Implementation of Quarterly Risk Assessments

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- Instructions on how to access the post webinar survey and obtain a Certificate of Completion will be provided at the end of the presentation.
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Learning Objectives

- Identify two high-risk areas that may warrant a risk assessment.
- Describe two tools that can be used to conduct a risk assessment.
- Create more robust action plans for quarterly risk assessments.

Polling Question #1

Risk assessments must be completed at least:

a) Quarterly

b) Annually

c) Monthly

Answer: Quarterly

Health Center Program FTCA Deeming Application

Application for Health Center Program Award Recipients for Deemed Public Health Service Employment with Liability Protections Under the Federal Tort Claims Act (FTCA)

- I attest that my health center has implemented an ongoing risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation and that this program requires the following:
  - **Completion of quarterly risk assessments by the health center.**

Risk Management Process

Traditional Steps of the Risk Management Process

National Patient Safety Foundation. *Free from Harm*. 2015.

Risk Management Process

"Learning organizations are preoccupied with the possibility of preventable harm in order to be poised to identify problems and develop corrective actions."

National Patient Safety Foundation. *Free from Harm*. 2015.

Risk Assessments

Risk Assessments (Slide 1 of 3)

A risk assessment is a structured process used to identify potential hazards at all levels of the organization.

Quarterly risk assessments reduce the risk of adverse outcomes that could result in medical malpractice or other health-related litigation.

Risk assessments generate information that can be used to proactively identify, prioritize, and address patient safety and risk management concerns.

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Risk Assessments (Slide 2 of 3)

Risk assessments should focus on areas that can potentially prevent or decrease the likelihood of medical malpractice claims (i.e., patient safety, clinically focused assessments).

Do not include non-clinical elements such as building maintenance and parking lot inspections. While important, these elements will typically not result in claims related to medical malpractice.

Risk Assessments (Slide 3 of 3)

The process for risk assessments should be included in the risk management plan.

Leadership commitment and support should be ensured.

Polling Question #2

FTCA requirements identify the following areas of high risk (choose all that apply):

a) Infection control and sterilization

b) Confidentiality (HIPAA)

c) Obstetrics

d) Tracking and follow-up of abnormal test results

e) All of the above

Answer: All of the above

Risk Assessments

Risk assessments should focus on organizational priorities and high-risk areas.

FTCA requirements identify the following areas of high risk:

- Tracking for diagnostic tests
- Tracking for referrals
- Tracking for hospital admissions
- Infection control and sterilization
- Confidentiality (HIPAA)
- Obstetrics

Risk Assessments: Other Areas of Risk

- Medication management
- Falls
- Patient identification
- Informed consent
- Telephone triage and management
- Communication and teamwork
- Patient satisfaction
- Complaints and grievances
- Emergency preparedness
- Equipment and supplies
- Safety and security
- Credentialing and privileging

Risk Assessments: Other Considerations

Also consider:

- Low frequency and/or low volume services.
- Services reflecting an expanded scope of project
  - E.g., Behavioral health, dental, obstetrics.

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Tools for Risk Assessments

Polling Question #3

The following tools can be used to conduct a risk assessment (choose all that apply):

a) Safety culture survey

b) Self-assessment questionnaires

c) Failure mode and effects analysis

d) All of the above

Answer: All of the above

Tools for Risk Assessments

- Safety culture survey
- Self-assessment questionnaires
- Failure mode and effects analysis (FMEA)
- Trigger tools
- Leadership safety rounds

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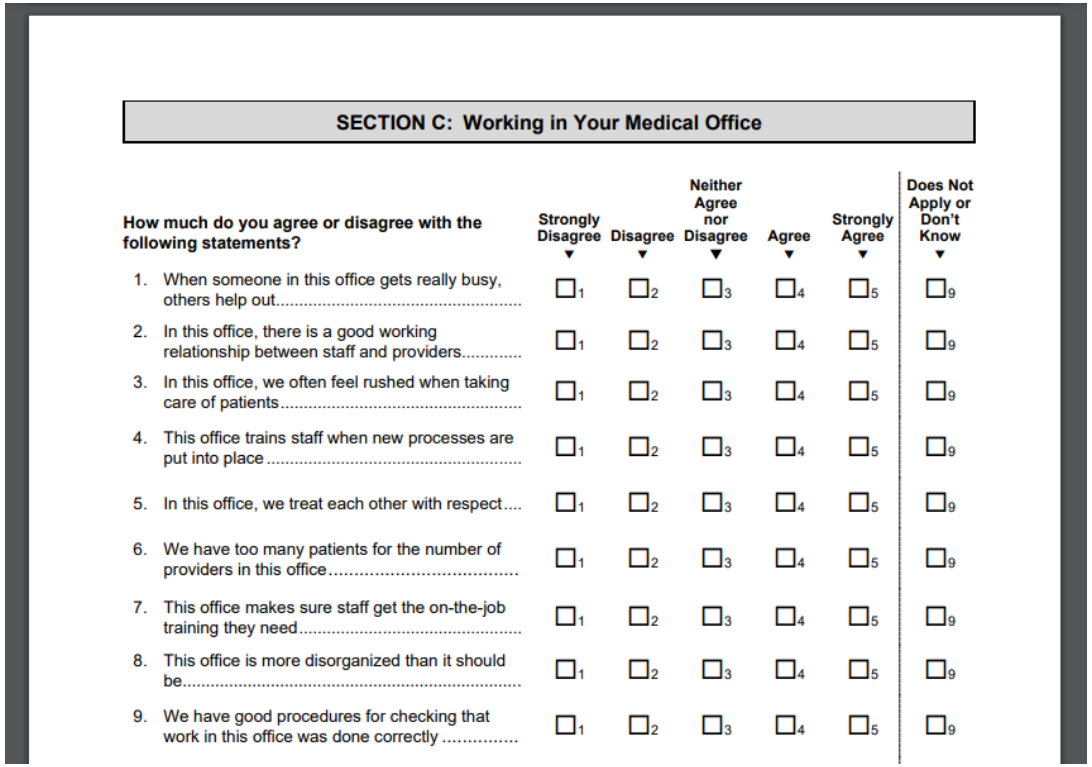
Safety Culture Survey (Slide 1 of 3)

AHRQ Medical Office
Survey on Patient Safety Culture



SECTION C: Working in Your Medical Office

How much do you agree or disagree with the following statements?	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Does Not Apply or Don't Know
1. When someone in this office gets really busy, others help out	☐1	☐2	☐3	☐4	☐5	☐9
2. In this office, there is a good working relationship between staff and providers	☐1	☐2	☐3	☐4	☐5	☐9
3. In this office, we often feel rushed when taking care of patients	☐1	☐2	☐3	☐4	☐5	☐9
4. This office trains staff when new processes are put into place	☐1	☐2	☐3	☐4	☐5	☐9
5. In this office, we treat each other with respect	☐1	☐2	☐3	☐4	☐5	☐9
6. We have too many patients for the number of providers in this office	☐1	☐2	☐3	☐4	☐5	☐9
7. This office makes sure staff get the on-the-job training they need	☐1	☐2	☐3	☐4	☐5	☐9
8. This office is more disorganized than it should be	☐1	☐2	☐3	☐4	☐5	☐9
9. We have good procedures for checking that work in this office was done correctly	☐1	☐2	☐3	☐4	☐5	☐9

- Communication about error.
- Communication openness.
- Office processes and standardization.
- Organizational learning.
- Overall perception of patient safety and quality.
- Leadership support.
- Patient care tracking/follow-up.
- Staff training.
- Teamwork.
- Work pressure and pace.

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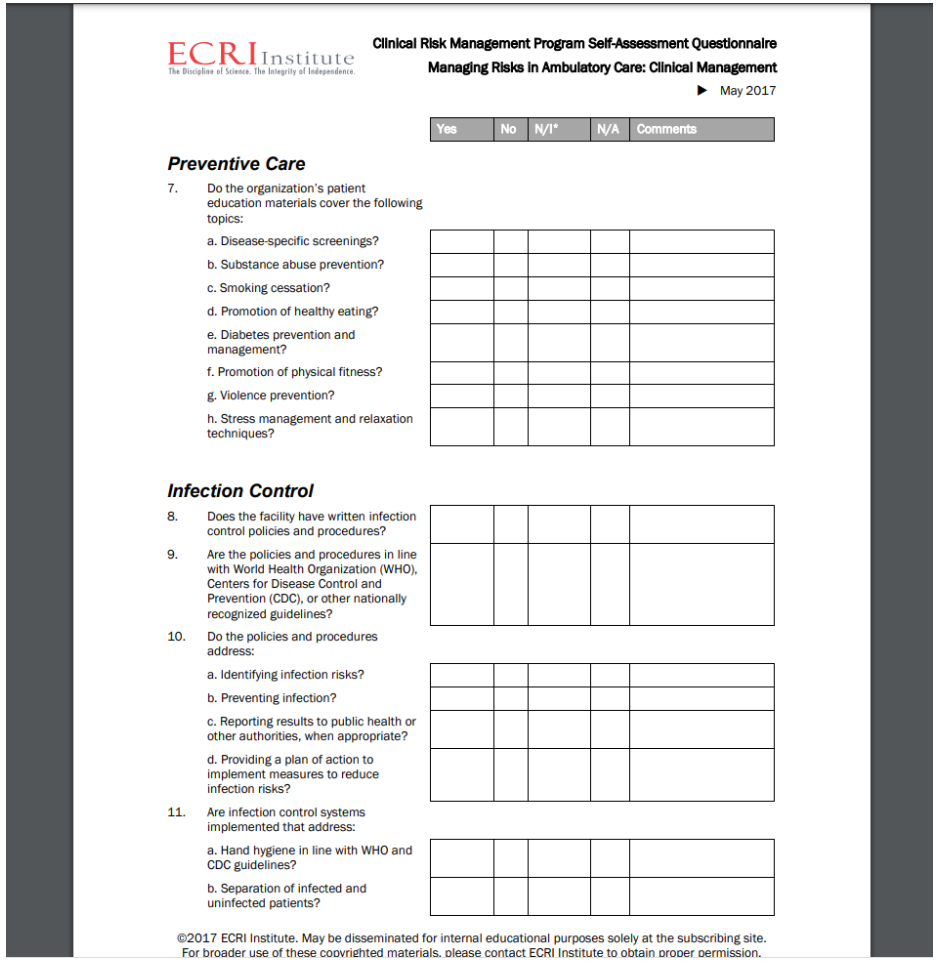
Safety Culture Survey (Slide 2 of 3)

- Ambulatory-care-specific safety attitudes questionnaire, called SAQ-A.
  - Developed by the University of Texas's (Houston) Center of Excellence for Patient Safety Research and Practice.
  - SAQ-A is a modification of the safety attitudes questionnaire for hospitals and has been validated as a reliable tool for assessing safety culture.

Safety Culture Survey (Slide 3 of 3)

- Physician Practice Patient Safety Assessment (PPPSA).
  - Created by the American Hospital Association's Health Research and Educational Trust, the Institute for Safe Medication Practices, and the Medical Group Management Association's Center for Research.

Self-Assessment Questionnaires



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Clinical Risk Management Program Self-Assessment Questionnaire
Managing Risks in Ambulatory Care: Clinical Management
▶ May 2017

	Yes	No	N/I*	N/A	Comments
Preventive Care					
7. Do the organization's patient education materials cover the following topics:					
a. Disease-specific screenings?					
b. Substance abuse prevention?					
c. Smoking cessation?					
d. Promotion of healthy eating?					
e. Diabetes prevention and management?					
f. Promotion of physical fitness?					
g. Violence prevention?					
h. Stress management and relaxation techniques?					
Infection Control					
8. Does the facility have written infection control policies and procedures?					
9. Are the policies and procedures in line with World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), or other nationally recognized guidelines?					
10. Do the policies and procedures address:					
a. Identifying infection risks?					
b. Preventing infection?					
c. Reporting results to public health or other authorities, when appropriate?					
d. Providing a plan of action to implement measures to reduce infection risks?					
11. Are infection control systems implemented that address:					
a. Hand hygiene in line with WHO and CDC guidelines?					
b. Separation of infected and uninfected patients?					

- Resources:
  - ISMP Medication Safety Self-Assessments
  - ECRI Self-Assessment Questionnaires
  - ECRI Get Safe! Series
  - ECRI Practice Alert! Series
  - ECRI Tools for Leadership
  - JC Sentinel Event Alerts

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Failure Mode and Effects Analysis (FMEA) (Slide 1 of 2)

- Systematic, proactive, multidisciplinary method of risk assessment that evaluates individual steps in a process.
  - Useful for evaluating and improving high risk or problematic processes, proposed changes to existing processes, or new processes.

Adapted from ECRI Ambulatory Risk Management Certificate Program: Introduction to Failure Mode and Effects Analysis.

Failure Mode and Effects Analysis (FMEA) (Slide 2 of 2)

- Diagram steps in a process.
- Identify potential failure modes.
  - What could go wrong?
- Calculate criticality to determine which failure modes need immediate attention.
  - Use a hazard matrix to define frequency, severity, and discoverability.
  - Score = F x S x D.
- Focus upon top-scoring failure modes.

Adapted from QI Essentials Toolkit: Failure Mode and Effects Analysis (FMEA) Tool. Institute for Healthcare Improvement, 2017.

Trigger Tools

- Trigger tools are ways of identifying and documenting patient harm using a systematic record review process on randomly selected medical records.
  - A trigger tool uses “triggers” (or clues) to identify adverse events (harm) and measure the rate of adverse events over time.
  - E.g., Institute for Healthcare Improvement (IHI) Global Trigger Tool for Measuring Adverse Events.

Institute for Healthcare Improvement (IHI) Global Trigger Tool for Measuring Adverse Events, 2009.

Leadership Safety Rounds (Slide 1 of 2)

- Leaders and/or the risk manager walk around the health center and ask employees about patient safety concerns while observing processes in action.

Leadership Safety Rounds (Slide 2 of 2)

- Specific questions should be asked, and feedback should be solicited.
  - What is your biggest safety concern?
  - What can be done to prevent the next adverse event?
  - Do you feel respected by everyone you work with?
  - If you prevent or intercept an error, do you always report it?
  - If you make or report an error, are you concerned about personal consequences?

Polling Question #4

Leadership safety rounds are only considered a risk assessment if findings are recorded and prioritized, and a corrective action plan is developed.

a) True

b) False

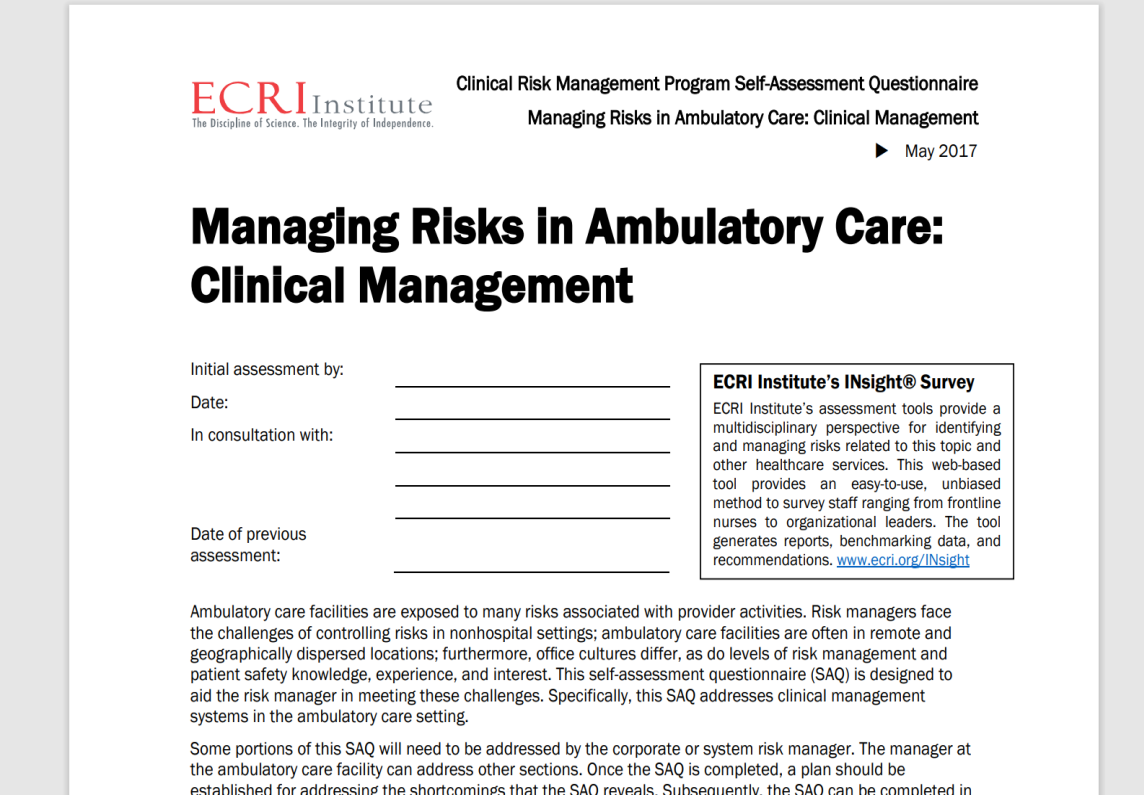
Answer: True

Where to Start

Where to Start (Slide 1 of 7)

- ECRI Institute Clinical Risk Management Self-Assessment Questionnaire
- High-Risk Areas Identified in the FTCA Requirements
- Safety Culture Survey
- Patient Satisfaction
- Complaints and Grievances

Where to Start (Slide 2 of 7)



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Clinical Risk Management Program Self-Assessment Questionnaire
Managing Risks in Ambulatory Care: Clinical Management
▶ May 2017

Managing Risks in Ambulatory Care: Clinical Management

Initial assessment by: _____
Date: _____
In consultation with: _____
_____
_____
Date of previous assessment: _____

ECRI Institute's INsight® Survey

ECRI Institute's assessment tools provide a multidisciplinary perspective for identifying and managing risks related to this topic and other healthcare services. This web-based tool provides an easy-to-use, unbiased method to survey staff ranging from frontline nurses to organizational leaders. The tool generates reports, benchmarking data, and recommendations. www.ecri.org/INsight

Ambulatory care facilities are exposed to many risks associated with provider activities. Risk managers face the challenges of controlling risks in nonhospital settings; ambulatory care facilities are often in remote and geographically dispersed locations; furthermore, office cultures differ, as do levels of risk management and patient safety knowledge, experience, and interest. This self-assessment questionnaire (SAQ) is designed to aid the risk manager in meeting these challenges. Specifically, this SAQ addresses clinical management systems in the ambulatory care setting.

Some portions of this SAQ will need to be addressed by the corporate or system risk manager. The manager at the ambulatory care facility can address other sections. Once the SAQ is completed, a plan should be established for addressing the shortcomings that the SAQ reveals. Subsequently, the SAQ can be completed in

- Self-assessment for:
  - Preventive care
  - Infection control
  - Sharp injury prevention
  - Lab tests and results
  - Medication safety
  - Health information management
  - Informed consent

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Where to Start (Slide 3 of 7)

- High-risk areas identified in the FTCA requirements:
  - Tracking for diagnostic tests.
  - Tracking for referrals.
  - Tracking for hospital admissions.
  - Infection control and sterilization.
  - Confidentiality (HIPAA).
  - Obstetrics.

Where to Start (Slide 4 of 7)

- Safety culture survey
  - Starting point for improving the safety culture.
  - Intended to gauge staff perceptions of the current patient safety climate.
  - Conduct a survey to obtain baseline information and then repeat the survey periodically to assess progress.

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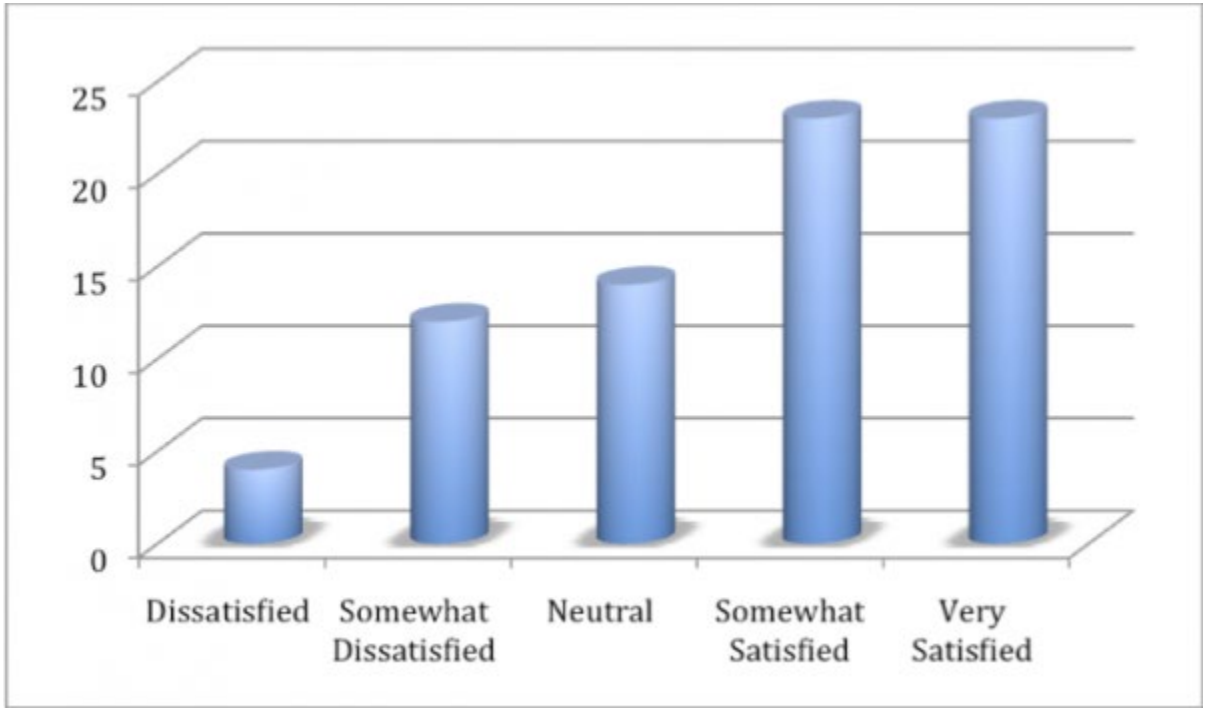
Where to Start (Slide 5 of 7)

- Patient satisfaction
  - An important risk management barometer.
  - An association between patient safety and patient satisfaction has been observed.*
    - Many patients who report being dissatisfied with care also report being harmed by care.



*ECRI, *Measuring Patient Satisfaction*, Health Risk Control, 2005.

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Where to Start (Slide 6 of 7)

- Complaints and grievances
  - A study of patient complaints and malpractice risk found that physicians who received more unsolicited patient complaints were more frequently the target of malpractice claims than other physicians.

Hickson, *Patient Complaints and Malpractice,* 2002.

Where to Start (Slide 7 of 7)

Other resources to identify areas of potential risk:

- Joint Commission National Patient Safety Goals
- Joint Commission Sentinel Event Alerts
- ECRI Top 10 Patient Safety Concerns
- ECRI Top 10 Health Technology Concerns
- ECRI Practice Alert! Series
- ECRI Get Safe! Series
- ECRI Tools for Leadership
- ISMP Medication Safety Alert! Newsletters

Conducting a Risk Assessment

Conducting a Risk Assessment (Slide 1 of 4)

- Convene a team to facilitate the assessment.
  - Leadership
  - Risk manager
  - QI personnel
  - Clinical staff
  - Office staff
  - Information technology
  - Other disciplines (i.e., pharmacy, social service)

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*. 2018.

Conducting a Risk Assessment (Slide 2 of 4)

- Choose an assessment tool.
  - Safety culture survey
  - Self-assessment questionnaire
  - Failure mode and effects analysis (FMEA)
  - Trigger tool
  - Leadership safety rounds

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*.

Conducting a Risk Assessment (Slide 3 of 4)

- Conduct risk assessments at least quarterly.
- Engage staff in the process, if applicable.
  - Communicate the benefits of collecting information about situations and practices that may expose patients to harm.
- Designate an individual who will document the findings of the assessment.

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*. 2018.

Conducting a Risk Assessment (Slide 4 of 4)

- Analyze results and prioritize areas for improvement.
  - Prioritize by evaluating the likelihood (probability an event will occur) and the impact or severity (level of harm of event if it occurs).
  - Select one to three areas for improvement rather than multiple initiatives.
- If possible, compare findings with previous performance or performance of other sites in the organization or other similar clinics.

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*. 2018.

Creation of an Action Plan

Creation of an Action Plan

- Identify specific performance improvement strategies.
- Identify individual(s) responsible for each strategy.
- Identify a specific, *measurable* goal for each strategy.
  - Goals should be challenging but attainable.
- Identify a specific date to reach the goal.
- Determine a plan to monitor for sustained change.

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*. 2018.

Improvement Strategies (Slide 1 of 3)

- Research guidelines and best practices published by authoritative organizations.
- Consider strategies that have been successful at other sites within your organization or at other organizations.
- Customize strategies to the practice setting based on available resources and existing workflow.

Improvement Strategies (Slide 2 of 3)

Strong	• Likely to eliminate or greatly reduce the likelihood of an adverse event.
Intermediate	• Likely to control the root cause or vulnerability.
Weak	• Less likely to be effective.

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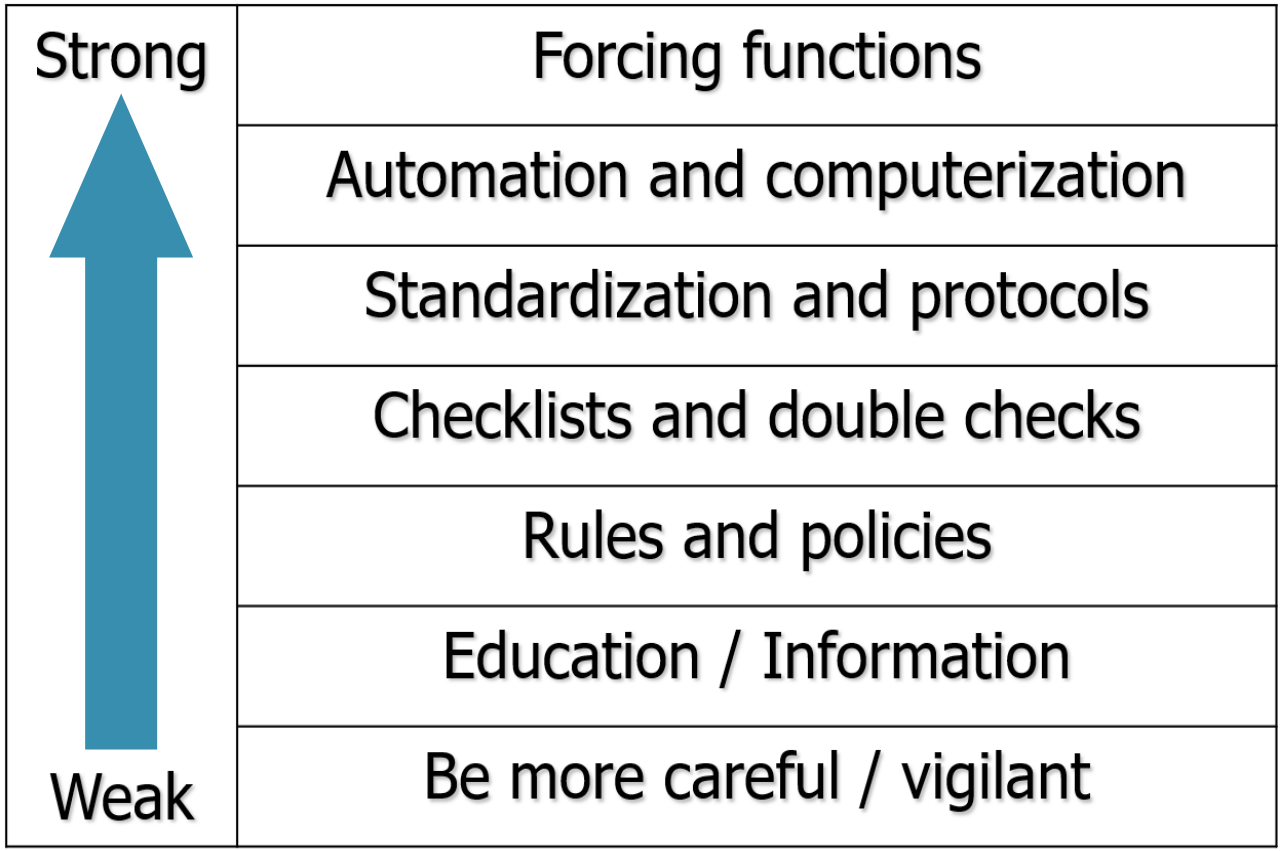
Improvement Strategies (Slide 3 of 3)



Goals for Improvement Strategies (Slide 1 of 2)

- Specific and measurable.
- E.g., Education will be completed for L&D staff, OB residents, OB physicians, and anesthesia physicians.
  - Goal: 100%
  - Metric: # staff educated / # eligible staff

Goals for Improvement Strategies (Slide 2 of 2)

- Specific and measurable.
- E.g., Medical record review demonstrates compliance with new process for tracking abnormal lab results.
  - Goal: 100%
  - Metric:
    - Sample size: Minimum of 5% or at least 30 (whichever is greater) medical records with abnormal lab values audited per month.
    - Numerator: Number of records that demonstrated compliance with the new process (compliance will be measured on an all or none basis).
    - Denominator: Total number of records reviewed.

Documentation of an Action Plan (Slide 1 of 2)

- Documentation should provide detailed information that allows a clear understanding of methodology and outcomes of the risk assessment.
  - Completion of action items should be documented.
  - Actions that are not completed should be tracked, and follow-up should be documented.
  - A plan to monitor for sustained change should be documented.

Documentation of an Action Plan (Slide 2 of 2)

Issue	Improvement Strategy	Responsible Party	Timetable for Implementation	Measures of Effectiveness	Status

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Risk Assessment Follow-Up

Close the Loop

- Action plans must be monitored to verify that goals are reached by target dates.

Communicate Findings of Risk Assessments

- Findings should be presented to the risk and/or quality committees.
- Action plans, progress toward meeting goals, and planned follow-up should be presented to the board at least annually.
- Improvements made in response to risk assessments should be communicated to all staff members.

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*. 2018.

Monitor for Unintended Consequences

- It is important to monitor for unintended consequences of improvement strategies.
  - E.g., workarounds, alert fatigue.

Risk Assessment Exercise: Diagnostic Test Tracking

FTCA Deeming Application Tracking Policies

	notification procedures.
DT.3	For **Critical Test Results**: • Time frame for communication of results to patients • Acceptable means of communication to provider and patient (e.g., verbal contact only) • Procedures for contacting back-up or surrogate providers if ordering provider is not immediately available to receive results • Every effort is made to contact patient for follow-up (e.g., visiting shelter, enlisting help from authorities) • Documentation of successful and unsuccessful attempts to contact patient • Tracking critical lab tests, monitoring to ensure no problems arise, audits reported to QI/QA committee as part of the program.
DT.4	For **Abnormal Test Results**: • Acceptable means of communication to provider and patient (e.g., verbal, electronic) • Timeframe for communicating results to patient (e.g., not to exceed 14 days) • Efforts made to contact patient for follow-up (e.g., visiting shelter, enlisting help from authorities) • Documentation of successful and unsuccessful attempts to contact patient (notification should include more than just a certified letter).

- Analyze results and prioritize areas for improvement.
  - Tracking for abnormal lab results does not demonstrate a closed loop process.
  - Abnormal lab results are not communicated to patients within an acceptable time frame.

Develop Improvement Strategies

- Revise process for tracking of abnormal lab values to include:
  - Time frames for follow-up.
    - Not to exceed 14 days.
  - Types and number of communications.
    - Two phone calls, certified letter, enlisting help from authorities, visiting shelter.
  - Individual(s) responsible for each step within the process.
  - Documentation of successful and unsuccessful attempts to contact the patient.

Create an Action Plan (Slide 1 of 2)

Issue	Improvement Strategy	Responsible Party	Timetable for Implementation	Measures of Effectiveness	Status
Tracking for abnormal lab results does not demonstrate a closed loop process.	Revise process for tracking abnormal lab values.	C. Smith	09/30/21	Diagnostic Tracking Procedure revised and approved.	Completed Policy revised and approved
	Provide education to staff.	D. Jones	10/15/21	Goal : 100% Metric: # staff educated / # eligible staff	Completed Goal achieved
	Monitor tracking of abnormal lab values monthly to assure compliance with new process.	C. Smith	Start 11/2021	Medical record review demonstrates compliance with new process. Goal : 100% Sample size: Min. of 5% or at least 30 (whichever is greater) medical records with abnormal lab values audited per month. Numerator: Number of records that demonstrated compliance with the new process. Denominator: Total number of records reviewed.	In progress

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Create an Action Plan (Slide 2 of 2)

Issue	Improvement Strategy	Responsible Party	Timetable for Implementation	Measures of Effectiveness	Status
Abnormal lab results are not communicated to patients within an acceptable time frame.	Update process to include defined time frame for reporting abnormal lab values (not to exceed 14 days).	C. Smith	09/30/21	Diagnostic Tracking Procedure revised and approved.	Completed Policy revised and approved
	Provide education to staff.	D. Jones	10/15/21	Goal : 100% Metric: # staff educated / # eligible staff	Completed Goal achieved
	Monitor monthly to assure compliance with defined timeframe for reporting abnormal lab values to the patient.	C. Smith	Start 11/2021	Medical record review demonstrates compliance with defined time frame. Goal : 100% Sample size: Min. of 5% or at least 30 (whichever is greater) medical records with abnormal lab results audited per month. Numerator: Number of records that demonstrated compliance with the defined timeframe. Denominator: Total number of records reviewed.	In progress

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Submit Documentation with Deeming Application

- Documentation must demonstrate that risk assessments were completed for each quarter.
- Documentation should be clear and organized so that the individual reviewing the application can clearly see what risk assessments were conducted and the status of improvement strategies and follow-up.

Key Takeaways

- Risk assessments must be conducted at least quarterly.
- Risk assessments should focus on areas that can potentially prevent or decrease the likelihood of medical malpractice claims (i.e., patient safety, clinically focused assessments).
- Documentation should provide detailed information that allows a clear understanding of the methodology used for the risk assessment, outcomes of the risk assessment, and the status of improvement strategies and follow-up.

Resources (Slide 1 of 3)

- HRSA - Health Center Program Compliance Manual
  https://bphc.hrsa.gov/programrequirements/compliancemanual/index.html
- ECRI - Risk Management Manual for Health Centers
  https://www.ecri.org/components/HRSA/Documents/RiskManagementManual.Pdf
- ECRI - Clinical Risk Management Services: Risk Management Toolkit
  https://www.ecri.org/components/HRSA/Pages/RMToolkit.aspx
- ECRI Practice Alert! - Conducting Risk Assessments: A Checklist
  https://www.ecri.org/components/HRSA/Pages/PracticeAlerts033018.aspx

Resources (Slide 2 of 3)

- ECRI Self-Assessment Questionnaire – Managing Risks in Ambulatory Care: Clinical Management
  https://www.ecri.org/components/HRSA/Resources/SAQ/SAQ2.2.pdf
- AHRQ - Medical Office Survey on Patient Safety Culture
  https://www.ahrq.gov/sops/surveys/medical-office/index.html
- IHI – Trigger Tools
  http://www.ihi.org/Topics/TriggerTools/Pages/default.aspx
- ECRI - Ambulatory Risk Management Certificate Program: Introduction to Failure Mode and Effects Analysis
  https://learning.ecri.org/rmcertificateprogram/content/level-4-course-2-introduction-failure-mode-and-effects-analysis#group-tabs-node-course-default2

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Resources (Slide 3 of 3)

- ECRI – Self Assessment Questionnaires
  https://www.ecri.org/Pages/SearchResults.aspx?k=*&Page=1&PageSize=20&Sort=newest&mo=true&r=ECRIinformationType:Self-assessment&ct=|hrsa|&dr=all
- ECRI - Practice Alert! Series
  https://www.ecri.org/Pages/SearchResults.aspx?k=*&Page=1&PageSize=10&Sort=newest&rs=Practice%20Alert
- ECRI - Get Safe! Series
  https://www.ecri.org/Pages/SearchResults.aspx?k=*&Page=1&PageSize=10&Sort=newest&rs=Get%20Safe
- ECRI – Tools for Leadership
  https://www.ecri.org/components/HRSA/Pages/LeadershipToolkit.aspx

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Thank You!