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CHAPTER 29

Promoting rational prescribing

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SUMMARY

The ultimate goals of studying and intervening in medicine use practices include—

- Improving quality of health care through effective and safe use of pharmaceuticals
- Improving cost-effectiveness of health care through economic and efficient use of pharmaceuticals

Before attempting an intervention to change medicine use practices, underlying reasons for problem behaviors must be understood. Interdisciplinary collaboration involving health and social science experts is of utmost importance in this task.

Strategies to improve rational prescribing can be characterized as targeted or system-oriented approaches. Targeted approaches include educational and managerial interventions, while system approaches include economic and regulatory interventions.

Educational strategies seek to inform or persuade and include—

- Training of prescribers (formal and continuing education, supervisory visits, group lectures, seminars, workshops)
- Printed materials (clinical literature and newsletters, treatment guidelines, medicine formularies, flyers, leaflets)
- Approaches based on face-to-face contact (educational outreach, patient education, influencing opinion leaders)

Managerial strategies seek to guide practice and include—

- Supervision, monitoring, and feedback
- Approaches to selection, procurement, and distribution (limited procurement lists, drug use review and

feedback, hospital and regional drug and therapeutics committees, cost information)

- Prescribing and dispensing approaches (structured medication order forms, standard diagnostic and treatment guidelines, course-of-therapy packaging)

Economic strategies seek to promote positive financial incentives while removing perverse incentives for prescribers. These economic strategies include changes in how health care providers are reimbursed; disallowing medicine sales by prescribers removes the financial incentive for overprescribing.

Regulatory strategies seek to use laws and regulations to influence prescribing through restrictions and requirements. They include—

- Pharmaceutical registration
- Limited medicine lists
- Prescribing restrictions
- Dispensing restrictions

An intervention should be focused on a specific problem behavior and targeted at the facilities or people that have the greatest need for improvement. Interventions should be carefully selected with regard to efficacy, feasibility for implementation in the existing system, and cost. Before wide-scale implementation of an intervention, evaluating its effectiveness and cost in the existing health setting is imperative.

Programs to ensure rational use of medicines should be an integral part of health and medical care services. The responsibility for promoting rational use of medicines belongs to decision makers, administrators, and clinicians as well as health care professionals, consumers, educators, and pharmaceutical companies.

29.1 Improving prescribing: a conceptual framework

Inappropriate prescribing is a manifestation of irrational medicine use that occurs when medicines are not prescribed in accordance with guidelines based on scientific evidence to ensure safe, effective, and economic use. The underlying reasons for such practices on the part of prescribers and consumers need to be understood and addressed in any intervention.

Qualitative methods of research are useful in understanding why inappropriate prescribing behaviors occur (see Chapter 28). This approach makes it possible to design interventions relevant to a particular situation that form part of a

systematic cycle directed at improving the quality of patient care. Most strategies for improving prescribing practices are mutually supportive.

The first step in developing a strategy to address irrational prescribing practices must be to consider who the prescribers are. In most developed countries, prescribers are doctors or other paramedical personnel who are highly trained. In many places, however, prescribers may include nurses, paramedics, and drug sellers. The latter, in particular, may have received little or no training in the use of medicines. A comprehensive policy should try to influence prescribing behavior at all levels of the system, focusing on the priority problems and targeting the prescribers involved. Box 29-1 has a list of core strategies to promote the rational use of medicines.

Box 29-1**Core strategies to promote rational use of medicines**

Establishing a mandated multidisciplinary national body to coordinate medicine-use policies. Ensuring rational medicine use requires many activities that need coordination among many stakeholders. Therefore, a national body is necessary to coordinate strategies and policy at the national level, in both the public and private sectors. This body should involve government, health professions, academia, pharmaceutical industry, consumer groups, and the national regulatory authority.

Implementing procedures for developing, using, and revising standard treatment guidelines (STGs). Standard treatment guidelines (or clinical guidelines or prescribing policies) are systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions. STGs are made more credible through the use of evidence-based recommendations. They vary in complexity from simple algorithms to detailed protocols on diagnostic criteria, patient advice, and costs.

Implementing procedures for developing and revising an essential medicines list (or hospital formulary) based on treatments of choice. An essential medicines list makes pharmaceutical management easier at all levels: procurement, storage, and distribution are easier with fewer items, and prescribing and dispensing are easier for professionals. A national essential medicines list should be based on national STGs, and both should be revised regularly.

Establishing a drug and therapeutics committee in districts and hospitals, with defined responsibilities for monitoring and promoting rational use of medicines. This committee, also called a pharmacy and therapeutics committee, is responsible for ensuring the safe and effective use of medicines in the facility or area under its jurisdiction. The committee should operate independently, and members should represent all the major medical specialties and the administration. The primary tasks of the committee are to develop and revise institutional STGs (based on national guidelines) and to maintain an institutional essential medicines list or formulary.

Using problem-based training in pharmacotherapy based on national STGs in undergraduate curricula. The quality of basic pharmacotherapy training for undergraduate medical and paramedical students can significantly influence future prescribing habits. Training is most successful when it is problem based, concentrates on common conditions, takes into account

students' level of knowledge, and is targeted to their future prescribing requirements. In most settings, rather than focusing on basic science, problem-solving skills should be promoted and interdisciplinary problem-based learning encouraged. If the existing focus is not on problem-based training in pharmacotherapeutics, national consultative workshops may help build awareness of the value of the approach.

Continuing in-service medical education as a licensure requirement and targeted educational programs by professional societies, universities, and the government. Unlike in developed countries, opportunities for continuing medical education in less developed countries are limited because continuing education is not required for licensure. Governments should support efforts by university departments and national professional associations to offer independent, unbiased continuing medical education courses to health professionals, including medicine dispensers. The most effective in-service training is likely to be problem based, repeated on multiple occasions, focused on practical skills, and linked to STGs.

Developing a strategic approach to improve prescribing in the private sector through regulation and collaborations with professional associations. Most efforts in improving use of medicines have focused on the public sector, but the private sector often provides greater access to pharmaceuticals. Changing practices in the private sector requires an understanding of the motivations of private prescribers. A range of strategies should be considered to improve rational medicine use, including licensing regulations with appropriate enforcement, accreditation and continuing education through professional associations, and financial incentives.

Monitoring, supervision, and using group processes to promote rational medicine use. Supervision that is supportive, educational, and face-to-face will be more effective with prescribers than inspection and punishment. Effective forms of supervision include prescription audit and feedback, peer review, and group processes of self-identifying medicine-use problems and solutions in a group of prescribing professionals. Group process interventions with practitioners and patients to improve prescribing practices have been effectively used to change prescribing behavior.

Training pharmacists and drug sellers to offer useful advice to consumers, and supplying independent medicine information. In many countries with shortages of

Box 29-1**Core strategies to promote rational use of medicines (continued)**

trained health professionals, pharmacies and medicine shops are a major source of information for consumers. Interventions have shown that the skills of untrained prescribers and dispensers can be upgraded. In addition, the only information about medicines that prescribers receive is from the pharmaceutical industry, which may be biased. Pharmaceutical information centers and drug bulletins are two useful ways to disseminate independent, unbiased information. They may be administered by the government, a university teaching hospital, or a nongovernmental organization, under the supervision of a health professional.

Encouraging involvement of consumer organizations, and devoting government resources to public education about medicines. Governments have a responsibility to ensure the quality of information about medicines available to consumers. Without sufficient knowledge about the risks and benefits of medicine use, people will often fail to achieve their expected clinical outcomes and may even suffer adverse effects. Regulation of consumer advertising and promotion by pharmaceutical companies, as well as public education activities led by

consumer organizations, may influence medicine use by the public.

Avoiding perverse financial incentives. Financial incentives may strongly promote rational or irrational use of medicines. Examples include the ability of prescribers to earn money from medicine sales; flat prescription fees that lead to overprescription; and dispensing fees that are calculated as a percentage of the cost of medicines, which encourages the sale of expensive medicines.

Ensuring sufficient government expenditure and enforced regulation. Appropriate regulation of the activities of all those involved in the use of medicines is critical to ensure rational medicine use. For regulations to be effective, they must be enforced, and the regulatory authority must be sufficiently funded and backed by the government's judiciary. Without sufficient competent personnel and finances, none of the core components of a national program to promote rational use of medicines can be carried out.

Sources: WHO/EDM 2002; Laing et al. 2001.

The next step in improving prescribing practices is to identify the nature and scope of the problem. As described in Chapter 28, this step may be accomplished by using a number of methods, such as carrying out an indicator-based prescription survey or a drug use review (DUR); looking at aggregate medicine consumption data using such tools as ABC and VEN (vital, essential, nonessential) analysis or therapeutic classification; measuring defined daily dose (DDD) consumption; collecting adverse drug reaction (ADR) data; measuring infection rates; analyzing pharmaceutical management data; or observing a particular practice or event.

If the investigation confirms that the prescribing practices are a significant problem in the health system or facility, the underlying causes should be clearly defined in step three. This process is also described in Chapter 28.

The fourth step is to plan a package of interventions focused on specific problems and targeting specific actors: prescriber, patient, and community. Inputs from the target audience are important when formulating and implementing the package of interventions, because different sets of interventions may be applied to address inappropriate prescribing practices and prevent them from recurring. Each set of interventions must be monitored and evaluated to assess its impact. Evaluation of impact needs to be directed at the

specific prescribing pattern or prescribing behavior that the intervention is designed to improve. Clearly ineffective interventions can be dropped, and those that are partially effective can be revised to improve their efficacy. Effective interventions can then be incorporated and, if required, replicated on a wider scale in the health care system; therefore, producing timely monitoring data on the impact of the interventions is key. The complete cycle of medicine-use interventions is described in Chapter 28, and the required actions for each step are depicted in Figure 28-1.

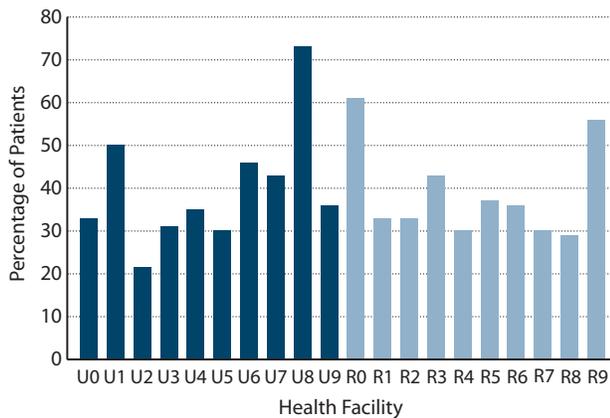
29.2 Characterizing interventions

Interventions to improve prescribing in clinical practice can be characterized as either targeted directly toward the prescriber, such as education and managerial or administrative tactics, or system-directed, which emphasize policies, regulation, and economic strategies.

Targeted interventions

In *educational* interventions, prescribers are persuaded, by information or knowledge provided to them. These strategies may be implemented in the form of face-to-face

Figure 29-1 Facility-specific percentage of patients receiving antibiotics in Tanzania



Source: WHO/DAP 1993.

education or training, seminars, and provision of written materials. A single-shot educational intervention without follow-up and monitoring is usually least effective, and the effect—if any—is not sustainable.

In *managerial* interventions, prescribers are guided in the decision-making process, through limiting lists for routine procurements, drug use review and feedback, supervision and monitoring, provision of treatment guidelines, and monitoring of prescribers' use of the guidelines.

System-oriented interventions

In *economic* interventions, prescribers are motivated by the promotion of positive financial incentives and the removal of perverse incentives. These economic strategies include changes in how health care providers are reimbursed, such as the institution of private or public patient-centered insurance plans, capitation-based reimbursement, and quality-based performance contracts. In addition, disallowing medicine sales by prescribers removes the financial incentive for overprescribing.

In *regulatory* interventions, prescribers are forced to restrict the decision-making process in prescribing. These strategies include policies encouraging use of generic pharmaceutical products, limitations on prescribing and dispensing, and withdrawal of questionable medicines from the market. These strong strategies are often unpopular with prescribers or consumers and may also bring about unintended effects, such as a change to other inappropriate prescribing practices.

A wide range of interventions is available to address irrational prescribing. These can be categorized as preventive or curative. Preventive approaches ensure that the prescriber starts off prescribing in an appropriate manner. Curative interventions attempt to reverse a pattern of irra-

tional prescribing. As is often true in medicine, prevention is often much easier than curing when it comes to prescribing problems.

Many interventions have a limited effect over time, and although temporary improvement may occur, prescribers may revert to their previous behavior if the intervention is not followed up. When interventions of different types are combined, the effect is likely to be synergistically increased; therefore, interventions should always be considered in sets.

Irrational prescribing is a universal problem. Considerable experience indicates which interventions are effective in high-income countries and in particular public health care systems, but those interventions cannot always be transferred to other settings. Therefore, it is important that a range of interventions be considered. Those that succeed in one country may not succeed elsewhere. Health care organizations, local communication channels, level of education, and other factors all influence the effectiveness of specific strategies in different environments.

29.3 Focus and target of interventions

For an intervention to be effective, it needs to be focused to achieve a specific goal and targeted at those prescribers who have a particular prescribing problem. For example, in a training intervention, a general lecture on pharmacology is unlikely to be effective in changing prescribing. A clearly focused presentation on the correct treatment of simple diarrhea—encouraging oral rehydration solution and discouraging antidiarrheals, antibiotics, and injections—or on the treatment of acute respiratory infections, and clearly specifying when an antibiotic is necessary is far more likely to achieve the desired results.

Quantitative surveys frequently find considerable variation among facilities. For example, a survey in Tanzania found that antibiotic use varied between 20 and 70 percent (Figure 29-1). Most facilities fell within the range of 20 to 40 percent. Only three facilities showed over 50 percent antibiotic use, and seven had over 40 percent use. These high-users would be the facilities to be targeted for any intervention. Both the potential impact and the cost-effectiveness of the intervention would be greater in these facilities.

29.4 Educational interventions

Educational interventions are the most common and are often disappointing in their sustainability and limited effect. Although the basic training of prescribers is essential for promoting rational use of medicines, educational components often need to be combined with managerial and regulatory interventions. Prescribers make many

decisions concerning medicine use, and their training occurs in formal and informal ways throughout their careers. See Chapter 52 for discussion of various types of training programs.

Training of prescribers

Formal education (preservice). The training of doctors and paramedical staff differs in content and approach. Doctors control the use of scarce pharmaceutical resources not only through their own prescribing practices but also through their influence as instructors, supervisors, and trendsetters for the often larger force of paramedics. Thus, sound training of doctors in good prescribing practices can have a significant effect on the rational use of medicines.

The curricula of most health personnel training institutions contain segments that deal with medicine treatment. Because prescribing is often not taught in these curricula, students often learn prescribing from what they see during clinical “model” practices. For doctors and paramedical personnel, training on pharmaceuticals and how to use them should cover—

Basic pharmacology: Principal mechanisms of pharmaceutical action, metabolism, absorption, distribution, and elimination. In learning basic pharmacology, students gain knowledge about interactions between medicines and living systems at the theoretical level.

Clinical pharmacology: Study of the various classes of medicines with regard to clinical efficacy, risks, clinical pharmacokinetics, drug-drug interactions, drug-disease interactions, drug-genetics interactions, the concept of clinical trials, and pharmacoeconomics. In clinical pharmacology training, students learn how to use medicines properly and rationally at a more practical level.

Therapeutics: The use of pharmaceuticals to treat disease.

Therapeutics is the practical application of basic and clinical pharmacology. It has traditionally received less attention than pharmacology in prescribers’ formal education.

A number of educational programs have been developed to improve the teaching of pharmacotherapy. The World Health Organization (WHO) developed a manual (WHO/DAP 1994) for undergraduate medical students on the principles of rational prescribing, intended for use in developed and developing countries. The *Teacher’s Guide to Good Prescribing* (Hogerzeil 2001) is its companion volume for university teachers. The *Guide to Good Prescribing* presents students with a normative model for pharmacotherapeutic reasoning. First, the students are taught to generate a standard pharmacotherapeutic approach to common disorders, resulting in a set of first-choice medicines, called “P[ersonal]-drugs.” In the course of developing their P-drugs, the students are taught to consult existing national

and international treatment guidelines, national formularies, pharmacology textbooks, and any other source of medicine information. Then they are shown how to apply this set of P-drugs to specific patient problems using a six-step problem-solving routine: (1) define the patient problem; (2) specify the therapeutic objective; (3) verify the suitability of your P-drug; (4) write a prescription; (5) inform and instruct the patient; and (6) monitor and/or stop the treatment.

The rationale behind this approach is that at some time in the course of their studies or early in their careers, medical students develop a set of medications that they will use regularly from then on. However, this choice is often made on irrational grounds, such as the prescribing behavior of their clinical teachers or peers, without really considering the alternatives or knowing how to choose among them. The manual not only helps students select P-drugs in a rational way but also teaches them to consult, understand, and use existing treatment guidelines in an intelligent way. For example, it teaches the students how to verify, for each individual patient, whether their P-drug is the most appropriate choice in this individual case and, if necessary, how to adapt the medicine, dosage form, dosage schedule, or duration of treatment. The training has been field-tested and evaluated in a number of medical schools, with a proven effect on the students (Country Study 29-1).

In addition to the safety and efficacy of a medicine, other important considerations for students include the use of generic names and attention to cost; supply logistics; and the effects of transportation, storage, and medicine quality on the availability and stability of medicines.

Experience shows that students usually learn about prescribing from their clinical tutors. The value of medical faculty trained in clinical pharmacology should not be underestimated. However, the task of incorporating and implementing the teaching of rational medicine use into the curricula is not solely the responsibility of clinical pharmacologists. It should become the concern and responsibility of staff from various disciplines involved in training, particularly clinicians.

In addition to giving increased attention to clinical pharmacology, medical faculties should increase their students’ awareness of the importance of pursuing medicine information throughout their clinical training and practice. As part of their training in clinical pharmacology and therapeutics in Yogyakarta, Indonesia, medical students learn to critically assess medicine information and advertisements as well as reports of clinical trials published in a local medical journal. This training has proved helpful in improving their knowledge, skills, and critical attitudes.

In the public sector, paramedical personnel are commonly the first point of contact for patients in most rural areas and in some health facilities in urban areas. Improper use of medicines by these health workers can be dangerous and wasteful, whereas prompt and appropriate use of

Country Study 29-1 Impact of a short interactive training course in pharmacotherapy

The impact of a short interactive training course in pharmacotherapy, using the *Guide to Good Prescribing*, was measured in a controlled study with 217 undergraduate medical students in Groningen, Netherlands; Kathmandu, Nepal; Lagos, Nigeria; Newcastle, Australia; New Delhi, India; San Francisco, United States; and Yogyakarta, Indonesia. The course was composed of four half-day small group seminars combined with meetings after hours and group work. Students were taught how to develop their own P-lists of drugs for common conditions and how to choose drugs from their P-lists. In addition, they were taught how to write prescriptions and how to educate their patients.

The impact of the training course was measured by three tests, each containing both open and structured questions on the medicine treatment of pain, using patient examples. Tests were taken before the training, immediately after, and six months later.

After the course, students from the study group performed significantly better in all patient problems presented than the control students, who had received “normal” teaching. This finding applied to all old and new patient problems in the tests and to all six steps of the problem-solving routine. The students not only remembered how to solve a previously discussed patient problem (retention effect) but also could apply that knowledge to other patient problems (transfer effect). At all seven universities, both retention and transfer effects were maintained for at least six months after the training session. Students in the course were able to choose appropriate medicines to use, write correct prescriptions, and better counsel patients.

Source: WHO/DAP 1994.

medicines can save lives and prevent patients from becoming more debilitated. Paramedics and nurses in a number of developing countries are not legally allowed to prescribe. In reality, however, they see and prescribe for the majority of patients arriving at health centers. Where this practice is technically illegal, developing formal continuing education for paramedics can be difficult.

Many countries find that limiting the medicines paramedics can prescribe to a specific list and providing a pocket medicine reference manual and standard treatment guideline based on that list can be a useful tool (see Chapter 17). Medical workers are encouraged to use the manual rather than depend on recall for selecting medicines and medicine dosages for all but the most frequently treated conditions. Figure 29-2 illustrates the content and format of a standard treatment guideline used in Ghana. These workers do, however, need to be taught to diagnose so that they can use the appropriate treatment guidelines. Formal training in pharmacology and therapeutics provides a sound basis for paramedics to prescribe standard medicines and to understand the uses of new products that are added to their medicine lists.

In the private sector, prescribers, especially in resource-limited countries, may not be trained health practitioners at all, but instead employees or owners of informal medicine outlets where prescribing and dispensing may occur at the same time. Although countries may regulate the prescribing and dispensing practices or the level of education required in such outlets, clerks still do not often have knowledge or

training in the rational use of medicines (Rutta et al. 2009). This group is challenging to address through traditional interventions, although they are increasingly being recognized as playing probably the major role in medicine usage in resource-poor settings.

Continuing education (in-service). After their formal training is completed, prescribers develop their own prescribing practices, which are then influenced by whatever medicine information and commercial pressure they receive, the diagnostic facilities available to them, the expectations of the community, and medicine availability. Continuing education provides an opportunity for prescribers to keep informed on changes in the use of medicines.

In some areas, local associations of physicians or auxiliary medical workers have identified their need for continued training in therapeutics and have participated in seminars and other medical meetings designed to keep them up-to-date with current medicine information. Government health programs sometimes sponsor presentations for health personnel. In many countries, however, continuing education is not available for most prescribers, including those in teaching hospitals. Even when it does occur, it is often dominated by promotional messages from pharmaceutical companies that sponsor the events and are necessarily biased in favor of their products. Most prescribers are not trained to evaluate such information critically and tend to accept whatever they are told. They must also deal with the enticement of gifts and incentives proffered by pharmaceutical company representatives.

Figure 29-2 Excerpt from a Ghanaian standard treatment guidelines manual

Meningitis
<p>Pharmacological Treatment (Evidence rating: A)</p> <p>ADULTS: Antibiotic treatment should be given for a total of 14 days. All treatment should be intravenous initially for a minimum of 7 days and should be started without delay. This may be subsequently changed to oral therapy with significant clinical improvement. Benzylpenicillin, IV, 4 MU 4 hourly (subsequently amoxicilline, oral, 500 mg 8 hourly for remainder of treatment course)</p> <p>PLUS Chloramphenicol, IV, 1 g 6 hourly (subsequently chloramphenicol, oral, 500 mg 6 hourly for remainder of treatment course)</p> <p>Alternatively, for all types of bacterial meningitis, ceftriaxone may be administered. Ceftriaxone, IV, 2–4 g daily for 7 days (subsequently amoxicilline, oral, 500 mg 8 hourly for remainder of treatment course)</p> <hr/> <p>CHILDREN: All treatment should be intravenous for a minimum of 10 days in children, and should be started without delay. Benzylpenicillin, IV, 0.2 MU/kg body weight 6 hourly</p> <p>PLUS Chloramphenicol, IV, 25 mg/kg body weight 6 hourly</p> <p>Alternatively, for all types of bacterial meningitis, ceftriaxone may be administered. Ceftriaxone, IV, 50–60 mg/kg body weight once daily for 7 days</p> <hr/> <p>If cerebral spinal meningitis is suspected give benzylpenicillin, IV: ADULTS: 4 MU 4 hourly for 14 days CHILDREN: 0.2 MU/kg body weight 6 hourly for 14 days</p> <p>PLUS Chloramphenicol, IV: ADULTS: 1 g 6 hourly for 14 days CHILDREN: 25 mg/kg body weight 6 hourly for 14 days</p> <hr/> <p>Prophylaxis for cerebrospinal meningitis</p> <p>Prophylactic treatment is recommended for patients 2 days prior to discharge and also for their close contacts. Ciprofloxacin, oral: ADULTS: 500 mg as a single dose (<i>avoid in pregnancy</i>) CHILDREN: 5–12 years: 250 mg as a single dose</p> <p>OR Ceftriaxone, IM: ADULTS: 250 mg as a single dose CHILDREN: > 12 years: 125 mg as a single dose</p>

Source: Ministry of Health, Ghana National Drugs Programme, 2004.

Like their physician counterparts, paramedical staff members tend to become more routine in their prescribing habits after they have been practicing for several years, which may lead to illogical prescribing. Regular teaching and monitoring by senior paramedical staff members or medical officers, with attention to the medical workers' prescribing habits, are essential.

Rational prescribing among paramedical staff can be promoted by—

- Requiring them to keep a brief listing of patients seen and diagnoses made
- Devising and making available a limited list of specific medicines with which paramedics must be familiar
- Ensuring regular monitoring and supervision, with frequent on-site refresher training

Supervisory visits. Personal supervision and case reviews are often difficult or impossible to perform. Therefore, in many programs, if paramedical staff keep a list of patients seen, with diagnoses and treatments prescribed, their prescribing habits can be quickly reviewed, and suggestions for improved medicine therapy can be made. In-service refresher courses and discussion of cases by paramedical personnel can be organized locally, using the health center as a base and the visiting doctor as educator. In this way, supervision can be educational and supportive, not punitive.

Group lectures, seminars, and workshops. Lectures, seminars, or workshops given to a relatively large number of people are the most widely practiced activities for continuing education. They may be effective in improving prescribers' knowledge but are likely to be ineffective in changing prescribing behavior. When such seminars are focused on

specific prescribing behavior, however, improvements can occur.

Printed materials

Printed materials carrying new information that is immediately relevant to the prescriber may help bring about a change in prescriber behavior. In general, however, printed materials may increase prescriber knowledge but rarely affect actual performance when used alone.

Printed materials are most useful when they are used in combination with other intervention strategies, especially those that involve active interaction between the party providing and the party receiving the information.

Clinical literature and newsletters. Many prescribers claim that they obtain information about therapeutics from medical journals. Unfortunately, many journals report research results that may not be directly applicable to daily practice. In addition, journals may overwhelm the prescriber with more information than can be digested, making it difficult to decide about the best prescribing choices.

Medical newsletters, such as the *Medical Letter* (www.medicalletter.com) or the *Drug and Therapeutics Bulletin* (www.dtb.org.uk), focus on a limited number of topics and provide summarized information in a form that is more immediately useful to the prescriber. Such information often compares and contrasts clinical choices and costs and provides recommendations about “optimal” treatments.

Treatment guidelines and medicine formularies. In many countries where an essential medicines list has been developed, treatment norms or guidelines have also been published (see Chapter 17). Such manuals are relatively inexpensive to produce and have several advantages over material from the pharmaceutical industry and sources from outside the country. They are not biased by commercial interest; include only those preparations available in the country; recommend doses that are appropriate for the local population; and provide special warnings that are relevant to local genetic, environmental, and epidemiological factors.

Consulting physicians and medical school faculty may oppose the preparation and distribution of reference manuals, fearing that they will lead to “cookbook” medicine. This fear seems to be largely unfounded, and physicians in the most prestigious medical schools in developed and developing countries are writing, using, and promoting such handbooks.

Illustrated materials (flyers, posters, and leaflets). Commercial pharmaceutical companies frequently use short, colorful, attractively printed materials to convey promotional messages. These materials usually contain only one or two ideas that are repeated in different ways, using text, drawings, tables, and charts. This type of mate-

rial is often used in conjunction with face-to-face educational outreach or focused meetings.

Approaches based on face-to-face contact

The most effective means of changing behavior has consistently been face-to-face contact. The pharmaceutical industry uses this method through its representatives because it works!

Educational outreach. One method found to be effective in improving prescribing practices after completion of training is targeted outreach education to individuals or small groups of prescribers. The efficacy of this approach has been demonstrated by the marketing done by pharmaceutical companies, whose salespeople promote their products on a one-to-one basis to carefully targeted prescribers.

In this method, principles of communications theory and behavioral science are combined with conventional educational techniques to provide information to physicians or other prescribers about medicines that are often used inappropriately and to promote their replacement with more therapeutic alternatives. Trained educators or opinion leaders can provide this contact, and it can be incorporated into the existing supervision system of health care services.

Principles of educational outreach include—

- Focusing on specific problems and targeting the audience of prescribers
- Addressing the underlying causes of the prescribing problems: misleading beliefs, poor knowledge, false perceptions
- Allowing an interactive discussion and involving the targeted audience
- Using concise and authoritative materials based on credible scientific information
- Giving sufficient attention to solving practical problems encountered by prescribers in real settings

The face-to-face approach can be successful, especially when combined with other interventions. A review of thirteen studies on the prescribing practices of health professionals found that a personal visit by a trained person to a health care provider in his or her own setting resulted in positive prescribing practice changes in every case (Thomson et al. 2000). In all instances, the face-to-face interventions consisted of several components, including written materials and feedback sessions. Face-to-face approaches have worked with non-health care professionals also. In Kenya, a vendor-to-vendor outreach program had success in improving malaria knowledge, changing prescribing practices in private medicine shops and kiosks (Tavrow et al. 2003). This outreach program also included giving dispensers job aids to help them remember the appropriate medicines and dosages to recommend.

Patient education. Patient or consumer education plays an important role in promoting rational use of medicines. Inappropriate prescribing patterns may derive from the demands or misconceptions of patients, although such demands are often exaggerated by prescribers to justify their prescribing habits.

One way to educate patients about the rational use of medicines is through individual communication during the contact between prescriber and patient. This communication often cannot take place, however, because of time constraints and a heavy patient load. In health facilities in developing countries, the average patient contact time is often only one to three minutes—too short for effective communication. Another reason may be the prescriber’s unwillingness to communicate with patients, or a lack of skill or interest in doing so. Prescribers are often not adequately trained in patient communication or are not sensitive to its importance.

Consumer education is carried out in many countries through mass campaigns by radio, television, or pamphlets and other printed materials (see Chapter 33).

Influencing opinion leaders

The attempt to train students in good prescribing practices can be frustrated by the environment in which they learn. For example, if a physician refers to medicines by their brand names during clinical training, the students will copy this practice and any other poor prescribing habits the physician may exhibit. Young doctors who have to prescribe according to the wishes of their senior colleagues can also pick up poor prescribing habits. One way of dealing with this situation is to identify the opinion leaders who influence the prescribing patterns of students and doctors in the establishment. Improving the prescribing practices of those leaders will indirectly influence the practices of the younger doctors and students.

29.5 Managerial interventions

Managerial interventions frequently require considerable effort to initiate and maintain. However, they can produce a sustained effect with small risk of adverse or unexpected consequences.

Monitoring, supervision, and feedback

Monitoring and supervision that are educational, conducted in person, and supportive—not punitive—will be more effective and better accepted by prescribers. Effective methods of supervision include prescription audit and feedback. Prescribers may be told how their prescribing compares with accepted guidelines or with that of their peers.

Box 29-2 Responsibilities of a drug and therapeutics committee related to rational prescribing

- Developing, adapting, or adopting clinical guidelines for the health institution or district
- Selecting cost-effective and safe medicines (for example, hospital or district medicine formulary)
- Implementing and evaluating strategies to improve medicine use (for example, medicine-use evaluation, liaison with antibiotic and infection-control committees)
- Providing ongoing staff education and training
- Controlling access to staff by the pharmaceutical industry and its promotional activities

Source: WHO/EDM 2002.

Involving peers in audits and feedback is particularly effective. Group processes include health professionals identifying a rational use issue and developing, implementing, and evaluating a strategy to correct the problem. This approach is used in the monitoring-training-planning methodology described in Chapter 52. Additional data can be used in behavior monitoring, such as facility-specific postoperative infection rates, morbidity rates, or, where available, local antimicrobial resistance rates.

Differences exist in carrying out monitoring and supervision activities in the public and private pharmaceutical sectors. Drug and therapeutics committees (DTCs) in health facilities and district health teams can serve as a feedback mechanism for rational medicine use in places like hospitals. In fact, governments may encourage hospitals to have DTCs by making it an accreditation requirement (see Box 29-2 for a list of DTC responsibilities).

Monitoring and supervision of prescription habits in the private sector, such as in retail medicine outlets, is difficult. Developing a method for monitoring, prescribing, and dispensing in such outlets remains a priority. The primary method is the use of simulated clients posing as patients with illnesses of public health importance (Madden et al. 1997).

Frequently, a formal inspection mechanism is legally mandated, but prescribing habits are rarely included in that inspection, and even then, resource limitations and a lack of good record keeping in private-sector operations make enforcing such inspection mandates difficult. Innovative public-private partnerships that use franchising and accreditation to improve services in private medicines outlets require rational medicine-use monitoring as part of the business model (see Chapter 32).

Selection, procurement, and distribution

Medicine use can be influenced by aspects of pharmaceutical management such as selection, procurement, and distribution. When the people responsible for these activities are consulted and informed, they are likely to cooperate in supporting rational prescribing.

Limited procurement list. The most common managerial intervention is selecting a limited list of medicines that will be routinely purchased. Other medicines may be made available, but require special approval (see Chapters 16 and 18). Managing a hospital formulary is therefore one of the key tasks of a DTC (see Chapters 16 and 17).

Drug use review and feedback. Drug use review is a tool to identify problems in the medication use process: medication prescribing, dispensing, administration, and monitoring. As problems are identified, strategies are developed and implemented to improve the use of medicines. If actions are successful, the result will be improved patient care and more efficient use of resources.

The approach to developing a program varies, but nine steps are important to follow—

Step 1: Establish responsibility for the DUR process. The DTC (or its equivalent) usually takes responsibility for the DUR program.

Step 2: Establish the scope for each study. A DUR focuses on the areas that show the most potential for improvement. A DUR may study one medication (such as ranitidine), a therapeutic class (H₂ antagonists), or a particular age group or diagnosis (patients older than sixty-five years of age with duodenal ulcers). DUR might focus on one step in the medication-use process, such as prescribing, or include other aspects, such as pharmaceutical product labeling or medicine administration. Pharmacists, nurses, and physicians are a major source of suggestions for focusing DUR studies. Formal mechanisms for identifying problem areas include ADR reporting, medication error reporting, or ABC and VEN analysis (see Chapter 40). DUR usually focuses on medicines or therapies that are high use, high cost, high risk, or problem prone. Table 29-1 is a decision matrix

for selecting DUR studies to undertake. The higher the score, the more likely that this problem should be studied.

Step 3: Establish criteria or indicators, including benchmarks or thresholds. Criteria usually include the following components—

Uses: appropriate indications, treatment of underlying conditions, appropriate treatment of symptoms in treating underlying diseases

Selection: efficacy (comparative), safety, cost (total), duplicative therapy

Dosing: indication-specific dosing (age, diagnosis), indication-specific duration, dosing intervals

Interactions: disease, food, medicine, laboratory

Preparation and dispensing: labeling, dispensing time, stockouts, correct medicine, correct dose, correct dosage form

Administration: patient identification, handwashing, administration technique, documentation (correct patient, medicine, time, dose, and route)

Monitoring: clinical, laboratory

Outcome: therapeutic, safety

Thresholds or benchmarks are established for each indicator to define the expectations or goals for complying with the criteria.

Step 4: Collect and organize data. Data collection forms can be developed based on the criteria and configured into simple yes-or-no or fill-in-the-blank questions (see Figure 29-3). Depending on the complexity of interpretation required, the data collectors may or may not need a medical background. Pharmacists, nurses, or medical records personnel usually carry out data collection for hospital-based DUR studies. In hospitals where computers are used, the data collection may simply require printing a report from the computer databases.

The most common data sources are patient charts. Other sources are dispensing records, medication administration records, and laboratory reports. Focusing on specific indications related to the problem is important; avoid collecting too much data. A cumulative report should

Table 29-1 Selection matrix for drug use review*

Medication/health problem	High use	High cost	High risk	Problem prone	Total score
Paracetamol	1	0	0	0	1
Acute respiratory infections	2	0	1	1	4
Ceftriaxone	1	2	0	0.5	3.5
Warfarin	0.5	0	1	2	3.5
H ₂ antagonists	1	1	0	1	3
Surgical antimicrobial prophylaxis	1	1.5	0.5	1	4

* Each medicine or health problem is rated 0–2 on the basis of the use, risk, cost, and probability of problems. The highest total scores may be targeted for the DUR.

Figure 29-3 Sample form used in drug use review

Date:		Drug: ANTIBIOTIC USE IN SURGICAL PROPHYLAXIS		Data collector's initials:					
		Patient Chart No.							
		Diagnosis							
		Age/Sex/Weight							
		Date Treated							
CRITERIA AND INDICATORS		Threshold	Observed	Yes	No	Yes	No	Yes	No
Justification for medicine being prescribed:				Yes	No	Yes	No	Yes	No
1. Class of surgery: clean contaminated, dirty contaminated, ruptured, or gangrenous		100%							
2. Antibiotic on approved list for surgical prophylaxis		100%							
Process Indicators:				Yes	No	Yes	No	Yes	No
3. Dose given only one time, and not more than 45 min. before incision		100%							
4. Antibiotic administered if surgery is prolonged, 4 or more hours later		100%							
5. Postoperative doses specified for no more than 24 hours		100%							
6. Antibiotic change recommended due to: (a) adverse reaction (b) decreased renal function (c) interaction (d) cost-effectiveness increased (e) documented infection		100%							
7. Nosocomial infection is documented prior to non-surgical prophylaxis use of antibiotic		100%							
Outcome Indicators: None*									

Source: Moore et al. 1997.

* In this case, the DUR focused on adherence to standard treatment guidelines. Outcome indicators that could be measured include postoperative infection rates or adverse drug reactions.

include data from at least thirty patients or at least 5 percent of the expected volume (whichever is greater).

Step 5: Analyze data. The data need to be tabulated and reported in a standard format for comparison with benchmarks.

Step 6: Develop conclusions. The DTC reviews the results of the data analysis and develops conclusions regarding reasons for differences between results and benchmarks.

Step 7: Make recommendations. The DTC recommends actions required to improve knowledge or change behavior. The committee may recommend a more focused study or a focus group to understand the issues more clearly.

Step 8: Take action. Implementation of recommendations must be part of every DUR.

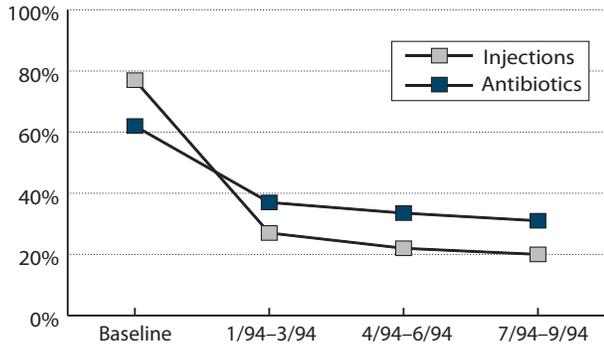
Step 9: Follow up. Did the intervention achieve its objectives? Whenever an intervention is undertaken, a follow-up evaluation should assess the impact of actions taken and determine whether further action is required. Such action may include refining the criteria and thresholds or

reanalyzing the causes of deficiencies and developing a new action plan.

Country Study 29-2 is an example of a DUR in a community hospital in the United States. Country Study 29-3 includes an example of a DUR in Kenya. The Kenya example is a variation of the methodology in Country Study 29-2 and a more appropriate application for that environment.

A self-monitoring program on medication use at health centers, based on the drug use indicators of WHO/International Network for Rational Use of Drugs, has been designed and implemented in a district day-to-day health management system in Gunungkidul district, Indonesia (Figure 29-4). With this program, prescribing indicators at the health centers are collected monthly. Prescribing data, based on these indicators, from different health centers are compared by the district health office and then fed back to the prescribers. The evaluation shows that such monitoring and feedback significantly improved prescribing patterns,

Figure 29-4 Changes in antibiotic and injection use with a self-monitoring program in Indonesia



Source: Gunungkidul District Health Office, Yogyakarta, Indonesia.

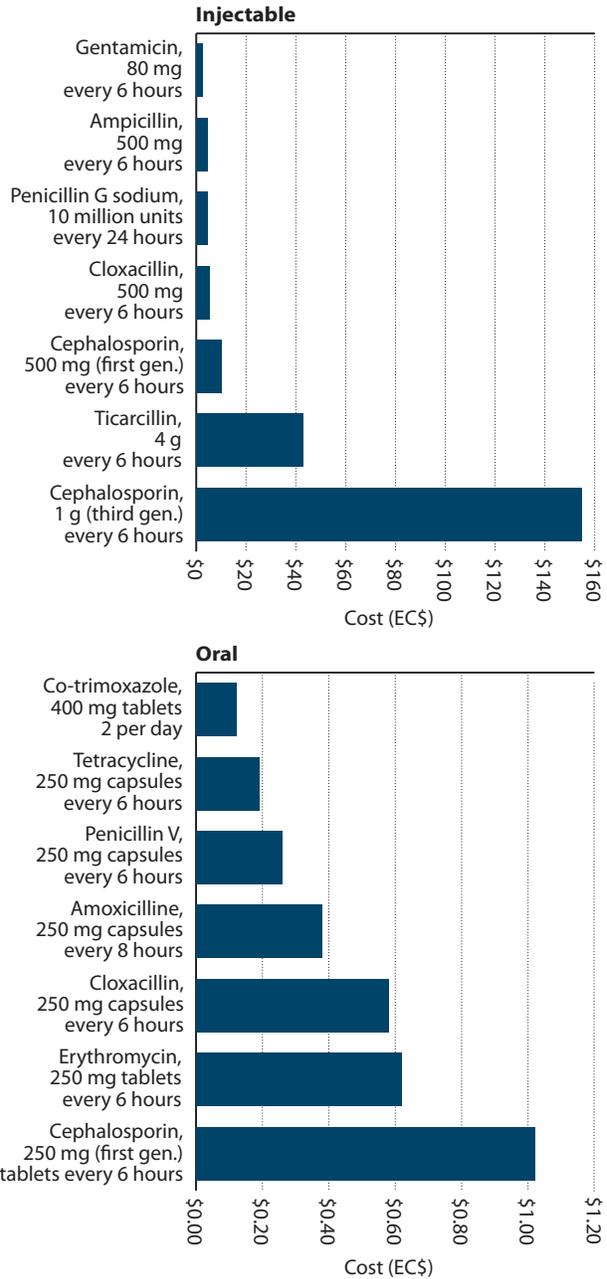
reducing polypharmacy and the use of antibiotics and injectable preparations. The average number of medications per prescription decreased from 4.2 to 3.1, and antibiotic and injection use also declined dramatically. The drug use indicators (WHO/DAP 1993) can themselves be used at the local level for self-audit and feedback.

Hospital and regional drug and therapeutics committees

Drug and therapeutics committees play an important role in improving prescribing practices at the national and regional levels, as well as at the district and institutional levels. Their role has expanded in some settings from selecting medicines for formularies to—

- Reviewing medication requisitions and revising them to fit budget allocations
- Determining which medicines should be made available to each type of health facility (if this determination is not made at the national level)
- Developing standard treatment norms for the common illnesses treated in the area or institution
- Establishing prescribing limitations aimed at controlling irrational medicine use (for example, limiting certain antibiotics to use only under the recommendation of a consultant)
- Limiting the amount dispensed at one time to curb abuse of particular medicines and reduce waste
- Reviewing antibiotic resistance patterns and revising guidelines for antibiotic use
- Stimulating medicine education activities among hospital staff
- Supervising and monitoring rational prescribing and safe medication-dispensing practices
- Developing and supervising an adverse drug event reporting system

Figure 29-5 Comparative daily cost of injectable and oral antibiotics in the eastern Caribbean



Source: Organisation of Eastern Caribbean States, Eastern Caribbean Drug Service 1993.

Cost information

Medication cost is an underappreciated aspect of prescribing. Expensive, newer medicines are frequently used when comparable well-established and cheaper ones are available for the same condition. Several different mechanisms have been used to encourage physicians and paramedical staff to consider cost in their medicine selections. These include

Country Study 29-2 Drug use review at a U.S. hospital

At a small community hospital on the West Coast of the United States, the Pharmacy and Therapeutics (P&T) Committee is responsible for a DUR program that evaluates four to six medicines or medicine therapies per year. One December, the committee received a report from the quality assurance coordinator noting that the rate of postoperative infections for abdominal surgeries was significantly higher than the national average. The pharmacy director informed the committee of his observation that cefoxitin was often used for these patients, a costly and inappropriate choice. The committee decided to undertake a DUR for antibiotic prophylaxis in abdominal surgery wound infection.

The health problem met all indications for a DUR: high use, high cost, high risk, and problem prone. The chief of surgery was a member of the P&T committee. He concurred with the committee that the criteria should be developed from recently published recommendations in the *Medical Letter*, which included medicine selection, dosing, and timing of administration. The accompanying table is a summary of the DUR study. It illustrates the benchmark targets for each indicator; the actual percentage of compliance based on quarterly data collection; and the conclusions, recommendations, actions, and follow-up.

Abdominal surgery wound infection antibiotic prophylaxis

Collection period: January–December the following year

Date of report: January, 13 months after the initial letter

Total number of cases: 162

Number of cases reviewed: 120 (74%)

Criterion	Benchmark (%)	Indicator: % Compliance per quarter			
		1st	2nd	3rd	4th
1. Antibiotic selection (per <i>Medical Letter</i>)	100	70	85	94	100
2. Correct dose (per <i>Medical Letter</i>)	95	65	90	94	97
3. Preoperative dose 0–2 hours before surgery	95	30	52	89	94
4. Postoperative dose only for dirty surgery	98	78	89	82	91
5. No postoperative infection	96	90	93	96	100
6. No adverse reactions to medicines	97	97	100	87	97

Conclusions

Criterion 1. Surgeons are selecting antibiotics that are not considered the medicine of choice for the indicated procedure.

Criterion 2. Surgeons are prescribing unnecessarily high doses of antibiotics.

Criterion 3. Preoperative doses are delayed: current procedure is for pharmacy to send medicine to operating room rather than preoperative area. Turnaround time for dispensing from pharmacy often delays medicine administration.

Criterion 4. Surgeons order postoperative antibiotics for patients who do not meet criteria for dirty surgery.

Criterion 5. High rate of postoperative infections may improve with compliance with criteria.

Recommendations

- Send letter to all surgeons with the following information—
 - Current postoperative infection rate versus national average

- Criteria and recommendations from the *Medical Letter*

- Results of the DUR data collection
- Estimated cost impact of inappropriate medicine selection and unnecessary medicine use

- Remove cefoxitin from formulary because of its disadvantages of short half-life and relative cost of therapy as compared with cefotetan.
- Change procedures to administer preoperative doses in the preoperative area rather than the operating room. Instruct in-service nursing and pharmacy staff on new procedures.
- Add approved antibiotics to floor stock in preoperative area for emergencies.

Actions

- The chief of surgery informed the surgery committee about the DUR and the criteria in February of the implementation year.
- A letter was sent to all surgeons in April.
- Cefoxitin was removed from the formulary.

4. New procedures for administration were adopted in June, and in-service training of staff members began in July.
5. Antibiotics were added to preoperative floor stock in July.

Follow-up

Criterion 1. Met benchmark in fourth quarter. The education of surgeons contributed to an improvement in antibiotic selection.

Criterion 2. Met benchmark in fourth quarter. The education of surgeons contributed to an improvement in antibiotic dosing.

Criterion 3. Changes in procedures, floor stock, and in-service training of staff improved the timing of preoperative antibiotics but still not meeting benchmark. Benchmark is unrealistically high because of multitude of contributing factors for emergency procedures. Lower the benchmark to 93 percent.

Criterion 4. Education decreased unnecessary postoperative antibiotic prescribing for a short time, then surgeons began to return to old practices. P&T committee sent individual letters to specific surgeons, and the practice improved in the last quarter of the year, but it was still not meeting benchmark. Report cases of noncompliance to surgery committee for peer review and recommendations.

Criterion 5. Postoperative infection rate gradually improved throughout the year, meeting and exceeding the benchmark.

Criterion 6. Allergic reactions increased in the third quarter because of the change in floor stock procedures and preoperative nurse failure to screen for patient allergies. Previously, the pharmacy screened for allergies prior to dispensing. Nurses received in-service training for allergy screening, and the allergic reaction decreased in the last quarter, meeting benchmark.

using cost bar graphs, preparing facility pharmaceutical budgets, and printing prices in pharmaceutical manuals and on requisition forms.

Cost bar graphs. In many countries, diagrams or charts showing side-by-side comparisons of prices for alternative medicines have been circulated (for examples, see Figure 29-5). The intention is not to mandate that practitioners always choose the least expensive medicine but rather to encourage them to take cost into consideration.

Facility pharmaceutical budgets. In health programs that receive budgetary funds for pharmaceutical procurement, specific pharmaceutical budgets may be allocated to individual districts, hospital areas, or health centers. When annual estimates of pharmaceutical needs are made, or when regular requisitions for medicines are prepared, the expected acquisition cost of the medicines is compared with available funds. If reductions in medicine requests are necessary—and they usually are—the medical practitioners at the hospital or health center can participate in making the choices. This strategy puts the decision making closest to the point of medicine use. In some settings, this level of involvement by practitioners has helped create a cost consciousness that makes even their daily prescribing more cost-effective.

Printing prices in pharmaceutical manuals and on requisition forms. Even when practitioners are not required to make their medicine use conform to a specific budget, cost consciousness can be promoted by including recent pharmaceutical prices in therapeutics manuals, medicine lists, and other forms used in prescribing or requisitioning medicines. Alone, this measure may accomplish little, but in combination with some of the other measures described,

it may be quite helpful. Again, physicians and paramedical staff need not be required to pick the least expensive medicine in all cases, but the price list may encourage them to make inexpensive choices.

Prescribing and dispensing approaches

Managers can guide the prescribing and dispensing process by intervening at crucial points of the process.

Structured pharmaceutical order forms. For medicines that are frequently prescribed in hospitals, such as antibiotics, standard forms can be devised to optimize correct medicine use. The prescriber is provided with a medication order sheet containing a preprinted list of preferred medicines and dosage regimens for key medicines. Such forms have increased the cost-effectiveness of prescribing for hospital inpatients in the United States. For example, the form for antibiotics would specify correct standard dosages and an antibiotic review after seventy-two hours.

Standard diagnostic and treatment guidelines. Specific guidelines can be abstracted from formulary and therapeutics manuals (see Chapter 17). Guidelines for common conditions, such as postoperative pain, hypertension, diabetes, and various forms of cancer, can be agreed upon by the staff. Patients are treated in a standard manner according to the protocols. This approach has many benefits. Garnering agreement to follow the institutional guidelines may be time-consuming, but the active involvement of prescribers in this process can lead to significant changes in clinical practice. These guidelines can also be used as the basis of DUR and procurement lists.

Country Study 29-3 Antibiotic use review in Kenya

Antibiotics represent one of the most widely prescribed forms of medicine therapy. In some cases, the antibiotics prescribed may be inappropriate or too expensive. To ensure that antibiotics are prescribed appropriately and rationally, pharmacists have to review antibiotic usage periodically. The aim of antibiotic use review (AUR) is to determine the pattern (rates, appropriateness, and costs) of antibiotic usage in a particular setting. The results of an AUR program are often communicated to those concerned individually, through a memorandum, or through a general bulletin showing the norm and peer comparisons. The starting point of an AUR program is the formation of criteria by the drug and therapeutics committee (DTC). Prescriptions are checked for appropriateness of dosage, therapeutic indication, duration of treatment, and so on, according to the criteria. Deviant cases are recorded. AUR studies can be set up such that various clinicians, wards, and facilities can be compared.

The steps for performing an AUR are—

1. Select the subjects of the program.
2. Draft criteria and standards that define acceptable quality of care for subjects selected in step 1.
3. Obtain endorsement of the criteria and standards from the DTC.
4. Evaluate the quality of services in question using the criteria and standards.
5. Identify deficiencies in quality (if any).
6. Analyze the causes of deficiencies.
7. Formulate a plan for eliminating deficiencies.
8. Implement the plan.
9. Reevaluate the quality of services, as in step 4.
10. If usage is not acceptable, reanalyze the causes of deficiencies and devise a new plan for their elimination.

The worksheet for an AUR for amoxicilline is shown in the accompanying table, which considers ten patients from one prescriber in Kenya.

Review Criteria from DTC	Patients									
	1	2	3	4	5	6	7	8	9	10
Indications ^a	Tonsillitis	Otitis media	Urethritis	Bowel sterilization	Severe gram-negative meningitis	Boils/abscess	Severe cystitis	Surgical prophylaxis	Pneumonia	Severe wound infection
Appropriate indication?	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes
Amoxicilline dosage ^b	250 mg tds	250 mg tds	250 mg tds	1,500 mg bd	500 mg tds	250 mg tds	500 mg tds	250 mg tds	250 mg tds	500 mg tds
Duration (usually 5 days)	5 days	7 days	7 days	1 day	10 days	7 days	5 days	5 days	5 days	7 days
Cost per capsule (KES)	30	30	30	30	30	30	30	30	30	30
Total cost ^c	470	650	650	380	1,800	650	920	470	470	1,280

^a Acceptable indications are upper or lower respiratory tract infections; genitourinary tract infections; septicemia; surgical prophylaxis; skin and soft tissue infection; osteomyelitis; and peritonitis.

^b Acceptable dosage is usually 250 mg tds. Dosage may be doubled in severe cases.

^c Total cost for usual dosage for 5 days = 470 Kenya shillings (KES). This amount includes dispensing fee of KES 20.

Calculations

1. Calculate the frequency of inappropriate prescribing—

$$2/10 \times 100 = 20\%$$

2. Total costs caused by inappropriate prescribing—

$$380 + 1,800 = \text{KES } 2,180 \text{ (a loss)}$$

Note: Only pharmaceutical costs are considered; medicines prescribed inappropriately are viewed as a waste.

Summary and comments

1. For patient #4: bowel sterilization would require a long-acting sulfonamide or neomycin tablets.
2. For patient #5: for severe gram-negative meningitis, patient would need a cephalosporin.

Source: Ministry of Health, Government of Kenya 1994.

Course-of-therapy packaging. Course-of-therapy (COT) packaging, often in the form of blister packs, has been widely used for oral contraceptives and, more recently, for tuberculosis therapy. Although such packaging adds to the cost of medicines, gains are experienced in convenience for both the dispenser and the patient. Comparative prices should be obtained before switching completely to COT; in many markets, the average difference between bulk and COT packaging is 10 percent or more. Prepacks (described in Chapter 30) are a form of COT packaging.

Country Study 29-4 shows how different sets of targeted interventions, including educational and managerial approaches, were used to improve rational medicine use among prescribers in four different countries.

29.6 Economic interventions

Financial incentives—both positive and negative—may strongly affect rational or irrational medicine use; for example, setting prices and changing the way fees are collected can result in different prescribing behaviors.

Price setting and fees

The price charged for pharmaceuticals can be used to encourage more rational use of them. For example, in cost-recovery programs, vital medicines (see Chapter 40) can be sold at prices below their real costs, and nonessential medicines can be sold at prices above their real costs. This cross-subsidization can encourage the use of vital effective medicines while discouraging the sale of nonessential, less effective medicines. Charging for a course of therapy rather than for each individual treatment (injection, tablet) encourages the patient to complete the prescribed therapy. Generic medicines are usually cheaper than their brand-name counterparts, making their use rational from a cost standpoint. Pricing incentives such as preferential markup on generics and reference pricing can be used to encourage generic substitution. (See Chapter 9 for more information on pricing policies.)

Flat prescription fees that cover all medicines within one prescription result in overprescribing; therefore, user charges should be made per medicine, not per prescription. Country Study 29-5 shows how prescription fee systems affected prescribing behavior in Nepal. Also, dispensing fees that are calculated as a percentage of the cost of the medicines promote the sale of more expensive medicines. A flat dispensing fee, not tied to the cost of the medication, is preferable.

Insurance

The concept of insurance is assuming a greater role in resource-limited countries. Insurance systems can be pro-

vided through the government (social health insurance), through private sources (for example, employers), and through community prepaid schemes. Not all insurance systems include pharmaceuticals in their list of benefits, but when they do, certain controls on payment, prescribing, and use can affect the rational use of medicines.

Capitation-based reimbursement

When a payment to health care providers is made by a third party, pharmaceutical costs are better controlled with a fixed per capita payment as compared to a per visit or per medicine reimbursement. But caution is needed to ensure that needed medicines are not underprescribed.

Medicine sales by prescribers

If the health worker receives the profit on medicine sales, as occurs in Japan and in some Bamako Initiative projects, there is an inducement to overprescribe and to prescribe more expensive medications. Although prescribers may deny this effect, the findings are consistent across cultures and countries: prescribers who benefit from medicine sales prescribe more than those who do not.

29.7 Regulatory approaches

Regulatory approaches aim to enforce decisions that are intended to improve prescribing. These methods are frequently used but sometimes have unintended or unexpected outcomes, which may result in extra costs or adverse patient consequences. Such effects have been noted in the United States (Country Study 29-6) with the use of a limit on the number of monthly prescriptions patients could receive. That study, however, does not rule out the use of carefully structured caps.

Although most countries have some sort of drug regulatory authority and legal requirements for registering medicines, a lack of resources can deplete their effectiveness. WHO estimates that fewer than one in six member states have well-developed pharmaceutical regulation and two in six have no or little pharmaceutical regulatory capacity (WHO 2004).

Pharmaceutical registration

Most countries have pharmaceutical regulations that limit pharmaceutical sales to registered pharmaceutical products. In countries where pharmaceutical registration is enforced, it limits the types and numbers of medicines available for prescribing. An effective registration process helps keep dangerous and ineffective medicines off the market. The requirements for registering new drug substances are

Country Study 29-4

Assessing the effect of targeted approaches in improving prescribing

Indonesia. Inappropriate prescribing at primary health centers (PHCs) has been a major public health concern in Indonesia. A study found that more than 90 percent of patients with acute respiratory infection (ARI) visiting health centers received antibiotics. Also, more than 85 percent of adult patients with muscle ache (myalgia) reportedly received unnecessary injections. An intervention featured interactive, systematic, problem-based training of physicians and paramedical personnel in 122 PHCs, which were compared with a control group of forty PHCs.

The intervention consisted of three sets of training modules: medication error, evidence-based medicine, and rational use of medicines, followed by self-monitoring, supervision, and feedback by a training team. The training evaluation on prescribing patterns was conducted six, twelve, and eighteen months following the intervention.

The use of antibiotics for ARI in the intervention group decreased significantly, from 92.3 percent before the intervention to 71 percent, 50 percent, and 30 percent, six, twelve, and eighteen months after the study ($p < 0.05$). No significant improvement was found in the control group. A significant decrease in antibiotic prescribing was also found in the treatment of diarrhea in the intervention group, from 90.3 percent before the study to 53 percent, 40 percent, and 26 percent, six, twelve, and eighteen months after the study ($p < 0.05$). No significant improvement was detected in the control group. Interactive, systematic problem-based training on rational use of medicines, followed by self-monitoring, supervision, and feedback, significantly improved prescribing patterns and resulted in significant cost savings.

Kenya. The Mission for Essential Drugs and Supplies (MEDS) conducts institutional training interventions in mission hospitals. These interventions consist of three phases: a baseline survey using the International

Network for the Rational Use of Drugs indicators, training, and a follow-up evaluation one year later. Some hospitals then complement the training with their own in-house continuous medical education (CME) programs. A retrospective before/after study of three mission hospitals in Kenya with a comparison group assessed the effect of combining training with a CME program. A prescription review in each hospital looked at four prescribing indicators, including the percentage of cases prescribed antibiotics and injections. All three hospitals went through the MEDS training program, with one hospital instituting a regular, in-house CME program organized by the drug and therapeutics committee.

The postintervention results showed that in one hospital, three of four indicators showed improvement, and one of four indicators deteriorated. In the second hospital, one of four indicators showed improvement, one of four did not change, and two of four deteriorated. In the third hospital, which had the CME program, all four indicators showed dramatic improvement, especially concerning antibiotic and injection use. Study researchers concluded that training by external facilitators had mixed success in improving prescribing habits, but a complementary CME program made for a much more successful educational intervention.

Lao P.D.R. In the Lao People's Democratic Republic (P.D.R.), standard treatment guidelines were introduced to all prescribers at provincial hospitals, but they were insufficient in improving treatment practices in malaria, diarrhea, and pneumonia. To evaluate the effects of an educational intervention, a randomized controlled trial was conducted in eight provincial hospitals, matched into four pairs. The hospital drug and therapeutics committees carried out the six-month intervention, which consisted of monthly audit sessions and feedback on treatment indicator scores.

stringent in some countries. In others, however, the facilities for assessing new products are not readily available, and monitoring and enforcement are unreliable.

Limited medicine lists

Limited medicine lists can be a managerial intervention, as described earlier, or a regulatory intervention, in which case certain medicines are completely banned. Limited medicine lists (formularies) have been used since the early

1970s to control costs and promote rational use in public- and private-sector pharmaceutical programs. In Tanzania, for example, *duka la dawa baridi* (private medicine shops) are legally restricted from selling most prescription medicines, although lax enforcement and a lack of alternatives mean that most do sell restricted products. In some cases, governments have gone further, banning certain medicines or pharmaceutical classes from both public and private markets. Limited medicine lists are the main mechanism to prevent the use of dangerous, ineffective, and

From the baseline assessment to six months postintervention, the total mean indicator score for all three diseases increased significantly more in the intervention group than in the control group. The individual scores for malaria and diarrhea also increased significantly more in the intervention group, but for pneumonia, the improvement was the same in both groups. Specific improvements in record keeping and rational prescribing were seen for all three diseases. Audit-feedback systems to improve quality of care can be feasible and effective in hospital settings in low-income countries.

Mexico. Most continuing medical education activities for primary care physicians in Mexico have not improved the quality of care provided, and physicians' practices are not always in accordance with updated clinical evidence. The Mexican Institute of Social Security conducted a nonrandomized prospective controlled study to evaluate the impact of a multifaceted educational intervention to

improve case management in 175 primary care physicians divided into a study and control group. The study intervention consisted of three components over seven months: developing clinical guidelines; training clinical tutors; and a three-stage intervention including interactive workshops, individual tutorials, and roundtable peer-review sessions.

In the intervention group, improvement in medication prescribing was considerable: for acute respiratory infection, 32.7 percent of physicians improved their prescribing for antibiotics; for hypertension, 29.0 percent improved their antihypertension prescribing; and for type 2 diabetes, 25.2 percent improved their prescribing for hypoglycemic medicines or insulin. For all three, the changes were statistically significant ($p < 0.01$). No significant changes occurred in the control group.

Sources: Mexico: Reyes et al. 2004; Kenya: Kiambuthi 2004; Indonesia: Dwiprahasto and Kristin 2004; Lao P.D.R.: Kounnavong et al. 2004.

Country Study 29-5

Using an economic strategy to improve prescribing practices in Nepal

A study including looking at practices pre- and postintervention compared with a control group was conducted in thirty-three health facilities in three districts in eastern Nepal. At the baseline, all three districts charged the same flat fee per prescription, covering all medicines, in any amount. Later, two districts instituted new fee systems, while the third kept the same fee structure. One district started charging a single fee per medicine item (using a one-band item fee), no matter what the medicine was, and covered a full course of the medicine. The second district charged a higher fee per expensive item (for example, antibiotics and injections) and a lower fee per inexpensive item (for example, vitamins) (using a two-band item fee) and covered a full course of the medicine. All the fees for two drug products equaled about 25

percent of the average daily household income. Prescribing was monitored in all health facilities before and after the changes.

The table that follows shows that both types of item fee were associated with significantly better prescribing quality than the prescription fee. The percentage of patients receiving antibiotics decreased, and the proportion of prescriptions conforming to standard treatment guidelines increased in both districts using item fees, compared with the control district. The one-band fee was associated with a reduction in prescribing of cheap vitamins and tonics, and the two-band fee with a reduction in prescribing of expensive injections.

Source: Holloway and Gautam 2000.

Effects of user fees on prescribing quality in Nepal

Fee system	Control flat fee/ prescription n = 12	One-band fee/medicine item n = 10	Two-band fee/medicine item n = 11
Average number of items/prescription	2.9 → 2.9 (0%)	2.9 → 2.0 (-31%)	2.8 → 2.2 (-21%)
Percentage of prescriptions with antibiotics	66.7 → 67.5 (+0.8%)	63.5 → 54.8 (-8.7%)	60.7 → 54.3 (-6.4%)
Percentage of prescriptions with injections	23.4 → 20.0 (-3.4%)	19.8 → 16.1 (-3.7%)	21.8 → 14.9 (-6.9%)
Percentage of prescriptions with vitamins or tonics	27.0 → 22.1 (-4.9%)	26.5 → 8.4 (-18.1%)	23.5 → 15.8 (-7.8%)
Percentage of prescriptions conforming to STGs	23.5 → 26.3 (+2.8%)	31.5 → 45.0 (+13.5%)	31.2 → 47.7 (+16.5%)
Average cost/prescription (NPR)	24.3 → 33.0 (+35.8%)	27.7 → 28.0 (+1.1%)	25.6 → 24.0 (-6.3%)

NPR = Nepalese rupee.

Country Study 29-6 Unintended effects of medicine restrictions

In the United States, poor patients' health care costs are covered by the Medicaid program. This program is administered by the states in different ways.

In 1992, New Hampshire decided to limit Medicaid outpatients to three medicines per month; another state, New Jersey, chose not to place limits. Researchers studied the medicine-use patterns and hospital and nursing home admissions for patients who had been taking more than three medicines per month.

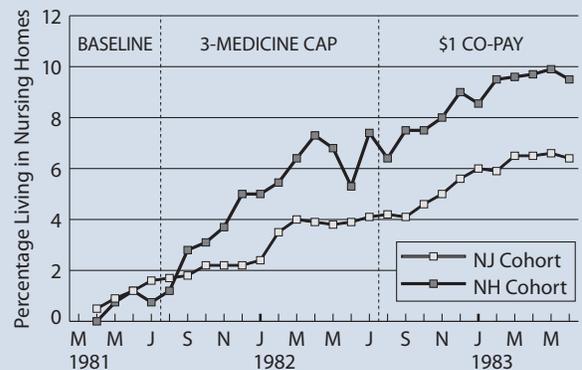
As expected, the number of medicines per patient decreased by 35 percent, but the dosages of the medicines prescribed increased. The unexpected outcome was a 120 percent increase in nursing home admissions and a 20 percent increase in hospital admissions.

After eleven months, the three-medicine limit was withdrawn and replaced with a USD 1 co-payment scheme. Admission rates and medication levels returned to the levels that existed before the medicine limit. In general, the patients who were admitted to nursing homes were not discharged.

In retrospect, the behavior of the physicians who admitted their patients to nursing homes was quite rational.

No medicine limits applied for inpatients, and patients could continue to receive their medications by entering nursing homes. Thus, Medicaid saved a little on medicine costs, but the cost of extra admissions outweighed these savings.

The monthly proportion of patients in nursing homes is shown in the accompanying graph.



Source: Adapted from Soumerai et al. 1991.

unnecessarily expensive medicines. However, the danger exists that when safe but relatively ineffective medicines (such as kaolin for diarrhea) are withdrawn from the list, they may be replaced by effective medicines (metronidazole, for example) used inappropriately. This occurred in one country when antidiarrheals were banned. Metronidazole use increased from 10 percent to 65 percent in cases of watery diarrhea.

Prescribing restrictions

In theory, after a pharmaceutical is registered, it can be prescribed by all medically qualified prescribers. Health authorities often restrict paramedical staff to a limited number of medicines on the national essential medicines list. Those limitations are imposed to reduce wasteful prescribing and inappropriate use of expensive medicines. At the health facility level, the use of expensive or powerful medicines may be limited to the more experienced prescribers. In some hospitals, the use of third-generation cephalosporins is restricted to specialist prescribers. Prescriptions by junior staff members have to be countersigned by the specialist. In some settings, the junior prescriber can prescribe such medicines only for twenty-four- to forty-eight-hour

use; any extension requires the authorization of the specialist. Prescribing limitations may take the form of pharmaceutical registration, limited medicine lists (essential medicines lists), medicine formularies, or prescribing and dispensing privileges by level of use (facility level and competence level of prescriber). Another possible restriction is to limit the number of medicines prescribed to two or three per patient. However, this restriction is easily evaded by issuing two separate prescriptions.

Dispensing limitations

Limiting the amount of medicines to be dispensed has been applied in some countries to control wasteful or potentially dangerous dispensing. Examples of this approach follow.

- One Asian country established a system of three- and five-day limits for all outpatient prescriptions, except those for chronic diseases. Most antibiotics are given for five days, and all other medicines for acute illnesses are limited to three-day courses.
- In South America, one large rural health program established a system of prepackaging medicines in unit-of-use plastic bags containing the minimum

amount of drug product needed for one course of therapy.

- The government-supplied university hospital in one Southeast Asian country put dispensing limits on items that may be abused, tend to be prescribed indiscriminately, or are potentially dangerous. Maximum dispensing quantities have been established for codeine, diazepam, vitamin C tablets, and vitamin B complex, among others.

Such limitations can have adverse effects on the treatment of some diseases. For example, antibiotic treatment for typhoid typically requires more than five days. Patients with chronic diseases such as epilepsy or diabetes are forced to visit health centers frequently and may end up missing treatments. Therefore, when setting restrictions on duration of therapy or dispensing quantities, exceptions must be built in to cover chronic diseases and exceptional cases.

29.8 Developing an intervention strategy

When a problem has been identified and quantified and its causes have been determined, a set of interventions needs to be selected. A wide range of possible interventions has been indicated in Sections 29.4, 29.5, and 29.6.

Selecting an intervention

The first step in selecting a set of interventions is to clearly define the problem to be solved. The behaviors specific to the particular health problem, as well as factors causing variability in performance, need to be identified. Assessing the beliefs and motivations of the prescribers that may contribute to the observed behavior is also important. These assessments will require further studies involving qualitative investigational methods. When the problem has been defined, a package of interventions can be considered.

Cost-effectiveness has to be considered in the selection process. The implementation of the selected interventions needs to be carefully designed. The use of a control group enhances the detection of differences. Key outcomes must be defined beforehand. An evaluation of the impact versus the cost of the intervention is also necessary. The outcome of the intervention must be fed back to the participants to reinforce the changes that have occurred.

The selection of an appropriate set of interventions should consider its—

Likely effectiveness: What intervention is most likely to be effective in addressing the specific medicine use problems and their underlying causes? Do any previous stud-

ies or documented experiences exist about this specific intervention?

Feasibility: Is the intervention feasible to implement, taking into account the existing health care system and the available personnel?

Cost: What is the cost of the intervention? Can it be borne by the available resources?

Potential effect: If the intervention is effective, what effect will it have, and what will be its magnitude? Can beneficial effects outweigh the cost and possible adverse effects?

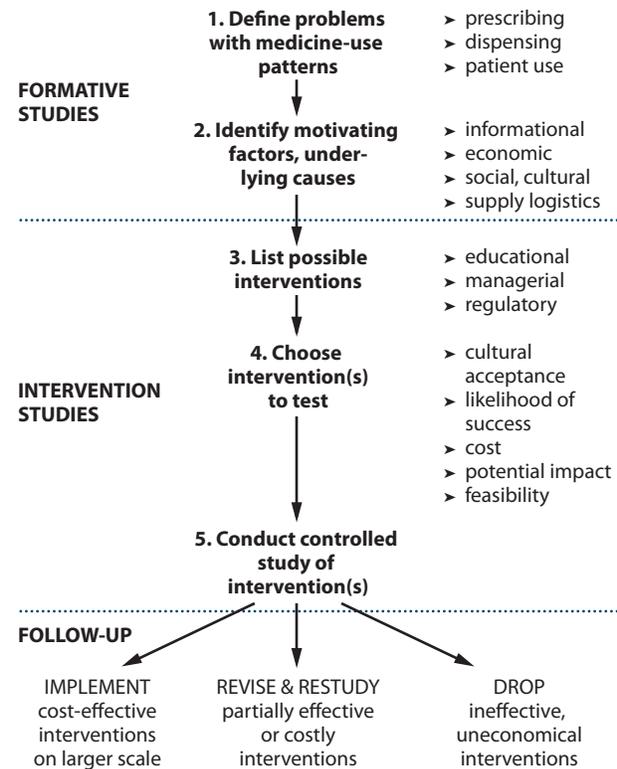
Unintended effects: What are the possible adverse effects of the intervention?

The framework for formative and intervention studies is described in Figure 29-6. The selected interventions need to be monitored carefully during implementation.

Combining interventions

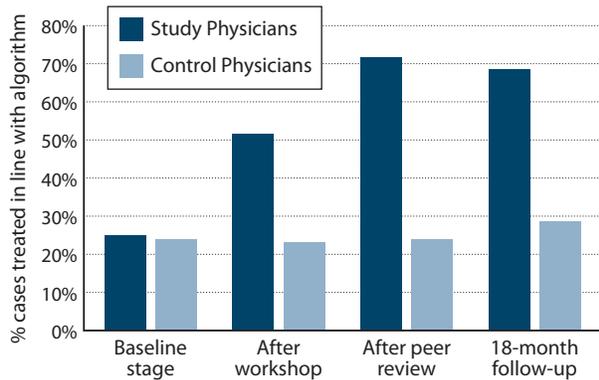
Interventions can be combined. This approach was taken in Mexico, where the treatment of diarrhea was unsatisfactory. The first intervention was an educational workshop, which improved prescribing from 24.5 to 51.2 percent compliance with a treatment norm. This intervention was

Figure 29-6 Framework for formative and intervention studies



Source: Quick et al. 1991.

Figure 29-7 Combined intervention strategy: Prescribing for acute diarrhea in Mexico City



Source: Gutierrez et al. 1994.

followed by a managerial intervention—peer review—that further improved prescribing to 71.6 percent compliance with the same norm. Only minor changes occurred in the control group (see Figure 29-7). After eighteen months, the improvement had been maintained.

Combining different types of interventions is usually more effective. A mixture of large-group education and small-group education, combined with audit and feedback, is more likely to produce sustained changes than is a repetition of the same intervention. Innovative approaches include an online, blended learning program that focuses on clinicians' beliefs about their prescribing habits, feedback on their prescribing backed with their own patients' data on antimicrobial resistance, and an introduction to how to work with patients to reduce unnecessary antibiotic prescribing (Simpson et al. 2009).

In general, regulatory interventions should be carefully structured, and active surveillance is essential to detect unexpected or unintended effects. Many countries do not have the capacity to monitor or enforce regulations, limiting the effectiveness of regulatory approaches.

Social marketing of interventions

Implementing interventions without taking into account the level of understanding and acceptance of the prescribers or consumers carries the risk of failure or unintended effects; therefore, involving key stakeholders in the intervention design and implementation is critical. For instance, a policy of prescribing generic medicines is in place in public health facilities in many countries. When prescribers are not well informed about the advantages of generics, they may not comply with generic prescribing, and they may transfer their negative perceptions to their patients, which, in turn, further jeopardizes the implementation of the policy (see Chapter 16). Withdrawing popular medicines from

the market without giving proper information to the public can create confusion and anxiety for consumers, especially for routine users of the medicines. Whenever regulatory or managerial action is taken, informational and educational approaches need to be incorporated for prescribers as well as consumers.

Evaluating the effect of an intervention

Evaluation of whether an intervention has caused the desired effect—that is, improvement in prescribing behavior in a cost-effective manner—is often neglected. An intervention strategy is often implemented without prior field-testing to prove that it works in the existing system and is effective in influencing prescribing practices. Many countries have implemented countrywide training programs without proper design and evaluation. In these cases, the waste of resources such as funds, time, and energy will only further increase the burden on health care services. Some health managers falsely assume that if any intervention program takes place, the desired goals have been accomplished. Yet the production and dissemination of treatment guidelines to health care facilities, for example, does not necessarily lead to prescribers' using the guidelines or improving their prescribing practices.

Evaluation of effects should be regarded as an important component of any intervention strategy, and ongoing production of timely data to steer the intervention design is invaluable. The following points should be considered in designing an evaluation approach—

- An evaluation plan should be devised when planning an intervention. Before implementing a program on a wide scale, field-testing is imperative to find out whether the evaluation can be implemented feasibly in the existing health care setting and whether it is effective in influencing prescribing practices.
- Evaluation of the impact of an intervention program should focus primarily on the indicators targeted by the intervention messages. Secondary indicators can also be selected, as appropriate. Depending on the objectives and scope of the intervention, evaluation may include relevant aspects, such as knowledge of the targets, changes in perception about a specific practice of interest, the process of care, and cost of prescribing.
- Apart from relevance, the selection of indicators for impact evaluation should take into account reliability and feasibility of collecting data from the existing system.
- The evaluation of any intervention should use appropriate design and methodology, with adequate sample size, sampling, and use of control groups or interrupted time series.

ASSESSMENT GUIDE

Indicators of prescribing quality

- Average number of medicines per encounter
- Percentage of medicines prescribed by generic name
- Percentage of encounters in which an antibiotic is prescribed
- Percentage of encounters in which an injection is prescribed
- Percentage of medicines prescribed from the essential medicines list or formulary
- Average consultation time
- Prescription in accordance with treatment guidelines
- Percentage of patients treated without medicines
- Percentage of patients satisfied with the care they received

Indicators of prescription costs

- Average cost per encounter
- Percentage of pharmaceutical costs spent on antibiotics
- Percentage of pharmaceutical costs spent on injections

Targeted approaches

Educational interventions

- Is there an official continuing education system on rational use of medicines for prescribers and dispensers?
- How many training sessions on medicine use were given for prescribers in the last year?
- What percentage of prescribers surveyed attended at least one training session in the last year?
- Of all the training sessions organized in the past three years, what percentage was related to medicine use?

- Is the concept of essential medicines part of the curricula in the basic training of health personnel?

Managerial interventions

- Is there a national therapeutic guide with standardized treatments?
- Do hospital drug and therapeutics committees exist? And if so, do they undertake drug use studies? What results are available?
- What kinds of managerial interventions have been tried? Were their effects evaluated?

Systems-oriented approaches

Economic interventions

- How are prices for pharmaceuticals set in the country? How do the prices compare to other countries' pharmaceutical prices?
- What are the prescription and dispensing fee systems in place? Are they flat fees or based on a percentage of the cost of the prescription?
- Are prescribers also allowed to sell medicines?
- Are there insurance or cost-sharing schemes? If so, who do they cover and what benefits do they provide?

Regulatory interventions

- At what levels of the system are limited medicine lists used?
- What other regulatory interventions have been used?
- What evaluations have been undertaken of the effect of regulatory changes?

Note: Chapter 28 contains additional indicators and measures for assessing prescribing and the effect of interventions to promote rational prescribing.

- Measuring the long-term sustainability of the effect of any intervention is always desirable. Changes in prescribing behavior and practice observed immediately after an intervention often return to their baseline levels after a longer period of time. Experience shows that changes in prescribing usually return to pre-intervention levels after six months unless the intervention messages are continued. The use of time series analysis may be particularly useful in showing effects over time.

Measurements of medicine use, including measurements of the effect of intervention strategies, are discussed in more detail in Chapter 28. ■

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