

### Principles of Patient Safety and Quality Improvement in Urology \*

*Learning Objective:* At the conclusion of this continuing medical education activity, the participant will be able to describe the tools and techniques used to investigate patient safety events and implement quality improvement efforts in urology.

*Kristin Chrouser, MD, MPH*

**Disclosures:** Nothing to disclose

Associate Professor of Urology  
University of Michigan  
Ann Arbor VA Health Care Center

*Helen Fuller, PhD*

**Disclosures:** Nothing to disclose

Biomedical Engineer  
Co-Director, VA Interprofessional Fellowship in  
Patient Safety  
National Center for Patient Safety

*Tina Nudell, MS*

**Disclosures:** Nothing to disclose

Program Specialist  
Co-Director, VA Interprofessional Fellowship in  
Patient Safety  
National Center for Patient Safety  
Ann Arbor, Michigan

and

*Douglas E. Paull, MD, MS, FACS,  
FCCP, CHSE*

**Disclosures:** Nothing to disclose

Clinical Adjunct Assistant Professor of Medicine  
Georgetown University School of Medicine  
Clinical Learning Environment Review (CLER)  
Field Representative  
Accreditation Council for Graduate Medical  
Education (ACGME)  
Washington, DC

**\*This AUA Update addresses the Core Curriculum topic of Ethics and the American Board of Urology Module: Core/General Urology.**

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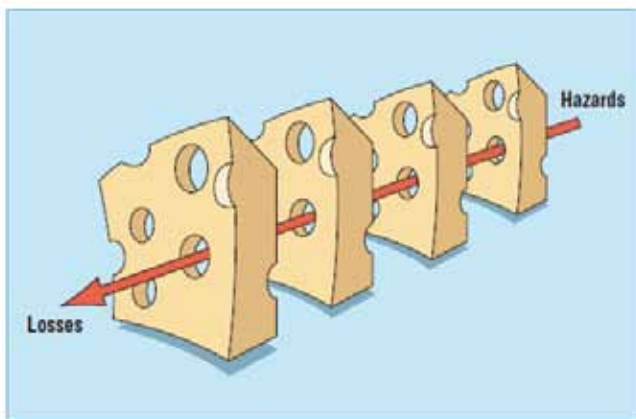
American  
Urological  
Association

Education and Research, Inc.  
1000 Corporate Boulevard  
Linthicum, MD 21090

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## PATIENT SAFETY

The purpose of patient safety is to prevent patient harm that occurs as a result of contact with the health care system and not to eliminate errors.<sup>1</sup> Patient safety systems promote a culture that recognizes human fallibility, implementing methods designed to prevent errors from reaching and causing harm to patients.<sup>1,2</sup> Reason's Swiss cheese model illustrates the system approach to medical errors (fig. 1).<sup>2</sup> Slices of cheese represent the various defense barriers protecting a patient from a hazard or unsafe condition. Individual slices might include teamwork and communication, equipment such as the electronic health record and organizational factors. However, there are holes within each of these slices representing latent errors (eg organization, inadequate staffing) that may have been present for some time.<sup>2,3</sup> An understanding of the Swiss cheese diagram and underlying latent conditions allows for building better defenses, filling in holes in existing barriers or constructing new barriers. Such system fortifications are far more likely to prevent future similar patient safety events and harm than simply focusing on who is to blame.



The Swiss cheese model of how defences, barriers, and safeguards may be penetrated by an accident trajectory

**Figure 1.** Swiss cheese diagram. Reprinted with permission.<sup>2</sup>

*Safe systems.* High Reliability Organizations: Industries such as aviation and nuclear power, where stakes are high but adverse events are low, address unsafe conditions before they cause harm.<sup>4</sup> **These high reliability organizations are characterized by leaders and workers who engage in ongoing team training, continually strive to optimize work processes to minimize error potential and willingly report unsafe conditions.** Health care organizations have less resilience than high reliability organizations. As an example, health care organizations often tolerate disrespectful or intimidating behavior in the workplace that discourages effective communication.<sup>5</sup> The 3 elements to

improve high reliability of health care offered by Chassin and Loeb are leadership commitment to eliminate patient harm, use of process improvement tools such as Lean and adoption of a safety culture throughout the organization that promotes reporting.<sup>4</sup>

*Adverse Event Reporting:* Common surgical adverse events include return to the operating room for procedural complications (eg bleeding), medication errors and health care acquired infections.<sup>6</sup> Reporting is fundamental to patient safety, not only the reporting of events causing patient harm, but also the reporting of close calls in which harm was narrowly avoided.<sup>1,3,4</sup> Reporting systems capture only a fraction of actual events. Nurses are more frequent reporters than physicians, and are more likely to understand what and how to report.<sup>3</sup> Close call and adverse event reporting designed to promote learning is often facilitated by web-based voluntary reporting systems in health care organizations. Many states also have mandatory reporting of serious patient safety events associated with harm (eg wrong-site surgery, retained surgical item, fire). The Joint Commission requires that an organization experiencing such a sentinel event conduct a timely root cause analysis to develop a plan to reduce the chance of recurrence.<sup>7</sup>

*Disclosure of Medical Errors:* Like many other health care providers, urologists are often unprepared to manage disclosure after a medical error. Shame, concern about one's professional reputation and fear of litigation are all barriers to transparency.<sup>8</sup> However, patients cite lack of transparency and poor communication as the main reasons they file lawsuits after a medical error or complication.<sup>9</sup> **Patients want to know what happened, why it happened, how the consequences will be managed and how this will be prevented in the future.**<sup>10</sup> They also want their physicians to apologize, although many physicians worry that apologies create legal liability. From a regulatory standpoint the Joint Commission and the American Medical Association codes of ethics require disclosure of unanticipated patient outcomes.<sup>11,12</sup> Some states mandate disclosure to patients, and many have apology laws to protect provider expressions of sympathy from being used in medical malpractice litigation.<sup>13</sup> Some medical schools and residencies provide hands-on training in error disclosure.<sup>14</sup> For those without access to such resources the Communication and Optimal Resolution process was designed to improve the disclosure and investigation of unexpected adverse events.<sup>15</sup> The process has been widely tested and training modules are available on the AHRQ (Agency for Healthcare Research and Quality) website.

*Safety culture.* Safety culture refers to the shared safety relevant individual values and institutional policies that influence attitudes and behavioral norms.<sup>16</sup> A closely related construct is "safety climate," which reflects the staff's perception of the organizational commitment to safety.<sup>17</sup> In surgical settings safety climate measures are correlated with safe behaviors such as intraoperative surgical checklist compliance and important patient outcomes such as postoperative mortality.<sup>18,19</sup>

*Culture Surveys:* Safety climate at the institutional level is measured using aggregated surveys such as the Safety Attitudes Questionnaire and the PSCHO (Patient Safety Climate in Healthcare Organizations) survey.<sup>17</sup> Most surveys assess dimensions related to safety, such as leadership, policies and

**ABBREVIATIONS:** MFI (model for improvement), QI (quality improvement), RCA (root cause analysis), VA (U.S. Department of Veterans Affairs)

procedures, staffing, communication and event reporting. Safety climate is used to compare institutions as well as to monitor change over time within an institution in response to intervention efforts.

**Just Culture:** Historically the organizational culture of health care tended to “shame and blame” individual providers who made errors. Unfortunately this led to fear of reprisal, poor rates of error reporting, and missed opportunities for institutional learning and improvement regarding adverse events and close calls. In contrast, an organization with a “just culture” balances individual and institutional responsibility, encourages transparency and error reporting, and promotes ongoing improvement.<sup>20</sup> All humans, including competent physicians, make mistakes. The work systems within which physicians practice influence the probability that error will lead to patient harm. In a just culture individuals are not held accountable for system failings outside their control, and physicians can admit their mistakes. At the same time a just culture maintains accountability by refusing to tolerate reckless physician behavior. Figure 2 illustrates a range of behaviors and responses.<sup>21</sup> The organization takes responsibility for designing safe work systems and learning from adverse events. **Just culture fosters mindfulness in workers, encourages individual and team accountability, and engages everyone in ongoing learning and system improvement.**<sup>22</sup>

**Surgical Culture:** The organizational culture within the operating room differs from the remainder of most health care organizations, likely due to increased production pressure, complex surgical equipment/technology, sick patients, intense personalities and stressful situations. **Traditional surgical teams are steeply hierarchical, with the surgeon as leader, potentially at the expense of the psychological safety required for high quality communication and teamwork.**<sup>23-25</sup> Surgeons more commonly engage in interpersonal conflict than other physicians and often struggle to navigate conflict without disrupting interpersonal relationships.<sup>26,27</sup> Poorly managed conflict can be a source of error resulting in patient harm.<sup>28</sup> Rudeness negatively impacts the cognitive skills of other team members, and impairs performance and teamwork.<sup>29</sup> Observational and interview studies note the vast majority of elective surgical cases have “high tension events,” most commonly between surgeons and nurses.<sup>30</sup> Tension may lead team members to withhold information or reduce collaboration, increasing the likelihood of mistakes.<sup>31</sup> In a survey of perioperative nurses 91% reported exposure to verbal abuse in the past year.<sup>32</sup> Reduction of disruptive behavior among health care workers has been targeted by the Joint Commission due to negative effects on patient care.<sup>33</sup>

**Tools for patient safety.** Team Training: Communication is the most common factor contributing to adverse events in health care.<sup>34</sup> Aviation has improved safety by deploying a set of


**STEP 1: Choose the column that best describes the employee's action. Read down the column for recommended responses.**

The employee was impaired by illegal or legal substances.	The employee wanted to cause harm.	The employee makes or participates in an error while working appropriately and in the patient's best interest.	The employee made a potentially unsafe choice. Faulty or self-serving decision making may be evident, or short cuts, or routine rule violations.	The employee knowingly violated a rule and / or made a dangerous or unsafe choice. The decision appears to have been made with little or no concern about risk.
<b>IMPAIRED JUDGEMENT</b>	<b>MALICIOUS ACTION</b>	<b>HUMAN ERROR</b>	<b>AT RISK Behavior</b>	<b>RECKLESS Behavior</b>
<ul style="list-style-type: none"> <li>Discipline is warranted if illegal substances were used.</li> <li>The employee's performance should be evaluated to determine if a temporary work suspension is helpful.</li> <li>Help should be actively offered to the caregiver.</li> </ul>	<ul style="list-style-type: none"> <li>Discipline and/or legal proceedings are warranted.</li> <li>The employee's duties should be suspended immediately.</li> </ul>	<ul style="list-style-type: none"> <li>The employee is not accountable.</li> <li>The employee should be consoled.</li> <li>The employee should be interviewed and consulted during any systems level analysis.</li> </ul>	<ul style="list-style-type: none"> <li>The employee is accountable and should receive coaching.</li> <li>The employee should participate in teaching others the lessons learned.</li> </ul>	<ul style="list-style-type: none"> <li>Discipline may be warranted</li> <li>The employee is accountable and should receive re-training/coaching as necessary.</li> <li>The employee should participate in teaching others the lessons learned.</li> </ul>

**STEP 2: If 3 other employees with similar skills and knowledge would do the same thing in similar circumstances. If YES proceed below.**

The system and/or culture supports error and requires improvement and/or re-design. Leaders are accountable and should apply error management in the system via human factors-based improvements.	The system and/or culture supports risky action and requires improvement and/or redesign. The employee is probably less accountable for the behavior. Leaders share accountability with the employee.	The system and/or culture supports reckless action and requires improvement and/or redesign. The employee is probably less accountable for the behavior. Leaders share accountability with the employee.
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**STEP 3: If history of repeated mistakes, the employee may be in the wrong position. Evaluation is warranted and coaching, transfer or termination should be considered. The corrective action should be modified accordingly.**



**NCPS**  
VA National Center for Patient Safety

*Safer Systems • Safer Care*

Adapted from: Leonard, M W, Frankel, A. The path to safe and reliable healthcare. Patient Edu. Course. 2019 Sep;50(3):298-292.

**Figure 2.** National Center for Patient Safety Just Culture Decision Support Tool.<sup>21</sup>

teamwork knowledge, skills and attitudes called “crew resource management.” Examples of crew resource management skills include conducting handoffs (such as situation, background, assessment, recommendation), assertiveness, closed loop communication (eg repeat back), participating in briefings and checklists.<sup>35</sup> Crew resource management, adapted and applied to health care as medical team training, has been associated with reduced patient morbidity and mortality, increased staff satisfaction and retention, and shorter lengths of stay.<sup>34,35</sup>

**Checklists:** WHO (World Health Organization) conducted a study of 3955 patients undergoing surgery with the use of a preoperative checklist at 8 global hospitals and compared the results to a group of 3733 patients undergoing surgery without the use of a checklist during a baseline period.<sup>36</sup> The 19-item checklist included a sign in (before anesthesia induction) when the surgical site is marked, equipment availability is ensured and pulse oximetry is placed; time-out when the patient’s identity, surgical site and procedure are confirmed, and any operative concerns or critical steps discussed; and sign out when counts are completed and confirmed, specimen labeling has been double-checked and any recovery concerns have been discussed. Use of the WHO checklist was associated with a decrease in mortality from 1.5% to 0.8% and a decrease in complications from 11% to 7%.<sup>36</sup> Neily et al examined the effect of medical team training in conjunction with checklist use.<sup>37</sup> Clinicians at 108 medical centers underwent medical team training and then implemented checklist guided, preoperative briefings and postoperative debriefings. There was a dose response relationship between mortality and the time when facilities used checklist guided briefings.

**Communication and Handoffs:** A handoff is the transfer of information and responsibility for providing care to a patient from a departing to an oncoming caregiver.<sup>38</sup> Poor handoffs have been associated with adverse events, delays in diagnosis and treatment, duplicate tests, and decreased staff and patient satisfaction. **Closed loop communication techniques, such as read and repeat backs, and minimizing distractions, improve the quality of handoffs.** Patient safety experts have advocated more widespread use of read and repeat backs (eg for communication in operating room) beyond those already required for critical laboratory tests and verbal orders.<sup>39</sup> Crew resource management techniques for minimizing distractions, such as the “sterile cockpit,” have been used to improve medication administration safety. Borrowed from aviation, sterile cockpit refers to the policy that no crew members engage in any activity or conversation during taxi, takeoff, landing or flight operations below an altitude of 10,000 feet that could distract them from their duties.<sup>40</sup> In the medical context nurses dispensing medications wear an orange vest. Signs warn patients, families and staff not to disturb the nurse. Implementation of such a sterile cockpit rule was associated with decreased distractions and medication error rate from 3.95 to 2.26 errors per 1000 bed-days.<sup>40</sup>

**Human Factors Engineering:** Human factors engineering is the scientific field of study concerned with understanding interactions between humans and other elements of a system by examining human capabilities and limitations, cognitive and physical, and other contributions to human behavior. It incorporates research findings from physiology, perception, cognition, memory, learning, motivation and stress. Some topics of study in human factors are shown in Appendix 1 (online issue

only). Human factors engineering is particularly relevant in the operating room, where teams physically interact with patients and a wide variety of instruments and technology, changing patient physiology and anatomy requires constant adjustment, and high stake decisions are commonplace. The area of human factors is important for patient safety because understanding interactions between humans and systems can aid understanding of how errors and adverse events occur as well as what system changes can reduce their probability, increase their detectability or mitigate resultant harm.

Human performance capability ranges across the population, and thus performance level for an individual is not always consistent and may be affected by external as well as internal factors. Context of use may also be variable, including user characteristics, task requirements and environmental constraints. It is important to account for this variability when designing technology, processes and work systems. For example, consider the variability in the task, the user and the environment when using surgical staplers.<sup>41</sup> The surgeon’s hand size and grip strength impact the ability to properly activate a stapler. Distraction or multitasking could result in a failure to load the stapler at the appropriate time, and a color vision deficiency or a change in the color scheme used by the manufacturer could lead the user to load the wrong cartridge. Also, a noisy environment or distraction could cause the surgeon to miss the auditory confirmation of the stapler firing.

Human factors engineering, sometimes referred to as usability engineering, applies principles, data and methods to optimize system performance and promote human well-being. This field focuses on changing the requirements of the task environment to fit the human rather than selecting the human to fit the task. It encourages permanent, physical changes when practical and recognizes that there are always design trade-offs. For example, powered staplers may be easier to fire for a surgeon with smaller hands but are also heavier and may increase strain on the upper extremity.

Saleem et al described the assessment of human factors problems in the surgical environment based on the following questions.<sup>42</sup> What level of mental workload will trigger a reduction in performance? How can this be detected or mitigated? Also, how does the design of a surgical tool impact performance, ease of use and ease of learning? Finally, how can the operating room be redesigned to enhance surgical performance and team communication?

Usability may be defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.”<sup>43</sup> Usability problems can lead to errors as well as injury to a patient or a clinician. In a study of defibrillators the button placement led some users to inadvertently shut off the device when they had intended to deliver a shock, resulting in a clinically significant delay.<sup>44</sup> Even minor usability problems increase task time and user frustration, leading to stress, work-arounds, opportunity costs and decreased trust in the system. Human factors practitioners understand the importance of iterative design and looking for usability concerns and unintended consequences. Techniques for evaluating usability include walk-throughs or observations, structured interviews, heuristic evaluations and usability testing. Reporting databases such as MAUDE (Manufacturer and User Facility Device Experience), and internal hospital reporting systems can also provide infor-

mation about usability problems that have been encountered. Manufacturers review the database and can opt to redesign a device associated with repeated reports of adverse events.

**Patient Safety Investigations:** Tools for analyzing and understanding safety events and risk are generally either retrospective or proactive. Either can be useful for understanding failures and improving patient safety.

**Root cause analysis is a technique for understanding why an adverse event or close call occurred. The goal is to identify underlying factors that contributed to the event and implement changes to prevent it from occurring in a similar way in the future.**<sup>45</sup> In a RCA an interdisciplinary team collects data and maps the sequence of events by interviewing subject matter experts and individuals involved in the event, focusing on systems and processes rather than individual performances. The team uses methods such as the “5 Whys” analysis, which was popularized by the Toyota Production System in the 1970s, to identify root causes. This strategy involves asking “why” a problem occurred and then repeating this question for the initial answer, often several times. Other RCA methods include the use of structured sets of analysis questions (“triage questions”) to identify possible causes and fishbone (Ishikawa) diagrams to sort causes into categories. Based on the analysis, the team generates recommended actions, which may be considered stronger, intermediate or weaker. Aggregating completed RCAs or conducting a joint RCA on multiple events, sometimes called an aggregated review, can generate additional information about the safety of a system by identifying common causes or areas of an organization that require attention. As an example, the VA National Center for Patient Safety collects safety reports and RCA submissions from all 132 VA surgical facilities. An analysis of incorrect surgery in the VA found that the top root cause was poor communication and the type of error varied by surgical subspecialty.<sup>46</sup>

**The Joint Commission requires hospitals to perform a proactive risk assessment every 18 months. One option is the VA’s Healthcare Failure Mode and Effect Analysis, in which a multidisciplinary team uses process flow diagramming to describe the process of interest.**<sup>47</sup> The team describes failure modes at each step and potential causes for each failure mode, and scores these using a hazard matrix that accounts for severity and probability. The team then uses a decision tree to determine whether to control, accept or eliminate the hazard. Finally, the team identifies actions and outcome measures, assigns a responsible party and obtains management concurrence for implementation. This analysis is particularly valuable for clinics and surgical centers to use before offering a novel procedure or technology.

## HEALTH CARE QUALITY

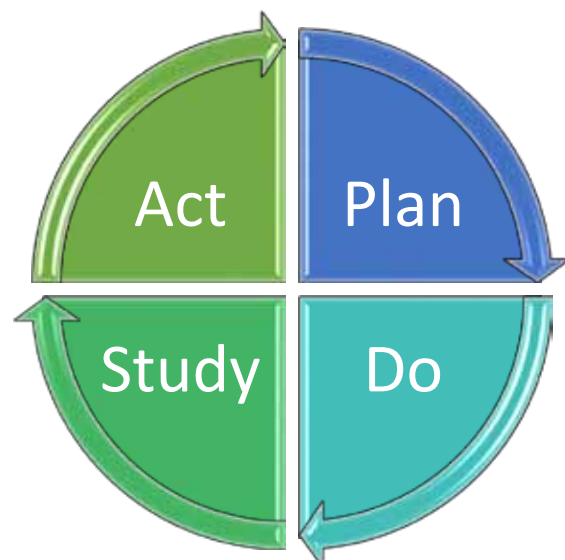
In the late 1980s manufacturing concepts of quality assurance and continuous quality improvement were initially adopted into health care. Institutional efforts often focused on improving efficiency and containing costs. Not surprisingly, there was tension between such efforts and those aimed at improving patient safety, which often require additional resources rather than immediate cost savings. The Institute of Medicine defines quality care as safe, effective, efficient, timely, patient centered and equitable (Appendix 2, online issue only).<sup>48</sup> Many patient safety advocates argue that safety is not simply a domain of quality health care, but rather its foundation. We acknowledge that safety is mission critical. However, since the tools used to

implement patient safety initiatives are similar to those used for other projects aimed at improving quality, we have included it here as a quality domain.

As urologists and leaders within our practices, hospitals and health systems, we can positively influence all the quality domains to varying degrees by improving the structure and processes of care. We can use evidence-based guidelines, the action items list of a recent local RCA or the results of patient safety intervention studies as starting goals for improving the care we deliver. Operationalizing these actions on a local level can benefit from several tools.

**Model for improvement.** The MFI was developed by Associates in Process Improvement and has been used by the Institute for Healthcare Improvement for a wide range of improvement efforts.<sup>49</sup> MFI starts with the questions 1) what are we trying to accomplish? 2) how will we know that a change is an improvement? and 3) what change can we make that will result in an improvement? Answering these questions promotes clear aims, measures of assessment and options for intervention/change. For example, to encourage a culture of safety, potential interventions include engaging in leadership rounds or establishing a non-punitive reporting policy for close calls and adverse events.<sup>50</sup> **Then small, rapid changes are tested on a small scale in a Plan-Do-Study-Act cycle** (fig. 3). “Plan” requires an assessment of what is necessary to set up this test of change and prediction of what might happen (and how to measure it). Potential data sources include patient medical records, institutional administrative data, observation of care episodes, and provider, staff and patient surveys/interviews. “Do” involves execution of the change itself and relevant data collection. “Study” involves description of the outcome measures and whether they are in line with predictions. Data can be plotted over time using a run chart for ease of assessment. “Act” requires deciding whether modifications are needed for the next cycle. After small-scale testing and refining through several cycles teams then develop strategies for sustaining change and assess the feasibility of implementation on a broader scale.

Change is required for improvement in health care. The MFI requires brainstorming ideas for change that will lead to



**Figure 3.** Quality improvement Plan-Do-Study-Act cycle.

improvement. Change concepts, combined with the practical expertise of local health care teams, can stimulate creative ideas for local incremental change for quality improvement. The change concepts in Appendix 3 (online issue only) have been applied to process improvement efforts in multiple industries but are of particular relevance to health care.<sup>49</sup>

*Lean, Six Sigma and Lean Six Sigma.* Lean and Six Sigma are also methodologies used to improve quality but in different ways.<sup>51,52</sup> Six Sigma, developed at Motorola in the late 1980s, is a data driven process focused on improving quality and maximizing profit by reducing variation in manufacturing and business processes using statistical tools. Adapted for health care, **Six Sigma focuses on the reduction of medical errors by removing variation and defects from processes of care using a defined sequence of steps, ie DMAIC (define, measure, analyze, improve, control).**<sup>52</sup> “Lean” principles, first used by Toyota to streamline vehicle production, have been adopted by some health care organizations as a strategy to decrease costs and improve quality. **Lean principles advocate identifying and eradicating waste to streamline processes and maximize quality.** In health care they are often used together, and such hybrid processes are known as Lean Six Sigma.

Categories of Lean waste are not mutually exclusive (Appendix 4, online issue only).<sup>53</sup> Figure 4 illustrates the 5 overarching principles of Lean. “Define value” is the first step in health care and requires learning what the patient desires, often through surveys and interviews. “Map value stream” involves identifying all activities that do not contribute to these values, then striving to eliminate or reduce them. “Create flow” ensures the flow of the remaining steps is smooth with minimal interruptions. “Establish pull” involves producing only what is needed when it is needed, which reduces inventory costs. “Pursuit of perfection” is what every employee should strive for, so the company is always learning and improving. While moving along



**Figure 4.** Five principles of lean. Reprinted with permission from Do D: The five principles of lean. The Lean Way, August 5, 2017; available at <https://theleanway.net/The-Five-Principles-of-Lean>.

this road map, there are Lean tools that can be useful.

A complete list of Lean tools can be found in a recent review of Lean principles in health care.<sup>55</sup> **These tools include Gemba walks, where managers go to the workplace to observe how work is done and engage with employees; value stream maps, which illustrate the process in order to quantify waste and cycle time; and A3 problem solving, known by the size of paper used (11" × 17"), which is similar to MFI and based on the Deming wheel or Plan-Do-Check-Act cycle.**<sup>51, 54</sup> Appendix 5 (online issue only) lists the A3 steps.<sup>49</sup> **Other tools include spaghetti diagrams, which help illustrate wasted physical motion of workers or patients, and a Kaizen blitz, which is a short-term intense project (rapid improvement event) used to improve a process.**<sup>55</sup> **Kaizen, literally “change good,” is the Japanese word for “improvement.”** In business kaizen refers to a culture that values ongoing improvement from the executive suite to the assembly line.<sup>55</sup> Professional certifications are offered by universities and consulting companies for Six Sigma, Lean Six Sigma (eg yellow, green and black belts) and Lean health care.

*Quality measures.* Quality measures are used to facilitate research and improvement efforts, assess performance of hospitals and providers, and assist patients in choosing where to access health care services. Most states require that hospitals report measures of health care associated infections such as catheter associated urinary tract infections. CMS (Centers for Medicare and Medicaid Services) has implemented quality initiatives to improve the care of beneficiaries. The Hospital Inpatient Quality Reporting Program reduces Medicare payments to hospitals that do not report their quality information to the federal government. The data from reporting hospitals are shown on the Medicare Hospital Compare website, which provides public access to clinical quality information (including surgical site infections and surgical complications/readmissions) at Medicare certified hospitals and VA medical centers. This website is designed to help assist patients in deciding where to obtain care and to encourage hospitals to improve. For the last 10 years hospitals have not been reimbursed by CMS for costs associated with wrong-site, wrong-procedure or wrong-patient surgery. More recently, CMS has begun to link individual provider compensation to quality measures through programs such as the Merit-Based Incentive Payment System.

Quality measures are not just used for reporting purposes. Dashboards containing quality measures are used by administrators along with key performance indicators such as average length of stay, readmission rates, wait times and patient satisfaction to identify areas of focus for institutional process improvement. Audit and feedback can be used as a quality improvement intervention when measures of local quality of care compared against benchmarks or peer performance are provided to physicians. Such dashboards appear to be most effective in bringing about positive change when performance is poor to start with, they are provided more than once and an action plan contains clear targets.<sup>56</sup>

**The Donabedian model, which proposes that structure (context/organization of care) influences processes (interactions and care provided) and thus affects outcomes (patient health), is the conceptual framework that forms the basis of health care quality evaluation.**<sup>57</sup> Quality measures, whether used in local QI initiatives or collected for regulatory or reimbursement purposes, can be categorized as assessing structure, process or outcomes. Structure and process measures must

be evaluable and valid (eg have a causal link to outcomes). A recent review indicated that the majority of perioperative structure and process measures lack high levels of scientific evidence of influencing patient outcomes.<sup>58</sup> Additionally, patient health outcomes (eg mortality, surgical site infection) are multifactorial with important determinants of health (genetics, personal behavior) that are outside the control of the health care system. Given these considerations, it is not surprising that use of quality measures to publicly assess quality or determine reimbursement is controversial.

*Facilitating quality improvement in urology.* QI efforts in urology can be motivated by patient outcomes, high costs or poor efficiency, or to satisfy regulatory or certification requirements. The “universal protocol” requiring identity verification, site marking and “time-out” before beginning surgery was enacted by the Joint Commission in 2004 to improve teamwork and decrease the risk of wrong-site surgery.<sup>59</sup> The literature contains many other patient safety strategies with adequate evidence to justify adoption into practice.<sup>60</sup> A systematic review of interventions used to decrease adverse events during surgery revealed a small number of medium to high quality interventions that effectively reduced surgical harm.<sup>61</sup> Those most amenable to ready implementation include surgical checklists, care pathways, participation in a national audit such as the ACS (American College of Surgeons) NSQIP® (National Surgical Quality Improvement Program) and engaging in team training. For urology specific interventions that optimize surgical outcomes the AUA has published 3 white papers (covering preoperative, intraoperative and postoperative settings) that are a rich resource for local QI intervention efforts.<sup>62-64</sup> Tools and free training online are available for many patient safety and QI interventions (Appendix 6, online issue only).

The majority of the published urology QI literature simply describes the effect of an intervention on process or outcome measures over time. Rarely do authors describe how the problem was clarified, the baseline data were collected, or the interventions were developed and refined. In contrast, Chartier et al published a useful series focused on QI in the emergency department, detailing steps and providing practical guidance and examples of intervention design using MFI.<sup>65</sup> Skeldon et al described a Lean initiative to improve efficiency in a urology clinic.<sup>66</sup> For clinicians interested in dissemination of QI interventions the Standards for Quality Improvement Reporting Excellence guidelines provide a useful framework for structuring reports on health care improvement initiatives.<sup>67</sup>

*Quality improvement collaboratives.* Although traditional quality improvement interventions are developed and implemented locally, there are also national and regional efforts designed to support and, in some cases, even guide QI efforts. The ACS NSQIP provides participating hospitals with risk adjusted surgical outcomes data and facilitates (optional) collaboratives within health systems or regions. National subspecialty collaboratives such as AQUA (American Urological Association Quality Registry) provide benchmarks and outcomes data for federal reporting requirements, quality improvement projects, health services research and maintenance of board certification. Regional urology collaboratives such as PURC (Pennsylvania Urologic Regional Collaborative) and MUSIC (Michigan Urological Surgery Improvement Collaborative) were developed to measure and improve the quality of patient care in urology practices. These entities collect

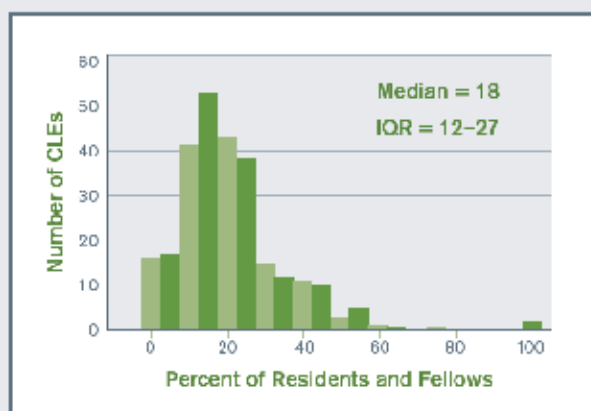
high quality data, which are analyzed and used for feedback to participants. Clinical areas of care with high variation and high cost are next identified. Collaborative participants subsequently explore strategies used by high performing practices to identify and then implement changes to improve outcomes. Finally, successful interventions are distributed across the collaborative to maximize benefit.<sup>68</sup>

## INTEGRATING PATIENT SAFETY AND QUALITY INTO GRADUATE MEDICAL EDUCATION

*ACGME and clinical environment review.* The Next Accreditation System instituted by the ACGME emphasizes resident and fellow education in patient safety and quality.<sup>69</sup> Advancement of curricula is encouraged to develop knowledge, skills and attitudes in systems based practice, communication and teamwork. Educational milestones, including these competencies, have been created.<sup>70</sup> Initial residency milestones will serve as the target for expected medical school achievement, while final residency milestones provide the launching point for independent practice and continued lifelong learning in patient safety and quality improvement. The Next Accreditation System highlights the role of the clinical learning environment in the development of future physicians, how they practice and their future patient outcomes. The Clinical Learning Environment Review program facilitates formative visits to health care facilities sponsoring graduate medical education every 18 to 24 months during which site visitors provide verbal and written feedback to facility leadership. Group sessions are held with executive, patient safety and graduate medical education leadership, residents, fellows, faculty and program directors. Frontline nurses and allied health care professionals are interviewed during rounds with the visitors. Patient safety and quality improvement are among the 6 focus areas of the Clinical Learning Environment Review.<sup>69</sup> Initial national findings have demonstrated the opportunity for improvement in resident and fellow reporting of patient safety events, including close calls, feedback to residents and fellows when they report, and resident and fellow participation in actual patient safety investigations (fig. 5).<sup>71</sup>

*Teaching patient safety and quality improvement.* **Emerging trends in patient safety and quality improvement education include a systems approach to medical errors, a just and fair culture, team training, role modeling, interprofessional education, experiential rather than purely didactic learning opportunities and the integration of patient safety, executive leadership and graduate medical education departments in the development of curricula.**<sup>72</sup> Modern training emphasizes a systems approach to the complexity of health care. This theme includes recognition of the fallibility of humans and acknowledging that errors will occur and are often due to latent contributing factors, such as suboptimal teamwork and communication, and human factors (eg fatigue, human-device interface issues).<sup>73</sup> Team training, role modeling and interprofessional educational experiences all have an important part in educational curricula.<sup>72</sup> Close call reporting can be learned through case studies. Patient safety investigation (eg RCA) education requires learning how to use specific tools (eg fishbone or cause and effect diagrams) and developing action plans. These competencies can be best learned during participation in real RCAs, although simulated/mock RCAs or case conferences may serve a complementary function. Objective structured clinical exami-

Percentage of residents and fellows who reported a near miss/close call event: Distribution across CLEs



**Figure 5.** Resident and fellow reporting of close call patient safety events. *CLEs*, clinical learning environments. Reprinted with permission.<sup>71</sup>

nations have been developed to assess learning of the patient safety investigation process.<sup>74</sup> Crew resource management training that is interprofessional, simulation based and recurrent leads to improved teamwork and communication.<sup>75</sup> The expectation is that health care executive leadership, patient safety leadership and educators will work together in achieving continuous patient safety education for staff and trainees while fostering a culture that promotes patient safety.

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# Study Questions Volume 39 Lesson 3

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1. Adverse events are most commonly associated with
  - a. understaffing
  - b. provider fatigue
  - c. communication issues
  - d. inadequate care planning
2. Multinational implementation of the WHO surgical checklist was associated with
  - a. no change in mortality and complications
  - b. increased mortality and decreased complications
  - c. decreased mortality and increased complications
  - d. decreased mortality and decreased complications
3. An organization with a just culture
  - a. understands that people make errors and that the use of appropriate discipline prevents repeat errors
  - b. balances individual and organization responsibility
  - c. is synonymous with a shame and blame culture
  - d. tolerates certain at risk and reckless behavior
4. Quality improvement efforts using Lean techniques are focused on
  - a. identifying and decreasing waste
  - b. decreasing process variation
  - c. improving profit margin
  - d. error identification
5. After an adverse event a hospital assigns a team to conduct a root cause analysis in order to
  - a. identify who was to blame for the error
  - b. prospectively prevent errors before they happen
  - c. provide accurate adverse event information to their malpractice defense attorney
  - d. understand the underlying factors leading to the event in order to prevent future adverse events

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