

ECRI's *Strategic Insights for Ambulatory Care* newsletter is being offered to CAPIC insureds at no cost. If you are interested in visiting any of the links in this edition, please contact Brad Dunkin, Assistant Vice President, at BDunkin@CAPphysicians.com.



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Strategic Insights for Ambulatory Care is a biweekly service provided by ECRI and Cooperative of American Physicians. We welcome your comments; please send them to AmbulatoryCareRM@ecri.org.



What's New?

- ECRI Blog: How To: Safe Administration of Vaccines [read now](#)

Spotlight on Event Reporting and Management

In order to improve patient safety and quality of care, healthcare organizations must identify the sources of failures and implement corrective actions to avoid future errors. Comprehensive event management processes (e.g., reporting, investigation, analysis, improvement, and disclosure) help organizations improve patient safety. Use these ECRI resources to plan and support the development and evaluation of your patient safety, quality, and risk management activities.



- [Essentials: Event Management](#)
- [Event Reporting](#)
- [Event Reporting Training Program](#)

- [Effective Communication and Disclosure Training Program](#)

Resource Collection: Event Reporting and Management

Patient Safety & Relations

Generative AI and Medical Professional Liability Risk

What's the news. Potential risk of medical professional liability associated with generative artificial intelligence (AI) include cybersecurity, privacy, incorrect or potentially harmful patient care or administrative output, and informed consent, according to a [recent article from the Medical Professional Liability Association](#). To mitigate these risks, organizations should establish policies regarding the use of AI in clinical care and follow regulations as they are enacted.

Why it matters. The adoption of AI technology comes with many potential risks and benefits. Organizations should consider how to best use AI while preventing liability risks.

How ECRI can help. The [Essentials: Health Information Technology](#) collection provides action recommendations and resources on aspects of health information technology, including privacy and cybersecurity.

Female-Specific Medical Devices Have Higher Rates of Life-Threatening Outcomes, Disabilities, Deaths

What's the news. Female-specific implantable medical devices had higher rates of life-threatening outcomes (1.6% versus 0.3%), disabilities (5.0% versus 4.3%), and deaths (0.6% versus 0.1%) compared with male-specific devices, according to a [study published in the October 2023 issue](#) of the *Journal of Patient Safety*. Additionally, female-specific devices were evaluated far less frequently by the manufacturer (4.5% versus 38.2%).

Why it matters. Increased adverse event reports for female-specific devices and associated high-grade complications emphasize the importance of improved evaluation and identification of problematic implantable devices.

How ECRI can help. [Taking Action: Strategies to Advance Health Equity](#) discusses strategies to identify and address disparities that patients may face.

DEA and HHS Extend Telemedicine Prescriptions through 2024

What's the news. The Drug Enforcement Agency (DEA) and the Department of Health and Human Services (HHS) announced they would extend the COVID-19 flexibilities allowing for telemedicine prescription of controlled medications without a prior in-person evaluation through December 31, 2024, according to an [October 13, 2023, article](#) from law firm Baker Donelson. Proposed permanent flexibilities are also under consideration.

Why it matters. The DEA and HHS intend to promulgate final telemedicine prescription rules by fall 2024. Organizations should continue to be aware of changing regulations.

How ECRI can help. The guidance article [Medication Safety](#) discusses how organizations can prevent medication-related adverse events and implement a medication safety program.

Legal & Regulatory

Avoiding Class Certification in Lawsuits against Healthcare Providers

What's the news. Law firm Baker Donelson provides five tips on avoiding class certification in an [October 11, 2023, article](#). Tips include framing contracts with patients around quality of services rather than quantifiable or measurable standards, ensuring adherence to all state and federal statutory requirements for healthcare services, and removing potential class actions to federal court.

Why it matters. In a class action, the plaintiffs are similarly situated individuals represented collectively by a plaintiff in a lawsuit against one or more defendants and alleging the same cause of action and damages. Courts will often grant class certification in lawsuits because healthcare providers use the same services for hundreds or even thousands of individuals. While class certification can increase efficiency, class actions often lead to healthcare providers paying massive amounts in settlements or damages, which can hinder their ability to provide crucial medical services.

How ECRI can help. ECRI's collected resources on this topic can be found in [Essentials: Litigation and Claims Management](#).

Death Blamed on Uncommunicated Abnormal PSA Results

In 2009, a patient (plaintiff/decedent) with a family history of prostate cancer was tested via a digital rectal exam (which was normal) and the prostate-specific antigen (PSA) lab test. The PSA test results were abnormally high. At trial, there was conflicting evidence as to whether this result was communicated to the patient, according to the September 2023 *Medical Malpractice Verdicts, Settlements & Experts*.

Evidence was offered by the patient that a voicemail message was left for him but only results related to high cholesterol number was relayed; the defense claimed the PSA test results were also relayed at that time. For the next two years, there was no evidence offered demonstrating that treatment options, including specialist consultations, were provided to the patient.

In 2011, the patient returned to the physician and was diagnosed with benign prostatic hyperplasia. Another PSA test was performed that again yielded abnormally high findings. Within two weeks after the test, the patient returned to the physician with symptoms including swelling, pain running down the right leg, an inability to empty his bladder. He was informed during this visit that he had an abnormal PSA result. On his departure from the physician's office, he saw the 2009 result and was subsequently examined by a urologist who diagnosed him with stage IV prostate cancer. He died within three years of the second abnormal PSA test.

The patient filed a lawsuit before his death that continued on his behalf after he died. The first trial ended in a mistrial. The second trial ended with a judgment as a matter of law (JNOV) where the judge contended the facts of the case were not sufficient to sustain a verdict for liability. The plaintiff appealed and the JNOV was overturned on appeal. After the third trial, the jury returned a defense verdict.

ECRI Resources:

- [Implementation Approaches for Closing the Loop](#)
- [Top 10 Patient Safety Concerns for 2022: Cognitive Biases and Diagnostic Error](#)
- [Top 10 Patient Safety Concerns for 2020: Missed and Delayed Diagnoses](#)
- [Resource Collection: Diagnosis: Test, Referral, and Hospitalization Tracking](#)

ECRI Commentary: Testing is a complex process that involves many healthcare professionals, processes, and technologies. Problems with test result reporting and follow-up can lead to diagnostic errors, such as missed, delayed, or inaccurate diagnoses. As noted here, failure to follow up on test results could lead to a patient's cancer going undiagnosed, possibly for years, with potentially life-threatening consequences. Treatment errors can result as well. Difficulties in coordinating care—with other providers or with patients themselves—may complicate an already labyrinthine process.

Other care coordination issues include lack of information regarding the patient's primary care provider, difficulty communicating results to providers outside the health system's network, lack of patient follow-up with the provider, and difficulties reaching the patient directly (e.g., due to outdated contact information). Ambiguous accountability can also prevent effective follow-up.

This abstract is a summary of a recent court decision, verdict, settlement, or other action affecting healthcare organizations and their risk management programs.

When reviewing this abstract, keep in mind that laws and court decisions vary among jurisdictions and that decisions of lower courts may be overturned on appeal. For specific legal guidance regarding the significance or applicability of this decision, contact legal counsel.



ECRI Headquarters, 5200 Butler Pike, Plymouth Meeting, PA 19462, 610.825.6000

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