Surgical never events and contributing human factors

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Introduction. *We report the first prospective analysis of human factors elements contributing to invasive procedural never events by using a validated Human Factors Analysis and Classification System (HFACS).*

Methods. *From August 2009 to August 2014, operative and invasive procedural "Never Events" (retained foreign object, wrong site/side procedure, wrong implant, wrong procedure) underwent systematic causation analysis promptly after the event. Contributing human factors were categorized using the 4 levels of error causation described by Reason and 161 HFACS subcategories (nano-codes).*

Results. *During the study, approximately 1.5 million procedures were performed, during which 69 never events were identified. A total of 628 contributing human factors nano-codes were identified. Action-based errors (*n *= 260) and preconditions to actions (*n *= 296) accounted for the majority of the nano-codes across all 4 types of events, with individual cognitive factors contributing one half of the nano-codes. The most common action nano-codes were confirmation bias (*n *= 36) and failed to understand (*n *= 36). The most common precondition nano-codes were channeled attention on a single issue (*n *= 33) and inadequate communication (*n *= 30).*

Conclusion. *Targeting quality and interventions in system improvement addressing cognitive factors and team resource management as well as perceptual biases may decrease errors and further improve patient safety. These results delineate targets to further decrease never events from our health care system. (Surgery 2015;158:515-21.)*

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It is estimated that physicians operating on bilateral structures have a 25% lifetime risk of wrong-site surgery, and an average-size surgical center reports the incidence of approximately 1 retained foreign object (RFO) per year.[1] Wrong site/side surgery, wrong implant, wrong procedure, and RFOs have been termed "never events" and are included in the 29 serious, reportable health care events as defined by the National Quality Forum and the Joint Commission.[2,3] Never events can lead to serious physical or psychologic harm for the patient, the teams caring for the patient, and the relationship between the patient and provider.[4] At an institutional level, such events add a serious financial burden as a consequence of their medical-legal implications as well as a negative impact on the reputation of the health care provider. Therefore, a better understanding of why these events occur and efforts directed at decreasing their frequency are important for patient safety, provider well-being, and society.

The current incidence of never events in the United States is poorly understood. Prospectively collected data on the incidence of never events are limited, and most studies involve voluntary reporting to external agencies with inherent bias. Retrospective analysis suggests a rate of never events 1 in 12,248 operations in the United States[5] and 1 in every 20,000 procedures in the National Health System in the United Kingdom.[6] Studies investigating adverse events and events, such as RFOs, suggest that the rate may be greater.[7] In addition, there is concern that the frequency of RFOs may be increasing.[5]

Health care professionals and systems engineers have been working to improve conditions in the operating room (OR) and procedural environment for more than a century to ensure these events do not occur. On the basis of a systems safety approach, the majority of medical errors are believed to be the product of inadequately designed systems that permit predictable human errors.[8] This concept has been formalized by Reason as the "Swiss cheese" model, where events occur as the result of a problem passing undetected through minor defects in multiple layers of a system's defenses, allowing a serious, potentially fatal event to occur.[9]

Another concept, Perrow's theory of "Normal accidents," holds that in modern, high-risk systems, the degree of system complexity, tight coupling of processes, and the inability of a single individual or small group of individuals to manage all the potential interactions will lead inevitably to accidents with catastrophic potential.[10] Both theories imply that errors and accidents cannot be designed around, because people make mistakes. Many problems arise from small beginnings and organizational failures may play an important role; individuals, however, remain at the tip of the spear in both contributing to and potentially preventing errors.[10] With a better understanding of human–system interactions, important gains have been made to understand why these events occur and to re-engineer the systems to prevent them in the future.[11]

Although systems play a major role in allowing errors to escape system notice, an essential component of medical care are the individuals who have the potential to recover from system error.[12] Understanding the contributing human factors and their effect on medical errors is essential. Once an event occurs, root cause analysis (RCA) is a standard method within health care organizations to evaluate medical errors. Unfortunately, RCAs with the resultant education initiatives and system redesign alone may not be sufficient to eliminate never events.[13] Human factors analysis, used widely in other industries, can enhance RCAs and provide an additional perspective on the system. To allow systematic analysis of human factors in accidents in military aviation, Wiegmann and Shappell[14] developed and validated the Human Factors Analysis and Classification System (HFACS). The HFACS methodology has been validated across several industries[15] as well as medicine.[16,17] In this study, we review the results from the prospectively applied HFACS methodology to surgical and procedural never events at our institution.

METHODS

From August 31, 2009, to August 31, 2014, an electronic incident-reporting system captured all reported (including anonymously reported) patient events and near misses for the quality management team at a tertiary-care hospital. All cases of wrong site/side surgery, wrong procedure, wrong implant, and unintended RFO after surgery or other invasive procedure were considered never events and included in our analysis. Operative or other invasive procedural never events underwent RCA with involved team members individually and at a joint meeting. The joint meeting included the team members involved (physicians, nurses, technicians, residents), quality management, clinical practice, and administrative leadership. The meetings occurred as contemporaneously as possible after the event was discovered to determine quickly the contributing systems and human factors involved. For the majority of the reporting period, RFOs were reviewed within 48 hours, and all events were reviewed on average within 2 days of identification.

In addition to the standard review, a trained, quality management specialist coded each event using the HFACS tool modified by Diller et al (Appendix, online version only).[16] Following the categories proposed by Reason, the never events were described in 4 categories: (1) unsafe actions, (2) preconditions for unsafe actions, (3) oversight/supervisory factors, and (4) organizational influences (Fig 1). *Unsafe actions* included issues with protocol compliance (eg, bending the rules or breaking the rules) or errors, such as perceptual errors (eg, misunderstanding a situation) and decision errors (eg, inadequate treatment). *Preconditions for actions* included environmental, patient, situational, and behavioral factors; examples of preconditions include poor hand-offs or inadequate operative lighting. *Oversight/supervisory factors* included factors such as supervisor oversight,