

September 29, 2017

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Floor 7
Washington, DC 20201

Dear National Coordinator Rucker:

Electronic health records (EHRs) have reshaped healthcare delivery—giving clinicians access to data to inform decisions, alerting doctors and nurses to potential safety risks, and enhancing efficiency. Yet, the use of EHRs has also contributed to new, unanticipated safety concerns that were not present with paper-based records, and left some safety hazards unmitigated. Many of these safety challenges directly affect care for pediatric patients. As the Office of the National Coordinator for Health Information Technology (ONC) implements provisions from the 21st Century Cures Act, we urge you to consider and incorporate improvements to safety—especially for pediatric patients.

EHR usability—which refers to their layout, design, how they fit into different workflows, and customizations made within healthcare facilities—can influence the efficiency of using these systems, user satisfaction with health information technology, and patient safety.

Several issues specific to children—such as weight-based dosing and age-related medical determinations—raise the risk that EHR usability can contribute to medical errors. For example, children’s weight affects the doses of medication received, which may differ from the dose typically administered to a fully grown adult. EHR design may influence how clinicians order weight-based doses of medications, and could contribute to children receiving incorrect drug doses. In a well-known example, the weight-based dosing usability of an EHR contributed to a 16-year old receiving 39 times the intended dose of a medication.

In another example, EHRs’ ability to correctly track pediatric patients’ height, weight and other vital indicators is necessary to ensure that children are within normal ranges. Incorrect or unclear information can cause clinicians to make care decisions negatively impacting the patient.

Provisions in 21st Century Cures can improve safety for children

Currently, EHR developers must test whether their products perform certain functions as laid out in ONC’s certification requirements; these requirements are not specific to the pediatric population. Additionally, those requirements do not focus on safety—for example whether certain functions can inadvertently contribute to medical errors.

The development of voluntary certification criteria for pediatric EHRs—as required by Section 4001 of the 21st Century Cures Act within two years (end of 2018)—offers ONC an opportunity to focus on improving the safety and usability of these health record systems.

Specifically, the criteria developed through this voluntary program should include provisions to detect potential safety concerns before EHR systems are installed and used, and after implementation to identify challenges associated with—for example—customization by a healthcare facility.

To develop safety-related provisions, ONC could leverage several existing efforts that focus on better testing and assessments of safety. For example:

- **National Quality Forum (NQF):** NQF has proposed several health IT-related measures that can be used to evaluate safety. NQF adopted the “Retract and Re-order” measure, which evaluates the frequency by which a clinician cancels a prescription for one patient, and re-orders it for another. The retract and re-order process suggests that the original drug was ordered on the wrong patient potentially due to—in part—usability-related concerns, such as multiple patient records being open on the same screen. ONC could integrate aspects of these measures into the pediatric EHR certification program.
- **The Leapfrog Group:** The Leapfrog Group has developed a [standard](#) for computer provider order entry that includes a test for inpatient EHRs that alerts clinicians to at least 50 percent of common, serious errors. This standard could serve as examples on how to test systems as part of the certification program.
- **ONC:** ONC has advanced safety in several ways that could inform the pediatric certification program. First, ONC has published the voluntary Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guides that document methods to evaluate EHRs installed within a healthcare facility for safety. ONC could review whether certain aspects of the SAFER guides could be utilized as part of the pediatric EHR certification criteria to test products during development of after implementation. Second, ONC has considered safety provisions in previous versions of the EHR certification criteria that were not ultimately adopted. ONC initially proposed an electronic prescribing standard that included dosing instructions (called National Council for Prescription Drug Programs SCRIPT) as part of the 2015 EHR certification criteria. Although this specific standard was not finalized, ONC could consider this standard for implementation as part of the voluntary pediatric certification program due to the necessity of having accurate medication dosing instructions to prevent overdoses in children, especially given weight-based dosing needs.

The development of voluntary certification criteria for pediatric EHRs affords ONC an opportunity to improve safety of children. We urge ONC to promptly begin work on the pediatric EHR certification criteria and to include provisions that monitor and test for safety through all of the stages of EHR development.

Thank you for your prompt attention to this important EHR safety issue. Should you have any questions or should you need additional information, please contact Ben Moscovitch, manager, health information technology, The Pew Charitable Trusts at bmoscovitch@pewtrusts.org.

Sincerely,

American College of Cardiology
American College of Physicians
American Medical Group Association
American Nurses Association
Children’s Hospital Association
The Pew Charitable Trusts