



SPECIAL REPORT

# Top 10 Patient Safety Concerns 2022

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# Top 10 Patient Safety Concerns 2022



## Introduction

Organizations across the continuum of care are striving to become high-reliability organizations, and part of being highly reliable means staying vigilant and identifying problems proactively.

This annual Top 10 list helps organizations identify imminent patient safety challenges. To select the Top 10, ECRI and our affiliate, the Institute for Safe Medication Practices (ISMP), analyzed a wide scope of data, including scientific literature, patient safety events or concerns reported to or investigated by ECRI or ISMP, client research requests and queries, and other internal and external data sources.

The Top 10 list also offers Action Recommendations and resources for addressing each concern.

## The List for 2022

1. Staffing shortages
2. COVID-19 effects on healthcare workers' mental health
3. Bias and racism in addressing patient safety
4. Vaccine coverage gaps and errors
5. Cognitive biases and diagnostic error
6. Nonventilator healthcare-associated pneumonia
7. Human factors in operationalizing telehealth
8. International supply chain disruptions
9. Products subject to emergency use authorization
10. Telemetry monitoring

### Repeat Patient Safety Concerns

Over the years, several patient safety issues have made repeat appearances on ECRI's list of Top 10 Patient Safety Concerns. See [Recurrent Patient Safety Challenges](#), at the end of this report, for a list of perennial patient safety issues.



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## Top 10 Patient Safety Concerns 2022

### Supporting Total Systems Safety

ECRI and ISMP's annual report on the Top 10 Patient Safety Concerns identifies serious safety threats and recommends systems-based approaches to eliminate them. In doing so, the report helps healthcare organizations achieve total systems safety.

A total systems approach facilitates real improvement in safety. Proactive rather than reactive, it anticipates risks and applies system-wide safety processes across the healthcare continuum. It demands the cross-stakeholder collaboration necessary to solve safety problems. (NSC) In its National Action Plan to Achieve Patient Safety, the National Steering Committee for Patient Safety describes four interdependent foundations that are essential to achieving total systems safety (NSC):

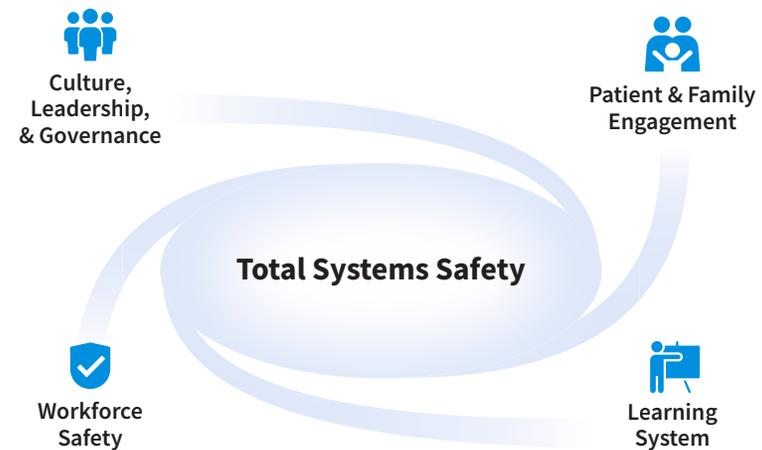
- Cultivating leadership, governance, and cultures that reflect a deep commitment to safety
- Engaging patients and families as partners in designing and producing care
- Fostering a healthy, safe, and resilient environment for the workforce
- Supporting continuous and shared learning to improve safety and quality of care

This annual Top 10 report is grounded on these pillars. It shares lessons from ECRI and ISMP's analysis of a wide range of data sources and offers strategies to support continuous improvement in healthcare, emphasizing the roles of culture and leadership, patient and family engagement, and workforce health. The report also illustrates ECRI and ISMP's deep understanding of how systems can contribute to harm—or drive safety.

### The 2022 Top 10: Reaching Farther for Safety

Reflecting the emphasis of total systems safety on system-wide processes and cross-collaboration, the theme for this year's Top 10 list is Reaching Farther for Safety.

For the items on this year's list, healthcare organizations may already have implemented measures to improve safety. Yet harm continues to occur. To address these safety concerns, healthcare organizations and their partners may need to reach farther. The items on this year's list may require more collaboration with community partners, more involvement across stakeholder groups, more interdepartmental planning and processes. For each, this report offers multifactorial recommendations to help organizations achieve total systems safety.



## Top 10 Patient Safety Concerns 2022

### Methods

To select these important patient safety concerns, ECRI invited its multidisciplinary personnel throughout ECRI and our affiliate, ISMP, to propose topics. To support each topic, nominators collected scientific literature. They also noted any trends in event reports, root cause analyses, and research requests submitted to ECRI and the ISMP PSO; medical device alerts, problem reporting, and evaluation; reported medication safety problems; accident investigations; lessons learned from consultation work; and other internal and external data sources.



An interdisciplinary team analyzed the supporting evidence and evaluated each topic using the following criteria:

- **Severity:** How serious would the harm to patients be if this safety concern were to occur?
- **Frequency:** How likely is it that the safety concern will occur?
- **Breadth:** If the safety concern were to occur, how many patients would it affect?
- **Insidiousness:** Is the problem difficult to recognize or challenging to rectify once it occurs?
- **Profile:** Would the safety concern place a lot of pressure on the organization?

Based on these criteria, the interdisciplinary team chose and ranked the Top 10 patient safety concerns.

The Top 10 list represents ECRI and ISMP's deep and vast expertise. Those who helped select and evaluate topics represented a wide range of disciplines, including medicine, nursing, pharmacy, aging services, health technology, patient safety, quality, risk, ethics, industrial and systems engineering, law, and many others.

## Top 10 Patient Safety Concerns 2022

### A Rigorous Approach to Improvement

Superficial attempts to improve patient safety are often insufficient to address serious concerns embedded in complex systems, such as the concerns on this Top 10 list. A rigorous approach is typically necessary to make real, lasting change.

Several models are available to help healthcare organizations identify the need for, implement, and sustain patient safety improvements. According to the Agency for Healthcare Research and Quality (AHRQ), examples include Lean, Six Sigma, and the Institute for Healthcare Improvement's Model for Improvement (AHRQ). Whichever method is used, it should include components designed to help the organization select which concerns to address, implement effective interventions, and sustain patient safety improvements. Common features of improvement models include the following (AHRQ):

- Leadership roles in communicating the vision and strategy, eliminating barriers to improvement, and holding people accountable
- Stakeholder roles as participants in and audiences for improvement processes
- Clear goals
- Measurement and analysis to identify issues and guide decisions
- Use of structured, iterative processes to undertake analyses and implement interventions
- Monitoring of frontline clinical work (e.g., through observation, through analysis of process data) to track implementation progress or assess the impact of changes
- Transparent metrics

To help organizations improve, this report offers Action Recommendations and links to ECRI resources and tools that offer in-depth guidance. Some resources are included in ECRI membership programs or through our partner patient safety organizations (PSOs). Please contact client services at (610) 825-6000, ext. 5891, or [clientservices@ecri.org](mailto:clientservices@ecri.org) to learn how to access resources that are not part of your membership.

### Safety across the Continuum

This Top 10 report highlights patient safety concerns across the continuum of care because patient safety strategies increasingly focus on collaborating with other provider organizations, community agencies, patients or residents, and family members. Each patient safety concern on this list may affect more than one setting and involve a wide range of personnel.

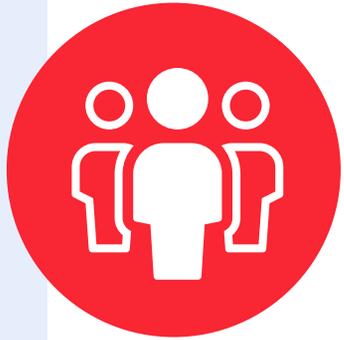
#### More Resources and Tools for ECRI's *Top 10 Patient Safety Concerns 2022*

- [Scorecard](#)
- [Customizable Risk Map](#)

### References

Agency for Healthcare Research and Quality (AHRQ). Section 4: Ways to approach the quality improvement process. 2020 Jan [cited 2021 Dec 23]. <https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/4-approach-qi-process/sect4part2.html>

National Steering Committee for Patient Safety (NSC). Institute for Healthcare Improvement (IHI). Safer together: a national action plan to advance patient safety. 2020 [cited 2022 Feb 15]. <http://www.ihl.org/Engage/Initiatives/National-Steering-Committee-Patient-Safety/Pages/National-Action-Plan-to-Advance-Patient-Safety.aspx>



## Top 10 Patient Safety Concerns 2022

# Staffing Shortages

# 1

Even before the COVID-19 pandemic, there was a persistent shortage of clinical and nonclinical staff across the continuum. Staffing shortages have continued to increase throughout the pandemic.



In 2020, hospital registered nurse (RN) turnover was **18.7%**.

Source: NSI Nursing Solutions, Inc.

A high proportion of nurses are at or near traditional retirement age, raising concerns that nursing shortages will greatly increase in the coming years:

- The median age of RNs in 2020 was **52 years**.
- Nearly **20%** of RNs are **65 years or older**.
- The median age of licensed practical or vocational nurses in 2020 was **53**.

Source: Smiley et al.

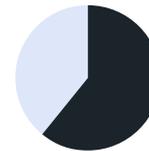
Nursing schools are unlikely to be able to supply enough nurses to replace retiring nurses, much less alleviate existing gaps. In 2019, **80,407 qualified nursing school applicants were turned away** due to insufficient resources (faculty, clinical sites, classroom space, clinical preceptors, and budget).

Source: AACN

Over a ten-year period (2016 to 2026), nursing assistants will be the top staffing need in long-term care.

- There will be **678,300 job openings**.
- But **368,100 workers** will move to another occupation.

Source: McKnight's



More than **61% of chief executive officers** noted a shortage of technicians, such as medical and laboratory technicians.

Source: ACE "Addressing"

By 2034, the physician shortage is projected to reach **17,800 to 48,000** in primary care and **21,000 to 77,100** in other medical specialties, raising concerns about access to care, disparities, and physician burnout.

Source: AAMC

In early 2021, many states predicted **shortages of critical care doctors, hospitalists, respiratory therapists, and pharmacists**.

Source: George Washington University

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## Action Recommendations

Organizations must implement a flexible recruitment and retention program in light of staffing shortages across the continuum.

- Develop an inclusive, culturally competent workforce.
- Establish flexible staffing models. The Centers for Disease Control and Prevention provides [Strategies to Mitigate Healthcare Personnel Staffing Shortages](#) to guide organizations during the COVID-19 pandemic.
- Consider [social factors](#) that disproportionately affect racial and ethnic minority.
- Design the system to respond to staff needs; assess for psychological safety.
- Evaluate the effect of staffing ratios on incidents and outcomes.
  - Map workloads on each shift, utilize care extenders, and offer flexible work hours.
- Vet temporary and agency staff and confirm competencies.
- Develop flexible action plans to deliver safe patient care during staff shortages, including closing units or diverting patients.
- Incorporate the use of tele-ICU capabilities to maximize critical care settings.
- Develop career progression pathways to promote growth of clinical leaders within the organization.
- Evaluate factors that lower departmental turnover rates.
- Conduct staff surveys to improve job satisfaction.
- Work with nursing schools to plan ways to expand capacity and resources.

Sources: ACHE "Ethical"; CDC

### ECRI Resources

Understaffing ([Health System Risk Management](#))

Supporting Resilience in Healthcare Workers ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

Burnout in Healthcare Workers: The Elephant in the Room ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

Burnout and Its Impact on Patient Safety ([Health System Risk Management](#))

Responsive Staffing and Scheduling in Aging Services: A Systems RETHinking Approach ([Health System Risk Management](#), [Aging Services Risk Management](#))

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at [clientservices@ecri.org](mailto:clientservices@ecri.org)

### References

American Association of Colleges of Nursing (AACN). Fact sheet: nurse faculty shortages. [cited 2021 Dec 1]. <https://www.aacnnursing.org/Portals/42/News/Factsheets/Faculty-Shortage-Factsheet.pdf>

American College of Healthcare Executives (ACHE):

Addressing personnel shortages in hospitals. 2020 [cited 2021 Dec 1]. <https://www.ache.org/-/media/ache/learning-center/research/2020-ceo-circle-white-paper.pdf>

Ethical issues related to staff shortages. 2017 Nov [cited 2021 Dec 1]. <https://www.ache.org/about-ache/our-story/our-commitments/ethics/ache-code-of-ethics/ethical-issues-related-to-staff-shortages>

Association of American Medical Colleges (AAMC). The complexities of physician supply and demand: projections from 2019 to 2034. 2021 Jun [cited 2021 Nov 30]. <https://www.aamc.org/media/54681/download?attachment>

Centers for Disease Control and Prevention (CDC). Strategies to mitigate healthcare personnel staffing shortages. 2021 Dec 23 [cited 2021 Dec 29]. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html>

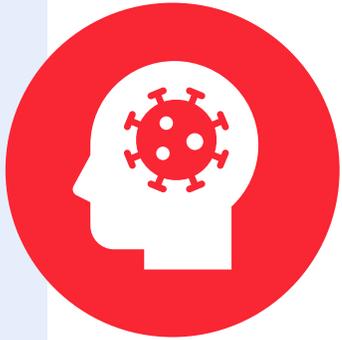
Chandra S, Hertz C, Khurana H, Doerfler ME. Collaboration between tele-ICU programs has the potential to rapidly increase the availability of critical care physicians. *Crit Care Explor* 2021 Mar 5; 3(3):e0363. [https://journals.lww.com/ccejournal/Fulltext/2021/03000/Collaboration\\_Between\\_Tele\\_ICU\\_Programs\\_Has\\_the.8.aspx](https://journals.lww.com/ccejournal/Fulltext/2021/03000/Collaboration_Between_Tele_ICU_Programs_Has_the.8.aspx)

Fitzhugh Mullan Institute for Health Workforce Equity. State hospital workforce deficit estimator projects shortages in next 30 days as COVID-19 cases surge. George Washington University. 2021 Jan 16 [cited 2021 Dec 9]. [https://www.gwhwi.org/uploads/4/3/3/5/43358451/about\\_the\\_estimator\\_01.16.21.pdf](https://www.gwhwi.org/uploads/4/3/3/5/43358451/about_the_estimator_01.16.21.pdf)

McKnight's Long-Term Care News. McKnight's workforce development: 2020 guide. 2020 Apr 15 [cited 2021 Dec 1]. <https://www.mcknights.com/resources/reports/workforce-development-guide-2020/>

Nursing Solutions, Inc. 2021 NSI national health care retention & RN staffing report. 2021 Mar [cited 2021 Dec 1]. [https://www.nsinursingsolutions.com/Documents/Library/NSI\\_National\\_Health\\_Care\\_Retention\\_Report.pdf](https://www.nsinursingsolutions.com/Documents/Library/NSI_National_Health_Care_Retention_Report.pdf)

Smiley RA, Ruttinger C, Oliveira CM, et al. The 2020 national nursing workforce survey. *J Nurs Regul* 2021 Apr; 12 (suppl). [https://www.journalofnursingregulation.com/article/S2155-8256\(21\)00027-2/pdf](https://www.journalofnursingregulation.com/article/S2155-8256(21)00027-2/pdf)



## Top 10 Patient Safety Concerns 2022

# COVID-19 Effects on Healthcare Workers' Mental Health

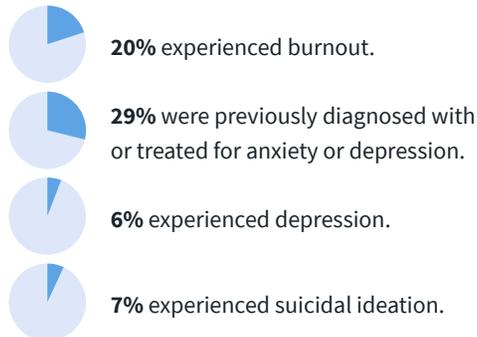
# 2

An often discussed but inadequately addressed collateral result of the COVID-19 pandemic is the toll it has taken on the mental health of healthcare workers.

Healthcare professionals' mental health was already at crisis level before the COVID-19 pandemic; both physicians and nurses were at risk of burnout, emotional exhaustion, or depression prior to 2020. **The pandemic has now forced a reckoning with healthcare workers' mental health needs.**

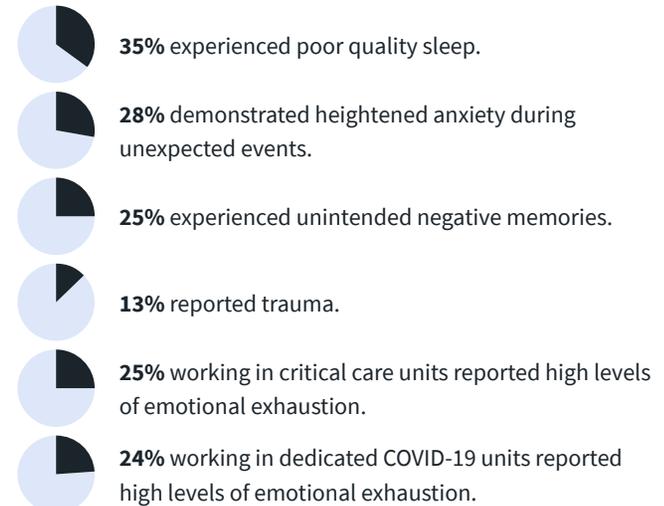
Source: Franza et al.

A survey of physicians published in June 2021 captured the following data:

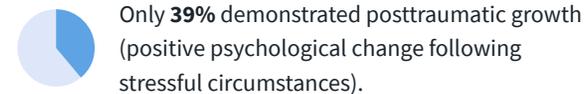


Source: Al-Humadi et al.

A survey of nurses published in February 2021 found the following:



In addition:



Source: Chen et al.

# TWO

## Action Recommendations

Throughout the COVID-19 pandemic, many healthcare workers have sacrificed their own mental health in order to deliver care. Healthcare organizations now need to support clinician resilience.

- Set an organizational tone of personal connection.
  - Be available to staff; use transparent, two-way communication channels.
  - Avoid pitfalls such as empty hero worship and ineffective communication.
  - Foster an organizational understanding that the effects of the COVID-19 pandemic are long-lasting and varied—like those of any disaster. Understand that frontline workers—by nature of their position—are vulnerable, and that long-term effects will manifest differently for each person.
    - Charge organization leaders with recognizing the reality and effects of burnout.
    - Use organizational data to identify areas of concern and their causes, and create effective wellness solutions in concert with frontline staff.
- Support practitioner wellness effectively.
  - Provide wellness programming and resources, recognizing the interconnections among job-related burnout, stress, psychological capital, and social support.
  - Engage professional development specialists who offer mindfulness practices to clinicians and staff.
  - Minimize the effort required for resilience activities while maximizing their effectiveness. Consider options like a portable toolkit containing stress-reducing items (e.g., aromatherapy, links to deep-breathing and guided meditation apps, coloring books), regular positive messaging, animal-assisted support, or a mental health hotline.

Sources: AHA; Andersen et al.; Jones-Schenk et al.; Liu et al.; Sawyer et al.; Shapiro et al.

## ECRI Resources

Resource Collection: Employee Health and Wellness ([Health System Risk Management](#))

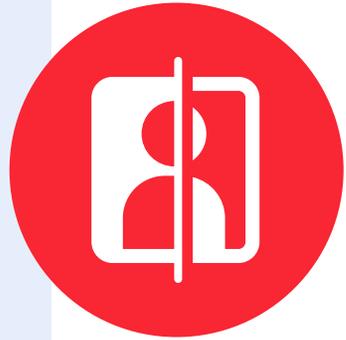
Supporting Resilience in Healthcare Workers ([Health Systems Risk Management](#), [Ambulatory Care Risk Management](#))

The Benefits of Establishing a Coaching and Mentoring Program ([ECRI and the ISMP PSO](#))

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## References

- Al-Humadi S, Bronson B, Muhlrads S, Paulus M, Hong H, Cáceda R. Depression, suicidal thoughts, and burnout among physicians during the COVID-19 pandemic: a survey-based cross-sectional study. *Acad Psychiatry* 2021;45:557-65. <https://link.springer.com/article/10.1007/s40596-021-01490-3>
- American Hospital Association (AHA). Team training: the hidden truth about emotional exhaustion and COVID from 250k healthcare voices. [webinar]. 2021 Sep 8 [cited 2021 Nov 4]. <https://www.aha.org/education-events/hidden-truth-about-emotional-exhaustion-and-covid-250k-healthcare-voices-september>
- Andersen S, Mintz-Binder R, Sweatt L, Song H. Building nurse resilience in the workplace. *App Nurs Res* 2021 Jun 1;59:151433. <https://dx.doi.org/10.1016/j.apnr.2021.151433>
- Chen R, Sun C, Chen JJ, Jen HJ, Kang XL, Kao CC, Chou KR. A large-scale survey on trauma, burnout, and posttraumatic growth among nurses during the COVID-19 pandemic. *Int J Ment Health Nurs* 2021 Feb;31(1):102-16. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7894338/>
- Franza F, Basta R, Pellegrino F, Solomita B, Fasano V. The role of fatigue of compassion, burnout and hopelessness in healthcare: experience in the time of COVID-19 outbreak. *Psychiatric Danub* 2020 Sep;32(suppl 1):10-14. <https://pubmed.ncbi.nlm.nih.gov/32890354/>
- Jones-Schenk J. Animal-assisted support: actionable intervention for burnout. *J Contin Educ Nurs* 2020 Nov 1;51(11):496-497. <https://pubmed.ncbi.nlm.nih.gov/33104807/>
- Liu Y, Aunguroch Y, Gunawan J, Zeng D. Job stress, psychological capital, perceived social support, and occupational burnout among hospital nurses. 2021 Mar 1. *J Nurs Schol*;53(4):511-18. <https://sigmapubs.onlinelibrary.wiley.com/doi/10.1111/jnu.12642>
- Sawyer AT, Bailey AK, Green JF, Sun J, Robinson PS. Resilience, insight, self-compassion, and empowerment (RISE): a randomized controlled trial of a psychoeducational group program for nurses. *J Am Psych Nurs Assoc* 2021 Jul 23. <https://journals.sagepub.com/doi/10.1177/10783903211033338>
- Shapiro DE, Duquette C, Abbott LM, Babineau T, Pearl A, Haidet P. Beyond burnout: a physician wellness hierarchy designed to prioritize interventions at the systems level. *Am J Med* 2019 May;132(5):556-63. [https://gme.med.wayne.edu/pdfs/shapiro\\_et\\_almaslow\\_s\\_hierarchy\\_dr\\_wellnessamer\\_j\\_med\\_2018.pdf](https://gme.med.wayne.edu/pdfs/shapiro_et_almaslow_s_hierarchy_dr_wellnessamer_j_med_2018.pdf)



Top 10 Patient Safety Concerns 2022

# Bias and Racism in Addressing Patient Safety

3

THREE

Racial and ethnic disparities have been well documented in how they affect access to care and outcomes. What is less well publicized is that disparities can even affect how adverse events are reported and responded to.

To learn more about other aspects of racial and ethnic disparities in health and healthcare, see [ECRI and the ISMP Deep Dive executive summary](#).



Although patients from racial and ethnic minority groups are more likely to experience an adverse event while in the hospital, providers are **significantly less likely to report harmful events for patients from minority groups** than for white patients.

In one study, the odds of reporting patient safety events in African American patients were only **0.65 times** the odds of reporting in white patients.

Sources: Thomas et al.; Thurtle et al.



**Black adult patients experienced significantly worse patient safety events in 6 of 11 health indicators** compared with white adult patients of the same gender, treated in the same hospital, and with similar insurance coverage.

Source: Gangopadhyaya

## Action Recommendations

Healthcare organizations should establish and implement policies designed to identify and eliminate racism and discrimination from within the organization.

- Recognize that racism and implicit biases may be present in your organization.
- Examine the racial demographics of reported patient safety events and root-cause analyses performed by the organization for serious events. Determine whether racial or ethnic disparities exist in the types of events being reported and analyzed.
- Train leaders on health equity and cultural competence, addressing topics that include health disparities, cultural competence, health outcomes among minorities, and other related issues.
- Work with community partners to promote health professions among people of color and other disadvantaged populations, and increase efforts to recruit diverse clinicians and staff.
- Perform health equity and cultural competence assessments. Repeat such assessments after implementing improvement initiatives and periodically thereafter.
- Launch ongoing educational programs designed to develop healthcare providers' cultural competence and cultural humility and to mitigate implicit bias.
- Establish policies designed to meet patients' cultural and linguistic needs from admission to discharge. Utilize resources from organizations such as [Joint Commission](#) and the [U.S. Department of Health and Human Services \(HHS\)](#).
- Take seriously all allegations of racism, bias, or discrimination that originate from within the organization, and implement appropriate measures to thoroughly investigate and address such reports and to ensure that such reports are not closed out inappropriately.

Sources: Joint Commission; Baruch; HHS

## ECRI Resources

Culturally and Linguistically Competent Care ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

Case Studies in Cultural Competence ([Health System Risk Management](#), [Aging Services Risk Management](#))

Culturally and Linguistically Competent Care Training Program ([Health System Risk Management](#))

Patients' Racist Requests and Behaviors: A Perspective from the PSO Database ([Health System Risk Management](#))

Deep Dive: Racial and Ethnic Disparities in Health and Healthcare ([ECRI and the ISMP PSO](#))

Refuse Patients' Racist Requests: Rely on Strong Policy, Civil Rights Act, and Legal Standards ([Health System Risk Management](#))

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## References

Baruch E. Health equity and leadership: the importance of leadership in achieving organizational cultural competency. The Colorado Trust. 2013 Sep [cited 2021 Sep 29]. [https://www.coloradotrust.org/sites/default/files/CT\\_LeadershipBrief\\_FINALv.pdf](https://www.coloradotrust.org/sites/default/files/CT_LeadershipBrief_FINALv.pdf)

Department of Health and Human Services (HHS). Office of Minority Health. National standards for culturally and linguistically appropriate services (CLAS) in health and health care. [cited 2021 Sep 29]. <https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf>

Gangopadhyaya A. Do black and white patients experience similar rates of adverse safety events at the same hospital? Robert Wood Johnson Foundation. 2021 Jul 20 [cited 2021 Sep 29]. <https://www.rwjf.org/en/library/research/2021/07/do-black-and-white-patients-experience-similar-rates-of-adverse-safety-events-at-the-same-hospital.html>

Joint Commission. Advancing effective communication, cultural competence, and patient- and family-centered care: a roadmap for hospitals. 2010 [cited 2021 Sep 29]. <https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/health-equity/aroamapforhospitalsfinalversion727pdf.pdf>

Thomas AD, Pandit C, Krevat SA. Race differences in reported harmful patient safety events in healthcare system high reliability organizations. J Patient Saf 2020 Dec;16(4):e235-e239. <https://pubmed.ncbi.nlm.nih.gov/30585888/> doi: 10.1097/PTS.0000000000000563

Thurtle DP, Daffron SB, Halvorson EE. Patient characteristics associated with voluntary safety event reporting in the acute care setting. Hosp Pediatr 2019 Feb;9(2):134-138. <https://pubmed.ncbi.nlm.nih.gov/30630876/> doi: 10.1542/hpeds.2018-0142



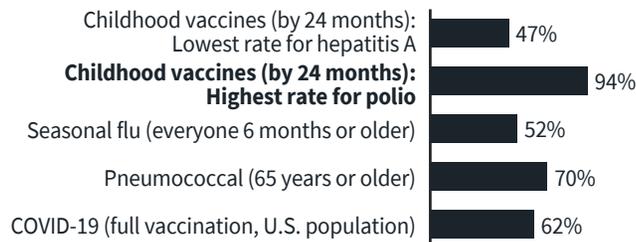
### Top 10 Patient Safety Concerns 2022

# Vaccine Coverage Gaps and Errors

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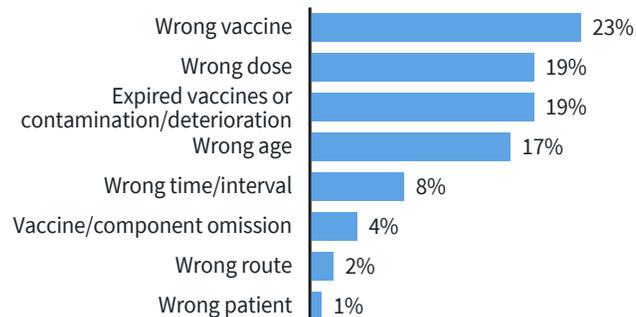
The success of any vaccine relies on correct, widespread administration to appropriate populations. Vaccine gaps and errors may harm patients or provide inadequate protection against serious diseases.

Vaccination rates show many opportunities for improvement:



Sources: CDC "ChildVaxView"; "FluVaxView"; "AdultVaxView"; Mayo Clinic

The most frequently reported vaccine errors include:\*



\*575 events submitted in 2017

Source: ISMP "Part I"

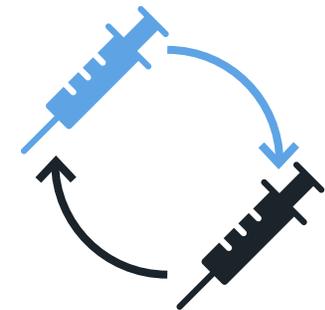
Vaccine administration errors pose the potential for consequences like:

- Inadequate immune protection
- Unintended patient harm
- Increased costs to providers
- Reduced confidence in the healthcare delivery system

Source: CDC

Many errors involving the COVID-19 vaccine, including mix-ups of age-related formulations and mix-ups between the flu and COVID-19 vaccines, have been reported.

Sources: ISMP "Age-Related"; ISMP "Mix-Ups"



FOUR

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## Action Recommendations

Healthcare organizations can take several steps to improve vaccine coverage and safety.

- Implement a comprehensive vaccine promotion program.
  - Consider components such as periodic evaluation of vaccination rates, community-based interventions and outreach, and patient engagement.
  - Implement a comprehensive vaccination and vaccine promotion program for clinicians and staff.
- Examine protocols for vaccine administration, including:
  - Full generic name, brand name, and the Centers for Disease Control and Prevention (CDC) standard abbreviation
  - Indication and vaccine schedules for routine and catch-up vaccinations
  - Criteria for screening patients for contraindications
  - Directions for preparing and administering vaccines, including dose, vials to use, route of administration, and precautions
  - Details regarding what (e.g., lot number, expiration date), where (e.g., vaccination record, vaccine registries), and how to document administration
  - Emergency protocols to follow if adverse reactions occur
- Store look-alike vaccines and doses on different shelves, and maintain proper temperatures.
- Keep vaccines with the earliest expiration dates in the front of storage units, and remove expired products.
- Structure treatment areas to accommodate one patient at a time.
- Utilize trained providers with demonstrated vaccination competencies, and train staff whenever vaccines are added or recommendations updated.
- Include a pharmacist on the immunization team.
- Give patients vaccine information in their preferred language.

Sources: ISMP "Part I"; ISMP "Part II"; CDC "You"

## ECRI and ISMP PSO Resources

- Vaccination Safety ([Ambulatory Care Risk Management](#))
- Deep Dive: Safe Ambulatory Care ([ECRI and the ISMP PSO](#))
- Policy and Procedure Builder: Vaccine Management ([ECRI and the ISMP PSO](#))
- Staff Educational Topics and Teaching Points to Prevent Errors During Vaccine Administration ([ISMP](#))
- Learning from Errors with the New COVID-19 Vaccines ([ISMP](#))
- ISMP Analyzes First Few Months of COVID-19 Vaccine Errors ([ISMP](#))
- Educate Parents: Childhood Vaccinations Are as Important as Ever ([Ambulatory Care Risk Management](#))

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## References

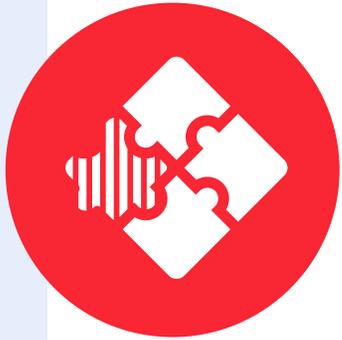
Centers for Disease Control and Prevention (CDC):

- AdultVaxView: Vaccination coverage among adults. 2021 May 14 [cited 2021 Dec 22]. <https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/data-reports/general-population/index.html>
- ChildVaxView: Vaccination coverage among young children (0 – 35 months). 2020 Sep 28 [cited 2021 Dec 22]. <https://www.cdc.gov/vaccines/imz-managers/coverage/childvaxview/interactive-reports/index.html>
- FluVaxView: Influenza vaccination coverage for persons 6 months and older. 2021 May 28 [2021 Dec 22]. <https://www.cdc.gov/flu/fluovaxview/interactive-general-population.htm>
- You call the shots. Jan 5, 2021. [cited 2021 Oct 11]. <https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf>

Institute for Safe Medication Practices (ISMP):

- Age-related COVID-19 vaccine mix-ups. 2021 Dec 6 [cited 2021 Dec 22]. <https://www.ismp.org/alerts/age-related-covid-19-vaccine-mix-ups>
- ISMP national vaccine errors reporting program 2017 analysis (part I): vaccine errors continue with little change. 2018 Jun 14 [cited 2021 Oct 11]. <https://www.ismp.org/acute-care/medication-safety-alert-june-14-2018>
- ISMP national vaccine errors reporting program part II: preparing for immunization activities and campaigns. 2018 Jun 28 [cited 2021 Oct 11]. <https://www.ismp.org/acute-care/medication-safety-alert-june-28-2018>
- Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines. 2021 Oct 15 [cited 2021 Dec 22]. <https://www.ismp.org/alerts/mix-ups-between-influenza-flu-vaccine-and-covid-19-vaccines>

Mayo Clinic. U.S. COVID-19 vaccine tracker: see your state's progress. [cited 2021 Dec 22]. <https://www.mayoclinic.org/coronavirus-covid-19/vaccine-tracker>



Top 10 Patient Safety Concerns 2022

# Cognitive Biases and Diagnostic Error

5

**Cognitive biases can result in misdiagnoses by skewing how clinicians gather and interpret evidence, take action, and evaluate decisions.**

## Four Common Clinician Biases



**Anchoring bias:** The clinician adheres to their initial impression in the face of conflicting evidence.

**Confirmation bias:** Information is “cherry picked” to support the diagnosis.



**The affect heuristic:** Actions are driven by emotions; this often manifests as strong feelings regarding a patient after an encounter.

**Outcomes bias:** Clinical results always follow prior decisions, preventing clinicians from considering feedback to improve their care delivery.



Source: Doherty et al.

## Delayed Diagnoses Due to Bias toward COVID-19

Patients who present with respiratory symptoms may be suspected of COVID-19 even after negative test results. Authors of one case expressed concern that “physicians have become blinded from the COVID pandemic and often anchor to the diagnosis of severe hypoxic respiratory failure from COVID-19.”

A sampling of the literature reveals that COVID-19 was an anchor for the following patient conditions, delaying appropriate care:

- Aseptic meningitis
- Disseminated coccidioidomycosis
- Pneumonia caused by fungal infection
- Lemierre’s syndrome
- Lyme disease and other tick-borne illness
- Mitral valve regurgitation

Sources: Harada et al.; Horowitz et al.; Karn et al.; Kawabata et al.; Patel B et al.; Patel N et al.

FIVE

## Action Recommendations

All cognitive biases are a danger to patient safety. They are difficult to perceive and even more difficult to dismantle. Nevertheless, failure to do so can result in misdiagnosis and delayed or inappropriate treatment.

- Recognize cognitive biases and their effects on diagnosis.
- Develop organizational understanding of the depth to which cognitive biases affect patient outcomes. **Simply recognizing that the bias exists may help overcome it.**
- Implement mindful procedures to support clinicians in overcoming bias (e.g., reflection or diagnostic time-outs).
- Use simulation training to help clinicians become aware of their biases and visualize their potential outcomes. Consider training with “cognitive forcing strategies,” such as intentional consideration of other diagnoses.
- Incorporate critical thinking methodologies to increase clinician objectivity.
- Limit patient descriptors, such as “frequent flyer” or “drug-seeking,” as well as other terms that may introduce bias into the clinician’s diagnostic process.

Sources: Doherty et al.; Joint Commission

## ECRI Resources

Essentials: Missed Diagnoses ([Health System Risk Management](#))

Diagnostic Errors: Monumental Problem or Enormous Opportunity? ([Health System Risk Management](#))

Culturally and Linguistically Competent Care ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

Racial and Ethnic Disparities in Healthcare ([Health System Risk Management](#))

Person-Centered Care in Acute Care ([Health System Risk Management](#))

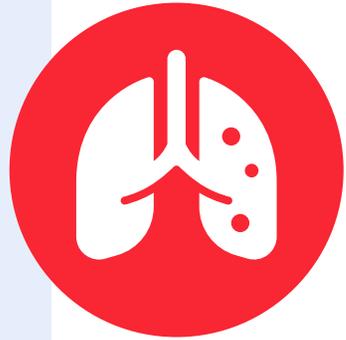
Person-Centered Care in Aging Services ([Aging Services Risk Management](#))

Person-Centered Care ([Ambulatory Care Risk Management](#))

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## References

- Doherty TS, Carroll AE. Believing in overcoming cognitive biases. *AMA J Ethics* 2020 Sep 1;22(9):E773-778. <https://journalofethics.ama-assn.org/article/believing-overcoming-cognitive-biases/2020-09> doi: 10.1001/amajethics.2020.773
- Harada T, Watari T, Miyagami T, Watanuki S, Shimizu T, Hiroshige J. COVID blindness: delayed diagnosis of aseptic meningitis in the COVID-19 era. *Eur J Cas Rep Intern Med* 2020 Oct 23;7(11):001940. <https://www.ejcrim.com/index.php/EJCRIM/article/view/1940> doi: 10.12890/2020\_001940
- Horowitz H, Behar C, Greene J. COVID-19 and the consequences of anchoring bias. *Emerg Infect Dis* 2021 Aug;27(8):2235-36. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8314836/> doi: 10.3201/eid2708.211107
- Joint Commission. Cognitive biases in health care. *Quick Safety*. 2016 Oct;28. [cited 2021 Nov 9]. [https://www.jointcommission.org/-/media/tjc/documents/newsletters/quick\\_safety\\_issue\\_28\\_oct\\_2016pdf.pdf](https://www.jointcommission.org/-/media/tjc/documents/newsletters/quick_safety_issue_28_oct_2016pdf.pdf)
- Karn MN, Johnson NP, Yaeger SK, Fugok KL. A teenager with fever, chest pain, and respiratory distress during the coronavirus disease 2019 pandemic: a lesson on anchoring bias. *J Am Coll Emerg Physicians Open* 2020 Sep 26;1(6):1392-4. <https://onlinelibrary.wiley.com/doi/10.1002/emp2.12261> doi: 10.1002/emp2.12261
- Kawabata A, Funakoshi H, Ito J, Santanda T, Norisue Y, Watanabe H. Diagnostic delay of acute mitral regurgitation during the coronavirus disease 2019 pandemic: a case report. *Int J Emerg Med* 2021 Jul 19;14(1):38. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8287556/> doi: 10.1186/s12245-021-00365-6
- Patel B, Jarret B, Bixby B. Diagnostic error and cognitive bias in the era of COVID-19: don't forget about endemic diseases. *Chest* 158(4)(suppl)2020 Oct: A541-2. <https://www.sciencedirect.com/science/article/pii/S0012369220326982?via%3Dihub> doi: 10.1016/j.chest.2020.08.512
- Patel N, Ilyas S, Mobin N, Tokarski M. Anchoring bias during the COVID-19 pandemic. *Chest* 2021 Oct;160(4) (suppl):A456. <https://www.sciencedirect.com/science/article/pii/S0012369221018997?via%3Dihub> doi: 10.1016/j.chest.2021.07.448

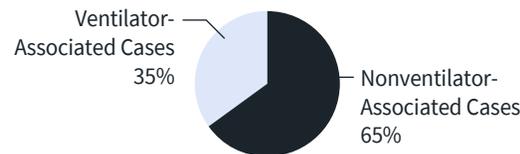


## Top 10 Patient Safety Concerns 2022

# Nonventilator Healthcare-Associated Pneumonia

6

Pneumonia is the most common healthcare-associated infection in the United States and is linked to substantial morbidity and mortality. Despite the attention placed on ventilator-associated pneumonia, nonventilator healthcare-associated pneumonia (NV-HAP) diagnoses in the United States make up **65% of the cases**, compared with **35% associated with ventilators**.

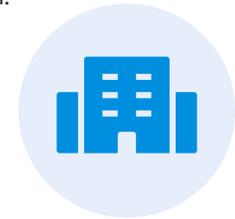


Source: Magill et al.

NV-HAP is a preventable event that is underreported as a healthcare complication. About **1 in every 100 hospitalized patients** experiences NV-HAP, with mortality rates ranging from **15%-30% for hospitalized patients** and **13%-41% for nursing home residents**.

The impact of NV-HAP on hospital utilization:

- length-of-stay extended by up to 15 days
- intensive care unit (ICU) admission required in up to 46% of non-ICU cases
- increased antibiotic use
- readmissions within 30 days in up to 20% of survivors



Sources: Munro et al.; Stamm et al.

NV-HAP prevention bundles should be integrated into patient or resident care standards, including:

- comprehensive oral care
- maintenance of mobility
- reduction of aspiration risks
- elevation of head of bed
- swallow assessments for dysphagia
- adequate nutrition
- stress ulcer prophylaxis
- glycemic control
- oral/nasogastric feeding tube assessments
- age-appropriate immunizations

Source: Munro et al.; Greene et al.

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## Action Recommendations

Proactive prevention of NV-HAP requires incorporating patient- or resident-care intervention bundles, providing staff education, conducting infection surveillance, and targeting performance improvement activities around NV-HAP risks.

- Use evidence-based criteria to standardize surveillance protocols and conduct regular surveillance to identify cases.
- Collaborate with infection preventionists to integrate NV-HAP as a quality and safety issue within the organization's safety and performance improvement plans.
- Develop provider competencies to address the pathogenesis of pneumonia and prevention strategies.
- Identify nurse and physician champions to lead efforts to promote prevention bundles.
- Design screening tools to proactively identify patients or residents at high risk of developing NV-HAP, including older adults with underlying medical conditions.
- Create structures and processes to improve and support effective handoffs and discharge planning for those identified as being at high risk for NV-HAP.
- Provide families and caregivers with education to prevent NV-HAP and encourage them to speak up when their loved ones need assistance with oral care or feeding.
- Leverage health information technology resources to hard wire risk assessments and reminders to complete NV-HAP prevention care activities.
- Promote holistic strategies such as providing smoking cessation strategies, encouraging personal/hand hygiene, evaluating aspiration risks, and assessing patient nutritional status.

Sources: Greene et al.; Davis and Finley

## ECRI Resources

High-Profile Healthcare-Associated Infections ([Health System Risk Management](#))

High Profile Infections ([Aging Services Risk Management](#))

Overview of Infection Prevention and Control ([Health System Risk Management](#))

Infection Prevention and Control ([Ambulatory Care Risk Management](#))

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## References

- Davis J, Finley E. A second breadth: hospital-acquired pneumonia in Pennsylvania, nonventilated versus ventilated patients. *Pa Patient Saf Advis*. 2018;15(3):1-12. [cited 2021 Sept 9]. [http://patientsafety.pa.gov/ADVISORIES/Pages/201809\\_NVHAP.aspx](http://patientsafety.pa.gov/ADVISORIES/Pages/201809_NVHAP.aspx)
- Greene LR, Baker D, Burdsall D, Davila S, Fine LS, Giuliano KK, Quinn B, Smathers S, Sposato KA, Vignari M. APIC implementation guide series: non-ventilator healthcare-associated pneumonia (NV-HAP). *Am J Infect Control* 2020;48(5S). [https://www.ajicjournal.org/issue/S0196-6553\(20\)X0005-8](https://www.ajicjournal.org/issue/S0196-6553(20)X0005-8)
- Magill SS, O'Leary E, Janelle SJ, et al. Changes in prevalence of health Care-associated infections in U.S. hospitals. *N Engl J Med* 2018;379(18):1732-1744. <https://pubmed.ncbi.nlm.nih.gov/30380384/> doi:10.1056/NEJMoa1801550
- Munro SC, Baker D, Giuliano KK, Sullivan SC, Haber J, Jones BE, Crist MB, Nelson RE, Carey E, Lounsbury O, Lucatoro M, Miller R, Pauley B, Klompas M. Nonventilator hospital-acquired pneumonia: a call to action. *Infect Control Hosp Epidemiol*. 2021 Aug;42(8):991-996. <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/nonventilator-hospitalacquired-pneumonia-a-call-to-action/3320E4A1D1367730EA5EF691A1884AAE> doi:10.1017/ice.2021.239
- Stamm DR, Katta S, Stankewicz HA. Nursing Home Acquired Pneumonia. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jul 19. <https://www.ncbi.nlm.nih.gov/books/NBK537355/>



## Top 10 Patient Safety Concerns 2022

# Human Factors in Operationalizing Telehealth

# 7

Overlooking human factors in the design, implementation, usability, and evaluation of telehealth systems may lead to a situation mirroring what happened during the widespread adoption of electronic health records (EHRs), which caused numerous issues for providers and patients alike, including:

- fractured adoption
- interrupted workflows
- user dissatisfaction
- **complete system failure**

A systematic review of studies on telehealth implementation and integration challenges identified issues involving stakeholders and system users as the top hurdle (79%); issues included the **lack of active involvement and collaboration to support a user-centered system design.**

Source: Ahmed et al.

**More than 20%** of U.S. adults had an appointment with a health professional using video or phone during September 2021.

Source: CDC



Another survey asked for which of the following services U.S. adults (n=1,700) would be willing to use telehealth and found the following:

-  **Common illnesses/infections: 69%**
-  **Follow-up visits: 66%**
-  **Talk therapy: 49%**
-  **Management for a chronic condition: 44%**
-  **Physical therapy: 18%**

Source: SingleCare

SEVEN

## Action Recommendations

Provider organizations often focus on technical specifications and integration with existing EHR systems and payment models. Accounting for user experiences from all stakeholders is critical to successful implementation, optimization, and sustainability.

- Administer end-user surveys, interviews, and focus groups to assess telehealth needs of providers and patients.
  - Include participants across clinical specialties (e.g., oncology), patient age groups (e.g., pediatrics, geriatrics), and care settings (e.g., home care).
  - Ask questions that solicit information about a user’s physical or working environment, technological capabilities, and expectations.
- Conduct user testing to ensure feasibility, to assess integration with EHR systems and patient portals, and to evaluate vendors.
  - Request documentation/data from vendors that support their claims of usability, flexibility, and effectiveness.
  - Address potential functional (e.g., visual, cognitive, hearing) knowledge (i.e., comfort with using technology), and access limitations of end users (i.e., socioeconomic disparities).
  - Facilitate a failure mode and effects analysis or use a [systems engineering framework](#) as proactive risk assessments prior to implementation.
- Use a phased implementation approach with small pilot/beta tests from a diverse pool of end users.
- Train staff and patients in system usage and common troubleshooting.
- Plan for routine quality improvement activities and sustainability.

Sources: Fouquet et al.; Demiris et al.; ECRI

## ECRI Resources

Telehealth: What’s on Your Radar? ([ECRI and the ISMP PSO](#))

Lab Webcast: Rapid Telehealth Adoption to Provide Routine Clinical Care during COVID-19 ([Device Evaluations](#))

Telehealth ([Health System Risk Management](#))

Telehealth for Clinical Support Staff (Ambulatory Care Risk Management)

[Part 1: Introduction to Telehealth](#)

[Part 2: Telehealth Teams and Workflows](#)

Technology for Independent Living ([Aging Services Risk Management](#))

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## References

Ahmed B, Dannhauser T, Philip N. A systematic review of reviews to identify key research opportunities within the field of eHealth implementation. *J Telemed Telecare* 2019;25(5):276-285. <https://journals.sagepub.com/doi/10.1177/1357633X18768601> doi: 10.1177/1357633X18768601

Centers for Disease Control and Prevention (CDC). Household pulse survey: telemedicine use. 2021 Oct 6 [cited 2021 Oct 7]. <https://www.cdc.gov/nchs/covid19/pulse/telemedicine-use.htm>

Demiris G, Charness N, Krupinski E, Ben-Arieh D, Washington K, Wu J, Farberow B. The role of human factors in telehealth. *Telemed J E Health* 2010 May 27;16(4):446-453. <https://www.liebertpub.com/doi/10.1089/tmj.2009.0114> doi: 10.1089/tmj.2009.0114

ECRI. Telehealth. 2020 Mar 3. <https://www.ecri.org/components/HRC/Pages/Telehealth.aspx>

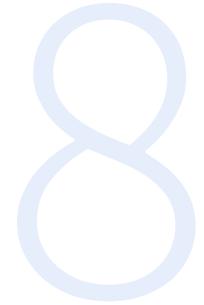
Fouquet SD, Miranda AT. Asking the right questions—human factors considerations for telemedicine design. *Curr Allergy Asthma Rep* 2020 Aug 29;20(11):66. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7456356/> doi: 10.1007/s11882-020-00965-x

SingleCare. 78% of patients are satisfied with virtual health care, according to telehealth survey. 2021 Mar 31 [cited 2021 Oct 12] <https://www.singlecare.com/blog/telehealth-survey/>



## Top 10 Patient Safety Concerns 2022

# International Supply Chain Disruptions



The United States heavily relies on international manufacturers to produce medical equipment, drugs, and other healthcare supplies. While medical supply and drug shortages have long been a problem in healthcare, this issue has been exacerbated by international supply disruptions resulting from the COVID-19 pandemic and other recent natural disasters.

There are two critical areas of concern:

1. **Manufacturers are having difficulty accessing raw materials**—for example, a magnesium shortage from China has resulted in a shortage of durable medical equipment (DME) products like crutches, canes, and walkers.
2. **Delivery disruptions have impacted the availability of shipping containers, unloading space, trucking capacity, and delivery workers**, creating logistical challenges to transportation and delivery of healthcare supplies.

Shortages of healthcare supplies such as drugs, diagnostic tests, DME, intravenous fluids, ventilators, examination tables, and monitors can disrupt routine patient care—threatening care quality and patient safety.

Sources: ECRI; Aepfel

### Examples of healthcare equipment shipping delays

	Prepandemic	September 2021
Portable plastic toilets	No delay	Up to 4 months
Heart defibrillators	2 weeks	Up to 3 months
Examination tables	6 weeks	Up to 5 months

Source: Aepfel

EIGHT

## Action Recommendations

Planning, preparation, communication, flexibility, and cooperation with outside collaborators are essential for safely navigating supply chain disruptions.

- Identify critical supplies and drugs for which your facility would be most vulnerable if a supply chain disruption were to occur. Identify alternatives for each supply; include both domestic and international alternatives when possible.
- Monitor drug shortages, employing resources from the American Society of Health-System Pharmacists (see [Current Drug Shortages](#)) and the U.S. Food and Drug Administration (FDA) (see [FDA Drug Shortages](#)), as well as information from wholesalers, manufacturers, and other healthcare organizations.
- To minimize the risk of future supply disruptions, demand transparency from distributors and manufacturers regarding:
  - Minimum inventory levels
  - Country of origin for product and raw material suppliers
  - Surge capacity plans
- Establish and maintain communication with local, state, and federal government agencies to determine which stockpiles are accessible during a crisis.
- Reexamine sole-source, dual-source, and multisource agreements. If there are supply disruption related to these agreements, reassess the partnership, insist on specific improvements, and terminate relationships, if necessary.
- Follow the recommendations in [Self-Assessment: Vetting Nontraditional Suppliers](#).
- Establish initial and routine quality control protocols for products from nontraditional suppliers.

Source: ECRI

## ECRI and ISMP Resources

[Lessons of COVID-19: Three Actions for a More Resilient Supply Chain](#)

ECRI/AHRMM Collaborations to Track Nontraditional Suppliers:

[Domestic Suppliers](#)

[International Suppliers](#)

Vetting Nontraditional Suppliers Self-Assessment ([Health Systems Risk Management](#))

“But We Don’t Have Any”: When Medication Shortages Hinder Patient Care ([ECRI and the ISMP PSO](#))

Top 10 Patient Safety Concerns for 2021 ([Health Systems Risk Management](#)):

4. [Supply chain interruptions](#)

5. [Drug shortages](#)

[Outbreak Preparedness and Response: The Essentials](#)

[Healthcare Recovery Center: COVID-19](#)

[COVID-19 Technology Management Resources](#)

[PriceGuide Functional Equivalents](#) [ECRI proprietary database]

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## References

Appel T. COVID creates shortages of an array of U.S. medical supplies. Reuters. 2021 Sep 20 [cited 2021 Oct 12]. <https://www.reuters.com/world/the-great-reboot/covid-creates-shortages-an-array-us-medical-supplies-2021-09-20/>

ECRI. Lessons of COVID-19: three actions for a more resilient supply chain. 2020 [cited 2021 Oct 13]. <https://www.ecri.org/covid-19-lessons-three-actions-resilient-supply-chain>



## Top 10 Patient Safety Concerns 2022

# Products Subject to Emergency Use Authorization

9

During emergencies, the U.S. Food & Drug Administration (FDA) can issue emergency use authorization (EUA) for drugs, devices, or biologics for serious diseases or conditions when no FDA-approved alternatives are available.

However, FDA requires **lower levels of evidence of safety and efficacy** for EUA issuance than for FDA approval.



EUAs allow **temporary** use of:

- Unapproved products
- Unapproved applications of approved products

EUAs:

- May be revised or revoked at any time
- Terminate when the emergency ends or FDA approves the product



In some circumstances, using a product after the EUA ends may risk **regulatory compliance problems** or **loss of federal liability protections**.



If necessary, a physician may continue an EUA product for a patient who started treatment with the product before revocation or termination.

After an EUA ends, the manufacturer and FDA determine product disposition:

- For unapproved products: disposition of the product or labeling
- For unapproved uses of approved products: disposition of product labeling

Use of an unapproved product after its EUA ends is subject to investigational product regulations.

Sources: 21 U.S.C. § 360bbb-3; FDA "Emergency"; FDA "Understanding"

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## Action Recommendations

Rigorous management of EUA products optimizes patient safety and minimizes risks.

- Assign supervision of EUA product management to an appropriate committee or committees (e.g., product evaluation, therapeutics, and/or medical device).
- Inventory all EUA products and documents.
- Monitor EUA status (e.g., by subscribing to [FDA's email alert services](#)).
- Inform providers which products have EUAs, and advise them to be alert for EUA product safety and efficacy risks.
- Implement methods for reporting EUA safety and efficacy concerns internally and to FDA and ECRI (see “ECRI Resources”).
- For revised EUAs, replace product documents with new versions as indicated.
- For EUA revocations and terminations (absent FDA approval of the product), inform providers and discuss disposition with the manufacturer.
  - If applicable, consider adding appropriate clinical decision-support alerts.
  - For revocations of unapproved products, secure the product, labeling it “do not use,” until disposition.
- Before continuing a permissible use after revocation or termination, consider safety issues (e.g., by reviewing revocation letters).
- See ECRI’s [Complexity of Managing Medical Devices with COVID-19 Emergency Use Authorization](#) and [Monitoring FDA’s Emergency Use Authorization Websites: Best Practices](#) for more guidance.

## ECRI Resources

Complexity of Managing Medical Devices with COVID-19 Emergency Use Authorization: Hazard #1 in ECRI’s Top 10 Health Technology Hazards for 2021 ([full article for ECRI members](#), [Executive Brief for nonmembers](#))

Webcast: Top 10 Health Technology Hazards 2021: An In-Depth Look at Managing Medical Devices with COVID-19 Emergency Use Authorization ([Device Evaluation](#))

Monitoring FDA’s Emergency Use Authorization Websites: Best Practices ([Device Evaluation](#))

[Alerts Workflow](#)

[Report a Device Problem](#)

[ISMP’s Report an Error](#)

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## References

21 U.S.C. § 360bbb-3.

U.S. Food & Drug Administration (FDA):

Emergency use authorization of medical products and related authorities: guidance for industry and other stakeholders. 2017 Jan [cited 2021 Oct 7]. <https://www.fda.gov/media/97321/download>

Understanding the regulatory terminology of potential preventions and treatments for COVID-19. 2020 Oct 22 [cited 2021 Dec 1]. <https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19>



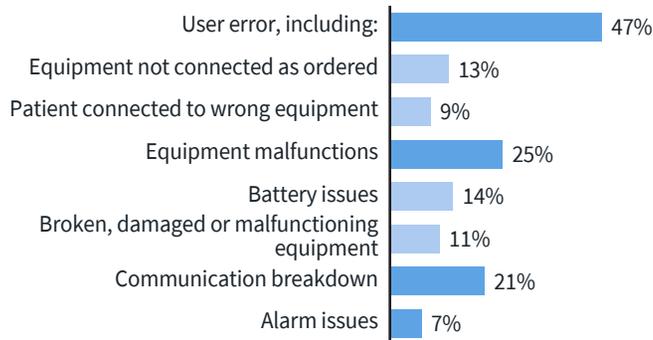
## Top 10 Patient Safety Concerns 2022

# Telemetry Monitoring

# 10

Telemetry monitoring (TM) provides real-time measurements of monitored physiologic parameters from a distance. Technological breakdowns as well as breakdowns related to clinician response increase the risk of patient harm by the **disruption in identification of critical and abnormal changes** in a patient's health status.

The Pennsylvania Patient Safety Reporting System identified 558 TM-related cardiac events submitted between 2014 and 2018, finding:



Source: Kukielka

### Common problems:

- Alarm fatigue**
- Poor safety culture **between departments**
- Infrastructure breakdowns leading to information **dropouts/lost communication** (e.g., malfunction/low battery at telepack, access points, or central monitoring unit [CMU])
- Lack of effective **emergency backup** plans during outages
- Extended downtime due to **confusion in roles and responsibilities** between information technology and computer engineering
- Cybersecurity vulnerabilities** (e.g., interrupting data transmission or data fidelity)
- Communication complications (e.g., extended turnaround time, missing data) between newly merged or acquired organizations using **different hardware/software** to communicate with a CMU

Source: ECRI

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## Action Recommendations

There are a variety of clinical and technical strategies available to improve TM.

- Clinical strategies:
  - Use a proper escalation notification system to ensure a prompt response.
  - Establish criteria for initiation, reassessment, and discontinuation of TM.
  - Permit nurses to adjust settings only within default limits. Require a physician's order to adjust settings outside the default limits.
  - Set pulse oximetry alerts to 90% to reduce nonactionable alarms.
  - Maintain proper skin preparation where leads attach to skin (e.g., clip hair and prepare skin).
  - Move leads every 24 hours.
  - Improve nursing ratios to ensure adequate patient coverage during shift change or times of high patient census and workflows to facilitate routine and timely patient observation.
  - Evaluate incidents when monitoring system alarm fails.
- Technological strategies
  - Implement a standardized battery replacement schedule.
  - Determine how many channels one person can safely monitor.
  - Improve waveform visibility by placing noninteractive remote displays throughout the care unit (e.g., hallway, bedside).
  - Create an emergency plan for telemetry equipment malfunction and scheduled downtime.
  - Adopt security measures to protect against remote interference (e.g., hackers silencing alarms or generating false alarms).
  - Update software regularly and use segregated networks, firewalls, virtual private networks, and network monitors.

Sources: ECRI; AHA

## ECRI Resources

How to Minimize Alert Fatigue and Provider Burden ([ECRI and the ISMP PSO](#))

The Alarm Safety Handbook ([Device Evaluations](#))

The Alarm Safety Workbook ([Device Evaluations](#))

Clinical Alarms ([Health System Risk Management](#))

Essentials: Health Information Technology ([Health System Risk Management](#))

Monitoring Telemetry Patients ([ECRI and the ISMP PSO](#))

Some ECRI resources are publicly available. To obtain other ECRI reports, contact us by telephone at (610) 825-6000, ext. 5891, or by email at [clientservices@ecri.org](mailto:clientservices@ecri.org)

## References

American Heart Association (AHA). Sandau, KE, Funk M, Auerbach A, Barsness GW, Blum K, Cvach M, Lampert R, May JL, McDaniel GM, Perez MV, Sendelbach S, Sommagren CE, Wang PJ; American Heart Association Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; and Council on Cardiovascular Disease in the Young. Update to practice standards for electrocardiographic monitoring in hospital settings: a scientific statement from the American Heart Association. 2017 Nov 7;136(19):e273-e344. <https://doi.org/10.1161/CIR.0000000000000527>

ECRI:

[Alarm management: the essentials](#). 2021 Mar 24.

[Improper customization of physiologic monitor alarm settings may result in missed alarms. Hazard #7—2019 Top 10 Health Technology Hazards](#). 2018 Sep 26.

[Improving patient surveillance in telemetry: don't just rely on the monitor](#). 2015 Sep 16.

[Relying on consumer-grade products can lead to inappropriate healthcare decisions. Hazard #5—2021 Top 10 Health Technology Hazards](#). 2021 Jan 28.

Kukielka E, Gipson KR, Jones R. A brief analysis of telemetry-related events. Patient Safety 2019 Dec; 1(2): 36-44. <https://patientsafety.com/index.php/patientsaf/article/view/telemetry?articlesBySameAuthorPage=2#articlesBySameAuthor> doi: 10.33940/biomed/2019.12.4

# Recurrent Patient Safety Challenges

## Lessons from ECRI's Past Top 10 Lists

Over the years, several patient safety issues have made repeat appearances on ECRI's list of Top 10 Patient Safety Concerns. The following patient safety concerns have appeared in several past Top 10 lists; the list begins with the most frequently mentioned. These issues deserve sustained attention in many organizations.

The linked ECRI resources offer guidance on these challenges. Some resources are included in ECRI membership programs or through our partner PSOs. Please contact client services at (610) 825-6000, ext. 5891, or [clientservices@ecri.org](mailto:clientservices@ecri.org) to learn how to access resources that are not part of your membership. Memberships often contain additional resources on these topics; the following are a selection of key resources.

### Medication Safety

[Institute for Safe Medication Practices \(ISMP\)](#)

[ECRI-ISMP Medication Safety Membership](#)

Medication Safety ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

Self-Assessment: Medication Safety ([Health System Risk Management](#), [Aging Services Risk Management](#))

Medication Safety Training Program ([Health System Risk Management](#), [Aging Services Risk Management](#))

Medication Administration ([Ambulatory Care Risk Management](#))

### Diagnostic Stewardship and Test Result Management

Diagnostic Errors: Monumental Problem or Enormous Opportunity? ([Health System Risk Management](#))

Deep Dive: Laboratory Events ([ECRI and the ISMP PSO](#))

Closing the Loop ([Partnership for Health IT Patient Safety](#))

Test Tracking and Follow-Up ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

Test Tracking and Follow-Up Toolkit ([Ambulatory Care Risk Management](#))

Self-Assessment: Waived Laboratory Practices ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

### Behavioral Health

Deep Dive: Meeting Patients' Behavioral Health Needs in Acute Care ([ECRI and the ISMP PSO](#))

Suicide Risk Assessment and Prevention in the Acute Care General Hospital Setting ([Health System Risk Management](#))

Mental Health in Aging Services ([Health System Risk Management](#), [Aging Services Risk Management](#))

Suicide Prevention in Aging Services ([Aging Services Risk Management](#))

Self-Assessment: Behavioral Health: Patient Safety ([Health System Risk Management](#))

### Health Information Technology and Patient Safety

Health IT Safe Practices ([Partnership for Health IT Patient Safety](#))

Deep Dive: Health Information Technology ([ECRI and the ISMP PSO](#))

Electronic Health Records: Functionality ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

Electronic Health Records: Operational Issues ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

Documentation: A Primer on Charting in the Medical Record ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

## Top 10 Patient Safety Concerns 2022

Self-Assessment: Establishing a Health Information Technology Safety Program ([Health System Risk Management](#))

Self-Assessment: EHR Vendor Checklist ([Health System Risk Management](#), [Ambulatory Care Risk Management](#))

### Detecting Changes in Patient Condition

Communication ([Health System Risk Management](#), [Aging Services Risk Management](#))

Documentation: A Primer on Charting in the Medical Record ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

Nursing Liability ([Health System Risk Management](#))

Clinical Alarms ([Health System Risk Management](#))

Beat the Buzzer: The Alarm Safety Game Show! ([Health System Risk Management](#))

Triage Toolkit ([Ambulatory Care Risk Management](#))

### Culture of Safety and the Infrastructure for Safety

Culture of Safety: An Overview ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

Measuring Safety Culture ([Health System Risk Management](#), [Aging Services Risk Management](#), [Ambulatory Care Risk Management](#))

Patient Safety and Quality Improvement Act ([Health System Risk Management](#), [Aging Services Risk Management](#))

Patient Safety, Risk, and Quality ([Health System Risk Management](#))

The Role of the Patient Safety Officer ([Health System Risk Management](#))

Culture of Safety 101 Training Program ([Ambulatory Care Risk Management](#))

### Device Cleaning, Disinfection, and Sterilization

[ECRI's Infection Prevention and Control Services](#)

Reprocessing of Reusable Medical Devices ([Health System Risk Management](#))

## Recurrent Patient Safety Challenges

Reprocessing of Flexible Endoscopes ([Health System Risk Management](#))

Overview of Infection Prevention and Control ([Health System Risk Management](#), [Aging Services Risk Management](#))

Infection Prevention and Control ([Ambulatory Care Risk Management](#))

Self-Assessment: Instrument Sterilization and Disinfection Practices ([Health System Risk Management](#))

Environmental Infection Control Toolkit ([Ambulatory Care Risk Management](#))

### Care Fragmentation and Poor Care Coordination

Deep Dive: Care Coordination ([ECRI and the ISMP PSO](#))

Inpatient Care Coordination ([Health System Risk Management](#))

Discharge Planning ([Health System Risk Management](#))

Transitions of Care ([Aging Services Risk Management](#))

Subacute Care ([Aging Services Risk Management](#))

Care Coordination and Transitions ([Ambulatory Care Risk Management](#))

Guidance for Patient Safety Toolkit: Handoff Communication ([ECRI and the ISMP PSO](#))

### Antimicrobial Stewardship

Physician Leader Huddle: Antimicrobial Stewardship ([ECRI and the ISMP PSO](#))

Overview of Infection Prevention and Control ([Health System Risk Management](#), [Aging Services Risk Management](#))

Infection Prevention and Control ([Ambulatory Care Risk Management](#))

### Patient Identification

Deep Dive: Patient Identification ([ECRI and the ISMP PSO](#))

Patient Identification: Implementation Guide and Toolkit ([Partnership for Health IT Patient Safety](#))

## Recurrent Patient Safety Challenges

### Top 10 Patient Safety Concerns 2022

Patient Identification ([Health System Risk Management](#))

Resident Identification ([Aging Services Risk Management](#))

Medical Records ([Ambulatory Care Risk Management](#))

Self-Assessment: Patient Identification ([Health System Risk Management](#))

Self-Assessment: Resident Identification ([Aging Services Risk Management](#))

### Emergency Preparedness

Emergency Preparedness: Planning and Mitigation ([Health System Risk Management](#), [Aging Services Risk Management](#))

Emergency Preparedness: Response and Recovery ([Health System Risk Management](#), [Aging Services Risk Management](#))

Emergency Preparedness: Epidemics, Pandemics, and Outbreak Response ([Aging Services Risk Management](#))

Outbreak Response in Aging Services ([Aging Services Risk Management](#))

Disaster Drills ([Health System Risk Management](#), [Aging Services Risk Management](#))

Evacuation ([Health System Risk Management](#), [Aging Services Risk Management](#))

The Hospital Incident Command System ([Health System Risk Management](#))

Self-Assessment: Emergency Preparedness ([Health System Risk Management](#))

Self-Assessment: Disaster Drills ([Health System Risk Management](#))