

What’s New in the Patient Safety World

February 2023

- **ECRI Top 10 Health Technology Hazards for 2023**
- **The Harvard Medical Practice Study 30 Years Later**
- **Dementia and Risk for Falling**
- **Cannabis and Surgery**

ECRI Top 10 Health Technology Hazards for 2023

Each year ECRI Institute publishes a list of its Top 10 Technology Hazards. The List for 2023 ([ECRI 2023](#)):

1. Gaps in Recalls for At-Home Medical Devices Cause Patient Confusion and Harm
2. Growing Number of Defective Single-Use Medical Devices Puts Patients at Risk
3. Inappropriate Use of Automated Dispensing Cabinet Overrides Can Result in Medication Errors
4. Undetected Venous Needle Dislodgement or Access-Bloodline Separation during Hemodialysis Can Lead to Death
5. Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems Can Result in Care Disruptions
6. Inflatable Pressure Infusers Can Deliver Fatal Air Emboli from IV Solution Bags
7. Confusion Surrounding Ventilator Cleaning and Disinfection Requirements Can Lead to Cross-Contamination
8. Common Misconceptions about Electrosurgery Can Lead to Serious Burns
9. Overuse of Cardiac Telemetry Can Lead to Clinician Cognitive Overload and Missed Critical Events
10. Underreporting Device-Related Issues May Risk Recurrence

We recommend you go to the full ECRI report for details on all 10 items. But we will comment on several of these that we’ve emphasized in many of our columns.

Item #4 “**Undetected Venous Needle Dislodgement or Access-Bloodline Separation during Hemodialysis Can Lead to Death**” was one of our earliest warnings. Our March 26, 2007 Patient Safety Tip of the Week “[Alarms Should Point to the Problem](#)” described an unfortunate case where inappropriate response to a low-pressure alarm in a dialysis patient led to cardiac arrest due to massive blood loss. That was not an isolated case. We went on to discuss almost identical cases in our Patient Safety Tips of the Week for April 25, 2017 “[Dialysis and Alarm Fatigue](#)”, December 10, 2019 “[Dialysis Line Dislodgements](#)”, and December 7, 2021 “[The Hidden Dialysis Catheter](#)”. It is essential that vascular access sites be secure and visible and that any alarms focus the responder’s attention on that site.

Item #9 “**Overuse of Cardiac Telemetry**” has been the subject of our columns listed below and the topic of our February 7, 2023 Patient Safety Tip of the Week “[Reducing Unnecessary Telemetry](#)”.

Item #3 “**Inappropriate Use of ADC Overrides**” is the subject of our many columns on safety issues related to automated dispensing cabinets and overrides (see list below).

Item #8 “**Common Misconceptions about Electrosurgery**” was discussed in detail in our July 28, 2020 Patient Safety Tip of the Week “[Electrosurgical Safety](#)” and our many columns on surgical fires and iatrogenic burns.

Item #1 “**At-home medical devices...**” highlights the problem of information about medical device recalls not reaching the end users. It is timely in view of a recent proposal to allow medical devices to be tracked on claims forms ([Kadokia 2023](#)).

Some of our prior columns on the hazards associated with telemetry:

- June 19, 2007 “[Unintended Consequences of Technological Solutions](#)”
- April 1, 2008 “[Pennsylvania PSA’s FMEA on Telemetry Alarm Interventions](#)”
- February 23, 2010 “[Alarm Issues in the News Again](#)”
- July 2011 “[What’s New in the Patient Safety World](#)”
- February 4, 2014 “[But What If the Battery Runs Low?](#)”
- May 22, 2018 “[Hazardous Intrahospital Transport](#)”
- June 23, 2020 “[Telemetry Incidents](#)”

Our prior columns related to ADC’s (automated dispensing cabinets):

December 2007	“ 1000-fold Heparin Overdoses Back in the News Again ”
August 23, 2016	“ ISMP Canada: Automation Bias and Automation Complacency ”
December 11, 2018	“ Another NMBA Accident ”
January 1, 2019	“ More on Automated Dispensing Cabinet (ADC) Safety ”
February 12, 2019	“ From Tragedy to Travesty of Justice ”
April 2019	“ ISMP on Designing Effective Warnings ”
June 11, 2019	“ ISMP’s Grissinger on Overreliance on Technology ”
September 7, 2021	“ The Vanderbilt Tragedy Gets Uglier ”

References:

ECRI Institute. Top 10 Health Technology Hazards for 2023 Executive Brief. ECRI 2023 <https://www.healthleadersmedia.com/technology/home-medical-device-safety-tops-ecris-list-healthcare-technology-hazards>

Kadakia K T, Dhruva S S, Ross J S, Krumholz H M. Adding device identifiers to claims forms—a key step to advance medical device safety BMJ 2023; 380 : p82 <https://www.bmj.com/content/380/bmj.p82>

Print “[February 2023 ECRI Top 10 Health Technology Hazards for 2023](#)”

The Harvard Medical Practice Study 30 Years Later

For over 30 years we have quoted statistics on hospital adverse events that came from the Harvard Medical Practice Study ([Brennan 1991](#), [Leape 1991](#)). That study was conducted on patients hospitalized in New York State in 1984. The study found that adverse events occurred at a rate of 3.7 events per 100 admissions. Of those, 28% were judged to have been caused by negligence, and 16% led to death or permanent disability.

That study played a big part in the publication of “To err is human: building a safer health system.” ([Kohn 2000](#)), considered a seminal publication in the patient safety movement. We’ve often criticized that publication in that it sensationalized (at least in the lay media) statistics about adverse events but ultimately had minimal impact on improving care.

In our January 2011 Patient Safety Tip of the Week “[No Improvement in Patient Safety: Why Not?](#)” we discussed 2 subsequent studies ([Landrigan 2010](#), [Levinson 2010](#)) that were similar to the Harvard Medical Practice Study. Both studies showed little improvement in adverse event rates.

So, another 10 years have passed. Are we doing any better now? We are not, at least according to a new study conducted in a sample of representative hospitals in Massachusetts. Bates et al. ([Bates 2023](#)) analyzed a random sample of hospital admissions in 2018. Nurses reviewed the patient charts for adverse events, also using trigger tool methodology, and then physicians reviewed those results to come to agreement on whether adverse events occurred and whether they might have been preventable.

In their random sample of 2809 admissions, they identified at least one adverse event in 23.6% of admissions. Among 978 adverse events, 22.7% were judged to be preventable and 32.3% had a severity level of serious or higher. A preventable adverse event occurred in 6.8% of all admissions. Preventable adverse events with a severity level of serious or higher occurred in 1.0%. Of seven deaths, one was deemed to be preventable. Categories of adverse events were: adverse drug events 39.0%, surgical or other procedural events 30.4%, patient-care events (defined as events associated with nursing care, including falls and pressure ulcers) 15.0%, and health care–associated infections 11.9%. Somewhat surprisingly, they identified only 10 diagnostic errors that resulted in an adverse event. There was considerable variation in event rates across hospitals, with larger hospitals in general having higher rates.

The authors urged some caution in comparing their results to those of prior studies in that there were some differences in methodologies and that their hospital and patient populations may not be representative of the nation’s hospitals as a whole.

Yet, the message should be clear – we still have a long way to go in improving patient safety.

References:

Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients — results of the Harvard Medical Practice Study I. *N Engl J Med* 1991; 324: 370-376

<https://www.nejm.org/doi/full/10.1056/NEJM199102073240604>

Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients — results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324: 377-384

<https://www.nejm.org/doi/full/10.1056/NEJM199102073240605>

Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Washington, DC: National Academies Press. 2000

<https://www.ncbi.nlm.nih.gov/books/NBK225182/>

Landrigan CP, Parry GJ, Bones CB, et al. Temporal Trends in Rates of Patient Harm Resulting from Medical Care. N Engl J Med 2010; 363: 2124-2134
<https://www.nejm.org/doi/full/10.1056/NEJMsa1004404>

Levinson DR. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Washington, DC: US Department of Health and Human Services, Office of the Inspector General; November 2010. Report No. OEI-06-09-00090
<http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf>

Bates DW, Levine DM, Salmasian H, et al. The Safety of Inpatient Health Care. N Engl J Med 2023; 388: 142-153
<https://www.nejm.org/doi/full/10.1056/NEJMsa2206117>

Print “[February 2023 The Harvard Medical Practice Study 30 Years Later](#)”

Dementia and Risk for Falling

Okoye et al. ([Okoye 2023](#)) analyzed a sample of 5581 community-dwelling adults aged 65 years and older who participated in the National Health and Aging Trends Study (NHATS). The NHATS is a population-based survey of health and disability trends and trajectories among Americans aged 65 years and older.

Patients with dementia had a significantly higher risk of falls than those without dementia (45.5% vs 30.9%; $P < .001$).

They also identified other factors associated with falls in this population. As you’d expect, a history of prior falls was significantly associated with subsequent falls among those with dementia (odds ratio 6.20). Similarly, impairment of vision also significantly increased the risk for falls (OR 2.22). Interestingly, living with a spouse vs alone was a risk factor (OR 2.43). The authors offer two possible explanations for this. One is that those living alone tend to be women with milder cognitive impairment and better

functional status. The other is that those living with a spouse who has dementia may have problems of their own that limit their ability to prevent their spouse from falling.

One finding that was counterintuitive was that some indicators of lower socioeconomic status (lower educational attainment and high neighborhood social deprivation) were associated with lower likelihood of falls. There was no obvious good explanation for this.

Perhaps we shouldn't be surprised by the findings of this study. We'll definitely add dementia to our list of risk factors for falls in the elderly.

Some of our prior columns related to falls:

- April 16, 2007 [“Falls With Injury”](#)
- July 17, 2007 [“Falls in Patients on Coumadin or Heparin or Other Anticoagulants”](#)
- January 1, 2008 [“Fall Prevention”](#)
- October 7, 2008 [“Lessons from Falls....from Rehab Medicine”](#)
- November 18, 2008 [“Ticket to Ride: Checklist, Form, or Decision Scorecard?”](#)
- August 4, 2009 [“Faulty Fall Risk Assessments?”](#)
- September 22, 2009 [“Psychotropic Drugs and Falls in the SNF”](#)
- December 22, 2009 [“Falls on Toileting Activities”](#)
- January 2010 [“Falls in the Radiology Suite”](#)
- June 2010 [“Seeing Clearly a Common Sense Intervention”](#)
- May 29, 2012 [“Falls, Fractures, and Fatalities”](#)
- June 5, 2012 [“Minor Head Trauma in the Anticoagulated Patient”](#).
- January 15, 2013 [“Falls on Inpatient Psychiatry”](#)
- March 2013 [“Sedative/Hypnotics and Falls”](#)
- December 3, 2013 [“Reducing Harm from Falls on Inpatient Psychiatry”](#)
- June 2014 [“New Glasses and Fall Risk”](#)
- July 8, 2014 [“Update: Minor Head Trauma in the Anticoagulated Patient”](#)
- August 2014 [“Cataract Surgery and Falls”](#)
- November 4, 2014 [“Progress on Fall Prevention”](#)
- March 2015 [“Another Paradox: Falls Due to Walking Aids”](#)
- June 9, 2015 [“Add This to Your Fall Risk Assessment”](#)
- July 28, 2015 [“Not All Falls Are the Same”](#)
- October 2015 [“Patient Perception of Fall Risk”](#)
- October 27, 2015 [“Sentinel Event Alert on Falls and View from Across the Pond”](#)
- February 16, 2016 [“Fall Prevention Failing?”](#)
- March 14, 2017 [“More on Falls on Inpatient Psychiatry”](#)
- July 2017 [“Mobility vs. Falls”](#)
- February 2018 [“Global Sensory Impairment and Patient Safety”](#)
- February 20, 2018 [“Delirium and Falls”](#)
- March 2019 [“Newborn Falls”](#)

- July 2019 “[Increasing Mortality After Falls in Elderly](#)”
- January 14, 2020 “[More on Newborn Falls](#)”
- June 16, 2020 “[Tracking Technologies](#)”
- October 2020 “[Pre-op Testing Before Cataract Surgery Leads to What?](#)”
- August 23, 2022 “[Yes, There is a Proper Way to Assess Orthostatic Hypotension](#)”
- September 13, 2022 “[Smart Socks and Robots for Fall Prevention?](#)”
- November 22, 2022 “[The Apple Watch and Patient Safety](#)”
- November 29, 2022 “[Preventing Newborn Falls](#)”

References:

Okoye SM, Fabius CD, Reider L, Wolff JL. Predictors of falls in older adults with and without dementia. *Alzheimer's Dement* 2023; 1-10
<https://alz-journals.onlinelibrary.wiley.com/doi/epdf/10.1002/alz.12916>

Print “[February 2023 Dementia and Risk for Falling](#)”

Cannabis and Surgery

Newly released guidelines suggest screening all patients for cannabis use prior to surgery or general anesthesia ([Shah 2023](#)). Why? Patients who regularly use cannabis may experience worse pain and nausea after surgery and may require more opioid analgesia.

More and more patients are using medical marijuana and recreational use of marijuana is now legal in many states. The potential complications of cannabis use during and after surgery apply whether the cannabis is smoked, vaped, or ingested.

The guidelines were consensus guidelines, arrived at by a panel of experts that included anesthesiologists, pain physicians, and a patient advocate, rather than being classic evidence-based guidelines. The panel was charged with drafting responses to key questions using a modified Delphi method with the overall goal of producing a document focused on the safe management of surgical patients using cannabinoids. A consensus recommendation required $\geq 75\%$ agreement.

The new guidelines, of course, go beyond just screening patients for cannabis use prior to surgery. They also include important recommendations regarding management of patients who have been using cannabis or cannabinoids.

The guideline has a table classifying the various forms of cannabis and cannabinoids, and has good discussion on the pharmacodynamics, mechanisms of action, and pharmacokinetics of the various forms. It also has a good section on the interactions between cannabinoids and various drugs.

The recommendations are made along with grades of evidence and a rating of “degree of certainty”. Grade A means there is high certainty that the net benefit is substantial, and this service should be offered or provided.

Four recommendations received the grade A classification:

- screen all patients before surgery
- postpone elective surgery for patients who have altered mental status or impaired decision-making capacity at the time of surgery
- counsel frequent, heavy users about the potential for cannabis use to impair postoperative pain control
- counsel pregnant patients about the risks of cannabis use to unborn children

One recommendation, given a Grade C evidence level but having considerable practical implications, is to delay elective surgery for a minimum of 2 hours after cannabis smoking. That is because smoking cannabis can cause increases in heart rate and blood pressure that is prominent within the first 1–2 hours of usage, and smoking cannabis may lead to a higher risk of perioperative acute MI within the first 1–2 hours. Smoking cannabis may have deleterious effects on airway resistance and respiratory adverse events.

See the full guideline ([Shah 2023](#)) for all their other recommendations. It’s a start but it is a recognition that use of cannabis and cannabinoids may pose a risk to patients about to undergo surgery.

References:

Shah S, Schwenk ES, Sondekoppam RV, et al. ASRA Pain Medicine consensus guidelines on the management of the perioperative patient on cannabis and cannabinoids. Regional Anesthesia & Pain Medicine 2023; Published Online First: 03 January 2023 <https://rapm.bmj.com/content/early/2023/01/05/rapm-2022-104013>

Print “[February 2023 Cannabis and Surgery](#)”

Print “[February 2023 What's New in the Patient Safety World \(full column\)](#)”

Print “[February 2023 ECRI Top 10 Health Technology Hazards for 2023](#)”

Print “[February 2023 The Harvard Medical Practice Study 30 Years Later](#)”

Print “[February 2023 Dementia and Risk for Falling](#)”

Print “[February 2023 Cannabis and Surgery](#)”

 The
Truax
Group
Healthcare Consulting
www.patientsafetysolutions.com

<http://www.patientsafetysolutions.com/>

[Home](#)

[Tip of the Week Archive](#)

[What's New in the Patient Safety World Archive](#)