Operational Research related to Rational Use of Drugs

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Report of a conference hosted by the International Children's Centre


We thank the members of the Scientific Secretariat:

Professor P.K.M. Lunde
Professor G. Tognoni
Professor G. Tomson

for their contribution to the meeting and to the preparation of the report.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PHC</td>
<td>Primary Health Care</td>
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<tr>
<td>EDP</td>
<td>Essential Drugs Programme</td>
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<td>DAP</td>
<td>Drug Action Programme</td>
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<td>APED</td>
<td>Action Programme on Essential Drugs</td>
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<td>INRUD</td>
<td>International Network for Rational Use of Drugs</td>
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<td>ICHM</td>
<td>International Course on PHC Managers in developing countries</td>
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<td>ICC</td>
<td>International Children's Centre</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>RUD</td>
<td>Rational Use of Drugs</td>
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<td>UNICEF</td>
<td>United Nations International Children's Fund</td>
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<tr>
<td>DUS</td>
<td>Drug Utilization Studies</td>
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<tr>
<td>ED</td>
<td>Essential Drugs = those drugs that satisfy the health care needs of the majority of the population</td>
</tr>
<tr>
<td>FGD</td>
<td>Focus Group Discussion</td>
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<tr>
<td>DURG-AFRO</td>
<td>Drug Utilization Research Group African Region</td>
</tr>
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<td>HAI</td>
<td>Health Action International</td>
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<td>OR</td>
<td>Operational Research</td>
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<td>HSR</td>
<td>Health Systems Research</td>
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<td>EDL</td>
<td>Essential Drugs List</td>
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<td>EDCP</td>
<td>Essential Drugs Concept &amp; Policy</td>
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<tr>
<td>DDD</td>
<td>Defined Daily Dose</td>
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<tr>
<td>IHCAR</td>
<td>Department of International Health Care Research</td>
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<td>IEC</td>
<td>Information, Education and Communication</td>
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<td>ISDB</td>
<td>International Society of Drug Bulletins</td>
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1. Background and Introduction

The performance of health services everywhere critically depends on the availability and use of pharmaceutical products. Not only are drugs needed to treat diseases but public confidence in health workers and satisfaction with health services depend upon the maintenance of a reliable and affordable supply of drugs. Unfortunately even when drugs are available, many of them are wasted because of unsafe and inappropriate drug prescription and use. The situation is even worse in the private sector where a broad range of drugs is generally available and where, in many developing countries, prescription drugs are frequently sold over the counter and dispensed by untrained retailers.

Since WHO launched the Revised Drug Strategy in 1986, the global community has gradually started to acknowledge the need for concerted and well coordinated actions to improve the availability and the use of drugs.

Rational Use of Drugs (RUD) is probably the most complex and difficult of all these issues; no country, even the most developed, has totally succeeded in improving the prescribing patterns of medical personnel or the use of drugs by the public. In such a complex issue, integrated action is necessary and research has an important role to play.

The major aim of the conference organized by the WHO Action Programme on Essential Drugs and UNICEF in Paris was to bring interested parties together to share experiences, to discuss priorities and ways to better coordinate strategies in operational research related to RUD. Although RUD is a global issue, the focus of the meeting was on developing countries.

The idea of such a conference was welcomed by the Management Advisory Committee (MAC) to the WHO Action Programme on Essential Drugs (APED), during its meeting in February 1991 in Geneva.

During recent years, several international organizations, universities, research groups and networks have been actively involved in research activities, attempts have been made to study ongoing drug utilization practices. Unfortunately, this literature is not easily available and some results are never published. This material includes success stories as well as failures, both being important for the development of Drug Utilization Studies (DUS) in developing countries. Relevant material should be compiled, critically scrutinized, and analysed before too many new activities are initiated.

One of the ideas of this meeting was to initiate such a process through which representatives from various countries and organizations could present results of relevance. It was foreseen that individuals with first-hand national and local experiences as well as internationally experienced persons should gather to discuss the next step in the attempt to increase the rational use of existing drugs globally.
Fully aware of the constraints and the short notice for all participants it was still considered important to hold this meeting to begin a collective reflection on RUD within and outside Essential Drugs Programmes (EDPs). Thus, the meeting was seen as a first attempt to gather representatives from various involved bodies, including research groups in developing countries, to explore the field, to delineate responsibilities, and to plan the necessary actions to be taken in short, medium, and long-term perspectives. It was also felt that the qualitative aspects of drug use needed to be highlighted at a time when the financial aspect of drug use tended to dominate the international discussion. The participants represented many governmental and nongovernmental organizations, universities from the North and the South (biomedical and social sciences) and donor agencies (Annex 1).

The meeting was opened by Dr J. Brouste of the International Children's Centre (ICC), the host organization. UNICEF and WHO were the other two organizers. Dr S. Otosu-Amaah (Senior Adviser, Bamako Initiative Management Unit, UNICEF) welcomed all on behalf of UNICEF. Mrs P. Brudon-Jakobowicz (Scientist at DAP/WHO) welcomed all on behalf of Dr F.S. Antezana, Programme Manager, Action Programme on Essential Drugs.

2. **Working procedure**

In order to make the best use of the meeting, plenary sessions were used for sharing past experience through presentations by representatives of countries and organizations/institutions (Section 3 and Annex 4).

Methods for problem identification, intervention studies, and research priorities were then subject to group work (Section 4, Annex 5) followed by plenary discussions resulting in recommendations for future actions (Section 5).

3. **Operational research in RUD: summary of presentations**

Although it is difficult to summarize a large number of very different presentations (see Annex 4), some salient points can be extracted.

- The field of research related to rational use of drugs is much broader than prescribing practices and patients’ attitudes. It extends to policy issues such as selection, legislation and procurement. Indeed little can be done at the prescriber's and consumer's levels if countries have not defined a pharmaceutical policy, developed a list of essential drugs and improve their availability. Furthermore many studies have documented widespread 'irrational' use of drugs by prescribers and consumers. They point to the complexity of the drug situation at the local level, showing how people often depend on informal, i.e. illegal, sources of drugs such as small grocery shops, and how people use drugs in accordance with their own ideas of drugs safety and efficacy. The findings imply that strategies towards a more rational use of drugs, which focus on
improving drug prescribing in public health centres are likely to have a limited impact on drug use by consumers and that research should also tackle these issues.

- A number of participants stressed that there is an urgent need to define ways in which drug use research can contribute to the development and implementation of effective rational drug use interventions. The combination of formative, descriptive studies with educational interventions was favoured by many; simple, cost-effective research methods - such as focus group discussions and mini surveys of drug distribution channels - can be used to gain insight in drug use perceptions and practices, simple indicators can assist in identifying problems. Such insight can help in the development of educational materials for the health personnel and the general public.

Also of importance is the evaluation of the relative impact of different strategies which have been used in developed and developing countries to improve drug use behaviour such as standard treatment protocols, drug kits, regulation interventions, social marketing and pharmaceuticals, etc.

- For research to contribute to the promotion of rational drug use, the participants identified some key principles:
  
  * the topics must be targeted precisely and be relevant to the needs of the countries;
  
  * the objectives should be clearly defined;
  
  * the research should be operational and problem solving oriented;
  
  * the quality should be high so that results are meaningful and convincing to policy makers; results should also be produced in a reasonably short period of time;
  
  * results should be widely disseminated and put into use at national and international level.

Participatory and multidisciplinary approaches were favoured by a majority of participants. More emphasis in the future should be given also to national capacity building.

- Among constraints related to operational research, the participants identified: lack of a national research policy, at both national and institutional levels; lack of a "critical mass" (trained human resources); lack of access to vital sources of information; inadequate skills for expanding research designs and analysis beyond census-type surveys; poor linkages between governmental and non-governmental organizations and between academics and policy makers; lack of dissemination of research findings; lack of integration between research and training programmes oriented toward rational drug use. Efforts to implement
operational research on the rational use of drugs must address these interrelated issues if the sustainability of research is to be ensured.

4. Priorities set up in group work

The two groups reviewed the main problems faced in developing operational research in RUD and proposed a list of priorities which can be described under three main topics:

(a) How to make research more meaningful and sustainable?

Proposals were:

* empowering developing countries to enable them to set their own research priorities;
* motivating change for more positive attitudes on research within countries;
* stimulating regional activities and south-south collaboration in research;
* emphasizing short and action oriented research in collaboration with community and consumer groups;
* establishing a global clearing house on drug utilization studies and methodologies.

(b) What kind of research tools are needed?

Proposals were:

* developing data base;
* refining and contextualizing existing indicators;
* developing rapid community assessment research tools;
* training people in using simple research tools for identifying problems.

An attempt was also made in one group to describe some different methods (Table 1).
### TABLE 1

Methods and their applicability in studying the different levels of drug use

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<thead>
<tr>
<th></th>
<th>Quantitative</th>
<th>Qualitative</th>
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<tr>
<td><strong>Prescribing</strong></td>
<td>Registration. EDL/standard treatment guidelines.</td>
<td>Participant observation</td>
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<td></td>
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<td>Focus group discussions.</td>
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<tr>
<td></td>
<td></td>
<td>Fictitious (surrogate) patients.</td>
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<tr>
<td></td>
<td></td>
<td>In-depth interviews.</td>
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<tr>
<td><strong>Dispensing</strong></td>
<td>Registration. Inventory. Financial/economy of retailing.</td>
<td>Participant observation</td>
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<td>Fictitious (surrogate) patients.</td>
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<td></td>
<td></td>
<td>Exit interviews.</td>
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<tr>
<td></td>
<td></td>
<td>In-depth interviews.</td>
</tr>
<tr>
<td><strong>Consumption</strong></td>
<td>Household surveys.</td>
<td>Participant observation.</td>
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<td></td>
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<td>Focus group discussions.</td>
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<td></td>
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<td>In-depth interviews.</td>
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(c) What research questions should be addressed in priority?

Proposals were to look at:

* effects of drug policies on prescribers;
* determinants of prescribing and use (‘why-research’);
* effects of drug intervention programmes on morbidity/health at community levels;
* effects of IEC on prescribing and use;
* identification of other components in addition to training necessary to change behaviour;
* influence of the Action Programme on Essential Drugs on drug utilization;
* conditions for cost-recovery programmes to be implemented;
* relationship between increased drug availability, access, use and health.
5. **Notes from the general discussion**

Some important points raised during the group work session were taken up in the general discussion. One major issue was research policy.

Research should be a systematic problem and action-oriented activity undertaken cooperatively between researchers, policy makers, and managers to find feasible, practical and affordable solutions. Moreover, it should be linked to the development of pharmaceutical policies and the results should be translated into clear policy recommendations.

The need to achieve long-term capacity building for sustainability in research was emphasized including the need for studies on the conditions for research. One problem identified here was the donor influence when setting priorities. Too often the donors were deciding on the terms while the developing countries were left in a passive role. More efforts should be made to facilitate the process of finding funds for project proposals as at present this was often a tedious process.

Strengthening of already existing networks and better co-ordination and harmonization of these were considered of major importance to operational research and rational use of drugs. In each country a critical mass of professionals is a much needed basis for such activities. Another element in this development should be to increase the South-South collaboration. It is important here to consider the risks of having a few individuals becoming involved in too many activities when various networks are not well co-ordinated. It was suggested to use the minutes of this meeting as a background paper for a potential 'network of networks' and to let this document be widely circulated.

The meeting discussed priorities and forms of research. More studies on the socio-economic and cultural determinants of prescribing was seen as one priority, more focus on the consumers as another. There was consensus on the point that rationality has to be contextualized and that there is no simple definition of rational use of drugs. Also, drug utilization studies needed to move from drug-oriented to health-oriented perspectives.

A stepwise approach was discussed, in which step I includes descriptive studies of a multidisciplinary nature, step II, training seminars in RUD and step III, the intervention with subsequent research-based evaluation. Innovative methods are needed as a basis for multidisciplinary studies on the health impact of drugs in the community and it is high time to start to develop such methods. Various methods should be tested and the protocols circulated. Some suggested a publication, including a compilation of the different methods, that could be used and that a follow-up workshop should discuss these in more detail. It was emphasized that previous experiences, successes as well as failures, must become more widely known through a more efficient information system.
The level of sophistication of research that should be used was debated and differences of opinion existed. Many emphasized the need for simple technologies, whereas others underlined the need to include the academia leading to appropriate teaching and training to contextualize research activities into the national health and drug policy systems. There was an agreement that to ensure sustainability every effort should be made to work at the country level. Local and national workshops were seen as important tools for promoting rational use of drugs in addition to improved basic teaching and training, improvement of the latter being necessary for long-term effects.

6. Recommendations

6.1 Research strengthening workshops

Every effort should be made to plan and launch national workshops and/or regional workshops depending on the prevailing conditions, including the human resources situation.

A number of already planned international workshops were listed:

- WHO /EURO/DURG, Verona, Italy, June 1991
- Social Cultural Aspects on Pharmaceuticals, Holland, Dept of Medical Anthropology, University of Amsterdam in collaboration with University of Copenhagen and IHCAR, October 1991.

6.2 Principles for research

A discussion on principles for research started during the meeting. The planned research support group of DAP should continue that discussion and could become a critical tool for defining principles for priorities. These principles should then be disseminated within various networks.

6.3 Methodologies

WHO is presently developing a manual on how to assess drug use at the community level in collaboration with the University of Amsterdam. This manual needs to be
complemented with something assessing prescribing. INRUD in cooperation with WHO is producing a manual on indicators for rational drug use.

The appropriate methodologies should be multidisciplinary in nature and the need for social and behavioural scientists should be acknowledged. Descriptive studies should be complemented by intervention studies. One unsolved problem is the level of sophistication and whereas a majority of the participants supported the use of simple, easy-to-apply methods, some were also in favour of more sophisticated university-based studies as a necessary element in research development.

6.4 Clearing house

WHO/APED has already played a role as a clearing house and is committed to continue.

WHO will begin regular publication of DAP-funded projects, but for other projects WHO could facilitate the process of expanding information activities.

Address lists already exist within WHO, INRUD, and HAI.

6.5 Dissemination of information

The following are some of the existing Newsletters and Bulletins:

- DURG-AFRO Newsletter: Centre for Tropical Clinical Pharmacology and Therapeutics, University of Ghana Medical School, PO Box 4236, Accra, Ghana.

- Essential Drugs Monitor: World Health Organization, CH-1211 Geneva 27, Switzerland.

- INRUD - Newsletter: 165 Allandale Rd., Boston MA 02130, USA.


- Country-specific Newsletters (e.g. Sri Lanka, Zambia, Zimbabwe). A complete list of individual Drug Bulletins can be obtained from ISDB.

'Grey' literature. There is a need to identify more journals which could publish the material and results produced. At present both Tropical Doctor and the Lancet are interested in the topic. The group should figure out ways in which, e.g. the type of studies conducted through WHO/APED could be published. The question was raised as to why UNICEF and WHO did not publish results of studies in their own journals and if not available, it was suggested that new journals should be started.
6.6 Structure for operational research in the future

The need for better coordination was felt by all participants. The meeting agreed that WHO offers a suitable structure for operational research and, albeit it is not very strong at the regional level, it is being strengthened at headquarters.

No new structure was suggested although during informal discussions some participants advocated intensified activities including local, national and regional bodies coordinated by a small university-based group with representatives from the North and the South. Regional and national training seminars and workshops were considered to be crucial for improving and developing operational research in RUD. Training centres in developing countries should be identified using local resources.

In conclusion, this conference in Paris clearly identified the need for strengthening of already existing networks and for better coordination and harmonization among the various actors; the Action Programme on Essential Drugs was encouraged to take the lead in developing, promoting and coordinating future activities.
# Annex 1

## List of participants

<table>
<thead>
<tr>
<th>NAMES</th>
<th>TITLES AND ORGANIZATIONS</th>
<th>ADDRESSES (telephone, fax)</th>
</tr>
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<tbody>
<tr>
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</tr>
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<td>Editor La revue PRESCRIRE</td>
<td>83, bd Voltaire B.P. 459 F-75527 Paris Cedex 11 Tel: 33.1.47.00.94.45 Fax: 33.1.48.07.87.32</td>
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<td>NAMES</td>
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<td>Château de Longchamp</td>
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Annex 2

Agenda

Day I (25 March 1991)

09.15-09.45  Welcome addresses
             CIE/ICC
             UNICEF
             WHO

09.45-10.00  Why this now (Scientific Secretariat)

10.00-11.00  Presentation of country experiences
             * Bangladesh
             * Benin
             * Ghana
             * Nepal
             * Panama
             * The Philippines
             * Zambia/Sri Lanka
             Brief Discussion

11.00-11.15  Coffee

11.15-13.15  Presentation of on-going work of participating organizations
             * CIE/ICC
             * DURG/AFRO
             * NAI/OCU
             * IHCAR
             * INRUD
             * UNICEF
             * WHO/APED
             * others
             Brief discussion

13.15-14.30  Lunch

(14.30-17.30) Problem identification and research
             Introduction

14.30-14.45  Group work
             ** Methods for problem identification
             ** Tracers/indicators on drug related issues
             ** Criteria: cultural congruence, feasibility, sustainability

14.45-15.45

15.45-16.00  Coffee
16.00-17.30  Presentation of group work
Discussion

Day II (26 March 1991)

09.15-09.30  Summing-up - problem identification etc.

09.30-09.45  Priorities in operational/health services research
Introduction

09.45-11.00  Group work
** Problem areas and related methods
** Levels of interventions, e.g., policy makers, prescribers,
dispensers, patient/public

11.00-11.15  Coffee

11.15-13.15  Presentation of group work
Discussion/suggestions

13.15-14.30  Lunch

14.30-15.45  Framework for future actions
* Short-term  ** Medium-term
(Scientific secretariat/organizations/participants)
Discussion/suggestions

15.45-16.00  Coffee

16.00-17.30  Agreements/conclusion

The members of the Scientific Secretariat (G. Tognoni, G. Tomson, P.K.M. Lunde) will act
as moderators and will be responsible for preparing the minutes of the meeting.
Annex 3

Explanatory notes to the agenda

Why this now?

A full overview of the meeting will be introduced after the official opening "ceremony".

Current political and economic trends have led to a renewed interest in revitalizing health systems in their entirety. A specific demonstration of this are the Health Goals of the 1990s which the vast majority of the countries are actively working towards. The need to focus on drug use in different contexts will be emphasized as a vital component of health services development.

The Paris meeting should, besides stimulating rational use of drugs, be a forum for discussion and planning different activities, disseminate lessons-learned from different experiences, advocate not only in order to avoid whenever possible duplicates of intervention but also to harmonize the various initiatives, and should create a pool of human resources for strengthening capacity building at country level in order to achieve sustainability. Research specifically, as a tool for identifying problems and solutions, with focus on the community, will be discussed and to more effectively establish an outline research agenda, interaction among organizations involved in research in this area is crucial.

Presentation of country experiences

A few countries representing different regions have been invited to present some problems and practical experiences related to ongoing research on drug use issues. Countries from the Americas, Asia and Africa will use several minutes per country describing methods used and problems identified. The emphasis should be on this and not extensive data presentations.

It is proposed that the presentations will give an overview of specific and common problems which will form a basis for the discussions. A similar format for presentations is suggested, including type of research, disciplines involved, methods, problems encountered and dissemination of results.

Presentation of ongoing work of participating organizations

Several organizations and networks have been involved in health systems research on drug use related issues during the last few years. The focus has varied between provider-oriented contexts to consumer-oriented ones.

A review of the past research where different organizations have been involved will focus on problem identification, type of research, methods, dissemination of results, capacity building and sustainability. This will serve as a background for the discussions of future strategies including tentative harmonization between the different strategies.
Problem identification and research

In order to meet the aims of the meeting, a participatory and interactive approach is needed. Thus the participants should be divided into groups during parts of the afternoon session (day I) and the morning session (day II). An effort will be made to bring together participants representing different disciplines in each group.

In the introduction to the group work, the basic concepts related to rational use of drugs will be addressed, including individual demands, community focus, private/public mix, etc.

The discussion on methods should include indicators (existing and development of new) for problem identification leading to supposed solutions. The use of different disciplines will facilitate a broad approach to problem and solution identification ultimately advocating multi or interdisciplinary action.

The complexity of the determinants of drug use are global and there is an increasing awareness of the need for multidisciplinary approaches to identified problems. Global experience indicates that training can only be effective if it is supported by ongoing monitoring of behaviour. There is a need to discuss frameworks for research that will also address these behavioural factors as well as being feasible and sustainable.

Priorities in operational/health services research

The discussions from day I which focus on research for problem identification will be summarized and form the basis for a much needed discussion of priorities in the field of rational use of drugs.

The same groups from day I will be asked to propose priorities according to areas and different levels of interventions in the community. They will also discuss related methods.

Framework for the future

Based on problems identified and priorities made, allocations of responsibilities for the future could be made. This includes harmonization of ongoing activities within and between networks and organizations such as African DURG, CIE, HAI, INRUD, UNICEF, WHO, etc. Operative strategies which have been used up to now and innovative ones at local, national and international levels, will be discussed in detail during the afternoon session.

The discussion will include the identification of criteria which should be considered when developing effective strategies for rational use of drugs.
Annex 4

Summary of Presentations

1. ONGOING ACTIVITIES OF ATTENDING ORGANIZATIONS

1.1 UNICEF, presented by Dr S. Ofosu-Amaah

Dr S. Ofosu-Amaah emphasized that UNICEF regards joint operational research on the RUD as an important initiative which should grow rapidly to fulfil a need, especially in developing countries.

UNICEF has procured drugs and many other supplies from its inception. In 1990 UNICEF through UNIPAC procured USD 35 million worth of drugs and USD 55 million for vaccines. Obviously the organization is concerned with the Rational Use of Drugs, considering present waste and suboptimal use.

The Bamako Initiative Resolution was endorsed by African Health Ministers in September 1987. This initiative for accelerating the development of district-based PHC, for assuring community participation and community financing, reflecting the critical importance of essential drugs, is being implemented in several African countries. This again underlines the need for assuring the rational use of drugs, using operational research as a tool.

UNICEF, as the world's advocate for children, instigated the recent World summit of 71 heads of state or government in September 1990. This summit agreed to a set of social objectives for the 1990s which included health goals on mortality reduction in infants, children, and mothers. The organization believes that the attempt to achieve the goals becomes a major priority for the United Nations. Effective interventions, including the use of drugs, are important elements in this strategy.

UNICEF therefore believes, continued Dr Ofosu-Amaah, that the meeting can set in motion a process of useful operational research which could serve immeasurably the cause of improving the well-being of people.

Mrs P. Carlevaro (Essential Drug Unit Adviser) stressed that the UNICEF's major strength is found at local level where it supports countries in improving delivery of social services. However, UNICEF regards research as a useful operational tool needed for better planning, revising, and reorienting of programme scope and action. Operational Research is thus seen by UNICEF as one component of programme implementation developed by local partners in the field.

Nevertheless, the following concerns can be revised vis-à-vis Operational Research:
Sometimes different organizations and institutions are doing identical or similar Operational Research in the same country.

There is little sharing of information on Operational Research and, most critical, outcomes of Operational Research sometimes do not reach those who would most benefit from them.

In the countries, utilization of the same resource persons by different organizations is frequent, which exposes these researchers to great pressure and work overload. However, groups or individuals with great potential for performing good work but who are less well-known (or less 'advertised') are not used as researchers.

This is why UNICEF sees this gathering of people from different disciplines (pharmacology, anthropology, social sciences, pharmacy) as a great opportunity for open discussions, creating a clearer idea for outlining actions in a more efficient and participatory way. It is important nevertheless to take into consideration that the follow-up actions taken by each of our institutions and organizations be in line with its own policies, priorities, and mandate.

Furthermore, there should be a better understanding of the complete meaning of 'Rational Use of Drugs.' What this definition comprises and to which level it is encompassed is not universally clear. Although much focus is given by many to prescribing practices and patient/consumer attitudes and knowledge, UNICEF believes that some policy issues such as drug selection and procurement are closely linked to rational use of drugs at the end point.

Little can or will be done at the prescriber's level if countries have not defined a pharmaceutical policy nor a National Formulary for use. Yet, if pharmaceutical laws have been drafted by countries, there can be no progress without ways to enforce these laws. In addition, clarification and better understanding of the role of both public and private sector and their inter-relation (not only the pharmaceutical one but also the medical professions) is needed.

Finally, being more specific on UNICEF involvement and work in line with Operational Research on Rational Use of Drugs, our 'plus' is mainly at country level where outcomes of Operational Research can, in fact, be practically taken into account. More specifically in the health sector, approximately 200 UNICEF medical doctors, pharmacists and health planners are working in different geographic areas in close collaboration with local partners in different fields. Planning basic and inservices training for health staff for a more efficient drug management system, and improved delivery of health services are some of the activities supported.

Furthermore, UNICEF is undertaking with different institutions Operational Research in areas such as health financing and equity, social mobilization/communication, human resources development, district systems
analyses, and quality of care - all rooted at community level and dovetailed on present programmes.

To just mention two examples of ongoing activities in this area: One is a joint WHO/UNICEF aim to study quality of drugs within the country level at different levels of the health system. Approximately 10 essential drugs from different sources will be analysed to evaluate whether their physicochemical characteristics are maintained in different climatic and storage conditions. The second project aims to provide better information on use of drugs to the peripheral health staff; a quarterly published newsletter will be produced and distributed worldwide to prescribers in different health facilities.

Some suggested areas of research:

- impact of educational tools so far developed to see if they have been successful in rationalizing use of drugs,
- assessment/evaluation of different drug supply systems,
- development of several indicators to better assess morbidity patterns, availability of drugs, accessibility and affordability of health services.

1.2 The WHO Action Programme on Essential Drugs, presented by Mrs P. Brudon-Jakobowicz

Mrs P. Brudon-Jakobowicz reminded the participants that since the launching of the Programme, access to essential drugs has increased in many developing countries. Over 100 countries have developed essential drugs lists, more than 90 have an essential drugs programme and supply and distribution systems have been improved. However, the use of drugs remains a problem.

The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community. Rational use implies proper management of the drugs vis-à-vis the patient and balancing benefit against risk and cost. More research is needed to improve the way pharmaceuticals are prescribed, dispensed and used. The question is what kind of research do we actually need? The APED/WHO has recognized this and in the recent years considerably strengthened its research component. Presently 7% of the funds have been budgeted for operational research covering four areas: policy and management, supply and logistics, rational use of drugs and quality assurance. RUD has received 45-50% of the funds for operational research.

The new research strategy of the Programme focusses on trying to identify constraints to implementation of country plans and emphasizes research at the national level whereas earlier projects were of a more global nature.
The objectives are:

- to gather factual information on the ways drugs are prescribed, dispensed and used in the public and private sector for evaluation and monitoring purposes,

- to detect and assist in solving problems and constraints which prevent the rational use of drugs at national level,

- to test new or improved methods, interventions and approaches in view of improving prescription, dispensing and use of drugs,

- to develop simple research methods for investigating problems related to the use of drugs.

A key part of the new strategy is to use and strengthen the research capacities of national institutions whenever possible.

A description of operational research in the Action Programme on Essential Drugs is given in the document DAP/MAC (3) 91.5 and several of the projects are described in the Essential Drugs Monitor No 11-1991.

Mrs P. Brudon-Jakobowicz continued her presentation with information on what the Action Programme has learnt in supporting operational research in developing countries:

A. To develop research on rational use of drugs in developing countries is an enormous challenge. Why?

The irrational use of drugs is a very complex issue, in both developed and developing countries, since drug use is the joint responsibility of policy-makers and regulatory authorities, the pharmaceutical industry, health care professionals and patients and the general public as consumers. Although the procurement or production and distribution of drugs require resources, knowledge and skills, these are fairly mechanical processes that do not call for changes in behaviour. This is not so for the use of drugs and no country, even the most developed ones, has totally succeeded in improving the prescribing patterns of medical personnel or the use of drugs by the public.

Furthermore it is not an easy task to identify the specific major issues in rational use of drugs in developing countries. The importance of the issues differs according to the actors: community, health personnel, industry and vendors, policy makers, economists and public health experts all have different interests and perspectives.

To set research projects in developing countries is a difficult endeavour. It must be recognized that there are a series of constraints that interfere with or limit the capabilities to perform research. They include:
- Insufficient human resources with the scientific knowledge and technical skills to generate and execute research projects. This is largely due to inappropriate training and inadequate motivation in terms of recognition, job security and economic incentives.

- Lack of research capability to enable countries to undertake research: adequate infrastructure is missing, background information is inaccessible, etc.

- Insufficient research capacity in the fields relevant to operational research including epidemiology, social/policy sciences.

- Low awareness of the utility of research and weak research demand among policy makers and managers in face of budgetary constraints and competing priorities.

- Lack of coordination, variety of interventions which tends to operate at cross purposes. Too many projects for too few people.

B. But for the research to be successful and therefore really contribute to the promotion of rational drug use, some core concepts or principles should be respected.

(a) The topics must be targeted precisely

Not everything can and should be researched. How should problems be identified? It is not easy to obtain consensus on problems among all those concerned, from decision-makers and health providers to the target population. Secondly not all problems are researchable. If the problem is researchable it should be clearly defined, analysed and eventually divided in small units and translated into a form suitable for scientific inquiry. Too much time and research have been spent on the identification and description of problems without trying to remedy them. To be able to develop more prospective, future oriented studies and formulate research questions which are likely to yield useful answers, we need better methodologies, indicators and cost-effective data collection techniques to identify the problems quickly.

(b) The objectives of the research should be clearly defined from the beginning

This means that the following questions should be addressed: why, for whom, where, how should the research be carried out?

(c) The research should be operational:

This means: a systematic problem and action oriented activity undertaken cooperatively between scientists, policy makers and managers to find feasible, practical and affordable solutions. It means that operational research should be
carried out in collaboration with the system, not against it or in isolation. It means that operational research must focus on specific problems (problem-solving) and be aimed at developing solutions (future-oriented); consideration for the subsequent use of the research findings should be integrated in the research process. Research in the field of drugs should be country specific and linked with the development of pharmaceutical policies so that those who will use the research findings are actively involved with researchers in identifying the problems for research and in supporting the research process. Operational research must lead to action and results should be translated into clear policy recommendations. Indeed problems emerge from the operations of the services (public or private) and from efforts to increase effectiveness and efficiency. Unless decision makers and managers see the problem as relevant to their interests, even a well formulated, properly designed and efficiently conducted research project may stand little chance to have its findings implemented.

Operational research also means research which is less concerned about the exact replicability of results; while its methodologies can be applied to similar problems in different countries, the findings and solutions of these problems are unlikely to be the same due to differences in cultural, social, economic and political realities.

(d) The quality of the research should be high so that results are meaningful and convincing to policy makers

The value of research can be judged by two basic criteria: the contribution it makes to improving the drug situation and its scientific validity.

How to ensure high quality in the prevailing conditions of many developing countries, how to strengthen research capabilities and capacity?

Research does not need to be methodologically sophisticated and in many circumstances should be simple. To ensure the quality, it is more relevant to keep the projects short and simple. Moreover, drug system research in our view is not limited to studies undertaken only by trained scientists.

(e) Research results should be widely disseminated and put into use at local/national level and by the international community

In order to ensure the utilization of research results, research should be a participatory activity; it requires active and continuous collaboration between those who identify the problems to be studied and who are the main potential users of the research results and those who search for facts and alternative solutions (researchers). Health policy makers and health workers should therefore 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 health workers and policy makers who are interested in the results. 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 theater presentations.

1.3 DURG-AFRO, presented by D. Ofori-Adjei

DURG/AFRO was established in 1988 and formally constituted as a non-profit making body in 1990. It has as its main objectives to promote development in the countries involved through drug utilization studies, to create a forum for discussions of related issues, to promote DUS in health-training institutions, to promote drug information centres, bulletins and relevant cooperation with other international organizations.

- To promote the social development of the populations of the countries involved in DURG-AFRO activities, through the analysis of the health systems with regard to drug utilization.

- To coordinate any activities of, or for, members of the organization.

- To create a forum for discussion of common issues affecting developing countries in which the organization shall be represented, especially matters related to drug utilization.

- To promote the concept and the methodology of drug utilization studies in health training institutions.

- To promote the establishment of independent drug information centres and bulletins with the aim of improving the quality of pharmaceutical products and their use, and to prevent misuse of medicines by both health professionals and patients/consumers.

- To promote cooperation with other international organizations which share the same objectives and principles.

DURG-AFRO provides a critical mass of researchers interested in DUS that makes it feasible to test various approaches.

1.4 ICHM experience, presented by Mr M.A. Omar

The International Course of PHC Managers in developing countries (ICHM), Rome, was first established in 1988 to provide management training to people working at district levels, including nationals from developing countries and Italians working in those countries. Research and training are closely integrated in ICHM's activities. However, any research carried out either by ICHM staff or
trainees should not to be academic, but oriented towards finding a solution to a pressing problem and practical application.

The subjects under study cover a wide range of interests and disciplinary areas, but a common framework is ensured by a number of general requirements. The research has to be:

- **relevant** to the needs of the PHC programme requesting the support;
- **operational** according to the decision-making process of the host programme;
- **appropriate**, producing adequate results in a reasonably short period of time and at a low cost;
- **participatory**, involving the host staff and/or local researchers in the study design, implementation and evaluation;
- **multi-disciplinary**, with respect to problem perspectives, research techniques and recommended solutions; and
- **culturally sound**, in so far as it pays due respect to the human and cultural peculiarities of the communities involved in the research area.

Research findings are discussed with the local counterparts soon after the study is over and a copy of the preliminary report is left with them including a copy of all raw data collected. Following editorial work the final report is also sent to the country where research is performed. Efforts are under the way to publish the results of research activities for wider dissemination.

ICHM feels that research on drugs must be considered as an integral component of the total health system and not carried out as a separate element. It is willing to collaborate with any interested body in joint efforts to carry out operational research concerning drug utilization in developing countries, using its experienced (multidisciplinary) human resources. Such collaboration will contribute to the overall development of health care systems in the developing world.

1.5 INRUD activities, presented by Dr R. Laing

The International Network for Rational Use of Drugs (INRUD) has been established to address the problem that pharmaceuticals are frequently used irrationally. The Network joins groups from four African (Ghana, Nigeria, Sudan, Tanzania) and three Asian (Bangladesh, Indonesia, Nepal) countries with support groups in Boston and Sweden. Detailed country analysis papers are prepared and formative or intervention studies are initiated.
Operational research related to rational use of drugs
UNICEF/WHO Action Programme on Essential Drugs

The Network functions as a participatory group in which members are involved in decision-making. In developing research projects, INRUD stresses the importance of a multidisciplinary perspective in adequately understanding the reasons underlying an appropriate use of drugs. The primary objective of the Network is to identify through a coordinated set of country-based research projects a set of effective interventions to recommend as policy options for the promotion of RUD.

The strategy chosen is to use formative behavioural research to discover and explore the motivations and expectations which underlie the drug use behaviours of providers and consumers. Once these factors are better understood, applied intervention trials are necessary to determine the relative impact of different strategies to improve drug use behaviour in a variety of high priority health problem areas.

Illustrative examples of research questions are:

* Standard Treatment Protocols - How useful have these been in promoting the use of specific drugs and dosages for specific problems?

* Drug Kit Distribution - Has the kit distribution system been effective in improving the clinical appropriateness of treatment for these problems?

* Monitoring Prescribing Practices - What is the best way to monitor prescribing practices in the public and in the private sectors?

* Regulation and Managerial Interventions - What are the impacts on services of services fees, banning of particular drugs, limitation on the number of drugs allowed per visit, limited lists for different levels of care, etc?

* Impact of Education - Can face-to-face models using trained health educators be conducted cost-effectively?

* Retailers and Drug Sellers - Is it possible to design educational programmes which acknowledge economic incentives but nevertheless promote therapeutically effective products?

* Traditional Healers - Is it possible to improve drug use patterns of traditional healers?

* Social Marketing of Pharmaceuticals - What is the impact of consumer advertising on the use of drugs?

* Microbial Resistance - How are long-term increases in the prevalence of microbial resistance to antibiotics, antimalarials, or other essential drugs affected by programmes which rationalize their use?
Each country group has been encouraged to develop research proposals for formative studies or interventions. In order to promote more generalizable and reliable drug use research, participants during the first INRUD workshop held in Indonesia in 1990 developed a draft set of indicators related to appropriate drug use. These covered five areas: policy, drug supply, marketing, prescribing, and patient care.

The Network support group produces a biennial newsletter.

By using a network approach and avoiding specific institutional affiliations, an attempt has been made to build on the strengths, expertise, and enthusiasm of the many varied individual members.

1.6 IHCAR activities, presented by Dr G. Tomson and Dr V. Diwan

IHCAR aspires to develop interdisciplinary methods and wants to generate and communicate knowledge through the combination of research, consultancy services including planning and evaluating essential drugs programmes, and teaching. The scientific activities fall within the field of health systems research applied on PHC, reproductive health, and assessment of health technologies including drugs and vaccines.

IHCAR has been involved in pharmaceutical issues since the mid 1980s. The focus has been policy activities such as two seminars on 'Another Development in Pharmaceuticals' conducted at the Dag Hammarskjöld Foundation in 1983 and 1984. Another activity was Medicines & Society - A challenge in health development, a multi-disciplinary workshop in Stockholm in 1987 with teams from 8 Asian countries resulting in 8 finalized projects on, e.g., monitoring of adverse drug reactions, drug availability, use of antibiotics, health seeking behaviour and drugs, drugs in households, and marketing through advertisements.

In 1991, the department was coorganizer of an International Conference on Social and Cultural Aspects of Pharmaceuticals and of a workshop "Society & Medicines - Essential Drug Information" held together with the Department of Pharmacology, University of Indonesia, Jakarta, and the Ministry of Public Health, Thailand.

Other research activities include:

- Drug utilization studies at different levels of health care in Sri Lanka including descriptive formative studies and medical anthropological studies where a double perspective (anthropologist and medical doctor) was applied to study perceptions and use of drugs.

- Multidisciplinary Information on Education intervention studies in Zambia and Sweden combining qualitative and quantitative methods. The study in
Zambia is conducted in collaboration with the Ministry of Health and integrated in the Essential Drugs Programme.

A multidisciplinary formative and intervention study in South India on the use of antibiotics and the prevalence of microbial resistance, etc.

Research priorities have been to adopt multi-disciplinary methods for problem identification including determinants of drug use and development of methods to study effects of information and education. Attempts have been made to establish long-term collaboration with Universities and Ministries of Health to ensure sustainability in research and development.

1.7 Istituto di Ricerche Farmacologiche 'Mario Negri', presented by Dr G. Tognoni

The Mario Negri Institute for Pharmacological Research is a non-profit institution actively involved in research activities in the field of drug evaluation for 30 years. The spectrum of interests is very broad, as the Institute now includes 25 Laboratories for a total of 500 investigators distributed in three main facilities in Milano, Bergamo, S. Maria Imbaro.

Besides groups working in molecular biology and experimental investigation, an important proportion of the activities is dedicated to clinical and epidemiological research in the main areas of medicine (from cardiovascular disease to oncology, neurology, psychiatry, perinatal care, obstetrics and gynecology). Interest for international health has become a key characteristic of the Institute starting from participation in the elaboration of the WHO programme of essential drugs in 1976. Since then, various projects have been developed in many Latin American and African countries, through training of people in clinical pharmacology and drug epidemiology, field missions, assistance in the development of research projects and cooperative networks.

Among the most recent commitments, it is worth recalling participation in the establishment of DURG-AFRO, coordination of the international study on drug use in pregnancy (where 22 countries took part, including representatives of Latin America, Africa, Asia), promotion and support (with PAHO) of a large project on mental health in Central America and Latin America.

1.8 Dutch Royal Tropical Institute activities, presented by Dr J. Chabot

Most experience is from implementation of PHC programmes in francophone Africa. Presently the institute participates in developing studies in collaboration with the Medical Anthropology Department, University of Amsterdam, and in one study with the WHO Action Programme on Essential Drugs, on the effects of Community Health Workers distributing drugs in Ghana and Thailand.
1.9 Activities of Medical Anthropology Unit, University of Amsterdam, including some Health Action International (HAI) linked activities, presented by Dr A. Hurdon

The Medical Anthropology Unit has been involved in drug use studies since the early 1980s. The focus of research has been on socio-cultural aspects of pharmaceuticals at the 'end of the pipe-line', in communities where users obtain pharmaceuticals from a variety of drug distribution channels, and often administer them without consulting a doctor.

In-depth studies have been conducted in Brazil, Cameroon, Ghana, and the Philippines. In addition, action-oriented research on drug use by children in eight Asian countries, a HAI project, and on the use of hormonal drugs by women in India, Indonesia, the Philippines, Peru, and Tanzania was coordinated by the research unit.

Current projects are:

- **Review of studies on drug use and provision in developing countries.** A database of around 230 drug use studies (including a large amount of unpublished material) has been developed, and is constantly being updated. Around 30 drug use researchers worldwide have participated in this project. The studies in this database have been reviewed and compiled in an annotated bibliography, which includes recommendations for action and research. This project was conducted together with Health Action International.

- **Research programme on community drugs use.** Based on the in-depth studies conducted by the unit and on the review of literature, a new operational research programme has been developed, together with the Primary Health Care Group of the Royal Tropical Institute, Amsterdam and a number of research institutions in developing countries. The aim of this project is to enhance the rational use of drugs by consumers through evaluating the impact of existing 'rational drug use interventions', and through the development of more appropriate ones.

- **Development of cost-effective methods to study community drug use.** One of the main aims of the research project conducted with Health Action Information Network in the Philippines, was to develop simple, cost-effective, methods to study drug use in Primary Health Care programmes. This included participatory methods to develop educational materials such as comics and slideshows.
- **People's perceptions and the political economy of pharmaceuticals in the Philippines: Implications for the National Drug Policy.** This project seeks to identify and analyse the socio-historical patterns of pharmaceutical production, distribution and utilization in the Philippines. The study will provide new insights as to the direction that the National Drug Policy in the Philippines might take in order to be effective.

- **The perception and use of medicines in a rural Ghanaian community.** This is an in-depth study on the way in which Ghanaian rural dwellers perceive and use drugs with particular reference to their expenditure on these products.

- **The use of injections.** Staff of the unit is involved as advisor in the Injection-practices research of the Action Programme on Essential Drugs, WHO.

- **Children's medicine use in Europe.** This project aims at describing how primary school children view medicines in five European countries. The results will be used in the development of educational materials.

- **User-perspective of new contraceptive methods.** This research project is still in its programming phase. It describes how users view safety and efficacy of contraceptives.

- **Conference on socio-cultural aspects of pharmaceuticals.** This conference is organized by the Medical Anthropology Unit in cooperation with the anthropology Department of the University of Copenhagen, IHCAR, INRUD, and DAP-WHO. It will allow researchers to discuss further a number of important socio-cultural research themes.

**Research priorities.** Very few studies evaluate the impact of 'rational drug use' interventions. Those that have been done focus on drug prescribing at the health centre level.

There is an urgent need to define ways in which drug use research can contribute to the development and implementation of effective 'rational drug use interventions'. At present, the main problem is not 'lack of research', but lack of effective training and educational efforts to enhance the rational use of drugs. Simple, cost-effective research methods - such as focus group discussions and mini-surveys of drug distribution channels - can be used to gain insight in drug use perceptions and practices. Such insight can help in the development of educational materials for the general public.
1.10 University of Heidelberg, experience presented by Dr C. Knauth

Drug Utilization Studies have been conducted in Bolivia and Peru with a focus on diarrhoea and acute respiratory infections.

So far, only limited effects have been seen of interventions, there has been a certain lack of sociocultural approach, and a main priority is to find out which is the optimal intervention and at what level.

1.11 University of Montreal, Dept of social Medicine, activities presented by Dr P. Fournier

Main experience is so far in health care evaluation in industrialized countries but more and more activities are also undertaken in developing countries. For example, studies of drug use and utilization of health services are carried out with a multidisciplinary approach including anthropologists, economists, etc.

1.12 University of Oslo (UoO), Department of Pharmacothapeutics, presented by Prof. P.K.M. Lunde

An interfaculty coordinating Centre for Environmental and Developmental Studies, including a Division for North-South University Collaboration (capacity building through exchange programmes on research, teaching, and training) has recently been established. Among others, operational research and training projects on relevant health and drug-related issues are planned in collaboration with some universities/countries in Africa (e.g. the University of Zimbabwe). Major emphasis is put on interdisciplinary approaches.

The Department of Pharmacotherapeutics (UoO), besides being a national centre for independent drug information, has university responsibilities in terms of research (clinical pharmacological/drug epidemiology etc) pre- and postgraduate teaching and training. The Department has also been informally involved in various global, regional and bilateral programmes and projects (e.g. the Drug Utilization Research Groups (DURG) EURO and AFRO, various training and teaching programmes for less developed countries in Asia, Africa, Latin America, and Europe). Recent projects relate to collaborative drug utilization studies (The Drugs in Pregnancy project, a capacity building project with the University of Zimbabwe), and an Evaluation of the Essential Drugs policy in the Gambia (dissertation thesis for a Gambian research fellow).

2. COUNTRY EXPERIENCES

2.1 Bangladesh, presented by Prof. A. Das

The regulatory approach of the Bangladesh Drug Policy formulated in 1982 has had a number of positive impacts:
- banning production of combination drugs,
- reducing the price level,
- limiting the number of drugs available at the different levels of the health system.

All this has contributed to improving prescribing and use of drugs to some extent. But there are still problems of polypharmacy, unnecessary prescribing of antibiotics, inadequate dosage, production and marketing of substandard drugs, improper storage, and patients' non-compliance. This indicates the urgent need for undertaking formative research and intervention studies designed to change, inter alia, prescribers' and consumers' behaviour. However, very few studies have so far been undertaken to optimize the positive impacts of the drug policy at the prescription and the consumption levels.

Why so few studies?
- The success story of the Drug Policy has resulted in 'smugness' that tends to pre-empt the possibility/need of further action.
- The quality issues with regard to care and drug use are not adequately understood by the administration.
- The system of accountability is inadequate and mostly quantity-oriented.
- There is a lack of assertiveness on the part of consumers.

Two projects, namely 'Strengthening Rational Use of Drugs' and 'Development of Health Care Quality Assurance' have been developed and have received initial approval by the government.

2.2 Ghana, presented by Dr D. Ofori-Adjei

Although a Provisional Essential Drugs List and a National Formulary exist since 1988, it was recognised that the successful implementation of the Essential Drugs Concept and Policy (EDCP) through the EDL required a strategy that included research and evaluation of any steps taken. The preferred approach in Ghana was to be problem-directed and was to include efforts to determine appropriate methodologies as well as measures of outcome.

The Centre for Tropical Clinical Pharmacology and Therapeutics of the University of Ghana Medical School acts as the focal point for the research activities. The general aim is to set up a permanent observatory of therapeutic practice, to be used for a better implementation of the therapeutic formulary and the general policy of drug selection, procurement, distribution and use.
Research studies include:

- Quantification of drugs imported into the country in order to identify drugs which while not on the EDL are heavily consumed. It will also provide information on the flow of drugs into the private sector.

The study is prospective and descriptive and covers all drug imports through the two main ports of entry - Tema Harbour and Kotoka International Airport.

Problems. Data collection is done by CEPS officials therefore returns are sometimes late.

Donations to Missionary health facilities come as assorted drugs in cartons making quantification difficult.

Outcome. A seminar was held at the end of the first year (1989). This was attended by senior officials (all in decision-making positions) of government ministries and agencies involved in the drug chain.

They were asked to provide solutions to the identified problems and make recommendations for their correction. To date most of the solutions and recommendations have been implemented except for the responsibilities of quality control laboratories.

The data base created has been a source of information to the MOH for monitoring the importation of various groups of drugs. Information on psychotropic substances has also been made available to the United Nations Fund for Drug Abuse Control on request.

- A baseline survey regarding the Bamako Initiative (BI) was undertaken to provide the necessary background information relating to intersectoral collaboration, community participation, drug management and supply and socio-cultural aspects of health care and drug use.

This was done not only to enable proper formulation and implementation of the Initiative but also to provide data for evaluation. Indeed, operational research was an integral part of the Ghana Bamako Initiative action plan.

A multi-disciplinary team of a sociologist, a psychologist, a computer scientist, a political scientist, an economist, two public health physicians, and a clinical pharmacologist was constituted to carry out the study.

Both qualitative and quantitative methods of data collection were used to gather information (questionnaires, interviews and in-depth interviews).

Problems. The operational research component of the implementation of the initiative is not evident at this point in time.
Experience from the Traditional Birth Attendants training programme indicates that dissociation of programme activity from research could influence the interpretation of research findings; especially when shortages/delays in supply are likely to occur.

It is important even at this early stage, to institute measures that will identify such administrative and managerial problems. The solutions to these may make national implementation more efficient.

An important drawback to implementation is the lack of effective communication between the various sectors that make up the health system at the district level; this was identified during the baseline survey.

**Outcome.** The results of the baseline survey were presented at a National Workshop and formed the basis for the development of guidelines for the implementation of the Bamako Initiative and the National Essential Drugs activities.

**On-going and future work:**

- **Assessment of the impact of didactic methods** of providing in-service training to Medical Assistants using malaria treatment as the probe.

  The methodology is a combination of qualitative and quantitative data collection using both secondary data (patient records), questionnaires and focus group discussions.

  The research team is made up of two social scientists, a computer scientist, a pharmacist, and a clinical pharmacologist. This is part of INRUD activity.

- **Development of an information data base** to monitor and improve drug use.

  This project has just been funded as part of DURG-AFRO activities.

  The government's commitment to operational research as an essential component of the health system has been demonstrated by the creation of a directorate for operational research within the MOH. A National Health Research Advisory Committee has been formed to support the Operational Research unit.

2.3 Nepal, presented by Dr K. Kafle

The following studies have been conducted in Nepal:

(a) Socio-cultural aspect of self-medication and its impact on essential drugs
(b) Private sector pharmaceuticals
(c) Traditional methods of treatment in rural Nepal  
(d) In addition a few other drug utilization studies.

Although Nepal supports the Essential Drugs Concept of WHO and is emphasizing strengthening PHC through essential drugs, important problems are encountered in conducting research on these issues. For example:

* Research is still given low priority in many institutions.
* Government clearance for project proposals is long to obtain.
* Communities are not always willing to participate in research activities without some remuneration.

2.4 Panama, presented by Dr. D. Lee

A number of drug utilization studies have been conducted in Panama over the past 15 years. Studies, of a descriptive nature, have involved review of prescription forms and patient charts in the outpatient and inpatient settings. Review of inventory data with the Defined Daily Dose (DDD) methodology have also been attempted. Although important as tools for the implementation of pharmaceutical policies, particularly relative to the Panamean Social Security System covering 65-85% of the population, the study of drug utilization has not yet been 'institutionalized.'

The main obstacles that may be identified are the lack of a research policy, at both national and institutional levels; the lack of a mechanism and funds for carrying out such studies; and the lack of a 'critical mass' (trained manpower). Efforts to implement operational research on the rational use of drugs must address these interrelated issues if the sustainability of research is to be ensured.

An informal network for permanent collaboration, the Drug Utilization Research Group - Central America, has recently been established. It is hoped that this may provide an effective mechanism for improving on the latter two obstacles to strengthening research capabilities, both in Panama and at a more Subregional level.

2.5 An overview of research on drug use in the Philippines, presented by Dr. M.L. Tan

The implementation of a National Drug Policy and a Generics Law in the Philippines has spurred interest in research on drug use issues as a basis for promoting rational drug use.

On a macro-level, industry sales figures have been reviewed to assess national consumption patterns but this type of work has its limitations since it is not possible to determine actual purpose of the drugs' usage. Nevertheless, the figures have been used to point out irrational use of medicines, such as the
widespread use of cough and cold remedies (estimated at 11% of total drug consumption), most of which are useless or irrational fixed dose combination drugs. Industry figures have also been used as part of training modules on rational drug use to emphasize that many of the top-selling drugs by brand names are not found in the Philippine National Drug Formulary listing of essential drugs.

Several community studies on drug utilization have been published. These include a study of a rural village, four urban poor communities and a detailed comparative study of two urban poor communities, one with a community-based health programme and one without.

Many other unpublished studies exist. These include rapid informal surveys of households and community stores conducted by health groups as a prerequisite for training workshops on rational drug use since this allows trainees to focus on the most popular medicines. Following the institution of courses in medical anthropology at the University of the Philippines, students (undergraduate and graduate) have been encouraged to probe drug utilization patterns in communities and among their peers.

In general, the findings in these surveys parallel industry sales figures but provide more detailed insights into popular uses of particular medicines, especially self-medication patterns.

The implementation of the Generics Act, which requires all drugstores to keep and record prescriptions would have provided rich material for 'audit research' but the requirement has been poorly enforced and the Department of Health has been more interested in checking the prescriptions for compliance with the Generics Act's provisions on prescribing (indicating the generic name of the medicine) rather than looking at what is prescribed. Informal surveys of drugstores by members of the Philippine Drug Action Network show widespread polypharmacy and irrational combinations of medicines. It is, however, a non-governmental coalition and often has difficulties in gaining access to the prescriptions.

The Department of Health, in coordination with the National Statistics Office, is about to conduct a nationwide survey (5000 households) of drug needs and utilization. There is, however, no provision on analysing the data to match reported illness and medicine used. The focus of the research is to determine accessibility to essential drugs in broad terms.

Hospital records and prescription would be another rich and accurate source of information on prescribing habits since diagnosis could be compared with prescriptions. This has not been done although we have requested the Department of Health to look into the feasibility of using such prescription audits as a method of evaluating effects of our ongoing training on rational drug use conducted for government hospital therapeutic committees. We have also suggested a review of government hospitals' procurement lists to assess effects of
the training but members of therapeutic committees point out that their hospitals have a separate procurement committee that is not coordinated with the therapeutic committee.

A more technical type of research is presently being conducted by the government's Research Institute for Tropical Medicine, to assess levels of resistance to antimicrobials through a surveillance system set up in Metro Manila hospitals. The non-governmental groups are also interested in looking into the use of antibiotics using a multidisciplinary approach that would include popular perceptions of this therapeutic category.

The growing linkages between health groups and women's organizations have spurred interest in the issue of women and pharmaceuticals. One group in Davao City has done a survey of availability and usage of hormonal drugs, especially high oestrogen-progesterone preparations.

Also in Davao City, the Davao Medical School Foundation is presently conducting a utilization survey focusing on drug use in the management of acute respiratory infections (Philippine Council for Health Research and Development 1990).

So far, only one study, conducted in the early 1980s, has focused on Metro Manila physicians' prescribing and their sources of information that contribute to those prescribing patterns.

A 'back to basics' research is presently being conducted by the author on popular perceptions of medicines among different socioeconomic groups and to look into macro-micro level linkages that may contribute in shaping these perceptions.

Problems and prospects. Drug utilization surveys in the Philippines are generally incorporated into training programmes among the non-governmental organizations. These tend to be rapid surveys tapping existing networks in communities, utilizing methods described by Van der Geest and Hardon.

Several problems can be identified at present, all of which are inter-related:

1. Lack of access to vital sources of information such as industry sales figures; hospital records and prescriptions; drugstore inventories and records of prescriptions.

2. Tendency to conduct drug utilization surveys in urban areas, particularly Metro Manila where, admittedly, there is more access to medicines. (This disregards the fact that non-use of pharmaceuticals and the reasons for non-use are also part of drug 'utilization'.)

3. Inadequate skills for expanding research designs and analysis beyond census-type surveys.
4. Minimal research on cultural aspects of drug utilization, including popular perceptions and expectations of medicines and specific therapeutic categories.

5. Minimal research on determinants of drug prescribing and consumption beyond biomedical constructs (i.e., morbidity). Industry promotions have been monitored more from the perspective of ethics rather than their actual impact on physicians, pharmacists, and consumers.

6. Poor linkages between government and non-governmental organizations; between the academia and development groups in the formulation of drug utilization research.

7. Lack of a review of past and present research (including grey literature such as students' theses) that may not necessarily focus on drug utilization but that may still yield important insights on the use of medicines. A preliminary attempt has been made to take stock of such research as part of the University of Amsterdam's international bibliography project for pharmaceutical anthropology.

8. Lack of dissemination of research findings, including analytical commentaries on the implications of the findings for policy formulation. Where research is published, it is often inaccessible or in a form that is too technical for communities and the general public.

9. Lack of integration between research and training programmes oriented toward rational drug use.

2.6 Drug information experiments - examples from Sri Lanka and Zambia

*presented by Dr V. Diwan*

The prescribers' decision to choose drugs for an individual patient is influenced by many and inter-dependent factors related to the patient, the prescriber, the healthcare and the diagnosis. The relative importance of each factor for prescribing outcome is not known. Although a number of direct administrative measures such as drug formularies and essential drugs lists have been employed, provision of the drug related information is a major indirect activity undertaken to promote rational drug prescribing.

Drug companies are the major source of drug information to prescribers in most countries, but in many industrialized countries this is complemented by a considerable amount of drug information from university departments, ministries of health etc. The fact that drug companies spend a vast amount of resources for promotional activities is an indication for the effectiveness of their drug information. The evidence, however, is not clear whether drug information from other sources is effective.
Generally the drug information is not evaluated for its effectiveness in the belief that drug information given on the basis of tradition is always valuable and promotes rational drug use. Often there is lack of clear objectives to be achieved by the drug information. The methodological and ethical problems prevent incorporation of evaluation in many drug information programmes. The prescribers are not generally cooperative and compliant and suspect all efforts to study their prescribing as interference in the 'sacred' doctor-patient relationship.

A review of the literature suggests that on a global level only few studies evaluating the effect of drug information have used a scientifically sound methodology.

In one of our studies in Sri Lanka, we have used an experimental design with health units as randomization unit (randomization by group). Using group of prescribers as unit of randomization some problem of contamination of the control prescribers can be overcome. Also prescribing statistics can be collected for prescriber groups and not for the individual prescriber. This helps to avoid to identify the prescribing practice of the individual, which is generally a sensitive issue. This method of randomization will assist the policy makers in developing feasible information programmes. Such evaluation will be in the natural work environment taking in consideration the group dynamics. Using groups will also help to overcome many ethical difficulties and objections from health care providers/administrators and the prescribers themselves.

Three major problems were however identified. One was that there was large variation in prescribing of antibiotics between the health units. Secondly, that the intervention was targeted towards general misuse of antibiotics and not directed towards a specific antibiotic or disease. Thirdly, that due to the large variance there was a low study power. All these problems are taken into consideration in a study carried out in Zambia. In this, the intervention is directed towards the use of standard treatment guidelines for the five most common diseases. The health units are matched for variation in prescribing with the help of preintervention drug utilization studies. Computer simulation studies have also been carried out including number of health facilities, prescribers, and patients. The results show that 10 health centres in the intervention and control groups, respectively, will give acceptable validity to the study.

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