#### **PROCEEDINGS**

# Toxicology in the Service of Patient and Medication Safety: a Selected Glance at Past and Present Innovations

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**Abstract** Medical and medication errors remain definite threats to patients in US health care. Medical toxicologists frequently encounter patients either harmed by or at risk for harm from adverse drug events, including medication errors and inadvertent exposures. An historical perspective, as viewed through the lens of specific disciplines, can be useful to trace systemic responses to safety threats. Early efforts to address anesthesia perioperative risks and recent actions in medicine, surgery, and obstetrics to introduce checklists, communication tools, and systems approaches are reviewed. Patient safety concepts can be utilized and disseminated by toxicologists to improve medication safety and drive innovative approaches to confront patient harm. Various approaches include simulation of high-risk scenarios which might predispose to medication error, assembling multidisciplinary groups of health care providers to review events and implement mitigation strategies, and proactive patient safety rounds in clinical areas to allow frontline staff to voice concerns and introduce solutions for administration, evaluation, and implemen-

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tation. We review selected lessons from the past and current innovations to achieve safe medication practice.

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#### Introduction

Medical and medication errors remain clear and present threats to patients in US health care [1, 2]. Practitioners of toxicology frequently care for patients either harmed by or at risk for harm from adverse drug events, including medication errors and inadvertent exposures. A brief historical perspective, as viewed through the lens of specific disciplines, can be useful to trace early systemic responses to safety threats. Starting with the risks prevalent in anesthesia decades ago, early investigations into the causes of intraoperative patient harm, the introduction of checklists, communication tools, and systems approaches to address root causes of errors can enlighten ongoing safety efforts. The subsequent emergence of attempts by other disciplines to resolve their own leading patient safety threats illustrate the success and difficulties of various approaches.

Patient safety concepts can be highlighted and disseminated by medical toxicologists to improve medication safety and drive innovative approaches to address patient harm. One approach is to convene multidisciplinary groups of health care providers to review events and implement mitigation strategies. An additional proactive method includes patient safety rounds in clinical areas to allow frontline staff to voice concerns and introduce solutions for administration, evaluation, and implementation. Simulation can be utilized to further deliberate practice in a protected manner. In these proceedings, we review selected lessons from the past and current innovations to achieve safe medication practice.



## Early specialty driven safety efforts

More than two decades prior to the Institute of Medicine's report on error in health care [2], the specialty of anesthesia recognized a crisis. The human impact of poor anesthesia care was substantial, leaving 1-2 dead per 10,000 anesthetics [3]. The financial impact of this inferior quality was similarly grave. While anesthesiologists comprised 3 % of the physician workforce and a similar percentage of overall malpractice claims, they accounted for 12 % of the medical liability insurance payouts [3]. Employing methodologies typically applied in aviation accident investigations [4], investigators determined that anesthesia mishaps were frequently a result of preventable human and technical factors [5]. Their results were striking. The most basic elements of sustaining life during anesthesia—the oxygen supply, gas connections, tracheal tube, and functioning vascular access—were vulnerable to and compromised by error. Human, equipment, and technical failures included gas supply disruption, inadvertent changes in gas flow (e.g., transpositions of the gas scavenger and gas reservoir connections), premature extubations, breathing circuit disconnections, intravenous disconnections, and "syringe swaps"—syringe interchange and unintended medication administration. Inadequate communication, deficient preparation, numerous distractions, and insufficient supervision were recognized as associated causal factors. These findings from 1978 still resonate with what safety science struggles to achieve in analogous health care settings today.

The specialty approached its challenges though multiple facets. Structural and administrative efforts led to the creation of a Safety and Risk Management committee in 1983 by the American Society of Anesthesiologists (ASA), and the founding of the multi-stakeholder Anesthesia Patient Safety Foundation (APSF) in 1985, with the vision that "no patient shall be harmed by anesthesia." Over a decade later, the APSF model would give rise to the National Patient Safety Foundation in 1996 at a conference on medical error organized by the American Medical Association and others [6]. Also, in 1985, anesthesia safety data gathering began in earnest with the initiation of the ASA Closed Claims database, which continues to provide important insight into clinical lessons learned, anesthesia safety threats, and risk trends to this day [7].

Structured tools for critical tasks in anesthesia and minimum intraoperative principles were implemented. The concepts of continuous anesthetist presence, patient cardiopulmonary monitoring, breathing system disconnection detection, and oxygen concentration analysis were elevated to *required* practice standards in 1986 [8]. A U.S. FDA endorsed document, "Anesthesia Apparatus Checkout Recommendations," followed in 1993 with minimum standards for utilization of pulse oximetry, capnography, and respiratory volume and pressure monitors [9]. This "preflight" anesthesia checklist

codified "obvious" minimum safety safeguards such as backup ventilation; sufficient gas supplies, pressure, flow, and scavenging; monitoring devices; and suction. The technological innovations in anesthesia monitoring (pulse oximetry, capnography, bispectral index) and equipment (fiber optics, supraglottic devices) supported safety goals.

Human factor issues were directly acknowledged and confronted through ergonomics and engineering design. For pipeline gas, the Diameter Index Safety System (DISS) made oxygen and other gas connections non-interchangeable. For cylinder gas, the issue was addressed via a Pin Index Safety System (PISS), with unique positions for holes and corresponding pins on gas cylinders and their yokes. Supporting color markings (e.g., oxygen, green; medical air, yellow; nitrous oxide, blue; and vacuum, white) were introduced for outlets and containers. "Hard-wired" proportioning systems (also known as hypoxic guard systems) were engineered—for example, linking oxygen and nitrous oxide to preclude delivering anything less than 25 % oxygen during nitrous oxide administration. This was a significant improvement over previously inadequately designed solutions to this known problem such as a square, protruding oxygen control knob intended to provide tactile distinction from the nitrous knob; that solution had engendered its own low flow oxygen failures when adjacent objects disrupted the protuberant oxygen knob [5]. Vaporizer interlock devices (vaporizer exclusion systems) precluded more than one vaporizer from functioning at a time and inadvertent delivery of unintended mixtures. Color-standardized syringe labeling aimed to mitigate "syringe swap" [10]. Standardization also included a systematic approach to crises. Cognitive decision support algorithms and protocols were introduced for hazards such as the difficult airway and malignant hyperthermia. Early anesthesia patient simulators were also introduced as some of the first forerunners for teaching and training, and the anesthesia training program duration was extended [10].

While some previously criticized the anesthesia model of safety as a myth [11], data support the notion of significant safety gains in the specialty through its multidimensional, systematic approach. A recent review of one quality assurance database concluded that the cardiac arrest rate directly and primarily attributable to anesthesia was only 6 per 100,000 administered anesthetics and that the cardiac arrest death rate directly attributable to anesthesia was only 2 per 100,000 administered anesthetics [12]. Another study determined an anesthesia-related death rate of 1.1 per million population per year and 8.2 anesthesia-related deaths per million hospital surgical discharges [13]. The concerns that this successful systemic approach to safety in anesthesia would cede undue individual autonomy to external authority went largely unrealized [8]. The systemic focus on safety also permitted rapid introduction in safety innovations, such as a "Checklist for



Treatment of Local Anesthetic Systemic Toxicity" [14], as new threats emerged.

## Other specialties' challenges

Hospital-acquired infections represented a fundamental dissonance in medical care—entering the hospital anticipating health improvement, one acquired illness. For example, central line-associated bloodstream infections (CLABSIs) occurred 3.73 to 7.7 times per 1000 catheter days, accrued approximately 80,000 infections annually, killed 28,000 patients, and cost approximately \$2.3 billion [15, 16]. A Comprehensive Unit-based Safety Program (CUSP) and similar strategies aimed to improve safety culture, teamwork, communication, and sharing and learning from safety defects [17]. Following culture interventions, the rates of nosocomial catheter-associated urinary tract infections (CAUTIs), CLABSIs, and ventilator-associated pneumonias (VAPs) demonstrated significant improvement following introduction of checklists and bundles [15, 16]. Proactive measure for deep vein thrombosis prophylaxis, falls, and decubitus ulcers followed. Importantly, the American Board of Internal Medicine Foundation, in launching its Choosing Wisely campaign (http://www.choosingwisely.org/), captured a critical element in the quality and safety conversation, engaging patients as partners in their own quality care and decision-making strategies [18].

Historically, the surgical services faced a different dangerous predicament. In an extraordinarily blasé fashion, The Joint Commission (TJC) remarked, "Mistakes can happen during surgery. Surgeons can do the wrong surgery. They can operate on the wrong part of your body. Or they can operate on the wrong person" [19]. Between 1998 and 2001, wrong-site surgeries in its sentinel event database increased from 15 to 150, likely due to improved reporting [20]. True numbers were likely much higher. In a 2003 confidential survey, 16 % of hand surgeons reported that they had prepared to operate on the wrong site but then noticed the error prior to incision (nearmiss), and 21 % reported that they had actually performed wrong-site surgery at least once during their careers [21]. Worse, in a 2008 study, 15 % of spine surgeons reported that they had prepared the incorrect spine level at least once and noticed the mistake before making incision (near-miss), but a full 50 % had performed one or more wrong-level surgeries during their career [22]. By way of analogy, the aviation community would have to experience every other pilot landing at the wrong airport at least once in their careers; this obviously does not occur in this high reliability industry.

An initial "sign the site" recommendation first proposed by an American Academy of Orthopaedic Surgeons (AAOS) task force in 1997 gained momentum as wrong-site surgeries persisted. A Surgical Safety Checklist expanded upon this to include not only the right site but also the correct patient, airway and cardiovascular checks, team introductions, antibiotic administration, etc. [23]. Evidence suggested significant declines in mortality following introduction on the world stage [24]. However, simply mandating a surgical checklist (e.g., in Ontario, Canada) without assuring adherence, teamwork, and culture change failed to improve outcomes [25]. Local adaptation, improved communication, behavior modification, engaged leadership, data collection, and the effort and dedication to appropriate implementation are also required [26].

In obstetrical care, similar standardizing measures, a dedication to teamwork and communication, and oversight and quality review have demonstrated significantly improved patient care and medical liability exposure. At Yale-New Haven Hospital, claims and payments decreased significantly in the 5 years following introduction of a comprehensive obstetric safety program (\$50.7 million vs. \$2.9 million) [27]. The comprehensive obstetric patient safety program initiated at New York Weill Cornell Medical Center similarly decreased average yearly compensation payments from \$27,591,610 between 2003 and 2006 to \$2,550,136 between 2007 and 2009, while sentinel events decreased from 1.04 per 1000 deliveries to 0/1000 in 2008 and 2009 [28]. Multiple institutions established an obstetrical "Safety Officer" or "Safety Nurse," unencumbered by specific patient assignments, to permit frequent rounding, oversight, and assistance. Infrequent but known major obstetric emergencies, such as postpartum hemorrhage, shoulder dystocia, eclamptic seizures, maternal collapse, and urgent cesarean section, were drilled. Some created specific response teams, such as for maternal hemorrhage. Protocols for high-risk medications such as magnesium, induction agents, and post-hemorrhage agents were standardized. Anonymous event reporting was encouraged, team training was undertaken, and provider re-training (e.g., in electronic fetal heart rate certification) was required. The surgical checklist was expanded to a birthing unit surgical safety checklist to include all the key elements of participation and communication by obstetrics, anesthesia, nursing, and pediatrics [29].

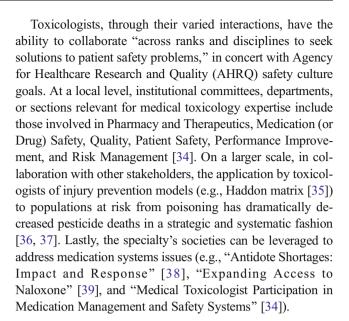
# Toxicologists as innovators for patient and medication safety

Other aspects of medicine such as medication safety have not been approached with the same degree of systematic rigor as in the aforementioned disciplines, leaving patients vulnerable [1]. In contrast with the remarkably low rates of anesthesia-related adverse events, roughly 15 % of an American College of Medical Toxicology (ACMT) Pre-Meeting Symposium conference audience at the 2014 North American Congress of Clinical Toxicology reported knowledge of a medication safety adverse event in the *past week alone*. However,



toxicologists can leverage skills already gained through training and experience to further patient safety goals. Toxicologists often respond to medication safety and unintended exposure events and their consequences. As a result of this experience, they appreciate systems issues and the concepts of faulty systems (as opposed to "faulty individuals"). These include the recognition of pervasive and persistent engineering, information technology, and design failures, such as those that lead to wrong-route intravenous-intrathecal or gastrostomyintravenous exchanges, look-alike/sound-alike lapses, and wrong-patient dispensing and administration. As efficiency demands and increased workload only increase the risk of crossing safe performance/operating limits, toxicology must remain vigilant to medication "near-misses" that exceed marginal performance/operating limits and counter performance pressures with safety interventions [30]. Toxicologists can draw upon their early standardizations in patient care and attention to complications (safety risks). In fact, the first earlygoal directed therapy, the "Scandinavian method" reported in 1961, was applied in toxicology. This systematic approach to the (poisoned) patient involved attention to vital signs, strict respiratory and vascular support, suctioning, frequent patient turning, and avoidance of non-specific analeptics. Derided as "therapeutic nihilism," it produced dramatic survival benefits in barbiturate-poisoned patients [31].

Medical toxicologists have the capacity to grasp care of large populations (e.g., through Poison Center interactions and educational outreach), as well as special populations (pediatrics, geriatrics, and those with specifically compromised organ physiology). Medical toxicologists comprehend the importance of case reporting either to Poison Centers, government agencies (e.g., MedWatch, the FDA Safety Information and Adverse Event Reporting Program), other organizational reporting programs (e.g., Institute for Safe Medication Practices, ISMP), or specialty society registries (e.g., ACMT's Toxicology Investigator's Consortium). These individual "case reports" are critical for surveillance and additionally serve as potential "sentinel events." The implications of xenobiotic release into large populations may be monitored. Toxicologists appreciate cost (risk)-benefit analysis and value at the level of the patient (to guide therapy) and the population (e.g., Poison Centers' immense savings to and access for communities [32]). The concepts of risk, risk mitigation, and risk communication are part of training. The discipline values the importance of proactive medication and product safety measures (child protective packaging, product and pesticide labeling, risk evaluation and mitigation strategies (REMS), and market restrictions or removal where appropriate). In this vein of attempting to preclude populations from exposures, toxicology can subsume safety systems strategies and hierarchies of control already common in industry [i.e., elimination, substitution, isolation, engineering controls, administrative controls, and (patient) personal protection [33].



# **Simulation**

Simulation provides an excellent resource for patient and medication safety. It can be employed to define roles of each team member (i.e., leader and followers) and enable team practice of these roles. Simulation can be performed with low-fidelity models (no equipment necessary) or with highfidelity mannequins. Practicing high-stress scenarios using a multidisciplinary team of nurses, prescribers, and pharmacists can ensure that communication tools are used and that the implications of specific safety words are understood [40]. These scenarios may include adult or pediatric resuscitation, anaphylaxis, chemotherapy administration, and other highrisk clinical situations. Scenarios involving high-alert medications, look-alike/sound-alike medications, and situations requiring calculations to ensure correct dosing under timecompression constraints are also particularly amenable to training. Examples of in situ simulations implemented in our Emergency Departments (EDs) include multi-trauma necessitating intubation, septic shock in pediatrics and the elderly, precipitous delivery, ST elevation myocardial infarction and dysrhythmias, and neurocritical care in non-hemorrhagic and hemorrhagic stroke complicated by anticoagulant therapy.

Communication skills are particularly important in clinical settings when verbal orders are unavoidably utilized. Effective communication tools include closed-loop communication and use of specific words to highlight concerns. Closed-loop communication using a sender-receiver-sender format ensures that both the sending provider (the provider giving orders) and the receiving provider (provider performing those orders) understand the medication to be used, its dosing, its route, and possibly, why it is being given. The read-back verification from the receiving provider allows the sending provider to



correct any mistakes or misperceptions in the verbal order. This is analogous to the three-step "Positive Transfer of [Flight] Controls" previously established in aviation to ensure unequivocal piloting of the aircraft in the wake of numerous accidents [41]. Another communication tool, borrowed from Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) training, uses specific words to escalate concerns when a safety concern remains unaddressed [42]. These words may be practiced in simulation scenarios to familiarize providers with hearing them and comprehending their meanings. This tool uses non-threatening words/phrases to alert everyone on the team to individual team members' concerns. TeamSTEPPS "CUS" words are, "I'm Concerned about..."; "I'm Uncomfortable with ..."; and "This is a Safety concern" [42]. Similar structured communication tools include the 3Ws employed in the National Center for Patient Safety's Clinical Team Training: "What I see is..."; "What I am concerned about is..."; and "What I want is..." [43]. These specific phrases allow for flexible escalation of safety concerns and constructively alerts the other team members until an issue is addressed. The more practice and familiarization with these communication tools and others through the use of simulation, the more useful they will be in the clinical arena. Prior to introduction, simulations and coordinated training are advisable with all team members to permit practice prior to a "go-live" date in the clinical area. For example, TeamSTEPPS provides simulation scenarios as part of its training to allow practice and introduction to a culture change prior to implementation. Increased patient safety knowledge and improved communication have been demonstrated in academic ED settings following completion of the TeamSTEPPS training [44]. After training with the 3Ws, nursing students were able to demonstrate communication skills competence [43].

#### Multidisciplinary teamwork

Teamwork is part of many different aspects or approaches to patient safety. High reliability organizations (HROs)—which emphasize flattening hierarchal structures and encouraging team members to vocalize potential issues—are reviewed elsewhere in this issue. Emergency Department (ED) teams include many different members with many different roles: physicians of all levels of training, mid-level providers, nurses, pharmacists, patient care technicians, and other ancillary staff. One innovative team approach is development of an emergency department-specific medication safety committee, aligned with AHRQ's CUSP program, which allows for individual units to address specific concerns by adapting best practices to the unit's unique needs [17]. This multidisciplinary group consists of ED pharmacists, the hospital's medication safety pharmacist, ED prescribers including toxicology attendings, resident physicians, mid-level providers, ED nurse administrators/clinical managers, charge nurses, and the ED quality and patient safety nurse. Providers from the inpatient services are invited to participate so that they are aware of the medication problems arising with admitted patients boarding in the ED. The group meets monthly to review medication events reported in the hospital's event reporting system and examines different approaches to prevent near-misses and errors in those events. Additional concerns, obtained from the ED pharmacists' notes, verbal reports from staff on safety rounds, ED quality reviews, and complaints from other departments and physicians, are discussed. Once strategies are identified, they are taken to ED administration and the institutional medication safety committee to "sign off" and "endorse" for implementation, ensuring coordinated oversight and monitoring for unintended consequences. The group's work is now fully integrated as part of the quality improvement process.

The ED medication safety team has been able to address multiple concerns in conjunction with the hospital's medication safety committee. Data collected by the ED pharmacists, the events reported in the event reporting system, and quality reports are evaluated for ongoing process improvement. Before team initiation, very few medications given in the ED required pharmacy verification prior to dispensing and administration. Timely pharmacy verification, due to lack of 24-h staffing for ED pharmacists, was not required for most medications. Instead, medications were usually verified after they had been given, sometimes hours later. This practice departed from standards in the rest of the hospital, in which every medication, except "CODE" medications, required pharmacy verification. Inpatient providers did not realize that the pharmacy did not verify their medication orders for admitted patients boarding in the ED. Provider confusion with medication formulations was a top priority based on concerns from the above sources. Multiple near-miss events, most notably with oral calcium channel blockers (CCBs) and beta-adrenergic antagonists (BAAs), were reported. Prescribers were choosing incorrect formulations when using computer prescriber order entry (CPOE). Nurses were removing wrong formulations from automated dispensing cabinets and bringing them bedside. Both mistakes placed patients at risk for serious cardiotoxicity. Pharmacy verification was implemented, harmonizing practice with the rest of the hospital, to prevent patients from receiving multiple tablets of immediate-release cardioactive medications. Another problem was formulation confusion of different insulins. The team recommended removing all insulin formulations not necessary to treat emergent conditions. Therefore, only regular insulin (for hyperkalemia, diabetic ketoacidosis, etc.) is stocked in the ED automated dispensing cabinets. Pharmacy verification was implemented for other formulations of insulin to mirror practice elsewhere in the hospital.

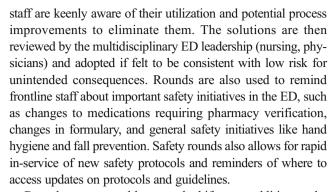


Multiple safety publications have addressed computerized physician order entry (CPOE) associated gains in safety (eliminating prescriber handwriting errors), as well as its unintended consequences due to screen arrangement, data entry errors (weight in pounds instead of kilograms), and wrong-patient orders [45, 46]. The ED medication safety team identified multiple local CPOE problems, such as the appearance of a medication on the ordering screen and trade/generic name confusion. ED CPOE issues, supported with event-reporting system cases and hospital data from other units, have been communicated to the hospital medication safety committee to resolve with hospital information technology services. The team has recommended warnings and changes to the automated dispensing system screens to aid nurses when choosing medications that are capable of override. Other specific data collected by the team has undergone submission to the institutional review board for research purposes. The team is also in the process of developing materials for other EDs to implement their own medication safety working groups.

#### Safety rounds

Another approach for improving patient and medication safety is patient safety rounds. These rounds are sometimes called Patient Safety Leadership WalkRounds<sup>TM</sup>, leadership walk rounds, or executive walk rounds [47]. The concept was first introduced when the Institute of Healthcare Improvement (IHI) asked a group of safety experts to build an ideal medication system. This group realized that hospital executives needed to be involved and aware of the safety concerns at the frontline of health care [47]. Patient safety rounds require hospital administration to enter clinical areas and obtain information from the staff regarding areas of potential patient harm and deliver solutions to alleviate them. Safety rounds, as described by this group, occur in all clinical areas of the hospital to increase awareness of safety concerns, (2) make safety a high priority for senior leadership, (3) educate staff about patient safety concepts such as non-punitive reporting, and (4) obtain and act on information elicited from staff about safety problems and issues [47].

The ED safety team of one hospital decided to implement patient safety rounds as a way to engage frontline staff and seek their knowledge and expertise and suggestions for ways to improve patient and medication safety, consistent with previous success with this methodology in identifying safety issues, and supporting a culture of safety [48]. The ED safety rounds involve ED administration including physician and nursing leadership, executives from Quality and Patient Safety, frontline staff, and residents during their administration rotation. Frontline staff are requested to provide examples of safety concern and suggest potential mechanisms for resolution. Some suggestions have focused on how to resolve work-arounds, as frontline



Rounds occur monthly on each shift as an addition to the daily shift huddles where the ED staff introduce themselves to each other and discuss their roles for the shift, and reminders for new guidelines and protocols are discussed. In the first 4 months following the institution of ED safety rounds at one of the author's sites, 55 issues were identified and 38 were addressed. In the first year of ED safety rounds, 104 issues were identified, 60 solutions were found, and 20 more are in the process of resolution. From a medication standpoint, several concerns have focused on medication administration. Nurses desired access to the hospital formulary and medication administration guide without having to interface with the internet (as computers in the nursing stations lacked internet access). This information was useful when a pharmacist was not present in the ED to check medication compatibilities, infusion rates, double-checking of doses, etc. Additional safety concerns related to the logistics of medication administration—the location and use of intelligent infusion pumps for intravenous medications. Nurses were wasting time searching for clean, ready-to-use pumps. They suggested a central location in each ED bay for clean pumps, just as there was a location already designated for used, dirty pumps.

#### **Conclusions**

Substituting "medication" for "anesthesia" in APSF's vision statement would yield the ambitious goal that "no patient should be harmed by medication." Toxicology's extant strengths can permit it to join with "those who refuse to accept harm as inevitable" [49]. The experience of other medical disciplines and industries outside of health care suggest viable systems constructs and feasible approaches to achieve this objective. Simulation, multidisciplinary medication teams, and dedicated evaluations of front line operations represent a few of multiple practical initiatives to launch patient and medication safety efforts.

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