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WHO/ADAMHA JOINT PROJECT ON DIAGNOSIS AND CLASSIFICATION  
OF MENTAL DISORDERS AND ALCOHOL AND DRUG-RELATED PROBLEMS  
TASK FORCE ON PERSONALITY DISORDERS

RESEARCH PROTOCOL  
INTERNATIONAL PILOT STUDY OF PERSONALITY DISORDERS

1. Objectives

The study will aim to accomplish the following:

1. Determine the feasibility of using a standardized structured interview, the International Personality Disorders Examination (IPDE), to identify and diagnose personality disorders and related conditions in different cultures.
2. Determine the inter-rater reliability of the IPDE in its several language versions within and across field research centres in different cultures.
3. Investigate selected aspects of validity of IPDE assessment.
4. Explore the value of IPDE for reaching a diagnosis of personality disorder and classifying it within the provisions of ICD-10 and national classification schemes (e.g. DSM-III-R).

2. Sample

A. Study population. The population under study will be patients in psychiatric and general health facilities. Each center will select and assess 50 or more out- or in-patients. Thirty of these patients should meet (ICD-10 and/or DSM III R) criteria for a personality disorder. The remaining 20 should have other common mental disorders\* important in the differential diagnosis of personality disorders. Both sexes should be in as equal distribution as possible, not to exceed 20% on either side of the midpoint.

B. Inclusion Criteria. The sample will include two components: patients with- and patients without- a clinical diagnosis of personality disorders. Inclusion criteria for both groups are:

- Presentation to a psychiatric service or general health service.

\* NOTE: Patients should not be excluded because they may also present with depressive, anxiety, obsessive-compulsive, dissociative, somatization, sleep, eating, and sexual disorders.

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- Age range 21-55 years.
- The presence of a common mental disorder important to the differential diagnosis of personality disorder (20 cases) or evidence of a long-standing and persistent pattern of symptomatology and behavior which in the context of the given culture is considered an abnormality of personality (for the 30 cases likely to be diagnosed as personality disorders). Specifically, the characteristics of personality disorder include:
  - a) markedly disharmonious attitudes and behaviour usually involving several areas of functioning, eg, affectivity, arousal, impulse control, ways of perceiving and thinking, and styles of relating to others;
  - b) the abnormal behaviour pattern is enduring and not limited to episodes of mental illness;
  - c) the abnormal behaviour pattern is pervasive and clearly maladaptive to a broad range of personal and social situations;
  - d) the above manifestations generally appear during childhood or adolescence and continue into adulthood;
  - e) the disorder is of sufficient severity to lead to considerable personal distress and/or the disorder is usually, but not invariably, associated with significant impairment in occupational and social performance.

C. Exclusion Criteria

A patient will be excluded from the study if at the time of the examination he shows:

- Clinical evidence toxic or organic brain disease.
- Moderate to profound mental retardation.
- Language or other communication difficulties preventing adequate assessment.
- Alcohol or drug use likely to prevent an adequate examination.
- Delusional disorders, acute transient or other florid psychotic state.
- Evidence that personality functioning may be significantly changed by another psychiatric disorder (e.g. psychosis) with the exception of those listed in the inclusion criteria.

### 3. Assessment Procedures

Depending on the nature of the facilities from which patients will be recruited, a chief centre investigator will define the way in which patients to whom the schedules will be applied will be selected.

Core assessment procedures include the screening evaluation, the IPDE interview, the Clinical Summary, reliability evaluations, and follow up evaluations. These are described below.

### 4. Screening Procedure

Each centre will designate one (or preferably two) experienced clinicians\* who will identify, among patients attending the facilities, those suitable for this study. These clinicians will review whatever clinical information is available on the patient and whenever necessary conduct their own clinical interview with the patient in order to make a preliminary diagnostic assessment. The clinicians will complete a Screening Form consisting of:

- a brief summary of information about the patient, including demographic data;
- the inclusion criteria checklist;
- the exclusion criteria checklist;
- a request for the clinical diagnosis (including a statement on whether or not the patient has a personality disorder);
- a confidence rating on the judgment concerning presence or absence of personality disorder.

Whenever possible, both clinicians at a site will review the clinical material jointly to arrive at a consensus decision on the presence or absence of personality disorder. For patients who are screened and found unsuitable for the study, the clinician will write a brief note on the Screening Form explaining the non-suitability.

### 5. IPDE Assessment

In addition to the experienced clinicians who will screen patients for inclusion, each centre will identify at least two experienced psychiatrists or clinical psychologists\*\* who will be trained in the use of the IPDE. These raters should conduct their IPDE interview blindly, i.e. without reviewing the Screening Form, the clinical chart, or other clinical information. Unless impossible, the interview should be conducted without an informant present, and the informant should not be consulted prior to the interview.

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\* Their names, with a brief description of their qualifications, should be sent to WHO Headquarters, Geneva.

\*\* Depending on the circumstances in the centre.

The rater should fill out the first column of the IPDE Scoresheet item by item as the interview progresses. If inconsistencies emerge later in the interview, the patient may be queried concerning them, and changes can be made in earlier ratings in the first column of the scoresheet. At the end of the blind interview, the rater should review the ratings and record his or her clinical diagnosis on the Scoresheet.

The IPDE rater should then review whatever additional clinical information is available, and whenever possible conduct a discussion with an informant. The informant should be a person who knows the patient well. The informant's identity should be marked on the score sheet. If this leads to changes in ratings, the rater should record only the changed ratings and changes in diagnosis in the second column of the Scoresheet. Under no circumstances should the rater make changes of the ratings in the first column of the IPDE Scoresheet entered at the time of the blind interview. The rater must not review the Screening Form at any point in the evaluation process.

#### 6. Clinical Summary

A clinical evaluation for each of the patients should be completed by the IPDE rater. Use of a semi-structured interview, such as the PSE or the SCID, is desirable. However, if this is not possible, a description of the patient, including the diagnosis by an experienced clinician, should be recorded. The possibility of using the HSCL 90 should be explored. The Centres should inform WHO/HQ which of the standardized measurement instruments (e.g. PSE, SCID) they will use. They should also explore whether the HSCL 90 can be used in their centre and inform HQ accordingly.

#### 7. Assessment of Reliability

Two types of reliability will be assessed in this study, one using interviews conducted within a centre (intracentre reliability), and one using tapes which will be shown to all raters (inter-centre reliability). If possible, intra-centre reliability assessments should be collected on every IPDE interview either by being present during the interview or by rating a videotape recording. Failing this, at least 10 patients per centre should be assessed by two raters. For the rater-observer technique, one rater will serve as the rater, while the other will silently observe. The rater/observer role should be alternated among investigators. The observer may not ask clarifying questions at all, or discuss the case with the rater until the completion of the six month follow up evaluation.

The Scoresheet (including personality disorder diagnosis) filled out by the observer should be clearly marked "observer".

Inter-centre reliability will be determined by circulating videotapes of interviews in English among the centres. These tapes will be produced by Dr Loranger and his team. The tapes will be rated by all the (rating) investigators in the centre. Five of the tapes will be rated at the beginning of the study, three mid-way through and three at the end of the study. If the tapes (or part of it) were viewed more than once before rating, this will be noted in the Scoresheet.

#### 8. Follow Up Evaluation

It would be desirable to have a follow-up assessment. The existing design of the follow-up part of this study will be finalized after the preparatory phase and discussions with centre investigators. Under no circumstances, however, should the number of follow-up interviews be done on less than 50% of the group. The follow-up interview should take place 1-6 months after the initial interview. The rating should be carried out in the same manner as on the first assessment (see above: IPDE assessment). The purpose of this follow up evaluation is to assess the stability of the IPDE. Whenever possible, the follow up assessment should be performed by the same rater. If possible, the clinical evaluation of the patient should be repeated at that point and the instrument used in the centre for the assessment of mental state will also be applied at this time.

Arrangements for the follow up assessment should be made by the original IPDE rater/rater at the completion of the initial assessment.

#### 9. Optional Assessment Procedures

The Personality Assessment Schedule (PAS) will be used in conjunction with a formal mental state examination to compare informant's and patient's assessment, and to test comparability with the IPDE. As a rule, it is expected that the PAS will be applied subsequent to the application of the IPDE, so as to ensure comparability of IPDE ratings across centres. Inter-centre and inter-rater reliability will be determined as described in the section on reliability. A separate rater will see an informant and administer the informant version of the PAS. This rater will have no knowledge of the subject's assessments. The PAS will be administered following the IPDE evaluation.

At follow up the procedure above will be repeated exactly, whenever possible, with the same interviewers seeing patient and informant.

#### 10. Instruments, Translation, and Back-Translation

The instruments will be translated into the local language of each centre participating in the study, preferably by a translator with professional background in psychology or psychiatry. In the process of translation particular attention should be given to ensuring that idiomatic or culture-bound phrasing of any of the original IPDE items is equivalently translated into the second language version. As a control of this, back translation into English should be undertaken by a person different from the one who had prepared the translation and without knowledge of the original English language version of IPDE. The original schedule and the back-translation will then be subjected to a target check to assess the degree to which the wording of the translation matches the target concepts underlying the wording of the original. If discrepancies are found, the translation/back translation process should be repeated until acceptable level of equivalence is achieved.

#### 11. Training and Monitoring

Training sessions will be conducted for all sites participating in the study. There will be three such sessions, in New York, in Luxembourg, and in Bangalore. The training sessions will include the principal investigator and

clinical interviewers for the IPDE. The sessions will include didactic instruction on the administration of the IPDE and definition of items, as well as discussion of details of the research protocol. Formal reliability assessment will be conducted. Prior to the training sessions, a videotape of the IPDE interview in English will be prepared by Dr. Loranger and circulated to participating centres for rating.

After the study is underway, Dr. Loranger will visit as many of the centres as possible to provide assistance and guidance in the conduct of the protocol.

#### 12. Data Processing and Statistical Analysis

The principal investigator in each site is responsible for ensuring that the various study scoresheets and forms are appropriately filled out and edited. A copy of a scoresheet containing each patient's index assessment data, of the screening sheet and the clinical evaluation sheet (without any personally identifying information) will be forwarded in batches of five (with the original kept locally) to Dr. Loranger. When the batch of evaluation forms is sent, the principal investigator will inform Dr Loranger that it was sent, by cable. Dr Loranger will confirm receipt of the batch by cable. Dr. Loranger will enter this data onto a computer-readable file as the data is received. A copy of this file will be forwarded to the Secretariat at WHO and at ADAMHA, updated every three months.

A proposal for the statistical analysis will be developed by Dr. Loranger and circulated for comment within one month. The data analysis will be the responsibility of the secretariat in collaboration with Dr. Loranger and the participating investigators. Data from the optional PAS study will be sent to Dr. Tyrer, and will be his responsibility. Dr Tyrer will forward a copy of the data file to WHO.

#### 13. Human Subjects

For each subject a research staff member will obtain informed consent. The subject, after learning about the study, will sign an Informed Consent Form, which explains its purposes and methods, and the risks and benefits of participation.

All information which might identify an individual subject will be kept in confidential files at the local site, and will be deleted from any records forwarded from the site.

#### 14. Publications

1. The policy and rules concerning the publication from the project will follow the WHO guidelines (see annex).

An announcement paper will be prepared now; the first author will be Dr Loranger.

The second publication will be a central paper describing the instrument and the experiences obtained during its use. All active participants in the study will be co-authors.

Papers will be written following the studies, using data from the central study. These papers will be written by the investigators who should clear the draft manuscripts with WHO/ADAMHA. These centre manuscripts cannot be published until the main publication, referred to in the above paragraph has been published.

The Personality Disorder Examination instrument developed by Dr Loranger will be utilized in these field trials under the name of "International Personality Disorder Examination (IPDE)" and there will be no identified authorship other than WHO when it is circulated or published.

#### 15. Coordination

The overall administrative coordination and monitoring of project activities will be carried out, on behalf of the WHO/ADAMHA Steering Committee, by WHO headquarters in Geneva in accordance with an agreed plan and timetable of work.

#### 16. Sites

National Institute of Mental Health and Neurosciences, Bangalore, India  
Harvard University, Boston, USA  
Bezirkskrankenhaus, Kaufbeuren, Federal Republic of Germany  
Faculteit der Sociale Wetenschappen, Rijksuniversiteit, Leiden, Netherlands  
Institute of Psychiatry, London, UK  
Service de Neuro-Psychiatrie, Centre Hospitalier de Luxembourg, Luxembourg  
Max-Planck Institute, Munich, Federal Republic of Germany  
Department of Psychiatry, University of Nairobi, Faculty of Medicine,  
Kenyatta National Hospital, Nairobi, Kenya  
Payne Whitney Psychiatric Clinic, Cornell Medical Center, New York, N.Y., USA  
Mapperley Hospital, Nottingham, UK  
Gaustad Hospital, Oslo, Norway  
Centro per la Prevenzione e la Terapia della Depressione, Istituto di Clinica  
Psichiatrica, Pisa, Italy  
School of Medicine, Keio University, Tokyo, Japan  
Psychiatric University Clinic, Vienna, Austria  
The New York Hospital-Cornell Medical Center, White Plains, N.Y., USA

#### Flow Sheet

See Annex I

Screening evaluation - see Screening Form, Annex II, containing

- Demographic data
- Inclusion Checklist
- Exclusion Checklist
- Consensus Clinical Diagnosis
- Confidence Rating
- Reasons for not including the patient.

#### Index Evaluation -

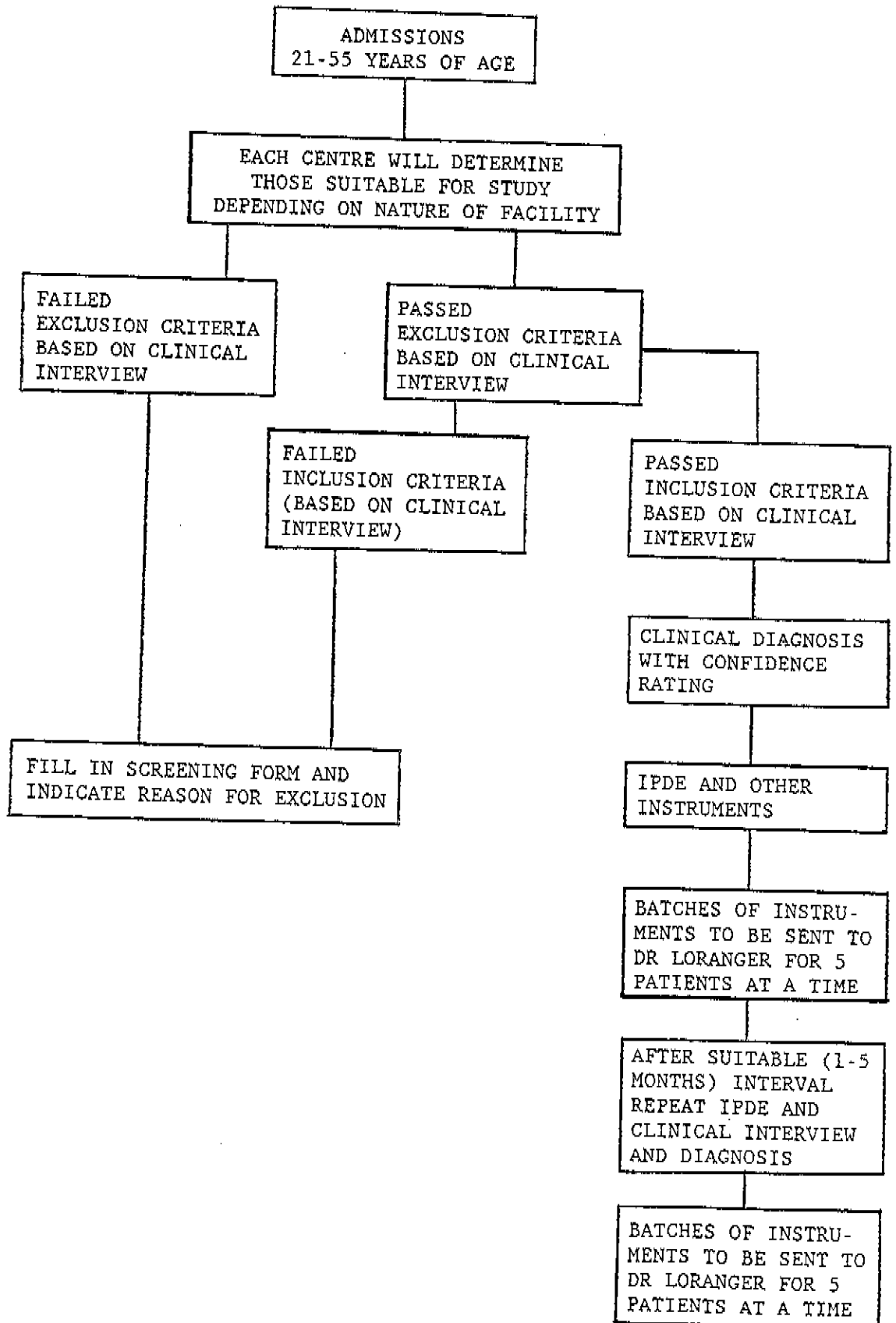
- IPDE Interview
- Clinical Evaluation Form (Annex III) containing  
Clinical summary, a diagnosis and a confidence rating
- Optional Assessments  
PSE or SCID  
Informant Interviews for PAS and IPDE  
Self Report Personality Inventories

Timetable

March, 1986	Preliminary protocol developed
March, 86-June, 87	Translation of the IPDE and Pilot study in the sites, Preparation of a new version of the IPDE to assess criteria for DSM III R and ICD 10
June - September 87	Conduct of training sessions
September - December 1987	Translations and back-translations completed and sent to Dr Loranger and WHO Secretariat
November 1987 - March/April 1988	Finalize IPDE Complete training of raters Complete 10 training cases per rater
March-April 1988	Visits to centres by Dr Loranger (Europe x 2, India, USA)
March 1988 - March 1989	Conduct study
Sept. - Oct. 1988	Meeting of investigators
Summer 1989	Complete follow-up
Summer 1989 - January 1990	Data analysis and publication of results

FLOW SHEET

ANNEX I



WHO/ADAMHA JOINT PROJECT ON DIAGNOSIS AND CLASSIFICATION  
OF MENTAL DISORDERS: PERSONALITY DISORDER EXAMINATION

ANNEX II

SCREENING FORM

1. IDENTIFICATION DATA

01 - 05

Centre at which interview  
was conducted: \_\_\_\_\_

06 - 10

Name of clinician who  
interviewed this subject: \_\_\_\_\_

11 - 12

Subject's registration  
number in facility \_\_\_\_\_

Subject's name or initial \_\_\_\_\_

WHO Number: \_\_\_\_\_

13 - 15

Sex:                      1 = male, 4 = female

16

Age in years:              (Estimate if necessary)

17 - 18

Date of interview:      (day, month, year)

19 - 24

2. CRITERIA FOR INCLUSION INTO THE STUDY

Exclusion criteria: Presence of any one of the following items:  
(0 = no, 1 = yes)

1. Clinical evidence of toxic or other  
brain disease

25

2. Diagnosis of mental retardation  
(based on clinical judgement)

26

3. Presence of severe language  
or hearing difficulties

27

4. Alcohol or drug use likely to  
confound the examination

28

5. Age below 21 or above 55

29

6. Presence of a delusional disorder,  
acute transient other psychotic  
state.

30

7. Likelihood that personality func-  
tioning was changed by another  
psychiatric disorder (e.g. psychosis)  
except those listed in the inclusion  
criteria

31



Summary of findings at present mental state examination:

44 - 48  
(leave blank)

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Has the subject had serious physical illness or disability? 0 = no  
1 = yes (specify \_\_\_\_\_) 49  
9 = uncertain    50 - 52  
(leave blank)

How long ago? (Number of months):   53 - 54

Has the subject ever had treatment for mental illness, or is there evidence of untreated mental illness before this admission? 0 = neither  
1 = outpatient treatment  
2 = inpatient treatment  
3 = out- and in-patient treatment  
4 = no treatment but evidence of untreated mental illness  
9 = unknown  55

If subject gives history of treatment for mental illness: what was the reason for treatment? (give diagnosis if available):    56 - 58  
(leave blank)

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How long ago? (No. of months)    59 - 60

Other clinical information which you consider important in this case:

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What is the main occupation of the subject?

71 - 73  
(leave blank)

What is the subject's current working status?

- 1 = self-employed
- 2 = employed
- 3 = unemployed
- 4 = On sick leave, currently employed
- 5 = On sickness (disablement), unemployed
- 6 = Not applicable (e.g. student, housewife, pensioner)
- 7 = Other (specify: \_\_\_\_\_)
- 9 = impossible to assess

74

If gainfully employed: does he/she work full-time or part-time?

- 0 = fulltime
- 1 = part-time
- 2 = other arrangements (specify: \_\_\_\_\_)

75

5. CLINICAL DIAGNOSIS

80

State diagnosis according to your own practice:

16 - 18  
(leave blank)

.....  
.....  
.....

ICD-10 diagnosis classification: Main

19 - 23

Subsidiary (1)

24 - 28

(2)

29 - 33

If two clinicians assessed the patients and their diagnoses differ, state diagnosis of second clinician

34 - 36  
(leave blank)

.....  
.....  
.....

How confident is your MAIN DIAGNOSIS

- 1 = very confident
- 2 = some doubt
- 3 = very uncertain

37

80

ANNEX III

WHO/ADAMHA JOINT PROJECT ON DIAGNOSIS AND CLASSIFICATION  
OF MENTAL DISORDERS: PERSONALITY DISORDER EXAMINATION

CLINICAL EVALUATION FORM

9 | M | 0 | 2 | 2

01 - 05

Centre at which interview  
was conducted: \_\_\_\_\_

| | | | |

06 - 10

Name of clinician who  
interviewed this subject: \_\_\_\_\_

| | |

11 - 12

Subject's registration  
number in facility \_\_\_\_\_

Subject's name or initial \_\_\_\_\_

WHO Number:

| | | |

13 - 15

Please give below a summary of the main findings relevant to your diagnosis:

| | | | | | | | |

16 - 25

(leave blank)

State diagnosis according to your own practice:

.....  
.....  
.....

26 - 28  
(leave blank)

ICD-10 diagnosis classification: Main

29 - 33

Subsidiary (1)

34 - 38

(2)

39 - 43

If two clinicians assessed the patients and their diagnoses differ, state diagnosis of second clinician

.....  
.....  
.....

44 - 46  
(leave blank)

How confident is your  
MAIN DIAGNOSIS

1 = very confident  
2 = some doubt  
3 = very uncertain

47

INTERNATIONAL PILOT STUDY OF PERSONALITY DISORDERS

1. Build up of patient documentation

The data will be transferred to 80-character records. Each record must be identifiable. Hence, centre number, patient's number etc are to be repeated not only on each instrument but also on each record. The identification consists of study number (pos. 01-04), instrument number (pos. 5), centre study number (pos. 06-10), interviewer number (pos. 11-12) and patient's number (pos. 13-15).

2. Study number and instrument number

These numbers are preprinted consisting of 5 characters that identify the study and instrument.

- In positions 01-04, code "OMO2" has been assigned as study number
- In positions 05, the following codes have been used for the identification of instruments
  1. Screening form for personality disorder
  2. Clinical summary and diagnosis
  3. International Personality Disorder Examination.

3. Centre study number

The number will be given to participating centres by WHO/HQ. This number which consists of 5 digits number will identify the region (pos. 6), country (pos. 07-08) and institution (pos. 09-10) at which the study is being carried out.

4. Interviewer number

Participating centre will assign to each investigator/assessor a unique two-digits number code and will communicate to WHO/HQ the numbers given with identification of the investigators.

5. Patient's number

In a chronological order, each subject entering the study will be given a unique three-digits number by the participating centre. This number will be used to identify the subject throughout the study.

6. Identification of records

See point 1 above. When an instrument consists of several records, each record is identifiable by a precoded number in position 80. This implies that only positions 16-79 are used for coding answers of questions/variables.

7. Codings

Boxes are provided on the right hand margin with identification of position on the record. Two types of boxes are provided: opened boxes are for questions with possible answers given in codes, closed boxes (accompanied by "leave blank") are for questions with an answer in narrative form.

The assessor should answer all questions on the left hand margin by either giving a code in the opened box or giving an answer on the lines provided. For the closed boxes, codes will be given at the central analytical centre.

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