ECRI INSTITUTE PSO DEEP DIVE: HEALTH INFORMATION TECHNOLOGY—TOOLKIT

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PATIENT SAFETY, RISK, AND QUALITY PROFESSIONALS' GUIDE TO HEALTH IT PROJECTS

ECRI Institute PSO's Deep Dive™ analysis of health information technology (IT)-related safety events identified a wide array of patient safety concerns that can arise from health IT use in healthcare organizations. The analysis identified events ranging from the incomplete transfer of data between health IT systems to data input in the wrong patient record. These unintended consequences of health IT systems can jeopardize patient care and safety. Although IT and patient safety, risk, and quality departments within healthcare operations have not traditionally worked together on projects, the Deep Dive analysis underscores the need for the involvement of patient safety, risk, and quality professionals in health IT system planning, design, implementation, and ongoing monitoring.

ECRI Institute PSO has developed this Self-Assessment Questionnaire (SAQ) to assist organizations in identifying risk management issues that must be addressed with their health IT system projects. The SAQ can be used to identify the strengths and weaknesses in the organization's risk management approach to health IT and focus on those areas requiring attention. The questions cover all three phases underpinning health IT adoption within healthcare organizations: (1) planning for new or replacement health IT systems, (2) health IT implementation, and (3) ongoing health IT system use and evaluation.

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Self-Assessment Questionnaire for Health IT Projects

Project Planning

	yes	no	n/a	in progress	notes
1. Does a representative from the patient safety, risk, and/or quality departments participate in health IT project planning to identify possible patient safety, risk, or quality issues involving health IT system selection, acquisition, or implementation?	☐	☐	☐	☐	
2. Does input from patient safety, risk, and/or quality departments about the health IT project include:					
a. Regulatory status of the health IT system (e.g., does the U.S. Food and Drug Administration [FDA] regulate the product?)?	☐	☐	☐	☐	
b. Certification, if needed for the health IT system, in meeting meaningful use criteria established by the U.S. Department of Health and Human Services?	☐	☐	☐	☐	
c. Measures to ensure the organization's compliance with federal and state privacy and security requirements for the health IT system?	☐	☐	☐	☐	
d. Human factors evaluation of the health IT system (e.g., ease of navigation, intuitive data display)?	☐	☐	☐	☐	
e. Staff training needs?	☐	☐	☐	☐	
f. Impact on staffing levels and staff productivity?	☐	☐	☐	☐	
g. Effect on patient care and outcomes?	☐	☐	☐	☐	
h. Documented risks, hazards, and problems with the health IT system?	☐	☐	☐	☐	
i. Legal exposure from the health IT system?	☐	☐	☐	☐	
3. Does the health IT project planning include an assessment of the organization's IT infrastructure and its capability to support the health IT system?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
4. Does the health IT project planning identify system redundancies that will be needed (e.g., extra workstations, multiple connections to the network) to minimize any disruptions to the health IT system?	☐	☐	☐	☐	
5. Does the health IT project planning identify multiple backup measures (ranging from multiple power sources to the use of paper-based systems and documentation) to ensure that patient care can be delivered during power interruptions affecting the health IT system?	☐	☐	☐	☐	
6. Are the work spaces where the health IT systems will be installed evaluated to ensure the space is adequate and free of clutter, distractions, and noise?	☐	☐	☐	☐	

Vendor Contract Review and Monitoring

7. Are vendor contracts for health IT system purchases reviewed for legal, risk management, and patient safety issues?	☐	☐	☐	☐	
8. Does the contract review include:					
a. Equipment specifications, including a statement about the necessary hardware, software, and third-party products required to run the health IT system's applications?	☐	☐	☐	☐	
b. Assurances that the health IT system software satisfies all federal and state regulatory requirements (including privacy and security obligations)?	☐	☐	☐	☐	
c. Demonstration that the product is certified, if appropriate, for meaningful use and that the product remains certified by an authorized testing and certification body?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
d. User licenses for any software required to run the health IT system's applications?	☐	☐	☐	☐	
e. Implementation plan and project timeline?	☐	☐	☐	☐	
f. Successful completion of acceptance testing and provisions if the vendor fails to achieve acceptance?	☐	☐	☐	☐	
g. Additional costs for new software releases, new functional capabilities, and other product upgrades or enhancements?	☐	☐	☐	☐	
h. Software maintenance?	☐	☐	☐	☐	
i. Commitments to work with the organization's IT department to build health IT system interfaces or, at a minimum, to provide, at no charge, the documentation to enable a facility to build and maintain its own interfaces?	☐	☐	☐	☐	
j. Adherence to standard formats (e.g., Digital Imaging and Communications in Medicine [DICOM]) that enable data sharing among health IT products?	☐	☐	☐	☐	
k. Technical support and response time?	☐	☐	☐	☐	
l. User training, including training for any updates and enhancements provided under the contract?	☐	☐	☐	☐	
m. Uptime guarantees?	☐	☐	☐	☐	
n. Notification of product problem reports?	☐	☐	☐	☐	
o. Measures to ensure continued operation of the health IT system if the vendor is acquired, goes out of business, or files for bankruptcy?	☐	☐	☐	☐	
p. Warranties and disclaimers?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
q. Hold-harmless and indemnification provisions (including indemnification to protect the purchaser from Health Insurance Portability and Accountability Act and privacy or confidentiality violations by the vendor and from third-party claims for harm, injury, or death caused by the vendor's personnel or products)?	☐	☐	☐	☐	
r. Provider ownership of data generated by the health IT system?	☐	☐	☐	☐	
s. Strict limitations on the vendor's use of patient information?	☐	☐	☐	☐	
t. Completion of a business associate agreement?	☐	☐	☐	☐	
9. Does the organization monitor equipment service provided by the health IT vendor and outside service vendors?	☐	☐	☐	☐	
10. Are all outstanding problems involving the health IT system reported to the vendor before expiration of the warranty period?	☐	☐	☐	☐	

Work Practices and Redesign

11. Does the health IT project planning identify all work practices (e.g., test results reporting, drug ordering) that will be affected by the health IT system?	☐	☐	☐	☐	
12. Are strategies in place to redesign these work practices for an electronic environment with input from clinicians and staff members who are affected?	☐	☐	☐	☐	
13. Is a process in place to evaluate clinical decision-support alerts, with input from appropriate stakeholders, to limit the number of alerts to those that are essential?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
14. Are the redesigned work practices evaluated for the potential to introduce new errors, hazards, or unsafe practices, and are these new risks addressed to prevent them from occurring?	☐	☐	☐	☐	

Policies and Procedures

15. Does a patient safety, risk, or quality professional identify any policies or procedures that must be developed (e.g., limits on copying and pasting notes from an electronic medical record, measures to reduce entry errors in the wrong patient record, requirements for documenting rationale for overriding clinical decision-support alerts) or revised (e.g., changes to medication ordering, changes to test results reporting processes) before the health IT system is fully implemented?	☐	☐	☐	☐	
16. Are measures in place to develop or revise those policies and to educate staff about them as part of the health IT implementation plan?	☐	☐	☐	☐	
17. Does the organization monitor health IT system users' compliance with the organization's health IT system policies and procedures and is the information incorporated into staff performance evaluations and clinician credentialing processes?	☐	☐	☐	☐	
18. Has the facility identified a realistic, but short-range, goal to phase out paper-based systems and proceed with full implementation of the health IT system rather than allow prolonged hybrid approaches to paper-based and electronic systems?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
19. Does the organization have a formal, written policy for monitoring hazards, recalls, and alerts involving the health IT system and for responding to any identified hazard, recall, or alert?	☐	☐	☐	☐	
20. Are there procedures for documenting the organization's response to any identified hazard, recall, or alert?	☐	☐	☐	☐	

Data Exchange

21. Has the organization assessed the extent of data exchange that it can achieve with the health IT system (i.e., the system's ability to share information across different health IT systems within the organization, as well as the retrieval of data from medical devices)?	☐	☐	☐	☐	
22. If the organization must build interfaces between health IT applications, does its IT department or a third party have the expertise to build those applications and access to the necessary vendor documentation?	☐	☐	☐	☐	

System Testing

23. Does the organization thoroughly test the health IT system to ensure the system will behave as expected (e.g., with the right data flowing into the right record) before it is fully implemented?	☐	☐	☐	☐	
24. When testing is performed in a live environment, are the test scenarios designed in a way to avoid merging test data with real patient information?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
25. Does the organization seek staff members' input (e.g., using surveys, conducting walkarounds) on the usability of the health IT system as it is implemented?	☐	☐	☐	☐	
26. Does the organization use the findings from user surveys and interviews to make improvements to the health IT system as it is implemented?	☐	☐	☐	☐	

Staff Training and Support

27. Are all health IT system users required to attend training sessions about the system before they are allowed to use the system for patient care?	☐	☐	☐	☐	
28. Do the training sessions include education about new or revised policies and procedures in place with the health IT system (e.g., policies to document rationale for overriding clinical decision-support alerts)?	☐	☐	☐	☐	
29. Do the training sessions include education about cleaning procedures for the equipment (e.g., system users and housekeeping staff are instructed on the appropriate cleaning products to use with the equipment)?	☐	☐	☐	☐	
30. Are health IT system users required to demonstrate competence in using the system after training is provided?	☐	☐	☐	☐	
31. Are health IT system users made aware of the new types of errors that can be introduced in an electronic system (e.g., entries posted near midnight could be recorded for the next day [24 hours later])?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
32. Is the time frame between health IT system orientation and implementation kept short so the information remains fresh for staff?	☐	☐	☐	☐	
33. Is additional staff training provided any time the health IT system undergoes a significant change?	☐	☐	☐	☐	
34. Does the organization provide periodic refresher training for users of the health IT system?	☐	☐	☐	☐	
35. Does the organization conduct drills, involving staff from all shifts, of procedures to follow when the health IT system is down?	☐	☐	☐	☐	
36. Are all new and temporary personnel who will need to use the health IT system instructed in use of the system before they begin work in their assigned department?	☐	☐	☐	☐	
37. Is documentation of each staff member's health IT system training (including training that is provided when upgrades are introduced) maintained?	☐	☐	☐	☐	
38. Do health IT system users have access, during all working hours, to health IT system support staff who can answer questions and respond to problems?	☐	☐	☐	☐	
39. Does the organization identify computer-proficient clinicians and staff members who are available as "super users" to help staff, particularly during the early stages of system implementation?	☐	☐	☐	☐	

Event Reporting and Response

40. Are health IT system users instructed on using the organization's patient safety adverse event reporting system to report events, near misses, and hazardous conditions involving the system?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
41. Does the organization encourage event reporting by supporting a nonpunitive (but accountable) approach to staff reporting of adverse events, near misses, and hazardous conditions involving the health IT system?	☐	☐	☐	☐	
42. Has a patient safety, risk, and/or quality professional reviewed the event report form to ensure that information pertinent to health IT-related events is collected in the report?	☐	☐	☐	☐	
43. Does the event report form use common language and terminology to prompt the sharing of data about events associated with health IT systems?	☐	☐	☐	☐	
44. Does the patient safety, risk, and/or quality department have a process in place to forward any event reports raising technical issues to the IT department for resolution?	☐	☐	☐	☐	
45. Does the patient safety, risk, and/or quality department have a process in place to identify health IT events requiring additional analysis to understand the systems issues that may have contributed to the event and to identify measures to prevent recurrence of similar events?	☐	☐	☐	☐	
46. Does a representative from the IT department, in addition to other appropriate stakeholders, participate in all follow-up systems analyses of health IT-related events?	☐	☐	☐	☐	
47. Is a process in place to track corrective actions identified as a result of a systems analysis of health IT-related events (e.g., identify the corrective actions, designate responsible department or individual, specify time frame for implementation)?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
48. Are the findings from the event analysis reported to appropriate departments and individuals within the organization?	☐	☐	☐	☐	
49. Is a mechanism in place to provide staff members with information about interventions and error-prevention strategies put in place as a result of information reported to the event reporting system?	☐	☐	☐	☐	
50. Is the organization's leadership kept informed of safety issues involving health IT systems identified by the event reporting program and processes to ensure that health IT safety is improved?	☐	☐	☐	☐	
51. Is there a plan in place for disclosing health IT-related events that result in unanticipated outcomes of care to patients and their families?	☐	☐	☐	☐	
52. Does the organization have a process to identify health IT-related events that will be reported to external organizations (e.g., ECRI Institute, Institute for Safe Medication Practices, the Joint Commission)?	☐	☐	☐	☐	
53. Does the organization have a process to determine whether adverse events involving health IT systems must be reported to FDA under the mandatory reporting provisions of the Safe Medical Devices Act?	☐	☐	☐	☐	
54. Does the organization set aside funds in its capital budget for ongoing maintenance and improvements to the health IT system?	☐	☐	☐	☐	
55. Does a representative from the IT department participate on patient safety, risk management, and/or quality committees to foster communication between the IT and patient safety, risk, and quality departments?	☐	☐	☐	☐	

	yes	no	n/a	in progress	notes
56. Does the organization identify metrics (e.g., percentage of system uptime, percentage of alerts overridden by clinicians) that it will use to monitor and report the effectiveness of the health IT system?	☐	☐	☐	☐	
57. Is data about the health IT system's effectiveness used to identify system strengths and weaknesses and areas for improvement?	☐	☐	☐	☐	
58. Does the organization incorporate automated surveillance techniques (e.g., screening for specific data suggestive of an adverse drug event) into its health IT system operations to enhance detection of patient care errors?	☐	☐	☐	☐	
59. Is pertinent data about the health IT system's effectiveness and its impact on patient care reported to the organization's senior leaders and board of trustees?	☐	☐	☐	☐	
60. Does the organization periodically evaluate its health IT system practices (e.g., test results reporting, medication ordering) to identify areas for improvement?	☐	☐	☐	☐	
61. Does the organization use proactive analysis, such as risk assessment or failure mode and effects analysis, to periodically evaluate high-risk processes associated with the health IT systems (e.g., reporting of critical test results) and to identify potential failure modes in those processes?	☐	☐	☐	☐	
62. Does the organization use the information learned from proactive analysis of the health IT system to make improvements to the system?	☐	☐	☐	☐	
63. Does the organization have mechanisms in place to identify workarounds that are adopted by health IT system users?	☐	☐	☐	☐	

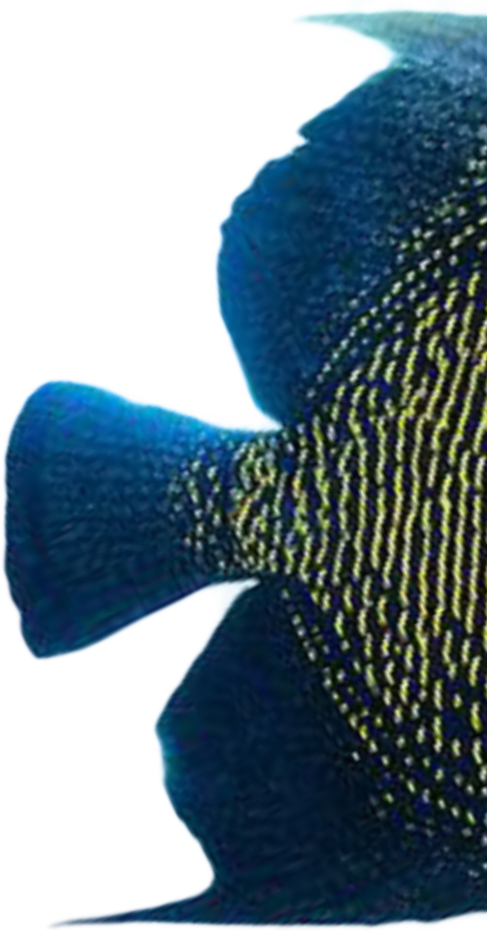
	yes	no	n/a	in progress	notes
64. Does the organization identify the reasons for health IT users to resort to workarounds and use that information to develop strategies that will eliminate the use of workarounds?	☐	☐	☐	☐	
65. Does the organization's senior leaders, or other appropriate managers, periodically interview staff members about their experience using the health IT system to identify areas for improvement?	☐	☐	☐	☐	
66. Does the organization maintain an inventory of interfaced devices and systems, including the software versions and configurations of the various interfaced components?	☐	☐	☐	☐	
67. Does the organization have policies and procedures for change management (i.e., a structured approach for ensuring that system modifications, such as software upgrades and scheduled maintenance, are performed in a controlled manner)?	☐	☐	☐	☐	
68. Does the organization's change management policy include processes to ensure that the privacy and security of patients' protected health information is not jeopardized by system modifications?	☐	☐	☐	☐	
69. Does the organization assess, approve, and implement changes (e.g., hardware and software upgrades, security changes, new applications, new work processes, planned maintenance) to interfaced medical devices and IT systems in a controlled manner to evaluate their impact on the various components of the networked devices and IT system?	☐	☐	☐	☐	
70. If any concerns are identified during testing of changes and updates to interfaced medical devices and IT systems, are they addressed before any changes are fully implemented?	☐	☐	☐	☐	

ACTION PLAN

Health Information Technology

question no.	action required	responsibility	target date	action completed	
				date	initials

question no.	action required	responsibility	target date	action completed	
				date	initials



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