The Office of the National Coordinator for Health Information Technology

SAFER Safety Assurance Factors for EHR Resilience

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Self-Assessment

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General Instructions for the SAFER Self-Assessment Guides

The SAFER Guides are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of electronic health records (EHRs) in the following areas.

- High Priority Practices
- Organizational Responsibilities
- Contingency Planning
- System Configuration
- System Interfaces
- Patient Identification
- Computerized Provider Order Entry with Decision Support
- Test Results Reporting and Follow-up
- Clinician Communication

Each of the nine 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. Following the Checklist, a Practice Worksheet gives a rationale for and examples of how to implement each recommended practice, as well as likely sources of input into assessment of each practice, and fillable fields to record team members and follow-up action. 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 <u>www.healthit.gov/SAFERGuide</u>.

The SAFER Guides are based on the best evidence available at this time (2016), including a literature review, expert opinion, and field testing at a wide range of healthcare organizations, from small ambulatory practices to large health systems. The recommended practices in the SAFER Guides are intended to be useful for all EHR users. However, every organization faces unique circumstances and will implement a particular practice differently. As a result, some of the specific examples in the SAFER Guides for recommended practices may not be applicable to every organization.

The SAFER Guides are designed in part to help deal with safety concerns created by the continuously changing landscape that healthcare organizations face. Therefore, changes in technology, 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 in which it is particularly important to address the implications of change for the safety and safe use of EHRs. Ultimately, the goal is to improve the overall safety of our health care system.

The SAFER Guides are not intended to be used for legal compliance purposes, and implementation of a recommended practice does not guarantee compliance with HIPAA, the HIPAA Security Rule, 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, HIPAA, and any other laws.

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

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Self-Assessment System Configuration

Introduction

The System Configuration SAFER Guide identifies recommended safety practices associated with the way EHR hardware and software are set up (i.e., "configured"). EHR configuration includes the creation and maintenance of the physical environment in which the system will operate, as well as the implementation of the required hardware and software infrastructure. Working through this guide with a multi-disciplinary team will focus the team's attention on configuration-related recommended practices to optimize the safety and safe use of the EHR.

Configuration of an EHR's hardware and software components within a particular environment is complex and vulnerable to errors. EHRs are profoundly influenced by their configuration, and numerous decisions must be made by the multi-disciplinary configuration team. Generally, this team should include practicing clinicians to ensure that technical components align with and support the clinical processes and workflows impacted by their decisions.

In addition to the substantial initial configuration effort, a continuous, reliable configuration review and maintenance process must be developed and followed. For example, periodic system review and improvements are necessary to maximize the potential benefits of the EHR, and these changes are often less disruptive to business operations and more likely to be successful if implemented through coordinated change management processes. EHR safety and effectiveness can be improved by establishing proper configuration procedures, policies, and practices.

Completing the self-assessment in the System Configuration SAFER Guide requires the engagement of people both within and outside the organization (e.g., EHR technology developers). Because this guide is designed to help organizations prioritize EHR-related safety concerns, clinician leadership in the organization should be engaged to assess whether and how any particular recommended practice affects the organization's ability to deliver safe, high quality care. Collaboration between clinicians and staff members while completing the self-assessment in this guide will enable an accurate snapshot of the organization's EHR configuration status (in terms of safety), and even more importantly, should 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 configurationrelated safety risks introduced by the EHR.

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		hecklist will automaticall	y update the r forksheet.	elated sec	tion			
The Recommended	Recommended Practices for	r <u>Domain 1 — Safe Health IT</u>			ementation S	tatus		
Practice(s) for the	The EHR supports and	uses standardized protocols for	Worksheet 1.1	Fully in all areas	Partially in some areas	implemented	(1221)	
topic appear below the associated	1.1 exchanging data with		TOTAL/CEL 1.1			V		Select the status
Domain.	1.2 systems, virus and ma	date versions of operating lware protection software, nd interface protocols are used.	Worksheet 1.2	0	0	0	reset	of implementation achieved by your organization for each
	1.3 System-to-system inte clinical vocabularies u applications.	rfaces support the standard sed by the connected	Worksheet 1.3	0	0	0	(22)	Recommended Practice.
	1.4 and tested to ensure t	rfaces are properly configured at both coded and free-text data ed without loss of or changes to	Worksheet 1.4	0	0	0	(122)	Your <i>Implementation</i> Status will be reflected on the Recommended
	1.5 consistent with its com	extent of interface testing is plexity and with the importance less, and reliability of the data face.	Worksheet 1.5	0	0	0	(REACE)	Practice Worksheet in this PDF.
	1.6 affects an interface, th procedures to evaluate administrators) on bott	or system change or upgrade that e organization implements a whether users (clinicians or n sides of the interface correctly formation that moves over the	Worksheet 1.6	0	0	0	(FEIG	
		or software on either side of the fore and monitored after go-live.	Worksheet 1.7	0	0	0	(C22)	
		nd software environment for physically separate from the live	Worksheet 1.8	0	0	0		
		es describe how to stop and f data across the interface in an	Worksheet 1.9	0	0	0	C 23	
	1.10 established for manag	ncluding role-based access, are ing and monitoring key interfaces and data exchange.	Worksheet 1.10	0	0	0	68	
				-				ce is a link in this PDF.

The Worksheet provides guidance on implementing the Practice.



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Reco	Recommended Practices for Domain 1 — Safe Health IT			elementation S	tatus	
			Fully in all areas	Partially in some areas	Not implemented	
1.1	There are an adequate number of EHR access points in all clinical areas.	Worksheet 1.1	\bigcirc	\bigcirc	\bigcirc	reset
1.2	The EHR is hosted safely in a physically and electronically secure manner.	Worksheet 1.2	\bigcirc	\bigcirc	\bigcirc	reset
1.3	The organization's information assets are protected using strong authentication mechanisms.	Worksheet 1.3	\bigcirc	\bigcirc	\bigcirc	reset
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.	Worksheet 1.4	\bigcirc	\bigcirc	\bigcirc	reset
1.5	Clinical applications and system interfaces are tested individually and as-installed before go-live and are closely monitored after go-live.	Worksheet 1.5	\bigcirc	\bigcirc	\bigcirc	reset
1.6	Computers and displays in publicly accessible areas are configured to ensure that patient identifiable data are physically and electronically protected.	Worksheet 1.6	\bigcirc	\bigcirc	\bigcirc	reset
1.7	There are processes in place to ensure data integrity during and after major system changes, such as upgrades to hardware, operating systems, or browsers.	Worksheet 1.7	\bigcirc	\bigcirc	\bigcirc	reset
Reco	mmended Practices for Domain 2 — Using Health IT	Safely	Imp	plementation S	tatus	
			Fully in all areas	Partially in some areas	Not implemented	
2.1	Clinical content used, for example, to create order sets and clinical charting templates, and to generate reminders within the EHR, is up-to-date, complete, available, and tested.	Worksheet 2.1	\bigcirc	\bigcirc	\bigcirc	reset
2.2	There is a role-based access system in place to ensure that all applications, features, functions, and patient data are accessible only to users with the appropriate level of authorization.	Worksheet 2.2	\bigcirc			reset



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Implementation Status Recommended Practices for **Domain 2**— Using Health IT Safely Fully in all areas Partially Not implemented in some areas The EHR is configured to ensure EHR users work in Worksheet 2.3 reset 2.3 the "live" production version, and do not confuse it with training, test, and read-only backup versions. Worksheet 2.4 reset System configuration settings that limit clinicians in 2.4 their practice are minimized, carefully implemented following clinician acceptance, and closely monitored. Worksheet 2.5 reset The human-computer interface is configured for 2.5 optimal usability for different users and clinical contexts. Recommended Practices for **Domain 3 — Monitoring Safety Implementation Status** Fully Partially Not in all areas in some areas implemented Worksheet 3.1 The organization has processes and methods in 3.1 place to monitor the effects of key configuration

settings to ensure they are working as intended.

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A multi-disciplinary team 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 Team Leader

Assessment Completion Date

Assessment Team Members

Assessment Team Notes



About the Recommended Practice Worksheets



Each *Recommended Practice Worksheet* provides guidance on implementing a specific *Recommended Practice*, and allows you to enter and print information about your self-assessment.



SAFER Self-Assessment System Configuration	Recommer 1.1 Worksh	nded Practice neet	Domain 1 — <u>Safe Health IT</u>
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Team</u>	Worksheet >	About the Practice Worksheets	>Practice Worksheets
Recommended Practice		Imp	lementation Status
1.1 There are an adequate number of EHR ac clinical areas. ¹ <u>Checklist</u>	cess points in all		
Rationale for Practice or Risk Assessment		Suggested Sources of In	put
Rapid, reliable access to the patient's computer-bar record is essential for safe and effective care. Such depends critically on configuring the EHR in clinical areas such that a computer is always conveniently	n access I care	Clinicians, support staff, and clinical administration	l/or Health IT support staff
		Examples of Potentially I	Jseful Practices/Scenarios
Assessment Notes		access by clinicians (e.g. feet to access an EHR; if	s minimum standards for EHR , clinicians walk no more than 50 there are waiting lines for access,
		they are minimal and ens be addressed).	ure that urgent clinical needs can
			to acquiring sufficient computer opriate access, in accordance with
			sical and logical) have been and timely access devices and / in clinical areas.
			R access point for every clinician nember in an outpatient clinic. ²
Follow-up Actions		the appropriate (e.g., a no printer available for use o	to access the EHR are mapped to earby) printer. There is at least one on all acute care nursing units or n outpatient exam room (e.g., less
		 There is a mapping table 	that shows the physical location of tached devices (e.g., end-user
		 Critical hardware is connected uninterruptible power sup 	o ,
Person Responsible for Follow-up Action			
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SAFER System Configuration **Recommended Practice** Domain 1 – 1.2 Worksheet Safe Health IT >Team Worksheet > About the Practice Worksheets >Table of Contents > About the Checklist >Practice Worksheets \mathbf{v} **Recommended Practice Implementation Status** The EHR is hosted safely in a physically and electronically \sim 1.2 secure manner.4 Checklist **Rationale for Practice or Risk Assessment** Suggested Sources of Input EHR developer Health IT support staff Whether the EHR is hosted locally or remotely, it can only provide reliable support for safe, effective care if it is available and secure. **Examples of Potentially Useful Practices/Scenarios** Key data required to take care of patients and run the organization are available 24 hours per day and 7 days per week, are not altered inadvertently or maliciously, and are Assessment Notes kept confidential. If the organization requires 24 hour per day, 7 day per week, 365 day per year access to their data, data and operational systems are maintained on at least two geographically distinct hosting sites that are mirrored in real-time (i.e., "hot" or "warm" sites).⁵ This redundancy reduces the risk of a single natural or man-made disaster to disable operating capacity. There are at least two physically distinct network connections between the hosting sites. Within a data center (i.e., hosting center), all servers are mirrored on physically separate servers. The healthcare organization has a contract in place that describes in detail how they will get functional access to their Follow-up Actions data in the event that either the EHR system developer or the remote hosting site goes out of business (e.g., EHR and database management software has been placed in escrow, current data backups are independently accessible).⁶ When multiple EHRs are being hosted on a remote hosting facility, the data from different healthcare organizations are maintained within separate virtual machine (VM) environments or on separate physical servers.7

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SAFER Self-Assessment System Configuration	Recommended Practice 1.3 Worksheet	Domain 1 — <u>Safe Health IT</u>		
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1.3 The organization's information assets are p strong authentication mechanisms. ⁸ <i>Checklist</i>		mplementation Status		
Rationale for Practice or Risk Assessment Failure to implement and manage secure processes authenticate access to any system or data (e.g., strapasswords, fingerprints, role-based access) is an avoidable source of erroneous data that can lead to harm. Assessment Notes	patient Examples of Potential The organization has regular risk assessme authentication. Access to the organization devices is password p Two-factor authentica servers' "administrativ Unix) and clinicians' rethree types of authent you know, something factor authentication in	Ily Useful Practices/Scenarios policies and procedures and conducts ents to define, implement, and monitor ation's "backbone network" via wireless		
Follow-up Actions	 number token), or info biometric such as iris All users have a uniqu (e.g., contains letters, changes to passwords Employee login crede employment ends. To the extent possible "single sign-on" solution 	ue username and "strong" password numbers, special characters). Periodic s are required. ¹⁰ entials are revoked as soon as their e, the organization has implemented a on that allows authorized clinicians to a disparate clinical applications without		
Person Responsible for Follow-up Action				
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SAF	ER Self-Assessment System Configu	Iration Recom	mended Practice ksheet	Domain 1 — <u>Safe Health IT</u>
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Recommended P	Practice		In	nplementation Status
1.4 operating	ardware and software re system) and their modif talled before go-live and	ications are tested in	dividually	
Rationale for Pra	ctice or Risk Assess	ment	Suggested Sources of	Input
software can lead t	ely test system hardwar to suboptimal performar onse time, reliability, an	nce as	Health IT support staff	
			Examples of Potentially	y Useful Practices/Scenarios
				ucture components, such as database rs, and end-user terminals are
Assessment Notes			 All system software up 	dates are installed and tested in the ore they are moved into the production nd re-tested. ¹⁴
			 The organization monit time.² 	ors system downtime and response
			installation potential sa	and/or procedures address post- fety hazards (e.g., 24 hour per day pport, help desk availability, ds). ¹⁵
Follow-up Actions			testing (e.g., testing in a testing, minimum numb associated with test car	and/or procedures define criteria for a simulated environment, day of week per of test cases, types of user roles ses, facility defined versus developer
			defined test cases).	
Person Responsible	for Follow-up Action			
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SAFER System Configuration Recommendation	nended Practice Domain 1 – scheet Safe Health IT
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1.5 Clinical applications and system interfaces are tested individually and as-installed before go-live and are close monitored after go-live. ¹⁶	Implementation Status
Rationale for Practice or Risk Assessment Safety events can result from poor configuration between critical applications, such as between CPOE and pharmacy. Failure to adequately test applications and their interfaces can lead to data integrity issues as well as impede response time, availability, and error-free operation.	Suggested Sources of Input Clinicians, support staff, and/or clinical administration
Assessment Notes	 Examples of Potentially Useful Practices/Scenarios New application software and updates (both major upgrades and small "patches") are installed and tested in the "test" environment before they are moved into the production or "live" environment, then re-tested and closely monitored in the "live" environment for several days.¹⁴ System-system interfaces between key clinical applications (e.g., CPOE and pharmacy, laboratory and EHR) are tested and continuously monitored to detect new errors. Simulations are conducted for clinical processes such as order entry, pharmacy review, nurse notification, medication fill, medication administration, and nursing documentation to ensure that the application addresses the organization's needs.¹⁷
Follow-up Actions	
Person Responsible for Follow-up Action	

SAFER System Configuration Recommended Practice 1.6 Worksheet			Domain 1 — <u>Safe Health IT</u>		
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Recommended Practice		Imp	lementation Status		
1.6 Computers and displays in publicly accert configured to ensure that patient identified and electronically protected. ¹⁸ <u>Checklist</u>					
Rationale for Practice or Risk Assessment	:	Suggested Sources of In	put		
Failure to physically protect patient identifiable of ensure that it is not inadvertently or maliciously changed, or deleted is vital to ensuring safe and effective use of clinical applications.	viewed,	Clinicians, support staff, and clinical administration	d/or Health IT support staff		
		Examples of Potentially	Useful Practices/Scenarios		
Assessment Notes		locations have an automa	s patient data in publicly accessible atic screen locking feature set, I setting (e.g., lock after idle for thre		
		 Devices used to access p facing away from publicly 	patient data have their screens accessible locations and/or have s that restrict screen viewing at		
			names on EHRs are masked (i.e., ent's name is visible in public areas		
		room is locked, there is n	vsical security controls in place (e.g. non-water-based fire suppression, prevent flooding, backups are kept		
Follow-up Actions		 All portable computing de have encrypted hard drive 	evices used to access EHR data es. ¹⁹		
		 Backups containing patie 	ent-identifiable data are encrypted.		
Person Responsible for Follow-up Action					

SAFER Self-Assessment System Config	uration Recomm	mended Practice ksheet	Domain 1 — <u>Safe Health IT</u>	
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Recommended Practice		Im	plementation Status	
1.7 There are processes in place to e after major system changes, such operating systems, or browsers. ²⁰ Checklist	n as upgrades to hard			
Rationale for Practice or Risk Assess Major system changes create the risk of le of patient data. Data persistence must be independent of hardware and software ch continuity of care. Losing data due to "imp	oss or corruption ensured anges to maintain	Suggested Sources of I Clinicians, support staff, ar clinical administration	· · · · · · · · · · · · · · · · · · ·	
underlying systems is not acceptable.		E construction of Defending		
Assessment Notes		 Examples of Potentially Useful Practices/Scenarios The organization has change management and internal control policies and procedures to ensure data integrity, these apply to all major system changes. Major system changes include, at a minimum, operating system or browersion upgrades, or adding new system software (e.g., protection upgrades). 		
		 There are processes in place to migrate existing data new system while ensuring it remains accurate, value accessible after changes to the:²¹ 		
		 Application (e.g., from 	om one EHR system to another)	
			ree text to structured data)	
			I., from ICD-9 to ICD-10)	
		 Storage mechanish hard drives) 	n (e.g., from magnetic tapes to solid state	
Follow-up Actions		 Standard, regularly used clinical and administrative (e.g., length of stay, readmission rates, alert over are generated and reviewed periodically to ensure data on which they are based has not changed in renders the report meaningless. When changes in data have the potential to lead to faulty conclusion notified as soon as possible, and repairs are impletimely manner. If data becomes corrupted, the organization has p processes for reverting to a backup version of the precedes the corruption. In addition, there are pol processes for: 		
		 Integrity checks to e to the backup 	ensure a successful recovery after revertir	
Person Responsible for Follow-up Action		 Downtime processe 	es to ensure access to critical data while th back to an uncorrupted state	
		 Methods for re-entr 	y of data generated (e.g., orders, notes) system corruption and subsequent	

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SAFER System Configuration	Recommended Practice 2.1 Worksheet	Domain 2 — <u>Using Health IT Safely</u>	
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2.1 Clinical content used, for example, to create clinical charting templates, and to generate the EHR, is up-to-date, complete, available Checklist	order sets and reminders within	plementation Status	
Rationale for Practice or Risk Assessment Clinical content drives significant parts of the user experience. Failure to update, test, and maintain th content can result in significant degradations in the accuracy and timeliness of information display and Assessment Notes	 Examples of Potentially There are no "broken lin information resources. The organization has a r 	nd/or Health IT support staff Useful Practices/Scenarios aks" to internet-based clinical naming convention and unambiguous	
	 sets, charting templates, "canned text").²³ Default values are availa medication order senten Items necessary to provior orderable items within the Clinical content is tested system are accurately tra- system interface and reconcerned. 	d to ensure that items entered in one ransmitted through the system-to- ceived by the remote system	
Follow-up Actions	annually.	ved by the organization at least	
Person Responsible for Follow-up Action			

SAFER Self-Assessment System Configuration	Recommended Practice 2.2 Worksheet	Domain 2 — <u>Using Health IT Safely</u>		
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Team</u>	Worksheet > <u>About the Practice Work</u>	>Practice Worksheets		
2.2 There is a role-based access system in pla applications, features, functions, and patier only to users with the appropriate level of a Checklist	nt data are accessible	Implementation Status		
Rationale for Practice or Risk Assessment Role-based access helps ensure that users can onlenter, or modify data when necessary to perform the jobs. Organizations are expected to configure and maintain the correct associations between the roless the functions of the EHR and maintain correct assig of user roles.	 by see, eir Clinicians, support s clinical administration of clinicadministration of clinicadministration of clinical administrata	 are defined for both clinical and non-clinical users. Within each of these groups, subcategories of users are defined with very specific capabilities (e.g., only credentialed MDs, DOs, or NPs can order Schedule 2 medications without a co-signature). There is a multi-disciplinary committee responsible for creating new roles and determining that the appropriate features and functions are assigned to each role. Employees who change jobs are reassigned to the appropriate roles promptly. 		
Follow-up Actions		aff members' roles and specific access various clinical systems and		
Person Responsible for Follow-up Action				

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SAFER Self-Assessment System Configuration	Recommended Practice 2.3 Worksheet	Domain 2 — Using Health IT Safely
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2.3 The EHR is configured to ensure EHR user production version, and do not confuse it wand read-only backup versions. ²⁵ <i>Checklist</i>	s work in the "live"	Implementation Status
Rationale for Practice or Risk Assessment Failure to clearly differentiate training, testing, and live EHR environments can lead to data review and entry errors.	There is a dedicated	ally Useful Practices/Scenarios
Assessment Notes	 testing and training v Both the training and possible (e.g., within users can enter and user, review laborate appropriately). There is a dedicated facilitates the configurand hardware update The read-only backut clearly identifiable as The EHR is configurated 	I test environments are as complete as the training and test environments sign orders that will display for another bry data, and see alerts firing "test" environment for the EHR that uration and testing of all new software es. p system is password protected and a read-only. ²⁶ ed to make it difficult to confuse the live
Follow-up Actions	 background color or be different). The organization has naming test patients. instead use unmistal for the name and inc Use of generic accou (e.g., "MD-Test" use role-based testing) a password changes, r 	vith other versions (e.g., the screen the color of the patient headers could as a policy and process for creating and . Avoid "cute" names like Dr. Spock, and kable test names like "ZZZ" as a prefix dude numbers in the name. ¹⁴ unts in the production environment d by HIT support staff and others for re tightly controlled (e.g., with regular restricted admin-level rights, regular t data that were accessed).
Person Responsible for Follow-up Action		

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> <u>Table of Contents</u> > <u>About the Che</u>	klist > <u>Team Worksheet</u>	> <u>About the Practice Worksheets</u> > Practice Worksheets		
System configuration settin practice are minimized, car clinician acceptance, and c <u>Checklist</u>	fully implemented followin			
Checklist Rationale for Practice or Risk Assessment Configuration decisions that result in mismatches between institutional policies, routine practices, and EHR settings often result in "work-arounds" by clinicians, which increase patient safety risks and lead to suboptimal use of EHRs. Assessment Notes		 Suggested Sources of Input Clinicians, support staff, and/or Health IT support staff clinical administration Health IT support staff Health IT support staff Health IT support staff Examples of Potentially Useful Practices/Scenarios EHR change/configuration management related organizational policies and procedures that address decisions to limit clinicians in their practice (e.g., mandatory clinical alert settings, hard stops that cannot be overridden by clinicians, alerts that cannot be turned off by clinicians) are developed with clinician input, judiciously implemented, and carefully monitored.²⁸ Organizational policy and procedures minimize configurations that limit clinicians' ability to continue practicing (e.g., enter new orders) due to incomplete work (e.g., overdue co-signatures, incomplete discharge summaries).		
Follow-up Actions				

Recommended Practice

2.4 Worksheet

SAFER Self-Assessment System Configuration

Domain 2 –

Using Health IT Safely

SAF	ER Self-Assessment System Configu	ration Recom 2.5 Wor	mended Practice rksheet	Domain 2 — <u>Using Health IT Safely</u>		
> <u>Table of Contents</u>	> <u>About the Checklist</u>	> <u>Team Worksheet</u>	>About the Practice Worksheets	>Practice Worksheets		
Recommended Practice In			Imple	plementation Status		
	n-computer interface is r different users and cli		al			
Rationale for Pra	ctice or Risk Assess	ment	Suggested Sources of Inp	out		
requirements for di	differences in user interl ifferent locations, specia suboptimal system safet	alties, and	EHR developer	Health IT support staff		
			Examples of Potentially U	seful Practices/Scenarios		
Assessment Notes		The EHR user interface (i.e., those aspects of an EHR that users see and use) is configured (and configurable) to enable users with different capabilities and requirements to use the system safely and effectively (e.g., fonts large enough for all users to see, reduced screen brightness on night shifts, variable color and contrast schemes to accommodate color-blind users).				
			 The EHR user interface is (e.g., user-reported usabili satisfaction, and is improved 	ity hazards) and user		
			 Default column widths, or enough to see key data.¹⁶ 	display fields, are set wide		
	 The EHR user interface specialty requirements "favorites" or 20 most clinical laboratory, and 		specialty requirements. Cl "favorites" or 20 most com	specialty requirements. Clinical specialties have their "favorites" or 20 most commonly ordered medications,		
Follow-up Actions			-	aging tests available on a single		

Person Responsible for Follow-up Action

reset page

SAFER Self-Assessment System Configuration Recommend 3.1 Workshe		mmended Practice /orksheet		Domain 3 — <u>Monitoring Safety</u>		
> <u>Table of Contents</u>	> <u>About the Checklist</u>	> <u>Team Workshee</u>	About the Practice Workshe	ets	>Practice Worksheets	
Recommended Practice			Impl	ementation Status		
3.1 monitor the	ization has processes a e effects of key configur g as intended. ³⁰					
Rationale for Pra	ctice or Risk Assess	ment	Suggested Sources	of Inj	put	
key clinical compor pharmacy) or proce	configuration settings as nents (e.g., CPOE interf esses (e.g., medication safety events that are o	ace to reconciliation)	EHR developer		Health IT support staff	
			Examples of Potentially Useful Practices/Scenarios			
Assessment Notes			 database servers de password strength, settings. The organ identify the key con responsible for mor The organization hat (e.g., by periodically presented within the System response til regularly.³¹ The interface error are identified and fix The alert override ratio 	edicate syster ization figurat itoring s a m check check e EHR me is r og is r ked pro ate is r	ethod of automatically monitoring king) all internet-based links measured and reported regularly reviewed and all errors	
Follow-up Actions			so) are re-evaluated Clinical decision su	d and f oport i		
Person Responsible	for Follow-up Action					

References

1. Howard, J., Clark, E. C., Friedman, A., Crosson, J. C., Pellerano, M., Crabtree, B. F., ... & Cohen, D. J. (2013). Electronic health record impact on work burden in small, unaffiliated, community-based primary care practices. Journal of General Internal Medicine, 28(1), 107-113.

2. Sittig, D. F., Campbell, E. M., Guappone, K. P., Dykstra, R. H., & Ash, J. S. (2007). Recommendations for monitoring and evaluation of in-patient computer-based provider order entry systems: results of a Delphi survey. American Medical Informatics Association Annual Symposium Proceedings, 2007, 671–675.

3. Haskins, M. (2002). Legible charts! Experiences in converting to electronic medical records. Canadian Family Physician, 48, 768.

4. Fernández-Alemán, J. L., Señor, I. C., Lozoya, P. Á. O., & Toval, A. (2013). Security and privacy in electronic health records: a systematic literature review. Journal of Biomedical Informatics, 46(3), 541-562.

5. Donaldson, S. E., Siegel, S. G., Williams, C. K., & Aslam, A. (2015). Enterprise Cybersecurity Capabilities. In Enterprise Cybersecurity (pp. 311-334). Apress.

6. O'Connor, K. J. (2005). Everything you always wanted to know about software escrow agreements--and then some! Journal of Healthcare Information Management, 19(1), 10.

7. Zissis, D., & Lekkas, D. (2012). Addressing cloud computing security issues. Future Generation Computer Systems, 28(3), 583-592.

8. Tipton, S. J., Forkey, S., & Choi, Y. B. (2016). Toward proper authentication methods in electronic medical record access compliant to HIPAA and CIA triangle. Journal of Medical Systems, 40(4), 1-8.

9. Sasse, M. A. (2013, August). "Technology Should Be Smarter Than This!": A Vision for Overcoming the Great Authentication Fatigue. Workshop on Secure Data Management (pp. 33-36). Springer International Publishing.

10. Clayton, P. D., Boebert, W. E., Defriese, G. H., Dowell, S. P., Fennell, M. L., Frawley, K. A., ... & Rindfleisch, T. C. (1997). For the record: protecting electronic health information. National Research Council. (Washington, DC: National Academy Press, 1997).

11. Cresswell, K. M., Mozaffar, H., Lee, L., Williams, R., & Sheikh, A. (2016). Safety risks associated with the lack of integration and interfacing of hospital health information technologies: a qualitative study of hospital electronic prescribing systems in England. BMJ Quality & Safety.

12. Berger, R. G., & Baba, J. (2009). The realities of implementation of Clinical Context Object Workgroup (CCOW) standards for integration of vendor disparate clinical software in a large medical center. International Journal of Medical Informatics, 78(6), 386-390.

13. Ancker, J. S., Singh, M. P., Thomas, R., Edwards, A., Snyder, A., Kashyap, A., & Kaushal, R. (2013). Predictors of success for electronic health record implementation in small physician practices. Applied Clinical Informatics,4(1), 12-24.

14. Wright, A., Aaron, S., & Sittig, D. F. (2016). Testing electronic health records in the "production" environment: an essential step in the journey to a safe and effective health care system. Journal of the American Medical Informatics Association.

15. Frankel, A., Grillo, S. P., Baker, E. G., Huber, C. N., Abookire, S., Grenham, M., ... & Gandhi, T. K. (2005). Patient safety leadership WalkRounds[™] at Partners HealthCare: learning from implementation. The Joint Commission Journal on Quality and Patient Safety, 31(8), 423-437.

16. Lowry, S. Z., Quinn, M. T., Ramaiah, M., Schumacher, R. M., Patterson, E. S., North, R., ... & Abbott, P. (2012). Technical evaluation, testing, and validation of the usability of electronic health records. National Institute of Standards and Technology.

17. Li, A. C., Kannry, J. L., Kushniruk, A., Chrimes, D., McGinn, T. G., Edonyabo, D., & Mann, D. M. (2012). Integrating usability testing and think-aloud protocol analysis with "near-live" clinical simulations in evaluating clinical decision support. International Journal of Medical Informatics, 81(11), 761-772.

18. Murphy, A. R., Reddy, M. C., & Xu, H. (2014, February). Privacy practices in collaborative environments: a study of emergency department staff. Proceedings of the 17th ACM Conference on Computer Supported Cooperative Work & Social Computing (pp. 269-282). ACM.

19. Benusa, A., & Chen, J. (2015). HIPAA compliance challenges: a case study of a small healthcare provider. Proceedings of the 5th International Conference on IS Management and Evaluation 2015: ICIME 2015 (p. 161). Academic Conferences Limited.

20. Nelson, R., & Staggers, N. (2014). Health informatics: an interprofessional approach. Elsevier Health Sciences.

21. Pageler, N. M., G'Sell, M. J. G., Chandler, W., Mailes, E., Yang, C., & Longhurst, C. A. (2016). A rational approach to legacy data validation when transitioning between electronic health record systems. Journal of the American Medical Informatics Association.

References

22. Ash, J. S., Sittig, D. F., Guappone, K. P., Dykstra, R. H., Richardson, J., Wright, A., ... & Middleton, B. (2012). Recommended practices for computerized clinical decision support and knowledge management in community settings: a qualitative study. BMC Medical Informatics and Decision Making, 12(1), 1.

23. Bobb, A. M., Payne, T. H., & Gross, P. A. (2007). Viewpoint: controversies surrounding use of order sets for clinical decision support in computerized provider order entry. Journal of the American Medical Informatics Association, 14(1), 41-47.

24. Wright, A., Ash, J. S., Erickson, J. L., Wasserman, J., Bunce, A., Stanescu, A., ... & Middleton, B. (2014). A qualitative study of the activities performed by people involved in clinical decision support: recommended practices for success. Journal of the American Medical Informatics Association, 21(3), 464-472.

25. Sittig, D. F., Gonzalez, D., & Singh, H. (2014). Contingency planning for electronic health record-based care continuity: a survey of recommended practices. International Journal of Medical Informatics, 83(11), 797-804.

26. Lincke, S. (2015). Designing Information Security. In Security Planning (pp. 115-133). Springer International Publishing.

27. Eikey, E. V., Murphy, A. R., Reddy, M. C., & Xu, H. (2015). Designing for privacy management in hospitals: understanding the gap between user activities and IT staff's understandings. International Journal of Medical Informatics, 84(12), 1065-1075.

28. Strom, B. L., Schinnar, R., Aberra, F., Bilker, W., Hennessy, S., Leonard, C. E., & Pifer, E. (2010). Unintended effects of a computerized physician order entry nearly hard-stop alert to prevent a drug interaction: a randomized controlled trial. Archives of Internal Medicine, 170(17), 1578-1583.

29. Middleton, B., Bloomrosen, M., Dente, M. A., Hashmat, B., Koppel, R., Overhage, J. M., ... & Zhang, J. (2013). Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA. Journal of the American Medical Informatics Association, 20(e1), e2-e8.

30. Meeks, D. W., Takian, A., Sittig, D. F., Singh, H., & Barber, N. (2014). Exploring the sociotechnical intersection of patient safety and electronic health record implementation. Journal of the American Medical Informatics Association, 21(e1), e28-e34.

31. Smith, M. W., Ash, J. S., Sittig, D. F., & Singh, H. (2014). Resilient practices in maintaining safety of health information technologies. Journal of Cognitive Engineering and Decision Making, 8(3), 265-282.

32. McCoy, A. B., Waitman, L. R., Lewis, J. B., Wright, J. A., Choma, D. P., Miller, R. A., & Peterson, J. F. (2012). A framework for evaluating the appropriateness of clinical decision support alerts and responses. Journal of the American Medical Informatics Association, 19(3), 346-352.

33. Wright, A., Hickman, T. T. T., McEvoy, D., Aaron, S., Ai, A., Andersen, J. M., ... & Bates, D. W. (2016). Analysis of clinical decision support system malfunctions: a case series and survey. Journal of the American Medical Informatics Association.