To Err is Human – To Delay is Deadly

Ten years later, a million lives lost, billions of dollars wasted

Executive Summary

Ten years ago the Institute of Medicine (IOM) declared that as many as 98,000 people die each year needlessly because of preventable medical harm, including health care-acquired infections (See sidebar: Preventable medical harm). Ten years later, we don't know if we've made any real progress, and efforts to reduce the harm caused by our medical care system are few and fragmented. With little transparency and no public reporting (except where hard fought state laws now require public reporting of hospital infections), scarce data does not paint a picture of real progress.

Based on our review of the scant evidence, we believe that preventable medical harm still accounts for more than 100,000 deaths each year – a million lives over the past decade. This statistic by all logic is conservative. For example, the Centers for Disease Control and Prevention (CDC) estimates that hospital-acquired infections alone kill 99,000 people each year. This needless death is unacceptable, and we must demand action from our health-care system.

> "How much of a problem is patient safety? The unsettling fact is that no one knows."
>
> - Dr. Lucian Leape, March 2008

In this report we give the country a **failing grade** on progress on select recommendations we believe necessary to create a health-care system free of preventable medical harm.

Few hospitals have adopted well-known systems to prevent medication errors and the FDA rarely intervenes.

While the FDA reviews new drug names for potential confusion, it rarely requires name changes of existing drugs despite high levels of documented confusion among drugs, which can result in dangerous medication errors. Computerized prescribing and dispensing systems have not been widely adopted by hospitals or doctors, despite evidence that they make patients safer.

A national system of accountability through transparency as recommended by the IOM has not been created.

While 26 states now require public reporting of some hospital-acquired infections, the medical error reporting currently in place fails to create external pressure for change. In most cases hospital-specific information is confidential and under-reporting of errors is not curbed by systematic validation of the reported data.

No national entity has been empowered to coordinate and track patient safety improvements.

Ten years after *To Err is Human*, we have no national entity comprehensively tracking patient safety events or progress in reducing medical harm and we are unable to tell if we are any better off than we were a decade ago. While the federal Agency for Healthcare Research and Quality attempts to monitor progress on patient safety, its efforts fall short of what is needed.

Doctors and other health professionals are not expected to demonstrate competency.

There has been some piecemeal action on patient safety by peers and purchasers, but there is no evidence that physicians, nurses, and other health care providers are any more competent in patient safety practices than they were ten years ago.

The U.S. health-care system needs nationwide mandatory, validated and public (MVP) reporting of preventable health care-acquired infections and medical errors. Medication errors—cited as a major problem by the IOM ten years ago—remain a serious problem today. The FDA, doctors, hospitals, and drug manufacturers must establish better practices at every stage of the treatment process to track and prevent harm from medication errors. Professional standards regarding patient safety should ensure competent care. While some progress has been made by private initiatives and through purchasing policies, regulators have not demanded universal competency testing for doctors and nurses.

Doctors and hospitals raise concerns that public reporting of medical harm will lead to frivolous lawsuits. But the best way to prevent claims is to put systems in place to prevent harm. Experience with public reporting in the states demonstrates the tort concerns about such disclosures is overstated. With a civil justice system weakened by limited compensation to harmed patients and inadequate oversight of health care, public reporting of preventable medical harm is today perhaps the only effective accountability measure we have.

The current health reform debate presents a remarkable opportunity for improving access to health care in America – but that health care should be safe. Patient safety needs to be a major part of these reforms.

Introduction

In November 1999 the Institute of Medicine (IOM) issued the report *To Err is Human*, detailing a problem the public knew of only anecdotally: doctors and other health care professionals can make mistakes. The report also revealed something that most people didn't know: the U.S. health-care system wasn't doing enough to prevent these mistakes, and preventable medical errors were killing as many as 98,000 people a year.[1] (See Sidebar: Behind the Statistics: Real Lives).

"Medical mistakes 8th top killer" screamed the headline in USA Today.[2] "Medical Errors Blamed for Many Deaths; As Many as 98,000 a Year in U.S. Linked to Mistakes" reported the front page of the Washington Post.[3] IOM report co-author Dr. Lucian Leape compared deaths from medical care to three fully loaded jumbo jets crashing every-other day, a sound-bite repeated by the New York Times editorial board.[4]

"Experts Say Better Quality Controls Might Save Countless Lives. Washington, Are You Listening?" asked the LA Times Editorial Board.[5] The country certainly was. The story was featured on three major network news shows the next morning, and carried in three major news magazines the next week.[6] A Kaiser Family Foundation survey over the following weeks found that more than half of Americans had heard of the IOM report and Kaiser called the report the "most closely followed health policy story of 1999."[7]

The IOM report estimated that medical errors cost the U.S. $17-$29 billion a year, and called for sweeping changes to the health-care system to improve patient safety (defined by the IOM as "freedom from accidental injury"[8]). The "combined goal of the recommendations" said the IOM, is to "… make errors costly to health-care organizations and providers, so they are compelled to take action to improve safety." The IOM also called for a measurable improvement in patient safety, stating "it would be irresponsible to expect anything less than a 50% reduction in errors over five years."[9]

Within days, the Clinton administration asked a federal task force to examine the IOM's recommendations.[10] The task force quickly agreed with the majority of the IOM's findings.[11] The IOM report spurred seven hearings on Capitol Hill over the following three months, and soon at least five federal bills were filed regarding medical errors.[12] Congress allocated $50 million to the Agency for Healthcare Research and Quality (AHRQ) for patient safety research grants in the 2001 budget, citing the IOM report as evidence of the need for work on the problem.[13]

Despite this initial flurry of activity, progress slowed once the media moved on to the next crisis. When the IOM published a follow-up report in March 2001, the release barely registered.[14] By 2004, the deadline for the IOM's goal of a 50% reduction in errors, no national medical error reporting bills had been passed and the initial outrage surrounding the report had faded. Movement towards systematic change to the health-care system remained "frustratingly slow."[15]

Today our country has an opportunity for dramatic changes to our fragmented healthcare system. Health reform to ensure that all Americans have access to high quality health care should also include significant and active mandates to reduce medical harm.

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Preventable Medical Harm: The IOM defined medical error as the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan (including failure to use a plan) to achieve an aim (error of planning).[1] Specific types of medical errors highlighted in the IOM report included error in the administration of treatment, failure to employ indicated tests, and avoidable delays in treatment.[2] The IOM agreed that many health care-acquired infections (HAIs)[3] are preventable, but relegated discussion of HAIs to an appendix of the report. In this report we use the term preventable medical harm to explicitly include both HAIs and other medical errors.

1 Kohn, 1999, p. 28.

2 Kohn, 1999, p. 36.

3 While the term "healthcare associated infections" is used by medical professionals, it obscures the cause-and-effect relationship under discussion. For clarity we use "health-care acquired infections" to refer to infections that patients contracted while interacting with the healthcare system. Most studies and information about healthcare- acquired infections focus specifically on hospital-acquired infections.

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1 Kohn LT, Corrigan JM, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine; 1999, p. 1.

2 Davis, Bob, and Julie Appleby. "Medical mistakes 8th top killer," USA Today, 11/30/99.

3 Weiss, Rick. "Medical Errors Blamed for Many Deaths; As Many as 98,000 a Year In U.S. Linked to Mistakes," The Washington Post, 11/30/99.

4 "Preventing Fatal Medical Errors," Editorial. New York Times, 12/1/99.

5 "Hospital Error's High Costs; Experts Say Better Quality Controls Might Save Countless Lives. Washington, Are You Listening?" Editorial. LA Times, 12/5/99.

6 Dentzer, Susan. "Media Mistakes in Coverage of the Institute of Medicine's Error Report," Effective Clinical Practice, November/December 2000.

7 Kaiser/Harvard Health News Index, November/December 1999 vol.4, No.6. Kaiser Family Foundation. Internet source: http://web.archive.org/www.kff.org/content/2000/1565/HNI+Nov-Dec1999.pdf (Accessed 4/16/09).

8 Kohn, 1999, p. 58.

9 Kohn, 1999, p. 4.

10 "Clinton orders task force to seek reduction in medical errors," CNN.com, 12/7/1999. Internet source: http://archives.cnn.com/1999/HEALTH/12/07/medical.errors.02/index.html (Accessed 3/16/09).

11 *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*, Report of the Quality Interagency Coordination Task Force, February 2000. Internet Source: http://www.quic.gov/report/errors6.pdf (Accessed 2/27/09).

12 Kenagy, John W. and Gary C. Stein. "Naming, Labeling, and Packaging of Pharmaceuticals," Am J Health-Syst Pharm 58(21):3033-3041, 2001.

Shuren, Allison Weber. "Health care delivery errors: Patient safety falls prey to politics," J Pediatr Health Care. 15, 42-44, 2001.

13 106 Congress. "Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001 Conference Report To Accompany H.R. 4577," U.S. Washington DC: Governmental Printing Office, p. 149.

14 Millenson, M L. "Pushing the profession: how the news media turned patient safety into a priority," Qual. Saf. Health Care 2002;11;57-63

15 Leape, Lucian L. and Donald M Berwick. "Five Years After To Err Is Human: What Have We Learned?" JAMA, May 18, 2005—Vol 293, No. 19.

Behind the Statistics: Real Lives

Lewis Blackman was 15 years old when his family brought him to the hospital for elective surgery. The surgery was predicted to be short, and he brought the book "Dune" to read while he recovered. Four days later he was dead; an autopsy revealed his abdomen was filled with almost three liters of blood and digestive fluids from an undiagnosed perforated ulcer. The ulcer had gone undiagnosed by the doctors-in-training attending Lewis despite indications of trouble for more than thirty hours prior to his death. Medical experts hired by Lewis's mother later said that his symptoms should have suggested a routine blood test that would have uncovered the problem.[1] A failure to order an indicated test is a medical error.[2]

As we reference the statistics of medical error in this report, remember that behind each number is the life of someone like Lewis.

One of the most widely cited statistics from To Err is Human was the estimate that "at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors."[3] What does this statistic mean? Where did it come from?

The number used by the IOM was based on two studies which performed after-the-fact reviews of a sample of medical records (one study in New York, the other in Utah and Colorado) to estimate the rate of preventable injuries caused by medical management. This preventable injury rate was applied to the 33.6 million hospital admissions in the U.S. to calculate the overall magnitude of medical errors.

The resulting 44,000 - 98,000 estimate has become one of the most widely cited statistics on medical error, but it is not without its critics. Several subsequent articles attacked the subjective nature of the estimate of whether or not a patient death could be attributed to a particular error.[4]

Nevertheless, defenders of the estimate focus on two reasons that the figures are far more likely an under-estimate of the magnitude of the problem of preventable medical harm in this country: First, the chart review process only catches errors that are recorded in the medical record, and evidence of many errors does not appear in the record. Second, the IOM number accounts for only medical harm in hospitals, and much health care is delivered outside of that setting. [5]

The medical error rate used to calculate the IOM's national estimate has also been supported by newer studies in Canada, Australia, and other developed countries. Based on the current state of knowledge of medical harm, two recent patient safety textbooks estimate that 5% of hospital admissions experience some type of adverse error, 30% of which cause consequen-

1 Monk, John. "How a hospital failed a boy who didn't have to die" The State, Columbia, South Carolina. Sunday, Jun. 16, 2002, p. A1, A internet source: http://www.lewisblackman.net/ (Accessed 4/2/09).

2 Kohn, 1999, p. 36.

3 Kohn, 1999, p. 26.

4 McDonald CJ, Weiner M, Hui SL. "Deaths due to medical errors are exaggerated in the Institute of Medicine report." JAMA. 2000;284:93-5.

See also: Sox HC, Woloshin S. How many deaths are due to medical error? Getting the number right. Effective Clin Pract. 2000;6:277-283.

5 Quality of Health Care in America Committee "The Institute of Medicine Report on Medical Errors: Misunderstanding Can Do Harm" Medscape General Medicine 2(3), 2000. 9/19/2000.

tial harm.[6] This estimate implies that more than half-a-million people in the U.S. were harmed by preventable medical errors last year.[7]

Studies of specific errors also suggest the IOM report underestimates the magnitude of medical harm. Some hospital-acquired infections were identified in the studies used by the IOM, yet the report hardly mentions them. In an appendix to the report, CDC statistics are given: 2 million hospital patients and 1.5 million long-term care patients are infected each year.[8] Most of these are now believed to be preventable.[9] A 2007 CDC study estimated that 99,000 deaths in the US in 2002 were associated with HAIs.[10] The IOM study found that 7000 deaths each year are caused by preventable medication errors.[11]

The lack of a reliable measurement of medical harm is a major challenge that must be addressed. But don't confuse the magnitude with the impact. We know the impact of the problem today. Just ask Lewis Blackman's family.

6 Wachter, Robert M. Understanding Patient Safety McGraw-Hill 2008, p. 10.

Vincent, Charles, Patient Safety, Elsevier, 2006, p. 42.

7 Author's calculations. 37.1 M (US Hospital Admissions in 2007) X 10% (of which are adverse events) X 50% (of which are preventable) X 30% (of which cause consequential harm) = 556,500

2007 US Hospital Admissions Information from "Fast Facts on US Hospitals" Internet Source: http://www.aha.org/aha/content/2008/pdf/fast_facts_2008.pdf (Accessed 4/3/09)

8 Kohn, 1999, p. 268.

9 The CDC estimates as many as 70% are preventable: Scott, R. Douglas II, "The Direct Medical Cost of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention," Division of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases, Coordinating Center for Infectious Diseases Centers for Disease Control and Prevention, March 2009, p.7.

10 Klevens et al. "Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002," Public Health Reports Vol. 122 March–April 2007.

11 Kohn, 1999, p.2

Ernst, Frank R. and Amy J. Grizzle "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," J Am Pharm Assoc 41(2):192-199, 2001.

Are we safer today than we were a decade ago? Are we doing what is necessary to end needless suffering from preventable medical harm? It is our search for answers to these questions that drives this report.

The IOM recommended dozens of changes to make our health-care system safer. In this report we evaluate how the country has fared on select recommendations we believe necessary to create a health-care system free of *preventable medical harm*.

We evaluate progress on the following IOM recommendations:

Prevent medication errors: Make the production, regulation, prescribing, and delivery of medications safer.

Create accountability through transparency: Identify and learn from medical harm through both mandatory and voluntary reporting systems.

Measure the problem: Establish a 'national focus' to track progress on patient safety.

Expect more: Raise standards for improvements and competency in patient safety for doctors and nurses and healthcare organizations, like hospitals.

Preventing Medication Errors

Implement safe medication practices.

To Err is Human identified medication errors, "as a substantial source of preventable error in hospitals."[16] The report recommended stronger oversight by the Food and Drug Administration (FDA) to address safety issues connected with drug packaging and labeling, similar named drugs, and post marketing surveillance by doctors and pharmacists.[17] In 2006 the IOM returned to the issue, publishing "Preventing Medication Errors," a report that reiterated many of the recommendations of the 1999 report and concluded that at least 1.5 million preventable medication errors cause harm in the United States each year. The 2006 report estimated that medication errors in hospitals alone cost $3.5 billion a year.[18]

Drug Confusion Errors

Many medication errors are caused by the confusion of medicines with similar names, such as primidone (a seizure medication) and prednisone (an anti-inflammatory medication). For example, the similarities of these names led to the death of an adolescent in California in a case reported in 2004, despite the fact that the potential for primidone-prednisone confusion had been identified three years earlier. [19,20] The confusion continues. A 2008 report listed Prednisone as commonly confused with 12 other drugs [21]

> **Medication errors** include administering or prescribing the wrong drug, wrong dose, or wrong route of administration to a patient. These include cases in which drugs are provided without regard to drug allergies or interactions with other medications the patient may be taking. [1]
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> 1 Hicks, R.W., Becker, S.C., & Cousins, D.D. (Eds.). (2008). MEDMARX data report. A report on the relationship of drug names and medication errors in response to the institute of medicine's call for action. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia, Preface.

Packaging and design can also contribute to drug confusion errors. In a high profile case in 2007 the twin babies of actor Dennis Quaid and his wife were given 1,000 times the prescribed dose of the blood thinner heparin. According to Quaid's testimony before Congress, the couple sued the drug manufacturer, charging that the manufacturer was negligent in packaging different doses of the product in similar vials with similar blue labels.[22] The court dismissed the case on jurisdictional grounds and it is now on appeal. This problem was not new. A year before, a similar mix-up occurred when six infants in a newborn intensive care unit at an Indianapolis hospital were given excessive doses of heparin, leading to the death of three of them, and two infants at the same Indianapolis hospital had received a similar overdose in 2001.[23] After the Indianapolis deaths, the manufacturer issued a letter warning hospitals of the potential for confusion, but the packaging was not changed for at least 12 months and the same packaging was still being used in the hospital treating the Quaid children.[24] After the Quaids threatened to sue the hospital where their twins were treated, the hospital agreed to pay the family $750,000 and invested $100 million in new technology to prevent similar harm in the future.[25] Regulators fined the hospital for failure to follow its own safety policies.[26]

Most victims of medication error do not have the same ability to drive media attention and prompt action. There were 25,530 look-alike and/or sound-alike drug confusion errors reported to two drug error reporting systems in the four years 2003-2006; drug labeling and packaging contributed to 7.8% of look-alike and/or sound-alike errors.[27] With a problem of this magnitude, we need a systematic solution to address all of the confusion errors, not just the few that get media attention.

The FDA has tested new drugs for potential name confusion since 1999 and monitors the market for instances of confusion, but few existing names are changed.[28] In an unusual action in 2005 the FDA called for the Alzheimer's drug Reminyl to be renamed after confusion with the diabetes drug Amaryl was implicated in two patient deaths. Reminyl was renamed Razadyne.[29]

The current statistics on look-alike/sound-alike error demonstrates that the FDA's effort is inadequate. The FDA is conducting a pilot program to expand pre-market drug testing to include name confusion evaluation by third parties, but the

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16 Kohn, 1999, p. 182.

17 Kohn, 1999, p. 136.

18 Aspden P, Wolcott J, Bootman JL, Cronenwett LR (eds), Committee on Identifying and Preventing Medication Errors: *Preventing Medication Errors: Quality Chasm Series*. Institute of Medicine of the National Academies. Washington, National Academy Press, 2006, pp. 112, 117.

19 Pestaner, JP "Fatal mix-up between prednisone and primidone." Am J Health Syst Pharm. 2004 Aug 1;61(15):1552.

20 "Use Caution—Avoid Confusion" USP Qual Rev. No. 76, March 2001.

21 Hicks, 2008, p. 186

22 Ornstein, Charles "Dennis Quaid files suit over drug mishap" Los Angeles Times 12/5/2007.

Testimony of Dennis Quaid and Kimberly Quaid Before the Committee on Oversight and Government Reform of the United States House of Representatives, May 14, 2008; http://oversight.house.gov/documents/20080514103204.pdf.

23 Martin, Deanna "3rd Ind. preemie infant dies of overdose" Associated Press 9/20/2006 Internet Source: http://www.boston.com/news/nation/articles/2006/09/20/3rd_baby_dies_from_drug_overdose_in_ind/ (Accessed 4/15/09)

Testimony of Dennis Quaid and Kimberly Quaid, 2008, p. 4.

24 Deutsch, Jonathan "IMPORTANT MEDICATION SAFETY ALERT BAXTER HEPARIN SODIUM INJECTION 10,000 UNITS/ML AND HEP-LOCK U/P 10 UNITS/ML" Dear Healthcare Provider Letter, Baxter. 2/6/2007. Internet Source: http://www.fda.gov/medwatch/safety/2007/heparin_DHCP_02-06-2007.pdf (Accessed 4/15/09)

25 Lin, Rong-gong "Dennis Quaid says 'time is running short,' is considering suing Cedars-Sinai" LA Times. 3/28/08   Internet Source: http://articles.latimes.com/2008/mar/28/local/me-quaid28 (Accessed 4/15/09)

"Dennis Quaid's Medical Nightmare," The Oprah Winfrey Show. 2/19/2009. Internet Source: http://www.oprah.com/slideshow/oprahshow/20090219-tows-dennis-quaid/5 (Accessed 4/12/09).

"Dennis & Kimberly Quaid Agree To $750,000 Settlement From Cedars Sinai Medical Center," December 15, 2008; http://www.accesshollywood.com/dennis-and-kimberly-quaid-agree-to-750000-settlement-from-cedars-sinai-medical-center_article_12649. (Accessed 5/8/09)

26 "Quaid Hospital Case Closed," World Entertainment News Network, 1/9/09.

27 Hicks, 2008, pp. 179, 193.

28 Holquist, Carol "How FDA reviews drug names" Drug Topics. 4/2/2001. Internet Source: http://www.fda.gov/CDER/drug/MedErrors/reviewDrugNames.pdf (Accessed 4/14/2009)

Cohen, Robert, Newhouse news, "What's in a name," 8/11/08.

29 Associated Press "J&J changes Alzheimer's drug name to avoid confusion" April 11, 2005.

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pilot program won't be finished until 2011, 12 years after the original IOM report highlighted the problem.[30] In addition, this FDA effort doesn't address the problem of look-alike/sound-alike drugs already on the market.

Consumers Union believes the FDA should use its authority to rigorously set and enforce the naming, labeling, and packaging standards necessary to reduce drug confusion errors among new and existing drugs.

Another means to reduce drug confusion errors is the use of technologies such as Computerized Physician Order Entry (CPOE) systems to write prescriptions and Bar-Code Medication Administration (BCMA) technology to check that patients get the right medication. Both technologies are estimated to cut medication errors in half or more.[31] CPOE systems can identify and warn prescribing physicians of medication allergies or interactions, remove the challenge of handwritten records, and provide decision support on standardized dosing.[32] CPOE systems can be electronically linked to pharmacies to directly transmit prescriptions, a process called "e-prescribing."[33]

E-prescribing systems can be used by individual doctors in outpatient settings as well as those working within a hospital system.

A 2008 survey of American Hospital Association members found that only 17% had a CPOE system in place and operational in all units of the hospital. Another 38% had partially operational systems or plans for systems, but al-

most half (45%) of respondents had no plans to implement a CPOE system.[34] The IOM called for all health-care providers to be using e-prescribing by 2010.[35] A federal law passed in 2008 offers bonus Medicare payments to physicians who use e-prescribing beginning this year. Doctors not using e-prescribing will face reductions in Medicare payments in 2012.[36]

While technology such as e-prescribing and bar-coding are not a panacea for medication errors, they hold promise to improve medication safety. The 2009 economic stimulus bill provided $19.2 billion for health information technology, which may encourage adoption of such systems.[37]

Drug Error Reporting Systems

Several voluntary reporting systems collect information on patient harm from medication, including FDA MedWatch, the ISMP Medication Errors Reporting Program (ISMP-MERP), and Quantros MEDMARX. While useful for learning about medication errors, some researchers believe that fewer than 1 in 100 are reported to these voluntary systems.[38] Although some state adverse event reporting laws include medication errors, no national system suitable for tracking progress on medication errors exists.

In 2008, Bruce Lambert, a Professor at the University of Illinois at Chicago, commented:

> *"Despite all the focus on prevention, there is little evidence of large-scale improvement in the wrong-drug error rate. We are not suggesting that no one has been successful at minimizing these errors, it is just that few have been able to demonstrate convincing evidence of success, especially on a national scale. ... This represents a serious gap in current knowledge about medication safety. The lack of a valid, reliable, and efficient method for detecting name confusion errors is the main reason for this gap in our knowledge. **It is a fundamental principle of quality control that if a process cannot be measured, it cannot be improved.**"* [Emphasis added] [39]

The bolded quote sums up a fundamental tenet of this report. As with other preventable medical harm, the lack of a mandatory, validated, and public (MVP) reporting system leaves us in the dark on whether or not we are making meaningful progress in eliminating preventable medication errors. (The concept of MVP reporting systems are discussed in more detail below.)

Are they Watching?

We may all have the best of intentions, but knowing we're being watched makes a difference in our actions. At the beginning of a study of ICU staff at an Australian hospital, only 12.4% of patient contacts were preceded by a hand washing. When informed that their hand washing was being monitored and group hand-washing rates were posted in the ICU, hand washing occurred prior to 68.3% of patient contacts, a more than five-fold improvement. [1]

Publishing the hand washing rates of individual doctors would likely have stimulated even greater improvement. A study of Wisconsin hospitals found that hospitals subject to publicly reported facility-specific quality measures put more effort into quality improvement activities than hospitals receiving confidential reports on their quality measures. This was especially true for low-performing hospitals.[2]

1 Tibballs, James "Teaching hospital medical staff to handwash" Medical Journal of Australia. April 1996. Internet Source: http://www.mja.com.au/public/issues/apr1/tibballs/tibball.html (Accessed 3/14/09).

2 Hibbard, Judith H., Jean Stockard, and Martin Tusler "Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts? Results from a study in Wisconsin suggest that making performance information public stimulates quality improvement." Health Affairs Vol. 22, No. 2. March/April 2003.

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30 Department of Health and Human Services Food and Drug Administration "Pilot Program To Evaluate Proposed Name Submissions; Concept Paper" Federal Register Vol. 73, No. 195. October 7, 2008.

31 Kohn, 1999, p. 191.

Poon et al. "Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy" Annals of Internal Medicine 9/19/2006 Vol. 145, NO.6, pp. 426-434.

32 Wachter, Robert M. Understanding Patient Safety Lange. 2008, pp. 139-140.

33 Virk, Pushwaz et al."Analyzing Transaction Workflows in an ePrescribing System" AMIA 2006 Symposium Proceedings, p.– 1129.

34 Jha AK et al. "Use of Electronic Health Records in U.S. Hospitals." N Engl J Med. 2009 Mar 25

35 Aspden, 2006, p. 211

36 Park, Carolyne. "Rx by computer moving to state Plan created to cut errors, costs." Arkansas Democrat-Gazette 8/4/08

37 Robert Steinbrook, M.D. "Health Care and the American Recovery and Reinvestment Act," N Engl J Med. Vol. 360 n.11 pp. 1057-1060 3/12/2009

38 Hicks, 2008, p. 12.

39 Hicks, 2008, pp. 11-12.

Hospital Acquired Infection Reporting Systems:

Recently passed state hospital infection disclosure laws will increase public accountability on Healthcare Acquired Infections (HAIs). Some 25 states now have mandatory reporting systems for HAIs.[1] All of these states require public disclosure of hospital-specific rates of select HAIs, and 12 state laws require systems to validate the data for accuracy.[2] Nebraska, Nevada, and Arkansas have passed laws that require hospitals to report infection data to state agencies, but this information is not disclosed to the public.[3]

Preliminary evidence in Pennsylvania – the only state reporting on all types of HAIs - shows public reporting is an effective tool for reducing infections: Pennsylvania's overall infection rate decreased by eight percent following two consecutive years of reporting comparable infection data.

Each state has established its own reporting program, although most are collecting data on similar types of infections via the CDC's National Healthcare Safety Network (NHSN), essentially creating a national standard for collecting information on this type of medical harm.[4],[5]

While much work remains, progress towards a National MVP (Mandatory, Validated, and Public at the facility level) reporting system for HAIs is underway.

1 "Reporting of Hospital Infection Rates," Consumers Union, October 2008. Internet Source: http://www.consumersunion.org/campaigns/Map_SHI_state_laws_10-08.pdf. (Accessed 3/27/09)

2 Validating states: CO, FL, IL, NY, NH, OH, OR, PA, RI, SC, TX, VT. Other states may be attempting to validate the data, but their laws do not specifically call for it.

3 "Summary of State Laws on Hospital-Acquired Infections," Consumers Union, October 2008. Internet Source: http://www.consumersunion.org/campaigns/CU%20Summ%20of%20HAI%20state%20rpting%20laws%20as%20of%2010-08.pdf

4 Besser, Richard E., "CDC's role in Preventing Healthcare Associated Infections," Testimony before the US House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, 4/1/09, p. 3. http://appropriations.house.gov/Witness_testimony/LHHS/Richard_Besser_04_01_09.pdf. (Accessed 4/12/09)

Stricof, Rachel, "New York State Approach to Health care Associated Infection Surveillance, Prevention, and Public Reporting," p. 3, Testimony before the US House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, http://appropriations.house.gov/Witness_testimony/LHHS/Rachel_Stricof_04_01_09.pdf. (Accessed 4/12/09)

5 GAO, "Health-Care-Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections," GAO-08-808 (Washington, D.C.: Sept. 2008), pp. 1, 11

Prevent Medication Errors - Conclusion

Progress on medication errors falls short of the IOM's vision. While the FDA reviews new drug names for potential confusion, high levels of error remain. Electronic prescribing systems have not been widely adopted, and no national reporting system for medication mistakes at the facility level exists that is Mandatory, Validated, and Public.

Create Accountability Through Transparency

Identify and learn from preventable medical harm through both mandatory and voluntary reporting systems.

Imagine two hospitals in your town. One slashed medication errors in half by investing in a computerized system to assist doctors with prescription writing (eliminating the no-torious "doctor scribble" problem). The other cuts costs by buying cheap ballpoint pens that smudge during prescription writing, leaving the orders illegible and doubling the rate of dispensing errors. Do you want to know which hospital is which?

You are not alone. Ninety-two percent of Americans believe that hospitals should be required to report serious medical errors, and 63% believe the reports should be public.[40] The IOM specifically recommended public reporting of harmful medical errors so that the public could hold local health-care systems (such as hospitals) accountable and encourage improvement.

The IOM panel recommended two separate national reporting systems: A mandatory and public reporting system designed to encourage *accountability*, (i.e. creating external pressure for change) and a voluntary and confidential system designed to facilitate *learning* about errors.[41]

Progress on reporting since 1999 has been almost entirely focused on voluntary, confidential, or aggregate reporting systems designed to facilitate learning about errors. Seventeen states had established confidential reporting systems by the time a federal framework for such "learning" systems was created in the Patient Safety and Quality Improvement Act of 2005.[42] This law prohibits the release of information about medical harm collected by Patient Safety Organizations (PSOs) and shields hospitals that report harm.[43] Finally implemented in 2008, any information collected by PSOs will not be publicly disclosed by hospital or health-care facility. Under this system hospitals can learn from their mistakes, but you can't.

The PSO system joins a reporting world crowded with confidential, learning-oriented systems. The Joint Commission (a private membership and accreditation body) collects information on certain errors causing serious injury or death in its Sentinel Event Database; the reports are voluntary and the information collected remains confidential.[44] Over 13 years this database has only received 113 reports of serious hospital-acquired infections, which CDC studies estimate claim almost 99,000 lives each year.[45] The electronic Patient Safety Reporting System was developed for Veterans Administration facilities. The identities of health-care facilities reporting to the system are confidential and it is operated

40 The Kaiser Family Foundation/Agency for Healthcare Research and Quality/Harvard School of Public Health "National Survey on Consumers' Experiences With Patient Safety and Quality Information" November 2004.

41 Kohn, 1999, pp. 86-89.

42 CT, FL, GA, KS, MD, ME, NJ, NV, OH, OR, PA, RI, SC, SD, TN, UT, WA.

Rosenthal, Jill and Mary Takach. "2007 Guide to State Adverse Event Reporting Systems," The National Academy for State Health Policy. December 2007.

43 "President Signs Patient Safety and Quality Improvement Act of 2005" Press Release. 7/29/2005. Internet Source: http://georgewbush-whitehouse.archives.gov/news/releases/2005/07/20050729.html (Accessed 3/16/09).

AHRQ website: http://www.pso.ahrq.gov/regulations/regulations.htm; Patient Safety and Quality Improvement Act of 2005, Public Law 109-41 109th Congress, http://www.pso.ahrq.gov/statute/pl109-41.htm. (Accessed 5/13/09)

44 The Joint Commission. "Sentinel Event Policy and Procedures" July 2007, pp. 1, 6, 7.

45 The Joint Commission. "Sentinel Event Statistics as of: December 31, 2008," Internet Source: http://www.jointcommission.org/NR/rdonlyres/241CD6F3-6EF0-4E9C-90AD-7FEAE5EDCEA5/0/SE_Stats12_08.pdf (Accessed 4/12/2009)

Klevens, 2007.

external to the Veterans Administration (by NASA).[46] These two systems mirror the internal secret systems operated by most hospitals; a recent survey indicates that 98% of hospitals operate some type of internal reporting system for medical harm.[47] The voluntary, confidential nature of these systems prevents assessment of whether they have any impact on the safety of patients.

The National Quality Forum (NQF) is a private membership group that works to set "national priorities and goals for performance improvement," and publishes a list of voluntary consensus standards related to patient safety.[48] In 2002 the NQF endorsed a list of medical events that should "never occur." This list, now formally called the list of "serious reportable events" is often referred to as the "Never Event" list. The list currently contains 28 serious medical errors.[49] State reporting systems based on this list cover only a small subset of preventable medical harm.

A national mandatory and public reporting system facilitating public accountability does not exist, although fragmented progress has been made at the state level. As of October 2007, 25 States and the District of Columbia operated some type of medical error reporting system. Almost half of these states use a variation of the "Never Event" list to determine what type of medical harm must be reported.[50]

Of the 26 mandatory medical error reporting systems, to date, only four publicly report facility-specific information on their websites.[51] Facility specific reporting is essential to facilitating accountability, and when this report uses the term "public" reporting, we refer to facility-specific reporting. Consider if Consumer Reports tested 50 cars and found some performed well and others unsafe, but refused to reveal which cars were which. The public would not be served by such evaluation. Error information is not useful unless it is publicly tied to the entity where the harm occurred.

Minnesota is one state that publishes facility-specific information about patient harm on a state Minnesota Department of Health website.[52] Seventy-two percent of Minnesota facilities surveyed in 2008 felt that the Minnesota error reporting law made them safer than they had been when reporting began in 2003. One respondent said, "(Our) focus was always on patient safety, however now safety efforts are better

understood by more of our staff and we prioritize this work ahead of other work. Data is helping us to create more sense of urgency for this work." [53]

The magnitude of certain events reported to the Minnesota system is on the low end of what would be expected from national estimates of the incidence of medical harm. For example, only one death and five significant disabilities resulting from medication errors in hospitals were reported in the 2008-reporting year. This may reflect underreporting to the system. Minnesota health officials do not perform regular audits to validate the reporting level, although they do compare event reports to death records and consumer complaints.[54] Without validation, diligent reporters may appear to perform more poorly than their peers who simply fail to report at all. More than half of states with reporting systems acknowledged that underreporting occurs in their system.[55]

Validation, generally through random chart audits or regular comparison to claims and billing data, counters systematic underreporting by participants. As of January 2008, only three states reported performing on-site audits to validate compliance. (Sixteen states reported using more limited validation techniques.)[56] Validation programs must be active, ongoing and funded to be effective. The New York City Comptroller recently reported that the state was not sufficiently enforcing or funding its reporting system, stating the ability of the state program "to more broadly improve the quality of care and reduce unnecessary costs has been seriously compromised" by these shortcomings.[57]

We do not have national reporting systems with the three elements needed for accountability: Mandatory, Validated, and Public at the facility level (MVP). MVP reporting systems are needed to create the external pressure needed to create systemic change. (See sidebar: HAI Reporting Systems)

MVP reporting would represent a sea-change in a health-care system accustomed to hiding errors.[58] Only 14% of doctors support public reporting of medical errors.[59] Shortly after the IOM report, the New York Times reported that both the American Medical Association and the American Hospital Association "vehemently opposed mandatory reporting of errors."[60] Much of this resistance is driven by concerns that public reporting would lead to frivolous lawsuits.

The best way to prevent negligence claims is to put systems in place to prevent medical harm. Legal claims are filed on behalf of a small fraction of patients who sustain

46 Patient Safety Reporting System Website. "Program Overview," Internet Source: http://www.psrs.arc.nasa.gov/flashsite/programoverview/index.html (Accessed 4/5/09)

47 Farley et al."Adverse-event-reporting practices by US hospitals: results of a national survey," Qual. Saf. Health Care 2008;17;416-423. (Author's calculation of weighted average of critical access and non-critical access respondents.)

48 National Quality Forum "Mission – About - National Quality Forum," Internet Site: http://www.qualityforum.org/about/mission.asp (accessed 3/16/09).

The National Quality Forum "Safe Practices for Better Healthcare," 2009. Internet Source: http://www.qualityforum.org/projects/ongoing/safe-practices/ (Accessed 4/20/09).

49 "National Quality Forum Updates Endorsement of Serious Reportable Events in Healthcare," Press Release. National Quality Forum. 10/16/2006 Internet Source: http://www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf (Accessed 3/31/09)

50 Rosenthal, Jill and Mary Takach. "2007 Guide to State Adverse Event Reporting Systems," The National Academy for State Health Policy. December 2007, p. 1.

51 NY, MN, MA, IN. See http://www.safepatientproject.org/2009/05/state_medical_error_report_lin.html

Rosenthal, Jill and Mary Takach. "2007 Guide to State Adverse Event Reporting Systems," The National Academy for State Health Policy. December 2007.

52 Minnesota Dept. of Health "Patient Safety - Minnesota Dept. of Health" Internet Source: http://www.health.state.mn.us/patientsafety/ (Accessed 3/16/09).

53 "Adverse Health Care Events Reporting System: What have we learned? 5-YEAR REVIEW," Minnesota Dept. of Health. January 2009. pp. 2, 9.

54 Lisa McGiffert interview with Diane Rydrych, MN Department of Health. 4/14/09.

55 "Adverse Events In Hospitals: State Reporting Systems," The Office of Inspector General of the Department of Health and Human Services. December 2008, pp. 12-13.

56 "Adverse Events In Hospitals: State Reporting Systems," 2008, pp. 12-13.

57 "The High Cost of Weak Compliance With the New York State Hospital Adverse Event Reporting and Tracking System" Office of New York City Comptroller. 2009, pp. 27-29.

58 Gibson, Rosemary, and Singh, Janardan Prasad, Wall of Silence, 2003, pp. 136-138.

59 Blendon, Robert J., et al. "Views of Practicing Physicians and the Public on Medical Errors" New England Journal of Medicine. Volume 347:1933-1940, 12/12/2002 Number 24.

60 Pear, Robert "Clinton to Order Steps to Reduce Medical Mistakes," The New York Times 2/22/2000.

injury through medical negligence. Of those filed, many do not result in an award.[61] Thus the legal system compensates patients for a miniscule portion of the injury sustained, and at tremendous personal cost. While physician and hospital resistance has slowed adoption of the IOM accountability reporting recommendations, experience with reporting lowers this resistance. A survey of hospital officers found that those in states with mandatory reporting systems were three times more likely to support facility-specific public reporting than hospitals without experience with mandatory reporting.[62]

Today, many states have passed tort reform laws that significantly increase the burden on people who have been harmed by medical care and protect doctors from suits over all but the most egregious behaviors.[63] With such a weakened civil justice system, and a weak and inadequate administrative oversight system in most states, public reporting of preventable medical harm – and the embarrassment that might accompany the public release of poor results – is today perhaps the only accountability measure we have that is both effective and reliable.

MVP reporting systems are necessary to hold all health-care facilities equally accountable for patient safety. Consumers Union recommends mandatory validated and public reporting of preventable medical harm (health care-acquired infections and medical errors), at the state and national level.

Accountability through Transparency - Conclusion

While a network of hospital-acquired infection disclosure systems is beginning to emerge, the scope of these only covers a small portion of the HAIs occurring. Medical error reporting systems currently in place fail to create external pressure for change. Most states do not publicly report facility-specific errors and many do not include a validation requirement. Twenty-four states do not have any medical error reporting requirements in place and half of the states do not require HAI reporting. The federal Patient Safety and Quality Improvement Act of 2005 is voluntary and keeps the medical error information gathered by Patient Safety Organizations confidential, thereby removing a key incentive for safety improvement.

Measure the Problem

Establish a 'national focus' to track progress on patient safety.

When products are connected with deaths, we investigate whether there are changes in them that might prevent accidents in the first place or minimize the harm from accidents when they happen. The seat belt, the child car seat, and many technical innovations were engineered into cars, for

example, based on this approach to accident prevention. Today, a car's National Highway Traffic Safety Administration "safety rating" is a key characteristic that buyers examine before they lay down their money. Health care has enjoyed no such national safety review.

"There is no cohesive effort to improve safety in health care," lamented the IOM in 1999.[64] The report stressed that the fundamental problem was not that individual doctors made errors. The fundamental problem was the failure of the health-care system to monitor these errors, anticipate them, and minimize the harm to patients. This failure, the IOM noted, required a national focus on fixing the health-care *system*, not just the errors of individual practitioners. The IOM recommended creation of a Center for Patient Safety within the federal Agency for Healthcare Research and Quality (AHRQ).[65]

A Simple Checklist.

Consider the case study of one common type of medical harm — preventable bloodstream infections. In early 2004, researchers measured catheter-associated infections across a set of Michigan-affiliated Intensive Care Units (ICUs) and found 7.7 bloodstream infections occurred for every 1000 days of catheter use. A statewide safety initiative called "Michigan Health and Hospital Association (MHA) Keystone: ICU" set a goal of reducing catheter-associated bloodstream infections. Inspired by and coordinated with the successful research of Dr. Peter Pronovost and others at Johns Hopkins, MHA Keystone instituted a short checklist of best-practices related to catheter use and empowered nurses to ensure that doctors were following those practices. The initiative then tracked catheter-associated bloodstream infection rates in 103 participating ICUs.[66]

The overall results were stunning. Bloodstream infections across the participating ICUs dropped to 1.4 per 1000 days of catheter use, less than 20% of the rate prior to implementation of the checklist and double-checking procedures.[67] MHA Keystone estimates that the initiative saved nearly 1,800 lives over four years.[68]

While the aggregate results were impressive, results were mixed across facilities. A year and a half after the study began, MHA reported at least 50% of the participating ICUs had completely eradicated catheter-associated bloodstream infections. A quarter of the ICUs, however, still had infection rates of 2.4 per 1000 days or higher.[69] Unfortunately, MHA Keystone does not identify which facilities lagged

61 Studdert, David M. et al "Claims, Errors, and Compensation Payments in Medical Malpractice Litigation" N Engl J Med May 2006;354:2024-33.

62 Weissman et al, "Error Reporting and Disclosure Systems: Views From Hospital Leaders," JAMA. 2005;293(11):1359-1366.

63 American Tort Reform Association, Medical Liability Reform, http://www.atra.org/issues/index.php?issue=7338. (Accessed 5/11/09)

Public Citizen, "The Inequitable Impact Of Non-Economic Damage Caps: Three Academic Studies Demonstrate Severely Injured and Female Patients Are Hurt the Most," 2005.

64 Kohn, 1999, p.75.

65 Kohn, 1999, p. 9.

66 Pronovost P, Needham D, Berenholtz S, Sinopoli D, Haitao C, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med 2006;355:2725-32. Internet Source: http://content.nejm.org/cgi/content/full/355/26/2725. (Accessed 4/16/09)

Berenholtz SM, Pronovost PJ, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. Crit Care Med 2004;32:2014-2020.

67 Author's calculations. 1.4/7.7 = 18%. Note that the hospitals used as a starting benchmark were a subset of the hospitals in the MHA Keystone project.

68 *2008 Annual Report.* MHA Keystone Center for Patient Safety and Quality, p. 6; four-year estimate was for 2004-2008.

69 Pronovost, 2006, p. 2730.

behind, preventing the public from discerning the hospitals with zero bloodstream infections from the ones without significant progress.

While the MHA Keystone: ICU initiative was not an MVP program as envisioned by this report, the results were widely reported and the process changes instituted by Keystone are now the focus of several national initiatives.[70] Dr. Pronovost won a MacArthur genius award for his work.[71] The project was recognized as a success in part because it measured the impact of its work. Without evidence of improvement, the initiative's changes may not have been continued by the participating ICUs, let alone spurred a national movement to adopt the process changes.

This is one local example of the type of focus the IOM envisioned at the national level. The panel recommended creation of an agency that would be a 'national focal point' on safety in health care, much the way MHA Keystone: ICU was a focal point for bloodstream infections in Michigan. This agency would research and promote best-practices for patient safety and, crucially, track and report our nation's progress towards ending preventable medical harm.

Tracking National Progress.

The AHRQ is the closest federal agency to the IOM's vision of a "Center for Patient Safety" coordinating national resources on patient safety.[72] AHRQ is charged with enhancing "the quality, appropriateness, effectiveness of health services" in the U.S. It funds numerous research projects on quality and safety and publishes the "National Healthcare Quality Report," (NHQR) to discuss and quantify progress on patient safety. [73]

The NHQR estimates national progress on patient safety primarily through claims data on patients in the Medicare system, hospital billing data from the states, and various other sources like vital statistics and census data.[74] It discloses no provider or facility-specific information – all data is presented in the national or state aggregate. The agency's Patient Safety Indicators focus attention mostly on surgical errors, and does not use data contained in less accessible forms (such as patient charts). [75] The data is also stale; the 2008 report (published in 2009) discusses patient safety data only through 2006. Such delays are a chronic problem with health data and reduce the relevance of the report as a

feedback mechanism. Widespread adoption of health information technology would allow more timely and accurate information from clinical records. In the meantime, much can be gleaned from claims data and hospitals should be held accountable for ensuring the data is accurate. The lack of timely, facility-specific information also limits its use as a tool for consumers in making health care decisions.

The 2008 NHQR report estimates that patient safety declined by almost 1% a year over the six years after the IOM report, but states "[d]ata remain incomplete for a comprehensive national assessment of patient safety." In what is an indicator of how little progress has been made towards accounting for preventable medical harm, the latest AHRQ report still uses the IOM's 1999 work as the best estimate of the magnitude of medical errors.[76]

Without comprehensive measures of progress, we can't say if the indicators examined by the NHQR data accurately represent the state of patient safety as a whole. While 17 of the 38 indicators tracked by AHRQ have declined somewhat over the last six years, in some areas not referenced by NHQR, there is evidence that patient safety is getting rapidly, not slowly, worse.[77] For example, the number of hospital discharges with Clostridium difficile-associated infections, which are primarily regarded as health care-acquired infections, more than doubled from 2001 to 2005.[78]

The 1999 IOM report contemplated tracking national progress on patient safety through a periodic survey of medical records, following the methods of the academic research that provided the basis for the IOM's original estimate 44,000-98,000 annual deaths from medical errors.[79] Such a periodic national survey has not been implemented and may be impractical, although the adoption of electronic medical records may make such a survey less costly and less labor intensive.

A national MVP reporting system on preventable medical harm would be able to fill the measurement role of a national survey. Variations in current reporting in voluntary systems may be due to changes in reporting compliance rather than changes in error rates; validation of mandatory systems minimizes such variation. A national MVP reporting system would have the additional benefit of tracking progress at the local, as well as national, level. As discussed above, such a system does not yet exist.

Measure the Problem - Conclusion

Ten years after *To Err is Human*, we have no national entity comprehensively tracking patient safety and we are unable

70 Brody, Jane. E. "A Basic Hospital To-Do List Saves Lives," The New York Times. January 22, 2008. Internet Source: http://www.nytimes.com/2008/01/22/health/22brod.html (Accessed 4/16/09).

"AHRQ Awards $3 Million To Help Reduce Central Line-Associated Bloodstream Infections in Hospital ICUs," Press Release, October 1, 2008. Agency for Healthcare Research and Quality, Rockville, MD. Internet Source: http://www.ahrq.gov/news/press/pr2008/clabipr.htm (Accessed 4/12/09)

71 "2008 MacArthur Fellows: Peter Pronovost," MacArthur Foundation Website. Internet Source: http://www.macfound.org/fellows/2008/pronovost (Accessed 4/15/09)

72 Kohn, 1999, pp. 78-79.

73 US Code Title 42. CHAPTER 6A, SUBCHAPTER VII, Part A,§ 299. Internet Source: http://www4.law.cornell.edu/uscode/42/usc_sec_42_00000299----000-.html (accessed 3/16/09).

Agency for Healthcare Research and Quality website. "2007 National Healthcare Quality & Disparities Reports" Internet Source: http://www.ahrq.gov/qual/qrdr07.htm (Accessed 3/16/09).

74 AHRQ website, NHRQ State Snapshots, Interpretation of Results, Examination of data sources, http://statesnapshots.ahrq.gov/snaps07/interpretation.jsp?menuId=39&state=ID#examination   (Accessed 5/11/09)

75 AHRQ Quality Indicators – Guide to Patient Safety Indicators. Rockville, MD: Agency for Healthcare Research and Quality, 2003. Version 2.1, Revision 2, (October 22, 2004). AHRQ Pub.03-R203. p. 23.

76 Agency for Healthcare Research and Quality. "2008 National Healthcare Quality Report." Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; May 2009. AHRQ Pub. No. 09-0001, pp. 8-9, 101.

77 AHRQ, May 2009, p. 9.

78 Elixhauser, Anne and Michael Jhung. "Clostridium Difficile-Associated Disease in U.S. Hospitals, 1993–2005" Healthcare Cost and Utilization Project Statistical Brief #50. April 2008

79 Kohn, 1999, p. 83.

to tell if we are any better off than we were a decade ago. AHRQ is attempting to do this. But without the comprehensive breadth needed to assess the problem, it falls short of what is needed.

Expect More

Raise standards for competency in patient safety for health-care professionals (like doctors and nurses) and health-care organizations (like hospitals).

Professional standards in health care are set by government agencies, purchasers, and professional peer groups. In 1999, the IOM recommended a greater focus on patient safety by regulators, accreditors and purchasers. The report called for periodic examinations of doctors and nurses to assess "both competence and knowledge of safety practices."[80] Over the past ten years, efforts to improve competency in patient safety standards have come mostly from the private sector. These efforts are laudable, but results are fragmented and no systematic process exists to promote and measure national improvement.

Fragmented Progress

The Institute for Healthcare Improvement (IHI)'s 100,000 Lives Campaign and subsequent Five Million Lives Campaign were created to stimulate and measure the impact of improved patient safety practices. This private non-profit provided tools and technical support to more than 3,700 hospitals, and the doctors and nurses working there, that agreed to provide IHI with measures of success on at least one of 12 patient safety practices supported by the campaigns.[81] A network of "mentoring" hospitals shared information regarding methods for system changes. These campaigns introduced many hospital workers to life-saving practices, though IHI did not reveal which hospitals implemented which practices. IHI publicized anecdotal evidence of the positive outcomes of the campaign, but did not provide the public with the results at individual hospitals.[82] Even though this was the broadest patient safety effort of the past decade, the decision to withhold specific validated results for the public makes it impossible to assess the full impact it had on improving the safety of patients.

Not all progress is private. One promising action – withholding payments to hospitals when patients are harmed - was recently initiated by Medicare, the largest health care purchaser in America. In October 2008, Medicare stopped paying for certain preventable hospital acquired conditions. These conditions include several hospital-acquired infections and some of the "never events" endorsed by the

National Quality Forum (NQF), such as surgeries performed on the wrong patient or part of a body and blood transfusions with the wrong blood type.[83]

Medicare's no pay policy has increased pressure for accountability, and given some time could have a significant impact on Medicare patients and costs. Numerous states and private health plans are following suit by adopting similar no pay policies for some or all of the Medicare and NQF preventable adverse events.[84]

A similar, but private, effort to use purchaser power to improve patient safety began shortly after the publication of *To Err is Human*. Several large employers formed The Leapfrog Group, which now includes many of the nation's largest corporations and some public agencies. The group agreed "to base their purchase of health care on principles that encourage quality improvement among providers."[85] Leapfrog publishes annual surveys rating the compliance of responding hospitals with specific quality and safety standards, and uses the collective purchasing leverage of its members to stimulate improved quality and safety.[86]

Insuring continuing provider competency is an important step towards creating a safe health-care system, and ongoing competency examination has been adopted by many specialty licensing boards. The American Board of Medical Specialties (ABMS) member boards require physicians to demonstrate specialty-specific skills, knowledge, and use of best-practice care to maintain their specialist certification.[87] The ABMS has recently added a patient safety self-assessment program to their recertification cycle, although the standards do not take effect until 2010.[88]

Systematic Failure

Despite the action taken by the ABMS, these continuing competency standards do not apply to the 15% of physicians not certified by one of the 24 ABMS member boards, or those physicians 'grandfathered' prior to the adoption of the standards.[89] These remaining doctors, as well as nurses and other health-care professionals, are primarily licensed at the

80 Kohn, 1999, pp. 11-12.

81 "Reaping the Harvest: A Review of the 5 Million Lives Campaign's First Year… and a Preview of What's to Come," The Institute for Healthcare Improvement. Undated Brochure. Internet Source: http://www.ihi.org/NR/rdonlyres/A528208C-8B71-4559-BFF3-F1FBDC4CD11C/0/ReapingtheHarvestBrochureFINALwebedition.pdf (Accessed 4/12/09).

IHI website, Overview, 5 million Lives Campaign, http://www.ihi.org/IHI/Programs/Campaign/Campaign.htm?TabId=1 (Accessed 5-11-09).

82 "New Results from IHI Programs" The Institute for Healthcare Improvement Website Internet Source: http://www.ihi.org/IHI/Results/NewfromIHIPrograms/#HAI (Accessed 4/12/09).

83 Tsai, Joyce. "Medicare, insurers to stop reimbursing for errors," Dallas Business Journal. 10/17/08. Author's note: Medicare policy withholds additional payment follow patient harm, but will not pay at all for wrong surgery: wrong patient, wrong site, wrong procedure.

84 Brown, Jill. "Blue Cross Plans, Providers Work to Develop 'Never-Events' Policies," AIS's Health Business Daily. 11/3/08. Internet Source: http://www.aishealth.com/Bnow/hbd110308.html. (Accessed 4/15/09)

Wolke, Anna "Infection Correction," State Legislatures Magazine. April 2009. Internet Source: http://www.ncsl.org/magazine/articles/2009/09slapr09_infection.htm#me, p. 22. (Accessed 4/15/09)

85 "Leapfrog Members," Leapfrog Group Website. Internet Source: http://www.leapfroggroup.org/for_members/who_are_members. (Accessed 4/12/09)

"The Leapfrog Group Fact Sheet" Internet Source: http://www.leapfroggroup.org/about_us/leapfrog-factsheet. (Accessed 3/29/09)

86 Leapfrog Group website,"For Members" Leapfrog Group Website. Internet Source: http://www.leapfroggroup.org/for_members. (Accessed 4/12/09)

Leapfrog Group website, "What does Leapfrog ask hospitals?" http://www.leapfroggroup.org/for_consumers/hospitals_asked_what. (Accessed 3/29/09)

87 "ABMS Maintenance of Certification," American Board of Medical Specialties. Internet Source: http://www.abms.org/Maintenance_of_Certification/ABMS_MOC.aspx (Accessed 3/30/09)

88 "New Standards Adopted to Elevate Physician Life-Long Learning Assessment for the ABMS Maintenance of Certification (MOC) Program" Press Release 3/26/09. Internet Source: http://www.abms.org/News_and_Events/Media_Newsroom/Releases/release_NewMOCStandards_03262009.aspx (Accessed 3/30/09)

89 American Board of Medical Specialties. "American Board of Medical Specialties Board Certification Editorial Background," Internet Source: http://www.abms.org/news_and_events/media_newsroom/pdf/abms_editorialbackground.pdf (Accessed 5/6/09)

state level. The IOM report called for such licensing bodies to "implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices."[90]

No state medical boards require routine testing of skills and competency.[91] Requirements for license renewal are generally limited to continuing education, despite research indicating that continuing education alone has little or no impact on practitioner competency.[92] Once practitioners earns medical license, they may never have to demonstrate their medical competency again. Professionals can become incompetent over time because they don't keep up with current medical knowledge, they suffer from drug addiction, alcoholism or mental illness, or they just weren't that good in the first place and their shortcomings only become evident as they treat patients day after day. Without ongoing testing, these kinds of problems may not be recognized by licensing agencies before serious harm occurs.

This compares poorly with standards in other high-risk fields. Ironically, New York City police officers must demonstrate firearms proficiency in requalification tests at least twice a year.[93] The Federal Aviation Administration (FAA) requires airline pilots to pass ongoing proficiency testing;[94] this testing is often implemented through the use of flight simulators. The technology for medical care training simulators exists and pending federal legislation envisions more of this kind of learning.[95] Nevertheless, the use of medical care simulation to assess physician competency is not widespread and is not required for maintaining a license.

> "The publication of To Err Is Human was the vanguard to improve patient safety. Upon nearing the report's 10-year anniversary, little appears to have changed with significant barriers encountered when attempting to track progress."
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> – Simon C. Mathews and Dr. Peter J. Pronovost, December 2008.[1]
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> 1 Mathews, Simon C. and Peter J Pronovost. "Physician Autonomy and Informed Decision Making: Finding the Balance for Patient Safety and Quality," JAMA. 2008; 300(24):2913-2915.

Hospital accreditation is another systematic attempt, like licensing, to ensure competency and adoption of patient safety standards. The Joint Commission adopted priorities and protocols to increase patient safety as accreditation standards in 2002.[96] These "National Patient Safety Goals" focus on the health care delivery process.[97]

The progress of individual hospitals on these goals is not publicly posted, so, after seven years of the program, the public cannot assess the program's impact, if any. Several studies have outlined shortcomings in the ability of the Joint Commission to detect serious deficiencies in its accreditation process. For example, a 2004 study by the GAO found that the Joint Commission failed to identify 60% of severe deficiencies in infection control procedures identified by state survey agencies.[98]

Finally, national leaders in patient safety remain concerned about the lack of competency in patient safety. In October 2008, the Lucian Leape Institute, founded by the National Patient Safety Foundation to provide strategic direction for the field of patient safety, held a meeting of experts on Medical Education Reform.[99] Discussions centered around the need to change the culture of medical education as well as the need to educate physicians on best practices supported by clinical research ("evidence-based medicine"). The meeting sought ideas for improving the patient safety competency of doctors, which most participants agreed as essential to reducing medical harm. The Institute intends to issue a report summarizing the recommendations of the roundtable, but it has not yet been released.[100]

Expect More - Conclusion

There has been some piecemeal action on patient safety by peers and purchasers, but no comprehensive national action by regulators, especially in regards to the IOM's practitioner competency recommendations. There is no evidence to assure the public that physicians, nurses, and other health-care providers are any more competent in patient safety practices than they were ten years ago. Relying on private organizations to provide increased awareness and improved patient safety practices is an arbitrary and fragmented process. Nothing is in place to assure the public that a health-care professional is competent. It is practicing 21st century medicine with 19th century oversight.

Conclusion:

National Failure on Patient Safety

Almost ten years ago, *To Err is Human* described the magnitude of the medical error problem in the U.S. health-care system. Despite a decade of work, we have no reliable evi-

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90 Kohn, 1999, pp. 134-135.

91 Our review of news reports and academic literature on continuing competency failed to identify any states requiring routine testing of physicians after receiving their initial license. We did find some references to voluntary programs.

92 Swankin, David, Rebecca Arnold LeBuhn, Richard Morrison. "Implementing Continuing Competency Requirements for Health Care Practitioners" AARP Public Policy Institute, July 2006, p. 9.

93 Rostker et al. "Evaluation of the New York City Police Department Firearm Training and Firearm-Discharge Review Process," RAND, 2008, p. xviii.

94 Code of Federal Regulations. 14CFR121.915 (b)(1)(i) U.S. Government Printing Office. January 1, 2008. Internet Source:

http://edocket.access.gpo.gov/cfr_2008/janqtr/14cfr121.915.htm (Accessed 3/16/09)

95 The Enhancing SIMULATION Act of 2009, H.R. 855 (111th Congress).

Press Release "Forbes Reintroduces Bipartisan Legislation to Reduce Health Care Costs," 2/17/2009.

96 The Joint Commission Website. "Facts about the National Patient Safety Goals," Internet Source: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/npsg_facts.htm (Accessed 3/16/09)

97 "Standards Improvement Initiative (SII): Chapter Outline; National Patient Safety Goals (NPSG); Program: Hospital," Joint Commission. Pre-publication copy. 2008

98 GAO "Medicare: CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals" GAO-04-850 July 2004, p. 14.

See also: OIG "The External Review of Hospital Quality: The Role of Accreditation" OEI-01-97-00051. July 1999, p. 2.

99 Press Release "Lucian Leape Institute Thought Leaders Define Strategies for Patient Safety," National Patient Safety Foundation. 10/30/08. Internet Source: http://www.npsf.org/pr/pressrel/2008-10-30.php (Accessed 4/15/09)

100 Comments of conference attendee Lisa McGiffert, Consumers Union. 4/12/09.

dence that we are any better off today. More than 100,000 patients still needlessly die every year in U.S. hospitals and health-care settings – infected because of sloppy compliance with basic cleanliness policies, injured by failure to follow simple checklists for safety – the equivalent of a national disaster every week of every year.[101]

Since the IOM report was issued, there have been countless task forces, conferences, editorials, and even episodes of Oprah focused on patient safety. But action on key recommendations has been sluggish, leaving us without reliable means to track our progress or hold the local health-care systems accountable for ending preventable patient harm. We have **failed** to make the systematic changes in health care needed to end preventable medical harm.

Next Steps

Patients, consumer organizations, and advocates alarmed by the lack of public accountability surrounding patient safety have issued a Patients' Call to Action to underscore the need for implementing the IOM's key recommendations, including:

- effective action by the FDA, drug manufactures, hospitals, doctors, and other health-care providers to prevent medication errors;
- increased accountability through mandatory, validated and public reporting of preventable medical harm, including health care-acquired infections; and
- better training in patient safety for doctors and nurses.

When the IOM sounded the alarm in 1999 it called for immediate action and asked "Must we wait another decade to be safe in our health system?"[102] Ten years later, we find ourselves asking the same question. As the nation begins to reform our health-care system, we have an opportunity to take effective and accountable action to make health care safer for all Americans. The time to act is now. We cannot wait another decade.

> Consumers Union's Safe Patient Project
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> Consumers Union's Safe Patient Project (www.safepatientproject.org) builds on the success of its Stop Hospital Infections campaign. It seeks to eliminate medical harm in our health-care system through public disclosure of health-care outcomes (such as hospital-acquired infection rates and incidents of medical errors) and information about health-care providers (such as complaints against and license violations of physicians and hospitals). The campaign also works to improve drug safety by ensuring that consumers have full information about prescription drugs by strengthening oversight of the FDA and by ending practices that create conflicts of interest, such as drug company gifts to doctors.
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> Consumers Union's Stop Hospital Infections campaign (www.stophospitalinfections.org) was launched in 2003 and has led a national consumer movement for public disclosure of infection rates in hospitals and other health-care facilities. To date, 26 states have enacted laws requiring publication of certain infection rates by hospital, and eight states have issued reports.[1]
>
> 1States that have passed laws: AL, CA, CO, CT, DE, FL, IL, MA, MD, MN, MO, NJ, NY, NH, OH, OK, OR, PA, RI, SC, TN, TX, VA, VT, WA, WVA (from "Summary of State Laws on Hospital-Acquired Infections," Consumers Union, May, 2009. Internet Source: http://cu.convio.net/hospital_infection_disclosure_laws)
>
> States that have issued reports: CO, FL, MA, MO, NY, PA, SC, VT. (See also: http://www.stophospitalinfections.org/learn.html)

Hospital-acquired infections
kill 99,000 Americans each year

That's the equivalent of a jumbo jet full of passengers crashing every other day

Safe Patient Project.org

Imagine the government response if planes started dropping from the sky.

Why isn't Washington doing more to protect patients from deadly hospital infections?

Consumer Reports Health

Safer patient care must be a priority in any health reform package passed by Congress, including:

- Increased public accountability for hospital infections and medical errors
- Better training in patient safety for doctors and nurses
- Aggressive action to prevent medication errors

To learn more, sign the petition and find out how you can help, visit:

www.SafePatientProject.org

101 We have adopted the 100,000 annual estimate as the absolute minimum lower boundary of deaths due to medical harm in hospitals in the United States. This includes 99,000 annual deaths from hospital-acquired infections estimated by the CDC plus 2,039 deaths among Medicare patients alone from "accidental puncture or laceration."

102 Kohn, 1999, p. 5.