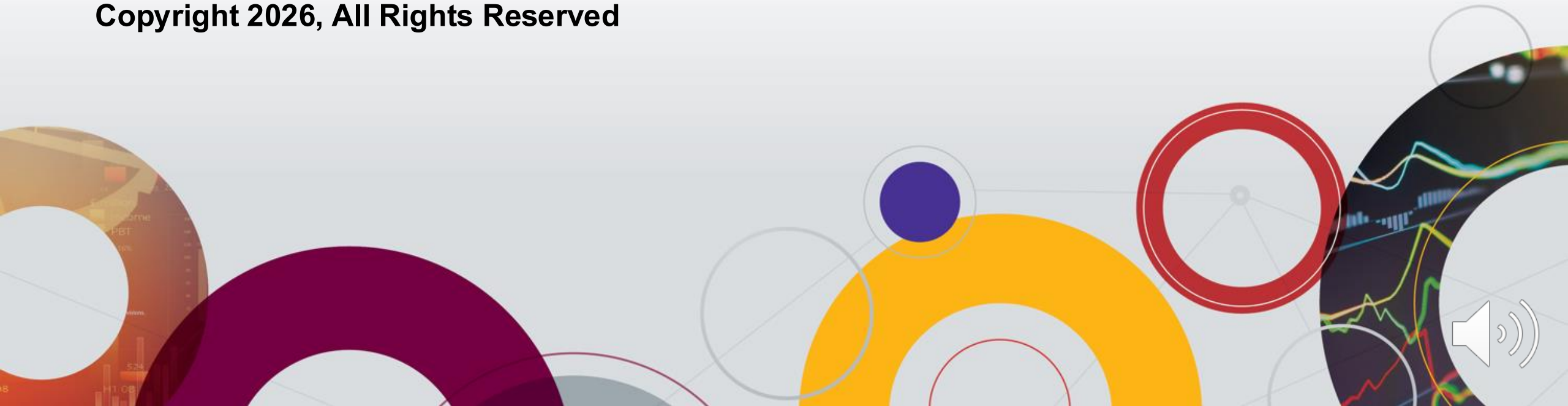


6.1b Patient Safety and Medical Errors

10x10 – Introduction to Biomedical Informatics & Artificial Intelligence
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Patient Safety and Medical Errors

Scope of the problem

Categories of medical error

Knowledge about human error

Interventions

Knowledge about human error

Two general types of errors (Leape, 1994)

- Slips – “Unconscious glitches in automatic activity,” usually due to diversion of attention
- Mistakes
 - Rule-based – wrong rule chosen due to misperception or misapplication
 - Knowledge-based – novel situation with no preprogrammed solution; lack of knowledge or misinterpretation of problem

Approach to human error (Reason, 2000)

- Person – individual blamed; improve by blaming, litigation, retraining, etc.
- System – put systems in place to capture and correct human fallibility
- In most complex systems, system approach more effective

Observations from “theory of error” (Bates, 2001)

“Operator error” often results from systems being poorly designed

Human-machine systems engineering calls for displays to be more “transparent”

- Airline industry now aims for “situational awareness” and not locking pilots into specific procedures

Machines err too

- Humans can be erratic but recover
- Overreliance on machines can lead to severe error

Infrequent errors give us less experience in knowing how to react to them

Most medical errors are process errors (Bates, 2001)

Majority of errors do not result from individual negligence, but from flaws in health system organization (or lack of organization) and systems that do not catch slips

Medical errors are often initiated by failures of information management

- Illegible writing in medical records
- Lack of integration of clinical information systems
- Inaccessibility of records
- Lack of automated allergy and drug interaction checking

We can learn from other industries

Aviation industry

- Aviation industry has developed processes for investigating, documenting, and disseminating information about errors (Helmreich, 2000)
 - Error less punished and better managed
 - Use of checklists
- Surgeons and anesthesiologists are more likely than pilots to deny effects of fatigue and stress and less likely to reject steep hierarchies (Sexton, 2000)
- Re-questioning assumptions – e.g., do autopilots “de-skill” pilots too much (Halsey, 2016)?

Human factors discipline – long history of methodologies to inform errors and safety (Carayon, 2018)

Interventions for human error

Acknowledging and addressing problem

Voluntary disclosure

Programs for improving patient safety

Checklists

Technology (other segments)

- Barcoding (Pruitt, 2023)
- Computerized decision support (CDS) and computerized provider order entry (CPOE) (Greenes, 2023; Syrowatka, 2024)
- Role of artificial intelligence (AI) (Classen, 2023; Topol, 2024)

Acknowledging and addressing problem

AHRQ [Patient Safety Indicators \(PSI\)](#) provide 27 measures at provider and area levels to identify and measure, e.g., obstetric trauma, iatrogenic pneumothorax, postoperative pulmonary embolism

Medicare has stopped paying for small number of preventable complications (“never events”) but some question “wisdom and justice” for some of them, e.g., ventilator-associated pneumonia (Pronovost, 2008)

Hospitals encouraged to develop “patient safety cultures”

- Must engage leadership and facilitate change management (Pronovost, 2006)
- Need to balance physician autonomy and decision-making (Mathews, 2008)

Voluntary disclosure

Not reporting errors is a “lost opportunity” (Garbutt, 2008)

Not to overlook: apology (Lazare, 2006)

Routine disclosure does not increase litigation in patients who have confidence in provider willingness to disclose (Helmchen, 2010)

Programs for improving safety

Agency for Healthcare Research & Quality (AHRQ) [Patient Safety Network](#) – [primers](#) on safety topics

[Food and Drug Administration Safety and Innovation Act \(FDASIA\)](#) – general program for increasing innovation and safety for medical drugs and devices

Joint Commission [National Patient Safety Goals](#) – sets new goals annually

[GoodDx](#) – resources for diagnostic accuracy and safety

Programs for improving safety (cont.)

Institute for Safe Medication Practices (ISMP)

- All medications should be checked for the “five rights”
 - Right patient
 - Right drug
 - Right time
 - Right dose
 - Right route
- High-Alert Medication List
- Confusing of drug names
- Tall man lettering
 - e.g., buPROPion / busPIRone

National Patient Safety Foundation – goals for system-based safety (2015)

Improving “diagnostic stewardship,” i.e., optimizing testing to reduce diagnostic error and improve diagnosis (Morgan, 2023)

EIGHT RECOMMENDATIONS FOR ACHIEVING TOTAL SYSTEMS SAFETY



1. ENSURE THAT LEADERS ESTABLISH AND SUSTAIN A SAFETY CULTURE

Improving safety requires an organizational culture that enables and prioritizes safety. The importance of culture change needs to be brought to the forefront, rather than taking a backseat to other safety activities.



2. CREATE CENTRALIZED AND COORDINATED OVERSIGHT OF PATIENT SAFETY

Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations.



3. CREATE A COMMON SET OF SAFETY METRICS THAT REFLECT MEANINGFUL OUTCOMES

Measurement is foundational to advancing improvement. To advance safety, we need to establish standard metrics across the care continuum and create ways to identify and measure risks and hazards proactively.



4. INCREASE FUNDING FOR RESEARCH IN PATIENT SAFETY AND IMPLEMENTATION SCIENCE

To make substantial advances in patient safety, both safety science and implementation science should be advanced, to more completely understand safety hazards and the best ways to prevent them.



5. ADDRESS SAFETY ACROSS THE ENTIRE CARE CONTINUUM

Patients deserve safe care in and across every setting. Health care organizations need better tools, processes, and structures to deliver care safely and to evaluate the safety of care in various settings.



6. SUPPORT THE HEALTH CARE WORKFORCE

Workforce safety, morale, and wellness are absolutely necessary to providing safe care. Nurses, physicians, medical assistants, pharmacists, technicians, and others need support to fulfill their highest potential as healers.



7. PARTNER WITH PATIENTS AND FAMILIES FOR THE SAFEST CARE

Patients and families need to be actively engaged at all levels of health care. At its core, patient engagement is about the free flow of information to and from the patient.



8. ENSURE THAT TECHNOLOGY IS SAFE AND OPTIMIZED TO IMPROVE PATIENT SAFETY

Optimizing the safety benefits and minimizing the unintended consequences of health IT is critical.



Improving safety – safe EHR use

IOM HIT safety report (2012)

[ONC Safety Assurance Factors for EHR Resilience \(SAFER\) Guides](#)

- Guides to optimize safe use of EHRs (Sitting, 2014)
- Now required by CMS for safety assessment of EHR (Sittig, 2022)
- Updated in 2025 (Sittig, 2025)

EHRs should be SMARTER - improve cognitive support via (Johnson, 2022)

- Synthesizing information and supporting goal-oriented search
- Monitoring care decisions, taking patient data and care setting into account, and suggesting better alternatives
- Automating routine tasks
- Recognizing trends toward or away from idealized patient models
- Translating important user actions into documentation
- Exposing contextually relevant data
- Reliably and consistently performing these functions

Safe EHR use (cont.)

Patient/family online reporting system for perceived ambulatory note mistakes (Bourgeois, 2019)

- One-quarter identified potential inaccuracies; more than half considered important

Encourage partnerships with EHR vendors (Sittig, 2020)

Best practices for safe use of scribes (Ash, 2021)

Structured information-sharing reduces error and improves treatment outcomes (Centola, 2023)

Checklists

Commonly used in aviation and other disciplines; popular attention due to Gawande book (2009)

Well-known Keystone Intensive Care Unit Project in Michigan implemented checklist of evidence-based quality improvements

- Wash hands with soap
- Clean patient's skin with chlorhexidine
- Put sterile drapes over entire patient
- Wear sterile mask, hat, gown and gloves
- Put sterile dressing over catheter site

During an 18-month period saved 1500 lives and \$100 million (Pronovost, 2006), with sustained reductions after three years (Pronovost, 2010; Lipitz-Snyderman, 2011)

Haynes/Gawande surgery checklist

<https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery/tool-and-resources>

 World Health Organization		
SURGICAL SAFETY CHECKLIST (FIRST EDITION)		
Before induction of anaesthesia ▶▶▶▶▶▶▶▶▶▶ Before skin incision ▶▶▶▶▶▶▶▶▶▶▶▶▶▶ Before patient leaves operating room		
SIGN IN	TIME OUT	SIGN OUT
☐ PATIENT HAS CONFIRMED • IDENTITY • SITE • PROCEDURE • CONSENT	☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE	NURSE VERBALLY CONFIRMS WITH THE TEAM:
☐ SITE MARKED/NOT APPLICABLE	☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM • PATIENT • SITE • PROCEDURE	☐ THE NAME OF THE PROCEDURE RECORDED
☐ ANAESTHESIA SAFETY CHECK COMPLETED		☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING	ANTICIPATED CRITICAL EVENTS	☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
DOES PATIENT HAVE A:	☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?	☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
KNOWN ALLERGY?	☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?	☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT
☐ NO	☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?	
☐ YES		
DIFFICULT AIRWAY/ASPIRATION RISK?	HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?	
☐ NO	☐ YES	
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE	☐ NOT APPLICABLE	
RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?	IS ESSENTIAL IMAGING DISPLAYED?	
☐ NO	☐ YES	
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED	☐ NOT APPLICABLE	



Research on surgical checklists

Surgical death rate reduced from 1.5% to 0.8%, complications from 11.0% to 7.0% in a global population (Haynes, 2009)

Dutch hospitals

- Reduced mortality by 47% (deVries, 2010)
- Reduced mortality in a teaching hospital from 3.13% to 2.85% (Van Klei, 2012)

Simulation found improved adherence to life-saving processes in operating-room crises (Arriaga, 2013)

- 6% failure to adhere with checklists, 23% without

Study in Canadian hospitals found no improvement (Urbach, 2014)

- May have been due to underpowered study (benefit in positive direction but not statistically significant) and poor uptake (Gawande, 2014)

Future of patient safety research and policy

Must “slay dragons” and not merely investigate them (Card, 2023)

Need to shift focus from root causes to system resilience (Farley, 2023)

Role for AI (Topol, 2024)? Use cases that could help (Singh, 2025; Sittig, 2025)

- Create widespread interoperability with longitudinal patient data
- Measure safety using data analytics and displays
- Predict adverse events proactively
- Analyze large, multiorganizational clinical databases
- Develop and evaluate generative AI