

SAFER Safety Assurance Factors for EHR Resilience

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General Instructions for the SAFER Self-Assessment Guides

The Safety Assurance Factors for EHR Resilience (SAFER) guides are designed to help healthcare organizations conduct proactive self-assessments to evaluate the safety and effectiveness of their electronic health record (EHR) implementations. The 2025 SAFER guides have been updated and streamlined to focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience in the following areas:

- Organizational Responsibilities
- Patient Identification
- Clinician Communication
- Test Results Reporting and Follow-up
- Computerized Provider Order Entry with Decision Support
- Systems Management
- Contingency Planning
- High Priority Practices A collection of 16 Recommendations from the other 7 Guides

Each of the eight SAFER Guides begins with a Checklist of recommended practices. The downloadable SAFER Guides provide fillable circles that can be used to indicate the extent to which each recommended practice has been implemented in the organization using a 5-point Likert scale. The Practice Worksheet gives a rationale for the practice and provides examples of how to implement each recommended practice. It contains fields to record team member involvement and follow-up actions based on the assessment. The Worksheet also lists the stakeholders who can provide input to assess each practice (sources of input). In addition to the downloadable version, the content of each SAFER Guide, with interactive references and supporting materials, can also be viewed on ONC's website at: https://www.healthit.gov/topic/safety/safer-guides.

The SAFER guides are based on the best available (2024) evidence from the literature and consensus expert opinion. Subject matter experts in patient safety, informatics, quality improvement, risk management, human factors engineering, and usability developed them. Furthermore, they were reviewed by an external group of practicing clinicians, informaticians, and information technology professionals. Each guide contains between 6 and 18 recommended practices including its rationale, implementation guidance, and evidence level. The recommended practices in the SAFER Guides are intended to be useful for all EHR users. However, every organization faces unique circumstances and may implement a particular recommended practice differently. As a result, some of the specific implementation guidance in the SAFER Guides for recommended practices may not be applicable to an organization.

The High Priority Practices guide consists of 16 of the most important and relevant recommendations selected from the other 7 guides. It is designed for practicing clinicians to help them understand, implement, and support EHR safety and safe use within their organization. The other seven guides consist of 88 unique recommendations that are relevant for all healthcare providers and organizations.

The SAFER Guides are designed in part to help deal with safety concerns created by the continuously changing sociotechnical landscape that healthcare organizations face. Therefore, changes in technology, clinical practice standards, regulations, and policy should be taken into account when using the SAFER Guides. Periodic self-assessments using the SAFER Guides may also help organizations identify areas where it is particularly important to address the implications of these practice or EHR-based changes for the safety and safe use of EHRs. Ultimately, the goal is to improve the overall safety of our health care system and improve patient outcomes.

The SAFER Guides are not intended to be used for legal compliance purposes, and implementation of a recommended practice does not guarantee compliance with the HIPAA Security or Privacy Rules, Medicare or Medicaid Conditions of Participation, or any other laws or regulations. The SAFER Guides are for informational purposes only and are not intended to be an exhaustive or definitive source. They do not constitute legal advice. Users of the SAFER Guides are encouraged to consult with their own legal counsel regarding compliance with Medicare or Medicaid program requirements, and any other laws.

For additional information on Medicare and Medicaid program requirements, please visit the Centers for Medicare & Medicaid Services website at www.cms.gov. For more information on HIPAA, please visit the HHS Office for Civil Rights website at www.hhs.gov/ ocr.



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Self-Assessment High Priority Practices

Introduction

As the modern healthcare delivery system continues to evolve, the safe and effective design, development, implementation, and use of electronic health records (EHRs) as the primary means of patient data collection, storage, retrieval, and communication becomes more apparent. The SAFER guides were designed to help clinicians, healthcare organizations, and EHR vendors carry out self-assessments of their EHRs as implemented within a healthcare delivery organization. Many of the SAFER recommendations require that EHR vendors design and develop the software required to enable users to complete the recommendation, but all recommendations require effort on the part of clinicians and healthcare delivery organizations to configure, implement, and use the EHR to its fullest extent to meet the recommendations.

The High Priority Practices SAFER Guide includes 16 recommendations selected from the other seven guides because of their relevance and importance for practicing clinicians to understand and support. While front-line clinicians need to be aware of the full complement of 88 recommendations across all of the guides, these are the most critical for clinicians to help mitigate safety risks while advocating for organization-wide prioritization of recommendations that have not yet been implemented.

SAFER recommendations should help healthcare organizations identify, prevent, measure, and monitor EHR-related patient safety risks. These risks result from both "social" (involving people, leadership, workflow, and policies) and "technical" (involving EHR hardware and software and system-to-system interfaces, EHR configurations, upgrades, and maintenance) challenges. This guide will help people responsible for EHR safety in each specific complex "sociotechnical" healthcare organization focus on the most important safety challenges and risks introduced by EHRs.

The 2024 revision of the High-Priority SAFER guide includes many new recommendations. One focuses on the safe and effective use of artificial intelligence (AI)enabled applications and another on the use of patient portals and patient-clinician communication. These relatively new features offer great promise for improvements in the delivery of safe and effective healthcare, but both have risks to patient safety that must be managed.

While each of the seven individual SAFER guides is designed to be used by a multi-disciplinary group, this High Priority Guide is for front-line clinicians. No one expects every clinician to understand the depth and breadth of every recommendation or the accompanying implementation guidance suggestions. The SAFER guides should prompt clinicians to ask questions and hopefully start a conversation among other clinicians, administrators, and information technology professionals as they work collaboratively to design, develop, and implement safe and effective electronic health record systems.

We hope that this collaboration will lead to a consensus about the organization's future path to optimize EHR-related safety and quality: setting priorities among the recommended practices not yet addressed, ensuring a plan is in place to maintain recommended practices already in place, dedicating the required resources to make necessary improvements, and working together to mitigate the highest priority safety risks introduced by the EHR.



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The Checklist is structured as a quick way to enter and print your self-assessment.

C A E E D Self Assessment

Select the level of implementation achieved by your organization for each Recommended Practice. Your Implementation Status will be reflected on the Recommended Practice Worksheet in this PDF. The implementation status scales are as followed:

Not Implemented (0%) The organization has not implemented this recommendation.	Making Progress (1 30%) The organization is in the early or pilot phase of implementing this recommendation as evidenced by following or adopting less than 30% of the implementation guidance.	Halfway there (31 60%) The organization is implementing this recommendation and is following or has adopted approximately half of the implementation guidance.	Substantial Progress (61 90%) The organization has nearly implemented this recommendation and is following or has adopted much of the implementation guidance.	Fully Implemented (91 100%) The organization follows this recommendation, and most implementation guidance is followed consistently and widely adopted.
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The organization should check the following box if there are some limitations with the current version of their EHR that preclude them from fully implementing this recommendation.

EHR Limitation - The EHR does not offer the features/functionality required to fully implement this recommendation or the implementation guidance.

	Recommended Practices for Domain 1 — Safe Health IT	Implementation Status
		0% 1-30% 31-60% 61-90% 91-100% Not Making Halfway Substantial Fully EHR Implemented Progress There Progress Implemented Limitation
The <i>Domain</i> associated with the <i>Recommended</i> <i>Practice(s)</i> appears at the top of the	1.1 Disaster recovery plans must be in place and reviewed at least annually, for computing and networking infrastructure that runs applications critical to the organization's clinical and administrative operations, including hardware duplication, network redundancy, and data replication.	Worksheet 1.1 Reset
column	1.2 An electric generator and sufficient fuel are available to support the EHR during an extended power outage.	Worksheet 1.2
	1.3 Paper forms are available to replace key EHR functions during downtimes.	Worksheet 1.3 C Reset
The Recommended	1.4 Patient data and software application configurations critical to the organization's operations are regularly backed up and tested.	Worksheet 1.4
	1.5 Policies and procedures are in place to ensure accurate patient identification when preparing for, during, and after downtimes. ²⁴	Worksheet 1.5
<i>Practice(s)</i> for the topic appears below the		
associated <i>Domain</i> .		To the right of reach <i>Recommended</i> <i>Practice</i> is a link to the Recommended Practice Worksheet in this PDF.
		The Worksheet provides guidance on

implementing the practice.

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Reco	mmended Practices for <u>Domain 1 — Safe Health IT</u>			In	npleme	entation St	atus	
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 Imp	Not	1- 30% Making Progress	31- 60% Halfway There	Substantial F	100% Jily EHR mented Limitation	
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						
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						
1.4	EHR-based secure messaging systems ensure accurate, reliable, and efficient transmission of high-risk information.	Worksheet 1.4						
1.5	Artificial Intelligence (AI)-enabled application developers, EHR vendors, and healthcare organizations using AI-enabled systems or EHRs with enhanced AI features or functions share responsibility (based on their ability and resources available) for ensuring AI safety. This shared responsibility includes appropriate clinical, technical, and administrative governance, policies, procedures, people, and technologies to ensure AI is monitored and that its use is safe, secure, private, ethical, and equitable. ²⁰	<u>Worksheet 1.5</u>						
Deee	mmanded Brastings for Domain 2 Using Health IT Sa	Folk (In	npleme	entation St	atus	
Reco	mmended Practices for Domain 2 — Using Health IT Sa t		Not		31- 60% Halfway There	Substantial F	100% ully EHR mented Limitation	
2.1	Healthcare organizations and EHR vendors share responsibility for identifying and addressing EHR safety concerns.	Worksheet 2.1						
2.2	The EHR inbox and its use is optimized to reduce inbox burden.	Worksheet 2.2						
2.3	Patient photographs are collected during patient registration and displayed in multiple places in the EHR to improve patient identification. ³⁷	Worksheet 2.3						
2.4	Written policies specify unambiguous responsibility for test result follow-up with a shared understanding of that responsibility among all involved in providing follow-up care. ⁴⁵⁻⁵⁴	Worksheet 2.4						



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Reco.	System hard and clinical a modifications individually a systems usin consists of: • Testing produc data im • Testing and rel collabo • Monito any ha • Notifyin after, p	actices for Domain 2 - lware, operating and net application version upda s, and local customization and in the context of oth ng a standardized appro- g before go-live and as in tion to ensure adequate tegrity g based on real-world, cl evant scenarios incorpo- prative workflows ⁵⁹ ring all systems for a sho rdware or software char ng end users before, and otentially impactful char tions or clinical content	work software, tes, ons are tested er integrated bach. This Installed in performance and inically authentic, rating ort time following tiges reminded them tiges to	afely Worksheet 2.5	0% Not Implemented	In 1- 30% Making Progress	npleme 31- 60% Halfway There	entation Status 61-90% 91-100% Substantial Fully EHR Progress Implemented Limitation	
2.6	guidance in points in the informative,	and reminders provide u the correct clinical conte workflow. Alerts and re actionable, and judicious ant, patient-specific not	ext at relevant minders are sly limited to the	<u>Worksheet 2.6</u>					
2.7	including how	ained on ransomware pr w to identify malicious e Illers asking for login acc 0,71	mails and fraudulent	<u>Worksheet 2.7</u>					
2.8	Staff are trai recovery pro	ned and tested on dowr cedures. ⁷⁹	time and	Worksheet 2.8					
Reco	mmended Pi	ractices for <mark>Domain 3 -</mark>	– Monitoring Safety	<u> </u>	0%	1- 30%	31- 60%	entation Status 61-90% 91-100% Substantial Fully EHR	
3.1	prevention,	ns have a strategy and i identification, measuren f high priority EHR safet	nent, monitoring, and	<u>Worksheet 3.1</u>	Not Implemented	Making Progress	Halfway There	Substantial Fully EHR Progress Implemented Limitation	
3.2	patient notifi	nal policies and procedu ication of both normal an the timeliness of notifica	nd abnormal test	<u>Worksheet 3.2</u>					
3.3	communicat	ables the monitoring of ion patterns related to c d patient portal notificati	linical messages,	<u>Worksheet 3.3</u>					

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Clinicians should complete this self-assessment and evaluate potential health IT-related patient safety risks addressed by this specific SAFER Guide within the context of your particular healthcare organization.

This Team Worksheet is intended to help organizations document the names and roles of the self-assessment team, as well as individual team members' activities. Typically, team members will be drawn from a number of different areas within your organization, and in some instances, from external sources. The Suggested Sources of Input section in each Recommended Practice Worksheet identifies the types of expertise or services to consider engaging. It may be particularly useful to engage specific clinician and other leaders with accountability for safety practices identified in this guide.

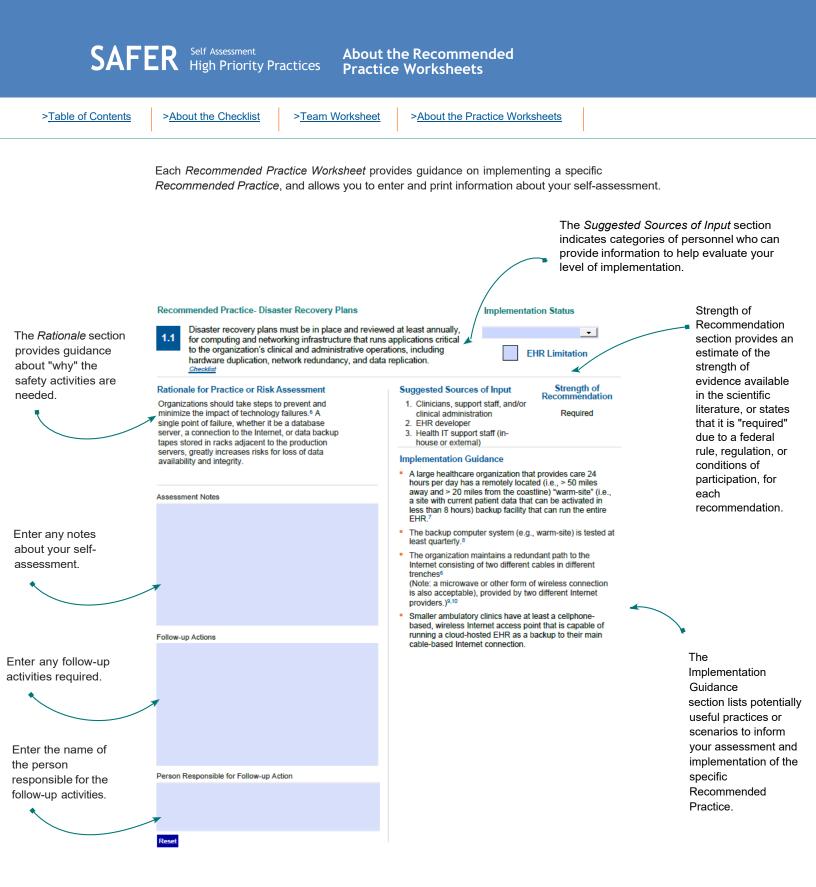
The Worksheet includes fillable boxes that allow you to document relevant information. The Assessment Team Leader box allows documentation of the person or persons responsible for ensuring that the self-assessment is completed. The section labeled Assessment Team Members enables you to record the names of individuals, departments, or other organizations that contributed to the self-assessment. The date that the self-assessment is completed can be recorded in the Assessment Completion Date section and can also serve as a reminder for periodic reassessments. The section labeled Assessment Team Notes is intended to be used, as needed, to record important considerations or conclusions arrived at through the assessment process. This section can also be used to track important factors such as pending software updates, vacant key leadership positions, resource needs, and challenges and barriers to completing the self-assessment or implementing the Recommended Practices in this SAFER Guide.

Assessment Completion Date

Assessment Team Members

Assessment Team Leader

Assessment Team Notes



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 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. <i>Checklist</i> 	Implement	tation Status EHR Limitation		
Rationale for Practice or Risk Assessment	Suggested Sources of Input	Strength of		
A culture of safety promoted by top executives encourages continuous learning, improvement, and engagement from all levels of the organization. By actively and transparently prioritizing safety, organizational leadership can help ensure systems and processes remain effective and responsive to emerging EHR-related threats and challenges. By prioritizing EHR safety, leadership promotes collaboration across all levels, engaging clinical staff, IT professionals, and administrative	 Large organization: Board of directors, President/Vice President, C-Suite executives, Clinical leaders Small organization: Owners, Clinical leaders, COO 	Recommendation Medium		
personnel in a unified approach to addressing safety concerns and implementing effective solutions. Ultimately, this high-level focus on EHR safety ensures strategic investments in reliable and efficient health IT systems, further solidifying the organization's commitment to safety and excellence.				
Assessment Notes	 High-level decision makers provide resources to ensure that safety is adoption and use of EHRs can be fashion.³ 	ssues associated with		
	 High-level decision makers revier safety assessments, such as thosuse. 			
	 High-level decision makers ident safety goals (e.g., percentage of results that are acknowledged wi appropriate for the importance, s setting or percentage of medicati 	abnormal laboratory test thin a timeframe everity, and healthcare		
Follow-up Actions	following barcode identification), goals are being reached, and ad shortcomings. ³			
	 High-level decision makers ident members who can provide system EHR vendors regarding perceive EHRs.⁴ 	matic feedback to the		
Person Responsible for Follow-up Action				

nended Practice 1.2 Domain 1 eet Safe Health IT
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Implementation Status
EHR Limitation
Suggested Sources of Input Strength of Recommendation
 EHR developer Health IT support staff Medium
Implementation Guidance
 During the creation of a new patient record, a phonetic algorithm such as Soundex⁸ is used to check for patients with similar sounding names in the system and display an alert or warning if one exists.
When looking up a patient, if the results list returns multiple patients with similar demographic data, the names are displayed in a visually distinct manner.
The system monitors for similar names, name variants (e.g., Robert, Rob, Bob, Robbie), or changed last names (e.g., marriage, divorce, adoption), when other demographics match.
An alert provides additional demographic information context for the existing patient to help the user confirm or rule out that it is the same patient.
Organizations implement an ID reentry intervention and/or a distinct naming intervention to reduce wrong-patient errors in the nursery or NICU, where sets of twins, triplets, and higher- order multiples are prevalent. ⁷
Name alerts in combination with other interventions (e.g., blood type testing) prevent patient record confusion in critical areas such as blood transfusions. ⁹

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Recommended Practice - Backup Data	Implementa	ation Status
1.3 Patient data and software application configuration settings critical to the organization's operations are regularly backed up and tested. ¹⁰ Checklist		EHR Limitation
Rationale for Practice or Risk Assessment Failure of electro-mechanical devices is inevitable.	Suggested Sources of Input 1. Clinicians, support staff, and/or clinical administration	Strength of Recommendation
Backup of mission-critical patient data and EHR system configuration allows system restoration to a "pre-failure" state with minimal data and time loss.	 2. EHR developer 3. Health IT support staff 	Required
	 Implementation Guidance The organization has a daily, off-s backup of patient data.¹¹ Critically important patient data sh 	
Assessment Notes	 close as possible to real-time. If using a remotely hosted EHR (e solution), the EHR provider backs Internet, redundant drives, or any allow full recovery from incidents. The off-site backup is tested regul system and patient data restore) (monthly basis).¹³ The content required to configure regularly (optimally every month a EHR or supporting computer system The organization maintains multip created at different times. Backup media are physically secutorial system and patient times. 	e.g., cloud-based up data with tape, means necessary to 12 larly (i.e., complete coptimally on at least a the system is backed up and always before every em upgrade). le backups, which are ured in a location
Follow-up Actions	 separate from the operational data The backup storage media should (e.g., Air gap) from normal file sto recovery from ransomware attack Backup media are rendered unrea to scramble media contents or phy media) before disposal. The organization has a "read-only that is updated frequently (optima least hourly). The read-only EHR system is test least weekly). Users can print from the read-only If there is a "unit-level" read-only be 	l be separate and distinct rage to facilitate s. ¹⁴ adable (i.e., use software ysically destroy/shred " backup EHR system lly in real-time, but at red regularly (optimally at y EHR system.
Person Responsible for Follow-up Action	isconnected to a local UPS or "red connected to the organization's bac	plug" (i.e., an outlet

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Recommended Practice - Secure Messaging	Implementation Status
1.4 EHR-based secure messaging systems ensure accurate reliable, and efficient transmission of high-risk information <u>Checklist</u>	
Rationale for Practice or Risk Assessment	Suggested Sources of Input Strength of
To avoid unnecessary interruptions and distractions, critical and time-sensitive messages and results to clinicians should be clearly differentiated from routine or information- only communication that does not require immediate attention or action.	 Clinicians Ancillary staff Laboratory and diagnostic imaging staff IT staff Vendors
Assessment Notes Follow-up Actions	 Implementation Guidance The EHR ensures close loop communication, which implies that "all patient data and information that may require an action are delivered and communicated to the right individuals, at the right time, through the right mode to allow interpretation, critical review, reconciliation, initiation of action, acknowledgment, and appropriate documentation."¹⁵ Critical and time-sensitive messages to clinicians are clearly differentiated from routine or information-only communication that does not require immediate attention or action.¹⁶ EHR allows urgency levels to be assigned to messages and presents urgent messages in a visually distinct manner. The organization provides guidance to promote succinct and intuitive message content.^{17,18} Messages can be marked for follow-up on a future date and are automatically re-sent on the specified date and appear as a new message.¹⁹ Organization policy for communication requires EHR documentation of patient-specific communication that occurs outside the EHR (e.g., e-mail or text messages sent via computer, smartphone, pager, wireless local area networkbased communication devices, or other communication
Person Responsible for Follow-up Action	 system not integrated with the EHR) within the patient's EHR. Information that should be recorded in the patient's EHR includes sender, recipient, content, time sent, and time acknowledged (if applicable). EHR messaging modules automatically capture and store message sender, recipient, content, time, and acknowledgment data. The EHR and the organization enable escalation of messages that are unread within a time period (or if no response has been received by the sender depending on urgency). Escalation could involve automatically forwarding the message to an alternate or supervising clinician if the intended recipient is unavailable.¹⁶

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Recommended Practice - Artificial Intelligence

Artificial Intelligence (AI)-enabled application developers, EHR vendors, and healthcare organizations using AI-enabled systems or EHRs with enhanced AI features or functions share responsibility (based on their ability and resources available) for ensuring AI safety. This shared responsibility includes appropriate clinical, technical, and administrative governance, policies, procedures, people, and technologies to ensure AI is monitored and that its use is safe, secure, private, ethical, and equitable.²⁰ Checklist

Rationale for Practice or Risk Assessment

The integration of AI-enabled systems in healthcare has the potential to revolutionize clinical decision-making, but it also introduces known and unknown risks that must be mitigated.²¹ As healthcare organizations adapt their clinical and administrative workflows to new Al-driven technologies, unintended adverse consequences will inevitably occur, particularly during the transition period. Early AI applications have already exhibited unintended biases and "hallucinations," leading to false information that can harm patients. To address these risks, healthcare organizations and AI/EHR developers must collaborate, leveraging their complementary expertise to ensure AI systems are robust, reliable, and transparent. Continuous monitoring and updating are crucial to maintain system integrity, prioritize patient safety, and ensure data security. Conducting a risk assessment of AI is essential to identify and mitigate these risks, build trust among users and stakeholders, and promote safe and effective adoption of AI in healthcare.

Assessment Notes

1.5

Follow-up Actions

Person Responsible for Follow-up Action

Suggested Sources of Input

- 1. Large organizations: Clinicians, Clinical Administration, Health IT Support Staff, EHR (or AI) developer, AI experts
- 2. Small organizations: Wait for better evidence

Implementation Guidance

- Organizations conduct ongoing real-world testing and monitoring with local data to minimize the risk to patient safety while these new AI-enabled systems mature.
- Healthcare organizations should conduct, or wait for realworld, clinical evaluations published in high-quality medical journals (e.g., NLM's new list of Clinically Useful Journals https://jmla.mlanet.org/ojs/jmla/article/view/1631) before they start using Al-enabled systems on a routine basis. While peer-reviewed publication does not ensure safety or effectiveness of any clinical or administrative intervention, it can provide an external, unbiased assessment of the development, testing, implementation, or use of an Alenabled system, tool, or intervention.
- Healthcare organizations should add additional people with AI expertise such as data scientists, informaticians, machine-learning and AI operational personnel, human factors experts, and clinical expert(s) to their existing multidisciplinary EHR or CDS oversight committee(s). These individuals, as a group, should be capable of understanding and evaluating the performance of AIenabled systems. These new committee members should meet regularly to review requests for new applications and proactively monitor the performance of AI- enabled applications in use.
- The committee should maintain an inventory of clinically deployed, AI-enabled systems that includes information on deployment date, current version, responsible personnel, last reviewed date, authorized users, authorized purpose, source of data used to generate, or train, the AI system, and external source(s) of validation, verification, and performance comparison.

Strength of Recommendation

Medium

EHR Limitation

omain 1 Ife Health IT

Implementation Status

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Recommended Practice - Artificial Intelligence (cont'd)

1.5 Artificial Intelligence* (AI)-enabled application developers, EHR vendors, and healthcare organizations using AI-enabled systems or EHRs with enhanced AI features or functions share responsibility (based on their ability and resources available) for ensuring AI safety. This shared responsibility includes appropriate clinical, technical, and administrative governance, policies, procedures, people, and technologies to ensure AI is monitored and that its use is safe, secure, private, ethical, and equitable.²⁰ Checklist

Implementation Guidance (cont'd)

- Before organizations use AI-enabled systems for patient care (e.g., respond to patient messages, generate differential diagnoses, treatment plans, or notes describing the findings from visits), they must have policies and procedures to ensure that patients and clinicians are aware, when possible, that AI-enabled systems are being used for clinical and/or administrative decision making.²²
- Organizations should ensure that patients understand when and where AI-enabled systems were developed, how they may be used, and the role of clinicians in reviewing the AI system's output before giving their consent.²³
- Al-generated recommendations should be reviewed and approved by humans who take responsibility for the recommendation(s) before they are sent to patients.
- Organizations should maintain and regularly review a transaction log of AI system use (i.e., similar to the audit log of the EHR) that includes the AI version in use, date/ time of AI system use, patient ID, responsible clinical user ID, input data used by the AI system, AI recommendation or output.
- Organizations have an internal process to evaluate Alenabled system performance on local data before routine clinical use and periodically following implementation to check for drift,²⁴ bias,²⁵ or decay,²⁶ for example.²⁷ This process should include ongoing regular testing of Al applications in the (live) production system to ensure the safe performance and safe use of these program's references.²⁸
- Organizations have high-quality training programs for clinicians interested in using AI systems that focus on the known and potential risks of using these systems.
- Organizations have a formal consent-style process, complete with signatures, to ensure clinicians understand the risks and benefits of using AI tools before their access is enabled.

- Organizations must provide clear written instructions and authority to enable anyone in the organization's information technology department to disable, stop, or turn off the artificial intelligence-enabled systems, 24 hours a day, seven days a week, in the event of a problem.²⁹
- Similar to an organization's preparation for an EHR downtime, organizations must have an established policy and procedure to manage clinical and administrative processes that have become dependent on AI automation, when the AI is not available.
- Organizations should have a clear process for reporting Alrelated safety issues and a process for analyzing these issues and mitigating risks.³⁰

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Recommended Practice - Involve EHR Vendor 2.1 Healthcare organizations and EHR vendors share responsibility for identifying and addressing EHR safety concerns. Checklist	Implementation Status EHR Limitation
Rationale for Practice or Risk Assessment By working together, healthcare organizations and EHR vendors leverage their respective expertise to prioritize and share responsibility for patient safety. Healthcare organizations bring firsthand knowledge of clinical workflows and real-world EHR applications, while vendors contribute technical expertise and understanding of the system's architecture. Through continuous collaboration, they can ensure EHR systems evolve to meet emerging needs, address new safety concerns, and optimize patient care. This joint approach fosters a culture of shared	Suggested Sources of InputStrength of Recommendation1. Large organization: Board of directors, EHR vendors, Clinical and IT leadership teamMedium2. Small organization: Owners, EHR developersEHR developers
accountability, driving ongoing improvement and mitigating risks associated with EHRs and AI integration. Assessment Notes	 Implementation Guidance Organizations should have a documented process for monitoring information provided by the EHR vendor with regard to existing defects. When defects that previously required workarounds are resolved, users receive appropriate training. EHR vendors create their own set of system-specific guidance to help their clients configure their EHRs to meet the SAFER Guide recommendations.³¹ Healthcare organizations and EHR vendors review the SAFER Guide recommendations annually.^{31,32} EHR vendors are provided feedback from clinicians on potential safety enhancements to the system.^{31,32}
Follow-up Actions Person Responsible for Follow-up Action	

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Recommended Practice - Inbox Design, Configuration,	
2.2 The EHR inbox and its use is optimized to reduce inbox burden. <u>Checklist</u>	EHR Limitation
Rationale for Practice or Risk Assessment	Suggested Sources of Input Strength of Recommendation
Inbox configuration aligned with its effective and efficient management can help clinicians focus on important and high-priority information.	1. CliniciansMedium2. Vendors3. IT staff
	Implementation Guidance
Assessment Notes	 High-priority messages, abnormal test results, or otherwise time-sensitive inbox messages and tasks are visually distinct from routine inbox communication.¹⁶
	 The EHR allows users to organize and prioritize inbox content, including allowing sorting, filtering, and flagging features preferred by individual clinicians (e.g., based on date, source, patient, urgency, message type).^{16,33}
	Inbox configuration and management allows support staff to triage and act on messages within their scope of practice (e.g., processing refill requests, communicating normal test results, scheduling visits) without requiring the clinician to read or sort through administrative and non- medical queries. ^{34,35}
	 Inbox functionality includes the ability to flag, forward, and add comments to messages and tasks.^{16,34}
Follow-up Actions	 Out-of-office messaging functionality is enabled to make it clear to the sender that an inbox is not being monitored.¹⁶
	 The EHR allows automatic message forwarding to a surrogate clinician during a specific time period or circumstance, such as when the clinician is absent from work.
	 The organization's clinical leadership actively works to identify and mitigate inbox-related burdens by implementing processes designed to facilitate team communication and streamline inbox content.³⁶
	 Appropriately tested and effective artificial intelligence solutions are integrated to help categorize messages and draft suggested responses to patients.³⁵
Person Responsible for Follow-up Action	

	ecommended Practice 2.3 /orksheet	Domain 2 Using Health IT Safely
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Recommended Practice - Patient Photographs	Implem	entation Status
2.3 Patient photographs are collected during patient registration and displayed in multiple places in the improve patient identification. ³⁷ Checklist		EHR Limitation
Rationale for Practice or Risk Assessment		Other ath of
The display of color patient photographs in the main	Suggested Sources of Input	Strength of Recommendation
banner of an EHR, in patient lists, and in other areas of the EHR, when utilized either on desktop computers or mobile devices, is an effective, non-interruptive method to improve patient identification and reduce wrong patient errors. ³⁷⁻⁴²	 EHR developer Registration Staff 	Strong
	Implementation Guidance	
Assessment Notes	registration, admission to the believe a change in appearar photograph. ^{37,38,43}	hs of age at the time of patient hospital, or any time staff nce warrants updating the
	 Patient photographs are displ functions of the EHR supporte patient banners, patient lists, search, and secure messagin 	ed by the vendor, including patient scheduling, patient ng.
	 Patient photographs are displ supported by the vendor inclumobile devices. 	layed in the EHR in all devices uding desktop computers and
Follow-up Actions	Policies and practices, that an and religious practices with re- coverings, are developed and guidance for capturing patient and how to capture them, and patient photo (e.g., the patient greater than 50% of the imag	egard to face and head d implemented that provide t photographs, including when d describing the optimal it's face is centered and
	 Reports are utilized to monito patient photographs, and per projects are utilized to improv 	formance improvement
Person Responsible for Follow-up Action		

SAFER Self Assessment High Priority Practices Worksh	mended Practice 2.4 neet	Domain 2 Using Health IT Safely
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Recommended Practice - Test Result Follow-up	Implement	tation Status
2.4 Written policies specify unambiguous responsibility for test result follow-up with a shared understanding of that responsibility among all involved in providing follow-up care. ⁴⁵⁻⁵⁴ <u>Checklist</u>	t	EHR Limitation
Rationale for Practice or Risk Assessment	Suggested Sources of Input	Strength of Recommendation
New workflows resulting from the introduction of EHRs can introduce new hazards related to miscommunication of responsibility for follow-up. Ambiguous responsibility increases the risk of follow-up failure. ^{55,56}	 Clinicians, support staff, and/or clinical administration Diagnostic services 	Medium
	Implementation Guidance	
Assessment Notes	 In the outpatient setting, the order responsible for follow-up unless hresponsibility (e.g., to a covering should be documented in the EH delegate.^{57,58} 	ne or she delegates this clinician). Delegation R and accepted by the
	 In organizations with trainees (e. ultimate responsibility defaults to in the event of a change of servic an ordering clinician. 	the supervising attending
	 Ordering clinicians in any setting follow-up care, unless that respon transferred to another clinician w responsibility.⁵² 	nsibility is unambiguously
Follow-up Actions		
Person Responsible for Follow-up Action		

2.5

System hardware, operating and network software, and clinical application version updates, modifications, or local customizations are tested individually and in the context of other integrated systems using a standardized approach. This consists of:

- Testing before go-live and as installed in production to ensure adequate performance and data integrity
- Testing based on real-world, clinically authentic, and relevant scenarios incorporating collaborative workflows⁵⁹
- Monitoring all systems for a short time following any hardware or software changes
- Notifying end users before, and reminded them after, potentially impactful changes to applications or clinical content assets

Checklist **Implementation Status Rationale for Practice or Risk Assessment** Failure to adequately test system hardware, software, and configuration or customization of **EHR Limitation** clinical applications can lead to data integrity issues and impede response time, reliability, Suggested Sources of Input and error-free operation. Strength of Recommendation 1. Health IT support staff 2. EHR vendor Medium Assessment Notes **Implementation Guidance** Software enhancements and updates are installed and tested in a test environment prior to moving into the production environment. New versions of the EHR system are enabled in a test environment with functionality sufficient for end-to-end testing of multidisciplinary workflows prior to release in the live/production environment. Customizations made by the organization, department, or user are tested to ensure they do not adversely impact other aspects of the system or interoperability Follow-up Actions with internal or external systems. Simulation training is conducted for clinical processes such as order entry, pharmacy review, nurse notification, medication fill, medication administration, and multidisciplinary clinical documentation to ensure that the application addresses the organization's needs. The organization has created a comprehensive test plan that validates the performance of each major function, including screen appearance, the graphic representation of data, alerts, and the accurate generation of reports.60 Person Responsible for Follow-up Action Data migration processes and protocols are in place to ensure data integrity after transmitting data from one EHR system to another, changing the format of data (e.g., free text to structured), and clinical code updates (e.g., SNOMED, ICD-10, LOINC). Users are provided with a concise, relevant summary of software or component updates that impact their

workflows or the data they rely on.

SAFER Self Assessment Recomm High Priority Practices Workshe	ended Practice 2.6 et	Domain 2 Using Health IT Safely
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 Recommended Practice - Alerts and Reminders CDS alerts and reminders provide unambiguous guidance clinical context at relevant points in the workflow. Alerts and the second second	ce in the correct	plementation Status
informative, actionable, and judiciously limited to the mos specific notifications. <u>Checklist</u>		EHR Limitation
Rationale for Practice or Risk Assessment Well-designed and configured alerts within clinical workflows can promote patient safety and positive patient outcomes without overwhelming ordering providers and other clinical staff with irrelevant information. Whether they are warnings about critical drug interactions or notifications based on preventive care guidelines, alerts should be tiered by severity and clearly and concisely describe the next action to take. Careful consideration should be given to	Suggested Sources of In 1. Clinicians 2. Clinical support staff 3. Clinical administration 4. Pharmacists 5. Nurses 6. Informatics staff 7. Health IT support staff 8. EHR developer	Recommendation Medium
defining alert levels, determining the context in which they will fire, and understanding the risks and benefits of potential clinical workflow disruptions (e.g., hard stops that require documentation of override rationale or soft stops that are dismissible without further action). Assessment Notes	 Implementation Guidance The organization's CDS governance has a process for developing, maintaining, and regularly revising alerts based on clinical user feedback, emerging knowledge, and high override rates.⁶¹ The EHR allows users to provide feedback on CDS content directly within the workflow.⁶² Alerts are designed to appear in the right place in the workflow for the right user (e.g., for the provider during order selection, the pharmacist during order fulfillment, and the nurse during medication administration).⁶³ 	

Follow-up Actions

Person Responsible for Follow-up Action

calculations are sufficiently explained (e.g., decision trees, templated text, or feature importance) along with its recommendations.⁶⁴

If CDS uses AI such as a predictive model, the model's

 The organization has established standards limiting the use of interruptive alerts to only the most critical warnings.⁶⁵

 Alerts requiring action include the ability to perform or jump directly to the intended action.⁶⁶

 Interaction checking occurs for all active medications when a new allergy is entered (i.e., reverse checking).

 Dose range and maximum daily dose checking occur before medication orders are submitted for dispensing.

Medication dosing alerts take into consideration relevant patient-specific data such as patient age, gender, and laboratory result values (e.g., metformin ordered for patients with impaired renal function as evidenced by decreased estimated glomerular filtration rate [eGFR]).^{67,68}

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Recommended Practice - Alerts and Reminders (cont'd)

2.6 specific notifications. Checklist

CDS alerts and reminders provide unambiguous guidance in the correct clinical context at relevant points in the workflow. Alerts and reminders are informative, actionable, and judiciously limited to the most significant, patient-

Implementation Guidance (cont'd)

- Order sets are configured to facilitate appropriate corollary or consequent orders and reflect changes made to the original order (e.g., rescheduling, renewing, or discontinuing).69
- Incomplete orders requiring further actions (e.g., answers to specific questions) are clearly communicated to the ordering provider during order entry and prior to submission.
- The organization has a robust process for managing feedback, responding to users, and tracking improvements made.⁶²

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Recommended Practice - Ransomware	In	nplementation Status
2.7 Users are trained on ransomware prevention strategies, to identify malicious emails and fraudulent telephone call login access or other privileged information. ^{70,71}		
<u>Checklist</u>		EHR Limitation
Rationale for Practice or Risk Assessment	Suggested Sources of	Pocommondation
Malicious email attachments or callers asking for personal login information are often the first point of entry for ransomware attacks.	 Clinicians, support st clinical administration EHR developer 	
	Implementation Guida	nce
Assessment Notes	 (Uniform Resource Loo and second, think above know the sender, does urgency or deadline to grammatical errors in t link or attachment if not (in a separate email) th requesting information The organization trains and spear-phishing me on potentially weaponi *.zip, *.rar, *.7z, *.js, *. 	rst, hover over links to see the URL cator) destination before clicking, ut the attachment or link -do you is the email have a sense of take action, are their spelling or the message? Do not click on the ot sure. When in doubt call or email he sender or the organization to confirm it is legitimate. ⁷² is users to identify spam, phishing, essages, and users avoid clicking ized attachments (such as *.exe, wsf, *.docm, *.xlsm, *.pptm, *.rtf, md, *.hta, *.scr, *.pif, *.reg, *.vbs,
Follow-up Actions	 (*.jpg, *.png, *.pdf, *.dd Training should reinformail messages (e.g., yyyour bank, your creditwork with) should alwarequirements: 1) never file attachments; 2) nepassword information; number you can call (i.be associated with an people can check in thwebsite links that displ (URL) to build trust. The organization restri 	r ask you to download and open ver ask for you to enter account or 3) always have a telephone .e., out-of-band check); 4) always email address and name that heir local directory; and 5) contain lay the complete internet address icts users' ability to install and run
Person Responsible for Follow-up Action	 software applications of Privilege", or minimized systems, services, and The organization consist the organization's comdition (i.e., sends fraudulent websites that appear to raise user's awareness The organization cond 	using the principle of "Least s users' access to only those d data required by their job. iders disabling the USB ports on puters. ⁷⁵ ucts simulated phishing attacks [but safe] email messages or o be from legitimate sources) to s of the problem. ⁷⁶ ucts simulated ransomware attack y drills from both the clinical ⁷⁷ and

SAFER Self Assessment High Priority Practices Workshe	ended Practice 2.8 Domain 2 Set Using Health IT Safely
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2.8 Staff are trained and tested on downtime and recovery procedures. ⁷⁹ Checklist	Implementation Status EHR Limitation
Rationale for Practice or Risk Assessment At any given time, many organizations are likely to have employees who do not know how to function in a paper record-based clinical or administrative environment. ⁸⁰	Suggested Sources of InputStrength of Recommendation1. Clinicians, support staff, and/or clinical administrationRequired
Assessment Notes	 Implementation Guidance Organizations establish and follow training requirements so that each employee knows what to do to keep the organization operating safely during EHR downtimes.⁸¹ Clinicians are trained in the use of paper-based ordering and charting tools. The organization offers a job aid, such as a small, self-contained reference card or checklist, to help clinical staff find available resources and actions during EHR downtimes.⁸²
Follow-up Actions	 The organization conducts unannounced EHR "downtime drills" at least once a year.⁸³ Clinicians have been trained on how and when to activate and use the "read-only" backup EHR system.⁸⁴ Clinicians and other staff members have reliable access to the login information for the emergency, downtime, read-only backup EHR system, which may be different than userspecific credentials used for the live or production EHR. The organization maintains a comprehensive list of system-to-system interfaces or computer connections that is reviewed on a regular basis (e.g., every six months or annually) as a part of on-going contingency planning. The list should have a specific indication of whether there are legal/regulatory issues that may require special notification to the other party if there is a downtime such as a state-based immunization registry or prescription drug monitoring program.⁸⁵
Person Responsible for Follow-up Action	

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 Recommended Practice - Risk Manag Organizations have a strategy and measurement, monitoring, and mit hazards. 	I mechanisms for prev	vention, identification,	ation Status
<u>Checklist</u> Rationale for Practice or Risk Assessr	nont	Suggested Sources of Input	
A robust strategy enables organizations to potential hazards, mitigating the most sign patient safety by focusing on high-priority I This approach is not only crucial for patien often mandated by regulatory bodies. By ic priority risks, organizations can allocate re- targeting efforts on critical areas and inforr training programs to enhance clinicians' sa	proactively manage ificant threats to EHR safety risks. t safety but also dentifying high- sources effectively, ning targeted fe and effective use	 Large organization: Board of directors, Clinical, Informatics, an IT leadership team, Safety officer Small organization: Owners, EHR vendors, Clinicians 	. Weddin
of the EHR system. This proactive risk ma healthcare organizations to minimize adver		Implementation Guidance	
EHR performance, and ensure compliance requirements.		 A plan exists for learning from inc safety.⁸⁶⁻⁸⁸ 	cidents to improve EHR
		 Real-time monitoring tools are de performance, detect anomalies, a potential issues.⁸⁹ 	
		 Organization EHR representative EHR vendor to discuss new or or 	
		 Bidirectional communication betw the EHR vendor ensures timely u support for the system. 	
Assessment Notes		 A multi-stakeholder committee or regular basis to review all high-p hazards.^{90,91} 	
Assessment Notes		 EHR-related incidents are categorized location (i.e., clinical and within the type to assess for any trends that 	he EHR), severity, and
		 The mechanism for anonymous, of EHR-related safety hazards is 	
Follow-up Actions		 Organization has a policy and pro- timeliness of addressing reported escalation process to organization established service level is not be being met. 	d errors, including an In leadership when the
		 Larger organizations use special to manage internal EHR error rep 	ized "help desk" software ports and their disposition.
		 The user who reported the issue, notified of the outcome when app 	
Person Responsible for Follow-up Action		 The organization regularly monito downtime events.⁹³ 	ors and reports on system
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Recommended Practice 3.1 Worksheet

Domain 3

Monitoring Safety

SAFER Self Assessment High Priority Practices

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Recommended Practice - Patient Notification		plementation Status
3.2 Organizational policies and proceedires e both normal and abnormal test results, a monitored. ⁵⁷ <u>Checklist</u>	and the timeliness of notification is	EHR Limitation
Rationale for Practice or Risk Assessment Failure in timely patient notification of test results major source of diagnostic error and liability. Standardized policies and procedures for timely patient notification reduce the risk of loss of follow up.	 and/or clinical administration 2. Diagnostic services 	Aff, Recommendation Required
Assessment Notes	Providers and Patients" "It is VHA policy that all by the diagnostic provid designee, within a time attention and appropria requiring action must be provider, or designee, t days from the date on w test results that require communicated by the o patients no later than 1- which the results are av	mmunicating Test Results to 'Directive 1088 ⁵⁷ states that: I test results must be communicated der to the ordering provider, or -frame that allows for prompt te action to be taken. All test results e communicated by the ordering to patients no later than 7 calendar which the results are available. For no action, results must be ordering provider, or designee, to 4 calendar days from the date on vailable. Depending on the clinical sults may require review and
Follow-up Actions	 Notification of test result timeliness (i.e., whether within the correct time f Certain time-sensitive to which clear, unambigued HIV status, cancer diag via the telephone rather 	Its to patients is monitored for r the clinician notified the patient
Person Responsible for Follow-up Action	 test results to patients w To explain their test res provided with a link to la www.testing.com/news/ com/). For patients who have n traditional methods suc to inform them of their n 	ent portals to automatically release who have activated their accounts. sults in more detail, portal users are ab test interpretations (https:// /labtestsonline-org-is-now-testing- not activated their online accounts, th as letters or phone calls are used results on a timely basis.
,	results are unable to be	e confirmed, alternative strategies ow-up (e.g., if the secure message is

SAFER H	SAFER Self Assessment High Priority Practices Recommended Practice 3.3 Worksheet		Domain 3 Monitoring Safety
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Recommended Practice - Monitor Communication Patterns

3.3 The EHR enables the monitoring of important communication patterns related to clinical messages, referrals, and patient portal notifications. Checklist

Rationale for Practice or Risk Assessment

Monitoring time-sensitive and important clinical communications can identify opportunities to improve safety by identifying and addressing potential problems related to informing and responding to messages between clinicians and the care team and ancillary staff, as well as to and from patients.

Assessment Notes

Follow-up Actions

Person Responsible for Follow-up Action

Implementation Status

EHR Limitation

Strength of

Recommendation

Medium

Suggested Sources of Input

- 1. Clinicians
- 2. Clinical staff
- 3. Quality improvement staff
- 4. Health IT support staff
- 5. Vendors

Implementation Guidance

- The organization monitors rates of unacknowledged clinician inbox messages, messages sent to patients in their portal's inbox, and tasks.⁹⁴
- The organization defines and tracks expected response time frames for specific types of messages (e.g., urgent referrals responded to within two days, hospital discharge summaries sent to primary care provider within three days of discharge, inpatient order to admit is signed off at or before the time of admission). Findings are used to identify and resolve any deficiencies.
- Inbox message monitoring identifies quality improvement projects and targets interventions for clinicians with higher rates of unacknowledged inbox messages and tasks.⁹⁵
- Physician burnout, turnover, productivity, and EHR use metrics are analyzed to identify opportunities to identify physicians at high risk of departure who may benefit from targeted inbox management interventions.^{96,97}
- Patient portal adoption and utilization rates are monitored and analyzed, including how these differ by patient language, race/ethnicity, and other demographics.⁹⁸
- Messaging content and response patterns are periodically reviewed to identify opportunities for improving communication quality.⁹⁹
- The organization provides sufficient administrative time for clinicians to appropriately manage inbox messages and the clinical work associated with them.^{33,34,100}



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