrenia were to determine psychotropic activity and toxicity. The subjects were male and female and their ages ranged from 23 years to 51 years. The study was classified as early phase II and the experimental design involved test drug only. The study was conducted under nonblind conditions. A no treatment drying out period of 2 weeks was utilized. The duration of drug administration was 12 weeks. The test drug, Normaline, was non FDA approved and was supplied by Creative Drugs. Its presumed clinical action is neuroleptic. Its chemical class is phenothiazine analogues & isoteres. It was administered in capsule form on a fixed/changing schedule. The minimum and maximum daily doses were 20.0 mg. and 100.0 mg. No concomitant therapies were permitted for the research population. The assessment schedule consisted of 1 pretreatment rating and 2 ratings at 6 week intervals during the course of the study.

Efficacy

All statistical significances cited are at the .05 level or greater. 10 subjects were available for analyses of variance-repeated measures model. On Clinical Global Impressions, significant differences were obtained on the following items : severity of illness, global improvement - all reflecting greater improvement at termination. On the Brief Psychiatric Rating Scale, significant differences were obtained on the following symptoms : emotional withdrawal, conceptual disorganization, tension, hallucinatory behavior, unusual thought content, and blunted affect and the factors of thinking disorder and anergia - all reflecting improvement at termination; anxiety and the factor of depression - reflecting improvement at week 6 with some dissipation at termination.

Toxicity

Under Normaline conditions, 22 symptoms were reported as occurring 37 times in 7 subjects across 4 rating periods. Efficacy indices (therapeutic effects divided by toxic effects) were : 06 = 1.65; 12 = 2.05. No static symptoms were reported. 3 subjects were asymptomatic throughout the study. Occurrences by symptom clusters were, 2.7 percent in adverse behavioral effects, 45.9 percent in central nervous system, 29.7 percent in autonomic nervous system, 21.7 percent in miscellaneous. The most cited symptoms were : rigidity and tremor. Antiparkinson or other remedial medication was required by 3 subjects. Premature termination of treatment was not required by any subjects.

Demography

All numbers are expressed in percent; NA = not ascertained.

Under Normaline conditions, males = 30.0; females = 70.0 : caucasoid = 80.0; race NA = 20.0 : subjects ever married = 30.0; never married = 70.0 : subjects from home situations, conjugal = 20.0; nonconjugal = 80.0 : social class distribution was class 3 = 10.0; 4 = 20.0; 5 = 40.0; NA = 30.0 : age distribution by decades was : 3rd = 10.0; 4th = 30.0; 5th = 40.0; 6th = 20.0 : subjects with rapid onset = 10.0; gradual onset = 90.0 : subjects with previous treatment = 100. : subjects with previous hospitalization = 100. : subjects whose age at first hospitalization was less than 20 = 40.0; more than 20 = 60.0 : subjects with history of family mental illness = 30.0; no history of family mental illness = 30.0; history of family mental illness NA = 40.0 : schizoid style of life definite : 30.0; questionable = 40.0;

NA = 30.0 : symptoms of an affective nature were present = 100. : subjects whose occupational adjustment was considered marginal = 70.0; inadequate = 20.0; NA = 10.0 : subjects with possible stress = 60.0; precipitating stress NA = 40.0 : subjects who entered treatment on initiative of others = 60.0; NA initiative = 40.0 : upon admission subjects were cooperative = 40.0; indifferent = 40.0; uncooperative = 20.0 : subjects currently hospitalized more than one year = 100. : subjects with no concurrent medical conditions = 100. : hospital adjustment prior to study was : withdrawn and vegetative = 60.0; partial ward participation = 40.0 : distribution of diagnoses was schizophrenia = 100.

This summary is an attempt to present the critical findings of the study in as succinct a form as possible. The first paragraph labeled Description presents data derived from the RPR. This paragraph describes the research protocol and presents what the investigator set out to do. The second and third paragraphs, Efficacy and Toxicity, present the results of the study. The narrative summary is non-judgmental in that it does not state directly that the hypothesis is proven or that the drug is good, bad, or indifferent. It states only the statistical results. There are reasons for this. There is a difference between statistically significant change, such as improvement on some psychiatric variable, and clinical change. It is easy to imagine that the amount of change on a given psychiatric symptom may be statistically significant, yet have little meaning in terms of the clinical status of a group of patients. The converse is equally true. Since the data package is constructed from judgmental data and not from direct knowledge of the patients themselves, the statements are restricted to statistical findings. This leaves the <u>interpretation</u> of these statistical findings to the investigator.

Reading the narrative summary gives an overview of the study. It can be seen that the investigator planned to study ten patients and ten patients were available for statistical analysis at the conclusion of the study. Should there have been less than ten used in the analyses, it would be necessary to ascertain the reason, e.g., missing ratings, dropouts, deletion of subjects, etc. All of the findings cited in the efficacy paragraph are in one direction, i.e., reflecting improvement. The investigator planned to use schizophrenic subjects and indeed from the demography paragraph it can be seen that all the subjects were schizophrenic. The significant changes cited were, on the whole, the primary symptoms of schizophrenia. Turning to the toxicity paragraph, note that the efficacy indices were all positive. That is, the beneficial effect of the drug was greater

than its toxic effects. Note further that Normaline, which is classified as a phenothiazine analogue, produced side effects similar to other phenothiazines. That is, it caused central nervous system symptoms such as rigidity and tremor. While three of the subjects required remedial medication, none were prematurely terminated because of toxicity.

The paragraph labeled Demography details the population itself. It is essentially a white and female population of which some 70% have never been married. This is a bit unusual as most predominantly female schizophrenic populations have a higher percentage of subjects classified as "ever married". The social class distribution is not unusual for hospitalized schizophrenics. Age distribution indicates that the majority of the population was 40 or older. A majority of subjects had a gradual onset to their illness and all had previous treatment and hospitalizations. Forty percent of the subjects were first hospitalized before the age of 20. A third were said to have had a schizoid style of life, and all were said to have had symptoms of an affective nature on admission. This latter figure is of interest because, from the later BPRS profile, this group could not be considered affectively disturbed. Perhaps this PDI item reflects historical rather than current information or a different rater, etc. Most subjects had made a marginally adequate occupational or role adjustment and while most of the subjects entered the hospital on the initiative of others, they were generally cooperative. Their hospital adjustment prior to the study was predominantly withdrawn and vegetative. On the whole, then, this is a population of chronic schizophrenics who do not appear dramatically different from most chronically hospitalized schizophrenic populations.

To review the strategy for looking at significant findings, see Table XVIII.

T A B L E XVIII

TREATMENT COMPARISONS

Variable	Level	Type	Direction
BPRS			
Somatic concern	N.S.	--	--
Anxiety	01	P	Greatest improvement at 06, dissipating at 12
Emotional withdrawal	01	P	Improvement at term
Conceptual disorganization	05	P	Improvement across time
Guilt	Omitted	- No variance	
Tension	05	P	Improvement across time
Mannerisms	10-20	P	Improvement across time
Grandiosity	N.S.	--	--
Depressive mood	10-20	P	Improvement across time
Hostility	N.S.	--	--
Suspiciousness	N.S.	--	--
Hallucinatory behavior	01	P	Improvement across time
Motor retardation	N.S.	--	--
Uncooperativeness	N.S.	--	--
Unusual thought	01	P	Improvement across time
Blunted affect	01	P	Improvement across time
Excitement	N.S.	--	--
Disorientation	N.S.	--	--
BPRS Factors			
Depression	05	P	Greatest improvement at 06; dissipating at 12
Thinking disorder	01	P	Improvement across time
Anergia	01	P	Improvement across time
Excitement-disorientation	N.S.	--	--
CGI			
Severity of illness	01	P	Improvement across time
Global improvement	01	P	Greater improvement at 12
Efficacy index	10-20	P	Highest at 12 (greatest benefit/risk ratio)

This is a summary of the significant ANOVA findings on the various psychiatric measures. It lists the variable, the level of statistical significance, the type of difference (P represents period difference), and finally, the direction of the change. Looking down the table it is clear that the statistical findings reflect improvement across time. In looking at a table such as this, which is a univariate analysis, the first interest is how many of the variables tested reached a significant level - here defined as .05 or greater. In this analysis there are 27 different variables. Of course, it would be possible to obtain a certain number of significant findings purely on chance. There is, in fact, a 10% probability of obtaining 3 significant findings out of 27 univariate analyses. In this study, 13 of the 27 variables reach the .05 level of significance. The probability is less than .001 that this number of significances would be due to chance alone. Being even more rigid, 10 variables reached the .01 level of significance. The probability that this is due to chance is less than .001 as well. Next glance to see whether or not the directional changes are unidirectional. Changes in both directions, i.e., toward improvement and toward worsening might reflect contradictory evidence or some sort of equivocation of the data. Of course, if the variables moving in one direction are all related to one another, i.e., forming some sort of a clinical syndrome, this might reflect a specific action for the drug, e.g., improvement in an anxiety syndrome indicating anxiolytic action rather than neuroleptic. Next see which variables had statistical change. If, in a schizophrenic population, variables such as anxiety, depression, guilt, etc., were changing, it would be hard to justify the drug as an antipsychotic.

Generally, after looking at this table of treatment comparisons, it can be said that the drug, indeed, looks promising. It appears to have psychotropic activity and its psychotropic activity appears to be antischizophrenic or neuroleptic. Being skeptical, however, it is necessary to look at the data more carefully and see if these statistical findings are justified. One thing of interest is whether or not the changes on these BPRS variables are due to a few subjects changing a great deal or whether the majority of subjects have changed a little bit. For this, there are the cross-tabulations.

While these cross-tabulations omit the middle assessment period, they do provide a useful picture of the pre to post changes. They give a frequency distribution as well, thus enabling a rather close scrutiny of the pattern of change on each variable. For example, the cross-tabulation for anxiety, shows that eight of the ten patients did not change at all.

Pretreat. = Per.0 H Posttreat. = Per.12

Anxiety		PRETREATMENT								
		NP	VM	MI	MO	MS	SV	ES	NA	post Sum
POSTTREATMENT	NP	0	0	0	0	0	0	0	0	0
	VM	0	8	0	2	0	0	0	0	10
	MI	0	0	0	0	0	0	0	0	0
	MO	0	0	0	0	0	0	0	0	0
	MS	0	0	0	0	0	0	0	0	0
	SV	0	0	0	0	0	0	0	0	0
	ES	0	0	0	0	0	0	0	0	0
	NA	0	0	0	0	0	0	0	0	0
	PS	0	8	0	2	0	0	0	0	

Tot. N. = 10 TN - NA = 10 No change = 8 (80.0)

\+ change = 2(20.0) - Change = 0(0.0)

Anxiety was rated VERY MILD at pretreatment and VERY MILD at posttreatment for of the subjects. Two of the subjects, however, were rated as having MODERATE anxiety, at pretreatment and they changed 2 points to VERY MILD at posttreatment. This is in contrast to emotional withdrawal in which 9 of the 10 patients changed in a positive direction. One patient changed, in fact, the maximum 6 points from EXTREMELY SEVERE to NOT PRESENT. Note that such magnitude is unusual. If there were many such changes, it would suggest enthusiastic raters.

The cross-tabulation does not give all of the information contained in the analysis of variance. Returning again to anxiety, note the cross-tabulation indicates that 8 of the subjects did not change. The ANOVA for this variable, however, produces a significant result :

Anxiety	DF	Sum of Squares	Mean Squares	F-Ratio
ANOVA error 1 - between	9	2.1667	0.2407	
ANOVA error 2 - within	18	5.1333	0.2852	
Period	2	8.8667	4.4333	15.5455

Level Means of Treatment Combination

Periods	Observations	
Period 1	10	2.40
Period 2	10	1.10
Period 3	10	2.00

There was a rather dramatic change on this variable (anxiety) at week 6 where the subjects showed a great deal of positive change. Had this middle assessment not been made, the fact that the drug had an initial, though apparently transient, effect upon anxiety, might have been missed.

Presented below is the summary of the cross-tabulations:

SUMMARY of PRE to POST-DRUG CHANGES on the BPRS

	No of pts rated asympt. at pre- and post-drug =		No of pts rated improved +		No of pts showing worsening		No of pts. showing no change 0		potential change S		actual change in points	per cent actual change S
	N	%	N	%	N	%	N	%	pts	index	points	change
Somatic concern	9	90.0	1	10.0	0	0.0	0	0.0	4	0.07	4	100.0
Anxiety	0	0.0	2	20.0	0	0.0	8	80.0	14	0.23	4	28.6
Emot. withdrawal	0	0.0	9	90.0	0	0.0	1	10.0	36	0.60	20	55.6
Concept disorg.	3	30.0	7	70.0	0	0.0	0.	0.0	29	0.48	18	62.1
Guilt feelings	10	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Tension	3	30.0	6	60.0	1	10.0	0	0.0	27	0.45	22	81.5
Mannerism-postur	1	10.0	7	70.0	2	20.0	0	0.0	22	0.37	9	40.9
Grandiosity	9	90.0	0	0.0	1	10.0	0	0.0	0	0.0	-3	0.0
Depressive mood	8	80.0	2	20.0	0	0.0	0	0.0	6	0.10	4	66.7
Hostility	6	60.0	2	20.0	2	20.0	0	0.0	10.	0.17	5	50.0
Suspiciousness	6	60.0	2	20.0	2	20.0	0	0.0	10.	0.17	3	30.0
Hallucic behavior	0	0.0	8	80.0	0	0.0	2	20.0	17.	0.28	13	76.5
Motor retardat.	1	10.0	6	60.0	3	30.0	0	0.0	17	0.28	4	23.5
Uncooperative	1	10.0	6	60.0	2	20.0	1	10.0	31	0.52	7	22.6
Unusual thought	3	30.0	7	70.0	0	0.0	0	0.0	31	0.52	23	74.2
Blunted affect	0	0.0	10.	100.0	0	0.0	0	0.0	36	0.60	23	63.9
Excitement	0	0.0	5	50.0	4	40.0	1	10.0	16	0.27	4	25.0
Disorientation	0	0.0	7	70.0	2	20.0	1	10.0	40	0.67	12	30.0
Totals	60	33.3	87	48.3	19	10.6	14	7.8	346	0.32	172	

Pts x Items Total = 180 Total Maximum Potential = 1080

Looking down column 1, Number of Patients rated Asymptomatic at Pre and Post Drug, it is apparent that somatic concern, guilt feelings, grandiosity, depressive mood, hostility and suspiciousness were not present in most of the population. These symptoms were simply not characteristic of the population. The next column, Number of Patients Rated Improved, presents how many patients changed in a positive way on each variable. It does not delineate, however, the degree of improvement. This is true of the column labeled Worsening as well. The next three columns are Potential Change, Actual Change in Points, and Percent of Actual Change. The idea behind potential change is to obtain an index of the degree to which any research population could change, given an active drug. The concept came about as an attempt to deal with the problem of assessing drug efficacy in chronic, severely deteriorated schizophrenic populations. Often these subjects, though severely ill, show very few ratable symptoms. In such a group it is difficult to demonstrate statistically significant changes as there is "nothing to change". It is <u>a priori</u> that a group must display some degree of symptomatology if a drug is to demonstrate effect upon this symptomatology. The BPRS potential takes as its base the theoretical maximum change possible. Since the BPRS scale runs from 7 to 1, there is a possibility of 6 change points for any given subject on any given symptom. Theoretically, the sickest possible patient would have a rating of 7 on all 18 symptoms, although in fact this is highly unlikely. For any given subject, then, 108 points of change are possible. In this study which has 10 subjects, 1,080 points of potential change are possible. From the summary table, this group's potential is 32% of the theoretical maximum in that there are 346 points which could change given the perfect drug. In actuality, 172 points of change were obtained or about 50% of the group's potential. This is quite high, and generally reflects that half of the symptomatology abated. The same is true for Item 1 (Global Severity of Illness) of the CGI in terms of potential :

Pretreatment Mental Status

		Norm	Bord	Mild	Modr	Mark	Sevr	Extr	N.A.	Total
POST TREATMENT	Normal	0	0	0	0	0	0	0	0	0
	Borderline	0	0	0	0	0	0	0	0	0
	Mildly	0	0	0	0	0	1	0	0	1
	Moderately	0	0	0	0	2	2	0	0	4
	Markedly	0	0	0	0	1	4	0	0	5
	Severely	0	0	0	0	0	0	0	0	0
	Extremely	0	0	0	0	0	0	0	0	0
	Not ascertained	0	0	0	0	0	0	0	0	0
	Total	0	0	0	0	3	7	0	0	10

Total N	= 10	Total N - N.A. = 10
No. asymptomatic	= 0	0.0%
Static symptoms	= 1	10.0%
Improved	= 9	90.0%
Worsened	= 0	0.0%
Potential change	= 47	
Actual change	= 13	
Percent change	=	27.7%

Here, for 10 subjects, the theoretical maximum is 60 points. This group's potential at pretreatment was 47 points or 78% of the theoretical maximum. This indicates that the group was rated as quite sick. It also reflects that the global judgment of the CGI seems to contain more than the separate rating of symptoms of the BPRS. That is, the group is apparently much sicker when rated on the global severity item than it is on the BPRS as a whole. Interestingly, greater actual point changes is noted on the BPRS as a whole than on the global severity item of the CGI. The actual global point change represents only 28% of the global potential at pretreatment. The rater seems to be indicating that although there was quite a bit of change on individual BPRS items, the population remained quite sick despite the positive effect of the drug. This may seem rather confusing in the context of a single study. The importance of the concept of potential is its use as an index in comparing populations across studies in terms of their symptomatology at pretreatment. Obviously a population with a high potential has a greater chance of changing than one with a very low potential and hence conclusions as to the efficacy of a drug may be positively or negatively biased.

Looking at the cross-tabulation of the global severity item, note that 9 of the 10 patients changed in a positive direction. The degree of change, however, was minimal. Six of these nine changed only 1 point.

Frequency distribution of the global improvement (Item 2 - CGI) is presented below :

Periods	6		12	
	Freq.	%	Freq.	%
V.M. improved	0	0.0	3	30.0
Much improved	0	0.0	6	60.0
Minim improved	7	70.0	1	10.0
No change	2	20.0	0	0.0
Minim worse	1	10.0	0	0.0
Much worse	0	0.0	0	0.0
V.M. worse	0	0.0	0	0.0
Not ascertained	0	0.0	0	0.0
Total improved	7	70.0	10	100.0
Total unimproved	3	30.0	0	0.0

Note that at week 06, 70% of the population had been rated as improved, all of them minimally improved. At week 12, 9 of the subjects had been rated as very much or much improved. This distribution indicates the greater improvement occurred at week 12.

Displays for the efficacy index (Item 3 - CGI) at weeks 6 and 12 are as follows :

Unit	Study	Patient	Period	Drug	Prig	Comp	EI
33	32	1	6	1	41	11	1.00
33	32	2	6	1	41	11	1.00
33	32	3	6	1	32	22	1.00
33	32	503	6	1	22	32	1.50
33	32	504	6	1	41	11	1.00
33	32	506	6	1	31	21	2.00
33	32	508	6	1	41	11	1.00
33	32	510	6	1	21	31	3.00
33	32	511	6	1	31	21	2.00
33	32	512	6	1	21	31	3.00

Missing data is indicated by EI = 0.0

Drug No. 1 N = 10 Mean EI score = 1.65

Frequency on the Matrix

Therapeutic effect	Side effects			
	None	Not Sig.	Signif.	Nullify
Marked	0	0	0	0
Moderate	2	1	0	0
Minimal	2	1	0	0
Unchanged	4	0	0	0

Unit	Study	Patient	Period	Drug	Prig.	Comp.	EI
33	32	1	12	1	31	21	2.00
33	32	2	12	1	21	31	3.00
33	32	3	12	1	32	22	1.00
33	32	503	12	1	22	32	1.50
33	32	504	12	1	41	11	1.00
33	32	506	12	1	21	31	3.00
33	32	508	12	1	41	11	1.00
33	32	510	12	1	21	31	3.00
33	32	511	12	1	31	21	2.00
33	32	512	12	1	21	31	3.00

Missing data is indicated by EI = 0.0

Drug No. 1 N = 10 Mean EI Score = 2.05

Frequency on the Matrix

Therapeutic effect	Side effects			
	None	Not Sig.	Signif.	Nullify
Marked	0	0	0	0
Moderate	4	1	0	0
Minimal	2	1	0	0
Unchanged	2	0	0	0

This item attempts to relate two areas of assessment, therapeutic effect, and side effects. It is a kind of benefit/risk ratio in which therapeutic effects are regarded as the benefit and side effects the risk. As discussed, an efficacy index greater than 1 indicates that therapeutic effects outweighed side effects, and thus some degree of benefit was obtained. This item has proved quite useful and appears to have discriminatory value.

In the ANOVA section, note that on global severity (Item 1 - CGI), a significant period difference was obtained :

	DF	Sum of Squares	Mean Squares	F-Ratio
ANOVA error 1 - between	9	4.6667	0.5185	
ANOVA error 2 - within	18	4.7333	0.2630	
Periods	2	8.6000	4.3000	I6.3521

Level Means of Treatment Combination

Periods	Observations	
period 1	10	5.70
period 2	10	4.90
period 3	10	4.40

Looking at the means for each of the rating periods, note that the change was straightforward across the periods.

Global improvement (Item 2 - CGI) is presented below :

	DF	Sum of Squares	Mean Squares	F-Ratio
ANOVA error 1 - between	9	6.8000	0.7556	
ANOVA error 2 - within	9	1.2000	0.1333	
Periods	1	12.8000	12.8000	96.0000

Level Means of Treatment Combination

Periods	Observations	
Period 1	10	3.40
Period 2	10	1.80

Again, a significant difference was found between week 6 and week 12. There is no pretreatment assessment of global improvement so only treatment ratings can be compared. This analysis states that at week 12 there was significantly greater improvement than at week 6. One cannot conclude there was no improvement at week 6 but simply that the greater improvement occurred at week 12.

The analysis of variance for the efficacy indices (Item 3 - CGI) is as follows :

	DF	Sum of Squares	Mean Squares	F-Ratio
ANOVA error 1 - between	9	11.0500	1.2278	
ANOVA error 2 - within	9	2.2000	0.2444	
Periods	1	0.8000	0.8000	3.2727

Level Means of Treatment Combination

Periods	Observations	
Period 1	10	1.65
Period 2	10	2.05

Here, only a trend finding was obtained. It reflects, however, that a higher index was obtained at week 12.

Having looked at the significant findings on the efficacy ratings, look now at the Treatment Emergent Symptoms Scale data and note that only 4 of the 22 symptoms cited required some action on the part of the investigator.

Summary of Symptom Occurrence

Occurrences	Tot	Mild	Severe	Mild +	Severe +	Static
	37	30	1	3	3	0

Symptoms	Tot	Static	Require Action
	22	0	4

Action/Occur

	None	Surveil	Contra	Reduce	Red + Contra	Suspend	Discont	Other
Abnormal lab. finding	0	0	0	0	0	0	0	0
Adverse behavior effects	0	0	0	1	0	0	0	0
Central nervous system	13	0	0	4	0	0	0	0
Autonomic nervous system	9	0	0	2	0	0	0	0
Miscellaneous	5	2	0	1	0	0	0	0
Total occurences	27	2	0	8	0	0	0	0

Similarly, only 4 occurrences were rated as severe out of the 37 cited. The most stringent action required was reduction of dose. No subjects were discontinued or suspended because of side effects.

The table below provides further information.

No. and percent of pat. asy pt. and static

	N	%	Tot. N
week 0	6	60.00	10
week 1	6	60.00	10
week 2	5	50.00	10
week 3	5	50.00	10

Patients who were asymptomatic at all periods = 3

This simply displays those patients who were asymptomatic at each period. Notice that 6 of the patients had no symptoms upon entering the study or, conversely, 4 subjects entered the study with "side effects". That is, they had somatic symptoms which might be related to whatever medication they were on prior to entering the study.

These symptoms obviously had persisted throughout the "drying out" period of two weeks which was part of the research protocol. Three of the 10 subjects had no side effects throughout the whole study. The treatment emergent clusters indicate that the symptoms were divided approximately half to the central nervous system cluster and half to the autonomic and miscellaneous clusters :

Summary of Treatment Emergent Clusters

Abnormal Lab. Finding

	persists	emerge	increase	decrease	remit	evolv %	reced %	total	cluster occur %	subjects
Period 0	0	0	0	0	0	0.0	0.0	0	0.0	7
Period 1	0	0	0	0	0	0.0	0.0	0	0.0	7
Period 2	0	0	0	0	0	0.0	0.0	0	0.0	7
Period 3	0	0	0	0	0	0.0	0.0	0	0.0	7
All	0	0	0	0	0	0.0	0.0	0	0.0	

Adverse Behavior Effects

	persists	emerge	increase	decrease	remit	evolv %	reced %	total	cluster occur %	subjects
Period 0	0	0	0	0	0	0.0	0.0	0	0.0	7
Period 1	0	0	0	0	0	0.0	0.0	0	0.0	7
Period 2	0	1	0	0	0	100.0	0.0	1	6.7	7
Period 3	0	0	0	0	1	0.0	100.0	0	0.0	7
All	0	1	0	0	1	50.0	50.0	1	2.7	

Central Nervous System

	persists	emerge	increase	decrease	remit	evolv %	reced %	total	cluster occur %	subjects
Period 0	0	0	0	0	0	0.0	0.0	0	0.0	7
Period 1	0	2	0	0	0	100.0	0.0	2	40.0	7
Period 2	2	6	0	0	0	100.0	0.0	8	53.3	7
Period 3	6	0	0	1	1	75.0	25.0	7	63.6	7
All	8	8	0	1	1	88.9	11.1	17	45.9	

(Summary of Treatment Emergent Clusters cont.)

Autonomic Nervous System

	persists	emerge	increase	decrease	remit	evolv %	reced %	total	cluster occur %	subjects
Period 0	1	0	0	0	0	100.0	0.0	1	16.7	7
Period 1	0	2	1	0	0	100.0	0.0	3	60.0	7
Period 2	2	2	0	1	0	80.0	20.0	5	33.3	7
Period 3	2	0	0	0	3	40.0	60.0	2	18.2	7
All	5	4	1	1	3	71.4	28.6	11	29.7	

Miscellaneous

	persists	emerge	increase	decrease	remit	evolv %	reced %	total	cluster occur %	subjects
Period 0	5	0	0	0	0	100.0	0.0	5	83.3	7
Period 1	0	0	0	0	5	0.0	100.0	0	0.0	7
Period 2	0	1	0	0	0	100.0	0.0	1	6.7	7
Period 3	0	2	0	0	1	66.7	33.3	2	18.2	7
All	5	3	0	0	6	57.1	42.9	8	21.6	

Total Occurences

	persists	emerge	increase	decrease	remit	evolv %	reced %	total	cluster occur %	subjects
Period 0	6	0	0	0	0	100.0	0.0	6	100.0	7
Period 1	0	4	1	0	5	50.0	50.0	5	100.0	7
Period 2	4	10	0	1	0	93.3	6.7	15	10.00	7
Period 3	8	2	0	1	6	58.8	41.2	11	100.0	7
All	18	16	1	2	11	72.9	27.1	37	100.0	7

Given all of this, what can be said about this study ? If one were the monitor for a pharmaceutical firm, would one want to continue to investigate the drug Normaline ? Would one invest the time and money and make a relative test of efficacy by comparing the drug to placebo or perhaps to some standard drug ?

It seems rather clear that statistical changes reflecting improvement occurred on those variables usually associated with schizophrenic illness. In that sense, the drug appears to have antipsychotic activity. On the negative side, one might be concerned with the occurrence of tachycardia, etc. Weighing these and other factors, we would say the documentation justifies further investigation of Normaline.

PART SEVEN

A DOCUMENTATION SYSTEM IN OPERATION

E. Evaluation of Documentation

TRIAL ASSESSMENT PROCEDURE SCALE

(TAPS)

The use of psychotherapeutic drugs is based on clinical observations verified in properly designed and conducted clinical experiments. While the basic principles of a good design are clearly established and frequently discussed, there is virtually no information available on the basic principles how to conduct properly a clinical experiment. Since the validity of the findings of a clinical trial is dependent on both, a Trial Assessment Procedure Scale (TAPS), which takes into consideration design and conductance, was developed in the Pharmacologic and Somatic Treatments Research Branch of the NIMH.

The TAPS is a systematic technique for evaluating the quality of a clinical trial, through an analysis of the study protocol, final report and/or journal article, in terms of many descriptive characteristics or attributes, organized under eight headings; each heading-category reflecting different aspects of trial quality. Introduction of the TAPS extended the scope of documentation by supplementing the documentation of the clinical trial and the documentation of individual patients participating in the clinical trial with an evaluative documentation of the clinical trial itself.

TRIAL ASSESSMENT PROCEDURE SCALE (TAPS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Trial Assessment Procedure Scale (TAPS)

Name of Rater
Affiliation
Address
Phone

Date

Card (21-22) 0 1

Study	Type	Treatment	Status	Phase	Rater	Form
(1-4)	(5-8)	(9-13)	(14)	(15)	(16-17)	(18-20)
- - - -	- - - -	- - - - -	-	-	- -	- - -

Trial Title and/or Identification Number

Type, Source and Date of Report

Name of Investigational Drug/s or Treatment/s

Trial Status (14) [1] Planned [2] Completed

Trial Phase (15) [1] I [2] Early II [3] Late II [4] III [5] IV

No. of Treatment Groups _____ (23) No. of Subjects in Trial : _____ (24-25)

INSTRUCTIONS

OVERVIEW. The Trial Assessment Procedure Scale (TAPS) is a systematic technique for evaluating the quality of a clinical trial. The technique involves an analysis of the report (e.g., protocol, completed study report, or journal article) in terms of many descriptive characteristics or attributes which reflect trial quality. The attributes are logically clustered into eight categories so that the quality of various components of the trial can be independently assessed. The intent is to rate the quality of the trial without regard to findings concerning treatment efficacy or safety.

As shown in the outline below, each category is composed of two to five related attributes. For example, the first category, Research Problem, is composed of two attributes labeled Background and Rationale and Objectives and/or Hypothesis. A separate rating page is provided for each attribute category, which lists the constituent attributes, along with examples of the kinds of factors that should be taken into account in evaluating each respective attribute. Examples are representative and do not exhaust all of the factors that may be considered when rating a given attribute.

RATING PROCEDURE. The TAPS rating procedure is identical for all attributes. The rating is made on a 5-point scale : totally satisfactory, satisfactory, marginal, unsatisfactory, or totally unsatisfactory. For each attribute, the rater is asked to check the appropriate box in the Quality Rating column, reflecting how well the trial under evaluation measures up on that attribute. The rater is encouraged to comment on the basis for the rating of any attribute, and space has been provided for this purpose.

RATING PROBLEMS. Because of differences in the nature and content of clinical trial reports, it may be difficult to rate meaningfully a given attribute. Thus, under the column heading Rating Problems and Explanation,
The first box, Not Applicable, pertains to the applicability of the attribute with respect to either the type of trial or type of report (e.g., protocol, journal article) through which the trial is being evaluated. This box is checked only when the attribute does not have meaning either in the context of the given trial or type of report, and therefore a quality rating should not be made. The second box, Poor Documentation, concerns the availability and clarity of the written des

needed to make a meaningful judgement about the given attribute; this box should be checked when the appropriate information is either lacking or

inadequate. Even after making a quality rating in response to the attribute, this box can be checked to indicate that the relevant documentation is poor.

Raters are advised to keep the following rules in mind. Lack of confidence about expertise in a specific area should not prevent the rater from making a rating. If the rater is having difficulty because the attribute is not applicable to the trial itself or to the type of report, the Not Applicable box is checked and explanation made in the space provided. No quality rating is given to that attribute. If the rater is having difficulty because no information is given in the report to permit a judgment on a given attribute (when it would have been applicable), the Poor Documentation box is checked. If the information given is unclear, incomplete, or has to be inferred, a quality rating is made and the Poor Documentation box is checked. Thus, whenever an attribute quality rating cannot be provided, either the Not Applicable or Poor Documentation box must be checked and an explanation given. If a quality rating is made, and the rater wishes to indicate that the documentation is poor, the box Poor Documentation is checked.

GLOBAL RATING. Once ratings have been completed for all attributes, a global rating is made indicating the rater's assessment of the Overall Quality or "goodness" of the entire trial. The overall rating should take into account all the individual ratings across the attribute categories, as well as any other considerations that may have been noted. For example, if the quality rating of an attribute is so unacceptable that the trial is "fatally flawed", then a very low global rating would be given even though other attributes had been judged Satisfactory or Better. As shown on the global rating sheet, the rating is made on a 0-to-100 scale, where 0 is "very poor" and 100 is "very good". Any number between 0 and 100 can be assigned. Below the global rating scale, space is available for comments about the overall rating for the trial. This area can also be used for additional comments about the trial, any of the ratings, or other relevant considerations.

RATING THE TRIAL REPORT: After the rater has become familiar with the format and content of TAPS, it is recommended that the report of the trial to be rated first be read in its entirety. Then, the attributes should be rated in the sequence presented in TAPS referring back to various sections of the trial report as often as necessary.

SCORING TAPS. After ratings have been completed, a series of numerical scores can be derived according to the Scoring Instructions on page .

Structure of Trial Assessment Procedure Scale (TAPS)

I. Research Problem
- A. Background and Rationale
- B. Objectives and/or Hypothesis

II. Research Management
- A. External Review/Monitoring
- B. Site Selection
- C. Personnel
- D. Trial Period

III Design Characteristics
- A. Independent Variables
- B. Design Configuration
- C. Subject Assignment
- D. Control of Treatment-Related Bias
- E. Control of Extraneous Variables

IV. Treatment Characteristics
- A. Description
- B. Dosage
- C. Duration

V. Subject Characteristics
- A. Selection Criteria
- B. Sample Representativeness
- C. Subject Induction
- D. Subject Compliance

VI. Data Collection
- A. Scope of Assessment
- B. Assessment Measures
- C. Assessment Schedule
- D. Conduct of Assessment

VII. Data Analysis
- A. Data Preparation
- B. Data Presentation
- C. Statistical Analysis
- D. Data Synthesis

VIII. Conclusions and Interpretation
- A. Focus
- B. Logic
- C. Application

I. RESEARCH PROBLEM

Attribute	Quality Rating		Rating Problems and Explanation	
A. Background and Rationale appropriate presentation of previous relevant research findings; justification of research need and basis/rationale for hypothesis to be tested.	(27) 5	Totally Satisfactory	(26) 1 Not Applicable	2 Poor Documentation
	4	Satisfactory		
	3	Marginal		
	2	Unsatisfactory		
	1	Totally Unsatisfactory		
B. Objectives and/or Hypothesis clarity of objectives, meaningfulness and precision of research question; relevancy of hypothesis for claims to be made.	(29) 5	Totally Satisfactory	(28) 1 Not Applicable	2 Poor Documentation
	4	Satisfactory		
	3	Marginal		
	2	Unsatisfactory		
	1	Totally Unsatisfactory		

Comments :

II. RESEARCH MANAGEMENT

Attribute	Quality Rating	Rating Problems and Explanation
A. External Review/Monitoring adequacy of scientific and ethical review by a qualified independent group; use of external monitoring of research practices, conditions and progress.	(31) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(30) 1 Not Applicable 2 Poor Documentation
B. Site Selection explicitness and objectiveness of clinical site selection; appropriateness of treatment and assessment setting.	(33) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(32) 1 Not Applicable 2 Poor Documentation
C. Personnel appropriateness of staff organizational structure, e.g., adequacy of supervision, professional skill of staff members for performing patient care, assessment ratings, and data analysis functions.	(35) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(34) 1 Not Applicable 2 Poor Documentation
D. Trial Period appropriateness of length of planning phase, data collection period and analysis period, as well as the appropriateness of the intervals between completion of data collection and initiation of analysis.	(37) 5 Totally satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally unsatisfactory	(36) 1 Not Applicable 2 Poor Documentation

Comments :

III. Design Characteristics

Attribute	Quality Rating	Rating Problems and Explanation
A. Independent Variables Choice of factors included in the design, e.g., treatments and choice of drugs within treatments (experimental drug, standard drug, placebo), patient diagnosis, periods of administration, etc.	(39) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(38) 1 Not Applicable 2 Poor Documentation
B. Design Configuration appropriateness and precision of experimental design, e.g., use of a cross-over or independent groups design, as required; avoidance of effects which may be confounded with the treatment factor, e.g., treatment order, time, setting, etc.	(41) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(40) 1 Not Applicable 2 Poor Documentation

(III. Design Characteristics cont)

C. Subject Assignment

adequacy of sample size (within each treatment group) for testing hypothesis; appropriate assignment of subjects to treatment groups by proper randomization, matching, sequential procedures, etc.

(43) 5 Totally Satisfactory (42) 1 Not Applicable 2 Poor Documentation
4 Satisfactory
3 Marginal
2 Unsatisfactory
1 Totally Unsatisfactory

D. Control of Treatment-Related Bias

adequacy of treatment and assessor blinding (e.g., double or triple blind); comparability of dosage schedule, dosage form, time of administration; provision to break blind for individual patient without breaking blind for all patients; utilization of explicit rules or criteria for dealing with marked improvement or worsening of subject illness, or occurrence of treatment-emergent side effects or toxicity.

(45) 5 Totally Satisfactory (44) 1 Not Applicable 2 Poor Documentation
4 Satisfactory
3 Marginal
2 Unsatisfactory
1 Totally Unsatisfactory

E. Control of Extraneous Variables

suitability of research environment, e.g., absence of marked investigator bias, "Hawthorne Effect", hopeless atmosphere, etc.; reduction of pretreatment bias by, e.g., the use of stratification, avoidance of carryover effects, etc.; limitation or control of other concurrent therapies including drugs other than those under study; utilization of explicit rules or criteria for dealing with such problems as intercurrent illness, change of residence, etc.

(47) 5 Totally Satisfactory (46) 1 Not Applicable 2 Poor Documentation
4 Satisfactory
3 Marginal
2 Unsatisfactory
1 Totally Unsatisfactory

Comments :

IV. TREATMENT CHARACTERISTICS

Attribute	Quality Rating	Rating Problems and Explanation
A. Description (49) Specification of relevant characteristics of experimental and control treatments, e.g. presumed clinical actions, side effects, duration of actions, pharmacological profile; rationale for choice of comparison agent, i.e., standard drug or placebo.	5 Totally satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(48) 1 Not Applicable 2 Poor Documentation
B. Dosage (48) adequacy of dosage levels, equivalence of dosage across standard and test drugs, criteria for dosage adjustment; appropriateness of schedule and pattern (fixed or variable) of administration with respect to duration of action, research design and phase of the trial; appropriateness of form or route of administration, degree of consistency with pharmacological properties.	5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(50) 1 Not Applicable 2 Poor Documentation

(IV. TREATMENT CHARACTERISTICS cont)

Attribute	Quality Rating	Rating Problems and Explanation
C. Duration necessity for, and appropriate length of, drying-out (pre-treatment) period, drug administration (treatment) period, and follow-up (posttreatment) period.	(53) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(52) 1 Not Applicable 2 Poor Documentation

Comments :

V. SUBJECT CHARACTERISTICS

Attribute	Quality Rating	Rating Problems and Explanation
A. Selection Criteria clarity, explicitness, appropriateness, and general acceptance of criteria used to diagnose patients and to include or exclude them in study.	(55) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(54) 1 Not Applicable 2 Poor Documentation
B. Sample Representativeness correspondence between sample and population in terms of illness-related characteristics (e.g., pattern and severity of psychopathology) and demographic/situation-related characteristics (e.g., age, sex, acuteness of illness, inpatient/outpatient status. etc.).	(57) 1 Totally Satisfactory 2 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(56) 1 Not Applicable 2 Poor Documentation

(V. SUBJECT CHARACTERISTICS cont)

Attribute	Quality Rating	Rating Problems and Explanation
C. Subject Induction appropriateness and consistency of subject recruitment procedure, and degree of adherence to requirements for obtaining informed, voluntary subject consent.	(59) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(58) 1 Not Applicable 2 Poor Documentation
D. Subject Compliance adequacy of techniques to check for and assure medication ingestion as well as compliance with assessment procedures and schedule.	(61) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(60) 1 Not Applicable 2 Poor Documentation

Comments :

VI. DATA COLLECTION

Attribute	Quality Rating	Rating Problems and Explanation
A. Scope of Assessment adequacy of breadth of measures for assessing areas such as sample (identification and recording of degree of illness, demographic information, etc.), efficacy (assessment to demonstrate improvement or worsening of patient illness), side effects (assessment to detect expected and unexpected treatment-emergent symptoms), dosage (recording of dosages actually administered), safety (use of appropriate laboratory tests which are specific to drug under study, general for assessing bodily functions, etc.), other relevant areas (depending upon illness, drug, or special assessment techniques, e.g., EEG, blood levels, behavioral measures, etc.)	(63) 5 Totally atisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(62) 1 Not Applicable 2 Poor Documentation
B. Assessment Measures appropriateness of measures and instruments selected with respect to areas being assessed; extent that rating scales and recording forms have been previously shown to be sensitive, reliable, and valid; degree to which measures have been generally used and accepted.	(65) 5 Totally atisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(64) 1 Not Applicable 2 Poor Documentation
C. Assessment Schedule appropriateness of frequency and schedule of ratings, collection of baseline measures prior to start of trial, etc.	(67) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(66) 1 Not Applicable 2 Poor Documentation

(VI. DATA COLLECTION cont)

Attribute	Quality Rating	Rating Problems and Explanation
D. Conduct of Assessment	(69) 5 Totally Satisfactory	(68) 1 Not Applicable
consistency throughout trial of application of rating and assessment techniques; attempt to maintain same rater for any given patient throughout trial; evidence to establish inter-rater reliability and rating validity within context of this trial.	4 Satisfactory	2 Poor Documentation
	3 Marginal	
	2 Unsatisfactory	
	1 Totally Unsatisfactory	

Comments :

VII. DATA ANALYSIS

Attribute	Quality Rating	Rating Problems and Explanation
A. Data Preparation	(24) 5 Totally Unsatisfactory	(23)* 1 Not Applicable
adequacy of data collection techniques (case report and recording forms, etc.); data checking, editing and verification techniques; use of standard computer analysis program vs. hand calculations, checking of intermediate data processing steps.	4 Unsatisfactory	2 Poor Documentation
	3 Marginal	
	2 Unsatisfactory	
	1 Totally Unsatisfactory	

* Card No 02 : Duplicate cols. 1-20
Punch 02 in cols. 21-22

Attribute	Quality Rating	Rating Problems and Explanation
B. Data Presentation clarity, meaningfulness and utility of data description, organization, and display; appropriate level of data detail or summarization.	(26) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(25) 1 Not Applicable 2 Poor Documentation
C. Statistical Analysis correctness of application of statistical procedures, e.g., data transformations, pooling of data, handling of dropouts and missing data, etc; use of statistical model appropriate to research design, e.g., parametric vs. nonparametric, analysis of variance vs. analysis of covariance, etc.; degree of statistical follow-through, e.g., use of multiple comparisons after finding a significant F-ratio, etc.	(28) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(27) 1 Not Applicable 2 Poor Documentation
D. Data Synthesis demonstration of systematic approach to answering research question; appropriate analysis of functional relationships (e.g., dose-response curves).	(30) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(29) 1 Not Applicable 2 Poor Documentation

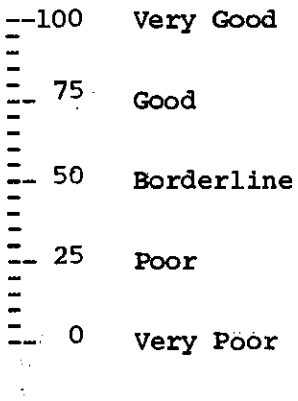
Comments :

VIII. CONCLUSIONS AND INTERPRETATION

Attribute	Quality Rating	Rating Problems and Explanation
A. Focus degree that conclusions (findings) and interpretation (explanation) presented are specific and clear; meaningful correspondence between conclusions and research hypothesis.	(32) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(31) 1 Not Applicable 2 Poor Documentation
B. Logic extent that conclusions are unambiguously supported, both logically and statistically, by the data collected in the study.	(34) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(33) 1 Not Applicable 2 Poor Documentation
C. Application appropriateness of generalization of conclusions from sample in study to the larger population (i.e., claims are not over-stated or over-generalized beyond the supporting data); appropriateness of interpretation with regard to other published findings).	(36) 5 Totally Satisfactory 4 Satisfactory 3 Marginal 2 Unsatisfactory 1 Totally Unsatisfactory	(35) 1 Not Applicable 2 Poor Documentation

Comments :

OVERALL QUALITY OF TRIAL



Assign any number between 0 and 100
in accordance with the scale at the left.

(37-39
- - -
Global Rating

(70-75)
- - | - - | - -
Date

Comments

Additional Space for Comments :

SCORING INSTRUCTIONS

This page provides instructions and space to derive numerical scores from the TAPS ratings. As scores are calculated, they are transferred to the SCORE SHEET on the next page. The specific scoring procedures are as follows :

Global Rating. Copy the Global Rating from page directly onto the SCORE SHEET.

Category Scores. These are derived from the attribute Quality Ratings previously recorded on pages - .

1) Convert each attribute Quality Rating in every category (I-VIII) into an equivalent numerical Attribute Score as follows :
   Totally Satisfactory = 100. Satisfactory = 75; Marginal = 50; Unsatisfactory = 25; Totally Unsatisfactory = 0. Record these scores on the appropriate lines in the table below.
2) Sum the Attribute Scores for each category and enter in the table. Note and enter the number of attributes rated in each category. Divide the Attribute Score Sum by the Number of Attributes Rated and record the resultant Category Score on the designated line in the table (if no attributes were rated in a given category, there would be no Category Score).

ATTRIBUTE	CATEGORY I	II	III	IV	V	VI	VII	VIII
A	____	____	____	____	____	____	____	____
B	____	____	____	____	____	____	____	____
C	____	____	____	____	____	____	____	____
D		____	____		____	____	____	
E		____						
Attrib. Score Sum	____	____	____	____	____	____	____	____
No. Attrib. Rated	____	____	____	____	____	____	____	____
CATEGORY SCORE	=====	=====	=====	=====	=====	=====	=====	=====

3) Transfer the Category Scores to the SCORE SHEET by completing the bar graph that has been provided. Draw a line at the level of the score for each category and write the numerical score above it. Shade the resulting column for clarity.

Total Score. Sum all Category Scores derived above and divide by the number of Category Scores (usually 8) :
Sum of Category Scores _____ : Number of Categories _____ = Total Score _____.
Transfer the Total Score to the Score Sheet.

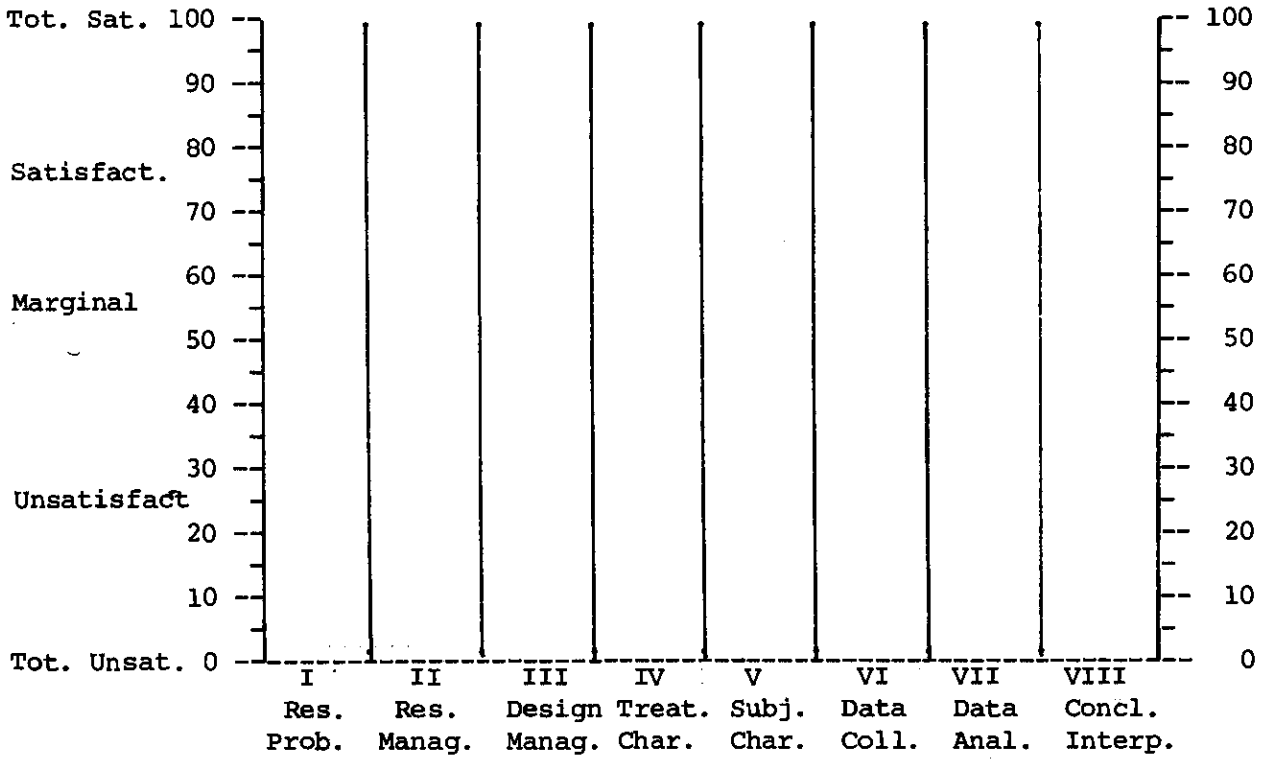
Difference Score. Compute the numerical difference (i.e., absolute value) between the Global Rating and the Total Score. Record the Difference Score on the Score Sheet.

Poor Documentation Score. Count the total number of attributes where the Poor Documentation box was checked and write the number directly on the Score Sheet.

SCORE SHEET

Global Rating _____ Total Score _____ Difference Score _____ Poor Documentation Score _____

Category Scores :



Comments :

INSTRUCTIONS for USERS

DEVELOPMENT - Developed in the Pharmacologic and Somatic Treatment Research Branch, the TAPS provides for a systematic analysis of the quality of the clinical trial. The evaluation is organized under eight headings: Research Problem, Research Management, Design Characteristics, Treatment Characteristics, Subject Characteristics, Data Collection, Data Analysis and Conclusions and Interpretation. There are two to five attributes under each heading; each attribute rated on a five-point scale from totally satisfactory through satisfactory, marginal and unsatisfactory, to totally unsatisfactory.

APPLICABILITY - For all research populations.

UTILIZATION - Once per study. To be completed after completion of the clinical trial with the final report and/or publication based on the study in hand.

PART EIGHT

ADDITIONAL ASSESSMENT INSTRUMENTS

The BLIPS/BDP is an open system, capable of adapting virtually to any assessment instrument. Thus, the rating scales presented here are not the only additional scales, which are suitable for BLIPS/BDP data processing. On the other hand, they are the rating scales which are the most frequently employed in clinical drug trials with psychotropic drugs.

The scales described are as follows :

Diagnostic Scales : Children's Diagnostic Scale
Hachinsky's Ischemic Score.

Scales in the Assessment of Change :

All Purpose: Wittenborn Psychiatric Rating Scale
Fischer Symptoms Checklist

Anxiety Disorders : Sheehan Scales
Physician Questionnaire
Brief Outpatient Psychopathology
Anxiety Status Inventory
Self-Rating Anxiety Scale

Depressive Disorders:
Raskin-Covi Scales
Newcastle Scale
Depression Status Inventory
Self-Rating Depression Scale
Bec Depression Inventory
Clyde Mood Scale
Bech-Rafaelsen Melancholia and Mania Scale

Manic States: Manic State Rating Scale

Schizophrenic Disorders :
Inpatient Multidimensional Psychiatric Scale
Fischer Symptom Checklist Neuroleptics

Psychogeriatric Disorders:
AGP Psychopathological Symptoms
Crichton Geriatric Rating Scale
Stockton Geriatric Rating Scale

Treatment Emergent Symptoms : AGP Somatic Signs
Rating Scale for Side Effects
Self-Rating Treatment Emergent Symptom Scale
Abnormal Involuntary Movement Scale
Physical & Neurological Examination for Soft Signs.

1. DIAGNOSTIC SCALES

Children's Diagnostic Scale (CDS)

CHILDREN'S DIAGNOSTIC SCALE (CDS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Children's Diagnostic Scale (CDS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _ Unit Number

(4-6) _ _ _ Study Number

(7-9) _ _ _ Subject Number
Male 001-499
Female 500-999

(10-12) _ _ _ Form Number

(13-15) _ _ _ Assessment Period*

(16-17) _ _ Rater Number

(18-19) _ _ Card Number

(76-80) _ _ _ _ _ Group to which Patient is Assigned

* The first 2 digits are provided for the number and the third one for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202, 3 weeks = 033, pretreatment = 000.

INSTRUCTIONS : Responses should be based on overall psychiatric judgments utilizing all data sources integratively; e.g., school reports, mother's reports, interview data, etc.
Rate current status only. Be sure to answer all items.
Complete at pretreatment only.

	not assessed	not present	very mild	mild	moderate	moderately severe	severe	extremely severe
1. Psychoticism. Gross impairment of relationship with people and environment, bizarre interaction, extreme preoccupation with internal stimuli; responses appear markedly inappropriate to external stimuli and/or displays distinct thinking disorders; neologisms, echolalia, incoherence; confused, irrelevant or tangential content, or confused about reality or morbid or bizarre ideation, delusions, hallucinations, or permeated by loosening of associations, illogical or contradictory assessments. (20)	0	1	2	3	4	5	6	7
2. Anxiety Reaction. Expresses feelings of nervousness, anxiety, unrealistic fears or worries, concern with feelings of inadequacy; inferiority, shyness, obsessions or compulsions. (21)	0	1	2	3	4	5	6	7
3. Withdrawal Reaction. Isolation, seclusiveness, withdrawal, detachment, inability to form close relationships. (22)	0	1	2	3	4	5	6	7
4. Unsocialized Aggressive Behavior. Overtly negative, defiant, hostile, and/or manipulative, evasive, guarded. Attempts to control others; aggressive, antisocial, overwhelmingly selfish. Denial of anxiety and personal responsibility for feelings and acts. Is in hostile conflict with the environments in a variety of social settings (family, school) which do not involve group expression of hostility. (23)	0	1	2	3	4	5	6	7

	not assessed	not present	very mild	mild	moderate	moderately severe	severe	extremely severe
5. Socialized Aggressive Behavior. (24) Is in delinquent or hostile conflict with the environment, primarily in association with members of a gang, rarely on own.	0	1	2	3	4	5	6	7
6. Explosive Aggression. (25) Unable to control appropriately his responses towards peers and/or adults. Physically aggressive, impulsive, often reacts to others before understanding the meaning or motives of their words or actions. Gets into numerous fights. Physically disruptive particularly in classroom where he may hit out at others with little or no provocation.	0	1	2	3	4	5	6	7
7. Chronic Hyperactivity. (26) High and conspicuous level of gross motor activity in a variety of settings such as school, home, stores, office, etc.	0	1	2	3	4	5	6	7
8. Immature and Inadequate Behavior. (27) Variable and poorly organized personality characteristics and coping techniques.	0	1	2	3	4	5	6	7

9. Presence of Gross Organic Impairment.

Do not include impression of minimal brain damage, but use all available examinational data such as neurological tests, EEG, etc. Gross organic impairment refers to findings which lead to a strong influence of anatomical lesions or organic diagnosis, e.g., hemiparesis, cerebral palsy, epilepsy, etc.

0 = no
1 = yes

If YES, specify psychiatric diagnosis (DSM III) in item 12b and/or 12c. Any neurologic diagnosis without associated psychopathology should be specified on the Physical and Neurological Examination form.

(28) _

10. Delirium. Gross acute impairment of orientation (time, place or person) and/or memory, with clouding of sensorium. Unlike Item 9, delirium should imply reversable organic impairment.

0 = No
1 = Yes

If YES, specify psychiatric diagnosis (DSM III) in Item 12b and/or 12c. Any neurologic diagnosis without associated psychopathology should be specified on the Physical and Neurological Examination form.

(29) –

11. Presence of Gross Mental Retardation.

Obvious to the examiner and/or found on psychometric tests. 0 = No

If YES, specify diagnosis in Item 12b and/or 12c. 1 = Yes

(30) –

12. Diagnosis

a) Specify one of the following diagnoses on row 12 OR record any other DSM III diagnosis under (b) and/or (c) below.

1. Schizophrenic disorder
2. Overanxious disorder
3. Undersocialized aggressive disorder
4. Attention deficit disorder with hyperactivity
5. Withdrawal reaction
6. Diagnosis cannot be formulated but significant psychopathology is present
7. No significant psychopathology

(31) –

b) Other diagnosis ≠≠ 1 (32-35) – – – –

c) Other diagnosis ≠≠ 2 (36-39) – – – –

13. Special Symptoms

		No	Yes
a) No symptoms	(40)	1	2
b) Speech disturbance	(41)	1	2
c) Specific learning disturbance	(42)	1	2
d) Tic	(43)	1	2

(13. Special Symptoms		No	yes
e) Other psychomotor disorder	(44)	1	2
f) Disorder of sleep	(45)	1	2
g) Feeding disturbance	(46)	1	2
h) Enuresis	(47)	1	2
i) Encopresis	(48)	1	2
j) Cephalalgia	(49)	1	2
		(70-75)	
DATE		- - | - - | - -	

INFORMATION for USERS

DEVELOPMENT - The CDS is a 13-item original scale developed by members of the Pediatric Psychopharmacology Workshop to explore and clarify some of the nosological problems within this age group. The first 8 items consist of behavioral syndromes to be evaluated on a 7-point scale derived from the adult Brief Psychiatric Rating Scale (BPRS). From the ratings obtained on the eight syndromes, construction of more precise typological entities may hopefully emerge. The remaining 5 items of the CDS are composed of specific diagnostic questions.

APPLICABILITY - Children to 15.

UTILIZATION - Once at pretreatment. May be used at termination at the discretion of the investigator.

TIME SPAN RATED - Current status only.

SPECIAL INSTRUCTIONS

Item 1-8. Descriptions of each of the syndromes are printed on the CDS. Raters should make their judgments within these contexts.

Items 9-11. These 3 items require a present (YES) or absent (NO) judgment. Appropriate diagnoses should be encoded under Items 12b and/or 12c.

Item 12a. The 7 most frequent diagnoses are printed on the CDS.

Items 12b-12c. Diagnoses other than the 7 listed in Item 12a are marked here.

Item 13. One or more of these Special Symptoms may be recorded as "present".

DOCUMENTATION

a. Raw score printout
b. Frequency tables
c. Means and standard deviations
d. Variance analyses.

Hachinski's Ischemic Score (ISCH)

HACHINSKI'S ISCHEMIC SCORE (ISCH)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Hachinski's Ischemic Score (ISCH)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) 1 8 3
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 4 8
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number and the third one for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

Features		yes	no
1. Abrupt onset	(20)	2	0
2. Stepwise deterioration	(21)	1	0
3. Fluctuating course	(22)	2	0
4. Nocturnal confusion	(23)	1	0
5. Relative preservation of personality	(24)	1	0
6. Depression	(25)	1	0
7. Somatic complaints	(26)	1	0
8. Emotional incontinence	(27)	1	0
9. History of hypertension	(28)	1	0
10 History of strokes	(29)	2	0
11 Evidence of associated atherosclerosis	(30)	1	0
12 Focal neurological symptoms	(31)	2	0
13 Foral neurological signs	(32)	2	0
Total score	(33-34)	-	-
	DATE	- -	- - | - -

INFORMATION for USERS

DEVELOPMENT - The ISCH is a 13-item scale, developed by Hachinski with the purpose of distinguishing multi-infarct from primary degenerative dementia.

REFERENCE

. Hachinski, V.C., Iliff L.D., Ziehka E., DuBoulay G.H., McAllister V.L., Marshall J., Russell R.W.R. and Symon L. : Cerebral blood flow in dementia. Arch. Neurol. 22 : 632-637, 1975.

APPLICABILITY - Psychiatric patients with a diagnosis of multi-infarct or primary degenerative dementia.

UTILIZATION - Once per subject.

SPECIAL INSTRUCTIONS - Score each of the 13 features with the score identified on form. By summing scores derive at a total score. Patients with a total score of 7 and above are classed as having multi-infarct dementia; and patients with a total score of 4 and below are classed as primary degenerative dementia.

2. SCALES IN THE ASSESSMENT OF CHANGE

a. All Purpose

Wittenborn Psychiatric Rating Scale (WITT)

WITTENBORN PSYCHIATRIC RATING SCALE (WITT)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Wittenborn Psychiatric Rating Scale (WITT)	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 5 2
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

1. The statements in the rating scales are arranged in steps from 0 (no pathology) through 3 (extreme pathology).
2. For each scale, select the one statement which best describes the most extreme manifestation during the past week.
3. If the behavior is doubtful or variable, select the alternative which is nearer to 3.
4. Rate every item, but base the rating on the specified period of observation only.
5. Record your rating by marking the appropriate response position on the - - -

I. ANXIETY

1. Threatened by Task	0 = Does not express any feeling of anxiety when confronted with a task, a test or new situation. 1 = When confronted with a task, a test or a new situation, the patient admits anxiety experiences. 2 = When confronted with a task, a test or a new situation, the patient admits anxiety experiences, and quality of performance is adversely affected. 3 = Feels threatened by a task, or new situation, and shows failure and blocking.	(20)
2. Sense of Foreboding	0 = Does not complain of premonitory experiences or any sense of foreboding. 1 = Has vague feelings of foreboding or misfortune. 2 = Has definite feeling that something is going to happen which will involve him or his family (but there is no evidence upon which to base a prediction). 3 = Definite feelings of impending, inescapable, personal doom or catastrophe (but there is no apparent basis for this strong fear).	(21)
3. Guilt	0 = No evidence that patient considers himself to be particularly unworthy or blameworthy. 1 = Patient tends to blame himself or refer to his unworthiness. 2 = Patient blames and criticizes self to an unrealistic and inappropriate degree. 3 = Patient appears to have a delusional belief that he is an extraordinarily evil, unworthy or guilty person.	(22)

	(I. Anxiety cont)	
4. Subjective Anxiety	0 = No complaint of subjectively experienced anxiety.	
	1 = Experiences at least minor feelings of anxiety.	
	2 = Experiences anxiety which is strong enough to make him express acutely uncomfortable feelings.	
	3 = Is desperately distressed by his anxiety and considers it to be intolerable.	(23) _
	II. SOMATIC-HYSTERICAL	
5. Attention Demanding	0 = Does not appear to be attention-demanding.	
	1 = In conversation, usually brings attention of others to his own role.	
	2 = Engages insistently in description of own role or difficulties.	(24) _
	3 = Dramatically attention-demanding.	
6. Uses Symptoms	0 = No discernible psychological use made of physical disease symptoms.	
	1 = Use is made of physical disease symptoms to gain attention or dramatize self.	
	2 = Use is made of physical disease symptoms for evading responsibilities, justifying failures, etc.	(25) _
7. Organic Involvement	0 = Presents no complaint or symptoms of organic pathology or malfunctioning	
	1 = Presents symptoms of organic pathology or malfunctioning which was not caused by emotional factors.	
	2 = Presents organic pathology or malfunctioning which may be caused in part or greatly aggravated by emotional factors.	
	3 = Presents organic pathology or malfunctioning which probably was caused by emotional factors.	(26) _
	III. OBSESSIVE COMPULSIVE-PHOBIC	
8. Phobic	0 = No complaint of phobias or phobic reactions (i.e., specific isolated, inappropriate fears).	
	1 = Patient experiences phobic reactions in certain situations.	
	2 = Phobic reactions have affected patient's current behavior.	
	3 = Patient's behavior is greatly disrupted or delimited by his phobies.	(27) _

(III. Obsessive Compulsive-Phobic cont)		
9. Obsessive	0 = No evidence for obsessional (repetitive, stereotyped) thinking. 1 = Obsessive thoughts recur but can be banished without difficulty. 2 = Patient is able to banish obsessive thoughts, but only with difficulty. 3 = Cannot be banished or control obsessive thoughts.	(28)
10. Compulsive	0 = No evidence of compulsive (repetitive, non-adaptive, uneconomical) behavior. 1 = Acts judged to be compulsive are performed from time to time but not every day. 2 = Compulsive acts occur daily. 3 = Compulsive acts are practically continuous.	(29)
IV. DEPRESSIVE RETARDATION		
11. Indecisive	0 = No evidence of difficulty in making decisions. 1 = Reports uncertainty and postponement of decisions. 2 = Cannot make decisions without advice or pressure. 3 = Cannot make decisions.	(30)
12. Avoids People	0 = No evidence of social withdrawal. 1 = Does not appear to seek out the company of other people. 2 = Avoids many people. 3 = Attempts to avoid almost all people.	(31)
13. Motoric Retardation	0 = No evidence of slowing of responses. 1 = Actions have a deliberate quality. No evidence of haste. 2 = Overt responses are slow and may appear to be delayed. 3 = All overt activity is at a minimum. Patient loath to move and all motions tend to be tediously slow.	(32)

	V. EXCITEMENT	
14. Overactive	0 = Is not particularly overactive. 1 = Moderately overactive, e.g., toys with objects, frequently changes his sitting position, etc. 2 = Noticeably restless. 3 = In almost constant movement.	(33) _
15. Irrelevant Words	0 = Does not use words in an obscure or irrelevant manner. 1 = Words not always clearly relevant to recognizable idea. 2 = Words used in such a manner that idea seems unclear and confused. 3 = Words not relevant to any recognizable, logical idea.	(34) _
	VI. PARANOIA	
16. Misinterprets Others	0 = No evidence that he misconstrues the intentions of others. 1 = May exaggerate the intentions of others. 2 = May seriously misinterpret the intentions of others. 3 = Arbitrarily misinterprets the intentions of others, apparently to conform with his delusional beliefs.	(35) _
17. Ideas of Influence	0 = No evidence that patient feels that others seek to spy upon or control his behavior or thought. 1 = Wonders if others have a particular interest in or desire to know about his thoughts or behavior. 2 = Wonders if others attempt to influence his behavior in some unknown manner or attempt to control his thoughts. 3 = Believes that others influence his behavior in some strange manner or control his thoughts.	(36) _
	DATE	(70-75) _ _ | _ _ | _ _

X

INFORMATION for USERS

DEVELOPMENT - The WITT is a 17-item scale, developed from the longer 72-item Wittenborn scale in response to the need for a brief assessment procedure to ascertain the rate and nature of symptomatic change. With one exception, items are rated on a 4-point scale.

REFERENCE - Wittenborn J.R., Manual : Wittenborn Psychiatric Rating Scales, 1955, Psychological Corporation, New York.

APPLICABILITY - Inpatient and outpatient adult populations.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the principal investigator.

TIME SPAN RATED - Now or during the past week.

SPECIAL INSTRUCTIONS

A. The Rating Procedure

1. It is necessary that the observational period on which the ratings are based be scrupulously defined and that the limits of this observational period be recorded in the appropriate space on the face sheet.
2. It is necessary that a rating be indicated for every scale. If there is no information on which to base a rating, the initial or least severe level is the appropriate rating.
3. The rating should always be the most pathological extreme observed during the rating period. Ratings should not be based on an average or general condition of the patient.
4. When informants are consulted as a basis for rating, the identity or the role of the informant should be recorded.
5. Wherever possible, a diagnosis should be indicated in the appropriate space. Because of the episodic and variable nature of psychopathological manifestations, it is understood that the diagnosis of the patient and the symptoms which are rated as currently descriptive may not always be consistent.

B. The Rater

1. Familiarity with the rating scales is an important determiner of the speed and ease with which ratings may be made. The rater should anticipate that

his initial experiences with the rating scales will seem tedious and time-consuming.

2. Most professionally trained raters, particularly psychiatrists, psychologists and social workers will be able to use the rating scales without personal instruction. In a research team, where standardization can be critical, it is useful for beginners to review their initial ratings with other members of the group.

3. Raters not professionally trained in psychopathology, e.g., occupational therapists, nursing personnel or other ward personnel, should have at least their first 6 rating forms reviewed by a professionally trained person who shares their knowledge of the patient. Although the language of the scales is simple, it involves conceptual and terminological usages which may be unfamiliar to nonprofessional raters, or at best only partially understood by them.

4. Almost any careful observer can be trained to make satisfactory ratings based on inpatient situations. Ordinarily, outpatient ratings should be provided only by professionally trained persons who are well acquainted with the patient.

C. The Observational Setting

Almost any standard observational setting can provide a useful basis for symptom ratings. For interpretive purposes, however, it is important that the observational setting be recorded on the face sheet of the form.

The observational setting which provides the most useful ratings will depend upon the manner in which the setting is used and the purposes of the assessment. In general, the ratings of psychiatrists and psychologists show very slight average differences. The ratings of nurses tend to be consistently different from those of psychiatrists, particularly in the sense that nurses' ratings will contain fewer indications of affective or conceptual deviation, but will emphasize matters relevant to ward routine, particularly matters concerning the patient's cooperation and participation.

Ratings by different personnel will differ according to the observational basis for the rating. Thus, ratings of the same patient by two different raters should be expected to differ somewhat unless the two raters are observing at the same time. Accordingly, differences between raters describing the same patient have no necessary implications for either the validity or the reliability of the scales and may reflect differences in the behavior sample on which the ratings

are based.

Where a fully comprehensive description is imperative, independent ratings by the psychiatrist, the psychologist, and the nurse should be sought. Scale by scale the different ratings from these persons may then be reconciled and combined by selecting as most valid the one rating which shows the greatest pathological extreme. The appropriateness of this procedure is based on the assumption that the most pathological manifestation is the most pertinent basis for the rating and on the further assumption that an observation of an extreme pathological manifestation is a valid basis for a descriptive rating, regardless of whether the observation was made by the nurse, the psychologist or the psychiatrist.

FACTOR COMPOSITION

Factor I - Anxiety

1. Threatened by task
2. Sense of foreboding
3. Guilt
4. Subjective anxiety

Factor II - Somatic-Hysterical

5. Attention demanding
6. Uses symptoms
7. Organic involvement

Factor III - Obsessive-Compulsive-Phobic

8. Phobic
9. Obsessive
10 Compulsive

Factor IV - Depressive Retardation

11. Indecisive
12. Avoids people
13. Motoric retardation

Factor V - Excitement

14. Overactive
15. Irrelevant words

Factor VI - Paranoia

16. Misinterprets others
17. Ideas of influence

$$\text{Factor Score} = \frac{\text{Sum of composite items}}{\text{No. of composite items}}$$

Factor score range = 0-4

Total Score = Sum of all items

Total score range = 0-68

DOCUMENTATION

a. Raw score printout
b. Factor score printout
c. Means and standard deviations for factor scores
d. Cross tabulations
e. Variance analyses.

Fischer Symptom Check List (FSCL)

FISCHER SYMPTOM CHECK LIST (FSCL)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Fischer Symptom Check List (FSCL)	Name of Rater

(1-3) _ _ _ Unit Number	(4-6) _ _ _ Study Number	(7-9) _ _ _ Subject Number Male 001-499 Female 500-999	(10-12) 2 5 4 Form Number
(13-15) _ _ (_) Assessment Period*	(16-17) _ _ Rater Number	(18-19) _ _ Card Number	(76-80) _ _ _ _ _ Group to which Patient is assigned

*The first 2 digits are provided for the number and the third for the unit of time.

Time units : pretreatment = 0, hours = 1, days = 2, weeks = 3, months = 4

Example : 20 days = 202, 3 weeks = 033, pretreatment = 000.

INSTRUCTIONS : Fill in the form after a non-suggestive, semi-structured interview (keyed to the items). Time span rated status at control day or maximally period since last rating. At pre-treatment now or within the last week.

Always cross one number		absent	mild	medium	severe
Mood / Affectivity					
Dejection/sadness	(20)	0	1	2	3
Feelings of hopelessness	(21)	0	1	2	3
Feelings of joylessness, anhedonia	(22)	0	1	2	3
Diminished affect	(23)	0	1	2	3
Feelings of asthenia	(24)	0	1	2	3
Feelings of inadequacy	(25)	0	1	2	3
Self reproach/guilt feelings	(26)	0	1	2	3
Daily Fluctuations/Diurnal Variation					
Worse in the morning	(27)	0	1	2	3
Worse at night	(28)	0	1	2	3
Anxiety / Fear					
Feelings of oppression	(29)	0	1	2	3
Feelings of pain	(30)	0	1	2	3
Diffuse anxiety, anxious feeling	(31)	0	1	2	3
Object-related fear	(32)	0	1	2	3
Tension	(33)	0	1	2	3
Inner restlessness	(34)	0	1	2	3
Sleep					
Disturbed onset of sleep (difficulty falling asleep)	(35)	0	1	2	3
Interrupted sleep	(36)	0	1	2	3
Early morning wakening	(37)	0	1	2	3
Psychomotor Activity					
Retardation/slowing	(38)	0	1	2	3
Agitation/overactivity	(39)	0	1	2	3
Thought Process					
Thought retardation	(40)	0	1	2	3
Impairment of concentration	(41)	0	1	2	3
Impairment of recent memory	(42)	0	1	2	3
Disturbed orientation	(43)	0	1	2	3
Thought Contents					
Hypochondriasis	(44)	0	1	2	3
Obsessional thoughts, acts	(45)	0	1	2	3

(Thought Contents, cont'd)		absent	mild	medium	severe
Phobias	(46)	0	1	2	3
Lack of insight into illness	(47)	0	1	2	3
Death wishes	(48)	0	1	2	3
Suicidal thoughts	(49)	0	1	2	3
Attempted suicide	(50)	0	1	2	3
Delusional ideas, experiences	(51)	0	1	2	3
Social Behavior					
Impaired social contact	(52)	0	1	2	3
Lack of interest	(53)	0	1	2	3
Social maladaptation	(54)	0	1	2	3
Impaired capacity work purposeful actions	(55)	0	1	2	3
Self-care impairment	(56)	0	1	2	3
Lack of cooperation	(57)	0	1	2	3
Aggressive behavior (verbal or active)	(58)	0	1	2	3
Autoaggressive impulse/action	(59)	0	1	2	3
Decrease in libido, potency	(60)	0	1	2	3

Total sum of 41 symptoms	(61-63) - - -
External stress (social environment)	(64) 0 1 2 3
other symptoms No 0 Yes 1	(65)
Which (print) :	
- -	(66) 0 1 2 3
- -	(67) 0 1 2 3
- -	(68) 0 1 2 3
- -	(69) 0 1 2 3
DATE	(70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The FSCL is a 41-item scale rated on a 4-point scale.

REFERENCE - Fischer-Cornelssen KA : The FSCL. CIPS Booklet (Collegium Internationale Psychiatriae Scalarum), Beltz Publ., Weinheim FRG, 2nd edition, 99-106, 1981.

APPLICABILITY - Inpatient and outpatient adult populations.

UTILIZATION - Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now, or during the past week, or at a maximum period since the last rating.

SPECIAL INSTRUCTIONS

The rater estimates the severity of the 41 symptoms on the basis of a non-suggestive, semi-structured interview following the items on the checklist (in sequence). Information obtained from nursing staff etc. and relatives can also be considered in the time span mentioned.

FACTOR STRUCTURE

I. Retardation-Depression

1. dejection, sadness
2. feelings of hopelessness
3. feelings of joylessness, anhedonia
4. diminished affect
6. feelings of inadequacy
7. self-reproach, guilt feelings
19 psychomotor retardation
21 thought retardation
22 impairment of concentration
32 delusional ideas/depressive
33. impaired social contact
34. lack of interest
35. social maladaptation
41. decrease in libido, potency

II. Anxiety-Agitation

12. diffuse anxiety
14. tension
16. difficulty falling asleep
17. interrupted sleep
20. agitation
39. aggressive behavior

III. Hypochondriasis

8. worse in the morning
10. feelings of oppression
11. feelings of pain
25. hypochondriasis

IV. Suicide

29. death wishes
30. suicidal thoughts
31. attempted suicide

V. Phobias/Obsessions

13. object-related fear
26. obsessional thoughts
27. phobias

$$\text{Factor score} = \frac{\text{Sum of scores of composite items}}{\text{No. of composite items}}$$

Cluster groups score range = 0 - 27

Total score = sum of all items = 0 - 123

DOCUMENTATION

a. Raw score printout
b. Cluster group score printout
c. Means and standard deviations
d. Cross tabulations
e. Variance analyses.

b. ANXIETY DISORDERS

Sheehan Scales

Sheehan Clinician Rated Anxiety Scale (SCRAS)

Panic & Anxiety Attack Scale (PAAS)

Phobia Scale (PS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Sheehan Clinician Rated Anxiety Scale (SCRAS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 5 6
Form Number

(13-15) _ _ _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS : Fill in the appropriate box. In rating, consider : 1) frequency 2) severity of average symptoms 3) description of last significant occurred.

HOW SEVERE HAS THE PATIENT'S SYMPTOM BEEN OVER THE PAST WEEK

		absent	mild	moderate	severe	very severe
1. Spells of dizziness/faintness, lightheadedness	(20)	0	1	2	3	4
2. Spells of rubbery legs	(21)	0	1	2	3	4
3. Spells of imbalance	(22)	0	1	2	3	4
4. Spells of dyspnea/hyperventilation	(23)	0	1	2	3	4
5. Spells of PVC's/tachycardia	(24)	0	1	2	3	4
6. Chest pain/pressure	(25)	0	1	2	3	4
7. Spells of choking sensation/lump in throat	(26)	0	1	2	3	4
8. Spells of paresthesias/numbness	(27)	0	1	2	3	4
9. Hot or cold spells	(28)	0	1	2	3	4
10. Nausea	(29)	0	1	2	3	4
11. Diarrhea	(30)	0	1	2	3	4
12. Pains in head/neck/back	(31)	0	1	2	3	4
13. Tires easily	(32)	0	1	2	3	4
14. Spells of increased sensitivity to sound, light, touch (startle)	(33)	0	1	2	3	4
15. Sweating	(34)	0	1	2	3	4
16. Derealization	(35)	0	1	2	3	4
17. Depersonalisation	(36)	0	1	2	3	4
18. Hypochondriasis	(37)	0	1	2	3	4
19. Feeling of mental decompensation (self control/sanity)	(38)	0	1	2	3	4
20. Spells of fear of dying or impending disaster	(39)	0	1	2	3	4
21. Spells of tremor/shaking	(40)	0	1	2	3	4
22. Waves of depression with little or no provocation	(41)	0	1	2	3	4
23. Emotional lability	(42)	0	1	2	3	4

How Severe has the Patient's Symptom been over the Past Week		absent	mild	moderate	severe	very severe
24. Dependent on others	(43)	0	1	2	3	4
25. Compulsive rituals	(44)	0	1	2	3	4
26. Obsessive thoughts	(45)	0	1	2	3	4
27. Initial insomnia	(46)	0	1	2	3	4
28. Middle insomnia	(47)	0	1	2	3	4
29. Phobias	(48)	0	1	2	3	4
30. Tension/nervousness/anxiety	(49)	0	1	2	3	4
31. Signs of anxiety at interview (tremor, facial pallor, dilated pupils, respiration or sighing, restlessness, fidgety, swallowing, burping, ↑ pitch and speed of speech)	(50)	0	1	2	3	4
32. Spontaneous panic attacks - Major attacks + (3+ symptoms)	(51)	0	1	2	3	4
33. Spontaneous anxiety or symptom attacks - Minor attacks (1-2 symptoms)	(52)	0	1	2	3	4
34. Anticipatory anxiety attacks	(53)	0	1	2	3	4

	(70-75)		
DATE	- -	- -	- -

PANIC & ANXIETY ATTACK SCALE (PAAS) - SHEEHAN

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Panic & Anxiety Attack Scale (PAAS) - Sheehan	Name of Rater

(1-3) _ _ _ Unit Number	(4-6) _ _ _ Study Number	(7-9) _ _ _ Subject Number Male 001-499 Female 500-999	(10-12) 2 5 8 Form Number
(13-15) _ _ _ Assessment Period*	(16-17) _ _ Rater Number	(18-19) 0 1 Card Number	(76-80) _ _ _ _ _ Group to which Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000

INSTRUCTIONS : Write the number in the appropriate box.

1. Sudden anxiety attacks with 3 or more symptoms that occur with little or no provocation		
a. Number in past week	(20-22)	_ _ _
b. Number in past month	(23-25)	- - -
c. Average duration (mins) (or enter "999" if anxiety lasts as long as you are exposed to phobia)	(26-28)	- - -
d. Average intensity (0 None - 10 Maximum)	(29-30)	- -
2. Sudden anxiety attacks with only 1 or 2 symptoms that occur with little or no provocation		
a. Number in past week	(31-33)	- - -
b. Number in past month	(34-36)	- - -
c. Average duration (mins) (or enter "999" if anxiety lasts as long as you are exposed to phobia)	(37-39)	- - -
d. Average intensity (0 None - 10 Maximum)	(40-41)	- -
3. Anxiety episodes that occur in anticipation of (before) facing a phobia (anticipatory anxiety episodes)		
a. Number in past week	(42-44)	- - -
b. Number in past month	(45-47)	- - -
c. Average duration (mins) (or enter "999" if anxiety lasts as long as you are exposed to phobia)	(48-50)	- - -
d. Average intensity (0 None - 10 Maximum)	(51-52)	- -
DATE	(70-75)	- - | - - | - -

PHOBIA SCALE (PS) - Marks-Sheehan

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Phobia Scale (PS) - Marks-Sheehan	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 5 7
Form Number

(13-15) _ _ | (13) _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

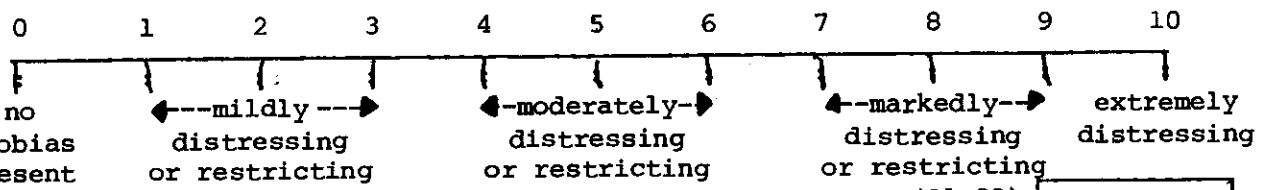
* The first 2 digits are provided for the number and the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000

How much do you fear and avoid												
6. Large open spaces	Fear Score (44-45)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (46)	0	1	2	3	4						
7. Feeling trapped or caught in closed spaces	Fear Score (47-48)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (49)	0	1	2	3	4						
8. Being left alone	Fear Score (50-51)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (52)	0	1	2	3	4						
9. The thought of physical injury or illness	Fear Score (53-54)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (55)	0	1	2	3	4						
10 Hearing or reading about health topics or disease	Fear Score (56-57)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (58)	0	1	2	3	4						
11 Eating, drinking or writing in public	Fear Score (59-60)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (61)	0	1	2	3	4						
12 Being watched or talked about or being the focus of attention	Fear Score (62-63)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (64)	0	1	2	3	4						
13 Being with others, because you are very self-conscious	Fear Score (65-66)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (67)	0	1	2	3	4						
14 Specific situations other than those listed above that frighten you	Fear Score (68-69)	0	1	2	3	4	5	6	7	8	9	10
	Avoidance (70)	0	1	2	3	4						
15 Specify furthest distance you can go alone									(71-73)		- -	-
1 = Yards 2 = Miles									(20)*		1	2

How would you rate the present state of your phobic symptoms overall on the scale below ? Write in the box the number you select



(21-22) ___ ___

DATE (70-75) _ _ | _ _ | _ _

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* Card no 02

Physician Questionnaire (PHYS)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Physician Questionnaire (PHYS)	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 0 8
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number and the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000

		not present	very mild	mild	moderate	moderately severe	severe	extremely severe
1. Anxiety (Apprehensive, tense, worried, frightened, anxious, nervous)	(20)	1	2	3	4	5	6	7
2. Depressive ood (Feelings of depression, unhappiness; sorrow, pessimism, sadness; hopelessness, tearfulness)	(21)	1	2	3	4	5	6	7
3. Irritability (Easily annoyed or angered)	(22)	1	2	3	4	5	6	7
4. Hostility (Expression of anger toward others)	(23)	1	2	3	4	5	6	7
5. Phobia-Obsession-Compulsion (Unrealistic fears, repetitive unwanted thoughts or actions)	(24)	1	2	3	4	5	6	7
6. Hypochondriasis (Preoccupation with physical health)	(25)	1	2	3	4	5	6	7
7. Somatization (Number and intensity of somatic and autonomic symptoms, [excluding headaches], backache, GI, sweating, trembling, dizziness, heart palpitations, etc.)	(26)	1	2	3	4	5	6	7
8. Insomnia	(27)	1	2	3	4	5	6	7
9. Appetite Disturbance ecreased ___ 1 (29) ncreased ___ 2	(28)	1	2	3	4	5	6	7
10. Headache (Frequency and intensity)	(30)	1	2	3	4	5	6	7
11. Psychomotor etardation (Slowness of thought, speech, motor activity)	(31)	1	2	3	4	5	6	7
12. Fatigue, tiredness, lethargy	(32)	1	2	3	4	5	6	7
13. Impairment of interpersonal relationships (Home, work, social)	(33)	1	2	3	4	5	6	7

		Not ill	Very Mild	Mild	Moderate	Severe	Severe	Extremely Severe
		1	2	3	4	5	6	7
14. Degree of Global Psychopathology (OGP) How ill is this patient now, compared to your experience with other neurotic patients?	(34)							

(70-75)
- - - - - -

Date

INFORMATION for USERS

DEVELOPMENT - The PHYS consists of 13 items plus a global rating of psychopathology. The original version of the scale consisted of the first 10 items and the "global". The PHYS was developed by Rickels and Howard as a simple measure of neurotic symptomatology and focussed on commonly observed symptoms familiar to non-psychiatric physicians. The scale has proved sensitive to changes occuring under drug treatment.

REFERENCE - Rickels,K. and Howard,K., The Physician Questionnaire: A Useful Tool in Psychiatric Drug Research, Psychopharmacologia, 17, 338-344, 1970.

APPLICABILITY - Neurotic outpatients.

UTILIZATION - Once at pretreatment; at least once at posttreatment. Additional assessments are at the investigator's discretion.

TIME SPAN RATED - Now or within the last week.

FACTOR COMPOSITION

Factor 1 - Anxiety
1. Anxiety
3. Irritability
4. Hostility
5. Phobia

Factor 2 - Somatic Concern
6. Hypochondriasis
7. Somatization

Factor 3 - Depression
2. Depressive mood
8. Insomnia
9. Appetite disturbance
10. Headaches

DOCUMENTATION
a. Raw score printout
b. Factor and cluster score printout
c. Factor means and standard deviations
d. Variance analyses.

Brief Outpatient Psychopathology (BOPS)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Brief Outpatient Psychopathology (BOPS)	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 1 1
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.

Time units : pretreatment = 0, hours = 1; days = 2; weeks = 3; months = 4

Example = 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

The symptoms below are described by physical signs observed and/or discomforts expressed by patients. Please use individual descriptions to orient your ratings.

		absent	very mild	mild	moderate	severe	disabling
1. Anxiety. Experiencing subjective feelings such as worry, fears of surroundings, apprehension of the future.	(20)	0	1	2	3	4	5
2. Depressive mood. Sadness, despondence, feeling helpless and/or hopeless.	(21)	0	1	2	3	4	5
3. Hyperactivity. Energy spent excessively in rapid, frequent movements.	(22)	0	1	2	3	4	5
4. Psychophysiologic disturbances. Headaches, gastrointestinal upset, respiratory effects, cardiovascular effects.	(23)	0	1	2	3	4	5
5. Tension. Subjective feeling of being wound up, taut energy pressing for release, sensing explosive potential.	(24)	0	1	2	3	4	5
6. Uneasiness. Ill at ease, sensitive to criticism, emotionally upset.	(25)	0	1	2	3	4	5
7. Guilt feelings. Concern, distress or remorse for personal activities in the past.	(26)	0	1	2	3	4	5
8. Feeling of inferiority. Feelings of inadequacy, negative self-image, loss of confidence.	(27)	0	1	2	3	4	5
9. Loss of interest. Reduced desire to work or participate in activities.	(28)	0	1	2	3	4	5
10. Agitation. Restlessness, fidgeting, shifting, pacing.	(29)	0	1	2	3	4	5
11. Motor disturbance. Involuntary muscular movements, tremor or other manifestations of nervousness that interfere with purposeful activity.	(30)	0	1	2	3	4	5
12. Fatigue. Constantly feeling tired, washed out, lacking energy.	(31)	0	1	2	3	4	5
13. Hypochondriasis. Vague somatic complaints, malaise, unsupported complaints of physical illness.	(32)	0	1	2	3	4	5

		absent	very mild	mild	moderate	severe	disabling
14. Skeletal muscular discomfort. Complaints of aches and pains of muscles and joints.	(33)	0	1	2	3	4	5
15. Sleep disturbance. Insomnia, cannot go to sleep, irregular sleep pattern, or early awakening.	(34)	0	1	2	3	4	5
	DATE		(70-75) - - | - - | - -				

INFORMATION for USERS

DEVELOPMENT - Revised from the Physician's Rating List and renamed, the BOPS has been designed to assess the primary symptom dimensions of outpatient psychopathology. Consisting of 15 items which were clinically derived from the factors of several standard rating scales, the BOPS employs generally familiar concepts and is suitable for rating by persons who are not specifically mental health professionals.

REFERENCES - 1. Free, S.M., and Guthrie, M.B., A Rating Scale for Evaluating Clinical Response in Psychoneurotic Outpatients, J. Clin. Pharmacol., 9, 3, 187-194, May-June, 1969.

2. Free, S.M., Factor Analysis of Outpatient Clinical Data, J. Clin. Pharmacol., 9, 3, 195-199, May-June, 1969.

3. Overall, J., Psychometric Characteristics of the Physicians Rating List, Psychometric Laboratory Reports, University of Texas Medical Branch, Galveston, June, 1971.

APPLICABILITY - Psychoneurotic outpatient adults.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - None specified by authors. Suggest "now or within last week".

FACTOR COMPOSITION - This factor composition is based on a recent analysis of the ratings obtained from 328 outpatients (Overall and Free, Personal Communication, 1976, to be published).

1. Anxiety
   1. Anxiety
   5. Tension
   6. Uneasiness
2. Depression
   2. Depressive mood
   7. Guilt feelings
   8. Feelings of inferiority
   9. Loss of interest
3. Psychomotor activity
   3. Hyperactivity
   10. Agitation
   11. Motor disturbance
4. Somatization
   4. Psychophysiological disturbances
   13. Hypochondriasis
   14. Skeletal muscular discomfort

Items not included in factor structure : 12, 15.

Total score = Sum of 15 items. Total score range = 0 - 75.

DOCUMENTATION

a. Raw score printout

b. Factor score printout

c. Factor means and standard deviations

d. Variance analyses.

Anxiety Status Inventory (ASI)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Anxiety Status Inventory (ASI) - Wm. W.K. Zung	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 5 1
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

The data upon which the judgments are based come from the interview with the patient The items in the scale are to be quantified by using all the information available to the rater. This includes both clinical observation and the material reported by the patient.

Use of the Interview Guide below assures coverage of all the areas on which judgments are required. However, the rater has the flexibility of modifying the questions or probing for details, which makes possible a smooth interview that does not sound like a question-answer examination. In rating the patient's current status, an arbitrary period of 1 week prior to the evaluation is adopted in order to standardize the data. In order to reinforce this, the interviewer should occasionally precede questions with "During the past week, have you..?".

Affective and somatic symptoms of anxiety	Interview guide for anxiety status inventory (ASI)	none	mild	moderate	severe
1. Anxiousness	(20) Do you ever feel nervous and anxious?	0	1	2	3
2. Fear	Have you ever felt afraid ? (21)	0	1	2	3
3. Panic	(22) How easily do you get upset? Ever have panic spells or feel like it ?	0	1	2	3
4. Mental disintegration	(23) Do you ever feel like you are falling apart ? Going to pieces ?	0	1	2	3
5. Apprehension	(24) Have you ever felt uneasy? Or that something terrible was going to happen ?	0	1	2	3
6. Tremors	(25) Have you had times when you felt yourself trembling ? Shaking ?	0	1	2	3
7. Body aches and pains	(26) Do you have headaches ? Neck or back pains ?	0	1	2	3
8. Easy fatigability, weakness	(27) How easily do you get tired ? Ever have spells of weakness ?	0	1	2	3
9. Restlessness	(28) Do you find yourself restless and can't sit still ?	0	1	2	3
10. Palpitation	(29) Have you ever felt that your heart was running away ?	0	1	2	3
11. Dizziness	(30) Do you ever have dizzy spells ?	0	1	2	3
12. Faintness	(31) Do you have fainting spells ? Or feel like it ?	0	1	2	3

			none	mild	mode rate	severe
13. Dyspnea	Ever have trouble with your breathing ?	(32)	0	1	2	3
14. Paresthesias	Ever have feelings of numbness and tingling in your fingertips ? Or around your mouth ?	(33)	0	1	2	3
15. Nausea and vomiting	Do you ever feel sick to your stomach or feel like vomiting ?	(34)	0	1	2	3
16. Urinary frequency	How often do you need to empty your bladder ?	(35)	0	1	2	3
17. Sweating	Do you ever get wet, clammy hands?	(36)	0	1	2	3
18. Face flushing	Do you ever feel your face getting hot and blushing ?	(37)	0	1	2	3
19. Insomnia - initial	How have you been sleeping ?	(38)	0	1	2	3
20. Nightmares	Do you have dreams that scare you?	(39)	0	1	2	3

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Developed by Zung, the Anxiety Status Inventory (ASI) is a 20-item 4-point scale, the clinician-rated counterpart of the Self-Rating Anxiety Scale (SAS). The ASI along with the SAS were designed specifically for the assessment of anxiety as a clinical disorder rather than as a trait or feeling state. Zung reports a product-moment correlation of .74 between the ASI and SAS for patients with diagnoses of anxiety neurosis (N = 22).

REFERENCE - Zung, W. K.: A Rating Instrument for Anxiety Disorders, Psychosomatics, 12 : 371-379, Nov.-Dec., 1971

APPLICABILITY - Adults with diagnoses of anxiety neurosis.

UTILIZATION - Once at pretreatment, at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or in the week prior to evaluation.

SPECIAL INSTRUCTIONS

The items in the scale are to be quantified by using all the information available to the rater. This includes both clinical observations and the material reported by the patient. In making judgments, the following rules should be observed.

1. Each item should be independently rated as a unit by itself in order to eliminate any "halo" effect.
2. Each score should be the average of the full range of responses observed or elicited, and not necessarily the extreme in severity.
3. The items are judged on a 4-point system, taking into account severity in terms of : intensity, duration, and frequency. These are defined as follows :

   1 = none or insignificant in intensity or duration, present none or a little of the time in frequency.
   2 = mild in intensity or duration, present some of the time in frequency.
   3 = of moderate severity, present a good part of the time in frequency.
   4 = severe in intensity or duration, present most or all the time in frequency.

   To help establish severity, the following questions may be necessary :

Intensity : "How bad was it ?" - Duration : "How long did it last ?" - Frequency : "How much of the time did you feel that way ?"

4. An item is scored positive and present when :
   a. Behavior is observed
   b. Behavior was described by the patient as having occured
   c. Patient admits that symptom is still a problem.

5. An item is scored negative and not present when :
   a. Symptom has not occured and not a problem or present
   b. Patient gives no information relevant to an item
   c. Response is ambiguous even after suitable probing.

Z SCORE - The Z score for the ASI is derived by dividing the sum of the raw item scores by the maximum possible score (80) multiplied by 100. See Table XIX for the conversion of raw scores to ASI and SAS indices. Zung has provided the following mean Z scores and standard deviations for 5 diagnostic groups :

Diagnosis	N	MN	
Anxiety disorder	22	62.0	13.8**
Schizophrenia	25	49.4	15.9
Depressive disorder	96	49.9	12.5
Personality disorder	54	52.6	13.6
Transient situational disturbances	12	42.0	8.1

** Significantly different from other 4 groups (p = .05)

TABLE XIX

The Conversion of Raw Scores to ASI and SAS Indices

Raw Score	ASI & SAS Index	Raw Score	ASI & SAS Index	Raw Score	ASI & SAS Index
20	25	40	50	60	75
21	26	41	51	61	76
22	28	42	53	62	78
23	29	43	54	63	79
24	30	44	55	64	80
25	31	45	56	65	81
26	33	46	58	66	83
27	34	47	59	67	84
28	35	48	60	68	85
29	36	49	61	69	86
30	38	50	63	70	88
31	39	51	64	71	89
32	40	52	65	72	90
33	41	53	66	73	91
34	43	54	68	74	92
35	44	55	69	75	94
36	45	56	70	76	95
37	46	57	71	77	96
38	48	58	73	78	98
39	49	59	74	79	99
				80	100

DOCUMENTATION

a. Raw score printout

b. Index score printout

c. Means and standard deviations of index scores

d. Variance analyses

Self-Rating Anxiety Scale (SAS)

SELF-RATING ANXIETY SCALE (SAS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Self-Rating Anxiety Scale (SAS) - Wm. W.K. Zung

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 5 4
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

Listed below are 20 statements. Please read each one carefully and decide how much of the statement describes how you have been feeling during the past week. Decide whether the statement applies to you NONE OR A LITTLE OF THE TIME, SOME OF THE TIME, A GOOD PART OF THE TIME, OR MOST OR ALL OF THE TIME. Mark the appropriate column for each statement.

	None or a little of the time	Some of the time	A good part of the time	Most or all of the time
1. I feel more nervous and anxious than usual (20)	1	2	3	4
2. I feel afraid for no reason at all (21)	1	2	3	4
3. I get upset easily or feel panicky (22)	1	2	3	4
4. I feel like I am falling apart and going to pieces (23)	1	2	3	4
5. I feel that everything is all right and nothing bad will happen (24)	1	2	3	4
6. My arms and legs shake and tremble (25)	1	2	3	4
7. I am bothered by headaches, neck and back pains (26)	1	2	3	4
8. I feel weak and get tired easily (27)	1	2	3	4
9. I feel calm and can sit still easily (28)	1	2	3	4
10. I can feel my heart beating fast (29)	1	2	3	4
11. I am bothered by dizzy spells (30)	1	2	3	4
12. I have fainting spells or feel like it (31)	1	2	3	4
13. I can breathe in and out easily (32)	1	2	3	4
14. I get feelings of numbness and tingling in my fingers, toes (33)	1	2	3	4
15. I am bothered by stomach aches or indigestion (34)	1	2	3	4
16. I have to empty my bladder often (35)	1	2	3	4
17. My hands are usually dry and warm (36)	1	2	3	4
18. My face gets hot and blushes (37)	1	2	3	4
19. I fall asleep easily and get a good night's rest (38)	1	2	3	4
20. I have nightmares (39) (40)	1	2	3	4

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Zung's Self-Rating Anxiety Scale (SAS) is a 20-item scale in which the subject rates his symptomatology on a 4-point scale of severity.

REFERENCE - Zung, Wm. W. K., A Rating Instrument for Anxiety Disorders, Psychosomatics, 12, 371-379, Nov-Dec., 1971.

APPLICABILITY - Adults with symptoms of anxiety.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - One week prior to rating.

SPECIAL INSTRUCTIONS - The rater should make certain that the subject fully understand the task and the correct method of recording his responses. When the subject finishes, the rater should check all items for omissions or multiple marks. Unless clinically inadvisable, the rater should urge subject to complete all items.

INDEX SCORES -
Table XVIII (ASI) gives the conversion of SAS raw scores into index scores. The following table from Zung presents mean index scores and standard deviations for 5 diagnostic groups :

		SAS Index	
Diagnosis	N	Mean	S.D.
Anxiety Disorder	22	58.7	13.5*
Schizophrenia	25	46.4	12.9
Depressive Disorder	96	50.7	13.4
Personality Disorder	54	51.2	13.2
Transient Situational Disturbances	12	45.8	11.9
Controls (Normals)	100	33.8	5.9**

* = significantly different from other 4 diagnostic groups (p = .05)
** = significantly different from all diagnostic groups (p = .01)

DOCUMENTATION

a. Raw score printout

b. Index score printout

c. Means and standard deviations for index scores

d. Variance analyses.

c. DEPRESSIVE DISORDERS

Raskin-Covi Scales (RCS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Raskin-Covi Scales (RCS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 3 4 9
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.

Time unit : pretreatment = 0 hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

Circle one number for each scale below to best describe the individual's current state during the past week including today.

Depression Scales (Raskin)							
ITEMS	CLUES		Not at All	Somewhat	Moderately	Considerably	Very Much
Verbal report	Feels sad; helpless, hopeless, worthless; complains of loss of interest; may wish to be dead; reports crying spells.	(20)	1	2	3	4	5
Behavior	Looks sad; cries easily; speaks in sad voice; appears slowed down; lacks energy.	(21)	1	2	3	4	5
Secondary signs	Insomnia, hypersomnia; GI complaints; dry mouth; recent suicide attempt; poor appetite; slow, mixed-up, ruminative thinking.	(22)	1	2	3	4	5
	Depression Total - - - - - - - - - - - - - - - - - -	(23-25)					

Anxiety Scales (Covi)							
ITEMS	CLUES		Not at All	Somewhat	Moderately	Considerably	Very Much
Verbal report	Feels nervous, shaky, jittery, jumpy; suddenly scared for no reason; fearful, apprehensive; tense, keyed up; has to avoid things, places, activities because frightened.	(26)	1	2	3	4	5
Behavior	Appears frightened, shaky, restless, apprehensive, jumpy, jittery.	(27)	1	2	3	4	5
Somatic signs	Sweating, trembling; heart pounding, racing; trouble getting breath; hot, cold spells; restless sleep; more frequent urination; discomfort at pit of stomach; lump in throat.	(28)	1	2	3	4	5
	Anxiety Total - - - - - - - - - - - - - - - - - -	(29-31)					
	DATE	(70-75)	- - | - - | - -				

Newcastle Scale

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Newcastle Scale (NCS)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 5 9
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0 · hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

		NO	YES
1. Age over 40 when first seen	(20)	0	1
2. Adequate personality	(21)	0	1
3. No adequate precipitants for illness	(22)	0	1
4. No adequate psychogenesis	(23)	0	1
5. Unvarying depression	(24)	0	1
6. No reactivity of depression	(25)	0	1
7. Distinct quality of depression	(26)	0	1
8. Weight loss in excess of 7 lb.	(27)	0	1
9. Constipation	(28)	0	1
10. Pyknic physique	(29)	0	1
11. Previous episodes of depression	(30)	0	1
12. Family history of endogenous depression	(31)	0	1
13. Early waking	(32)	0	1
14. Depression worse in mornings	(33)	0	1
15. Depressive psychomotor activity	(34)	0	1
16. Anxiety	(35)	0	1
17. Delusions of retribution	(36)	0	1
18. Nihilistic delusions	(37)	0	1
19. Somatic delusions	(38)	0	1
20. Paranoid delusions or gross ideas of reference	(39)	0	1
21. Persistent suicidal ruminations and/or determined suicidal attempt (psychotic suicidal)	(40)	0	1
22. Depressive hallucinations	(41)	0	1
23. History of over 1 year with no symptom-free intervals	(42)	0	1
24. Family history of neurosis, psychopathy or drug addiction	(43)	0	1
25. Depression worse in evenings	(44)	0	1
26. Tendency to blame others for illness	(45)	0	1
27. Self-pity	(46)	0	1
28. Hopeful attitude towards illness	(47)	0	1
29. Hypochondriasis	(48)	0	1
30. Suicidal threats or half-hearted suicidal gestures (neurotic suicidal)	(49)	0	1
31. Irritability	(50)	0	1

		NO	YES
32. Phobias	(51)	0	11
33. Hysterical features or attitude	(52)	0	1
34. Initial insomnia	(53)	0	1

35. Guilt	(54)	Guilt Free 0	Guilt Feel 1	Delus. of Guilt 2

DATE	(70-75)		
	- -	- -	- -

INFORMATION for USERS

DEVELOPMENT - The possibility of dichotomous distribution of depressive states was investigated in a retrospective study of the case histories of 101 patients admitted to the psychiatric unit of the Newcastle General Hospital during the years 1956, 1957 and 1958. To these case histories was applied a diagnostic index compiled from items considered on clinical grounds to be valuable in discriminating between endogenous and neurotic depressions. On the basis of this study 45 features were chosen. The Newcastle Scale consists of 35 of these 45 items.

REFERENCES - Carney, M.W.P., Roth M. and Garside R.F. : The Diagnosis of Depressive Syndromes and the Prediction of ECT Response. Brit. J. Psychiat. III : 659-674, 1965.

Carney M.W.P. and Sheffield B.F. : Depression and the Newcastle Scales. Their Relationship to Hamilton's Scale. Brit. J. Psychiat. 121 : 35-40, 1972.

APPLICABILITY - Adults with depressive symptoms.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or in the last week.

SPECIAL INSTRUCTIONS

Definitions: Most of the terms used are self-explanatory. However, the following require further explanation.

Adequate personality : This describe subjects free from any history of neurotic breakdown and without disabling neurotic symptoms or serious social maladjustment.

Precipitants : Psychological and/or physical events impressively related to the onset of symptoms and which appeared likely on other grounds to have played some part in the development of the illness.

No adequate psychogenesis : No psychological stress or difficulty continuing to operate after the onset of symptoms and adequate to explain perpetuation of the illness.

Unvarying depression : Absence of marked fluctuations of affect from day to day or week to week.

No reactivity : Absence of definite mood change in response to changes in the external environment.

Distinct quality : Some patients may describe their depression as similar to "normal" sadness or gloom, differing in degree only; others describe their mood as having a quality quite distinct from the depression with which they normally react to adversity. It is to this latter type of depression that this feature refers.

Pyknic physique : The assessment of somatotype was made by clinical impression according to criteria laid down by Kretschmer (1926).

Depressive psychomotor activity : This term is used inclusively to describe any objective evidence of psychomotor slowing, stupor or agitation.

Nihilistic delusions : Delusions of doom, imminent destruction, somatic dissolution or poverty of the patient and/or his family.

Somatic delusions : Delusions of bodily change or disease, usually of a bizarre nature.

Hypochondriasis : Excessive or morbid preoccupation with bodily sensations which have little or no organic basis.

A score of one was assigned to each clinical feature if present, and a score of nought if absent, except in the case of guilt, when "delusions" scored two, "feelings" one and "guilt free" nought.

Depression Status Inventory (DSI)

DEPRESSION STATUS INVENTORY (DSI)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Depression Status Inventory (DSI) - Wm. W.K. Zung	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) _ _ _
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) _ _
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

The data upon which the judgments are based come from the interview with the patient. The items on the scale are to be quantified by using all the information available to the rater. This includes both clinical observation and the material reported by the patient.

Use of the Interview Guide below assures coverage of all the areas on which judgments are required. However, the rater has the flexibility of modifying the questions or probing for details, which makes possible a smooth interview that does not sound like a question-answer examination. In rating the patient's current status, an arbitrary period of 1 week prior to the evaluation is adopted in order to standardize the data. In order to reinforce this, the interviewer should occasionally precede questions with "During the past week, have you ...?"

Signs and symptoms of depression	Interview guide		none	mild	moderate	severe
1. Depressed mood	Do you ever feel sad or depressed ?	(20)	1	2	3	4
2. Crying spells	Do you have crying spells or feel like it ?	(21)	1	2	3	4
3. Diurnal variations	Is there any part of the day when you feel worse ? Best ?	(22)	1	2	3	4
4. Sleep disturbance	Frequent and early AM waking	(23)	1	2	3	4
5. Decreased appetite	How is your appetite ?	(24)	1	2	3	4
6. Weight loss	Have you lost any weight ?	(25)	1	2	3	4
7. Decreased libido	Do you enjoy looking, talking or being with attractive men/ women ?	(26)	1	2	3	4
8. Constipation	Do you have trouble with constipation ?	(27)	1	2	3	4
9. Tachycardia	Have you had times when your heart was beating faster than usual ?	(28)	1	2	3	4
10. Fatigue	How easily do you get tired ?	(29)	1	2	3	4
11. Psychomotor agitation	Do you find yourself restless and can't sit still ?	(30)	1	2	3	4
12. Psychomotor retardation	Do you feel slowed down in doing the things you usually do ?	(31)	1	2	3	4
13. Confusion	Do you ever feel confused and have trouble thinking ?	(32)	1	2	3	4
14. Emptiness	Do you feel life is empty for you ?	(33)	1	2	3	4

Signs and symptoms of depression	Interview guide		none	mild	moderate	severe
15. Hopelessness	How hopeful do you feel about the future ?	(34)	1	2	3	4
16. Indecisiveness	How are you at making decisions ?	(35)	1	2	3	4
17. Irritability	How easily do you get irritated ?	(36)	1	2	3	4
18. Dissatisfaction	Do you still enjoy the things you used to ?	(37)	1	2	3	4
19. Personal devaluation	Do you ever feel useless and not wanted ?	(38)	1	2	3	4
20. Suicidal ruminations	Have you had thoughts about doing away with yourself?	(39)	1	2	3	4

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The DSI, developed by ZUNG, has been designed as the professionally-rated analogue of the patient-rated Zung Depression Scale (SDS). With appropriate contextual changes, it consists of the same 20 items as the SDS; and, based on 209 cases, the author reports a Pearson product moment correlation of .87 between the 2 scales. The DSI provides a global measure of the intensity of depressive symptomatology.

REFERENCE - Zung, W.W.K., The Depression Status Inventory : An Adjunct to the Self-Rating Depression Scale, J. Clin. Psychol., 28 : 539-543, 1972.

APPLICABILITY - Adults with depressive symptoms.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or in the last week.

SPECIAL INSTRUCTIONS

The following rules and guidelines should be used in rating the patient's psychopathology :

A. Each item should be rated independently as a unit in order to eliminate the "halo" effect.

B. Each score should be the average of the full range of responses observed or elicited, and not necessarily the extreme in severity.

C. The items are judged on a 4-point system that takes into account severity in terms of : intensity, duration and frequency. These are defined as follows :

1 = none or insignificant in intensity or duration, present none or a little of the time in frequency.
2 = mild in intensity or duration, present some of the time.
3 = of moderate severity, present a good part of the time.
4 = severe in intensity or duration, present most or all of the time in frequency.

To help establish severity, the following questions may be necessary : Intensity : "How bad was it ?". Duration : "How long did it last ?". Frequency : "How much of the time did you feel that way ?".

D. An item is scored positive and present when a) behavior is observed, b) behavior was described by a patient as having occurred and c) patient admits that symptom is still a problem.

E. An item is scored negative and not present when a) symptom has not occurred and not a problem or present, b) response is ambiguous even after suitable probing, or c) patient gives no information relevant to an item.

SCORE

The Z score is derived by dividing the sum of the raw item scores by the maximum possible score (80) multiplied by 100. See Table XX for the Conversion of Interviewer-Rated Raw Scores to the DSI Z Scores. Zung has provided the following mean DSI "Z" scores for various diagnostic groups :

Diagnosis	N	Mean DSI Z Scores
Depressive disorders	96	61*
Schizophrenia	25	48
Anxiety disorder	22	51
Personality disorders	54	52
Transient situational disturbances	12	44

* = significantly different from other diagnostic groups ($p < .01$).

DOCUMENTATION

a. Raw score printout

b. Z score printout

c. Z score means and standard deviations

d. Variance analyses.

TABLE XX (from Zung)

THE CONVERSION of INTERVIEWER-RATED RAW SCORES to the DSI Z SCORES

Raw Score	DSI Z Scores	Raw Score	DSI Z Scores	Raw Score	DSI Z Scores
20	25	40	50	60	75
21	26	41	51	61	76
22	28	42	53	62	78
23	29	43	54	63	79
24	30	44	55	64	80
25	31	45	56	65	81
26	33	46	58	66	83
27	34	47	59	67	84
28	35	48	60	68	85
29	36	49	61	69	86
30	38	50	63	70	88
31	39	51	64	71	89
32	40	52	65	72	90
33	41	53	66	73	91
34	43	54	68	74	92
35	44	55	69	75	94
36	45	56	70	76	95
37	46	57	71	77	96
38	48	58	73	78	98
39	49	59	74	79	99
				80	100

Self-Rating Depression Scale (SDS)

SELF-RATING DEPRESSION SCALE (SDS)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Self-Rating Depression Scale (SDS) - Wm.W.K. Zung	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 7 3
Form Number

(13-15) _ _ | _
Assessment Period *

(16-17) _ _
Rater Number

(18-19) _ _
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time unit : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

Listed below are 20 statements. Please read each one carefully and decide how much of the statement describes how you have been feeling during the past week. Decide whether the statement applies to you for NONE OR A LITTLE OF THE TIME, SOME OF THE TIME, A GOOD PART OF THE TIME, OR MOST OR ALL OF THE TIME. Mark the appropriate column for each statement.

EXAMPLE

STATEMENT	none or a little of the time	some of the time	a good part of the time	most or all of the time
If the statement "I feel nervous" describes the way you have felt "A GOOD PART OF THE TIME", you would mark column 3 "A GOOD PART OF THE TIME" as shown.	1	2	3	4

STATEMENT		none or a little of the time	some of the time	a good part of the time	most or all of the time
1. I feel downhearted and sad	(20)	1	2	3	4
2. Morning is when I feel the best	(21)	1	2	3	4
3. I have crying spells or feel like it	(22)	1	2	3	4
4. I have trouble sleeping at night	(23)	1	2	3	4
5. I eat as much as I used to	(24)	1	2	3	4
6. I still enjoy sex	(25)	1	2	3	4
7. I notice that I am losing weight	(26)	1	2	3	4
8. I have trouble with constipation	(27)	1	2	3	4
9. My heart beats faster than usual	(28)	1	2	3	4
10. I get tired for no reason	(29)	1	2	3	4
11. My mind is as clear as it used to be	(30)	1	2	3	4
12. I find it easy to do the things I used to do	(31)	1	2	3	4
13. I am restless and can't keep still	(32)	1	2	3	4

STATEMENT		none or a little of the time	some of the time	a good part of the time	most or all of the time
14. I feel hopeful about the future	(33)	1	2	3	4
15. I am more irritable than usual	(34)	1	2	3	4
16. I find it easy to make decisions	(35)	1	2	3	4
17. I feel that I am useful and needed	(36)	1	2	3	4
18. My life is pretty full	(37)	1	2	3	4
19. I feel that others would be better off if I were dead	(38)	1	2	3	4
20. I still enjoy the things I used to do	(39)	1	2	3	4

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The SDS is a 20-item scale in which the subject rates his symptomatology on a 4-point scale of severity. The SDS is the patient-rated version of the Depression Status Inventory.

REFERENCE - Zung, W.W.K., A Self-Rating Depression Scale, Arch. Gen. Psychiat. 12, 63-70, 1965

Zung, W.W.K., Factors influencing the Self-Rating Depression Scale, Arch. Gen. Psychiat., 16, 543-547, 1967.

APPLICABILITY - Adults with depressive symptoms.

UTILIZATION - Once at pretreatment; at least one post-treatment ratings. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - The rater should make certain that the subject fully understands the task and the correct method of recording his responses. When the subject finishes, the rater should check all items for omissions or multiple marks. Unless clinically inadvisable, the rater should urge subject to complete all items.

INDEX SCORES - Table XX gives the conversion of SDS raw scores into index scores. The following table from Zung presents mean index scores for 5 diagnostic groups :

Diagnosis	N	Mean SDS Index
Depressive disorders	96	65*
Schizophrenia	25	51
Anxiety disorder	22	53
Personality disorders	54	56
Transient situational disturbances	12	48

*Significantly different from other 4 groups ($p < .01$)

DOCUMENTATION

a. Raw score printout
b. Index score printout
c. Means and standard deviations for index scores
d. Variance analyses.

Beck Depression Inventory (BECK)

BECK DEPRESSION INVENTORY (BECK)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Beck Depression Inventory (BECK)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 0 3
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0 ; hours = 1; days = 2 ; weeks = 3 ; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS

This is a questionnaire. On the questionnaire are groups of statements. Please read the entire group of statements in each category. Then pick out the one statement in that group which best describes the way you feel today, that is right now! Circle the number beside the statement you have chosen. If several statements in the group seem to apply equally well, circle each one.

Be sure to read all the statements in each group before making your choice.

1. (Sadness)

0 I do not feel sad

1 I feel sad

2 I am sad all the time and I can't snap out of it

3 I am so sad or unhappy that I can't stand it

(20) _

2. (Pessimism)

0 I am not particularly pessimistic or discouraged about the future

1 I feel discouraged about the future

2 I feel I have nothing to look forward to

3 I feel that the future is hopeless and that things cannot improve

(21) _

3. (Sense of failure)

0 I do not feel like a failure

1 I feel I have failed more than the average person

2 As I look back on my life, all I can see is a lot of failures

3 I feel I am a complete failure as a person (parent, husband, wife)

(22) _

4. (Dissatisfaction)

0 I am not particularly dissatisfied

1 I don't enjoy things the way I used to

2 I don't get satisfaction out of anything anymore

3 I am dissatisfied with everything

(23) _

5. (Guilt)

0 I don't feel particularly guilty

1 I feel bad or unworthy a good part of the time

2 I feel quite guilty

3 I feel as though I am very bad or worthless

(24) _

6. (Self-dislike)

0 I don't feel disappointed in myself

1 I am disappointed in myself

2 I am disgusted with myself

3 I hate myself

(25) _

7. (Self-harm)

0 I don't have any thoughts of harming myself

1 I feel I would be better off dead

2 I have definite plans about committing suicide

3 I would kill myself if I had the chance

(26) _

8. (Social withdrawal)

0 I have not lost interest in other people

1 I am less interested in other people than I used to be

2 I have lost most of my interest in other people and have little feeling for them

3 I have lost all my interest in other people and don't care about them at all

(27) _

9. (Indecisiveness)

0 I make decisions about as well as ever

1 I try to put off making decisions

2 I have great difficulty in making decisions

3 I can't make any decisions at all any more

(28) _

10. (Self-image change)

0 I don't feel I look any worse than I used to

1 I am worried that I am looking old or unattractive

2 I feel that there are permanent changes in my appearance and they make me look unattractive

3 I feel that I am ugly or repulsive-looking

(29) _

11. (Work difficulty)

0 I can work about as well as before

1 It takes extra effort to get started at doing something

2 I have to push myself very hard to do anything

3 I can't do any work at all

(30) _

12. (Fatigability)

0 I don't get any more tired than usual

1 I get tired more easily than I used to

2 I get tired from doing anything

3 I get too tired to do anything

(31) _

13. (Anorexia)

0 My appetite is no worse than usual

1 My appetite is not as good as it used to be

2 My appetite is much worse now

3 I have no appetite at all anymore

(32) -

(70-75)

DATE - - | - - | - -

Note : The item titles should be omitted from the subject's copy of the scale.

INFORMATION for USERS

DEVELOPMENT - The short form of the BECK consists of 13 items from the original 21-item scale and has been developed to measure the depth of depression as well as for the rapid screening of depressed patients. A self-rating instrument, the clinically derived items are rated on a 4-point scale (0-3). The authors state that the 13-item version correlates 0.96 with the longer 21-item scale and 0.61 with clinician's ratings of depression.

REFERENCES - Beck, A.T., Depression : Clinical, Experimental and Theoretical Aspects, Hoeber Medical Division, Harper and Row, New York, 1967.

Beck, A.T. and Beamesderfer, A., Assessment of Depression : The Depression Inventory in Psychological Measurements in Psychopharmacology, Vol. 7, 151-169, Ed. P. Pichot, Karger, Basel, 1974.

APPLICABILITY - Psychiatric and medical patients with depressive illness.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - "Right now", i.e., at the time of the rating.

SPECIAL INSTRUCTIONS - Raters are urged to familiarize themselves with the volume cited in Reference 1. As with all self-rating instruments, the examiner should make certain that the patient fully understands the instructions and that the scale is properly and - as far as possible - completely filled out.

SEVERITY OF DEPRESSION

Total score = Sum of all items Total score Range = 0-39

The authors have provided the following estimates of the severity of depression based on total score :

Score	Severity
0- 4	None or minimal
5- 7	Mild
8-15	Moderate
16 +	Severe

DOCUMENTATION

a. Raw score printout

b. Total score means and standard deviations

c. Variance analyses.

Clyde Mood Scale (CLYDE)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Clyde Mood Scale (CLYDE)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 3 9
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

		not at all	a little	quite a bit	extremely
1. good-natured	(20)	1	2	3	4
2. troubled	(21)	1	2	3	4
3. efficient	(22)	1	2	3	4
4. dependable	(23)	1	2	3	4
5. clear thinking	(24)	1	2	3	4
6. lonely	(25)	1	2	3	4
7. humorous	(26)	1	2	3	4
8. rude	(27)	1	2	3	4
9. kind	(28)	1	2	3	4
10. daring	(29)	1	2	3	4
11. considerate	(30)	1	2	3	4
12. boastful	(31)	1	2	3	4
13. defiant	(32)	1	2	3	4
14. fatigued	(33)	1	2	3	4
15. unhappy	(34)	1	2	3	4
16. businesslike	(35)	1	2	3	4
17. friendly	(36)	1	2	3	4
18. grouchy	(37)	1	2	3	4
19. sleepy	(38)	1	2	3	4
20. sad	(39)	1	2	3	4
21. bossy	(40)	1	2	3	4
22. impulsive	(41)	1	2	3	4
23. jittery	(42)	1	2	3	4
24. bold	(43)	1	2	3	4
25. playful	(44)	1	2	3	4
26. afraid	(45)	1	2	3	5
27. able to work hard	(46)	1	2	3	4
28. warm-hearted	(47)	1	2	3	4
29. sick to the stomach	(48)	1	2	3	4
30. alert	(49)	1	2	3	4
31. tired	(50)	1	2	3	4
32. shaky	(51)	1	2	3	4
33. demanding	(52)	1	2	3	4
34. sociable	(53)	1	2	3	4
35. nagging	(54)	1	2	3	4

		not at all	a little	quite a bit	extremely
36. sarcastic	(55)	1	2	3	4
37. pleasant	(56)	1	2	3	4
38. quarrelsome	(57)	1	2	3	4
39. independent	(58)	1	2	3	4
40. depressed	(59)	1	2	3	4
41. drowsy	(60)	1	2	3	4
42. able to concentrate	(61)	1	2	3	4
43. dizzy	(62)	1	2	3	4
44. reckless	(63)	1	2	3	4
45. downhearted	(64)	1	2	3	4
46. worried	(65)	1	2	3	4
47. forceful	(66)	1	2	3	4
48. polite	(67)	1	2	3	4

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The CLYDE is a 48-item scale for measuring aspects of mood that may be influenced by drugs and may be employed as a self-rating as well as an observer-rated instrument. The scale has been shown to be sensitive to drug effects.

REFERENCE - Clyde, D.J., Manual for the Clyde Mood Scale,Clyde Computing Service, Box 166, Coconut Grove Station, Miami, Florida, 33133, 1963. This manual may be obtained from the author.

APPLICABILITY - Wide range of patients and normals.

UTILIZATION - Once at pretreatment; at least one posttreatment assessment. Additional assessments are at the discretion of the investigator.

TIME SPAN RATED - "Now"; at the time of the rating.

FACTOR COMPOSITION

I. Friendly
- 1. good-natured
- 9. kind
- 28. warm-hearted
- 37. pleasant

II. Aggressive
- 8. rude
- 12. boastful
- 36. sarcastic
- 47. forceful

III. Clear thinking
- 3. efficient
- 5. clear thinking
- 30. alert
- 42. able to concentrate

IV. Sleepy
- 14. fatigued
- 19. sleepy
- 31. tired
- 41. drowsy

V. Unhappy
- 2. troubled
- 20. sad
- 45. downhearted
- 46. worried

VI. Dizzy
- 23. jittery
- 29. sick to the stomach
- 32. shaky
- 43. dizzy

NOTE - Higher scores reflect greater "pathology" for all factors except factors 1 and 3.

DOCUMENTATION

a. Raw score printout

b. Factor score printout

c. Factor means and standard deviations

d. Variance analyses.

Bech-Rafaelsen Melancholia & Mania Scale (BRMMS)

BECH-RAFAELSEN MELANCHOLIA & MANIA SCALE (BRMMS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Bech-Rafaelsen Melancholia & Mania Scale (BRMMS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _ Unit Number

(4-6) _ _ _ Study Number

(7-9) _ _ _ Subject Number
Male 001-499
Female 500-999

(10-12) 2 6 0 Form Number

(13-15) _ _ _ Assessment Period*

(16-17) _ _ Rater Number

(18-19) 0 1 Card Number

(76-80) _ _ _ _ _ Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000

BECH-RAFAELSEN MELANCHOLIA SCALE		not present or habitual	mild	moderate	marked	severe or extreme
1. Decreased motor activity	(20)	0	1	2	3	4
2. Decreased verbal activity	(21)	0	1	2	3	4
3. Retardation (intellectual)	(22)	0	1	2	3	4
4. Anxiety (psychic)	(23)	0	1	2	3	4
5. Suicidal impulses	(24)	0	1	2	3	4
6. Lowered mood	(25)	0	1	2	3	4
7. Self-depreciation	(26)	0	1	2	3	4
8. Retardation (emotional)	(27)	0	1	2	3	4
9. Sleep disturbances	(28)	0	1	2	3	4
10. Tiredness and pains	(29)	0	1	2	3	4
11. Work and interests	(30)	0	1	2	3	4
Total score					(31-32)	

BECH-RAFAELSEN MANIA SCALE		not present or habitual	mild	moderate	marked	severe or extreme
1. Increased motor activity	(33)	0	1	2	3	4
2. Increased verbal activity	(34)	0	1	2	3	4
3. Flight of thoughts	(35)	0	1	2	3	4
4. Voice/Noise level	(36)	0	1	2	3	4
5. Hostility/Destructiveness	(37)	0	1	2	3	4
6. Mood (feelings of well being)	(38)	0	1	2	3	4
7. Self-esteem	(39)	0	1	2	3	4
8. Contact	(40)	0	1	2	3	4
9. Sleep	(41)	0	1	2	3	4
10. Sexual interest	(42)	0	1	2	3	4
11. Work	(43)	0	1	2	3	4
Total core					(44-45)	

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The BRMMS consists of two 11-item, 5-point scales developed by Bech and Rafaelsen for the assessment of melancholia and mania.

REFERENCES - Bech P., and Rafaelsen O.J. : The use of rating scales examplified by a comparison of the Hamilton and the Bech-Rafaelsen Melancholia Scale. Acta psychiat. scand., suppl. 285 : 128-131, 1980.

Bech, P., Rafaelsen O.J., Kramp P., and Bolwig T.G. : The mania rating scale : Scale construction and interobserver agreement. Neuropharmacology 17 : 430-431, 1978.

APPLICABILITY - Adults with melancholia and/or manic symptoms.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - The interviewer should judge the patient's condition at the time of interview when assessing the presence and grade of the individual items. Some items are, however, less suitable for a "here and now" evaluation, e.g., sleep disturbances. It is here necessary to judge the condition during the 3 days prior to the interview. When in doubt the interviewer should solicit information from ward personnel or relatives.

The duration of the interview should be no less than 15 minutes and no more than 30 minutes. In principle, the interview technique is not different from clinical tradition. Pressure should not be exerted on the patient who, as far as possible, should be allowed to explain his situation in his own words. The interviewer should remain unaffected by spontaneous intermissions as these represent an integral part of the observation.

The rating should always take place at a fixed hour, e.g., between 8.00 and 9.30 a.m. to avoid the influence of diurnal variation.

The scale is basically quantitative; it has been constructed for the sole purpose of rating the actual clinical picture, and it is not to be considered a diagnostic tool. When the scale is applied in repeated (weekly) ratings, each assessment shall rest in itself. The rater should therefore avoid taking a look at or recalling former interviews and likewise should not ask for changes that might have taken place from the last interview; instead he should elucidate the patient's condition during the preceding 3 days.

For the various items, it is assumed that each scale step contains the lower steps, e.g., scale step 3 includes the statements of scale steps 2 and 1. Normal function is always rated as 0.

The following glossary represents guidelines for ratings for the first part of the scale.

I. Activity (motor)

0 Normal motor activity, adequate facial expression.

1 Slightly decreased motor activity, facial expression slightly rigid (retarded).

2 More pronounced motor retardation (e.g., reduced gestures; slow pace).

3 All movements very slow.

4 Motor retardation approaching or including stupor.

II. Activity (verbal)

This item includes changes in flow of speech and the capacity to verbalise thoughts and emotions.

0 Normal verbal activity.

1 Slightly reduced verbal expression or inertia in conversation.

2 More pronounced inertia in conversation, e.g., a trend to longer intermissions.

3 When the interview is clearly prolonged due to long latencies and brief responses.

4 When the interview can be completed with ma ked difficulties only.

III. Retardation (intellectual)

0 Normal intellectual activity

1 The patient has to make an effort to concentrate on his work.

2 Even with a major effort it is difficult for the patient to concentrate or make decisions. Less initiative than usual. The patient easily experiences "brain fatigue".

3 Marked difficulties with concentration, initiative and decision-making. For example, can hardly read a newspaper or watch television. Score 3 as long as the retardation has not clearly influenced the interview.

4 When the patient during the interview has shown marked difficulties in following normal conversation.

IV. Anxiety (psychic)

This item includes tenseness, irritability, worry, insecurity, fear and apprehension approaching panic. It may often be difficult to distinguish between the patient's experience of anxiety ("psychic" or "central" anxiety phenomena) and the physiological ("peripheral") anxiety manifestations which can be observed, e.g., hand tremor and sweating. Most important is the patient's report

of worry, insecurity, uncertainty, experiences of fear and panic, i.e. the psychic ("central") anxiety.

0 When the patient is neither more nor less anxious, insecure or tense than usual.

1 When the patient is somewhat more anxious, tense or insecure than usual.

2 When the patient clearly expresses a state of anxiety, insecurity, worry and tenseness which he finds difficult to control and which therefore may interfere with his daily work.

3 When the anxiety or insecurity from time to time is very marked and experienced as panic, i.e., when anxiety gets out of control.

4 When the patient is more constantly in a state of panic. It may be difficult to distract the patient from his feeling of panic and this might interfere with the interview.

V. Suicidal impulses

0 No suicidal impulses.

1 The patient feels that life is not worthwhile, but he expresses no wish to die.

2 The patient wishes to die, but has no plans to end his own life.

3 It is probable that the patient contemplates committing suicide.

4 If the patient during the days prior to interview has tried to commit suicide, or if he is under special observation in the ward due to suicidal risk.

VI. Lowered mood

This item covers both the verbal and the non-verbal communication of sadness, depression, despondency, helplessness and hopelessness.

0 Neutral mood.

1 The patient vaguely indicates that he is more despondent and depressed than usual.

2 The patient spontaneously indicates (or does so readily on questioning) that he is more despondent and depressed than usual. There are only a few signs to be noticed, e.g., occasional weeping.

3 The patient shows clear non-verbal signs of depression, e.g., repeated weeping, pale and greyish face, frowning and unsteady voice, and/or communicates verbally to be in a severe depressive mood.

4 The patient's remarks on despondency and helplessness or the non-verbal signs from which the patient cannot be distracted dominate the interview.

VII. Self-depreciation and guilt feeling

This item covers lowered self-esteem.

0 No self-depreciation or guilt feeling.

1 Vague self-depreciation, the patient feels that he has not lived up to expectations, that he may have failed.

2 Self-depreciation or guilt feeling is more clearly present and is concerned

with more than the fact that the patient may have been a burden to the family or at his job due to reduced work capacity during the actual episode. It is important to note whether the patient unreasonably reproaches himself for small omissions or failures, such as not having done his duty or having harmed others. Such self-accusations are often focused on incidents in the past, prior to the actual episode.

3 The patient suffers from severe guilt feelings. He will often express the feeling that the actual suffering is some sort of a punishment. Score 3 as long as the patient intellectually can see that his view is unfounded.

4 The guilt feeling is firmly maintained and resists any counter argument, thereby becoming a paranoid idea.

VIII. Emotional retardation

This item covers the reduced emotional contact with other human beings. When reduced, the wish or ability to communicate one's own feelings and opinions and to share joy and sorrow is normally experienced by the patient as alien and painful.

0 Normal emotional contact with others.

1 A reduced wish or ability to be together with new or distant acquaintances.

2 The patient isolates himself to a certain degree. He has no need or ability to establish closer contact with people he meets away from home (work, mates, fellow patients, ward personnel).

3 The patient also isolates himself in relation to family members. He feels emotionally indifferent even to near friends and family.

4 Totally isolated. Is unable to feel anything in human contact. Considers himself emotionally dead.

XIX. Sleep disturbances

This item covers only the patient's subjective experience of sleep length (hours of sleep per 24-hour period) and sleep depth (superficial and interrupted sleep versus deep and steady sleep). The rating is based on the 3 preceding nights, irrespective of the administration of hypnotics or sedatives.

0 Usual sleep length and sleep depth.

1 Sleep length reduced (e.g., due to difficulties in falling asleep), but no change in sleep depth.

2 Sleep depth is now also reduced, sleep being more superficial. Sleep as a whole somewhat disturbed.

3 Sleep length as well as sleep depth is markedly changed. The broken sleep periods total only a few hours per 24-hour period.

4 It is here difficult to ascertain sleep length, as sleep depth is so shallow that the patient speaks of short periods of slumber or dosing, but no real sleep.

Tiredness and pains

This item includes weakness, faintness, tiredness, fullness and soreness merging into real pains more or less diffusely located in muscles or inner organs.

Muscular fatigue is normally located in the extremities. The patient may give this as the reason for difficulties in his work as he has a feeling of tiredness or fullness in arms and legs.

Muscle pains are often located in the back, neck or shoulders and are perceived as tensions or headache. The feeling of fullness and heaviness increasing to real sensations of pain is often broadly located as "chest discomfort" (different from heart pains), abdominal pains, head pains (different from simple headache). It is often difficult to discern between "psychic" and "physical" pains. Special notice should be taken of vague "psychic" pains.

0 The patient is neither more nor less tired nor troubled by bodily discomfort than usual.

1 Vague feelings of muscular fatigue or other somatic discomfort.

2 Feelings of muscular fatigue or somatic discomfort are more pronounced. Painful sensations sometimes occur.

3 Muscular fatigue or diffuse pain is clearly present so as to interfere with the patient's daily work.

4 Muscular fatigue and diffuse pains are constantly causing the patient severe distress.

XI. Work and interests

This item includes both motivation and work actually carried out. Especially for housewives it may be difficult to assess this item, as such patients are less prone to remark that they have difficulties with their daily housework. They will often use circumlocutions, such as "I have been less scrupulous lately".

A. At first rating of the patient

0 Normal work activity.

1 The patient expresses insufficiency due to lack of motivation and/or trouble in carrying out the usual work-load which he manages to do without reduction, however.

2 More pronounced insufficiency due to lack of motivation and/or trouble in carrying out the usual work. Here the patient has reduced work capacity, cannot keep normal speed, copes with less on the job or at home; the patient may stay home some days or try to leave early.

3 The patient has been sick-listed; or he has been hospitalized (as a day-patient or with full hospitalization) but can participate for some hours per day in the ward activities.

4 The patient is fully hospitalized and generally unoccupied without participation in the ward activities.

B. At weekly ratings

0 a. The patient has resumed work at his/her normal activity level.

b. The patient will have no trouble resuming normal work.

1 a. The patient is working, but at reduced activity level, either due to lack of motivation or due to difficulties in the accomplishment of his normal work.

b. The patient is not working, and it is still doubtful that he can resume his normal work without difficulties.

2 a. The patient is working, but at a clearly reduced level, either due to episodes of non-attendance or due to reduced work time.

b. The patient is still hospitalized or sick-listed, participates more than 3-4 hours per day in ward (or home) activities, but is only capable or resuming normal work at a reduced level.

If hospitalized, the patient is able to change from full stay to day-patient status.

3 The patient is unable to undertake normal work, but participates for 3-4 hours per day in ward activities. It may be considered desirable to change the patient's hospitalization to day-patient status, but discharge is not recommendable.

4 The patient is still fully hospitalized and on the whole unable to participate in ward activities.

d. MANIC STATES

Manic State Rating Scale

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Manic State Rating Scale (MSRS)	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 6 1
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80 _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

Part A - Frequency (how much of the time ?)								Part B - Intensity (how intense is it?)					
	none	infrequent	some	much	most	all		very minimal	minimal	moderate	marked	very marked	
	0	1	2	3	4	5	The Patient	1	2	3	4	5	
(20)							1. looks depressed						(21)
(22)							2. is talking						(23)
(24)							3. moves from one place to another						(25)
(26)							4. makes threats						(27)
(28)							5. has poor judgment						(29)
(30)							6. dresses inappropriately						(31)
(32)							7. looks happy and cheerful						(33)
(34)							8. seeks out others						(35)
(36)							9. is distractable						(37)
(38)							10. has grandiose ideas						(39)
(40)							11. is irritable						(41)
(42)							12. is combative or destructive						(43)
(44)							13. is delusional						(45)
(46)							14. verbalizes depressive feelings						(47)
(48)							15. is active						(49)
(50)							16. is argumentative						(51)
(52)							17. talks about sex						(53)
(54)							18. is angry						(55)

Part A - Frequency (how much of the time?)							Part B - Intensity (how intense is it?)					
none	infrequent	some	much	most	all	The Patient	very minimal	minimal	moderate	marked	very marked	
0	1	2	3	4	5		1	2	3	4	5	
						(56) 19. is careless about dress and grooming						(57)
						(58) 20. has diminished impulse control						(59)
						(60) 21. verbalizes feelings of well-being						(61)
						(62) 22. is suspicious						(63)
						(64) 23. makes unrealistic plans						(65)
						(66) 24. demands contact with others						(67)
						(68) 25. is sexually preoccupied						(69)
						(20)* 26. jumps from one subject to another						(21)

* Card no. 02

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - Developed by Beigel, Murphy and Bunney, the MSRS is a 26-item scale.

REFERENCE - Beigel A., Murphy D.L. and Bunney W.E. : The manic state rating scale. Arch. Gen. Psychiatry 25 : 256-262, 1971.

APPLICABILITY - Adults with manic symptoms.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - The scale consists of 2 parts : part A and part B. Part A measures frequency (how much of the time) on a 6-point scale and Part B measures intensity on a 5-point scale.

e. SCHIZOPHRENIC DISORDERS

Inpatient Multidimensional Psychiatric Scale

(IMPS)

INPATIENT MULTIDIMENSIONAL PSYCHIATRIC SCALE (IMPS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Inpatient Multidimensional Psychiatric Scale (IMPS)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) _ _ _
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) _ _
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0 hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

Compared to the Normal Person, to What Degree Does the Patient		not at all 0	very slightly 1	a little 2	mildly 3	moderately 4	quite a bit 5	distinctly 6	markedly 7	extremely 8
1. Manifest speech that is slowed, deliberate, or labored ?	(20)	0	1	2	3	4	5	6	7	8
2. Give answers that are irrelevant or unrelated in any immediately conceivable way to the question asked or topic discussed ?	(21)	0	1	2	3	4	5	6	7	8
Cues : Do not rate here wandering or rambling conversation which veers away from the topic at issue (see item 4). Also do not rate the coherence of the answer.										
3. Give answers that are grammatically disconnected, incoherent, or scattered, i.e., not sensible, or not understandable ?	(22)	0	1	2	3	4	5	6	7	8
Cues : Judge the grammatical structure of his speech, not the content which may or may not be bizarre.										
4. Tend to ramble, wander, or drift off the subject or away from the point at issue in responding to questions or topics discussed ?	(23)	0	1	2	3	4	5	6	7	8
Cues : Do not rate here responses that are obviously unrelated to the question asked (see item 2).										
5. Verbally express feelings of hostility, ill will, or dislike of others ?	(24)	0	1	2	3	4	5	6	7	8
Cues : Makes hostile comments regarding others such as attendants, other patients, his family, or persons in authority. Reports conflicts on the ward.										
6. Exhibit postures that are peculiar, unnatural, rigid, or bizarre ?	(25)	0	1	2	3	4	5	6	7	8
Cues : Head twisted to one side, or hand and arm held oddly. Judge the degree of peculiarity of the posture.										

Compared to the normal person, to what degree does he ...		not at all	very slightly	a little	mildly	moderately	quite a bit	distinctly	markedly	extremely
		0	1	2	3	4	5	6	7	8
7. Express or exhibit feelings and emotions openly, impulsively, or without apparent restraint or control ?	(26)	0	1	2	3	4	5	6	7	8
Cues : Show temper outbursts; weep or wring hands in loud complaint; joke or talk boisterously; gesture excitedly.										
8. Exhibit indifference or apathy towards such matters as his treatment, his release from the hospital, or plans for the future ?	(27)	0	1	2	3	4	5	6	7	8
Cues : Content to stay. Willing to "leave it to the doctor". Sees no need for treatment. Seems to have no goals or expectations.										
9. Manifest speech that is hurried, accelerated, or pushed ?	(28)	0	1	2	3	4	5	6	7	8
Cues : Pressure of speech.										
10. Manifest overt signs of tension ?	(29)	0	1	2	3	4	5	6	7	8
Cues : Moves or shifts restlessly; body musculature appears taut, strained or tense; fingers clothing; scratches, drums or fiddles with objects; face or neck muscles twitch; exhibits startle reactions; palms feel sweaty.										
11. Express a feeling or attitude of contempt, disdain, or scorn towards other people as unworthy or beneath him ?	(30)	0	1	2	3	4	5	6	7	8
Cues : Derogatory or snide comments about others; sarcasm or ridicule of others; condescending.										
12. Exhibit an elevation in mood, a sense of well-being or euphoria, or an optimistic and hopeful attitude towards himself and others ?	(31)	0	1	2	3	4	5	6	7	8
Clues : Everything is wonderful and this is the best of all possible worlds.										

Compared to the normal person, to what degree does he ...		not at all 0	very slightly 1	a little 2	mildly 3	moderately 4	quite a bit 5	distinctly 6	markedly 7	extremely 8
13. Exhibit a facial expression that is fixed, immobile, and without discernible play of feeling or expression ?	(32)	0	1	2	3	4	5	6	7	8
14. Tend to blame, criticize, condemn or otherwise hold himself responsible for past or present, real or fancied, thought or actions ?	(33)	0	1	2	3	4	5	6	7	8
Cues : Blames self for failure, difficulties, and frustration in family, relations, work, or finances.										
15. Exhibit in demeanor, and/or in verbalizations an attitude of self-importance, superiority, or conceit ?	(34)	0	1	2	3	4	5	6	7	8
Cues : Speech is pompous or stilted; boasts of his accomplishments; demands and expects special privileges.										
16. Manifest movements or gestures that are slowed, deliberate, labored, or delayed ?	(35)	0	1	2	3	4	5	6	7	8
Cues : Acts as if he is fatigued; walking and moving seem to require special effort.										
17. Dramatize or seek to attract the attention of others to himself or his symptoms ?	(36)	0	1	2	3	4	5	6	7	8
Cues : Seems to enjoy being observed by others; histrionic in his gestures; affected or artificial; a "show-off".										
18. Manifest a hostile, sullen, or morose attitude towards others, by tone of voice, demeanor, or facial expression ?	(37)	0	1	2	3	4	5	6	7	8
Cues : Seems to have a chip on his shoulder; slams door or bangs chair; sarcastic tone. Try not to judge on the basis of content of remarks.										
19. Exhibit a deficit in his memory for events of the last week ?	(38)	0	1	2	3	4	5	6	7	8
Cues : Does not know what he had for supper last night, what he did yesterday, or what treatment he received the past week.										

Compared to the normal person, to what degree does he ...		not at all	very slightly	a little	mildly	moderately	quite a bit	distinctly	markedly	extremely
		0	1	2	3	4	5	6	7	8
20. Manifest speech that is loud, boisterous, and/or intense in tone ?	(39)	0	1	2	3	4	5	6	7	8
21. Report or admit being uneasy or anxiety in anticipation of specific future difficulties or problems ?	(40)	0	1	2	3	4	5	6	7	8
Cues : Worried about his symptoms, his family, or his finances.										
22. Manifest blocking, halting, or irregular interruptions in his speech ?	(41)	0	1	2	3	4	5	6	7	8
Cues : Stuttering or stammering should not be rated here.										
23. Exhibits apathy, indifference or lack of response in feeling to a discussion of his own problems, of his family, or to his surroundings ?	(42)	0	1	2	3	4	5	6	7	8
Cues : Does not laugh , smile or react when kidded; neither sad nor angry; does not seem to care what goes on; discusses emotional matters in a flat, detached manner.										
24. Report or admit feeling anxious, apprehensive or worried in the anticipation of vague indefinable future misfortune or outcome?	(43)	0	1	2	3	4	5	6	7	8
Cues : Feels worried about coming events but does not know why.										
25. Manifests irritability, grouchiness, annoyance or anger ?	(44)	0	1	2	3	4	5	6	7	8
Cues : one of voice; sharpness of response; explosiveness of retorts; use of profane or obscene language resulting from irritation.										
26. Exhibit overactivity, restlessness and/or acceleration in body movements ?	(45)	0	1	2	3	4	5	6	7	8
Cues : Paces or shifts about restlessly. Bearing, posture and gestures suggest excitement or agitation.										

Compared to the normal person, to what degree does he ...		not at all 0	very slightly 1	a little 2	mildly 3	moderately 4	quite a bit 5	distinctly 6	markedly 7	extremely 8
27. Exhibit in his general demeanor or his verbalizations an attitude of self-depreciation, inadequacy or inferiority ?	(46)	0	1	2	3	4	5	6	7	8
Cues : Talks about his faults and lack of accomplishment. Underrates his skills.										
28. Tend to blame, criticize or hold other people, objects or circumstances responsible for his difficulties, failures or frustrations ?	(47)	0	1	2	3	4	5	6	7	8
29. Manifest verbally or in demeanor a dejection or depression in mood and a despondent or despairing attitude ?	(48)	0	1	2	3	4	5	6	7	8
Cues : Says he does not want to talk; complains of loss of interest and enjoyment, lack of energy; discouraged about being helped; expresses lack of hope; may wish he were dead; reports crying spells or tearfulness; expects the worst, everything seems flat and stale.										
30. Exhibit a slovenly, unkempt or disordered appearance and/or asocial manners?	(49)	0	1	2	3	4	5	6	7	8
31. Express feelings of guilt, sorrow or remorse for having done wrong, that are accompanied by a desire to make amends ?	(50)	0	1	2	3	4	5	6	7	8
Cues : Says he has been a terrible father or husband; claims sexual misdeeds; recounts past "sins"; has let people down and brought suffering upon others; has neglected his friends, family or work, wants to atone for his sins or misdeeds.										
32. Express feelings of bitterness and resentment because he feels others have wronged, cheated, injured or slighted him?	(51)	0	1	2	3	4	5	6	7	8
33. Manifest speech that is low, weak, whispered or difficult to hear ?	(52)	0	1	2	3	4	5	6	7	8

Compared to the normal person, to what degree does he ...		not at all 0	very slightly 1	a little 2	mildly 3	moderately 4	quite a bit 5	distinctly 6	markedly 7	extremely 8
34. Manifest in facial expression, gesture, voice and manner a mood of dejection and sadness?	(53)	0	1	2	3	4	5	6	7	8
Cues : Rate only on the basis of external appearance and manifest behavior.										
35. Express feelings of dejection, sadness and unhappiness ?	(54)	0	1	2	3	4	5	6	7	8
Cues : Rate only on the basis of what the patient spontaneously reports or admits to on questioning. Do not rate external appearance here.										
36. Complain, criticize, gripe or find fault with people and conditions in or out of the hospital ?	(55)	0	1	2	3	4	5	6	7	8
Cues : Complains about everything and anything : The medical care, the food, the aides, fellow patients, the routine, the hospital, people in general.										
37. Exhibit an excess of speech ?	(56)	0	1	2	3	4	5	6	7	8
Cues : Difficult to stop flow of speech once started or to get a word in edgewise. Judge the amount of speech and not its rate or relevance.										
38. Express suspicion of people or their motives ?	(57)	0	1	2	3	4	5	6	7	8
Cues : Expresses lack of trust in others; feels or suspects others are hostile towards him; questions motives of examiner; questions fidelity of wife.										
39. Express feelings of discouragement, loss of hope or despair about the future?	(58)	0	1	2	3	4	5	6	7	8
Cues : Doubts things will improve. Discouraged about being helped. Despairs of finding solutions. Feels hopeless and "at the end of the rope". Says "I'll never get well" or its equivalent.										

Compared to the normal person, to what degree does he ...		not at all 0	very slightly 1	a little 2	mildly 3	moderately 4	quite a bit 5	distinctly 6	markedly 7	extremely 8
40. Try to dominate, control or direct the conduct of the interview ?	(59)	0	1	2	3	4	5	6	7	8
Cues : Number of times he interrupts or "talks down" the interviewer. Tries to control or dominate the conversation.										
41. Fail to respond to questions, answer in monosyllables or give only minimal responses ?	(60)	0	1	2	3	4	5	6	7	8
Cues : Answers "yes" or "no"; stares blankly; has to be pushed to get an answer. Judge amount, not rate or relevance of speech.										
42. Express attitudes and feelings indicative of reduced self-esteem ?	(61)	0	1	2	3	4	5	6	7	8
Cues : Says he has failed as a person (friend, husband, parent, etc.). Says he is useless, worthless, a failure.										
43. Show a lack of insight regarding himself or an inability to recognize that he has problems ?	(62)	0	1	2	3	4	5	6	7	8
Cues : Offers physical illness as an explanation. Believes he is in a rest home or prison. Asks to be sent home immediately. Denies illness or need for treatment.										
44. Show outer signs of inner agitation and anxiety ?	(63)	0	1	2	3	4	5	6	7	8
Cues : Wrings hands, pulls on hair or skin, bites nails, purses or bites lips; moans and sighs.										
45. Express sense of personal helplessness and powerlessness to alter or remedy his condition ?	(64)	0	1	2	3	4	5	6	7	8

Answer the following on the basis of the patient's reports or admissions. If a symptom is not present rate "not at all." To What Extent Does He Appear Preoccupied With...		not at all 0	once or twice 2	a few times 4	fairly often 6	very often 8
46. Suicidal thoughts or impulses ? (Says life is not worth living. Wishes he were dead. Threatens or plans suicide.)	(65)	0	2	4	6	8
47. Unwanted thoughts that recur persistently and are difficult to control ? (He must recognize these ideas as irrational.)	(66)	0	2	4	6	8
48. Specific morbid fears of objects, persons or situations ? (e.g., crowds, enclosed spaces, catching a disease.)	(67)	0	2	4	6	8
49. Urges or compulsions to perform a repetitive act or ritual which he recognizes to be unnecessary or illogical, but difficult to control ? (e.g., counting, handwashing.)	(68)	0	2	4	6	8
50. Delusional beliefs or convictions ? (e.g. ideas of persecution, reference, control. etc.)	(69)	0	2	4	6	8
51. Hallucinatory sounds or voices ? (e.g. singing, buzzing, laughing, blaming voices.)	(70)	0	2	4	6	8
How Often During the Interview Did He ...						
52. Grin or giggle inappropriately ? (exclude reactions resulting from embarrassment.)	(71)	0	2	4	6	8
53. Grimace peculiarly or otherwise exhibit unusual or bizarre frowns or other facial expressions ?	(72)	0	2	4	6	8
54. Exhibit peculiar, inappropriate or bizarre repetitive gestures and/or manneristic body movements (e.g., rhythmic neck twisting, lip smacking, odd gestures) ?	(73)	0	2	4	6	8
55. Use phrases or coin words not found in the ordinary language or the dictionary (neologisms) ?	(74)	0	2	4	6	8
56. Mechanically repeat certain words or fixed phrases in a seemingly meaningless way (stereotypy) ?	(75)	0	2	4	6	8
57. Talk, mutter or mumble to himself without an apparent provoking stimulus ?	(20)*	0	2	4	6	8
58. Glance around at and/or appear to be startled as if hearing voices ?	(21)	0	2	4	6	8

* Card No. 02

Inquire about the patient's view of his cognitive functioning, ability to make decisions, level of interest in people, work and sex, energy level, and ease of sleeping for the past week. If, and only if, he admits or complains of disturbances, ask how frequently these occur.		not at all	once or twice	a few times	fairly often	very often
How Often During The Past Week Did He ...						
59. Experience difficulty in making decisions, even about little things, without help ?	(22)	0	2	4	6	8
60. Observe a decrease in, or loss of, ability to concentrate, remember things, or solve problems ?	(23)	0	2	4	6	8
61. Feel tired, worn out, or lacking in energy ?	(24)	0	2	4	6	8
62. Observe a reduction or loss of interest or enjoyment in people, social activities or hobbies ?	(25)	0	2	4	6	8
63. Experience a difficulty or inability to get started, to work at, or to keep interest up in anything ?	(26)	0	2	4	6	8
64. Experience a decrease in, or loss of, sexual interest, pleasure or potency ?	(27)	0	2	4	6	8
65. Experience difficulty in falling asleep or remaining asleep without sedatives ?	(28)	0	2	4	6	8
Answer on the basis of evidence obtained in the interview that the patient NOW has or during the past week had hallucinatory experiences or delusional beliefs.						
How Often Did He ...						
66. Hear voices that accused, blamed or said "bad" things about him (e.g., he is a spy, homosexual, murderer) ?	(29)	0	2	4	6	8
67. Hear voices that praised, extolled or spoke to him about divine mission ?	(30)	0	2	4	6	8
68. Hear voices that threatened punishment, torture or death ?	(31)	0	2	4	6	8
69. Hear voices that ordered him to carry out or perform certain tasks ?	(32)	0	2	4	6	8
70. See actual visions ? (Note : check carefully as this is infrequent except in organic cases.)	(33)	0	2	4	6	8
71. Have other hallucinatory experiences : tactual, gustatory, olfactory (e.g. sensations of crawling on the skin, smells queer or foul odors, food or drink tastes peculiar or "bad") ?	(34)	0	2	4	6	8

How often during the past week did he ...		not at all	once or twice	a few times	fairly often	very often
72. Experience self-estrangement, i.e., feel or think he is no longer the same person; feel changed, unreal, unfamiliar or detached (e.g., feel numb, dead, like a corpse, or without feeling; as though floating in space) ?	(35)	0	2	4	6	8

Does He Believe That ...		No	Yes
73. Some people talk about, refer to, or watch him ?	(36)	0	8
74. He is being blocked, cheated, deprived, discriminated against, or persecuted ?	(37)	0	8
75. Certain people are plotting or conspiring against him (e.g., secret police, criminals, international spies) ?	(38)	0	8
76. Certain people are trying to or now do control his actions or thinking ?	(39)	0	8
77. Certain external forces (e.g., machines, electronic devices) are influencing or controlling his behavior and thinking ?	(40)	0	8
78. He has unusual or extraordinary abilities, powers or knowledge (e.g., scientific or religious) ?	(41)	0	8
79. He is a well-known present day or historical personality (e.g., president, Christ) ?	(42)	0	8
80. He is unworthy, sinful, evil and/or guilty of unpardonable sins and crimes ?	(43)	0	8
81. Familiar things, people, or surroundings have changed and are unreal ?	(44)	0	8
82. His body is diseased, distorted or that his internal organs are rotted or missing ?	(45)	0	8
83. He has a distinct divine mission, that he received commands from God or that he has other religious "calls" ?	(46)	0	8

Does He Know ...			
84. That he is in a hospital ?	(47)	1	0
85. In what state the hospital is located or the nearest large city ?	(48)	1	0
86. The name of at least one person in the hospital?	(49)	1	0
87. The season of the year (allow for transitional periods) ?	(50)	1	0
88. The calendar year ?	(51)	1	0
89. His own age ?	(52)	1	0

DATE (70-75) |__|__|__|__|__|__|

INFORMATION for USERS

DEVELOPMENT - Extensively revised in 1966, the IMPS consists of 89 items rated on the basis of observations made during a psychiatric interview. The scale has been designed to measure psychotic syndromes and has undergone extensive psychometric analysis.

REFERENCES - 1. Lorr M., Klett C.J., McNair D.M. and Lasky J.J., Manual : Inpatient Multidimensional Psychiatric Scale, Consulting Psychologists Press, Palo Alto, California, 1966.

2. Lorr M. and Klett C.J., Inpatient Multidimensional Psychiatric Scale (Revised Edition), Consulting Psychologists Press, 1966.

APPLICABILITY - Functional psychotic or severely neurotic adults who can be interviewed.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Observations based on behavior during the interview.

SPECIAL INSTRUCTIONS - Detailed descriptions on administration, statistical analyses and norms are provided in Lorr and Klett's Manual, and raters are advised to familiarize themselves with its contents.

FACTOR COMPOSITION

I. Excitement	II. Hostility and Belligerence
7. Unrestrained	5. Verbal
9. Hurried speech	11. Contempt
12. Elevated mood	18. Attitude
17. Dramatization	25. Irritability
20. Loud	28. Blames others
26. Overactive	32. Bitter
37. Excess speech	36. Complaints
40. Dominates	38. Suspicious

III. Paranoid projection
- 50. Delusional
- 73. Reference
- 74. Persecution
- 75. Conspiracy
- 76. People controlling
- 77. External controlling
- 82. Body destruction

IV. Grandiose expansiveness
- 15. Superiority
- 67. Voices extoll
- 78. Unusual powers
- 79. Great personality
- 83. Divine mission

V. Perceptual distortion
- 51. Hears voices
- 66. Voices accuse
- 68. Voices threaten
- 69. Voices order
- 70. Visions
- 71. Other hallucinations
- 81. Ideas of change

VI. Anxious intropunitiveness
- 14. Blames self
- 21. Anxiety (specific)
- 24. Apprehensive
- 27. Self-depreciating
- 29. Depressed
- 31. Guilt
- 43. Insight
- 46. Suicidal
- 47. Obsessive
- 48. Phobic
- 80. Sinfulness

VII. Retardation and apathy
- 1. Slowed speech
- 8. Lack of goals
- 13. Fixed facies
- 16. Slowed movements
- 19. Memory deficit
- 22. Speech blocking
- 23. Apathy
- 30. Slovenly
- 33. Whispered speech
- 41. Failure to answer

VIII. Disorientation
- 84. Hospital
- 85. State
- 86. Knows no one
- 87. Season
- 88. Year
- 89. Age

XIX. Motor disturbances
- 6. Posturing
- 10. Tension
- 52. Giggling
- 53. Grimacing
- 54. Repetitive movements
- 57. Talks to self
- 58. Startled glances

X. Conceptual disorganization
- 2. Irrelevant
- 3. Incoherent
- 4. Rambling
- 55. Neologisms
- 56. Stereotypy

DOCUMENTATION

a. Raw score printout

b. Factor score printout

c. Factor means and standard deviations

d. Variance analyses.

Fischer Symptom Checklist Neuroleptics (FSCL-NL)

FISCHER SYMPTOM CHECKLIST NEUROLEPTICS (FSCL-NL)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Fischer Symptom Checklist Neuroleptics (FSCL-NL)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 5 5
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4.

INSTRUCTIONS

Fill in the form after a non-suggestive semi-structured interview keyed to the items. Time span rated : status at control day or maximal period since last rating. At pretreatment now or within the last week.

Always cross one number		absent	mild	medium	severe
Mood					
Tension, irritability	(20)	0	1	2	3
Anxious mood	(21)	0	1	2	3
Depressed mood	(22)	0	1	2	3
Dysphoria	(23)	0	1	2	3
Indifference, apathy	(24)	0	1	2	3
Euphoria	(25)	0	1	2	3
Affect					
Blunted or impoverished	(26)	0	1	2	3
Inadequate or incongruous	(27)	0	1	2	3
Incontinent	(28)	0	1	2	3
Labile	(29)	0	1	2	3
Ambivalent	(30)	0	1	2	3
Psychomotor behaviour					
Retardation, slowing	(31)	0	1	2	3
Motor stiffness	(32)	0	1	2	3
Mannerisms	(33)	0	1	2	3
Stereotypy	(34)	0	1	2	3
Agitation, overactivity	(35)	0	1	2	3
Orientation consciousness					
Disorientation	(36)	0	1	2	3
Confusion	(37)	0	1	2	3
Delirium	(38)	0	1	2	3
Sleep					
Disturbed onset of sleep	(39)	0	1	2	3
Interrupted sleep	(40)	0	1	2	3
Early morning wakening	(41)	0	1	2	3

		absent	mild	medium	severe
Thought processes					
Thought retardation	(42)	0	1	2	3
Blocking	(43)	0	1	2	3
Disconnections/incoherence	(44)	0	1	2	3
Flight of ideas	(45)	0	1	2	3
Paralogia, neologisms	(46)	0	1	2	3
Thought contents					
Lack of insight into illness	(47)	0	1	2	3
Increased self-esteem	(48)	0	1	2	3
Delusions of grandeur	(49)	0	1	2	3
Phobias	(50)	0	1	2	3
Obsessions	(51)	0	1	2	3
Delusional ideas and experiences	(52)	0	1	2	3
Perceptual disturbance					
Hallucinations	(53)	0	1	2	3
Personality					
Depersonalisation	(54)	0	1	2	3
Derealization	(55)	0	1	2	3
Social behaviour					
Mutism	(56)	0	1	2	3
Difficulties in establishing contact	(57)	0	1	2	3
Negativism	(58)	0	1	2	3
Lack of inhibitions	(59)	0	1	2	3
Aggressive tendency	(60)	0	1	2	3
Aggressive action	(61)	0	1	2	3
Autoaggressive impulse, action	(62)	0	1	2	3
Social maladaptation	(63)	0	1	2	3
Disturbance of work and activity	(64)	0	1	2	3
Appetite					
Lack of appetite	(65)	0	1	2	3
Other symptoms	(66)	No 0			Yes 1
If yes, which (print) :	(67)	0	1	2	3
	(68)	0	1	2	3
	(69)	0	1	2	3
		DATE	(70-75)		_ _ | _ _ | _ _

INFORMATION for USERS

DEVELOPMENT - Developed by Fischer-Cornelssen, the FSCL-NL is a 46-item scale.

REFERENCE - K.A. Fischer-Cornelssen, The FSCL, CIPS-Booklet (Collegium Internationale Psychiatriae Scalarum), Beltz Publ., Weinheim FRG, 2nd edition, 99-106, 1981.

APPLICABILITY - Adults with schizophrenic disorder.

UTILIZATION - Once at pretreatment; at least one posttreatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - The rater estimates the severity of the 46 symptoms on the basis of a non-suggestive, semi-structured interview following the items on the checklist (in sequence). Information obtained from nursing staff etc. and relatives can also be considered in the time span mentioned.

DOCUMENTATION

a. Raw score printout
b. Cluster group score printout
c. Means and standard deviations
d. Cross tabulations
e. Variance analyses.

f. PSYCHOGERIATRIC PATIENTS

Hachinski's Dementia Score (HDS)

HACHINSKY DEMENTIA SCALE (DEM)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Hachinsky Dementia Scale (DEM)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 4 9
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

Changes in performance of everyday activities		Yes	No
1. Inability to perform household tasks	(20)	1	0
2. Inability to cope with small sums of money	(21)	1	0
3. Inability to remember short list of items, e.g., in shopping	(22)	1	0
4. Inability to find way about indoors	(23)	1	0
5. Inability to find way about familiar streets	(24)	1	0
6. Inability to interpret surroundings	(25)	1	0
7. Inability to recall recent events	(26)	1	0
8. Tendency to dwell in the past	(27)	1	0
Changes in habits			
9. Eating			
Messily with spoon only	(28)	1	0
Simple solids, e.g., biscuits	(29)	2	0
Has to be fed	(30)	3	0
10. Dressing			
Occasionally misplaced buttons etc.	(31)	1	0
Wrong sequence, commonly forgetting items	(32)	2	0
Unable to dress	(33)	3	0
11. Sphincter control			
Occasional wet beds	(34)	1	0
Frequent wet beds	(35)	2	0
Doubly incontinent	(36)	3	0
12. Increased rigidity	(37)	1	0
13. Increased egocentricity	(38)	1	0
14. Impairment of regard for feelings of others	(39)	1	0
15. Coarsening of affect	(40)	1	0
16. Impairment of emotional control	(41)	1	0
17. Hilarity in inappropriate situations	(42)	1	0
18. Diminished emotional responsiveness	(43)	1	0
19. Sexual misdemeanor (appearing de novo in old age)	(44)	1	0
20. Hobbies relinquished	(45)	1	0
21. Diminished initiative or growing apathy	(46)	1	0
22. Purposeless hyperactivity	(47)	1	0
TOTAL	(48-49)		
DATE	(70-75)	- - - - - -	

INFORMATION for USERS

DEVELOPMENT - Developed by Hachinski et al with the aim of identifying the degree of dementia, the DEM is a 22-item scale. The higher the total score, the greater (more severe) the dementia.

REFERENCE - Hachinski V.C., Illif L.D., Zilhka E., Du Boulay G.H., McAllister V.L., Marshall J., Russell R.W.R. and Symon L. : Cerebral blood flow in dementia. Arch. Neurol. 22 : 632-637, 1975.

APPLICABILITY - Geropsychiatric patients.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - At a maximum, the interval since the last assessment. At pretreatment, a span of one week is suggested.

CARD FORMAT - To be developed.

SPECIAL INSTRUCTIONS - Score, if present, each of the 22 features with the score (1 or 2) identified on the sheet. By summing scores derive at a Total Score. As higher Total Score as more severe is dementia.

AGP Psychopathological Symptoms (AGP-PS)

AGP PSYCHOPATHOLOGICAL SYMPTOMS (AGP-PS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
AGP Psychopathological Symptoms (AGP-PR)

Surname
First Name
Additional Patient ID-Number
Date

(1-3) - - -
Unit Number

(4-6) - - -
Study Number

(7-9) - - -
Subject Number
Male 001-499
Female 500-999

(10-12) 2 5 2
Form Number

(13-15) - - -
Assessment Period*

(16-17) - -
Rater Number

(18-19) 0 1
Card Number

(76-80) - - - -
Group to Which Patient is Assigned

*The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

		AB	MI	MO	SV	NA
Disturbed Consciousness	(20)	0				
1. Lowered	(21)	0	1	2	3	9
2. Narrowed	(22)	0	1	2	3	9
3. Clouded	(23)	0	1	2	3	9
4. Hypnagogic	(24)	0	1	2	3	9
5. Parasomnia	(25)	0	1	2	3	9
Disturbed Orientation	(26)	0				
6. Time	(27)	0	1	2	3	9
7. Place	(28)	0	1	2	3	9
8. Situation	(29)	0	1	2	3	9
9. Self	(30)	0	1	2	3	9
Disturbed Attention/Memory	(31)	0				
10. Apperception	(32)	0	1	2	3	9
11. Concentration	(33)	0	1	2	3	9
12. Memorization	(34)	0	1	2	3	9
13. Mem. numbers	(35)	0	1	2	3	9
14. Mem. words	(36)	0	1	2	3	9
15. Mem. objects	(37)	0	1	2	3	9
16. Mem. forms	(38)	0	1	2	3	9
17. Mem. people	(39)	0	1	2	3	9
18. Mem. colours	(40)	0	1	2	3	9
19. Recent memory	(41)	0	1	2	3	9
20. Remote memory	(42)	0	1	2	3	9
21. Forgetfulness	(43)	0	1	2	3	9
22. Ecmnesia	(44)	0	1	2	3	9
23. Hypermnesia	(45)	0	1	2	3	9
24. Confabulation	(46)	0	1	2	3	9
25. Paramnesia	(47)	0	1	2	3	9
26. Suggestibility	(48)	0	1	2	3	9
Disturbed Thinking	(49)	0				
27. Inhibited	(50)	0	1	2	3	9
28. Retarded	(51)	0	1	2	3	9
29. Circumstantial	(52)	0	1	2	3	9
30. Restricted	(53)	0	1	2	3	9

(Disturbed Thinking, cont'd)		AB	MI	MO	SV	NA
31. Perseverative	(54)	0	1	2	3	9
32. Rumination	(55)	0	1	2	3	9
33. Pressured	(56)	0	1	2	3	9
34. Flight of ideas	(57)	0	1	2	3	9
35. Paralogia	(58)	0	1	2	3	9
36. Blocking	(59)	0	1	2	3	9
37. Incoherence	(60)	0	1	2	3	9
38. Neologisms	(61)	0	1	2	3	9
39. Accelerated	(62)	0	1	2	3	9
40. Impaired abstraction	(63)	0	1	2	3	9
41. Conceptual impairment	(64)	0	1	2	3	9
42. Impaired judgment	(65)	0	1	2	3	9
Fears, Compulsions	(66)	0				
43. Suspiciousness	(67)	0	1	2	3	9
44. Hypochondriasis	(68)	0	1	2	3	9
45. Phobias	(69)	0	1	2	3	9
46. Obsess. thoughts	(70)	0	1	2	3	9
47. Compulsive impulses	(71)	0	1	2	3	9
48. Compulsive actions	(72)	0	1	2	3	9
Delusions	(73)	0				
49. Delusional mood	(74)	0	1	2	3	9
50. Delusional perception	(75)	0	1	2	3	9
51. Sudden delusional thought	(20)*	0	1	2	3	9
52. Delusional ideas	(21)	0	1	2	3	9
53. Systematic delusions	(22)	0	1	2	3	9
54. Delusional dynamics	(23)	0	1	2	3	9
55. Delusional reference	(24)	0	1	2	3	9
56. Delusional persecution	(25)	0	1	2	3	9
57. Delusional jealousy	(26)	0	1	2	3	9
58. Delusional guilt	(27)	0	1	2	3	9
59. Delusional impoverish	(28)	0	1	2	3	9
60. Hypochondrical delusion	(29)	0	1	2	3	9
61. Delusional grandeur	(30)	0	1	2	3	9
62. Other delusions	(31)	0	1	2	3	9

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* Card No. 002

		AB	MI	MO	SV	NA
Disturbed Perception	(32)	0				
63. Illusions	(33)	0	1	2	3	9
64. Verbal hallucinations	(34)	0	1	2	3	9
65. Other auditory hallucinations	(35)	0	1	2	3	9
66. Visual hallucinations	(36)	0	1	2	3	9
67. Bodily hallucinations	(37)	0	1	2	3	9
68. Olfact/gust. hallucinations	(38)	0	1	2	3	9
Disturbance of the Ego	(39)	0				
69. Derealization	(40)	0	1	2	3	9
70. Depersonalization	(41)	0	1	2	3	9
71. Broadcasting	(42)	0	1	2	3	9
72. Withdrawal	(43)	0	1	2	3	9
73. Insertion	(44)	0	1	2	3	9
74. Other influences	(45)	0	1	2	3	9
Disturbed Affect	(46)	0				
75. Perplexity	(47)	0	1	2	3	9
76 Loss of feeling	(48)	0	1	2	3	9
77. Blunted	(49)	0	1	2	3	9
78. Loss of vitality	(50)	0	1	2	3	9
79. Depression	(51)	0	1	2	3	9
80. Hopelessness	(52)	0	1	2	3	9
81. Anxiety	(53)	0	1	2	3	9
82. Euphoria	(54)	0	1	2	3	9
83. Dysphoria	(55)	0	1	2	3	9
84. Irritability	(56)	0	1	2	3	9
85. Inner restless	(57)	0	1	2	3	9
86. Complaintative	(58)	0	1	2	3	9
87. Inadequacy	(59)	0	1	2	3	9
88. Overconfidence	(60)	0	1	2	3	9
89. Feelings of guilt	(61)	0	1	2	3	9
90. Impoverishment	(62)	0	1	2	3	9
91. Ambivalence	(63)	0	1	2	3	9
92. Parathymia	(64)	0	1	2	3	9
93. Lability	(65)	0	1	2	3	9
94. Incontinence	(66)	0	1	2	3	9
95. Rigidity	(67)	0	1	2	3	9

		AB	MI	MO	SV	NA
Disturbance Drive/Motility	(68)	0				
96. Lack of drive	(69)	0	1	2	3	9
97. Inhibited drive	(70)	0	1	2	3	9
98. Stuporous	(71)	0	1	2	3	9
99. Inc. drive	(72)	0	1	2	3	9
100. Motor restless	(73)	0	1	2	3	9
101. Parakinesis	(74)	0	1	2	3	9
102. Mannerisms	(75)	0	1	2	3	9
103. Histrionic	(20)*	0	1	2	3	9
104. Mutism	(21)	0	1	2	3	9
105. Logorrhea	(22)	0	1	2	3	9
106. Negativistic	(23)	0	1	2	3	9
107. Indecisive	(24)	0	1	2	3	9
108. Psychoorganic syndrome	(25)	0				
Site local _____ diffuse _____ NA _____	(26)					
Severity	(27)		1	2	3	9
Duration (years) <1 ___ 1<2 ___ 2<3 ___ 3<4 ___ 4<5 ___ 5<6 ___ <10 ___ NA						
Global Performance Disturbance	(29)	0				
109. Aphasia	(30)	0	1	2	3	9
110. Agnosia	(31)	0	1	2	3	9
111. Apraxia	(32)	0	1	2	3	9
Localized Brain Dysfunction	(33)	0				
Front-parietal disturbance	(34)	0				
112. Frontal aprax	(35)	0	1	2	3	9
113. Facial aprax	(36)	0	1	2	3	9
114. Prefront I.S.	(37)	0	1	2	3	9
115. Fronto-basal I.S.	(38)	0	1	2	3	9
116. Motor aphasia	(39)	0	1	2	3	9
Occipital disturbance	(40)	0				
117. Color recogn.	(41)	0	1	2	3	9
118. Color/naming	(42)	0	1	2	3	9
119. Color/visual	(43)	0	1	2	3	9
120. Visual agnosia	(44)	0	1	2	3	9
121. Prosopagnosia	(45)	0	1	2	3	9
122. Dysmorphopsia	(46)	0	1	2	3	9

Card No. 003

		AB	MI	MO	SV	NA
Parieto-Occipital Disturbance	(47)	0				
123. Stereoagnosia	(48)	0	1	2	3	9
124. Somatagnosia	(49)	0	1	2	3	9
125. Anosognosia	(50)	0	1	2	3	9
126. Conduct. aphasia	(51)	0	1	2	3	9
127. Alexia	(52)	0	1	2	3	9
128. Agraphia	(53)	0	1	2	3	9
129. Acalculia	(54)	0	1	2	3	9
130. Ideomotor apraxia	(55)	0	1	2	3	9
131. Ideational apraxia	(56)	0	1	2	3	9
132. Construc. apraxia	(57)	0	1	2	3	9
Temporal Disturbance	(58)	0				
133. Amnestic aphasia	(59)	0	1	2	3	9
134. Sensory aphasia	(60)	0	1	2	3	9
Circadian Disturbance	(61)	0				
135. Worse in AM	(62)	0	1	2	3	9
136. Worse in PM	(63)	0	1	2	3	9
137. Better in PM	(64)	0	1	2	3	9
138. Nighttime exacerb.	(65)	0	1	2	3	9
139. Symp. alteration	(66)	0	1	2	3	9
Disturbed Sleep/Vigilance	(67)	0				
140. Difficulty fall asleep	(68)	0	1	2	3	9
141. Interrupted sleep	(69)	0	1	2	3	9
142. Early waking	(70)	0	1	2	3	9
143. Prolonged sleep	(71)	0	1	2	3	9
144. Shortened sleep	(72)	0	1	2	3	9
145. Night restlessness	(73)	0	1	2	3	9
146. Night confusion	(74)	0	1	2	3	9
147. Drowsiness	(75)	0	1	2	3	9
148. Day-night reversal	(20)*	0	1	2	3	9
149. Inc. dreaming	(21)	0	1	2	3	9
Disturbed Social Behavior	(22)	0				
150. Reduced social contact	(23)	0	1	2	3	9
151. Excessive social contact	(24)	0	1	2	3	9
152. Aggressive	(25)	0	1	2	3	9

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* Card No. 04

(Disturbed Social Behavior, cont'd)		AB	MI	MO	SV	NA
153. Suicidal	(26)	0	1	2	3	9
154. Self-mutilation	(27)	0	1	2	3	9
155. Lack of feeling ill	(28)	0	1	2	3	9
156. Lack of insight	(29)	0	1	2	3	9
157. Refuse treatment	(30)	0	1	2	3	9
158. Dissimulation	(31)	0	1	2	3	9
159. Self-neglect	(32)	0	1	2	3	9
160. Refuse nourish.	(33)	0	1	2	3	9
161. Decreased libido	(34)	0	1	2	3	9
162. Increased libido	(35)	0	1	2	3	9
Social - Nursing	(36)	0				
163. Financial needs	(37)	0	1	2	3	9
164. Housekeeping	(38)	0	1	2	3	9
165. Medical needs	(39)	0	1	2	3	9
166. Walking	(40)	0	1	2	3	9
167. Dressing self	(41)	0	1	2	3	9
168. Personal hygiene	(42)	0	1	2	3	9
169. Eating	(43)	0	1	2	3	9
170. Leisure activities	(44)	0	1	2	3	9
171. Transportation	(45)	0	1	2	3	9
172. Chewing disturb.	(46)	0	1	2	3	9
173. Bedridden	(47)	0	1	2	3	9
174. Urinary incontinence	(48)	0	1	2	3	9
175. Fecal incontinence	(49)	0	1	2	3	9
176. Smearing	(50)	0	1	2	3	9
Reliability	(51)	0	1	2	3	9

		No	Yes
Additional Examinations	(52)	0	
EKG	(53)	0	1
EEG	(54)	0	1
Echoencephalogram	(55)	0	1
CAT	(56)	0	1
Scintigram	(57)	0	1
Dopplersonogram	(58)	0	1
Angiogram	(59)	0	1

(Additional Examinations, cont'd)		No	Yes
ENG	(60)	0	1
LP	(61)	0	1
PEG	(62)	0	1
EMG	(63)	0	1
Psych. tests	(64)	0	1
RCPF	(65)	0	1
Other	(66)	0	1
(specify)	(67)	0	1

DATE (70-75) | - - | - - | - - |

INFORMATION for USERS

DEVELOPMENT - The AGP-PS is a 176-item, 4-point scale developed by the Geronto-psychiatric Division of the Free University of Berlin and the Psychiatric Clinic of the University of Lausanne, in consultation with the Psychiatric Clinic of the University of Freiburg during the early and middle 1970's. It was translated from the German by William Guy and Thomas A. Ban in collaboration with John Hoenig, Siegfried Kanowski, Alice Leeds and Jan Libiger.

APPLICABILITY - Psychogeriatric patients.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - In assessing psychopathological symptoms, the rater makes use of two sources of information : objective data based on direct behavioral observations of his own, of other professional personnel and the patient's relatives and upon the subjective data obtained directly from the patient.

Crichton Geriatric Rating Scale
(CRICHT)

CRICHTON GERIATRIC RATING SCALE (CRICHT)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Crichton Geriatric Rating Scale (CRICHT)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 0 1
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

SCORE	1	2	3	4	5	
1. Mobility	fully ambulant (incl. stairs)	usually independent (not stairs)	walks with supervision	walks with artificial aids or under careful supervision	bedfast or mainly so; chairfast	(20)
2. Orientation	complete	orientated in ward and identifies persons correctly	misidentifies persons and surroundings but can find way about	cannot find way to bed or to toilet without asssistance	lost	(21)
3. Communication	always clear and retains information	can indicate needs; can understand simple verbal directions; can deal with simple information	understands simple verbal and non-verbal information but does not indicate needs	cannot understand simple verbal or non-verbal information but retains some expressive ability	no effective contact	(22)
4. Cooperation	actively cooperative	passively cooperative	requires frequent encouragement and/or persuasion	rejects assistance and shows some independent but poorly directed activity.	completely resistive or withdrawn	(23)
5. Restlessness	none	intermittent	persistent by day	persistent by day with frequent nocturnal restlessness	constant	(24)
6. Dressing	dresses correctly unaided	dressing imperfect but adequate	dressing adequate with minimum supervision	dressing inadequate unless continually supervised	unable to dress or retain clothing because of mental impairment	(25)

Score	1	2	3	4	5	
7. Feeding	feeds correctly unaided at appropriate times	feeds adequately with minimum supervision	does not feed adequately unless continually supervised	defective feeding because of physical handicap or poor appetite	unable to feed because of mental impairment	(26)
8. Continence	fully continent	nocturnal incontinence unless toileted. Occasional accidents (urine or faeces)	continent by day if regularly toileted	urinary incontinence in spite of regular toileting	regularly/ frequently doubly incontinent	(27)
9. Sleep	normal (hypnotic not required)	requires occasional hypnotic; or occasionally restless	sleeps well with regular hypnotic, or usually restless for a period every night	occasionally disturbed in spite of regular standard hypnotic	disturbed even with heavier sedation	(28)
10. Mood Objective	normal and stable affective response and appearance	fair affective response, or not always appropriate or stable	marked blunting or impairment of mood or inappropriateness of of affect	emotional lability or incontinence of affect; retarded, lacks spontaneity but can respond	hallucinations or nihilistic delusions of guilt or somatic dysfunction	(29)
11. Mood Subjective	well-being or euphoria	self-reproachful, listless, dejected, indecisive, lacks interest (not completely well though no specific complaint	marked somatic or hypochondriacal concern; preoccupation	severe retardation or agitation. marked withdrawal though responds to questioning	suicidal or death wishes; mute, or agitated to the point of incoherence	(30)

(70-75)

DATE - - | - - | - -

INFORMATION for USERS

DEVELOPMENT - The 11-item CRICHT was developed as a part of a geriatric treatment program and was designed to assess the level of behavioral functioning. Derived from clinical observation, the items are rated on a 5-point scale ranging from normality (1) to complete failure of function (5).

REFERENCE - Robinson, R.A., The Diagnosis and Prognosis of Dementia, Current Achievements in Geriatrics, W.F. Anderson, Ed., Cassell 1964, 190-203.

APPLICABILITY - Elderly psychiatric patients.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - None stated by author. Now or within the past week is suggested.

LEVEL OF DETERIORATION

Total Score = Sum of the 11 items. Total Score provides a useful index of deterioration according to the author :

Total Score	Deterioration
10-20	Mild
21-30	Moderate
31+	Severe

DOCUMENTATION

a. Raw score printout

b. Means and standard deviations

c. Variance analyses.

Stockton Geriatric Rating Scale

(SGRS)

STOCKTON GERIATRIC RATING SCALE (SGRS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Stockton Geriatric Rating Scale (SGRS) - Meer	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 6 2
From Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

1. The patient will fall from his bed or chair unless protected by side rails or soft ties (day or night) 0 - never 1 - sometimes 2 - frequently	(20) _
2. The patient helps out on the ward (other than a regular work assignment) 0 - often helps out 1 - sometimes helps out 2 - never helps out	(21) _
3. The patient understands what you communicate to him (you may use speaking, writing or gesturing) 0 - understands almost everything you communicate 1 - understands some of what you communicate 2 - understands almost nothing you communicate	(22) _
4. The patient is objectionable to other patients <u>during the day</u> (loud or constant talking, pilfering, soiling furniture, interfering in affairs of others) 0 - rarely or never 1 - sometimes 2 - frequently	(23) _
5. Close supervision is necessary to protect the patient, due to feebleness, from other patients 0 - rarely or never needs protection 1 - sometimes needs protection 2 - frequently needs protection	(24) _
6. The patient keeps self occupied in constructive or useful activity (works, reads, plays games, has hobbies, etc.) 0 - almost always occupied 1 - sometimes occupied 2 - almost never occupied	(25) _
7. The patient communicates in any manner (by speaking, writing or gesturing) 0 - well enough to make himself easily understood at all times 1 - can be understood sometimes or with some difficulty 2 - can rarely or never be understood for whatever reason	(26) _

8. The patient engages in repetitive vocal sounds (yelling, moaning, talking, etc.) which are directed to no one in particular or to everyone 0 - never 1 - sometimes 2 - frequently	(27) _
9. When bathing or dressing, the patient requires 0 - no assistance 1 - some assistance 2 - maximum assistance	(28) _
10. The patient socializes with other patients 0 - does establish a good relationship with one or more patients 1 - has some difficulty establishing a good relationship with one or more patients 2 - has a great deal of difficulty establishing a good relationship with one or more patients	(29) _
11. The patient knows his own name 0 - almost always responds to his name 1 - sometimes responds to his name 2 - almost never responds to his name	(30) _
12. The patient threatens to harm other patients, staff or people outside the hospital either verbally (e.g., "I'll get him") or physically (e.g., raising of fist) 0 - never 1 - sometimes 2 - frequently	(31) _
13. With regard to walking, the patient 0 - shows no sign of weakness 1 - walks slowly without aid, or uses cane 2 - is unable to walk, or if able to walk needs walker, crutches or someone by his side	(32) _

14. The patient, without being asked, physically helps one or more patients in various situations (pushing wheel chair, helping with food tray, assisting in shower, etc.) 0 - often helps without being asked 1 - sometimes helps without being asked 2 - never helps without being asked	(33) _
15. The patient wants to go home or leave the hospital 0 - expresses great eagerness in leaving 1 - expresses some interest in leaving 2 - expresses almost no interest in leaving	(34) _
16. The patient is objectionable to other patients during the night (loud or constant talking, pilfering, soiling furniture, interfering in affairs of others, wandering about, getting into some other patient's bed, etc.) 0 - rarely or never 1 - sometimes 2 - frequently	(35) _
17. The patient is incontinent of urine and/or feces (day or night) 0 - never 1 - sometimes (once or twice per week 2 - frequently (3 times per week or more often)	(36) _
18. The patient takes the initiative to <u>start</u> conversations with others (exclude side remarks not intended to open conversations) 0 - often takes the initiative 1 - sometimes takes the initiative 2 - never takes the initiative	(37) _
19. The patient <u>accuses</u> others (patients, staff, or people outside the hospital) of doing him bodily harm or stealing his personal possessions (if you are <u>sure</u> the accusations are true, rate 0, otherwise rate 1 or 2) 0 - never 1 - sometimes 2 - frequently	(38) _
20. When eating, the patient requires 0 - no assistance (feeds himself) 1 - a little assistance (needs encouragement to eat) 2 - considerable assistance (spoon feeding, etc.)	(39) _

21. The patient has a regular work assignment 0 - away from the ward 1 - on the ward 2 - no regular assignment	(40) _
22. The patient is destructive of materials around him (breaks furniture, tears up magazines, sheets,clothes, etc.) 0 - never 1 - sometimes 2 - frequently	(41) _
23. The patient is confused (unable to find his way around the ward, loses his possessions, etc.) 0 - almost never confused 1 - sometimes confused 2 - almost always confused	(42) _
24. The patient knows the personnel by name 0 - knows names of more than one member of the personnel 1 - knows name of only one member of the personnel 2 - knows name of none of the personnel	(43) _
25. The patient engages in apparently useless repetitive movements (pacing, rocking, wringing of hands, making random movements,etc) 0 - never 1 - sometimes 2 - frequently	(44) _
26. The patient is in bed during the day (bed does <u>not</u> include couch, settee, etc.) 0 - never 1 - sometimes 2 - almost always	(45) _
27. The patient has privileges to leave the ward (companion or full ground privileges or town pass) 0 - has privileges and gets to use them often 1 - has privileges but only sometimes gets to use them 2 - does not have privileges, or has privileges but never gets to use them	(46) _
28. The patient hoards apparently <u>meaningless</u> items (wads of paper, string, scraps of food, etc.) 0 - never 1 - sometimes 2 - frequently	(47) _

29. When left to his <u>own devices</u>. the patient's appearance (clothes and/or hair, including beard for males) is 0 - almost never disorderly 1 - sometimes disorderly 2 - almost always disorderly	(48) _
30. If patient were allowed the freedom of the grounds alone, he would be able to protect himself from the weather (come in out of the rain or sun) or from getting lost 0 - would never need supervision outdoors 1 - would sometimes need supervision outdoors 2 - would always need supervision outdoors	(49) _
31. The patient's sleep pattern at night is 0 - almost never awake 1 - sometimes awake 2 - often awake	(50) _
32. The patient's meals consist of 0 - a regular solid diet, no limitations 1 - a normal diet with modifications (extra milk, soft or ground food) or limitations (no additional salt or bread) 2 - a special diet (diabetic, low salt, pureed, etc.)	(51) _
33. The patient is willing to do things suggested to or asked of him 0 - often goes along 1 - sometimes goes along 2 - almost never goes along	(52) _

(70-75)

DATE - - | - - | - -

g. TREATMENT EMERGENT SYMPTOMS

AGP-Somatic Signs (AGP-SS)

SOMATIC SIGNS (AGP)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Somatic Signs (AGP)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 2 5 2
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

1. Global state of health	(20)	good		fair		poor
		AB	MI	MO	SV	NA
Somatic disorders	(21)	0				
Cardiovascular disorders	(22)	0				
2. Insufficiency	(23)	0	1	2	3	9
3. Dysrhythmia	(24)	0	1	2	3	9
4. Hypertension	(25)	0	1	2	3	9
5. Other	(26)	0	1	2	3	9
6. Respiratory disorders	(27)	0	1	2	3	9
Gastrointestinal disorders	(28)	0				
7. Hypersalivation	(29)	0	1	2	3	9
8. Dry mouth	(30)	0	1	2	3	9
9. Nausea	(31)	0	1	2	3	9
10. Constipation	(32)	0	1	2	3	9
11. Diarrhea	(33)	0	1	2	3	9
12. Other	(34)	0	1	2	3	9
Urogenital disorders	(35)	0				
13. Urinary insuff.	(36)	0	1	2	3	9
14. Urinary diff.	(37)	0	1	2	3	9
15. Other	(38)	0	1	2	3	9
16. Movement disorders	(39)	0	1	2	3	9
Metabolic disorders	(40)	0				
17. Diabetes mellitus	(41)	0	1	2	3	9
18. Other	(42)	0	1	2	3	9
19. Chronic pain	(43)	0	1	2	3	9
20. Chronic consumpt. dis.	(44)	0	1	2	3	9
Other somatic disorders	(45)	0				

		AB	MI	MO	SV	NA
21. Blurred vision	(46)	0	1	2	3	9
22. Excessive sweating	(47)	0	1	2	3	9
23. Chills	(48)	0	1	2	3	9
24. Excessive thirst	(49)	0	1	2	3	9
25. Reduced thirst	(50)	0	1	2	3	9
26. Excessive appetite	(51)	0	1	2	3	9
27. Decreased appetite	(52)	0	1	2	3	9
28. Headache	(53)	0	1	2	3	9
29. Dizziness	(54)	0	1	2	3	9
30. Other	(55)	0	1	2	3	9
Neurological disturbances	(56)	0				
31. Olfactory disturbances	(57)	0	1	2	3	9
Vision disturbances	(58)	0				
32. Central visual	(59)	0	1	2	3	9
33. Peripheral visual	(60)	0	1	2	3	9
34. Central ocular paresis	(61)	0	1	2	3	9
35. Oculomotor paresis	(62)	0	1	2	3	9
36. Kinetic nystagmus	(63)	0	1	2	3	9
37. Spontaneous nystagmus	(64)	0	1	2	3	9
Hearing disturbances	(65)	0				
38. Middle ear	(66)	0	1	2	3	9
39. Inner ear	(67)	0	1	2	3	9
Central motor disturbances	(68)	0				
40. Hemiparesis	(69)	0	1	2	3	9
41. Paraparesis	(70)	0	1	2	3	9
42. Tetraparesis	(71)	0	1	2	3	9
Central sensory disturbances	(72)	0				
43. Hemihypesthesia	(73)	0	1	2	3	9

		AB	MI	MO	SV	NA
44. Transverse	(74)	0	1	2	3	9
Peripheral motor disturbances	(75)	0				
45. Distal	(20)*	0	1	2	3	9
46. Proximal	(21)	0	1	2	3	9
47. Peripheral sensory	(22)	0	1	2	3	9
Spinal cord disturbances	(23)	0				
48. Cervical	(24)	0	1	2	3	9
49. Thoracic	(25)	0	1	2	3	9
50. Sacrolumbar	(26)	0	1	2	3	9
Extrapyramidal signs	(27)	0				
51. Rigidity	(28)	0	1	2	3	9
52. Gross tremor	(29)	0	1	2	3	9
53. Fine tremor	(30)	0	1	2	3	9
54. Akinesia	(31)	0	1	2	3	9
55. Akathisia	(32)	0	1	2	3	9
56. Acute dyskinesia	(33)	0	1	2	3	9
57. Tardive dyskinesia	(34)	0	1	2	3	9
Coordination disturbances	(35)	0				
58. Intention tremor	(36)	0	1	2	3	9
59. Pointing ataxia	(37)	0	1	2	3	9
60. Postural ataxia	(38)	0	1	2	3	9
61. Gait ataxia	(39)	0	1	2	3	9
Primitive reflex	(40)	0				
62. Perioral reflex	(41)	0	1	2	3	9
63. Grasp reflex	(42)	0	1	2	3	9
64. Palmomental reflex	(43)	0	1	2	3	9
65. Other	(44)	0	1	2	3	9

* Card no.02

		AB	MI	MO	SV	NA
66. Equilibrium disturbance	(45)	0	1	2	3	9
Bulbar disturbance	(46)	0				
67. Speaking	(47)	0	1	2	3	9
68. Swallowing	(48)	0	1	2	3	9
Cerebral seizures	(49)	0				
69. Gen. primary	(50)	0	1	2	3	9
70. Gen secondary	(51)	0	1	2	3	9
71. Localized	(52)	0	1	2	3	9
72. Unclassified	(53)	0	1	2	3	9
Other CNS	(54)	0				
73. Peripheral	(55)	0	1	2	3	9
74. Central	(56)	0	1	2	3	9
75. Psychogenic	(57)	0	1	2	3	9
76. Handedness	(58)	0-4	5-9	10-14	9	
					(70-75)	
				DATE	- - | - - | - -	

INFORMATION for USERS

DEVELOPMENT - The AGP-SS is a 76-item, 4-point scale developed by the Gerontopsychiatric Division of the Free University of Berlin and the Psychiatric Clinic of the University of Lausanne, in consultation with the Psychiatric Clinic of the University of Freiburg during the early and middle 1970's. It was translated from the German by William Guy and Thomas A. Ban in collaboration with John Hoenig, Siegfried Kanowski, Alice Leeds and Jan Libiger.

APPLICABILITY - Psychogeriatric patients.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Nor or within the past week.

SPECIAL INSTRUCTIONS - The assessment of intensity often has to be based on the subjective clinical impression of the examiner, since evidence upon which to judge severity is not available.

The global judgment of general health should reflect an estimation of all somatic disturbances given the practical limitations of the examination.

The symptoms listed in Part 2 are global and are meant to evaluate the functional deficit of individual organ systems without making syndromal, nosological or causal determinations.

The third section, Neurological Disturbances, on the contrary, is a very detailed review of neurological signs which, however, does not represent a systematic neurological assessment. It is rather a framework to be combined and elaborated upon through a specific neurological examination.

Rating Scale for Side Effects (RSSE)

RATING SCALE FOR SIDE EFFECTS (RSSE)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Rating Scale for Side Effects (RSSE)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 3 8 0
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4,
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS - For each side effect present, rate the degree of intensity (I) and rate relationship (R) and action (A) using the following codes :

- Relationship : 0 = none
  1 = remote
  2 = possible
  3 = probable
  4 = defined

- Action taken : 0 = none
  1 = increased surveillance
  2 = contraactive RX
  3 = change dose
  4 = change dose plus contraactive RX
  5 = suspend RX
  6 = discontinue RX

I. Are side effects present at this time ? (20) No ___ Yes ___ (proceed to II)			
II. Side effects	I ___	R ___	A ___
Physical tiredness (20-22) 0 = None 1 = Slightly tired but needs no extra rest 2 = Has to lie down and rest at times or very tired but unable to rest 3 = Lies all day			
Sleep disturbance with or without hypnotics (23-25) 0 = Normal sleep 1 = Slight sleep disturbance 2 = 3-6 hours sleep 3 = Less than 3 hours sleep			
Headache, regardless of analgesics (26-28) 0 = None 1 = Occasional 2 = Constant moderate, or occasional severe 3 = Constant severe			
Dizziness (29-31) 0 = None 1 = Occasional slight dizziness 2 = Constantly slightly dizzy, or occasional severe dizziness 3 = Constant severe dizziness; has to lie down			

		I	R	A
"Orthostatic" symptoms				
0 = None	(32-34)			
1 = Feels slightly like fainting on sudden raising				
2 = Has to rise slowly to avoid feeling like fainting				
3 = Fainting frequently independent of position				
Palpitations	(35-37)			
0 = None				
1 = Slight palpitations				
2 = Occasional disturbing palpitations				
3 = Frequent disturbing palpitations				
Tremor	(38-40)			
0 = None				
1 = Slight tremor, movements not affected				
2 = Obvious tremor, small movements impaired				
3 = Severe tremor				
Perspiration	(41-43)			
0 = Normal				
1 = Slightly increased				
2 = Obviously increased				
3 = Profuse				
Dryness of mouth	(44-46)			
0 = None				
1 = Some, but not subjectively disturbing				
2 = Obvious but not severe or painful				
3 = Severe, makes speaking difficult				
Constipation	(47-49)			
0 = None				
1 = Slight constipation				
2 = Definite problem				
3 = No bowel movement for 4 days or more				
Micturition disturbances	(50-52)			
0 = None				
1 = Slight difficulties in passing water				
2 = Definite difficulties in emptying bladder (treatment needed)				
3 = Urinary retention				

		I	R	A
Drowsiness 0 = None 1 = Slight 2 = Moderate, some interference 3 = Severe, interference to daily routine marked	(53-55)			
Interference with sexual function 0 = None 1 = Slight impairment 2 = Moderate impairment 3 = Severe impairment	(56-58)			
Other	(59-61)			
1 = Slight impairment 2 = Moderate impairment 3 = Severe impairment	(62-64)			
Other	(65-67)			
1 = Slight impairment 2 = Moderate impairment 3 = Severe impairment	(68-70)			
Other	(20-22)*			
1 = Slight impairment 2 = Moderate impairment 3 = Severe impairment	(23-25)			
DATE	(70-75) - - | - - | - -			

* Card No. 02

Self-Rating Treatment Emergent Symptom Scale (STESS)

SELF-RATING TREATMENT EMERGENT SYMPTOM SCALE (STRESS)

National Institute of Mental Health (USA)
University of Pisa (Italy)
Institute of Clinical Psychiatry of Pisa
Center for Clinical Psychopharmacology Data Documentation (CCPDD)
Self-Rating Treatment Emergent Symptom Scale (STESS)

Surname
First Name
Additional Patient ID-Number
Date
Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 3 8
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS - Since the last time here, have you been bothered with or had trouble with any of the items listed below ? If this is your first visit, have you been bothered by any of these items in the last week ? Mark the number which best tells how much you were bothered. When filling out form for the child, mark on the basis of what you have seen or what the child has complained about. If you are unsure, mark "don't know".

		Not at all	Just a little	Pretty much	Very much	Don't know
Example :	Cramps ?	0	1	2	3	4

Have you had trouble with : (ITEM)		Not at all	Just a little	Pretty much	Very much	Don't know
1. Eating ?	(20)	0	1	2	3	4
2. Drinking ?	(21)	0	1	2	3	4
3. Dry mouth and lips ?	(22)	0	1	2	3	4
4. Wetness in mouth ?	(23)	0	1	2	3	4
5. Fewer bowel movements (constipation)	(24)	0	1	2	3	4
6. More bowel movements (diarrhea) ?	(25)	0	1	2	3	4
7. Stomach aches ?	(26)	0	1	2	3	4
8. Muscle cramps ?	(27)	0	1	2	3	4
9. Being sick to your stomach ?	(28)	0	1	2	3	4
10. Wetting the bed ?	(29)	0	1	2	3	4
11. Urinating ?	(30)	0	1	2	3	4
12. Itchy or scratchy skin ?	(31)	0	1	2	3	4
13. Rashes ?	(32)	0	1	2	3	4
14. Colds or sniffles ?	(33)	0	1	2	3	4
15. Headache ?	(34)	0	1	2	3	4
16. Dizziness ?	(35)	0	1	2	3	4
17. Playing sports ?	(36)	0	1	2	3	4
18. Shakiness ?	(37)	0	1	2	3	4

Have you had trouble with :		Not at all	Just a little	Pretty much	Very much	Don't know
19. Pronouncing words ?	(38)	0	1	2	3	4
20. Doing things with your hands ?	(39)	0	1	2	3	4
21. Sitting still ?	(40)	0	1	2	3	4
22. Tiredness ?	(41)	0	1	2	3	4
23. Feeling sleepy ?	(42)	0	1	2	3	4
24. Trouble getting or staying asleep ?	(43)	0	1	2	3	4
25. Bad dreams ?	(44)	0	1	2	3	4
26. Getting along with parents ?	(45)	0	1	2	3	4
27. Getting along with other kids ?	(46)	0	1	2	3	4
28. Crying ?	(47)	0	1	2	3	4
29. Getting mad ?	(48)	0	1	2	3	4
30. Not being happy ?	(49)	0	1	2	3	4
31. Being sad ?	(50)	0	1	2	3	4
32. Paying attention ?	(51)	0	1	2	3	4

DATE (70-75) - - | - - | - -

INFORMATION for USERS

DEVELOPMENT -

The Subject's Treatment Emergent Symptom Scale (STESS) was developed within the ECDEU programm and is an independently formatted 32-item scale designed to elicit information on the presence and degree of physical complaints. It may be completed by the child, parent or other knowledgeable adult. Although focussed on possible treatment emergent symptoms, STESS does not ask the rater to judge the relationship of his "symptoms" to the drug he is taking. A 4-point scale of severity is used with an additional response position for "don't know".

APPLICABILITY - Children to the age of 15.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Now or within the past week.

SPECIAL INSTRUCTIONS - STESS may be used as an independent scale for the periodic evaluation of treatment emergent symptoms (physical complaints) as :

a. perceived by the subject,
b. observed by one or both parents or parent surrogates,
c. observed by other raters, e.g., nurses, counselors, aides, etc.

Along with its use as an independent measure, the completed scale may also be referred to by the physician as a screening device in his assessments of treatment emergent symptoms.

As with all scales filled in by lay raters (patient, parent, etc.) be certain that the rater understands the instructions and knows how to mark his responses. Immediate monitoring of the completed form is suggested whenever possible to check that each item has been marked properly and that there are no multiple answers.

TOTAL SCORE - Sum of all items. Ranges from 0 to 96.

DOCUMENTATION

a. Raw score printout including total score.
b. Total score means and standard deviations by period and rater where applicable.
c. Symptom frequencies by period and rater where applicable.
d. Variance analyses.

Abnormal Involuntary Movement Scale (AIMS)

National Institute of Mental Health (USA) University of Pisa (Italy) Institute of Clinical Psychiatry of Pisa Center for Clinical Psychopharmacology Data Documentation (CCPDD) Abnormal Involuntary Movement Scale (AIMS)	Surname First Name Additional Patient ID-Number Date Name of Rater

(1-3) _ _ _ Unit Number	(4-6) _ _ _ Study Number	(7-9) _ _ _ Subject Number Male 001-499 Female 500-999	(10-12) 1 1 7 Form Number
(13-15) _ _ (_) Assessment Period*	(16-17) _ _ Rater Number	(18-19) 0 1 Card Number	(76-80) _ _ _ _ _ Group to which Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.

Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4

Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

INSTRUCTIONS - Complete examination procedure before making ratings.

Movement ratings : Rate highest severity observed. Rate movements that occur upon activation one less than those observed spontaneously.

Code : 0 = None
1 = Minimal, may be extreme normal
2 = Mild
3 = Moderate
4 = Severe

	None	Minimal	Mild	Moderate	Severe
Facial and oral movements	0				
1. Muscles of facial expression (20) e.g., movements of forehead, eyebrows, periorbital area, cheeks; include frowning, blinking, smiling, grimacing	0	1	2	3	4
2. Lips and perioral area (21) e.g., puckering, pouting, smacking	0	1	2	3	4
3. Jaw (22) e.g., biting, clenching, chewing, mouth opening, lateral movement	0	1	2	3	4
4. Tongue (23) Rate only increase in movement both in and out of mouth, NOT inability to sustain movement	0	1	2	3	4
Extremity movements					
5. Upper (arms, wrists, hands, fingers) (24) Include choreic movements (i.e., rapid, objectively purposeless, irregular, spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine) Do NOT include tremor (i.e. repetitive, regular, rhythmic)	0	1	2	3	4
6. Lower (legs, knees, ankles, etc.) (25) e.g., lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot	0	1	2	3	4
Trunk movements					
7. Neck, shoulders, hips (26) e.g., rocking, twisting, squirming, pelvic gyrations	0	1	2	3	4

Global judgments		None	Minimal	Mild	Moderate	Severe
8. Severity of abnormal movements	(27)	0	1	2	3	4
9. Incapacitation due to abnormal movements	(28)	0	1	2	3	4
		no Awareness	None	aware - distress Mild	Moderate	Severe
10. Patient's awareness of abnormal movements. Rate only patient's report	(29)	0	1	2	3	4

Dental status		No	Yes
11. Current problems with teeth and/or dentures	(30)	0	1
12. Does patient usually wear dentures ?	(31)	0	1

(70-75)

DATE - - - - - -

EXAMINATION PROCEDURE

Either before or after completing the Examination Procedure, observe the patient unobtrusively, at rest (e.g., in waiting room).

The chair to be used in this examination should be a hard, firm one, without arms.

---

1. Ask patient whether there is anything in his/her mouth (i.e., gum, candy, etc.) and if there is, to remove it.
2. Ask patient about the current condition of his/her teeth. Ask patient if he/she wears dentures. Do teeth or dentures bother patient now ?
3. Ask patient whether he/she notices any movements in mouth, face, hands, or feet. If yes, ask to describe and to what extent they currently bother patient or interfere with his/her activities.
4. Have patient sit in chair with hands on knees, legs slightly apart, and feet flat on floor (look at entire body for movements while in this position).
5. Ask patient to sit with hands hanging unsupported. If male, between legs, if female and wearing a dress, hanging over knees (observe hands and other body areas).
6. Ask patient to open mouth (observe tongue at rest within mouth). Do this twice.
7. Ask patient to protrude tongue (observe abnormalities of tongue movement). Do this twice.
- 8. Ask patient to tap thumb, with each finger, as rapidly as possible for 10-15 seconds; separately with right hand, then with left hand (observe facial and leg movements).
9. Flex and extend patient's left and right arms (one at time). (Note any rigidity and rate on DOTES).
10. Ask patient to stand up (Observe in profile. Observe all body areas again, hips included.)
- 11. Ask patient to extend both arms outstretched in front with palms down. (Observe trunk, legs and mouth.)
- 12. Have patient walk a few paces, turn, and walk back to chair. (Observe hands and gait.) Do this twice.

- Activated movements

INFORMATION for USERS

DEVELOPMENT - The AIMS is a 12-item scale designed to record in detail the occurence of dystkinetic movements.

APPLICABILITY - Patients receiving neuroleptic drugs.

UTILIZATION - Once at pretreatment; at least one post-treatment rating. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Period of the examination only.

TOTAL SCORE - Sum of the items. Ranges from 0 to 42.

DOCUMENTATION

a. Raw score printout

b. Means and standard deviations

c. Variance analyses.

Physical and Neurological Examination for Soft Signs (PANESS)

PHYSICAL & NEUROLOGICAL EXAMINATION FOR THE SOFT SIGNS (PANESS)

National Institute of Mental Health (USA)	Surname
University of Pisa (Italy)	First Name
Institute of Clinical Psychiatry of Pisa	Additional Patient ID-Number
Center for Clinical Psychopharmacology Data Documentation (CCPDD)	Date
Physical & Neurological Examination for the Soft Signs (PANESS)	Name of Rater

(1-3) _ _ _
Unit Number

(4-6) _ _ _
Study Number

(7-9) _ _ _
Subject Number
Male 001-499
Female 500-999

(10-12) 0 4 1
Form Number

(13-15) _ _ | _
Assessment Period*

(16-17) _ _
Rater Number

(18-19) 0 1
Card Number

(76-80) _ _ _ _ _
Group to which
Patient is Assigned

* The first 2 digits are provided for the number, the third for the unit of time.
Time units : pretreatment = 0; hours = 1; days = 2; weeks = 3; months = 4
Example : 20 days = 202; 3 weeks = 033; pretreatment = 000.

1. Age		(20)
a. Coded in : Months = 1 Years = 2	a	-
		(21-22)
b. Age	b	- -
2. Height		(23)
a. Coded in : Inches = 1 Centimeters = 2	a	- -
		(24-26)
b. Height	b	- - -
3. Weight		(27)
a. Coded in : [illegible] = 1 [illegible] = 2	a	-
		(28-30)
b. Weight	b	- - -
4. Head circumference		(31)
a. Coded in : Inches = 1 Centimeters = 2	a	-
		(32-33)
b. Head circumference	b	- -
5. Pulse		(34-36)
a. No. per minute	a	- - -
		(37)
b. Regular = 0 Irregular = 1	b	-
6. Blood pressure		(38-40)
a. Systolic	a	- - -
		(41-43)
b. Diastolic	b	- - -
7. Visual acuity (code numerator only)		(44-46)
a. Right	a	- - -
		(47-49)
b. Left	b	- - -
8. Ophtalmoscopic		(50)
Normal = 0 Abnormal = 1 Not ascertained = 9		-
9. Audiogram		(51)
Normal : 0 Abnormal = 1 Not ascertained = 9		-
10. Handedness		(52)
Right = 1 Left = 2 Mixed = 3 Not ascert. = 9		-

11. Physical examination Specify any abnormal findings.		Normal	Abnormal	Not ascertained
a. Head	(53)	0	1	9
b. Neck	(54)	0	1	9
c. Cardiovascular	(55)	0	1	9
d. Pulmonary	(56)	0	1	9
e. Liver	(57)	0	1	9
f. Kidney	(58)	0	1	9
g. Spleen	(59)	0	1	9
h. Other abdominal	(60)	0	1	9
i. Musculoskeletal	(61)	0	1	9
j. Gross neurologic	(62)	0	1	9
k. Skin	(63)	0	1	9
l. Lymphatics	(64)	0	1	9
m. G.U.	(65)	0	1	9

12. Was the neurological examination for soft signs conducted and coded on this form ? No = 0 Yes = 1	(66)	_

13. Past medical history Describe only CONTRIBUTORY illness, accidents, operations, etc.		
a.	(20-22)	*- - -
b.	(23-25)	- - -
c.	(26-28)	- - -
d.	(29-31)	- - -

14. Abnormal physical findings Specify all abnormalities noted on physical and gross neurologic examination (item 11). (Soft signs are coded on pages .)		
a.	(32-34)	- - -
b.	(35-37)	- - -
c.	(38-40)	- - -
d.	(41-43)	- - -

* Card No. 02

15. Diagnosis Specify all physical and neurological diagnoses here. Please use ICD-9 classifications.		
a.	(44-46)	- - -
b.	(47-49)	- - -
c.	(50-52)	- - -
d.	(53-55)	- - -

See instructions in assessment manual for details.

Use this code for items 1-20

1 = Performed correctly

2 = Performed but not well

3 = Performed poorly or only after repeated instruction and demonstration

4 = Unsuccessful even after repeated demonstration

9 = Not done or not ascertained.

1. Touch your finger to your nose.	(20)*	_
2. Touch your other finger to your nose.	(21)	_
3. Close your eyes and touch your finger to your nose.	(22)	_
4. Close your eyes and touch your other finger to your nose	(23)	_
5. Touch one heel to your other leg	(24)	_
6. Do the same with your other heel	(25)	_
7. Close your eyes and do it again	(26)	_
8. Now the other heel	(27)	_

Child writes name at the top of separate sheet of paper. Trace a "6" in each palm and identify it for the child. Figure is drawn in palm as child would see it. "Close your eyes and I will draw a mark on your hand. Now open your eyes and draw it on paper."

9.	□	right hand	(28) _
10.	X	left hand	(29) _
11.	O	right hand	(30) _
12.	□	left hand	(31) _
13.	X	right hand	(32) _
14.	3	left hand	(33) _
15.	O	right hand	(34) _
16.	3	left hand	(35) _

* card no 03

Close your eyes and tell me what I am putting in your hand.

17. Coin	Right hand	(36)	-
18. Ring	Left hand	(37)	-
19. Safety pin	Right hand	(38)	-
20. Key	Left hand	(39)	-

Scoring : Count number of errors (more than 3 scored as 3). An error is definite deviation from the line or steps incorrectly done.

21. Walk the line to the end on your toes.	(40)	0	1	2	3	9
22. Walk back on your heels	(41)	0	1	2	3	9
23. Hop on one foot to the end of the line	(42)	0	1	2	3	9
24. Now hop back on the other foot	(43)	0	1	2	3	9
25. Walk to the end this way (show tandem)	(44)	0	1	2	3	9
26. Now walk backwards the same way (6 steps)	(45)	0	1	2	3	9
27. Face-hand. Brush face and/or hand gently with equal stroke (patient's eyes closed)	(46)	0	1	2	3	9
28. Face-noise. Brush face and/or click toy cricket ipsilateral ear (patient's eyes closed)	(47)	0	1	2	3	9
29. Two point discrimination 1 cm. separation dorsum of digiti minimi	(48)	0	1	2	3	9

Persistent measurements

Period uninterrupted success (stopwatch)

		Seconds				
		20	15-19	10-14	0-9	NA
30. Stick out your tongue until I tell you to stop	(49)	1	2	3	4	9
31. Raise your arms out in front of you until I tell you to stop.	(50)	1	2	3	4	9
32. Close your eyes until I tell you to open them	(51)	1	2	3	4	9
33. Stand on one foot until I tell you to stop	(52)	1	2	3	4	9
34. Now stand on the other	(53)	1	2	3	4	9
35. Close your eyes and stand still until I tell you to stop	(54)	1	2	3	4	9
Tendency to fall ?	(55)			No 0	Yes 1	9
36. Now do it again like this (demonstrate tandem).	(56)	1	2	3	4	9
Tendency to fall ?	(57)			No 0	Yes 1	9

Scoring : These are 5-second tests. Always demonstrate with a 4-second beat. three scores are recorded for each test

a. Number of taps :
1 = 20
2 = 15-19
3 = 10-14
4 = 0-9
9 = ot ascertained.

b. Number of movements :
1 = 1
2 = 2
3 = 3
4 = 4 or more
9 = Not ascertained

c. Quality :
1 = Performed correctly
2 = Performed but not well
3 = Performed poorly or only after repeated instruction and demonstration
4 = Unsuccessful even after repeated demonstration
9 = Not done or not ascertained.

Test			A	B	C
37. Tap this fast with your finger	- left	(20-22)*			
38.	- right	(23-25)			
39. Tap this fast with your foot	- left	(26-28)			
40.	- right	(29-31)			
41. Tap with your finger and foot	- left	(32-34)			
	- right	(35-37)			

43. String test

Mark the number of times child successfully followed the 5 motions.

To the left	(38)	1	2	3	4	5
		not present	right		left	NA
NYSTAGMUS	(39)	1	2		3	9
To the right	(40)	1	2	3	4	5
N		not present	right		left	NA
NYSTAGMUS	(41)	1	2		3	9

* Card No. 04

44. Global improvement

Rate degree of improvement since admission to the study

(At initial rating mark "not assessed".)

	(42)	Much improved	Minimally improved	No change	Minimally worse	Much worse	NA
		1	2	3	4	5	9

45. The conditions of the examination were :

Satisfactory 1 Unsatisfactory 2 (43)

DATE (70-75) _ _ | _ _ | _ _

INFORMATION for USERS

DEVELOPMENT - The physical examination section has been developed within the ECDEU program; while the neurological section has been developed by Abbott Laboratories and Dr. Close.

APPLICABILITY - Children to age 15.

UTILIZATION - Once at pretreatment; at least one post-treatment assessment. Additional ratings are at the discretion of the investigator.

TIME SPAN RATED - Present status.

SPECIAL INSTRUCTIONS

Physical Examination It may be used independently or in conjunction with the neurological examination for soft signs. All items should be "filled in" - whether or not all items (examinations) were conducted. For those examinations not done, code a field of "9's".

Note : Although the physical examination section was designed specifically for children, the items - with the exception of item 4, perhaps - are applicable for all populations. Investigators with adult populations may use this section of PANESS to submit medical data for BLIPS/BDP processing.

Item 12 : This item MUST BE COMPLETED.

Neurological Examination for Soft Signs EXAMINERS MUST BE THOROUGHLY FAMILIAR WITH THE PROCEDURES FOR CONDUCTING THIS EXAMINATION GIVEN IN THE SECTION "SCORED NEUROLOGICAL EXAMINATION". DO NOT ALTER OR MODIFY THE MANNER IN WHICH THE TESTS ARE TO BE GIVEN.

Item 17 - The child need not name the correct denomination of the coin - merely recognize it as a coin.

Item 18 - The response "circle" is acceptable for "ring".

Items 27 and 28 - These tests are performed only ipsilaterally.

Items 30 and 34 - The scale points for these items are in time intervals rather than quality of performance. No second chances are given with these items.

Item 32 - Use clinical judgment as to whether eyes are closed tightly.

Items 35-36 - These 2 items require judgments on the subject's tendency to fall in addition to recording time intervalls. No second chances are given with these items.

CLUSTER COMPOSITION

Cluster	Items	Cluster Score Range
1. Synergy	1-8	8-32
2. Graphesthesia (right)	9, 11, 13, 15	4-16
3. Graphesthesia (left)	10, 12, 14, 16	4-16
4. Graphesthesia (both)	9-16	8-32
5. Stereognosis (right)	17, 19	2- 8
6. Stereognosis (left)	18, 20	2- 8
7. Stereognosis (both)	17-20	4-16
8. Gait	21-26	0-18
9. Topognosis	27-29	0- 9
10. Persistence	30-36	7-30*
11. Rapid movements (left)	37, 39, 41	9-36
12. Rapid movements (right)	38, 40, 42	9-36
13. Rapid movements (both)	37-42	18-72
14. String (left)	43a	2- 5**
15. String (right)	43b	2- 5**
Total score	All	

* Score : Sum of Items 30-36 + 35b + 36b

** Score = No of Movements + [absence (1) or presence (2, 3) of Nystagmus]

DOCUMENTATION

a. Raw score printout

b. Cluster score printout

c. Frequency tables

d. Means and standard deviation of cluster scores.

e. Variance analyses.

PART NINE

DATA BANK IN USE

RPR Information Retrieval System

During the years of its initial four years of operation from 1967 to 1971, BLIPS/ECDEU received approximately 630 Research Plan Reports (RPRs). This constituted a rich file of information on drug studies carried out during that period.

In order to use the information on this file as well as the information from the 10 to 15 new studies received per month, an efficient information search and retrieval system had been developed. In short, with an online computer system (the Conversational Programming System) of the Division of Computer Research and Technology NIH, all information on RPR forms was placed on a searchable computer file. This file was accessible from a typewriter terminal (IBM-2741) located at the Psychopharmacology Research Branch. Using this terminal, data from RPR forms (studies) could be entered to or retrieved from the existing file. Data on the files were stored as a sequence of individual records each representing a single study (RPR form). Using the online data retrieval system, it was possible to request studies dealing with any item or combination of up to five items within the RPR form. The information retrieved could be a count (number) of studies or a narrative English-language paragraph describing each of the studies meeting the criteria. Thus, in a sense,, the data from the file could be "analyzed" by specifying the search criteria.

The information contained in this file was of immediate interest to the Psychopharmacology Research Branch in that it reported which studies were being conducted through the ECDEU/BLIPS program. However, the information was also of interest to the larger scientific community. Such questions as "has drug A been compared to drug B in schizophrenic patients ?" were easily answered.

Data Bank for Psychopharmacology

The concept of the RPR Information Retrieval System was further elaborated in the concept of Data Bank for Psychopharmacology, referred to as BDP (from the Italian).

The BDP consists of three essentially separate components dealing with data entry, selection and analysis , in other words, clinical data, collected in a standard format, are stored in a data bank. A conversational program allows a high degree of interaction between the machine and the investigator who can select any group of patients and any portion of the data from the stored information for analysis. The program allows the investigator a great deal of scope, as it will accept complex combinations of desired conditions. For example, all the

data connected with one or more clinical trials or one or more patients may be selected. By means of the selection program, different files may be created in order to process different sets of data utilizing the most appropriate statistical procedure selected from a wide number of statistical techniques available in the system. The statistical tests available and routinely used are : chi square, t-test, variance and covariance analyses, discriminant analysis, and factor, regression and cluster analyses. The routines were adapted for conversational use, for the tabulation of results and presentation in graphic form.

In terms of data analytic capabilities, the merging of the BLIPS and the BDP has led to a very unique and powerful analytic tool. The formal data documentation techniques of BLIPS, and not just the RPR, are utilized in a data bank of clinical trials which is readily analyzable through the use of a general selection program and access to a variety of statistical programs as well as rerunning through BLIPS itself. For example "new studies" composed of parts of old studies can be readily assembled and analyzed. If two studies of new antidepressants used amitriptyline as the standard comparison drug, a "new study" comparing amitriptyline in study one and study two can be created to see if the patients in the two studies showed a similar response to the same drugs. This opens new possibilities for clinical psychopharmacological research by providing the maximum amount of information about a drug, using the least number of patients.