

NATIONAL ACTION ALLIANCE
for Patient and Workforce Safety

Engineering Safety into Practice through Implementation of the 2025 SAFER Guides

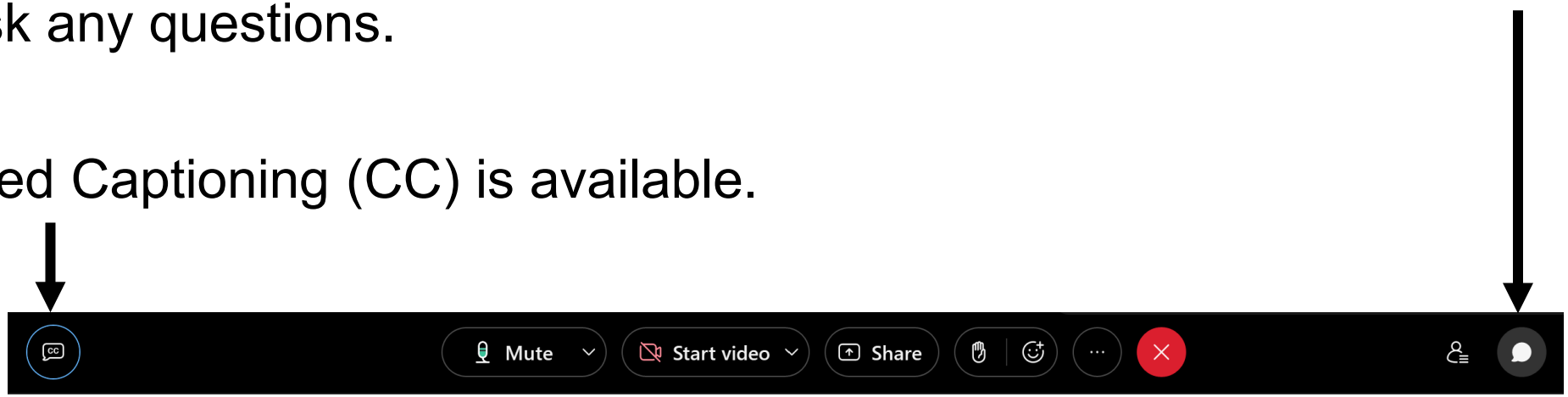
NATIONAL WEBINAR SERIES

JANUARY 21, 2024

Housekeeping Instructions

NATIONAL ACTION ALLIANCE for Patient and Workforce Safety

- This webinar will be recorded and available for viewing on the NAA website.
- Please use the ‘Chat’ function to engage with us throughout the webinar and to ask any questions.
- Closed Captioning (CC) is available.



NATIONAL ACTION ALLIANCE for Patient and Workforce Safety

Thank You for Your Commitment To Advance Patient and Workforce Safety!

Event Outline

- David Hunt, MD – Introduce topic and speakers
- Hardeep Singh, MD, MPH – Overview of the need for proactive EHR risk assessment
- Dean Sittig, PhD – Describe 2025 SAFER guides and updating process
- Patricia Sengstack – DNP – Describe use of SAFER guides
- Q/A

Questions to Run On

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- **Why are the SAFER Guides needed?**
- **What are the SAFER Guides?**
- **How can the SAFER Guides be used in a healthcare organization?**

Share With Us

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What are your questions and concerns with using the SAFER guides in your organization?

Speaker Welcome

Hardeep Singh, MD, MPH

Houston VA Center for Innovations in Quality, Effectiveness & Safety (IQuESt) and Baylor College of Medicine

Types of Health IT Safety Concerns

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- Software malfunction
- Order entry errors
- Unsafe workarounds for entering orders, notes, or referrals
- Data entry or review of the wrong patient's data
- Lack of follow-up on critical information
- Errors in IT system interfaces
- Information and cognitive overload

Health IT Concerns => Patient Harm

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- Errors in prescribing or administering medications
- Incorrect or delayed treatment (e.g. lost referrals)
- Delays or missed diagnoses (e.g. no follow-up of cancer-related test results)
- Patient misidentification
- Missed preventive screenings

EHR Safety Defined: 3 domains

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- **Domain 1: Safe EHR**
  - Events unique/specific to EHRs
  - Clinical data that is Corrupt, Lost, Incorrectly displayed or Failed in Transmission (CLIFT)
- **Domain 2: Using EHR safely**
  - Unsafe or inappropriate use of technology
  - Unsafe changes in the workflows that emerge from EHR use
- **Domain 3: Using EHR to improve safety**
  - Leveraging EHRs to identify unsafe care processes and potential patient safety concerns before harm

The Need for Proactive Risk Assessment

- HHS-sponsored “Safety Assurance Factors for EHR Resilience (SAFER)” Guides
- Developed for organizational risk assessment and guidance
- First released 2014 & revised 2016 & 2024
- Self-assessment using recommended practices:
  - ► Focused on high-risk areas
  - ► All guides freely available

SAFER: Safety Assurance Factors for EHR Resilience

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- **Foundational Guides**
  - High Priority Practices
  - Organizational Responsibilities
- **Infrastructure Guides**
  - System Management
  - Contingency Planning
- **Clinical Process Guides**
  - Patient Identification
  - Computerized Provider Order Entry with CDS
  - Test Results Reporting and Follow-up
  - Clinician Communication

http://www.healthit.gov/safer

Speaker Welcome

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Dean F. Sittig, PhD
University of Texas Health Science Center at Houston
Informatics Review LLC

SAFER Self-Assessment High Priority Practices Checklist

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

			Implementation Status						
			0% Not Implemented	1- 30% Making Progress	31- 60% Halfway There	61- 90% Substantial Progress	91 - 100% Fully Implemented	EHR Limitation	
1.1	Highest-level decision makers in the organization (e.g., boards of directors, owners of physician practices, C-suite executives, and clinical leaders) commit to promoting a culture of safety that incorporates the safety and safe use of EHRs.	*Worksheet 1.1*	○	○	○	○	○	■	Reset
1.2	Users are warned when they attempt to create a record for a new patient whose first and last names are the same as another patient, or when a patient search result returns multiple patients with the same or similar names.[5]	*Worksheet 1.2*	○	○	○	○	○	■	Reset
1.3	Patient data and software application configuration settings critical to the organization's operations are regularly backed up and tested.[10]	*Worksheet 1.3*	○	○	○	○	○	■	Reset
1.4	EHR-based secure messaging systems ensure accurate, reliable, and efficient transmission of high-risk information.	*Worksheet 1.4*	○	○	○	○	○	■	Reset

Recommended Practice - Backup Data

1.3 Patient data and software application configuration settings critical to the organization's operations are regularly backed up and tested.[10]
Checklist

Implementation Status

Not Implemented
Making Progress
Halfway There
Substantial Progress
Fully Implemented

Rationale for Practice or Risk Assessment

Failure of electro-mechanical devices is inevitable. Backup of mission-critical patient data and EHR system configuration allows system restoration to a "pre-failure" state with minimal data and time loss.

Assessment Notes

n Guidance

ion has a daily, off-site, complete, encrypted backup of patient data.[11]

- Critically important patient data should be backed up as close as possible to real-time.
- If using a remotely hosted EHR (e.g., cloud-based solution), the EHR provider backs up data with tape, Internet, redundant drives, or any means necessary to allow full recovery from incidents.[12]

Evidence level	Definition
Required	A rule, regulation, or law requires something identical or similar to this recommendation.
Strong: Research-level evidence	Randomized controlled clinical trials, large clinical before/after studies or case studies have demonstrated increased patient safety associated with the recommendation.
Medium: Practice-level evidence	Reports of adverse patient outcomes have been associated with failure to implement this practice or recommendation or consensus expert opinion support the recommendation.
Low: Context-level evidence	High-performing healthcare organizations routinely follow this best practice or recommendation.

allow full recovery from incidents.[12]

Implementation Guidance

- The organization has a daily, off-site, complete, encrypted backup of patient data.[11]
- Critically important patient data should be backed up as close as possible to real-time.
- If using a remotely hosted EHR (e.g., cloud-based solution), the EHR provider backs up data with tape, Internet, redundant drives, or any means necessary to allow full recovery from incidents.[12]

allow full recovery from incidents.[12]

Overview of Changes Made…

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- **Expert Input**: Engaged subject matter experts from clinical medicine, patient safety, informatics, quality improvement, risk management, human factors engineering, and usability
- **Expanded topics include:** patient-clinician communication, patient access to clinical notes/test results (21st Century Cures Act), use of AI in clinical care, cybersecurity, and enhanced software testing practices.
- **Key Updates Principles**:
  - Eliminated, combined, or clarified recommendations.
  - Incorporated feedback from users and recent research.

Comparison of Original SAFER Guides vs. Revised SAFER Guides

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Feature	Original SAFER Guides (2014)	Revised SAFER Guides (2025)
Number of Guides	8 Guides + High Priority Practices Guide	7 Guides + High Priority Practices Guide
Total Recommendations	147	88
Implementation Examples	540	524
Focus	Initial recommendations for EHR safety	Updated based on new evidence and stakeholder feedback
Alignment with Policies	Supported early adoption of EHR safety practices	Designed to meet current regulatory and clinical needs

Artificial Intelligence Recommendation

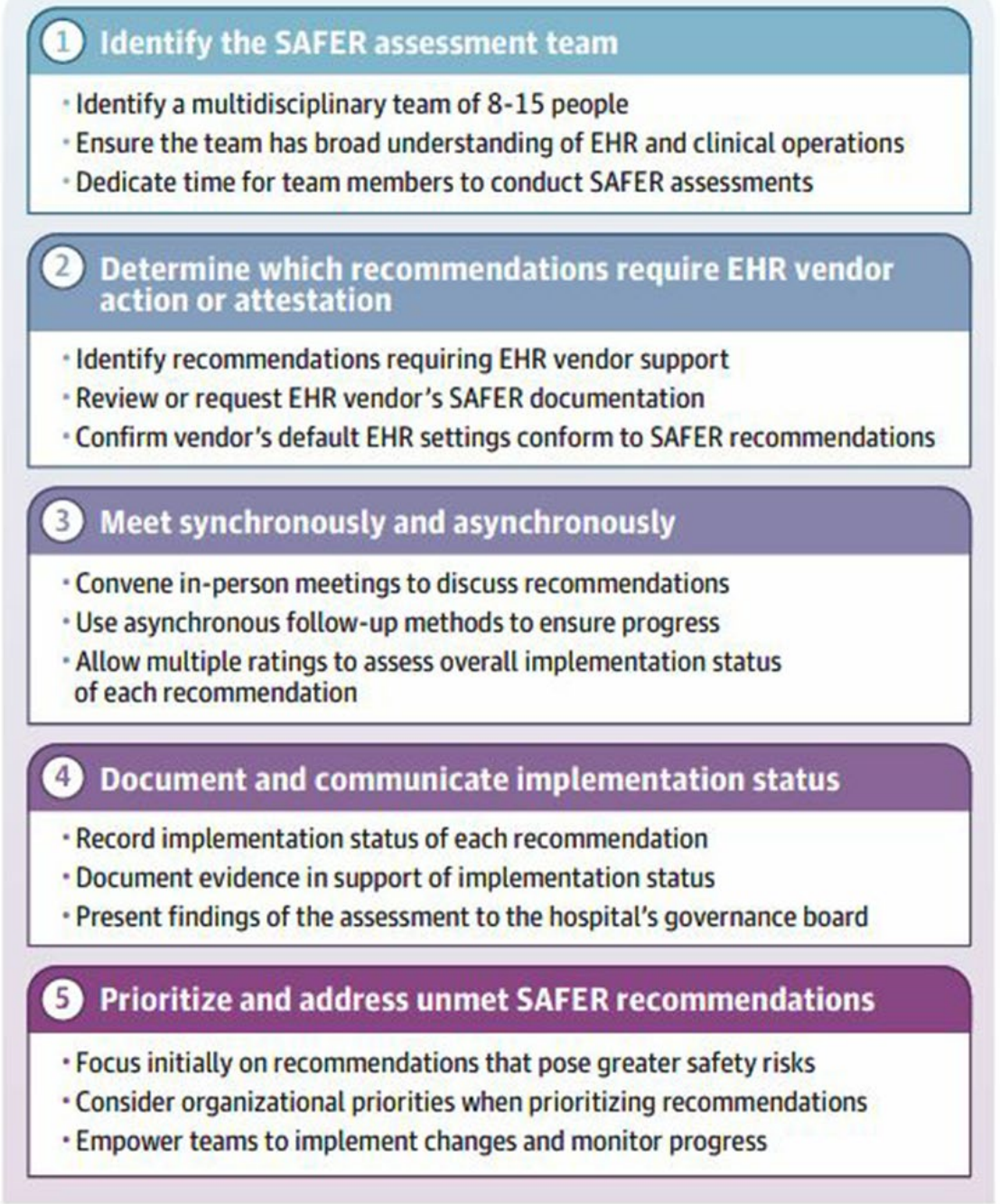
- Conduct or review real-world clinical evaluations published in high-quality, peer-reviewed journals before implementing AI systems.
- Perform independent real-world testing with local data to reduce risks to patient safety.
- Conduct iterative risk-based assessments
- Form a multidisciplinary AI governance and safety committee or expand existing committees to include:
  - Data scientists, informaticians, AI experts, human factors specialists, and clinicians.

Sittig DF, Singh H. Recommendations to Ensure Safety of AI in Real-World Clinical Care. *JAMA*. Published online November 27, 2024. doi:10.1001/jama.2024.24598

Artificial Intelligence Recommendation

- Provide high-quality training programs for clinicians, including:
  - Awareness of risks and benefits.
  - Consent-style agreements acknowledging understanding of risks.
- Ensure patients are educated about the development, use, and oversight of AI systems.
- Require human review and approval of AI-generated recommendations before they are sent to patients.
- Establish reporting mechanisms for clinicians and patients to flag AI-related safety issues.
- Implement a multidisciplinary process to analyze and address reported safety concerns.

Sittig DF, Singh H. Recommendations to Ensure Safety of AI in Real-World Clinical Care. *JAMA*. Published online November 27, 2024. doi:10.1001/jama.2024.24598



EHR indicates electronic health record, and SAFER indicates safety assurance factors for EHR resilience.

VIEWPOINT

February 7, 2022

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

Dean F. Sittig, PhD[1]; Patricia Sengstack, DNP, RN-BC[2]; Hardeep Singh, MD, MPH[3]

» Author Affiliations

JAMA. 2022;327(8):719-720. doi:10.1001/jama.2022.0085

Sittig DF, Sengstack P, Singh H. Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides. JAMA. 2022 Feb 7. doi: 10.1001/jama.2022.0085.

Speaker Welcome

Patricia Sengstack, DNP, NI-BC, FAAN, FACMI
Vanderbilt University School of Nursing

SAFER Guide Review - Vanderbilt

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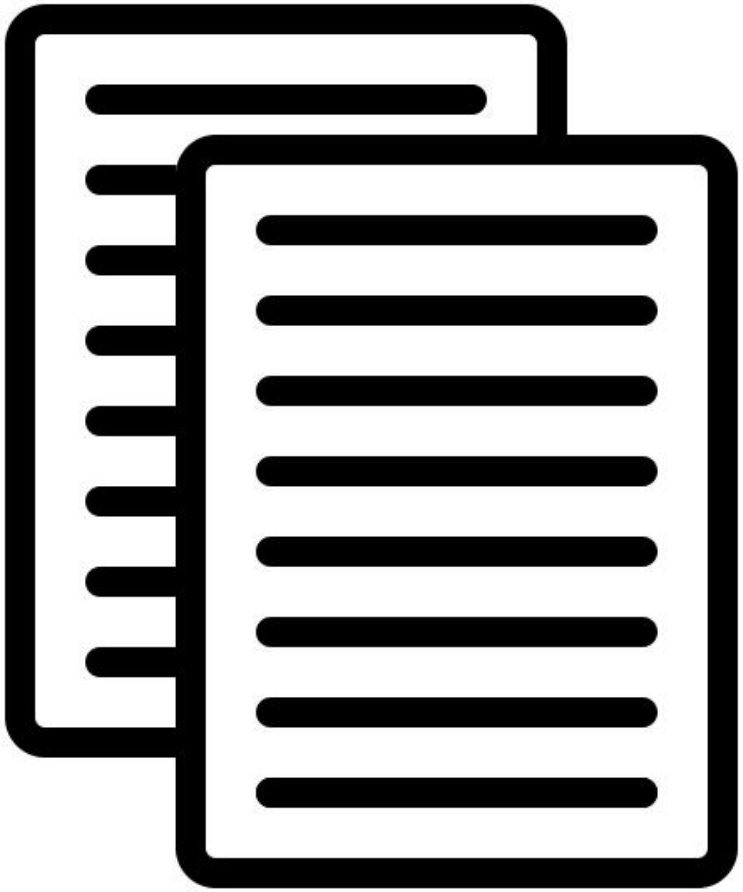
Process

- Bi-Weekly Health IT Clinical Director meetings
- Health IT Clinical Directors 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

- Post in-person (virtual) meetings – transitioned to asynchronous approach
- Program manager:
  - Created electronic surveys
  - Managed logistics around distribution of survey
  - Nudged participants when they hadn't completed the survey
  - Summarized data and created a report
- Started - March 2022

SAFER Guides Survey Created



- Survey was created for each guide.
- Respondents were asked to rate each recommendation using one of the following choices:
  - Fully Implemented
  - Partially Implemented
    - % implemented was required
  - Not Implemented
- Comments could be added to provide further assessment and information

Survey Question Example

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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)

reset

Comments

Expand

Please indicate % of partial implementation:

System Configuration Guide - Results

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1.2	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.	100% - **FULLY IN ALL AREAS** *(Dees, Hughart, Kumah, Nelson, Sengstack, Wanderer, Zafar)*
1.3	The organization's information assets are protected using strong authentication mechanisms.	100% - **FULLY IN ALL AREAS** *(Dees, Hughart, Kumah, Nelson, Sengstack, Wanderer, Zafar)*
1.4	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.	100% - **FULLY IN ALL AREAS** *(Dees, Hughart, Kumah, Nelson, Zafar)*

High Priority Practices Guide - Results

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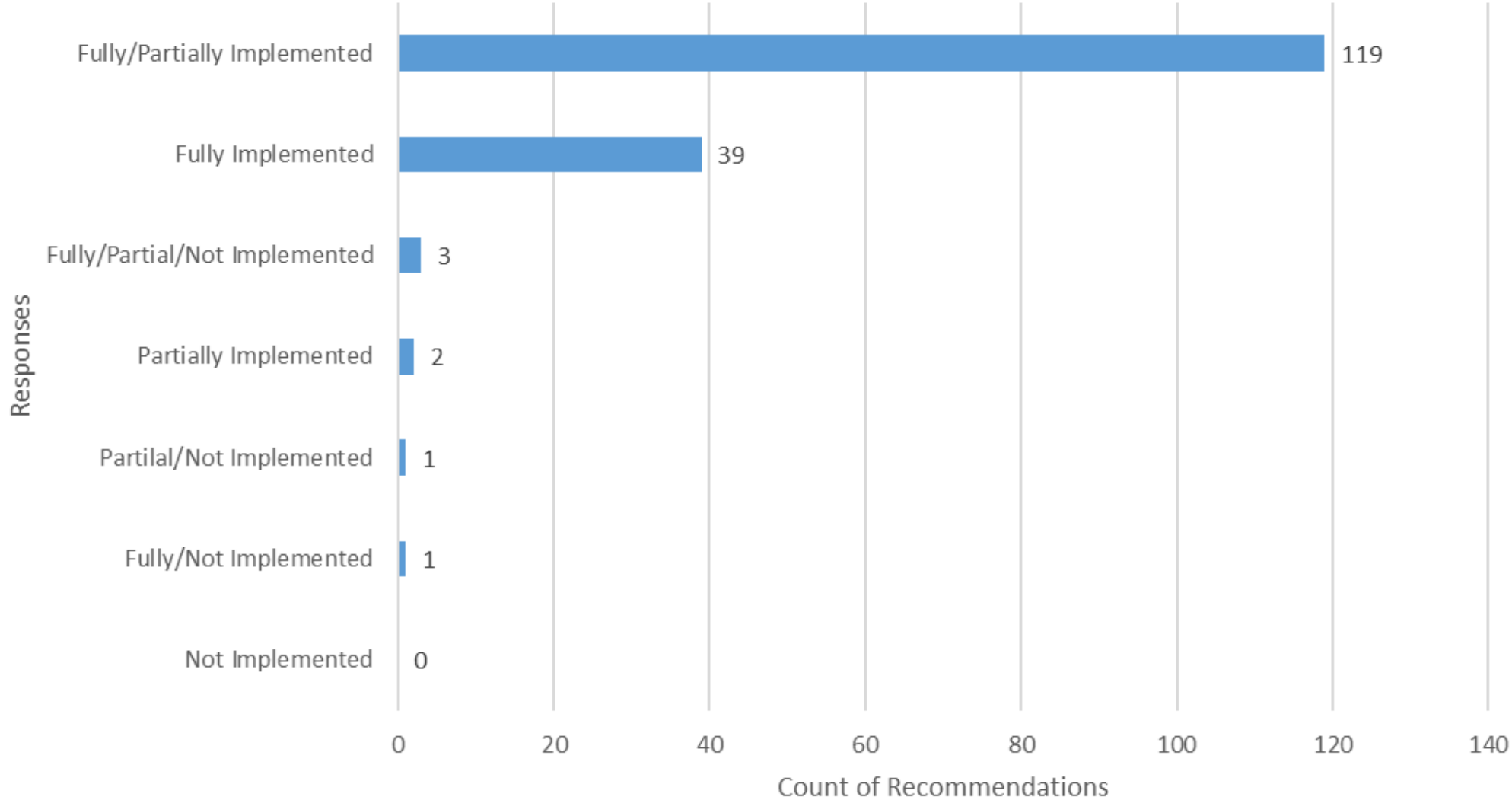
1.3	**Allergies, Problem List entries, and diagnostic test results, including interpretations of those results, such as 'normal' and 'high', are entered/stored using standard, coded data elements in the EHR.** ***Comments:*** • We do not have approval to require that all allergies be coded, some are 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



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Areas of Focus Identified

- First, we wanted to identify any recommendations where respondents indicated that we have “not implemented” the recommendation – (by one or more respondents)
- **OR** - any recommendations where they indicated ≤ 50% partial implementation:
- Contingency Planning - 3
- Computerized Provider Order Entry with CDS - 3
- Clinical Communication - 1

Follow-up Actions

- Discussions at synchronous bi-weekly meetings to review recommendations with differing opinions regarding implementation status.
- Determined priority areas in need of focused attention
- Presented findings to VUMC leadership with recommendations for opportunities for improvement
- Prepare for next year!

Photo: Getty Images

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Thank you!

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- HardeepS@bcm.edu
- Dean.F.Sittig@uth.tmc.edu

Question & Answers

Let us know!

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Based on what you have learned today,

How will your organization use the SAFER Guides in 2025?

***Please submit your response in the chat**

Key Takeaways

- Ensuring EHR safety is a complex undertaking
- SAFER Guides can help (updated in 2025)
- CMS asks healthcare organizations to attest to their review
- Conducting an organizational assessment of their EHR helps improve patient safety

Upcoming Events of Interest

Thank You!

Announcing the Next NAA Monthly National Webinar

Safety Culture: Psychological Safety

Tuesday, February 18, 2025 (Noon- 1:00 PM ET)

Registration is open and can be found on the NAA website

https://cma.ahrq.gov/naafeb2025

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