Contents

array of adverse events has always been in question. The electronic health record (EHR) contains clinical data that can be systematically reviewed to identify adverse events and improve adverse event detection. Active use of an automated trigger tool that is embedded in an EHR can identify systematic issues with delivery of high-risk medications and is cost-effective and efficient. Further development of an automated adverse event detection protocol for pediatrics is needed to apply this approach systematically across pediatric institutions.

Despite increasing attention and discussion, patient harm remains an important issue in health care. Defining and identifying harm remains challenging, and little standardization in approach exists. This summary describes an approach to identifying hospital-wide preventable harm with focused safety efforts using the Preventable Harm Index as a measure of progress and as a metric to motivate improvement. Our hospital's significant decrease in serious safety events, mortality, and preventable harm is outlined.

Since the launch of the 100,000 Lives Campaign by the Institute for Healthcare Improvement (IHI), preventing medical adverse events to reduce avoidable mortality has emerged as a central focus for health care providers, institutions, regulators, insurance companies, and patients. Evidence-based interventions targeting the 6 interventions in the campaign have been associated with a reduction in preventable hospital deaths in the United States. The generalizability of the IHI's campaign to the pediatric population is only partly applicable. Pediatric experiences with rapid response teams and preventing central-line infections parallel the published experience of adults, with promise to significantly reduce preventable pediatric mortality.

The morbidity and mortality conference (M&M) is a long-standing practice in medicine. Originally created to identify errors and improve care, the primary focus of M&M has moved toward an emphasis on education of trainees. A structured format for the M&M conference can help the interdisciplinary team address causes of adverse patient outcomes and identify opportunities for systems improvement.

Sleep deprivation is common among resident physicians and clinical fellows. Current evidence about sleep science, performance, shift work,

and medical errors consistently demonstrates positive impact from reduction of excessive duty hours, particularly when shift length is shortened. This article provides an overview of this literature, highlighting research on diminished physician cognitive performance due to sleep deprivation and the increase in the number of medical errors that is seen under these conditions. Accreditation Council on Graduate Medical Education trainee duty hour guidelines are reviewed. Practical approaches to evidence-based scheduling of shift-work are also discussed, with attention to improving patient safety.

Sharon Griswold, Srikala Ponnuru, Akira Nishisaki, Demian Szyld, Moira Davenport, Ellen S. Deutsch, and Vinay Nadkarni

Simulation-based educational processes are emerging as key tools for assessing and improving patient safety. Multidisciplinary or interprofessional simulation training can be used to optimize crew resource management and safe communication principles. There is good evidence that simulation training improves self-confidence, knowledge, and individual and team performance on manikins. Emerging evidence supports that procedural simulation, deliberate practice, and debriefing can also improve operational performance in clinical settings and can result in safer patient and population/system outcomes in selected settings. This article highlights emerging evidence that shows how simulation-based interventions and education contribute to safer, more efficient systems of care that save lives.

Daniel R. Neuspiel and Erin H. Stubbs

Understanding of the types and frequency of errors among children in the outpatient setting is paramount. The most commonly described errors involve medical treatment, communication failures, patient identification, laboratory, and diagnostic errors. Research suggests that adverse events and near misses are frequent occurrences in ambulatory pediatrics, but relatively little is known about the types of errors, risk factors, or effective interventions in this setting. This article will review current information on the descriptive epidemiology of pediatric outpatient medical errors, established risk factors for these errors, effective interventions to enhance reporting and improve safety, and future research needs in this area.

Marilyn Neder Flack, Thomas P. Gross, Joy Samuels Reid, Thalia T. Mills, and Jacqueline Francis

Special initiatives exist in FDA's Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research to ensure the safety and effectiveness of medical products used in the vulnerable pediatric population. This article focuses on the special programs, projects, and special studies

Contents

implemented by CDRH to ensure this safety and effectiveness in devices used in pediatric patients throughout the devices' total product life-cycles. Pediatricians play a major role in keeping medical devices safe for use in children by reporting device problems to FDA.

Angela Mickalide and Kate Carr

Unintentional injuries are predictable and preventable. Yet every hour, a child in the United States dies from an unintentional injury. Globally, the number is even more staggering, with nearly 1 million children dying from unintentional injuries each year. Motor vehicle–related injuries, burns, drowning, falls, suffocation or choking, and poisoning are just a few of the unintentional injury risks threatening children. Patient safety requires a three-pronged strategy of behavior change, use of safety devices, and improvement of laws and regulations to ensure that all children lead healthy and productive lives.