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

APRIL 25, 2022 - HL7 EHR WG/REDUCING CLINICIAN BURDEN PROJECT TEAM

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SAFER Guides: Safety Assurance Factors for EHR Resilience

- **Proactive, checklist-based, risk-assessment tools**
  - 147 recommended practices to help clinicians, hospitals, and EHR vendors design, develop, configure, implement, use, and monitor EHRs in a safe and effective manner

- **Guides focus on EHR**
  - Hardware, software, networking equipment, and ancillary systems that facilitate data management or exchange patient data with the EHR

- **SAFER assessment requires extensive knowledge and experience**
  - EHR governance, configuration, workflow customizations, implementation & use

- **Clinicians should be involved in the process**
  - Learn how EHR can be configured & optimized for safety and how to identify and close safety gaps
SAFER Guides: Safety Assurance Factors for EHR Resilience

Foundational Guides
- High Priority Practices
- Organizational Responsibilities

Infrastructure Guides
- System Configuration
- System Interfaces
- Contingency Planning

Clinical Process Guides
- Patient Identification
- Computerized Provider Order Entry with CDS
- Test Results Reporting and Follow-up
- Clinician Communication

Available at: https://www.healthit.gov/topic/safety/safer-guides

SAFER checklists

Recommended Practices for **Phase 1 — Safe Health IT**

1. Data and application configurations are backed up and hardware systems are redundant. **Worksheet 1**

2. EHR downtime and reactivation policies and procedures are complete, available, and reviewed regularly. **Worksheet 2**

3. Allergies, problem list entries, and diagnostic test results (including interpretations of those results, such as “normal” and “high”), are entered/stored using standard, coded data elements in the EHR. **Worksheet 3**

4. Evidence-based order sets and charting templates are available for common clinical conditions, procedures, and services. **Worksheet 4**
SAFER Worksheet – Practice 3

Rationale for Practice or Risk Assessment

Free text data cannot be used by clinical decision support logic to check for data entry errors or notify clinicians about important new information.

Assessment Notes

Suggested Sources of Input

Clinicians, support staff, EHR developer and/or clinical administration

Examples of Potentially Useful Practices/Scenarios

- RxNorm is used for coding medications and NDF-RT for medication classes.
- SNOMED-CT is used for coding allergens, reactions, and severity
Rationale for Practice or Risk Assessment

Free text data cannot be used by clinical decision support logic\textsuperscript{22} to check for data entry errors or notify clinicians about important new information.
SAFER Worksheet – Practice 3

Recommended Practice

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Rationale for Practice or Risk Assessment

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- Clinicians, support staff, and/or clinical administration
- EHR developer

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- RxNorm is used for coding medications and NDF-RT for medication classes.
- SNOMED-CT is used for coding allergens, reactions, and severity.
- SNOMED-CT, ICD-10, or ICD-9 is used for coding clinical problems and diagnoses.
- LOINC and SNOMED-CT are used for coding clinical laboratory results.
- Abnormal laboratory results are coded as such.

See the Computerized Provider Order Entry with Decision Support Guide and Test Results Reporting and Follow-Up Guide for related recommended practices.
CMS Regulations Regarding the SAFER Guides


- **November 19, 2021** - required clinicians eligible for MIPS to attest to having conducted an annual self-assessment using the high-priority practices SAFER guide. Federal Register. 2021;86(221):65475-77

- No specific guidance on how hospitals should perform a self-assessment of these recommended practices

https://www.federalregister.gov/
Identify the SAFER Assessment Team

- Multidisciplinary team of 8-15 people
- Representatives from health IT, ancillary clinical departments, clinical & administrative users
- Members should have a strong ability to break down barriers and facilitate action
- Broad understanding of clinical, technical, and administrative EHR functionality, patient safety, and prior experience working with vendors
- Dedicated time to review guide recommendations and participate in meetings
- Additional experts may be needed to review specific recommendations
SAFER Guide Review - Vanderbilt

**Process**

• Bi-Weekly Health IT Clinical Directors meetings

• Represented a diverse group of stakeholders and disciplines (core group)
  • Each guide introduced and discussed (synchronous)
  • Determined if the team had the right stakeholders or if we needed to recruit others
SAFER Guide Review - Vanderbilt

- September 2021 – March 2022

- Program manager:
  - Created RedCap surveys
  - Managed logistics around distribution of each guide
  - Nudged participants when they hadn’t completed the survey
  - Summarized data and created a report
Determine Which Recommendations Require EHR Vendor Action or Attestation

- Adherence requires shared responsibility between vendor and hospital
- Vendor responsibility greater in certain hospitals
  - Hospitals using remote, cloud-hosted EHR with limited local configuration capabilities
  - Smaller, rural, and critical-access hospitals may need additional external support
- Obtain a copy of the vendor’s annual SAFER assessment
- Confirm EHR default settings conform to SAFER recommendations
- Review and maintain a copy of the vendor’s EHR implementation guide
  - Use the vendor’s attestation as evidence of meeting (or not) specific recommendations
- If unavailable, hospitals should encourage their vendor to create one

Example EHR Vendor SAFER Implementation Guides


https://galaxy.epic.com/
Meet Synchronously and Asynchronously

- Requires substantial depth and breadth of knowledge that no single person is likely to have
- Use a mix of in-person and virtual meeting strategies
  - Asynchronous follow-up methods to ensure progress
  - Establish a series of 1- to 2-hour biweekly sessions, each focused on a particular guide
  - Gather variety of inputs on how well a practice has been implemented
Document and Communicate Implementation Status

- Maintain comprehensive documentation
  - Core SAFER team members and roles
  - Meeting date(s) and guides reviewed
  - Meeting participants and roles
  - Summary of responses to items in each guide
  - Contact information of people responsible for providing the information
- If opinions differ about recommendations
  - Evidence used to adjudicate their status should be noted
- Present findings to the hospital’s governance board
  - Describe the status of adherence to SAFER recommendations
  - Show how the EHR is safe, being used safely, and helping improve the safety of patient care
SAFER Guides Created in RedCap®

- Redcap survey was created for each guide.
- Each item was rated using one of the following:
  - Fully Implemented
  - Partially Implemented (% implemented was required)
  - Not Implemented
- Comments could be added to provide further assessment and information
1.1 Staff members are assigned to regularly monitor and maintain EHR hardware, software, and network/internet service provider (ISP) performance and safety.

- Fully in all areas
- Partially in some areas
- Not implemented
- Skip question (Inexpert)

Comments

Please indicate % of partial implementation:
Prioritize and Address Unmet SAFER Recommendations

- No CMS mandate that recommends practices be fully implemented
- Moving a recommendation to fully implemented takes considerable time & effort
- Prioritize practices:
  - Affect large numbers of patients
  - Present the greatest safety risk
  - Closely align with existing organizational priorities
- Empower a multidisciplinary team, include clinicians
  - Clearly identify scope, schedule, roles, and responsibilities
  - Include periodic monitoring and time for revisions to achieve safety objectives
## System Configuration Guide - Results

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Percentage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>The EHR is hosted safely in a physically and electronically secure manner. Comments: We have time outs, audit processes, and other measures in place to ensure security.</td>
<td>100%</td>
<td>FULLY IN ALL AREAS (Dees, Hughart, Kumah, Nelson, Sengstack, Wanderer, Zafar)</td>
</tr>
<tr>
<td>1.3</td>
<td>The organization’s information assets are protected using strong authentication mechanisms.</td>
<td>100%</td>
<td>FULLY IN ALL AREAS (Dees, Hughart, Kumah, Nelson, Sengstack, Wanderer, Zafar)</td>
</tr>
<tr>
<td>1.4</td>
<td>System hardware and software required to run the EHR (e.g., operating system) and their modifications are tested individually and as-installed before go-live and are closely monitored after go-live.</td>
<td>100%</td>
<td>FULLY IN ALL AREAS (Dees, Hughart, Kumah, Nelson, Zafar)</td>
</tr>
</tbody>
</table>
Allergies, Problem List entries, and diagnostic test results, including interpretations of those results, such as 'normal' and 'high', are entered/stored using standard, coded data elements in the EHR.

Comments:
- We do not have approval to require that all allergies be coded, some are still in free text format.
- Allergic reactions are not always specified
- Problem lists and medications still include some non-coded, legacy data.
- Some age-based reference labs don't have age-based references

50% - FULLY IN ALL AREAS
(Kumah, Mize, Nelson, Wanderer)

50% - PARTIALLY IN SOME AREAS
Range: 70-95% Average 83%
(Alrifai, Hughart, Parr, Shave)
Most recommendations received a combination of both fully and partially implemented responses from the group of stakeholders.

- Fully/Partially Implemented: 119
- Fully Implemented: 39
- Fully/Partial/Not Implemented: 3
- Partially Implemented: 2
- Partial/Not Implemented: 1
- Fully/Not Implemented: 1
- Not Implemented: 0
1. Identify recommendations where respondents indicated that we have “not implemented” the recommendation – (by one or more respondents)

<table>
<thead>
<tr>
<th>SAFER Guide</th>
<th>Recommendation</th>
<th>% Fully Implemented</th>
<th>% Partially Implemented</th>
<th>% Not Implemented</th>
</tr>
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<tbody>
<tr>
<td>Contingency Planning</td>
<td>3.1 There is a comprehensive testing and monitoring strategy in place to prevent and manage EHR downtime events.</td>
<td>67%</td>
<td>0%</td>
<td>33%</td>
</tr>
<tr>
<td>Computerized Provider Order Entry with Decision Support</td>
<td>1.1 Coded allergen and reaction information (or &quot;no known allergies&quot; [NKA]) are entered and updated in the EHR prior to any order entry</td>
<td>78%</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>Computerized Provider Order Entry with Decision Support</td>
<td>2.13 Clinicians are required to re-enter their password, or a unique PIN, to “sign” (authenticate) an order</td>
<td>0%</td>
<td>66%</td>
<td>34%</td>
</tr>
<tr>
<td>Computerized Provider Order Entry with Decision Support</td>
<td>2.14 When appropriate, corollary (or consequent) orders are automatically suggested and linked together with the original order such that changes are reflected when the original order is rescheduled, renewed, or discontinued</td>
<td>20%</td>
<td>60%</td>
<td>20%</td>
</tr>
<tr>
<td>Clinical Communication</td>
<td>1.2 Policies and training facilitate appropriate use of messaging systems and limit unnecessary messaging.</td>
<td>40%</td>
<td>40%</td>
<td>20%</td>
</tr>
</tbody>
</table>
2. Identify any recommendations where ≤ 50% of respondents indicated “fully implemented” AND the average “partial implementation” percentage is ≤ 55%.

<table>
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<th>SAFER Guide</th>
<th>Recommendation</th>
<th>% Fully Implemented</th>
<th>% Partially Implemented</th>
<th>Average % Implemented (Scale 0 – 100%)</th>
<th>% Not Implemented</th>
</tr>
</thead>
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<tr>
<td>High Priority Practices</td>
<td>3.1 Key EHR safety metrics related to the practice/organization are monitored.</td>
<td>50%</td>
<td>50%</td>
<td>53%</td>
<td>0%</td>
</tr>
<tr>
<td>Contingency Planning</td>
<td>2.1 Staff are trained and tested on downtime and recovery procedures.</td>
<td>25%</td>
<td>75%</td>
<td>50%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>2.2 A communication strategy that does not rely on the computing infrastructure exists for downtime and recovery periods.</td>
<td>33%</td>
<td>67%</td>
<td>51%</td>
<td>0%</td>
</tr>
<tr>
<td>Computerized Provider Order Entry with Decision Support</td>
<td>2.12 A process is in place to review interactions so that only the most significant interaction-related alerts, as determined by the organization, are presented to clinicians.</td>
<td>50%</td>
<td>50%</td>
<td>30%</td>
<td>0%</td>
</tr>
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</table>
Next Steps

• Complete formal report with summary and analysis
• Present to VUMC leadership with recommendations for opportunities for improvement
• Make SAFER surveys available in RedCap Library – done
• Prepare for next year!
Annual SAFER Assessment Updates

- Revisit prior year’s SAFER assessments
- Quick review of recommendations from previous year
- Obtain updates for recommendations for which implementation plans were developed
- Update SAFER documentation with overview of actions taken and progress made
Thank you!

Questions?

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