The Office of the National Coordinator for Health Information Technology

SAFER Safety Assurance Factors for EHR Resilience

>Table of Contents

> About the Checklist

><u>Team Worksheet</u>

> About the Practice Worksheets

>Practice Worksheets

 \checkmark



Self-Assessment

Contingency Planning

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> The Office of the National Coordinator for Health Information Technology

SAFER Safety Assurance Factors for EHR Resilience

><u>Table of Contents</u>

>About the Checklist

>Team Worksheet

> About the Practice Worksheets

>Practice Worksheets

 \checkmark



Self-Assessment Contingency Planning

Introduction

The Contingency Planning SAFER Guide identifies recommended safety practices associated with planned or unplanned EHR unavailability—instances in which clinicians or other end users cannot access all or part of the EHR. Occasional temporary unavailability of EHRs is inevitable, due to failures of software and hardware infrastructure, as well as power outages and natural and man-made disasters. Such unavailability can introduce substantial safety risks to organizations that have not adequately prepared. Effective contingency planning addresses the causes and consequences of EHR unavailability, and involves processes and preparations that can minimize the frequency and impact of such events, ensuring continuity of care.

EHR unavailability, which will occur in every EHR-enabled healthcare environment,¹ represents a significant potential patient safety hazard that directly affects patient care. Documented potential hazards include an increased risk of medication errors,² unavailability of images,³ and canceled procedures. The potential impact of EHR unavailability increases as such systems are deployed across multiple, geographically dispersed facilities within a healthcare system.⁴ The contingency planning team should include practicing clinicians to ensure that the technical components align with and support the clinical processes and workflows impacted by their decisions. The substitute workflows that must be designed and then employed during downtimes are particularly sensitive to clinician input and cooperation. In addition to the substantial initial contingency planning effort, a continuous, reliable review and maintenance process must be developed and followed. EHR safety and effectiveness can be improved by establishing proper downtime procedures, policies, and practices. The collaboration between clinicians and staff members in completing the self-assessment in this guide will enable an accurate snapshot of the organization's EHR contingency planning 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.

Interaction with HIPAA

While this guide focuses on patient safety, many of its recommendations overlap with standards and implementation specifications of the HIPAA Security Rule, which focuses on ensuring the confidentiality, integrity, and availability of electronic protected health information. Because the focus of the guide differs from that of the Security Rule, completing the checklist here will not equate with compliance with HIPAA. However, creating a contingency plan as required by the HIPAA Security Rule will address many, but not all, of the recommended safety-oriented practices in this guide. We encourage coordination of completion of the self-assessment in this SAFER Guide with contingency planning for purposes of HIPAA compliance to provide a uniform approach to patient safety and data protection.

The Office of the National Coordinator for Health Information Technology

SAFER Safety Assurance Factors for EHR Resilience

>Table of Contents	>About the Checklist	> <u>Team Worksheet</u>	>About the Practice Worksheets		>Practice Worksheets	~	
	1			1			



Self-Assessment

Contingency Planning

Table of Contents

General Instructions	1
Introduction	<u>2</u>
About the Checklist	4
Checklist	<u>5</u>
Team Worksheet	<u>7</u>
About the Recommended Practice Worksheets	<u>8</u>

The SAFER Self-Assessment Guides were developed by health IT safety researchers and informatics experts:

Joan Ash, PhD, MLS, MS, MBA, Professor and Vice Chair, Department of Medical Informatics and Clinical Epidemiology, School of Medicine, Oregon Health & Science University;

Hardeep Singh, MD, MPH, Associate Professor of Medicine at the Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine and Chief of the Health Policy, Quality and Informatics Program at the Houston VA HSR&D Center of Excellence, and Director of the Houston VA Patient Safety Center of Inquiry; and

Dean Sittig, PhD, University of Texas School of Biomedical Informatics at Houston, UT–Memorial Hermann Center for Healthcare Quality & Safety.

This guide was developed under the contract Unintended Consequences of Health IT and Health Information Exchange, Task Order HHSP23337003T/HHSP23320095655WC.

The ONC composite mark is a mark of the U.S. Department of Health and Human Services. The contents of the publication or project are solely the responsibility of the authors and do not necessarily represent the official views of the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology.



>Table of Contents	> <u>About the Checklist</u>	> <u>Team Worksheet</u>	> <u>About the P</u>	ractice Wo	rksheets	>P	ractice V	Worksheets
	The		y update the ro forksheet.	elated sec	tion			
The Recommended	Recommended Practices for	or <u>Domain 1 — Safe Health IT</u>		Imp	elementation SI	tatus		
Practice(s) for the				Fully in all areas	Partially in some areas	Not		
topic appear below the associated	1.1 The EHR supports an exchanging data with	d uses standardized protocols for other systems.	Worksheet 1.1	O	0	0	(reze)	
Domain.	1.2 systems, virus and ma	-date versions of operating alware protection software, and interface protocols are used.	Worksheet 1.2	O	0	0	(TESE)	Select the level of <i>Implementation</i> achieved by your organization for each
		erfaces support the standard used by the connected	Worksheet 1.3	0	0	0	(22)	Recommended Practice.
	1.4 and tested to ensure t	erfaces are properly configured that both coded and free-text data ted without loss of or changes to	Worksheet 1.4	0	0	0		Your <i>Implementation</i> <i>Status</i> will be reflected on the <i>Recommended</i>
	1.5 consistent with its con	extent of interface testing is nplexity and with the importance ness, and reliability of the data rface.	Worksheet 1.5	0	0	0	(22)	<i>Practice Worksheet</i> in this PDF.
	1.6 affects an interface, the procedures to evaluate administrators) on both	or system change or upgrade that te organization implements e whether users (clinicians or h sides of the interface correctly nformation that moves over the	Worksheet 1.6	0	0	0	(7223)	
		or software on either side of the fore and monitored after go-live.	Worksheet 1.7	0	0	0	reset	
		nd software environment for s physically separate from the live	Worksheet 1.8	0	0	0		
	10	es describe how to stop and of data across the interface in an	Worksheet 1.9		0	0	æa	
	1.10 established for manage	including role-based access, are jing and monitoring key f interfaces and data exchange.	Worksheet 1.10	0	Ø	0	(हडर)	
					ch Recom nded Prac			e is a link in this PDF.

The Worksheet provides guidance on implementing the Practice.



				1.1		
>Table of Contents	> <u>About the Checklist</u>	> <u>Team Worksheet</u>	> About the Practice Worksheets		>Practice Worksheets	\checkmark

Recommended Practices for Domain 1 — Safe Health IT			Implementation Status				
1.1	Hardware that runs applications critical to the organization's operation is duplicated.	Worksheet 1.1	Fully in all areas	Partially in some areas	Not implemented	reset	
1.2	An electric generator and sufficient fuel are available to support the EHR during an extended power outage.	Worksheet 1.2	\bigcirc	\bigcirc	\bigcirc	reset	
1.3	Paper forms are available to replace key EHR functions during downtimes.	Worksheet 1.3	\bigcirc	\bigcirc	\bigcirc	reset	
1.4	Patient data and software application configurations critical to the organization's operations are backed up.	Worksheet 1.4	\bigcirc	\bigcirc	\bigcirc	reset	
1.5	Policies and procedures are in place to ensure accurate patient identification when preparing for, during, and after downtimes.	Worksheet 1.5	\bigcirc	\bigcirc	\bigcirc	reset	

Recommended Practices for **Domain 2 — Using Health IT Safely**

Implementation Status

			Fully in all areas	Partially in some areas	Not implemented	
2.1	Staff are trained and tested on downtime and recovery procedures.	Worksheet 2.1	\bigcirc	\bigcirc	\bigcirc	reset
2.2	A communication strategy that does not rely on the computing infrastructure exists for downtime and recovery periods.	Worksheet 2.2		\bigcirc	\bigcirc	reset
2.3	Written policies and procedures on EHR downtimes and recovery processes ensure continuity of operations with regard to safe patient care and critical business operations.	Worksheet 2.3	\bigcirc	\bigcirc	\bigcirc	reset
2.4	The user interface of the locally maintained backup, read-only EHR system is clearly differentiated from the live/production EHR system.	Worksheet 2.4	\bigcirc		\bigcirc	reset
2.5	Users are trained on ransomware prevention strategies including how to identify malicious emails.	Worksheet 2.5	\bigcirc	\bigcirc	\bigcirc	reset



>Table of Contents	> <u>About the Checklist</u>	>Team Worksheet	> <u>About the Practice Worksheets</u>		>Practice Worksheets	~	
				· · · ·			

Reco	ommended Practices for Domain 3 — Monitoring Safety		Imp	lementation St	atus	
3.1	There is a comprehensive testing and monitoring strategy in place to prevent and manage EHR downtime events.	Worksheet 3.1	Fully in all areas	Partially in some areas	Not implemented	reset
3.2	Functional system downtimes (i.e., unacceptably slow response time) are identified and addressed proactively.	Worksheet 3.2	0	\bigcirc	\bigcirc	reset
3.3	Review unexpected extended system downtimes greater than 24 hours using root-cause analysis or similar approaches.	Worksheet 3.3		\bigcirc	\bigcirc	reset



>Table of Contents

> About the Checklist

>Team Worksheet

> About the Practice Worksheets

>Practice Worksheets

 \mathbf{v}

A multidisciplinary 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 Completion Date

Assessment Team Members

Assessment Team Leader

Assessment Team Notes



>Team Worksheet

> About the Checklist

>Table of Contents



>Practice Worksheets

 \mathbf{v}

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



SAFER Self-Assessment Contingency Plannin	SAFER Self-Assessment Contingency Planning Workshe		Domain 1 — <u>Safe Health IT</u>
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Te</u>	eam Worksheet	> About the Practice Workshee	ets > Practice Worksheets
Recommended Practice	to the organizat		Implementation Status
1.1 operation is duplicated. Checklist Rationale for Practice or Risk Assessment Organizations should take steps to prevent and minimize the impact of technology failures. A sir point of failure greatly increases risks both for thavailability and integrity of data. Assessment Notes	ngle	 Suggested Sources o Clinicians, support staff, clinical administration Examples of Potentia A large healthcare org per day has a remote 20 miles from the coa current patient data th hours) backup facility The warm-site is teste The organization main consisting of two diffe (a microwave or other acceptable), provided 	of Input f, and/or EHR developer Health IT support staff ally Useful Practices/Scenarios rganization that provides care 24 hours ely located (i.e., > 50 miles away and > astline) "warm-site" (i.e., a site with that can be activated in less than 8 y that can run the entire EHR. ⁵
Follow-up Actions Person Responsible for Follow-up Action		 wireless Internet acce cable-based Internet of If using a remotely ho insist that your EHR p 	ess point as a backup to their main t connection. osted EHR (e.g., cloud-based solution), provider back up data with tape, drives, or any means necessary to allow

SAFER Self-Assessment Contingency Planni	ng Worksh	mended Practice 1.2 neet	Domain 1 — <u>Safe Health IT</u>
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>1</u>	Team Worksheet	> <u>About the Practice Worksheets</u>	>Practice Worksheets
Recommended Practice		Imp	plementation Status
1.2 An electric generator and sufficient fue support the EHR during an extended p <u>Checklist</u>	l are available to ower outage. ⁹		
Rationale for Practice or Risk Assessmen	t	Suggested Sources of In	nput
Most healthcare organizations must be able to continue running their health IT infrastructure a preserve data and communication capabilities i cases of sustained power outages.		Clinicians, support staff, and clinical administration	d/or Health IT support staff
		Examples of Potentially	Useful Practices/Scenarios
Assessment Notes		and to business operatio down the EHR, and imple	he consequences to patient safety ns due to loss of power that shuts ement concrete plans to keep the nt needed to avoid unacceptable
		consequences.	
		power supply (UPS), eith	ailure, there is an uninterruptible her batteries or a "flywheel," antaneous power to maintain the tes.
		 The UPS is tested regula basis). 	arly (optimally on at least a monthly
		EHR functions critical to	trical generator is able to maintain the organization's operation (e.g., ry, clinical documentation). ¹⁰
Follow-up Actions		 The organization maintai on-site. 	ins 2 days of fuel for the generator
		 The generator is tested r monthly basis). 	egularly (optimally at least on a
		•	ator are kept in secure locations d.
Person Responsible for Follow-up Action			

JAF	ER Self-Assessment Contingency Pla	anning Worksh	leet	Safe Health IT
>Table of Contents	> <u>About the Checklist</u>	> <u>Team Worksheet</u>	> About the Practice Worksheets	>Practice Worksheets
Recommended P	Practice		Imp	lementation Status
1.3 Paper form downtimes <u>Checklist</u>	ns are available to replac . ¹¹	ce key EHR function	s during	
	ctice or Risk Assessing istrative operations need on the operations need on the operations of a downtime.		Suggested Sources of In Clinicians, support staff, and clinical administration	•
Assessment Notes		 The organization maintain patients on an in-patient u forms could include those document the administration radiology on each unit.¹² There is a process in place recorded on paper during reconciled into the EHR forms 	Jseful Practices/Scenarios as enough paper forms to care for unit for at least 8 hours. Paper e required to enter orders and ion of medications, labs, and et to ensure that the information the downtime gets entered and collowing its reactivation (e.g., oded data, scanning of paper	
Follow-up Actions				

Person Responsible for Follow-up Action

	mmended Practice 1.4 Domain 1 — sheet Safe Health IT
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Team Worksheet</u>	> <u>About the Practice Worksheets</u> >Practice Worksheets
Recommended Practice	Implementation Status
1.4 Patient data and software application configurations the organization's operations are backed up. ¹³ Checklist	critical to
Rationale for Practice or Risk Assessment	Suggested Sources of Input
Backup of mission-critical patient data and EHR system configuration allows system restoration to a "pre-failure" state with minimal data loss. In the event of failure, you are able to rely upon reliable back-up data.	Clinicians, support staff, and/or clinical administration Health IT support staff
	Examples of Potentially Useful Practices/Scenarios
	 The organization has a daily, off-site, complete, encrypted backup of patient data.¹⁴
Assessment Notes	 The off-site backup is tested regularly (i.e., complete restore) (optimally on at least a monthly basis).¹⁵
	 The content required to configure the system is backed up on a regular basis (optimally on a monthly basis and before every system upgrade).
	 The organization maintains multiple backups, created at different times.
	 Backup media are physically secured.
	 Backup media are rendered unreadable (i.e., use software to scramble media contents or physically destroy/shred media) before disposal.
Follow-up Actions	 The organization has a "read-only" backup EHR system that is updated frequently (optimally at least hourly).
	 The read-only EHR system is tested regularly (optimally at least weekly).
	 Users can print from the read-only EHR system.
	 If there is a "unit-level" read-only backup EHR system, it is connected to a local UPS or "red plug" (i.e., an outlet connected to the organization's backup electrical generator).
Person Responsible for Follow-up Action	
(reset page)	

	commended Practice 1.5 Domain rksheet Safe Hea	
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Team Workshi</u>	> <u>About the Practice Worksheets</u> >Practice Worksh	heets
Recommended Practice	Implementation Statu	IS
1.5 Policies and procedures are in place to ensure activity identification when preparing for, during, and after <u>Checklist</u>		
Rationale for Practice or Risk Assessment	Suggested Sources of Input	
Without policies, procedures, and processes in place to manage patient identification during downtimes, mismatches and lost records could compromise patient confidentiality, data integrity, and patient safety.	Clinicians, support staff, and/or EHR develo clinical administration	per
	Examples of Potentially Useful Practices/S	Scenarios
	 The read-only EHR system should have user passwords (i.e., should not employ a shared all users). 	
Assessment Notes	 There is a mechanism in place to register ne during downtime, including assignment of un temporary patient record numbers along with reconciling these new patient IDs once the E back online. Ensure that paper documents created during protected using standard HIPAA safeguards 	ique a process for HR comes downtime are
Follow-up Actions		
Person Responsible for Follow-up Action		
reset page		

SAFER Self-Assessment Contingency P	lanning Worksh	mended Practice 2.1 neet	Domain 2 — Using Health IT Safely
> <u>Table of Contents</u> > <u>About the Checklist</u>	>Team Worksheet	> <u>About the Practice Worksheets</u>	>Practice Worksheets
Recommended Practice		Impl	ementation Status
2.1 Staff are trained and tested on do procedures. ¹⁶ <u>Checklist</u>	wntime and recovery		
Rationale for Practice or Risk Assess	ment	Suggested Sources of Inp	but
In organizations that have not had a significant downtime in more than a year, there is an increased risk of having employees who do not know how to function in a paper environment.		Clinicians, support staff, and clinical administration	/or
		Examples of Potentially U	Iseful Practices/Scenarios
Assessment Notes		so that each employee kn	nd follow training requirements ows what to do to keep the fely during EHR downtimes. ¹⁷
Assessment Notes		 Clinicians are trained in us and charting tools. 	se of the paper-based ordering
		C	s unannounced EHR "downtime
		,	ed on how and when to activate

Follow-up Actions

Person Responsible for Follow-up Action

SAF	ER Self-Assessment Contingency Pl	lanning Recom	mended Practice 2.2 neet	Domain 2 — <u>Using Health IT Safe</u> t
> <u>Table of Contents</u>	> <u>About the Checklist</u>	> <u>Team Worksheet</u>	> <u>About the Practice Worksheets</u>	>Practice Worksheets
Recommended Practice			ementation Status	
	nication strategy that do ure exists for downtime			
Rationale for Pra	actice or Risk Assess	ment	Suggested Sources of Inp	out
	eeds to be prepared to key personnel without i		Clinicians, support staff, and, clinical administration	/or Health IT support staff
			Examples of Potentially U	Iseful Practices/Scenarios
Assessment Notes			 The organization has meth (i.e., not email, Twitter, vo organizational administrative when the EHR is down (ei unplanned).^{18, 20} 	ice-over-IP) to notify key ors and clinicians about times
			 The organization has a me 	echanism in place to activate R system and notify clinicians
				echanism in place to notify s back on-line (either planned
Follow-up Actions				
Person Responsible	e for Follow-up Action			

SAFER Self-Assessment Contingency Pla	nning Recomr Worksh	nended Practice 2.3 eet	Domain 2 — <u>Using Health IT Safely</u>
> <u>Table of Contents</u> > <u>About the Checklist</u>	> <u>Team Worksheet</u>	> <u>About the Practice Worksheets</u>	>Practice Worksheets
Recommended Practice		Imp	lementation Status
2.3 Written policies and procedures on recovery processes ensure continut to safe patient care and critical bus <u>Checklist</u>	ity of operations with		
Rationale for Practice or Risk Assessn	nent	Suggested Sources of In	put
Policies and procedures on EHR downtime keep everyone "on the same page" so they care for patients and maintain critical busine during inevitable downtimes, whether plann unplanned.	are able to ess operations	Clinicians, support staff, and clinical administration	/or Health IT support staff
		Examples of Potentially L	Jseful Practices/Scenarios
Assessment Notes		 when a downtime should communication will be del during the downtime (both side); how everyone will be collected during the down The EHR downtime policy 2 years.²³ The EHR downtime policy backup process should be system has been down for A paper copy of the current policy is available on clinit A paper copy of the current policy of the current policy is available on clinit 	ribes key elements such as be called; how often further livered; who will be in charge in on the clinical and technical be notified; and how information time is entered into the EHR. ²² y is reviewed at least every y describes when the warm-site e activated (ideally, before the or 2 hours). Int EHR downtime and recovery cal units.
Follow-up Actions		policy is stored in a safe,	on-site location.
Person Responsible for Follow-up Action			

SAFER Self-Assessment Contingency Plann	ing Worksh	mended Practice 2.4 leet	Domain 2 — Using Health IT Safely
> <u>Table of Contents</u> > <u>About the Checklist</u> >	Team Worksheet	> About the Practice Worksheets	>Practice Worksheets
2.4 The user interface of the locally mainta EHR system is clearly differentiated free EHR system. Checklist		ad-only	ementation Status
Rationale for Practice or Risk Assessmer When the usual system is unavailable, a read- can enable access to patient records, though i support adding or editing patient data. If it look users it could easily result in attempts to enter not be recorded.	only copy t can't is the same to	Suggested Sources of Inp Clinicians, support staff, and/ clinical administration	
Assessment Notes		 Access to the "read-only" icons on the computer scravailable) during periods of The user interface of the rivisibly different than the full is a different background of across screens, data entry 	ead-only backup EHR system is illy operational system (e.g., there color for screens, a watermark
Follow-up Actions			
Person Responsible for Follow-up Action			

SAFER Self-Assessment Contingence	y Planning Works	mended Practice 2.5 neet	Domain 2 — <u>Using Health IT Safely</u>	
> Table of Contents > About the Checklis	t > <u>Team Worksheet</u>	> About the Practice Worksheets	> Practice Worksheets	
2.5 Users are trained on ransomwincluding how to identify malic <i>Checklist</i>			lementation Status	
Rationale for Practice or Risk Ass Malicious email attachments are often point of entry for ransomware attacks.				
Assessment Notes		 spear-phishing messages, and users avoid clicking on potentially weaponized attachments (such as *.exe, *.zip, *.rar, *.7z, *.js, *.wsf, *.docm, *.xlsm, *.pptm, *.rtf, *.msi, *.bat, *.com, *.cmd, *.hta, *.scr, *.pif, *.reg, *.vbs, *.cpl, *.jar files). Safe file attachment formats include (*.jpg, *.png, *.pdf, *.docx, *.xlsx, and *.pptx).²⁴ Training should reinforce that legitimate organizational mail messages (e.g., your employer's IT department, your bank, your credit card company, companies you work with) should always meet the following requirements: 1) never ask you to download and run file attachments; 2) never ask for you to enter account or password information; 3) always have a telephone number someone can call (i.e., out-of-band check); 4) always be associated with an email address and name that people can check in their local directory; and 5) 		
Follow-up Actions		 address (URL) to build tru The organization restricts software applications usin or minimizes users' access services required by their The organization consider organization's computers. The organization conduct sends fraudulent (but safe 	users' ability to install and run ng the principle of "Least Privilege," as to only those systems and job. rs disabling the USB ports on the ²⁵ s simulated phishing attacks (i.e., e) email messages or websites that ate sources) to raise user's	
Person Responsible for Follow-up Actior				

SAFER Self-Assessment Contingency Plannin	Recomi Worksh	mended Practice 3.1 neet	Domain 3 — Monitoring Safety
>Table of Contents >About the Checklist >Te	eam Worksheet	> About the Practice Worksheets	>Practice Worksheets
Recommended Practice 3.1 There is a comprehensive testing and n place to prevent and manage EHR dow Checklist			nplementation Status
Rationale for Practice or Risk Assessment Comprehensive testing and monitoring strategies prevent and minimize the impact of technology to Assessment Notes	es can	 The organization regularisystem downtime event The organization regularisystem response time (important clinical tasks patient look-up).²⁷ The organization has a different hardware, soft testing procedures. The organization maint Unplanned downtimes 	and/or EHR developer Health IT support staff y Useful Practices/Scenarios arly monitors and reports on
Follow-up Actions Person Responsible for Follow-up Action			

SAFER Self-Assessment Contingency Planning Works	mended Practice 3.2 Domain 3 — neet Using Health IT Safely
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Team Worksheet</u>	> About the Practice Worksheets > Practice Worksheets
3.2 Functional system downtimes (i.e., unacceptably slow response time) are identified and addressed proactive <u>Checklist</u>	
Rationale for Practice or Risk Assessment	Suggested Sources of Input
Slow computer response times significantly impede user efficiency and can result in "type ahead" errors in which the computer saves commands (e.g., repeated enter key presses) and enters them (unbeknownst to the user) in the default data entry field once the form loads, resulting	Clinicians, support staff, and/or EHR developer clinical administration
in unexpected behavior.	Examples of Potentially Useful Practices/Scenarios

•

Assessment Notes

Follow-up Actions

Person Responsible for Follow-up Action

any hourly mean response time greater than 5 seconds or 3 standard deviations above the mean.²⁷
The organization creates easy mechanisms for users to

report slow system response time to the IT Helpdesk.

Create strategies to calculate system response times. One

such strategy is to create an application to submit a simple medication order for a "test patient" every day of the year

at midnight and run a simple automated query to request this order's details be displayed on a workstation in a clinical setting every minute for the next 24 hours

(i.e., 1440 times). Mean system response time is the time from order being requested until the time the details are available. Functional system downtime can be defined by

SAFER Self-Assessment Contingency Planning	Recommended Practice 3.3 Worksheet	Domain 3 — <u>Using Health IT Safely</u>
> <u>Table of Contents</u> > <u>About the Checklist</u> > <u>Team V</u>	/orksheet > About the Practice Workshe	eets > Practice Worksheets
Recommended Practice		Implementation Status
3.3 Review unexpected extended system down 24 hours using root-cause analysis or simila <u>Checklist</u>		
Rationale for Practice or Risk Assessment	Suggested Sources	s of Input
Experiences with an unexpected downtime over 24 hours are likely to provide learning opportunities for future management and prevention of similar events	Clinicians, support sta clinical administration	
	Examples of Potent	tially Useful Practices/Scenarios
Assessment Notes	 clinicians and IT pr management, iden future prevention o The organization cr experts in IT system recommendations 	onvenes a multi-disciplinary group of rofessionals to review the event and its tify potential root causes, and discuss in mitigating procedures. onsiders consulting with additional m reliability to review and report on for improvements in key system gurations, and policies and procedures.
Follow-up Actions		
Person Responsible for Follow-up Action		

References

1. Kilbridge, P. (2003). Computer crash-lessons from a system failure. New England Journal of Medicine, 348(10), 881-882.

2. Hanuscak, T. L., Szeinbach, S. L., Seoane-Vazquez, E., Reichert, B. J., & McCluskey, C. F. (2009). Evaluation of causes and frequency of medication errors during information technology downtime. American Journal of Health-System Pharmacy, 66(12).

3. McBiles, M., & Chacko, A. K. (2000). Coping with PACS downtime in digital radiology. Journal of Digital Imaging, 13(3), 136-142.

4. Sittig, D. F., & Singh, H. (2012). Electronic health records and national patient-safety goals. New England Journal of Medicine, 367(19), 1854-1860.

5. Lee, O. F., & Guster, D. (2012). Virtualized disaster recovery model for large scale hospital and healthcare systems. Advancing Technologies and Intelligence in Healthcare and Clinical Environments Breakthroughs, 307.

6. Sittig, D. F., & Singh, H. (2011). Defining health information technology-related errors: New developments since To Err Is Human. Archives of Internal Medicine, 171(14), 1281-1284.

7. Dooling, J. A. (2013). Meaningful Use and Disaster Infrastructure Q&A: HIM Professionals Share Lessons Learned. Journal of AHIMA, 84(10), 64-65.

8. Schweitzer, E. J. (2012). Reconciliation of the cloud computing model with US federal electronic health record regulations. Journal of the American Medical Informatics Association, 19(2), 161-165.

9. Jacques, C. C., Boston, M., & Mitrani-Reiser, J. (2014). Quantifying the performance of healthcare facilities in disasters: a multihazard approach. Tenth U.S. National Conference on Earthquake Engineering Frontiers of Earthquake Engineering July 21-25, 2014; Anchorage, Alaska.

10. Hiller, M., Bone, E. A., & Timmins, M. L. (2015). Healthcare system resiliency: The case for taking disaster plans further-Part 2. Journal of Business Continuity & Emergency Planning, 8(4), 356-375.

11. Lei, J., Guan, P., Gao, K., Lu, X., Chen, Y., Li, Y., ... & Zheng, K. (2014). Characteristics of health IT outage and suggested risk management strategies: An analysis of historical incident reports in China. International Journal of Medical Informatics, 83(2), 122-130.

12. McKinney, M. (2007). Technology. What happens when the IT system goes down? Hospitals & Health Networks/AHA, 81(12), 14.

13. 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.

14. Piliouras, T. C., Suss, R. J., & Yu, P. L. (2015, May). Digital imaging & electronic health record systems: Implementation and regulatory challenges faced by healthcare providers. In Systems, Applications and Technology Conference (LISAT), 2015 IEEE Long Island (pp. 1-6). IEEE.

15. Schackow, T. E., Palmer, T., & Epperly, T. (2008). EHR meltdown: how to protect your patient data. Family Practice Management, 15(6), A3.

16. Brazelton, N. C., & Lyons, A. (2014). Health Information Systems: Downtime and Disaster Recovery. PROP-Healthcare Information Systems Custom, 256.

17. Oral, B., Cullen, R. M., Diaz, D. L., Hod, E. A., & Kratz, A. (2015). Downtime Procedures for the 21st Century. American Journal of Clinical Pathology,143(1), 100-104.

18. Genes, N., Chary, M., & Chason, K. W. (2013). An academic medical center's response to widespread computer failure. American Journal of Disaster Medicine, 8(1), 2.

19. Poterack, K. A., & Gottlieb, O. (2016). Are you ready for EHR downtime? Questions to ask. ASA Newsletter, 80(2), 30-31.

References

20. Nelson, N. C. (2007). Downtime procedures for a clinical information system: a critical issue. Journal of Critical Care, 22(1), 45-50.

21. Menon, S., Singh, H., Meyer, A. N., Belmont, E., & Sittig, D. F. (2014). Electronic health record-related safety concerns: A cross-sectional survey. Journal of Healthcare Risk Management, 34(1), 14-26.

22. Scholl, M., Stine, K., Hash, J., Bowen, P., Johnson, A., Smith, C., & Steinberg, D. (2008). An introductory resource guide for implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule. NIST Special Publications 800-66 Revision 1; October 2008.

23. Fernández, M. T., Gómez, A. R., Santojanni, A. M., Cancio, A. H., Luna, D. R., & Benítez, S. E. (2014). Electronic Health Record System Contingency Plan Coordination: A Strategy for Continuity of Care Considering Users' Needs. Studies in Health Technology and Informatics, 216, 472-476.

24. Hoffman, C. (2014). How To Spot A Dangerous Email Attachment. Make Use Of (a website).

25. Wright, A., & Sittig, D. F. (2007). Security threat posed by USB-based personal health records. Annals of Internal Medicine, 146(4), 314-315.

26. Blecker, S., Austrian, J. S., Shine, D., Braithwaite, R. S., Radford, M. J., & Gourevitch, M. N. (2013). Monitoring the pulse of hospital activity: electronic health record utilization as a measure of care intensity. Journal of Hospital Medicine, 8(9), 513-518.

27. Sittig, D. F., Campbell, E. M., Guappone, K. P., Dykstra, R. H., & Ash, J. S. (2007, October). Recommendations for Monitoring and Evaluation of In-Patient Computer-based Provider Order Entry Systems: Results of a Delphi Survey. In AMIA.

28. Sittig DF, Singh H. (2010, May). (author reply) Monitoring and evaluating the use of electronic health records. JAMA. 303(19): 1918-9.