Patients’ Understanding of and Compliance With Medications: The Sixth Vital Sign?

The problem of patients not understanding their disease(s) or its importance and their noncompliance with their physicians’ recommendations is one of gigantic proportions, in both morbidity and mortality as well as in costs. Estimates of patients’ compliance with using medications as recommended vary from 25% to 50%, with the likelihood that assessments are not overestimated because the most common approach for assessing noncompliance is patients’ recounting of activity. Furthermore, we cannot measure the blood levels of most drugs, and even if we could, it would be too expensive. If this problem is to be fixed, we must assume that a large fraction of the fault lies with the physician and his or her partners in health care delivery.1

In the early 1990s, it was estimated that the direct costs of noncompliance of medication use were greater than $50 billion and that indirect costs were an additional $50 billion.2 During that same period, prescription drug–related morbidity and mortality costs were estimated at $76 billion, with a range of $30 billion to $137 billion, putting the total in the range of nearly $200 billion per year related to the use, misuse, and nonuse of prescribed medications.3 This dollar amount does not take into account over-the-counter drug use, including alternative drugs. In that same article, Johnson and Bootman3 estimated that 40% of patients who were receiving medication would have a drug-related problem—assuming they were taking their medication—and that about 5% of patients with a drug-related problem would require admission to the hospital.

The problems with drug compliance, independent of compliance with recommendations for lifestyle changes, are multiple and far easier to list than solve. Essentially every practicing clinician could list most of the problems I address and could probably add more. I collectively refer to the issues contributing to misunderstanding and medication noncompliance as the sixth vital sign because in many ways they are as important as the well-known 4 vital signs and the new fifth vital sign of pain. An impaired sixth vital sign can result in setbacks and readmissions to the hospital as easily as the other 5 signs.4,5

Physician Communication
Physician communication or the lack of it is probably one of the most important factors for patient noncompliance.6-11 In the current issue of the Mayo Clinic Proceedings, Makaryus and Friedman12 point out the difficulty physicians encounter with patient compliance. All of their 43 patients spoke English. Only 28% of the patients were able to list all their medications (mean number of medications was 3.89 per patient, but the authors did not mention what the percentage would be if patients were taking 6 or more drugs), 37% knew the purpose of all their medications, 14% were able to state the common side effect(s), and 42% could list their diagnoses. The authors did not follow up these patients to assess their compliance but presumed that compliance would be poor because of their findings. Their 1 recommendation was that the physician spend more time educating the patient. In my opinion, this will not happen.

We physicians often assume that because of our authoritative position the patient and family comprehend all issues that we discuss with them. Furthermore, the directions for taking the drugs are on the container. Amusingly, we are extremely surprised when we find out later that patients are not taking the medication as directed or not at all. Other problems with physician-patient communication are sex, sex differences, perceived physician arrogance, talking only in medical terms, not repeating the instructions, racial and cultural differences, and a lack of concordance, which is a mutual agreement by covenant that enhances trust between the 2 parties.6,13-15

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Lack of continuity of care contributes to a rift between the physician and the patient, especially if the physician does not seem interested in the importance of the individual patient. The patient will be more compliant if he or she is allowed to select his or her primary care physician rather than having a physician assigned. These rather obvious factors can improve compliance by a third.6

The physician, a trained registered nurse, or a health educator needs to spend time explaining the nature of the disease(s) and why he or she has selected the specific medications, even though the patient may be asymptomatic as with hypertension or diabetes. The physician should also list the more important side effects. This should be done in an empathetic manner.13 Asking the patient to repeat these directions is important and may be enlightening. The patient should appreciate that the physician loses trust in the patient and eventually interest in the patient if he or she is noncompliant. Mutual respect is important for both parties.

PATIENT CONCERNS
Patient concerns are numerous. An estimated 15% of the English-speaking people in the United States are illiterate, and another 15% are only marginally literate.16 This is a total of 90 million people (Institute for Healthcare Advancement, www.iah4health.org and http://foundation.acponline.org/healthcom/hli.hstm). Many of these people live in poverty, and one fourth have some physical and/or mental impairment. For another 15% to 20% of the US population, English is not their primary language, and these people have essentially no understanding of medical terminology (www.census.gov/prod/2003pubs/c2kbr-29.pdf). Using a family member to interpret can lead to problems. Because of cultural differences, a family member may never explain to the patient that he or she has a life-threatening condition, and the information given can be misleading in regard to what the physician wants the patient to know. Title VI of the Civil Rights Act of 1964 requires that interpretive services be available to people who speak limited or no English.17 The United States needs many more multilingual physicians, especially those conversant in Spanish because at least 30 to 40 million US inhabitants speak Spanish exclusively at home. At least another 20 million people speak languages other than English or Spanish exclusively at home. Becoming conversant in Spanish could become a requisite for a medical and RN degree. The same standard might be applied to health educators.

Because of other cultural differences, ethnic minorities have many preconceived notions about diseases and medications and are reluctant to change their thinking, even with an effort to educate them. Explaining the side effects of their medications to them is frequently a reason they are noncompliant. They may remember the benefits, but primarily they remember the small chance of a side effect of liver disease or a rash or a worsening of their condition. They may nod their head “yes” but know they will not take the medication. Later, they read about every possible side effect in the package insert.

Alternatively, at a follow-up visit, they hear their physician tell them that their blood pressure is well controlled or that their blood sugar is better. Now they think they can stop taking their medication, and they do so; at the next visit they are surprised to find out that they are not “cured” of their disease. They may state that they are taking the medication as directed because they do not want to offend the physician.

Mental illness reportedly affects nearly one half of the US population sometime in life.18 To clinically depressed patients, their obesity or the symptoms of their heart disease or obstructive pulmonary disease may be of greater overriding importance than drug compliance. Depressed patients with somatic complaints will consume considerably more health care dollars than when the depression is treated. Of those treated with antidepressants, nearly 50% discontinue therapy after 1 year because they feel better, but a fourth do not tell their physician.19 Many of these people are lonely, live alone with no family support, or live in a dysfunctional family, sometimes with 1 or more family members being an enabler or selling the medication. The patient with psychosis presents an even more difficult problem.18

For reasons that are unclear to me, transplantation health care teams have a compliance problem with the patient not taking immunosuppressives, resulting in transplant rejection.20 Chapman20 reported 5% noncompliance at 5 months, which increased to 48% by 12 months. How does a physician deal with the noncompliant patient with a rejected organ who now wants a second transplant?

Asthma affects at least 15 to 25 million people in the United States.21 The National Institutes of Health has spent many millions of dollars to establish a standardized approach to the treatment of asthma.22 A summary has been sent free more than once to most clinicians, or it has been published in appropriate journals. As a pulmonologist, I agree with the recommendations. However, there are 3 problems: (1) the primary care physician often does not follow these guidelines; (2) thus, the patient (and family) is poorly educated; and (3) there is only 1 effective way to use metered dose inhalers, a method that when done properly could prevent more than 75% of flare-ups. Less than half of asthma patients are instructed in the correct use, even by physicians.22 A small but significant percentage are never able to use the inhaler correctly because of hand-inhalation incoordination. The asthma patient is greatly undertreated, resulting in many billions of dollars of costs and millions of days lost from work and school.22
The age of the patient is directly proportional to non-compliance for many reasons. A study of 325 elderly persons, with an average age of 78 years, reported that 39% were unable to read the prescription labels, 67% did not fully understand the information given to them, and as a result 45% were noncompliant. These problems were especially prevalent in men and in patients older than 85 years. The actual percentage of noncompliance is almost certainly higher on the basis of aforementioned issues.

The problem of economics is inestimable. A common story is that Social Security checks do not cover drugs and other medical expenses for elderly patients. Thus, they do not purchase the drug, but many elderly persons tell their physicians that they are taking their medications as recommended because they are too proud to admit the truth. Alternatively, they purchase “cheap” versions of the medication of biologic uncertainty through the Internet. There are no easy solutions for this issue. Another scenario is when parents pay $150 for an antibiotic for a child’s ear infection, discontinue the medication when the child gets better in 2 days, and save the medication for the child’s next upper respiratory infection even though they were clearly told that it is important that the child takes the full course of treatment. Some metered dose inhalers cost more than $100; it is not surprising that patients and their families hoard medicines or share them with their sisters-in-law.

What is the patient’s motivation to get better? What is the patient’s attitude about his or her overall health? Is the patient supportive of partnering with a physician? Does the patient perceive responsibility for his or her overall health? What about the patient with undiagnosed mild cognitive impairment?

The Sixth Vital Sign

The sixth vital sign can be defined by what the health care team knows, what is recorded regarding the medications the patient is taking or not taking, and whether the patient will take the medications as recommended—that is, is the patient truly compliant? Often, when a physician tells the patient to bring all his or her medications to the clinic or hospital, the patient brings them in one big container, not in the original containers. Conversely, the patient does not think, for example, that the β-adrenergic blocking eye drops or the over-the-counter drugs are important and does not bring them in. Alternatively, most commonly, the patient forgets to bring the medications. Since many patients “doctor shop,” it is imperative that each “new” physician knows the medications that the patient is taking or should be taking. Optimally, the patient should bring in all the medications he or she has at home, even if the patient is not taking them. At a minimum, the patient should always carry in his or her wallet a list of all the medications the patient is taking, including the strength and dosage. It is important for the physician to compliment the compliant patient. I cannot stress this enough.

Recommendations

Because of the tremendous costs and morbidity associated with the lack of education of the patient and in turn the far less than ideal compliance with the physician’s recommendations, something must be done and done soon. This sixth vital sign is in dire straits. The United States is currently in a “Save 100,000 Lives” campaign (Institute for Healthcare Improvement [IHI] 100K Lives Campaign, www.ihi.org). Improving patient compliance will save some lives, maybe more than we will ever know. The following are my ideas for improving this dilemma.

• Educating patients and the public at large about the importance of compliance should begin in primary school. It is imperative that patients begin to assume more responsibility for their own health, and it may be necessary to establish a reward system.

• With a new diagnosis, the patient and family could be given information, written at their education level, about the disease or condition. http://medlineplus.gov/ is an excellent source of material on a multitude of diseases that can be printed out in the office or hospital and given to the patient. Many of these materials are written in Spanish. MayoClinic.com is another good resource. It would be appropriate for physicians’ offices to have 1 or more education computer kiosks that the patient could use with the help of office personnel to find appropriate information. If patients have access to a computer at home or elsewhere, they can continue to obtain more information. As patients read the information, they could write questions in the margin to ask their physician at the next visit. Many hospitals and large clinics have patient education centers, staffed by health educators. These should be pointed out to the patient and family well before dismissal in the situation of the hospitalized patient.

• Consider a plan to stratify the patient’s likelihood of compliance or noncompliance.

Class I: Patient is otherwise healthy, young, and educated, has good family support, has a primary care physician, and is taking 1 or 2 medications. Patient is motivated and conveys sense of autonomy regarding his or her health.

Class II: Patient is similar to class I except older (but <65 years), is taking 2 or 3 drugs, and has only 1 major medical problem. If patient has depression, it is mild. Patient is less motivated than class I and is a female (females are more compliant than males1).

Class III: Patient has limited understanding of English, is a man older than 65 years, and is taking 4 or 5 medica-
tions. Patient may or may not have a primary care physician, is unemployed, and has 2 or 3 major medical problems.

Class IV: Patient has been admitted to the hospital 1 or more times because of noncompliance. Patient does not speak English, has depression and alcoholism, is taking 5 or more medications, does not have a primary care physician, and has little family support. Patient may also have other conditions such as brittle diabetes, corticosteroid-dependent asthma, chronic congestive heart failure, and poorly controlled seizures.

Classes I and II are fairly straightforward, and patients are likely to respond to usual educational efforts. When the patient has been identified to be in either class III or IV, appropriate efforts should be made to address the issues aggressively, not just at the time of dismissal. It is intuitive and has been shown in the older literature that these efforts will be cost-effective. Determining the best approach will require trial and effort and ideally should be done with research protocols.

A number value could be assigned to the various factors that I listed within the classes—the greater the number the greater the challenge.

• Each medical center might consider convening a continuous improvement committee on how to establish a uniform approach throughout the center. The cost savings of reducing 1 day of extended stay or 1 day of readmission would cover any approach the committee might devise. Grant opportunities may exist. A consensus conference could be considered in which various continuous improvement groups could share ideas.

• Most major medical centers employ 1 or more health educators; they must become part of the team. Some will need to be multilingual. Their efforts will need to begin long before the patient is dismissed from the hospital and should be ongoing depending on the patient’s response. For class III and IV patients, follow-up visits to the patient’s home by the health educator or even a trained volunteer who speaks the patient’s language, similar to visits by a social worker or visiting nurse, could enhance patient compliance, improve the family situation, motivate the patient, and result in a reworking of the dismissal plan to minimize setbacks in the patient’s health status. It would be cost-effective to train a potential health educator who speaks the language and knows the culture of a large diverse ethnic group(s) in the specific town.

• Knowledge of the cultural mores of most ethnic groups must be part of the context of the patient’s outpatient and inpatient dismissal plan. Ongoing courses or a grand rounds type of format could be beneficial to the education of all involved with ethnic groups. A health educator could be responsible for organizing these programs. Failure to comply with ethnic mores will almost certainly contribute to worsening of compliance (www.nih.gov/sigs/bioethics/culturalcomp.html, http://medicine.ucsf.edu/resources/guidelines/culture.html).

• Physicians should remember that directly observed therapy (DOT) has worked effectively in treating the patient with drug-resistant tuberculosis and is now used for most patients with non–drug-resistant tuberculosis. For the difficult class IV patient, DOT may be a reasonable approach, at least early in the course of the program. As stated previously, highly motivated educated volunteers could be incorporated in this plan.

• A discharge summary for the hospitalized patient written directly for him or her in a language the patient can understand would be of great value. It would include the diagnoses, the treatment plan, and the medications with directions. Translating it into the appropriate language is obviously necessary.

• Focus groups have proved effective for patients with congestive heart failure. Such groups should be considered for all class III and IV patients with a chronic illness.25 A video CD with a description of each drug the patient is taking could easily be made by industry. It would show what the drug looks like and explain what the drug is for and how the drug will benefit the patient. A computer in the pharmacy would produce a CD that lists the various drugs the patient is taking, delete the discontinued drugs, and add the newer drugs. There would also be a brief presentation on the absolute importance of being compliant, of keeping the medications in the original containers, and of bringing all medications when the patient comes to the office or hospital.

• Prescription containers need better labeling. Containers should be large (eg, 4 inches tall) so that a large label in big print can be used; thus, a description of the drug’s indication and all the instructions would be seen easily. The label could extend out so that all information in large print is available, similar to the tag on checked luggage at airports.

We physicians need to acknowledge that much of the problem is of our own doing, and we need to figure out a way to address it without being consumed by the solution. Each day without some answers is costing some lives and millions of dollars.

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