In a May 3 article in the British Medical Journal, Dr. Martin Makary and Michael Daniel challenge the current practice of using International Classification of Disease (ICD) codes to document cause of death on death certificates. Causes of death not associated with ICD codes, such as human and system factors, are not captured. (Makary, Daniel, “Medical Error: The Third Leading Cause of Death in the United States”, BMJ, 5/3/16).

Since the Institute of Medicine (IOM) report, “To Err is Human” was published in 1999 a number of studies have estimated preventable death by medical error. Estimates range from 98,000 (“To Err is Human”) – 440,000 (Journal of Patient Safety, John James) per year. Makary and Daniels calculated a mean rate of death from medical error of 251,454 annually, but state that this is probably an underestimate because studies cited rely on errors identified and extracted from health records and include only inpatient deaths. Even at this understated rate, medical error is the third leading cause of death in the U.S., after heart disease (614,348 deaths/year) and cancer (591,699 deaths/year).

In a May 1 letter to Thomas Freidan, Director, U.S. Center for Disease Control and Prevention (CDC), Makary, et al call for a change in the way the CDC collects vital health statistics related to common causes of death. Current policy requires that death certificates can only be tabulated with an ICD billing code; a patient who dies directly from a medical error is not counted in national statistics. Makary, et al recommend that the CDC allow clinicians to list medical error as the cause of death on death certificates and in the interim, list medical error as the third most common cause of death in the U.S.

Makary, et al, point out that research for heart disease and cancer prevention is well-funded, unlike prevention of medical errors. Makary states, “It is time for the country to invest in medical quality and safety proportional to the mortality burden it bears.”

What are the implications of underreported deaths due to medical errors for Maine? The rate of death due to medical error per 1,000 patient days can be calculated using the total number of patient days in the U.S. and the estimated number of deaths due to medical error:

- The American Hospital Directory reports 148,698,602 patient days in the U.S. per year;
- For the lower estimate of 98,000 deaths due to medical error the rate per 1,000 patient days is 0.66;
- For the upper estimate of 440,000 deaths due to medical error the rate per 1000 patient days is 2.96;
- Using these rates and the 714,366 inpatient days in Maine (American Hospital Directory), there could be between 471 and 2,114 preventable deaths due to medical errors in our state each year.

In 2015, 202 sentinel events were reported for all reasons, not just unanticipated death. Comparing this with the estimates of death due to medical error listed above, one could conclude that Maine is either a much safer state in which to be hospitalized, or that Maine hospitals are grossly underreporting unanticipated deaths due to medical errors. We believe that neither of these conclusions is accurate. Rather, it points to the fallibility of research related to preventable deaths due to medical error, and speaks to the need for a more systematic approach to collect this important data. In absence of such an approach, hospitals and other healthcare facilities must continue to focus on patient safety and heighten surveillance of processes to identify risks and mitigate the impact of medical errors.
END OF THE ROAD FOR ANTIBIOTICS

A 49-year-old female treated at a military clinic in Pennsylvania was found to have e-coli in her urine, resistant to colistin, the antibiotic of last resort. According to CDC Director Tom Friedan, M.D. this discovery “basically shows us that the end of the road isn’t very far away for antibiotics – we may have patients in our intensive care units, or patients getting urinary tract infections for which we do not have antibiotics.” (The Washington Post, 5/27/16)

This is one more indication that we are entering into the post-antibiotic era, the result of over-prescribing and misuse of antibiotics. In 2014, the CDC recommended that all U.S. acute-care hospitals implement an antibiotic stewardship program to guide efforts to improve appropriate and necessary antibiotic use, and released the Core Elements of Hospital Antibiotic Stewardship Programs. This can be accessed at: http://www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf

The accompanying CDC Checklist can be accessed at: http://www.cdc.gov/getsmart/healthcare/implementation/checklist.html.

In May 2016, the National Quality Forum (NQF) released “Antibiotic Stewardship in Acute Care: A Practical Playbook”. This document offers practical strategies for implementing high-quality antibiotic stewardship programs in hospitals nationwide and can be accessed at: http://www.qualityforum.org/Publications/2016/05/Antibiotic_Stewardship_Playbook.aspx?utm_source=internal&utm_medium=link&utm_term=ABX&utm_content=Playbook&utm_campaign=ABX

On June 13, CMS announced that it is proposing to update the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in Medicare and Medicaid. Under the proposed rule, hospitals and CAHs would be required to:

- Have hospital-wide infection prevention and control and antibiotic stewardship programs for the surveillance, prevention and control of hospital-associated infections and other infectious diseases, and for the appropriate use of antibiotics;
- Designate leaders of the infection prevention and control program and the antibiotic stewardship program who are qualified through education, training, experience or certification. This requirement allows for flexibility in staffing in order to suit the needs of each hospital and CAH.

Additionally, these proposed changes would reflect current standards of practice and support improvements in care by: reducing admissions, reducing barriers to care, addressing workforce shortage issues and improving patient protections.

There is a 60 day comment period for the proposed rule. For more information visit: https://www.federalregister.gov/public-inspection.

LEADERSHIP IN PATIENT SAFETY

CONFERENCE HELD

The important role leaders play in creating and maintaining an environment that supports patient safety was the theme of the Sentinel Event-sponsored Patient Safety Conference, held May 4. Dr. Allan Frankel, international patient safety expert and consultant, was the keynote speaker. Dr. Frankel discussed the framework for clinical and operational excellence. He emphasized the importance of leadership in creating an environment that supports teamwork that identifies and acts upon defects and that also supports a safety climate and resilience. Burnout in healthcare is endemic, he said, and creating resilience and mitigating burnout requires leaders to balance job demands with resources. Dr. Frankel addressed the importance of local department/unit-level management and managers as leaders. Research has shown that the most significant factor in determining job satisfaction is the employee’s relationship with his/her immediate supervisor.

Jeffrey Brown, a consultant in human factors and cognitive systems engineering, provided examples of unanticipated consequences of decision making across high-risk industries. Mr. Brown also illustrated the reactionary approach that many healthcare facilities have toward patient safety where safety gains attention after a serious adverse event and reverts to a state of complacency over time. This ‘accident seesaw’ can be dampened through highly sensitive surveillance, such as identification of risk triggers, prospective investigation, team debriefing, safety reporting and walk-arounds.

The importance of leadership in supporting patient safety was emphasized by the five leaders from various healthcare facilities in Maine who presented their personal experiences. Bob Peterson, CEO Millinocket Hospital discussed the challenges faced by critical access hospitals – although smaller, CAHs have the same issues as larger hospitals. Peterson said “running a hospital is not a job for the meek; doing the right thing often takes courage”. He encouraged learning from unexpected events. Serious adverse events can happen at any hospital. He underscored the importance of collective learning from sentinel events, regardless of where the events occur.

Mary Jane Krebs, CEO of Spring Harbor Hospital, described her experience in building a culture of safety by establishing trust within an organization that had experienced significant upheaval. Krebs discussed the challenge of maintaining a commitment to a blame-free environment and outlined her leadership approach:

- Be consistently person-centered in word and deed;
- Be a regular, authentic presence at the front line and a visible champion of improvement;
LEADERSHIP IN PATIENT SAFETY CONFERENCE (CONTINUED)

- Remain focused on the vision and strategy;
- Require transparency about results, progress, aims and defects; and
- Encourage and practice systems thinking and collaboration across boundaries.

Jeffrey Wigton, Director of Operations and Dr. James Timoney, Partner, Central Maine Orthopedics, discussed patient safety from an ambulatory surgical center perspective. In their setting, culture is tied to physician leadership. Organizational vision is based on managing from metrics and standardization of care. Wigton presented examples of both quality and organizational metrics. Dr. Timoney emphasized the importance of patient selection in ensuring patient safety. ASCs have limited resources, and must select patients based on established standards. ASCs can be a cost-effective surgical option for provision of safe, quality care.

Jeffrey Sanders, COO and Erin Graydon-Baker, Director of Risk Management, Maine Medical Center (MMC) discussed patient safety at a tertiary care center. The importance of ‘values in action’ was explored. For MMC, this includes patient centeredness, integrity, respect, ownership and innovation. Sanders reviewed steps MMC has taken in transforming its organizational culture and the importance of celebrating staff accomplishments. Graydon-Baker discussed safety reporting as a measure of culture and the benefits of safety reporting. MMC’s electronic reporting system allows managers to receive reports of events in a timely manner and enhances the ability to resolve serious cases.

The Patient Safety Conference was well-attended, with participants representing 30 hospitals, six ASCs and eight ESRDs. Evaluation forms were provided. Of those completing evaluations, all agreed that the program met their expectations. Ninety-six percent felt that the program caused them to think about their work differently and 88 percent indicated that they learned something that would cause a change in practice. Responders indicated that they would like future programs to address patient safety, changing the culture of safety, quality/risk/safety, sentinel events, sharing of lessons learned, strategies to prevent staff burnout and root cause analysis.

Some of the comments that were made on the evaluation forms include the following:
- “Dynamic speakers with a constant message presented from different angles”;
- “Enjoyed collegial approach to facing patient safety challenges – specifically with other teams in Maine”
- “Great variety of topics”
- “Truly one of the most beneficial seminars I’ve attended.”

SENTINEL EVENTS TEAM ON-SITE REVIEWS

The Sentinel Events Team began conducting on-site reviews to ensure that facilities are in compliance with applicable regulations in 2015, to date, eight on-site reviews have been completed. The on-site reviews include an assessment of facilities’ compliance with the administrative requirements that are outlined in the 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events, Chapter 2, Facility Responsibilities. A review of medical records is also conducted, based on facility-specific history of sentinel events, state-wide sentinel events being reported, and adverse events gaining national attention.

As part of the on-site reviews, the SET identifies positive aspects of facilities’ patient safety programs. Below are some of the ‘best practices’ that have been identified:

- **Routine use of root cause analysis to review events – even those that do not rise to the level of a sentinel event.** This demonstrates organizational commitment to continuous learning from adverse events and implementing process changes that may prevent a sentinel event from occurring in the future;

- **A multi-disciplinary committee that includes physicians, board members, hospital administration, nursing and other clinical staff and community members.** This demonstrates the organization’s willingness to be transparent about quality and safety, and includes the ‘patient voice’ in the committee activities;

- **Patient safety reports and discussions at board meetings.** This shows that patient safety is an organizational priority and that board members are kept apprised of sentinel events and patient safety activities taking place in the facility;

- **Use of control charts to track data for readmissions, average length of stay and falls, allowing for identification of common cause and special cause variation, and the impact of process changes.** Looking at data over time, and understanding variation is important in process improvement efforts;

- **Review of all new projects and process redesigns to conduct assessments using concepts of Failure Mode Effect Analysis to assess potential risks and identify risk mitigation strategies.** Failure mode effect analysis is a proactive approach to safety management;

- **Identifying the need to support staff involved in sentinel events.** This is essential in a ‘just culture’, and acknowledges impact on staff of sentinel event.
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DIVISION OF LICENSING AND REGULATORY SERVICES,
MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES
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SENTINEL EVENT TEAM
UPDATES AND ANNOUNCEMENTS

The Muskie School of Public Health’s Patient Safety Academy will take place on Thursday, September 8 at the Abromson Center, USM Portland Campus, featuring Dr. J. Bryan Sexton, Director of Duke Patient Safety Center, Duke University Health System. Dr. Sexton will present two seminars:

- Intersection of Safety Culture, Psychological Safety and Workforce Resilience; and
- Resilience Enhancing Tools: Cultivating Kindness, Moments of Awe and Wonder.

Registration link: https://usm.maine.edu/muskie/psa

Next Collaborative Workgroup – the SET is planning the next Collaborative Workgroup regarding fall prevention, and is looking for facilities to present their challenges and successes in fall prevention. Interested parties, please contact Joe Katchick joseph.katchick@maine.gov; or Madeline Orange madeline.orange@maine.gov.

Mini-workshops – the SET plans to develop and present mini-workshops related to conducting root cause analysis and performance measurement. These will be offered in various parts of the state. More to come regarding times/places.

SENTINEL EVENT TEAM
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