Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides

On August 13, 2021, the Centers for Medicare & Medicaid Services (CMS) released a final rule requiring eligible hospitals to attest annually that they performed a safety assessment of their electronic health record (EHR) system using SAFER (Safety Assurance Factors for EHR Resilience) Guides. This milestone affects virtually all US hospitals, but there is no specific guidance on how hospitals should perform a self-assessment of these recommended practices. To address this gap, pragmatic guidelines were developed to provide a streamlined, stepwise approach for conducting a systematic EHR safety assessment that optimizes organizational resources, minimizes process inefficiencies, and maximizes EHR vendor involvement.

Context for Hospitals and Clinicians
The SAFER Guides are proactive, checklist-based, risk-assessment tools with 146 recommended practices to help clinicians, hospitals, and EHR vendors understand how to design, develop, configure, implement, use, and monitor EHRs in a safe and effective manner. SAFER practices assess health information technology (IT), its governance, and the way clinicians use it to create and maintain patients’ health records. The guides focus on the EHR, along with hardware, software, networking equipment, and ancillary systems that facilitate data management or exchange patient data with the EHR (eg, clinical laboratory, radiology, or pharmacy systems).

SAFER assessment requires extensive knowledge and experience with the EHR’s governance, configuration, workflow customizations, implementation, and use. For organizations with multiple CMS certification numbers that use the same instance of an EHR (ie, a single patient database and the same EHR application), it is more efficient for a multidisciplinary group representing these sites to conduct a preliminary assessment. Due to variations in local control, site representatives must then review the larger group’s preliminary assessment before making the final attestation to CMS.

Clinicians should be involved in the SAFER assessment process to help ground the improvement of clinical care. Through their involvement, clinicians can learn how the EHR can be configured and optimized for safety and how to identify and close safety gaps. Furthermore, on November 19, 2021, the CMS published a rule that requires clinicians eligible for the merit-based incentive payment system to attest to having conducted an annual self-assessment using the high-priority practices SAFER guide.

SAFER Assessment Process for Hospitals
Hospitals should follow 5 key steps to complete the SAFER assessment (eFigure in the Supplement).

Identify the SAFER Assessment Team. A multidisciplinary team of 8 to 15 people, including representatives from health IT, ancillary clinical departments, and clinical and administrative users, should be assembled. Team members should have a strong ability to break down barriers and facilitate action, and team expertise should represent a broad understanding of clinical, technical, and administrative EHR functionality, patient safety, and prior work with vendors. Team members should have dedicated time to review all guide recommendations and participate in meetings, which may span several months. Additional experts may be needed to review specific recommendations (eg, if the core team does not have adequate expertise in test result management, it could identify an appropriate person from laboratory medicine to help with the test results reporting and follow-up guide).

Determine Which Recommendations Require EHR Vendor Action or Attestation. Adherence with several SAFER practices require shared responsibility between the EHR vendor and the hospital. The need for vendor responsibility and level of support for EHR implementation may be even greater in certain types of hospitals. For example, in hospitals using a remote, cloud-hosted EHR with limited local configuration capabilities, the vendor bears substantial responsibility for attestation compared with hospitals using on-premise database and application servers and considerable local customizations or configurations. Smaller, rural, and critical-access hospitals may need additional external support.

The EHR vendor should also conduct an annual assessment and attest to the ability of their product to be configured to meet each of the SAFER recommendations. The hospital should obtain a copy of the vendor’s annual SAFER assessment along with an attestation that it is complete, correct, and current. In addition, hospitals should confirm EHR default settings conform to SAFER recommendations. Hospitals also should review and maintain a copy of the vendor’s EHR implementation guide to learn how the hospital can configure the EHR to meet the SAFER recommendations. For items that are the responsibility of the EHR vendor, the hospital should use the vendor’s attestation as evidence of meeting (or not) that particular recommendation. If such a guide is unavailable, hospitals should encourage their vendor to create one. This includes both the SAFER assessment and the EHR implementation guide.

Meet Synchronously and Asynchronously. Assessing the implementation status of each SAFER practice requires substantial depth and breadth of knowledge that no single person is likely to have. To create a shared...
understanding and collective responsibility for practices, hospitals should use a mix of in-person and virtual meeting strategies along with asynchronous follow-up methods to ensure progress. Meetings could involve a series of 1- to 2-hour biweekly sessions with each focused on a particular guide; whereas asynchronous work could facilitate getting a variety of inputs on how well a practice has been implemented. For example, one hospital system created an online survey that allowed team members to rat the implementation status of the specific SAFER recommendations assigned to them and provide free-text comments for context and next steps.

Document and Communicate Implementation Status. To provide evidence of self-assessment, hospitals should maintain comprehensive documentation, including core SAFER assessment team members and their roles, meeting date(s) and guides reviewed, meeting participants and their roles, a summary of responses to items in each guide, and contact information of people responsible for providing the information. If the team’s opinions differ about recommendations, evidence used to adjudicate their status should be noted, including email correspondence, hardware or service contracts, pages from the vendor’s help or system configuration manuals, screen print-outs, or the vendor’s SAFER attestation documentation.

Upon completion of the assessment, the team should present findings to the hospital’s governance board. Governing boards are accountable for the safety of patient care and must be made aware of the large EHR-related investments, their effect on hospital operations and patient safety, and potential improvements that can be made. The team should describe the status of adherence to SAFER recommendations and provide details to show how the EHR software is safe, being used safely, and helping improve the safety of patient care.

Prioritize and Address Unmet SAFER Recommendations. The assessment identifies vulnerabilities and opportunities for improvement, and thus, risk-mitigation plans must follow. Actions to move a single recommendation from not implemented to fully implemented can take considerable time and effort. While there is no CMS mandate that recommends that practices be fully implemented, hospitals are increasingly striving for zero harm and high reliability and should make every effort to proactively mitigate risks.

Hospitals should prioritize implementation of practices that affect large numbers of patients, present the greatest safety risk, or closely align with existing organizational priorities. For example, a hospital with a recent hardware failure or a ransomware attack leading to extended downtime may decide to focus on unmet recommendations in the contingency planning guide whereas hospitals in which patients experienced harm from failure to follow-up abnormal test results may decide to focus on unmet recommendations in the test results guide. For newly identified gaps, a multidisciplinary team, including clinicians, should be formed with clearly identified scope, schedule, roles, and responsibilities. Plans should include periodic monitoring and revisions to achieve safety objectives.

Annual SAFER Assessments

In subsequent years, hospitals should revisit their prior year’s SAFER assessments. If the initial assessment is rigorously done and follows recommendations, a quick review of the recommendations from the previous year should be used to determine whether their status has changed. Updates should be obtained for SAFER recommendations for which implementation plans were developed. Each year, eligible hospitals should update their SAFER documentation with an overview of actions taken and progress made toward mitigating risk.

Summary

New CMS regulations establish a robust foundation for safety and safe use of EHRs. These guidelines can help hospitals and clinicians systematically identify EHR-related features, functions, workflows, and organizational efforts to reduce safety risks to a level as low as reasonably achievable. Improving patient safety using a safe and effective EHR should be the goal of every hospital and clinician.

REFERENCES


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