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PEACE OF MIND | EXPERTISE | CHOICE | THE MEDPRO GROUP DIFFERENCE

Risk Management Mentor Program

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Program Disclaimer

Modules

1. Risk Management Fundamentals
2. Enterprise Risk Management
3. Applications
4. Healthcare Providers
5. Clinical and Patient Safety
6. Legal and Regulatory
7. Claims and Litigation
8. Risk Financing

Topics

- Web links
  - Primary sources
  - Templates
  - Questions
  - Responses

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Module 3: Part 1
Applications

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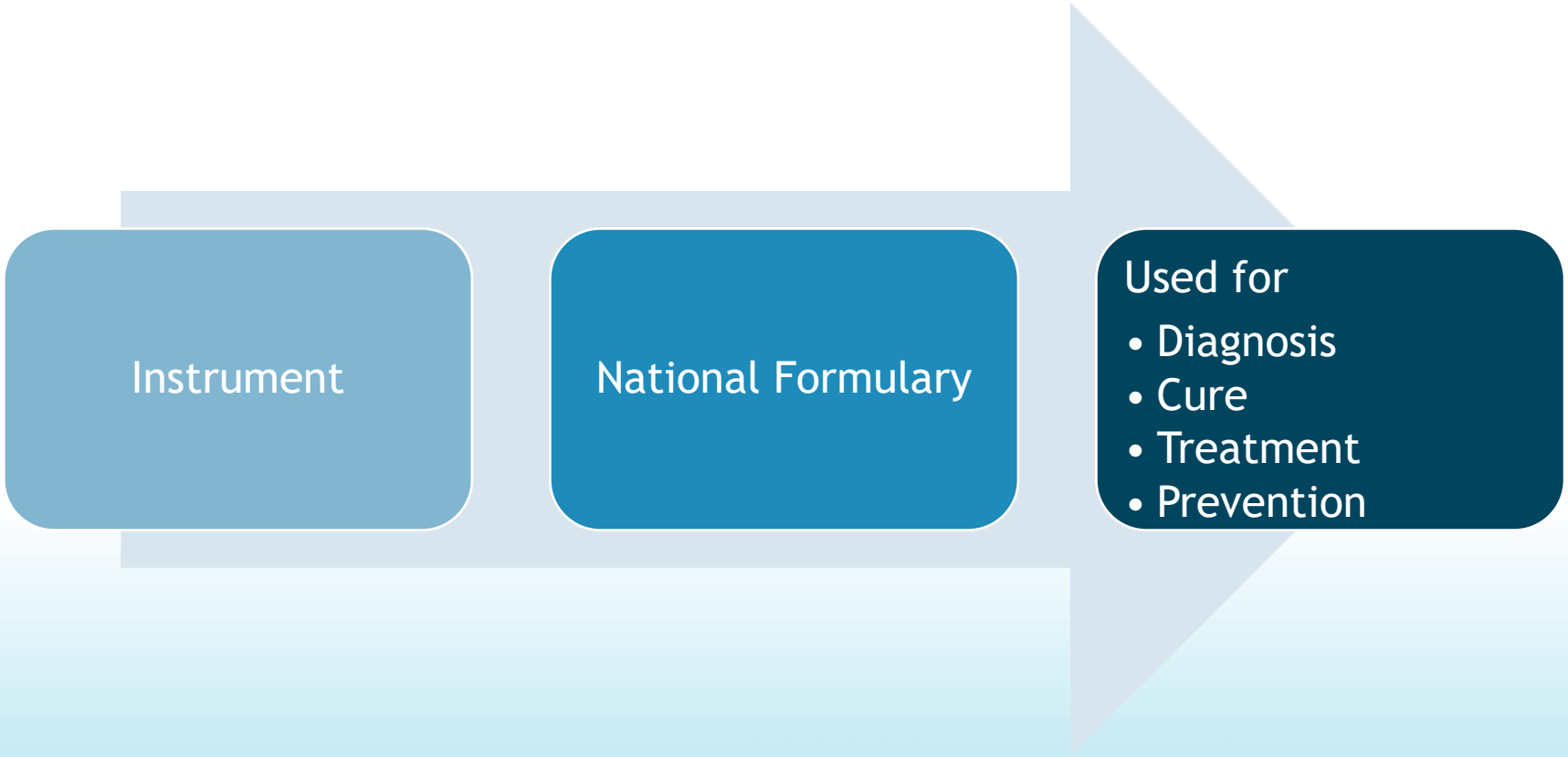
Medical Device Management

Objectives

- Define medical devices
- Discuss the key components of a medical device management program
- Examine the process in handling malfunctioning medical devices
- Define the Safe Medical Device Act

Medical device definition



Source: Quality and Regulatory Associates. (2003). Overview: FDA regulation of medical devices. Retrieved from http://www.qrasupport.com/FDA_MED_DEVICE.html

Medical devices

Defined by class based on

- Benefit versus risk
- Safety and effectiveness

Examples

- Surgical lasers
- Stents
- Pacemakers
- Intraocular lenses
- Orthopaedic pins
- Surgical mesh

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Program Components

Designated oversight

Biomedical Department

Maintenance Department

Material Management Department

Environmental Safety Department

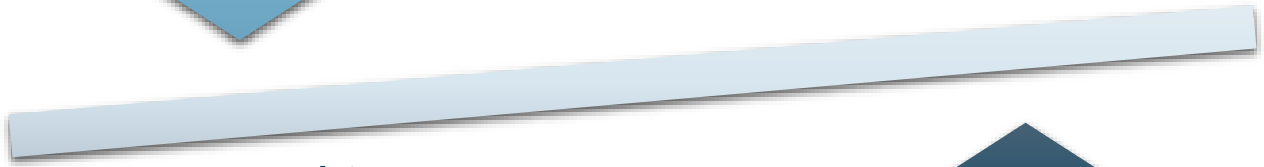
Risk Management

Patient Safety

Policies and procedures

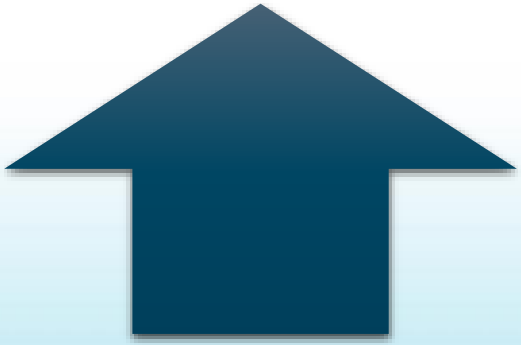
Inventory

- Device types
- Operational needs
- Troubleshooting methods



Usage tracking

- Logs
- Locations
- User training and competency



Policies and procedures

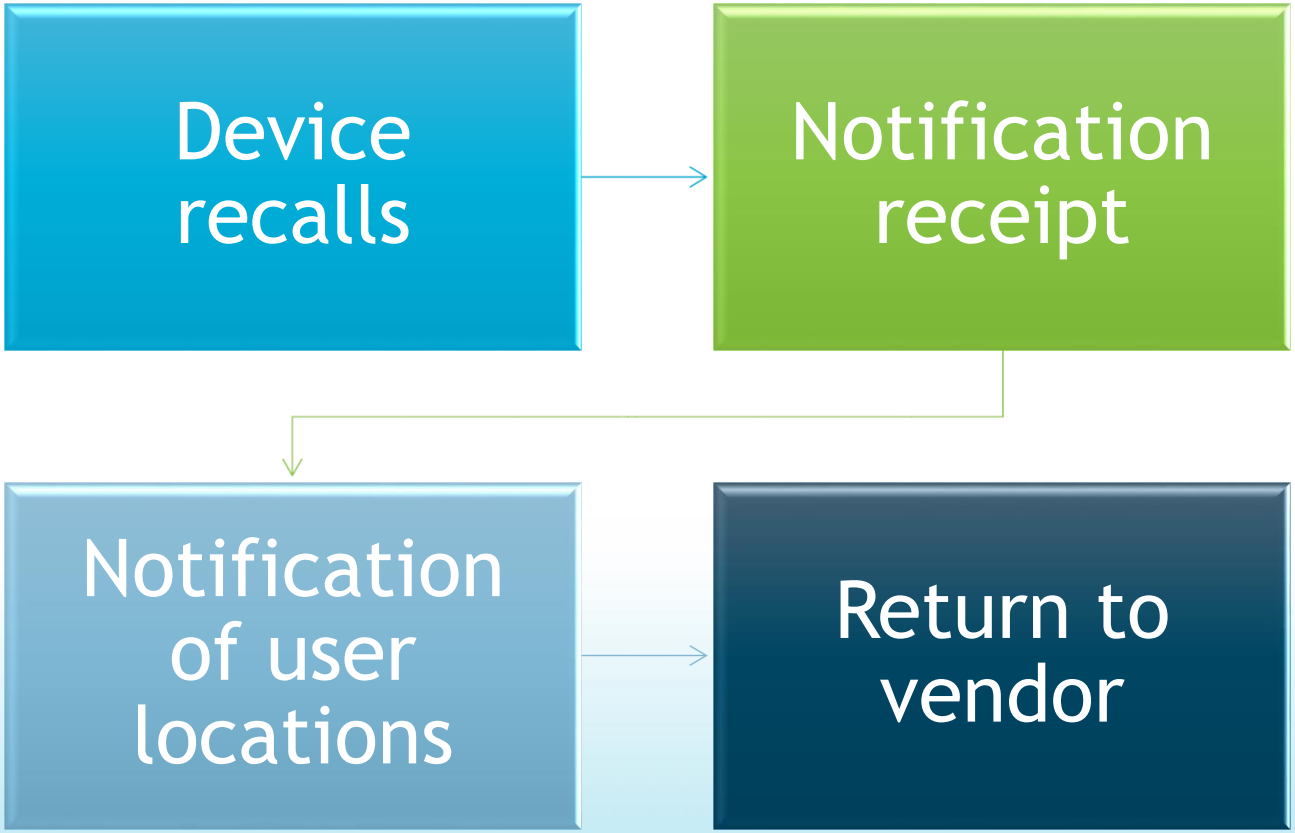
Calibration and maintenance

- Manufacturer recommendations
- Onsite or vendor
- Frequency
- Passed versus failed calibration

Periodic in-situ testing and auditing

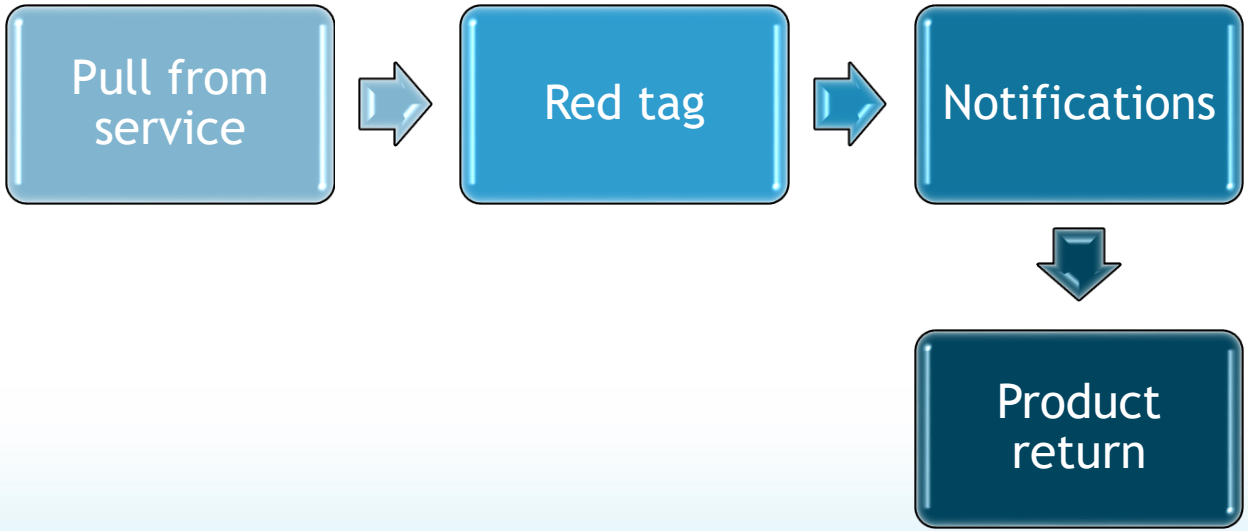
- Frequency
- Features tested
  - Alarm settings
  - Alarm decibels based on distance

Policies and procedures



Policies and procedures

Malfunctioning equipment: Noninjury related



https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8306

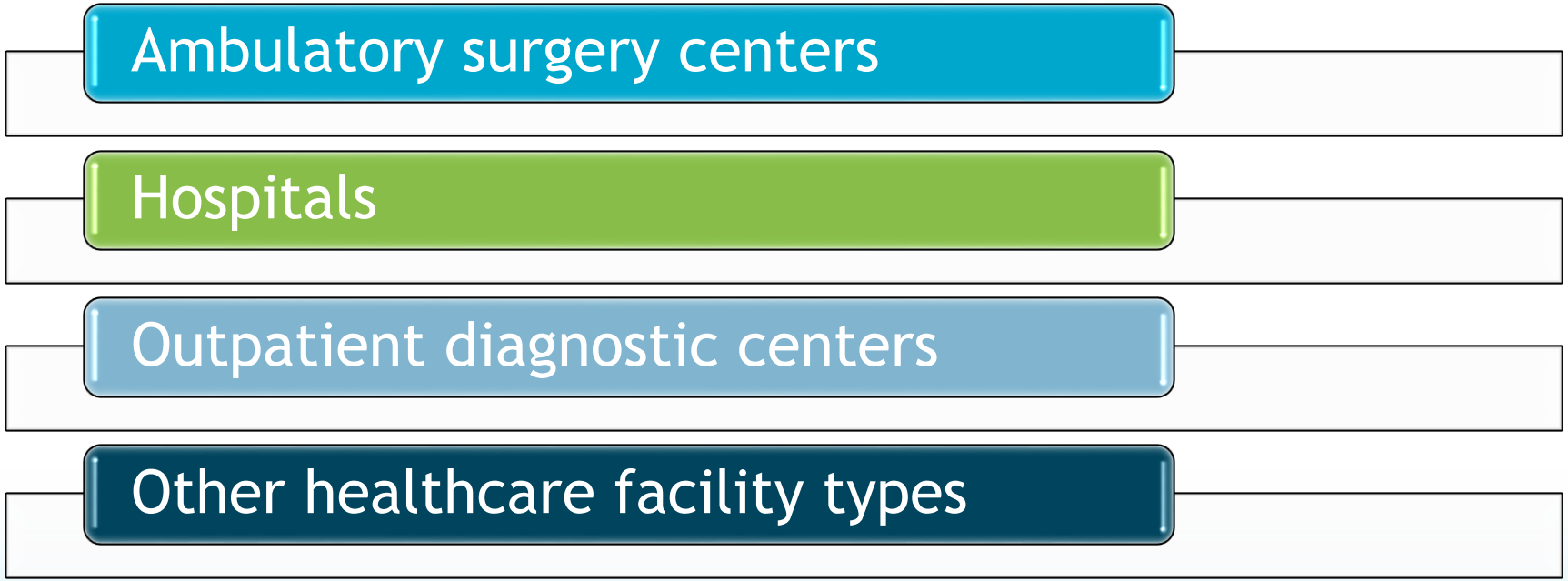
Policies and procedures

Malfunctioning equipment: Injury related

- Pull from service
- Red tag
- Notifications
- Sequestration of device and accessories used
- Failure device analysis
- FDA MedWatch Form (SMDA)

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf

Safe Medical Device Act (SMDA)



https://www.congress.gov/bill/101st-congress/house-bill/3095

Quiz question

If a medical device fails while being used for a patient and no visible harm is noted, what should be done with the device?

A. After removing it from service, immediately send it to the manufacturer to get a new device

B. Continue to use it for patient care

C. Immediately report it to the FDA

D. Remove and sequester the device from service along with any accessories being used at the time

Response

D. Remove and sequester the device from service along with any accessories being used at the time

Rationale: Although no visible patient harm is noted at the time of the event, some form of injury can still surface within a few hours, days, or weeks as a result of the device failure. Immediately returning the device to the manufacturer will result in loss of evidence if the device did cause patient harm. Continuing to use a device that is known to fail will be impossible to defend if a claim of patient harm is made. Immediately reporting the device to the Food and Drug Administration is not required unless serious patient harm or injury or death has occurred. Therefore, any time a medical device fails while being used for patient care that has the potential to result in harm—whether sooner or later—it should be immediately removed and sequestered along with any accessories used at the same time.

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Root Cause Analysis (RCA)

Objectives

- Define root cause analysis (RCA)
- Examine the formal RCA process
- Explore the components of an action plan
- Discuss reporting of RCA findings
- Review a sample RCA

RCA definition

- Investigation
- Potential/probable causes
- Current process
- Gaps where misinterpretation can occur
- Human behavior/factors/just culture
- Determine actual causes
- Action plan
- Evaluate effectiveness of changes
- Periodic surveillance

http://www.npsf.org/?page=rca2
https://www.jointcommission.org/framework_for_conducting_a_root_cause_analysis_and_action_plan/

Events and reporting

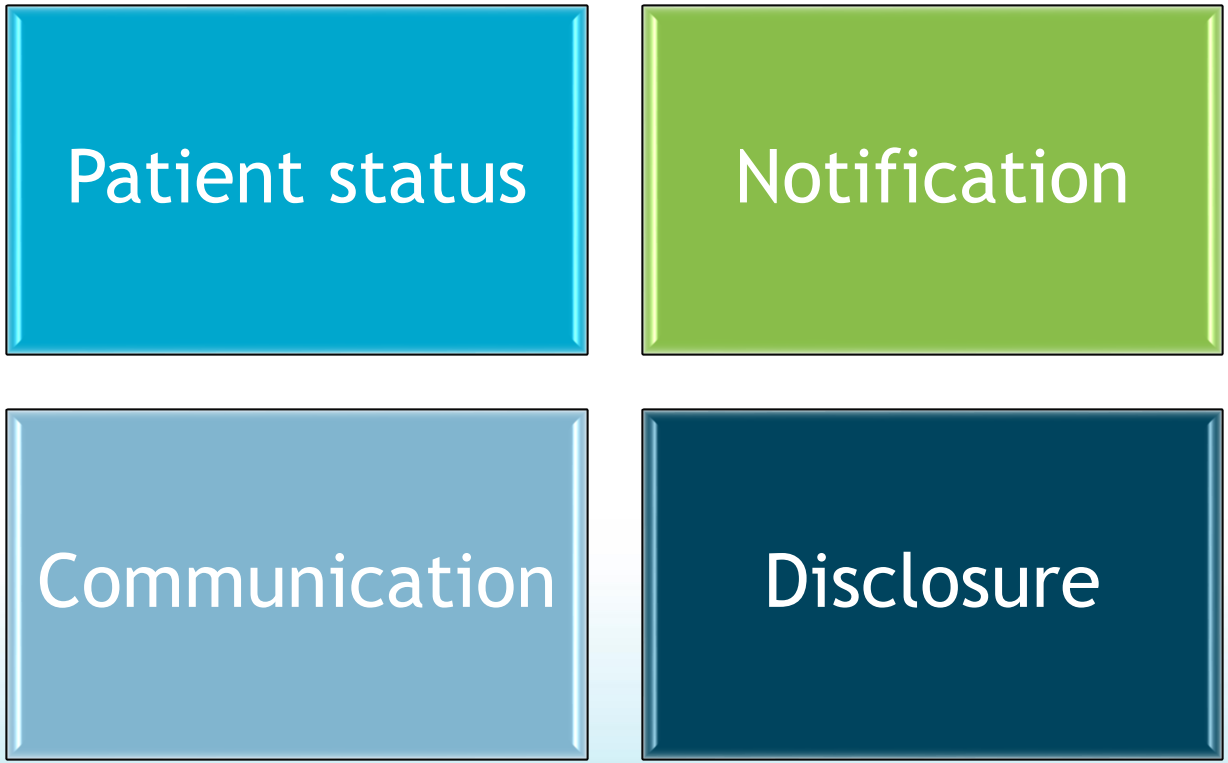
Define events requiring RCA

- Sentinel
- Serious reportable event/Never event
- Near miss
- General liability events

Reporting requirements

- Type of event
- Timely reporting
- Action plan
- Follow up

RCA process



https://www.medpro.com/documents/10502/2837997/Guideline_Disclosure+of+Unanticipated+Outcomes.pdf

RCA process

Investigation

- Sequestration
- Interviews
- Second victim syndrome
- Assemble RCA team
- Policies, procedures, protocols
- Re-enactment
- Open-mindedness
- Determine root causes
- Patient Safety Organization (disclosure protections)

Sources: (1) Agency for Healthcare Research and Quality. (2011). The second victim phenomenon: A harsh reality of health care professions. Retrieved from https://psnet.ahrq.gov/perspectives/perspective/102/the-second-victim-phenomenon-a-harsh-reality-of-health-care-professions; (2) MedPro Group. Presentations. Retrieved from https://www.medpro.com/rm-presentations; (3) Agency for Healthcare Research and Quality. Patient Safety Organization (PSO) Program. Retrieved from https://www.pso.ahrq.gov/

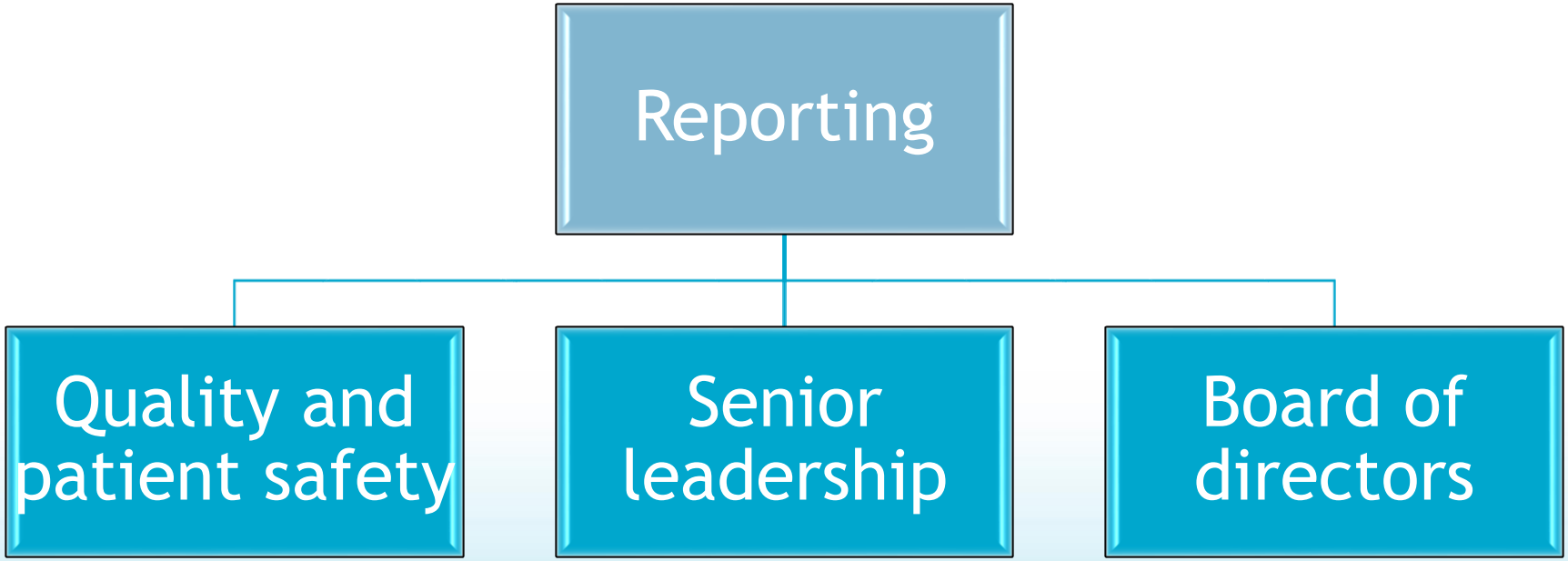
RCA process

Action plan development

- New or revised tasks/processes
- Responsible individual
- Implementation timeline
- Effectiveness monitoring
- Sustainment of changes
- Compliance surveillance

Centers for Medicare and Medicaid Services RCA template can be retrieved from:
https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/guidanceforrca.pdf

RCA process


Reporting
Quality and patient safety
Senior leadership
Board of directors

Sample RCA

An 82-year-old female had been admitted for sepsis resulting from a urinary tract infection. During a critical stage of her treatment, she had inadvertently been given hypertonic IV fluid, which resulted in her death.

Source: Minnesota Department of Health. Root cause analysis toolkit. Retrieved from http://www.health.state.mn.us/patientsafety/toolkit/rcaonlytemplate.pdf

Possible causes

Active Errors	Latent Errors
Patient in crisis	Various IV fluids available
Shortage of staff	IV fluids stored in the same location
Float staff providing direct care	No discernible difference in appearance besides IV fluid type
IV fluid retrieved by another staff member	Bin markings similar and not visible from all vantage points
Float staff rushed	IV bags often found in wrong bins
	Departmental culture (no assistance provided to new or float staff)
	Disruptive behavior from team leader
	No training for unit staff regarding medical emergency response

Sample RCA action plan

Error #1	Proposed change	Implementation date	Measure of effectiveness	Responsible individual
Storage of IV fluids (same location, similar bins)	Revised storage (NSS and LR stored in color-coded bins; other IV fluids stored in automated inventory system)	01/01/2018	Billing charges for IV fluid coincide with provider orders; daily audits of bins and IV fluid infusions	John Doe

Quiz question

Root cause analysis should be conducted for (select all that apply):

A. Critical events involving patient harm
B. General liability events involving visitors
C. Near miss events that do not reach the patient
D. All of the above

Response

Root cause analysis should be conducted for (select all that apply):

D. All of the above

Rationale: RCAs are required to be conducted for all critical events involving patient harm as mandated by CMS Conditions of Participation. However, due to the fact that sentinel events rarely occur, opportunities to promote proficiency in conducting RCA and to proactively investigate and prevent future adverse events—whether involving patients, visitors, or staff—should be conducted. Performing RCAs on a routine basis demonstrates the organization's commitment to fostering a positive culture of safety.

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