

# Developing a Strategic Plan

## ♦ What is a reasonable first-year strategic plan to better address medication errors in psychiatry?

**Editor's Note:** To encourage attention to medical errors in psychiatry, *Psychiatric Services* has introduced the Patient Safety Forum, a quarterly feature in which expert discussants address important questions in this area. Benjamin Grasso, M.D., is guest editor of the forum. The first forum appeared in the November 2003 issue. Contributing to this month's forum are James B. Conway, senior vice-president and chief operations officer of the Dana-Farber Cancer Institute (e-mail, james\_conway@dfci.harvard.edu); Robert M. Hayes, president, and Tamar Reiss, education associate, of the Medicare Rights Center (e-mail, rhayes@medicarerights.org and treiss@medicarerights.org); Geetha Jayaram, M.D., M.B.A., physician advisor in the department of psychiatry at Johns Hopkins Hospital (e-mail, gjayara1@jhmi.edu); and Harvey V. Fineberg, M.D., Ph.D., president of the Institute of Medicine (e-mail, fineberg@nas.edu).

## Leadership for Organizational Change

James B. Conway

The patient safety journey of our organization—the Dana-Farber Cancer Institute—and the work of many others has taught us the importance of beginning the journey with the personal engagement of leadership at the board, clinical, and administrative levels (1–5). Available data must be assembled and presented honestly and openly, with a focus on improvement, not blame. Leaders must listen directly to consumers, patients, family members, and staff in order to understand the sobering realities of today's practice. The issues that staff are losing sleep over today—currently buried in minutes or, more likely, in the minds of individual people—must be identified. Although not everything can be fixed right away, issues must be identified so that they can be understood, prioritized, and, ultimately, acted on. Focused improvement is essential.

A patient safety journey requires

leaders to read and to return to the classroom to learn about safety, the management of high-risk environments, the management of change, and human factors. Current mental health care models have been built under different cultures and faulty perceptions that must now be challenged and shed and new models built.

Industries such as aviation, nuclear power, and the chemical industry have evolved models to address safety issues; a similar evolution in health care is long overdue. Failure must be identified and mitigated. The potential of risk, failure, and harm to patients can be extraordinary levers for creating the tension for change, and these drivers of change should be better understood. Organizations require teams to examine safety, and these teams should include respected content experts and clinicians. Given the dramatic culture changes required, executive leadership

must also be at the table.

The engaged leader must declare the current state to be unacceptable. If the leader's research into his or her own organization has not uncovered enough failure to warrant such a declaration, the leader has not looked hard enough. Failures in our systems are routine and cause tension, disruption, harm, suffering, and death. They involve multiple victims: our patients, members of their families, and staff. Resources are wasted because we are not getting it right the first time or because we need to reverse the implications of initial system failure. System failures—and the lack of transparency around them—set up an erosion of trust with patients and family members that can lead to an erosion of reputation and one's ability to recruit and retain staff.

It does not appear that patient safety in psychiatry is being broadly and systematically investigated. Some significant areas of error and harm as well as best practices are emerging in the areas of medication safety, seclusion and restraint, and inpatient suicide. Recent discussions with mental health professionals have identified additional areas of patient safety and risk: elopement, "out-of-control" patients, fragmented or uncoordinated care, management of the psychiatric patients' underlying medical conditions, off-unit care of the psychiatric patient as in intensive care, after-hours operations, overdependence on confidentiality as a hedge against transparency, the punitive environment of psychiatry, and the failure to include patients and their families in decisions about care.

Leaders must internalize the notion that "our systems are too complex to expect merely extraordinary human beings to perform perfectly 100 percent of the time." Care systems are

complex, and staff suffer from being human. As leaders of people we must implement systems that support safe practice. These systems can range from computer-based order entry, pharmacy, and bar-coding systems to systems that support effective communication and hand off to templated order sets and highly simplified approaches to the work. Also, systems that encourage interdisciplinary practice must be in place; this is not the work of virtuoso performers. Accountability warrants significant attention at the institutional, system, team, and individual levels. The long-standing nature of a punitive culture in health care will require strong signs of movement to a more fair and just culture before staff take risks.

Whom we include in building this new culture of patient safety deserves note. Patients, their family members, and staff who are close to the point of care all have a clear understanding of the realities of practice—much clearer than most leaders. They must be engaged in the system's design, measurement, assessment, and improvement. Eight years of experience with such an approach, in which staff members are routinely engaged in all processes and root cause analysis, has shown no downside. In an even more "risky" approach, for six years we have had patients and family members on most institutional operating committees, and nothing terrible has happened—the risk has not materialized, and the learning is enormous. It is time that we accept the reality that no one understands our systems better than our patients and families and the staff who interact with them.

In closing, it is important to underscore what a privilege it has been to work in health care these past 35 years with amazing professionals who are committed to delivering high-quality services to patients and their families. As an industry, we are excellent, but we are not perfect. Focusing on patient safety, error, risk, and harm does not lessen the excellence of the work but acknowledges health care as a high-risk environment that requires a relentless focus on what doesn't work and on what could fail. The Dana-Farber Cancer Institute's quality-improvement plan outlines one organization's view of where we need to go:

- ♦ We continue to develop a shared vision of quality and safety
- ♦ We hold to the idea that safety is "the way we do the work"
- ♦ Our leadership and staff participate in a balanced process
- ♦ All our work is patient and family centered
- ♦ Our processes are data driven and involve a commitment to measurement
- ♦ We remain a learning organization that embraces knowledge transfer
- ♦ Our work is focused, prioritized, and systematic, with goals and objectives
- ♦ Our processes have high reliability
- ♦ We achieve synergies and mitigate failures of teams
- ♦ There is clear accountability, responsibility, and competence

- ♦ There is constant creative tension arising from seeking, learning, and changing.

During our journey, we have learned that we carry the burden for patients who have suffered and died as a result of our system's failures—and so we should. But not enough. We have the responsibility to learn everything we can from past harm to mitigate the chances that it will happen again. We also have enormous power from the tension of these events to help our organization and other organizations get to a better place. In the first year, psychiatry should understand its burden, focus on prioritized improvement, and honestly share the journey from those success stories to go to a better place for patients, family members, and staff. These individuals deserve nothing less.

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## Medicare Overhaul of 2003

**Robert M. Hayes**  
**Tamara Reiss**

Medication errors are one of many forces that jeopardize the health of persons insured through Medicare. Structural inadequacies of the Medicare system itself—for example, its complexity, the lack of an accessible meaningful prescription drug benefit, reluctance to adopt requirements for electronic prescriptions, a lack of parity in mental health coverage, a relative lack of regulatory oversight of medication errors, and discriminatory fee schedules for mental health services—have adverse consequences for all patients. These consequences arguably hit psychiatric patients disproportionately hard. The Medicare overhaul legislation that was signed into law last December by President George W. Bush does little to fix these structural problems, which allow—and in some ways facilitate—medical error in psychiatric practice.

Consumer knowledge, structured around principles of health literacy, remains the most valuable force for combating medical errors. Consumers who are informed—both about their own health and about how to get the care they need—play a critical role in preventing errors in the first place. But it

is impossible for Medicare enrollees to be proactive in securing needed care when they cannot understand a painfully complex system. Unfortunately, the new Medicare law only makes the system more complicated and inaccessible.

The Medicare Rights Center, a non-profit national consumer organization, receives more than 70,000 calls and hundreds of thousands of hits on its Web site ([www.medicarerights.org](http://www.medicarerights.org)) each year from Medicare enrollees seeking help getting the care they need. Too often, Medicare enrollees—especially those who have psychiatric or cognitive disabilities—cannot comprehend their basic coverage rights. Bewildered before they even enter a doctor's office, they are anything but able to stand as a final defense against medical error.

Of the approximately 41 million American men and women who are insured through Medicare, some 35 million are older than 65 years. The other six million qualify for Medicare as a result of a serious disability. According to data presented as part of a congressional briefing in June 2001, one in five adults over the age of 65 has a mental

health condition—most commonly anxiety, depression, dementia, substance abuse, or schizophrenia. And according to a report by the Henry J. Kaiser Family Foundation, more than half of the people who qualify for Medicare because of a disability have a mental health condition—some 10 million Americans in all. Medicare enrollees who require psychiatric treatment are among the most susceptible to medication errors, because they frequently receive multiple medications, often live in nursing homes that provide minimal physician input, and lack the protection of vigorous regulatory oversight of medical errors.

Because Medicare does not cover most outpatient prescription drugs, patients often must choose between paying the full cost of their medications or going without. The fact that many prescriptions are never filled—because the people who need them cannot afford to pay for them—is one of the most glaring deficiencies of the modern Medicare system. Sadly, the inadequacy of the drug benefit scheduled to begin in January 2006, combined with its immense complexity, will continue to leave many older adults and persons who have disabilities without drug coverage.

For patients who are able to fill their prescriptions, electronic prescribing of medications has the potential to substantially reduce medication errors by preventing transcription errors from occurring. But the new Medicare law fails to push aggressively for an electronic prescription mandate to be implemented safely and quickly. Although the law requires development of standards for electronic prescriptions, implementation of these standards may be delayed until 2008. Furthermore, the law does not mandate the use of electronic prescriptions once such standards are adopted.

Although computerized prescription entry is not a panacea—we must still address errors in medication selection, distribution, and administration—an accelerated plan to institute this approach systemwide is an important step. Much criticism has been leveled at the Bush Administration and at congressional leadership for failing to use the buying power of a Medicare drug benefit to reduce pharmaceutical

prices in the United States. (The 2003 law expressly prohibits the federal government from using its market strength to negotiate lower prices with drug companies.) This same criticism can be directed toward the failure to take the opportunity of the unprecedented Medicare overhaul to coordinate an aggressive electronic prescription timeline.

Left unchanged in the new law is continued discriminatory coverage for psychiatric treatment. Medicare still reimburses mental health professionals for only 50 percent of the cost of visits and treatment, compared with the 80 percent it pays to other medical professionals. Underuse of mental health services is due largely to this bias that Medicare and other insurers have shown in their mental health care policies. The inequality in coverage of mental health care perpetuates the stigma of mental health care and discriminates against persons seeking mental health treatment. It also means that Medicare enrollees who cannot afford to pay the 50 percent coinsurance often go without care.

More than two-thirds of older nursing home residents have mental or behavioral illnesses, but, according to the American Psychological Association, less than three percent receive treatment from a mental health professional. The American Society of Consultant Pharmacists reports that, among those who do receive medications, adverse drug effects often go undetected among nursing home residents, given that these individuals tend to be taking numerous medications and tend to have multiple chronic and acute illnesses. Although initiatives such as the Food and Drug Administration's Med-Watch program have helped by implementing voluntary-reporting procedures, no national mandatory standardized process exists for reporting these medication errors.

Psychiatric professionals should urge constructive reforms of the Medicare program to attack systematically the continuing epidemic of medication errors. First, we must continue to advocate for a comprehensive and accessible prescription drug benefit that makes prescription drugs affordable to those who need them. Second, an easy-to-use electronic prescription system

must be placed on the fast track to development so that it will eventually become the only way for physicians to prescribe medications. Third, parity in the payment for mental health treatment is crucial. Fourth, regulatory oversight of the reporting of medication errors must be heightened. Fifth, consumer education, especially through the national State Health Insurance Assistance Programs, must receive more significant resources.

As we work toward these goals, alliances between the psychiatric profession and consumer groups that advocate for mental health will be crucial to the development of a Medicare program that is more patient friendly, more accessible, and more resistant to medical errors. And, as Medicare goes, so goes—for better or for worse—the U.S. health care system.

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## Steps in Planning for Change

**Geetha Jayaram, M.D., M.B.A.**

The first year of strategic planning addresses the question, How can we assess medication errors in psychiatry in the current environment, given regulatory processes, the size and structure of the institution, the case mix of patients served, and current technology? Planning involves four steps: creation of a multidisciplinary leadership team; assessment of strengths and weaknesses of the current system as well as opportunities for improvement; identification of a reasonable objective for the first year, such as development of a method to measure errors; and statement and dissemination of the team's goal, for example, reduction of medication errors by .5 percent in two years.

Such planning has taken place in the department of psychiatry at Johns Hopkins Hospital, for which I serve as physician advisor. Here I briefly describe current safety initiatives undertaken using the above method.

Step 1: The leadership team comprises the chairman of the department, the clinical director, the physician advisor, the director of nursing, the pharmacy representative to psychiatry, and

the quality assurance representative from the nursing department.

Step 2: We assess medication errors by consensus, using a common taxonomy on a medication event data collection form. The form was developed internally over a decade, was refined and modified, and was ultimately placed online for ease of reporting on each inpatient-nursing unit. Errors of prescribing, dispensing, administration, and recording are noted. Several subheadings under each category are provided, with space for descriptions. Outcomes for patients are classified on a scale of 0 to 4; 0 is used if the event did not reach the patient, 1 is used if the event reached the patient and no treatment or increased monitoring was necessary, 2 is used if the event reached the patient and increased monitoring was required, 3 is used if the event reached the patient and unplanned treatment or an increased hospital stay (probable or actual) was required, and 4 is used if the event reached the patient and the event was life-threatening or if serious morbidity or death occurred, and the event may have contributed to morbidity or mortality. Near misses are also recorded.

Step 3: All data are systematically entered into a data set and discussed at monthly performance improvement meetings attended by all unit chiefs in the nursing and psychiatry departments; representatives from pharmacy, nutrition, and social work; and all attending physicians, chief residents, and chiefs of outpatient programs. Administrative points for attendance are mandatory for all attending physicians. Learning points are communicated to residents.

Step 4: The central pharmacy reports data for each department in the hospital on a grid, and a graph is used to compare rates monthly. All rates that are two standard deviations above the mean for the hospital are examined in detail and discussed for areas of improvement. This information is disseminated among nursing and pharmacy staff. Identification numbers track physicians' errors. Residents who make more than one prescribing error are counseled. Random chart audits are performed and the results circulated to all medical staff.

However, better planning and ob-

jective analysis of medication errors is needed. Self-report is fraught with problems. Errors are self-reported at significantly lower rates than observed errors or those obtained by chart reviews of the same patients (6). How many chart audits should be conducted by random selection to review error rates? How often should staff members be given feedback? Clearly, audits will support, educate, and improve processes for providing medications to patients, especially if all members of the treatment team are included in conducting audits. Who will finance these activities?

The literature shows that the rate of errors on psychiatric units (7 percent) exceeds that on medical units (4 percent) (7–10). We know patients are not always harmed, but near misses occur, and these should be discussed with concern. What do we call them if they are not really errors? What predisposes psychiatric units to more errors? Is it because the patients are more vulnerable and unable to participate in the process? At Johns Hopkins, we use handouts that are modified to a fifth-grade reading level. Yet patients' cognitive difficulties interfere with learning.

Strategic planning must consider the fact that no clear method is applicable for estimating the impact of the multiple variables that affect the system. Evidence-based research involving case-control studies in uniform groups of patients—where the error or lack thereof is directly linked to demonstrable, valid outcomes, or diagnostic causality—are needed. Some of the questions to consider are as follows: Is there a dose-response relationship? Is the association consistent from group to group? In an otherwise stable system, does an identified intervention decrease the rate of error? Does the systematic education of patients and their participation in medication administration decrease risks? How can risk reduction be measured in a psychiatric population, given the inherent difficulties in communication that can occur?

We should systematically include family members, whenever possible, when we teach patients about medications. We should eliminate disparities in error rates between medical and psychiatric services. Confidence

in the system of psychiatric care is the responsibility of the system (11).

A climate of self-examination with a view to improving systems and processes indeed cultivates better reporting practice. However, for most physicians and nurses, the fear of public accountability often undermines assurances of confidentiality. Including patients and family representatives in a general discussion of sources of error can greatly assist in recognition of harm. Confidence in the review process can be established as error rates decline noticeably. Fear of exposure and reprisal will decrease.

Integrity and patient safety are inherent to good medicine and should not be "enforced." Shouldn't *caveat emptor* become *credat emptor*? Patients' complaints must be taken seriously and analyzed to alert physicians to the possibility of error. Studies have demonstrated that good communication skills prevent error and foster patient satisfaction (12). At Johns Hopkins, patient complaints in psychiatry are routinely processed and addressed, yet no patterns emerge that are applicable to all situations, other than improvement in communication with patients.

Each system has unique faults. Clusters of events are more meaningful when studied over time. For example, a delay in blood draws on morning shifts may be the fault of an individual; first-degree burns during electroconvulsive therapy among several patients may be due to the faulty application of electrolyte paste by a new nurse; and a delay in posting of laboratory reports or "panic values" on the electronic patient record may be a systems problem. We can be confident about confirming these errors. Tracking processes are familiar to the manufacturing and engineering industry (13). They have been applied to medical processes with excellent results. Lazarou and associates (14) used a meta-analysis to identify factors that caused serious adverse drug reactions. Such analyses obviate bias and increase confidence in error detection.

Errors occur and will continue to occur. Once planning has been completed, error management to reduce serious errors and to eliminate minor ones is a continual process of education, training, review, and administrative oversight.



## Focusing on Quality of Care

Harvey V. Fineberg, M.D., Ph.D.

The Institute of Medicine (IOM) ([www.iom.edu](http://www.iom.edu)) serves as advisor to the nation for the purpose of improving health. Established in 1970 as part of the National Academy of Sciences, the IOM strives to provide advice that is unbiased, evidence based, and grounded in science. Often the IOM's work is prompted by questions from Congress and government agencies. Other projects originate from foundations or with the IOM itself, including suggestions from members. Although recommendations of the IOM are typically aimed at policy makers, they are often directly pertinent to health care professionals and the public.

The quality of health care has been a significant theme of the IOM's work for a number of years. *To Err Is Human* (15) and *Crossing the Quality Chasm* (16) are two signal reports that raised public awareness of critical deficiencies in health care and provided a blueprint for the design of a 21st century health care system. The first report estimates that tens of thousands of hospitalized patients lose their lives every year because of errors. The most common type of error is with medications: the patient does not receive the intended drug in the intended dose at the right time; this is as much a concern for psychiatry as it is for other fields of medical practice (17).

The second report defines six dimensions of health care as the key elements of quality: care that is safe, effective, patient centered, timely, efficient, and equitable. The report stresses the need to understand systems—how interdependent components interact to produce results—and to change processes of care to effect lasting improvements in outcomes.

A number of workshops, studies, and other activities have continued the theme of improving the quality of care, including summits on the education of health professionals (18) and, just recently, another summit that brought together health leaders from 15 communities to design local approaches to implementing quality improvements. Studies of quality and

safety include the work environment of nurses (19), data standards for patient safety (20), and opportunities for leadership in federal programs (21). Of special interest to psychiatry is a report on priority areas for national action (22). Two of 20 priority areas identified in the report were major depression (screening and treatment) and severe and persistent mental illness. Throughout the IOM's work on quality of care, the emphasis on systems improvement, data standards, and process improvements as ways to avoid errors is as pertinent to psychiatry as to any branch of medicine.

I salute the editors of *Psychiatric Services* for undertaking this special series on patient safety in psychiatry. We at the IOM look forward to working closely with our colleagues in professional associations and health care settings to advance the quality of psychiatric care.

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