Phase I: Preparation and training (12 weeks; April – June, 2000)

Key tasks in this initial phases will be:

- identify and recruit members of research team;
- review study protocol with study coordinators and make amendments as required across all sites;
- PC's undertake translation and piloting of study questionnaire;
- gather and review secondary data sources on methamphetamine use by each participating centre;
- participate in site training with coordinating centres;
- recruit and train local interviewers
- secure ethical approval for study from relevant local body (if required)
- pilot test research instrument

Phase II: field work (6-8 months; July, 2000-Dec, 2000)

In the second stage tasks will be:

- recruitment of interview participants
- interviewing
- establishment of study refusal register
- establishment of study follow up register
- establishment of data management and validation procedures
- computer systems review and analysis planning arrangement
- site visits and liaison

Phase III: Analysis of data (3 months; Jan, 2001-March, 2001)

- quantitative and qualitative analyses of main and secondary questions
- feedback of key results

Phase IV: Report preparation and recommendations (3months: April, 2001-June, 2001)

- participate in meeting of sites to present preliminary data and determine further action (coordinated by WHO)
- preparation of main report
- action planning for intervention options
- review and further action

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Appendix I

SAMPLE INFORMED CONSENT FORM
WHO Project on Psychological Problems associated with Methamphetamine Use
Study co-ordinators: Dr. Robert Ali & Dr. John Marsden

Introduction. This form describes the purpose and procedures of a World Health Organisation (WHO) Study on adverse consequences and health problems associated with methamphetamine use. The study is being conducted here in Japan and also in Australia, Thailand and the Philippines. The regional co-ordinator for the study is Dr. Robert Ali, Drug and Alcohol Services Council, Adelaide, South Australia. Some 200 participants are being recruited to help the project understand more about the psychological health problems associated with methamphetamine use and the experiences of people who use the drug. We want to learn more about the health and psychological problems which people who take the drug can experience and how we can make treatment services more effective. We hope the results of the study will help develop better clinical procedures.

Before agreeing to take part, please read this form carefully and discuss any questions or concerns you have with the researcher.

Summary of research. In taking part in the study you will be asked a series of questions in the form of a personal interview with the researcher. This will take about 1 hour. The researcher will ask you about your experiences with methamphetamine and other drugs and your views about the drug. These questions have been developed for the study and are being asked of each of the participants. Some of the questions are quite personal but remember that we are asking these to everyone. Please also note that you may refuse to answer any question if you wish without giving a reason why and, if you wish, you may withdraw from the study at any point.

While not included in the current research, we may wish to reinterview you at a future date and if you agree we will require details of how to contact you. Please note that it is not compulsory for you to agree to this future contact to participate in the initial study. You may also withdraw your consent at a later stage.

Confidentiality. Your name will not be recorded anywhere on the interview. In order to preserve your confidentiality, only an anonymous subject number will be associated with the information you provide. Your name will not appear on any report or publication or be released to anyone. The information we are

collecting will be compiled into a report for the WHO and no individual participant will be identified.

Risks. There are very few risks associated with you taking part in the study. However, a possible risk is that taking part in the interview may make you think about things in your life that then upset you or make you anxious. If this happens we will stop the interview immediately.

Benefits. Although there are no specific benefits for you in taking part in the study, your participation may help us understand more about the psychological and other health problems that methamphetamine users experience and we can better provide services to help them. If you want further information about drugs and treatment services your interviewer will be happy to provide this.

Other information. Your participation in the study is entirely voluntary. Choosing not to participate at any time is entirely up to you. Please feel free to ask questions about the study at any time. Please feel free to ask about anything you do not understand. Please consider this research and consent form carefully before you agree to participate. You can take as much time as you life to think about helping us in the study as you wish.

Authorisation. I, the undersigned, have understood the above explanation and give my consent to my voluntary participation in this research project. I understand that a copy of my signature below will be separated from this form and kept securely and confidentially by the study co-ordinator.

_____ _____

Participant's signature Signature of person obtaining consent

_____ _____

Name (please print) Location

_____

Date

.....

Informed Consent Form – Project on methamphetamine use

I, the undersigned, have understood the above explanation and give my consent to my voluntary participation in this research project.

Participant's signature Signature of person obtaining consent

_____ _____

Name (please print) Location

_____

Date

I, the undersigned, have understood the above explanation of the option for future contact and give my consent to my voluntary participation in this future research project.

Participant's signature	Signature of person obtaining consent
_____	_____
Name (please print)	Location

_____

Date

Contact details

_____

_____

_____

_____

Appendix II: Draft questionnaire

Appendix III

GUIDELINES FOR THE USE OF THE MANCHESTER SCALE

GUIDELINES FOR THE USE OF THE FIVE-POINT SCALES

In making these ratings the psychiatrist is expected to use his clinical judgement to make overall assessments about the patients in each particular area. For example, in making the rating for depression the rater should be expressing his own clinical assessment of the severity of depression, based on both the patient's demeanour and behaviour during the interview and the history that the patient has given concerning depression. It should be emphasised that a morbid rating (2,3, or 4) for depression does not imply that the principal diagnosis made will necessarily be an affective illness.

General rules for the Five-Point Scale

Rating "O" Absent:	The item is for all practical purposes absent
Rating "1" Mild:	Although there is some evidence for the item in question, it is not considered pathological.
Rating "2" Moderate:	The item is present in a degree just sufficient to be regarded as pathological.
Rating "3" Marked:	) See individual definitions
Rating "4" Severe:	)

DEPRESSION

This does not include the actual behaviour observed at interview – dejected pose, sad despondent manner – but should be a clinical rating which expresses the overall assessment of depression, and the contribution that this abnormality of affect is making to the abnormal mental state being rated. Whether there is a discrepancy between depression observed at interview and depressed mood reported as having been experienced in the past week, the rating made should be the greater of the two ratings.

Rating "O" Absent:	Normal manner and behaviour at interview. No depressive phenomena elicited.
Rating "1" Mild:	Although there may be some evidence of depression – occasional gloominess, lack of verve, etc – the rater

does not consider that it is pathological, or takes it to be an habitual trait not amounting to clinically significant depression.

Rating "2" Moderate: The patient is thought to be clinically depressed, but to a mild degree

or

Occasional depressed feelings which either cause significant distress or are looked upon by the patient as a significant departure from his usual self, in the past week.

Rating "3" Marked: The patient is thought to be clinically depressed, in marked degree

or

Frequent depressed feelings as described in "2" in the past week, or occasional extreme distress caused by depression.

Rating "4" Severe: The patient is thought to be clinically depressed in extreme degree. Major depressive phenomena should be present; strongly held suicidal ideas, uncontrollable weeping, etc.

or

Depression has caused extreme distress frequently in the past week.

ANXIOUS

In addition to direct evidence of anxiety observed by the rater at interview, this rating should express the rater's view of the contribution which morbid anxiety is making to the mental state under consideration. (There may be some physiological signs of sympathetic overactivity, moist palms, mild tremor, blotchy patches on skin, etc). Where anxiety is of such a degree that there is associated motor agitation, this will be rated on this key as not less than "3". Where there is a discrepancy between anxiety as observed at interview and anxiety expressed in the previous week the rating made should be the greater of the two ratings.

Rating "0" Absent: Normal mood at interview

Rating "1" Mild" Such tenseness as the patient displays is thought either to be an habitual trait not amounting to pathological proportions or is thought to be a reasonable response to the interview situation.

Rating "2" Moderate: The patient is thought to display a mild degree of clinically significant anxiety or tension

or
Anxiety sufficient to cause significant distress has occurred occasionally in the past week

Rating "3" Marked: The patient is thought to display a marked degree of clinically significant anxiety or tension. He may be apprehensive about the interview and need reassurance, but there are only minor disruptions of the interview due to anxiety. There may be associated motor agitation of mild degree.
or
Anxiety sufficient to cause significant distress has occurred frequently in the past week or anxiety has caused extreme distress for the individual concerned occasionally in the past week.

Rating "4" Severe: The patient is thought to display an extreme degree of clinically significant anxiety or tension. He may be unable to relax, or there may be major disruptions of the interview due to anxiety. There may be associated motor agitation of marked degree, or a fearful pre-occupation with impending events.
or
Anxiety has caused extreme distress for the individual concerned frequently in the past week.

FLATTENED, INCONGROUS AFFECT

Flatness refers to an impairment in the range of available emotional responses; the patient is unable to convey the impact of events while relating his history and cannot convey warmth or affection while speaking about those near to him.

Rating "0" Absent: Normal mood at interview

Rating "1" Mild: The patient may be laconic, taciturn or unresponsive in discussing emotionally charged topics but the rater considers that this is an habitual trait rather than a sign of illness.

Rating "2" Moderate: Clinically significant impairment of emotional response of mild degree. Definite lack of emotional tone discussing important topics *or* occasional but undoubted incongruous emotional responses during the interview.

Rating "3" Marked: Clinically significant impairment of emotional response of marked degree. No warmth or affection

shows. Cannot convey impact of events when giving history, no concern expressed about future:
or
frequent incongruous responses of mild degree or occasional gross incongruity.

Rating "4" Severe: Clinically significant impairment of emotional response of extreme degree: no emotional response whatever elicited.
or
gross frequent incongruity; fatuous, supercilious, giggling, etc in such a way as to disturb interview.

PSYCHOMOTOR RETARDATION

Rating "0" Absent: Normal manner and speech during interview. Questions answered fairly promptly; air of spontaneity and changes of expression.

Rating "1" Mild" Although there may be evidence of slowness or poor spontaneity the rater considers that this is either an habitual trait or that it does not amount to clearly pathological proportions.

Rating "2" Moderate: The rater detects slowness, or lack of spontaneity at interview and attributes this to psychiatric illness; it is just clinically detectable. Delays in answering questions would merit this rating providing that the rater considers that it is part of a morbid mental state rather than an habitual trait of the patient.

Rating "3" Marked: Psychomotor retardation attributable to psychiatric illness is easily detectable at interview and is thought to make a material contribution of the abnormalities of the patient's present mental state.

Rating "4" Severe: Psychomotor retardation is present in extreme degree for the individual concerned.

COHERENTLY EXPRESSSED DELUSIONS

Rating "0" Absent: No abnormality detected at interview.

Rating "1" Mild: Eccentric beliefs and trivial misinterpretation: that bad weather is caused by nuclear tests, superstitions, religious sects, etc.

Rating "2" Moderate: Over valued ideas and ideas of reference, or undoubted misinterpretations. Special meanings.

Rating "3" Marked:	Undoubted delusions or delusional perceptions are described as having occurred in the past month, but the patient denies that he still holds the beliefs at present. *or* delusional ideas are expressed but they are not strongly held or incorrigible.
Rating "4" Severe:	Undoubted delusions are present and are still held by the patient.

HALLUCINATIONS

The rater must therefore decide whether hallucinations have occurred in the past week; if so, whether they are true – or pseudo-hallucinations and how frequently they have occurred.

Rating "O" Absent:	No evidence of hallucinations.
Rating "1" Mild:	The hallucinatory experiences reported to the rater are not definitely morbid, hypnogogic hallucinations, eidetic images and illusions.
Rating "2" Moderate:	Pseudo-hallucinations of hearing and vision; hallucinations associated with insight – e.g. those following bereavement.
Rating "3" Marked:	True hallucinations have been present in the past week but have occurred infrequently.
Rating "4" Severe	True hallucinations have occurred frequently in the past week.

INCOHERENCE AND IRRELEVANCE OF SPEECH

Rating "0" Absent:	No evidence of thought disorder.
Rating "I" Mild:	Although replies are sometimes odd the abnormalities fall short of those required for thought disorder. It is always possible to understand the connection between ideas.
Rating "2" Moderate:	Occasional evidence of thought disorder elicited, but patient is otherwise coherent.
Rating "3" Marked:	Frequent evidence of thought disorder but meaningful communication is possible with the patient *or* several episodes of incoherent speech occur.

Rating "4" Severe:	Replies difficult to follow owing to lack of directing associations. Speech frequently incoherent, without a discernible thread of meaning.

POVERTY OF SPEECH, MUTE

Rating "0" Absent:	Speech normal in quantity and form.
Rating "1" Mild:	Patient only speaks when spoken to; tends to give brief replies.
Rating "2" Moderate:	Occasional difficulties or silences but most of interview proceeds smoothly: *or* conversation impeded by vagueness, hesitancy or brevity of replies.
Rating "3" Marked:	Monosyllabic replies: often long pauses or failure to answer at all *or* reasonable amount of speech, but answers slow and hesitant, lacking in content, or repetitions and wondering, that meaningful conversation was almost impossible.
Rating "4" Severe:	Mute throughout interview or speaks only two or three words *or* constantly murmuring under breath (prosectic catatonia)

Appendix IV

M.I.N.I. PLUS

Version 5.0.0

GENERAL INSTRUCTIONS

The M.I.N.I. was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-IV and ICD-10. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization for lay interviewers for ICD-10). The results of these studies show that the M.I.N.I. has acceptably high validation and reliability scores, but can be administered in a much shorter period of time (mean 18.7 ± 11.6 minutes, median 15 minutes) than the above referenced instruments. It can be used by clinicians, after a brief training session. Lay interviewers require more extensive training. The M.I.N.I. Plus is a more detailed edition of the M.I.N.I. Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I. The M.I.N.I. Plus has questions that investigate these issues.

INTERVIEW:

In order to keep the interview as brief as possible, inform the patient that you will conduct a clinical interview that is more structured than usual, with very precise questions about psychological problems which require a yes or no answer.

GENERAL FORMAT:

The M.I.N.I. Plus is divided into **modules** identified by letters, each corresponding to a diagnostic category.

•At the beginning of each diagnostic module (except for psychotic disorders module), screening question(s) corresponding to the main criteria of the disorder are presented in a **gray box**.

•At the end of each module, diagnostic box(es) permit the clinician to indicate whether diagnostic criteria are met.

CONVENTIONS:

Sentences written in « normal font » should be read exactly as written to the patient in order to standardize the assessment of diagnostic criteria.

Sentences written in « CAPITALS » should not be read to the patient. They are instructions for the interviewer to assist in the scoring of the diagnostic algorithms.

Sentences written in « **bold** » indicate the time frame being investigated. The interviewer should read them as often as necessary. Only symptoms occurring during the time frame indicated should be considered in scoring the responses.

Answers with an arrow above them (□) indicate that one of the criteria necessary for the diagnosis(es) is not met. In this case, the interviewer should go to the end of the module and circle « **NO** » in all the diagnostic boxes and move to the next module.

When terms are separated by a *slash (/)* the interviewer should read only those symptoms known to be present in the patient (for example, questions M20-M23).

Phrases in (parentheses) are clinical examples of the symptom. These may be read to the patient to clarify the question.

RATING INSTRUCTIONS:

All questions must be rated. The rating is done at the right of each question by circling either Yes or No. Clinical judgment by the rater should be used in coding the responses. The rater should ask for examples when necessary, to ensure accurate coding. The patient should be encouraged to ask for clarification on any question that is not absolutely clear.

The clinician should be sure that <u>each dimension</u> of the question is taken into account by the patient (for example, time frame, frequency, severity, and/or alternatives).

<u>Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I.</u> The M.I.N.I. Plus has questions that investigate these issues.

At the end of the interview, go to the diagnostic algorithms for psychotic disorders. Consult items **m11a** and **m11b**:

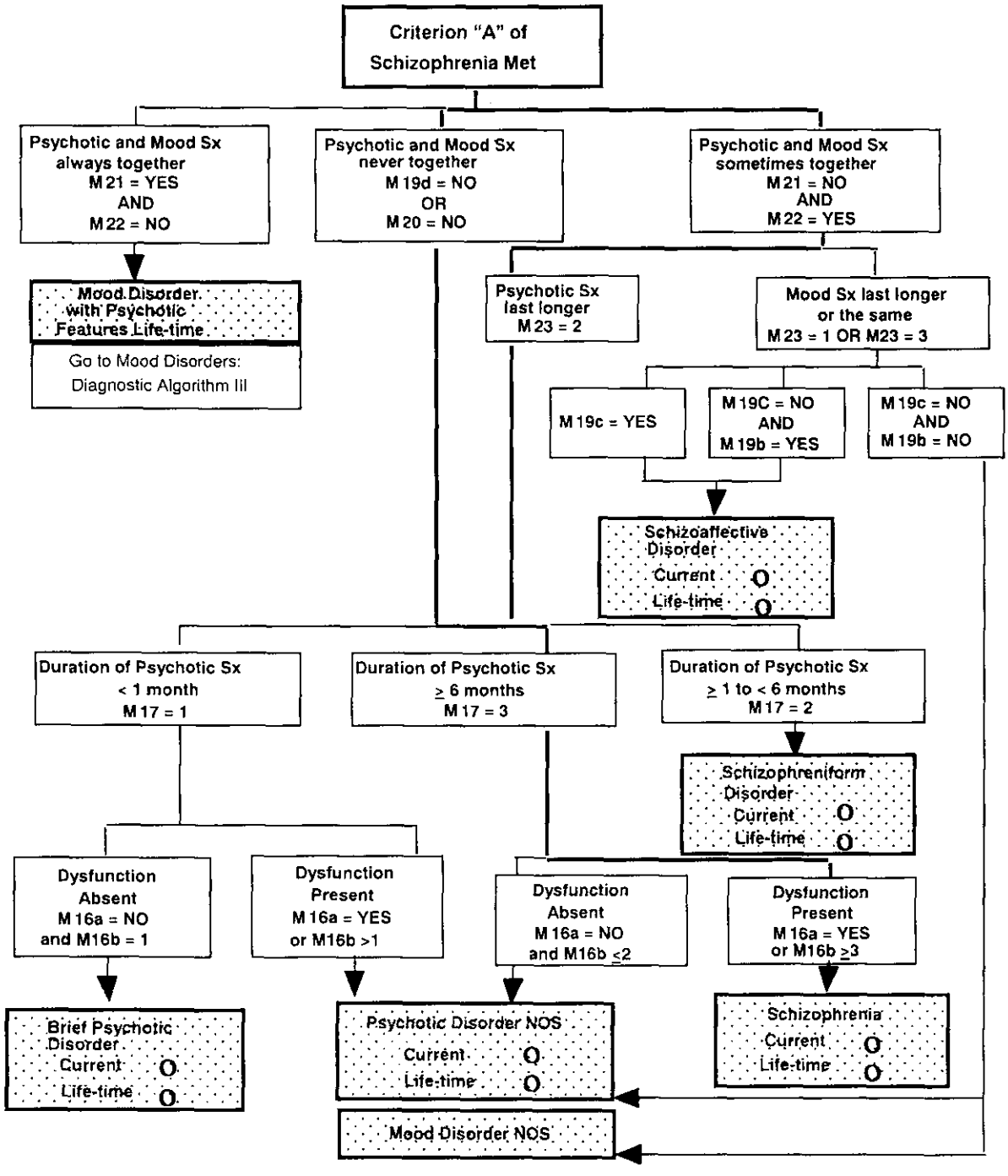
If the criterion "a" of schizophrenia is met (**m11c** and/or **m11d** = **yes**) go to diagnostic algorithms I

If the criterion "a" of schizophrenia is not met (**m11c** and/or **m11d** = **no**) go to diagnostic algorithms II

For mood disorders go to diagnostic algorithm III.

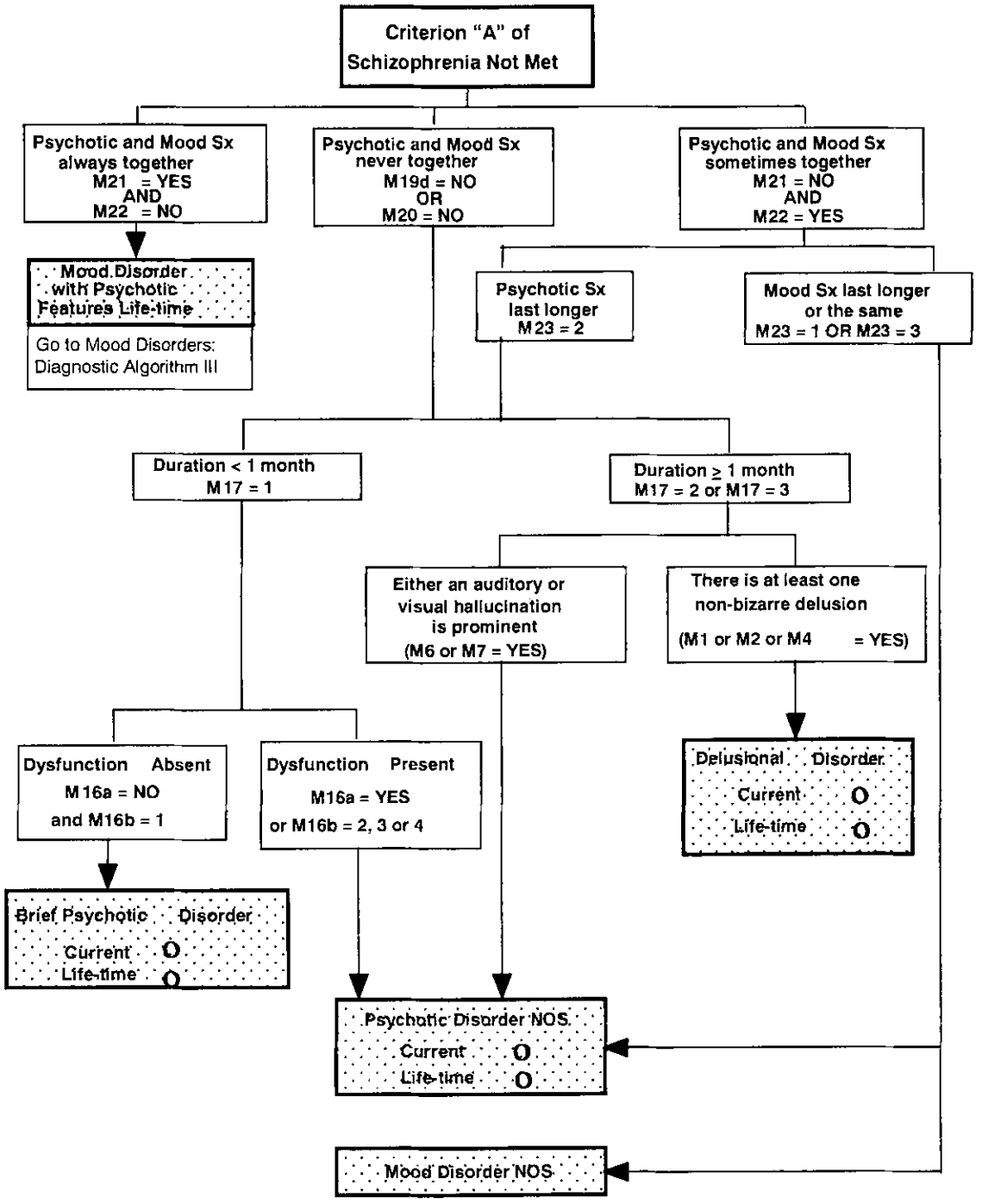
PSYCHOTIC DISORDERS: DIAGNOSTIC ALGORITHMS I

Circle the appropriated diagnostic box both for current and life-time diagnosis. One positive diagnosis excludes the others. If criterion A of schizophrenia is not currently met, but is present in life-time, current and life-time diagnosis may be different.



PSYCHOTIC DISORDERS: DIAGNOSTIC ALGORITHMS II

Circle the appropriated diagnostic box both for current and life-time diagnosis. One diagnosis excludes the others. If criterion A of schizophrenia is not currently met, but present in life-time, current and life-time diagnosis may be



MOOD DISORDERS: DIAGNOSTIC ALGORITHM III

Consult Modules:
A [Major Depressive Episode]
D [(Hypo)manic Episode]
M [Psychotic Disorders]

MODULE M:

1 a IS **M20** CODED **NO**? NO YES ž GO TO **2c**

b IS **M21** CODED **NO** AND **M22** CODED **YES**? NO YES ž CODE **NO** IN **2c**, **2d** AND **2e**

c IS **M21** CODED **YES** OR **M22** CODED **NO**? NO YES

MODULES A and D:

2 a IS A DELUSIONAL IDEA IDENTIFIED IN **A3e**? No Í Yes ☐

b IS A DELUSIONAL IDEA IDENTIFIED IN **D3a**? No Í Yes ☐

c Is **A8 = YES** (Major Depressive Episode present)
and
D6 and D7 = NO (Hypomanic and Manic Episodes absent)?

Specify:
WITHOUT Psychotic Features: IF **1a = YES** and **2a = NO**
WITH Psychotic Features: IF **1a = NO** and **2a = YES**

Specify if last depressive episode is current or past
(Question A8)

NO	**YES**
	MAJOR DEPRESSIVE DISORDER
without PF	ÍÉ
with PF	☐É
current	☐É
past	☐

d Is **D7 = YES** (Manic Episode present)?

Specify:
WITHOUT Psychotic Features: IF **1a = YES** and **2a = NO** and **2b = NO**
WITH Psychotic Features: IF **1a = NO** and **2a = YES** and **2b = YES**

Specify if the last mood episode is current or past
(Question A8 or D6 or D7)

NO	**YES**
	BIPOLAR I DISORDER
without PF	ÍÉ
with PF	ÍÉ
current	ÍÉ
past	Í

e Is **A8 = YES** (Major Depressive Episode present)
and
D6 = YES (Hypomanic Episode present)
and
D7 = NO (Manic Episode absent)?

Specify if the last mood episode is current or past
(Question A8 or D6)

NO	**YES**
	BIPOLAR II DISORDER
current	ÍÉ
past	ÍÉ

資料　2

＜資料２＞

WORLD HEALTH ORGANIZATION

CONSULTATION DRAFT

覚せい剤精神病に関する WHO多施設プロジェクト 研究プロトコル

2000年 6 月

Management of Substance Dependence
Mental Health and Substance Dependence Department
WORLD HEALTH ORGANIZATION