Solution: A Practical Framework for Patient Care Teams to Identify and Mitigate Clinical Hazards

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IDENTIFICATION:
A primary AHRQ focus is to identify risks, hazards, and causes of patient injury associated with the delivery of health services. Indeed, one of the greatest challenges facing both practitioners and risk managers is the identification of previously unknown hazards. These threats to patient safety often lie at the apex of available knowledge and are rarely—if ever—obvious. With the rapid proliferation of new healthcare services, unknown hazards may propagate as new therapies are integrated into the existing healthcare system. The main goal of risk analysis is to make these hazards visible by proactively searching and probing the system. However, a comprehensive approach by which to safely integrate new therapies into the existing clinical environment has yet to be clearly articulated. The objective of this Patient Safety Solution is to describe a framework that patient care teams can use to prospectively identify and mitigate potential hazards for patients and caregivers when introducing new therapies in the clinical setting. We conclude with a presentation of three case examples.

PROCESS:
The methodology underlying this framework takes advantage of various types of simulation, including "talk-through" (i.e., a verbal description of activities to identify requirements for success and possible failure modes), "walk-through" (i.e., a step-by-step review of the care process, using all equipment and supplies that are used with patients), and "in situ" simulation (i.e., simulation in the actual operating room with actual practitioners) with a human-patient simulator (SimMan, Laerdal, NY) to identify defects. A hazard analysis is conducted to determine the severity, probability, and risk of the potential defects. After these defects are corrected, a multidisciplinary protocol and safety checklist are drafted, and a second in situ simulation is performed to pilot the checklist and ensure that the process is safe. We applied this framework to three operative scenarios: intraoperative radiation therapy (IORT), hyperthermic intraperitoneal chemotherapy (HIPEC), and an interventional pulmonology (IP) program. In each case, data were collected from simulation sessions held in the operating room that would be used for delivering the therapies to actual patients. All uncovered concerns and defects, provider interventions, reaction times, and outcomes during each session were recorded.

SOLUTION:
This framework identified and corrected 20 defects for IORT, 5 defects for HIPEC, and 18 defects for IP procedures. Each 4-hour simulation session was estimated to cost between $5000 and $10,000, factoring in personnel and facility utilization. To date, 15 patients have received IORT, 7 have received HIPEC, and 42 have undergone rigid bronchoscopies (as part of the IP program). One adverse outcome for a HIPEC patient was noted, with no adverse outcomes noted for IORT or IP patients.
When new healthcare services are introduced in the clinical environment, many organizations lack an organized method by which to reliably and efficiently identify a multidisciplinary course for safe implementation. As these healthcare services have universal components, using a comprehensive framework will help institutions to streamline their efforts and will increase the opportunity for learning across hospitals. As described here, simulation can be used to test processes and reorganize existing systems to introduce new therapies while prospectively identifying and mitigating hazards. The onsite-simulated environment has resulted in familiarity and comfort with procedures, amelioration of associated staff concerns, and standardization of practice, and has facilitated teamwork and communication between the distinct clinical cultures working in the perioperative environment. The use of simulation in this manner has been successful in three distinct clinical scenarios and is an efficient means by which to safely introduce new therapies, train teams, and mitigate risks prior to patient exposure.