

6.1a 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

Scope of the problem

Early concerns

- Leape (1994) – among the first to characterize
- Chantler (1999) – “Medicine used to be simple, ineffective and relatively safe; now it is complex, effective and potentially dangerous”

Seminal event was IOM “errors report” (IOM, 2000)

- Launched “patient safety movement” (Wachter, 2009)
- Has led to focus on the “science” of patient safety (Shekelle, 2011)

Lack of success often contrasted with aviation safety procedures and results (Pronovost, 2009)

- [Annual reports of commercial aviation safety](#) from International Air Transport Association (IATA)

State of science

- AHRQ Making Healthcare Safer reports (2020, 2021)
- Retrospective of patient safety movement (Leape, 2021)

IOM report, *To Err is Human* (IOM, 2000)

Estimated 48,000-96,000 deaths per year in US due to medical errors

Randomly selected hospital discharges from New York (30,000 cases) and Colorado/Utah (15,000 cases)

- Adverse events occurred in 2.9-3.7% of hospitalizations
- 50% were minor, temporary injuries
- 7-14% resulted in death
- 2.6% resulted in permanent disabling injury
- 53-58% were preventable
- 28% were due to negligence, i.e., failed to meet reasonable standard of care

LEADING CAUSES OF DEATH ¹	
Diseases of the Heart	726,974
Cancer (malignant neoplasms)	539,577
Cerebrovascular Disease	159,791
Chronic Obstructive Pulmonary Disease	109,029
Medical Errors ²	44,000–98,000
Accidents and Adverse Effects (motor vehicle accidents = 43,458; all others = 52,186)	95,644
Pneumonia and Influenza	86,449
Diabetes	62,636
Suicide	30,535
Kidney Disease	25,331
Liver Disease	25,175

SOURCES: 1. Centers for Disease Control and Prevention, 1997. 2. IOM, *To Err Is Human: Building a Safer Health System*, 2000.

(Courtesy, Dan Masys, MD)

Challenges to the IOM report

Some challenged the numbers

- Reliability and reproducibility for these subjective assessments not measured (Sox, 2000)
- Overstated due to sampling problems and underlying illness (McDonald, 2000)

Another study found different results (Hayward, 2001)

- While 22.7% of deaths rated as possibly preventable, only 6.0% probably or definitely
- Only 0.5% of those who died would have lived 3 months in good cognitive health

Additional British study found similar results (Hogan, 2012)

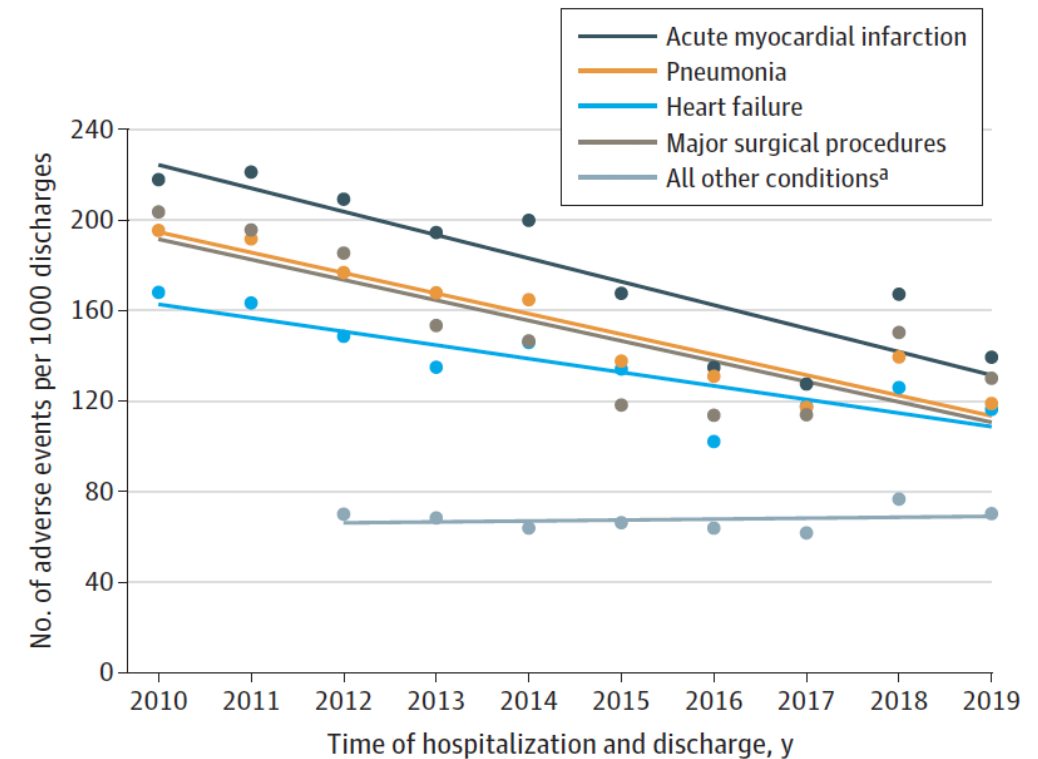
- Only 5.2% of deaths preventable
- Median life expectancy of those with preventable deaths was 6 months

Safety problems persist in hospitals and outpatient settings

Hospitals with lower Leapfrog safety scores (A-F scale) had higher mortality (Austin, 2019)

- Hospitals with D-F had 92% higher mortality rate
- Resulting in estimated 160,000 avoidable deaths per year

From 2010-2019, adverse events in hospitalized patient for four major medical conditions decreased about 5% per year (Eldridge, 2022), but ticked back up with onset of COVID-19 pandemic (Fleisher, 2022)



Safety problems persist (cont.)

In random sample of 2809 Massachusetts hospitalizations, at least one adverse event occurred in 23.6% of patients (Bates, 2023)

- 22.7% judged preventable
- 32.3% had severity level of serious or higher
- Preventable adverse event occurred in 6.8%
- Adverse drug events most common

In 11 outpatient sites in Massachusetts in 2018, 7.0% of patients had 1 or more adverse events (Levine, 2024)

- Of adverse events, most common were drug (63.8%), health care-associated infections (14.8%) and surgical or procedural events (14.2%)
- 23.2% of adverse events deemed preventable
- Higher rate in elderly patients

ECRI “Technology Hazards” (2026)

1. The Misuse of AI Chatbots in Healthcare
2. Unpreparedness for a “Digital Darkness” Event
3. The Growing Challenge of Combating Substandard and Falsified Medical Products
4. Recall Communication Failures for Home Diabetes Management Technologies
5. Tubing Misconnections Remain a Threat Amid Slow ENFit and NRFit Adoption
6. Underutilizing Medication Safety Technologies in Perioperative Settings
7. Deficient Device Cleaning Instructions Continue to Endanger Patients
8. Cybersecurity Risks from Legacy Medical Devices
9. Technology Designs or Configurations That Prompt Unsafe Clinical Workflows
10. Water Quality Issues During Instrument Sterilization

Classification of error in medicine

Adverse events (AEs, or for drugs – adverse drug events [ADEs])

- Preventable (“nonintercepted”)
- Nonpreventable

Errors

- Adverse outcome (“preventable” AEs)
- Error made but did not reach patient (“near miss”)

Some adverse events are not preventable, while some errors do not result in any adverse event

Categories of medical error

Medication

Surgical

Diagnostic

Healthcare system

Interruptions

Information technology

Other

Medication error and ADEs

First documented by Bates (1995)

- 6.5 ADEs and 5.5 potential ADEs per 100 hospital admissions
- Of all ADEs, 1% were fatal (none preventable), 12% life-threatening, 30% serious, and 57% significant
- Cost per ADE was about \$3,244
 - Excluding injuries to patient, malpractice litigation, costs of later admissions
- 28% of ADEs were associated with error
- Errors more likely to occur at ordering (56%) vs. administration (34%) stage
- Conventional methods to detect errors and injuries discovered very few

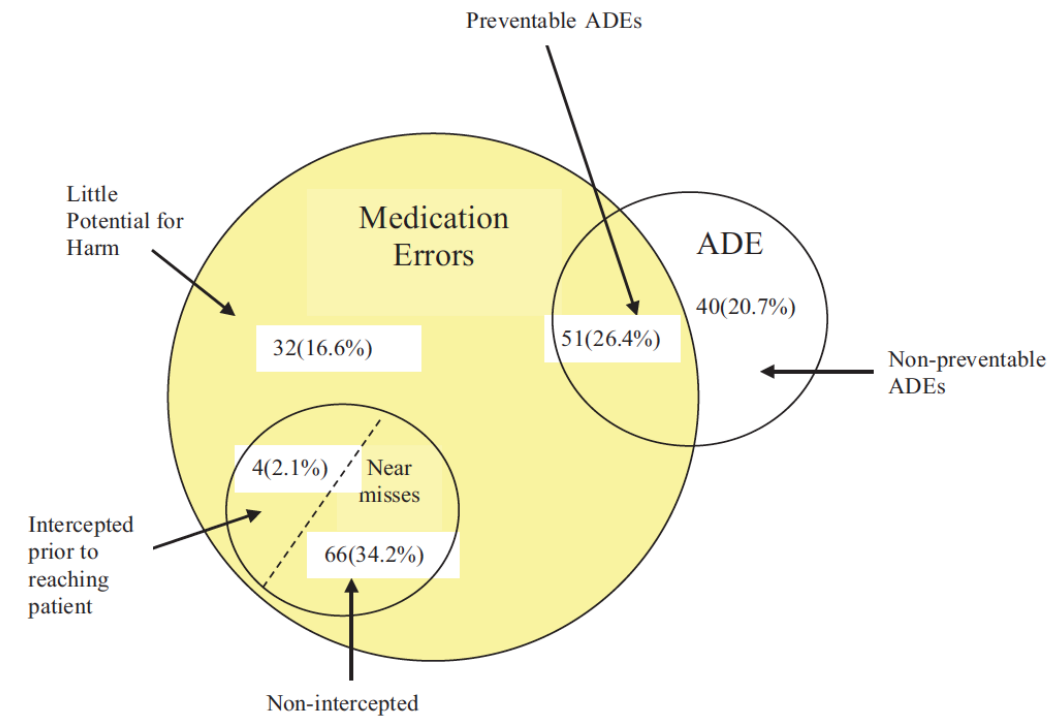
Medication error – inpatient

In a large teaching hospital, pharmacists identified 62.4 errors per 1000 medication orders, 31% of which were rated clinically serious (Bobb, 2004)

In consecutive surgeries in a large teaching hospital, 1 in 20 medication administrations led to medical error or ADE (Nanji, 2016)

In review of operating room medication error reports, 95% deemed preventable with CDS (Amici, 2024)

High-risk medication (HRM) prescribing errors at 2 pediatric hospitals found 20% of errors had 1 or more errors, with 24% technology-related and 33% potentially serious (Merchant, 2026)



(Nanji, 2016)

Medication error – outpatient

Patients misunderstand directions from clinicians (Davis, 2006; Tarn, 2006)

Errors not caused by just a few “bad apples” (Nicholson, 2006)

Systematic review of 29 studies found preventable ADE rate of 5.6 per 1000 person-months, with 0.45% requiring hospitalization (Thomsen, 2007)

In a general medicine clinic, 28% of prescriptions contained errors although only 0.2% caused harm (Devine, 2007)

In a large primary care network, 77% of patients had at least one discrepancy between medication list in record and pharmacy claims data (Comer, 2015)

In non-healthcare settings at rate of 1.73 per 100,000 people per year (Hodges, 2018)

Another source of error is abbreviations (Brunetti, 2007; ISMP, 2021)

Abbreviation or dose designation	Problem	Correction
u (units)	Misinterpreted as 0 or 4	Write "units"
IU (international units)	Misinterpreted as IV or 10	Write "International Unit"
qd (daily)	Misinterpreted as qid	Write "daily"
qod (every other day)	Misinterpreted as qid or qd	Write "every other day"
Use of zero after decimal point	Decimal point may be missed	Do not use trailing zeroes
Failure to use zero before decimal point	Decimal point may be missed	Always use leading zero before decimal point
MS or MSO4	Magnesium vs. morphine sulfate	Write "magnesium sulfate" or "morphine sulfate"

"Do not use" lists from [Joint Commission](#) and [Institute for Safe Medication Practices \(ISMP\)](#)



Surgical error

Mostly occur in routine operations on complex patients (Regenbogen, 2007)

Problems persist long after patient leaves hospital (Encinosa, 2008)

Wrong-side and wrong-patient errors persist (Stahel, 2010)

- Wrong-side errors most often due to judgment and not performing “time-out”
- Wrong-patient errors most often due to diagnostic or communication errors

Fatigue common among surgical residents, with fatigue increasing risk of error by 22% (McCormick, 2012)

Diagnostic error

IOM report (2015) estimated

- 18 million diagnostic errors per year, leading to an estimated
 - 74,000 deaths
 - 5% of all outpatient office visits
 - 12% of hospital adverse events
 - 10% of hospital inpatient deaths
- Nearly every American will experience a diagnostic error in their lifetime

Validated with more recent research

- Misdiagnosis rates for big three diseases (cancer, vascular, infections) – 11.1% error and 4.4% serious harm, with number harmed annually as high as 795K (Newman-Toker, 2024)
- For patients transferred to intensive care unit (ICU) or died, missed or delayed diagnosis took place in 23% and 17% of errors caused temporary or permanent harm (Auerbach, 2024)
- 7% of hospitalized patients who received general medical care experienced an adverse diagnostic error within 90 days of admission (Dalal, 2024)

Diagnostic error (cont.)

As many as 40,000 patients die in ICUs each year due to diagnostic error (Winters, 2012)

Diagnostic errors most frequent cause (22-28%) and highest amount (35.2%) of paid malpractice claims (Saber Tehrani, 2013; Gupta, 2017)

- Higher risk of disability and death (Gupta, 2017)

Most errors in primary care settings occur with common conditions – most frequent errors included (Singh, 2013)

- Not ordering further tests (57.4%)
- Error taking medical history (56.3%)
- Error related to physical exam performance (47.4%)
- Failure to review previous documentation (15.3%)
- Failure to refer to expert (10.0%)

Physicians not always good in applying probabilities to interpreting lab tests (Morgan, 2018)

Use of “illness scripts” may lead to premature and incorrect diagnoses; need to incorporate pathophysiological reasoning, especially in era of AI (Schwartzstein, 2025)

Error due to healthcare system issues

Decreased staffing levels of nurses in hospitals and nursing homes worsens patient outcomes (Hickam, 2003)

Nurses working longer shifts and overtime more likely to make errors (Rogers, 2004)

Interns made substantially more errors (Landrigan, 2005) and reported more motor vehicle accidents (Barger, 2005) when working 24+ hour shifts

In radiology department, most common errors due to order entry, mostly from outside department, followed by incorrect follow-through and patient identity issues (Thornton, 2011)

Reports of lab results in ICU rounds often having missing or incorrect data, usually not detected (Artis, 2017)

Healthcare system issues (cont.)

Blood sugar better controlled in language-concordant Hispanic patients (Parker, 2017)

Hospital team “faultlines” can have ripple effects on patient outcomes (Li, 2023)

Poor communication between healthcare practitioners and patients and between different groups of practitioners has been found to affect patient safety in different ways (Keshtkar, 2025)

Accuracy of radiology imaging interpretation impacted by human factor issues such as distractions, interruptions, and fatigue, and by cognitive biases (Cowen, 2025)

Error due to interruption and multitasking

Multitasking and interruption in emergency department led to errors in patient handoffs (Laxmisan, 2007)

Physicians interrupted 6.6 times per hour, during 11% of all tasks, leading them to delay or not complete 18.5% of all tasks (Westbrook, 2010)

Interruption doubled rate of error during medication administration by nurses (Westbrook, 2010)

Smartphones are increasing source of physician interruption, peaking at 3-4 times per hour per day (Vaisman, 2017)

HIT can reduce but also increase error

Wrong patient identification (Gray, 2006; McDonald, 2006)

Barcode administration systems may result in workarounds that lead to harm (Koppel, 2008)

“Hard stop” order entry may reduce error but also cause relevant treatment delays (Strom, 2010)

Transitioning between EHR systems associated with error (Abramson, 2011)

Information hidden in plain sight (Singh, 2013; March, 2013)

Default values in systems can lead to errors, especially wrong time and wrong dose (Sparnon, 2013)

Half-million women not notified for breast cancer screening due to “algorithm failure” (Charette, 2018)

Error from copy and paste

Long-time known source of error from HIT has been “copy and paste,” propagating outdated or wrong information (Hirschtick, 2006; Yackel, 2006; Thornton, 2013; Cimino, 2013)

Continues to be a well-documented problem (ECRI, 2015; Tsou, 2017; Lowry, 2017)

One analysis of 23,630 notes of 460 clinicians found 18% of text manually entered, 46% copied, and 36% imported (Wang, 2017)

Growing body of EHR safety concerns

Collection of lessons learned (“HIT or Miss,” Leviss, 2019)

Experience of

- VA (Meeks, 2014)
- England’s National Program for IT (Magrabi, 2015)
- Joint Commission (Castro, 2016)

Several among annual [“Top 10” patient safety concerns and technology hazards](#) of ECRI

Known major contributor to physician burnout (Gardner, 2019)

Vary by hospital and EHR vendor (Classen, 2020)

Association between frontline user–rated EHR usability and EHR safety performance (Classen, 2023)

Specific EHR safety concerns

Patient identification (Choudhury, 2020)

Usability issues (Howe, 2018)

Computerized provider order entry (CPOE)

- Analysis of safety events found most common errors were dose omission, wrong dose or overdosage, and extra dose (Lawes, 2017)
- In pediatric patients due to (Tolley, 2017; Ratwani, 2018)
 - Lack of drug dosing alerts
 - Generation of inappropriate dosing alerts
 - Inappropriate drug duplication alerts
 - Dropdown menu selection errors
 - System design issues
- 4 years after introduction of CPOE with CDS, rate of pediatric technology-related prescribing errors unchanged (Raban, 2024)

Down time – infrequent but can be prone to errors when happens (Larsen, 2018)

HIT leads to malpractice claims

Involved in about 1% of all malpractice claims
(Graber, 2015)

Top issues in malpractice claims related to EHRs
(Ruder, 2014)

Rate of cases increasing (Ranum, 2019)

Figure 2. Top Issues in Claims with EHR Factors*

	% cases*
Incorrect information in the EHR	20%
Hybrid health records/EHR conversion issues	16%
System failure - electronic routing of data	12%
System failure - unable to access data	10%
Pre-populating / copy & paste	10%
Failure of system design to meet the need	9%
EHR (user) training and/or education	7%
Lack of integration/ incompatible systems	7%
EHR-related user error (other than data entry)	7%

Results from an analysis done in 2013 by CRICO of 147 medical malpractice cases that were found to have an EHR-related contributing factor.

**A case will often have multiple factors identified.*

Vendor accountability for HIT safety

Vendor “hold harmless” clause in contracts may exacerbate problem (Koppel, 2009)

AMIA adopted policy statement regarding ethics, safety, best practices, and oversight regarding HIT vendors (Goodman, 2011) – recommendations include

- Patient safety should trump all other values
- Vendor concerns about liability and intellectual property should not override other considerations
- Transparency and commitment to patient safety should govern vendor contracts
- Institutions should provide ethics education to purchasers and users, and publicly commit to standards of conduct
- All parties should encourage and assist in each others’ efforts to adopt best practices

Vendor response: EHR Association Code of Conduct (2016)

Rules from 21st Century Cures Act prohibit developer gag clauses for discussion and demonstration of EHR problems