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Clinical Informatics and Patient Safety at the Agency for Healthcare Research and Quality

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A b s t r a c t   In 1998, the Institute of Medicine (IOM) issued a report on medical errors, which estimated that up to 98,000 people die in U.S. hospitals each year from errors. This report raised concerns that medical errors have become a national public health problem that should be addressed in the same manner as other epidemics such as heart disease, diabetes, and obesity. In 2001, the IOM released a follow-up report encompassing a broader range of quality issues. They concluded that the U.S. healthcare system is outmoded and incapable of providing consistent, high-quality care. They outlined a strategy for redesigning U.S. healthcare delivery to achieve safe, dependable, high-quality care, which emphasizes information technology as an integral part of the solution. AHRQ's fiscal year 2001 appropriation included $50 million dollars for initiatives to reduce medical errors and improve patient safety. AHRQ responded to this mandate by developing a series of research solicitations that form an integrated set of activities to design and test best practices for reducing errors in multiple health care settings. This paper discusses the components of this program and the central role of medical informatics research in the Agency's efforts to improve the safety of medical care in America.

Introduction

In 1998, the Committee on the Quality of Health Care in America, established within the Institute of Medicine (IOM), was appointed to identify strategies for achieving substantial improvement in the quality of health care in America. The committee's first report, *To Err is Human: Building a Safer Health System*, was released in November 1999 and focused on quality concerns relating to patient safety.[1] The report indicated that 44,000 to 98,000 people die in U.S. hospitals each year as a result of medical errors, making them the 5th to 8th leading cause of death in the United States. To put these numbers in context, medical errors are estimated to cause more deaths each year than breast cancer, AIDS, or motor vehicle accidents. About 7,000 people are estimated to die each year from medication errors alone—approximately 16% more than the number attributable to work-related injuries. The number of patients experiencing morbidity as a

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result of errors is not known, but is thought to be even greater.

Medical errors also result in a large financial burden to the health care system. The IOM report estimates that medical errors cost the U.S. approximately $38 billion per year, with about $17 billion of those costs associated with preventable errors.

Agency for Healthcare Research and Quality and Patient Safety

For the past thirty years, the Agency for Healthcare Research and Quality (AHRQ), and its predecessors (the National Center for Health Services Research, "NCHSR," and the Agency for Health Care Policy Research, "AHCPR"), have investigated and funded much of the seminal research in medical errors and patient safety, including the work of Lucian Leape, M.D. and David Bates, M.D., two of the pioneers in patient safety research. Until the IOM report, however, medical errors did not receive the widespread attention that they deserved. In the late 1990s, as medical errors and patient safety issues moved higher on the national public policy agenda, AHRQ took on a leadership role in this area.

In 1998, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry presented its final report on Quality to the President of the United States—*First: Better Health Care for All Americans*. Reduction of medical errors was listed as one of its top priorities. With the subsequent release of the IOM's report in November 1999 on patient safety, awareness of this epidemic of medical errors grew significantly and led to a call for an aggressive, comprehensive response to this urgent issue.[1]

When Congress reauthorized and renamed the Agency in late 1999, it specifically directed AHRQ to conduct and support research and build public-private partnerships to (1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate effective strategies throughout the health care industry. AHRQ's reauthorization also directed the Agency to evaluate informatics applications, decision support systems, and computerized patient records to reduce medical errors, improve patient safety, and promote quality improvement in diverse patient settings.

In early 2000, the Quality Interagency Coordination Task Force (QuIC), with AHRQ as lead agency, responded with its report to the President—*Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*. This report, which outlined a plan of action including more than 100 activities, addressed issues such as identifying and learning from medical errors, setting performance standards and expectations for safety, building public and purchaser awareness, working with providers, using decision-support systems and information technologies (IT), using standardized procedures, addressing and strengthening standards, and integrating data for reporting and analysis.[2]

In March 2001, the Committee on the Quality of Health Care in America released its second and final report—*Crossing the Quality Chasm: A New Health System for the 21st Century*, which addressed a broad range of quality issues and provided a strategic direction for redesigning the health care delivery system.[3] The committee reported that the U.S. health care system is in need of repair, for it is plagued by a variety of quality problems. These problems are the result of an outmoded and inadequate health care delivery system that is not capable of providing consistent, high-quality care to its population. If Americans want safe, dependable, high-quality health care, a significant redesign of our system will have to occur. The committee stated that IT must play a key role if substantial improvements in quality are to be achieved.

Clinical Informatics and Patient Safety

As the delivery of health care becomes increasingly complex, the reliance on effective systems to prevent medical errors will become increasingly critical. Health care continues to take place in isolated systems with little standardization and few safeguards, especially when compared to other industries.[4] In this complicated and fragmented environment, it is not surprising that medical errors frequently occur.

The overwhelming amount of medical information, coupled with the rapid growth in new pharmacotherapies and technologies, increasing time constraints placed on providers, mounting pressures to reduce costs, and suboptimal systems for delivering care, make it virtually impossible for individual clinicians to provide high-quality, error-free care on a consistent basis.

In the vast majority of cases, medical errors are not the result of individual negligence or incompetence. They occur for two main reasons: First, as stated by Clement McDonald, M.D., a leader in clinical informatics,[5] "Humans are inherently fallible information processors." Thus, despite our best intentions and efforts, errors occur because we are humans, and humans make mistakes.[6] This reliance on imperfect memory, processing, and decision-making can lead to increased rates of medical errors and compromised patient safety.[7] Second, most errors occur because of faulty system designs that allow such errors to occur. As stated by Donald Berwick, M.D., a national leader in quality improvement, "Systems produce the outcomes they are designed to produce."[8] The solution lies in redesigning systems of care to minimize the probability of human error. These changes will require the use of information systems to assist providers in making the best possible clinical decisions.

Evidence has shown that computerized decision support systems can improve patient safety. The data processing capacity of computers has been harnessed by a number of electronic systems designed to assist in clinical decision-making. These systems range from computerized reminders about preventive services to alerts about drug-drug interactions to computerized ventilator management.

There are several examples of clinical informatics applications that have been shown to improve patient safety. At LDS Hospital in Salt Lake City, Utah, a computerized decision support system with physician order entry (POE) reduced the incidence of adverse drug events related to antibiotic administration by 75%.[9] It also significantly reduced orders for drugs for which patients reported allergies and adverse effects that were caused by antibiotics.[10] At the Regenstrief Institute for Health Care in Indianapolis, Indiana, researchers demonstrated that automated computerized reminders increased orders for recommended interventions from 22% to 46%.[11] At the Brigham and Women's Hospital in Boston, Massachusetts, use of a POE system with decision support led to increased use of appropriate medications for high-risk clinical situations, such as an increase in the use of subcutaneous heparin to prevent venous thromboembolism from 24% to 47%. Medication errors were also reduced by 19% to 84%.[12] These changes persisted throughout the 1- and 2-year follow-up periods.[13]

A 1998 systematic review that assessed the effects of 68 computer-based clinical decision support systems demonstrated a beneficial, though variable, impact on physician performance in 43 out of 65 studies (66%) and a beneficial effect on patient outcomes in 6 out of 14 studies (43%).[14]

These examples illustrate that POE systems with decision support can help reduce medication errors, improve prescribing patterns and guide treatment decisions. Despite these successes, only a small number of health care systems in the United States have such systems in place. In addition, most of the work on IT and patient safety has occurred in the inpatient setting. Yet most of health care delivery occurs in non-inpatient settings, such as physician offices, urgent care centers, emergency departments, nursing homes, pharmacies, and home care, where IT penetration has occurred to an even lesser extent. Research and demonstrations projects are greatly needed in these settings.

While recent innovations in information technology have been touted over the past several years, many of these applications have not been adequately evaluated in the health care arena. For example, wireless hand-held computers, such as personal digital assistants (PDA), offer great potential as portable communication tools that can provide information and decision support. In one study, these devices were shown to improve the detection and prevention of adverse events in an ICU setting.[15] However, more research is needed in this area to evaluate their effects on important patient outcomes in various health care settings.

Other technologies may also play a role in the patient safety arena. Medication bar codes and automated medication dispensers are being utilized in some health care settings to reduce errors. The use of scannable patient bracelets containing drug, allergy and other medical information has also generated interest. Such devices could help ensure the appropriateness of medications, blood products, and other therapeutics that are administered to patients. They could also be used to generate alerts about allergies, drug-drug interactions, and other potential problems before erroneous administration occurs. The Veterans Health Administration and Department of Defense have been national leaders in this area.

Smart cards are electronic devices the size of credit cards that store and process medical information on a microprocessor chip. The Department of Defense has been a leader in the use of this technology. In much the same manner that ATM cards allow consumers to access banking services from virtually anywhere in the

world, these smart cards would give patients a portable means of carrying their medical information, which could then be accessed electronically by providers or healthcare facilities at disparate locations. Interactive smart cards could also generate alerts about potential adverse events resulting from medication and other types of errors. While promising, this technology remains in development and has not been utilized or evaluated to a significant degree in the clinical setting.

While clinical informatics has the potential to greatly improve patient safety and quality of care, much more work is needed in terms of implementation and evaluation of these technologies and their impact on important outcomes. Research is needed to evaluate IT tools that alert providers to information that may be critical to the provision of high quality care, develop strategies to address barriers to successful adoption of innovative IT applications, document the costs and resources associated with the IT applications, and evaluate transferability to other settings.

Research Agenda

AHRQ's fiscal year 2001 appropriation included an increase of $50 million dollars for initiatives to reduce medical errors and improve patient safety. AHRQ responded to this mandate by developing a series of six research solicitations that form an integrated set of activities to design and test best practices for reducing errors in multiple health care settings, develop the science base to inform these efforts, improve provider education to reduce errors, capitalize on the IT advances to translate proven effective strategies into widespread practice, and build capacity to further reduce errors.

Research themes were generated through a variety of mechanisms, including reviews of the literature, key stakeholder meetings, and national public and private sector summits on medical errors, patient safety, and informatics. The result of these efforts was the development of a "user driven" research agenda, wherein those who will eventually use the products of patient safety research, including patients, providers, plans, purchasers, and policymakers, identified the areas where AHRQ should concentrate its efforts. Based on this input, we selected three areas on which to focus.

The first of these areas was the use of technology to improve patient safety, which includes: 1) The effect of clinical informatics tools in reducing medical errors and improving the quality of patient care; 2)

The use of evidence-based, real-time, decision support systems that provide information critical to the delivery of high-quality care and their effects on patient/provider decision-making, patient safety, and outcomes; 3) Determining data elements that are necessary to identify and classify medical errors across various health care settings; 4) The use of interactive technology, such as electronic mail, web-based medical records, hand-held wireless devices, computer kiosks, and electronic patient assessment tools that facilitate informed, shared decision-making and result in improved patient safety; 5) Data exploration technologies (e.g., data mining) to assess patterns of medical errors; and 6) The strengths and limitations of existing systems that provide information on patient safety and medical errors.

The second area was in assessing barriers to the acceptance and adoption of IT for improved patient safety and quality of care. This includes: 1) The impact of IT on efficiency, productivity, time management, workload, training, satisfaction, and return on investment; 2) The influence of human factors on the acceptance and utilization of IT and decision support systems; 3) The sociology and culture of health care professionals and patients that limit acceptance of new technology; 4) The cost-effectiveness, value and return-on-investment of IT solutions for improving patient safety and quality; and 5) Development of effective strategies to overcome these barriers.

The third area involved developing effective strategies for ensuring patient confidentiality, which includes: 1) Understanding patient and provider preferences regarding privacy and the use of medical information; 2) Developing methods of ensuring data security; and 3) Determining the appropriate balance between maintaining the confidentiality of personal health information and using data for research and quality improvement efforts that can result in safer and better health care for all.

Research Solicitations

Among the components of this competitive demonstration program is the Clinical Informatics to Promote Patient Safety (CLIPS) RFA, a solicitation to support research on the use of IT to reduce errors and improve patient safety.[16] Through this RFA, AHRQ is funding projects that evaluate the use of innovative technologies in clinical settings. The objective is to better understand the opportunities and barriers to using IT to improve the process and outcomes of care

for patients and providers in different health care settings and among priority populations. Research projects supported under this RFA should generate new knowledge that can be used by providers, patients, payers, plans, and policymakers to promote the use of IT for reducing medical errors and improving patient safety. They should also improve our understanding of the circumstances under which informatics solutions work best.

The CLIPS RFA generated a great deal of interest from the informatics community. Proposals were received from a large number of investigators and institutions throughout the U.S., including academic medical centers, community hospitals, long-term care facilities, home health care agencies, community outpatient clinics, engineering schools, and state public health agencies. Many of the proposals involved research using handheld wireless devices, electronic medical record systems, computerized decision support tools, or electronic prescribing applications. Other areas of proposed research included simulation models for education and training, automated error alerting mechanisms, structured electronic data sets, digital eye technology, database applications, computerized patient self-monitoring and communication tools, wearable mini computers, internet and intranet applications, cognitive science, human factors engineering, data mining, and barriers to electronic prescribing.

In addition to CLIPS, AHRQ is supporting other safety-related research projects, including projects on: 1) Error reporting, analysis, and safety improvement; 2) Development of multidisciplinary teams to expand the capacity of patient safety research; 3) Development of centers of excellence in patient safety research; 4) Projects that examine the effects of working conditions on patient safety; and 5) New approaches to educate providers about patient safety and disseminate important research findings. Information technology will play an important role in many of these patient safety programs as well. For example, the work of the reporting demonstrations will require the development of standardized approaches to data definitions and coding. The Centers of Excellence will be engaging in interdisciplinary research which is likely to include such IT related issues as human-technology interactions. The dissemination and education work will likely include the use of IT-based simulators and distance learning technology. More detailed information on these RFAs can be found on the AHRQ website at www.ahrq.gov.

Conclusions

Medical errors are a national public health problem that result in substantial morbidity and mortality. The U.S. health care system must address this epidemic in the same manner that it targets diseases such as cancer, diabetes, heart disease, and obesity. The federal government is aggressively taking action to reduce medical errors and improve patient safety, as demonstrated by the efforts of the Quality Interagency Coordination Task Force (QuIC) and recent Congressional action to appropriate $50 million in AHRQ's 2001 budget for initiatives to improve patient safety.

A major re-engineering of the health care delivery system will be needed if significant progress is to be made, which will require changes in technical, sociological, cultural, educational, financial, and other important factors. Although IT is not the sole remedy, it is an integral part of the solution. Research is needed that will: 1) contribute to our basic understanding of medical errors, including epidemiology, prevention, detection, and treatment; 2) evaluate the role of informatics in improving clinical decision-making, reducing errors, and advancing patient safety; 3) assess barriers to implementation of IT that can improve safety and quality of care as well as strategies to overcome these barriers; and 4) evaluate the optimal role of IT in building a safer health care environment.

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