表69　過去1ヶ月間で、その場限りの相手とのセックス時のATS使用

その場限りの相手なし	8/19 (42.1)
毎回	0/19 (0)
しばしば	0/19 (0)
時々	1/19 (5.3)
まれに	1/19 (5.3)
一度もなし	3/19 (15.8)
セックスなし	5/19 (26.3)
回答拒否	1/19 (5.3)

表70　過去1ヶ月間での、支払いを受け手のセックス経験

なし	12/19 (63.2)
あり	1/19 (5.3)
セックスなし	5/19 (26.3)
回答拒否	1/19 (5.3)

表71　過去1ヶ月間での、支払いを受け手のセックス時のコンドーム使用

その種のセックスなし	12/19 (63.2)
毎回	0/19 (0)
しばしば	0/19 (0)
時々	0/19 (0)
まれに	1/19 (5.3)
一度もなし	0/19 (0)
セックスなし	5/19 (26.3)
回答拒否	1/19 (5.3)

表72　過去1ヶ月間で、支払いを受け手のセックス時のATS使用

その種のセックスなし	12/19 (63.2)
毎回	0/19 (0)
しばしば	0/19 (0)
時々	0/19 (0)
まれに	0/19 (0)
一度もなし	1/19 (5.3)
セックスなし	5/19 (26.3)
回答拒否	1/19 (5.3)

表73　過去1ヶ月間での、肛門性交経験

なし	13/19 (68.4)
あり	0/19 (0)
セックスなし	5/19 (26.3)
回答拒否	1/19 (5.3)

XI. 健康状態（表74～表79）

表74　過去1ヶ月間の健康状態

きわめて良好	0/19 (0)
とても良好	1/19 (5.3)
良好	4/19 (21.1)
悪くはなかった	5/19 (26.3)
悪かった	9/19 (47.4)

表75　過去1ヶ月間での活動への影響

	大変制約された	少し制約された	全く制約されなかった
a. ﾃｰﾌﾞﾙを動かしたり、家を掃除するなどの中等度の活動	4/19 (21.1)	10/19 (52.6)	5/19 (26.3)
b. 階段を何階分か上がる	2/19 (10.5)	8/19 (42.1)	9/19 (47.4)

表76　過去1ヶ月間での、健康状態による活動への影響

a. 望んでいた量をこなせなかった	12/19 (63.2)
b. その種の仕事やその他の活動において能力を発揮できなかった	12/19 (63.2)

表77　過去1ヶ月間での、情緒的問題による活動への影響

a. 望んでいた量をこなせなかった	9/19 (47.4)
b. その種の仕事やその他の活動において能力を発揮できなかった	10/19 (52.6)

表78　入院前の1ヶ月間、「痛み」が普段の仕事（外での仕事および家事の両方を含む）の妨げになったことはどのくらいありましたか？

全くない	11/19 (57.9)
少し	2/19 (10.5)
どちらとも言えない	3/19 (15.8)
かなり	3/19 (15.8)
きわめて	0/19 (0)

表79　入院前1ヶ月間の状況

	常に	ほとんどいつも	かなりの時間	時々	まれに	全くなかった
a. 穏やかで平和に感じましたか？	5.3	5.3	0	26.3	5.3	57.9
b. エネルギーにあふれていましたか？	5.3	5.3	0	36.8	21.1	31.6
c. 落胆したり、落ち込んだりしましたか？	5.3	10.5	21.1	21.1	26.3	15.8
d. 身体的または精神的な健康状態が社会活動（友人や親戚を訪ねる等）の妨げになりましたか？	5.3	26.3	21.1	5.3	15.8	26.3

XII. MINI PLUS（表80～表93）

表80　M. 精神病性障害　（調査票のA欄とB欄のいずれかにあれば、カウントしたもの。A欄とは患者の自覚であり、B欄とは臨床家による判断。）

		はい
M1 a	今までに、誰かがあなたをつけ回していたり、あなたを罠にはめようとしたり、あなたを傷つけようとしているなどと確信したことがありますか？	14/19 (73.7)
b	「はい」なら：現在もそのように確信していますか？	8/19 (42.1)
M2 a	今までに、誰かがあなたの心を読んだり、あなたの考えを聞くことができたり、または、あなたが実際に人の心が読めたり、人の考えを聞くことが出来ると確信したことがありますか？	5/19 (26.3)
b	「はい」なら：現在もそのように確信していますか？	1/19 (5.3)
M3 a	今までに、誰か、または外部からの何らかの力によって、あなた自身の考えではないことを心に吹き込まれたり、普段のあなたならしないようなことをさせられたりしたと確信したことがありますか？今までに、何かに取り憑かれたと感じたことがありますか？	6/19 (31.6)

	b 「はい」なら：現在もそのように確信していますか？	3/19 (15.8)
M4	a 今までに、テレビやラジオ、新聞などからあなた向けの特別なメッセージが送られたり、個人的には知らなかった人があなたに特別な関心を抱いていると確信したことがありますか？	6/19 (31.6)
	b「はい」なら：現在もそのように確信していますか？	6/19 (31.6)
M5	a 今までに、あなたの親族や友人から、あなたの信じていることはおかしいとか普通じゃないと指摘されたことがありますか？	13/19 (68.4)
	b「はい」なら：彼らは今でもあなたの信じていることはおかしいと思っていますか？	3/19 (15.8)
M6	a 今までに、他の人には聞こえない、たとえば声などを聞いたことがありますか？	12/19 (63.2)
	b 「奇異」なら：ここ1カ月以内にもそのような声は聞こえていますか？	9/19 (47.4)
M7	a 今までに、あなたは、起きているときに幻を見たり、他の人には見えないものが見えたりしたことがありますか？	10/19 (52.6)
	b 「はい」なら：ここ1カ月以内にもそのようなものが見えていますか？	7/19 (36.8)
M8	b 現在患者には、支離滅裂さや、解体した会話、明らかな連合弛緩が認められる？	3/19 (15.8)
M9	b 現在患者には、解体型、または緊張型の行動が見られる？	2/19 (10.5)
M10	b 面接中、たとえば、明らかな感情の平板化、会話の貧困さなどの他、何か新しいことを始めようとしたり、目的に向かって行動し続けることが出来ないといった精神分裂病の陰性症状が明らかに認められる？	0/19 (0)

表81 M13 b 症例は物質誘発性の精神病性障害か？

いいえ	1/19 (5.3)
はい（生涯）	4/19 (21.1)
はい（現在及び生涯）	14/19 (73.7)

表82 M18 a 病的体験の初発時期 (n=17)

平均年齢±SD	28.9±9.4 (20 - 50)

表83 A8 症例は大うつ病エピソードか？

いいえ	17/19 (89.5)
はい（現在）	0/19 (0)
はい（過去）	2/19 (10.5)

表84 A9 症例は身体疾患を伴う気分障害か？

いいえ	17/19 (89.5)
はい（現在）	0/19 (0)
はい（過去）	2/19 (10.5)

表85 A10 症例は物質誘発性の気分障害か？

いいえ	15/19 (78.9)
はい（過去）	2/19 (10.5)
はい（現在及び過去）	2/19 (10.5)

表86 A11 抑うつ症状の初発時期 (n=6)

平均年齢±SD	29.0±5.7 (23 - 36)

表87　B5　症例は気分変調症か？

いいえ	19/19 (100)

表88　D6　症例は軽躁病エピソードか？

いいえ	19/19 (100)

表89　D7　症例は躁病エピソードか？

いいえ	17/19 (89.5)
はい（現在）	1/19 (5.3)
はい（過去）	1/19 (5.3)

表90　D8　症例は身体疾患を伴う（軽）躁病エピソードか？

いいえ	19/19 (100)

表91　D9　症例は物質誘発性の（軽）躁病エピソードか？

いいえ	16/19 (84.2)
はい（現在）	2/19 (10.5)
はい（過去）	1/19 (5.3)

表92　D10　躁病/軽躁病エピソードの初発時期 (n=3)

平均年齢±SD	21.7±3.2 (18 - 24)

XIII. MANCHESTER SCALE

表93　MANCHESTER SCALE

	なし	軽度	中等度	顕著	重症	不明
抑うつ	42.1	26.3	10.5	0	5.3	15.8
不安	15.8	5.3	26.3	26.3	10.5	15.8
まとまりをもった妄想	15.8	5.3	26.3	36.8	15.8	15.8
幻覚	15.8	15.8	5.3	21.1	26.3	15.8
滅裂思考	36.8	10.5	15.8	15.8	5.3	15.8
寡言、無言	63.2	15.8	0	5.3	0	15.8
感情の平板化、不適切な感情	36.8	26.3	15.8	5.3	0	15.8
精神運動抑制	63.2	10.5	5.3	5.3	0	15.8

XIV. 治療

表94　B型肝炎ワクチン摂取を受けたか？

はい	0/18 (0)
いいえ	16/18 (88.9)
不明	2/18 (11.1)

表95　これまでの入院回数（薬物/アルコールは除く）

0回	9/18 (50.0)
1回	5/18 (27.8)
2回	0/18 (0)
3回	1/18 (5.6)
4回	0/18 (0)
5回	1/18 (5.6)
6回	1/18 (5.6)
7回	0/18 (0)
8回	1/18 (5.6)

表96　過去12ヶ月間での入院回数
（薬物/アルコールは除く）

0回	17/18 (94.4)	
1回	1/18 (5.6)	25日間

表97　情緒的、心理的問題による治療既往
（薬物/アルコールは除く）

あり	3/19 (15.8)
なし	15/19 (78.9)
不明	1/19 (5.3)

表98　心理的問題による生涯治療既往回数（薬物/アルコールは除く）n=18

	0回	1回	2回	3回	4回	5回
病院/他の入寮型	88.9	0	5.6	0	5.6	0
地域精神保健チーム	100	0	0	0	0	0
病院外来	88.9	5.6	5.6	0	0	0
その他	100	0	0	0	0	0

表99　心理的問題による過去1年間での治療既往回数（薬物/アルコールは除く）n=18

	0回	1回	2回	3回	4回	5回
病院/他の入寮型	94.4	0	0	5.6	0	0
地域精神保健チーム	100	0	0	0	0	0
病院外来	94.4	5.6	0	0	0	0
その他	100	0	0	0	0	0

表100　メタンフェタミンのための治療既往回数

0回	8/18	(44.4)
1回	4/18	(22.2)
2回	1/18	(5.6)
3回	1/18	(5.6)
4回	2/18	(11.1)
5回	0/18	(0)
6回	0/18	(0)
7回	1/18	(11.1)
8回	0/18	(0)
9回	0/18	(0)
10回	1/18	(11.1)

表101　メタンフェタミンのための治療開始年齢
(n=11)

平均±SD	28.1± 9.5 (20 - 53)

表102　メタンフェタミン使用のための生涯治療既往回数(n=18)

	0回	1回	2回	3回	4回	5回以上
病院入院	44.4	22.2	11.1	5.6	5.6	11.1
入寮リハビリ	88.9	5.6	5.6	0	0	0
病院外来	55.6	22.2	5.6	11.1	0	5.6
その他	94.4	5.6	0	0	0	0

表103　覚せい剤精神病のための治療既往回数

0回	8/18	(44.4)
1回	4/18	(22.2)
2回	2/18	(11.1)
3回	2/18	(11.1)
4回	1/18	(5.6)
5回	0/18	(0)
6回	0/18	(0)
7回	0/18	(0)
8回	0/18	(0)
9回	0/18	(0)
10回	1/18	(5.6)

表104　覚せい剤精神病治療の原因が覚せい剤以外の物質使用によるものであった既往

0回	10/17	(58.9)
1回	4/17	(23.5)
2回	0/17	(0)
3回	0/17	(0)
4回	1/17	(5.9)

表105　覚せい剤精神病治療の原因が治療遵守しなかったためによるものであった既往

0回	11/17	(64.7)
不明	6/17	(35.3)

表106　覚せい剤精神病治療の原因がストレスを引き金とした発症によるものであった既往

0回	12/17	(70.6)
1回	1/17	(5.9)
不明	4/17	(23.5)

表107　ATS以外の薬物のために受けた治療の回数

0回	16/17	(94.1)
1回	0/17	(0)
2回	0/17	(0)
3回	0/17	(0)
4回	1/17	(5.9)

該当症例では32歳時に初めて治療を受けた。

表108　ATS以外の薬物のために受けた治療既往回数(n=17)

	0回	1回	2回	3回	4回	5回以上
病院入院	94.1	0	0	0	5.9	0
入寮リハビリ	100	0	0	0	0	0
病院外来	94.1	0	5.6	0	0	0
その他	100	0	0	0	0	0

資 料　1

WORLD HEALTH ORGANISATION

WHO MULTI-SITE PROJECT ON METHAMPHETAMINE INDUCED PSYCHOTIC DISORDERS

STUDY PROTOCOL

June 2000

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

Introduction

This protocol describes the background, rationale, research design and operational procedures of the WHO project on methamphetamine induced psychotic disorders in Australia, Japan, Philippines and Thailand. The study focuses exclusively on methamphetamine only from the range of amphetamine-type stimulants (ATS) reflecting the marked prevalence of this ATS in Australia, Japan, Philippines and Thailand.

The protocol has been developed by:

Dr. Robert Ali, Drug and Alcohol Services Council, Adelaide, South Australia (Tel. +61-8-82743349), e-mail: rali@medicine.adelaide.edu.au

Dr. John Marsden, National Addiction Centre, Institute of Psychiatry, London (Tel. +44 207 848 0830); e-mail: J.Marsden@iop.kcl.ac.uk

The project is a 15 month study to assess the nature and clinical management of psychotic disorders induced by methamphetamine use among patients who are referred to specialist inpatients clinical settings (psychiatric hospital facilities).

The project will be conducted at four collaborating centres, referred to as participating centres (PCs), under joint coordination by Drs. Ali and Marsden Adelaide and London, respectively.

PCs
1. Australia
2. Japan
3. Thailand
4. Philippines

The reasons for selecting these four PC's reflect the high prevalence rates of psychotic symptoms induced by methamphetamine use in patients who come into health services. A balance between developing and developed countries will be sought and each site must have easy access to clinical services attending these patients.

Study aims

The aim of the project is to address several broad questions concerning the nature of adverse health, psychotic and other psychiatric symptoms and their management amongst methamphetamine users. These are to identify the:

- extent and nature of physical and psychiatric symptoms and disorders and their social consequences among admissions to clinical services of amphetamine users with a psychotic episode;
- extent and pattern of methamphetamine use, route of administration, other substance use, in those patients;
- source of referral, treatment and care provided to those patients, length of stay, discharge, follow up, mental health status at discharge, past admissions;
- relationship between psychotic symptoms and methamphetamine use

The project will identify potential opportunities for culturally appropriate intervention(s) for patients who experience methamphetamine induced psychotic disorders. It is envisaged that a future stage of this project will be the development and trialing of intervention(s) that prevent relapse into methamphetamine use.

While not a feature of the current study, if funding becomes available, there may be an opportunity to follow participants up at a future stage. The protocol makes provision for this subsequent contact. However agreement for subsequent follow up is not conditional for participation in the initial study. A second consent form is required to provide details for future contact.

Introduction

Psychosis has been recognised as a complication of chronic amphetamine use since the 1930s (Davis and Schlemmer 1980). Amphetamine induced psychosis is a paranoid psychosis characterised by ideas of reference, delusions of persecution and auditory or visual hallucinations in a setting of clear consciousness (Wada & Fukui, 1990, 1991). Thought disorder and disorientation are unusual while stereotyped behaviour and social withdrawal are commonly noted. (US Department of Human Services 1997, Davis and Schlemmer 1980, King and Ellinwood 1997). Amphetamine psychosis usually abates within a week but persistent psychosis may be a complication in some individuals (US Department of Human Services 1997; Suwaki, Fukui & Konuma 1997).

Amphetamine psychosis occurs in chronic users after periods of high frequency use of high doses and both incidence and severity are related to dose and route of administration. Psychosis is particularly associated with rapid routes of

administration such as injecting and smoking (US Department of Human Services 1997, Davis and Schlemmer 1980, King and Ellinwood 1997).

The occurrence of psychosis is a direct effect of the drug and is related to changes in the dopamine system in the brain. There is wide individual variation in response to administration of amphetamines and psychosis has been reported after doses ranging from 55mg to greater than 1000mg. There is considerable evidence that sensitisation occurs and that once an individual has experienced a psychosis a relapse may be precipitated by a single large dose (Davis and Schlemmer 1980, Sato 1992). Evidence from Japan suggests that relapse can also occur as a result of insomnia, stress or alcohol consumption (Suwaki, Fukui & Konuma 1997).

The incidence of psychosis is higher among psychostimulant users than among the general population (US Department of Human Services 1997) and is higher after amphetamine use than cocaine use (King and Ellinwood 1997). Studies carried out in the 1970's indicated that after exposure to amphetamines 80% of subjects without pre-existing psychosis developed psychosis (US Department of Human Services 1997). A study of regular drug injectors in Sweden found that 80% of those who had used amphetamines had experienced at least one psychotic episode (Kall 1997).

Patients presenting to emergency departments and psychiatric hospitals with amphetamine psychosis need appropriate treatment of their psychiatric problem and ongoing management of their drug problem. Generally mental health services do not have the resources or clinical experience to identify and respond to amphetamine induced psychosis. This represents a major problem for management of these people. Referral to appropriate treatment interventions can also be problematic as Alcohol and other Drug services don't have expertise in their care.

Background

The project was initially discussed during a meeting of WHO international experts held in Bangkok 22-26 November 1999. The participants considered the framework of the Rapid Assessment and Response technology developed by the WHO and explored other epidemiological and quantitative methods. At the meeting, a consensus was reached that a priority area for study should be the nature and clinical management of psychotic disorders induced by methamphetamine use in high prevalence countries among patients who present to acute psychiatric in-patient treatment services.

Rationale for the study

The need for the study arises from several conclusions from the available data about the risks for psychotic symptoms that result from protracted methamphetamine use. Route of administration, quantity used, frequency of administration and the presence of pre-existing psychiatric co-morbidity appear to be relevant considerations in determining the risk of onset. Some data from Japan also indicates there may also be a genetic predisposition.

In Australia amphetamines (predominantly in the form of methamphetamine) are manufactured illegally. ATS are the second most common illicit drug used after Cannabis. There has been a steady increase in lifetime use of ATS since 1988. Recent use of ATS almost doubled between 1995 and 1998, with 3.6% of those aged 14 and over reporting use of amphetamines in the 12 months prior to the survey. In the same period lifetime use of amphetamines increased from 5.8% to 8.7%.

Polydrug use is almost universal among ATS users and there is a very high level of injecting. The majority of ATS users are male. Use occurs primarily in social settings and in the company of others. ATS users report significant levels of physical, psychological and social harms related to ATS use. Co existing psychiatric disorders are common and are aggravated by ATS use. Higher levels of harm are associated with severity of dependence and with injecting as the route of administration. Prevalence of HIV is low among injecting drug users (less than 3% of needle exchange attenders) but there is a significant pool of HCV infection (65% of needle exchange attenders). Prevalence of HCV infection is significantly lower among ATS users than those using heroin.

Although stable or decreasing at certain times since the war, abuse in Japan has again increased since 1996, resulting in a range of health and social problems. 1997 survey data indicate that lifetime prevalence of any illicit drug abuse was 2.3% of those aged over 15. Methamphetamine abuse was reported by 0.3%, the third most common drug ever abused after solvents (1.8%) and cannabis (0.5%). A 1998 survey of high school students found that 0.5% had ever abused methamphetamine. The majority of drug related mental disorders (including drug dependence) are attributed to methamphetamine. The main health problem associated with ATS dependence in Japan is methamphetamine psychosis.

Methamphetamine abuse is estimated to account for 95% of the substantial drug problem that exists in the Philippines (1.2 million abusers in metropolitan Manila). Current estimates suggest that the number of abusers is increasing by 10 to 20% annually. The main route of administration is snorting and so the risk of blood borne diseases is low. ATS are widely available, mainly as a

result of the flourishing clandestine laboratories in the country. Treatment centres offering detoxification or rehabilitation exist in a small number of regions but the location and cost put them out of reach of most drug abusers.

Thailand has experienced considerable ATS abuse since the 1960s, and has recognised a major problem during the 1990s, with ATS abuse exceeding heroin abuse in the late 1990s. Methamphetamine and ecstasy are the most prevalent ATS and while abuse is spread across the country it is most widespread in the north. Methamphetamine is the most concerning because of the significant increase in its production, trafficking and abuse over the last decade..

A 1995 survey showed ATS abuse in approximately 6% of a sampled student population. Over 90% of abusers administer ATS by inhaling the fumes from heating ATS tablets. Dependent ATS abusers in the treatment population are younger than heroin abusers in treatment and about half are students. Increasing numbers of ATS abusers with mental disturbances are appearing in mental hospitals.

The participating centres and teams

The research teams in each of the four participating centres will be comprised of substance misuse clinical research professionals with experience in the planning and implementation of quantitative clinical research methods, particularly with amphetamine-type stimulants in inpatient settings.

Study design and methods

The study utilises a patient clinical interview design to determine the nature and of severity methamphetamine induced psychotic disorder and its history. The study contains the following components:

- each PC to review and summarise existing local data and studies on methamphetamine use
- each PC to review and summarise the findings from any local studies on the treatment of methamphetamine dependence and induced psychotic disorders
- coordinators review and contrast inpatients clinical management procedures for patients with methamphetamine dependence
- coordinators review an contrast clinical management procedures for methamphetamine induced psychotic disorder
- clinical interview study with a sample of patients with methamphetamine induced psychotic disorder (history and current presentation) following admission

- utilisation of clinical records to determine:
  - results of physical examination
  - results of urinalysis for illicit drug metabolites and other biological screening procedures (as used in the participating centres)
  - analysis of treatments delivered
  - duration of stay
  - residual symptomatology at completion of index treatment
  - follow up plan post discharge

Participants

The target population for the study is male and female methamphetamine users between 18 and 59 years of age. The inclusion criteria are as follows:

- methamphetamine use occurred (but need not be limited to) within the week prior to admission to the clinical inpatient facility;
- subjects who have used ATS within the week prior to admission with psychosis should be interviewed within the 3-7 days of their admission
- evidence of drug induced psychotic disorder;
- Ability to understand the purpose of the study and complete study interview materials

The exclusion criteria are as follows:

- Prior history of non substance induced psychotic disorders
- Risk of violence to clinical staff
- Severe risk of self-harm
- Impaired sensorium

Sample size

A sample of 50 participants in each PC who meet the inclusion criteria will be recruited to the study. The overall total sample size for the study across the four PCs will be 200.

Study procedures

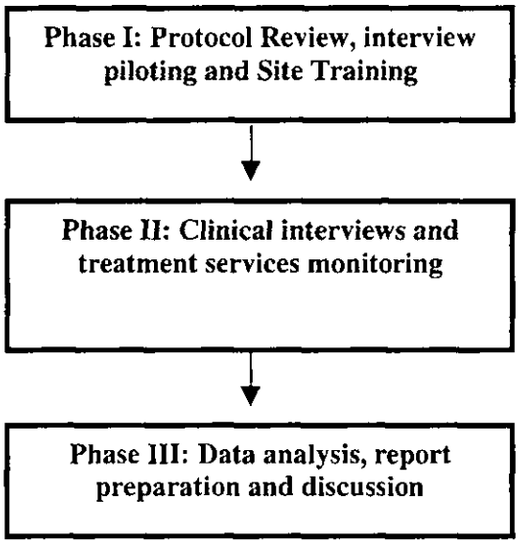
The key phases of the study in each participating site are shown below. The study will proceed across three sequential phases.

Firstly a review of the study protocol by each PC. Necessary amendments will then be made to the study interview schedule and protocol. With these changes completed and agreed, site training will be held in each PC. Following site

training and protocol review piloting of the study interview instrument will take place with 3 eligible participants.

Following any further necessary amendments the clinical interviews will be undertaken with patients. PC's will also record treatment plans and treatment services for both methamphetamine dependence and psychosis.

Finally data analysis and report preparation will occur.



Existing data sources

Participating centres should review all relevant secondary data sources on methamphetamine and apply to their country context. Data from psychiatric hospitals should be identified and summarised on treatment utilisation information for cases of methamphetamine induced psychotic disorder – with particular emphasis on treatment duration, frequency of repeated admissions, and any other relevant clinical information. Data sets and service utilisation data from hospital emergency services for these case should also be summarised.

The following law enforcement data concerning methamphetamine should also be identified and summarised - number of people convicted of methamphetamine related offences (possession, supply, manufacture); number and quantity of police/customs seizures of methamphetamine and associated precursors). Content analysis of seizures for purity and presence of other psychoactive substances should occur.

Sampling procedures

Sampling refers to the method, criteria and procedures used to select participants from a target population for a study. A population is defined as a group of people or objects that share common characteristics. In the present study context, participants will be each consecutive eligible patient during the recruitment period.

Participants will be interviewed at a suitable point following admission based on the local clinical management protocol. This should commence as early as practicable during the admission, preferably between days 3 and7 following admission. At that time at least the Mini-Plus and Manchester scales should be administered. The remainder of the interview should be completed no later than Day 15 or prior to discharge (which ever comes first).

The draft of the study instrument is shown in Appendix I. The instrument addresses the following areas:

- Date of admission
- Date of interview
- Identification of patient, sex, age, occupation, education
- Substance use: quantity, frequency, using period, types of drug, route of administration, context of use, association with other psychoactive drugs, injecting drug use, time and date of last use
- Legal issues
- HIV risks (HRBS Scale)
- Past psychiatric history (M.I.N.I. Plus) (Clinical assessment)
- Psychiatric symptoms (Manchester scale) (M.I.N.I. Plus)
- ATS Abuse/Dependence Diagnosis
- Past Medical History
- Quality of life assessment (SF-12)
- Current medications
- Previous treatments (psychiatric and drug abuse)
- Diagnosis at discharge *
- Duration of episode of care *
- Date of discharge *
- Discharge medications *
- Residual psychiatric symptoms * ; and

- Post discharge after care arrangements *.

* NOTE: it is critically important to establish a local mechanism which will enable the participant number code (see front sheet of instrument) to be linked to case records so that these data can be extracted and recorded on the instrument at the time of discharge. The data set for each patient is NOT COMPLETED until this information is recorded.

Guidelines for interviewers

Interviews will be professional, trained researchers with clinical interviewing experience with people with psychoactive substance use disorders. This study will require clinical psychologists or psychiatrists to interview the patients.

Key points

Key points to adhere to when conducted interviews are as follows:

- As far as possible the interviewer should be satisfied that the respondent cannot be overheard or distracted during the interview;
- The interviewer should remain neutral throughout the session (neither agreeing nor disagreeing or show approval etc. as this could bias the answers given);
- The interviewer should read the preambles to the interview and self-completion session deliberately and confirm that the participant understands;
- Effort should be made to ensure that the interview keeps flowing so that the participant is less likely to get distracted or bored;
- If a participant talks about an unrelated matter during an interview, the interviewer should try to gently steer them back to the questions;
- The interviewer should emphasise in the preamble that it is their responsibility to make the questions understandable;
- If a question has to be reworded to assist comprehension the interviewer should ensure that the meaning does not change.

It is crucial that the respondent understands at the start of the interview that anything that they tell you as an interviewer is confidential and that data storage and reporting will be anonymous. Before the beginning of the interview, it should be clearly stressed that:

- that the completed interviews will be stored securely at the participating centre and that no one else will see them;
- no information they give will be passed on to any third party;

- information the respondents give will be aggregated with information from the other respondents and therefore nothing about them as individuals could be ascertained from research papers or reports.

Probing

Some questions indicate that 'probes' may be required.

Interviewers should always probe if there is an 'other' category included in a question or where answers are incomplete. It is important that you probes are neutral. Examples of neutral probes are:

Could you explain that a little more?
Did you take another drug on that occasion?

Inconsistent answers

In some interviews, a participant may give inconsistent answers. In this situation, the inconsistency should be pointed out in a tactful way with the goal of probing establish the correct answer. This might mean having to re-do some few questions.

Use of filters or "skips"

Some questions will not be relevant to certain participant. At various points "skips" indicate which questions can be omitted.

Use of prompt cards

Several prompt cards are used in the interview and these are designed to show the respondent a range of answers and enable them to select one without having to listen and remember a long list of options. The interview must ensure that the use of cards is not confusing – do not give the respondent the set of cards and ensure that clear instructions are given as which card corresponds to the question asked. If this is possible, it is better to have the file on a table or desk and to you turn the pages over and point out each prompt card to the client as the interview progresses.

Manchester Scale

Guidance on the scoring of the Manchester scale appears in Appendix III.

MINI Plus Scale

Guidance on the scoring of the MINI Plus scale appears in Appendix IV.

Coping with questions

The participant might ask questions about the interviewer and their personal opinions. It is important that the interviewer does not offer any information of this nature to them as it could affect the way that the participant takes part in the interview.

Data storage and retention

Study data must be recorded in a durable and appropriately referenced form and should comply with relevant data protection and privacy protocols.

Quality Assurance Protocol

Quality Assurance (QA) is commonly used in research studies as a way of maintaining and enhancing the reliability and validity of data and data gathering procedures. It is the responsibility of each Participating Centre to implement data gathering procedures in accordance with this protocol and to ensure that the study is undertaken in an appropriate, timely and efficient manner. Deviation from this protocol can diminish the overall quality and value of the study and reduce the impact and utility of the research reports produced.

PC's will establish, enter and maintain the data base in SPSS, or Epi Info format. At least one in ten interview records will be re-entered to ensure accuracy of data entry. PC's will undertake analysis of data and develop reports for their site while coordinating centres in London and Adelaide will analyse and report on between site comparisons.

Everyone in the study has a shared responsibility in making the study a success and in meeting the study objectives. Overall responsibility for quality control in the study rests with the joint coordinating centres in Adelaide and London and rests overall with WHO in Geneva.

Informed Consent Procedures and Participant Information

Before participating in the study, all participants will receive an explanation of the purpose of the study and its procedures. PC's will establish and maintain a register of all refusals to enter the study that will include gender, reason for refusal and approximate age of the individuals.

It is essential that all participants understand the purpose of the study and what will be required of them in taking part. Questions from potential participants will be addressed at this stage, particularly issues of anonymity, confidentiality

and data protection. Participants will be asked to sign a consent form if they wish to participate, following resolution of any questions.

Confidentiality of gathered information from the participants will be achieved by a numbered reference system and maintained by each Participating Centre Coordinator (PCC). Each consent form contained the name of the participant will be kept separately in a file which will be kept in a locked filing cabinet by the PCC. A "key" containing reference material will be kept in a separate locked filing cabinet. It is the responsibility of the PCC to ensure that all data gathered during the study is kept securely.

An example Informed Consent Form (ICF) is included below as a guide. This should be adapted as required in order to meet the requirement of research ethics as dictated by ethical standards and procedures in each PC. The ICF contains four sections:

Section 1. Describes the rationale, aims and procedures of the study and its intended benefits.

Section 2. Describes what the participant will be asked to do in taking part in the study. This section stresses the anonymity and confidentiality issues and how these will be maintained. All participants are free to withdraw their participation at any time.

Section 3. The final section requires the consenting participant to sign their name twice to indicate that they understand the purpose and procedures of the study and that they agree to take part. The signature of the recruiting researcher is also required next to participant together with the date of recruitment. The second part of the form containing the second signature of the participant and recruiting researcher is then detached and retained by the researcher. The rest of the ICF is retained by the participant as a record.

Research ethics

This study protocol describes the procedures to be followed with respect to human subjects and ethical standards. Each PC co-ordinator should adapt the material in this document and prepare a submission to their appropriate ethical review committee if required.

Project time table

The study will be implemented across a 15 month period in four interconnected Phases: