August 10, 2020

Frederic Blavin
Principal Research Associate
Christal Ramos
Senior Research Associate
The Urban Institute
500 L'Enfant Plaza, SW
Washington, DC 20024

RE: Electronic Health Record Reporting Program: Request for Public Feedback on Draft Voluntary User-Reported Criteria for the EHR Reporting Program

Dear Mr. Blavin and Ms. Ramos:

Thank you for providing the opportunity to submit comments on the voluntary user survey portion of the congressionally required electronic health record (EHR) reporting program. Established as part of the 21st Century Cures Act (Cures), the program will involve data collection on the capabilities of EHRs and has the potential to give health care providers, health information technology developers, and researchers better data to address barriers in the effective, efficient, and safe use of digital systems, and improve them accordingly. While the reporting program as a whole will involve critical data submission requirements from EHR developers, the proposed survey component offers an important opportunity for doctors, nurses, and other clinicians to provide their assessment of the technology, and should include a greater focus on aspects that can influence patient safety.

These comments are informed by a collaboration between The Pew Charitable Trusts and MedStar Health's National Center for Human Factors in Healthcare. In March 2020, Pew and MedStar released recommendations for how the Office of the National Coordinator for Health Information Technology (ONC) could embed safety into the usability criteria of the EHR reporting program. The recommendations were designed based on a review of EHR safety and usability literature and expert interviews. These recommendations were provided to Urban during the 2019 stakeholder engagement process and are appended to this comment letter.

Pew is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products, and enhancing the coordination of care. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs.

MedStar Health is a not-for-profit ten hospital healthcare system, the largest in the mid-Atlantic region of the United States. The MedStar Health National Center for Human Factors in

Healthcare is an internationally recognized applied research group with extensive expertise in health information technology usability and safety focused on improving frontline clinical practice as well as federal policy.

ONC contracted with the Urban Institute, a nonprofit research organization, to develop one of the last remaining health information technology provisions of Cures: the EHR reporting program. Specifically, Cures required ONC to develop the EHR reporting program to collect information from technology developers and publicly disclose the data to provide transparency on their functions. ONC will then publish those findings on its website to illuminate the gaps and deficiencies of EHR systems, while also providing trends across the industry and giving users comparative information to assist with their health information technology purchasing decisions.

This draft survey, which is only proposed as a portion of the EHR reporting program, will serve to gain insights across the health information technology lifecycle, including after the system's deployment in facilities. A forthcoming proposal on data collection from vendors will also serve as an opportunity to gain data on functions, performance, and developer practices. In these comments, we provide feedback on the draft survey and offer preliminary input on the content that should be included in the forthcoming data collection effort from EHR developers related to usability and safety.

EHR usability can affect patient safety

Congress required that the EHR reporting program address usability, which refers to whether clinicians can efficiently, effectively, and satisfactorily interact with the technology. Usability challenges can result from the initial design of systems, how they are customized by facilities, unique workflows, user training, and other factors.[1] Usability-related safety problems can emerge from confusing interfaces and cause clinicians to place orders for medications, labs, or diagnostic images or complete other important tasks to deliver inefficient care.[2] These types of inefficiencies precipitate the need to develop workarounds, create an overabundance of unnecessary alerts, and can lead to many other issues given the central role that EHRs increasingly have in helping clinicians review health information, obtain decision support, and order procedures.[3]

For example, research published in 2018 showed that EHR usability contributed to approximately a third of 9000 health information technology-related medication errors examined across three health care organizations that care for children; 609 of these usability related events reached the patients.[4] In one case involving the birth of newborn twins, clinicians could not create a record for one of the infants, which delayed a necessary blood transfusion. Ordering a transfusion for the sibling provided a life-saving workaround that added time and opportunity for error.[5] In another case, a clinician entered a child's weight in pounds when the EHR was configured in kilograms, doubling the child's weight and resulting in the patient receiving twice the appropriate medication dose.[6]

Another recent study examined the safety of different EHR systems implemented in facilities.[7] Using the Leapfrog Computerized Physician Order Entry (CPOE) tool, which assesses the EHR's ability to alert clinicians to medication-related safety issues, researchers studied data on

safety from 8657 hospitals over a 10-year period (2009-2018). The researchers found that, despite progress, EHRs failed to detect safety issues up to a third of the time. Notably, even when examining the same system implemented differently in separate facilities, the researchers identified trends across those systems—meaning that aggregate data from EHRs used in distinct sites can still provide product-specific insights. This finding is notable for the EHR reporting program survey, wherein data on implemented systems would be combined to shed light on the overall functionality of EHRs.

These issues can detrimentally affect care, add to physician burden, and increase costs due to complications associated with medical errors.

Recommendations for proposed survey data to improve EHR usability and add transparency on safety

The draft voluntary survey of end users—which includes physicians, nurses, and other clinicians—focuses on the aspects of EHR functionality specified by Cures: interoperability; conformance to certification testing; privacy and security; usability and user-centered design; and other factors. The draft survey solicits input on two primary components: providing greater detail on the general usability; and safety of the system and assessing particular functions, such as the EHR's ability to alert clinicians to medication errors.

1) *Providing a more detailed focus on usability and safety to reduce risk*

In Section 7 of the proposal, the survey would collect rating information from users on their overall satisfaction with EHRs, such as whether the system enables the clinician to provide high-quality care, if it improves patient safety, and whether alerts appropriately prevent errors. Users would rate their EHR using a 5-point scale from "Very satisfied" to "Very dissatisfied" or "Don't know/Not applicable."

This section appropriately requests user input on aspects of EHR design known to introduce frustration on clinicians and those elements tied to safety. For example, the survey would collect data on whether the EHR has generally intuitive workflows—which can both affect the time needed by clinicians when using the system and contribute to errors.

The survey can include an even greater focus on safety by collecting data on areas known to introduce simultaneous usability challenges and safety risks. For example, the survey should include the following criteria for responses:

- Enables simple and intuitive entry of patient information
- Provides uncluttered pick lists for placing medication orders
- Provides intuitive visual displays that enhance safety

Finally, to obtain more in-depth information on usability concerns and perceived safety risks, the survey should also include an additional open-ended question related to safety. For example, the survey could request open-ended data on the following: "What safety risks do you feel exist within your EHR?"

2) Assessing high-risk functions to reduce patient harm

In Section 8, Urban asks end users to rate various features and functionalities based on their ease of use—from "Very easy" to "Very difficult." For some of these functions, which are low risk, focusing on their ease of use would help provide information to reduce clinician burden.

Based on existing research, the following functions proposed in the survey do not represent significant risks and would be appropriate to rate on their ease of use:

- Data analytics;
- Image receipt and review;
- Structured templates;
- Telemedicine capabilities;
- Integrated chronic care management tool;
- Mobile accessibility;
- Remote accessibility;
- Voice recognition/Voice-to-text capabilities;
- Optical character recognition;
- User-configured interfaces;
- Documentation; and
- Workflow support.

However, other functions present higher risk, and understanding their likelihood to introduce errors would more appropriately capture their effect on care quality and clinician experience. For example, research indicates that 38% of usability-related errors that reached the patient and caused harm occurred because of challenges with order placement, which can occur due to default values, order sets, and other reasons.[8] Similarly, research shows that patient harm occurred in 27% of EHR usability events involving data entry.[9] Finally, research reveals that 22% of EHR usability-related safety events involving alerts contributed to harm.[10]

Therefore, Urban should update the survey for these high-risk functions by instead including a 5-point scale from "Very likely" to "Not very likely" in response to this question: "How likely is it for this functionality to present a risk to patient safety?" Of the functions listed in the draft survey, the following categories are high-risk and should be rated based on safety and not ease of use:

- Default values for common orders;
- Evidenced-based order sets and charting templates;
- E-prescribing of controlled substances;
- Data entry; and
- Patient reminders/alerts.[11]

Finally, the survey should include an additional open-ended question to seek more in-depth information on usability concerns and perceived safety risks to strengthen the EHR reporting program's comparative information. Specifically, the survey should request information on: "What EHR functions include prominent usability issues that contribute to burden or patient safety errors?"

Collecting robust vendor data on usability and safety will improve medical errors

While the proposed survey promises to share important feedback from end users, the data that health information technology vendors provide on their development practices will also serve as a foundation to an effective reporting program. Therefore, as Urban develops recommendations for vendor reporting, we encourage you to consider safety- and usability-related efforts as integral to data collection from EHR developers.

ONC's certification program's safety enhanced design (SED) requirements already capture some data that could be useful as part of the usability components of the EHR reporting program. Still, SED lacks certain data, such as number of clicks it takes to perform certain tasks or videos of different functions.

However, many of the approaches taken by EHR developers for SED differ; for example, technology vendors may not use the same test scenarios, which are designed to reflect realistic patient conditions and how health care providers treat individuals. 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. Because test cases in use often do not overlap with high-prevalence safety hazards, some important EHR features may not be sufficiently evaluated.

In 2018, Pew, MedStar Health, and the American Medical Association published a report summarizing findings from a meeting with EHR developers, health care providers, usability experts, and other stakeholders to define rigor for test case scenarios and create 14 such assessments.[12] The Pew, MedStar Health, and AMA developed test cases focus on areas of known usability and safety issues, and meet the identified rigorous criteria to ensure that they are representative, contain concrete goals, test risks, and focus on the intended audience. ONC should consider requiring use of these test case scenarios—or those similar in rigor—and collect more data on the SED requirements for them. Such an approach would provide meaningful data on the general usability processes and safety.

Examples of how to include data from EHR developers in the reporting program are also included in the appended report.

Conclusion

EHRs affect and can improve nearly every aspect of patient care, yet when problems occur, they can be devastating—even deadly. The proposed survey represents the first step in leveraging the EHR reporting program to collect data to improve usability, and ultimately safety. Urban should further build out the survey to provide a more detailed focus on safety and usability and to assess high-risk functions for potential harm. Urban should also consider the importance of collecting data on safety when developing criteria for vendor reporting.

Thank you for the opportunity to comment on these proposed criteria. Should you have any questions or if Pew or MedStar can be of assistance, please contact Ben Moscovitch at (202)540-6333 or bmoscovitch@pewtrusts.org or Raj Ratwani at (202)244-9815 or Raj.M.Ratwani@medstar.net.

Sincerely,

Ben Moscovitch
Project Director, Health Information Technology
The Pew Charitable Trusts

Raj M. Ratwani
Director
MedStar Health National Center for Human Factors in Healthcare

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Tom Werner / Getty Images

Effective Reporting Could Improve Safe Use of Electronic Health Records

New government effort can collect data to help reduce patient harm

Overview

Despite the near ubiquitous adoption of electronic health record (EHR) systems to replace paper files in hospitals and doctors' offices across the country, minimal data exist on the capabilities of different technologies, including the safety of these products. That omission inhibits the ability of EHR developers, health care providers, and government to address deficiencies in technology that contribute to patient harm. Greater information on the functions of EHRs could help provide solutions to existing gaps prevalent across many products, encourage technology developers to address deficiencies, and provide comparative data for hospitals and clinician offices that purchase electronic medical record systems.

To foster this type of transparency, Congress—through the 21st Century Cures Act—created a program to collect information from technology developers and clinicians that can be used to assess EHR performance. The federal agency that oversees EHRs, the Office of the National Coordinator for Health Information Technology (ONC), will administer the program by collecting data on the design of products, security, information exchange among

systems, and other capabilities of different technologies. The agency will then publish findings on its website to illuminate the strengths and weaknesses of EHR systems, and trends across the industry.

ONC collected public input on factors to prioritize in the EHR reporting program in 2018. In response, health information technology experts, clinicians, and key medical organizations emphasized that the program should address patient safety challenges born out of poor EHR usability—how doctors, nurses, and other staff interact with systems. Usability-related safety problems can result in patients obtaining the wrong drug dose, delays in care, and myriad other potentially deadly events. These usability challenges can occur as a result of EHR design, customizations by facilities, and varying workflows within sites of care. For example, recent data gathered from three hospital systems indicate that approximately a third of the health information technology-related medication safety events occurred in part because of EHR usability.

Given the broad interest in using the EHR reporting program to reduce harm, The Pew Charitable Trusts and the MedStar Health National Center for Human Factors in Healthcare investigated how ONC could incorporate patient safety into the usability aspects of the initiative. To identify and assess the safety-related data to include in the reporting program, Pew and MedStar Health conducted a literature search and interviewed usability experts, EHR vendors, policymakers, and health care providers. That analysis led to the identification of 15 examples of data to collect through the EHR reporting program that could shed light on usability-related safety issues.

By adopting some of these recommendations as criteria in the EHR reporting program, ONC can fill a critical gap in the information available on how medical record systems function—including their contributions to medical errors. Greater transparency on system functions can ensure that better information exists to identify industry-wide gaps, encourage an enhanced focus on safety by product developers, and give clinicians greater insight on the functions of the digital systems that they use. These measures could help make certain that patients entering the hospital are less likely to face harm associated with the computer systems that physicians and nurses use.

Usability and patient safety are intertwined

Opportunities exist throughout the EHR life cycle to remedy usability challenges with electronic systems. During design, technology developers can adopt best practices to identify and address usability deficiencies, such as by testing new functions. The implementers of EHRs—including executives at hospitals and doctors' offices—can also apply strategies to detect and resolve poor usability. Given the contribution of site-specific factors such as unique workflows or customizations, health care providers can also unearth problems by monitoring usability and safety issues.

When unaddressed during development or implementation, EHR usability challenges can contribute to two key safety problems.[1] First, the usability of systems can directly contribute to medical errors. For example, researchers evaluated 9,000 health information technology-related medication safety events across three pediatric health care facilities. The researchers found that subpar EHR usability contributed to 3,243 of those events, often related to patients obtaining or at risk of receiving an inappropriate drug dose. In one case, inadequate usability contributed to delays in a necessary blood transfusion for a newborn. In another case, a transplant patient missed several days of an organ rejection medication. Second, deficient usability can lead to clinician burnout when using EHRs. In turn, clinicians who experience higher rates of burden are more susceptible to making medical errors.

EHR reporting program offers opportunity to address usability, safety

Recognizing the importance of usability to the effective implementation of EHRs, Congress included this topic as a central aspect of the EHR reporting program, alongside security, interoperability (e.g., the exchange of health

data), conformance of the technology to certification criteria outlined in federal regulations, and other factors as deemed appropriate.

Better data through the EHR reporting program would have three main benefits:

1. **Identifying industry-wide gaps and opportunities.** The aggregation of data on EHR functionality in a single location can help illuminate gaps across multiple products. For example, findings that few technology developers involve a breadth of different user types—such as physicians and nurses with different specialties—in the testing of systems can signal that EHRs on the market may not effectively consider the diverse group of end users. Similarly, data indicating an emerging approach by some vendors for quality improvement—such as aggregating and analyzing data to identify care gaps—may spur more EHR developers to add in that capability.
2. **Encouraging developers to address challenges.** Transparency on the functions of EHRs may also highlight those technology developers that adopt best practices to improve system performance, and those vendors that may lag. Highlighting that discrepancy can encourage developers with less favorable public data to address their deficiencies and prioritize improvements, particularly those related to safety.
3. **Offering purchasing support to providers.** The reporting program can also give the purchasers of systems—such as hospital administrators or clinicians who operate their medical practice—the data they need to compare the capabilities of different systems. The information can also help shed light on the strengths of different products in certain settings—such as for a specific medical subspecialty—so that purchasers can select the EHR system most appropriate for their practice. These data may be particularly meaningful for smaller practices or hospitals in underserved communities that may lack resources or expertise to conduct robust comparisons across products they intend to purchase.

In the 21st Century Cures Act, Congress did not specify the type of data that ONC should collect. Instead, Congress instructed ONC to determine the data to obtain from the developers of EHRs. Technology developers that fail to supply data could lose certification for their products. EHR developers seek product certification so that health care providers can use these systems to participate in certain federal payment programs, such as those administered through Medicare.

ONC may also obtain information from other sources such as health care providers or the accrediting bodies that certify EHRs to ONC criteria. Similarly, ONC may already have some information, including data submitted to the agency for the Certified Health IT Product List (CHPL), a database that contains some information on systems though is not intended for comparison across technologies.

Although Congress did not explicitly reference safety, the usability-related criteria developed in the EHR reporting program could focus on ways to reduce medical errors given the clear association between system design and medical errors. Therefore, ONC should embed safety into the usability-related criteria developed in the program.[2]

Proposed criteria for the EHR reporting program

Pew and MedStar Health collaborated to develop examples of how ONC could embed safety into the usability criteria of the EHR reporting program. The example criteria were designed based on a review of EHR safety and usability journal articles and other literature. In addition, MedStar Health interviewed 18 experts from academia, government, health technology development, and other organizations, including from outside health care, to provide ideas from other industries.

The example criteria fall into four categories:

1. General processes used to ensure usability and safety.
2. Effectiveness of alerts to potential safety concerns.
3. Data entry capabilities, such as entering medications.
4. Visual display of information, which refers to the ability to retrieve information documented in systems.

The first category reflects criteria that would address various EHR functions. Meanwhile, research has shown that the latter three categories—alerts, data entry, and visual display—are commonly associated with safety and usability problems. Prior research examined a database with more than 1.7 million patient safety reports and identified those three EHR usability-related functions as the ones most commonly associated with errors.[3] More than half of all the EHR usability and safety issues reported were related to these categories. Consequently, focusing reporting criteria on these issues would address known patient safety-related usability challenges.

Each category includes an assessment of example criteria with the following information:

- **General criteria.** Describes the criterion topic.
- **Rationale.** Explains background and justification for why ONC should consider each example criterion.
- **Usability assessment method.** Includes which one of four common ways to assess usability would be employed to evaluate each recommended criterion. The four common usability assessment methods are:
    - User-centered design (UCD) processes. UCD involves understanding the needs of the intended user population through observations, development of personas (which refer to fictional characters used to depict common roles in testing systems), designing prototypes, and refining technology based on user feedback.[4]
    - Objective usability testing. This often involves using test scenarios to objectively evaluate whether clinicians can effectively interact with technology, and should resemble the actual EHR systems that clinicians would use.[5]
    - Subjective assessments of usability. These assessments capture information on perceptions of usability, as opposed to measures of actual usability, through the use of surveys, focus groups, or interviews.[6] Developers of EHRs or organizations that test EHRs for conformance to federal criteria could embed these types of subjective evaluations into product development or reviews of different systems, respectively.[7]
    - EHR data on user behaviors. This approach uses data collected within the EHR, such as audit log information, to understand how clinicians actually use systems.[8] These data indicate what happens within an EHR—for example, the buttons pressed or the precise time that clinicians enter orders—and can be used to identify challenges in system design.[9]
- **Data sources.** Outlines whether the data already exist or whether new data will need to be created for analysis.
- **Specific criteria.** Describes in depth the specific criteria that ONC could embed in the EHR reporting program and how to measure or assess the data received.

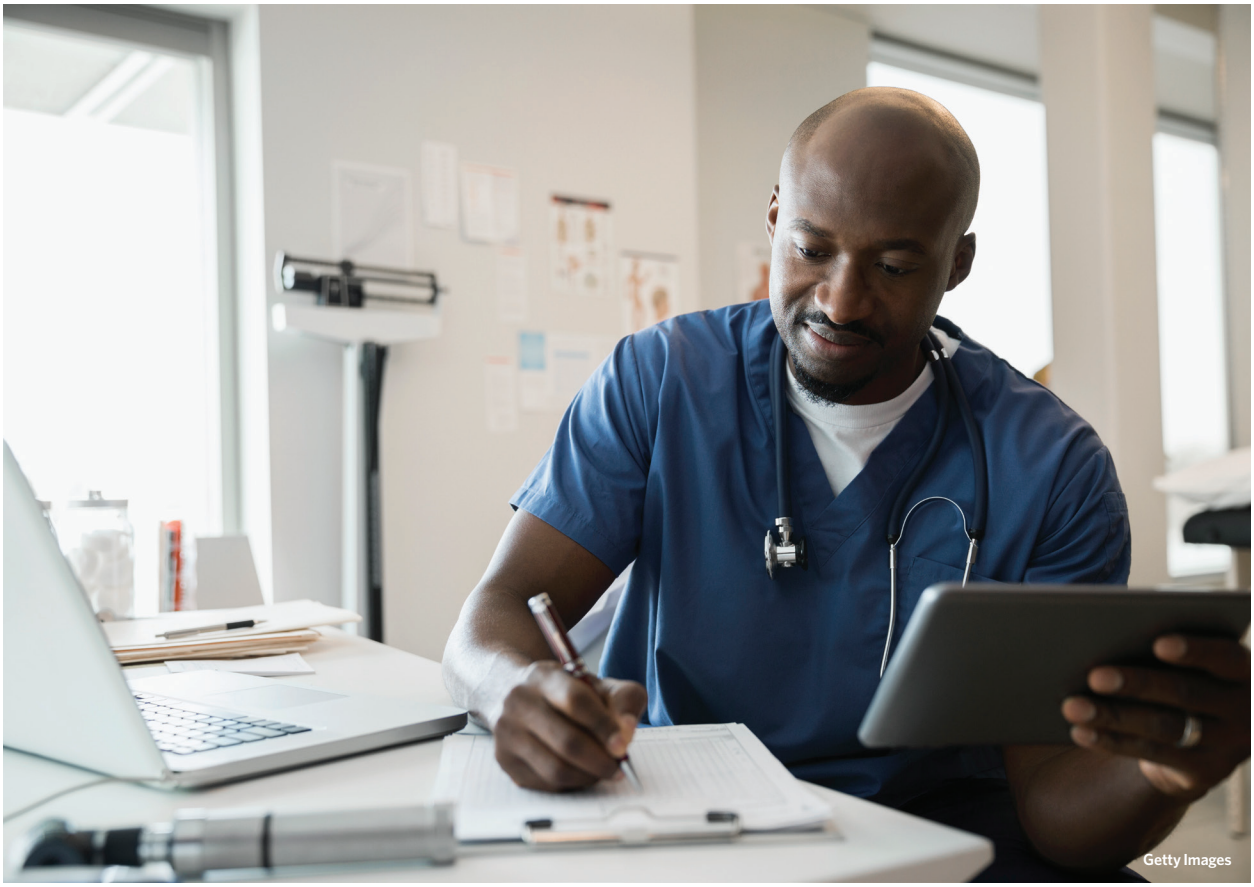
Criteria can build on safety-enhanced design

Many of the data that could be used for the EHR reporting program are already developed and captured as part of the safety-enhanced design (SED) requirements in ONC's health technology certification program. SED requirements include reporting on the types of participants used to evaluate systems, the test results of different tasks, narrative assessments of the system, and many other factors that can provide data on the usability and safety of technology.

Though important, SED may lack certain data such as the number of clicks it takes to perform certain tasks or videos of different functions. Through the EHR reporting program, enhancements to SED could generate meaningful comparative data across products.

Standard reporting of existing and expanded SED requirements to a range of safety-focused criteria would meet the goals of the EHR reporting program. However, many of the approaches taken by EHR developers for SED differ; for example, technology vendors may not use the same test scenarios. Therefore, the program should ensure that at least some of the test case scenarios are the same across products to ensure accurate comparisons across vendors through the EHR reporting program.

Pew, MedStar Health, and the American Medical Association convened EHR developers, health care providers, usability experts, and other stakeholders to define rigor for test case scenarios and created 14 such assessments.[10] The developed test cases focus on areas of known usability and safety issues. ONC should consider requiring use of these test case scenarios and expanding SED requirements to them. Such an approach would provide meaningful data on both the general usability processes and the three known risk areas—alerts, data entry, and visual display—previously mentioned.



General user-centered design process and usability testing criteria

Criteria on general UCD process and usability testing are not related to specific functionalities but rather focus on processes that can improve the overall safety of systems. These criteria provide insight into the rigor of the UCD process and testing being used, particularly by system developers. Overall, these criteria mostly rely on data that already exist, though often are not reported or publicly released.[11]

Table 1

Proposed Criteria: General User-Centered Design (UCD) Process and Usability Testing

General criteria	Rationale	Usability assessment method	Data sources	Specific criteria
Rigor of the UCD process	Using a rigorous UCD process that includes observations in clinical environments, personas of intended users, and iterative testing of prototypes promotes a more usable product.[16] Demonstrated benefits of this approach include reductions in time to complete tasks, fewer errors, and increased satisfaction.[17]	*UCD process:* EHR vendors are required by ONC's 2015 edition certification to use a UCD process. The byproducts of this process, such as personas and test results, can serve as evidence of using a rigorous testing approach.	Data already exist, but not all data are reported as part of certification.	*Measured by:* Attest to creating and using personas [yes/no]; provide and publish personas or the criteria used to create personas as evidence. Attest to conducting observations [yes/no]; if yes, provide general field notes as evidence; if no explain why no observations were needed.
Number of usability test participants	Final usability testing should include at least 10 participants because testing with this number of participants generally identifies 80 percent of usability issues. Testing with 15 participants generally captures 90 percent of issues.[18]	*Objective testing:* The number of participants in the usability testing conducted by the EHR vendor is reported in the safety-enhanced design report to ONC's accrediting bodies and published in the Certified Health IT Product List (CHPL) database.	Data already exist in certification reports.	*Measured by:* Number of participants used to test each capability (e.g., computerized provider order entry): [numeric value as submitted by the vendor]
Representation of usability test participants	Test participants should represent the end-user population that is intended to utilize the product. Otherwise, the individuals evaluating the system will not have the necessary knowledge to identify challenges. For example, for EHR functions that are intended for physicians, they should be tested with practicing physicians.[19]	*Objective testing:* The background of test participants in usability testing conducted by the EHR vendor is reported in the safety-enhanced design report to ONC's accrediting bodies and published in the CHPL.	Data already exist in certification reports.	*Measured by:* Number of participants who have the appropriate experience and clinical background for the capability being tested: [numeric value as submitted by the vendor] For example, medication ordering through computer-physician order entry systems should include doctors and nurses.
Rigor of test case scenarios	Test cases should represent actual clinical scenarios and be complex enough that they will serve to identify usability and safety challenges.[20] Unrealistic test cases and cases that are too simple will not serve to test functionality of the EHR as used in the live clinical environment.[21]	*UCD process:* The test case scenarios employed in usability testing conducted by the EHR vendor are reported in the safety-enhanced design report to ONC's accrediting bodies and published in the CHPL.	Some data already exist in certification reports; use of new, rigorous test case scenarios.	*Measured by:* Attestation to the use of rigorous test case scenarios (such as ones developed jointly by Pew, MedStar Health, and the American Medical Association), and the submission of the safety-enhanced design (SED) data for them. *Measured by:* A subjective rating by the accrediting body of low, medium, or high for the test cases used by each vendor to assess the usability of their product.

Alerting-based criteria

EHR alerts can give clinicians critical information to avert medical errors, such as prescribing drugs to which an individual is allergic. However, alerts that are not accurate, trigger at the wrong time, or are ambiguous can have negative patient safety implications. Clinicians may dismiss—or reflexively ignore—alerts, resulting in health care providers missing critical information. Alerts that do not trigger at the right time may not guide the clinician appropriately, and may occur too early or too late to be effective.[12] In one case examined in prior research, a patient had an allergy to gelatin that was documented in the EHR, yet an alert did not trigger to the clinician when a medication order was submitted that could cause harm.[13] Clinicians may ignore alerts for a range of reasons, including that they were not designed properly or if the health care facility policies required alerts at inopportune times.

Reporting criteria focused on alerts can provide data on whether they are evidence-based and triggered in high-risk situations in a manner most useful to the end users. Alerts should present information to the user clearly, concisely, and accurately, and should not be interruptive unless the situation warrants it.

The use of test case scenarios—with SED requirements—can provide meaningful data on alert practices. Additional data on the utility of alerts, including for both the designed and implemented product, can provide information on whether institutional practices or the base technology affect the utility of alerts.

Table 2

Proposed Criteria: Alerting

General criteria	Rationale	Assessment method	Data sources	Specific criteria
Alert override rates	High alert override rates may indicate poorly designed alerts or ones triggered at an inopportune time. This may result in clinicians missing critical information.[22]	***Audit log or usage data:*** These data can be used to identify how many alerts are triggered and overridden. Data can be assessed as part of the vendor's testing under ONC's safety-enhanced design 2015 certification requirement or can be conducted on the implemented EHR product.	Some but not all data exist.	***Measured by:*** Number of alerts overridden relative to the number of alerts triggered: [# overridden/# triggered]. The focus could be on a limited number of alerts that are recognized as being critical to safety (e.g., drug-allergy contraindications). The Leapfrog Group, a nonprofit organization led by large employers focused on improving patient safety, has developed a testing tool that includes many high-risk medication alerts and could be used as a model for how to structure a reporting program.
Alert design and interpretability	Alerts should be designed to provide information to the provider in a way that is easily interpretable. Alerts should not be confusing or require significant clinician time to respond.[23]	***Audit log or usage data:*** These data can be used to identify the time it takes to take an action—such as dismiss an alert or change a prescription—after an alert is triggered. Vendors could collect these data under ONC's safety-enhanced design certification requirements or directly from the implemented EHR product.	Some but not all data exist.	***Measured by:*** Time to interpret the alert measured in seconds from time the alert triggers to time the clinician acknowledges the alert: [seconds to interpret alert]
		Usability testing: EHR vendors could modify existing testing scenarios to evaluate how long it takes to interpret alerts and whether appropriate actions are taken following the alert. In addition, EHR vendors could solicit user feedback specifically about the alert. EHR accrediting and testing bodies could help collect the necessary data.	Some but not all data exist.	***Measured by:*** Time to interpret the alert measured in seconds from time the alert triggers to time the clinician acknowledges the alert: [seconds to interpret alert] ***Measured by:*** Appropriate adherence to the alert given the clinical scenario [yes/no] assessed by study moderators. ***Measured by:*** Post-test question asking whether the alert was presented at the right time and whether it was clearly presented [yes/no]
		Surveys/interviews: Clinical users can be surveyed or interviewed about the design and interpretability of the alerts they receive. EHR vendors or accrediting bodies could perform these analyses.	New data likely need to be generated.	***Measured by:*** A series of questions developed. Example: Considering the alerts you receive when prescribing penicillin to a patient who has a documented allergy to this medication, please rate the usability of the alert (is the alert timely and does it provide a clear message)? [1-5 Likert scale, 1 strongly disagree, 5 strongly agree]

Data entry-based criteria

EHR developers should ensure that clinicians can enter data intuitively, with users inputting the correct information into the appropriate fields on the interface. Difficult data entry can result in clinicians entering information in the wrong place within the EHR or omitting data because the user cannot determine where to record it. In one case identified in prior research, a physician attempted to place an order for an X-ray of the left elbow, wrist, and forearm, but because of a confusing display, ordered the images for the right arm, exposing the patient to unnecessary radiation.[14]

Table 3

Proposed Criteria: Data Entry

General criteria	Rationale	Assessment method	Data sources	Specific criteria
Error prone EHR data entry interfaces	The design of data entry displays may promote certain types of errors, such as entering the wrong medication dose or route.[24]	***Audit log or usage data:*** These data can be used to identify when EHR order details are entered and then modified or canceled within a specified duration of time. This should be conducted on the implemented EHR product. For example, methods already exist to use this information to determine if clinicians ordered—and then canceled—prescriptions entered on the wrong patient.[25]	Some but not all data exist.	***Measured by:*** Number of orders that are modified or canceled for select medications relative to the total number of medication orders placed [modified or canceled orders/total orders placed]
Data entry display design	Data entry fields that are inconsistent across screens, poorly arranged, or poorly labeled can lead to time delays and errors that affect patient care.[26]	***Usability testing:*** New or existing clinical scenarios could be modified for clinicians to enter complex medication, lab, or diagnostic orders. Time and number of clicks to complete these orders and number of errors can be documented.	Some but not all data exist.	***Measured by:*** Time and number of clicks to complete the clinical scenario relative to the optimal time and clicks, as indicated by the EHR vendor [actual time/ optimal time and click]. ***Measured by:*** Number of errors when completing each scenario [number of accurately completed scenarios/total number of scenarios]
		Survey: Users can be surveyed by an independent stakeholder, such as ONC's accrediting bodies, to identify the intuitiveness of the data entry displays. This should be done on the implemented EHR product.	New data need to be generated.	***Measured by:*** A series of questions developed. Example: Considering the data entry displays in your EHR for entering medication orders, rate the intuitiveness of the display [1-5 Likert scale, 1 not at all intuitive, 5 very intuitive]

Visual display of information

The EHR visual display should not be confusing, cluttered, or present inaccurate information to the user. Confusing visual displays can lead to the wrong medication, lab, or diagnostic image order. These displays can also precipitate the wrong medication prescribed or medications administered at the incorrect time. As an example of this challenge identified in previous research, a physician attempted to order 500 mg of a pain medication to be provided orally, but because of a confusing visual display that listed more than 70 different types of the drug, the clinician selected the wrong product.[15]

Table 4

Proposed Criteria: Visual Display

General criteria	Rationale	Assessment method	Data sources	Specific criteria
Cluttered pick lists, which are lists of orders from which clinicians can choose	Pick lists for placing medication and other types of orders should not be cluttered and should contain only relevant information.[27]	***Usability testing:*** New or existing clinical scenarios could be modified for clinicians to enter orders for medications that would be selected from a pick list. Time and number of clicks to complete these orders and number of errors can be documented. EHR developers or testing bodies could administer these assessments.	Some but not all data exist.	***Measured by***: Time and number of clicks to complete the clinical scenario relative to the optimal time and clicks, as indicated by the EHR vendor [actual time/ optimal time and clicks] ***Measured by:*** Number of errors when completing each scenario [number of accurately completed scenarios/total number of scenarios]
		Survey: Users can be surveyed by an independent stakeholder, such as ONC's accrediting bodies, to assess whether order pick lists are cluttered.	New data likely need to be generated.	***Measured by***: A series of questions developed. Example: Considering the pick lists when ordering [*insert medication name*], how cluttered is the list with irrelevant options? [1-5 Likert scale, 1 very cluttered, 5 not at all cluttered]
Intuitive visual displays for medication administration	Interfaces displaying information on medications to be administered should be intuitive and contain the necessary information to complete the task. Information should be truncated only in low-risk situations and when necessary. Generally, the number of clicks should be minimized.[28]	***Usability testing:*** Clinical scenarios could be created for clinicians to view a list of medications that should be administered to a patient. The clinician can be asked to write down what should be administered, and error rates can be determined. EHR developers or testing bodies could administer these assessments.	Some but not all data exist.	***Measured by:*** Number of errors when completing each scenario [number of accurately completed scenarios/total number of scenarios]
		Survey: Users can be surveyed by an independent stakeholder, such as ONC's accrediting bodies, to assess whether medication pick lists are cluttered.	New data likely need to be generated.	***Measured by***: A series of questions developed. Example: Considering the medication administration interfaces you typically use, how easy to use are they? [1-5 Likert scale, 1 not easy to use, 5 very easy to use]

Emerging themes offer guidance for the EHR reporting program

The analysis and development of these example criteria for the EHR reporting program illustrated four key themes to consider as part of data collection.

1. **Incorporate safety-enhanced design and standard safety tests.** ONC should include safety—as outlined in the tables above—in the usability measures of the EHR reporting program. Many subject matter experts interviewed underscored that the program offers a critical opportunity to enhance patient safety, as also reflected in written feedback many organizations provided ONC in 2018.

   SED criteria from ONC's existing certification program could provide meaningful data. However, ONC should expand SED requirements to areas of known safety risk and standardize the test case scenarios used so that the assessments are comparable across technologies. Similarly, ONC should build on the SED requirements, including by expanding the data submissions (for example, to incorporate the number of clicks it takes to complete tasks and to include video images).

2. **Leverage data collected.** ONC should ensure that the program not only inform potential purchasers of systems, but also serve as a tool for policymakers and EHR developers to identify nationwide gaps and product-specific flaws. Several experts interviewed indicated that the EHR reporting program represents a promising opportunity to identify common usability and safety challenges that persist across many systems so that researchers, technology developers, and policymakers can identify solutions. In addition, the identification of industry-wide challenges can signal to health care providers the areas on which to focus during implementation and what to monitor once systems are in use. In parallel, EHR developers can use the collected data as a guide on how their products and processes compare to other vendors. Where they lag, developers can make adjustments to adopt best practices and further enhance the safety of their systems.

3. **Collect data on implementation.** ONC should ensure that measures in the EHR reporting program reflect both the designed products (e.g., pre-implementation) and those systems in use to identify customization and implementation challenges. Testing prior to implementation can identify usability and safety issues during EHR development so that the vendors can make necessary adjustments. However, many experts said that assessments of implemented products can provide even greater value, though this would likely require more dedicated resources. In addition, technology developers expressed some concern that variations in product implementation inaccurately reflects the designed product—a factor typically outside their control. However, some technologies may be more susceptible to usability and safety errors once customized than other systems. Data from the EHR reporting program can shed light on whether health care providers should take extra precautions when deciding on whether and how to customize certain systems. As a result, data collection from both phases of development and implementation would collect the most meaningful information.

   To obtain data on implemented products, ONC should allow health care providers to submit information. As currently designed, data submission to the EHR reporting program on implemented products would be voluntary from providers. Health care facilities could choose to respond to surveys or submit their own test results given that many organizations already evaluate their products, as evidenced by the thousands of sites that have used a medication-ordering test developed by the Leapfrog Group. Additionally, health care providers could submit data from their audit logs, which likely reflect the best opportunity to obtain real-world data on the performance of implemented systems. ONC should work with physicians and vendors to develop standard approaches to audit logs so that the information can be uniformly and easily submitted to the EHR reporting program and measured.

In the future, vendors could submit data on implemented products such as via the collection of log file data on their systems. In addition, data on implemented products collected by EHR testing and accreditation bodies could also inform the program.

4. **Enhance the program over time.** Once ONC launches the EHR reporting program, the agency should build on the initial design of the initiative in the future. For example, ONC could focus the first iteration of the program on SED criteria and other recommendations from the tables where data already exist or could be more readily obtained. Future versions of this program should expand on those initial criteria by, for example, collecting log file data and incorporating the recommendations in the tables that ONC elects not to include in the initial iteration of the initiative.

Conclusion

EHRs affect and can improve nearly every aspect of patient care, yet when problems occur, they can be devastating—even deadly. However, little data exist on the performance of EHRs and critical functions, including the contribution of these systems to medical errors, such as individuals obtaining the wrong dose of a medication.

Congress recognized the gap in data on EHR functions and created a reporting program, which can equip product developers with new information to understand deficiencies in technology, and give health care providers more information when purchasing or implementing new systems.

ONC now has an opportunity to leverage this program to collect better data to improve the usability—and, consequently, safety—of care. The first iteration of the EHR reporting program should incorporate some of these safety-focused usability criteria to begin informing EHR developers and health care providers on opportunities to reduce medical errors. ONC could begin with those criteria that either already have data available or would provide the greatest insights. As the initiative evolves, ONC should build on these criteria to collect even more robust data on the usability of systems.

Through the reporting program, ONC has an opportunity to collect data on how EHRs function to equip clinicians and technology developers with more robust information that can improve system usability and reduce patient harm.

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Contact: Mandy Dorn, program director
Email: mandy.dorn@medstar.net
Project website: medicalhumanfactors.net

Contact: Ken Willis, communications officer
Email: kwillis@pewtrusts.org
Project website: pewtrusts.org/healthIT

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