TQIP mortality reporting system case reports: Unanticipated mortality due to inadequate preoperative ICU "clearance"

Samuel W. Ross, MD, MPH, David G. Jacobs, MD,
and **the ACS TQIP Mortality Reporting System Writing Group**, *Chicago, Illinois*

CONTINUING MEDICAL EDUCATION CREDIT INFORMATION

Accreditation

In support of improving patient care, this activity has been planned and implemented by CineMed and the American Association for the Surgery of Trauma. CineMed is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

AMA PRA Category 1 Credits™

CineMed designates this enduing material for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

Objectives

After reading the featured articles published in the *Journal of Trauma and Acute Care Surgery*, participants should be able to demonstrate increased understanding of the material specific to the article. Objectives for each article are featured at the beginning of each article and online. Test questions are at the end of the article, with a critique and specific location in the article referencing the question topic.

Disclosure Information

In accordance with the ACCME Accreditation Criteria, CineMed must ensure that anyone in a position to control the content of the educational activity (planners and speakers/authors/discussants/moderators) has disclosed all financial relationships with any commercial interest (termed by the ACCME as "ineligible companies", defined below) held in the last 24 months (see below for definitions). Please note that first authors were required to collect and submit disclosure information on behalf all other authors/contributors, if applicable.

Ineligible Company: The ACCME defines an "ineligible company" as any entity producing, marketing, selling, re-selling, or distributing health care goods or services used on or consumed by patients. Providers of clinical services directly to patients are NOT included in this definition.

Financial Relationships: Relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

The ACCME also requires that CineMed manage any reported conflict and eliminate the potential for bias during the session. Any conflicts noted below have been managed to our satisfaction. The disclosure information is intended to identify any commercial relationships and allow learners to form their own judgments. However, if you perceive a bias during the educational activity, please report it on the evaluation. All relevant financial relationships have been mitigated.

AUTHORS/CONTRIBUTORS

Samuel W. Ross, David G. Jacobs, and the ACS TQIP Mortality Reporting System Writing Group have nothing to disclose.

EDITORIAL BOARD MEMBERS

First Name	Last Name	Disclosure?	Name of Commercial Interest	What was Received?	What was the Role?
Michael	Nance	Yes	Endo Pharmaceuticals	Consulting fee	Consultant
Heena	Santry	Yes	NBBJ	Salary	Employee
Jose	Diaz	Yes	Acumed/Acute Innovations	Consulting fee	Consultant
Lena	Napolitano	Yes	Merck Global Negative Advisory Board/Abbvie Critical Care Working Group	Consulting fee	Advisor/ Consultant

Roxie Albrecht, Walter Biffl, Karen Brasel, Clay Cothren Burlew, Raul Coimbra, Todd Costantini, Rochelle Dicker, Tabitha Garwe, Kenji Inaba, Rosemary Kozar, David Livingston, Ali Salim, Deborah Stein, Alex Valadka, Robert Winchell, Bishoy L. Zakhary, and Ben Zarzau have no disclosures or conflicts of interest to report. The Editorial Office staff has no disclosures to report.

Claiming Credit

To claim credit, please visit the AAST website at http://www.aast.org/ and click on the "e-Learning/MOC" tab. You must read the article, successfully complete the post-test and evaluation. Your CME certificate will be available immediately upon receiving a passing score of 75% or higher on the post-test. Post-tests receiving a score of below 75% will require a retake of the test to receive credit.

Credits can only be claimed online

Cost

For AAST members and Journal of Trauma and Acute Care Surgery subscribers there is no charge to participate in this activity. For those who are not a member or subscriber, the cost for each credit is $25.

Questions

If you have any questions, please contact AAST at 800-789-4006. Paper test and evaluations will not be accepted.

ABSTRACT: The Trauma Quality Improvement Program Mortality Reporting System is an online anonymous case reporting system designed to share experiences from rare events that may have contributed to unanticipated mortality at contributing trauma centers. The Trauma Quality Improvement Program Mortality Reporting System Working Group monitors submitted cases and organizes them into emblematic themes. This report summarizes unanticipated mortality from a case of inadequate clearance by the intensive care unit service before surgical intervention in an injured patient and presents strategies to mitigate these events locally with the hope of decreasing unanticipated mortality nationwide. (*J Trauma Acute Care Surg.* 2023;94: 743–746. Copyright © 2023 Wolters Kluwer Health, Inc. All rights reserved.)

KEY WORDS: Quality improvement; wounds and injuries; cause of death; medical errors/prevention and control; trauma centers.

The American College of Surgeons Trauma Quality Improvement Program (ACS TQIP) Mortality Reporting System collects anonymous self-reported cases from participating trauma centers in a structured format. The purpose of this system is to collect and describe cases with opportunities for improvement that may not be widely recognized due to the rare nature of these events, and to disseminate evidence-based strategies to improve care nationally. A total of 395 reports have been submitted to the TQIP Mortality Reporting System, with 119 (30%) of the adverse events occurring in the intensive care unit (ICU), followed by the trauma bay (22%), the patient ward (10%), and the operating room (8%). Communication errors were identified as a contributing factor in 41% of cases, and 20% of cases had lapses in appropriate tracking and follow through of patients while in the ICU. In addition, of the 56 patients that underwent a surgical intervention around the time of their event, 46% had the appropriate surgical procedure performed but the timing of the procedure was inappropriate for the clinical scenario. This case review illustrates the impact of breakdown in communication between surgical specialists and ICU teams related to timing of surgical procedures and presents strategies to prevent these failures.

ILLUSTRATIVE CASE REPORT FROM THE TQIP MORTALITY REPORTING SYSTEM

Case Report from the TQIP Mortality Reporting System:

A 42-year-old man was admitted to the ICU after a motor vehicle crash with a severe traumatic brain injury (TBI) and an open left tibia fracture. He was intubated with a Glasgow Coma Scale of 6 T and had an intracranial pressure (ICP) monitor in place. His ICP stabilized, and Orthopedics scheduled him for fracture stabilization on post-injury day two. Serum sodium levels declined from 140 to 132 mEq/L throughout post-injury day one, and was 124 mEq/L at 4 am on the day of the planned orthopedic procedure. He was taken to the OR by orthopedics as the first case of the day, prior to being seen by the trauma surgeon on morning ICU rounds. His hyponatremia was unrecognized by both orthopedics and anesthesia, and he developed refractory intracranial hypertension intraoperatively that ultimately led to progression of neurologic injury, cerebral edema, and eventual brain death.

CASE DISCUSSION

This case highlights the necessity for all trauma centers to have processes in place to ensure timely, appropriate, and efficient communication between the multiple subspecialty services caring for ICU trauma patients. A standardized pre-operative ICU "clearance" process may be helpful in facilitating such communication. The ICU team, acting as the gatekeeper to the OR, is uniquely qualified and positioned to perform this pre-operative "clearance" function. In addition, there should be a standard mechanism in place to communicate the "clearance" status to all critical stakeholders, especially the operating surgical service, anesthesia, and perioperative nursing.

While the OR clearance process is an everyday occurrence for high-risk patients undergoing elective surgical procedures, there is no established "best practice" when it comes to operative clearance for trauma ICU patients. The Hierarchy of Effectiveness of Interventions is a useful framework developed as part of the medication error prevention "toolbox" from the Institute for Safe Medical Practices[1,2] (Fig. 1). This framework may be useful when considering potential options for ICU clearance processes. In general, "low leverage" processes, which are dependent on a single individual, increased vigilance, or provider education, tend to be less effective, and burn out prior to cultural adoption. "High leverage" processes, which rely on automated, systems-focused, and forced processes are more effective, but harder to implement. Utilizing this framework, we will discuss high- and medium-leverage strategies that could potentially be implemented to minimize adverse outcomes related to untimely operative procedures on ICU trauma patients.

HIGH LEVERAGE PROCESSES

1. Forcing functions: computerized order entry is a standard example of a forced function. Requiring an "operative clearance" order to be entered by the ICU team for each trip to the operating room would ensure the awareness and approval of the ICU team of the appropriateness and timing of each operative procedure. The clearance order empowers not only the bedside nurse to delay transport to the operating room but should also impose a "hard stop" on preoperative

Submitted: September 12, 2022, Revised: December 28, 2022, Accepted: December 29, 2022, Published online: February 4, 2023.

From the Division of Acute Care Surgery, Atrium Health Carolinas Medical Center, Charlotte, North Carolina.

Writing Group: This article is submitted on behalf of the American College of Surgeons (ACS) Trauma Quality Improvement Program (TQIP) Mortality Reporting System Writing Group.

Address for correspondence: Aaron R. Jensen, MD, MEd, MS, FACS, FAAP, UCSF Benioff Children's Hospital Oakland, 744 52nd Street, 4th Floor OPC, Pediatric General Surgery, Oakland, CA 94609; email: Aaron.Jensen@UCSF.edu.

DOI: 10.1097/TA.0000000000003885

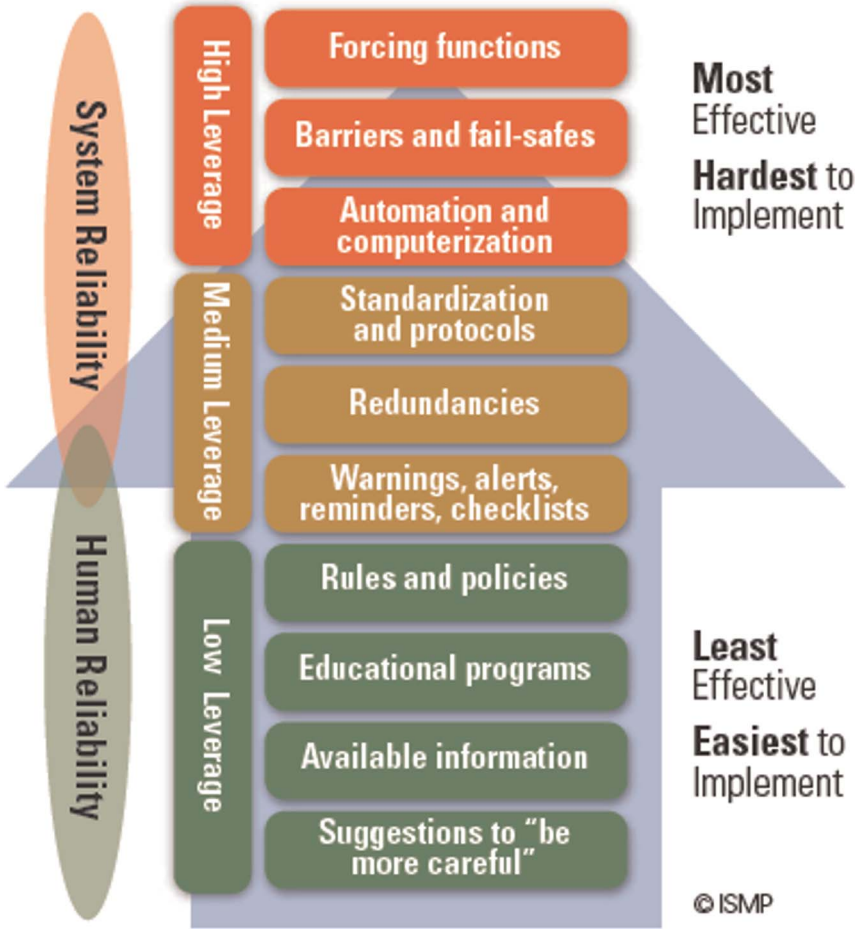

Figure 1. Hierarchy of effectiveness of interventions. From education is "predictably disappointing," ISMP Medication Safety Alert! Acute Care, Vol 25, Issue 11, (Fig. 1). Reprinted with permission.

nursing, anesthesia, and the operating service to verify the clearance order before moving forward with their phase of care. The process could be further enhanced by an electronic "gate-keeping" system that would prevent opening of the electronic record in the OR without the mandated clearance order. The major drawback of this strategy is the timing of the order placement, as a delay in order writing would cause OR delays. Conversely, an order written prematurely (e.g., the night before) may not take into account the patient's current appropriateness for surgery. This approach would require the ICU team to assess all OR candidates in a timely fashion, for example, a 6:00 AM assessment for any first-start case.

2. Barriers and fail-safes: for ICU clearance, a fail-safe can be implemented in the chart for OR clearance, such as a note. If a clearance note has not been entered, the patient cannot leave the ICU even if verbal clearance has been provided. This approach could be enhanced by requiring multiple stakeholders to sign off on the note (bedside ICU nurse, preoperative holding nurse, anesthesia, etc.), prior to transfer to the OR. This process might incorporate a checklist for important values like hemoglobin, lactate, and associated injuries, but such a checklist without the actual barrier structure (e.g., the clearance note) is not as effective because there is no incentive to use the checklist. In the case presented above, a standardized note incorporating a TBI checklist with sodium levels completed by the ICU team, and cosigned by other stakeholders, might have prevented this complication and death. Importantly, another fail-safe that is required by the joint commission was critical in this case. The timely reporting of critical laboratory values to the treatment team is required and imperative. In this case a fail-safe of critical laboratory alert to the ICU team would have prompted evaluation, potentially improved communication and coordination between providers, and prevented the error altogether.
3. Automation and Computerization: An automated computer algorithm to process an electronic checklist of laboratory values, vital signs, and physiologic monitoring (e.g., ICP) could be utilized to generate an automatic ICU clearance that could be administered in real time by the bedside nurse. This would depend upon the algorithm's ability to capture all clinically relevant details. With rapid progress in the field of data science, utilizing machine learning, artificial intelligence algorithms, and computerized decision support, this approach may become feasible in the near future. An EMR-based

algorithm for ICU clearance utilizing serum sodium could have alerted the ICU team, and potentially pre-empted the orthopedic procedure.

MEDIUM LEVERAGE PROCESSES

1. Standardization and protocols: many centers have standardized internal processes for ICU operative clearance that might involve patients being screened by the overnight ICU resident using specific criteria, an algorithm, or a checklist. Any identified issues that might result in delay or cancellation of the scheduled procedure would then be further evaluated by an attending physician and clearance, or lack thereof, relayed to the operative team via some agreed-upon communication platform (EMR notes, email, text pages). This type of preoperative nighttime check would theoretically have identified the hyponatremia in the above case, and clearance withheld. A protocol further requiring ICU *attending* clearance at the time of handover to the OR transport staff could further enhance the effectiveness of this process.
2. Redundancies/double-checks: double-checks require that two independent parties review predetermined factors and agree to proceed with a critical intervention to ensure that appropriate rule-based decision-making is being implemented. Double-checks may help eliminate rule-based errors but assume that the proper assessment has been completed in a timely fashion with rapidly changing data. Reverifying a process, such as a checklist or clearance communication, which was initially completed hours previously, is not likely to catch errors in dynamic scenarios, such as those involving a critically ill ICU trauma patient. Redundancies and double checks would only be useful if they were conducted in close proximity to the planned operative procedure and required the inclusion of the most up-to-date patient data.
3. Risk assessment, warnings, alerts, reminders, and checklists: automated reminders triggered in the EMR at specific timepoints before a patient departs for the OR may assist in reminding the bedside nurse to verify operative clearance by the ICU team. A potential drawback to this approach, however, is alert fatigue, which occurs when there are so many alerts, warnings, reminders, or checklists that caregivers become immune to the alerts and ignore them. Even if the alert itself is not ignored, if those who are alerted are not empowered or motivated to address the issue, in this case, lack of ICU clearance, this approach is not likely to succeed.

The above discussion highlights some obstacles and opportunities in achieving preoperative clearance for ICU trauma patients. No single approach is foolproof, and even the most well-intentioned "forcing function" system can be thwarted by human error or unusual circumstances. Clearance processes using multiple layered interventions may be more successful in avoiding "Swiss cheese" scenarios like the one described above. The hierarchy of effectiveness of interventions can be used to guide whether a practice is more likely to result in effective and lasting change, or more likely to fail. Partnerships with surgical specialists, especially orthopedics and neurosurgery, and with the ICU team are paramount to ensuring the optimal timing for surgical procedures in ICU patients.

AUTHORSHIP

D.M.H., A.R.J., B.P. participated in the case curation and selection. All authors participated in the critical discussion and analysis of error mitigation strategies. S.W.R., D.G.J. participated in the article drafting. All authors participated in the critical revision and approval of final article.

DISCLOSURE

J.W.S. receives funding from the Agency for Healthcare Research and Quality as principal investigator on grant K08-HS028672 and as a co-investigator on grant R01-HS027788. J.W.S. also receives salary support from BlueCross BlueShield of Michigan through the collaborative quality initiative known as Michigan Social Health Interventions to Eliminate Disparities (MSHIELD). All other authors have no relevant disclosures. No conflicts relevant to this article are declared for the other authors.

ACS TQIP Mortality Reporting System Writing Group: Aaron R. Jensen, MD, MEd, MS—Writing Group Lead, Department of Surgery, University of California San Francisco, and UCSF Benioff Children's Hospitals, Oakland, CA; Frederic J. Cole, MD, Legacy Medical Group—Trauma and General Surgery, Legacy Emmanuel Medical Center, Portland, OR; Kimberly A. Davis, MD, MBA, Division of General Surgery, Trauma and Surgical Critical Care, Yale School of Medicine, New Haven, CT; Richard Dutton, MD, MBA, Chief Quality Officer, US Anesthesia Partners, Dallas, TX; Doulia M. Hamad, MD, Department of Surgery, Sunnybrook Health Sciences Center and the University of Toronto, Canada; Jonathan I. Groner, MD, Department of Surgery, The Ohio State University College of Medicine, and Nationwide Children's Hospital, Columbus, OH; David G. Jacobs, MD, Division of Acute Care Surgery, Atrium Health Carolinas Medical Center, Charlotte, NC; Samuel P. Mandell, MD, MPH, Division of Burn, Trauma, Acute and Critical Care Surgery, UT Southwestern Medical Center and Parkland Health and Hospital System, Dallas, TX; Avery Nathens, MD, PhD, MPH, American College of Surgeons, Chicago, IL, and Sunnybrook Health Sciences Centre, University of Toronto, Toronto, ON, Canada; Bhavin Patel, MPH, American College of Surgeons, Chicago, IL; Samuel W. Ross, MD, MPH, Division of Acute Care Surgery, Atrium Health Carolinas Medical Center, Charlotte, NC; John W. Scott, MD, MPH, Division of Acute Care Surgery, University of Michigan, Ann Arbor, MI; Regan F. Williams, MD, MS, Division of Pediatric Surgery, Le Bonheur Children's Hospital, and The University of Tennessee Health Science Center, Memphis, TN.

REFERENCES

1. Institute for Safe Medical Practices. Education is "predictably disappointing" and should never be relied upon alone to improve safety. https://www.ismp.org/resources/education-predictably-disappointing-and-should-never-be-relied-upon-alone-improve-safety Last accessed December 28, 2022.
2. Woods DM, Holl JL, Angst D, Echiverri SC, Johnson D, Soglin DF, et al. Improving clinical communication and patient safety: clinician-recommended solutions. https://www.ncbi.nlm.nih.gov/books/NBK43654/pdf/Bookshelf_NBK43654.pdf Last accessed December 28, 2022.