OPERATIONAL RESEARCH IN THE ACTION PROGRAMME ON ESSENTIAL DRUGS

REPORT OF AN INFORMAL CONSULTATION

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I. INTRODUCTION

An informal consultation convened by the Action Programme on Essential Drugs was held on 23 and 24 June 1992 at WHO Headquarters, Geneva.

The purpose of the consultation was to assist the Action Programme to review the policies, objectives and strategies of its operational research component and to propose changes where appropriate.

The consultation was attended by researchers from or working in Sri Lanka, Thailand and Zimbabwe and WHO staff from the Action Programme on Essential Drugs (DAP) (list of participants in Annex 1).

II. BACKGROUND

DAP goals and mandate:

The WHO Action Programme on Essential Drugs performs two critical functions. The first is to cooperate with Member States and international, bilateral and non-governmental organizations in the formulation and implementation of national drug policies and essential drugs programmes. The second is to provide conceptual leadership and advocacy in mobilizing and coordinating a global collaborative effort to improve the world drug situation.

The Programme seeks to ensure that all people, wherever they may be, are able to obtain the drugs they need at a price that they and their country can afford; that these drugs are safe, effective and of good quality; and that they are prescribed and used rationally.

World drug situation:

The Programme has long recognized that more information is required to determine effective ways of reaching its overall goals. Acknowledgement of the many problems characterizing the pharmaceutical situation is not recent, but goes back to 1975. However, it is only in the last few years that the difficulties in developing and implementing drug policies in the complex social, cultural, political and economic environment especially of the developing world has been fully understood. The challenge is enormous: despite the fact that more than 110 countries have drawn up their own essential drugs list and over 60 have formulated national drug policies, approximately one half of the world’s population still lacks regular access to needed drugs. Lack of government commitment, low capacity to design and implement appropriate drug policies, poor performance of the public sector, including inefficient procurement and inadequate distribution, limited affordability of essential drugs in the private sector, lack of regulatory mechanisms and quality assurance systems, and irrational use of drugs are still common. In addition, during the eighties, many developing countries experienced a significant economic decline combined with the introduction of structural adjustment policies which lead to a decrease in the availability and affordability of essential drugs, the extension of a non-controlled private sector and a deterioration in the social infrastructure - the public sector drug infrastructure being especially hard hit.
Operational research goals:

The changing public health environment means an ever increasing role for operational research in identifying and solving the many problems faced in implementing rational drug policies. The goal of such research is to prepare the Programme and countries to meet present and future challenges and to identify innovative and viable approaches to ensure the availability, affordability and appropriate use of essential drugs within a framework of equity.

The Programme’s operational research mandate reflects its global mandate. This is to play a catalytic and sensitizing role in promoting and supporting operational research, both technically and financially, and to take the lead at the international level in the development and coordination of research activities related to essential drugs and national drug policies.

A grant from SIDA/SAREC in 1984 was instrumental in getting research off the ground and led to its inclusion in Programme activities. Since then, operational research has been a major area of work which during 1990-91 accounted for 7% of the Programme’s budget. This research encompasses the four technical areas of the Programme: policy and management, supply and logistics, rational use of drugs and quality assurance.

The research undertaken and promoted by the Programme aims at examining national and global constraints to developing and managing sound national drug policies and programmes, and at filling some of the many gaps in existing knowledge about the best means of selecting, procuring, financing, and distributing drugs - especially essential drugs - and their use by prescribers and consumers.

It is intended to lead to action by:

- answering practical problems related to the implementation and operations of national drug policies and programmes, thereby providing elements for decision-making;

- testing new approaches which will aid policy formulation.

Programme research strategies:

The Programme uses many research strategies to meet its goals. These include:

- Research which is initiated, followed up and funded directly by the Programme. This applies to the majority of the Programme’s research and takes place at two levels: national and global. At the national level, research is not a separate initiative but rather an integral part of ongoing essential drugs programmes and national drug policies. Most of the projects are action-oriented and seek to solve specific problems, detect constraints, and test measures and intervention strategies, as identified by national authorities. At the global level, research takes place on issues that are of regional, interregional or global importance, that are common to several countries, or when comparisons among countries are useful (e.g. drug stability).

Until the beginning of 1990 most of the research initiated by the Programme was global but DAP research policy evolved after an informal review showed the problems linked with global research and with the use of such research results. The review suggested that research which was not directly linked to national programmes did not exert significant influence on country programmes and policy decisions, and that findings received little
application at macro and micro levels in the countries directly concerned. Therefore, DAP is now giving priority to country-specific research (see DAP/MAC(3)/91.5 - Operational research in the Action Programme on Essential Drugs).

- Research initiated by others and submitted to DAP can also receive Programme support provided it meets policy goals and is action/intervention oriented. However, the Programme has not yet developed a formal mechanism to review research proposals and does not have a clear policy on its role in this connection. Decisions to support a research proposal are made by the Director after discussions with the staff member most concerned and with the Research Coordinator.

- The Programme has increased its collaboration with other organizations in the field of research (e.g. UNICEF) and provides guidance and support to networks such as INRUD, DURG-AFRO, etc. and to institutions involved in operational research.

- An important aspect of Programme strategy has been to provide training and technical expertise to the researchers involved in projects supported by DAP. This is to ensure the quality of the results and also to promote research capacity at country level. One approach has been to create links between institutions in the North and the South, e.g. in a research project on injection practices, three research teams in Indonesia, Senegal and Uganda have received continuous support from the University of Amsterdam. The development of simple research methodologies is also part of this strategy, e.g. a manual on "How to investigate drug use at community level" was recently developed by the Programme and will be field-tested in 1993.

- Finally dissemination of research results has received more priority in 1992; reports are being published regularly in a new DAP series with a specific logo and disseminated to a wide audience.

As shown above, the Programme has developed a number of approaches to improve the effectiveness of its research activities and to perform its role. However, achievements have not matched expectations. One main constraint has been the lack of time that DAP staff were able to devote to research, but other constraints exist which include:

- At country level, insufficient human resources with the scientific knowledge and technical skills to generate and execute research projects, low awareness of the utility of research among policy makers and managers in face of budgetary constraints and competing priorities, and slow dissemination of results, have resulted in research of uneven quality and use.

- At global level, there are similar constraints, plus an overemphasis on descriptive studies and insufficient effort to translate research results into realistic policy recommendations. This has induced the Programme to invest more in training and provision of expertise, with the consequence that fewer projects can be executed with the same amount of funds.

- Although the Programme participates in and supports an increasing number of meetings and networks, it has not yet been able to take the leading role and to propose to others "a global research agenda", mainly because of staffing problems and lack of clear strategies.
1992-93 research plan:

In view of the above, the research plan for 1992-93 proposed to the Management Advisory Committee of the Programme stressed the following:

Activities

The Programme will emphasize the importance of problem and action oriented research when assisting countries in the development of their national programmes. It will support the formulation and implementation of focused research activities aimed at providing decision makers, managers, prescribers and the community with the information to make more rational decisions about drugs and health care in all DAP supported projects. It will facilitate the quality of the research by providing technical expertise from developed and developing countries at the various stages of the work: development of protocols, field work, data analysis and report writing. It will continue to publish research results as DAP documents and to assist in their national and international dissemination.

At global level, the Programme will focus research activities on a few main priorities related to important policy questions. A research agenda will be developed with research priorities and questions for each technical area of the Programme. Policy and rational use will receive the main share of the budget. A series on research methodologies and tools will be developed including how to investigate drug use at different levels, guidelines for establishing or evaluating indicators, etc. Links will be strengthened with research institutions and the Programme will continue to support, through research projects, networks such as DURG-AFRO, INRUD, and the informal network on social and cultural aspects of pharmaceuticals.

The Programme will strengthen its operational capacity in order to be able to take the lead at international level in research related to essential drugs and national drug policies. This will be done by reallocating some staff time and by improving coordinating mechanisms.

Targets

- To increase awareness by decision makers, ministries of health, and managers of how operational research can assist in drug policy formulation and system management.

- To identify five priority issues relevant to all essential drugs programmes and national drug policies and to launch research projects on these issues at global level.

- To make available instruments (indicators, questionnaires, etc.) to help policy makers, managers and international agencies measure progress in formulating and implementing a national drug policy.

- To include in all new country programmes an element of operational research and monitoring to help ensure efficient implementation - and long-term success - of country programmes.

- To strengthen the coordinating role of the Programme in research on drug issues at international level.

- To develop ready-to-use tools for correcting, refining and improving the implementation of national essential drugs programmes.
Programme review:

Although activities and targets have already been proposed for 1992-93 in planning documents, the Programme considered that an informal consultation was needed to carefully review the relevance of the research policy and objectives, to assess the strategies developed and to make suggestions on how the Programme can best perform its role in the near future.

III. RECOMMENDATIONS

The participants of the consultation reviewed the various issues put forward in the agenda (Annex 2) and made the following recommendations.

1. The group stressed the importance of operational research for the work of the Programme whether country support or development work. The operational research component should be a central component and should provide information for policy and management decisions in all categories of DAP work. It also acknowledged that the need for coordination was increasing at global level as more actors became involved in operational research related to drugs: WHO was seen as the logical organization for this coordination. In view of these many responsibilities, and their time-consuming nature, the group was concerned by the lack of staff to develop this component. For DAP to fulfill its mandate, additional staff should be recruited.

2. The group felt that the issue of dissemination of research results should be made explicit in the mandate of DAP. The mandate should now read as follows:
   
   * to play a catalytic and sensitizing role by promoting and supporting operational research at national and global levels, technically and financially;
   * to promote and ensure the use of research results at national/global levels by decision makers and all persons concerned;
   * to lead and coordinate the global effort in research related to essential drugs and national drug policies.

3. It was agreed that the aim and the specific objectives of the operational research component had never been clearly spelt out in DAP documents, and what were referred to as "objectives" were in fact the types of research undertaken. A consensus was reached on the following aim and objectives:

   Aim: to empower countries to generate and utilize information needed to achieve the objectives of their national drug policies based on essential drugs;

   Objectives:
   * to generate information which would provide a scientific basis for further implementation of the essential drugs concept;
   * to assist countries in generating and utilizing information based on operational research results;
   * to strengthen research capabilities at country level;
to identify priority research areas and assist countries to draw up a research agenda based on the identified priority areas.

The group felt that the four types of research undertaken were appropriate:

* to gather factual information needed for achieving successful essential drugs programmes and national drug policies;

* to detect and solve problems and constraints which at each level of the drug supply system hinder the implementation of sound policies;

* to appraise new or improved methods or approaches in essential drugs programmes and policies and to adapt them to national contexts;

* to develop relevant research methods so as to make it easier to investigate problems related to the availability and use of drugs.

4. In order to identify how the Programme could achieve its objectives, taking into account the financial and human resource constraints, the strategies used up to now were carefully reviewed. The group considered that although these strategies were appropriate some prioritization should be made. To facilitate implementation, the Programme needed to better organize and structure the research component through the development of management guidelines, the creation of data bases and the establishment of advisory groups.

The participants in the consultation recommended the following strategies for the operational research component:

* **Country specific research projects:** these projects should continue and be integrated into the programmes of collaboration between DAP and the country. However, some problems need to be solved for this strategy to succeed:

  - problem solving research should be promoted by DAP staff as an essential element for ensuring the success of essential drugs programmes and national drug policies;

  - relevant researchers need to be identified at country level and ministries of health convinced to use them to carry out DAP supported research. Advantage should be taken of health system research units when they exist at country level or of any other research set-ups, e.g. initiated by another WHO programme. These units will often work on subjects related to drugs and diseases and can be an important source of information. For instance, in WHO/AFRO Subregion III, the Joint WHO/NGIS/RTI-HSR project for Southern Africa is now operational and provides training to researchers of the region;

  - although this country specific research should be managed by the country, DAP will need to support it by sending materials and by providing technical assistance when needed.

Guidelines for the management of country specific research and the establishment of a list of key people at country level who could act as resource persons in technical fields should be established as soon as possible.
* Global research projects: the Programme should be involved in a limited number of meaningful global research projects. Priorities should be set by DAP with support from advisory groups. By setting this agenda, DAP would be in a position to globally lead and influence research in the drug area. Global projects should be subcontracted to reputable institutions with a previous track record of good research and involvement in this field. Such research, when involving institutions of a developed country, should be carried out jointly with institutions from developing countries for the purpose of strengthening research capability.

* Dissemination and use of research results: this is part of the mandate of the Programme and was seen by the group as a very important strategy. Previous experience shows that to publish reports is not enough to ensure the use of the findings. Although the creation of a data base of key people, and the exchange of information through networks, will probably facilitate future dissemination and use of research results, it is clear that the Programme should do more in this field and assist researchers in transforming their research results into specific, action-oriented recommendations and programmes. Funding for activities such as workshops at country level at the completion of any research project should be included in research proposals.

* Development of methodologies: standardized research methodologies should be developed in each field after an inventory has been made of the methods previously used in research supported by DAP. Work on the development of indicators to monitor progress was seen as a priority for the near future.

* Stimulating linkages between research institutions in the North and the South was perceived as a fruitful strategy, although it often happens that such links cease when the project is finished. Global research projects should be an occasion for creating such links and should as far as feasible include a training component which would facilitate transfer of knowledge from North to South and contribute to the creation of a critical mass of researchers. Networking is also a means to stimulate exchange of experiences and DAP should continue to support networks that contribute to generating needed information and skills through training and sharing of experiences. DAP should identify researchers, universities and institutions involved in projects related to the drug sector and set up a data base containing this information. It should also support other parties, such as universities and networks, in maintaining a data base on the current research findings at global and national levels, and act as a clearing house and an overall coordinator.

* Training of researchers: training is an important way of strengthening research capability at country level. However, this should continue to be carried out as part of research projects at global or national level or through support to networks’ activities. Awareness of the potential utility of operational research into drug-related issues could also be created through the inclusion of such research methodologies in the curricula of medical and paramedical training institutions.

* Support to various research projects: although not seen as a priority, the group felt that valuable information could be generated by small projects initiated by individual researchers or institutions and that in certain circumstances DAP should support such projects. For areas where more information is needed, DAP could make a call for project proposals through the Essential Drugs Monitor or professional journals. These proposals could then be reviewed twice a year by a steering committee.
IV. CONCLUSIONS

The Group concluded that the adoption and development of the recommended strategies would enable DAP to take a leading and coordinating role in the field of operational research related to drug policy, selection, supply, distribution, financing and use. Although this might seem ambitious in the light of the present situation, the setting up of mechanisms, procedures, data bases, and the availability of guidelines for research management, would facilitate the work. A prerequisite, however, would be the availability of additional human resources both through the recruitment of additional staff and consultants to set up certain of the mechanisms.

The Group also had on its agenda the identification of priority issues for research during 1992-93. However, due to the non availability of certain invited participants the Group considered that it was too limited in number to adequately tackle this task. Nevertheless, as a first step, it produced a list of subjects (Annex 3) which appeared important to all the participants.

V. FOLLOW-UP

The recommendations and suggestions of the group will be presented to the Management Advisory Committee of the Action Programme on Essential Drugs in February 1993 for comments and approval prior to implementation.
ANNEX 1:

LIST OF PARTICIPANTS

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ANNEX 2:

AGENDA

DAY 1, Tuesday 23 June 1992

Introduction
- Opening presentation: Dr F.S. Antezana
- Introduction to the consultation: Mrs P. Brudon-Jakobowicz
- "Past developments in DAP operational research: an overview"

Session 1: Policy, objectives and strategies
- DAP operational research within the overall programmatic approach of the Programme
- DAP operational research policy and objectives: relevance and changes needed
- DAP strategies: appropriateness and suggestions for change

DAY 2, Wednesday 24 June 1992

Session 2: Role of the Programme in operational research
- How can the Programme best perform its role in the future?

Session 3: Research priorities
- Identification of main priority issues for research for 1992-1993

Concluding remarks
ANNEX 3:

LIST OF RESEARCH ISSUES PROPOSED BY THE PARTICIPANTS
(without prioritization)

* Impact of essential drugs programmes on the drug situation
* Impact on the health systems and on the drug situation of the increased longevity of the population in developing countries
* Influence of migration on health care
* Self-medication
* Impact of the essential drugs concept on drug policies
* Impact of privatization/structural adjustment policies on affordability and rational use of drugs
* Impact of the new trade blocks (EC, ASEAN, etc.) on procurement and availability of drugs
* Price comparison/price information
* Evaluation of the effectiveness of various guidelines produced by WHO, including the manual on quantification of drug needs
* Influence of AIDS on drug consumption
* Analysis of drug procurement agencies: what works, what does not
* Information, education, communication: what has worked, where and when
* Provision of drug information by various sources and its effect on prescribing and use of drugs
* Drug use interventions: what has worked and where

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In 1981 WHO's Action Programme on Essential Drugs was established to provide operational support to countries in the development of national drug policies based on essential drugs and to work towards the rational use of drugs.

The Programme seeks to ensure that all people, wherever they may be, are able to obtain the drugs they need at a price that they and their country can afford; that these drugs are safe, effective and of good quality; and that they are prescribed and used rationally.

Research analysing the impediments to developing and managing sound national drug policies and programmes is an important element of country support activities. The Programme undertakes and promotes operational research aimed at filling some of the many gaps in existing knowledge about the best means of selecting, procuring and distributing drugs, and their use by prescribers and consumers.

This document is part of a series reporting on Action Programme research activities and guidelines.

Research that leads to breakthroughs in pharmaceutical technology or in highly sophisticated and expensive techniques of biomedical practice may superficially appear to be more "glamorous". But the operational research that WHO's Action Programme on Essential Drugs undertakes has a direct bearing on the ways in which vital medicines can be made available and accessible to the greatest number of people.