Chapter 1
Toward Sustainable Supply and Rational Use of Drugs

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INTRODUCTION

Summary

Most leading causes of death and disability in developing countries can be prevented, treated, or at least alleviated with cost-effective essential drugs. Despite this fact, literally hundreds of millions of people do not have regular access to essential drugs. Many of those who do have access are given the wrong treatment, receive too little medicine for their illness, or do not use the drug correctly.

Managing Drug Supply is concerned with practical ways in which government policy-makers, essential drugs program managers, non-governmental organizations (NGOs), donors, and others can work to ensure that high-quality essential drugs are available, affordable, and used rationally. Drugs are of particular importance because they can save lives and improve health, and they promote trust and participation in health services. They are costly, and there are special concerns that make drugs different from other consumer products. In addition, substantive improvements in the supply and use of drugs are possible.

Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid-1950s to the mid-1970s, basic drug management concepts began to evolve in countries as diverse as Norway, Papua New Guinea, Sri Lanka, Cuba, and Peru.

In 1975, the World Health Organization (WHO) defined essential drugs as those drugs that meet the health needs of the majority of the population. Over the last twenty years, countries have acquired considerable experience in managing drug supply. Broad lessons that have emerged from this experience include:

- National drug policy provides a sound foundation for managing drug supply.
- Wise drug selection underlies all other improvements.
- Effective management saves money and improves performance.
- Rational drug use requires more than drug information.
- Systematic assessment and monitoring are essential.

Although much has been achieved over the last two decades, many challenges remain:

- Achieving financial sustainability through greater efficiency and financing mechanisms that increase availability while ensuring equity (financing options include public financing, user charges, health insurance, voluntary and other local financing, and donor financing);

- Improving efficiency in public drug supply through strategies that build on public sector strengths while incorporating greater flexibility and competitiveness;

- Changing the behavior of providers, patients, and the public to promote effective, safe, and economical prescribing, dispensing, and patient use of drugs;

- Reinventing the role of government to improve the availability, affordability, and rational use of drugs in the private sector, which supplies 60 to 80 percent of the drugs consumed in developing countries;

- Regulating safety, efficacy, and quality through legislation and regulations that ensure that all drugs meet basic quality standards.

Managing Drug Supply is organized around the four basic functions of the drug management cycle:

- selection
- procurement
- distribution
- use

At the center of the drug management cycle is a core of management support systems:

- organization
- financing and sustainability
- information management
- human resources management

The entire cycle rests on a policy and legal framework that establishes and supports the public commitment to essential drug supply (Part II of this manual). Other major sections of the manual are devoted to each of the main functions of the drug management cycle (Part III) and management support (Part IV).

This manual provides concepts and approaches that can produce measurable health improvements through greater access to and more rational use of drugs. Governments, private organizations, donors, and others who use this manual must provide the will and the resources to put these concepts and approaches into action.

Interest in human health and illness is as old as humanity. Scientific study of human anatomy and human diseases can be traced to the Greek physician Hippocrates and earlier. Yet as recently as 100 years ago, the best that medicine could offer was a handful of demonstrably effective preparations. Penicillin, the first antibiotic, and
chloroquine, the first modern antimalarial, are scarcely fifty years old. Drugs for common conditions such as diabetes are only forty years old. And oral contraceptives have been generally available for only thirty years.

In industrialized countries, the age of modern pharmaceuticals has eliminated or dramatically reduced mortality from most common infections, allowed families to plan their growth, extended the lives of millions of people suffering from chronic illnesses, and provided relief from pain and suffering for hundreds of millions more people. From the simple discovery of penicillin in 1941 has grown a $200 billion-a-year pharmaceutical industry. The research efforts of that industry continually provide safer, more effective products. The industry's distribution networks ensure ready access to thousands of products for people throughout the industrialized world.

But for people in many parts of the world, it is as if penicillin had never been discovered and the age of modern pharmaceuticals had never dawned. In the late 1970s, it was estimated that 60 to 80 percent of people in the developing countries lacked regular access to even the most essential drugs. By the early 1990s, it was estimated that half the world's population—over 2 billion people—still lacked regular access to essential drugs (WHO 1992). Perhaps only one-third of the 435 million people in sub-Saharan Africa had access to essential drugs as of 1990 (Foster 1991).

It constitutes a fundamental failure of health and pharmaceutical supply systems that such a large share of the world's population still cannot benefit from simple, safe, effective pharmaceuticals and that literally millions of children and adults die each year from acute respiratory infections, diarrheal diseases, malaria, pregnancy-related anemia, and other common conditions that can be prevented or treated with modern drugs.

For those who do have access to essential drugs, many receive the wrong drug, the wrong dosage, or a quantity insufficient for their needs. In some countries, over half of all potent modern medicines are dispensed without prescription by untrained and unlicensed drug sellers. Even when patients and consumers receive the correct drug, between one-third and two-thirds do not consume it correctly.

Managing Drug Supply is concerned with practical ways in which government policy-makers, essential drugs program managers, nongovernmental organizations, donors, and others can work to close the huge gap between the need for essential drugs and public access to them—between the vast number of people who could benefit from modern pharmaceuticals and the much smaller number of people who actually do benefit. This manual is also concerned with closing the gap between the availability of drugs and their rational use.

This chapter focuses on the role of drugs in health care and health policy. It describes the essential drugs concept, reviews major lessons in drug management from the last twenty years, and summarizes major challenges still facing the pharmaceutical sector.

1.1 Why Worry about Drugs?

To clinicians facing the sick and injured on a daily basis, the importance of drugs is obvious. But it is useful to consider the reasons that ministers of health, directors of health programs, donors, and others involved in the health sector should be concerned with drugs. Accessible health services and qualified staff are necessary components of any health care system, but drugs have special importance for at least five reasons:

- Drugs save lives and improve health.
- Drugs promote trust and participation in health services.
- Drugs are costly.
- Drugs are different from other consumer products.
- Substantive improvements in the supply and use of drugs are possible.

These observations were the primary motivation for the preparation of this manual. The richness and diversity of opportunities for practical, effective improvements in drug supply and use are the focus of most of the following chapters.

Drugs Save Lives and Improve Health

Most leading causes of discomfort, disability, and premature death can be prevented, treated, or at least alleviated with cost-effective essential drugs. Although the relative frequencies of specific conditions vary among countries, outpatient services throughout the world are presented with a fairly common set of health problems for which essential drugs have an important role: acute infections, skin diseases, gastrointestinal complaints, musculoskeletal conditions, and injuries.

Mortality figures across developing regions (see Figure 1.1) reflect a huge burden of illness that can be substantially reduced if carefully selected, low-cost pharmaceuticals are available and appropriately used. Essential drugs have a major impact on common causes of morbidity and mortality, including acute respiratory infections (ARIs), diarrheal diseases, measles, malaria, maternal and perinatal mortality, sexually transmitted diseases (STDs), tuberculosis, and cardiovascular and other chronic diseases (see Box 1.1).
## INTRODUCTION

### Figure 1.1 Mortality from Infectious, Chronic, and Other Conditions in Developing Countries, 1990

<table>
<thead>
<tr>
<th>Condition</th>
<th>All Ages</th>
<th>0-4 Years</th>
<th>5 Years and Above</th>
<th>India</th>
<th>China</th>
<th>Asia</th>
<th>Africa</th>
<th>Latin America</th>
<th>Middle East</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious and parasitic diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Respiratory infections</td>
<td>3,984</td>
<td>2,710</td>
<td>1,274</td>
<td>1,096</td>
<td>411</td>
<td>691</td>
<td>1,029</td>
<td>211</td>
<td>546</td>
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<tr>
<td>Diarrheal diseases</td>
<td>2,866</td>
<td>2,474</td>
<td>392</td>
<td>825</td>
<td>95</td>
<td>432</td>
<td>887</td>
<td>171</td>
<td>456</td>
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<tr>
<td>Tuberculosis</td>
<td>1,978</td>
<td>72</td>
<td>1,906</td>
<td>452</td>
<td>356</td>
<td>353</td>
<td>536</td>
<td>112</td>
<td>170</td>
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<tr>
<td>Other infections and parasites</td>
<td>1,027</td>
<td>443</td>
<td>584</td>
<td>278</td>
<td>94</td>
<td>97</td>
<td>331</td>
<td>98</td>
<td>131</td>
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<tr>
<td>Measles</td>
<td>1,006</td>
<td>863</td>
<td>144</td>
<td>276</td>
<td>9</td>
<td>123</td>
<td>473</td>
<td>11</td>
<td>115</td>
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<tr>
<td>Malaria</td>
<td>926</td>
<td>632</td>
<td>294</td>
<td>28</td>
<td>—</td>
<td>74</td>
<td>805</td>
<td>12</td>
<td>7</td>
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<tr>
<td>Tetanus</td>
<td>505</td>
<td>450</td>
<td>54</td>
<td>160</td>
<td>22</td>
<td>65</td>
<td>175</td>
<td>8</td>
<td>76</td>
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<tr>
<td>Pertussis</td>
<td>321</td>
<td>277</td>
<td>44</td>
<td>82</td>
<td>13</td>
<td>33</td>
<td>134</td>
<td>18</td>
<td>42</td>
</tr>
<tr>
<td>Measles</td>
<td>248</td>
<td>56</td>
<td>192</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>218</td>
<td>29</td>
<td>—</td>
</tr>
<tr>
<td>Meningitis</td>
<td>232</td>
<td>121</td>
<td>111</td>
<td>62</td>
<td>22</td>
<td>40</td>
<td>50</td>
<td>21</td>
<td>37</td>
</tr>
<tr>
<td>Syphilis</td>
<td>192</td>
<td>77</td>
<td>115</td>
<td>26</td>
<td>2</td>
<td></td>
<td>153</td>
<td>12</td>
<td>—</td>
</tr>
<tr>
<td>Chronic and other noninfectious diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Cerebrovascular disease</td>
<td>3,181</td>
<td>14</td>
<td>3,168</td>
<td>619</td>
<td>1,271</td>
<td>350</td>
<td>389</td>
<td>224</td>
<td>227</td>
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<tr>
<td>Ischemic heart disease</td>
<td>2,469</td>
<td>2</td>
<td>2,467</td>
<td>783</td>
<td>442</td>
<td>589</td>
<td>109</td>
<td>269</td>
<td>277</td>
</tr>
<tr>
<td>Chronic obstructive lung disease</td>
<td>1,714</td>
<td>20</td>
<td>1,694</td>
<td>141</td>
<td>1,320</td>
<td>76</td>
<td>47</td>
<td>67</td>
<td>62</td>
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<tr>
<td>Inflammatory cardiac disease</td>
<td>1,229</td>
<td>68</td>
<td>1,161</td>
<td>528</td>
<td>92</td>
<td>130</td>
<td>234</td>
<td>122</td>
<td>123</td>
</tr>
<tr>
<td>Diabetes</td>
<td>483</td>
<td>0</td>
<td>483</td>
<td>145</td>
<td>60</td>
<td>87</td>
<td>25</td>
<td>86</td>
<td>82</td>
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<tr>
<td>Rheumatic heart disease</td>
<td>440</td>
<td>2</td>
<td>438</td>
<td>141</td>
<td>163</td>
<td>34</td>
<td>65</td>
<td>8</td>
<td>30</td>
</tr>
<tr>
<td>Asthma</td>
<td>147</td>
<td>9</td>
<td>138</td>
<td>33</td>
<td>56</td>
<td>18</td>
<td>15</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Malignant neoplasms</td>
<td>3,698</td>
<td>43</td>
<td>3,655</td>
<td>776</td>
<td>1,408</td>
<td>541</td>
<td>305</td>
<td>341</td>
<td>327</td>
</tr>
<tr>
<td>Maternal and perinatal causes</td>
<td>2,830</td>
<td>432</td>
<td>2,402</td>
<td>795</td>
<td>319</td>
<td>398</td>
<td>627</td>
<td>265</td>
<td>447</td>
</tr>
<tr>
<td>Other causes</td>
<td>9,611</td>
<td>1,709</td>
<td>7,902</td>
<td>2,146</td>
<td>2,731</td>
<td>1,389</td>
<td>1,333</td>
<td>897</td>
<td>1,117</td>
</tr>
<tr>
<td>All deaths</td>
<td>39,088</td>
<td>12,443</td>
<td>26,645</td>
<td>9,371</td>
<td>8,885</td>
<td>5,519</td>
<td>7,937</td>
<td>2,992</td>
<td>4,384</td>
</tr>
</tbody>
</table>


Not only are essential drugs effective against common health problems, they are also cost effective. It is undeniable that long-term health gains can be made by investing in prevention through health education and other programs to improve nutrition, sanitation, water supply, housing, environment, and personal health habits. At the same time, essential drugs provide a direct, low-cost response for many diseases.

### Drugs Promote Trust and Participation in Health Services

The credibility of health workers depends on their ability to save a dying village elder with a course of penicillin, to restore life to a limp child with oral rehydration, or to relieve an irritating skin infection with a simple ointment. Aside from their direct health impact, however, the availability of essential drugs attracts patients, who can then also receive preventive and public health messages. It has been observed that provision of essential drugs is one element of primary health care that families everywhere take an interest in and that brings them to health facilities.

Household and patient surveys in Africa, Asia, and Latin America find that drug availability is a major determinant of where patients go for health care and how satisfied they are with that care. A rural health survey in one Asian country revealed that the villagers valued drugs more than they did the health workers or the clinic. In Africa, more expensive mission health facilities are preferred by many patients, in part because their drug supply is reliable.

Availability of drugs and supplies also affects the productivity of health staff. When drug supplies fail to arrive, patient volume drops, and health workers are left idle. In many settings, irregular drug supply is a greater constraint on program effectiveness than inadequate numbers or inadequate training of health workers.

### Drugs Are Costly

Although drugs are cost effective, they can still be quite costly for an individual, a household, a government health system, or a country.

At the individual and household levels, drugs represent the major out-of-pocket health expenditure. A survey from Mali found that 80 percent of household health expenditures were for modern drugs. 13 percent for traditional medicine, 5 percent for provider fees, and 2 percent for transportation costs (Diarr and Coulibaly 1990).
Pakistan and Côte d'Ivoire, more than 90 percent of household health expenditures was related to drugs (World Bank 1993).

Of importance from a health perspective is the fact that household expenditures on drugs are closely tied with household income. In Ghana, for example, annual per capita drug expenditures varied from US$1.45 per person in the lowest-income households to $3.32 in middle-income households to $8.50 in the highest-income households (World Bank 1994).

For ministries of health in most developing countries, drugs expenditures are second only to staff salaries and benefits, accounting for perhaps 50 to 90 percent of nonpersonnel costs. Payment of personnel costs is standardized and largely unavoidable as long as staff are employed. Drug expenditures, therefore, represent the largest expenditure over which ministries have year-to-year discretionary control. This makes drug expenditures both extremely important and extremely vulnerable—vulnerable to fluctuations in the availability of public funding as well as to various political pressures.

At the national level, pharmaceuticals represent 10 to 20 percent of health expenditures for leading industrialized countries. But for most developing countries, they may represent one-third to two-thirds of total public and private health expenditures (WHO/DAP 1996). In the Mali survey, drugs not only accounted for most household health expenditures but also represented 66 percent of total recurrent health expenditures (Diarra and Coulibaly 1990).

In absolute figures, the amounts that countries spend on drugs vary tremendously. For most developing countries, the figure was under US$20 per capita in 1990 (see Figure 1.2); for industrialized countries in the same year, the figure ranged from $89 in Norway and $97 in the United Kingdom to $222 in Germany and $412 in Japan (Ballance et al. 1992). In general, drug expenditures increase with gross national product (GNP), such that a 10 percent rise in per capita GNP is associated with an 11 to 13 percent increase in per capita drug expenditures (World Bank 1994).

**Drugs Are Different from Other Consumer Products**

Since pharmaceuticals are produced by a competitive industry that responds to demand, it might be expected that their production and sale could be left almost wholly to the play of market forces. In that case, politicians and lawmakers would have only the same sorts of concerns that apply to other forms of trade—prevention of fraud, protection of trademarks, and so forth. But drugs are different and require special attention, because

- the consumer (patient or parent) often does not choose the drug—it is prescribed by a clinician or recommended by pharmacy staff;
- even when the consumer chooses the drug, he or she is not trained to judge its appropriateness, safety, quality, or value for money;
- neither the average medical practitioner nor the average pharmacist is equipped to independently assess

<table>
<thead>
<tr>
<th>Box 1.1 Impact of Essential Drugs on Common Causes of Morbidity and Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory infections,</strong> which accounted for nearly 4 million deaths in 1990 (10 percent of all developing country deaths) are usually cured readily with inexpensive oral antibiotics.</td>
</tr>
<tr>
<td><strong>Diarrheal diseases,</strong> the second leading cause of childhood mortality, can be prevented through improved water and sanitation. They can be treated in the home with simple fluid preparations. Mortality would be greatly reduced with widespread availability of simple glucose-electrolyte solutions and selective use of antimicrobial drugs.</td>
</tr>
<tr>
<td><strong>Measles,</strong> another leading cause of childhood mortality, is preventable through immunization. But when immunization is missed, much of the resulting mortality can still be eliminated through the treatment of respiratory, diarrheal, and other potentially fatal complications.</td>
</tr>
<tr>
<td><strong>Malaria,</strong> once on the decline, is responsible for nearly 1 million deaths each year; nearly 90 percent of fatal cases are in Africa, and almost half are among children. Prompt treatment with antimalarial drugs, especially for the very young, is lifesaving.</td>
</tr>
<tr>
<td><strong>Maternal and perinatal mortality</strong> can be reduced through antenatal care and nondrug interventions such as high-risk case management. But maternal anemia, a major contributing factor to maternal and perinatal morbidity and mortality, can be reduced with preventive doses of iron-folate preparations. In addition, child spacing through family planning (using largely oral, injectable, and implanted contraceptives) improves both maternal and neonatal outcomes.</td>
</tr>
<tr>
<td><strong>Sexually transmitted diseases (STDs)</strong> are epidemic in many areas, and drug resistance is increasingly common. Yet proper diagnosis and treatment of STDs are possible, besides being a cost-effective measure to reduce transmission of the human immunodeficiency virus (HIV). In addition, although a cure for AIDS does not yet exist, AIDS patients benefit from treatment of tuberculosis, respiratory infections, diarrhea, and other common illnesses that are frequently seen in AIDS patients in developing countries.</td>
</tr>
<tr>
<td><strong>Tuberculosis (TB),</strong> once on the decline, is now on the increase. Although TB drugs are costly and resistance is growing, short-course chemotherapy is curative, and the investment is highly cost effective.</td>
</tr>
<tr>
<td><strong>Cardiovascular and other chronic diseases</strong> are rapidly increasing in developing countries as socioeconomic development, immunization, and other improvements increase life expectancy. Health services are facing a growing demand for essential drugs to treat hypertension, ischemic heart disease, diabetes, and other chronic diseases.</td>
</tr>
</tbody>
</table>
**1.2 Substantive Improvements Are Possible**

Substantive improvements in the supply and use of pharmaceuticals are possible. In most health systems, the potential for improving the supply process is tremendous, reflecting in part the magnitude of current inefficiencies and waste.

Figure 1.3 shows a hypothetical example of a program in which a US$1 million annual expenditure on drug supply results in only $300,000 worth of therapeutic benefit to the patient. Lack of careful selection, incorrect quantification, high prices, poor quality, theft, improper storage, expiration of drugs, irrational prescribing, and incorrect drug use by patients result in losses totaling 70 percent of the original expenditure.

However, much can be accomplished with a great deal of effort, a moderate amount of know-how, and relatively little additional funding. Examples of significant improvements in specific areas of drug management are cited later in Section 1.3.

Some drug management improvements require an initial investment in systems development, training, physical infrastructure, and other development initiatives. But the potential cost reductions and therapeutic improvements are dramatic. Even small improvements, when made in a number of related areas of drug management, can yield substantial overall savings.

## 1.2 Public Health Objectives and the Essential Drugs Concept

Public health is concerned with using available resources to achieve maximum health improvements for the population. The perspective is not that of the individual patient, who may well benefit from a costly drug, but of the entire community or population, which will benefit most if safe, effective drugs are accessible to all who need them.

Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid-1950s to the mid-1970s, basic drug management concepts began to evolve in countries as diverse as Norway, Papua New Guinea, Sri Lanka, Cuba, and Peru. In 1975, WHO defined essential drugs as "indispensable and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society." And in 1978, the WHO Conference at Alma Ata recognized essential drugs as one of the eight elements of primary health care. (See Chapter 2 for additional historical background.)

The first WHO Model List of Essential Drugs, containing about 200 products and a description of the essential drugs concept, was published in 1977. Since 1977, the WHO model list has been revised every two to three years, and over 120 countries have adopted essential drugs lists.

Consistent with a public health perspective, the essential drugs concept embraces the following guiding principles:

- The vast majority of health problems for most members of the population can be treated with a small, carefully selected number of drugs.
- In practice, most doctors and other health professionals routinely use fewer than 200 drugs. Training and clinical experience should focus on the proper use of these few drugs.
- Procurement, distribution, and other supply activities can be carried out most economically and most efficiently for a limited number of pharmaceutical products.
Figure 1.3 Waste in Drug Management and Potential for Improvement

- Patients can be better informed about the effective use of drugs when the number of drugs they are confronted with is limited.

Implementation of these principles occurs through the adoption of national drug policies and through practical drug management improvements. The major goals of such initiatives are outlined in Figure 1.4.

1.3 Lessons in Drug Management
Over the last twenty years, countries have acquired considerable experience in managing drug supply. Although many important lessons have emerged from this experience, five broad themes capture the most important insights:

1. National drug policy provides a sound foundation for managing drug supply.
2. Wise drug selection underlies all other improvements.
3. Effective management saves money and improves performance.
4. Rational drug use requires more than drug information.
5. Systematic assessment and monitoring are essential.

Within these five broad areas are many specific lessons, some of which are referred to below, and most of which are covered in detail in the chapters that follow.

National Drug Policy Provides a Sound Foundation for Managing Drug Supply
A national drug policy (NDP) is a guide for action; it is generally a document containing the goals set by the government for the pharmaceutical sector and the main strategies for reaching those goals. It provides a framework to coordinate activities by the various actors in the pharmaceutical sector: the public sector, NGOs, the private sector, donors, and other interested parties.

The NDP concept began receiving support during the 1980s, when piecemeal approaches were leaving important problems unsolved. A focused NDP, suited to the needs of the particular country and with clear priorities, was found to have a significant impact on the availability and use of pharmaceuticals in such countries as Australia, Bangladesh, Colombia, and the Philippines.

Comprehensive, officially adopted policies can focus efforts to improve access to drugs, drug use, and drug quality. At the same time, the policy formulation process
Figure 1.4 Goals for National Drug Policies and Drug Management Improvements

Health-Related Goals
- Make essential drugs available to the entire population.
- Ensure the safety, efficacy, and quality of medicines manufactured and distributed in the country.
- Increase attendance at health facilities by increasing the credibility and acceptance of the health system.
- Promote rational prescription, dispensing, and patient use of medicines.

Economic Goals
- Lower the cost of drugs to the government, other health care providers, and the public.
- Reduce foreign exchange expenditures for drugs without reducing the supply.
- Provide jobs in pharmaceutical supply and possibly production.

National Development Goals
- Increase skills of personnel in management, pharmacy, and medicine.
- Improve internal communication systems.
- Encourage, where appropriate, the evolution of industrial competence in packaging, formulation, and other production areas.

sometimes engenders such strong opposition that all energy becomes focused on the policy, effectively stalling other useful but less controversial efforts to improve the availability and use of drugs.

Some countries have been successful by having a clear strategy without an official policy. Papua New Guinea in the 1960s, Peru and Malaysia in the 1970s, and Kenya and the eastern Caribbean states in the 1980s are all examples of countries that achieved some notable successes with strategies that addressed specific needs but did not have formal NDPs.

Formal NDPs provide a sound foundation for managing essential drugs programs. Of equal or greater importance, however, is the underlying strategic planning process: What are the long-term goals of the pharmaceutical sector? What strategies should be involved? How can key stakeholders be engaged in the process? The experiences of the last two decades suggest that governments and programs with clear objectives and strategies can make progress in the pharmaceutical sector.

Wise Drug Selection Underlies All Other Improvements
Establishing and using a limited list of carefully selected essential drugs is perhaps the single most cost-effective action that any health care system or health care provider can take to promote regular supply and rational use of drugs.

By 1995, over 120 countries had adopted national essential drugs lists. In contrast, in the mid-1970s, few countries had selective drug lists organized by generic name. Many of the national formularies that did exist were unselective and often contained over 1,000 products. Ministry of health procurement lists were commonly dominated by brand-name drugs.

Studies of the economic impact of essential drugs lists and formulary lists demonstrate that considerable savings can be achieved, primarily through careful choices for those few high-unit-cost and high-volume items that consume the major share of the drug budget.

An essential drugs list or formulary list that identifies drugs by level of care becomes the basis for all training in therapeutics; for estimating drug requirements; for competitive procurement by generic name; for planning distribution to health facilities; and for efforts to promote rational, cost-effective drug use. The national essential drugs list or formulary list can also guide public education efforts, local production, and private-sector drug management. The list, based on WHO criteria, should be updated regularly (usually every two to three years), divided by level of care, and accompanied by a clear policy on its application for procurement, distribution, and use of drugs.

Effective Management Saves Money and Improves Performance
Effective management makes a vital difference in all aspects of drug supply. This is especially true with respect to the procurement and distribution of essential drugs. The basic principles of efficient procurement and distribution have been known for several decades. Over the last fifteen years, the benefits of applying these principles have been demonstrated in individual essential drugs programs in Africa, Asia, the Caribbean, Latin America, and the western Pacific.

Examples of the positive consequences of good management include savings of 40 to 60 percent in drug costs through competitive procurement in Brazil, the eastern Caribbean, Mozambique, and Thailand; improved drug availability as a result of better quantification in Belize, Fiji, and Zimbabwe; and more reliable delivery as a result of redesigned distribution systems in Indonesia, Peru, and South Africa.

Good pharmaceutical procurement practices include restriction of purchases to the essential drugs list (national formulary list), determination of order quantities based on reliable needs estimation, competitive tendering from qualified suppliers, separation of key functions, prompt
payment, regular audits, and a formal system of supplier qualification and monitoring.

Effective distribution management is achieved by designing an efficient network of storage facilities with the fewest number of levels appropriate to the country's geography, selecting the appropriate strategy for delivery, keeping reliable records of drug stocks and consumption, allocating supplies based on actual workload and treatment needs, maintaining accountability procedures and secure storage at each level of the system, constructing or renovating facilities appropriate for storing drugs, managing storage facilities to maintain drug quality and efficiently serve health units, making reliable transport arrangements, and reinforcing reporting and supervision arrangements. Kit system distribution has both benefits and costs; it should be used only when necessary to ensure that supplies reach lower levels of the system.

Rational Drug Use Requires More Than Drug Information

Although 50 percent or more of drug expenditures may be wasted through irrational prescribing, dispensing, and patient use of drugs, most methods for promoting rational drug use have never been scientifically evaluated. Among those methods that have been properly studied, most have been found to have little, if any, measurable effect on drug use.

The actual use of pharmaceuticals is influenced by a wide range of factors, including drug availability, provider experience, economic influences, cultural factors, community belief systems, and the complex interactions among these factors. Drug use patterns reflect human behavior and must be viewed from a social science perspective rather than a biomedical perspective.

Drug companies succeed in changing the habits of doctors and patients because they understand what influences these habits. Interventions to promote rational drug use often fail because they are based on the notion that simply improving knowledge will improve drug use. Examples of interventions that are likely to fail include lifeless drug bulletins that dryly present "the facts," standard treatment manuals distributed to health staff without an active orientation, withdrawal of dangerous or ineffective products with no advice for prescribers on what to prescribe instead, and campaigns to discourage injection use that do not address the reasons that many patients prefer injections.

Fortunately, much has been learned during the 1980s and 1990s about principles for promoting rational drug use. These principles involve informed, focused, active, engaging approaches for changing drug use practices by prescribers, dispensers, and patients. Examples of specific interventions that have been effective include standard treatment guidelines (provided they are actively implemented); training linked to improved drug supply, as in Yemen and other countries; and guided discussions among mothers and providers, which in Indonesia led to a persistent decrease in the use of injections.

Systematic Assessment and Monitoring Are Essential

One of the most basic, yet most significant, advances in drug management has been the introduction of objective standard indicators for assessing, comparing, and monitoring drug policies and management effectiveness. Since their introduction in the early 1990s, drug use indicators have been developed for the assessment of virtually all key aspects of drug management and NDPs. Examples of standard indicators include the percentage of government drug purchases conforming to the national essential drugs list, the ratio of local drug prices to world market prices, the number of drugs per patient prescription, and the percentage of key drugs available at health facilities.

Measured at one point in time, such indicators allow a program to compare itself to a target level of performance, to identify areas of relative strength and weakness, and to make comparisons with other programs for which data are available. Measured over time, such indicators can be used to set and monitor performance targets for pharmaceutical sector improvements.

Systematic assessment and monitoring based on standard indicators are becoming a routine part of planning, program management, and donor evaluation in the field of essential drugs and drug management. Each country and program needs to select, develop, and adapt indicators to suit local circumstances and needs, but the basic concept of objective indicators should be considered in any essential drugs program.

1.4 Challenges for Drug Management

Although much has been achieved over the last two decades, huge gaps remain between the need for drugs and the supply of drugs, especially among poorer, less urbanized populations. A gap also remains between the availability of drugs and their rational use.

Major challenges for policy-makers and managers include achieving financial sustainability; improving efficiency in public drug supply; changing the perceptions and behaviors of providers, patients, and the public; reorienting the role of government; and regulating safety, efficacy, and quality.
Achieving Financial Sustainability

Financial sustainability is achieved only when expenditures and financial resources balance and are sufficient to support a given level of demand. If demand for drugs exceeds the available resources, the health system is left with only four options: improve efficiency, increase financial resources, reduce demand, or accept a decline in quality of care. When the components of financial sustainability are not in balance, it simply defies economic reality to promise constant availability of high-quality essential drugs without improving efficiency, increasing financing, or limiting demand.

Efficiency means getting the most benefit from available resources. Much of this manual is devoted to improving therapeutic efficiency through better selection and drug use and improving operational efficiency through better organization, procurement, and distribution of drugs.

To achieve financial sustainability, policy-makers and essential drugs program managers must become familiar with economic concepts and methods related to cost containment, efficiency, cost-effectiveness analysis, public expenditure decisions, the roles of the public and private sectors, and the economics of regulation. High-income countries have become increasingly reliant on economic concepts and methods and perspectives. Countries with more limited resources must also make maximum use of the insights offered by the field of economics.

Health-sector reform is concerned with improving efficiency through changes in the organization and allocation of health care resources. It is also concerned with health care financing.

People pay for health care in different ways: collectively, through national health insurance or through the taxes they pay on goods, services, or income; in groups, through premiums paid for voluntary health insurance; or individually, through user fees at government facilities or private out-of-pocket health expenditures. Local funding for recurrent health expenditures may be supplemented by external development assistance. In fact, it is sometimes impossible for the poorest countries to provide certain basic health services, including essential drugs, without some external assistance. But in most countries, the primary burden for health financing falls directly or indirectly on the people of the country.

Public financing provides an essential foundation for a country's health system and, in particular, for health promotion and preventive services. But providing free drugs through public resources has proved unsustainable in many developing as well as developed countries. Government budgets are squeezed, and donor funds are directed to a variety of other worthy causes. The policy of free drugs is often, in practice, a policy of shortages.

Full or partial cost recovery through user fees is one way to supplement public financing. Revolving drug funds and community drug schemes linked to strengthening primary health care (such as the Bamako Initiative) are operating in scores of countries in Africa, Asia, and Latin America. Some programs have led to a serious decline in utilization, with no visible improvement in drug availability. Yet other user fee programs have increased both equity of access and quality. Exemptions and other protection mechanisms, good management, community supervision, and phased implementation are important for success.

Social health insurance (compulsory health insurance or social security), private health insurance, and community health insurance schemes finance drug supply for a small but growing portion of the population in developing countries.

In the face of changing epidemiologic patterns, increasing demand for modern health care, and growing populations, the challenge for countries is to implement those drug financing strategies that best ensure equity of access and a continuous supply of drugs. For many countries, this means taking a pluralistic approach—one that uses different approaches to serve different needs and different groups and that combines the benefits of public financing, user fees, health insurance, voluntary financing mechanisms, and (in some cases) donor support.

Improving Efficiency in Public Drug Supply

The twenty-year history of the essential drugs concept has witnessed a mixture of successes and failures in public drug supply. As of 1988, countries as diverse as Algeria, Costa Rica, Cyprus, Indonesia, Kenya, Malaysia, Papua New Guinea, and Sri Lanka were all judged to have achieved reasonable success in selection, procurement, distribution, and coverage for essential drugs. Other countries had achieved fair to poor results in these areas, including Cameroon, Côte d'Ivoire, El Salvador, Haiti, Honduras, Madagascar, Niger, and Tunisia (WHO 1988).

Since 1988, some countries have continued to progress, but others have experienced setbacks. Aside from the problem of financing, public-sector drug supply in many countries continues to be plagued by ineffective management systems, lack of staff incentives, inability to control fraud and abuse, political pressures that channel drug supplies to better-off areas, and inefficient drug selection and use. There are examples of successful central supply systems, but there are also numerous examples in which the conventional central medical stores (CMS) approach to drug
procurement and distribution continues to result in chronic drug shortages—even after considerable investment in training, management systems, and physical infrastructure.

Sustainability is the extent to which a program will continue to achieve its policy and drug supply objectives without additional outside financial or technical support. Key factors for program sustainability are motivated, capable staff; effective management systems; and political support. Low pay, inadequate training, lack of incentives, inappropriate recruitment, and ineffective disciplinary measures undermine staff performance. Civil service reform, which is being considered or initiated in a number of countries, may help address these constraints.

At the same time, alternative strategies for public drug supply are attracting interest. These include formation of an autonomous supply agency, direct delivery, the prime vendor system, various privatized models, and mixed systems. Alternative strategies for public drug supply have been implemented in Benin, Indonesia, South Africa, and Uganda.

With an autonomous supply system, bulk procurement, storage, and distribution are managed by an autonomous or semi-autonomous agency. With the direct delivery (non-CMS) system, the government tenders to establish prices and suppliers for essential drugs, which are then delivered directly by suppliers to districts and major health facilities. With the prime vendor system (another non-CMS system), the government drug procurement office establishes a contract with a single prime vendor as well as separate contracts with drug suppliers. The prime vendor is contracted to manage drug distribution by receiving drugs from the suppliers and then storing and distributing them to districts and major facilities. In private models, public administration of drug supply is minimized, with drugs being provided by independent pharmacies within government facilities or through other mechanisms; various financing and reimbursement arrangements can be used.

Selection, procurement, and distribution can each be carried out in centralized, partially decentralized, or fully decentralized systems. Decentralization aims to improve the responsiveness, quality, and efficiency of health services. Improvements are far from certain, however. Problems with attempts to decentralize drug management functions have included lack of local management capacity, increased costs (due to loss of savings from bulk purchasing), lack of local staff trained in drug management, inadequate financial resources, self-interested interference by local officials, and poor drug quality (due to difficulty in selecting and monitoring suppliers).

For managing drug supply, it may be useful to think in terms of a task-specific approach to decentralization. Examples of tasks that may be better performed centrally include development of essential drugs lists, preparation of standard treatment guidelines, management of competitive tenders, selection and monitoring of suppliers, quality assurance, and development of training programs in rational drug use.

Tasks that can be decentralized include those that do not require uncommon technical skills. Decentralization is advisable when local information is required, local circumstances are important and variable throughout the country, and local interests favor improved performance. Examples of such tasks include adapting drug lists or standard treatments to local needs, quantifying drug requirements, coordinating local distribution, conducting training in rational drug use, and monitoring drug use at health facilities.

The effectiveness of the drug supply system in achieving a reliable supply of essential drugs must be continually and objectively assessed. Fundamental restructuring of drug supply arrangements challenges the status quo and may threaten a variety of interests. But continuing to support an ineffective supply system wastes precious resources and denies patients access to lifesaving essential drugs.

Changing the Perceptions and Behaviors of Providers, Patients, and the Public

One of the greatest challenges is to change the way in which providers, patients, and the public view and use pharmaceuticals. Major problems, noted earlier, include prescribing and dispensing incorrect, harmful, or unnecessary drugs; failure by patients to use needed medications correctly; and wasteful or harmful self-medication practices.

The basic methods and alternatives for improving selection, procurement, and distribution have been well understood for some time. The difficulty has been in implementation. In contrast, there are few demonstrably effective—and cost-effective—methods for improving drug use. Examples of apparently effective methods are discussed above in Section 1.3.

Given the huge share of public and private drug expenditures that may be wasted through irrational drug use, it is essential that governments, NGOs, and others continue to explore effective, sustainable ways of improving drug use patterns.

Reorienting the Role of Government

Access to health care, including essential drugs, is a fundamental human right. Realization of this right may involve
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Various combinations of public and private financing and provision of services. In high-income countries, public financing of pharmaceuticals predominates. In low- and middle-income countries, the public-private mix varies remarkably, from 90 percent provision of drugs in Papua New Guinea and Bhutan to roughly 90 percent private market supply and financing of drugs in Nepal and the Philippines. Typically, however, 60 to 80 percent of drugs are obtained on the private market, even among low-income households.

Overprescription by health care providers is common, as is self-medication, which in some countries accounts for the majority of “prescription” drug consumption. Although even the poorest are willing to pay for drugs, the combination of high prices and lack of information may delay treatment and too often results in the purchase of subtherapeutic doses. Pharmacy surveys in some countries have found that most antibiotics are purchased in quantities sufficient for only one to three days’ treatment—insufficient for most conditions requiring an antibiotic. Studies of self-administration of antimalarials show similar underdosing. When purchasing power is concentrated in urban areas and the number of pharmacists is limited, the availability and range of drugs may decline significantly in remote areas.

From a public health perspective, therefore, the main concerns with the private pharmaceutical market are availability (geographic access), affordability (economic access), and rational use of drugs. Measures to improve availability include certification and training of pharmacy aides and other drug sellers; licensing provisions and incentives for wholesalers, pharmacies, and other drug outlets; dispensing by doctors and other clinicians in selected areas; and community drug schemes. Affordability can be improved with greater insurance coverage, better price information, price competition through generic substitution, regulation of producer prices, and modification of retail sales margins. Finally, rational drug use can be promoted through regulation of drug information and marketing; inclusion of essential drugs concepts in basic medical education; focused continuing education for health professionals; enforcement of licensing requirements for doctors, pharmacists, and other health professionals; and active public and patient education.

The public health challenge is to work with the private sector and NGOs to achieve universal access to essential drugs and rational use of drugs. This involves mutual understanding, constructive partnerships, and the right incentives. Among other things, greater coverage of essential drug needs through the private sector means that public resources can be focused on prevention, on control of communicable diseases, and on the poorest segments of the population.

Regulating Safety, Efficacy, and Quality

Regulatory control, often neglected in the pharmaceutical sector, is an indispensable foundation for ensuring the safety, efficacy, and quality of drugs in a country. With increasing private-sector supply, it is incumbent upon governments to ensure that all drugs meet basic standards. And the same quality standards applied to the open market must also apply to drugs procured through the public sector. Drug legislation and regulation also establish basic professional standards in both the public and the private sectors.

In industrialized countries, regulatory capacity has developed in phases over many decades. It is reasonable to expect that most developing countries also will require time to develop effective regulatory capacity. Such capacity requires a firm legislative basis, trained personnel, specific technical resources, adequate funding, and—perhaps most important—public commitment to establishing and maintaining basic standards.

1.5 The Drug Management Cycle

Drug management involves four basic functions: selection, procurement, distribution, and use (Figure 1.5). Selection involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual drugs and dosage forms, and deciding which drugs will be available at each level of health care. Procurement includes quantifying drug requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring drug quality, and ensuring adherence to contract terms. Distribution includes clearing customs, stock control, stores management, and delivery to drug depots and health facilities. Use includes diagnosing, prescribing, dispensing, and proper consumption by the patient.

The drug management cycle is truly a cycle: each major function builds on the previous function and leads logically to the next. Selection should be based on actual experience with health needs and drug use, procurement requirements follow from selection decisions, and so forth. Costs rise, shortages become common, and patients suffer when the separate tasks are performed not as parts of a system but independently and disjointedly.

At the center of the drug management cycle is a core of management support systems: organization, financing and sustainability, information management, and human resources management. These management support systems...
hold the drug management cycle together. Although individual parts of the cycle may function independently for a short time, the cycle as a whole will soon cease to operate and patient care will suffer without a functional organizational structure, adequate financing, reliable management information, and motivated staff.

Finally, the entire cycle rests on a policy and legal framework that establishes and supports the public commitment to essential drug supply.

1.6 Managing Pharmaceutical Sector Improvements

This manual is meant to provide policy-makers and managers with practical, accessible advice on a wide range of topics relevant to managing drug supply. The basic functions of management are planning, implementation, and monitoring.

Effective planning requires thoughtful reflection on basic goals, systematic assessment of the current situation, creative consideration of all reasonable strategies for improvement, and selection of strategies based on defined criteria.

Implementation is an interactive process that involves organizing people, finances, and other resources to achieve the desired results. The test of any policy or plan is in its implementation. Gradual phasing-in of new initiatives can help build management systems, which can then support full-scale implementation. Active decision-making and problem-solving are fundamental to the implementation process.

Finally, ongoing monitoring and periodic evaluation are needed to measure progress, to adjust implementation plans, and to assess the impact of drug management improvements. Objective indicators and specific program targets provide concrete measures against which actual performance can be compared. Without such indicators, it is difficult to judge the success and, therefore, the value of human and financial investments in pharmaceutical sector improvements.

The experiences of countless countries and programs demonstrate that substantive, sustainable improvements in the supply and use of drugs are possible. But an equal or greater number of negative experiences demonstrate that success is by no means assured. Clear goals, sound plans, effective implementation, and systematic monitoring of performance are essential ingredients in pharmaceutical sector development.
References and Further Readings


