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REGIONAL
HEALTH
INITIATIVE**

*Spreading Quality,
Containing Costs.*

EXECUTIVE SUMMARY

December 2009

A NATIONAL PATIENT SAFETY AGENCY: TIME FOR RAPID CORRECTIVE ACTION?

~Please Engage in a Dialogue with PRHI~

December 2009 marks the 10th anniversary of the Institute of Medicine (IOM) groundbreaking patient safety report, "To Err Is Human." IOM found that up to 98,000 Americans were dying annually as a result of medical errors.

Notwithstanding significant attention and the creation of a national patient safety movement, hopes for dramatic improvement have not been realized. The Agency for Healthcare Research and Quality (AHRQ) 2008 *National Healthcare Quality & Disparities Report* describes virtually no improvement in standardized patient safety measures.

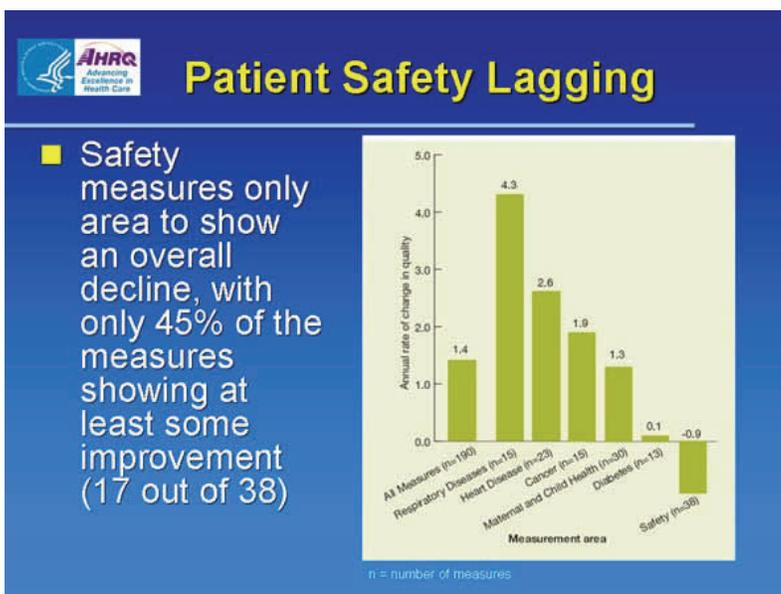
There is agreement about the need for more effective action, but no consensus has emerged about ideas for renewed action, including a national reporting system for medical errors, enforcing physician accountability and more safety research.

PRHI proposes creation of a federal patient safety agency—with an explicit focus on identifying recurring medical errors that cause serious patient injuries, and authority to require expedited compliance with preventive steps that have been shown to be effective.

PRHI's concept is summarized on the next page. Comments from health policy experts are in this issue, too. The purpose of this Executive Summary is to stimulate discussion. We invite and encourage your response. Please go to: <http://prhi.blogspot.com/2009/12/should-congress-create-federal-patient.html> read what others have said, and add your ideas to the discussion.

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Source: Agency for Healthcare Research and Quality, 2008 National Healthcare Quality Report, <http://www.ahrq.gov/qual/nhqr08/slides/gr08slides.htm>

Federal Patient Safety Agency (FPSA) **A Catalyst for Rapid Corrective Action**

Federal regulation has been a powerful catalyst for improving safety in other industries (e.g., aviation). Rather than overwhelm the healthcare delivery system with onerous regulatory burdens, PRHI proposes limited federal intervention, requiring only modest public resources, that could be implemented rapidly with significant savings for Medicare and Medicaid, as well as consumers and employers.

Identification of recurring serious, recurring medical errors. No new reporting of medical errors would be required. The FPSA would use existing public and private medical error reporting systems (e.g., Pennsylvania Patient Safety Authority data, Pennsylvania Health Care Cost Containment Council Hospital-Acquired Infections reports) to identify sources of recurring patient injuries.

Research and Prevention. Other government agencies are already engaged in medical errors research (e.g., National Institutes of Health). The FPSA would use these resources to identify the best knowledge about medical errors prevention, from which the FPSA staff would recommend regulatory action (e.g., in cases of medication errors due to look-alike drug packaging, an immediate requirement for physical separation of look-alike medications on pharmacy shelves, coupled with expedited alteration of look-alike packaging by the manufacturer).

Independent evaluation. Staff recommendations and supporting information would be evaluated by an appointed Patient Safety Review Commission of private and public medical and safety experts. No FPSA regulatory action would be taken until the Committee concurred with, rejected, or modified staff recommendations.

Issuance of regulations. Recommendations approved by the Review Commission would be converted into proposed federal regulations, which would go through the normal federal regulatory review process.

Enforcement. The FPSA would not have enforcement resources. As instances of non-compliance would come to the agency's attention – through the existing medical errors reporting systems referred to above – the FPSA would be authorized to issue warnings, public reports, levy fines, and refer to federal law enforcement for action.

A PRHI monograph that details the FPSA proposal, “Congress Should Create a Federal Patient Safety Agency” <http://www.prhi.org/docs/The%20Need%20for%20a%20Federal%20Patient%20Safety%20Agency.pdf> has been circulated widely. It has also been featured in healthcare publications, including *Patient Safety and Healthcare Quality* <http://www.psqh.com/septemberoctober-2009/242-enforceable-regulations-for-patient-safety.html> and *Physicians News Digest* (<http://www.physiciansnews.com/?s=pittsburgh+regional+health+initiative>).

Reactions to PRHI's Federal Patient Safety Agency Proposal

"1) A federal patient safety agency may be a desirable approach; it certainly is doable, but it doesn't sound like it gets to zero tolerance for medical errors in my lifetime.

2) I think one could argue, as Karen Davis and I did in her July President's column, (http://www.commonwealthfund.org/~media/Files/Publications/Blog/Davis_Schoenbaum_Blog_July_09.pdf) that we need a national goal-setting process – ideally the responsibility of the President. If one of our goals were to have zero medical errors, you can bet that we would configure our national support efforts, whether or not they included a dedicated patient safety agency, to achieving the goal.

3) Delivering evidence-based effective care involves doing some things for all patients, not just some, who meet certain criteria and also not doing some things for all patients, not just some patients, who meet certain other criteria. I think it is critically important to recognize that the line between more effective care and more error-free care is blurry, and that both must be achieved. Would you prefer not to have an unnecessary procedure than to have it performed error-free? You shouldn't have to choose. You should be the beneficiary of both evidence-based effective care and error-free care.

4) In a different vein, I'm not sure how much of what you want has been considered/rejected in the current wave of reform legislation; or, if not considered, whether this is a time when one can introduce "new ideas" or whether that will have to come in a later wave."

*Stephen C. Schoenbaum, MD, MPH
Executive Vice President for Programs
The Commonwealth Fund*

"Our well-trained healthcare professionals are capable of delivering better, safer care. Safe systems require rapid corrective action – health systems lag behind other high risk, complex environments in building an infrastructure to protect the consumer from harm. The committed clinician should welcome a support vehicle to produce danger alerts. Right now, responsibility for protecting patients from recurring system failures is diffused. If a streamlined and focused Patient Safety Agency would save lives, I would find it hard to reject the proposal."

*Arthur S. Levine, M.D.
Senior Vice Chancellor for the Health Sciences
Dean of the School of Medicine
University of Pittsburgh*

"The question isn't whether we need a federal patient safety agency in the United States. Nor is it whether one will be established. The issue is when. How many more people have to be harmed, how many more families fractured by loss, before lawmakers address the national need to regulate effectively on behalf of all Americans?"

*Martin J. Hatlie, JD
President
Partnership for Patient Safety*

"Medical errors don't discriminate between Republicans and Democrats. With moral clarity and policy savvy, this proposal shows how targeted and limited government action can and must help bring an end to the seemingly unlimited toll of preventable patient deaths."

*Michael L. Millenson
Author, Demanding Medical Excellence:
Doctors and Accountability in the Information Age*

Reactions continued on Page 4

Reactions to PRHI's Federal Patient Safety Agency Proposal (cont'd)

"It is imperative that we finally wrestle with medical errors that are foreseeable and preventable. Aggressively addressing medical errors holds the clear benefits of improving quality of patient care and lowering costs for purchasers, payers and providers.

The PRHI proposal puts addressing foreseeable and preventable medical errors on the front burner. What is proposed will lead to overall improvement in the quality of care and take advantage of known or newly identified broad based "quality" concerns in a meaningful way. Improving the quality of care will no longer be a part of individual dinner conversations, but will be elevated to priority status by health care providers. This is particularly important because many of the common foreseeable and preventable medical errors can be corrected if the providers make it a priority.

For example, Hospital-Acquired Infections were the subject of dining room conversations until a Pennsylvania state agency aggregated the data which made the data actionable. Prior to aggregating the data, as is proposed in this PRHI proposal for the National level, hospital-acquired infections were simply anecdotes. Once Pennsylvania aggregated the HAI data, HAIs moved from anecdotes to action, and the Pennsylvania General Assembly adopted legislation with time lines to end these foreseeable and preventable hospital acquired infections.

Averting HAIs or other foreseeable and preventable medical errors is simply a matter of priority -- not new science. It is the direct opposite of directing providers to find a cure to cancer or be penalized. In the overwhelming majority of cases, ending foreseeable and preventable medical errors is simply a matter of institutional priority. The thrust and value of the PRHI proposal is to put well-known anecdotes --recurring prescription errors for example -- on the table as priority issues. Were the thrust of the PRHI proposal adopted, patients would get better care, lives would be saved and there would be a dramatic reduction in costs. This bundle of benefits from a focus on quality issues must be the core of any serious effort to reform the healthcare system in the United States."

David Wilderman
Former Executive Director
Pennsylvania Health Care Cost Containment Council

"As I travel the country to consult with hospitals, I am awed by the intense efforts to improve quality and service at every institution. These efforts are rarely touted in the media or in journals because they are continuous, incremental and simply a part of the professionalism of medicine and management. Although even one unnecessary death due to medical errors is too many, I do not believe that federal government regulation is the appropriate response. The healthcare industry is already the most regulated industry in the country. Government regulation can stifle innovation, grow bureaucracies, increase costs, miss the target and create unintended consequences. One must not confuse regulation with results."

Diane Peterson, FACHE
President
D. Peterson & Associates

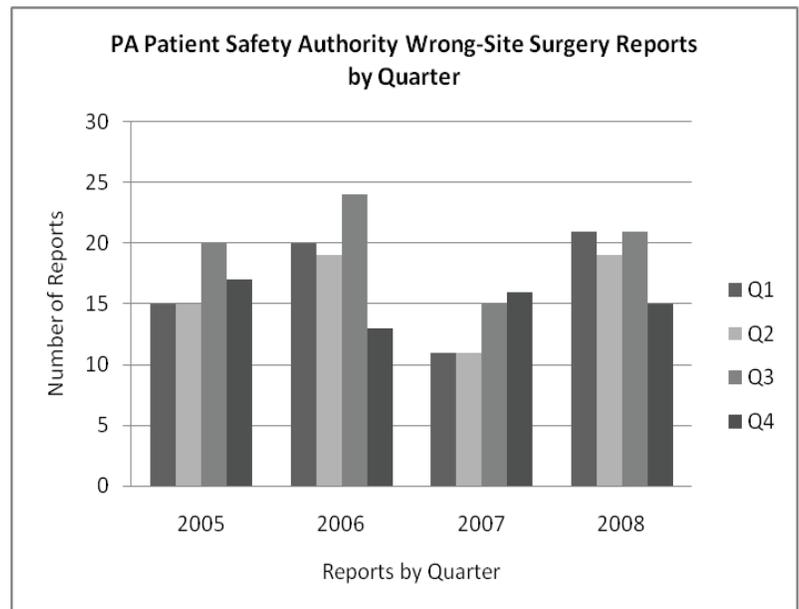


Exhibit 1: Wrong-Site Surgery Reports in Pennsylvania

Please go to <http://prhi.blogspot.com/2009/12/should-congress-create-federal-patient.html> and add your ideas to the discussion of how to improve patient safety.