CHAPTER 34

Medicine and therapeutics information

SUMMARY

Prescribers, dispensers, and users of medicines all require information on medicines. The sources of this information can be classified as primary (articles or papers on original research), secondary (reviews of the primary literature), and tertiary (formulary manuals, standard treatment manuals, textbooks, and review articles, or pharmaceutical product information approved by drug regulatory agencies). Promotional literature has limited utility because it provides biased information designed to promote sales of commercial products.

The skills required to evaluate medicine information sources can be provided by a medicine information center (MIC); ideally, every country should have one. An MIC can be established in an accessible hospital or university department. The center should provide information proactively as well as respond to queries. The center requires trained staff with access to both text and computer information sources.

MIC activities include sending staff out to provide information; developing, producing, and disseminating a drug bulletin based on modern communication principles; and teaching.

Funding the center may be difficult, but diversified funding should be sought whenever possible. Funding from pharmaceutical companies may appear to affect the center's impartiality and should generally be used only for capital projects. Other problems that may affect the center include—

- Inadequate information sources
- Lack of acceptance
- Inadequate communication systems
- Lack of political will to establish or sustain the center

34.1 The important role of medicine and therapeutics information

Access to clinically relevant, up-to-date, user-specific, and objective information is required to make appropriate decisions for medicine prescribing, dispensing, and use. A health care system can provide access to the highest-quality medicines, but if those medicines are not properly used, they may have negligible, or even harmful, effects. Although access to good information about medicines does not guarantee appropriate decisions and use, it is a basic requirement for good decision making.

Medicine information comes in many forms, both printed and electronic, and the need for medicine information varies among different types of health care providers and patients. For example, physicians and pharmacists need access to the full range of information about generic and brand-name medicines, indications and contraindications for use, medicines of choice and therapeutic alternatives, dosing, precautions for use, drug interactions, side effects, adverse effects, clinical features and treatment of overdose, dosage forms and strengths, and cost of a course of treatment. Patients need basic instructions for using prescribed and self-care medicines. In addition, consumers increasingly expect, and are being provided with, more comprehensive medicine information as they become more involved in decisions regarding their own treatment and care (Chapter 33). This trend has accelerated with the growth of the Internet and the huge repositories of information that are easily accessible (see Box 34-1).

Identifying and accessing needed medicine information resources are important activities for a pharmaceutical management program. When limited funds do not allow the program to provide systemwide access to necessary information resources and individual practitioners are unlikely to be able to purchase information themselves, a centralized medicine information service should be considered.

The primary role of an MIC is to give clear and definitive information on medicines and promote their appropriate use. A secondary role of the center is to keep up-to-date with pharmacological and therapeutic advances and disseminate relevant information when it becomes available. This activity is particularly important to support a hospital's drug and therapeutics committee and the work it does in maintaining its formulary, treatment guidelines, and formulary manual (Chapter 17).

34.2 Types of medicine information

Information falls into three categories depending on its source—primary, secondary, or tertiary. Primary sources are the foundation on which all other medicine information resources are based. They provide original thinking and results of original research. Primary literature can be found as published articles or unpublished reports that provide detail on the research and its findings. Published information has typically gone through a peer-review process to assess scientific soundness and merit. Publications or reports would provide information on medicine-related subjects, such as clinical pharmaceutical trials, case studies, and pharmacological research.

Secondary sources are more difficult to define because interpretations vary as to what exactly they are. In essence, however, secondary resources function as a guide to or review of the primary literature and include, for example, indexing and abstracting services (for example, PubMed), commentaries on primary literature, review articles, drug bulletins, and meta-analyses or systematic reviews, such as Cochrane evaluations. Secondary sources are typically easy to access and use and to link to the primary literature.

Tertiary sources draw from primary and secondary literature and provide "processed" information that represents the interpretations and conclusions of the individuals or organizations doing the development. They are convenient and easily used but at the same time carry the risk of being less than objective. Examples include textbooks, general reference books, and pharmaceutical compendia. Obtain the most current edition available when using secondary or tertiary sources.

A selected list of medicine information sources that can be accessed online appears in Annex 34-1. All information sources have limitations, and medicine information users should recognize both their advantages and disadvantages.

Evaluation of information sources

Evaluating information sources is an important skill (see Box 34-2). The *Teacher's Guide to Good Prescribing* (Hogerzeil et al. 2001) contains a useful section on assessing literature. *Studying a Study and Testing a Test* (Riegelman 2004) is a valuable primer on evaluating medical literature.

Primary sources. Evaluating primary literature is difficult. The most reliable evidence comes from reports on randomized controlled clinical trials. Appropriate evaluation of these trials requires considerable time and experience, but they are by far the best source of objective information. To use primary literature effectively, the user needs a certain level of knowledge about research methodology and statistics. Keeping up with the volume of published information is also difficult. Thousands of journals are published regularly, with each containing many articles. Even if reading is limited to journals in a specific area of interest and expertise, the amount of information may preclude staying abreast of the latest findings. Therefore, many readers simply trust the journals' peer-review processes and assume that the process will identify any problems with the studies.

In judging published primary literature, the reader cannot assume that the results of a study or a research paper

Box 34-1
Medical products and the Internet

The Internet provides people with quick and easy access to vast amounts of information on practically any subject. It is a valuable source of health information on topics such as diseases, conditions, therapies, medical products, and health and medical organizations. The quality of information, however, varies, and consumers as well as health care professionals must be careful when using the Internet as a source of health information.

The World Health Organization (WHO) created a guide on medical products and the Internet to help people obtain reliable, independent, and comparable information. The guide has five key points—

1. The Internet is a valuable source of information, but the consulted source should be known and trusted. Consumers need to judge whether or not the information is reliable, complete, and up-to-date.
2. Determining and verifying the source of a website can be difficult, so consumers should look for the following—
   - Clear indication of the name and contact address of the website owner
   - Clear indication of funders, services, or other support to the website
   - Whether advertising or sponsorship is a source of funding
   - Intended audience (consumer, health professional, other)
   - Date of the last information update
3. When searching for and evaluating products, such as pharmaceuticals, if information sounds too good to be true, it probably is. Information should include active ingredients, other ingredients, side effects, interactions, how to use a product, how to store it, and contact information.
4. Consumers need to be cautious about buying medical products on the Internet. They can be illegal, risky, poor quality, a waste of money, and lacking in safety and efficacy assurance. Instructions for use may be inadequate.
5. Although the Internet can be a good source of information, consumers should not substitute it for an actual consultation with a health care provider.

Sources: WHO 2001, 1999.

Box 34-2
Evaluating information sources

Questions to ask when reviewing original clinical articles

- In which journal was the article published? What is the reputation of the journal? Is it known to have high standards for the acceptance of articles? Are articles peer reviewed?
- Who is the author, and what is his or her affiliation?
- Does the article report the results of a properly designed clinical study, or is it based on case reports or observations? If a clinical study, what was the sample size, and how were participants selected? Were controls used? Was the study prospective or retrospective? Is the report adequately referenced?
- Are reasonable conclusions drawn?
- Who funded the study? Does any potential exist for conflict of interest?

Questions to ask about bibliographic, abstracting, or indexing services

- What journals or information resources are covered by the service, and are these resources the ones that are essential for the particular purpose?
- What is the lag time between the publication of a journal and its inclusion in the service?
- How easily can the service be used? Are key words indexed? Are subject headings used?
- If abstracts are provided, who develops the abstracts, and how accurately do they reflect the primary source?

Questions to ask about consensus-generated documents

- How is consensus defined, and how are the individuals participating in the consensus definition process selected?
- How good is the consensus-generation process?
- Are references provided and accessible?
- Is the consensus process open to public review and comment?
- Is the information based on evidence published in peer-reviewed literature, or is it simply a compilation of use patterns reported as being accepted by the medical community?
- When was the consensus document published, and how frequently is the information updated?
- Who published the information, and what kind of reputation does the publisher have?

Questions to ask about secondary and tertiary references written by individuals or groups of individuals

- Who is the author, and what are his or her qualifications?
- Who is the publisher, and what is its reputation?
- Who paid for the development of the information? Does it come from a special-interest group? If the publication is reporting proceedings from a conference, who organized the conference, and do the organizers have a special interest?
- Has the information been peer reviewed? How good is the peer-review process?
- When was the information developed, and how current is it?
- Are references included in the article, or can the references be accessed by other means?

are valid simply because it has been accepted for publication. However, considering the source of a study or paper is useful when determining quality. A number of respected medical and pharmacy journals whose high standards for acceptance and publication make it unlikely that a research article containing erroneous, fraudulent, or misrepresented data would survive the editorial and review process. Annex 34-1 lists some English-language journals that have strong editorial policies and peer-review processes that include conflict-of-interest disclosure requirements to minimize the possibility of biased or unsupportable conclusions being reported. One way to monitor such problems is to read the letters to the editor published in journals. If questionable conclusions survive the peer-review process, some reader will undoubtedly write to the journal editor and state his or her observations or concerns. Reputable journals readily share this type of correspondence, often allowing the authors of criticized articles the opportunity to respond.

Information published in journals without a strong review process needs to be more carefully scrutinized. "Throwaway" or controlled-circulation publications, provided free of charge, often by a special-interest group (a pharmaceutical manufacturer, for example), require careful review to determine what biases, if any, exist. Determining who is

publishing these types of journals and what the peer-review process is, if any, for acceptance of an article is a good idea. In addition, note conflict-of-interest declarations.

Clinical trial databases and unpublished reports (known as gray literature) are also considered primary literature. Although not always readily available, this type of information can provide valuable insights. For example, some companies or researchers may elect not to publish results because the findings were negative. This decision presents an ethical problem in that negative findings, although potentially detrimental to the financial success of a particular product, are valuable in making evidence-based decisions on the use of a medicine. Finding information on clinical trials has been facilitated in recent years through the creation of clinical trial registries that are available online. For example, the Duke University Medical Library has a guide to searching the gray literature and clinical trials, including those on pharmaceutical company websites (http://guides.mclibrary.duke.edu/content.php?pid=224463&sid=1861375). The reader needs to carefully interpret unpublished data, however, because there may be negative underlying reasons why the data have not been published in peer-review journals.

Secondary and tertiary resources. Secondary and tertiary information resources are essentially derivations of

Box 34-3
The Cochrane Collaboration

The Cochrane Collaboration was established in 1993 in England to support the systematic, up-to-date review and synthesis of scientific research, which can be used to help people make well-informed decisions about health care. The collaboration is based on the ideas of Scottish doctor Archie Cochrane, who said in 1979 that health professionals should have an updated critical summary of all relevant randomized clinical trials (RCTs) to provide evidence-based care that is proven effective.

The Cochrane reviews are prepared mainly by health care professionals who follow an established methodology. The reviewers systematically study all reports of RCTs for treatment of a specific problem while focusing on identifying the benefits and risks of different interventions. The group often uses a technique called meta-analysis, which combines the results of different RCTs to get around problems of small sample sizes that can lead to statistical errors. After extensive peer review, the documents are published and updated periodically.

Cochrane reviews cover treatments for many different diseases. Specific groups of reviewers focus on particular subjects, such as eyes and vision, arthritis treatment, and neonatal health. An example of a Cochrane review is *Co-trimoxazole Prophylaxis for Opportunistic Infections in Children with HIV Infection,* published in 2006. The review found a significant reduction (33 percent) in mortality in HIV-positive children one to fifteen years of age taking co-trimoxazole versus a placebo. Co-trimoxazole is cheap and effective against a wide range of organisms that commonly cause opportunistic infections in children with HIV. The reviewers concluded that the use of co-trimoxazole prophylaxis was beneficial for HIV-infected children in Zambia, and whether this conclusion can be extrapolated to other resource-poor settings must be decided.

Although the Cochrane Collaboration has centers in Australia, Canada, Denmark, England, Italy, and the United States, it is beginning to influence far-reaching health policies in developing countries. Through its Developing Country Network, it encourages people from these countries to become reviewers and to register all RCTs throughout the world, so that the information is available and useful to researchers and the public. For example, the African Trials Register involves tracking down all controlled trials conducted in Africa by searching global and regional databases and hand-searching African journals. This project intends to ensure that trials conducted in Africa are documented so they can be used in Cochrane reviews.

The collaboration publishes its reviews in the Cochrane Library, primarily through CD-ROM and the Internet. Free access to abstracts and summaries of the reviews are available to the public, but most full-text documents require a subscription. Access to the reviews is steadily improving for people in low- and middle-income countries through free national subscriptions or global initiatives promoting free access to health care information, such as the HINARI Access to Research in Health Programme (http://www.who.int/hinari/en). Since it was established, the information disseminated by the Cochrane Collaboration is having a "significant impact on education, practice, research and policy" (Volmink et al. 2004).

E-mail: secretariat@cochrane.org

Web: http://www.cochrane.org

Sources: Grimwade and Swingler 2006, Volmink et al. 2004.

the primary literature. Some review articles summarize the results and conclusions of a number of reports from the primary literature (usually with comments by the reviewer). Systematic reviews of data from multiple trials addressing the same research question (meta-analyses) are particularly useful. The Cochrane Collaboration (see Box 34-3) undertakes this type of work.

Bibliographic, abstracting, or indexing services provide listings or compilations of published articles. Some list the addresses of the principal authors; others contain abstracts of articles, along with key words or subject headings to help users find the articles or references for which they are looking. Examples of such services include PubMed, Embase, International Pharmaceutical Abstracts, Index Medicus, Excerpta Medica, and the Iowa Drug Information Service. Different systems cover different journals and may, for instance, omit letters to the editor. A lag period exists between initial publication of a primary source and its inclusion in such secondary sources. Not relying entirely on one secondary source is therefore important.

Drug bulletins can be valuable in helping prescribers and supply system managers determine the relative merits of new medicines and keep up-to-date. Drug bulletins can have a variety of sponsors, such as government agencies, professional bodies, university departments, philanthropic foundations, and consumer organizations. They are published in many countries, sometimes free of charge, and many are highly respected because of their unbiased information. Examples in English are *Drug and Therapeutics Bulletin* (United Kingdom), *Medical Letter on Drugs and Therapeutics* (United States), and *Australian Prescriber* (Australia). *Prescrire International* is available in both French and English. National drug bulletins appear in many other countries, including Bukina Faso, Nepal, and Pakistan. The main advantages of national drug bulletins are that they can select topics of national relevance and use the national language.

Tertiary references, written by individuals or groups, are often developed with the input of consultant authors and reviewers and may be widely peer reviewed. In general, the more thorough the review process is, the more sound the information is likely to be. In many countries, the most widely available tertiary resources are formulary manuals and standard treatment manuals produced by the health system. These important resources are discussed in Chapter 17. Box 34-4 also lists selected tertiary sources.

Probably the most widely accepted secondary and tertiary information sources are those that report the consensus of experts, a process that involves a high level of scrutiny and feedback. A consensus statement is the closest one can come to agreement among experts. In most instances, consensus is defined as having addressed and considered all dissenting views so that, at a minimum, all disagreements have been publicly stated and considered. The consensus documents developed by the U.S. National Institutes of Health, such as the *NIH Consensus Development Conference Statement on the Management of Hepatitis B* from 2008, are good examples of this approach to information development.

Manufacturer-provided medicine information

Information provided by pharmaceutical companies is so commonly available and widely used that it warrants a separate discussion. This information can be technical, such as product labeling approved by a country's regulatory agency, textbooks, and journal reprints, or promotional information. Promotional information seeks to show how one company's product is better than another's or how a new product can treat a serious or not-so-serious medical condition. Although both technical and promotional information are ultimately intended to increase sales, the two differ greatly in

Box 34-4
Basic references for a medicine information library

- American Hospital Formulary Service medicine information
- *British National Formulary*
- Cochrane Library
- Medicine availability reference (specific for the country or region)
- *Dart, Medical Toxicology,* or another clinical toxicology or poisoning text
- *Goodman and Gilman, The Pharmacological Basis of Therapeutics,* or another basic pharmacology text
- *Index Nominum: International Medicine Directory*
- *Martindale: The Complete Drug Reference*
- National formulary or essential medicines list
- PubMed
- Price reference (specific for the country or region)
- *International Drug Price Indicator Guide*
- Textbook of internal medicine (such as *Harrison's Principles of Internal Medicine* or the *Oxford Textbook of Medicine*)
- Tropical medicine reference (in countries where appropriate)

Box 34-5
Medicine information and promotion: Educating medical and pharmacy students about medicine promotion

Understanding the relationship between health professionals and medicine promotional information produced by the pharmaceutical industry is important. Research has shown that doctors who rely more on industry promotional information tend to prescribe less appropriately, prescribe more often, and adopt new medicines more quickly; therefore, medical and pharmacy students need to be educated about recognizing medicine promotion and responding appropriately.

In 2005, an international cross-sectional survey, Educational Initiatives for Medical and Pharmacy Students about Medicine Promotion, examined the extent to which students are educated about the pharmaceutical industry and medicine promotion. The results are based on a survey of 228 pharmacy and medical school educators from sixty-four countries.

In the survey, nearly three-quarters of educators reported that education about medicine promotion is part of their required curriculum but that most students devoted less than one-half day to this topic. The regional breakdown is illustrated in the table below.

The survey reported what survey respondents felt were the main objectives of their medicine promotion curriculum—

- Of educators from all regions, 70 percent or greater, except the eastern Mediterranean (56 percent), said the main objective of their curricula was to teach critical appraisal of medicine promotion.
- Of educators from all regions, 70 percent or greater said that the main objective was to increase students' use of independent resources.
- Only 14 to 26 percent of the educators felt that the main objective was to decrease students' use of medicine promotion.

Many pharmacy and medical educators have recognized the need for education about medicine promotion, but they frequently mention a lack of integration into the main curriculum and inadequate time allocation as barriers to a successful program.

In some cases, students themselves are taking an active role in opposing the influence of medicine promotion. In 2002, the American Medical Student Association launched its PharmFree campaign, which educates medical students about the influences of the pharmaceutical industry on medical training and the problems with using biased industry-based information to choose which medicines to prescribe. The association encourages students to refuse any gifts from pharmaceutical representatives as a way to show that they are not influenced by them, and they encourage the use of sources such as the *Medical Letter* to get unbiased evaluations of new medications.

Sources: Moghimi 2006, Mintzes 2005, Norris et al. 2005.

Educators' report of the role of medicine promotion in international pharmacy and medical school curriculum

Role of medicine promotion	Europe (%)	Americas (%)	Western Pacific (%)	Africa (%)	Eastern Mediterranean (%)	Southeast Asia (%)
Promotion is part of curriculum	81	83	67	86	70	91
Promotion is part of *required* curriculum	75	64	81	85	65	56
One-half day or less spent on promotion	30	32	39	25	20	20
Ten or more hours spent on promotion	40	34	32	50	45	44

terms of source and presentation. The information provided by pharmaceutical manufacturers varies considerably from country to country, depending on a government's regulatory requirements and its ability to effectively monitor and enforce those requirements. Box 34-5 covers an initiative to increase medical and pharmacy students' knowledge of medicine promotion.

Technical information. The information developed as part of a new medicine approval process by a country's drug regulatory authority has been thoroughly reviewed and should accurately reflect a product's basis for approval. It defines what information manufacturers are required by law to include with their product—that which is affixed to a bottle or package (the labeling) and more detailed

information that needs to accompany the product (package insert). Approved product information guides prescribers, dispensers, and patients on use of a particular medicine and defines what the manufacturer can legally say (advertise) about its product. This information includes, for example, the medicine's approved indications for use, precautions, potential adverse effects, and dosing, as well as the product's strength, composition, and packaging and storage requirements. In addition, more and more countries are providing information for the patient in easy-to-read language on how to use the product correctly. Because this information is approved by the drug regulatory authority, it carries significant impact both clinically and legally.

Many health professionals and patients regularly use references that compile government-approved product information or brief descriptions of a product's physical characteristics and use that are based on approved product information. In the United States, the most common reference of this type is the *Physicians' Desk Reference,* where pharmaceutical companies pay to include their products (making it marketing focused). In the United Kingdom, the Association of the British Pharmaceutical Industry *Data Sheet Compendium* is commonly used; and in many other countries, the country-specific or regional edition of *MIMS* (*Monthly Index of Medical Specialties*) provides brief sets of information for products marketed in that country or region. The limitations of these types of publications must be kept in mind, particularly related to what is included (older, less-profitable products are more likely to be excluded) and the information omitted because of

Box 34-6
WHO ethical guidelines for medicine promotion

Since 1967, WHO has been concerned about improper pharmaceutical advertising. A new statement on ethical criteria for medicine promotion was adopted in 1988. At the 1997 Roundtable on WHO's Ethical Criteria for Promotion of Medicinal Drugs, participants agreed that inappropriate medicines promotion remained a problem both in developing and developed countries. The movement for a major project on pharmaceutical promotion originated at the May 1999 meeting of the WHO/public-interest nongovernmental organization, Roundtable on Pharmaceuticals.

Promotion of pharmaceuticals should support the national pharmaceutical policy. The WHO ethical criteria state that advertisements should be consistent with the approved scientific data sheet and should be fully legible. Advertisements to the public should be for nonprescription medicines only. Medical representatives should have appropriate training and should present information in an accurate and responsible manner, without offering incentives to prescribers or dispensers. They should make unbiased information on products available.

Under the criteria, free samples may be provided in modest quantities to prescribers. The criteria also state that providing free samples of nonprescription medicines is difficult to justify from a health perspective. When a pharmaceutical company sponsors a symposium or scientific meeting, its involvement should be clearly stated in advance at the meeting and in any publications.

The criteria recognize that postmarketing surveillance is important but caution that it should not be misused as a disguised form of promotion. The criteria also define standards in packaging and labeling, patient information, and promotion of exported medicines. Many, but not all countries and some companies have adopted these criteria as a guide for marketing practices.

Copies of the ethical criteria are available from WHO offices and have also been published in full in the *WHO Essential Drugs Monitor* 17 (1994).

Other helpful resources related to pharmaceutical promotion include—

- Health Action International has a website devoted to medicine promotion (http://www.haiweb.org/03_other.htm). It includes downloadable resources related to promotion to consumers, promotion in health education, and drug industry sponsorship.
- The organization Healthy Skepticism (http://www.healthyskepticism.org), formerly the Medical Lobby for Appropriate Marketing, is a nonprofit advocacy group that initially focused on revealing harmful medicine promotion activities in developing countries but now documents information from all countries. Its online library of medicine promotion information includes more than 19,000 items.
- *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide* (WHO/HAI 2010) is designed to summarize medicine marketing and promotion issues for medical and pharmacy students (http://www.haiweb.org/10112010/DPM_ENG_Final_SEP10.pdf).

Box 34-7
Questions to ask about manufacturer-supplied information

- Has the information been approved by the country's drug regulatory body?
- Are references to the medical literature provided or available? Do they come from peer-reviewed journals?
- Was the information unsolicited, or was it provided in response to a request or question?
- Does the information contain negative references to the use of other medicines that might be substitutes or therapeutic alternatives to the medicine in question? If so, are such negative references warranted?
- Do the claims for the medicine's effectiveness appear overly positive, sensational, or one-sided?
- Is the information balanced with the negative outcomes related to the use of a medicine (such as side effects or adverse effects)?
- Are cost comparisons included?
- Does the information included in the product insert or the labeling reflect current medical practice and standards?
- Are references dated and current?
- Is the information in a language suitable for the consumer?

space limitations. They are not comprehensive information sources.

Promotional information. Promotional materials developed by a pharmaceutical company typically present only favorable views of the sponsor's products, and the materials may not furnish adequate information to make good prescribing decisions. Although most countries have regulations defining acceptable pharmaceutical marketing, in practice, governments often have difficulty controlling what information companies provide. A multinational advocacy organization, Healthy Skepticism, monitors misleading advertisements, as does Health Action International. WHO has developed ethical guidelines for pharmaceutical promotion (see Box 34-6).

This does not mean that manufacturers' information is universally bad and should not be used at all, because manufacturers can supply very timely and useful medicine information. However, health care professionals or patients using manufacturer-supplied sources need to recognize the potential for bias and make a judgment about the materials' value (see Box 34-7).

34.3 Setting up a medicine and therapeutics information center

A medicine and therapeutics information center is a vital part of efforts to promote appropriate medicine use. In a small country with limited means, this center may be a small office in the national hospital with a shelf of books and WHO publications and where a hospital pharmacist is responsible for answering queries. Ideally, however, countries should develop formal MICs as part of their national health programs. An MIC should work closely with the national essential medicines program, provide support for development and maintenance of formulary and standard treatment guidelines, and be involved in the production of national medicine-related materials.

To be successful, an MIC requires a stable location and environment, a philosophical commitment to providing needed medicine information, physical space to house the center, basic information references, staff, and equipment to support information access and dissemination.

An MIC and a poison control center are two different services, although they are often combined. Poison control is usually an emergency service requiring rapid response. A medicine information service deals with both urgent requests for therapeutic information and requests that require a more detailed review and synthesis of information.

Philosophical commitment

An MIC should be both reactive and proactive. Reactive or passive duties include providing information for people who call or come to the center with questions. Although this function is important, it certainly should not define the limits of a center's activities. A center's effect will be greater if it functions proactively by reaching out with medicine information for people who need it, in a format that is convenient and effective. This task will be easier if a medicine information service is based on a cooperative model, involving all health care disciplines and using existing resources to the greatest extent possible. The center not only should be driven by the needs and expectations of its users but also should work to create demand and raise expectations.

Site identification

Ideally, an MIC is in or near a major hospital or other major health care facility. Location within a hospital, university, or other academic institution provides a network of medical disciplines that can support and enrich the work, allowing

MEDICINE INFORMATION SHOULD BE RESPONSIVE TO CLIENTS' NEEDS

better access to medicine information and to libraries, research facilities, expertise, and academic and educational activities. Possible alternative sites include a facility within or adjacent to a medical or pharmacy association or a relevant governmental agency (such as the ministry of health, drug regulatory authority, pharmaceutical approval unit, or quality-control laboratory).

A secure location in one or two rooms allows space for office work, space for storage of references, and space for visitors to use the MIC's resources. Involving several institutions in the support of an MIC may be necessary. In some countries, a mutual agreement exists that the MIC at the university provides services on behalf of the ministry of health. In turn, the government covers some recurrent expenses.

Staffing and equipment requirements

An MIC needs dedicated staff who will not be diverted to other activities and duties and who can provide dependable coverage for the center's stated business hours. This need translates into one or two full-time employees, including a full-time clinical or hospital pharmacist who specializes in clinical pharmacology, therapeutics, or toxicology. Additional staffing may be required if activities other than information, such as pharmacovigilance, are part of the center's mission.

The training and experience of the staff must be clinically based. The user population for any information service is primarily clinicians, and expertise in pharmacotherapy is essential to communicate effectively with them. When an appropriately trained person is not available, every effort should be made to train someone to fill the position. Other relevant professionals—medical, paramedical, or nonmedical—and specialists in information communication techniques may be required to help develop materials and provide specific information and services. When medicine information specialists are not available, a medical doctor with some training in clinical pharmacology should be considered to head the center. Ideally, the center should have qualified administrative staff to help establish, maintain, and update the information access and dissemination processes.

Proper photocopying, communications (including Internet access), and computer equipment are important in establishing a viable medicine information service. A computer, CD-ROM/DVD drive, printer, and appropriate software programs are highly desirable because access to electronic medicine and therapy databases is critical. However, small centers can provide important medicine information services using basic texts and other printed references if electronic access is not possible.

Basic information resources

The latest editions of the textbooks listed in Box 34-4 could form the core of a basic library for an MIC, along with journals and newsletters, WHO materials, and computer databases (see Annex 34-1). Although the most flexible and efficient of these resources are the computer databases, cost may limit their availability. Print resources, if kept up-to-date, can adequately cover basic information needs. Some print and electronic databases can be accessed free of charge.

Although subscriptions to medical and pharmacy journals and newsletters are expensive, some basic subscriptions should be considered if the funds are available. Many scientific journals are now available via open access or are free of charge. A list of many such journals can be found at the Directory of Open Access Journals (http://www.doaj.org). Because acquiring and updating information is costly, establishing a link to a medical library is very important. The addresses of organizations that produce widely accepted medicine newsletters or bulletins, which are inexpensive and useful sources of information, can be obtained from the International Society of Drug Bulletins (ISDB).

Electronic access to information is critical for an MIC because most databases and journals are online. If Internet access is unavailable or unreliable, however, or if the costs of online access are prohibitive, CD-ROMs might be an alternative resource. Databases to consider including in an MIC include—

- PubMed (online)
- British National Formulary (online)
- Cochrane Library (online and CD-ROM)
- DrugDex (online)
- Poisindex (online and CD-ROM)
- Martindale: The Complete Drug Reference (online and CD-ROM)
- AHFS Drug Information (online)
- International Pharmaceutical Abstracts (online)
- Embase (online)
- Iowa Drug Information Service (online, CD-ROM, and microfiche)

34.4 Managing a medicine information center

An MIC should provide a variety of services, from responding to patients' and doctors' queries to making proactive efforts such as publishing newsletters or drug bulletins, participating in clinical activities, and organizing formulary and treatment guideline committees (see Country Study 34-1). MIC staff members are also likely to be involved in training health professionals and regularly evaluating the performance of the center's staff. Although MICs tend to be small units, each one should have a well-developed annual plan.

Proactive outreach

Health care professionals in both the public and private sectors often have little time or funds to spend on medicine information resources. An MIC can fill this gap, but the service must be effectively marketed.

Medicine information professionals need to work to build credibility and improve perceptions of their accessibility and value to health care providers, specifically, and to the health care system overall. This can be done by—

Country Study 34-1
Therapeutics Information and Pharmacovigilance Center in Namibia

As the Namibian government began rolling out antiretroviral therapy, an assessment identified lack of a source of information about medicines and lack of a monitoring system for adverse drug reactions as critical gaps in Namibia's ability to deliver AIDS treatment. To fill this gap, the Rational Pharmaceutical Management Plus Program conceptualized a model that integrated medicines information and pharmacovigilance activities into one service unit called the Therapeutics Information and Pharmacovigilance Center (TIPC). Although most countries separate these activities, this integrated model was driven by the potential synergies between the two services, opportunities for leveraging resources, and human resource constraints. The model placed the TIPC under the Namibia Medicines Regulatory Council with existing Ministry of Health and Social Services committees serving as the advisory body.

The TIPC provides unbiased therapeutics information and serves as the official reference center for medicine safety monitoring in Namibia. It provides broad-based medicine-safety services, such as how to avoid potential drug interactions, and communicates point-of-care therapeutic information to health care providers and the public through a hotline, fax, and e-mail. Anyone can request medicine or therapeutics information by filling out a form on the TIPC website. The TIPC also publishes the *Namibia Medicines Watch,* a drug bulletin for health care providers and consumers.

The center implemented a nationwide system for spontaneous reporting of adverse drug reactions in 2007, through which it collects reports from health care providers and the public of adverse effects of medicines. The TIPC has also collaborated with partners to conduct trainings for health care workers in therapeutics information and pharmacovigilance and basic research methods.

Source: SPS Program n.d.

- Building alliances with the most influential clinicians, providing them with particular information they request, and involving them as consultants and reviewers
- Ensuring that they are readily accessible by telephone or in person and providing responses to queries promptly
- Making an extra effort to find answers for clinicians who have raised unusual medicine-related questions
- Participating in national essential medicines list committees, hospital drug and therapeutics committees, and standard treatment guidelines committees
- Preparing short, problem-oriented, practical bulletins on medicine-use problems specific to the country, district, or hospital
- Making patient rounds with doctors and other clinical staff
- Providing in-service training to health facility staff
- Making short presentations to outpatient groups
- Making presentations to community organizations

Drug bulletins

The development, production, and dissemination of newsletters or drug bulletins that address relevant medicine information issues often help develop the market for an MIC. These periodicals should promote rational medicine therapy and appear at regular intervals, ranging from weekly to quarterly, depending on their purpose and on the capacity of the MIC. Drug bulletins should provide impartial assessments of medicines and practical recommendations, based on a comparison of treatment alternatives and on the consensus of the main specialists in the field.

Drug bulletins are more likely to be effective if they take the following principles into account (see Figure 34-1)—

Understanding the reasons for prescribing behavior: As mentioned in Chapter 29, providing information alone does not change undesirable behavior. Understanding the reasons for the behavior is a necessary first step in developing appropriate messages.

Being oriented toward decisions and actions: Prescribers need information that is immediately useful in their daily work.

Emphasizing and repeating only a few key messages: If too many ideas are brought up in the bulletin, none will be absorbed. A few messages that are the focus of the bulletin and are repeated are more likely to be retained.

Capturing attention with headlines and visually appealing illustrations: An effective bulletin grabs the reader's attention with attractive graphics that emphasize key messages.

Keeping text brief and simple: Although readers of the bulletin may be well educated and knowledgeable, a bulletin should provide immediately accessible information.

Referencing the best research and having respectable sponsorship: The bulletin should be affiliated with a credible organization or institution such as a medical society or medical school. Key messages in each issue should be supported by a few well-chosen and respected references. Three references to the *Lancet*, *New England Journal of Medicine*, *British Medical Journal*, or *Journal of the American Medical Association* are better than twenty references to unpublished reports.

Being relevant: Materials in the bulletin should relate to clinical issues that affect the target audience and should discuss medicines that are available in the audience's country or health system.

The ISDB produces a regular newsletter, organizes regional workshops for international editors of bulletins and newsletters, and provides a forum for the exchange of high-quality information and ideas related to promoting effective dissemination of information. Box 34-8 includes information on starting or strengthening a drug bulletin.

Training

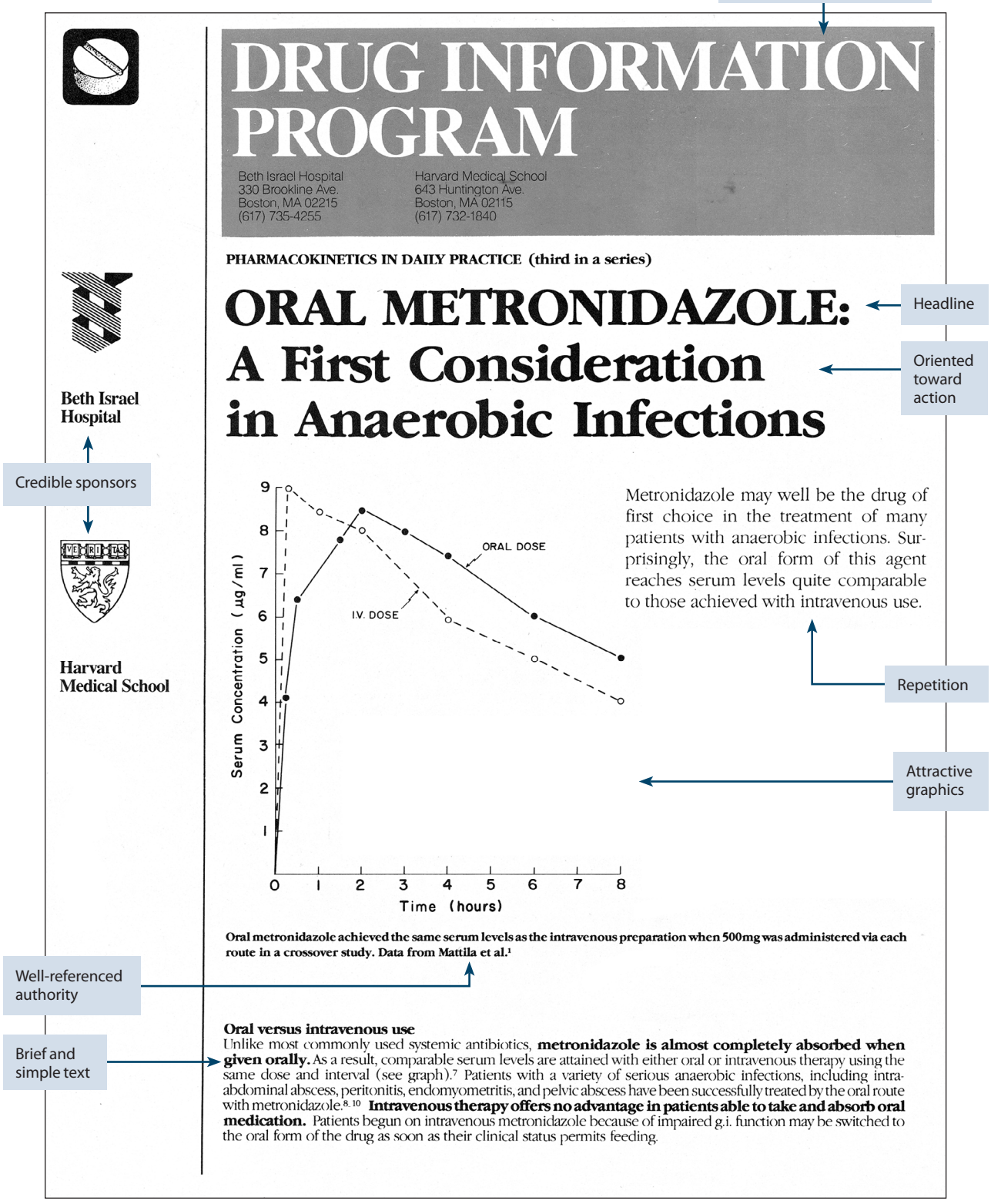
Training in the management of an MIC or a medicine information service is necessary for key personnel, as is training on medicine information retrieval, literature evaluation, publication development, and sustainability planning and funding. In addition, communications skills, including ability to write succinctly using language appropriate for the target audience, are critical. A large medicine information service should ideally have a career structure similar to those of academic or educational institutions. All staff members should have the opportunity for additional training and advancement within their own capabilities. When appropriate, professional staff should be encouraged to undertake relevant research activities.

Evaluation

Ongoing monitoring and evaluation is particularly important for services such as an MIC, where resources are limited and getting the most out of the available funding is essential. Monitoring should be built in from the start and should include documenting the questions asked, responses provided, references used, complaints and compliments received, timing of responses, and services provided (such as new medicine evaluations). The queries should be analyzed, and the results summarized in the annual report. In addition, periodic input from users of the medicine information service should be sought through personal contacts, questionnaires, or focus groups.

This information can help the center's manager make good decisions about future programs and budgeting. For example, if a certain inquiry has been made several times by

Figure 34-1 Example of a credible drug bulletin



different individuals, the question may be a good topic for an article in the medicine information newsletter or bulletin. If the same complaint about MIC service is made repeatedly, perhaps a review of the center's operations is in order. If a certain textbook or database is not frequently used, perhaps it should be replaced by another one.

Sources of help

Funding for the establishment of an MIC may come from government resources, donors supporting essential medicines projects, professional associations, university or other training programs, nongovernmental organizations, or a combination of several of these funding sources.

Several programs allow developing countries to more easily access health and medicine information and resources. For example, the International Pharmaceutical Federation's Pharmabridge program helps provide books, journals, and electronic resources to those who need them in developing countries (http://www.fip.nl/pharmabridge). WHO's HINARI Access to Research in Health Programme also allows developing countries to use a large collection of scientific and medical literature (http://who.int/hinari/en). WHO also has "blue trunk libraries" that have over 100 books arranged by topic, including essential medicines (www.who.int/ghl/mobile_libraries/bluetrunk/en). Blue trunk libraries are available in English, French, Portuguese, and Arabic. Collaboration between centers in developing and developed countries is very valuable and enables the exchange of information and staff for teaching and training. The ISDB is also a useful channel for support.

Box 34-8
Starting or strengthening a drug bulletin

Drug bulletins are a fundamental tool for promoting rational use of medicines, and locally produced bulletins are an effective approach to providing reliable and unbiased comparative information on medicines and therapies for prescribers, patients, and the public within the context of local needs and uses. The information should focus on using medicines safely and correctly and help people make better decisions about medicines.

WHO and the ISDB have worked together to develop guidelines called *Starting or Strengthening a Drug Bulletin: A Practical Manual,* which shows global experiences related to developing drug bulletins.

The objectives of the ISDB and WHO manual include—

- Illustrating what makes bulletins independent
- Reflecting the diversity found among drug bulletins
- Helping people make choices about what is appropriate for their bulletin
- Showing useful methods and models and helping people learn from the successes and failures of others
- Helping people decide whether to set up a bulletin, how to set up a bulletin, or how to strengthen their existing bulletin

The manual has sections on planning, production, and the editorial process, as well as a detailed discussion of books and journals that are good references for bulletins.

How drug bulletins provide unbiased information on pharmaceuticals in Kyrgyzstan

According to WHO, an underlying factor in irrational medicine use in Kyrgyzstan is the lack of access to independent medicine information. Working closely with the National Drug Committee, Kyrgyzstan's drug information center has taken on the important role of providing independent medicine information to health care providers. The center publishes a quarterly drug bulletin to disseminate unbiased and updated pharmaceutical information and to promote rational medicine use and information on health reform. Previously addressed topics include medical errors related to the name of medicines, medicine interactions, and modified-release preparations of pharmaceuticals.

How drug bulletins provide unbiased information on pharmaceuticals in Nicaragua

In Nicaragua, *Boletin AIS-COIME* is produced by a national nongovernmental organization, AIS-Nicaragua. It distributes free copies of its twelve-to-sixteen-page bulletins to all doctors working in public hospitals and primary health care units, pharmacy and medical students and teachers, nongovernmental organizations, and some private pharmacies. The bulletin is produced by a small team of three to four people and some volunteers. The team works together in a small room with access to a fax, photocopier, store, library, and meeting room. The country's drug information center provides them with information and reviews and helps with distribution of the bulletin.

Source: ISDB/WHO 2005.

ASSESSMENT GUIDE

Medicine information center

- Does a medicine information unit or center exist? If so, how is it funded and staffed?
- Does the medicine information unit or center (or another independent body) provide regular information on medicines to prescribers and dispensers?
- How many issues of independent drug bulletins are published each year?
- What percentage of prescribers receives copies of independent drug bulletins?
- What level of financial support did the medicine information center receive?
- How many queries did the medicine information center respond to in the past year?
- What current information resources are available? Which are most frequently used?

Local medicine information resources

- Has a national essential medicines list or formulary been officially adopted and distributed countrywide?
- Does a national publication (formulary bulletin or manual), revised within the past five years, provide objective information on medicines?
- Does a national therapeutic guide exist with standardized treatments for common diseases?
- What percentage of advertisements violates regulations on the ethical promotion of medicines, and how many sanctions have been implemented?
- What percentage of prescribers and dispensers has direct access to a (national) medicine formulary and standard treatment guidelines?

Funding issues

The source of funding may affect how an MIC functions. No matter how it is financed, the integrity of the unit is paramount. No special interests should be able to influence what information is or is not given out.

Obtaining initial capital funding from the sources listed previously may be possible. These organizations often provide funds for the purchase of items such as computers or photocopiers. For sustainability, it is wise to purchase a two- or three-year maintenance contract for such equipment as part of the initial capital costs.

Obtaining an adequate level of recurrent funding, particularly for staff salaries and journal, online database, or CD-ROM subscriptions, can be more difficult. Therefore, while establishing the center, every effort should be made to secure recurrent funding. For example, if a donor provides the start-up capital, the government may be persuaded to commit funding for a full-time pharmacist at the center. If a hospital is located near the center, it could be a source for long-term funding. In some countries, implementing user fees may be possible; however, this approach should be taken gradually, after the MIC has been accepted by users and they have given their input in determining services and fees.

Pharmaceutical companies may be willing to support a center, but this support should be considered cautiously. If medicine information critical of a sponsoring company's product is disseminated, the company may withdraw support. In general, funding from a pharmaceutical company should be used for discrete projects, such as replacement of a photocopier. Remember, however, that even the perception of bias toward a sponsoring company's products can harm an MIC's reputation.

Medicine information professionals in developing countries inevitably become fund-raisers to maintain activities. For example, in Cameroon, a consortium of donors was mobilized to share support for the drug bulletin. ■

References and further readings

General

★ = Key readings.

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★ ISDB/WHO (International Society of Drug Bulletins and World Health Organization). 2005. *Starting or Strengthening a Drug Bulletin: A Practical Manual*. Geneva: ISDB/WHO. <http://www.who.int/medicines/areas/rational_use/startingstrengdrugbulletin.pdf>

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Medicine promotion and marketing

HAI (Health Action International). 1992. *Promoting Health or Pushing Drugs?* Amsterdam: HAI.

★ Healthy Skepticism. <http://www.healthyskepticism.org> An international nonprofit organization with the aim of improving health by reducing harm from misleading drug promotion. It maintains an online library of information related to drug promotion.

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Annex 34-1 Information sources

Medical and therapeutic journals

Annals of Internal Medicine
http://www.annals.org

BMJ
http://bmj.bmjjournals.com

Journal of the American Medical Association
http://jama.ama-assn.org

Lancet
http://www.thelancet.com

New England Journal of Medicine
http://content.nejm.org

PLoS Medicine
http://www.plosmedicine.org

Drugs and toxicology information and pharmacology journals

British Journal of Clinical Pharmacology
http://www.blackwellpublishing.com/journal.asp?ref=0306-5251&site=1

Clinical Toxicology
http://informahealthcare.com/loi/ctx

European Journal of Clinical Pharmacology
http://www.springer.com/biomed/pharmaceutical+science/journal/228?changeHeader

Human and Experimental Toxicology
http://het.sagepub.com

International Journal of Clinical Pharmacology and Therapeutics
http://www.clinpharmacol.com

Pharmacy journals

American Journal of Health-System Pharmacy
http://www.ajhp.org

Annals of Pharmacotherapy
http://www.theannals.com

Journal of Clinical Pharmacy and Therapeutics
http://www.wiley.com/bw/journal.asp?ref=0269-4727

Pharmaceutical Journal UK
http://www.pjonline.com

Essential medicines lists, therapeutic formularies, and standard treatment guidelines

British National Formulary
http://www.bnf.org/bnf

Medicines Policy Documents from Selected African Countries, World Health Organization, 2005
http://collections.infocollections.org/whocountry/en

WHO Model Formulary 2008
http://apps.who.int/medicinedocs/en/m/abstract/Js16879e

WHO Model List of Essential Medicines: The Use and Selection of Drugs, 16th list (updated), March 2010
http://www.who.int/medicines/publications/essentialmedicines/en

Drug information newsletters

Australian Prescriber
http://www.australianprescriber.com

BTA (Boletín Terapéutico Andaluz) (Spanish)
http://www.easp.es/web/cadime/cadime_bta.asp?idCab=303&idSub=378&idSec=303

Butlletí Groc (Catalan)
http://www.icf.uab.es/ca/productes/bg/butlletigroc.html

Drug and Therapeutics Bulletin
http://dtb.bmj.com

FNT (*Fichas de Novedad Terapéutica*) (Spanish)
http://www.easp.es/web/cadime/cadime_fnt.asp?idCab=303&idSub=378&idSec=303

Medical Letter on Drugs and Therapeutics
http://www.medletter.com

La revue Prescrire/Prescrire International (French/English)
http://www.prescrire.org

Therapeutics Letter
http://www.ti.ubc.ca/TherapeuticsLetter

WHO Drug Information
http://www.who.int/medicines/publications/druginformation/en/index.html

WHO Pharmaceuticals Newsletter
http://www.who.int/medicines/publications/newsletter/en/index.html

Worst Pills, Best Pills
http://www.worstpills.org

Miscellaneous resources

Agency for Healthcare Research and Quality (US)
http://www.ahrq.gov

Cochrane Library
http://www.thecochranelibrary.com

electronic Medicines Compendium (UK)
http://emc.medicines.org.uk

International Network for the Rational Use of Drugs
Tools and Resources
http://www.inrud.org/Resources.cfm
Bibliographies
http://www.inrud.org/Bibliographies/index.cfm

U.S. Centers for Disease Control and Prevention
http://cdc.gov

U.S. Food and Drug Administration
http://www.fda.gov

U.S. National Institutes for Health
http://nih.gov

WHO Essential Medicines Teaching Resources
http://www.who.int/medicines/training/en

WHO Medicines Publications and Documentation
http://www.who.int/medicines/publications/en
http://apps.who.int/medicinedocs/en