The Pew Charitable Trusts

Ways to Improve Electronic Health Record Safety

Rigorous testing and establishment of voluntary criteria can protect patients

Contents

Acknowledgments

Overview

Electronic health records have transformed modern medicine, giving doctors and nurses better data to guide care, supporting enhanced patient safety through new automated tools, and creating more efficient processes by connecting different health systems.

However, the design, customization, and use of electronic health records (EHRs) by doctors, nurses, and other clinicians can also lead to inefficiencies or workflow challenges and can fail to prevent—or even contribute to—patient harm. For example, an unclear medication list could result in a clinician ordering the wrong drug for a patient. Laboratory tests that are displayed without the date and time of the results could lead to clinical decisions based on outdated information. And failures of systems to issue alerts about harmful medication interactions—situations that can stem from changes made by facilities, how clinicians enter data, or EHR design—could lead to medical errors.

These safety hazards can be associated with EHR usability, which refers to the design and use of the technology and how individuals interact with it. Usability challenges can frustrate clinicians because they make simple tasks take longer, lead to workarounds, or even contribute to patient safety concerns. These challenges can stem not only from the layout of EHRs, but also from how the technology is implemented and operated in health care facilities; how clinicians are trained to use it; and how the EHR is maintained, updated, and customized. Each stage of EHR development and use—the software life cycle from development through implementation and use in a health care environment—can affect the usability and safety of the technology.

While usability and patient safety are related, not every usability challenge will represent a risk to patients, and not every risk to patients stems from an EHR usability problem. In fact, some changes to EHRs might improve safety but result in less-efficient workflows—for example, if clinicians were prompted to enter "lbs." or "kg." every time they entered a patient's weight. But when a system is challenging to use or patient information is difficult for a clinician to find, safety risks could occur.

As part of federal criteria that provide the certification standards for EHRs, technology developers must state that they engage end users and conduct usability testing during design and development. However, the certification requirements can fall short in two ways when it comes to assessing whether the use of products contributes to patient harm.

First, current federal testing criteria do not address circumstances in which customized changes are made to an EHR as part of the implementation process or after the system goes live. Instead, current rules focus only on the design and development stage of the EHR. While federal regulations mandate the testing of certain safety-related features—such as medication-allergy checks—the requirements do not focus on whether those functions operate in a safe way.

The second key challenge is the absence of requirements and guidance on how to test clinician interaction with the EHR for safety issues. Clinical test cases, which are scenarios that reflect realistic patient conditions and how health care providers treat individuals, can help detect hazards. However, there are no clear criteria for what constitutes a rigorous test scenario. Similarly, some of the scenarios for certification, while testing that certain functions work, may not effectively evaluate the EHR for usability or safety. Current certification test cases can be too specific, lack relevant details, or may not test aspects of the EHR that are recognized as posing safety risks. Unlike many other high-risk sectors, such as the airline and medical device industries, there is no standard for routinely testing health care software for safety issues and concerns.

To address these two challenges, The Pew Charitable Trusts, MedStar Health's National Center for Human Factors in Healthcare, and the American Medical Association conducted a literature review and convened a multidisciplinary expert panel composed of physicians, nurses, pharmacists, EHR vendors, patients, and health information technology experts. This information led to the development of:

- Recommendations on how to advance usability and safety throughout the EHR software life cycle, which can be used as the foundation for a voluntary certification process for developers and EHR implementers.
- Criteria detailing what constitutes a rigorous safety test case and the creation of sample test case scenarios based on reported EHR safety challenges.

Use of the voluntary certification tenets and test cases by health care facilities and technology developers can improve the usability and safety of EHRs. They also allow for the proactive identification of potential harm associated with the implementation and customization of EHRs.

Existing usability tests for certification fall short

EHR software must meet minimum certification criteria established by the federal government to ensure that it can share data, provide key capabilities to clinicians, and protect patient privacy. The current EHR certification program—implemented by the federal Office of the National Coordinator for Health Information Technology (ONC)—is intended to set the baseline standards that EHRs must meet so that hospitals and health care providers can confidently adopt and use the technology to meet requirements in certain federal programs. Under current certification requirements for EHR usability, which were released in 2015, developers must:

- Document how they consider the needs of doctors, nurses, and other clinicians in developing the product submitted for certification. Known as user-centered design, this process focuses on understanding the needs of the intended users throughout software development and deployment to improve usability of the product.[1] EHR developers attest to and describe their user-centered design process in this documentation.

- Conduct formal usability testing for certain capabilities identified by the federal government.[2] These tests include measures of efficiency, effectiveness, and satisfaction as clinicians complete representative test cases of certified criteria using the EHR product.[3] Developers can use test cases established by the National Institute of Standards and Technology (NIST) or develop their own scenarios.[4] When developing scenarios, developers must conduct a risk analysis of the product and build test cases to address challenges identified.[5]

Regardless of which test cases are used, ONC's usability criteria require the testing of certain EHR functions, such as the ability to order medications electronically and receive medication alerts. The NIST-developed test cases do not explicitly address each of the required functions laid out in ONC's certification regulations.[6] Because these cases do not overlap with high-prevalence safety hazards, some important EHR features may not be sufficiently evaluated.

EHR Certification Program

The Health Information Technology for Economic and Clinical Health (HITECH) Act, passed in 2009, established the Medicare and Medicaid EHR Incentive Program—known as Meaningful Use—to provide financial incentives for hospitals and doctors' offices to purchase and utilize electronic health records. The program has provided more than $37 billion[7] for the adoption of EHRs. To obtain those incentive payments, hospitals and doctors had to demonstrate that they used EHRs in certain ways—such as by sending prescriptions to pharmacies electronically instead of on paper.

To provide assurances to hospitals and doctors that the EHRs they use can perform those functions, HITECH also created the EHR certification program administered by ONC. This establishes technological requirements for EHRs, including their functions, how to record information, and security features. ONC has periodically updated the requirements. The initial certification requirements were published in 2010 (2011 Edition), with updates in 2012 (2014 Edition) and 2015 (2015 Edition).

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To obtain certification, EHR developers submit data on their products to accredited testing labs for review. The labs forward their findings to an ONC-authorized certification body, which issues a certification based on the lab's finding.

In September 2017, ONC modified its testing requirements to require health IT developers to state that they meet 30 certification criteria (approximately half of the total) instead of having them reviewed by an accredited testing lab.[8] This reflected a major change in the approach to vendor certification.

In 2016, ONC issued regulations giving it direct authority to enter health care facilities and review and test EHRs that posed serious risks to patients. If a risk was found, ONC could require the health IT developer to fix the problem or suspend certification of products with unresolved problems.[9] In 2017, ONC announced it would no longer require testing labs to perform random surveillance to allow labs to focus on complaint-based investigations.[10]

ONC has also indicated that it will not update the 2015 Edition.[11] However, the 21st Century Cures Act requires health IT products to meet new criteria for EHRs used in the care of children, which affords another opportunity to improve safety.[12]

Best practices already adopted to improve safety

Many EHR developers and health care providers have engaged in additional efforts to improve usability and safety throughout the product life cycle:

- Members of the Electronic Health Records Association commit to adhere to a code of conduct that includes patient safety and usability as key focus areas.[13]
- EHR developers commit to review safety incidents with designated patient safety officers and groups of product users, and to share information across health care facilities.[14]
- Health care providers use safety experts to advise on implementation, customization, and use of the EHR.[15]
- Health care providers conduct EHR safety surveys or have safety teams to identify potential problems.[16]
- EHR developers and health care providers use enhanced training methods, such as simulated clinical environments or expert trainers observing clinicians to provide direct feedback.[17]
- The Leapfrog Group, a nonprofit organization founded by large employers and health care purchasers to improve health care safety and quality for their employees, sponsors an EHR test utilizing test cases in its annual hospital safety survey.[18]
- Medical associations recommend using standardized test cases, developing a set of measures for adverse events, and performing formal usability assessments.[19]

These practices can serve as the foundation for a more comprehensive certification program during product development and after implementation to improve EHR safety.

Opportunities to improve usability certification test cases

Several factors throughout the EHR life cycle affect usability and safety. Current certification tests are focused on evaluating the usability of key system requirements. According to published articles and experts consulted, best practices for testing, which are not required, include:

- **Consideration of all key tasks.** Developer usability testing performed for certification focuses on EHR functions required by ONC. Some vendors develop test cases that include tasks to evaluate safety, but this practice is not pervasive.[20] Test cases should also focus on more key tasks in which the use of these systems can affect safety.[21] Risks that are discovered should inform future test cases.

- **Involvement of representative end users.** ONC's most recent certification criteria require that vendors include at least 10 participants in testing system usability. The agency recommends that they be representative of end users but does not require it.[22]

- **Real-world testing.** Usability testing performed for certification is intended to be conducted under reproducible laboratory conditions that do not replicate the actual clinical use of the product, which can limit the tester's ability to discover risks that reflect real-world situations.[23]

- **Assessments of the total product life cycle.** Certification testing is performed on the EHR product presented to the evaluating lab. Various stages of the product life cycle, including how the product is modified by health care facilities and how software upgrades are implemented, can present different usability and safety challenges.[24]

- **Focus on the socio-technical environment.** Certification testing, conducted before implementation in health care facilities, focuses on the released EHR product and may not control for other factors that can influence safety.[25] For example, the type of training clinicians receive determines their knowledge of the EHR's features, including how to order medications, diagnostic images, and lab tests efficiently and safely. Additionally, the health care facility may make decisions during EHR implementation about how to organize information in the system, which affects how clinicians interact with the technology.[26]

Given the gaps of current regulations and practices implemented by health care facilities and technology developers, the literature review and expert panel discussions identified additional initiatives that could improve EHR safety.

Criteria to support usability and safety throughout the EHR life cycle

Several additional best practices, criteria, and factors emerged from the literature review and expert panel discussions that could help EHR developers and health care facilities improve product usability and safety. These criteria could provide a foundation for a voluntary certification program. Given that both EHR developers and health care providers have roles in ensuring the safe use of products, specific criteria were established for each. Additional standards for improving safety are also under development by the American Association of Medical Instrumentation.

Table 1

Overview of EHR Product Life Cycle Stages

Component	EHR developer and health care provider processes	Importance to usability and safety
Culture of safety	Encourage a culture of safety that prioritizes usability and safety hazards and works to optimize EHR systems to mitigate hazards.	Developer or provider organizations without a culture of safety are less likely to identify and prioritize usability and safety challenges.[*]
Product design and development	Support the design and development of the EHR product.	The design and development of EHRs shape how information is entered and displayed, as well as the overall workflow.[†]
Acquisition	Identify the appropriate product to meet health care provider needs.	When acquiring an EHR, user needs and product capabilities must be aligned, otherwise the technology may not provide adequate support to providers—resulting in potential unsafe workarounds.[‡]
Customization and configuration	Customize the EHR through tailored coding and configuration of the product to meet specific needs of the health care organization.	Customization and configuration decisions shape how information is entered and displayed, and affect overall workflow.[§]
Implementation and system upgrades	Implement and maintain a safe and usable EHR product.	Implementation determines how well the product supports user workflow, and system upgrades may resolve recognized safety challenges.[‖]
Training	Train clinicians and other end users to safely and effectively use the EHR product.	If providers do not receive adequate training, they may not know how to use the EHR safely.[#]

[*] Dean F. Sittig, Joan S. Ash, and Hardeep Singh, "The SAFER Guides: Empowering Organizations to Improve the Safety and Effectiveness of Electronic Health Records," *American Journal of Managed Care* 20, no. 5 (2014): 418–23, https://www.ncbi.nlm.nih.gov/pubmed/25181570.

[†] Dean F. Sittig, Elisabeth Belmont, and Hardeep Singh, "Improving the Safety of Health Information Technology Requires Shared Responsibility: It Is Time We All Step Up," *Healthcare* 6, no. 1 (2018): 7–12, http://dx.doi.org/10.1016/j.hjdsi.2017.06.004; Maryam Zahabi, David B. Kaber, and Manida Swangnetr, "Usability and Safety in Electronic Medical Records Interface Design: A Review of Recent Literature and Guideline Formulation," *Human Factors* 57, no. 5 (2015): 805–34, http://dx.doi.org/10.1177/0018720815576827.

[‡] Richard J. Holden, "What Stands in the Way of Technology-Mediated Patient Safety Improvements? A Study of Facilitators and Barriers to Physicians' Use of Electronic Health Records," *Journal of Patient Safety* 7, no. 4 (2011): 193–203, http://dx.doi.org/10.1097/PTS.0b013e3182388cfa.

[§] John R. Horn et al., "Customizing Clinical Decision Support to Prevent Excessive Drug-Drug Interaction Alerts," *American Journal of Health-System Pharmacy* 68, no. 8 (2011): 662–64, http://dx.doi.org/doi:10.2146/ajhp100465.

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‖   Emily Patterson et al., "Enhancing Electronic Health Record Usability in Pediatric Patient Care: A Scenario-Based Approach," *Joint Commission Journal on Quality and Patient Safety* 39, no. 3 (2013): 129–35, https://www.ncbi.nlm.nih.gov/pubmed/23516763; Linda W. Peute et al., "Anatomy of a Failure: A Sociotechnical Evaluation of a Laboratory Physician Order Entry System Implementation," *International Journal of Medical Informatics* 79, no. 4 (2010): e58-e70, http://dx.doi.org/10.1016/j.ijmedinf.2009.06.008.

\#   Sima Ajami and Tayyebe Bagheri-Tadi, "Barriers for Adopting Electronic Health Records (EHRs) by Physicians," *Acta Informatica Medica* 21, no. 2 (2013): 129–34, http://dx.doi.org/10.5455/aim.2013.21.129-134; A. Aktta Patel and A. Ant Ozok, "Exploring Training Issues in Healthcare: Towards Identifying Barriers to Increase Electronic Medical Records Adoption by Healthcare Professionals," in Andreas Holzinger and Klaus-Martin Simonic, eds., *Information Quality in E-Health* (Berlin: Springer, 2011), 657–71, https://link.springer.com/chapter/10.1007/978-3-642-25364-5_47; Leslie A. Miller et al., "Novice Nurse Preparedness to Effectively Use Electronic Health Records in Acute Care Settings: Critical Informatics Knowledge and Skill Gaps," *Online Journal of Nursing Informatics* 18, no. 2 (2014), https://www.himss.org/novice-nurse-preparedness-effectively-use-electronic-health-records-acute-care-settings-critical.

Several discrete actions and criteria were also identified that developers and health care providers should undertake. A voluntary certification program that encompasses these components could ask developers and providers to consider each criterion and, where appropriate, to adopt and implement these methods and processes. While the criteria provide a framework for factors that can be included in voluntary certification programs, each institution creating such a program would have to tailor it to its specific goals and mission.

Table 2

Specific Criteria for Each Usability and Safety Component

EHR life cycle stage or factor	Usability and safety optimization opportunities	
	For EHR developers	**For health care providers**
Culture of safety	• Embed a culture of safety throughout the organization's policies so that all personnel recognize its importance. • Create a risk-free environment to report potential hazards. • When hazards are identified, perform root-cause analysis, collect corrective actions, and make sure they are implemented. • Participate in a health IT safety improvement organization—such as a safety collaborative or patient safety group—with other health care providers and vendors to share and discuss safety information and events. • Employ trained personnel to review internally and externally identified potential and actual safety hazards. • Use dedicated personnel with credentials in patient safety and risk management to categorize, trend, and act on identified challenges. • Enable methods for employees and clients to report safety hazards and receive direct communication about the reported hazard. • Communicate identified safety hazards and suggested solutions to potentially affected client sites as needed. Disseminate upgrades or mitigating strategies to these clients. • Prioritize safety by requiring all staff who interact with the software to be trained in the developer's patient safety reporting process. • Provide research and development personnel with focused education on identification and mitigation strategies for high-risk areas of the application (e.g., medication management, test result reporting). • Ensure that client-facing personnel (account managers, support centers) know how to escalate a patient safety issue. • Use an active safety surveillance process to detect misconfiguration that could lead to hazards, based on EHR data, without the need to solicit reports from health care facilities. • Address safety hazards in current and future iterations of the technology and into testing. • Provide additional guidance for smaller organizations and health care providers with resource constraints on how to detect and address safety challenges.	• Create a risk-free environment to report potential hazards. • When hazards are identified, perform root-cause analysis, collect corrective actions, and make sure they are implemented. • Participate in a health IT safety improvement organization—such as a safety collaborative or patient safety organization—with other health care providers and vendors to share and discuss safety information and events. • Prioritize safety with initiatives to ensure that all personnel recognize its importance. • Establish methods for personnel to report health IT-related safety hazards. • Permit access for automated surveillance to detect misconfiguration that could lead to hazards. • Create an organizational structure to collect, review, and address reported safety hazards in a timely fashion with clear methods to elevate events to the developer, patient safety organizations, a health IT safety collaborative, or similar entities that promote safety. • Use teams that have embedded health IT expertise, particularly for larger organizations that have internal experts.

EHR life cycle stage or factor	Usability and safety optimization opportunities	
	For EHR developers	**For health care providers**
Product design and development	• Identify needs and requirements of health care providers to inform design and development, such as through workflow observations and interviews with providers. • Follow principles of user-centered design, such as by obtaining frequent user feedback at multiple points in development and establishing user "personas" that reflect the typical needs of different types of clinicians. Conduct iterative formative usability testing with representative end users, such as through test cases and walk-throughs of the technology with small groups of clinicians. • Identify training requirements. • Test in the formative process. • Conduct testing before a product's release that focuses on high-risk functions and includes representative intended users and rigorous test case scenarios.	• Provide opportunities for developer personnel to observe workflows and technology use by clinical staff. • Allow clinicians and subject matter experts to shape usability and safety design and testing.
Acquisition	• Provide information—such as through clear documentation—for the health care provider to understand features of the EHR product upfront and projected costs to assess feasibility.	• Assess clinician needs and requirements for the EHR product and detail these needs, including budget constraints, for potential vendors.
Customization and configuration	• Describe risks associated with product customization (for elements the provider wishes to customize, especially when it goes against the recommendations of the developer) and provide experience-based feedback from previous implementations and customizations. • Document known high-risk customizations that contradict developer guidance and why they can contribute to patient harm. • Communicate about hazards of certain functionality or integration with third-party products, such as other systems or medical devices. • Clarify applicable definitions, resources, and roles (vendor, provider, third-party products) with providers. • Assess provider resources and knowledge to customize the product and communicate with the provider. • As customization in each facility is unique based on its workflows, configuration can help optimize the safe use of the system. However, customization can also introduce risk.	• Assess internal capacity and knowledge to customize product based on discussions with the vendor. • Develop clear justification and use cases for why customizations should be made. • Document customizations that are made and develop a risk mitigation plan.

EHR life cycle stage or factor	Usability and safety optimization opportunities	
	For EHR developers	**For health care providers**
Implementation and system upgrades	• Develop an implementation plan, based on experience, and share with the health care provider's implementation teams. • Identify resources available from health care providers to support implementation, and identify and communicate gaps that will hinder optimal performance. • Describe core functionality and workflows to health care facilities' implementation teams, including key end users such as physicians and nurses. • Assist the organization in conducting safety testing with actual provider personnel on the implemented product to optimize workflows. • Encourage facilities to evaluate risk management processes, resources, and needs to ensure that a system exists to monitor safety. • Commit to providing safety-based software upgrades and general system maintenance at a reasonable cost and in a feasible manner. • Maintain a well-qualified and -supported IT team to provide ongoing support. • Maintain reasonable backward compatibility (e.g., to ensure that new software can integrate with older versions), address safety fixes, and provide adequate documentation of changes so that organizations recognize changes that will require additional configurations and other modifications and/or clinical risk analysis and mitigation before the changes go into production.	• Develop a clear governance structure to support implementation processes and address safety challenges that arise. • Assess necessary resources and their alignment with vendors' recommendations on resource needs for implementation. • Create knowledgeable, multidisciplinary implementation teams that develop consensus on functionality and workflow. • Conduct safety testing on the implemented product to optimize workflows. • Identify a set of representative users to test the implemented product. • Discuss risk management process and availability of resources to support implementation. • Commit to install appropriate software upgrades, particularly when recognized safety enhancements are included. • Implement system upgrades in a timely manner upon release. • Utilize unit tests and test case scenarios to check key features of the upgrade to ensure usability and safety. • Review changes included with upgrades to identify areas that will need additional build, configuration, and/or clinical risk analysis and mitigation.
Training	• Disclose training recommendations for both clinical end users and IT staff, as well as associated costs, early in the purchase process. • Conduct training within the actual setting of use and use workflows with realistic data. • Incorporate rigorous, safety-focused training scenarios. • Involve hands-on participation by the end users in training exercises and emphasize high-risk functions in addition to high-use functions. • Offer refresher training after all major system changes and upgrades. • Provide training by individuals professionally qualified or certified in the purchased technology.	• Document the training process and costs. • Provide rigorous training to all users. • Prioritize training by making clear it's an institutional priority and release associates from normal duties to complete training. • Stagger training so no unit is left staffed only with backup or less-familiar personnel. • Training should be tailored to the needs of the trainees and be readily accessible. This type of training can occur through the use of simulations around workflows, refresher training at various intervals, continuous access to training materials, and an opportunity for enhanced training to those in need. • Understand and consider vendor-recommended best training practices.

Source: National Center for Human Factors in Healthcare, MedStar Health

By focusing on the entire EHR life cycle and having specific criteria in place to improve usability and safety, the voluntary certification framework can augment the current certification process. Adherence to these recommendations by EHR developers and health care providers can reduce the likelihood of unintended patient harm from clinician use of this technology.

Establishing rigorous, safety-focused test case scenarios

To identify and address usability and safety challenges with EHRs before health care facilities use them in patient care, one method developers typically use is to evaluate their products with clinical test cases.[27] These cases are scenarios that reflect realistic patient conditions as well as the clinician tasks that would occur in caring for an individual. The scenarios allow for the observation of clinicians interacting with the EHR so that specific usability and safety challenges can be identified and addressed.

Given the importance of detecting safety challenges early, test cases should focus on EHR interactions that have the potential for serious harm in addition to low-risk but frequent interactions that are unlikely to adversely affect the patient. These test cases should also reflect real-world clinical interactions so that unique workflows and the opportunity for clinicians to make mistakes can be factored in.

Challenges with current certification usability test case scenarios

Despite the importance of test case scenarios for evaluating and improving EHR usability and safety, the usability scenarios submitted for certification can lack rigor. They were simple, did not reflect realistic clinical conditions, or included prescriptive instructions that may not be present in a clinical setting—making it more difficult to identify challenges that may arise when using the technology for actual care.[28] Here is an example of a test case scenario that lacks rigor:[29]

"Looking at patient John Leeroy's record, enter a new lab order for the patient."

Specific shortcomings of this type of test case include:

- It does not reflect how a clinician would actually use the EHR because clinicians do not select any lab order but rather have a specific order or set of orders they are looking for.
- It does not reflect the complexities of clinical care.
- There is no clear way to evaluate whether usability and safety challenges exist since selection of any order would be identified as a success.

Developing test case criteria and relevant cases

To address the need for enhanced safety-focused test cases, specific criteria were developed to help guide the creation of rigorous scenarios. Fourteen cases, based on seven identified EHR usability and safety challenges, were developed based on the criteria.

Making these criteria and test cases available for use by both EHR developers and health care providers can help clinician interaction with EHRs be tested more effectively to identify usability and safety challenges before patients are harmed. These test case scenarios can be used in conjunction with other tools—such as the tests from Leapfrog or safety-related guides from ONC—to evaluate safety.

Criteria development for rigorous test cases

The insights from the EHR developers, clinicians (including physicians and nurses), researchers, and other stakeholders on the expert panel were integrated with existing literature, and four general features of a rigorous test case were defined. They should:

- **Be representative.** Test cases should be representative of the expected users of the technology, address key socio-technical factors—such as how different members of the care team may interact with EHRs—and represent realistic clinical care processes to identify usability and safety challenges that may occur when treating patients.

- **Contain concrete goals and measures.** Each test case should be shaped around a clinically oriented goal, with clear measures of success and failure. The lack of such goals and measures for each test case could complicate the ability to assess the use of EHRs in concrete ways, although goals and measures may vary from implementation to implementation.

- **Test areas of risk or inefficiency.** The test cases must include known risk areas, functions that contribute to inefficiency, frequently used tasks, tasks that are unfamiliar to the user, or intrinsically challenging tasks (such as drug dose tapering). Testing known areas of risk will help to identify these challenges and prevent them from persisting in the product. Focusing on areas that could produce inefficiencies or challenging tasks can help to implement corrections that can address clinician concerns.

- **Define the audience.** The test cases should be designed for use by a specific set of stakeholders (e.g., vendors, providers) and should clearly stipulate the intended participants (e.g., nurses, physicians, technicians). If test cases do not provide this information, they may be used with the wrong clinical audience, which could invalidate the results.

Each of these feature categories were further divided into subfeatures.

Table 3
Features, Subfeatures, and Descriptions of Rigorous Test Cases

Feature	Subfeature	Description
Be representative	Users	Use different types of clinicians (e.g., physicians, nurses) with varying levels of clinical and computer expertise (novice to expert) to the extent that it would be realistic for those users to perform the workflow under test.
	Workflow	When possible, represent complete workflows that involve multiple types of clinicians participating in the scenario simultaneously.
	Environment	Include realistic clinical variables such as noise, interruptions, incomplete data, missing data, wrong data, and imperfect processes or customization.
	Third-party technologies	Evaluate how third-party technologies—such as medication infusion pumps—are used in care and communicate with the EHR.
	Clinically relevant	Include realistic clinical information and scenarios. Consider, for example, adult vs. pediatric populations and inpatient vs. outpatient settings, and include time pressures to evaluate the use of shortcuts instead of the recommended—and potentially more time-consuming—approach.
Contain concrete goals and measures	Specific goal	Identify one or more specific goals for each test case that include realistic and appropriate variations in how clinicians may respond to a task. Goals should be meaningful and focused but not prescriptive. Overly prescriptive goals test an individual's ability to follow granular instructions but do not evaluate real-world use of products where clinicians use the system without strict directions.
	Definable	Define clear start and stop points.
	Reproducible	Ensure that each test case is reproducible and has quantitative success measures.
	Clear measures	Articulate clear measures of success and failure, and identify some potential sources of safety risks before testing
Test areas of risk or inefficiency	Risk, frequency, routine events	Focus on frequent, high-risk actions with a few events that rarely occur but can cause serious patient harm when they do. Functionally, test cases should focus on routine events (e.g., a single patient birth) with an occasional non-routine action (e.g., delivering triplets).
	Complex and cognitively demanding	Use safety data and known complex activities that require difficult cognitive processes, like integrating information from multiple sources, evaluating the handoffs of care for patients among health care providers, and communication between members of the care team.
	Efficiency and safety	Establish expectations or benchmarks for efficiency of common workflows. For workflows that are not consistently completed according to preset parameters, assess why clinicians deviated from the preferred process and identify how to address challenges they faced in completing tasks as designed.
Define the audience	Intended stakeholders	Identify the intended stakeholder (e.g. vendor, provider, other) that is conducting the scenario.
	Intended users/participants	Articulate the specific clinical and nonclinical participants—including patients—using the product and participating in the test.

Source: National Center for Human Factors in Healthcare, MedStar Health

Developing and using test cases that adhere to these criteria will provide greater rigor to the evaluation of clinician interaction with EHRs and can serve to better highlight specific usability and safety challenges in the design, customization, or use of products before patients are harmed.

Test cases for prevalent usability and safety challenges

The criteria were used to develop 14 test use cases to demonstrate how scenarios can adhere to the identified principles and address prevalent usability and safety challenges. This includes two use cases each for seven prevalent patient safety hazards. The safety challenges were previously identified through an analysis of 557 patient safety event reports—free-text descriptions of potential patient safety hazards submitted by health care facilities—related to EHRs.[30]

Table 4

7 Usability and Safety Challenges, Definitions, and Clinical Examples

Usability or safety issue category	Definition	Clinical examples from reports submitted
1. Data entry	EHR data entry is difficult or not possible given the clinicians' work process, preventing the clinician from appropriately entering desired information.	A clinician attempted to process the order of a drug to be administered every 24 hours. However, in selecting the frequency of administration, the clinician did not realize that the order in which options were populated changed. This led to the wrong frequency being selected.
2. Alerting	EHR alerts or other feedback from the system are inadequate because they are absent, incorrect, or ambiguous.	A clinician was not alerted to the patient's gelatin allergy when prescribing a medicine despite that allergy being listed in the EHR.
3. Interoperability	Interoperability is inadequate within components of the same EHR or from the EHR to other systems, hindering the communication of information.	Clinicians could not access lab values for a hospital patient from records held in a different part of the hospital.
4. Visual display	EHR display of information is confusing, cluttered, or inaccurate, resulting in clinicians having difficulty interpreting information.	A physician attempted to order 3.125 mg. of a heart failure medicine, but the EHR listed only a 6.25-mg. prescription, with a 3.125 dose listed in small print, confusing the clinician.
5. Availability of information	EHR availability of clinically relevant information is hindered because information is entered or stored in the wrong location or is otherwise inaccessible.	Hospital lab staff did not have access to a section of the patient's health record where the clinician ordered diagnostic tests. Thus, the tests were not conducted.
6. System automation and defaults	The EHR automates or defaults to information that is unexpected, unpredictable, or not transparent to the clinician.	A clinician ordering an anticoagulant attempted to start the dosing at a set time, but the date automatically defaulted to the following day.
7. Workflow support	The EHR workflow is not supported due to a mismatch between the EHR and intent of the end user.	A physician ordered diagnostic tests for a patient's thyroid function and included directions for the lab in a special instructions field without knowing that this information would not be visible to lab staff. As a result, the lab tests were not conducted.

Note: These safety challenges were identified through an analysis of 557 reports submitted by clinicians. The categories represent the classes of identified health IT-related safety challenges.

Source: Jessica L. Howe et al., "Electronic Health Record Usability Issues and Potential Contribution to Patient Harm," *Journal of the American Medical Association* 319, no. 12 (2018): 1276-78, http://dx.doi.org/10.1001/jama.2018.1171.

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For each of these usability and safety challenges, we developed both a basic and advanced test. The basic scenarios are more narrowly scoped tasks that represent a single aspect of the entire clinical workflow focused on a single clinical process and generally do not involve interaction with other EHR components or clinical processes. The advanced cases represent a more detailed aspect of the clinician's workflow, including factors such as teamwork and communication with other clinicians.

The use of both basic and advanced cases helps test the range of EHR capabilities and supports evaluation of a product early in design. Basic cases can help evaluate single EHR features but should be used in combination with advanced ones throughout development and implementation. The advanced cases should be used to test broader workflows that involve several system features and interactions with multiple clinicians. The use of both types of test cases during development and after implementation can help detect problems.

The test cases include both inpatient and outpatient clinical settings. Each test case is provided on a template to support use by EHR developers, health care providers, or other stakeholders. The template provides a standardized format for each of the test cases, detailing:

- The usability topic to be tested.
- How safety could be affected.
- A rough estimate of the time needed for the test.
- Clinical setting addressed.
- Necessary users and participants.
- How the test case demonstrates robustness.
- Scenario descriptions.
- Tasks that need to be performed.
- Scoring guide.

Sample test case scenario

Below is an example of a basic scenario. The remaining scenarios are listed in the appendix.

This example describes challenges with how clinicians may enter allergy information. Based on how clinicians enter data and the design of systems, prescribing medication to which the patient is allergic should trigger an alert. This example is a basic scenario that tests the usability and safety of the allergy alerting function if allergies are entered in the EHR using the free-text option. Many allergies are entered as structured text, which is generally predefined allergies already in the system. However, clinicians sometimes need to enter free-text descriptions when structured options are not available or hard to find.

Free-Text Allergy

Usability topic: Alerting	**Estimated time:** 15 minutes
Setting: Inpatient	**User/audience:** Nurse

Scenario summary: The patient has an allergy to penicillin entered as free text—not encoded—already entered into the EHR. Later, an order is entered for a piperacillin-tazobactam (Zosyn) injection, which is in the same family of antibiotics as penicillin and should trigger a meaningful alert or notification to the user.

Particular area of risk or inefficiency: Accurate listing of allergies to medications, food, and materials like latex are critical. Depending on the usability of the allergy input system, a user may choose to insert a "free-text allergy" into the patient record that may look like it was correctly entered but may have major safety implications for how new medications and orders are checked against the potential allergy. The allergy that is entered by free text may not be checked against medication, food, and other materials used with the patient.

Realism/generalizability: Free-text allergy hazards are a significant risk in any system that allows them to be entered. If the tested system does not allow a free-text allergy to be entered, then this scenario will focus on confirming that a basic drug-allergy alert is present. A system may allow free-text allergy entry in the event that a patient has an allergy that is not in its database (e.g., uncommon food allergy or allergy to non-U.S. medication).

This basic case focuses on the presence of the alert. Testing organizations may choose to make the case more complex and confirm that users are correctly interpreting the alerts and making appropriate decisions. Organizations may also focus on how the system is designed to alert providers to the presence of allergies listed as free text and whether the alerts are useful and effective at gaining providers' attention.

Begin scenario

A 27-year-old male patient is transferred from a local ED for a possible postoperative infection. The patient is seven days post-op from an exploratory laparotomy at your hospital post gunshot wound and was discharged two days ago. He presented to an outside ED earlier today with worsening pain, fever, and vomiting. The patient was accepted for direct admission to your hospital by the surgeon who cared for him last week. The patient was admitted to a medical/surgical bed for re-evaluation and potential postoperative infection. The surgical team is tied up in another case and was able only to place basic admission orders for the patient. You note that the patient has a fever and no antibiotic orders. [The patient should have a free-text allergy for "penicillin" and the reaction is anaphylaxis.]

Task

1. The surgical team returns the page and requests that it wants two sets of blood cultures. Please place the order under Dr. Rebecca Smith. [Note if the free-text alert is triggered.]

2. The surgeon calls back and says she will be held up in the current case and wants to start antibiotics now. She gives a verbal order for "Zosyn 3.375 grams IV every 6 hours." As the patient's nurse, enter this order in the system under Dr. Rebecca Smith.

3. **If an alert pops up for the "unknown" allergy:** *Please interpret the alert and choose to keep the medication order or cancel the order and page the surgeon.* If they choose to keep the order, then the scenario is over. If no alert pops up, then the scenario is over.

4. **If the user decided to cancel the order and page the physician, read the following:** *The surgeon calls back and you inform her that the patient has a history of anaphylaxis to penicillin. She asks for you to place an order instead for ciprofloxacin 400 mg. IV every 12 hours and says the patient will be assessed by the team soon. Please place the order.* [It is likely that the free-text allergy alert will fire again. Make note of this finding.]

Measures

The scenario fails if:

• Piperacillin-tazobactam (Zosyn) remains ordered on the patient.

Note

Ciprofloxacin may not be the best choice of antibiotic in institutions with a high level of resistance to the antibiotic. If the participant has a question about the antibiotic selection, just repeat the instruction. Sites may decide to choose a different antibiotic that their users are less likely to question.

If the system triggers an alert when entering the blood cultures, the free-text alert is at high risk of being missed due to alert fatigue when a true drug allergy is entered into the system. If the alert is triggered only when the ciprofloxacin is ordered, it may be triggered only for specific types of orders, such as medications and not laboratory or radiology orders. The site should further investigate how this free-text allergy hazard can be reduced or eliminated.

As a basic scenario, this test case aims to represent a single aspect of the clinical workflow and identify whether the EHR supports the provider's expectation that an allergy alert will be triggered if there are relevant known allergies. This basic test case reflects the mental process a clinician would use with the EHR and the complexities of clinical care in a way that can be clearly evaluated.

The background information provided in the testing and robustness sections enable nonclinical moderators to understand the nature of the test. The clear scoring definition helps testers establish whether the system passed or failed the assessment.

Inclusion of the nonspecific EHR terms, necessary participants, and estimated completion time support use of this test case across institutions and EHR systems. This type of test case is one example of a more rigorous case that better represents how EHRs might be used in the actual clinical environment.

The test scenarios are based on actual patient safety reports that involve technology and potential harm. Having these test cases available as examples of more rigorous scenarios will allow both developers and providers to create their own usability and safety assessments.

Conclusion and next steps

Usability challenges associated with EHRs frustrate clinicians and can pose safety risks that contribute to patient harm.[31] These challenges stem from the design of EHRs, decisions of health care facilities that implement the technology, and how clinicians use the systems. While the government, EHR developers, and health care providers have initiatives focused on improving the usability and safety of EHRs, gaps still exist with the scope and depth of federal requirements and in the test cases used to evaluate systems.

We sought to fill these gaps through the development of a more comprehensive certification framework focused on the entire EHR life cycle that engages both developers and providers, and by developing test case criteria with examples based on prevalent usability and safety challenges. Achieving the benefits of both the certification framework and test cases requires their adoption by EHR developers and health care providers. Once adopted, the test cases should be evaluated for their ability to detect safety events, assessed for challenges that arise in their use, and adjusted accordingly.

Adoption of the voluntary criteria

Some EHR developers and health care providers may choose to adopt the criteria to improve the safety and usability of systems. However, their adoption by other organizations may also require some financial or nonmonetary incentives, since resources will be required to adhere to the recommendations. We examined four potential approaches for adoption:

1. **The ONC could recognize elements of this certification as alternatives to its current requirements.** However, given that these voluntary certification criteria include provisions that surpass those in federal regulations and address the entire life cycle and provider roles, such recognition by ONC is unlikely, though the agency could highlight private sector efforts.

2. **EHR developers and health care organizations could voluntarily adopt the criteria as an indication that they prioritize safety.** EHR developer adoption would provide greater transparency to purchasers—such as hospitals—on the actions that vendors take to enhance safety. Meanwhile, health care facilities adopting these requirements would communicate to patients that safety is an institutional priority and help mitigate hazards that could become liabilities, such as high-risk customization made despite EHR developer concerns. To assist organizations in knowing what and how to evaluate their systems and processes, third parties could create voluntary certification programs to offer guidance and certificates upon meeting the expectations.

3. **Organizations that are already prioritizing health IT safety could embed these recommendations into their programs.** For example, The Leapfrog Group has encouraged hospitals to take its computerized physician order entry tool to analyze the ability of clinicians to safely prescribe medicines.[32] Hospitals take these tests and strive to achieve good scores, because the results are made public, fueling adoption throughout the industry. Similarly, the Association for the Advancement of Medical Instrumentation is publishing several standards associated with health IT safety and encourages their adoption. Adherence to the standards can be used to show that health IT safety is a priority.[33]

4. **Organizations that have some role in overseeing health care facilities, including the Joint Commission (which serves to accredit health care providers in order to promote safety and more effective care), may be able to drive health care providers to incorporate these recommendations and pressure EHR vendors to also incorporate best practices.** The Joint Commission could incorporate these criteria into its requirements, so that its inspectors seek evidence that health care facilities—and perhaps the technology they use—adhere to best practices. While not all health care organizations receive Joint Commission accreditation, its program is influential and provides guidance for all organizations on how to improve safety.

Use of the test case criteria and sample test cases

Adoption of the test case criteria and sample test cases by EHR developers and health care facilities can enhance safety by better evaluating products throughout the system life cycle.

For developers, use of these test cases can take place early in design and development and as the product matures. Because federal regulations do not stipulate the rigor needed in these scenarios, the thoroughness and depth of the test cases used show wide variability. The test scenario criteria can serve as a potential standard for the EHR accrediting bodies and a resource for developers. Adoption of these criteria by the accrediting bodies as to the level of rigor for test cases could immediately improve the current certification process and help identify safety risks before use of the product. Similarly, these criteria could be incorporated into future updates to ONC's EHR certification requirements for usability scenarios or if other organizations develop their own criteria and test products.

Health care organizations can use the test criteria and sample cases to evaluate the usability and safety of their product during the implementation phase, after changes are made, and to inform customization decisions. The criteria can be used to develop test cases for specific areas that are recognized by the health care provider as potential areas of risk. Organizations can immediately leverage the example test cases to quickly evaluate system safety to identify challenges and prevent harm.

The future of health IT

EHRs have revolutionized health care delivery by giving clinicians and patients better tools to foster safe, higher-quality care. Despite the benefits, however, system design, health care organization implementation decisions, and their use by clinicians can contribute to unintentional safety challenges. The adoption of best practices—including the tenets of the safety-focused certification criteria and more robust testing scenarios—can help give EHR developers and health care facilities better information to detect challenges and reduce the potential of avoidable patient harm.

Appendix A: Test cases

This report summarizes the importance of test cases to evaluate the safety of EHR systems. Test cases should represent a variety of tasks that would realistically be completed in a user's clinical environment. The following 14 cases represent the seven usability issues previously identified. Each usability issue has two cases, one basic and one advanced:
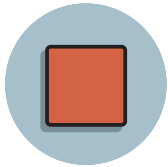
Basic scenarios.

The basic scenarios are more narrowly scoped tasks that represent one aspect of the clinical workflow. These scenarios focus on a single clinical process and generally do not involve interaction with other EHR components or clinical processes. Basic cases may be used early in the EHR design and development process or early in the implementation process.
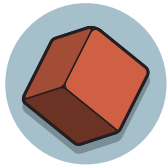
Advanced scenarios.

The advanced cases generally represent a more detailed aspect of the clinician's workflow, including activities like teamwork and communication with other clinicians. Both basic and advanced cases are important in evaluating the range of tasks that are realistically completed using an EHR. The advanced cases may be more appropriate near the end of implementation before general use. Table A.1 provides an overview of the usability issue, type of scenario, the clinical setting in which the scenario takes place, and the complexity of the scenario.

Table A.1
7 Usability Issue Addressed by Each Scenario

| Usability issue	Scenario	Definition	Setting
1. Accessibility	1-Basic	Pulmonary nodule	Ambulatory
	1-Advanced	Buried Ebola	Emergency department
2. Alerting	2-Basic	Free-text allergy	Inpatient
	2-Advanced	Food-drug alert	Ambulatory
3. System default	3-Basic	Hydromorphone overdose	Emergency department
	3-Advanced	Medication scheduling	Inpatient
4. Data entry	4-Basic	Weight-based dosing error catching	Ambulatory
	4-Advanced	Prednisone taper	Inpatient
5. Display/visual clutter	5-Basic	Missing potassium	Emergency department
	5-Advanced	Duplicate order sets	Inpatient
6. Interoperability	6-Basic	Prescription drug monitoring program data access	Emergency department
	6-Advanced	Canceling eRx	Ambulatory
7. Workflow support	7-Basic	Rapid strep test reflex testing	Ambulatory
	7-Advanced	Physician-nurse simultaneous ordering	Inpatient

Description of each test case

Each test case contains descriptive information to help facilitate use of the scenarios. This information includes:

- **Usability topic.** Refers to the specific usability challenge being assessed from the seven challenges identified.

- **Estimated time.** Provides information on the estimated time for the participant to complete the test case.

- **Setting.** Describes the typical clinical setting in which the test scenario would take place. This is intended to facilitate the type of test environment that may be considered when conducting the assessment.

- **User/audience.** Describes the intended participant population for which the test case was designed.

- **Particular area of risk or inefficiency.** Provides a short summary of the specific risk or EHR inefficiency that is being tested by the case.

- **Realism/generalizability.** Describes the situation in which the test case scenario may occur in the clinical environment.

- **Scenario summary.** Provides a brief overview of the clinical scenario that is the basis for the test case.

- **Measures.** Provides a description of the key measure of success for that test case and what may indicate failure.

- **Notes.** Provides additional supporting comments for the test case and references to additional material.

Directions for using test cases

- **Testing personnel and processes.** To use these test cases effectively it is important to have a moderator who can appropriately guide participants to complete the test cases without interfering. A human factors expert or someone trained in usability testing methodologies should moderate each session and provide instructions to participants. For the purposes of this document, information to be read to the participant is italicized and notes for the moderator are displayed in brackets. Participants may be provided with paper and pen to take notes but should not receive a copy of the test cases. Instructions for participants may be repeated as often as needed, but the moderator should not assist the participant in completing any task or provide any suggestions on correct task completion. These details are found in the "Begin scenario" and "Task" section of each test case. Moderators should score the participant based on the measure description.

- **Testing environment.** The testing environment will depend on the goals of assessment. Testing can take place in a quiet room if the goal is to examine controlled interaction with the EHR or can take place in a busier environment if the goal is to mimic possible live clinical conditions. In either case, the equipment used, such as the computer and monitor, should be the same as what is used in the actual clinical environment.

- **Participants.** Participants should represent the intended end users. These test cases are intended for clinical participants, and each test case description notes the appropriate user group.

- **Preparation.** Test cases may require information to be populated in the EHR environment being tested before the assessment. If this is a requirement of the test case, it is described in the test case setup instructions. Time required to pre-populate the EHR will be system- and resource-dependent, but facilities should allow at least two weeks to populate the test environment with necessary test patient information for all 14 scenarios. Allow approximately 30 minutes to enter information per test patient.

- **User and adaptability.** Health care organizations should use these test cases or adapt them to fit the unique workflows or technologies in use. The test cases can also serve as examples for how to develop more robust test cases on other topics.

Use-case test scenarios
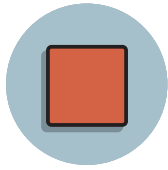
Scenario 1-Basic
Pulmonary Nodule

Usability topic: Accessibility	**Estimated time:** 10 minutes
Setting: Ambulatory	**User/audience:** Physician

Scenario summary: A patient needs follow-up for a lung nodule, but the physician realizes mid-order that results from previous studies are necessary.

Particular area of risk or inefficiency: Frequently, clinicians need to access details of prior tests while ordering new diagnostic tests. If this clinical workflow need is not accounted for in the design of the EHR, the clinician may start placing a new diagnostic test order, have to cancel that order, navigate to the prior test results, review those results, and then return to placing the original diagnostic order. These extra steps introduce an unnecessary interruption in the clinician's workflow that may lead to errors in recall, with the clinician potentially forgetting the primary task and delaying care.

Realism/generalizability: This scenario may be easy to complete in an EHR that allows the user to review diagnostic testing and/or automatically pulls up previous results to similar tests that are being ordered. This scenario will present significant challenges to users of systems that require them to cancel an order that is currently being placed to review previous diagnostic results in other parts of the EHR. This case may be adapted for use with laboratory tests (e.g., cardiac troponin test) to make the case less challenging.

Begin scenario

A 71-year-old male patient presents for a follow-up visit for a lung nodule last evaluated six months ago. The patient has a history of smoking (a pack a day for 30 years), chronic obstructive pulmonary disease (COPD), and hypertension. The patient takes hydrochlorothiazide 25 mg. daily and tiotropium 18 mcg. daily with no allergies to any medications.

Task

1. Begin an order for a CT scan of the chest with contrast to evaluate a pulmonary nodule, but do not sign the order.

2. While ordering the CT scan, you decide to review the last two CT scans and to document in the order the previous size of the nodule. [On review of the prior chest CT scans, the participant will see a CT scan from six months prior with an 8-mm. right-upper-lobe nodule and 12 months prior with a 6-mm. nodule in the same position.]

3. Now sign the order after including the findings from the previous CT scan reports.

Measures

The scenario fails if the participant is unable to:

- Add requested information to the order.
- Place the CT scan as specified.
- Review previous results without losing the new CT scan order.

Continued on next page

Note

Not recommending close follow-up for a pulmonary nodule can result in significant delays in care for patients with lung cancer. This can prove to be the difference between successful treatment and death for patients. One EHR review found 37.8 percent of 587 patients with lung cancer had delays in care.[*]

[*] Hardeep Singh et al., "Characteristics and Predictors of Missed Opportunities in Lung Cancer Diagnosis: An Electronic Health Record-Based Study," *Journal of Clinical Oncology* 28, no. 20 (2010): 3307–15, http://ascopubs.org/doi/10.1200/JCO.2009.25.6636.
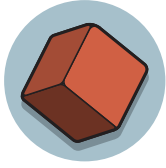
Buried Ebola

Usability topic: Accessibility	**Estimated time:** 15 minutes
Setting: Emergency department	**User/audience:** Nurse/physician

Scenario summary: A patient is triaged in the emergency department and is recognized to be at high risk for infection with Ebola. The information is entered into the EHR during triage but not recognized by the primary ED provider. It is important that this triage information is seen by the primary ED physician and care team.

Particular area of risk or inefficiency: It is critical that all members of the care team have access to the same information in a timely manner. If the system does not support accessibility of information between interfaces, then significant safety issues may occur.

Realism/generalizability: This scenario tests the accessibility of important information from the triage team in the ED to the care team in the main part of the ED. Frequently, important information about a patient is captured during triage and noted in the triage component of the EHR. This information may not be conveyed to the screens that are generally used by other ED staff when the patient is being treated. Critical information about the patient, including infectious disease risks, abnormal and violent behavior, and concerns regarding abuse, may be missed by the main ED staff. There is always a need to screen high-risk patients for risk factors and provide accurate guidance to front-line staff. This capacity should be built into any EHR. This was most recently seen with Ebola, and previously with avian flu and SARS.

Begin scenario

A 54-year-old male presents to the ED with chief complaints of fever, fatigue, diarrhea, and body aches. The patient is initially triaged and sent back from the triage area. The patient's vital signs are as follows:

• Heart rate: 114.
• Blood pressure: 115/82.
• Oxygen saturation: 97% on room air.
• Respiratory rate: 18.

[Nursing triage note should state, "Recent travel to Ebola outbreak area one week ago." Any screening in the implemented system should be filled out to trigger an Ebola alert for the patient.]

Continued on next page

Task

1. As the nurse or physician, review the patient's chart before seeing the patient. Order the following:

a. Complete blood count.
b. Basic chemistry profile.
c. Lactic acid.
d. Urinalysis.
e. Chest X-ray posterior-anterior and lateral (or not), based on your current chart review.

2. Place appropriate nursing, IV fluids, antipyretic and isolation orders. [If the participant immediately wants to order Ebola testing or look up detailed Ebola information, the proctor can state, "The ED secretary has contacted the infectious disease physician on call, who will be down shortly to assist in ordering the appropriate diagnostic tests."]

3. After eight hours in the ED, the patient is requesting discharge home with relatives with whom he is living while visiting the United States. [If the participant has recognized the patient is at high risk of Ebola, make note of this and encourage the participant to complete the task as directed.] *Please place a discharge order for follow-up in the medicine clinic in 7-10 days if symptoms persist.*

4. The ED technician repeated vital signs and notes that the patient appears sicker and is bleeding from his eyes. The team is highly concerned for Ebola; please place appropriate Ebola isolation orders, if not already performed earlier. The infectious disease team has been contacted and will be present shortly to assist in the patient's care.

Measures

The scenario fails if:

• The participant does not recognize the patient is at risk for Ebola based on the system configuration (e.g., participant says he or she did not see the triage note and/or no alert is triggered in the system).

• Appropriate isolation orders are not placed in the system. These should be strict isolation, not just droplet or airborne. The name of the isolation order may vary by location, but it should be clear that it is not standard/droplet/contact/enteric/airborne precautions, none of which are appropriate for this patient.

Note

This scenario simulates the need to support clinical decision-making around outbreaks of infectious diseases that will require EHR flexibility to address in a timely manner. While in a high-risk situation like this case, we would expect verbal communication between the nurse and physician, but we know that does not always happen due to breakdowns in systems or processes. A similar scenario could apply to epidemics as a result of influenza, SARS, etc. This Ebola case was specifically chosen because it is similar to a real incident that occurred during the 2014 epidemic.[*]

The Centers for Disease Control and Prevention guidelines regarding the isolation for patients under investigation for Ebola virus are much more stringent than common diseases found in the hospital and may not be available in the EHR. More in-depth descriptions can be found on the CDC's website.[†]

For those facilities that do not have infectious disease services available, the testing site can contact the CDC or other appropriate organizations.

This advanced scenario simulates the predictably unpredictable outbreaks of infectious diseases that will require EHR flexibility to address in a timely manner.[‡] It is included to illustrate some extremely rare scenarios that clinicians can encounter and in which the use of EHRs may be critical.

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[*]   Divvy Upadhyay, Dean F. Sittig, and Hardeep Singh, "Ebola US Patient Zero: Lessons on Misdiagnosis and Effective Use of Electronic Health Records," *Diagnosis* 1, no. 4 (2014): 283–87, https://doi.org/10.1515/dx-2014-0064.

[†]   Centers for Disease Control and Prevention, "When Caring for Patients Under Investigation (PUIs) or Patients With Confirmed Ebola Virus Disease (EVD)," last modified Dec. 29, 2015, https://www.cdc.gov/vhf/ebola/healthcare-us/evaluating-patients/think-ebola.html.

[‡]   Yalini Senathirajah, David Kaufman, and Suzanne Bakken, "When Speed Is Essential: Rapid Configuration of a User-Configurable 'Web 2.0' Based EHR for H1N1 Decision Support" (5th International Symposium on Human Factors Engineering in Health Informatics, Trondheim, Norway, 2011), https://www.researchgate.net/publication/260991205_When_speed_is_essential_Rapid_configuration_ of_a_user-_configurable_'web_20'_based_EHR_for_H1N1_decision_support.
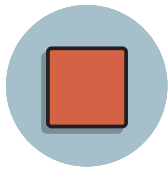
Scenario 2-Basic
Free-Text Allergy

Usability topic: Alerting	**Estimated time:** 15 minutes
Setting: Inpatient	**User/audience:** Nurse

Scenario summary: The patient has an allergy to penicillin entered as free text—not encoded—already entered into the EHR. Later, an order is entered for a piperacillin-tazobactam (Zosyn) injection, which is in the same family of antibiotics as penicillin and should trigger a meaningful alert or notification to the user.

Particular area of risk or inefficiency: Accurate listing of allergies to medications, food, and materials like latex are critical. Depending on the usability of the allergy input system, a user may choose to insert a "free-text allergy" into the patient record that may look like it was correctly entered but may have major safety implications for how new medications and orders are checked against the potential allergy. The allergy that is entered by free text may not be checked against medication, food, and other materials used with the patient.

Realism/generalizability: Free-text allergy hazards are a significant risk in any system that allows them to be entered. If the tested system does not allow a free-text allergy to be entered, then this scenario will focus on confirming that a basic drug-allergy alert is present. A system may allow free-text allergy entry in the event that a patient has an allergy that is not in its database (e.g., uncommon food allergy or allergy to non-U.S. medication).

This basic case focuses on the presence of the alert. Testing organizations may choose to make the case more complex and confirm that users are correctly interpreting the alerts and making appropriate decisions. Organizations may also focus on how the system is designed to alert providers to the presence of allergies listed as free text and whether the alerts are useful and effective at gaining providers' attention.

Begin scenario

A 27-year-old male patient is transferred from a local ED for a possible postoperative infection. The patient is seven days post-op from an exploratory laparotomy at your hospital post gunshot wound and was discharged two days ago. He presented to an outside ED earlier today with worsening pain, fever, and vomiting. The patient was accepted for direct admission to your hospital by the surgeon who cared for him last week. The patient was admitted to a medical/surgical bed for re-evaluation and potential postoperative infection. The surgical team is tied up in another case and was able only to place basic admission orders for the patient. You note that the patient has a fever and no antibiotic orders. [The patient should have a free-text allergy for "penicillin" and the reaction is anaphylaxis.]

Task

1. *The surgical team returns the page and requests that it wants two sets of blood cultures. Please place the order under Dr. Rebecca Smith.* [Note if the free-text alert is triggered.]

2. *The surgeon calls back and says she will be held up in the current case and wants to start antibiotics now. She gives a verbal order for "Zosyn 3.375 grams IV every 6 hours." As the patient's nurse, enter this order in the system under Dr. Rebecca Smith.*

3. **If an alert pops up for the "unknown" allergy:** *Please interpret the alert and choose to keep the medication order or cancel the order and page the surgeon. If they choose to keep the order, then the scenario is over. If no alert pops up, then the scenario is over.*

4. **If the user decided to cancel the order and page the physician, read the following:** *The surgeon calls back and you inform her that the patient has a history of anaphylaxis to penicillin. She asks for you to place an order instead for ciprofloxacin 400 mg. IV every 12 hours and says the patient will be assessed by the team soon. Please place the order.* [It is likely that the free-text allergy alert will fire again. Make note of this finding.]
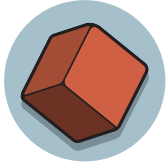
Continued on next page

Measures

The scenario fails if:

• Piperacillin-tazobactam (Zosyn) remains ordered on the patient.

Note

Ciprofloxacin may not be the best choice of antibiotic in institutions with a high level of resistance to the antibiotic. If the participant has a question about the antibiotic selection, just repeat the instruction. Sites may decide to choose a different antibiotic that their users are less likely to question.

If the system triggers an alert when entering the blood cultures, the free-text alert is at high risk of being missed due to alert fatigue when a true drug allergy is entered into the system. If the alert is triggered only when the ciprofloxacin is ordered, it may be triggered only for specific types of orders, such as medications and not laboratory or radiology orders. The site should further investigate how this free-text allergy hazard can be reduced or eliminated.

Food Drug Alert

Usability topic: Alerting	**Estimated time:** 15 minutes
Setting: Ambulatory	**User/audience:** Primary care physician

Scenario summary: A patient presents to the ambulatory practice requesting an influenza shot. The patient has a severe egg allergy. The case will test to see if the system is able to alert the provider to a food-drug allergy and provide up-to-date guidance from the CDC.

Particular area of risk or inefficiency: Although systematic comparison of drugs against allergies is in place in the vast majority of EHRs, drug-food allergies are often not enabled due to alert fatigue. There are specific guidelines around the care of patients with severe food allergies that may be missed if the alerts are not enabled in a usable and useful manner.

Realism/generalizability: This scenario focuses on the CDC guidelines for patients with severe egg allergies receiving the influenza vaccine. Other food-drug interactions could also be tested, such as pork and insulin or heparin.

Begin scenario

A 47-year-old male patient presents to the clinic on his lunch break and is requesting a flu shot quickly so that he can return to work. His regular doctor is on vacation, and you have never met this patient before. The patient has a history of hypertension and prediabetes. He is not taking any medications and smokes a pack of cigarettes a day. The patient is unsure if his vaccines are up to date or when he got his last influenza vaccine. [Patient will have a documented allergy to eggs with a reaction history of angioedema.].

Task

1. Review the patient's vaccination record to determine if he is due for the influenza vaccine. [On review of the record, the participant will see records of tetanus, diphtheria, and acellular pertussis (TDaP) from seven years prior and Pneumovax three years prior.]

2. Order the influenza vaccine for the patient. [Influenza vaccine IM (intramuscular) x 1 would be the correct order. If the participant recognizes the egg allergy before entering the order, acknowledge the allergy and request that the clinician determine whether to still place the vaccine order. If the clinician does not place the order, end the scenario.]

3. The patient receives the vaccine and immediately asks to leave. Please provide flu vaccine discharge/visit instructions. [The scenario is over. Make note if an alert was triggered, what the content of the alert was, and how the participants responded.]

Measures

The scenario fails if:

• The wrong vaccine or route is ordered.

• No alert is triggered that the vaccine can be administered but "should be done under supervision of a provider who can manage severe allergic reactions" or similar language. Per CDC guidelines, the patient needs a higher level of precautions than the average patient receiving the flu vaccine due to his life-threatening egg allergy, although it is highly unlikely that patients with egg allergies will have a significant reaction.

• Provider sees the alert and decides not to give the vaccine because of the allergy. As stated above, while egg allergies may trigger alerts, CDC guidelines have indicated that these patients should still receive the vaccine. Failure to administer the vaccine could put the patient's health at risk.

• Participant cannot find the patient's previous vaccine records.

Note

Previously the CDC recommended no vaccines for people with severe egg allergies. In 2016-17, it recommended 30 minutes of observation by a trained physician. For 2017-18, only a previous severe reaction to the flu shot will prevent a patient from getting the vaccine but recommendations state that "Those who have a history of severe allergic reaction to egg (i.e., any symptom other than hives) should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic conditions."[*]

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* Centers for Disease Control and Prevention, "Flu Vaccine and People With Egg Allergies," last modified Dec. 28, 2017, https://www.cdc.gov/flu/protect/vaccine/egg-allergies.htm.
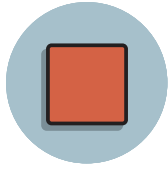
Hydromorphone Overdose

Usability topic: System default	**Estimated time:** 10 minutes
Setting: Emergency department	**User/audience:** Physician or advanced practice provider

Scenario summary: A high dose of opioid pain medications will be ordered; the dose would be lethal to most patients. Increased monitoring will be ordered to address the increased patient risk.

Particular area of risk or inefficiency: Opioid medications are important in treating patient pain. However, they also have important safety implications and can cause respiratory depression, essentially making patients so sleepy they forget to breathe and could die. The EHR system should not facilitate the default ordering of high doses of pain medications that could be lethal for the majority of patients.

Realism/generalizability: Testing sites may adjust the dosing to titrate to various levels of safety. For example, 0.5–1 mg. of hydromorphone is standard dosing and roughly equal to 4-8 mg. of IV morphine. Setting the testing threshold to 4 mg. of IV hydromorphone may increase the safety threshold but potentially capture some patients, like those with cancer, who require high dosing that would harm patients who are opioid naive. In addition, other medications like fentanyl have very different parameters and are measured in micrograms, where 25-100 mcg. is appropriate dosing. A single 1,000 mcg. dose would be lethal and should not be orderable in the system.

Begin scenario

A 28-year-old male presents with severe flank pain consistent with previous episodes of similar pain but worse than usual. Patient has allergies to acetaminophen, ibuprofen, and morphine but had tolerated hydromorphone (Dilaudid) if given with IV diphenhydramine (Benadryl). He also states that his pain is usually hard to control and that he needs high doses of pain medications.

Task

1. Please order the following medications for pain:

a. Hydromorphone 10 mg. IV STAT.
b. Diphenhydramine 25 mg. IV STAT.

2. Due to the large dose of opioids, you decide to monitor the patient more closely. Order the following:

a. Cardiac monitoring.
b. Pulse oximetry monitoring.
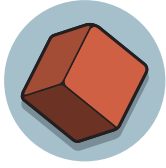*c. End tidal carbon dioxide monitoring.*

Measures

The scenario fails if:

• 10 mg. IV hydromorphone is able to be ordered without an alert indicating that this is outside of normal limits.

• 4 mg. or higher is a default or available option from a list of potential doses. While providers may not have control over contraindicated default options, their presence may lead to safety challenges.

Note

Testing sites may want to review different opioids and can refer to clinical opioid calculators or equal analgesic tables, such as one at Stanford University.*

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*   Stanford School of Medicine, "Equivalency Table," https://palliative.stanford.edu/opioid-conversion/equivalency-table.

Scenario 3-Advanced
Medication Scheduling

Usability topic: System default	**Estimated time:** 10 minutes
Setting: Inpatient	**User/audience:** Internal medicine/hospitalist

Scenario summary: A physician places admission orders for a patient with home medications and must perform a complicated medication scheduling task.

Particular area of risk or inefficiency: The timing of medication orders is important to maintaining patient's home medications as well as treatment of acute processes in the hospital such as infections and abnormal vital signs. Errors in timing of medication doses can lead to potential delays in care or medication overdoses.

Realism/generalizability: The timing of the next dose of the medication may need to be adjusted based on when the participant is taking the test. For example, if the participant is performing the use case at 11 a.m., the next dose of medications would be the following, in order: 1100 (now), 1800, 0000, 0600; but if done at 4 p.m., the following times would be more appropriate: 1600 (now), 0000, 0600, 1200. In addition, the site may choose to add or remove medications to make the case more or less challenging to the participant, especially if introducing medications that the user is less familiar with or are not on formulary and may require conversions to other medications. The scenario may need to be slightly modified for institutions where nurses or pharmacists schedule medication.

Begin scenario

A 78-year-old female is seen in the ED for hypertensive urgency after having a blood pressure of 227/115 and a headache. The patient's current vital signs are:

- *Heart rate: 83.*
- *Blood pressure: 187/96.*
- *Respiratory rate: 20.*
- *Oxygen saturation: 97% on room air.*

After stabilization in the ED, the patient's blood pressure is 152/86. She is ready for admission to the hospital and requires her home medications.

Task

Order the patient's following home medications with the first dose now and the next closest start times:

1. Hydralazine 40 mg. PO (oral) Q6 hours (i.e., 0600, 1200, 1800, 0000).

2. Isosorbide dinitrate 20 mg. Q8 hours (i.e., 0800, 1600, 0000).

3. Aspirin 81 mg. daily (i.e., 0800).

*4. Metformin 1,000 mg. Q12 hours (i.e., 0800, 2000).*

Measures

The scenario fails if:

• The medication schedule is partially inaccurate, including if the first dose is ordered within two hours of the next dose. Sites may choose to use shorter or longer time periods to be more or less sensitive to errors. If an error is noted, test proctors may choose to review the final list of medication orders with participants to confirm if it represents their mental model and assigned task, to identify if they changed the orders intentionally based on clinical preference.

• The times are clinically incorrect and unintentional. See above to confirm the time changes were not intentional.

Note

Many EHRs do not allow for the visualization of planned medications and often require the ordering provider to use paper or their memory when scheduling medications. This frequently leads to missed doses or duplicate dosing of medications.
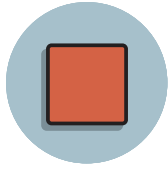
Scenario 4-Basic
Weight-Based Dosing Error Catching

Usability topic: Data entry	**Estimated time:** 10 minutes
Setting: Ambulatory	**User/audience:** Technician/nurse

Scenario summary: The participant entering the patient's information accidentally records the weight in pounds in the EHR.

Particular area of risk or inefficiency: To reduce this error, EHRs may be implemented to allow only metric measurements. However, some EHRs and health care organizations still allow for multiple units of measure (kilogram or pounds) and may display information in a confusing manner that increases the risk of errors in dangerous weight-based medication orders. Even if only kilograms can be entered, staff may use estimated weights from the patient that are typically communicated in pounds or scales that may display pounds.

Realism/generalizability: Test sites may choose to use measurements that are closer together, making it harder to catch the discrepancy that is being tested. While this scenario tests the user's ability to convert measurements and to avoid accidentally entering measured kilograms into a field for pounds, sites should evaluate the scenario where the user enters pounds into a kilogram field [e.g., in this scenario, the 3-year-old patient receives a weight of 31 kg. (68 lbs.) instead of the actual weight of 31 lbs. (14 kg.)].

Begin scenario

The patient is a 3-year-old girl presenting with urinary tract infection symptoms. On arrival at the office, the patient's height and weight are recorded and documented in the EHR. [The patient should have a weight of 12 kg. (approximately 26.5 lbs.) and length of 85 cm. (33.5 in.) from approximately one year before the usability test date.]

Task

1. Enter a height of 3 ft., 1.5 in. and a weight of 14 lbs. in the patient's chart. [Check for any alerts that note a large fluctuation in the patient's weight from 12 kg. (26.5 lbs.) previously to 14 lbs. (6.35 kg.) or height (33 in.). Note if the user has difficulty converting 3 ft., 1.5 in. (37.5 in.) into 95 cm. and if an external device like a smartphone is used for calculations. If the user recognizes the weight error, make note of his or her resilient behavior and state: *For this scenario only, please enter the weight as recorded by the technician and further instructions will be provided.*]

2. On review of the growth curves during the visit, you note that there was a large change from the previous weight in the patient's chart (12 kg. one year ago—50th percentile—at her 2-year checkup). After reweighing the patient, you note that she is 14 kg., not 14 lbs. Please enter this change in the patient's chart, replacing the previously recorded weight.

Measures

The scenario fails if:

• The weight change is not fixed by the end of the scenario (unlikely given the direction).

• There is no alert/notification to the user that there may be an error with the weight given the dramatic fluctuation.
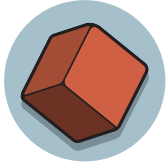
Note

There are multiple potential routes for this error to occur. For example, an office may have an old scale that records only in pounds. In addition, most patients and staff think of their own weight in terms of pounds, not kilograms. If a staff member does not weigh a patient and asks for an estimated weight, the patient or family member is likely to report a weight in pounds that must be converted, either manually by the EHR user or within the EHR itself.

If the participant notices that the patient's weight should be in kilograms, not pounds, please note in the testing scenario and ask them to enter 14 pounds as described in the scenario. The testing site may choose to use a different combination of heights and weights to make the user less likely to catch the error. Please refer to the CDC growth charts to choose a different combination.*

*   Centers for Disease Control and Prevention, "CDC Growth Charts," https://www.cdc.gov/growthcharts/cdc_charts.htm.

Prednisone Taper

Usability topic: Data entry	**Estimated time:** 20 minutes
Setting: Inpatient	**User/audience:** Internal medicine, hospitalist, emergency medicine physician

Scenario summary: A patient is admitted to the hospital from the ED with a severe asthma exacerbation. On discharge, she requires a tapering dose of prednisone.

Particular area of risk or inefficiency: Writing tapering doses of medications is very complicated compared to traditional directions, both for patients to follow and for physicians to calculate. Written prescriptions allowed a degree of freedom that could allow the physician to have the pharmacist perform the calculations, instead of having to know the total number of pills to be dispensed when writing the prescription. Stopping prednisone or other steroid medications too quickly in a patient who has been on them chronically can lead to a metabolic crisis that requires hospitalization and can cause significant harm.

Realism/generalizability: The site may choose to adjust the prednisone taper to shorter or longer durations between dosing adjustments. This will make the calculations more or less challenging for the user. For example, a 60 mg. taper reducing by 10 mg. every two days—(6 tabs x 2 days) + (5 tabs x 2 days) + (4 tabs x 2 days) + (3 tabs x 2 days) + (2 tabs x 2 days) + (1 tab x 2 days) = 42 tablets—is easier than a taper reducing the dose by 10 mg. every week: (6 tabs x 7 days) + (5 tabs x 7 days) + (4 tabs x 7 days) + (3 tabs x 7 days) + (2 tabs x 7 days) + (1 tab x 7 days) = 147 tablets.

Begin scenario

A 24-year-old female is admitted to the hospital from the ED with a history of asthma. Her asthma is poorly controlled, with monthly visits to the ED and two prior endotracheal intubations. The patient takes the following:

• Albuterol MDI 2 puffs Q4 hours.

• Salmeterol/fluticasone 50 mcg./100 mcg. inhaled daily.

She has also been taking 5 mg. of prednisone daily for the last month from leftover pills. The patient also admits to smoking "three to four cigarettes per day" and just got a new cat at home. After two days on the medical floor, the patient is ready for discharge.

Task

1. Begin the discharge process for the patient, including a discharge diagnosis of "asthma exacerbation," asthma discharge instructions, and follow-up with her primary care doctor in one week.

2. Complete a medication reconciliation to continue all of her medications.

3. Due to the recent use of steroids, you decide to order a prednisone taper. Order prednisone 60 mg., reduced by 10 mg. every three days.

4. Instruct the patient to follow up with her primary care doctor in one week and return for fever, chest pain, or shortness of breath.

5. Place a discharge order.

Measures

The scenario fails if the prednisone prescription is not spread over 18 days and does not match the content of one of the following (the specific notation used by physicians may differ):

• 10 mg. tablets: (6 tabs x 3 days) + (5 tabs x 3 days) + (4 tabs x 3 days) + (3 tabs x 3 days) + (2 tabs x 3 days) + (1 tab x 3 days) = 63 tablets.

• 20 mg. tablets: (3 tabs x 3 days) + (2.5 tabs x 3 days) + (2 tabs x 3 days) + (1.5 tabs x 3 days) + (1 tab x 3 days) + (0.5 tab x 3 days) = 32 tablets.

Note

Tapering prednisone is less common due to research showing otherwise healthy patients can tolerate high-dose steroids and then stop them without significant side effects. Patients who are chronically on steroids or have other medical problems may lose the ability to make their own steroids/hormones and require a tapering dose to regain that ability. Some users may ask to order prepackaged steroid tapers, such as a MethylPREDNISolone Dose Pack, to avoid the complex task of ordering a taper. These users should be asked to complete the task as directed.
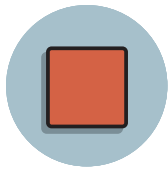
Scenario 5-Basic
Missing Potassium

Usability topic: Display/visual clutter	**Estimated time:** 10 minutes
Setting: Emergency department	**User/audience:** Physician

Scenario summary: A patient's laboratory work is returned and is missing a critical result that has the potential to be life-threatening if missed.

Particular area of risk or inefficiency: Multiple EHR systems have been noted to allow laboratory staff to release incomplete sets of labs without a place holder for the unreported components of the blood test. For example, a basic metabolic profile typically consists of seven elements (sodium, potassium, chloride, bicarbonate, blood urea nitrogen, creatinine, and glucose), and the user would expect to get results for all seven when ordering the test. If only six results come back normal and the provider misses the seventh result, the patient could be discharged with a life-threatening condition. This lack of usability in the system has led to patient harm and death.

Realism/generalizability: The sites may choose to use other tests to determine if there are hazards present. Blood tests like white/red blood cell counts, sodium, lipase, and others have all been implicated in this type of error because the critical results frequently take longer to obtain than the remaining elements in the test group.

Begin scenario

A 63-year-old male patient presents with vomiting and diarrhea for the last five days and unable to tolerate food or water. The patient has a history of hypertension and glaucoma. He takes a "blood pressure pill and some eyedrops."

Task

1. Review the patient's recent lab work. [This should include a basic chemistry panel. There will be multiple abnormal results that are mild-moderate, including decreased kidney function (BUN 65, creatinine 2.67) but no potassium reported because the lab is confirming the result and wanted to be helpful by releasing the results on the other tests. This should not be pointed out to the user.]

2. Order 1000 ml. normal saline bolus IV x 1 STAT.

3. The nurse notices that the potassium is missing on the chemistry panel. You call the lab, which states that the potassium is being repeated because it was elevated but the other results were released for the basic metabolic profile. Place an order for an EKG to evaluate for hyperkalemia [elevated potassium] *while the potassium results are pending.*

4. The EKG shows normal sinus rhythm and shows no signs of hyperkalemia. Review the results again. [Potassium will be elevated at 5.8] *You believe the results are consistent with renal dysfunction from persistent vomiting and diarrhea. Order a second 1000 ml. of normal saline and a repeat basic metabolic profile after the IV fluids to reassess the patient's response.*
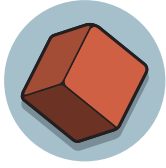
Measures

The scenario fails if:

• There is no indication anywhere on the screen that there is a pending lab result.

• The participant does not make it clear in the electronic order that the second bloodwork should be sent after the second round of IV fluids is complete.

Note to moderator: Record if EHR does not have a place holder for the pending potassium test.

Note

The moderator should note what the participant is able to see in the lab results section. For example: Is there a place holder for potassium in the chemistry panel of seven to eight results? Is it a missing row with no visual cue that one of the elements is still being tested and the panel is incomplete? Is there a reminder in a remote part of the screen that there are still pending results? The full basic chemistry profile will be sodium 136/potassium 5.8/chloride 104/carbon dioxide (CO_2) 18/BUN 65/creatinine 2.67/glucose 152/calcium 9.4.

Scenario 5-Advanced
Duplicate Order Sets

Usability topic: Display/visual clutter	**Estimated time:** 20 minutes
Setting: Inpatient	**User/audience:** Physician

Scenario summary: A patient is having severe pain status post-orthopedic surgery and has a history of requiring high doses of opioid pain medications before surgery. The participant will need to gather data from the electronic medication admission record and make dosing adjustments.

Particular area of risk or inefficiency: Patients frequently require strong pain medications while in the hospital that may require frequent dose adjustments and additions by multiple providers. A physician may be asked to adjust a patient's medications that they are unfamiliar with while covering a night or weekend period. Some EHRs may place medications in different parts of the record—standing orders versus PRN (as needed) versus continuous IV medications—leading to significant visual clutter or a clinician's reliance on short-term memory to coordinate these high-risk medications. Furthermore, various opioids with different strengths, onset times, and durations can create a confusing cocktail of medications that puts the patient at risk for poor pain control and/or adverse events.

Realism/generalizability: The study site may add or reduce the number of opioid pain medications or add additional non-opioid pain medications to make the discovery of pain medications more challenging to the participant.

Begin scenario

The patient is a 67-year-old male having severe pain following a total knee replacement. The patient was taking oxycodone 10 mg. every six hours as needed for pain (four doses per day) and oxycodone extended release 80 mg. every 12 hours before the surgery for severe osteoarthritis. You are called by the nurse to address the patient's severe pain on the first postoperative day. In addition to using non-opioid pain medications, you decide to temporarily increase the patient's opioid pain medications.

[The patient will be on a morphine patient-controlled analgesia (PCA) pump with a basal rate of 1 mg. per hour and 1 mg. bolus every 20 minutes, oxycodone 5 mg. PO (oral) every six hours PRN pain, hydromorphone 0.5 mg. IV every four hours PRN severe pain. The patient has been receiving all of the medications consistently on time as requested. As explained in Task 2 below, this configuration of narcotics may be unsafe; EHRs may be used to help notify clinicians when unsafe conditions exist based on medications that are not discontinued.]

Task

1. Review the patient's electronic medical administration record and determine what opioid pain medications the patient is taking. Please calculate the patient's total oral morphine equivalents for their home and current inpatient medication regimens and compare to any calculations by the EHR. Use the following conversion factors: morphine 10 IV = 30 oral morphine equivalents (OMEs); oxycodone 20 mg. = 30 mg. OME; hydromorphone 1.5 mg. IV = 30 mg. OME; fentanyl 15 mcg./hour = 30 mg. OME per day. [Administrator should record participant's calculation versus any supplied automatically by the EHR].

2. After determining that the patient's PCA pain management is suboptimal and potentially unsafe, based on the patient's home medications, you cancel the orders for oxycodone and hydromorphone.

3. Please increase the patient's PCA basal rate of morphine to 2 mg. and decrease the lockout time from 20 minutes to 15 minutes. This will provide 144 OME per day with potential to receive an additional 288 mg. oral morphine through bolus dosing if needed.

4. Order the patient to be placed on continuous end-tidal CO2 monitoring and scheduled bowel regimen of senna two tablets PO nightly.

5. Order a pain medicine consult for further management of this patient's complex medical needs.

Measures

The scenario fails if:

▪ User does not view the PCA order—for example, if it is located in a different part of the chart than the Electronic Medication Administration Record.

▪ PCA pump orders are on paper, since this would create a significant hazard if a user is not aware they are on a PCA and alters the orders in the EHR.

▪ The OME calculated by the EHR is missing any of the medications the test patient is taking in Step 1. Calculations by the EHR should be checked by a clinical expert to confirm that differences with the test scenario are clinically equivalent due to different conversion factors and not errors.

Note

The following calculations were used in the scenario above and may differ slightly with different conversion factors:

▪ Home OMEs (360 mg.) (Task 1).
  ▪ Oxycodone 20 mg. Q6 hours = 80 mg. = 120 mg. OME.
  ▪ Oxycodone ER 80 mg. Q12 hours = 160 mg. = 240 mg. OME.

▪ Initial hospital OME (Task 2).
  ▪ Morphine PCA.
    ▪ Continuous = 1 mg./hour IV x 24 hours = 24 mg./day x 3 (IV > oral conversion) = 72 mg. OME.
    ▪ Bolus = (1 mg./20 min. x 3 doses) x 24 hours = 72 mg. x 3 (IV > oral conversion) = 216 mg. OME.
  ▪ Oxycodone 5 mg. PO Q6 hours = 20 mg. = 30 mg. OME.
  ▪ Hydromorphone 0.5 mg. IV Q4 hours = 3 mg. IV per day/1.5 (IV > oral conversion) x 30 (hydromorphone to morphine conversion) = 60 mg. OME.
  ▪ **Total = 378 mg. OME.**

▪ Adjusted morphine PCA dosing (Task 3).
  ▪ Continuous = 2 mg./hour IV x 24 hours = 48 mg./day x 3 (IV > oral conversion) = 144 mg. OME.
  ▪ Bolus = (1 mg./15 min. x 4) x 24 hours = 96 mg. x 3 (IV > oral conversion) = 288 mg. OME.
  ▪ **Total = 432 mg. OME.**

▪ Calculations performed using Stanford University's Equivalency Table.* Individual testing sites or users may use a different conversion table. The case itself can be adjusted based on institutional standards. Users who relied on their own resources should be asked after the case to either provide their calculations on paper or the conversion factors to determine if any errors were made.

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*   Stanford School of Medicine, "Equivalency Table," https://palliative.stanford.edu/opioid-conversion/equivalency-table.
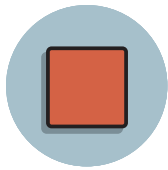
Scenario 6-Basic
Prescription Drug Monitoring Program Data Access

Usability topic: Interoperability	**Estimated time:** 15 minutes
Setting: Emergency department	**User/audience:** Emergency medicine physician/advanced practice provider

Scenario summary: A patient presents to the ED with opioid-seeking behavior requesting a medication refill. The physician must review external prescriptions and e-prescribe acetaminophen and ondansetron for the patient on discharge due to concerns for opioid abuse.

Particular area of risk or inefficiency: There is a national opioid abuse epidemic, with prescription drugs playing a large role. Useful and usable access to prescription drug monitoring programs (PDMPs) in the EHR is an important component of recognizing patients at risk for opioid abuse and providing them appropriate treatment. Without access to patients' controlled substance records, ordering providers are likely to continue to fuel the national crisis.

Realism/generalizability: The details of the patient's prescriptions can be altered to make the presentation more or less subtle. In addition, some testing sites may have order sets for discharging patients with the opioid antidote naloxone and the ability to dispense it directly from the hospital. Although many state PDMPs may not have direct interoperability with an EHR, the integration of PDMP data into the EHR plays a significant role in the usability of the EHR for patient safety in the opioid crisis. If the data are not easily accessible and integrated into the workflow in a usable manner, it is unlikely that it will be integrated into the decision-making for patient care. This may present a challenge in EHRs that must provide access to data from multiple state PDMPs, especially those that are not integrated into a single source. Health care organizations may have substantially different integrations that should be accounted for in the scenario.

Begin scenario

A 32-year-old female patient presents to the ED with a complaint of chronic back pain, severe whole-body pain, vomiting, and diarrhea for two days. The patient states she ran out of her medications, including oxycodone 10 mg. Q6 hours and oxycodone extended release 20 mg. Q12 hours. She states she has not had any of her pain medications for four days.

Task

1. Review the patient's external prescription history. [On review of the patient's outpatient prescriptions, there will be two prescriptions: 1) oxycodone 10 mg. PO Q4 hours PRN pain #240 tablets and oxycodone 20 mg. PO Q12 hours #120. Both were filled two days before from a physician outside of the testing institution's system. Note whether any alerts/warnings are triggered to notify the ordering provider about the recent prescriptions.]

2. After assessing the patient and determining that she appears well, you remind the patient that she filled 360 tablets of oxycodone two days before and that she will need to follow up with her doctor to get refills for her medications.

3. Discharge the patient with prescriptions for acetaminophen, ondansetron, and naloxone (due to the large amount of opioids she is taking). [The directions are left intentionally vague to see if the EHR is capable of writing a prescription for naloxone, a relatively new method for treating community opioid overdoses.]
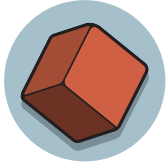
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Measures

The scenario fails if the participant is:

• Unable to access either external prescriptions or a PDMP directly from the EHR.

• Unable to write an appropriate prescription for naloxone (as defined by naloxone 0.4-2 mg. IM or nasal spray).

• Required to enter a separate username and password from what was used to log in to the EHR (partial credit may be given if the need to enter that information is not at the control of the health care organization or EHR developer).

• Has to create a free-text prescription because naloxone is not in the medication database.

Note

Some institutions may have no ability to review external prescription databases or PDMP data and therefore may fail the case due to factors outside of the EHR developer or provider's control. These institutions would fail the case due to lack of interoperability. This includes a partial failing grade if the participants are required to log in to an external website with a new set of credentials. With the meaningful use requirements for electronic prescriptions, the vast majority of health care organizations using these test cases should have the capability to review outside prescriptions through the EHR. Fewer will have direct feeds of PDMP data into the patient's chart. The health care organization may need to work with the PDMP hosting organization to develop test cases in a live/production environment that link to test cases in the PDMP. If a production environment is used, the case scenario may have to be modified to ensure that the prescriptions are not actually generated.

Scenario 6-Advanced
Canceling eRx

Usability topic: Interoperability	**Estimated time:** 20 minutes
Setting: Ambulatory	**User/audience:** Physician

Scenario summary: A pediatric patient presents with a urinary tract infection (UTI) and requires appropriate antibiotics to be sent electronically to the pharmacy. A urinalysis in the office is positive for an infection. The patient appears well and does not require transfer to a higher level of care.

Particular area of risk or inefficiency: With the adoption of electronic prescriptions, there are safety concerns with canceled prescriptions. Although the Surescripts network is capable of transmitting a cancellation request, not all pharmacies are capable of processing the cancellation and not all EHRs will provide feedback to the user that the cancellation was successful.

Realism/generalizability: This scenario requires testing of the electronic prescription system and may require testing and coordination with pharmacies in addition to the health care organization's EHR. This system should also be tested with electronic transmission of controlled substance prescriptions where applicable. Performing this scenario with an already implemented EHR may expose risks in the system that were previously unknown if they were not explicitly tested. Other evaluations not focused on usability could also uncover these risks. This test case represents a different modality to identify EHR usability issues that ideally would have been addressed before implementation.

Begin scenario

A parent brings her 3-year-old daughter to the pediatrician with a fever and history of UTIs. She otherwise appears well and nontoxic. She weighs 14 kg. with no known drug allergies.

Task

1. Review the urinalysis results. [Specific gravity 1.030, leukocyte esterase large, nitrite large, otherwise negative.]

2. Order a weight-appropriate dose of amoxicillin. [Should be 25 mg./kg./day divided Q12 hours or 20 mg./kg./day divided Q8 hours.]

3. As you provide instructions to the parent, she recalls that the patient had hives and vomiting the last time she was given amoxicillin for a UTI. Cancel the electronic prescription for amoxicillin and add the allergy to the patient's record. [Check to see if there is an alert to warn the user if the eRx is not actually canceled in the pharmacy's system and the pharmacy should be contacted directly.]

4. Order a weight-appropriate dose of trimethoprim-sulfamethoxazole (TMP-SMX). [This should be 8-10 mg./kg./day divided BID = 56-70 mg. twice a day @ 14 kg.]

Measures

The scenario fails if:

• Wrong medication dose is given.

• No warning that eRx cancellation was not transmitted if that is the case.

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Note

This scenario may be difficult to test completely without use of a production environment and cooperation with the e-prescription vendor. If performing the case scenario is not possible, the health care organization should assess the hazards represented in this case and consider what happens if a pharmacy cannot process a cancellation request and how that integrates into the clinical work of the ordering provider.
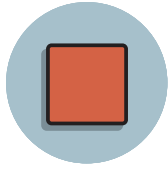
Rapid Strep Test Reflex Testing

Usability topic: Workflow support	**Estimated time:** 10 minutes
Setting: Ambulatory	**User/audience:** Primary care

Scenario summary: A patient presents with a sore throat and requires a rapid strep test and follow-up throat culture.

Particular area of risk or inefficiency: The integration of validated clinical decision support (CDS) rules are key to safe, quality, evidenced-based care for patients. If the CDS is not integrated well with the clinician's workflow, there may be mistreatment and the potential for error.

Realism/generalizability: This case scenario could be modified to investigate the application of other CDS rules such as the HEART score used to identify low-risk chest pain or Quick Sepsis Related Organ Failure Assessment* (qSOFA) score for identifying patients at risk for sepsis.

Begin scenario

A 7-year-old boy presents to the family medicine clinic. The parents state he had had a sore throat for the last two days with no cough. Several of the child's classmates are also out of school with a fever and sore throat.

Task

1. After consideration of the patient's exam findings, you suspect possible strep pharyngitis. The patient has positive tonsil exudates, no lymphadenopathy, and positive fever (39 degrees Celsius or 102 degrees Fahrenheit). You decide to review and document Centor criteria on this patient. [This clinical decision rule should be integrated into the EHR, but the user may use a mobile device or the internet to calculate. The score should equal 4. For testing purposes, the user may document in a stand-alone note and not have to generate a whole patient visit note with medical history, exam findings, etc. Calculating the Centor criteria should provide updated guidance that recommends testing and not empiric treatment.]

2. The updated recommendations regarding the treatment of strep pharyngitis recommend no empiric treatment, regardless of Centor score. Please order a rapid strep test with a reflex (follow-up) throat culture if the rapid test is negative. [This step can help clinicians who are unaware that they are using outdated guidelines or when the CDS tools in EHRs are based on outdated guidelines.]

3. The rapid strep test comes back negative. Please discharge/complete the visit summary for the patient with instructions for sore throat/ pharyngitis and inform the parents that results of the cultures will be available in two to three days.

Measures

The scenario fails if:

• The participant has to order both tests separately and is not able to order a reflex test. This could result in the patient getting charged for an unnecessary throat culture even if the rapid strep test is positive for strep throat.

• The participant orders antibiotics for the patient that are not indicated. Centor criteria should equal 4.

• Centor criteria and appropriate guidance are not integrated in the EHR (e.g., based on outdated guidelines and where the participant was unaware of the updated guidelines).
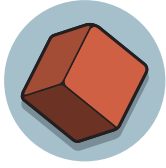
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Note

Recommendations regarding the diagnosis and treatment of strep throat, a common infection, have evolved. This led to the initial overuse of antibiotics, then to clinical decision rules like the Centor criteria to guide empiric treatment. The most recent evidence recommends only treating for positive strep throat tests to prevent antibiotic resistance and other potential downsides of unnecessary antibiotic use.

The Centor criteria have been a mainstay of care, yet more recently multiple sources of evidence have disproved the utility of the Centor criteria and now recommend treating patients with antibiotics only if they test positive for strep throat. There are probably many practitioners who use this rule inappropriately, leading to overprescribing of antibiotics. The ability to anticipate potential errors based on outdated recommendations and to easily order the appropriate tests and treatments is critical to a safe and useful EHR.[†])

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Physician-Nurse Simultaneous Ordering

Usability topic: Workflow support	**Estimated time:** 15 minutes
Setting: Inpatient	**User/audience:** Nurse/physician

Scenario summary: A rapid response team in the hospital is called to a patient on the floor for a possible heart attack. In this scenario, a nurse and a physician will be placing orders simultaneously.

Particular area of risk or inefficiency: As health care providers become more advanced and team oriented, the EHR must safely support the team-based care of patients that often occurs with nurses and physicians who communicate asynchronously. Multiple people may be using the patient's record, placing orders, and documenting information at the same time, and the system should be designed to accommodate this but eliminate duplicate orders and wasted time if two users are entering orders at once.

Realism/generalizability: This scenario can be adjusted to represent a physician and pharmacist, an attending and resident physician, or any combination of care providers. The specific medications for the heart attack protocol and unit names may also need to be adjusted.

Begin scenario

A 60-year-old patient in the observation unit starts complaining of pressure in his chest and has a history of diabetes, hypertension, hypercholesterolemia, and a history of tobacco use. The nurse calls the attending to assess the patient. The electrocardiogram (EKG) shows a clear ST elevation myocardial infarction [STEMI, or heart attack], and the physician leaves the room to contact the interventional cardiologist while the team initiates the myocardial infarction (MI) protocol.

[While the physician is away, the nurse stays to finish the assessment and initiates the MI protocol/standing orders.]

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Task

1. [A second usability moderator will play the role of a nurse unknown to the participant. The "nurse" will have the following orders per protocol:

a. Complete blood count.
b. Basic metabolic panel.
c. Troponin.
d. Prothrombin time.
e. Partial thromboplastin time.
f. Portable chest X-ray.
g. Clopidogrel 300 mg. PO x 1.
h. Heparin 5,000 units IV x 1.
i. Aspirin 324 mg. PO x 1.

These orders should be cued up in advance but not signed/ordered until just before the participant signs his or her orders.]

2. After discussing with the interventional cardiologist, place the following orders on the patient while they await the cardiac care team:

a. Complete blood count.
b. Basic metabolic panel.
c. Troponin.
d. Prothrombin time.
e. Partial thromboplastin time.
f. Portable chest X-ray.
g. Aspirin 325 mg. PO x 1.
h. Clopidogrel 600 mg. PO x 1.
i. Heparin 4,000 units IV.
j. Eptifibatide 180 mcg./kg. bolus over 1-2 min., and then 2 mcg./kg./min. IV (assuming normal kidney function).

3. [If no alerts are issued:] *The nurse notes that there are duplicate orders, one from the protocol that she placed and one that you as the provider placed. She wants to know which you would like to cancel (specific order or one entire set). Cancel the duplicate orders for clopidogrel 300 mg., heparin 5,000 units, and aspirin 324 mg. and duplicate labs.*

4. [If an alert is issued:] *Please reconcile the duplicate orders to represent what the cardiologist asked you to perform.*

5. The cardiac catheterization team arrives and is ready for the patient. Place an order to put the patient in observation status in the cardiac care unit under Dr. Singh with a diagnosis of STEMI.

Measures

The scenario fails if:

• No alert for duplicate/harmful doses of the medications.

• Partial fail if it does not catch duplicate diagnostic testing (labs).

Note

If the facility is an academic institution, this case could also integrate residents.

This case can be run with multiple participants representing different clinical roles at the same time to simulate the interactions between the team members. A less complicated process is to have the usability expert play the role of the other clinical team member.

Endnotes

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