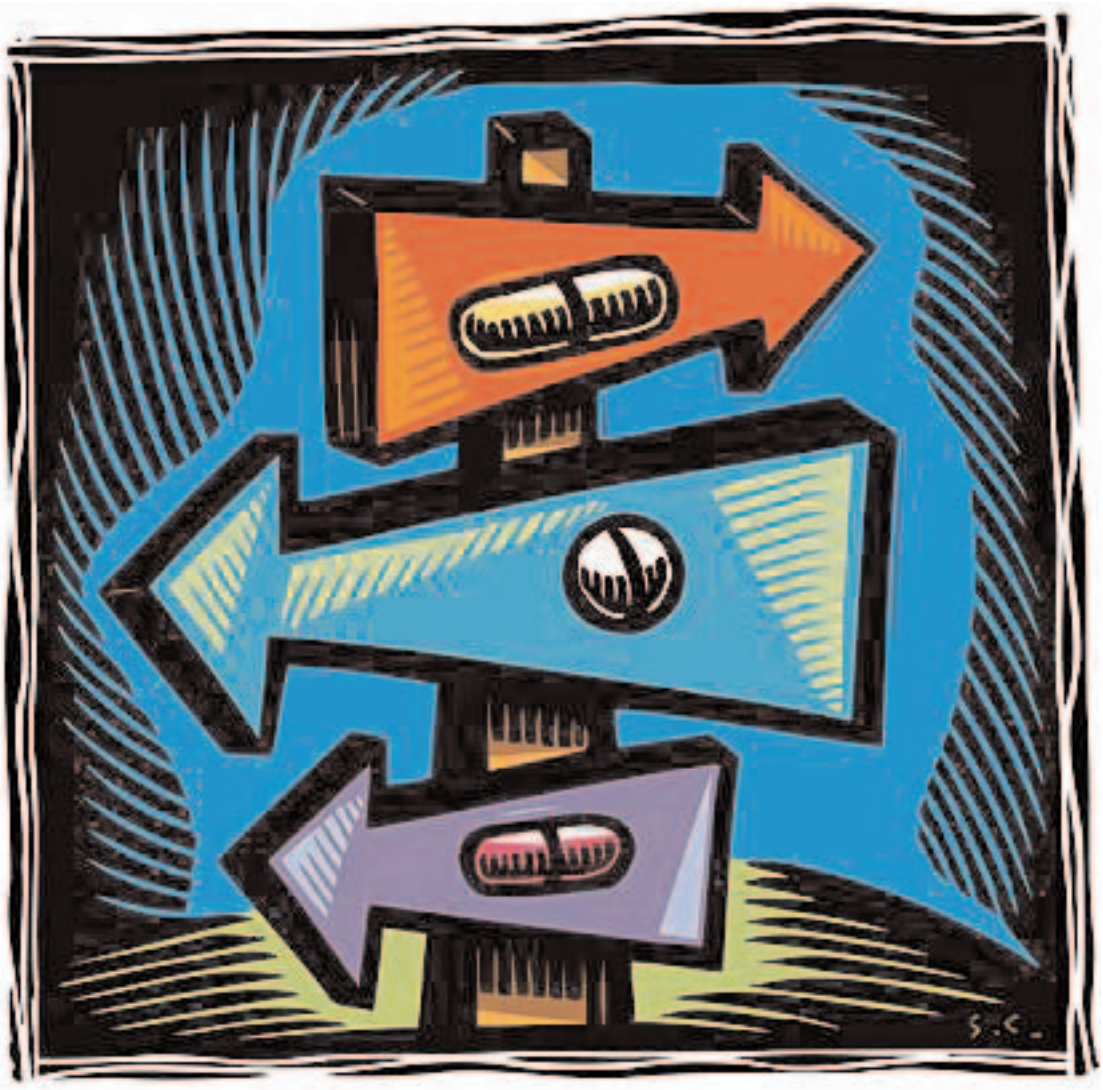
California HealthCare Foundation



Rx for Affordability: Helping Patients Cope with Medication Costs

November 2005

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Rx for Affordability: Helping Patients Cope with Medication Costs

Prepared for

California HealthCare Foundation

by

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About the Foundation

The **California HealthCare Foundation**, based in Oakland, is an independent philanthropy committed to improving California's health care delivery and financing systems. Formed in 1996, our goal is to ensure that all Californians have access to affordable, quality health care. For more information, visit us online (**www.chcf.org**).

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Overview

Clinicians can employ a variety of prescribing practices to lighten patients' cost burden while providing effective treatment for chronic health problems.

HIGH OUT-OF-POCKET DRUG COSTS CAN LEAD patients to forgo prescribed medications, with consequences for their health. Helping patients cope with medication costs requires a multipronged approach, including minimizing the overall cost of drug regimens, ensuring people have a way to pay, and encouraging them to stick with their medications despite financial hardship. This report describes a framework for developing solutions to patients' medication cost problems. It also details what is known about the assistance that is available to patients who have trouble affording their prescriptions and identifies avenues for providing greater support.

Patients and clinicians seldom discuss the potentially high cost of taking prescription drugs. Clinicians rarely assess how well patients are adhering to their drug regimens, and few talk about the problem in the context of cost pressures. Effective screening for medication cost problems and frank discussions about whether patients can afford their treatments can form the foundation of any effort to decrease the rate at which they underuse medications.

Clinicians can draw upon a variety of prescribing practices to lighten patients' cost burden while still providing effective treatment for chronic health problems. One major barrier is that many physicians are unaware of the costs of patients' prescriptions. A comprehensive plan to promote appropriate use of generics and to educate patients about their value could reduce costs to health systems as well as to consumers. Pill-splitting—which takes advantage of pricing structures that favor buying drugs in high doses—is an infrequently used but effective way to cut costs, and several studies suggest that pill-splitting is as safe and effective as whole-tablet dosing. Free medication samples can lower patients' medication costs in the short-term, but prescribers must balance these short-term benefits against the potential long-term consequences, both for individuals and for society as a whole.

Even when clinicians are sensitive to all of these issues, it is unavoidable that some patients' regimens will remain costly. Nor do patients always avail themselves of resources for which they may be eligible, either because the bureaucratic process is too daunting or they are never informed that such assistance exists. Drug cost patient assistance programs (PAPs) are one such resource, and new approaches may increase their benefits by overcoming barriers associated with traditional models.

Not all patients respond the same way to medication costs, and other factors—such as race, health literacy, and the nature of the treatment—may influence patients' likelihood of cutting back on their prescriptions. Even when burdensome drug costs are unavoidable, clinicians and health systems may be able to address cost-related underuse by lowering other barriers to medication use and improving patients' relationships with their health care providers.

I. Background

The proportion of personal health expenses going to prescription drugs has increased more than 10 percent annually since 1997.

Prescription medications are essential for managing most serious and prevalent chronic illnesses. The costs of these treatments, however, pose a growing burden to health care payers and patients. In the United States, the average number of prescriptions per person more than doubled between 1977 and 1998.[1] Some $162 billion dollars was spent on prescription drugs in 2002 (a 15 percent increase from the previous year),[1] and that amount is expected to more than triple by the year 2012.[2] Problems caused by medication costs fall disproportionately on those without drug coverage; however, even patients with pharmacy benefits are bearing more of the costs of their drug therapy.[3,4] The proportion of personal health expenses going to prescription drugs has increased more than 10 percent annually since 1997.[5] Outcry over prescription cost pressures has played a role in national political debates and has contributed to social tensions such as layoffs[6] and labor strikes.[7] Patients, clinicians, and researchers have all called for policies to minimize the potentially harmful effect of these costs on patients' health and well-being.[8-11]

Numerous studies[12-21] demonstrate that higher out-of-pocket medication costs can cause patients to take less of their medications than prescribed. Not surprisingly, the rates of cost-related medication underuse are greater among patients with lower incomes, higher out-of-pocket prescription drug costs, and less generous prescription benefits.[16,18,22] Problems caused by medication costs can extend beyond the impact on patients' treatment.[23] In a study of older Americans,[24] 22 percent of respondents reported cutting back on necessities such as food or heat to pay medication costs, and 16 percent reported increasing their debt burden. Among those with low incomes, nearly 40 percent said that medication cost pressures led them to forgo basic needs (Figure 1).

Cutting back on medications to save money can jeopardize patients' health,[25-27] leading to increased rates of hospitalization, long-term care use, and death.[18] One study[25] found that a program assisting indigent cardiac patients with drug costs lowered their blood pressure, LDL cholesterol, and hospitalization rates. Another[18] found that requiring indigent patients to pay a larger share of their drug costs increased rates of adverse events. In a nationwide survey of chronically ill older adults,[28] patients who reported underusing their prescription drugs because of cost were almost twice as likely as other patients to experience a significant decline in their health status (32 percent versus 21 percent). Among study participants with cardiovascular disease, those who reported cutting back on medication use because of the cost were 50 percent more likely to experience angina, non-fatal heart attacks, or strokes.

More and more, clinicians and health systems recognize that prescribing decisions cannot be based solely on patients' clinical indications but must also take patients' cost pressures into account. Although this can be daunting, providers can employ certain helpful strategies. Helping patients cope with medication costs requires a multipronged approach (Table 1). Clinicians need to ensure that the costs patients incur are as manageable as possible, minimizing the expense of patients' drug therapy and helping patients find financial resources. In addition, clinicians need to help patients stick to their regimens knowing that they will inevitably face cost pressures. Of course, clinicians and safety-net health systems face enormous challenges in assisting patients with medication cost problems. Limited staffing, inadequate budgets, and patients with complex personal circumstances all conspire against addressing this problem. As a result, the strategies described in Table 1 represent goals that may not be achievable in all systems of care. However, the purpose of this report is to describe a framework for developing solutions to patients' medication cost problems. Using this framework, clinicians, health system managers, and policymakers may be able to collaborate about which approaches may be attainable and have the greatest impact on patient care.

Figure 1. Chronically Ill Patients' Strategies for Coping with Out-of-Pocket Drug Costs, by Annual Household Income

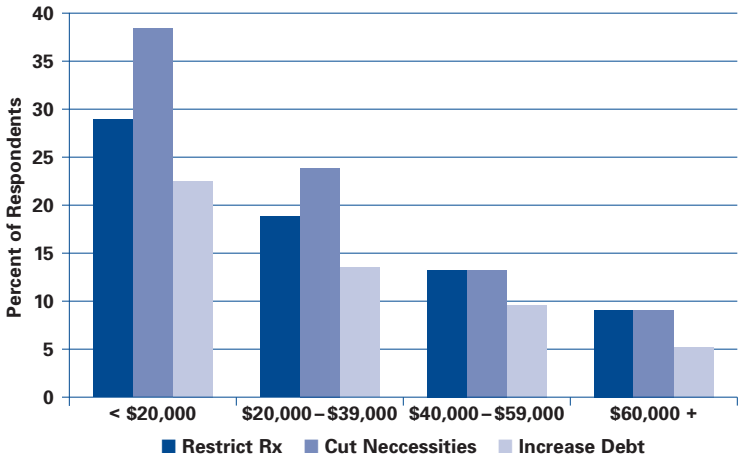


Table 1. Strategies Clinicians and Health Systems Can Use to Assist Patients with Medication Cost Problems

Minimize Cost Pressures

- Identify patients at risk for medication cost problems
- Ensure that prescriptions reflect the most affordable options
  - Support prescribers with information about medication costs
  - Minimize the number of medications and eliminate drug duplication
  - Use generic alternatives
  - Use pill-splitting
  - Use free samples with caution
  - Develop formularies that promote cost-effective prescribing
- Ensure that patients can get financial support
  - Help patients identify sources of lower-priced drugs
  - Help patients understand drug benefits and how to apply
  - Help patients access patient assistance programs
- Maintain updated information about what treatments are available to patients through various formularies

Support Adherence

- Collaboratively develop regimens that reflect patients' values, priorities, and resources
- Ensure that patients understand the purpose of each medicine and the implications of non-adherence
- Understand the factors that can worsen or ease patients' medication cost problems, including patients' sociodemographic characteristics, the characteristics of their regimens, relationships with clinicians, and structural barriers to acquiring medications

This report describes what is known about the assistance that patients with medication cost problems can receive. The report also identifies options for providing greater support. The report is based on information from three sources: (1) a systematic literature review to identify studies addressing the role of medication cost pressures in patients' adherence and health outcomes; (2) interviews with national experts in the role that patient assistance programs (PAPs) play in alleviating patients' medication cost problems; and (3) research by the author and his colleagues. These latter studies include surveys of clinic-based[26,29-31] and community-based[13,24,27,28,32-34] samples of chronically ill adults to identify the ways in which they and their clinicians are coping with medication costs.

Several of the analyses highlighted below come from a study surveying a nationally representative sample of chronically ill older adults from the Knowledge Networks (KN) panel.[13,24,27,33,34] KN panel members are identified based on random-digit dialing and complete periodic surveys over the Internet. We identified all KN participants 50 and older who reported prescription medication use for diabetes, depression, hypertension, hyperlipidemia, or heart disease. Some 4,055 respondents age 50 and older completed the informed consent and survey. Respondents reported detailed information about their use and cost-related underuse of medication for 16 chronic health problems, as well as other information about the ways they were coping with medication cost pressures.

II. Minimizing Patients' Medication Cost Pressures

Clinicians rarely asses whether patients are taking their medications as prescribed, and conversations about potential cost problems often do not take place.

PATIENTS AND PROVIDERS TOO SELDOM DISCUSS medication cost problems. Many providers lack the information they need to identify low-cost regimens. Often, many patients need help identifying sources of low-cost medications or other financial benefits for which they are eligible.

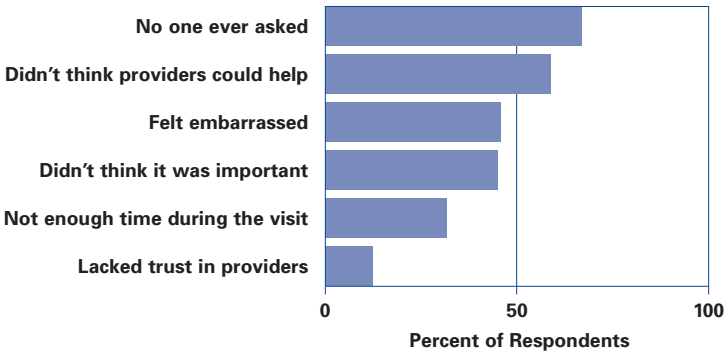
Identifying Patients with Medication Cost Problems

Clinicians rarely assess whether patients are taking their medications as prescribed, and conversations about potential cost problems often do not take place.[30] In the KN study, only 16 percent of respondents said they were asked by their doctors whether they could afford a new prescription, and only 33 percent of those who reported cutting back on medication because of cost told a doctor or nurse in advance.[32] Non-white patients or those with little education were only half as likely to report alerting clinicians about such problems as other patients.

Other analyses from the KN study found that only 26 percent of those who had cut back on basic needs because of medication costs had been asked whether they could afford their prescriptions, and only 24 percent of those who worried about medication costs had been asked. Controlling for their demographic characteristics and income, patients reporting cost-related medication underuse were no more likely to be asked about their ability to pay for prescription medications than other patients. Respondents' race or ethnicity was the only patient characteristic associated with patients' likelihood of being asked by providers about possible medication cost problems. In other words, clinicians focused their attention on patients' medication costs according to the patient's race but were not at all successful in focusing their attention on patients who were experiencing serious problems affording their prescriptions.

Chronically ill patients' clinical encounters are extremely complex, and both patients and clinicians face numerous barriers to discussing medication costs. Patients often believe that doctors and nurses cannot help them, report that they are embarrassed to raise this issue with clinicians, or say that there is insufficient time to discuss medication costs during a visit[30,32] (Figure 2). Clinicians also face serious constraints on their abilities to identify concrete solutions to patients' medication cost problems in the absence of significant insurance reform.[31] Some physicians feel that their limited time is best spent addressing patients' medical, rather than financial, concerns or that they lack knowledge about available programs and ways to discuss this issue appropriately. More generally, patients' financial constraints present ethical challenges for physicians striving to deliver high-quality care consistent with practice guidelines while adjusting regimens so that they are realistic given a patient's ability to pay. Formularies for various public and private drug payment programs are continually in flux, which adds to the difficulty that both providers and patients face in identifying and maintaining the most affordable and effective regimens.

Figure 2. Reasons Chronically Ill Patients Who Underuse Medication Because of Cost Do Not Alert Their Providers in Advance



Recognizing these barriers, it is important to note that the primary reason patients in the KN study said that they had not alerted providers to their cost-related adherence problems was that no one had asked. Efforts by clinicians and health systems to demonstrate an appreciation for patients' potential medication cost concerns may be an important step toward identifying affordability problems and building the trust needed to promote adherence in the face of cost pressures.

Minimizing the Cost of Patients' Regimens

Clinicians can employ a variety of prescribing practices, including pill-splitting, using generics, and minimizing polypharmacy—the duplication of drugs from multiple physicians or pharmacies—to lower patients' burden from medication costs while providing effective treatment for their chronic health problems. Unfortunately, these approaches are often underused.

Prescribers' awareness of medication costs. One major barrier to clinicians' ability to address the cost of patients' regimens is that many clinicians often are unaware of the cost of common medications.[35,36] In a study of general medicine attending physicians and housestaff members,[36] 80 percent reported that they often felt unaware of medication costs. Only a third had easy access to drug cost information, and only 13 percent had received formal education about drug costs. Physicians' estimates of the cost for 33 commonly used medications were accurate only 45 percent of the time, and 40 percent of the time physician estimates of patients' costs were too low. An interactive 45-minute group educational conference with physicians—along with a pocket guide—may increase the proportion of doctors who ask patients whether they can afford their medications and improve physicians' knowledge of the cost for common treatments.[35]

Using generic equivalents. Medicaid and other payers could save millions of dollars annually by promoting broader use of generic equivalents.[37] Unfortunately, fewer than half of chronically ill older adults report having had a medication changed to a generic or cheaper brand in the previous year. Several strategies, including prescriptive formularies and physician education and feedback, could promote broader use of generics. However, patient barriers to generic use may need to be addressed as well. Some patients perceive generic drugs as riskier or less powerful than branded drugs[38] and may need education to promote adherence. A comprehensive plan to promote the appropriate use of generics and educate patients about their value could reduce costs to health systems as well as to consumers. Interventions that are focused on the patient-clinician interaction, as well as targeted public-health approaches, could be valuable in educating users about generic drugs and providing an alternative source of information to the often overwhelming marketing of branded drugs.

Pill-splitting. Pill-splitting often provides opportunities to save money both for health plans and patients, because drugs can often be purchased at twice the strength for no extra cost. Patients who split pills under the direction of a doctor or pharmacist save on copayments by stretching out the length of time between refills. Drugs from multiple classes such as cloazepam, atorvastatin, and paroxetine are amenable to splitting pills. However, pill-splitting is infrequent, and as little as 2 percent of the potential cost savings is being realized.[39] Despite concerns about patients' ability to split pills, Department of Veterans Affairs studies have shown that pill-splitting is safe and produces similar health outcomes as whole-tablet dosing.[40] As a result of this research, the VA now mandates pill-splitting as a cost-saving strategy. Other clinicians and health systems should also consider using splitting more widely, particularly for high-cost branded drugs such as Lipitor.

Minimize use of free samples. Free samples are the most common way physicians try to minimize their patients' medication costs.[30,41] Although useful in the short-term, free medication samples can increase patients' out-of-pocket costs in the long term by adding treatments to their regimen that are of limited value or for which effective generic equivalents are available. Free samples represent more than $6.6 billion of the $12.7 billion cost of drug promotion in the United States; they can inflate retail costs for prescription drugs and can lead providers to prescribe more expensive regimens.[42,43] For all of these reasons, samples may worsen, rather than ease, the problem of cost-related medication underuse. Prescribers must remain vigilant when using free samples to balance patients' short-term appreciation and financial benefits against the long-term consequences both for those individuals and society as whole.

Increasing Patients' Access to Low-Cost Drugs and Financial Assistance

Even with the most cost-sensitive prescribing, some patients' regimens are unavoidably complex or costly for other reasons. Nevertheless, patients' cost pressures can often be reduced if they are able to take advantage of opportunities to buy drugs more cheaply or receive financial support through third-party payers. Unfortunately, patients rarely receive assistance identifying resources for paying their drug costs. Only 22 percent of KN study participants reporting cost-related adherence problems were given information from their clinicians about financial programs that could assist them, and only 18 percent were given information about where to purchase medication more cheaply. Allied health professionals may be ideally suited to provide this type of information; however, only 8 percent of patients in the KN study who cut back on medication use because of cost said that they had been referred to a social worker or other staff member for help.

Chronically ill patients can benefit from help with enrolling and using potential financial resources. Patients often do not understand their health insurance coverage,[44-46] and prescription drug coverage can be particularly difficult to fathom. In one study, more than a third of low-income diabetes patients treated in a county health care system reported cost-related medication underuse even though they were almost universally eligible for prescription drug coverage with no deductible.[26] In the KN study, 3,119 of respondents reported having prescription drug coverage; however, nearly a third (28 percent) were unable to report their copayment amount, and 43 percent did not know whether there were limits on their coverage. Being non-white and having low income were both risk factors for lack of knowledge about these aspects of pharmacy benefits. Respondents who did not know the limits of their coverage were at increased risk for cutting back on medication use because of cost pressures, forgoing basic needs because of medication costs, borrowing money to pay for their prescriptions, and worrying about their medication costs. These findings suggest that many patients do not avail themselves of assistance programs for which they are eligible and that policy changes alone may be insufficient to buffer them from the adverse effects of medication cost pressures. High rates of problems understanding drug insurance are particularly worrisome with regard to their implications for implementing the planned Medicare prescription drug benefit, which has been criticized because of its expected complexity.

The federal 340B Discounted Drug Cost Program offers substantial savings on covered drugs purchased by organizations serving the most vulnerable patients, including federally qualified health centers, disproportionate share hospitals, and migrant health centers. The 340B program requires drug manufacturers to sell covered outpatient drugs to participating organizations at a statutorily determined reduced price. Eligibility determination and participation in the drug program can be complex, but resources are available both through the federal Health Resources and Services Administration Pharmacy Services Support Center as well as non-governmental consulting groups. Participating in the 340B program is an important way for safety-net providers to lower their own drug costs as well as the costs paid by their most vulnerable patients.

Drug Cost Assistance Programs

Drug cost patient assistance programs (PAPs) provide free or low-cost access to brand-name prescription drugs for qualifying patients. On the whole, PAPs have provided substantial financial support. According to one industry report, as many as 5.5 million patients received drug cost assistance through PAPs in 2002, enabling them to buy medications valued at $2.3 billion.

Unfortunately, several barriers make it difficult for potentially eligible patients to make use of these programs. Perhaps the most notable problem is that there are few centralized repositories of information about the many programs offered by pharmaceutical companies. Some Web sites try to provide this service,[47] but many PAP Web sites can be difficult to navigate for clinicians and allied health personal and almost impossible for uninsured patients. Most PAPs require documentation of eligibility that can be cumbersome to collect and can introduce substantial delays before patients are able receive their medication.

Often, patients' eligibility must be recertified several times each year, adding additional bureaucratic burdens to providers and an unacceptable level of uncertainty about many patients' ability to purchase their treatments. Most PAPs require patients to provide their Social Security numbers, and, as a result, these programs are almost universally unavailable to undocumented patients.

One strategy for simplifying the PAP process would be for drug manufacturers to provide medicine in bulk to safety-net providers at low or no cost, and then have health systems identify eligible patients and distribute the medication directly. However, strict laws restrict these arrangements because of the potentially coercive influence on health systems' formulary decision-making. Institutional PAPs, such as those developed and managed by the Franklin Group, can serve as a buffer between multiple manufacturers and health care providers and can guarantee that medication dispensed through the program is distributed only to qualified patients. Creative organizational arrangements such as institutional PAPs can expand the number of vulnerable patients who receive drug cost assistance and may even save administrative costs by simplifying the eligibility determination process for manufacturers.

Benefits of Lowering Patients' Medication Costs

Given that medication underuse can lead to serious health consequences, some researchers and policymakers have suggested that selectively lowering patients' prescription costs might actually improve adherence and decrease the overall cost of their care.[48] For example, angiotensin-converting enzyme (ACE) inhibitors are highly effective in preventing cardiovascular consequences among people with diabetes, and no-deductible coverage of these drugs for diabetics could save both lives and money.[49] One company recently tested the potential impact of lowering copayments for diabetes and asthma drugs and found that overall health care expenditures dropped more than 12 percent for both patients groups.[50] Although increased patient copayments continue to be the norm, raising them may be short-sighted. Selectively lowering out-of-pocket drug costs for people with chronic diseases could save money for patients and third-party payers by preventing acute health problems.

III. Helping Patients Cope with Unavoidable Costs

The challenge is to understand each patient's situation and tailor solutions that meet his or her unique needs.

SOME MEDICATION COST PRESSURES ARE inevitable for chronically ill patients, and health system efforts to minimize those costs can still leave patients expressing concern about their ability to afford their treatments. However, not all patients respond the same way to a given level of medication cost pressure. Other factors might influence patients' likelihood of cutting back on medication in response to costs. Variation in patients' responses suggests that opportunities might exist for clinicians and health systems to support patients in sticking with their medications despite the cost and ensure that patients' decisions about their regimens are consistent with their overall financial resources, values, and priorities. The challenge to clinicians and health systems is to understand each patient's situation and to tailor solutions that meet his or her unique needs.

Most patients report taking their medication as prescribed even in the face of high out-of-pocket costs, low incomes, and lack of prescription medication coverage. In one study, only 13 percent of those with monthly prescription costs of more than $100 reported cutting back on their medication because of cost pressures,[12] and other studies have found that rates of cost-related underuse are between 18 and 28 percent.[13,23] Although these figures are certainly far too high, they do demonstrate that most patients report adhering to their treatments despite the cost and suggest that patients who respond to cost pressures by cutting back on their medications might be different in important ways than patients who continue to take them as prescribed. Small increases in copayments (less than $2) can significantly reduce refill rates,[20,21,51,52] and a recent study[27] found that 13 percent of diabetes patients with moderate to high incomes ($60,000 per year or more) reported the cost prompted them to underuse medications despite their apparent ability to afford these treatments. All of these findings suggest that patients' willingness to pay, as well as their financial ability to pay, may determine medication adherence. Understanding the factors that can intensify or ease patients' medication cost problems may allow clinicians and health systems to provide needed assistance and anticipate problems that could occur as a consequence of a regimen change.

Variation in Underuse among Demographic Groups

Patients' age, race, ethnicity, and gender may affect how they respond to medication cost pressures. For example, one study[12] found that nonwhite older adults were three times as likely to report cutting back on medication use because of cost problems than their white counterparts, even when controlling for out-of-pocket costs, drug coverage, and income. Low-income African American patients use fewer prescriptions than their white counterparts with a similar ability to pay,[53] and older patients are less likely to forgo medication when facing cost pressures than their younger counterparts.[12,13]

The reasons for these demographic differences in patients' responses to cost pressures are unclear. They may reflect variation in patients' perceived need for treatment,[54,55] belief in treatment effectiveness, trust in providers and health care systems,[29,56,57] or knowledge of financial assistance programs.[44] They may also reflect unmeasured differences across groups in patients' financial resources or commitments. Future research will be needed to determine the ways in which cultural beliefs and attitudes influence how patients respond to medication costs and how similar cost pressures affect communities differently depending on their unique financial stressors and resources.

The Relationship Between Causes

Fewer than 50 percent of patients with chronic diseases take their essential medications as prescribed.[58] The principal factors that have been associated with underuse are low health literacy,[59] depression,[60] impaired cognitive function,[61] social isolation,[60] problems managing complex medication schedules,[62] and beliefs about prescribed medication.[63] Other predictors include the patient's confidence in a motivation to use their drugs (self-efficacy) and their ability to monitor their own adherence (self-management).[64,65] Patients' race, gender, or other demographic characteristics are poor predictors of medication-adherence problems.[66] One study found that underuse is often intentional because of factors such as perceived side effects, inadequate therapeutic response, and high cost.[67] Poor patient–provider communication can be a barrier and may be especially important among those with medication cost concerns.[68] Moreover, addressing patients' adherence problems as a matter of affordability may affect their overall approach to their self-management, as well as their health and well-being.

Almost no studies have examined whether adherence problems caused by medication costs are more common among patients experiencing these problems for other reasons. However, in a nationwide sample of older adults with diabetes,[29] a study found that rates of cost-related medication underuse were three to four times higher among patients who also reported that they cut back on their medication for some other reason than among patients who did not report such behavior. Patients with significant symptoms of depression had more than twice the risk of cost-related underuse compared to those without

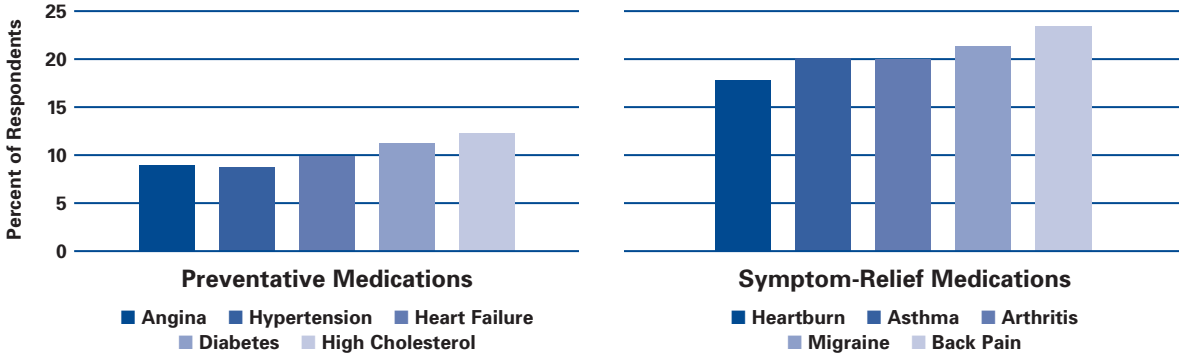
depression. These findings suggest that many of the same patients may struggle with both cost and non-cost adherence problems. For some, understanding and addressing barriers to medication use other than cost may also decrease their propensity to forgo treatment when facing cost pressures.

Variation in Underuse across Diseases and Medication Types

Most older adults who use prescription medications take more than one, and almost a third use four or more.[69] Although higher out-of-pocket costs lead to decreased demand across almost all medication types, the likelihood of responding to costs with underuse varies across clinical categories.[15,17,19,21,70]

Many clinicians believe that patients value short-term health benefits of medication (such as reduction in pain) more than future outcomes (such as living a longer life).[71] However, patients may value medications that treat asymptomatic but life-threatening chronic conditions more than is often assumed. A recent study based on drug refill data found that patients were more cost-sensitive with respect to symptom-relieving medications such as antihistamines and nonsteroidal anti-inflammatory drugs than when using medications treating high cholesterol, hypertension, or diabetes.[17] In the KN study (Figure 3),[13] older chronically ill adults were least likely to report cutting back on medication use due to cost pressures for medications that control or prevent disease, such as hypertension (9 percent), heart failure (10 percent), and diabetes (11 percent). In contrast, patients' likelihood of foregoing medication due to cost was roughly twice as high for treatments mainly intended for symptom relief, such as drugs for asthma (20 percent), arthritis (20 percent), and back pain (23 percent). In still another study,[70] researchers assessed changes in the rates of drug-related medication claims before and after coverage was reduced. They found that after the benefit reduction, medication refill decreases were greatest for "nonessential" drugs and smaller for "essential" medicines such as insulin and antihypertensives. A survey of Medicare beneficiaries found that increased prescription cost sharing was disproportionately associated with decreases in the use of medication for less serious health problems such as colds, allergies, and backaches.[15] Similar findings were reported after an increase in copayment levels among members of a health maintenance organization.[21]

Figure 3. Variations in Cost-Related Medication Underuse



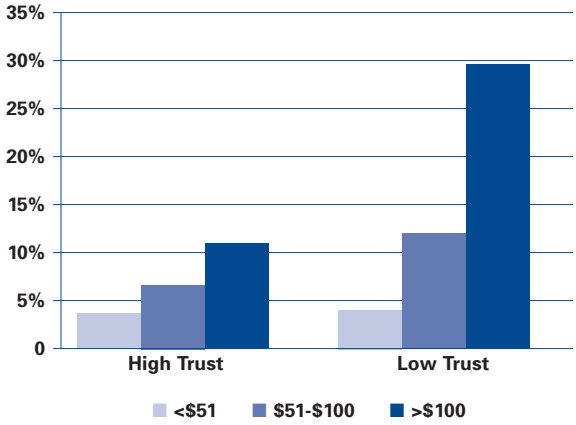
These studies suggest that characteristics other than cost alone shape patients' decisions about which medications to take in the face of cost pressures. Patients' choices may be influenced by how they rate their personal need for each medication and the medicine's perceived effectiveness in controlling symptoms relative to their concerns about potential adverse effects.[72,73] Patients may also take into account the extent to which over-the-counter alternatives are available.[15] As described above, some patients may value generic medications less than brand-name drugs[38,74] and may be more likely to cut back on generic medication given comparable costs. Patients may also be more likely to cut back on medications they take episodically than those they take on a regular basis. Understanding the characteristics of medication regimens that patients consider when choosing to pay for their drugs could help clinicians have more effective discussions about adherence and could help them anticipate when a change in regimen could create problems. Given the limited information about these difficult choices, frank discussions between prescribers and patients about their medication use may be the best way to uncover and address patients' beliefs about medication benefits and adverse effects.

The Role of Clinician Trust

Patients have better chronic disease self-management and treatment outcomes when their clinicians involve them in making decisions about self-care problems and goals.[75,76] For example, patients are more likely to take their medications when their clinicians actively assess potential barriers to adherence and provide clear messages about the importance of self-care.[68,77]

A study of more than 900 diabetes patients examined the extent to which patients' trust in their physicians moderated the impact of economic constraints and other risk factors for underusing medications.[29] Patients with higher out-of-pocket costs were more likely to forgo medications because of cost pressures when their trust in their physican was low (Figure 4). Having a low income was associated with cost-related adherence problems only in the context of low physician trust. This study suggests that trusting physician relationships can moderate the impact of cost pressures on patients' medication adherence. Eliciting patients' concerns about their medication costs, as well as collaboratively setting treatment goals, could address cost-related adherence problems by promoting greater trust in providers and health systems and educating patients about their medication needs.

Figure 4. Proportion of Diabetes Patients Reporting Cost-Related Medication Underuse Within Groups, by Monthly Medication Costs and Level of Physician Trust



Variation in Cost-Related Underuse across Health Systems

Even relatively minimal prescription drug costs may precipitate underuse when patients face other barriers to adherence. Unfortunately, low-income patients treated in public health care systems often have many additional barriers to medication use, including long waits for medication refills or cumbersome application processes for prescription drug assistance programs.

Some health systems represent both a site of care and a point of access for specific type of financial coverage for prescription drugs. Department of Veterans Affairs (VA) medical centers offer more comprehensive medication benefits than almost any other public or private payer. A study of diabetes patients treated in a variety of health system types[26] found that fewer VA patients reported cost-related medication underuse (9 percent) than patients with private insurance (18 percent), Medicare (25 percent), Medicaid (31 percent), or no health insurance (40 percent). In the KN study,[34] VA patients reported lower out-of-pocket costs and were less likely to report cost-related underuse (12 percent) than patients with Medicaid (25 percent), private health insurance (15 percent), Medicare (22 percent), or no insurance (35 percent). Importantly, VA patients' rates of cost-related underuse continued to be lower even when controlling for their actual out-of-pocket costs. This suggests that other structural characteristics of the VA health care system (e.g., mail-order pharmacies and automated reminders when patients need refills) may assist patients in taking their medication as prescribed despite cost pressures.

IV. Conclusions

Creative strategies are badly needed for patients and their physicians.

MULTIPLE FACTORS—INCLUDING THE characteristics of patients, their regimen and medical conditions, and their interactions with clinicians and health systems—contribute to decisions about adherence in the face of cost pressures (Table 2). As a result, there may be opportunities for clinicians and health systems to help patients both by reducing their cost burdens and promoting adherence despite such pressures.

Strategies for Improving Patient Care

Support prescribers in addressing patients' medication cost problems. Physicians and other prescribers should have information about the cost of common treatments in general and, ideally, the specific cost of individual patients' regimens. However, even with this information, detailed discussions with patients about cost-related adherence problems may best be handled by allied health personnel with expertise in behavioral medicine and benefit programs.

Screen patients for medication cost problems. Failure to identify patients with medication cost problems may be an important and under-recognized factor associated with poor clinical outcomes among chronically ill patients. When the health of these individuals does not improve, typical clinician responses, such as switching drugs or adding augmentation therapy, may exacerbate the problem by inadvertently increasing patients' cost burden. Unfortunately, clinicians may interpret "medication failures" as an indication of patients' lack of commitment to the treatment plan or lack of effectiveness for the specific agent.

Medical practices might want to include questions about problems paying for prescribed medications in previsit questionnaires or intake interviews, a practice that has successfully increased use of preventive services and the identification of other health problems.[78,79] An example of the types of questions that may be helpful in identifying patients with medication cost problems and monitoring efforts to assist them is provided in Table 3 on page 22.

Table 2. Factors Affecting Patients' Responses to Out-of-Pocket Medication Costs

Other Cost Pressures

- Income
- Other health care costs
- Non-health care expenses

Characteristics of the Regimen

- Perceived adverse effects
- Convenience of use
- Refill frequency
- Perceived effectiveness

Characteristics of the Illness

- Effects on quality of life and functioning
- Symptom burden
- Effects on life expectancy

Patient Characteristics

- Cultural beliefs
- Mental status
- Self-efficacy
- Health literacy

Patient-Clinician Interactions

- Discussions about medication costs and adherence
- Establishing trust
- Therapeutic choice

Health System Factors

- Barriers to refilling prescriptions
- Barriers to applying for benefits
- Information-system support for prescribers
- Incentives for cost-effective prescribing

Minimize patients' medication cost pressures. Many clinicians resist efforts to lower the cost of patients' prescriptions because of concerns that lower costs mean less aggressive management for illnesses that can be effectively treated with medication. However, there are opportunities to address at least some of patients' medication cost problems while providing care of equal or even higher quality than standard practice. Greater adherence to recommended standards of care could save billions of dollars nationally for treatment of hypertension alone.[80]

System-level changes may be the most effective strategy for supporting clinicians and patients in identifying cost-effective regimens. Formulary management can be a powerful tool to ensure that patients have access to effective treatments but at minimum cost to them and third-party payers. General guidelines for determining what to include in the formulary for safety-net health care systems have been described.[81,82] Central to this process, however, are evidence-based decisions regarding which drugs are essential and which are most cost-effective. Many provider organizations lack the resources to conduct a thorough review of the evidence for these formulary decisions, and maintaining a current formulary can be difficult. The Department of Veterans Affairs health system has made available a large number of evidence-based reviews conducted as part of its own formulary development.[83] Other evidence-based reviews and cost comparisons have been developed by the University of California at Davis in collaboration with the California HealthCare Foundation.[84] These reviews focus on six common conditions managed in primary care (gastroesophageal reflux, osteoarthritis, hypercholesterolemia, depression, asthma, and allergic rhinitis). For each disease, the project provides important findings in an easy-to-read summary format, as well as more detailed literature reviews comparing

classes of treatment. These reports can help safety-net health care providers make formulary decisions, particularly about drugs used to treat common chronic diseases such as hypertension, diabetes, and depression.

Clinician education and feedback can be important tools to promote cost-effective prescribing.[85] Computerized order entry[86] and prior authorization requirements[87] can have a dramatic impact on both the cost and quality of care. Like chronic illness care itself, helping prescribers manage chronically ill patients' medication cost problems might require a commitment to addressing health system, clinician, and patient barriers.

Clinicians and health systems need to decide which PAPs are sufficiently useful to merit the increased workload associated with helping patients obtain these benefits. Volunteers in Health Care (VIH) has developed excellent guides that include sample application forms, sample letters certifying patient needs, and a list of useful Web sites.[47] VIH reports also include detailed information for community-based organizations that wish to develop a comprehensive PAP to help patients get low-cost or free medication from a variety of resources.[88] Medicine for People in Need (Medpin) teams up with other organizations to improve patients' access to prescription drugs. The organization's Web site (www.medpin.org) provides resources that safety-net health systems and individual clinicians can use to identify available resources and develop medication cost management strategies. Institutional PAPs can increase access to industry-sponsored programs while decreasing the administrative burden both to patients and their health care providers.

Promote adherence in the face of cost pressures. In most research to date, the role of cost in patients' adherence has been viewed as purely economic. However, patients consider cost as one of many factors that determine their adherence to self-management regimens, and cost-related adherence problems should be viewed within this larger context. Research described above suggests that patients' responses to medication costs may be amenable to change through clinician intervention even if the costs themselves cannot be completely eliminated. Promoting a more trusting relationship may minimize the extent to which patients respond to cost pressures by cutting back on medications. Clinicians should work with patients to identify a regimen that is both economically feasible and consistent with the patients' goals. Strategies such as "closing the informational loop"[89] can be effective in ensuring that patients understand their regimens, the benefits of their treatments, and the potential adverse consequences of medication underuse. Efforts to improve communication about medication adherence and costs may be particularly important among patients with health literacy limitations, who often have difficulty understanding and following treatment regimens.[59]

Table 3. Questions to Identify Patients Experiencing Medication Cost Problems

1. Not counting the costs paid by your insurance, how much do your prescription medications cost you and your family each month? In other words, how much do you typically pay "out-of-pocket" per month for prescription medications?
2. In the past 12 months, how often did you worry about being able to pay for your prescription medications?
3. During the last 12 months, have you spent less on food, heat, or other basic needs so that you would have enough money for your medicines?
4. In the past 12 months, did you ever have to borrow money from a friend or relative outside of your household to pay for your prescription medications?
5. In general, over the past 12 months did you have to increase the amount of credit card debt you carried month-to-month because of the cost of your prescription medications?
6. In the past 12-months, how often have you ever done any of the following because you were concerned about the cost of your prescription medication:
    - A. Take fewer pills or a smaller dose
    - B. Not fill a prescription at all
    - C. Put off or postpone getting a prescription filled
    - D. Use herbal medicines or vitamins when you felt sick rather than take your prescription medication
    - E. Take the medication less frequently than recommended to stretch out the time before a refill
7. In the past 12 months, did someone at your health center ever...
    - A. Arrange for you to meet with a social worker or other professional to help you find a way to pay for your medications?
    - B. Talk with you about which medications you definitely should not skip?
    - C. Ask you whether you could afford the medication when they gave you a prescription?
    - D. Give you information about where to get less expensive medications?
    - E. Give you information about programs that help people pay for their medications?

Implications for Policy

Public and private health care payers are struggling with how best to finance patients' medication use while maintaining financial solvency. Creative strategies are badly needed to better target available resources while providing appropriate incentives for patients and their physicians to use prescription drugs wisely. Tiered copayment systems charge one price for low-cost generic drugs, higher copayments for standard branded drugs, and the highest copayments for treatments that are the most expensive or have the least evidence of effectiveness.[90] Other efforts to promote optimal medication use include reference-based pricing[91] and benefit-based copayment, in which out-of-pocket costs for a given treatment are based in part on the treatment's expected impact on a patient's clinical outcomes.[48] To be effective, such plans require information about patients' clinical risk profiles, as well as an understanding of the factors patients consider in choosing which medications they will pay for.

Greater understanding of the mechanisms underlying the differential responses of demographic groups to similar cost pressures will enhance the design of new prescription benefit programs. Based on studies described above, non-white patients may be more likely to forgo medications because of cost than their white counterparts, and when non-white patients are using medications associated with higher rates of cost-related underuse (such as treatments for chronic pain or depression), they might be at especially high risk. Given that race is strongly associated with patients' ability to pay, racial variations in response to medication cost pressures are even greater than predicted by models that control for these economic variables. Changes in patients' drug coverage that fail to address the mechanisms underlying these variations may aggravate existing disparities in health care access and outcomes.

Ideally, efforts to address the underuse of medication because of its cost will be integrated within larger efforts to improve adherence[58] and provide more effective chronic disease care.[92,93] Besides coverage reforms, patients need effective education to enable them to make appropriate medication decisions, access available assistance programs, and take full advantage of their benefits. The same components necessary to improve chronic disease care—self-management support, delivery system design, decision support, and clinical information systems—are integral to improving identification and support for patients who are having difficulty affording their medications.

The Medicare Drug Benefit

Medicare beneficiaries pay for more prescription drugs than any other single group of Americans, and studies consistently show that these patients often restrict medication use because of cost pressures.[9,23,94] By providing at least $410 billion over 10 years in new drug benefits, the new program may help many older adults, particularly those with low incomes, who are struggling with the cost of prescriptions. The Medicare Modernization Act (MMA) represents the most sweeping changes in the Medicare program since its enactment. The Medicare drug benefit is complex, with variable deductibles, copayments, and premiums depending on a patient's income and annual drug costs.[95,96] Because the drug benefit will be offered only through private insurers with varying formularies, beneficiaries will face an array of choices just to decide on a plan. Deductibles and spending limits under the Medicare benefit are indexed to rise with drug costs, ensuring that the actual thresholds of coverage will be a continually shifting set of rules that beneficiaries must track, along with their own accumulating drug costs.[97]

Some of the most economically vulnerable Medicare beneficiaries eligible for both Medicare and Medicaid could face significant challenges when the Medicare drug coverage is implemented. These patients currently receive comprehensive drug coverage through Medicaid and often pay nominal or no copayments for covered medicines. In 2006, dual-eligible beneficiaries will qualify for the new coverage and lose their Medicaid plans, even if they have not yet enrolled. Although premiums and copayments are subsidized for these patients, choosing a plan and enrolling will be extremely complex, and many could face periods without any drug benefits. The array of drugs covered by various plans may vary widely, and these patients will need advice from their clinicians about which plans are best suited to them given their medical needs. Information about the plans is provided for under the MMA legislation; however, no agency at the federal or state level is specifically charged with the responsibility for educating dual-eligible beneficiaries about the choices they face.

It will be essential to develop effective campaigns to educate older adults about the planned Medicare drug policy, including the costs that will and will not be covered. These initiatives will be particularly important among older adults at highest risk both for gaps in knowledge about their drug benefits and for significant burdens from their out-of-pocket medication costs, including members of racial minorities, those with low incomes, and those on multiple medications. However, even well-educated consumers can experience substantial difficulties in understanding the Medicare program.[98] Funding by the Centers for Medicare and Medicaid Services (CMS) is insufficient for educating beneficiaries about the current system, much less meet the greater needs that will arise with the highly complex new drug benefit.[99] Only $1 billion in new funding has been set aside to cover all aspects of implementing the drug benefit. Even if half of these resources were devoted to beneficiary education, that would mean an average of only $12 per enrollee, and the amount will probably be much lower.[96] Although private plans will probably devote considerable resources to advertising, potential beneficiaries will need independent information about their benefits and considerable assistance in navigating the maze of different plans.

Summary

Medication cost problems will adversely affect the care of chronically ill patients for the foreseeable future. Higher costs can lead to medication underuse, forgoing basic needs, and, ultimately, poorer health outcomes. Patients' responses to medication cost pressures are shaped by multiple factors, and there may be opportunities to assist patients on several levels. Effectively countering medication cost problems requires a multifaceted approach: Interventions must consider the characteristics of patients, their treatment, communication with clinicians, and health system influences. Understanding these relationships will enable clinicians and health systems to respond to this growing problem and help patients take their medication as prescribed.

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