ADVANCING THE PATIENT SAFETY AGENDA
IN THE UNITED STATES

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Carolyn M. Clancy, M.D., serves as director for the Agency for Healthcare Research and Quality (AHRQ). Prior to her appointment as director on February 5, 2003, she had served as AHRQ's acting director since March 2002 and before that director of AHRQ's Center for Outcomes and Effectiveness Research (COER). She is a general internist and health services researcher, and a graduate of Boston College and the University of Massachusetts Medical School. Following clinical training in internal medicine, Clancy was a Henry J. Kaiser Family Foundation Fellow at the University of Pennsylvania. She was also an assistant professor in the Department of Internal Medicine at the Medical College of Virginia in Richmond prior to joining AHRQ (then named the Agency for Health Care Policy and Research) in 1990. Her major research interests include women's health, primary care, access to care, and the impact of financial incentives on physicians' decisions. She also holds an academic appointment as clinical associate professor, Department of Medicine at George Washington University School of Medicine, and serves as senior associate editor of *Health Services Research.* Clancy is a member of multiple editorial boards (*American Journal of Public Health; Annals of Family Medicine; Journal of General Internal Medicine;* and *Medical Care Research and Review*), and has published widely in peer-reviewed journals and has edited or contributed to five books. Her work in women's health was recognized by an award from the Women's Caucus of the American Public Health Association. Active in multiple professional organizations, she has been recognized as a leader within the Society of General Internal Medicine. Before becoming the director of COER in 1997, Clancy served as director of the Center for Primary Care Research. She is also a member of The Commonwealth Fund's coordinating committee for its International Program in Health Policy and Practice.

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INTRODUCTION

Hospitals and other health care delivery systems provide millions of Americans each year with important, frequently life-saving care. Yet, as we all know, medical errors and patient safety issues represent a national problem of epidemic proportions. And, as we have seen from recurring headlines, no institution is exempt, and everyone who uses the health care system is at risk.

However, there is good news. In the United States, our health care system is committed to improving the quality and safety of the care provided to our nation's citizens. That commitment has never been stronger as shown by the vision and dedication of health care professionals, including those who gather annually at Pennyhill Park.

Over the last three years, thanks to the U.S. Congress, the Agency for Healthcare Research and Quality (AHRQ) has dedicated $165 million to patient safety research. AHRQ is proud to say that it is now the leading funder of patient safety research in the world.

As you know, the key message of the landmark Insitute of Medicine (IOM) report, *To Err Is Human,* and its sequel, *Crossing the Quality Chasm,* is "it's the system." Health care professionals are human, and humans are prone to mistakes. We need to make sure that health care professionals work in systems that are designed to prevent mistakes and catch problems before they cause harm. Unfortunately, three years after the publication of *To Err Is Human,* its message does not appear to have found much traction.

Yet, this is the first step in creating a culture in hospitals and elsewhere in the health care system that focuses on continuous quality improvement. To advance a safe and secure health care system in the U.S., we need to let go of outdated views on how to deal with errors. We need to shift from "naming, blaming, and shaming," to learning from errors and making sure they never happen again. This is not easy, but it is the right thing to do.

SAFE INDUSTRIES

We know that other industries have done this successfully. All of us involved in health care delivery can learn a lot from Starbucks, which has concrete systems in place to prevent mistakes. The next time you go in for a latte, notice how many people repeat your order after you place it. Then, look at the check marks on your cup made to back up

the verbal order. Starbucks relies on teamwork and a well-designed system, and fosters a culture that encourages employees to embrace the system.

Obviously, making a latte is not as complex and challenging as providing patient services in today's health care system. For example, a study found that an intensive care patient might have 178 different tasks performed on him or her by medical personnel in a single day. Each time a task is performed, there is a chance of injury or error.

However, many of the lessons from Starbucks apply. We need to build in redundancy—both within and across professional disciplines. Most importantly, we need much more repetition of instructions, called "read back" in the jargon, for almost all interactions in clinical care. If Starbucks does this for coffee drinks, shouldn't health care providers do it for patients as well?

The aviation industry also provides lessons for improving safety. Between 1967 and 1976, the risk of dying in a domestic jet flight was one in two million. That risk fell to one in eight million by the 1990s. How did the aviation industry achieve this dramatic reduction? They designed systems to automate and standardize many tasks and controls, and employ "read back" and other techniques to increase communication and teamwork. The aviation industry also has instilled a culture that emphasizes learning over blame. Pilots and other aviation workers are encouraged to report errors and near misses without fear of recrimination.

In another example, former Treasury Secretary Paul O'Neill created a culture of improvement and safety at Alcoa in the 1990s. The company reduced its lost work per day rate from 1.87 in 1987 to 0.42 in 1997, and it is continuing its efforts to improve. To achieve this success, the company uses an online safety data system to track incidents, analyze their causes, and share solutions and information on how to prevent them from occuring again. To further foster the culture of safety, Alcoa employees at all levels are encouraged not only to report errors and near misses but also to suggest solutions and improvements. The lessons from Alcoa are already being put to work in the company's hometown. The Pittsburgh Regional Healthcare Initiative, cofounded by Secretary O'Neill in 1997, is a coalition of approximately 30 area hospitals, major insurers, and corporate and civic leaders commited to improving health care quality and safety using the principles of continuous quality improvement.

The Veterans Health Administration (VHA) within the Department of Veterans Affairs (VA) provides another excellent example of how reengineering and a

comprehensive effort have improved quality and safety. An article in the May 29, 2003, issue of the *New England Journal of Medicine* details the success of the VHA in dramatically improving the care it provides. In Fiscal Year (FY) 2000, 90 percent of patients in VA health care facilities received appropriate care as measured by scores on nine of 17 quality indicators that were directly comparable to those used by Medicare and nationally recognized quality organizations. These included mammography, receiving appropriate heart medications, diabetes testing, and cervical cancer screening. More than 70 percent of patients received appropriate care for 13 of the 17 indicators. The VA reports that 18 of their indicators are national benchmarks that are directly comparable to indicators used by Medicare and other nationally recognized quality organizations.

This dramatic improvement resulted largely from a concerted effort in the 1990s to improve the care provided in VA facilities. This effort included the implementation of a systematic approach to the measurement and management of health care as well as development of a systematic approach to accountability for quality. The article in the *New England Journal of Medicine* indicates that, after this period of improvement, VA facilities outperformed Medicare fee-for-service care, which has been undergoing improvements of its own.

OBSTACLES TO PATIENT SAFETY
These organizations represent the leading edge of success, and we need to learn from them. However, we have some basic obstacles to overcome in health care, particularly in terms of reporting medical errors.

- The first obstacles are patient and physician perceptions of medical errors. According to a study published in the December 12, 2002, *New England Journal of Medicine,* both patients and physicians thought that the published estimates of the numbers of avoidable deaths were much too high. Also, neither group bought the "it's the system" message. In the case of surgical errors, both groups thought the surgeon should be held responsible, and the public was likely to cite the institution as well.

- A second obstacle is that we need to uproot the deepseated fear of change within the health care industry. An integral part of this obstacle is that we need to develop a system that allows people to discuss and report errors without fear of recrimination or of being sued.

An AHRQ-sponsored research study has shown that improving communication can improve safety. However, other research funded by AHRQ published in the *Journal of the American Medical Association* in February 2003 found that open communication about errors still does not happen.

Based on 13 focus groups between April and June 2002, researchers found that patients and physicians largely agreed that patients should be told about errors that cause them harm. However, they disagreed on what to disclose about such errors. Patients unanimously wanted an apology, information about the error and how it happened, an explanation of the implications the error had for their health, how the problem could be corrected, and assurances that the error would be prevented in the future. Physicians, while wanting to be truthful, were reluctant to provide this basic information to patients because of fears of malpractice lawsuits or damage to their reputations.

- Other obstacles to improving patient safety and reducing medical errors include the lack of technology and the need for greater and better evidence about what does and does not work in making the health care system safer.

EARLY PATIENT SAFETY SUCCESSES

To meet these challenges, AHRQ has funded an ambitious patient reasearch agenda that was formed through extensive collaboration with the users of AHRQ research, consumers, health care providers, hospitals, and our international community. While much of this research is still ongoing, the following are a few examples of AHRQ's findings and successes to date:

- A study cofunded by AHRQ and the National Institute on Aging at the National Institutes of Health found that Medicare patients treated in outpatient settings may suffer as many as 1.9 million drug-related injuries a year because of medical errors or adverse drug reactions not caused by errors. About 180,000 of these injuries are life-threatening or fatal, and more than half are preventable, according to the researchers.

When the researchers analyzed why the preventable adverse drug events occurred, they found that 58 percent involved errors made in the prescribing of medications, such as ordering the wrong drug or dose, not educating the patient adequately about the medicine, or prescribing a medication for which there was a known interaction with another drug the patient was taking.

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The investigators also found 61 percent of preventable adverse drug events involved mistakes made in monitoring medications, such as inadequate monitoring or a delayed response to symptoms of drug toxicity in the patient.However, the failure of patients to adhere to medication instructions contributed to more than 20 percent of the preventable drug-related injuries.

- Another AHRQ-funded study found that sponges or medical instruments are left inside more than 1,500 surgical patients anually, an error that can lead to serious problems ranging from bowel perforation and blood infection to death. The study found that one or more cases each year would be typical of a large hospital. The study reveals for the first time that instruments and sponges associated with surgery are more likely to be left behind in cases involving emergency surgery, obese patients, or unplanned changes in the surgical procedure.

  Researchers concluded that a $100 X-ray following high-risk categories of operations could prove a cost-effective way of ensuring that no foreign body is left in patients after surgery.

- To make it easier for hospitals to encourage a culture of safety, AHRQ developed a website modeled on the format of morbidity and mortality (M&M) conferences that are routinely held within individual hospitals across the country. At M&M conferences, clinicians discuss specific cases that raise issues regarding medical errors and safety improvement. However, the findings from these conferences are not routinely shared outside each individual hospital. This is a lost opportunity for learning.

  The AHRQ M&M website (http://webmm.ahrq.gov), includes a peer-reviewed patient safety journal and an online conference aimed at improving patient safety through analyses of submitted cases. The site features five cases a month, which are submitted anonymously and then discussed in forums on the site.

  The AHRQ M&M website is already recognized as an important teaching and learning resource on medical errors. It is being used in hospitals and teaching facilities, and there are more than 2,000 registered users with the numbers continuing to grow. It fills a badly needed gap in training and education about medical errors and patient safety.

- The AHRQ also supported the development of an evidence report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices.* This report includes a systematic review of the scientific literature, identifies 79 patient safety "best practices," and reviews the evidence on their effectivness. This report received a tremendous amount of attention, with several thousand requests for it over the past two years. It represents the first compilation of patient safety practices supported by a review of the related evidence behind them.

  To help further the implementation of these patient safety practices by hospitals and others, AHRQ and the Centers for Medicare & Medicaid Services asked the National Quality Forum (NQF) to use the AHRQ evidence report to develop specific recommendations that could be used by other organizations seeking guidance on adoption and implementation of safe practices. The NQF is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting.

  The NQF used the AHRQ evidence report as a starting point for the consensus development process and supplemented it with information from several other sources. Last month in Los Angeles, AHRQ and the NQF released the consensus report, which recommends 30 practices with good evidence and broad-based support.

- AHRQ has developed a free, Web-based tool that can help hospitals enhance their patient safety performance by quickly detecting potential medical errors in patients who have undergone medical or surgical care. Hospitals use the AHRQ Patient Safety Indicators (PSI) to determine whether the problems detected were caused by potentially preventable medical errors or have other explanations. The PSIs allow for the detection of 26 types of adverse events, such as complications of anesthesia, blood clots in the legs or lungs following surgery, fracture following surgery, and four types of birth-related injuries.

  Although the PSIs were developed primarily for hospitals to use in their quality improvement programs, other kinds of organizations will find the tool useful. For example, hospital associations can show member hospitals how they perform for each indicator when compared with their peer group, the state as a whole, or other comparable states.

  Recently, two research articles demonstrated the power of the PSIs. The first, published in the March 2003 issue of *Health Affairs,* found that the number of

potential safety-related events of most non-obstetric procedures included in the PSIs decreased between 1995 and 2000. The study found that most technical complications, such as postoperative hemorrhage or reopening of a wound, decreased between 1995 and 2000, except for a 7 percent rise in the number of accidental punctures and lacerations. Also during that time, obstetric trauma decreased about 3 percent, foreign bodies left during procedures decreased 7 percent, anesthesia complications decreased 18 percent, and transfusion reactions decreased 40 percent.

The second study was published in the June 2003 issue of the journal *Pediatrics*. Use of the PSIs to examine the types of patient safety problems that children experience in hospitals found that the rates of such problems range from 0.2 (foreign body left during procedure) to 154.0 (birth trauma) problems per 10,000 discharge records. The study also found that those who experienced a patient safety problem in the hospital faced a two to 18 times greater risk of death than children who did not have such a problem.

FISCAL YEAR 2003 AND BEYOND
In FY 2003, AHRQ is poised to begin two exciting new programs under our patient safety initiative.

The first program is the development of a Patient Safety Improvement Corps—a cadre of specially trained patient safety experts who will provide technical assistance to states, local governments, and health care institutions on improving patient safety using evidence and proven best practices.

For the second program, AHRQ will fund Safe Practices Implementation Challenge Grants. The grants are intended to help hospitals and other health care institutions assess safety risks to patients, devise ways to prevent them, and implement safe practices that show evidence of eliminating or reducing known risks.

These are examples of evidence-based practices that can help make the health care system safer. But, this is only the beginning. With every science-based method and tool available to AHRQ, our goal is to support hospitals, clinicians, and other health care systems in their efforts to build and sustain a culture of continuous quality and patient safety improvement.