Development of indicators for monitoring national drug policies
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.
REPORT OF AN INFORMAL CONSULTATION ON THE DEVELOPMENT OF INDICATORS FOR MONITORING PROGRESS TOWARD NATIONAL DRUG POLICIES

Geneva, 1992
REPORT OF AN INFORMAL CONSULTATION ON THE DEVELOPMENT OF INDICATORS FOR MONITORING PROGRESS TOWARD NATIONAL DRUG POLICIES

I. An informal consultation convened by the Action Programme on Essential Drugs was held on 9 and 10 December 1991 at WHO Headquarters, Geneva.

The purpose of the consultation was to prepare guidelines for the development of a set of indicators for monitoring progress toward national drug policies.

The consultation was attended by the Comptroller of Health Technical Services of Malawi, researchers from the Harvard School of Public Health and CREDES, WHO staff from the Division of Epidemiological Surveillance and Health Situation and Trend Assessment, Unit of Monitoring, Evaluation and Projection Methodology (HST/MEP) and from the Action Programme on Essential Drugs (DAP) (List of participants in Annex 1).

II. BACKGROUND

1. The WHO Action Programme on Essential Drugs and Vaccines became operational in 1981. The Programme was given the objective of supporting Member States in ensuring a regular supply of a selected number of drugs to their entire population. The drugs must be safe, effective, of acceptable quality, and available at the lowest possible cost. When WHO's drug strategy was revised in 1986 the mandate of the Programme to provide support for the formulation and implementation of national drug policies was emphasized and expanded to cover such aspects as the rational use of drugs.

2. The targets of the Programme are to assist countries:

   - in formulating national drug policies and legislation and strengthening national capability for their implementation, to ensure quantification of needs, procurement, production as feasible, regular distribution and improved rationality in the use of drugs.

   - in ensuring the availability at the primary health care level of the most needed and affordable essential drugs and vaccines (EDV/MTP/88.1).

3. In order to report on the achievements of the targets, very simple indicators have been set up:

   Essential drugs programme under development
   Essential drugs programme operational
   Essential drugs list adopted
   National drug policy formulated.

Information is collected through country situation analysis or country reviews.

4. The most important attempt at creating a mechanism for the ongoing monitoring of the drug situation at country and global level is the structure developed for analysis of the world drug situation which resulted in the WHO publication of that name. Indicators were chosen to reflect the progress made by countries towards achieving the objectives of a national drug policy.
(Annex 2). They also serve as a basis for comparison among countries at a given moment in time and provide an overall view of the drug situation in countries. However, these indicators, when developed, were only regarded as a starting point. Since then, ad hoc indicators have been developed for various purposes.

5. In addition, the Programme has divided its work at country level into 4 technical areas for intervention:

- policy and management
- supply and logistics
- rational use
- quality assurance

and has adopted a system which enables staff to monitor and report progress on objectives, activities and expenditures of each project, in terms of what was planned versus what was accomplished. This is done through the use of the "DAP menu". This menu consists of 18 sub categories (Annex 3).

6. In conclusion, although a number of indicators are used in different situations, the Programme still lacks a set of indicators which will allow it to monitor progress in the implementation of national drug policies, to objectively assess the performance of pharmaceutical policies or/and programmes and to readjust strategies accordingly.

In order to fill this gap, the Programme is working with the Harvard School of Public Health, the International Network on Rational Use of Drugs (INRUD) and others on the development of such indicators. This informal consultation was organized to prepare a set of guiding principles and criteria to create a common approach for groups working on indicator development in the field of pharmaceuticals.

III. ELEMENTS TO TAKE INTO CONSIDERATION

The participants of the consultation reviewed the various approaches to the development of indicators used in WHO programmes and in other organizations. They went through the process of building indicators for monitoring progress in national drug policies using practical examples and testing criteria. The following are the main conclusions of the meeting.

1. Monitoring and evaluation are important at global and national levels, but the aims may differ.

At the international level, there is a need for organizations such as WHO to measure progress toward goals and targets and to evaluate overall strategies. At the national level, monitoring is needed to assess policies and readjust strategies. It is also needed for management purposes at the district and periphery levels. Although no clear distinction was made during the consultation between policy and management indicators in terms of guiding principles, it was agreed that the discussion should focus on indicators needed to monitor drug policies at global and national levels.
2. What should be monitored?

To be effective, a pharmaceutical policy must be based on three principles:

- clear objectives;
- consistent strategies adapted to national resources;
- technical means to reach the stated objectives.

Although the objectives of a national drug policy, as stated in WHO documents and resolutions, are basically the same in every country, strategies can differ according to the political, economic and social situations of each country. However, a number of components of the pharmaceutical system are universal, and some are of key importance for achieving the objectives. These key components should be monitored with simple indicators.

DAP has identified in the past a list of key components (see Annex 3). The group felt that this list should be carefully reviewed and indicators developed on the basis of a revised list. This international list of key components may be adapted for specific national conditions.

This logical succession of steps from objectives to strategies and key components for definition of what to monitor was seen by the group as a prerequisite for the selection of meaningful indicators.

3. Guiding principles

The main principle of DAP in the development of indicators should be to help strengthen national drug policy and programme management including problem solving. This means that the indicators developed by DAP should not be devised primarily as a means to promote goals and targets set up at the international level but should assist decision makers at the national level to monitor the progress of the implementation of their drug policy.

4. Criteria for selecting indicators

The group decided that the number of criteria for selecting indicators should be limited. The group discussed the indicator criteria proposed by HST/MEP and then developed a comprehensive list of possible criteria. The criteria were then used to evaluate several specific indicators for drug policy. Based on this test, the group agreed on a final list of six criteria.
Table 1: Criteria for developing and/or evaluating indicators

1. **Clarity:** The indicator should express a single idea that is generally agreed to be important.

2. **Ease of generation/measurement:** The data should, as far as possible, result from the regular data collection system. If the indicator requires an additional survey, the survey should be within the capability and responsibility of staff at the level it is performed. Such an indicator should be selected only after it has been determined whether the survey can later be incorporated into the regular data collection system. Feasibility in terms of cost should also be taken into consideration.

3. **Consistency and validity:** The indicator should be proven capable of being recorded throughout the system with an acceptable degree of validity and reliability.

4. **Usefulness for action:** The data required for the indicator should be useful for decision making and action at the national/international level (end user). As far as possible, it should be useful for the person doing the recording and contribute to action at his/her level. This will increase the reliability of data collected.

5. **National relevance:** The indicator should serve to measure progress toward the goals, objectives, and targets stated in national policy.

6. **Ease of comparison:** The indicator should provide quantitative data that can be compared to specific norms and objectives.

IV. FURTHER CONSIDERATIONS

1. Several types of indicators were briefly discussed. No decision was taken on the need for input indicators. It was agreed that two types of indicators are necessary: structural indicators (also called implementation indicators), which measure the capacity to perform the work which has to be done, and process indicators, which measure the effectiveness and efficiency of the procedures/systems used. Health impact indicators were advocated by some participants but rejected by others because of difficulties in selecting reliable ones directly related to use of drugs. A consensus was reached on the need for some kind of outcome indicators.

2. It was agreed that indicators developed by DAP should be accompanied by a brief statement for each indicator to include:

   - description of the indicator;
   - definition of the indicator including numerator and denominator;
- data collection and measurement: sources and methods;
- consistency and validity;
- intended use;
- national/international relevance;
- comparison to norms.

3. The next steps in these efforts on indicator development should be to test the draft guidelines in a limited number of countries and, together with the groups which are collaborating with DAP in this work, finalize the guidelines for inclusion in a booklet on indicators for monitoring progress toward national drug policies.
ANNEX I

LIST OF PARTICIPANTS

- Professor P.R. Khonje, Comptroller of Health Technical Services, Ministry of Health, Lilongwe, Malawi

- Dr J.D. Rainhorn, Harvard School of Public Health/Centre de Recherches et d’Etudes pour le Développement de la Santé (CREDES), Paris

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- Dr H.V. Hogerzel, Technical Officer, Action Programme on Essential Drugs
ANNEX 2

1988

INDICATORS USED IN THE WORLD DRUG SITUATION

- They have been chosen to monitor progress made by countries towards achieving the objectives of a national drug policy.

- The OBJECTIVES of a national drug policy were defined as follows:

  (1) to make effective, safe, low-cost drugs available to meet the needs of the entire population (essential drugs);

  (2) to ensure that drugs are used rationally;

  (3) to develop, where economically and technically feasible, national pharmaceutical production that supports economic growth and the overall development strategy of the country.

INDICATORS for availability of essential drugs of good quality at low cost:

  (1) the existence and use of an essential drug list;

  (2) the extent of an operating system for procurement;

  (3) the extent of an operating system for distribution;

  (4) the extent of quality assurance;

  (5) the extent of regulatory mechanisms;

  (6) the extent of coverage.

INDICATORS for the rational use of drugs:

  (7) the existence of a functioning system that regularly provides objective information on drugs to health workers and patients;

  (8) the existence of a system of continuing education for all types of personnel dealing with drugs;

  (9) the existence of a monitoring system, covering adverse drug reactions, and post marketing surveillance.
INDICATORS on commitment of the government:

(10) the existence of a pharmaceutical policy.

INDICATORS for production:

(11) the extent of local production.

Each indicator is divided into 2, 3 or 4 levels.

Example:

Quality assurance

1. No quality assurance exists.
2. Some quality assurance mechanisms exist, but there is no quality control laboratory.
3. A quality assurance system, including a quality control laboratory, exists, but does not function adequately.
4. A fully functioning quality assurance system, including a quality control laboratory, exists.
ANNEX 3

The DAP Menu -- Old and New

Project monitoring and budgeting in DAP is done through use of the "DAP menu". This menu was restructured in 1990 to streamline management and make technical information more easily accessible.

The previous menu consisted of nine categories with 37 sub-codes. The new menu consists of four subject areas (i.e., the four technical areas for intervention) with 18 sub-categories. Across these categories there is a great deal of overlap; and activities in training, research, and strengthening management capabilities cross-cut all these areas.

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<td>Research on implementation of policies</td>
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### Subject areas

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