

# Executive Brief

## Establishing a Health Information Technology Safety Program



### Why Is a Formal Health Information Technology Safety Program Important?

The success of a health information technology (IT) safety program hinges on the ability of system users to recognize, react to, and report health IT-related events for analysis and action (e.g., vendor reporting, PSO reporting, vendor modifications). Two overarching factors support a health IT safety program: the organization's culture of safety and the ability to "do the right thing, even if it's not standard procedure," Christoph Lehmann, MD, FACMI, FAAP, professor of pediatrics and biomedical informatics, Vanderbilt University School of Medicine, said to participants at the September 16, 2016, meeting of the *Partnership for Health IT Patient Safety*.

Once an event is identified and reported to the appropriate parties, it can be analyzed and solutions can be developed. A health IT safety program also allows for feedback, which meeting participants identified as a key component to the safe and effective implementation and use of health IT. The provision of feedback about health IT-related issues and the actions taken within a provider organization can be accomplished in different ways; for example, two methods mentioned during the meeting were communication by managers to staff and the distribution of information on a dashboard. Vendors typically distribute information in regular or special publications, as appropriate.

A health IT safety program within a provider organization requires support from all levels of the organization, including leadership and patients, as well as vendors. Executive walkrounds and proactive patient queries can help crystallize staff members' reported concerns or demonstrate the effects of implemented solutions. Such proactive knowledge can help prioritize safety interventions and vendor actions.

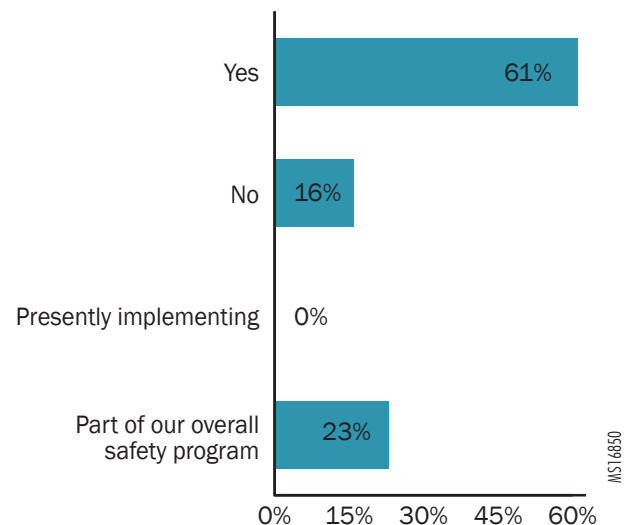
### Did You Ask?

- Does the health IT safety program incorporate the electronic health record (EHR), networked equipment, and all other technologies used and interactive with systems throughout the organization?
- Are members of the executive team, senior leadership, and/or clinical care teams accountable for and engaged in health IT system safety as an integrated part of a safety strategy and safety program? And are there provisions for evaluating and testing when new systems, equipment, or upgrades occur?
- Is feedback provided to staff members who report health IT safety concerns either internally or externally to the vendor?

### WHAT PARTICIPANTS ARE SAYING

When *Partnership* participants were asked whether they have a health IT safety program, more than half responded that they do. An additional one-quarter responded that it is part of their larger safety program, while the rest of respondents indicated that they do not have a health IT safety program.

**Figure. Do You Have a Health IT Safety System in Place?**





## Self-Assessment Questionnaire: Establishing a Health Information Technology Safety Program

Use this self-assessment questionnaire in conjunction with the following resources to review and further develop an effective health information technology (IT) safety program. Then, use the attached action plan template to track resulting projects, initiatives, and reviews.

- ECRI Institute guidance article: Health information security standards [https://www.ecri.org/components/HRC/Pages/LawReg19\\_1.aspx](https://www.ecri.org/components/HRC/Pages/LawReg19_1.aspx)\*
- ECRI Institute PSO Deep Dive: Patient identification <https://www.ecri.org/Pages/Patient-Identification-Deep-Dive.aspx>
- Office of the National Coordinator for Health Information Technology (ONC) SAFER guide: organizational responsibilities [https://www.healthit.gov/sites/safer/files/guides/safer\\_organizationalresponsibilities\\_sg002\\_form\\_0.pdf](https://www.healthit.gov/sites/safer/files/guides/safer_organizationalresponsibilities_sg002_form_0.pdf)

	yes	no	n/a	in progress	notes
<b>Foundation</b>					
1. Does the organization rely on a standard definition of health IT safety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Does this definition include safe use of the technology?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Does this definition include the equipment itself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Does this include using health IT to improve safety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. If there is no freestanding health IT safety program, is the health IT safety program integrated into other existing and maintained programs (e.g., patient safety, quality, risk, or others)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is the organization alert for health IT safety events as well as events in which health IT safety plays a role?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Does the health IT safety program incorporate the electronic health record (EHR), all networked equipment, and all technologies used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Does the health IT safety program address or support IT security measures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Does the health IT safety program address or support equipment security measures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Does this program address personal device use (e.g., bring-your-own-device policies)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Is the health IT safety program or program component reviewed regularly for effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

\* Some materials are included in memberships to ECRI Institute products and services. For information about these reports, contact [clientservices@ecri.org](mailto:clientservices@ecri.org)



	yes	no	n/a	in progress	notes
7. Is education provided to staff as a part of the health IT safety program?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Does this education occur upon hire and whenever new upgrades, systems, modifications, or other system changes occur?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Is this education documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Does this education include the importance of awareness, reporting, and security practices?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Does the organization use evidence-based assessments, such as those included in the ONC SAFER guides?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Are human-factors specialists part of health IT evaluations and health IT safety and usability considerations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Are clinicians engaged in health IT safety practice development and assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11. Are proactive failure modes and effects analyses (FMEAs) conducted for health IT-related issues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. Are designated resources regarding health IT safety identified and made available to staff?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### Using Leadership Roles to Champion Health IT Safety

13. Are sufficient resources dedicated to health IT safety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. Are experts available as part of health IT safety program resources?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Do executives and senior leaders participate in walkrounds?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Do these walkrounds include consideration of health IT safety-related issues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Do these walkrounds include consideration of workflow (i.e., are leaders asked to be aware of the potential for—and reasons behind—workarounds and to attempt to resolve the need for them)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Is a member of the executive team or senior leadership accountable for and engaged in health IT safety?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



	yes	no	n/a	in progress	notes
17. Is patient feedback sought regarding health IT system use or concerns?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Is this feedback brought to the attention of the health IT safety committee?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Is this feedback, when appropriate, brought to the attention of the vendor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Is it used to analyze and implement improvements to the health IT system?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### Event Reporting and Analysis

18. Does the organization have a surveillance mechanism (automatic or manual) in place to identify and flag health IT-related issues (e.g., patient queries, failure modes and effects analysis, root-cause analysis, walkrounds, PSO reporting, feedback loops, or vendor-provided safety information)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19. Does this method of identifying health IT-related issues include—					
a. Review of relevant adverse-event report data by a designated staff member?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Coordination as appropriate with internal IT staff and the vendor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Reviewing equipment failures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Identifying and reviewing the source of use errors or workaround?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Encouraging staff to report technology hazards, such as difficult interfaces or confusing elements that may lead to potential errors or workarounds?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Review of safety committee findings?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Tracking compliance with equipment inspection and preventive maintenance schedules?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. Monitoring downtime and the impact it has on health IT-related issues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. Reviewing relevant patient complaints and concerns?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j. Looking for workarounds?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
k. Raising awareness of vendor-reported issues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



	yes	no	n/a	in progress	notes
l. Are health IT-related events reported to the appropriate individual (e.g., risk manager, IT staff, vendor, medical director)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20. Does the organization analyze the frequency and severity of identified health IT-related safety problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Does this evaluation include review of the factors contributing to the health IT-related safety problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Does this evaluation include comparing typical work practices (i.e., actual practices, including potential work-arounds) with current standards and procedures (i.e., recommended or ideal practices)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21. Are the findings of analyses communicated to the appropriate individuals (e.g., the safety committee, risk manager, IT leadership, chief medical informatics officer, designated safety representative, department leaders, vendors)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22. When conducting a root-cause analysis (RCA) for a safety event, are health informatics personnel, IT, and clinicians part of the process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23. Does the organization share its learnings—					
a. Within the reporting facility?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Across the organization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. With the vendor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Outside the organization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Through a relationship with a patient safety organization (PSO)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24. Does the organization use data from its PSO for further learning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25. Does an event trigger a search for previous or other potential similar events?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Engaging Providers, Staff, and Patients</b>					
26. Are clinicians aware of and engaged in health IT safety practices?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
27. Do patients have access to their information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Do they have a way to indicate the information's validity or error?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



	yes	no	n/a	in progress	notes
b. Are potential security issues with patient access to information addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Are staff aware of the risk of IT security breach from:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Computer viruses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Phishing, spamware, or other malware attacks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Equipment theft or loss?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Intentional or unintentional HIPAA [Health Insurance Portability and Accountability Act] violations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
28. Is the reporting of health IT safety events, near misses, or hazardous conditions encouraged and supported?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
29. Is feedback provided to those who do report?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a. Is a dashboard used to provide feedback?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Are safety-reporting feedback and updates provided to staff members?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



# Action Plan

## Establishing a Health Information Technology Safety Program

Assessment completed by: \_\_\_\_\_ Date: \_\_\_\_\_

QUESTION NO.	ACTION REQUIRED	RESPONSIBILITY	TARGET DATE	ACTION COMPLETED	
				DATE	INITIALS