

Drug selection for safety-net-provider formularies

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Am J Health-Syst Pharm. 2002; 59:1675-78

Safety-net pharmacies provide prescription drugs and pharmaceutical services to the poor, the uninsured, and other vulnerable populations. This mission has come under pressure because of increasing numbers of uninsured patients, growth of prescription drug use, higher pharmaceutical costs, the introduction of expensive new drugs, reduced or unchanging government funding, and declining payments from commercial and other non-government payers. To maintain the financial viability of safety-net pharmacies and health systems, a formulary that meets patient care goals with low resource use must be designed. A thoughtful and directed approach to formulary development can minimize the impact of adverse economic factors.

Most safety-net pharmacies are funded by government sources, and nearly all lack the financial resources necessary to provide pharmaceutical services to all patients in need. In designing a prescription drug formu-

lary for an indigent population, only those drugs that offer the greatest public health benefits can be included. A population-based approach, endeavoring to do the most good for the greatest number of people with the resources available, must be used when constructing a pharmacy benefit.

This article discusses drug selection for formularies in safety-net organizations. In determining which pharmaceuticals offer the greatest health benefits to the indigent, we propose three levels of evaluation for formulary inclusion: (1) Is the drug essential? (2) Does the selected drug product offer the greatest pharmacoeconomic benefit when compared with alternatives? (3) Which of the drug products meeting the first two tests represents the best use of available resources?

Definition of essential drugs

To determine which drugs should be included on a safety-net formulary, we must first recognize those drugs that are the staples of pharma-

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The support of the Public Hospital Pharmacy Coalition, the American Society of Health-System Pharmacists, Norman Carroll, Ph.D., David Holdford, Ph.D., Michael Pyles, Ph.D., and William Zellmer, M.P.H., is acknowledged.

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cotherapy. Several sources provide insight into this area. The term “essential drug” was coined by the World Health Organization (WHO). WHO considers a drug essential if it is necessary to satisfy the health care needs of a majority of the population. Essential drugs should be available at all times in adequate amounts, in appropriate dosage forms, and at prices that individuals and the community can afford.¹

WHO considers pharmaceutical use from a societal perspective, noting that essential drugs should have a profound health impact, increase health-system effectiveness, and maximize the cost-effectiveness of pharmaceutical expenditures.² Examples of drugs with a profound health impact include agents for HIV infection, malaria, tuberculosis, cardiovascular disease, and cerebrovascular disease. These conditions have far-reaching effects on the welfare of a nation, and they affect poor populations disproportionately, detracting from health gains and delaying progress in other areas, such as education and economic development.

Essential drugs increase health-system effectiveness by encouraging the investment of resources in the system.² Since drugs are costly, those selected for use should be those that reliably provide better outcomes. The message of WHO is clear: Drugs that offer the greatest benefits should receive highest priority in funding and coverage.

Soumerai et al.,³ in a study of Medicaid prescription drug use, proposed a collateral definition of essential drugs. These authors divided essential drugs into drugs that decrease morbidity and mortality and agents prescribed primarily for symptomatic relief. The former category corresponds with the WHO definition, indicating that for a drug to be essential, it must reduce disease or death. The first category of drugs named as essential in the study included insulin, thiazide and loop diuretics, and

digoxin. The second category included analgesics and antiinflammatory drugs.

Information on morbidity and mortality is not always readily available, since these are generally long-term outcomes that take time to measure. Because of this temporal relationship, the cost-effectiveness of a drug for achieving a positive final outcome can be measured by using a clinical surrogate. A clinical surrogate is a physical sign, laboratory value, or other indicator or endpoint that predicts clinical benefit and is based on epidemiologic, therapeutic, pathophysiologic, or other evidence.⁴ This surrogate must be meaningfully related to morbidity or mortality. When FDA places a drug on the “fast track” for approval, clinical surrogates may be used in place of final outcomes.

A study designed to examine the health and resource-utilization consequences of cost-sharing programs for poor and elderly patients proposed a similar, if stricter, definition.⁵ Essential drugs were defined as medications that prevent deterioration in health or prolong life. The authors further proposed a category of less essential drugs that relieve symptoms but have no effect on the underlying disease.

The Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) defined services or supplies as medically necessary if they are needed for the diagnosis or treatment of a medical condition, meet community standards of good practice, and are not mainly used for the convenience of the patient or physician.⁶ These are more general principles, but they underscore the need for pharmaceuticals to be both appropriate and necessary.

Holistic approach to essential drug therapy

Previous definitions of essential drugs focused primarily on clinical treatment outcomes and failed to

consider other aspects of drug therapy. The American Pharmaceutical Association proposes that qualitative measures of health status and quality of life (QOL) also be considered.⁷ Therefore, a more holistic approach should be taken in evaluating pharmacotherapy. The ECHO model examines the value of a health care intervention in terms of economic, clinical, and humanistic outcomes.⁸ On the basis of this model, drug therapy should be measured in terms of clinical, economic, and humanistic outcomes.

Clinical outcomes. All drugs that reduce mortality should be considered essential. However, not all products that reduce disease necessarily fit this category. A broad array of drugs address the technical definition of disease: “an interruption, cessation, or disorder of bodily functions, systems, or organs.”⁵ Yet, referring back to the WHO definition, essential drugs should also have a “profound health impact.” Those disease-reducing products that do not have a significant impact on health status should not be considered essential.

Economic outcomes. Drug products should also be evaluated on the basis of their ability to reduce the total cost of health care. Drug therapy can decrease total resource use by controlling or preventing disease and leading to more efficient health systems. Even if a treatment does not affect morbidity and mortality, the drug should be considered for formulary inclusion if it has the potential to save money in other areas in excess of its cost.

However, the foremost goal of pharmacotherapy is to reduce disease and death. Financial concerns cannot be the primary determining factor when deciding if a treatment is essential, as reductions in disease and death do not necessarily decrease the total cost of care. For example, some advanced cancer chemotherapies may increase total economic expen-

ditures, since it would be less expensive to let the patient die without treatment. Nevertheless, chemotherapy reduces disease and death and is still essential.

Humanistic outcomes. The ultimate purpose of drug treatment is not just to decrease morbidity and mortality but also to decrease them in a way that benefits QOL. Some products may not decrease mortality and morbidity and may increase the total cost of care but have such a prodigious effect on QOL that they should be considered essential. For example, drugs for the treatment of severe pain fall into this category. While morphine administered after a surgical procedure does not decrease mortality or morbidity and increases the overall cost of care, it prevents or mitigates excruciating pain, making it a necessary agent.

Not all drugs that affect QOL should be considered essential. All pharmaceuticals have the potential to improve QOL; otherwise, there would be little incentive for patients to use them. The pharmaceutical industry often uses QOL measures as a marketing tool for drug products in competing therapeutic classes, focusing on differences in tolerability, adverse effects, and patient preference. However, drugs that offer only a marginal QOL advantage cannot be considered essential across the full range of definitions. Essential drugs have a "profound health impact," as evidenced by dramatic improvements in QOL, which in these instances may more appropriately be referred to as "relieving suffering."

Drugs that do not decrease morbidity and mortality, that increase the overall cost of care, and that do not improve QOL to such a degree that they have a profound impact on health do not qualify as essential. For example, sildenafil and finasteride may offer many personal benefits to patients, but the effect on QOL and thus health status is marginal com-

pared with the attenuation of severe pain.

In summary, essential drugs are those that preserve or prolong life or have a profound impact on health by reducing or preventing disease or relieving suffering.

Steps in selecting drugs for the formulary

Step 1: Identify essential drugs. If a drug is not essential, then it should not be included on the formulary. Examples of drugs that may be considered nonessential under this definition include antihistamines, antiimpotence products, sleep aids, nicotine-replacement products, and antitussives. A provider-based pharmacy and therapeutics (P&T) committee should make this determination.

Step 2: Evaluate pharmacoeconomic benefits. When a drug has been classified as essential, the individual product that offers the greatest pharmacoeconomic benefit should be selected. Questions to be answered in determining the pharmacoeconomic benefits of a drug product include the following:

- Is the drug cost-effective compared with nondrug or nonprescription treatments?
- Is the product cost-effective compared with agents in the same or different pharmacologic classes?
- If a specific agent is not more effective and less costly than the alternatives, is the additional cost for the selected agent worth the additional benefit?

The additional reductions in morbidity and mortality achieved by spending more money on a different product may or may not be worthwhile. This requires a subjective interpretation. If the product is designed to relieve suffering, cost-utility analysis can be performed, which usually states the relative costs and benefits in terms of the cost per quality-adjusted life year. This should be done in the same manner as cost-effectiveness

analysis by comparing the treatment with nondrug, nonprescription drug, and other prescription drug treatments. Unless a particular therapy is clearly superior, a judgment call is required. If one is using a much more expensive drug for the treatment of severe pain, is a given improvement in QOL worth the price?

Step 3: Maximize the public health impact. When drug treatment has been classified as essential and the individual product that offers the most pharmacoeconomic benefit has been identified, the overall integrity of the safety-net health system must be considered. Safety-net pharmacies are under intense pressure to control costs. With limited funds available to provide a pharmacy benefit in indigent care plan, resources must be used as efficiently as possible. To maximize the public health impact, a population-based approach to the formulary must be taken. Therapy should be targeted at those drugs that offer the greatest improvements in health for the money (e.g., vaccines).

Working with limited funding, safety-net health systems may not be able to include some drugs or categories of drugs that fit the definition of essential. To determine which products will and will not be covered, the cost-benefit ratio of each must be examined.

Conclusion

In selecting drugs for inclusion on safety-net-provider formularies, P&T committees should prioritize alternatives on the basis of health impact, potential pharmacoeconomic benefit, and resource availability.

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