



Leah Binder, MA, MGA

President and CEO, The Leapfrog Group





Steve Burrows Writer and Director, *Bleed Out*

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Leah Binder, MA, MGA

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Joe Kiani

Founder, Patient Safety Movement Foundation; Founder and CEO, Masimo

PANEL

What Patients and Employers Expect for Patient Safety



Leah Binder, MA, MGA CEO, The Leapfrog Group MODERATOR



Sally Welborn Former SVP Global Benefits, Walmart



Robert Otto Valdez, Ph.D., M.H.S.A.

Director, Agency for Healthcare Research and Quality (AHRQ)





Barbara Wentworth, PhD Program Manager, Health Net



Krista Hughs, BCPA Founder and CEO, Hughes Advocacy



Sue Sheridan, MIM, MBA, DHL Director of Patient Engagement Emeritus, Society to Improve Diagnosis in Medicine (SIDM)



Costs of Care is a leading non-profit cultivating change agents who will lead the creation of a more affordable and equitable health system.



2023 Steven Schroeder Award for Outstanding Healthcare CEO Winner



Charles Holland

President and CEO, St. Bernard Hospital

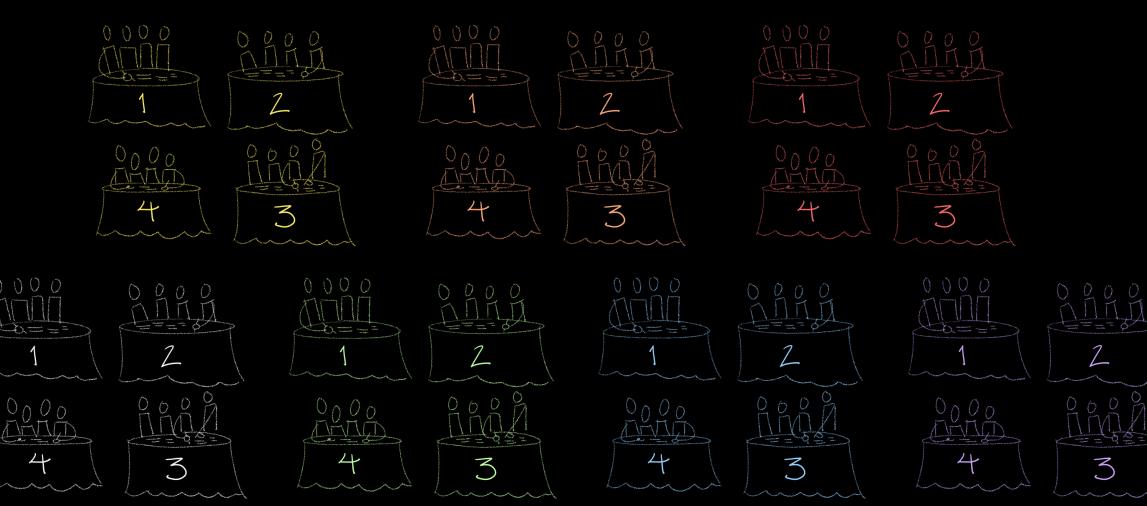


Conversations to Transform Tomorrow









12/2



1. What do you think is the best way to get consumers to use Leapfrog data? 2. How might new technology like Al impact patient safety?

4. What do you think should be the next leap forward in patient safety? 3. How might we, as Leapfrog stakeholders, better address health equity?



PANEL

Healthcare-Associated Infection (HAI) Spike: Is it Over?



Karen van Caulil, PhD CEO, Florida Alliance for Healthcare Value MODERATOR



Lee A. Fleisher, MD Former CMO and Director, Center for Clinical Standards and Quality for CMS



Stephanie Taylor, MD, MArch CEO, Building 4 Health, Inc



Shaunté Walton, MS, CIC, FAPIC

System Director, Clinical Epidemiology and Infection Prevention UCLA Health

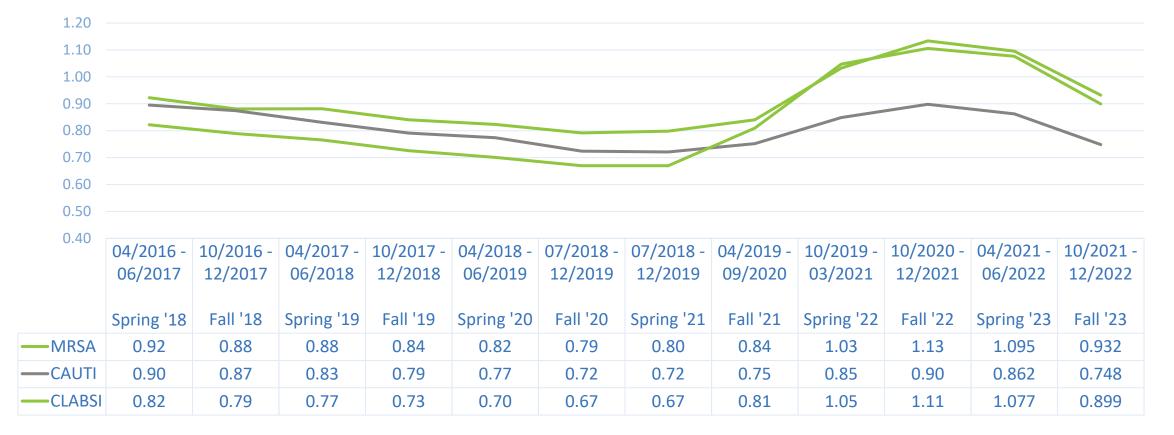


Rebecca Bartles, DrPH, CIC, FAPIC

Vice President, Government Affairs, Association for Professionals in Infection Control and Epidemiology (APIC)



Average HAI SIRs Reached 5 Year High in 2021 (Fall 2022 Safety Grade)



CAUTI (shown in gray) has returned to pre-pandemic levels. However, **CLABSI and MRSA** remain significantly higher than pre-pandemic levels but have significantly decreased since the fall 2022 Safety Grade.



Factors Impacting HAIs During COVID

Higher Acuity Patients

- More comorbidities (both COVID and non-COVID)
- Longer length of stay
- More lines, drains, and tubes
- Steroids and anti-inflammatories impacting immune status
- Prolonged ventilation
- Febrile, diaphoretic patients, often with incontinent diarrhea
- Proning resulting in wet dressings, challenges with bathing and linen changes, and inability to assess device insertion sites

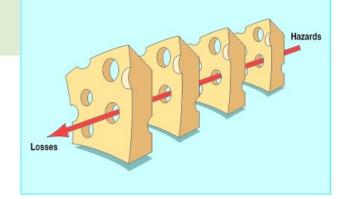
Shortages

• Staffing :

- Stress, fear, exhaustion, trauma
- Increased nurse to patient assignments
- Increased traveler use and reassigned HCWs
- Physicians inserting lines and providing ICU level care when they typically do not
- Products:
 - PPE shortages
 - Clinical product shortages
 - Product replacements and unfamiliar products

Crisis Practices

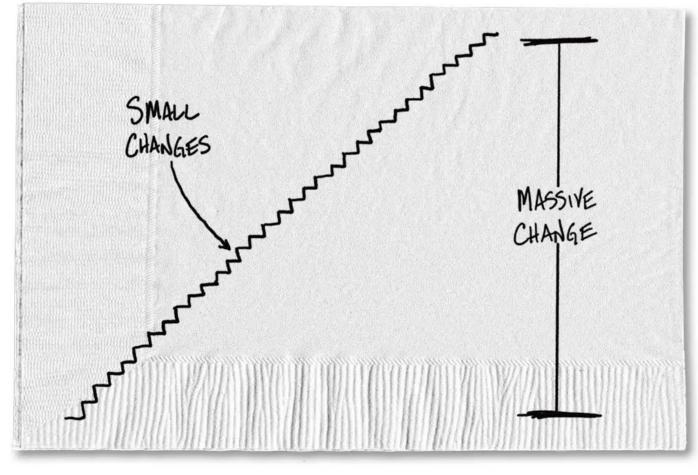
- Reduced environmental cleaning
- Changes in patient placement locations, addition of new airflow types to create negative pressure
- Patient hygiene deprioritized
- Lines inserted sooner and remaining in place longer
- Pumps outside doors with long lengths of tubing
- Reduced quality improvement strategies





Key Impacted Processes

- Multidisciplinary rounds
- Huddles and auditing
- Culture ordering stewardship
- Culture collection processes
- Patient bathing and hygiene
- Device selection and utilization



The New York Times, 2017. The Best Path to Long-Term Change is Slow, Simple, and Boring. <u>https://www.nytimes.com/2017/07/31/your-money/the-best-path-to-long-term-change-is-slow-simple-and-boring.html</u>



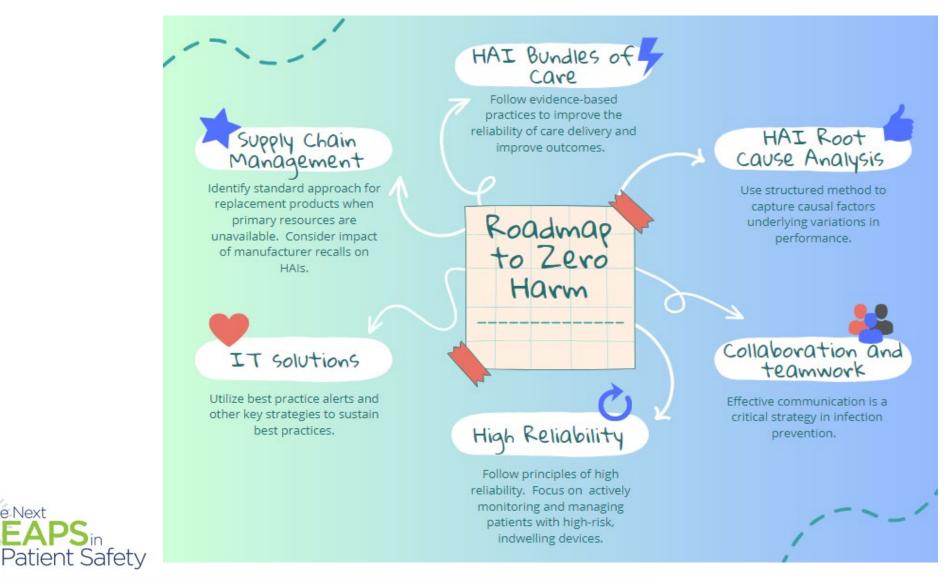
Remember Our Heroes In Healthcare



- HCWs are confronted with patients' emotional traumas daily
 - Compounded during the COVID-19 pandemic
 - American Hospital Association reported:
 - 93% HCW stress
 - 86% HCW anxiety
 - 77% HCW frustration
 - 76% HCW exhaustion and burnout
 - 75% reported overwhelmed
 - Only 13% receive behavioral health support
 - Studies exist that show emotional exhaustion were related to psychosocial aspects, which in turn had significant impact on HAIs.



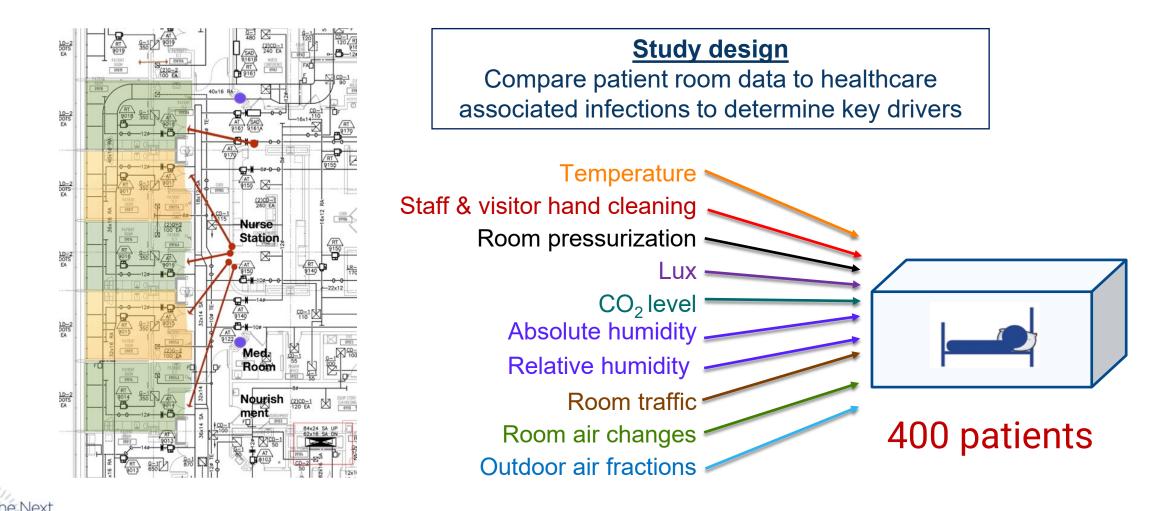
Back To Infection Prevention Basics



2023 Leapfrog Annual Meeting & Awards Dinner | December 5, 2023 | Washington, D.C.

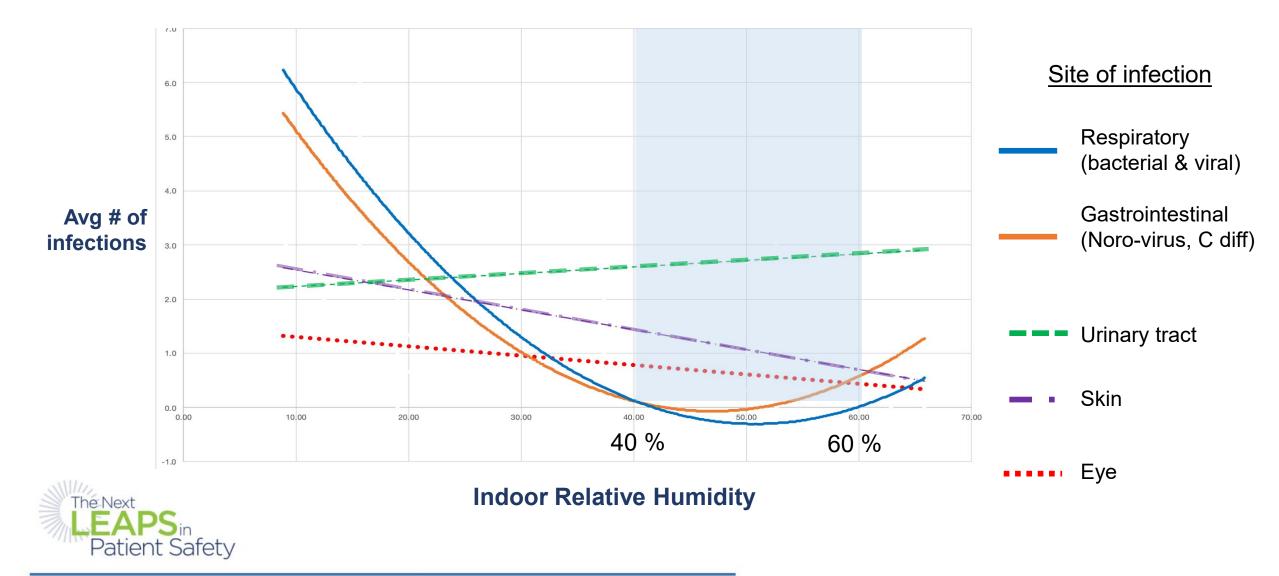
he Next

2014 study on HAIs and patient room environment



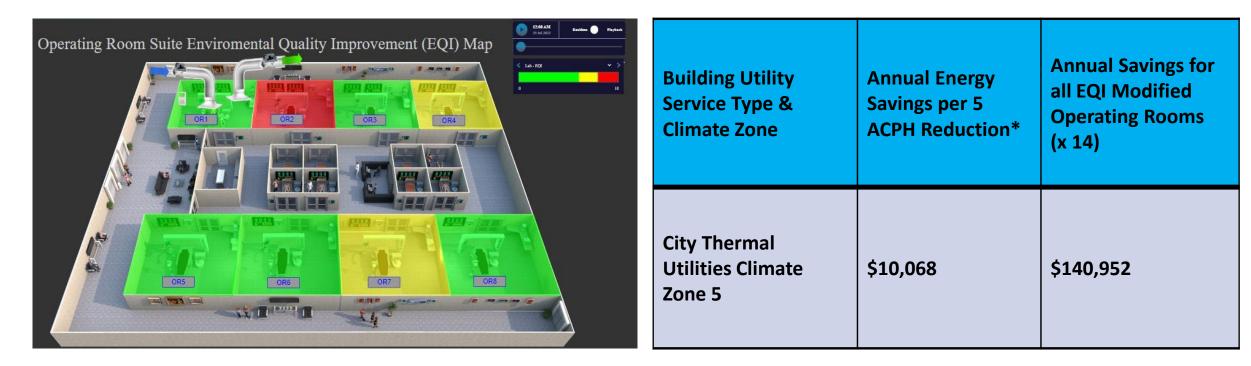
Patient Safety Monitor 10 rooms over 13 months = 8M datapoints

As patient room RH when down, infections went up!



Holistic Indoor Air management in ORs: reduced SSIs and energy consumption





87% reduction in SSI's (3.8% to 0.5%) AND

Significant energy savings



2023 Leapfrog Annual Meeting & Awards Dinner | December 5, 2023 | Washington, D.C.

https://doi.org/10.18103/mra. v10i10.3179



The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Health Care Safety during the Pandemic and Beyond — Building a System That Ensures Resilience

Lee A. Fleisher, M.D., Michelle Schreiber, M.D., Denise Cardo, M.D., and Arjun Srinivasan, M.D.

We have observed substantial deterioration on multiple patient safety metrics since the beginning of the pandemic, despite decades of attention to complications of care. Centralline–associated bloodstream infections in U.S. hospitals had decreased by 31% in the 5 years preceding the pandemic; this promising trend was almost totally reversed by a 28% increase in the second quarter of 2020 (as compared with the second quarter of 2019). There were also increases in catheter-associated urinary tract infections, ventilator-associated events, and methicillin-resistant Staphylococcus aureus bacteremia.



N Engl J Med 2022; 386:609-611

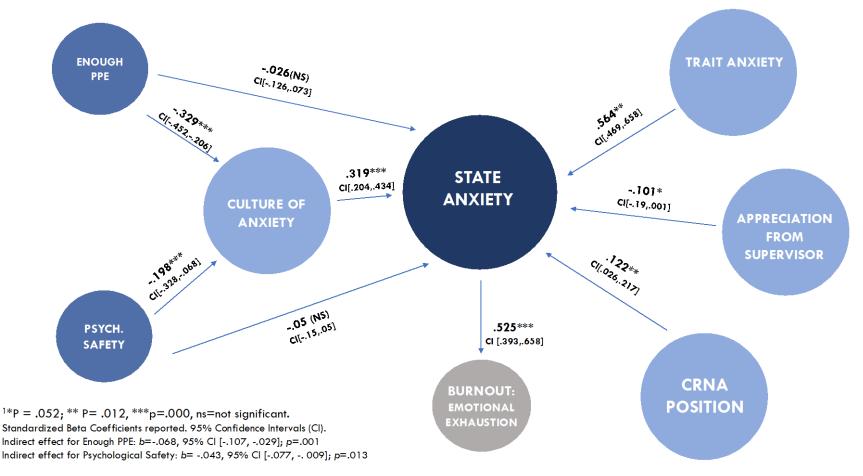
STRESS

The Contagion We Can Control

by Sigal Barsade

March 26, 2020

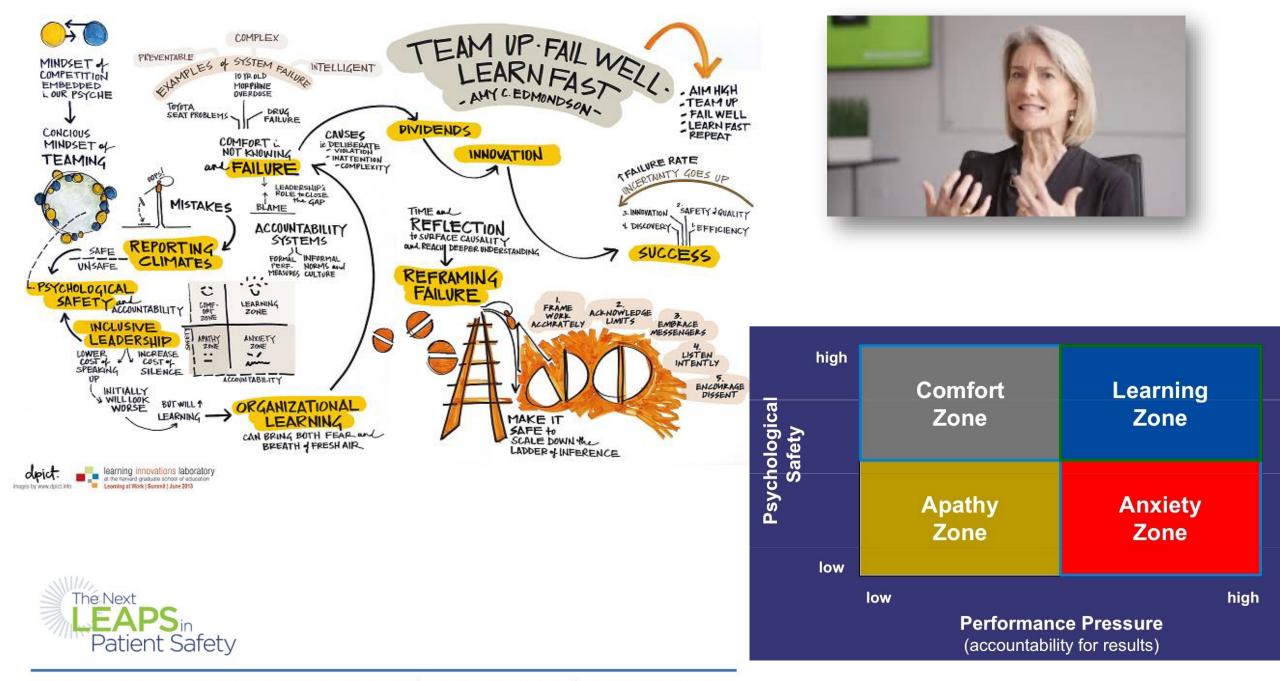
Figure 1. Constellation of Factors Related to Clinician State Anxiety¹





2023 Leapfrog Annual Meeting & Awards Dinner | December 5, 2023 | Washington, D.C.

Managing Anxiety in Anesthesiology and Intensive Care Providers during the Covid-19 Pandemic: An Analysis of the Psychosocial Response of a Front-Line Department. NEJM Catalyst July 8, 2020



THANK YOU TO OUR PLATINUM SPONSOR!





Michelle Martin, MBA Board Chair, The Leapfrog Group





David Bates, M.D., M.Sc.

Chief of General Internal Medicine, Mass General Brigham; Professor, Harvard Medical School and Harvard T.H. Chan School of Public Health



Using Artificial Intelligence to Improve Patient Safety

- David W. Bates, MD, MSc
- Medical Director for Clinical and Quality Analysis, Mass General Brigham Health Care
- Director of the Center for Patient Safety Research and Practice

• Leapfrog Group, 2023

Safety backdrop

Since "To Err Is Human"

Overview

Why AI is important

Potential impact of AI by type of harm

Conclusions

The Extent of Medical Injury

Location	Year	Adverse Event Rate
New York MPS	1991	3.7%
Colorado/Utah	1999	3.3%
Australia	1995	13%
UK Pilot	2000	11%
New Zealand	2001	13%
Denmark	2001	9%
Canada	2004	7.5%

How safe is care today? Results from Safe Care published January 12, 2023

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

The Safety of Inpatient Health Care

David W. Bates, M.D., David M. Levine, M.D., M.P.H., Hojjat Salmasian, M.D., Ph.D., M.P.H., Ania Syrowatka, Ph.D., David M. Shahian, M.D., Stuart Lipsitz, Sc.D., Jonathan P. Zebrowski, M.D., M.H.Q.S., Laura C. Myers, M.D., M.P.H., Merranda S. Logan, M.D., M.P.H., Christopher G. Roy, M.D., M.P.H., Christine Iannaccone, M.P.H., Michelle L. Frits, B.A., Lynn A. Volk, M.H.S., Sevan Dulgarian, B.S., B.A., Mary G. Amato, Pharm.D., M.P.H., Heba H. Edrees, Pharm.D., Luke Sato, M.D., Patricia Folcarelli, Ph.D., R.N., Jonathan S. Einbinder, M.D., M.P.H., Mark E. Reynolds, B.A., and Elizabeth Mort, M.D., M.P.H.

ABSTRACT

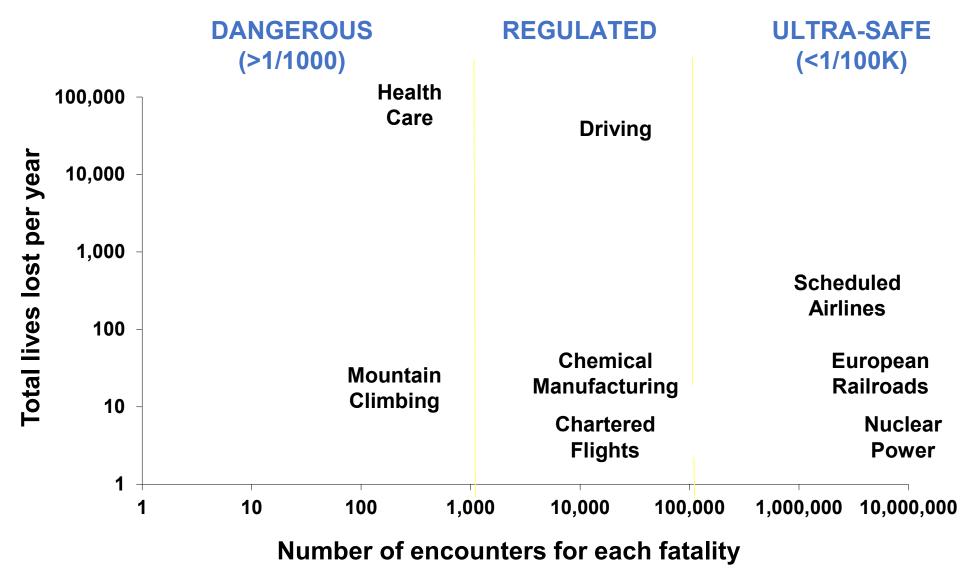
BACKGROUND

Adverse events during hospitalization are a major cause of patient harm, as documented in the 1991 Harvard Medical Practice Study. Patient safety has changed substantially in the decades since that study was conducted, and a more current assessment of harm during hospitalization is warranted.

Safety of Care Today

Study	Population	Year Data Collected	Adverse Event Rate
Bates et al	All adults	2018	24%
Office of the Inspector General	Medicare Patients	2018	27%
Adler et al	All adults	2009-2012	26%

How Hazardous Is Health Care?



Progress Since To Err Is Human: What Organizations Have Done

- HAIs
- Medication safety
- Handoffs
- Surgical checklists
- Pressure ulcers, falls, failure to rescue
- Infrastructure
 - Reporting systems
 - Learning healthcare systems

Electronic Record Should be Used to Find Adverse Events

- Already good for hospital-acquired infections
- Reasonable too for adverse drug events though needs refinement
- Mediocre to poor for DVTs/pulmonary embolism
- Hasn't yet been added for falls, pressure ulcers
- Not yet trained for decompensation
- Works very poorly for diagnostic errors
- But mandating across institutions soon would be major forward step
- Not yet set up for outpatient setting

Artificial Intelligence

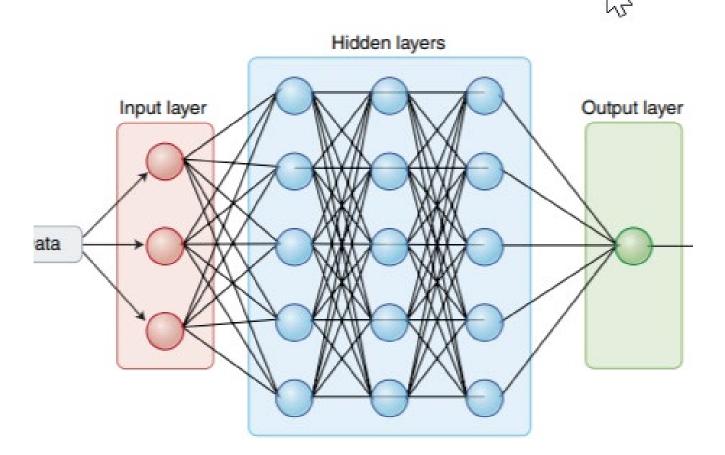
Artificial intelligence (AI) refers to the simulation of human intelligence in machines that are programmed to think like humans and mimic their actions. The term may also be applied to any machine that exhibits traits associated with a human mind such as learning and problem-solving. Mar 13, 2020



Term was coined at a conference at Dartmouth in 1956—so has been around. Have been a number of cycles of hype around this.

Deep Learning

- Only widely accepted as viable in 2012
- Consists of digitized inputs, like image or speech, that go through multiple layers of "neurons" that progressive detect features and turn into output
- Hidden layers 5-1000
- Better than humans in Go, Texas Hold'em among others
- Main technology in self-driving cars
- Often not validated in real world
- Lack of annotated datasets biggest issue



1 A deep neural network, simplified. Credit: Debbie Maizels/Spring ure

Best Use Cases

- Pattern recognition using deep neural networks
 - Scans, pathology slides, skin lesions, retinal images, electrocardiograms, endoscopy, vitals signs
 - Usually compared with physician assessment comparing true-positive vs. false-positive rates with receiver operating characteristic (ROC) curves, and area used to express accuracy
- Main areas: radiology, dermatology, pathology, ophthalmology, cardiology, with emerging areas being GI, mental health
- Can also help health systems make better choices, help patients directly, help with data analysis

Example: Chest Radiographs

Detection of pneumonia for 112,000 images was compared with 4 radiologists

Algorithm outperformed radiologists, but AUC was just 0.76

Google team used same image set for 14 diagnoses

AUC ranged from 0.63 for pneumonia to 0.87 for heart enlargement or collapsed lung

Algorithms typically much faster than humans—up to 150 times

But in nearly all instances human + algorithm does best

Topol EJ, Nature Medicine 2019

FOCUS | REVIEW ARTICLE

NATURE MEDICINE

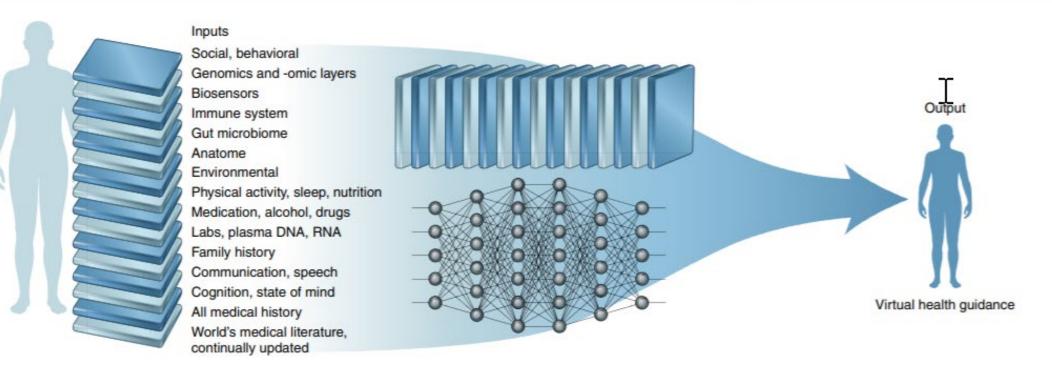


Fig. 3 | The virtual medical coach model with multi-modal data inputs and algorithms to provide individualized guidance. A virtual medical coach that uses comprehensive input from an individual that is deep learned to provide recommendations for preserving the person's health. Credit: Debbie Maizels/ Springer Nature

Topol EJ, Nature Medicine 2019

Examples of Applications With Safety Benefits Preceding AI/ML

- Medications (CPOE, bar-coding, smart pumps)
- Coverage application
- Computerized notification about critical test results
- Tracking abnormal test results
- Patient monitoring

Main Types of Harm in Hospital

Туре	Consequences	Potential for AI/ML
Hospital-acquired infection	High	Moderate. Already great benefit with known solutions
Adverse drug events	High	High, but mainly for predicting which patients are at specific risk of ADEs
DVTs and PEs	High	Moderate, already great benefit with known solutions
Surgical injuries	High	Modest, won't discuss further
Pressure ulcers	Moderate	Moderate to high
Falls	Moderate	Moderate—known approaches already very helpful
"New" types		
Decompensation	High	Very high—current approaches not effective
Missed diagnoses	High	Very high, but the most complex of the use cases

Bates, DW npj Digital Medicine, 2021

Hospital-Acquired Infections

- Overall: already fairly big improvement
 - Especially for specific types: CLABSI, VAP, CAUTI
 - But levels of implementation vary
- Opportunities for improvement:
 - In detection
 - Also for prevention in many areas
- Key use cases for AI:
 - Early identification of patients with infection including but not limited to sepsis
 - Assistance with triage decisions in infected patients
 - Linkage between isolates from multiple patients

Detecting Adverse Drug Events

- Overall: substantial recent improvement here also, mainly in reducing rates of prescribing, administration errors
- Opportunities for improvement:
 - Most currently implement clinical decision support not yet delivering value
- Key use cases:
 - Which patients may experience ADEs, leveraging:
 - Genetic/genomic data
 - Clinical information
 - Which patients should have specific testing for certain SNPs
 - Which patients should get specific prophylaxis

Thromboembolic Disease

- Overall: has been improvement here, robust evidence about which preventive strategies work
- Opportunities for improvement:
 - Implementation is still uneven, many patients don't get what has been shown to work, or best prevention for them
- Key use cases for AI:
 - Thromboembolic risk in cancer patients
 - Which patients might benefit most from specific types of prophylaxis
 - Which patients with thromboembolism should have further diagnostic testing

Pressure Ulcers

- Overall: these still occur far too frequently, some strategies with documented benefit
- Opportunities for improvement: better sensing, especially for fluid, and when a patient is not moving
 - Leveraging the data that come out of hospital beds
- Key use cases for AI:
 - Identifying which patients are at imminent risk using both clinical data and sensing
 - Determining which patients may benefit most from expensive interventions

Falls

- Overall: strategies such has FALLTIPS have proven benefit, though still not implemented in most organizations
 - 25% decrease in main study—Dykes, JAMA 2010
- Opportunities for improvement: reduction of rates, implementation of prevention strategies for high-risk groups
- Key use cases:
 - Improvement of risk stratification
 - Linkage with real-time monitoring especially from sensors
 - Use in new settings such as long-term care, post-discharge patients who are high-risk

Potential Role for Al in Detecting and Improving Management of Decompensation

- Overall: Has been some attention e.g. with rapid response teams, but overall hasn't been very effective especially outside of ICUs
- Opportunities for improvement: detection of decompensation overall and for specific reasons such as sepsis or bleeding
- Key use cases:
 - Early identification of decompensation overall
 - Early identification of sepsis
 - Early identification of post-operative bleeding
 - Decompensation in a variety of settings—post discharge high-risk, long-term care

Special Article

Automated Identification of Adults at Risk for In-Hospital Clinical Deterioration

Gabriel J. Escobar, M.D., Vincent X. Liu, M.D., Alejandro Schuler, Ph.D., Brian Lawson, Ph.D., John D. Greene, M.A., and Patricia Kipnis, Ph.D.

N Engl J Med Volume 383(20):1951-1960



Outcomes in the Eligible Population, with Comparison between the Intervention Cohort and Comparison

Variable	Study Population	Adjusted Relative Risk or Hazard Rate Ratio (95% CI)
Target population		
No. of hospitalizations	43,949	
No. of patients	35,669	
ICU admission within 30 days after alert		0.91 (0.84-0.98)
Death within 30 days after alert		0.84 (0.78-0.90)
Favorable status at 30 days after alert†		1.04 (1.02–1.06)
Hospital discharge, as assessed by proportional-hazards analysis		1.07 (1.03–1.11)
Survival, as assessed by proportional-hazards analysis		0.83 (0.78-0.89)
Nontarget population		
No. of hospitalizations	504,889	
No. of patients	313,115	
ICU admission within 30 days after admission		0.94 (0.89–0.99)
Death within 30 days after admission		0.97 (0.93-1.02)
Favorable status 30 days after admission†		1.00 (0.99–1.00)
Hospital discharge, as assessed by proportional-hazards analysis		0.98 (0.97–0.99)
Survival, as assessed by proportional-hazards analysis		0.99 (0.96-1.03)

* The analysis included 548,838 hospitalizations and 326,816 patients (a patient could be included in both the target and nontarget populations, so the numbers of patients do not sum to 326,816). For the first three analyses (ICU admission, mortality, and favorable status within 30 days after an alert), the adjusted relative risk is for whether the patient was in the intervention condition (alerts led to a clinical response), as compared with patients in the comparison condition (usual care, with no alerts). For the nontarget population, the analytic approach was the same as for the target population, except that the cohorts involved patients on the ward whose condition did not trigger an alert; since there was no alert, we used 30-day mortality. We used Cox proportional-hazard models to assess the effects of the intervention on the hospital length of stay, with censoring of a patient's data at the time of death, and long-term survival (median follow-up in the target population, 0.8 years [IQR, 0.1 to 1.8]; median follow-up in the nontarget population, 1.4 years [IQR, 0.5 to 2.4]; maximum follow-up in both populations, 3.6 years). For the hospital length of stay, the hazard rate ratio refers to the instantaneous rate of discharge from the hospital divided by the instantaneous rate of discharge from the hospital in the comparison group; a rate ratio greater than 1 indicates that the intervention shortened the time to discharge. The hazard rate ratio corresponding to long-term survival refers to the long-term mortality in the intervention group as compared with the comparison group; a ratio lower than 1 indicates lower mortality in the intervention group. Additional details are provided by Harrell,³⁴ Basu et al.,³⁵ Hosmer and Lemeshow,³⁶ and Mihaylova et al.³⁷ Confidence intervals (CIs) were calculated with the use of bootstrapping to control for within-facility and within-patient correlations; see Goldstein et al.39

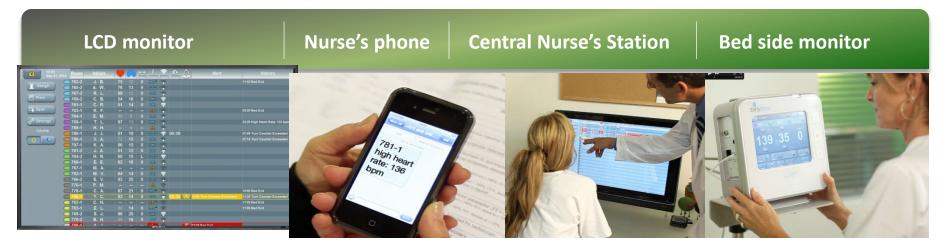
† Favorable status at 30 days indicates that, at 30 days after an alert (in the target population) or at 30 days after admission (in the nontarget population) the patient was alive, was not in the hospital, and had not been readmitted at any time.

Sepsis Examples

- Hospital Corporation of America (HCA) has developed a real-time tool called SPOT (Prediction and Optimization of Therapy) with 2.5 million patients
 - Estimate 8000 lives saved as a result over 5 years
- Duke also has rolled out a system called "Sepsis Watch"—trained on 50,000 patient records, 32 million datapoints
- Many other organizations working on this area

• Spectrum.ieee.org

EarlySense: Continuous Patient Supervision on General Care Floors



Full floor overview at a glance Real time alerts to nurses & supervisors + reports on team performance Nurse / physician communication support Facilitation of critical thinking by nurse



Continuous Monitoring in an Inpatient Medical-Surgical Unit: A Controlled Clinical Trial

100	Study Outcomes Comparing Study Units Before and After Implementation of Monitor								
		Control Unit			Intervention (Study) Unit			3 Arms p value*	
141		Baseline (Pre)	Control (Post)	P Value	Baseline (Pre)	Intervention (Post)	P Value	% Reduction	
	LOS in Med. Surg./ Units (mean)	3.80 (1.26- 4.25)	3.61 (1.19- 4.12)	0.07	4.00	3.63	0.02	9%	< 0.01
	LOS in ICU for patients coming from Med/Surg. units (mean)	1.73 (1.06- 2.28)	4.48 (0.94- 4.09)	0.01	4.53 (2.33)	2.45 (1.85)	0.1	45%	0.04
	Code Blue Events/ 1000 Pt.	3.9	2.1	0.36	9 (6.3)	2 (0.9)	0.05	86%	0.01

* P – value comparing 3 arms: intervention unit post, intervention unit pre and control unit post

Alert Frequency and Positive Predictive Value

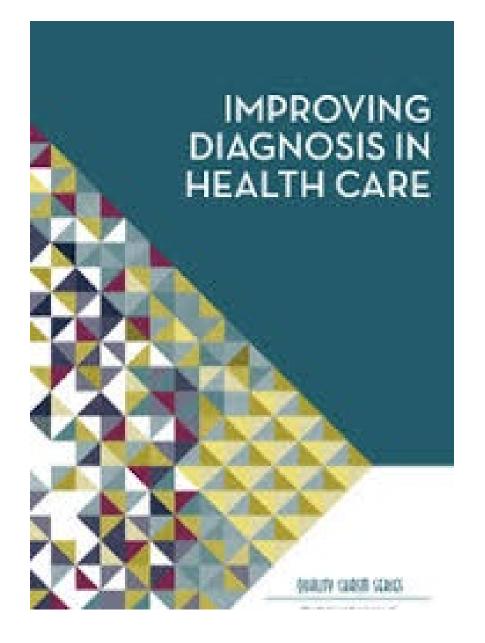
- EarlySense had 2.2 alerts per 100 recording hours
 - 50% result in nurse action
- Pulse oximetry, telemetry, cardiovascular monitors have 161-730 alerts per 100 hours
 - Much lower proportions result in action

Economic Analysis of Smart Monitor

• Modeled only ICU length of stay and pressure ulcers

	5-year ROI	Annual Benefit	Breakeven
Base Case	\$9.1 million	\$2.1 million	0.5 years
Conservative	\$3.3 million	\$0.66 million	0.75 years

Slight, Critical Care Medicine 2014



Missed and Delayed Diagnoses

Missed and Delayed Diagnoses

- Overall: appears to represent a very large problem, especially in outpatient setting— inpatient is less clear (see NAM Report)
- Opportunities for improvement—many, especially specific diagnoses like pulmonary embolism; also huge opportunity for reducing delays in diagnosis especially for common malignancies (lung, colon, breast, prostate)
- Key use cases:
 - Identifying clinical situations in which a diagnosis may have been missed
 - Putting together constellations of findings
 - Identifying scenarios in which there has been a delay longer than an acceptable alternative

Limitations/Reflections

Many other causes of harm

More focus on inpatient setting than others

Many areas not traditional considered safety issues like decompensation are on border but represent big opportunities

Will help a lot to have better measurement of inpatient/outpatient safety routinely

Patient engagement will play a big role have just done a study of showing patients their own risk for safety events

- But these are the biggest—uses pareto principle
- Outpatient setting deserves more attention

Keys to Success in Getting Benefit from AI/ML

- Making good predictions is not the hard part—many good approaches to generating good predictions
 - More important to use a model vs. which one you use
- Picking good use cases is critical
 - Needs to match clinical need—may be e.g. which therapy to pick vs. identifying diagnosis
 - Want to have a gap between performance and ideal
- Most important is getting suggestions to right clinician at right time
 - Clinicians are overwhelmed with suggestions now and LAST thing they want is more
 - Need ability to find right clinician
 - Often need to do in real time
 - Should leverage AI/behavioral economics techniques to improve behavior, leverage what has been learned about nudges

Integrating with Clinical Care

- Kaiser has done some of the best work in health care
- Estimating risk of complications—at admission, evaluation, transfer
 - Need detailed guideline that clarifies how the algorithm will inform care
- Examples
 - Evaluating newborns for early onset sepsis
 - Emergency department composite scores to predict decompensation
- Have to get information to the right person in ED in very timely way

ORIGINAL RESEARCH

Early detection, prevention, and mitigation of critical illness outside intensive care settings

J. Hosp. Med. 2016 November;11(1):S5-S10

By: Gabriel J. Escobar, MD ⊠, R. Phillip Dellinger, MD



https://neonatalsepsiscalculator.kaiserpermanente.org/

Policy Implications

- Research
 - Should be federally sponsored
- Regulation will be required to mandate that organizations measure harm frequency
- Measurement related policy implications must be considered, including tension b/w measures for public reporting/accountability vs. quality improvement
- Moving to a health-IT enabled health system—policies should reflect that

Conclusions

- Al is transformational—medicine is late to the party
- Adverse events are still far too frequent and represents a huge issue, especially in hospital
 - One major opportunity is simply broader and more uniform implementation of strategies already documented to work
- Will help a lot to have more routine measurement of safety which will be possible through HIT
 - A Leapfrog requirement for hospitals to do this would be a big step—and is available now
- Artificial intelligence will enable additional major improvements in safety
 - For many of the main types of harm improvement will likely be incremental
 - For harm types which have received relatively less attention, like decompensation and diagnostic error, radical/transformational improvement possible
- Many of the improvements will involve leveraging multiple technologies like AI and other big data techniques, sensing, communication, IoT, all linked to tracking of performance



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