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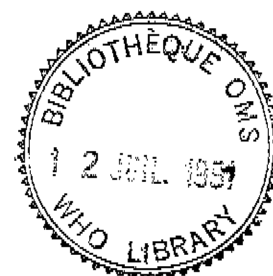
REPORT OF AN INFORMAL WORKSHOP ON INJECTION PRACTICES RESEARCH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Geneva, Switzerland
May 2 - 5, 1990

REPORT OF AN INFORMAL WORKSHOP ON INJECTION PRACTICES RESEARCH

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Action Programme on Essential Drugs and Vaccines
World Health Organization
Geneva

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EXECUTIVE SUMMARY

This report contains the proceedings of an informal workshop on injection practices research, that was organized by the Action Programme on Essential Drugs (DAP) of the World Health Organization, 2-5 May 1990 in Geneva.

The main aim of the workshop was to finalize the plans for a collaborative research project on the use of injections in three developing countries, notably Senegal, Uganda and Indonesia. Prior to the workshop country research teams had written provisional research protocols. These protocols were revised during the workshop, based on the suggestions of resource persons and discussion with members of the other country research teams. Thirteen researchers from the countries involved, from WHO headquarters and from the University of Amsterdam participated in the workshop.

The result of the workshop is a series of revised country protocols, which have been standardized with respect to core data collection instruments and data analysis techniques. This will allow for comparison of the research results, without compromising the need for country specific modifications in the conduct of the research. The participation of the country teams in the formulation of the collaborative research protocol is expected to contribute substantially to the successful conduct of such a multi-country research project.

The main objectives of the research project are to:

* estimate the extent to which injections are used as a route for the administration of medications;
* determine the type and degree of improper and unsafe practices in the process of administration of injections;
* gain insight into why injections are so popular;
* develop a simple, and rapid survey methodology for future assessments of the extent of inappropriate injection use.

The study is exploratory in nature. Both quantitative and qualitative research methods will be used. The researchers plan to present the results to policy makers and health workers in country workshops after completion of the projects.

Within the WHO headquarters in Geneva, the Action Programme on Essential Drugs, the Expanded Programme on Immunization and the Global Programme on AIDS have been involved in the formulation of this research project.

1. INTRODUCTION

1.1 Background and objectives of the workshop

The Informal Workshop on Injection Practices Research was the final step in the development of a collaborative research protocol to be used in a study on the use of injections in Indonesia, Senegal and Uganda. It followed a series of country visits during which researchers were identified and a provisional research protocol was discussed.

The workshop took place in Geneva, 2-5 May 1990, and was organized by the Action Programme on Essential Drugs (DAP) of the World Health Organization together with the Expanded Programme on Immunization, and in consultation with the Medical Anthropology Taskforce of the University of Amsterdam.

The overall aim of the workshop was to finalize the country research protocols and strengthen the research capabilities of the country teams, specifically to:

1. Present preliminary data on country situations, and present country research protocols.

2. Discuss appropriate anthropological and epidemiological research perspectives and techniques.

3. Standardize the research protocols, by developing common research techniques, and drug use measures.

4. Finalize the individual research protocols.

Thirteen participants attended the workshop (see appendix I), including: researchers from Indonesia, Senegal and Uganda; resource persons (an epidemiologist, a medical anthropologist, and a statistician/database designer); coordinators of the World Health Organization and the University of Amsterdam.

The workshop was informal in nature. The group, with input from the resource persons, worked together to improve the protocols, and develop a common methodology and perspective.

1.2 Introduction to the research project

Opening remarks

In his opening remarks Dr F.S. Antezana, DAP Programme Manager, explained why the Programme is interested in research. In the ten years that the programme has been operating the staff has come to realize that elements which are not "biomedical" affect the implementation of essential drugs programmes. In order to confront this operational research is needed. One of the research areas of DAP is socio-cultural research. Socio-cultural research can help elucidate the meaning of certain practices within a national/societal context. It can provide insight into the manner in which new technologies should be introduced. He stressed that DAP intends to assist countries to build up national and regional research capabilities.

Background to the study

Mrs P. Brudon-Jakobowicz gave a brief history of the Injections Research Project. For some years DAP has been increasingly concerned about the widespread misuse of injections in developing countries:

* From a health point of view administering injections without adequate medical knowledge or sterilization procedures leads to risks of transmitting serious diseases such as AIDS and hepatitis. In addition the drug that is injected is often not medically needed and potentially dangerous.

* From an economic point of view administering injections is undesirable if it causes poor families to spend scarce resources on injections when the money could have been better spent.

She emphasized that the belief in injections as a very powerful way of restoring or maintaining health is shared by providers and lay people alike in many different cultures. In fact the problem of injection misuse is so complex that it cannot be solved by training alone. Even if the health personnel is trained and refuse to administer injections for irrelevant reasons, this does not eliminate the misuse. Informal injection providers will administer injections to clients in their homes, market places, etc.

Given this situation the DAP research staff thought that it would be appropriate to initiate research on the unanswered question: why are injections so popular? To answer this question the causal and contextual factors behind the popular demand for injections need to be explored. This was seen to require anthropological research.

The research plans were discussed with staff of the Expanded Programme of Immunization (EPI). Before initiating an in-depth study on why injections are so popular, EPI proposed to add a first research phase to estimate the extent of injection misuse, since research on this subject has so far been limited. EPI was especially interested in the extent to which vaccines are administered unhygienically.

At this stage of the research the Global Programme on AIDS (GPA) expressed interest in the project, especially since it would result in rapid and simple methods to estimate the prevalence of injection use.

DAP presented a preliminary funding proposal to the donors, focusing on what is now referred to as the first phase of the project, which is a survey type of study with the following objectives:

1. estimate the extent to which injections are used as a route for administration of medication;

2. determine the type and degree of unsafe and improper use of injections;

3. gain insight into why injections are so popular;

4. develop a simple and rapid survey methodology for future assessments of the extent of injection misuse.

The third objective will be the focus of the second phase of the research project, in which the main aim is to elucidate why injections are so popular. This will be done by in-depth interviewing, focus group discussions and participant observation. The second phase will be initiated after completion and based on results of the first phase.

In the second part of her introduction Mrs Brudon-Jakobowicz stressed the importance of dissemination and utilization of research results. The ultimate objective is to improve drug use and injection practices at the country level.

In order to ensure the utilization of research results health policy makers and health workers should be involved in the research from the very start: while designing the research protocol, during the implementation of the project and on completion. When the research protocol is being developed a strategy for dissemination of results should be outlined. During the implementation phase of the research, progress reports can be distributed to those interested in the project, an advisory committee can be established and community meetings and workshops organized. On completion the results should be fed back to the respondents of the study, and to interested health workers and policy makers. Results should be disseminated in a final research report, but also in popularized articles, in oral presentations, and - if appropriate - by other means such as slide shows or theatre presentations.

The provisional research protocol

Dr A. Hardon introduced the provisional research protocol, that had served as a basis for the country research protocols. The provisional research protocol resulted from discussions with DAP, EPI, and GPA on the aims of the project.

She stressed that it should not be seen as a blueprint but as a number of suggestions for consideration by the country teams. In order for the country research projects to meet the needs of the country concerned it is important that the objectives of the country proposals are based on a country specific problem identification. Methods have to be adapted to local conditions. She stated that given the exploratory nature of the study and the limited time span (one year) in which results are expected, it is essential that methods are simple. The study should furthermore be cost-effective and feasible.

The provisional protocol lists the main objectives of the study, as outlined by Mrs P. Brudon-Jakobowicz (see above), and gives a list of more specific questions concerning:

* the types of health care providers administering injections;
* the indications for which injections are used;
* the appropriateness of injection use;
* why injections are so popular.

The methods are divided into user-oriented methods, and provider-oriented methods. The underlying assumption is that in order to be able to identify informal injection providers, one needs to start by asking users where they obtain their injections. Suggestions for use of secondary sources of information on injection use are also covered in the protocol.

Dr Hardon stressed that in designing the research it is important to balance various aspects of the study:

* The descriptive objectives (how often are injections used, how and for what?) and the analytical objectives (why are injections so popular?) for example need to be balanced. Description without explanation is not very useful. However an in-depth study that does not indicate the extent to which the practices occur is also of limited use.

* In line with the above, the quantitative methods and qualitative methods of the study need to be balanced. The quantitative research methods may require the researchers to cover a large study population, leaving them little time to do more in-depth interviewing through which they can find out why injections are so popular.

* In a multi-country study a balance also needs to be struck between the comparative nature of the study, and the country specific aims and objectives. The workshop is intended to clarify which aspects are intended to be comparative, and which aims and objectives are country specific.

* In accordance with this a balance needs to be struck between standardized and rigidly implemented research methods, and a more flexible approach. The workshop aimed to reach agreement on the methods to be used in all studies,

thus enhancing the comparative nature of the study, leaving the country teams freedom to add to and complement these methods.

* A balance also needs to be struck between doing field research and relying on secondary data. Often in research projects the tendency is to go to the field and collect data. Secondary data and literature, however, can provide very valuable sources of information, which complement, and at times even substitute for, part of the planned field research.

* Finally it is important to strike a balance between being comprehensive and doing cost-effective research. Data collection techniques should be line with the objectives of the project. The objectives have to be defined very precisely. Too often researchers are attracted towards extending and broadening a project, in order to gain more insight and understanding. The time and funds necessary for the data collection and analysis are not necessarily justified in terms of the type of data that are required for the planning of appropriate actions and interventions. The research may be so extended that the results become available at a stage in which policy has already been set and action undertaken, and are therefore of no use at all.

2. THE USE OF INJECTIONS IN UGANDA, SENEGAL AND INDONESIA: THE COUNTRY RESEARCH PROPOSALS

In this session Dr R. Salan (Indonesia), Ms H. Birungi (Uganda) and Dr L. d'Almeida (Senegal) presented their research plans. Here a brief overview will be given of the country research projects, referring to the provisional research protocol, and focusing on the similarities and differences between the projects. First, however, some background on the health situation in the countries and the use of injections is presented.

2.1 Health conditions and the use of injections

Health conditions

Health conditions in Indonesia, Senegal and Uganda differ, and the use of injections can be expected to differ accordingly. Where in Senegal and Uganda malaria, for example, is the most common diagnosis at health facilities, in Indonesia this is acute respiratory infections, with malaria accounting for only 6% of the illness cases reported to government health facilities. The infant mortality rate (see table 1) is much higher in Senegal (129), than in Uganda (104) and Indonesia (85). With respect to AIDs incidence, Uganda has a much higher number of reported cases (7375 as of 1 December 1989), than Senegal (207), and Indonesia (only 6). There are also differences in other major health-related variables such as fertility rate, immunization coverage, and the implementation of an essential drugs programme.

In Uganda and Indonesia there is a fairly well developed national essential drugs policy, with essential drugs being provided to government health centres and clinics. In both countries an essential drugs list exists. This is not the case in Senegal.

In all three countries the private sector and informal health care sector are reported to play an important role in health care. Thus the researchers aim at covering these sectors in their research projects.

TABLE 1

Some background statistics on the health and drug situation in Indonesia, Senegal and Uganda

VARIABLE	Indonesia	Senegal	Uganda
Infant mortality rate '87	85	129	104
Under-five mortality rate	120	220	172
Total number of AIDS cases reported on Dec. 1 1989	6	207	7375
Urban population '87	27%	37%	10%
Fertility rate '87	3.1	6.3	6.9
Contraceptive prevalence '81-'85.	40%	4%	1%
Percentage fully immunized one-year-olds '86-87			
* Tuberculosis	82%	92%	74%
* DPT	69%	53%	39%
* Polio	70%	53%	40%
* Measles	61%	70%	48%
Population with access to essential drugs '86-87	30 - 60%	< 30%	30 - 60%
Essential drugs list	Yes	No	Yes
Systematic provision of information on drugs	semi-organized	none	none

Sources:
The State of the World's Children 1989. UNICEF: New York
The World Drug Situation. 1988 WHO: Geneva
Weekly Epidemiological Record on AIDS. WHO: Geneva.

Injection use

In general there is a lack of accurate data on injection use in the three countries. However the data that are available point to serious problems concerning both the medical rationality of injection use, and the hygienic conditions under which injections are administered.

The Ugandan researcher reported on the use of injections in government health programmes. The Essential Drugs Programme is supplying kits to the government health clinics. These kits contain six injectables, of which penicillin and chloroquine are the most commonly used. The kits also contain reusable syringes and needles. A certain amount of these needles and injectables reportedly "leaks out" of the health facilities for private use. The Uganda National Expanded Programme on Immunization is currently promoting reusable syringes, after having supplied disposables in 1984 and 1985. However shortages in kerosene supply and lack of training in sterilization techniques are constraints to their proper use. The Central Medical Store accepts disposable needles from abroad, and they are readily available in the country. They are boiled and reused even in government facilities. During the AIDS campaign people got worried about infection through needles, and many doctors advised them to keep their own syringe at home, resulting in widespread self-medication.

The Indonesian research team referred to results of a study on drug management and distribution in government health centres. Key findings of this study are:

* one out of every four drugs given is an injection;
* nearly 50% of infants and children, and 75% of patients five and over, receive one or more injections when visiting a health centre;
* the highest use of injections was for skin, musculo-skeletal and nutritional and vitamin deficiences;
* the rate of injection use showed no relation to illness category.

For Senegal no specific injection use data were presented.

2.2 The objectives of the research projects

The provisional research protocol listed the following general and specific objectives:

General research objectives:

1.a Estimate the extent to which injections are used as a route for the administration of medications.

1.b Determine the type and degree of improper and unsafe practices in the process of administration of injections.

1.c Gain insight into why injections are so popular, and how their use can be improved.

1.d Develop a simple and rapid survey methodology for future assessments of the extent of inappropriate injection use.

Specific research questions:

Concerning the types of health care providers administering injections:

2.a Which health care institutions and which practitioners are administering injections in a certain region?

2.b Which institutions and practitioners - both formal and informal - are most often visited by people for injections?

Concerning the distribution channels of injections:

2.c Where do the institutions and practitioners obtain the injections that they administer to patients? Do they obtain the injections from a government source, or from the commercial private sector?

Concerning the indications for which injections are generally used:

2.d What are the main indications for which the health institutions and practitioners administer injections?

2.e What are the disorders for which people seek injection treatment?

2.f Why are injections chosen for these indications?

Concerning the appropriateness of injection use:

2.g To what extent do people use injections to treat:
- cough
- fever
- an additional three indications identified under 2d-e, that do not warrant injection treatment.

2.h Why are injections administered in the above five tracer conditions, while their use is not medically justified?

2.i Which types of injections are used in the treatment of the five "tracer conditions" mentioned in 2g.

2.j What did the injections cost in the above cases? What would an alternative non-injectable therapy have cost?

2.k To what extent are the injections that are administered for the five tracer conditions given intravenously?

2.1 To what extent are injections administered in sub-standard hygienic conditions?

Concerning the reputed efficacy of injection use:

2.m What is the expected effect/or experienced effect of the injectable medication.

If appropriate:

2.n Why did the practitioner choose an injection instead of an oral medication?
2.o Why did the patient want an injection instead of an oral medication?
2.p Why are injections administered in an unhygienic manner? Do people lack training? Do they lack resources? etc.

The Indonesian and Uganda country teams referred to the objectives and questions in the provisional research protocol, and indicated that they had used this framework as a basis for the development of their interview forms. The questions concerning cost (2j) and concerning the mode of administration (2k) were, however, left out in both country proposals. Also the question concerning the manner in which injection use can be improved (1c) is not considered appropriate in this phase of the research. The Ugandan team places more emphasis on the qualitative aspects of the research (questions 2n - p), than the Indonesian team. The Ugandan researchers also pointed out that they intend to monitor adverse effects of injections use, e.g. the occurrence of abcesses.

In the Senegalese research presentation a list of country specific objectives was presented following the lines of the provisional research protocol. In addition however, the Senegalese researchers intend to enquire into the manner in which people view their body, their health problems, the therapies that are involved, and the risks related to these therapies. This would require anthropological research methods.

It must be noted that general objective 1d "Develop a simple, and rapid survey methodology for future assessments of the extent of inappropriate injection use" will not be met in any of the individual country projects. This will need to be done separately, by an inventory of the methods that the various teams have used, and the validity and reliability of the results.

2.3 Methods

The provisional research protocol listed a whole range of methods that the country teams could use. An overview is given below of the methods that the country teams have adopted (see Table 2).

TABLE 2

Overview of the research methods proposed in the country protocols

	Indonesia	Senegal	Uganda
Users			
* Interviews with key informants on provision and use of injections	no	yes	yes
* Focus group discussions on health, illness and injection use	no	yes	yes
* Household interviews with recall of treatment given for health problems that occurred in the past two weeks	yes	yes	yes
* Household interviews, with questions concerning treatment of hypothetical illness cases	yes	yes	yes
* Household interviews, with recall of last time an injection was used in the family	no	yes	yes
Providers			
* Structured interviews on indications for which and conditions under which injections are used	yes	yes	no
* Self-reporting on indications for which injections are used	no	no	yes
* Interviews on hygienic practices	yes	yes	yes
* Interviews of patients at health facilities	yes	no	no
* Review of prescriptions	no	yes	no
* Focus group discussions	no	yes	no

From this overview it is clear that the Senegalese and Uganda research teams intended to use more qualitative research techniques (interviews with key informants, and focus group discussion) than the Indonesian team.

Concerning the user-oriented methods, the use of a two week illness recall, and the use of hypothetical illness cases emerge as common research methods.

The Ugandan team reported some problems with the use of hypothetical illness cases as a way of probing on therapy choice. The researchers said that the respondents would ask the interviewer for more details. There are many types of fever, the researcher explained, and the treatment depends on the type of fever that is being suffered. It was suggested that this problem can be circumvented by giving people a detailed case history for which they are asked to suggest a treatment. This is proposed in the Senegalese research protocol (see further the discussion on so-called "tracer conditions" in section 4.4 of this report).

Concerning the provider-oriented methods, the three country teams do not totally agree on the method that is most appropriate to study to what extent the prescription of injections is medically justified. The Indonesian team intended to interview patients visiting health facilities. The Senegalese team planned to review prescriptions and the Ugandan team preferred to let providers report themselves on the indications for which injections are prescribed. It was noted that self-reporting, as proposed in Uganda, requires a very good rapport with the providers.

The data-collection instruments have been pre-tested in Uganda and Indonesia. The Indonesian team pointed out that the two-week morbidity recall method may not yield many results if people are not often ill, or do not often receive injections. Out of the 60 households interviewed in their pilot-study only 6 reported the use of an injection. In Uganda a high rate of injection use was reported. Most families in fact keep a syringe in their homes, which they use for penicillin ("PPF") administration in common cough and cold cases.

Both teams commented that the manner in which the research is introduced can influence the data-collection to a large extent. In Uganda the pre-test was done in an area where the researcher knew the people well. There people were willing to discuss openly injection use with her. In Indonesia in one area the research was perceived to be a form of policing injection prescribing, and people were initially reluctant to report on injection use in the area.

2.4 Research areas and sampling frames

In the provisional research protocol it is stated that the research is intended to cover a variety of health care settings, in order to gain insight into the extent of injection use in various settings. The available budget and exploratory nature of the study do not allow for results that are representative for the country.

The Indonesian and Senegalese research teams reported that they intend to do the survey in two areas: one relatively near the capital, and one more remote. In both

these provinces/districts three health care settings are selected: one urban, one semi-rural and one remote. In each health care setting two communities are to be surveyed. Up to this point the sampling frame is purposive. At the community level the teams intend to randomly select 60 households with pre-school children. A total number of 720 households (360 in each district/province) will be surveyed in both countries.

The Ugandan team reported that they intend to do the research in one area, and to select two communities in the urban, semi-rural and remote settings. The team does not intend to do the research in an area near the capital, arguing that the percentage of urban population is so limited in Uganda. The team only intends to survey 360 households, leaving the team more time to do the time-consuming qualitative aspects of the research.

3. TOWARDS A COLLABORATIVE RESEARCH PROJECT

In the following sessions of the workshop various aspects of the study were discussed by resource persons and the participants. Refinements and revisions of the research protocols were agreed upon.

Dr Michael Tan, and Dr Richard Biritwum had been invited as resource persons to give the participants some background in medical anthropological and epidemiological research perspectives and techniques. Mrs P. Brudon-Jakobowicz and Mr P. Evans gave suggestions for evaluation of the appropriateness of injection use. Below the main points of the contributions are summarized, together with the resulting discussion and decisions concerning:

(1) common themes for qualitative research on injection use; and
(2) common measures and indicators for quantitative research.

3.1 Medical anthropological perspectives and techniques

Dr Tan discussed with the participants various approaches in medical anthropology that can be used to elucidate the question of why injections are so popular. He explained that traditional anthropological research is often purely descriptive, resulting in extensive descriptions of what people do. Applied anthropology, he commented, has tried to contribute to health programmes by studying the gap between knowledge, attitudes and practices. However often a simplistic framework of analysis is used. He suggested that cognitive or symbolic anthropology is a useful theoretical perspective for the study on injection practices, as it points towards patterns of cognition and understanding among the users of injections, thus elucidating "the lay perspective". According to Dr Tan, the "explanatory model" (EM) concept, as developed by Kleinman[1] could be of use to the researchers. In this model biomedical, traditional and popular EM's are distinguished and are considered to interact with each other.

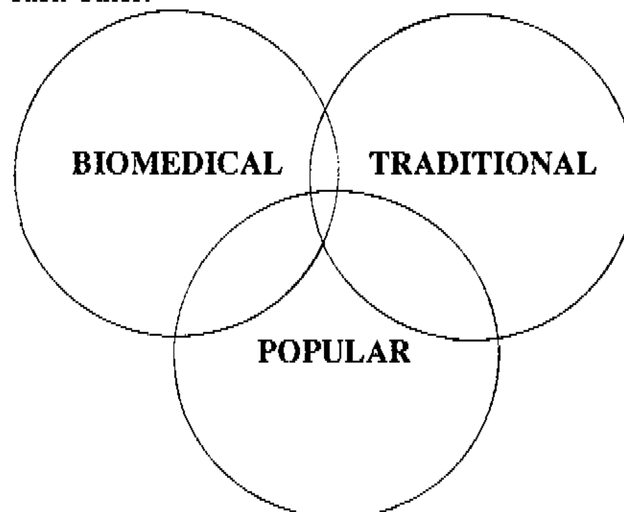

Figure: Explanatory models as put forward by Kleinman.

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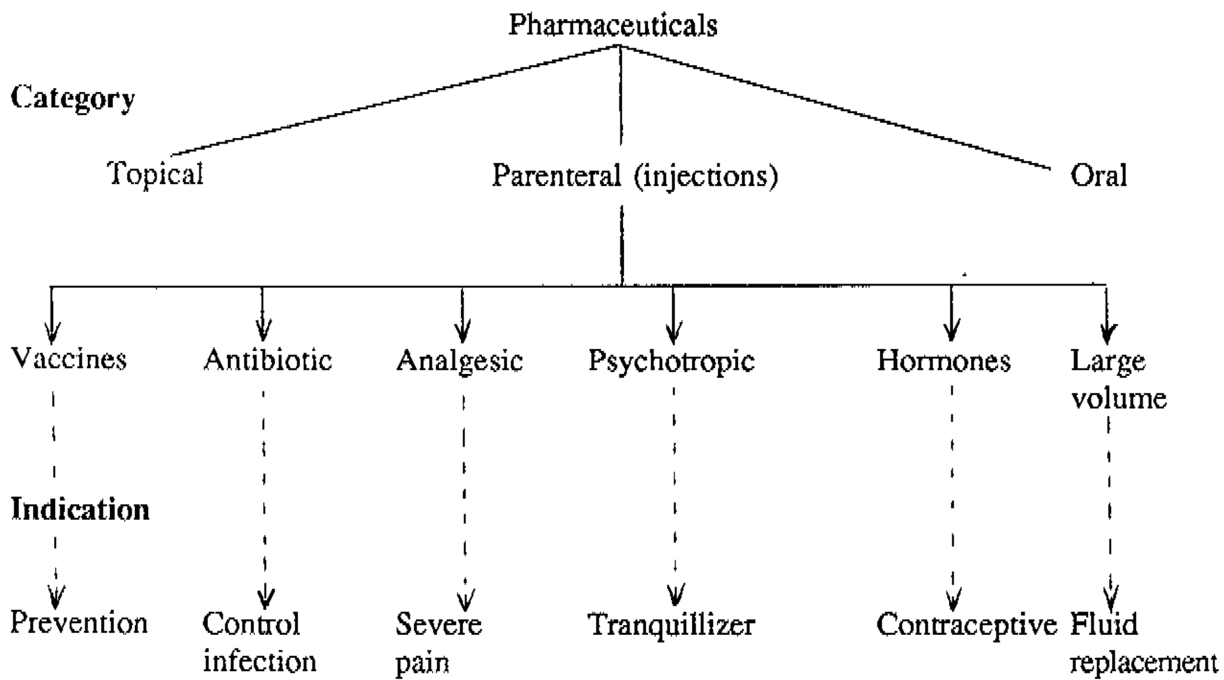
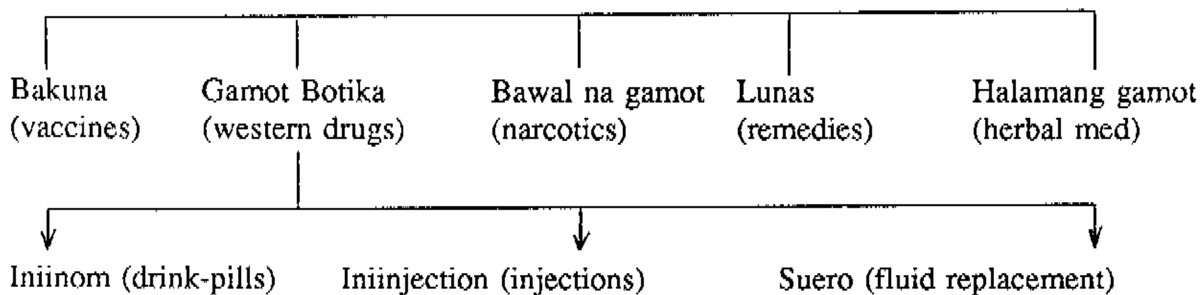
[1] Kleinman, A. 1980 Patients and Healers in the Context of Culture. Berkeley: University of California Press.

Such EMs should be viewed in their socio-historical context. He illustrated some differences between a biomedical EM and a popular one, by looking at the manner that injections are classified in these two explanatory frameworks. For the biomedical classification, he referred to categories used in pharmacology, and for the popular classification he referred to findings of a Philippine (tagalog) study on drugs. An overview of the two classifications is given below.

BIOMEDICAL CLASSIFICATION



POPULAR CLASSIFICATION



What is apparent in the above example is that in the popular classification vaccines are not categorized as injections. This implies that if in the Philippines the interviewer asks if a respondent has received an injection, then the respondent is not likely to report the administration of a vaccine.

Dr Tan suggested that information can be gained on people's perceptions of injections by, for example, asking them what they think of when hearing the word "injection". In the Philippines this resulted in the following terms: **masakit** (painful); **mahal** (expensive); **mabilis** (fast, rapid); **malakas** (strong); **mabisa** (effective); **mainit** (hot).

A problem with this type of inquiry is that not all ideas that people have about drugs are "manifest". Some may remain "latent" and thus hard for the researchers to identify. Dr Susan Whyte, a medical anthropologist consultant to the Ugandan research team, pointed out that there are different levels of explanation for the question "why are injections so popular". Some key informants may give you explanations that the survey respondents did not. The survey respondents may, for example, point to the reputed efficacy, while key informants may comment that the fact that the injection causes pain contributes to its popularity. The anthropologist herself may have a different explanation of the popularity of injections based on her observations. She may view the whole injection procedure as a ritual, and may suggest that it is the ritualized aspect of the injection procedure that appeals to the users.

Another concept that is useful for the study on injection practices according to Dr Tan is the "Total Drug Effect"[2]. This concept states that the "total" effect of a drug depends on:

* attributes of the drug itself (including taste, shape, colour and name);
* attributes of the patient (experience, education and socio-economic status);
* attributes of the provider (status and training);
* setting in which the drug is administered (doctor's office, home, ritualized aspects).

In addition he stressed that it is always important to relate people's view of injections to the expectation that both users and providers have of the drug, based on (1) the diagnosis of the problem; (2) the perceived solution to the problem; and (3) the expected outcome.

With respect to the methods that can be used in the research on injection use, Dr Tan suggested focus group discussions as a convenient way to gain insight into popular views on injections. It may be a good idea to combine this method with

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[2]. See Helman 1984 Culture Health and Illness. Bristol: Wright-PSG, p 106. Helman refers to the manner in which Claridge used this concept.

projective techniques, i.e. use certain attributes or illustrations to stimulate reactions and discussion. Participant observation can also be used. He pointed out that these techniques need not be as time-consuming as is often expected of anthropological research. What is needed is a sharp focus of what is being studied, and good recording techniques. Even a small number of focus group discussions, and informal talks with respondents can provide a lot of insights to complement the data collected in the more structured survey.

3.2 Discussion on qualitative aspects of the study

General

It is recognized that this phase of the project is exploratory in nature. The medical anthropological component of the research has to be kept simple and appropriate in relation to available resources. It aims at eliciting popular perceptions of injections.

The "qualitative" component of the research contributes to the overall research project by:

* generating appropriate questionnaires (i.e. quantitative research instruments) by identifying specific local terms for pharmaceuticals and health problems, and by generating interesting insights and themes for further study;

* validating quantitative data, through so called "triangulation";

* complementing the quantitative component of the study by providing concrete examples (surfacing the human side behind the statistics), and by giving explanations for the observed trends.

Methods

The country teams agreed that the following three anthropological methods are of particular use to the research on injection practices:

* **Interviews with key informants**: These are useful in the preparatory phase of the research and can be used to develop appropriate questionnaires. Key informants can be community executives, informal leaders in the community, teachers, friendly mothers, and community health workers. It is best if a number of different informants are interviewed.

* **Case studies**: During the household interviews (quantitative research) interviewers are likely to be confronted with households in which a person is sick and being treated with an injection. The interviewers can be trained to probe in these cases. This can be done in an informal manner, and documented afterwards. Such case histories can provide more insight into when and why people resort to injections.

* **Focus group discussions**: A group of users or providers share their experiences. In these discussions the researchers can be creative, using projective techniques, role-playing and other approaches to maximize participation. They can prepare a checklist of questions covering certain themes for discussion (see below).

Ultimately these methods should help the research teams in: "cognitive mapping": identifying people's perceptions of injections; and "social mapping": identifying the social transactions involved in injection practices, including patterns of resort (when, where and from whom do people receive injections).

Common themes for the qualitative study

The objective of understanding "why people like injections" is a broad one that requires more specific themes/questions to explore. In fact even "liking" of injections must be taken as a hypothesis to be tested. Some themes that are essential for the comparative and exploratory study are:

(1) What is an injection?

(2) What qualities or attributes are associated with injections?

a. This can be instrumental, referring to the syringe and needle, and
b. Specific, referring to particular injection brands.

(3) What are perceived advantages and disadvantages of injections?

The advantages and disadvantages of injections can be explored relative to:

a. other medical interventions, such as oral medication or herbal medication;
b. indications (using popular illness descriptions among users and non-formal practitioners, and biomedical disease terms among professional practitioners);
c. patient's age, and sex.

Methodological constraints

(1) **Language**: The researchers envisage that they will be confronted with language problems. In Indonesia for example the team has difficulty in finding a social scientist who speaks the language in the "remote" province, Lombok.

(2) **Rapport**: Given the time limitation of the study, it will be hard to establish a good rapport with the respondents in the communities. This will limit the depth of the qualitative research. Related to this, the researchers may be constrained by the delicacy of the subject, in situations in which self-medication with injections or the provision of injections by informal healers is illegal.

(3) **Who to interview**: It will not be possible to interview the mothers - who are expected to know most about the health of their children - in all the countries. In Senegal the interviewer will have to interview the fathers, who then will pass on the questions to the mothers. In Uganda and Indonesia the interviewers can directly approach the mothers.

3.3 Epidemiological perspectives and methods

Dr R. Biritwum introduced the epidemiological aspects of the study and put forward some of the issues that would need to be discussed.

Concerning the epidemiological - or quantitative - component of the study he summarized that it contains:

- structured interviews with users and providers;
- a review of records and prescriptions.

Measures that are proposed in the provisional protocol, and the various country studies include:

- the extent of injection use in the past two weeks, in relation to age, sex, provider, and reason for use;
- last time an injection was received;
- the percentage of prescriptions containing injections;
- percentage injections that are medically justified;
- percentage injections which are administered under proper hygienic conditions.

Concerning the users he drew attention to the multi-stage sampling frame involving:

- 2 districts/provinces;
- three health system level;
- 2 communities per level;
- 60 randomly selected families per community.

Concerning the providers he noted that for a formal sample size calculation the prevalence of injection use would need to be estimated. Given the exploratory nature of the study, this would be hard. It is therefore suggested to leave out the formal sample size calculation and to simply interview 100 providers. This should give sufficient baseline information. The following points would need to be noted in the further development of the protocol:

- **What are the objectives**? Dr Biritwum commented that most of the country teams have not made their objectives explicit. He noted that for every question in the questionnaires it should be clear which objective it is intended to answer.

* **How is a household defined?** He suggested that people who eat and live together are considered a household. The Ugandan researcher however commented that this definition leads to problems as one husband may have several wives with separate "households". It was decided that in such situations only one wife and her children are included in the sample.

* **Which household is considered "eligible"?** In the provisional protocol it is suggested to include only families with children below the age of five.

* **What type of injections are covered?** (this was also discussed under 4.1).

* **What tracer conditions are used?** (see section 3.4 of this report).

* **What sampling procedure is used?** Concerning this last point it is suggested to do a so called "cluster" sampling. This is done by first "randomly" selecting a direction in which to begin the household visits in the community (for example by spinning a bottle around in one of the central areas), and then visiting every household that has a child below five in that direction. When leaving a house, the nearest entrance to a next house is located and visited.

As noted above, it is agreed that not more than one wife-cum-household per husband will be included in the sample.

* **How are results validated?** The results need to be validated. Dr Biritwum suggested that this can be done by revisiting a sample of households, by comparing the results of the household interviews with the results of the focus groups discussions, and by comparing the results of the user-oriented methods with the results of the provider-oriented methods. He stressed that a prescription analysis can be an accurate source of additional information for validation purposes.

3.4 Evaluating the appropriateness of injection use

During this session Mrs P. Brudon-Jakobowicz, and Mr P. Evans discussed the extent to which (1) injections are medically justified; and (2) the extent to which they are administered in an hygienically acceptable manner can be determined. The main aim was to agree on a common approach for the evaluation.

Medically justified

In consultation with the country researchers it was decided that the aim of the research would be to assess the extent to which injections are given to treat common health problems that do not need injection therapy. For this purpose the teams agreed to define two "universal" tracer conditions that meet the following criteria:

* The condition is a common health problem for which injections appear to be used often, while they are not medically justified.

* The condition can be described accurately in local illness terms.

* A well defined treatment norm exists for the condition.

The conditions that were chosen to meet these criteria are:

a. A cough **and** cold case in a patient of any age.

b. A diarrhoea case in a child who is less than five years old. The child suffers less than five watery stools per day, and does not suffer from other complications such as blood in the stool, vomiting or high fever.

Each country will select two additional country specific conditions.

Hygienically appropriate

Mr Evans presented to the participants guidelines for evaluating hygienic use of injections (see appendix III). It was agreed that the hygienic criteria to be used in the study:

* should be defined at the country level in consultation with national policy makers;

* should be simple;

* should cover the procedures (1) before administration of the injections, (2) during administration, and (3) after administration of the injection.

3.5. Discussion on common variables and measures

Variables

It was agreed that the following variables will be covered in the three country studies:

a. Demographic

- age category:
  * 0 - 4 years;
  * 5 - 14 years;
  * 15 and up.

- sex:
  * female;
  * male.

b. Type of illness

- tracer conditions:
  * cough and cold, any age;
  * diarrhoea, less than five watery stools per day, in under-five;
  * at least two additional country specific conditions.

- other indications for which injections are used, described with terms used in the specific health care setting

c. Treatment:
* injection only;
* oral medication only;
* injection and oral medication;
* others.

d. Type of injection:
* therapeutic (small volume);
* infusions (large volume)
* immunizations
* contraceptives

e. Health facility at which injection was received (specific levels can be identified by each country team):
* government facility;
* private facility;
* non-formal facility;
* home.

f. Who administered the injection:
* physician;
* nurse/midwife or allied health professional;
* person with no formal training.

It should be noted that the person who prescribed the injection is not necessarily the person who administered the injection. Both are categorized as "providers" in the protocols. In the interview questions and in the records, the investigators should make sure that it is clear who actually "administered" the injection in addition to who "prescribed" or "provided" the drug.

<u>Measures</u>

A number of core injection use measures were developed and defined in the discussion on the epidemiological aspects of the study, and the evaluation of injection use. These are given below.

I. Prevalence of injection use

The following descriptive measures were agreed upon:

(Ia) The percentage of households (HHs) in which one or more injections were given in the past two weeks.

Expressed as:

Number of HHs in which at least one family member was administered an injection in the past two weeks
-------------------------------------- x 100
Total number of HHs

(Ib) The percentage of HHs that received a specific type of injection in the past two weeks.

This can be calculated as above (a) with as numerator "the number of households in which at least one family member was administered a **specific** type of injection in the past two weeks". As specific types of injections the group identified the following categories:

* therapeutic injections
* infusions (large volumes)
* contraceptives
* immunizations

(Ic) The percentage of people in a certain age category of the study population[3] who have received at least one injection in the past two weeks.

Expressed as:

Number of people in a specific age category of the study population who have received at least one injection in the past two weeks
-------------------------------------- x 100
Total number of people in specific age category of the study population

[3]. Defined as all members of all households that are included in the study.

As age categories the researchers decided to use the following:

0 - 4 years of age
5 - 14 years of age
15 years and up.

(Id) The percentage of females and the percentage of males in the study population who received at least one injection in the past two weeks.

This is calculated as in (c).

(Ie) Frequency of injection administration per health facility. A simple frequency distribution can be made listing how often certain health facilities are reported as source of the injections in the study population. Health facilities can be categorized into:

* Government facilities
* Private facilities
* Non-formal facilities
* Homes.

This calculation can be done for the injections reported in the two-week recalls, and for the injections reported in the additional questions "when was the last time that you received an injection".

(If) Percentage of patients at a certain health facility who received at least one injection, expressed as;

$$\frac{\text{Number of patients receiving at least one injection during a predetermined observation period}}{\text{Total number of patients visiting the health facility during the observation period}} \times 100$$

Or, if the team decides not to interview patients at health facilities, a similar measure can be made based on an analysis of prescriptions:

Percentage of prescriptions at a certain health facility that list at least one injection, expressed as:

Number of prescriptions written in a certain observation period containing at least one injection
-------------------------------------- x 100
Total number of prescriptions written in the given observation period

II. Evaluation of the appropriateness of injection use

(IIa) Percentage of injection use in certain tracer conditions.

Expressed as:

Number of times that a certain tracer condition was treated with an injection in the study population
-------------------------------------- x 100
Total number of times that the tracer conditions were reported in the two week recalls in the given study population

This measure can be calculated for the following types of medication:

* injection only
* oral medication only
* injection and oral medication
* other medication

in order to contrast the percentage of injection use with that of oral and other medications.

(IIb) Percentage of injection use in "hypothetical" tracer conditions. In addition to the calculation of injection use prevalence based on the two week recalls it is advisable to present mothers with hypothetical cases (covering the identified tracer conditions), and asking them what they **would** do if this condition occurred.

The measure is then expressed as:

Number of times an injection was
reported as therapy for the
"hypothetical illness case"
-------------------------------------- x 100
Total number of respondents
that participated in the interview.

As was pointed out in IIa, this measure can be calculated for the following types of medication:

* injection only
* oral medication only
* injection and oral medication
* other medication

in order to contrast the percentage of injection use with that of oral and other medications.

(IIc) If prescription patterns of providers are monitored, then the percentage of injection prescription in the specified tracer conditions can also be calculated.

(IId) Frequency distribution of types of injections given per tracer condition. The injections can be categorized by generic and by brand name.

(IIe) Percentage of providers who do not observe minimal hygienic standards <u>before</u> administering an injection.

Expressed as:

Number of providers who do not
follow minimal hygienic standards
-------------------------------------- x 100
Total number of providers who
were interviewed

(IIf) Percentage of providers who do not observe minimal hygienic standards <u>during</u> administration of an injection.

This can be calculated as in (IIe)

(IIg) Percentage of providers who do not observe minimal hygienic measures <u>after</u> administration.

The measures IIe-g can be calculated for the various types of injection providers.

The following categories of providers were put forward:

* trained physicians
* nurse/midwife/allied health professional
* person with no formal training

It was stressed that the above are minimal measures that should be used in all the country studies. The categories (types of injections, age categories, types of providers etc.) that are proposed should be used as a basis for the study, while country specific sub-categorization can be made. It is essential that these measures are followed as otherwise the comparative aspects of the study are compromised.

It is also recognized that many of the measures are rough. The prevalence of injection use by age and sex, for example, is not a population based estimate, as the study covers only families with pre-school children. Also the percentage of households using injections is a rough measure since average HH size will differ from country to country. This will have to be considered during the comparative analysis phase of the research. However the researchers and resource persons agreed that for the given aims of the study the above measures are accurate enough.

Concerning the sampling frames the researchers agreed to follow the multi-stage sampling frame that was put forward in the provisional research protocol, resulting in a total study sample of 720 households per country. The Ugandan research team agreed to revise their protocol in accordance with this decision. There was however some discussion on the appropriate number of injection providers that should be observed in each country. The teams were concerned about the time limitations involved. The teams consider between 60 and 100 providers per country feasible.

4. DATA PROCESSING AND ANALYSIS

Mr J. Hetzke gave an introduction on the subject of data processing and analysis in research projects. He made the following points:

With respect to the computerized processing of questionnaires and/or interview data, it is very important to establish a reliable framework for the major components, i.e. for collecting, processing and analyzing the research data.

* A critical step in any research study is the selection of variables to be included. Once the variables have been set the investigators can decide how the data will be recorded.

* Whatever type of data base the investigator intends to develop, the investigator should start with a clear conception of the data tables required for the analysis. It should be clearly stated what data categories will be used, how the data tables will be arranged, and which individuals will be included or excluded (sample size).

* Given the exploratory nature of the study it is advisable to adopt a process-orientation in the analysis of the results. By continuous analysis of results during the study, the focus is narrowed and data become available as early as possible. The use of an easy to handle data storage programme facilitates such ongoing analysis.

* In some cases where investigators would like a higher degree of flexibility in information processing, it might be preferable to perform information storage and statistical information processing with two separate software packages. Data base management programs such as "dBase" could for example be used for simple entry and storage of information obtained from the interview/questionnaires. The analysis of those data could then be left to statistical packages.

4.1 Data processing

(1) Data collection

Data collection should only start when processing resources are confirmed, and all aspects of coding and editing have been tested and proved reliable. Programme systems should be tested before use on "live" data either by using a sample of real data or by pre-filled test questionnaires.

Computer processing is accepted as necessary for most surveys owing to large sample size, number of data items, complexity of sample weighting or extent of cross-classification or other analyses.

A field investigation is usually too pressing to offer the chance to learn new computer skills or try previously untested software. Computer operations that will be used in the field should be practised under other circumstances so that there is reasonable assurance that they will succeed. Small problems in data formats or understanding a program can consume large amounts of time unexpectedly.

(2) Data identification and classification

Data records must be uniquely identifiable to facilitate easy access and amendment. In this respect, questionnaires for data entry that allow for record identification to facilitate easy access and inter-record linkages are necessary. Record identifiers will help to reflect the sample design for subsequent sample weighting and variance calculation. Some of the problems such as loss of data, data duplication or misclassification are caused by mismatching of records, which can occur during recoding or data entry of a record identifier. They can be avoided by including data for cross checking.

As far as an exhaustive classification of data is concerned, all possible cases should be covered by the classification process (frequently achieved through an "other" grouping at the end of a classification), whereas a clear and distinct definition of cases must be observed.

With regard to mutually exclusive classification, particular attention should be paid that no possible case can be given more than one code. For large and complex classification, a code list showing items in alphabetical order is recommended in addition to a normal numerical code list. National or international standard classifications are recommended wherever possible to speed processing, to minimize processing errors and to improve the integration of the statistical system for the country.

(3) Data editing

Data editing checks that:

- data records are complete;
- data items are logically consistent with each other;
- the sequencing is correct: that there are no answers for questions that should have been skipped, but there are answers for questions that should not have been skipped;
- there are no invalid characters (e.g. alphabetic in a numeric field);
- the value for a particular item is within the valid range for that item.

When errors are detected, the records are amended and then re-edited. The edit/amend cycle needs to be continued until all errors have been removed (or those remaining are considered negligible). The data should always be verified in a reliable manner. Missing values should be marked as such and not as blank or zero, and the investigators should make sure that the data are cross-checked for plausibility of data input. The type and range of acceptable data can easily be checked by a small programme that performs all types of data checkings.

(4) Data coding

Processing the huge amount of information to be gathered from the questionnaires/interview and entered into a computer readible medium such as diskettes or hard disks, involves coding. Coding allows:

1) for classification and tabulation of data, and
2) editing of data to a stage where errors have been removed or minimized.

Data processing also includes manipulation of data to derive values from the items collected. In this regard, it should be mentioned that questionnaires may need to be designed for direct data entry. Direct data entry is preferable to that of data transcription by clerks on separate data entry sheets. Coding may be built into the questionnaires and, depending on whether direct data entry is used, either the form or the data in the data base can be coded.

It is important to strike a balance between clerical and computer editing. Computer processing is fast, consistent but inflexible. Clerical processing allows discretion and flexibility in accepting or rejecting a particular record. This can be useful if the record is complex or unusual, but problems may arise in interpreting the data, for instance if data processing staff proceed with inconsistent criteria.

A computerized data processing system should be carefully designed and resources for processing should be identified before starting data collection. Planning charts should be prepared showing activities and estimates of their duration. The number of data processing staff, computer equipment and other resources should be well defined in advance. Also, a systems analyst/programmer who will prepare the computer processing system, should be involved in survey planning at an early stage.

In many cases, questionnaires are designed in such a way that the interviewer ticks the appropriate answer to a question, looks at the code preprinted alongside the ticked box, and transfers this code into the data entry column. When errors are detected, the records are amended and then re-edited until all errors have been removed.

If a questionnaire is to be used for direct data entry only, the data to be entered can be noted by writing in a separate data column. This column should contain only the data that are to be entered, i.e. data in code form.

After the scales of measurement have been defined, decisions on precoding must be taken. Data may be coded (by marking the appropriate numerals) at the time of investigation or at a later stage. In any case, a written key to the code is required. If the data are to be coded the instructions must be clear and unambiguous in order to enhance coding reliability. Depending on the selected statistical software package, recoding might not be allowed at a later stage.

4.2 Data analysis

Data tabulation and analysis considerations occur at the same stage of a survey: the planning stage when questions are being considered for inclusion in the questionnaires. Data analysis is usually more closely tied than a tabulation scheme to the technical or policy issues on which the health survey is based. Different health questions require different combinations of what might be the dependent or the independent variable. In an analysis dealing with the correlates of health status, use of health services might be an independent or explanatory variable, education might be an intervening variable, and, some measure of health status the dependent or outcoming variable.

Under this concept, the variables of the study can function as independent, intervening or dependent variables in an analytic scheme according to the health issue being addressed by the survey. Each issue will generate one or more analytic plans involving different combinations of hypothesized independent, intervening or dependent variables, which can be specified in more detail and more precision.

The potential number of tables will usually far exceed that produced in a standard tabulation plan. In some cases, they address specific issues included in the aims of the survey. The more clearly stated the health issues in the aims of the survey, the more fruitful will be the analytic schemes.

As a first step to addressing the analysis, a series of tabulations of the marginal frequencies of each of the explanatory, intervening and outcoming variables should be prepared. This is a standard precautionary measure usually done at the data processing stage in order to edit out-of-range values, input missing values.

In addition, it allows for the collapsing of categories for small populations, thereby ensuring that the categories are producing the expected frequencies, useful for the analysis. A series of cross-tabulations of the explanatory with intervening variables, and intervening variables with outcoming variables is needed. Since, at this stage, there is a likelihood that definitions of certain variables will need revision by remanipulating the raw data (pooling of disease groups, changing categories, defining multivariable indicators), it is important that the marginal distributions and cross-tabulations can be quickly produced and revised.

During data analysis it is worth examining measures of precision, preferably both from the unweighted data and from the weighted data. In order to facilitate analyses of crucial relationships among variables and ensure that basic issues are dealt with, priority should be placed on the promotion of appropriate analyses. In this respect, the research report should provide some guidance. It should outline the methodology used to collect the data, and document most of the survey conclusions with the appropriate measures of validity, reliability, and precision. Typically, survey conclusions include a large number of tabulations, often giving the distribution of each variable included in the questionnaires.

In this regard, a series of analytic steps should be taken:

1. Development of a conceptual framework.

2. Definition of a set of priority questions to be answered within a framework.

3. Translation of priority questions into a set of operationally defined variables which can be measured with the necessary validity and precision.

4. Specification of sets of relational and comparative data to be generated.

5. Construction of sets of marginal tabulations, preferably with measures of precision such as coefficients of variation and number of observations.

6. Computation of multiway tables (cross-tabulation).

7. Construction of scales transforming defined variables into indices suitable for analysis (socio-economic status, access to health services, education).

8. Creation of secondary tables relating the variables of interest.

9. Construction of summary statistics, such as means, rates, proportions, appropriate confidence intervals, tests of significance.

10. Interpretation of the results of the statistical analysis in the light of the questions to be answered in the survey. The interpretation might also generate the need for new sets of intervening variables.

4.3 Choice of software for data processing and analysis

The entry, editing, amendment and manipulation of data can be done by using a variety of statistical analysis software and business software packages. In most cases, these programmes can be used to process data, in conjunction with some word processing and graphics software.

* SPSS PC+ and EPI Info are statistical packages that offer file import and conversion facilities that allow for reading ASCII files created with software packages such as dBase.

* But as far as the design of a data base structure and its related variables is concerned, it should be noted that data sets and records created with dBase are not automatically compatible with the arrangement and definition of variables of EPI Info data files or the SPSS PC+ standard data files.

In this respect, the definition of the original dBase file/record structure, location of variables and values is crucial to fit the information processing requirements of a statistical package that is different from the primary information collection package.

Following these suggestions for data processing and analysis, Mr Hetzke gave some illustrations of dBase, and EPI Info file organization, and showed the participants how some simple calculations could be performed.

In the discussion it became clear that the **Indonesian** investigators have access to a well equipped dataprocessing unit. The Ugandan team requested support in developing a database for data storage during the fieldwork. All teams could use DBase III+ for initial data storage. In Indonesia statistical analysis would be done with SPSS, in **Senegal** with Epidemio and in **Uganda** probably with EPI Info.

Given the agreement on common measures for the description on injection use, it seems advisable to standardize the relevant variables, and values of these variables (as was done in section 3.5). This will allow for efficient compilation of the data in a common database during the comparative analysis of the research.

5. CONCLUSIONS

During the final session of the workshop the country teams presented their revised research proposals. Compared with their initial presentation it was apparent that the workshop had led to substantial refinements of the research protocols, and had resulted in greater potential for comparison of the research results, without compromising the need for country specific data. The participation of the country teams in the formulation of the collaborative research protocol is expected to contribute substantially to a successful conduct of the multi-country research project.

The country proposals aim at answering the same research questions, and use similar sampling frames, definition of key variables, and drug use measures. All opt for a combination of quantitative and qualitative data techniques. A number of core quantitative techniques and qualitative techniques can be found in all three proposals, notably the two week recall of health and injection use, the use of tracer conditions as "hypothetical illness cases", the observation of injection practices, focus group discussions and interviews with key informants.

In the revised proposals the Indonesian team pays more attention to the qualitative aspects of the study than in their initial outline. The Ugandan team has adopted a sampling frame which is more in line with the sampling frame of the Indonesian and Senegalese studies, and all three protocols are now more specific about the objectives, the variables that are studied, and the drug use measures that will be used in the analysis.

The country proposals differ to a certain extent in the manner in which the researchers intend to describe and evaluate injection practices of providers. In Indonesia the team intends to interview patients leaving the health facilities. In Uganda the team intends to ask providers to record the indications that they are confronted with and the type of treatment that they advised, and in Senegal the researchers intend to use existing records to get an impression of the percentage of patients that receive injections at certain health facilities.

The country protocols are still weak with respect to plans for utilization and dissemination of the results, perhaps reflecting the exploratory nature of the study or possibly resulting from the limited time that was left for discussion on these issues. This should be discussed in future meetings on the research project.

Apart from resulting in improved research protocols, the workshop also produced some preliminary insights into how injections are used in the countries involved and what we know about injection use at this stage. In Senegal little is known about injection use, but in both Indonesia and Uganda injections appear to be misused on a wide scale. In Uganda an unusual situation exists as a result of the AIDS epidemic, in which ironically fear of the disease seems to have led to an increased use of injections in self-medication, with people keeping their own family syringe at home in order to prevent contamination by "others".

6. FOLLOW-UP PLANS

The research will be coordinated by Mrs P. Brudon-Jakobowicz of the Action Programme on Essential Drugs, in consultation with Dr J. Clements of the Expanded Programme of Immunization, and Dr R. Biritwum of the Global Programme on AIDS. The Action Programme will serve as secretariat of the project, disseminating results and useful materials to the country teams and consultants. Mr J. Hetzke will give ad hoc advice concerning computer use for storage and analysis of the results. Dr A. Hardon of the Medical Anthropology Taskforce of the University of Amsterdam will continue to give technical support to the research teams in cooperation with the consultants Dr M.L. Tan and Dr. S Whyte. Dr A. Hardon will also support the synthesis of the results and, based on the experiences in the countries, develop simple and rapid methods for future study of injection use (the fourth overall objective of the research project).

On request a number of country visits will be made to provide further support to the country research projects. Dr M.L. Tan has been requested to support the Indonesian team in training a researcher for the qualitative aspects of the study, and Dr S. Whyte will aid the Ugandan team in the qualitative component of the study. In a later phase support may be needed in the analysis, validation and interpretation of the results.

After completion of the research projects the results will be distributed in both popular and scientific publications. The results will also be presented in country workshops for policy makers and health workers, for which separate funding should be secured by the country teams. In these country workshops plans for interventions, and their evaluation can be made.

APPENDIX 1

WORKSHOP ON INJECTION PRACTICES
World Health Organization
Geneva, 2-5 May 1990

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APPENDIX 2

WORKSHOP ON INJECTION PRACTICES

AGENDA

DAY 1, Thursday 3 May 1990, Chairperson: Dr C.J. Clements

Session I: Introduction

09:00-09:30	Opening of Workshop, by Dr F.S. Antezana
09:30-09:50	Introduction to WHO research by Mrs P. Brudon-Jakobowicz
09:50-10:00	Introduction to provisional research protocol and agenda workshop, by Dr A. Hardon
10:00-10:15	Break

Session II: Presentation provisional country proposals and short discussion

10:30-11:00	Indonesia country research, by Dr R. Salan
11:00-11:30	Uganda country research, by Dr H. Birungi
11:30-12:00	Senegal country research, by Dr L. D'Almeida

Session III: Medical-anthropological and epidemiological research perspectives and techniques

Discussion of medical-anthropological and epidemiological research perspectives and techniques. The resource persons will discuss the approach of other drug use studies, and relate these to the present study on injection practices. They will give suggestions for strengthening the protocols, and standardizing them.

12:00-12:30	Medical-anthropological research: perspectives and techniques, by Dr M. Tan.
14:00-15:15	Discussion on socio-cultural aspects of injection use in the countries involved, and on the qualitative research questions and techniques that are proposed in the country research projects.
15:15-15:30	Break
15:30-16:30	Epidemiological drug use research: perspectives and techniques, with specific attention to sampling methods, memory recall periods, use of "tracer conditions", questionnaire content and design, and validation of research results, by Dr R. Biritwum.

16:30-17:30	Introduction on ethical aspects, by Dr J. Dunne, followed by discussion.
Evening	Discussion on the quantitative research questions and techniques that are proposed in the country research projects. Choice of sampling frames, research techniques and drug use measures.

DAY 2, Friday 4 May 1990

Session IV: Data-processing and analysis

09:00-09:45	Evaluating the appropriateness of injection use, group discussion in which norms for appropriate injection use are set for the various tracer conditions, and conditions for hygienic use are defined.
09:45-10:30	Introduction to data storage, processing and analysis in the country projects using simple computer data-bases, by Mr J. Hetzke.
10:30-10:45	Break
10:45-12:30	Workshop in which country researchers from Uganda, Senegal and Indonesia select common research techniques and measures. Each country research team adjusts their research protocol. The revised protocols include a detailed description of research methods, sample-questionnaires, and workplans. Computers and secretarial assistance will be available to support the country teams, and they will have access to resource materials. Subgroup of resource persons develops database design for data storage, processing and analysis.
14:00-15:00	Continuation

Session V: Presentation of data collecting instruments

15:00-15:30	Presentation Indonesia, by Dr R. Salan.
15:30-16:00	Presentation Uganda, by Dr H. Birungi.
16:00-16:30	Presentation Senegal, by Dr L. D'Almeida.
16:30-17:30	Discussion on follow-up of the collaborative research project. Definition of roles and responsibilities of WHO, the country research teams, and the University of Amsterdam, and agreements on workplans.

DAY 3, Saturday 5 May 1990 (MORNING only)

Submission of proposals.

Closing and summing-up of WHO Workshop on Injection Practices.

APPENDIX 3

GUIDELINES FOR EVALUATING HYGIENIC ASPECTS OF INJECTIONS
(To be adapted according to national standards)

1. What injection equipment is used?

   a. Disposable syringe and needle

      1. If disposable equipment is used is it still in its original sterile pack?
      2. If not in original pack has it been used before?
         Has it been re-sterilized?
         Is it sterile now?

   b. Sterilizable syringe and needle

      1. Is sterilized equipment still kept in a sterile or aseptic condition?

2. Sterilization or high level disinfection

Are correct techniques used to successfully sterilize or disinfect the equipment?

Are syringes and needles flushed with water after use and before sterilization?

   a. Steam sterilization

      1. Is air purged from the sterilizer before timing starts?
      2. Is the temperature correct (121°C for 15 minutes)?
      3. Is the time long enough?
      4. Is the equipment packed to allow for steam penetration?

   b. Hot air

      1. Is the temperature sufficient?
      2. Is the time sufficient?

   c. Boiling

      1. Is there at least 20 minutes from the time the last piece of contaminated equipment is placed in the boiling water?

   d. Chemical

      1. Is the chemical suitable for sterilization?
      2. Has the solution been prepared correctly?
      3. Is the equipment prepared to allow for contact with all surfaces?
      4. Has the equipment been soaked for long enough?

3. Injection techniques

a. If the equipment is sterile before the injection starts is the injection carried out hygienically?

1. Does anything not in an aseptic condition come into contact with the fluid path?
2. Is the needle guided into the septum of a vial, or into the patient by the finger?
3. Is the uncapped needle in contact with a non aseptic surface.

4. After injection protection of equipment

a. Are disposable syringes and needles placed into a final disposal container?
b. Are disposable needles recapped before disposal?
c. Are syringes and needles disposed of?
d. Are sterilizable syringes and needles flushed with water after use and then separated?

5. Type of injection (optional)

a. What type of injection is given?

Intradermal
Subcutaneous
Intramuscular
Intravenous

b. Is blood sucked back into the syringe?

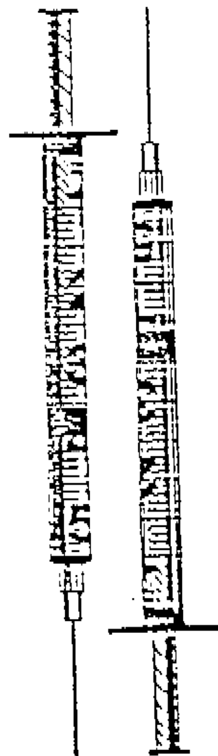
6. Multidosing

Are several patients injected from the same syringe (even if needle is changed)?

APPENDIX 4

PROVISIONAL RESEARCH PROTOCOL

The use of injections in Indonesia, Senegal and Uganda



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Provisional Research Protocol

The use of injections in Indonesia, Senegal and Uganda

1. INTRODUCTION

This is a provisional protocol for the study of injection practices in developing countries. It analyzes the problem, identifies major actors towards whom the research should be oriented, formulates research objectives and questions, and suggests methods.

The need to study the use of injections in developing countries arises from concern over the alleged widespread inessential and unhygienic use of these pharmaceutical preparations. In this research project the aim is to gain understanding of the reasons for the overuse and abuse of injections, and to assess the extent to which this takes place.

Although the study is done in three countries simultaneously, the aim is not to follow an identical protocol. It is important that in each country the research team identifies country specific problems and actors, poses research questions, and selects appropriate methods. It is hoped that this provisional protocol is useful in this process. During a workshop in the initial phase of the research, the various country specific proposals will be discussed and standardized as far as possible, to allow for comparison of the research results.

2. THE PROBLEM

Numerous studies point out that injections are preferred over oral medications by patients and healers[1] for a variety of health problems, even when their administration is not medically justified. One study[2] relates the popularity of injections to the spectacular cures achieved with injections such as quinine to treat malaria, and penicillin to treat yaws. Apart from their reputed efficacy, economic factors may also determine their widespread use. It is evident that healers can

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1 See for example:
Nichter, M. 1980 The layperson's perception of medicine as perspective into the utilization of multiple therapy systems in the Indian context. Social Science and Medicine 14B: 225-33.
Michell, J.M. 1985 Why do people like medicines? A perspective from Africa. The Lancet January 26:210-11; and Wyatt, H.V. 1984 The popularity of injections in the Third World: origins and consequences for poliomyelitis. Social Science and Medicine 19(9):911-15.

2 See Wyatt 1984 op. cit.

ask for a higher fee when they have administered an injection, than when they have given the patient a prescription for tablets.

In developing countries where the practice of medicine is uncontrolled, a variety of unofficial practitioners administer injections. Drug peddlers, pharmacists, nurses and traditional healers reportedly provide them. Even in government health services injections may be misused, due to the high demand by patients. In a study in Indonesia[3] it was found that in the government health centers nearly 50% of the infants and children and 75% of the patients five-and-over visiting the centers received one or more injections. The highest use of injections was for skin disorders, musculoskeletal problems, and nutritional and vitamin deficiencies. These are conditions which are generally not medical emergencies or urgencies which require intravenous or intramuscular therapy. The inessential use of injections is an unnecessary burden to household and health center budgets that are generally already limited, and in Africa are diminishing due to the economic crises.

Apart from the use of injections as therapeutic substances, it is important to assess the use of injectable contraceptives and vaccines. The aim of the Expanded Programme on Immunization to reach universal coverage requires health personnel to administer injections in health care settings, with often sub-optimal hygienic conditions. It is important that these channels of injections receive sufficient attention.

The unhygienic use of injections raises concern about possible transmission of a range of potentially serious pathogens, including hepatitis B, HIV and streptococcus. HIV transmission is a major threat to health and the health services in many countries. With respect to this specific pathogen it is important to note that the HIV virus will remain active in contaminated needles and syringes for days in both wet and dried states. Evidence from the US and Europe suggests that both superficial and deep wounds[4], as well as intravenous drug abuse occurring with contaminated needles can result in conversion from an HIV seronegative to an infected state.

In order to improve the use of injections we need to know who is administering them; how often they give injections and for what purposes; why they are used; if they are used when there is no medical justification for their use; and what the hygienic measures are. Only then can an intervention strategy be developed that focuses on the main areas of misuse.

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3 See Management Sciences for Health 1988. Where does the Tetracycline go? Health center prescribing and child survival in East Java and West Kalimantan, Indonesia. Child Survival Pharmaceuticals in Indonesia, Part II. Report of the Ministry of Health, and Management Sciences for Health.

4 See for example: Okesenhedler, E. et. al. 1986. HIV infection with seroconversion after superficial needlestick injury to the finger. New England Journal of Medicine 315: 582;
Worsmer, G.P. et. al. 1988 Frequency of nosocomial transmission of HIV infection among health care workers. New. England Journal of Medicine. 319(5):307.

A problem in this endeavour is that although many studies have identified and described the misuse of injections, most are anecdotal without a systematic description and quantitative assessment of the problem. Few studies have been analytical in nature - attempting to understand why it happens and none seem to have been designed to develop appropriate interventions.

3. STUDY APPROACH

This study is to be undertaken in countries where the misuse of injections has been identified as a problem, or where HIV infection is increasingly rapidly. It aims at providing the baseline data that are needed for the design of intervention studies.

It is important to note that in this first phase of the research project little is known about the use of injections. Therefore the study will need to cover a variety of health care settings, and start with an exploration of the channels by which injections are distributed and administered. It seems best to start by asking the recipients of injections where, and for what reason they received injections in the past two weeks. This will lead us to the providers of injections, and help us answer questions on the medical need and the hygienic standards employed. Both users and providers can be asked about the reasons for using injections.

4. OBJECTIVES AND RESEARCH QUESTIONS

4.1 Main objectives are to:

1.a Estimate the extent to which injections are used as a route for the administration of medications.

1.b Determine the type and degree of improper and unsafe practices in the process of administration of injections.

1.c Gain insight into why injections are so popular.

1.d Develop a simple and rapid survey methodology for future assessments of the extent of injection misuse.

4.2 Specific research questions are:

Concerning the types of health care providers administering injections:

2.a Which health care institutions and which practitioners are administering injections in a certain region?

2.b Which institutions and practitioners - both formal and informal - are most often visited by people for injections?

Concerning the distribution channels of injections:

2.c Where do the institutions and practitioners obtain the injections that they administer to patients? Do they obtain the injections from a government source, or from the commercial private sector?

Concerning the indications for which injections are generally used:

2.d What are the main indications for which the health institutions and practitioners administer injections?

2.e What are the disorders for which people seek injection treatment?

2.f Why are injections chosen for these indications?

Concerning the appropriateness of injection use:

2.g To what extent do people use injections to treat:

- A cough and cold case in a patient of any age.

- A diarrhoea case in a child who is less than 5 years old. The child suffers less than 5 watery stools per day and does not suffer from other conditions such as blood in the stool, high fever, etc.

- Two additional country specific conditions identified under 2d-e, that do not warrant injection treatment.

2.h Why are injections administered in the above four tracer conditions, while their use is not medically justified?

2.i Which types of injections are used in the treatment of the four tracer conditions mentioned in 2g.

2.j What did the injections cost in the above cases? What would an alternative non-injectable therapy have cost?

2.k To what extent are the injections that are administered for the four tracer conditions given intravenously?

2.l To what extent are injections administered in sub-standard hygienic conditions?

Concerning the reputed efficacy of injection use:

2.m What is the expected effect/or experienced effect of the injectable medication?

If appropriate:

2.n Why did the practitioner choose an injection instead of an oral medication?

2.o Why did the patient want an injection instead of an oral medication?

2.p Why are injections administered in an unhygienic manner? Do people lack training? Do they lack resources? etc.

5. EVALUATION OF THE APPROPRIATENESS OF THE INJECTION THERAPY

Questions 2g to 2l in the above deal with the question whether the injections are administered appropriately. Two main criteria are used to determine this:

a. If the use of the injections is medically justified.
b. If the injection is administered in proper hygienic conditions.

In order to limit the focus of the study a number of so called "tracer conditions" are identified. These are conditions in which injections are often used (as determined in response to research questions 2d and 2e), but are generally not medically justified. In order to ensure some comparability of data from the various countries, it is suggested to include two identical conditions as tracer conditions. The other two tracer conditions can be defined in the country concerned.

Likewise a number of practices that are considered hygienic can be defined. Through questioning the researcher can determine if these practices are followed. If this is not the case then the administration of the injections is considered "unhygienic". It is important to note that an injection can be "unhygienic" because of:

- contamination risks during the administration procedure itself,
- contamination risks during the sterilization procedures entailed before the injection is administered.

6. SAMPLING

The sampling frame is designed to cover a variety of health care settings in each country, in order to assess to what extent in different settings injections are used. It is purposive in nature.

It seems appropriate to cover (1) urban areas, where a great variety of health care institutions exist, (2) "semi"-rural areas, where people still have relatively good access to formal health care and (3) remote rural areas, where access to formal health care is very limited.

In each country two districts or provinces can be chosen, and in each of these districts two communities can be selected in each of the above health care settings. In practice this means selecting two communities in the town center, selecting two communities near a main road going to town with a health center nearby and a hospital relatively accessible, and selecting two communities where people have to walk and travel far to get to a health center and hospital. It is expected that in the remote area informal health care providers play a more dominant role.

6.1 The injection users

Within the communities it seems appropriate to focus on the families with pre-school children. These families are likely to frequent immunization facilities as well as family planning clinics. In future research other population groups such as the elderly and adolescents can be covered. Within the households the person most responsible for health care of the households members (usually the "mother") should be interviewed.

In each community a random sample of 60 families with pre-school children should be selected from the total population of families with pre-school children. The method of sampling depends on the extent to which information on the community population exists. This will be further developed at the country level. It is best if an accurate and up to date census of the community exists. This will however rarely be the case. If it does not exist, then the researchers will either have to make a list of families with pre-school children themselves, or they will have to estimate the number of families, and visit every nth family with pre-school children that they encounter, when walking in a certain direction through the community. The direction that they choose can be determined by spinning a bottle around, in a central space/square of the community.

The sampling frame is summarized in the figure below:

Step 1: Per country two districts or provinces are selected

Step 2: Per district or province three health care settings are selected: one urban area, one semi rural, and one remote rural area.

Step 3: In each health care setting at least two communities are selected.

Step 4: In each community 60 families with pre-school children are selected at random from the whole population with pre-school children.

Step 5: In the households the person responsible for health care of the children is selected as key respondent.

If this procedure is followed then a total of 720 respondents will be interviewed.

6.2 The injection providers

The health care providers that should be interviewed are selected from the list of providers that are mentioned by the respondents in the communities as sources of injections. Ideally all categories of providers in each health care setting (i.e. covering two communities) should be covered. This most probably includes the following:

a. Health workers in government health facilities, including immunization teams and family planning clinics.

b. Private (profit-oriented) practitioners.

c. Private practitioners in non-profit health facilities, such as mission health centers and hospitals.

d. "Non-Formal" practitioners, such as drug peddlers, nurses providing injections in their communities, traditional healers, etc.

e. Commercial drug channels, such as pharmacies, small shops and market places.

At each of these outlets a representative number of patients is interviewed. It is important to visit each provider at two different times (for example one weekday and one weekend, or one morning and one afternoon) to minimize bias. The calculation of the sample size should ideally be based on the rate of injection use that is expected. A statistician should be consulted to calculate this for the different outlets. However time constraints with respect to data collection and analysis are likely to limit the sample size that is feasible. If five different outlets are surveyed, then around 30 patients per outlet

can be considered a feasible number, leading to a total of 150 patients per health care setting, 450 per district, and a total of 900 for the entire country.

7. SUGGESTED METHODS

The study will focus on users and providers of injections. These two categories will be treated separately in this section. In addition to this, the researchers are encouraged to collect secondary data.[5]

7.1 User-oriented methods

The approach that is presented is this protocol is based on the premise that if one wants to describe drug use patterns it is best to start with the end-users of these drugs. Only by interviewing these people can one find out what the various channels of drug administration are.

The data that we intend to collect from users in this phase of the research are very limited. We want to find out where people go for injections (research question 2a); how often people go to these institutions for injections (2b); for which disorders people seek injections (2e); why they seek injections for these disorders (2f); what effect they expect/experience when having received an injection (2m); why they prefer an injection over an oral medication for specific conditions (2o).

The following methods can be used at the community-level. The interview guides and forms will need to be developed at country level.

a. Interviews with key informants

Select a few key informants in the communities (for example leaders of a number of community organizations) and explain what the aims of the research are. Check if the above mentioned research questions and interview forms that have been developed at country level are understood and develop, together with the key informants, appropriate interview forms. Ask some general questions about living conditions in the community and health care structure. These initial interviews can give the researchers some understanding of the local health care situation, and help them to adapt the interview forms to the local conditions.

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5 More suggested methods can be found in:
Van der Geest, S and A.P. Hardon. Drug-use: Methodological suggestions for field research in developing countries. Health policy and planning 3(2):152-158.

b. Structured interviews

This is best done by asking the families if they have been ill in the past two weeks, and then probing if they had any of the four tracer conditions (see under 5). If one of the tracer conditions occurred the researcher should record whether the patient received an injection, and if not what the "alternative" therapy was. The recall period should not be longer than two weeks because people are likely to forget what they did and why. The researchers should visit the families again after two weeks to ask the same questions. Then they can refer to the time-span between the two visits, and the answers are most probably more accurate. In addition the researcher should ask when the last time was that the patient received an injection, and what it was for. In the interviews it is important to draw people's attention to the various forms of injections: therapeutic injections, contraceptives and vaccines.

Apart from using a two-week recall, the researcher can ask hypothetical questions on the therapy that people seek for the four tracer conditions mentioned above. This is best done by confronting the respondent with a hypothetical illness case, for example a non-severe respiratory disorders and asking her what she would do if her child suffered this disorder. This can complement the data that were collected in the two week recalls.

c. Focus group discussions

In addition to the structured interviews it seems appropriate to talk more in-depth with the people in the communities. Ask one or two people with whom a fairly good rapport was established during the initial interview if they are willing to talk further about the subject. If yes, ask them to invite a few neighbours (not more than six) for a discussion on the use of injections. Discuss with this group the research questions that you want to have answered, but focus more on the reasons for using injections in some disorders, and their reputed efficacy. The discussion leader will need to speak the local language well, and should probe more on certain issues. Stimulate the respondents to explain what they do and why in detail. Tape the session and make extended notes. These data can provide insights that the more quantitative data cannot.

7.2 Provider-oriented methods

With respect to the injection-providers, we want to find out: where they obtain their injections (2c); what the main indications are for which they administer injections (2d); how often injections are given for the four tracer conditions compared to alternative therapies; why injections are chosen (2h and 2n); and how appropriate the use of injections is (2.g-l).

In order to obtain reliable data it is best to combine interviews and research of records.

a. Interviewing providers

In interviews the interviewer can describe hypothetical disorders and ask what the provider would prescribe. Of course this does not apply for the use of injections as contraceptives and vaccines. The interviewer can also ask what the main indications are for which the provider gives injections, which injection he or she gives, and why? The interviewer should also use checklists to discuss the hygienic procedure with the practitioner and the reasons for not following agreed procedures.

b. Interviewing patients at injection outlets

Patients leaving the various outlets can be asked whether they have one of the above tracer conditions, and what therapy was given, and whether they were given an injection. Questions about the type of injections, the cost and the expected effect can be added. Some minimal demographic information also needs to be collected.

c. Records

Hospitals, health centers, private clinics and doctors are likely to keep records. The researchers can ask if they can use the records to study prescription practices.

7.3 Secondary sources

Apart from the user-oriented and provider-oriented methods the researchers can consider using some additional sales data and other data on drug use and distribution that are available at the national level. These data can allow the research to assess which injections are commonly used, and it what quantities they are sold or distributed.

a. Existing studies

Few studies focus on the use of injections, but more general studies on therapy choice and drug use may present specific findings on the use of injections. At the national level it is important to do a review of existing studies. A problem is that often such studies are not published. The Ministry of Health, and institutions such as UNICEF, may be involved in monitoring of health care that covers relevant data. Such data should be identified by the researcher and used.

b. Sales data

Also useful are industry sales data. These data can be obtained from International Monitoring Services (IMS) at great cost. In some countries there are also private companies that monitor sales of pharmaceuticals for local industries. Here one can ask for the sales of certain products that are commonly used according to the results of the field research.

c. Procurement statistics

Agencies that are involved in the procurement of drugs for government or private health services most likely keep records of the amounts of drugs that they procure, and the turn-over of these drugs at the drug outlets. If a kit system is used, then the composition of the kits can be checked.

8. MEASURES

To describe the extent to which injections are used as a route of administration it is best if certain standardized measures are used in the various countries, and within the countries in the various health care settings.

Measures that seem appropriate for this study are:

Concerning prevalence of injection use:

1. The percentage of households (HHs) in which one or more injections were given in the past two weeks.

2. The percentage of HHs that received a specific type of injection in the past two weeks.
   Specific type:
   - therapeutic injections
   - infusions (large volumes)
   - contraceptives
   - immunizations

3. The percentage of people in a certain age category of the study population who have received at least one injection in the past two weeks.

4. The percentage of females and the percentage of males in the study population who received at least one injection in the past two weeks.

5. The frequency of injection administration per health facility. Health facilities can be categorized into:
   - government facilities
   - private facilities
   - non formal facilities
   - homes

6. The percentage of patients at a certain health facility who received at least one injection/or percentage of prescriptions at a certain health facility that contain at least one injection.

Concerning appropriateness of injection use:

7. Percentage of injection use in certain tracer conditions.

8. Percentage of injection use in "hypothetical" tracer conditions.

9. Percentage of prescriptions that contain one injection for the specified tracer conditions.

10. Percentage of providers who do not observe minimal hygienic standards before administering an injection.

11. Percentage of providers who do not observe minimal hygienic standards during administration of an injection.

12. Percentage of providers who do not observe minimal hygienic standards after administration of an injection.

9. TIME PLANNING AND RESOURCES

Time planning

The time-schedule is as follows:

A. Preparatory phase in three countries, including interviews with researchers and policy makers of the Ministry of Health, adaptation of research protocol to local situation. Pilot study in one community (4 months).

B. Workshop, with participants from the three participating countries, at which the country research protocols are presented, and in consultation with each other and a number of resource persons (epidemiologist, medical anthropologist, and statistician/computer expert) are finalized, and plans are made for data processing and analysis (including the design of an appropriate database).

C. Six months of field work: two months preparatory work, three months field work in two districts simultaneously and one month data processing.

D. Preliminary analysis and writing of interim report (2 months).

E. Country level workshop in which results are presented and intervention strategies developed. Finalization of country reports, including recommendations (3 months).

F. Writing final report which includes country reports, and country synthesis; review of research methodology and process, and development of simple, rapid survey methodology (2 months).

Staffing and resources

In each country there will have to be at least one project coordinator and two assistants to do the fieldwork, one in each district. They will need ad hoc support of a statistician, and computer analyst in the data-processing. The fieldwork will not cost much, as only paper, pens and transportation is needed. However for the analysis it is desirable for the research team to have access to a personal computer, and a data typist who can enter the data that are collected in the two districts. This ongoing data-processing will ensure quick analysis of the data.

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