

# Promoting rational use of medicines: core components

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## Definition of rational use of medicines

**P**atients receive medications 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 their community.” (WHO, 1985).

## The problem of irrational use

Irrational or non-rational use is the use of medicines in a way that is not compliant with rational use as defined above. Worldwide more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients fail to take them correctly. Moreover, about one-third of the world's population lacks access to essential medicines. Common types of irrational medicine use are:

- the use of too many medicines per patient (poly-pharmacy);
- inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections;
- over-use of injections when oral formulations would be more appropriate;
- failure to prescribe in accordance with clinical guidelines;
- inappropriate self-medication, often of prescription-only medicines.

Lack of access to medicines and inappropriate doses result in serious morbidity and mortality, particularly for childhood infections and chronic diseases, such as hypertension, diabetes, epilepsy and mental disorders. Inappropriate use and over-use of medicines waste resources – often out-of-pocket payments by patients – and result in significant patient harm in terms of poor patient outcomes and adverse drug reactions. Furthermore, over-use of antimicrobials is leading to increased antimicrobial resistance and non-sterile injections to the transmission of hepatitis, HIV/AIDS and other blood-borne diseases. Finally, irrational over-use of medicines can stimulate inappropriate patient demand, and lead to reduced access and attendance rates due to medicine stock-outs and loss of patient confidence in the health system.

## Assessing the problem of irrational use

To address irrational use of medicines, prescribing, dispensing and patient use should be regularly monitored in terms of:

- **the types** of irrational use, so that strategies can be targeted towards changing specific problems;
- **the amount** of irrational use, so that the size of the problem is known and the impact of the strategies can be monitored;
- **the reasons** why medicines are used irrationally, so that appropriate, effective and feasible strategies can be chosen. People often have very rational reasons for using medicines irrationally. Causes of irrational use include lack of knowledge, skills or independent information, unrestricted availability of medicines, overwork of health personnel, inappropriate promotion of medicines and profit motives from selling medicines.

There are several well-established methods to measure the type and degree of irrational use. Aggregate medicine (drug) consumption data can be used to identify expensive medicines of lower efficacy or to compare actual consumption versus expected consumption (from morbidity data). Anatomical Therapeutic Classification (ATC)/Defined Daily Dose (DDD) methodology can be used to compare drug consumption among institutions, regions and countries. WHO drug use indicators (Box 1) can be used to identify general prescribing and quality of care problems at primary health care facilities.

Focused drug use evaluation (drug utilization review) can be done to identify problems concerning the use of specific medicines or the treatment of specific diseases, particularly in hospitals. The qualitative methods employed in social science, (e.g. focus group discussion, in-depth interviews, structured observation and structured questionnaires), can be used to investigate the motives underlying irrational use. The data collected can then be used to design appropriate interventions and to measure the impact of those interventions on medicine use.

WHO, with partners, runs several international courses on how to measure medicine use and



### Box 1 Selected WHO/INRUD\* drug use indicators for primary health care facilities (WHO, 1993)

#### Prescribing Indicators:

Average number of medicines prescribed per patient encounter  
% medicines prescribed by generic name  
% encounters with an antibiotic prescribed  
% encounters with an injection prescribed  
% medicines prescribed from essential medicines list or formulary

#### Patient Care Indicators:

Average consultation time  
Average dispensing time  
% medicines actually dispensed  
% medicines adequately labelled  
% patients with knowledge of correct doses

#### Facility Indicators:

Availability of essential medicines list or formulary to practitioners  
Availability of clinical guidelines  
% key medicines available

#### Complementary Drug Use Indicators:

Average medicine cost per encounter  
% prescriptions in accordance with clinical guidelines

\* International Network for the Rational Use of Drugs

implement interventions to promote more rational use of medicines (Box 2).

## Working towards rational use of medicines

A major step towards rational use of medicines was taken in 1977, when WHO established the 1<sup>st</sup> Model List of Essential Medicines to assist countries in formulating their own national lists. The present definition of rational use was agreed at an international conference in Kenya in 1985. In 1989, the International Network for the Rational Use of Drugs (INRUD) was formed to conduct multi-disciplinary intervention research projects to promote more rational use of medicines (email: [inrud@msh.org](mailto:inrud@msh.org) website: <http://www.msh.org/inrud>). Following this, the WHO/INRUD indicators to investigate drug use in primary health care facilities were developed and many intervention studies conducted. A review of all the published intervention studies with adequate study design was presented at the 1<sup>st</sup> International Conference for Improving the Use of Medicines (ICIUM) in Thailand in 1997. Box 3 shows a summary of the magnitude of prescribing improvement by type of intervention. The effect varied with intervention type, printed materials alone having little impact compared to the greater effects associated with supervision, audit, group process and community case management. Furthermore, the effects

### Box 2 Training courses related to the rational use of medicines

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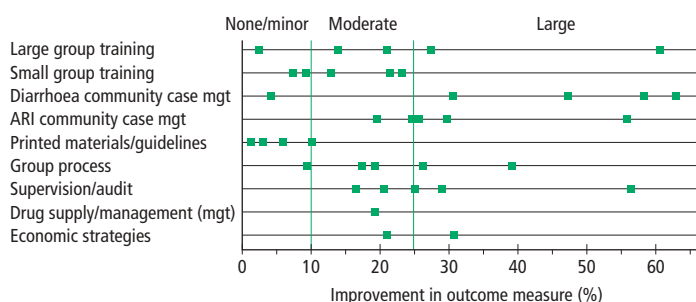
- **Promoting the rational use of drugs (medicines)**, in collaboration with the International Network for the Rational Use of Drugs (INRUD) coordinated by Management Sciences for Health, USA. This course teaches the investigation of medicine use in primary health care and how to promote rational use of medicines by providers.
- **Promoting rational drug (medicine) use in the community**, in collaboration with the University of Amsterdam, The Netherlands. This course teaches the investigation of medicine use in the community, and how to promote rational use of medicines by consumers.
- **Drugs and therapeutics committees**, in collaboration with the Rational Pharmaceutical Programme coordinated by Management Sciences for Health, USA. This course teaches methods for evaluating medicine utilization and how to promote rational use of medicines in hospitals and districts.
- **Problem-based pharmacotherapy teaching**, in collaboration with Groningen University, The Netherlands, the University of Cape Town, South Africa, the University of La Plata, Argentina (in Spanish) and the National Centre for Pharmacovigilance, Ministry of Health, Algiers, Algeria (in French). This course teaches a problem-based approach to rational prescribing based on WHO's *Guide to Good Prescribing*.
- **Pharmacoeconomics**, in collaboration with the University of Newcastle, Australia. This course teaches how to do economic evaluation in medicine selection.
- **Drug (medicine) policy issues for developing countries**, in collaboration with Boston University, USA. This course teaches about general medicines policy including aspects relating to promoting more rational use of medicines.
- **ATC/DDD methodology for medicine consumption**, in collaboration with the WHO Collaborating Centre for Drug Statistics Methodology. This course provides an introduction to the application of ATC/DDD methodology in measuring medicine consumption.

of training were variable and often unsustainable, possibly due to differences in training quality and the presence or absence of follow-up and supervision.

## Core policies to promote more rational use of medicines

Although many gaps remain in our knowledge, a summary of what is known concerning core policies, strategies and interventions to promote more rational use of medicines is presented in the following sections and summarized in Box 4.

### Box 3 Review of 30 studies in developing countries size of drug use improvements with different interventions



Adapted from: *Essential Drugs Monitor*, 1997

ARI=Acute Respiratory Infection

### Box 4 Twelve core interventions to promote more rational use of medicines

1. A mandated multi-disciplinary national body to coordinate medicine use policies
2. Clinical guidelines
3. Essential medicines list based on treatments of choice
4. Drugs and therapeutics committees in districts and hospitals
5. Problem-based pharmacotherapy training in undergraduate curricula
6. Continuing in-service medical education as a licensure requirement
7. Supervision, audit and feedback
8. Independent information on medicines
9. Public education about medicines
10. Avoidance of perverse financial incentives
11. Appropriate and enforced regulation
12. Sufficient government expenditure to ensure availability of medicines and staff

#### 1. A mandated multi-disciplinary national body to coordinate medicine use policies

Many societal and health system factors, as well as professionals and many others, contribute to how medicines are used. Therefore, a multi-disciplinary approach is needed to develop, implement and evaluate interventions to promote more rational use of medicines. A national regulatory authority (RA) is the agency that develops and implements most of the legislation and regulation on pharmaceuticals. Ensuring rational use will require many additional activities which will need coordination with many stakeholders. Thus a national body is needed to coordinate policy and strategies at national level, in both the public and private sectors. The form this body takes may vary with the country, but in all cases it should involve government (ministry of health), the health professions, academia, the RA, pharmaceutical industry, consumer groups and non-governmental organizations involved in health care. The impact

on medicine use is better if many interventions are implemented together in a coordinated way, single interventions often having little impact.

#### 2. Clinical guidelines

Clinical guidelines (standard treatment guidelines, prescribing policies) consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions. Evidence-based clinical guidelines are critical to promoting rational use of medicines. Firstly, they provide a benchmark of satisfactory diagnosis and treatment against which comparison of actual treatments can be made. Secondly, they are a proven way to promote more rational use of medicines provided they are: (1) developed in a participatory way involving end-users; (2) easy to read; (3) introduced with an official launch, training and wide dissemination; and (4) reinforced by prescription audit and feedback. Guidelines should be developed for each level of care (ranging from paramedical staff in primary health care clinics to specialist doctors in tertiary referral hospitals), based on prevalent clinical conditions and the skills of available prescribers. Evidence-based treatment recommendations and regular updating help to ensure credibility and acceptance of the guidelines by practitioners. Sufficient resources are needed to reimburse all those who contribute to the guidelines, and to cover the costs of printing, dissemination and training.

#### 3. Essential Medicines List based on treatments of choice

Essential medicines are those that satisfy the priority health care needs of the population.

Using an essential medicines list (EML) makes medicine management easier in all respects; procurement, storage and distribution are easier with fewer items, and prescribing and dispensing are easier for professionals if they have to know about fewer items. A national EML should be based upon national clinical guidelines. Medicine selection should be done by a central committee with an agreed membership and using explicit, previously agreed criteria, based on efficacy, safety, quality, cost (which will vary locally) and cost-effectiveness. EMLs should be regularly updated and their introduction accompanied by an official launch, training and dissemination. Public sector procurement and distribution of medicines should be limited primarily to those medicines on the EML, and it must be ensured that only those health workers approved to use certain medicines are actually supplied with them. Government activities in the pharmaceutical sector (e.g. quality assurance, insurance reimbursement policies and training), should focus on the EML. The WHO Model List of Essential Medicines can provide a starting point for countries to develop their own national EML.



## 4. Drugs and therapeutics committees in districts and hospitals

A drugs and therapeutics committee (DTC), also called a pharmacy and therapeutics committee, is a committee designated to ensure the safe and effective use of medicines in the facility or area under its jurisdiction. Such committees are well-established in industrial countries as a successful way of promoting more rational, cost-effective use of medicines in hospitals (Box 5). Governments may encourage hospitals to have DTCs by making it an accreditation requirement to various professional societies. DTC members should represent all the major specialities and the administration; they should also be independent and declare any conflict of interest. A senior doctor would usually be the chairperson and the chief pharmacist, the secretary.

Factors critical to success include: clear objectives; a firm mandate; support by the senior hospital management; transparency; wide representation; technical competence; a multidisciplinary approach; and sufficient resources to implement the DTC's decisions.

### Box 5 Responsibilities of a drugs and therapeutics committee

- developing, adapting, or adopting clinical guidelines for the health institution or district;
- selecting cost-effective and safe medicines (hospital/district drug formulary);
- implementing and evaluating strategies to improve medicine use (including drug use evaluation, and liaison with antibiotic and infection control committees);
- providing on-going staff education (training and printed materials);
- controlling access to staff by the pharmaceutical industry with its promotional activities;
- monitoring and taking action to prevent adverse drug reactions and medication errors;
- providing advice about other drug management issues, such as quality and expenditure.

## 5. Problem-based training in pharmacotherapy in undergraduate curricula

The quality of basic training in pharmacotherapy for undergraduate medical and paramedical students can significantly influence future prescribing. Rational pharmacotherapy training, linked to clinical guidelines and essential medicines lists, can help to establish good prescribing habits. Training is more successful if it is problem-based, concentrates on common clinical conditions, takes into account students' knowledge, attitudes and skills, and is targeted to the students' future prescribing requirements. The *Guide to Good Prescribing* describes the problem-based approach, which has been adopted in a number of medical schools.

## 6. Continuing in-service medical education as a licensure requirement

Continuing in-service medical education (CME) is a requirement for licensure of health professionals in many industrialized countries. In many developing countries opportunities for CME are limited and there is also no incentive since it is not required for continued licensure. CME is likely to be more effective if it is problem-based, targeted, involves professional societies, universities and the ministry of health, and is face-to-face. Printed materials that are unaccompanied by face-to-face interventions, have been found to be ineffective in changing prescribing behaviour. CME need not be limited only to professional medical or paramedical personnel, but may also include people in the informal sector such as medicine retailers. Often CME activities are heavily dependent on the support of pharmaceutical companies, as public funds are insufficient. This type of CME may not be unbiased. Governments should therefore support efforts by university departments and national professional associations to give independent CME.

## 7. Supervision, audit and feedback

Supervision is essential to ensure good quality of care. Supervision that is supportive, educational and face-to-face, will be more effective and better accepted by prescribers than simple inspection and punishment. Effective forms of supervision include prescription audit and feedback, peer review and group processes. Prescription audit and feedback consists of analysing prescription appropriateness and then giving feedback. Prescribers may be told how their prescribing compares with accepted guidelines or with that of their peers. Involving peers in audit and feedback (peer review) is particularly effective. In hospitals, such audit and feedback is known as drug use evaluation. Group process approaches amongst prescribers consist of health professionals themselves identifying a medicine use problem and developing, implementing and evaluating a strategy to correct the problem. This process needs facilitation by a moderator or supervisor. Community case management is a special type of supervised group process involving community members in treating patients.

## 8. Independent medicine information

Often, the only information about medicines that practitioners receive is provided by the pharmaceutical industry and may be biased. Provision of independent (unbiased) information is therefore essential. Drug information centres (DICs) and drug bulletins are two useful ways to disseminate such information. Both may be run by government or a university teaching hospital or a nongovernmental organization, under the supervision of a trained health professional. Whoever runs the DIC or bulletin must (1) be independent of outside



influences and disclose any financial or other conflict of interest, and (2) use evidence-based medicine and transparent deduction for all recommendations made. The *WHO Model Formulary* provides independent information on all medicines in the WHO Model List of Essential Medicines.

## 9. Public education about medicines

Without sufficient knowledge about the risks and benefits of using medicines and when and how to use them, people will often not get the expected clinical outcomes and may suffer adverse effects. This is true for prescribed medicines, as well as medicines used without the advice of health professionals. Governments have a responsibility to ensure both the quality of medicines and the quality of the information about medicines available to consumers. This will require:

- Ensuring that over-the-counter medicines are sold with adequate labelling and instructions that are accurate, legible, and easily understood by laypersons. The information should include the medicine name, indications, contra-indications, dosages, drug interactions, and warnings concerning unsafe use or storage.
- Monitoring and regulating advertising, which may adversely influence consumers as well as prescribers, and which may occur through television, radio, newspapers and the internet.
- Running targeted public education campaigns, which take into account cultural beliefs and the influence of social factors. Education about the use of medicines may be introduced into the health education component of school curricula or into adult education programmes, such as literacy courses.

## 10. Avoidance of perverse financial incentives

Financial incentives may strongly promote rational or irrational use. Examples include:

- Prescribers who earn money from the sale of medicines (e.g. dispensing doctors), prescribe more medicines, and more expensive medicines, than prescribers who do not; therefore the health system should be organized so that prescribers do not dispense or sell medicines.
- Flat prescription fees, covering all medicines in whatever quantities within one prescription, lead to over-prescription; therefore user charges should be made per medicine, not per prescription.
- Dispensing fees, calculated as a percentage of the cost of the medicines, encourage the sale of more expensive medicines; therefore a flat dispensing fee irrespective of the price of the medicine is preferable. Although it may lead to price increases for cheaper medicines, it lowers the price of higher cost medicines.

- Patients prefer medicines that are free or reimbursed. If only essential medicines are provided free by government or reimbursed through insurance, patients will pressure prescribers to prescribe only essential medicines. If medicines are only reimbursed when the prescription conforms to clinical guidelines, there may be an even stronger pressure on prescribers to prescribe rationally.

## 11. Appropriate and enforced regulation

Regulation of the activities of all actors involved in the use of medicines is critical to ensuring rational use (Box 6). If regulations are to have any effect, they must be enforced, and the regulatory authority must be sufficiently funded and backed up by the judiciary.

### Box 6 Regulatory measures to support rational use

- registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market and that unsafe non-efficacious medicines are banned;
- limiting prescription of medicines by level of prescriber; this includes limiting certain medicines to being available only with a prescription and not available over-the-counter;
- setting educational standards for health professionals and developing and enforcing codes of conduct; this requires the cooperation of the professional societies and universities;
- licensing of health professionals – doctors, nurses, paramedics – to ensure that all practitioners have the necessary competence with regard to diagnosis, prescribing and dispensing;
- licensing of medicine outlets – retail shops, wholesalers – to ensure that all supply outlets maintain the necessary stocking and dispensing standards;
- monitoring and regulating medicine promotion to ensure that it is ethical and unbiased. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. WHO's ethical guidelines (1988) may be used as a basis for developing control measures.

## 12. Sufficient government expenditure to ensure availability of medicines and staff

Lack of essential medicines leads to the use of non-essential medicines, and lack of appropriately trained personnel leads to irrational prescribing by untrained personnel. Furthermore, without sufficient competent personnel and finances, it is impossible to carry out any of the core components of a national programme to promote rational use of medicines. Poor clinical outcome, needless suffering and economic waste are sufficient reasons for large government investment.



Governments are responsible for investing the necessary funds to ensure that all public health facilities have sufficient, appropriately trained health professionals and enough essential medicines at affordable prices for all the population, with specific provisions for the poor and disadvantaged. Achieving these will require limiting government procurement and supply to essential medicines only, and investing in adequate training, supervision and health staff salaries.

**Monitoring medicine use and using the collected information to develop, implement and evaluate strategies to change inappropriate medicine use behaviour are fundamental to any national programme to promote rational use of medicines. A mandated multi-disciplinary national body to coordinate all activities and sufficient government funding are critical to success.**

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The documents marked with \* are also available on <http://www.who.int/medicines/>

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