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Testimony of Consumers Union
U.S. Senate Committee on Health, Education, Labor and Pensions
Subcommittee on Primary Health and Aging
More Than 1,000 Preventable Deaths a Day Is Too Many:
The Need to Improve Patient Safety
July 17, 2014

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to speak to the Subcommittee on Primary Health and Aging about an urgent health care crisis – medical errors and health care-acquired infections that kill as many as 440,000 people[1] and harm an estimated 8.5 million[2] every year in this country.

The impact on patients varies – from minor harm that is addressed quickly to permanent disability to years of recovery to death. People who are harmed lose their jobs, their homes, their health insurance. Many go bankrupt trying to pay the medical bills that they would not have had if they had not been harmed by a health care provider. These are the very real consequences of the failure to take action to address the problem of medical errors. They are our sisters and brothers, parents, and children. They have been betrayed by the system in which they placed their trust. Not because we expect perfection from nurses and doctors, but because we trust that they will use the best knowledge, diligent adherence to the best practices, pay attention to what we tell them and ask of them, understand that when we pay for their services we expect it will include doing all they can to keep us safe from harm, and when they make a mistake they will realize it, admit it, and correct it.

Since 2003, Consumers Union's Safe Patient Project has conducted a national campaign to eliminate hospital acquired infections and medical errors. A major strategy for reaching this goal is to improve public transparency about these mostly preventable events. We developed model legislation and initiated debates in nearly every state on whether hospitals should disclose their infection rates. Thirty–one states passed laws based on our hospital infection model before a federal program required such reporting for most U.S. hospitals. Public disclosure is a critical element to preventing these events from happening – it informs people about health care outcomes and motivates health care providers to do more to prevent errors.

Our work includes organizing patients and their families who have been harmed by medical care and who are working to improve the health care system to prevent harm from happening to others – in their communities and nationally. Many of them sent letters to their Congressional members last week urging them to create a National Patient Safety Board and to step up efforts to address this national crisis.

We acknowledge that many individuals, hospitals and other health care institutions are working to eliminate medical errors. Their work and progress is often the subject of Congressional hearings. But today's hearing, highlighting this national tragedy, is a call to action for a very big problem –millions of Americans are at risk for death and serious injury but the response by our leaders fails to match the scope of this epidemic.

Consider this headline: "House to push for answers on why GM failed to recall cars despite

knowledge of flaws ultimately linked to 13 deaths." The CDC home page this week highlighted salmonella infections from sprouted chia powder and pet bearded dragons and ecoli from raw clover sprouts – but nothing on infection outbreaks in US hospitals. The VA faces significant actions for delays in care, but is anyone asking about medical errors that occur at the VA and put soldiers in harms way? Diabetes kills nearly 70,000 people each year and there is a significant emphasis in our health care system to eradicate this disease. But what about the third leading cause of death? Where are the programs reaching out to help patients who are suffering from medical errors? Where is the demand for accountability of the deaths caused by preventable hospital-acquired infections?

MEDICAL ERRORS: THE THIRD LEADING CAUSE OF DEATH IN THE U.S.

Many names are given to medical errors and some, like "mishaps" and "misadventures" are offensive to the patients affected. The most frequently used list of medical errors was developed by the National Quality Forum (NQF). These are commonly referred to as "never events" but officially named "serious reportable events." The never events name was appropriate because these are things that should never be happening to patients in hospitals. The list includes surgical errors (such as surgery on the wrong patient, the wrong body part or leaving a foreign object in the body), care management (such as medication errors, blood errors, maternal or infant deaths during normal deliveries, serious bed sores), product or device related events (such as contaminated drugs, death due to intravascular air embolism in the use of an IV), environmental events (such as electrical burns, falls, electric shocks), and criminal and patient protection issues (such as abduction of a patient, sexual assault of a patient, suicide).

In 2011, Consumer Reports polled Americans about patient safety and asked them the terms they would use to describe these events. Medical errors and medical mistakes topped the list (48% combined). "Adverse events," a term commonly used by professionals was barely recognized (4%). How we refer to these events is critical to raising public and professional awareness. Using understandable terms like hospital-acquired infections rather than "nosocomial infections" is a small but critical step towards creating a culture focused on eliminating them.

While medical harm spans all providers – hospitals, doctors, dialysis centers, nursing homes and outpatient surgical centers – most of what we know is limited to what happens in hospitals. And what we know about hospitals is a very small part of the comprehensive problem.

More than ten years ago, the Institute of Medicine (IOM) estimated that annually 98,000 patients lost their lives due to medical harm.[3] Even then it was contradicted by CDC data that estimated 88,000 deaths from infections alone.[4] Using 2002 data, CDC updated their estimate to 99,000 deaths from hospital-acquired infections.[5] And the agency's 2014 prevalence estimate, based on a 2011 study was 722,000 infections in 648,000 patients and 75,000 deaths. This reflected a change in the incident rate from 5% to 4% of hospital patients or on any given day, 1 in every 25 patients will get an infection.6 Clearly this is very slow progress that cries out for more attention. CDC's media statement said, "Although there has been some progress, today and every day, more than 200 Americans with healthcare-associated infections will die during their hospital stay."

Further, antibiotic resistant infections are reaching epidemic proportions, creating another crisis

in the treatment of infections that occur. Even if there were many drug developers working on new antibiotics, the scientists cannot keep up with the bugs. By the time new antibiotics are on the market, resistances to them are forming. We cannot research our way out of this problem. The only way out is rigorous infection prevention and aggressive antibiotic stewardship programs throughout the country.

When it comes to tracking medical errors, we don't really know how many hospital patients are harmed because there is no national effort to collect this information or to make it public. But three landmark studies in 2010 and 2011 gave us some solid estimates of how often these errors and infections happen.

The studies rocked the confidence of experts in the field who assumed piecemeal efforts to prevent medical harm were having an overall effect on improving patient safety. All of these studies looked at all harm – from minor to major – and included both errors and infections. All emphasized the need for the system to focus on a broader array of adverse events than the National Quality Forum list of serious adverse events. All used techniques that avoided the underreporting problems common to hospital self-reporting and misleading billing data.

- US Health and Human Services Office of Inspector General (OIG) based its study on Medicare data and found that 27% of Medicare patients hospitalized in October 2008 were harmed from medical care. One in seven of them endured long-term and serious harm from hospital care (defined as events resulting in prolonged hospitalization, permanent disability, life-sustaining intervention, or death).[7] The OIG estimated that 44 percent of the harm identified was preventable.
- New England Journal of Medicine (NEJM) study revealed similar findings - one in four hospital patients are harmed.[8] This study was done in North Carolina where there had been a high level of engagement in efforts to improve patient safety during the six years covered by the study. Despite this work, the surprising findings showed little evidence that harm had decreased substantially over that 6-year period. At the time, no public reporting of infections or errors was required of North Carolina hospitals. Without information about medical harm, the public cannot hold these hospitals accountable for their errors. The NEJM study found that 63% of these events were preventable and made the important point that "preventability" changes over time as new ways to keep patients safe are tried and measured.
- Health Affairs study using the Institute for Healthcare Improvement's global trigger tool[9] found that one in three hospital patients are harmed.[10] The study compared three methods for detecting adverse events in patients hospitalized in three large tertiary care centers, all teaching hospitals with well established patient safety programs, and found the most common methods used to track patient safety in the U.S. – self reporting and pulling information from administrative billing documents - missed 90% of adverse events.

A 2013 study, "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care," translated existing research into a reliable estimate of how many patients die from medical errors each year. Based largely on the findings cited above, the study estimated that the premature deaths of more than 400,000 patients each year was associated with preventable medical errors.[11] When undetected diagnostic errors were added to that number, the study estimated up to 440,000 patients are harmed each year. These new estimates established medical harm as the third leading cause of death in the US.

THE ROLE OF PUBLIC TRANSPARENCY IN IMPROVING SAFETY

Consider if Consumer Reports tested 50 cars and found some performed well and others were unsafe, but refused to reveal which cars fell into each category. The public would not be served by such evaluation and it would seem ridiculous to go to the trouble of looking at this information and then hiding it. But that is how reporting on patient safety issues was traditionally handled. Summaries that do not identify the hospital or physician in charge of patients' care when errors occurred are not useful - the information should be publicly tied to where the harm occurred. In recent years, the trend has been changing and it has provided useful tools for improvement – fundamentally, one cannot measure progress unless metrics are being documented.

In the past ten years, 31 states and the District of Columbia have mandated public reporting of certain hospital-acquired infections and these hospital-specific reporting laws have stimulated more activity around infection prevention than this nation has ever seen. And, now federal hospital payment policies have created incentives for reporting infections that hospitals in non-reporting states cannot ignore. Although this infection reporting is still giving us a limited snapshot, new measures are being added each year. Only two states – Pennsylvania and California – require the kind of comprehensive reporting needed to evaluate hospitals' overall infection safety.

However, current requirements for reporting other types of medical harm 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. Currently, about half of the states require hospitals to report certain types of medical harm, but only 10 require reporting this information by hospital. At the federal level, some medical complication information is revealed through the Hospital Compare website, but it is limited. Without hospital-specific information, key elements for stimulating change are missing: public accountability and hospitals' awareness of their record and that of their peers.

Another hurdle exists in deciding which events should be reported. A 2010 series in the Seattle Times clearly illustrated the problems arising from narrowly defining "harm" in a way that ensures most harm will not be reported. One article told of a man who entered the hospital for a simple outpatient arthroscopic shoulder surgery and, according to state investigation records, sustained brain damage and died due to nursing errors, including a misadministration of pain medication. This was clearly a case of preventable medical harm but the harm did not fit into any definitions under Washington state's reporting law, so was not reported. These are the issues that the previously mentioned studies by the Office of Inspector General and the NEJM pointed to in their conclusions – we need a system that identifies all preventable harm, not just those that fit into a narrow definition.

The question often asked is whether public transparency improves safety. While it is impossible to parse out the impact of public reporting mandates from the prevention activities they have stimulated and the programs that followed to tie payments to performance, we do have some evidence that transparency is making a difference.

In a report issued last March, the Center for Disease Control and Prevention (CDC) documented a 44% decrease in central line associated bloodstream infections between 2008 and 2012. This is the one measure that almost every state with an infection disclosure law required to be reported. Further, CDC reported that the rates of other types of infections are coming down: 20

percent decrease in infections related to the 10 surgical procedures tracked between 2008 and 2012; four percent decrease in hospital-onset MRSA between 2011 and 2012; and two percent decrease in hospital-onset C. difficile infections between 2011 and 2012.

Many states have documented similar reductions from year to year in their public reports. For example, in New York, overall surgical site infection rates had decreased by 16% between 2007 and 2012, resulting in a cost savings estimated to be between $12.1 million and $35.4 million since 2007. And, bigger improvements were made in specific surgical procedures such as coronary artery bypass surgery, a 23% - 47% decrease since 2007.[12] New York is probably the most reliable state, as it has validated the infection data each year.

There are cultural changes that come with public transparency. Minnesota is one state that publishes facility-specific information about medical errors on a state Minnesota Department of Health website. 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."

Evidence of individual hospital successes to reduce errors abound and federal programs recently documented a nine percent decrease in hospital acquired conditions and an eight percent decrease in readmissions, which are often connected to errors or infections.[13] None of this documentation would be possible without public reporting mandates.

ANOTHER KIND OF TRANSPARENCY IS NEEDED

Transparency at the patient level is absolutely critical to ending medical errors. When patients are harmed, they often are subjected to additional harm when caregivers fail to disclose or explain what happened. Medical records are withheld or altered or never documented accurately. Many families have to file lawsuits just to get information about how their loved ones' died. This is the underbelly of medical errors – the cover-ups and the insults to injury. We must create a more just and fair system that encourages discussions without requiring patients' rights in exchange, that compensates patients for their losses and that treats them with dignity and respect.

RECOMMENDATIONS

Because of the significant scope of this problem – tens of thousands of service delivery points and hundreds of millions of patient contact points – the solutions can seem overwhelming. Many programs are in place today but they are fragmented and the results of their efforts are difficult to track. Fundamentally, as a nation, a comprehensive, coordinated approach is needed. This is why Consumers Union and many of the advocates with whom we work are supporting the creation of a National Patient Safety Board, modeled after the National Transportation Safety Board. We would welcome the opportunity to work with members of Congress to develop a plan for creating this oversight agency.

Some additional recommendations are briefly listed below. More information about them can be provided upon request.

- Support the infrastructures needed for public reporting and tracking of infections and errors. For example, the CDC's National Healthcare Safety Network (NHSN) collects information from more than ten thousand providers. We need to sustain this system and ensure that it can grow in capacity into the future. This should include funding to the states to validate data being reported.
- Expand hospital infection reporting so that infections are being documented throughout the hospital and consumers have a clear picture of a hospital's overall infection rate.
- Mandates are needed for antibiotic stewardship. Require hospitals to report on antibiotic usage and resistant infections using CDC-NHSN's new modules for this purpose.
- Require medical error reporting. Electronic billing records could be used as a resource for documenting these events by improving their accuracy. Create a rigorous validation process that includes fines for hospitals that fail to accurately document patient stays.
- Require death certificates to indicate when infections or errors are the cause of death and document the presence of these events preceding or at the time of death.
- Hospital infection outbreaks should be disclosed to the public, the patients in the hospital, and patients being admitted.
- Make the National Practitioner Data Bank public so patients can refer to it to check on physicians that have licenses in multiple states.
- Continue adding measures to Medicare pay for performance programs and consider standardizing how incentives and penalties are calculated. Keep the programs growing but simplify the calculations.

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[2] http://www.aha.org/research/reports/tw/chartbook/2014/table3-1.pdf. According to the AHA, in 2012 approximately 34 million people were admitted to American hospitals; one in four is calculated as 8.5 million patients.

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

[4] MMWR Weekly, February 25, 2000; "Fourth Decennial International Conference on Nosocomial and Healthcare-Associated Infections;" http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4907a4.htm

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[9] http://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx

[10] David C. Classen, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C. Whittington, Allan Frankel, Andrew Seger, and Brent C. James; "'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured," Health Affairs, April 2011, 30:4

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[12] "Hospital Acquired Infecitons, New York State, 2012," New York State Department of Health, Albany, NY, September 2013; page 4; https://www.health.ny.gov/statistics/facilities/hospital/hospital_acquired_infections/2012/docs/hospital_acquired_infection.pdf

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