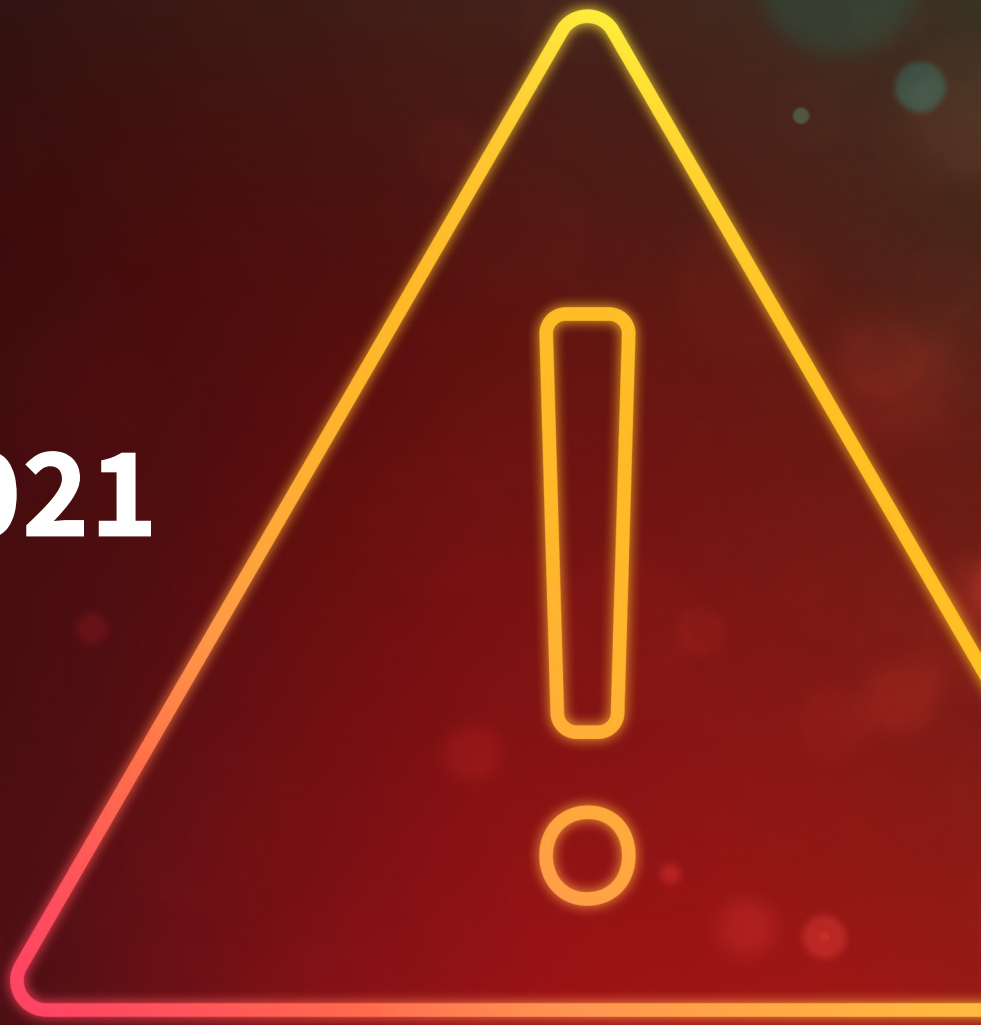
SPECIAL REPORT

Top 10 Health Technology Hazards for 2021

Expert Insights from *Health Devices*

EXECUTIVE BRIEF

www.ecri.org/2021hazards



ECRI

The Most Trusted Voice in Healthcare

Top 10 Health Technology Hazards for 2021

Executive Brief

ECRI is providing this abridged version of its 2021 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report—including detailed problem descriptions and ECRI's step-by-step recommendations for addressing the hazards—is available to members of ECRI programs through their membership web pages.

The List for 2021

1. Complexity of Managing Medical Devices with COVID-19 Emergency Use Authorization
2. Fatal Medication Errors Can Result When Drug Entry Fields Populate after Only a Few Letters
3. Rapid Adoption of Telehealth Technologies Can Leave Patients and Data at Risk
4. Imported N95-Style Masks May Fail to Protect Healthcare Workers from Infectious Respiratory Diseases
5. Relying on Consumer-Grade Products Can Lead to Inappropriate Healthcare Decisions
6. Hasty Deployment of UV Disinfection Devices Can Reduce Effectiveness and Increase Exposure Risks
7. Vulnerabilities in Third-Party Software Components Present Cybersecurity Challenges
8. Artificial Intelligence Applications for Diagnostic Imaging May Misrepresent Certain Patient Populations
9. Remote Operation of Medical Devices Designed for Bedside Use Introduces Insidious Risks
10. Insufficient Quality Assurance of 3D-Printed Patient-Specific Medical Devices May Harm Patients

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Persevering through Challenging Times

This 14th edition of our Top 10 list was developed under the shadow of the most significant healthcare challenge of our time, the COVID-19 pandemic. During this global public health emergency, healthcare workers have stepped up to devise new processes, often in the face of significant adversity, to provide the level of care that their patients deserved. Clinicians, clinical engineers, supply chain professionals, patient and medication safety advocates, executives, IT specialists, environmental services staff, administrative assistants—everyone played a role. The significance of their contribution cannot be overstated. And the world's gratitude for it cannot be sufficiently expressed.

As we move into 2021, we know the challenge remains, but we are hopeful that a return to normalcy is not too far in the distance. Many of the topics on this year's list address that theme: the need to move from just trying to cope during an emergency to building stronger and more resilient processes, utilizing the innovations developed and the lessons learned along the way.

The Purpose of the List

The safe use of health technology—from simple devices to complex information systems—requires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood that adverse events will occur. This list will help healthcare facilities do that.

Produced each year by ECRI's device evaluation group, the Top 10 Health Technology Hazards list identifies the potential sources of danger that we believe warrant the greatest attention for the coming year. The list does not necessarily enumerate the most frequently reported problems or the ones associated with the most severe consequences—although we do consider such information in our analysis. Rather, the list reflects our judgment about which risks should receive priority *now*.

All the items on our list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. With the additional content provided in the full report, the list serves as a tool that healthcare facilities can use to efficiently and effectively manage the risks.

How Topics Are Selected

This list focuses on what we call generic hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies. It does not discuss risks or problems that pertain to specific models or suppliers.

ECRI engineers, scientists, clinicians, and other patient safety analysts nominate topics for consideration based on their own expertise and insight gained through:

- Investigating incidents
- Testing medical devices in the ECRI lab
- Observing operations and assessing hospital practices
- Reviewing the literature
- Speaking with clinicians, clinical engineers, technology managers, purchasing staff, health systems administrators, and device suppliers

Staff also consider the thousands of health-technology-related problem reports that we receive through our Problem Reporting Network and through data that participating facilities share with our patient safety organization, ECRI and the Institute for Safe Medication Practices PSO.

After the topic nomination phase, professionals from ECRI's many program areas, as well as external advisors, review these topics and select their top 10. We use this feedback to produce the final list, weighing factors such as the following:

- **Severity.** What is the likelihood that the hazard could cause serious injury or death?
- **Frequency.** How likely is the hazard? Does it occur often?
- **Breadth.** Is the hazard likely to be experienced in many facilities? Or, if the hazard occurs, are the consequences likely to spread to affect a great number of people, either within one facility or across many facilities?
- **Insidiousness.** Is the problem difficult to recognize? Could the problem lead to a cascade of downstream errors before it is identified or corrected?
- **Profile.** Is the hazard likely to receive significant publicity? Has it been reported in the media, and is an affected hospital likely to receive negative attention? Has the hazard become a focus of regulatory bodies or accrediting agencies?
- **Preventability.** Can actions be taken now to prevent the problem or at least minimize the risks? Would raising awareness of the hazard help reduce future occurrences?

All the topics we select for the list must, to some degree, be preventable. But any one of the other criteria can, on its own, warrant including a topic on the list. We encourage readers to examine these same factors when judging the criticality of these and other hazards at their own facilities.

Not all hazards on the list will apply to all healthcare facilities. Also note that the exclusion of a topic that was included on a previous year's list should not be interpreted to mean that the topic no longer deserves attention. Most of these hazards persist, and hospitals should continue working toward minimizing them. Rather, our experts determined that the topics listed here should receive greater attention in 2021.

FOR MEMBERS ONLY: LOG IN TO ACCESS THE FULL REPORT AND SOLUTIONS KIT

This Executive Brief helps raise awareness of critical health technology hazards—a key step in patient safety efforts. The next steps involve taking action to prevent the problems from occurring. The 2021 Top 10 Health Technology Hazards Solutions Kit—available online to members of ECRI programs—will help with that effort.

The Solutions Kit provides a comprehensive discussion of each topic, actionable recommendations for minimizing the risks of harm, and lists of useful resources for more information about each topic. Log in to your membership web page to access this valuable content.

Complexity of Managing Medical Devices with COVID-19 Emergency Use Authorization

1

ONE

To meet the unprecedented need for medical equipment and supplies during the COVID-19 public health emergency, FDA temporarily authorized the use of hundreds of medical devices that had not previously been approved for use. Through its Emergency Use Authorization (EUA) authority, FDA can designate previously unapproved products—or new uses for previously approved products—as acceptable for use during an emergency.

Two factors must be considered when using EUA devices:

First, these devices are authorized only for the duration of the pertinent EUA. When the health emergency ends or FDA revokes an EUA—which can happen at any time—EUA devices revert to unapproved status. At that time, the legal protections that support the use of EUA devices on new patients are terminated.

Second, EUA devices may not be as safe or effective as devices that have been through FDA's normal clearance process. FDA can issue an EUA if it determines that the device *may be effective* for the specified use, and if it judges that the benefits of the product outweigh the known and potential risks of the product. But this is a lower standard for checking safety and effectiveness than FDA uses for its normal process. Thus, EUA device users must be mindful of the potential for problems.

Healthcare facilities that use EUA devices face a complex challenge: They must manage inventories of EUA devices and their documentation, monitor each device's status daily to determine whether the EUA remains active and unchanged, and determine what to do with these devices once the EUA ends. ECRI offers comprehensive guidance to help healthcare facilities complete each of these steps.

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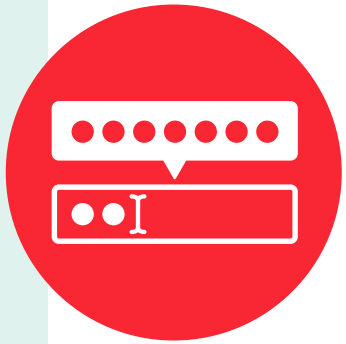

Fatal Medication Errors Can Result When Drug Entry Fields Populate after Only a Few Letters

2

TWO

To make drug searching and selection faster and easier for the user, many medication ordering, storage, and delivery systems allow the practitioner to enter only a few letters of a drug name before the system populates the drug selection field with a list of drugs to choose from. This feature, designed to be a convenience, displays similar-looking drug names as options, which increases the risk that users will mistakenly select an incorrect drug. The Institute for Safe Medication Practices (ISMP) has reported on several incidents in which selection errors associated with the display of similar-looking drug names have led to severe harm or death.

This drug searching and selection functionality exists in a variety of technologies, including electronic health records (EHRs), computerized provider order-entry (CPOE) systems, ambulatory prescribing systems, automated dispensing cabinets (ADCs), inpatient and community pharmacy systems, and infusion pumps.

The likelihood of such errors could be significantly reduced if systems are designed or configured to require entry of, at minimum, the first five letters of a drug name before populating search fields. An ECRI analysis of drug names found that 92% of FDA-approved drugs have the same first three letters as at least one other drug, compared with only 58% when looking at the first five letters. Thus, increasing the number of characters entered from three to five greatly reduces the possible number of matches.

The Institute for Safe Medication Practices (ISMP) has reported on several incidents in which selection errors associated with the display of similar-looking drug names have led to severe harm or death.

Rapid Adoption of Telehealth Technologies Can Leave Patients and Data at Risk

THREE

3

The COVID-19 pandemic has prompted many healthcare delivery organizations to rapidly implement or expand telehealth programs, sometimes in a matter of days or weeks. The need to conserve personal protective equipment (PPE), protect clinical personnel and patients, and continue providing healthcare services during stay-at-home orders has helped drive the surge in telehealth use.

While the sudden change in healthcare practices has been necessary to meet the immediate need—and represents a trend that is likely to continue—deploying telehealth solutions so quickly can create its own problems and challenges. As facilities seek to transition from the pandemic response to new telehealth care delivery models, programs may struggle to provide sufficient user training, to coordinate patient care, or to overcome technology resource inequalities among patients. Also, some of the technologies adopted may not be suitable for long-term use (e.g., if temporary regulatory exemptions expire) or may not integrate well with existing clinical workflows and systems.

Failure to address these challenges could adversely affect patient care: It could lead to suboptimal treatment, increase the risk of medical errors, or hinder certain populations from accessing care. An additional concern is that a rushed implementation could lack adequate cybersecurity controls, putting the patient's and the facility's data at risk.

The solution may involve switching, modifying, reconfiguring, or ceasing the use of some of these technologies. Key recommendations include conducting technology assessment and workflow planning steps that might have been skipped, verifying that you have a clear patient-selection methodology (not all patients are good candidates for telehealth), and conducting a cybersecurity risk assessment.

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Imported N95-Style Masks May Fail to Protect Healthcare Workers from Infectious Respiratory Diseases

4

FOUR

Not every healthcare worker requires the level of protection afforded by a NIOSH-certified N95 respirator. But for individuals at high risk of being exposed to aerosols from COVID-19 patients, a mask that provides reliable, N95-level respiratory protection is essential. Unfortunately, some imported N95-style masks fail to provide the level of protection claimed. Of particular concern are KN95 masks imported from China.

N95 masks—more accurately referred to as N95 filtering facepiece respirators—are certified by the U.S. National Institute for Occupational Safety and Health (NIOSH) as being able to block at least 95% of airborne particles under specified test conditions. With N95 respirators in short supply during the COVID-19 pandemic, healthcare organizations have sought alternatives. KN95 respirators from China are one such alternative.

Although KN95s have not been certified by NIOSH, they are marketed as meeting the requirements of a Chinese standard that aligns with NIOSH's N95 mask requirements. However, ECRI testing through December 2020 found that, of the imported non-NIOSH-certified respirator alternatives tested, more than 60% failed to filter airborne particles as well as claimed.

Use of less-effective respirators, especially for aerosol-generating procedures, may increase staff and patient exposure to infectious respiratory diseases. Organizations considering the use of non-NIOSH-certified respirators should verify that the models have been properly tested before they are put into use during the treatment of COVID-19 patients. If you've acquired respirators that fail to meet the N95 standard, consider using them for non-surgical, no-splash procedures in which surgical or procedure masks are currently used.

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Relying on Consumer-Grade Products Can Lead to Inappropriate Healthcare Decisions

5

FIVE

Consumer-grade healthcare products can be useful to monitor a patient's physiologic trends, but users should not rely on these products to make healthcare decisions. The measurements or other results from these products may not be sufficiently accurate or may be misleading.

Products such as consumer-grade finger pulse oximeters, blood pressure cuffs, and glucose monitors are being used not only in the home, but elsewhere within the healthcare continuum. Patients and clinicians alike are increasingly interested in such products to provide some level of care when a traditional medical device is unavailable, inappropriate, inconvenient, or too expensive.

During the COVID-19 pandemic, for example, healthcare providers have considered using consumer-grade devices, even in the acute care environment, as a means to reduce bedside visits (thereby reducing exposure risks) and to address medical device shortages and other resource limitations.

However, most consumer-grade devices have not been through FDA's medical device approval process. Thus, users cannot be sure that they are as accurate or reliable as products that have been cleared by FDA for marketing as medical devices. This limitation makes the devices insufficiently reliable for use in identifying situations that may require medical attention.

Within the healthcare environment, ECRI recommends avoiding the use of consumer-grade devices whenever possible, particularly when monitoring critically ill patients. If such a device must be used, do so only for the time that's necessary and only on the condition that the clinical team knows how to use it and understands how its performance could differ from that of medical-grade equipment.

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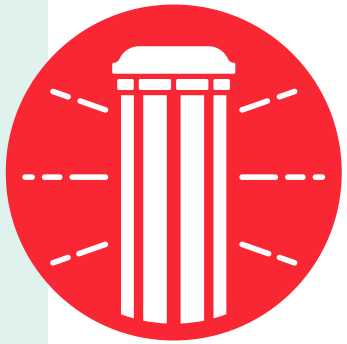

Hasty Deployment of UV Disinfection Devices Can Reduce Effectiveness and Increase Exposure Risks

6

SIX

At the right wavelengths and with an appropriate exposure time, ultraviolet (UV) light can be used to disinfect surfaces and spaces, making UV disinfection technologies an effective supplement to normal cleaning and disinfection processes. However, if not used properly, UV disinfection devices may not deliver a high enough dose to inactivate microorganisms, leaving individuals at risk of exposure to infectious pathogens. Improper use could also expose operators or bystanders to unsafe levels of UV radiation.

The need to combat the SARS-CoV-2 virus has prompted healthcare facilities, public health officials, private companies, and consumers to consider UV disinfection technologies for a host of new applications. But decisions to use this technology should be proactive and deliberate, not hasty; and prospective purchasers will first need to do their homework.

UV disinfection devices are not typically regulated by FDA (most are not considered medical devices), and they're not required to demonstrate safety and effectiveness according to any standardized protocol. Thus, understanding the capabilities and limitations of each device is vital.

Furthermore, users must understand the conditions required to achieve disinfection. Effective disinfection with UV light depends on the dose that reaches the microorganism. That, in turn, is a function of the intensity of the light emitted by the device, the duration of exposure, and any complicating factors, such as distance or shadowing. Surfaces to be disinfected should be in a direct line of sight, and should first be cleaned of soil. In addition, users must take appropriate safety precautions to protect themselves and others from UV light exposure.

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SEVEN

Vulnerabilities in Third-Party Software Components Present Cybersecurity Challenges

7

Third-party software components that are incorporated into medical devices pose unique cybersecurity challenges. Specifically, efforts to remediate vulnerabilities in third-party operating systems and other off-the-shelf software components can be hindered by:

- Difficulties identifying which medical devices include the affected software
- Delays in receiving guidance while the medical device vendor audits its product lines, validates third-party patches, and develops recommendations for remediating the problem
- Practical challenges associated with applying the mitigation in a clinical environment where equipment might be in continuous patient use or delivering life-sustaining therapy

A software vulnerability that is not remedied could allow a medical device to be compromised, which could disrupt patient care—possibly on a system-wide level—or could lead to a data breach. The WannaCry ransomware attack in 2017 demonstrated how the exploitation of a vulnerability in third-party software could have devastating and far-reaching effects. More recently, healthcare organizations have had to respond to Ripple20, SweynTooth, Urgent/11, and other vulnerabilities that have the potential to adversely affect patient care.

Protecting against such vulnerabilities requires assessing a medical device supplier's ability to manage the software on its devices, obtaining security information for the devices in inventory (such as that available from an MDS^2 form or a software bill of materials), and using appropriate tools to store and retrieve this information.

A software vulnerability that is not remedied could allow a medical device to be compromised, which could disrupt patient care—possibly on a system-wide level—or could lead to a data breach.

EIGHT

Artificial Intelligence Applications for Diagnostic Imaging May Misrepresent Certain Patient Populations

8

Artificial intelligence (AI) technologies are starting to make an impact in healthcare. In diagnostic imaging, for example, AI applications have been used to help distinguish COVID-19-related lesions from other lung-related pathologies.

With AI, however, the quality of the output depends on the quality of the data used to train the AI application. Unreliable AI functionality can lead to misdiagnoses or can prompt inappropriate care decisions. In ionizing imaging systems that use AI, for example, inaccurate interpretation of an image could affect the patient's treatment plan or the radiation dose delivered.

A key challenge associated with developing and refining an AI algorithm is overcoming bias in the data. AI applications are dependent on the data that is used to train them, and thus are inherently biased toward patient populations that "look like" the population used in developing the algorithm. If that data does not accurately represent a particular patient population, the resulting output may not be appropriate for those patients.

Obtaining large, high-quality, relevant, and broad-based datasets for developing and refining AI implementations is a challenge for AI developers. For healthcare providers, the challenge is determining how much trust to place in the AI application, since users have little visibility into how an AI implementation makes decisions.

Conducting a risk-benefit assessment of AI functionality can help healthcare institutions assess the safety and effectiveness of medical technologies that incorporate AI. A key part of this process will involve verifying that the data used to train the algorithm is sufficiently representative of the organization's patient population.

AI applications are dependent on the data that is used to train them, and thus are inherently biased toward patient populations that "look like" the population used in developing the algorithm.

Remote Operation of Medical Devices Designed for Bedside Use Introduces Insidious Risks

9

NINE

During surge periods of the COVID-19 pandemic, methods for remotely operating ventilators, infusion pumps, and other devices have been deployed as a way to conserve personal protective equipment (PPE), minimize healthcare worker exposure to infected patients, and avoid delays associated with donning PPE in order to respond to certain clinical conditions.

However, when medical devices that were designed to be operated primarily at the bedside are instead operated remotely—whether by positioning the devices outside the patient room or by some other means—it can result in various problems for the patient and personnel. Concerns include:

- Less frequent direct visual assessment of the patient, which may prevent staff from observing clinically relevant conditions or device complications
- Adverse effects on device performance associated with the use of longer tubing sets, for example, or with staff being unable to see or hear the functioning of the device
- Infection risks associated with increased connection points on infusion tubing or with compromised patient isolation (e.g., if cables are channeled through an ajar door)
- Obstacles resulting from placing devices in the hallways, including tripping hazards and overcrowding that can hinder transportation within the care unit
- The potential for unauthorized device access or tampering

Remote device operation should be considered only during highly unusual circumstances (such as a public health emergency), only for as long as necessary, only after assessing the risks and benefits based on the individual patient's condition, and only after verifying that the concerns outlined above can be mitigated.

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Insufficient Quality Assurance of 3D-Printed Patient-Specific Medical Devices May Harm Patients

10

TEN

3D printing, also referred to as additive manufacturing, is a method of building an object by fusing together layers of raw material. 3D-printing technology is now being used to create a range of patient-specific devices, including implants, anatomical models for surgical planning, surgical guides for orthopedic procedures, and prostheses.

If a 3D-printed patient-specific device is created without appropriate clinical verification of the design, quality control of the manufacturing process, and validation of the end product, the resulting object may not accurately represent key patient anatomy or may not perform as intended. The use of an improperly created 3D-printed device could lead to procedure delays, surgical complications, infection, or patient injury.

Building a 3D-printed object requires first creating a digital design of the object. For patient-specific devices, high-resolution patient imaging files, such as from CT or MRI, are used to create the design. Accurate conversion of the imaging data into a digital design and considerable engineering expertise are then required to make the final object. Without appropriate measures to manage all of the variables in the design and manufacturing processes, patient care could be adversely affected.

Unlike with traditional medical devices, the particular physician who will be using the patient-specific 3D-printed device plays a key role in the design process. Thus, providers bear increased responsibility for verifying that sufficient quality assurance measures have been followed. Healthcare facilities should establish a written acceptance policy specifying the need to approve the object design, as well as the quality of the finished device, before a 3D-printed patient-specific medical device is accepted for clinical use.

Without appropriate measures to manage all of the variables in the design and manufacturing processes, patient care could be adversely affected.

ECRI Resources for Addressing the Hazards

Members of certain ECRI programs can access resources such as the following to learn more about the topics included on this year's list:

1. COVID-19 Emergency Use Authorization Devices

[COVID-19] Use of unapproved devices or new applications for existing medical devices to address COVID-19 shortages without an EUA may jeopardize patient or staff safety [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 May 21. Accession No. H0612.

[COVID-19] Ventilators on FDA emergency use authorization list: hospitals should seek clarity on post-EUA status before purchasing [ECRI Exclusive Special Report]. *Health Devices Alerts* 2020 Apr 29. Accession No. S0399.

2. Drug Entry Fields and Drug Selection Errors

Looks like a duck, sounds like a duck, but isn't: look-alike/sound-alike medications. *PSO Compass Points* 2020 Jan 16.

Pharmacy Technology and Medication Management: The Essentials. This web page features a collection of *Health Devices* resources on medication safety topics and technologies related to medication preparation, storage, compounding, packaging, and dispensing.

3. Rapid Adoption of Telehealth Technologies

Cybersecurity risks in the connected home healthcare environment. Hazard #7—2020 top 10 health technology hazards. *Health Devices* 2019 Sep 26.

Telehealth: The Essentials. This page contains our complete collection of guidance, tools, and other resources associated with telehealth technologies.

Lab webcast series: Telehealth during the COVID-19 pandemic:

- Making cybersecurity a priority in telemedicine with ECRI's guidance (2020 Sep 9).
- Rapid telehealth adoption to provide routine clinical care during COVID-19 (2020 Jul 1).
- Telehealth—patient monitoring in the age of COVID-19 (2020 Jun 17).

4. Imported N95-Style Mask Filtration Failures

Addressing shortages—usage strategies and reuse considerations:

- COVID-19 Q&A: addressing N95 respirator shortages. *Health Devices* 2020 Apr 29.
- [COVID-19] Strategies for addressing expected or known N95 respirator shortages [ECRI Exclusive Hazard Report]. *Health Devices Alerts* Updated 2020 Apr 22. Accession No. H0577.
- [COVID-19] Strategies for addressing expected or known shortages of powered air-purifying respirators and accessories [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 May 12. Accession No. H0609.
- [COVID-19] Strategies to conserve existing supplies of personal protective equipment [ECRI Exclusive Special Report]. *Health Devices Alerts* 2020 May 4. Accession No. S0400.
- Webcasts—Addressing Respirator Shortages:
  - Use of imported N95-style masks, without NIOSH certification or independent lab validation, may put healthcare workers and patients at risk (2020 Sep 29).
  - N95 respirators—new guidance for addressing shortages (2020 Apr 15).
  - Safe respirator usage when supplies are short (2020 Mar 25).
- The following resources provide ECRI's guidance for decontaminating N95 respirators. ECRI cautions, however, that respirator reprocessing methods that have received FDA Emergency Use Authorization for such applications are not authorized for use on KN95 FFRs.
  - COVID-19 evaluation background: UV solutions for contingency and crisis decontamination of N95 respirators. *Health Devices* 2020 Jun 8.
  - [COVID-19] Decontamination of N95 respirators: UV light may be considered for limited reuse situations [ECRI Exclusive User Experience Network] [Update]. *Health Devices Alerts* 2020 Sep 3. Accession No. S0394 01.

Assessing performance:

- [COVID-19] Use of imported N95-style masks, without NIOSH certification or independent lab validation, may put healthcare workers and patients at risk during the COVID-19 pandemic [ECRI Exclusive Hazard Report]. *Health Devices Alerts* Updated 2020 Sep 18. Accession No. H0642.

Identifying alternative suppliers:

- Alternate Supplier List: Personal Protective Equipment—This is a comprehensive directory of go-to sources to supplement the usual suppliers. It is organized by equipment type: respirators, shoe covers, masks, etc.
- Functional Equivalents: Personal Protective Equipment Supply Equivalents—This periodically updated ECRI database provides the best matches for the three most popular brands of exam gloves, face shields, isolation gowns, air-purifying respirators (e.g., N95, PAPRs), safety eyewear, shoe covers, and surgical masks based on key performance indicators (KPIs) and functional equivalence.
- Nontraditional PPE Suppliers (Domestic and International)—ECRI is collaborating with the Association for Health Care Resource & Materials Management (AHRMM) to provide lists of nontraditional suppliers offering PPE supplies. In the collaboration, AHRMM is tracking nontraditional domestic suppliers, and ECRI is tracking nontraditional international suppliers. The combined effort and solution will help providers vet nontraditional suppliers and provide assurance that they have been assessed by each organization.
- Webcast: Navigating nontraditional PPE suppliers, and key findings from N95 testing (2020 Aug 5). Available here: Navigating the Purchase of PPE from Nontraditional Suppliers.

5. Relying on Consumer-Grade Products

Evaluation background: consumer-marketed baby vital signs monitors. *Health Devices* 2018 Oct 24.

Evaluation background: consumer-marketed wearable and handheld blood pressure devices. *Health Devices* 2019 Oct 31.

Evaluation background: smartphone-enabled ECG monitors. *Health Devices* 2018 May 2.

[COVID-19] Home-use SpO_2: considerations before prescribing or using consumer-grade pulse oximeters in the home care environment [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 Jun 4. Accession No. H0619.

Subcutaneous continuous glucose monitor accuracy for monitoring critically ill adults. Plymouth Meeting (PA): ECRI; 2020 May 26. (Clinical Evidence Assessment).

The growing use of consumer-grade medical devices: advice for physicians and their patients. *Health Devices* 2019 Aug 7.

6. Hasty Deployment of UV Disinfection Devices

Alerts and Hazard Reports from *Health Devices Alerts:*

- [COVID-19] UV disinfection devices—Health Canada warns against false claims for COVID-19 [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 Nov 25. Accession No. H0653.
- UV room disinfection devices: improper use of motion sensors may contribute to UVC exposure [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2018 Dec 28. Accession No. H0482.

Evaluations and guidance articles from *Health Devices:*

- Avoiding misuse of UVC room disinfection technology. *Health Devices* 2018 Nov 14.
- Evaluation background: UV room disinfection devices. *Health Devices* 2020 Apr 30.
- Evaluation background: countertop UV disinfection devices. *Health Devices* 2019 Mar 6.
- Technology background: large- and small-area environmental disinfection methods. *Health Devices* 2020 Nov 18.
- Using UV disinfection safely and effectively: technology challenges during the COVID-19 pandemic. *Health Devices* 2020 May 27.

Technology Briefings from *Health Devices:* ECRI's disinfection device Technology Briefings explore how and where a given technology is used, which applications it is best suited to, the strength of the evidence to support its use, and more. Technologies covered in this series include:

- Far-UVC disinfection devices. *Health Devices* 2020 Sep 10.

- Filtration and germicidal UV light for HVAC applications. *Health Devices* 2020 Oct 21.
- Handheld UV disinfection devices. *Health Devices* 2020 Oct 21.
- Portable air cleaners and UV air purifiers. *Health Devices* 2020 Oct 21.
- Upper-air UV disinfection devices. *Health Devices* 2020 Sep 10.
- UV mobile device disinfection boxes. *Health Devices* 2020 Nov 18.
- UV room disinfection devices. *Health Devices* 2020 Sep 10.
- UV shoe sole disinfection devices. *Health Devices* 2020 Sep 10.

Webcast:

- Effective use of UV disinfection (2020 Mar 18), available here: Cleaning and disinfection practices during the COVID-19 pandemic.

7. Vulnerabilities in Third-Party Software Components

General guidance:

- Cybersecurity: The Essentials. This web page features a collection of *Health Devices* resources on cybersecurity topics.
- Cybersecurity: understanding key terms and concepts. *Health Devices* 2020 Apr 8.

Alerts and Hazard Reports:

- Regarding Microsoft OS vulnerabilities—Below, we list a few relevant ECRI exclusive Hazard Reports (from January through December 2020); members can search *Health Devices Alerts* for numerous additional reports related to Microsoft OS vulnerabilities:
  - BD—Various medical device systems: may possess critical Windows domain name server vulnerability [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 Nov 23. Accession No. H0654.
  - Malicious spoofed files and websites can bypass certificate validation in Microsoft Windows 10, Windows Server 2016, and Windows Server 2019 [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 Jan 22. Accession No. H0563.
  - Windows 7 and Windows Server 2008 end of support in 2020 may leave medical devices vulnerable [ECRI Exclusive Hazard Report] [Update]. *Health Devices Alerts* 2020 Jan 13. Accession No. H0509 01.
- Regarding Ripple20 vulnerabilities:
  - Baxter—SIGMA Spectrum and Spectrum IQ infusion pumps: wireless battery modules possess Ripple20 vulnerabilities [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2020 Jul 1. Accession No. H0629.
- Regarding SweynTooth vulnerabilities:
  - Abbott—Confirm Rx insertable cardiac monitors: "SweynTooth" cybersecurity vulnerabilities may exist. *Health Devices Alerts* 2020 Apr 24. Accession No. A34822.
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- How can providers navigate potential liability concerns related to artificial intelligence? 2019 Oct 9.
- Machine learning can diagnose "cancer" and "not cancer," but "maybe" is an important diagnosis too. 2019 Dec 18.
- Machine learning may be useful to predict in-hospital mortality rates for adult patients upon admission. 2020 Feb 12.
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