



WHO CONSULTATION ON VALIDATION OF
 SELF-REPORT DATA ON SUBSTANCE USE
 San Diego, USA, 13-17 November 1990

REPORT

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 Project Pilot Phase on State Markers of
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PHASE I SUMMARY REPORT -- Training Session for WHO/ISBRA Collaborative Project on Pilot Phase on State Markers of Alcohol Use, 13-15 November 1990

I.1 Introduction

The meeting began with a series of opening remarks by Mr Trujillo (Director of the San Diego Affairs Medical Center), Dr Parthemore (Chief of Staff), Dr Schuckit, Mr M. Grant, and Dr Tabakoff.

Dr Schuckit then presented a history of the development of the WHO/ISBRA collaborative project, reminded participants that the first phase of the project would focus on state markers of heavy drinking while setting the stage for more elaborate studies on trait markers. The immediate goal was to facilitate the development of a study focusing on 20 subjects in each clinical centre (namely those in Australia, Brazil, Finland, Japan, USA and Switzerland).

I.2 Review of Background to Project

Dr Rapaport then offered a brief overview of the history of the interview instrument and outlined a series of issues that needed to be addressed for its optimal implementation. This was followed by a more detailed page-by-page review by Dr Schuckit, offering information on why each section was included and some options for additional information.

The general discussion progressed to a review of general administrative issues. The reliability and validity of the interview to be used for the main study must be established, although that is not directly a focus of the pilot work. Whenever possible, the interview was structured to focus on information that might impact on interpretation of potential blood markers of heavy drinking while also gathering family history information that might be important for the feasibility of a genetic trait marker study. It was agreed all sections of the interview must be completed by all centres, although some might decide to gather additional information. When ancillary information is gathered, all other centres should be informed so that the possibility that the additional data will also be forwarded to the central core data repository can be considered.

I.3 Interview Procedures

The first demonstration of the interview occurred with Dr B. Grant interviewing Ms Bacon as a mock subject. This session took the group through the alcohol section of the interview, after which a page-by-page detailed review was carried out correcting information within the interview, changing relevant information within the cards, and offering additional questions for possible inclusion.

A subsequent session took up additional questions and suggestions regarding the interview beyond the alcohol section. This was followed by a detailed page-by-page discussion of these final sections resulting in the inclusion of a new brief series of questions regarding: personality disorder for both the subject and family members; major depression for the subject; a tobacco section for the subject; information relating to facial flushing; and the decision that each interview will have a clinical rating sheet to be added at the end. This latter will require that all interviews be reviewed by an experienced clinician who will note whether she or he is using DSM-III, DSM-III-R, or ICD-10 criteria. Diagnoses will be offered for the subject (up to four possible diagnoses), as well as for all relevant first-degree relatives.

The group then broke into two sections -- with one having the goal of incorporating the changes already discussed into a new draft of the interview. The remainder of the group discussed a variety of procedural issues. Among the decisions made were: the modification that the definition of heavy drinkers will be individuals who consume 210 or more grams of ethanol per week; the request that all interviews be reviewed by at least two individuals (including the interviewer) before final coding is established; the need for each centre to obtain human subjects review with an informed consent approval for both the interview and the blood before the interview is carried out (each centre should forward a copy of the approved human subjects application to Drs Tabakoff and Schuckit); the decision to obtain 100 cc of urine as well as the 20 to 30 cc of blood for each subject; the need for each centre to carry out analyses of MCV as well as counts for RBCs, WBCs, and platelets; the requirement that seven tubes of blood and one tube of urine per subject be produced; and the decision that there will be three mailings of materials -- the first relating to "dummy" interviews and bloods, the second dealing with the first half of the subjects, and the third dealing with the second half of the subjects -- since samples can be frozen at -70 degrees Centigrade for up to one month.

The group also reviewed how data and samples will flow between centres. Each centre will forward the interview and the bloods related to the same subjects at approximately the same time, keeping a copy of the interview themselves. Confidentiality must be maintained -- meaning that all identifying information regarding a subject should be kept in a locked file cabinet and that no identifying information be sent on as part of the interviews (only coded subject numbers). The importance that all bloods be handled with Safety Level 2 procedures as demonstrated in pages 12-16 and 107-116 in the handout was emphasized. All blood samples and interviews will be sent to Denver to Dr Tabakoff; he will distribute the interviews to the NIAAA and the urine and blood samples to the relevant assay centres; those centres will then forward results back to Denver to Dr Tabakoff; and he will then send those results to NIAAA for consolidation. Thus, the coordination of data handling and monitoring of completeness will rest with Dr Tabakoff and his group.

I.4 Finalization of Instrument

The group reconvened to test the altered interview through a demonstration with a mock subject, then with an alcoholic patient, and finally to hold two smaller sessions where subgroups of people from the meeting observed patients being interviewed. After all of these interactions it appears that major difficulties within the interview have been appropriately altered, that the interview takes approximately an hour to administer, even with an alcoholic patient, and that the flow and content of the interview is functioning well. While minor problems remain, most of the work has been accomplished.

Dr B. Grant will carry out the further alterations and discuss them with the San Diego group; it is hoped to distribute the reformatted interview to participants early in 1991.

PHASE II SUMMARY REPORT -- Biochemical Validation of Data on Drug Use,
16-17 November 1990

II.1 Introduction

The meeting was convened by Mr Marcus Grant, who, in his opening remarks, announced the establishment of WHO's new Programme on Substance Abuse. Mr Grant then stated the charge of the meeting: to develop suggestions for a programme of work on biochemical markers for the validation of self-report measures of substance use and abuse. Mr Grant reminded the meeting that WHO is responsible for the promotion, development, and advocacy of international health and health research needs. In this context, WHO has the capacity to commission reviews of pertinent research and clinical issues, promote international scientific networks, develop advisory guidelines for Member States on issues of import, and convene special meetings on topics of international health significance. Mr Grant suggested that part of the charge of the meeting should be to advise WHO on how best to use its resources to promote the development of accurate biological markers to validate self-report information for substance abuse. There then followed a general discussion which set priorities for the development of a programme for the evaluation of biological markers to validate self-report data of substance abuse.

II.2 General Discussion

Dr Balant began the discussion with a review of the COST-B1 programme and its innovative work on pharmacogenetics. He reviewed the progress that this European consortium had made, and the implications of their initial findings that Western Europeans as a group could be considered homogeneous with respect to the pharmacokinetics of drug metabolism. He described the power of this approach, and gave an example of how certain known polymorphisms may potentially explain differential susceptibility to substance dependence problems. There was a lively discussion stimulated by Dr Balant's comments. Both Dr Schuckit and Dr von Wartburg suggested that this would be a potential topic for a WHO initiative in the area of substance abuse.

Dr von Wartburg then expanded on the theme of the importance of new technologies, and their potential value in the development of an international programme for the biological validation of self-report data. He speculated that the development of so called "dry chemistry" could potentially have profound effects on this area. Dr von Wartburg defined "dry chemistry" as laboratory tests, such as the body fluid "dipstick," where the assay is pre-packaged and standardized so that all a subject needs to do is add a drop of appropriate bodily fluid to the test kit to yield a result. Dr Whitfield agreed that this new technology might have a profound impact on the development of treatment paradigms for substance abuse. There was consensus amongst participants that this was a topic that warranted further investigation.

The implications of the development of alternative treatment paradigms stimulated discussion of the need for creating both an international network for communication regarding research and treatment in the field of substance abuse, and the creation of a forum which would stimulate interaction between biological and psychosocial researchers involved in substance abuse work. The participants felt that both of these interrelated goals fell well within the purview of WHO. The group then spent some time speculating about common themes that might be used as foci for both the establishment of an international network of experts in this area and for potential interdisciplinary symposia. Possible symposia topics included genetic markers of substance abuse, biological markers of substance abuse, methodologies for the biological assessment of the injection of psychoactive substances, the Lederman curve and its implications for the international study of substance abuse, and mechanisms for determining the concordance between government and manufacturers' measures of substance availability and figures derived from community-based prevalence measures of substance use.

Mr Grant noted that WHO had concerns about the endemic use of psychoactive substances in regions of the developing world. He discussed the endemic use of marijuana in parts of Africa, the widespread chewing of cocoa leaves in parts of South America and the eating of opium in certain parts of the Indian subcontinent. The group observed that these were all areas of relative poverty and that malnutrition was common to all of these regions. Dr Rapaport wondered if there might be a causal relationship between malnutrition and the endemic use of psychoactive substances; in particular, that the chewing of cocoa leaves and the eating of opium might be attempts by the people of these regions to blunt their sense of craving. He postulated that nutritional interventions might decrease the amount, and the prevalence of the use of psychoactive substances in these impoverished regions.

Mr Grant summarized the general discussion and synthesized a list of topic areas which were then assigned to working groups. The second part of the meeting was divided into two segments: work within the smaller task groups, and a general discussion of the proposals generated by the task groups.

II.3 Topics for the Task Groups

- a) The generation of a list of possible topics for commissioned reviews of important topics. (Chair Dr Moniero).
- b) The development of a proposal for a study of the efficacy of a nutritional intervention in decreasing substance dependence. (Chair Dr Rapaport).
- c) The development of a pilot pharmacogenetics project exploring the role of causative and protective genetic factors in substance abusing populations. (Co-chairs Drs Balant and Whitfield).

d) The formulation of a mechanism to encourage closer working ties between biological and psychosocial researchers. (Co-chairs Mr Tipp and Dr von Wartburg).

II.4 Task Group Proposals

II.4.1 Subgroup on Recommendations for Literature Reviews

This group developed guidelines for four topic areas for reports to demonstrate current knowledge on drug use to help guide future work:

Proposal I: A review on the genetics of drug abuse or dependence, including pharmacogenetic differences in drug metabolizing and biological reactions to drugs in general especially as applicable to drugs of abuse.

A recent report written by Dr Anthenelli of the University of California demonstrated that little relevant literature is available to address this topic. However, in the absence of such literature, it is possible to offer guidelines for a future report. Any report considering this topic should consider the following problems which studies of drug use genetics face. In such studies it is imperative that the research design control for third diagnoses. One common example is AntiSocial Personality Disorder (ASPD). In addition, the genetic factors related to each drug may differ thus affecting the evaluation of poly-drug users. Third, there are cohort effects inherent in drug studies due to variation in the availability of drugs over time. Lastly, important characteristics may vary across geographical, cultural, and political boundaries. Despite these considerations, some data on genetics are available regarding tobacco, caffeine, and heroin as it relates to alcohol.

Proposal II: A paper preparing for a consultation meeting on state markers of drug use, abuse, and dependence.

A consultation in state markers of this type would require extensive reviews of existing methods, as well as the sensitivities and specificities of urine and blood testing. It is currently understood that some drugs are detectable in urine for some time. Marijuana, for example is detectable for up to 3 weeks, whereas cocaine may only be detectable for several weeks after use, and that methadone is also detectable in urine for some time after use.

Other possible points of measure include hair. Recently, persuasive evidence has offered hair analysis as a qualitative measure of drug use. It is necessary to gain a fuller understanding of the status of this relatively new technology. In addition, some drugs (eg. barbitruates and benzodiazepines) cause liver microsomal system changes. Tests of the magnitude of these changes and the rates of return to normal status could provide more persistent state marker measures. Opiate receptor changes in platelets could also be a longer

lasting state marker of opiate use. Similar statements might also apply to serotonin measures as seen in platelets.

Once these strategies are evaluated and potential markers found, a WHO-ISBRA international study could be conducted regarding cross-cultural application of these measures. A series of animal studies could also follow to delineate further potential markers and processes.

Proposal III: A paper discussing possible state markers of injecting drugs.

Due to the increasing problems developing internationally with regards to injection born disease, further research in this area is needed. Unfortunately, there is lack of available data to address this issue. This paradox must be the first issue addressed in the proposed paper. The major emphasis should be on animal and human research methods to be developed:

- a) Identify how to determine the presence of impurities likely to be seen after injection. These could be identified themselves, or their metabolites, or perhaps antibodies to the impurities most likely to be specific to injectable forms.
- b) Develop a physical sign profile that identifies an individual as a highly likely injector.
- c) Tests of the pharmacokinetics of drugs of abuse may reveal different patterns in injectors than oral users.

Proposal IV: A paper discussing possible new technologies to be used to monitor treatment outcome.

This topic generally relates to ways of identifying when an individual has returned to alcohol or drug use. The best method at present is multiple interviews with the patient, resource persons, and record reviews. Of course these reports present validation problems. The data on state markers of heavy drinking data recording their change over time, both with and without use, are important here.

The paper should also consider the relevance of dry chemistry. For example, some effort has already been devoted to the examination of the use of sweat patches to detect alcohol and drugs. As well, the use of urine and blood "dipsticks" may serve as dry chemistry measurement instruments. Changes in the pharmacokinetics of drugs and reactions to various challenges may also be useful measures. Lastly, any data developing from the paper on state markers of drug use described under proposal III above could inform this paper also.

II.4.2 Subgroup on the Effects of Nutritional Intervention on the Use of Psychoactive Substances in Regions of Endemic Use

Psychoactive substance use is endemic to certain regions of the world. These regions are almost exclusively poor, under-industrialized, and sites of endemic malnutrition. It has been postulated that the widespread use of psychoactive substances (which are frequently considered substances of abuse in the majority of the industrialized world) might represent a compensatory effort by these cultures. Since the majority of these agents have the side effect of being appetite suppressants, it is possible that the endemic use of these substances might actually be a compensatory mechanism for ameliorating physiological symptoms of hunger.

It is proposed that a multidisciplinary, multi-national study be undertaken to evaluate the effectiveness of a nutritional intervention in decreasing endemic substance use. It is hypothesized that chronic malnutrition may play a causative role in stimulating and sustaining culturally syntonically dependent dependence on psychoactive substances like chewing cocoa leaves and eating opium.

METHODS:

Two sites would be selected for a pilot study of the relationship between nutrition and endemic psychoactive substance use. These sites should be geographically and culturally distinct, and the substance of endemic use should be different for each site. For example, one site might be in South America where cocoa chewing is prevalent, and a second site could be in Asia in a region where opium eating is common. Each study team would need to include local experts, anthropologists, nutritionists, medical and laboratory personnel and experts in the area of substance abuse. There would also have to be an oversight team insuring that the two sites functioned in a similar manner.

Phase 1:

Interviewer assessment of substance and nutritional intake as documented by an interview and an observer journal. The team working at the site would spend at least one week observing the study population in order to assess substance and nutritional intake. There would also be noninvasive morphometric measures of body fat and muscle strength, and blood samples to assess overall health and circulating levels of psychoactive substances.

Phase 2:

A nutritional supplementation programme which would be consistent with the normal dietary patterns and traditions of the culture will be instituted. This programme would involve both an acute phase during which the participating area would have its food supply augmented, and a more extensive educational phase. In this second phase, which would begin concurrently with the supplementation phase, training and technology would be introduced to the participating region in a

culturally acceptable fashion so that the nutritional changes instituted would be more likely to become permanently incorporated into the tradition of the region.

Phase 3:

The participants be reassessed with the same battery of tests as in Phase 1 at the 3,6,12,18 and 24 month points. It is postulated that as the participants become normal weight for their size, metabolism, and body structure, their intake of psychoactive substances will decrease. Eventually use of these substances within these areas where nutrition has been supplemented will more closely parallel industrialized regions. It is recognized that since the use of these agents is accepted in the culture and part of the traditions of the culture the rate of use will differ from other regions of the world, but it is postulated that quantity/frequency measures of psychoactive substance use would demonstrate a marked decline.

II.4.3 Subgroup on Recommendations for Research on the Genetics of Drug Abuse and Intoxication

Following discussion among members of the larger group, it was determined that greater understanding of the genetic influences of drug use is necessary. This subgroup therefore developed a research design to improve such understanding.

Hypotheses:

- a) Drug abuse may be influenced by the nature or degree of response (i.e. intoxication) following drug use;
- b) The nature or degree of response may be affected by the pharmacokinetics of the drug;
- c) These responses may show genetic variation between and within populations.

Initially, this subgroup recommended research efforts focus on opiates, benzodiazepines, cocaine, amphetamines, and cannabinoids. However, before any investigations may begin, a thorough search of the literature is necessary to illuminate the current state of knowledge concerning drug use and abuse patterns.

Some literature is currently available concerning this topic. For instance, literature exists on interracial differences in drug metabolism (not all on drugs of abuse), but further information is necessary. In addition, literature is available on possible probe drugs (inactive modifications which may be administered with fewer ethical problems in research than the active drug itself). These probe drugs may also be suitable for use as radioactive probes for in-vivo studies. After the completion of the literature review, a study may be more focused on specific drugs.

Any study on this topic should consider the following three key aspects:

i) Population Diversity

The groups included for study should vary in environment and genes. Undoubtedly this will include groups from many regions and countries around the world. Genetically similar populations should also receive attention. This may be evaluated through family, adoption, or twin studies.

ii) Ethical Issues

It is difficult to justify the administration of drugs of abuse to normal volunteers, high risk volunteers, or drug abusers. Therefore, it is necessary to utilize drug analogues, in-vitro methods, and in-vivo labelled drugs in low amounts in this research.

iii) Technical Issues

Many aspects of the study outlined here will require high technology approaches. In fact, appropriate methodology may require the development of new technologies. A recommended model to follow is that of the ISBRA-WHO collaborative study which utilizes both clinical and laboratory centres.

It is hoped that the approach described here will result in both multidisciplinary and multinational applications. Successful use of this approach may lead to further cooperative work across disciplinary, geographic, cultural, and political subdivisions.

II.4.4 Subgroup on the Promotion of Interchange Between Biomedical and Psychosocial Researchers

One major stumbling block to refining the validity of self-report data on drug use is the lack of interaction between biomedical and psychosocial researchers on an international level. As demonstrated by the Lederman curve for alcohol use, a minority of a population uses drugs heavily while the majority of the same population uses drugs minimally or not at all. This phenomenon illustrates that an interaction of biological and psychosocial factors determines risk for developing dependence from drug use. Simply stated, both biological and environmental factors play an important part in determining risk. However, most studies focus only on one of these factors, rather than the intersection of the two. Thus, the validity of self report data suffers from one overriding problem -- poor independent measures to confirm the observed phenomena.

Improvement in the validity of self report data requires better communication between biomedical and psychosocial researchers. Communication between biomedical and psychosocial researchers is strained by the lack of both opportunity and a common vocabulary. For instance, the International Society for Biomedical Research on Alcoholism (ISBRA) and the Kett:1 Bruun Society are on the polar sides of research on alcoholism. The field would greatly benefit from interactions between member researchers of both groups. However, it is apparent that these groups are strongly entrenched in their respective methodologies. As a result, both groups remain relatively isolated in their research efforts.

Because of respective research isolation, each field has developed an extensive language to describe the phenomena observed. Researchers of the basic sciences and medical community commonly communicate in a highly technical language. While the language of psychosocial researchers is less technical, it retains both operational and taxonomic difficulties. These language differences hamper the current state of understanding of the intersection between biological and psychosocial determinates of risk. As a result, few collaborative projects develop between members of these two groups.

Several areas of study are both conducive to, and beneficial of collaboration between biomedical and psychosocial researchers. These areas can be identified according to two criteria: a) areas susceptible to biomedical and psychosocial explanations where a substantial body of research exists among both groups; and b) areas with international variation which would benefit from international collaboration. These areas include, though not exclusively: Etiology; Natural History; Diagnosis; Prevention; Intervention; Risk Factors; Treatment; and Codependency.

A basic plan should therefore be developed to promote communication and collaboration between biomedical and psychosocial researchers in the area of drug use. It is proposed that WHO identify a panel derived from both biomedical and psychosocial research backgrounds to advise current and future research. These individuals would be chosen based on prominence in their fields and their potential ability to foster communication between the two groups. The former characteristic is important in that prominent individuals have great influence over the future of research in their area. Given a substantive commitment toward cross-disciplinary research on the part of prominent researchers, others are likely to follow. The latter characteristic is essential in that the first step in fostering communication and collaboration is the development of a common language.

The first charge of this new panel would be the development of a common interdisciplinary vocabulary. This vocabulary should lay the groundwork from which researchers from a variety of fields may converse about phenomena, compare hypotheses, and develop new methodology. Only

after this foundation is laid may the panel proceed to advise and instruct current research on improvements in methodology derived from cross-disciplinary discussion.

Afterward, this panel would be charged with advisory responsibility. Innumerable research efforts exist which would benefit from the observations and comments of this panel. The panel would review and advise research efforts on improvements to illuminate the intersection of biomedical and psychosocial determinates of drug use. In this way, refinements in methodology would progress with discoveries resulting from, and reinforcing this interdisciplinary approach. It is expected that the benefits of such interaction across disciplines would benefit drug use research such that it would lead to the organization of congresses, and possibly formal associations.

II.5 Summary Statement

The meeting concluded by reviewing the task group reports and developing a consensus position. The consensus of the participants was that the areas identified in the task group reports could be thought of either as independent projects each of which could be developed independently, or as a series of interlocking proposals. Thus, the reviews could serve as focal points for both the development of an international network of biomedical researchers in the area of substance abuse, and as stimulus for interdisciplinary meetings on substance abuse. The projects on pharmacogenetics and on nutritional interventions could also be envisioned as serving as specific foci for interdisciplinary and international collaborations.

The participants agreed that, although either method of viewing the recommendations of the meeting was appropriate, the latter perspective was more consistent with the goals outlined in the scope and purpose of the meeting.

APPENDIX A

WHO CONSULTATION ON VALIDATION OF
SELF-REPORT DATA ON SUBSTANCE USE
San Diego, USA, 13-17 November 1990

List of Participants

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Mr Leland TOWLE, International and Intergovernmental Affairs
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* invited but unable to attend

APPENDIX B

WHO CONSULTATION ON VALIDATION OF SELF-REPORT
DATA ON SUBSTANCE ABUSE
San Diego, USA, 13-17 November 1990

AGENDA

Phase I - Training session for WHO/ISBRA collaborative project pilot phase
(13-15 November) on alcohol use

1. Opening
2. Background and design of project
3. Introduction to interview instruments
4. Training in use of instruments
5. Collection of data
6. Data analysis and preparation of report
7. Conclusions and recommendations

Phase II- Consultation on biochemical validation of data on drug use (16-17
November)

1. Opening
2. Review of current knowledge regarding biochemical markers
of drug use
3. Identification of gaps in current knowledge and
opportunities for collaborative work
4. Conclusions and recommendations

APPENDIX C

WHO CONSULTATION ON VALIDATION OF SELF-REPORT
DATA ON SUBSTANCE USE
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SCOPE AND PURPOSE

This meeting will be in two phases.

The purpose of phase I is to train participants in the pilot phase of the WHO/ISBRA collaborative project on state markers of alcohol consumption. By the end of this phase of the meeting, participants will be able to undertake the agreed interview procedures in a consistent manner. Final agreement will be reached on reporting procedures for the pilot phase of the project and recommendations will be made for its future development.

The purpose of phase II is to review current knowledge on biochemical markers of drug use, with a view to identifying gaps in current knowledge and opportunities for future work. Recommendations will be formulated for action to be taken by WHO (including work in collaboration with clinical and/or research institutions, and in collaboration with ISBRA). These recommendations will be used to guide the development of future WHO/PSA activities in this area.