MyMichigan Health Adverse Event Investigation and Root Cause Analysis Process

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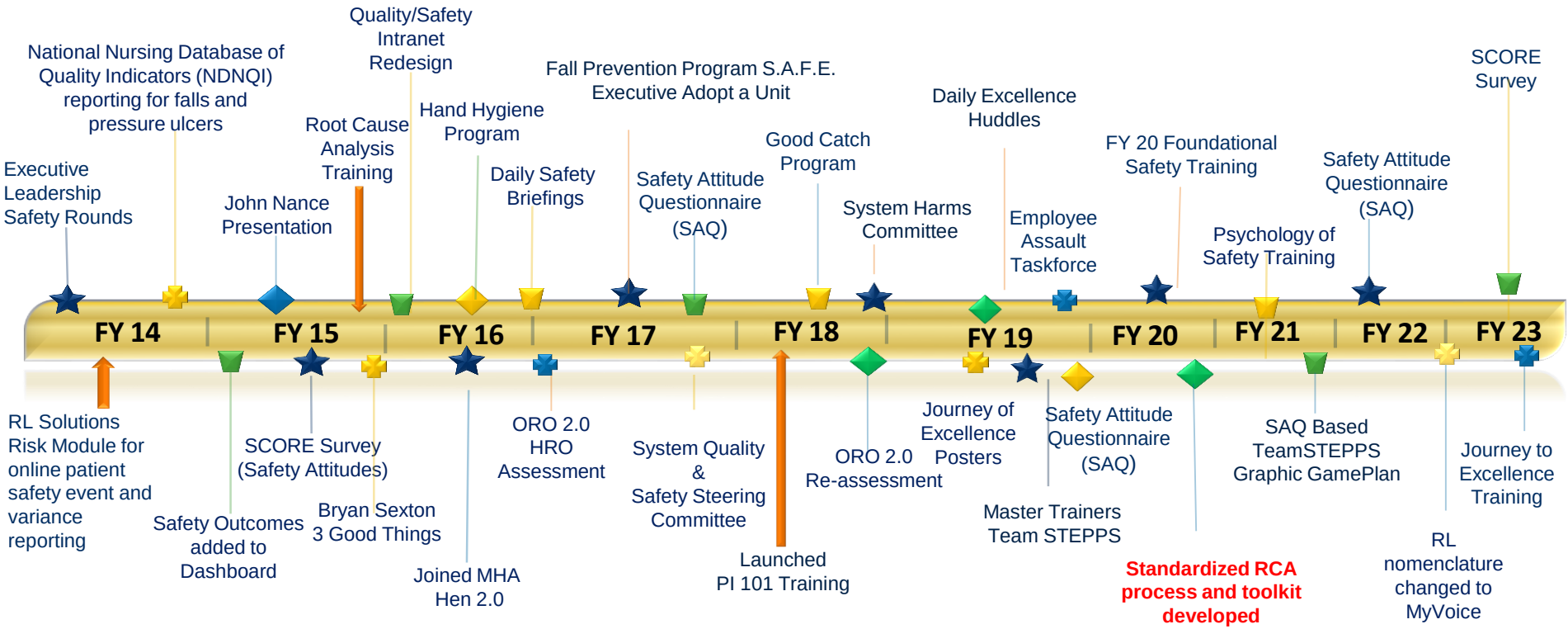
An Overview of MyMichigan Health

- Non-profit health system headquartered in Midland, Michigan
- Serving more than 981,000 residents in a 25-county region
- More than 10,180 employees, volunteers and physicians and other personnel
- More than 1,200 associated physicians and advance practice providers
- More than 400 volunteers
- 789 hospital and 51 long-term care beds at nine hospitals
- Full continuum of care across a wide array of settings, including urgent care centers, home health, virtual care, as well as medical offices in more than 80 specialties and subspecialties

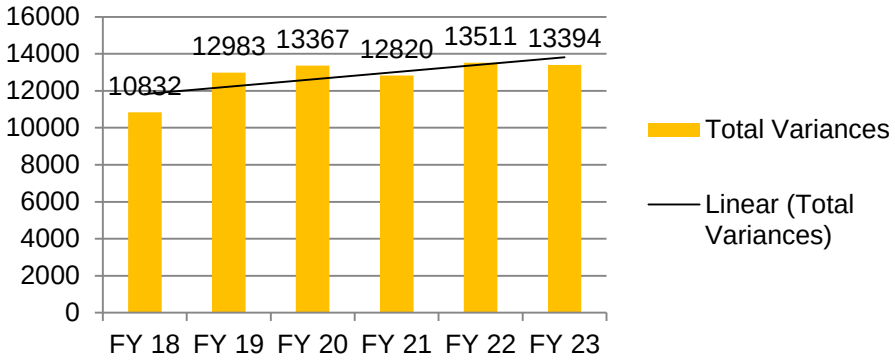
Our Purpose Creating Healthy Communities - Together

Journey to Excellence…Getting to Zero Harm

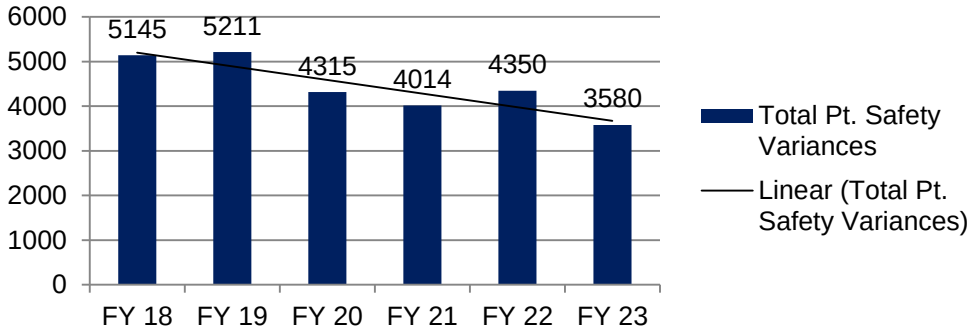


MyMichigan Health Variance Volumes

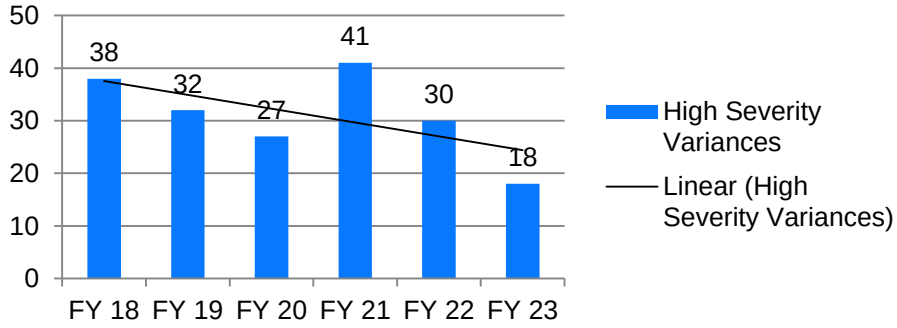
Total Events



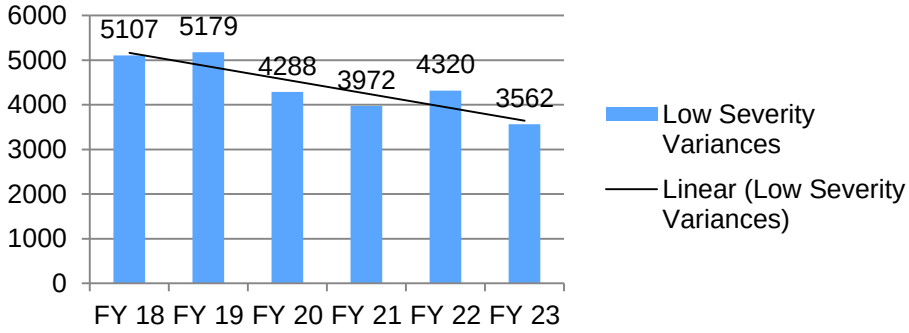
Total Pt. Safety Events



High Severity Events (SSE 1, 2 and SE 3)



Low Severity Events (SE 4, 5, PPE 6)



MMH Harm Prevention & Mitigation

- Key Processes
  - Surveillance, Mitigation and Prevention of harm
- Quality & Patient Safety team (team of 6 people)
  - 5 quality safety specialists RN, 1 RN manager
  - Monitor & prioritize all patient safety events reported
  - Partner and facilitate all RCAs
- Variance Triage Process
  - Defines pathways for review of events
- Root Cause Analysis
  - All serious safety events
  - No Harm/Near Miss events with potential serious harm to patient

Event Investigation & RCA Processes

- Industry resources

Institute for Healthcare Improvement → RCA² (Root Cause Analysis & ACTION)

AHRQ Agency for Healthcare Research and Quality → **Communication and Optimal Resolution (CANDOR) Toolkit**

The Joint Commission → **Framework for Root Cause Analysis and Corrective Actions**

RCA Process Issues

- Length of time to complete
- Variability in processes
  - RCA2 structured, limits involvement to RCA team only
  - TJC framework, lengthy tool 24 questions
  - CANDOR, 5 components, focus on high-risk events
- Limited resources available to complete lengthy processes, multiple meetings, often burden on quality safety SME

Opportunities for Improvement

- Streamline process, eliminate non-value steps (busy work)
- Include roles & responsibilities to partner with local leaders
- Limit meetings to those necessary
- Standardize tools for consistent practice and summary of events
- Develop training to leaders on RCA process, toolkit and their roles

Event Follow-Up & RCA Process

Event reporting

Review, prioritize and triage

Event is determined to require an RCA as indicated by:

- SSE event occurs
- Requested
- Meets triage criteria

Sequester evidence, if indicated

Event Review

Key Communications if needed

- Crisis intervention for staff
- Stakeholders' notification
- Potential disclosure
- Billing holds

Interviews of individuals involved

Event Investigation and Analysis

Investigation

- Chronological Timeline
- Policy/Literature review

Event debriefing

- Review timeline
- Tell “story” of what happened
- Additional fact-finding opportunity

Leadership Analysis/Action Plan

Culpability & Accountability

Event and RCA Process

Subsidiary:	Dept.:	Event Date:	RCA Date:
Event Title:			RL File #:

Purpose: To provide a checklist of actions needed to be taken following an event
Who should use this tool? Leaders and teams needing to respond to patient safety events
How to use this tool: Use the checklist to ensure that appropriate action is taken following a patient safety event

Process	Steps	Details *Red indicates escalation process	Responsible Party	Time Frame
Event Report				
Receipt of Report	How report was received: • RL Solutions • Claims Committee • Other Committees • Complaint/Grievance • Local Event Triage		Staff Manager Director Leadership Quality/Safety	As soon as possible
Assess and Inform	• Ensure the patient is stable and provide emotional support to the patient/family • Assess event for potential serious safety event (SSE 1 or SSE2). Refer to Serious Safety Event policy and Response Pathway • Utilize Deviation Decision Tool to determine if event meets patient safety event criteria • If not a SSE 1, 2 or 3, then utilize Safety Event Triage document to determine is RCA is needed • Report any serious safety events to Patient Safety	Event is determined to require an RCA as indicated by: • Serious Safety/Sentinel event occurs • Request from oversight committees, e.g. Claims, Medication Safety, etc. • Event meets triage criteria via RL Solutions variance or departmental requests	Manager Director Committee Chairs Quality/Safety	If SSE, refer to SSE Response Pathway for time frames Committee requests vary in time frames Ideally within 72 hours
Sequester Evidence	• Equipment/Supplies if involved • Do not move, turn off or change equipment settings involved in event • Do not throw away disposables involved in event (medication vials, IV bags, catheters, medical devices, etc.)		Manager Director Quality/Safety	As soon as possible

	• Keep all monitor strips/records, if involved in event • Secure photos/video recordings (OR/Procedural) and/or security monitoring video			
Event Review				
Initial Key Communications	• Consider timely event debriefing with involved staff • ESPYR Staff in Crisis Intervention (800)-896-0276 24/7 if needed • Consider additional care provider referrals to Employee Assistance Program (EAP) and/or peer support programs • Prepare strategy for ongoing communication with key stakeholders and patient/family • Identify a patient/family liaison if needed • Advise care providers on appropriate medical record documentation post event • Initiate process to hold hospital and professional fee billing if indicated • Notify appropriate individuals of the event (e.g. Local Leadership, Patient Safety, Claims Committee, legal and others as identified) • Identify each employee/provider to be interviewed	RCA Notification • SSE and RL requests: Q/S to email manager within 4 days. Manager is responsible to provide the following: ○ Timeline of Events ○ Key staff involved including providers ○ Dates and times that work for the event debriefing ○ If information not received, Q/S to call manager and alert Q/S and Department directors via email ○ If information still not received, escalate to CNO and VP Q/S • Oversight Committee Requests: Chairs of committee sends letter to manager requesting RCA completion ○ If RCA not completed in timely manner, chair of the committee will reach out to manager and their direct leadership for resolution Determine RCA debriefing attendees and meeting date: • Attendees: Should include all members of the care team involved in the event. Involved providers should attend the debriefing meeting. Local	Quality/Safety Manager Director Committee Chairs	4-7 days after initial request or identified by committee request Ideally within 14-21 days of event

		leadership, director and local executive leader should attend. • Meeting: Should be scheduled by Q/S or manager and should be held 14-21 days after or knowledge of the event and identify gaps in practice and processes. The meeting is a systems based approach and does not include culpability. Q/S will send out RCA information and ground rules to attendees prior to the meeting		Ideally within 14-21 days of event
Event Interviews	• Schedule in-person interviews with key staff • Refer to Triggering Questions flip book to prepare for interviews • Conduct interviews in private setting • Have no more than 2 team members conduct the interview • Inform interviewee that the RCA process is about identifying system issues and that is not a punitive process • Encourage interviewee to tell their story of the event • Have someone take notes of the interview • If not able to conduct interview in person, obtain written statement of event. Document must be signed and dated by individual • Consider additional care provider referrals to EAP and/or peer-support program		Manager Director	Prior to event debriefing
Event Investigation and Analysis				
Event	• Event timeline/chart review – Use	Data Collection (gather before the debriefing		Timeline to

Investigation	Chronological Timeline of Events template ○ Highlight relevant details regarding event that led up to the event, the actual event and what the outcome was to the patient. • Do not copy and paste entire progress notes and diagnostic reports • Identify organizational policies and procedures that apply to the event to determine whether they: ○ Were followed, and/or ○ Are in need of revision • Conduct a literature review, if applicable ○ Consider standards of care ○ Known complications • Peer review if needed • Flow chart the process as applicable • Enter all information into RL • Keep leadership up to date on the process • Continue to monitor patient/family status and needs	meeting): • Brief summary – what happened, when (day, date, time) and outcome. Utilize Chronological Timeline of Events template • Detailed sequence of events leading up to event – the story • Describe current process or procedure as it is supposed to work. Bullet points of key parts of process • Information from the chart that reflects the event and interventions should be included in the timeline. Do not copy and paste full notes and diagnostic results into the timeline • Equipment/device/photos/foreign body/etc. – Have samples/actual equipment/device involved in the event available at the meeting to help team understand/visualize, if available • Review and have available Policies and Procedures, Standards of Practice, etc. pertinent to the event • Any safety/preventative maintenance logs as pertinent if equipment involved • Any unrelated unusual circumstances happening concurrently in the department/unit at time of event • Literature search – search any literature for similar events, recommended practice, safety issues, sentinel alerts, etc. • If data collected not completed at least 5 days prior to meeting, Quality/Safety will call manager and alert Quality/Safety and Department	Manager Director Any sequestered items will be overseen by Quality/Safety	Quality/Safety within 7 days of event. All other data collected must be available and ready for the event debriefing meeting Sequester equipment/supplies at time of event

		directors via email • If information still not received prior to meeting, accountability will escalate to CNO and VP Quality/Safety		
Event Debriefing	• If indicated, conduct event debriefing meeting with all key players involved in event to review event and timeline of events ○ Refer to Triggering Questions flip book to prepare for event debriefing • Utilize RCA SBAR Summary template ○ Complete SBA sections to pull all gathered information together prior to RCA • Utilize Fishbone template to identify causal/contributing factors	RCA event debriefing meeting: Team Roles: • Facilitator: assures guidelines of RCA analysis are considered. Keeps meeting on track and supports a just culture of safety including psychological safety for all team members • Local leader(s): leadership representative of the unit/department where the event occurred • Executive Sponsor: provides executive support for RCA completion and action plan. Usually CNO, can be any executive level • Subject Matter Expert (SME): provides best practice input for their area of expertise as necessary • Scribe: takes attendance and notes of discussion. To be assigned by Quality/Safety • Care team involved in event: tells the story ○ Reviews each step of the event focusing on processes ○ Identifies how process should have occurred ○ Uses 5 whys to identify root cause ○ Identifies opportunities for improvement	Quality/Safety to facilitate RCA event debriefing	Average 1-2 hours
Leadership Analysis and	• Conduct consensus meeting with leadership and appropriate key	• Identified leaders, key stake holders, executive sponsor and SME will meet	Quality/Safety Manager	Time will vary depending on event

Action Planning	stakeholders to review findings and determine next steps
	• Complete recommendation section of the RCA SBAR Summary
	  ○ Identify action items, MOS, action item owners and due dates
	  ○ Utilize Evaluation of Effective Performance Improvement tool
	• Implement changes to process, procedures and policies as appropriate
	• Consider use of It Really Happened here to educate staff throughout the Health System
	• Collect MOS data as identified
	• 90 day follow up provided to appropriate committee/leadership
		to analyze all information gathered through the RCA process and identify root cause and counter measures to develop the action plan
		• Prior to meeting RCA SBAR Summary and Fishbone diagram will be completed
		• Root causes will be determined
		• Action plan will include:
		  ○ Root Cause for each action item
		  ○ Action item with counter measures
		  ○ Metrics for each measure of success
		  ○ Estimated due date of completion for each action
		  ○ Owner for each action
		  ○ Owner for oversight of entire action plan to assure completion
			Director	and action plan items

Culpability and Accountability	• Consider Culpability and Accountability • Use the Culpability Decision Tool to determine Culpability and Accountability • Include HR in events that lead to individuals needing coaching and/or discipline	• Accountability is the acknowledgement and assumption of responsibility • Culpability is the degree of one's responsibility • Always identify root causes of error/event before determining culpability • Use the Culpability Decision Tool • System Failures should not result in punishment of individuals involved • Include HR in events that lead to individuals needing coaching and/or discipline	Manager Director	

****All Documents must be attached to the RL and sent to Quality/Safety**

Event and RCA Checklist

Subsidiary:	Dept.:	Event Date:	RCA Date:
Event Title:			RL File #:

Purpose: To provide a checklist of actions needed to be taken following an event
Who should use this tool? Leaders and teams needing to respond to patient safety events
How to use this tool: Use the checklist to ensure that appropriate action is taken following a patient safety event

Process	Steps
Event Report	
Receipt of Report	How report was received: • MyVoice • Claims Committee • Other Committees • Complaint/Grievance • Local Event Triage
Assess and Inform	• Ensure the patient is stable and provide emotional support and apology to the patient/family. • Assess event for potential serious safety event (SSE 1 or SSE2). Refer to Serious Safety Event policy and Response Pathway • Utilize Deviation Decision Tool to determine if event meets patient safety event criteria • If not an SSE 1, 2 or 3, then utilize Safety Event Triage document to determine if RCA is needed • Report any serious safety, sentinel or never events to Patient Safety
Sequester Evidence	• Equipment/Supplies if involved • Do not move, turn off or change equipment settings involved in event • Do not throw away disposables involved in event (medication vials, IV bags, catheters, medical devices, etc.) • Keep all monitor strips/records, if involved in event • Secure photos/video recordings (OR/Procedural) and/or security monitoring video
Event Review	
Initial Key Communications	• Consider timely event debriefing with involved staff • ESPYR Staff in Crisis Intervention (800)-896-0276 24/7 if needed • Consider additional care provider referrals to Employee Assistance Program (EAP) and/or peer support programs • Prepare strategy for ongoing communication with key stakeholders and patient/family • Identify a patient/family liaison if needed • Interview patient and/or family who are willing and able to gather evidence for root cause analysis • Advise care providers on appropriate medical record documentation post event • Initiate process to hold hospital and professional fee billing if indicated • Notify appropriate individuals of the event (e.g. Local Leadership, Patient Safety, Claims Committee, legal and others as identified) • Identify each employee/provider to be interviewed

Event and RCA Checklist

Event Interviews	• Schedule in-person interviews with key staff • Refer to Triggering Questions flip book to prepare for interviews • Conduct interviews in private setting • Have no more than 2 team members conduct the interview • Inform interviewee that the RCA process is about identifying system issues and that is not a punitive process • Encourage interviewee to tell their story of the event • Have someone take notes of the interview • If not able to conduct interview in person, obtain written statement of event. Document must be signed and dated by individual • Consider additional care provider referrals to EAP and/or peer-support program
Event Investigation and Analysis	

Event Investigation	• Event timeline/chart review – Use Chronological Timeline of Events template
	  ○ Highlight relevant details regarding event that led up to the event, the actual event and what the outcome was to the patient.
	• Do not copy and paste entire progress notes and diagnostic reports
	• Identify organizational policies and procedures that apply to the event to determine whether they:
	  ○ Were followed, and/or
	  ○ Are in need of revision
	• Conduct a literature review, if applicable
	  ○ Consider standards of care
	  ○ Known complications
	• Peer review if needed
	• Flow chart the process as applicable
	• Enter all information into RL
	• Keep leadership up to date on the process
	• Continue to monitor patient/family status and needs

Event Debriefing	• If indicated, conduct event debriefing meeting with all key players involved in event to review event and timeline of events
	  ○ Refer to Triggering Questions flip book to prepare for event debriefing
	• Utilize RCA SBAR Summary template
	  ○ Complete SBA sections to pull all gathered information together prior to RCA
	• Utilize Fishbone template to identify causal/contributing factors

Leadership Analysis and Action Planning	• Conduct consensus meeting with leadership and appropriate key stakeholders to review findings and determine next steps
	• Complete recommendation section of the RCA SBAR Summary
	  ○ Identify action items, MOS, action item owners and due dates
	  ○ Utilize Evaluation of Effective Performance Improvement tool
	• Implement changes to process, procedures and policies as appropriate
	• Consider use of It Really Happened here to educate staff throughout the Health System
	• Consider use of It Really Happened here to educate staff throughout the Health System
	• Monitor changes to ensure results
	• Collect MOS data as identified
	• 90 day follow up provided to appropriate committee/leadership

Culpability and Accountability	• Consider Culpability and Accountability • Use the Culpability Decision Tool to determine Culpability and Accountability • Include HR in events that lead to individuals needing coaching and/or discipline

****All Documents must be attached to the RL and sent to Quality/Safety**

3/29/2023 Q/S Team

Event Reporting

Variance reporting program using
RL Solutions online reporting platform

Quality Safety Specialists monitor all events reported

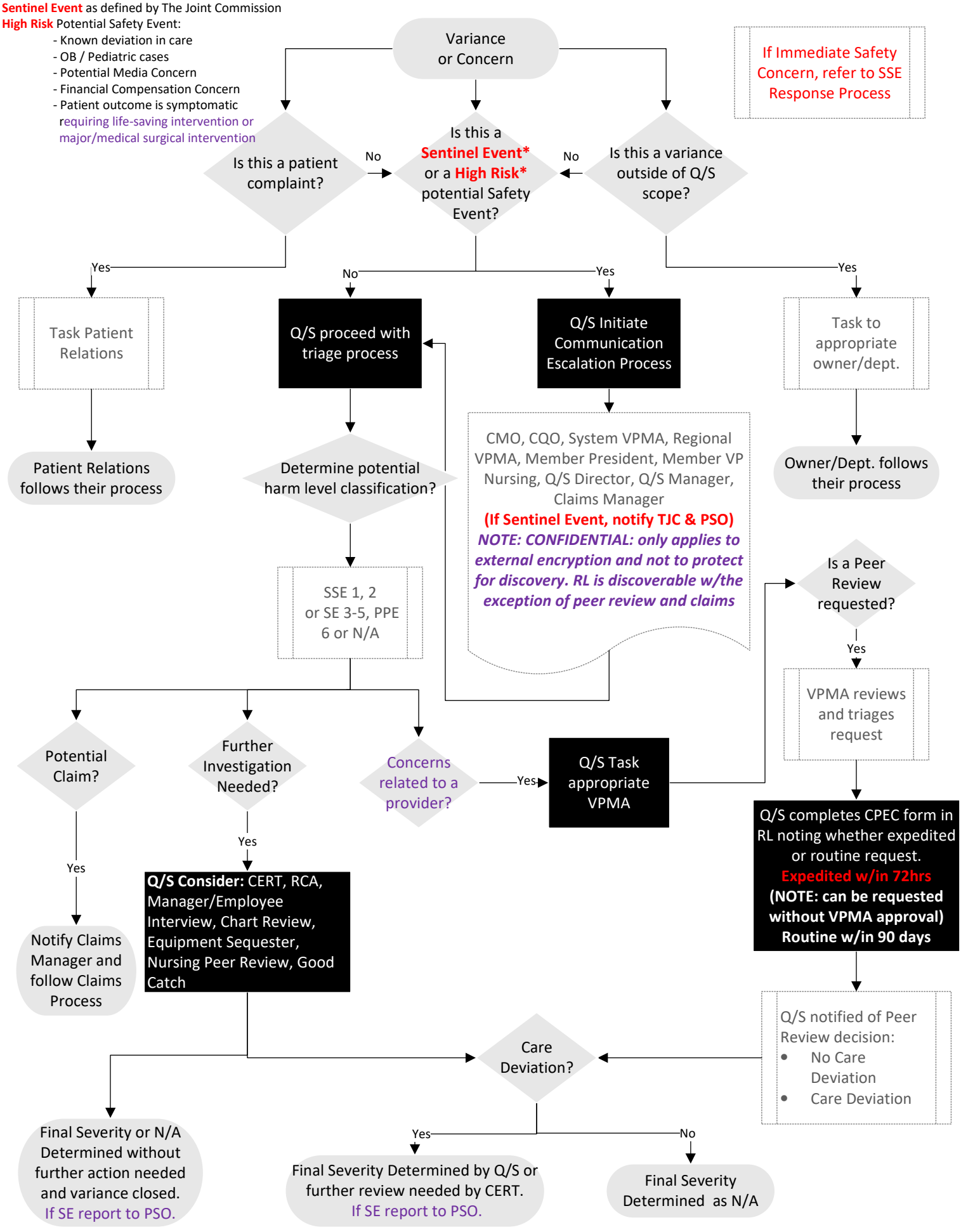
Review, Prioritize and Triage

- Determine pathway for investigation and follow-up
- Sentinel and high-risk events trigger quality safety to initiate the investigative process within 72 hours of knowledge
- All other events are investigated by local for resolution
- Serious Safety event pathway

Quality and Patient Safety (Q/S) Variance Triage Process

November 1, 2022

* **Sentinel Event** as defined by The Joint Commission
* **High Risk** Potential Safety Event:
- Known deviation in care
- OB / Pediatric cases
- Potential Media Concern
- Financial Compensation Concern
- Patient outcome is symptomatic requiring life-saving intervention or major/medical surgical intervention



Serious Safety Event (SSE) Response

Phase 1 — Immediate Actions (At the time of the event)

STOP!!! SSE Event

Stabilize Patient

Notify
Provider, Manager or Supervisor who will notify admin on call

Sequester Equipment
and Supplies if they contributed to the event, save packaging, etc

Dislcosure
Provide support, disclosure if needed, see policy

Document
Event facts in EMR, File RL Variance

***ESPYR**
Staff in Crisis Intervention (800)-896-0276 24/7 if needed

Phase 2 — Investigation (Occurs within 72 hours and completed within 10 days)

Investigation Begins
Manager and Patient Safety will begin to investigate within 72 hours of knowledge of event

Leaders Notified
Patient Safety via email, will notify subsidiary President & CNO and claims of potential SSE

***CERT Team Needed**
After initial investigation, Patient Safety will determine if CERT review is needed. (CERT ideally scheduled within 7 days of event)

CERT Convenes
Reviews case and classifies harm level if know, and *RCA need, determines if reported to The Joint Commission as a sentinel event.

***TJC Report**
Patient Safety will notify President and CNO of report to TJC. Report occurs within 10 days of event or known severity

Phase 3 — Root Cause Analysis & Action Plan Development (1st meeting ideally within 14-21 days, action plan due in 45 days)

Identify Team
Facilitator & manager identify core team and key members. Executive sponsor identified. First meeting scheduled ideally within 14-21 days

1st Meeting RCA
Event time line and debrief
Identify deviations
Determine contributing factors
Determine root causes

2nd Meeting Action Plan
Core Team meets
Identify counter measures
Establish MOS
Assign action owners

RCA Summary Report
Facilitator writes report. If TJC event, submit online report. Once complete, report is sent to all core team members and action owners for final input.

CERT Review
RCA action plan will be reviewed by the CERT team for their approval. Due date for MOS assigned

Phase 4 — Action Plan Follow-up and Measures of Success (MOS) (Ideally completed with 90 days of plan approval)

Joint Commission Call
If reported, Joint Commission call will be scheduled to review submitted RCA and action plan, assign MOS due date
Facilitator to coordinate

Action Owner Hand Off
Accepted action plans become the responsibility of the owner(s) to implement actions and collect any data needed for MOS

Action Plan Monitoring
Facilitator will reach out to owners at least once during the 90 days to insure MOS data is collected

MOS Submission
MOS data must be submitted to TJC and CERT teams by established due date

RCA Tracking
Patient safety will track all RCA's and sentinel events and provide updated reports to executives and boards as needed

*TJC= The Joint Commission
*CERT= Critical Event Review Team
*RCA= Root Cause Analysis
*ESPYR Employee assistance program at MidMichigan Health

Draft 10/23/2020 Patient Safety

Sequester Evidence

- Equipment/Supplies if involved
- Do not move, turn off or change equipment settings involved in event
- Do not throw away disposables involved in event (medication vials, IV bags, catheters, medical devices, etc.)
- Keep all monitor strips/records, if involved in event
- Secure photos/video recordings (OR/Procedural) and/or security monitoring video

Event Review

- Immediate Post Event Huddles/Debriefings
- Support care team, identify need for crisis intervention
- Communicate potential serious safety events to key leaders
- Pre disclosure huddle if indicated: Critical Event Review Team (CERT)
- Billing holds if indicated
- Interview of staff involved Triggering Questions Tool

Triggering Questions

for Root Cause Analysis

- Instructions
- Communication
- Training
- Fatigue/Scheduling
- Environmental/Equipment
- Rules/Policies/Procedures
- Barriers

Version: May 2021

MidMichigan Health
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

Instructions – WHEN and HOW to use this Flipbook

- When conducting an interview for an investigation on an RL
- During an RCA, event debriefing, collaboration meetings

Instructions

Bagian, J. P., M.D., P.E., & DeRosier, J. M., P.E., C.S.P. (n.d.). *Triggering Questions for Root Cause Analysis* [Pamphlet].

Instructions

Communication Questions (Page 1 of 3)

1. Was the patient correctly identified?
2. Was information from various patient assessments shared and used by the members of the treatment team on a timely basis?
3. Did existing documentation provide a clear picture of the work-up, the treatment plan, and the patients response to treatment? (e.g., Assessments, consultations, orders, progress notes, mediation administration record, x-ray, lab)
4. Was communication between management/supervisors and front line staff adequate? (i. e., Accurate, complete, unambiguous, using standard vocabulary and no jargon)

Communication

Communication Questions (Page 3 of 3)

5. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?
6. Did management establish adequate methods to provide information to employees who needed it in a timely manner that was easy to access and use?
7. Did the overall culture of the department/work area encourage or welcome observations, suggestions, or “early warnings” from staff about risky situations and risk reductions? (Also, if this has happened before, what was done to prevent it from happening again?)
8. Did adequate communication across organizational boundaries occur?

Communication

Communication

Communication Questions (Page 2 of 3)

9. Was communication between front line team members adequate?
10. Were policies and procedures communicated adequately?
11. Was the correct technical information adequately communicated 24 hours/day to the people who needed it?
12. Were there methods for monitoring the adequacy of staff communications? (e.g., Read back, repeat back, confirmation messages, debriefs)
13. Was the communication of the potential risk factors free from obstacles?
14. Was there a manufacturer's recall/alert/bulletin issued on the medication, equipment, or product involved with the event or close call? If yes, were relevant staff members made aware of this recall/alert/bulletin?

Communication

Training Questions

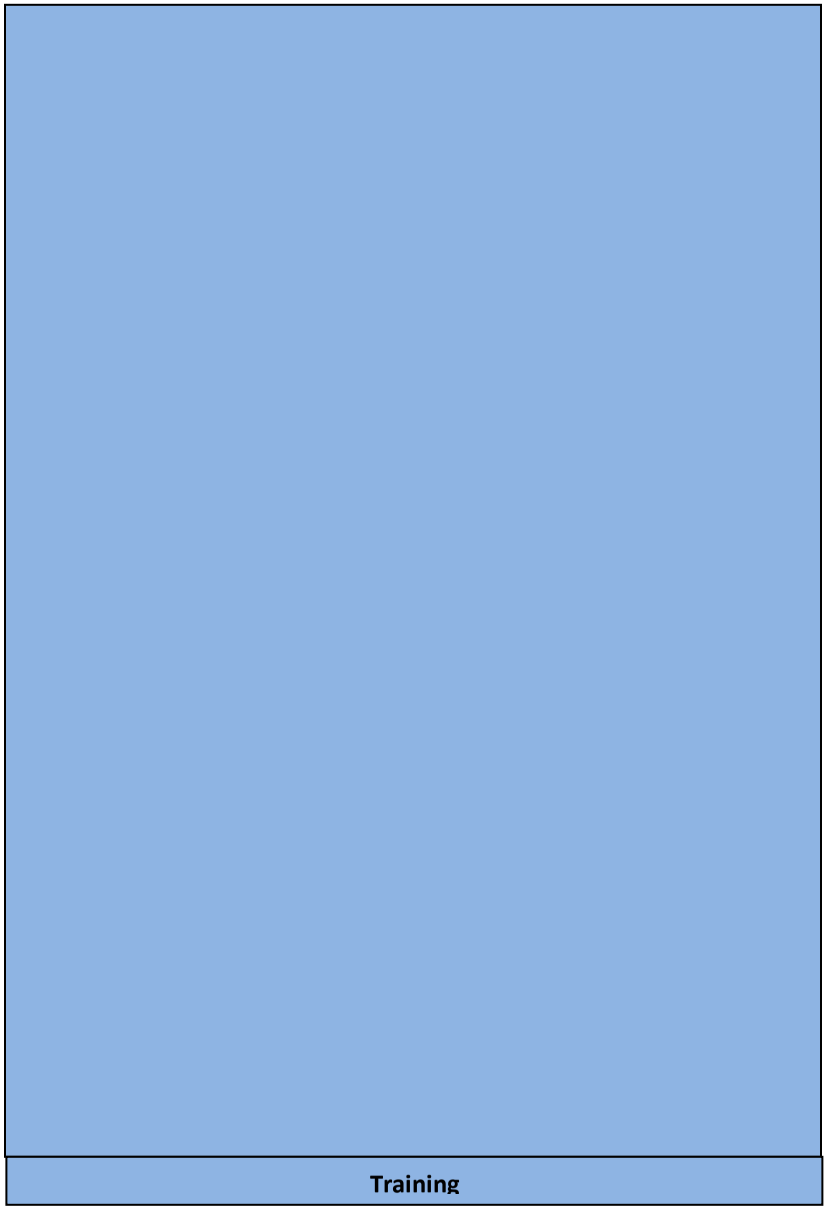
15. Was there an assessment done to identify what staff training was actually needed?
16. Was training provided prior to the start of the work process?
17. Were the results of training monitored over time?
18. Was the training adequate? If not, consider the following factors; supervisory responsibility, procedure omission, flawed training, and flawed rules/policy/procedure.
19. Were training programs for staff designed up-front with the intent of helping staff perform their tasks without errors?
20. Were all staff trained in the use of relevant barriers and controls?

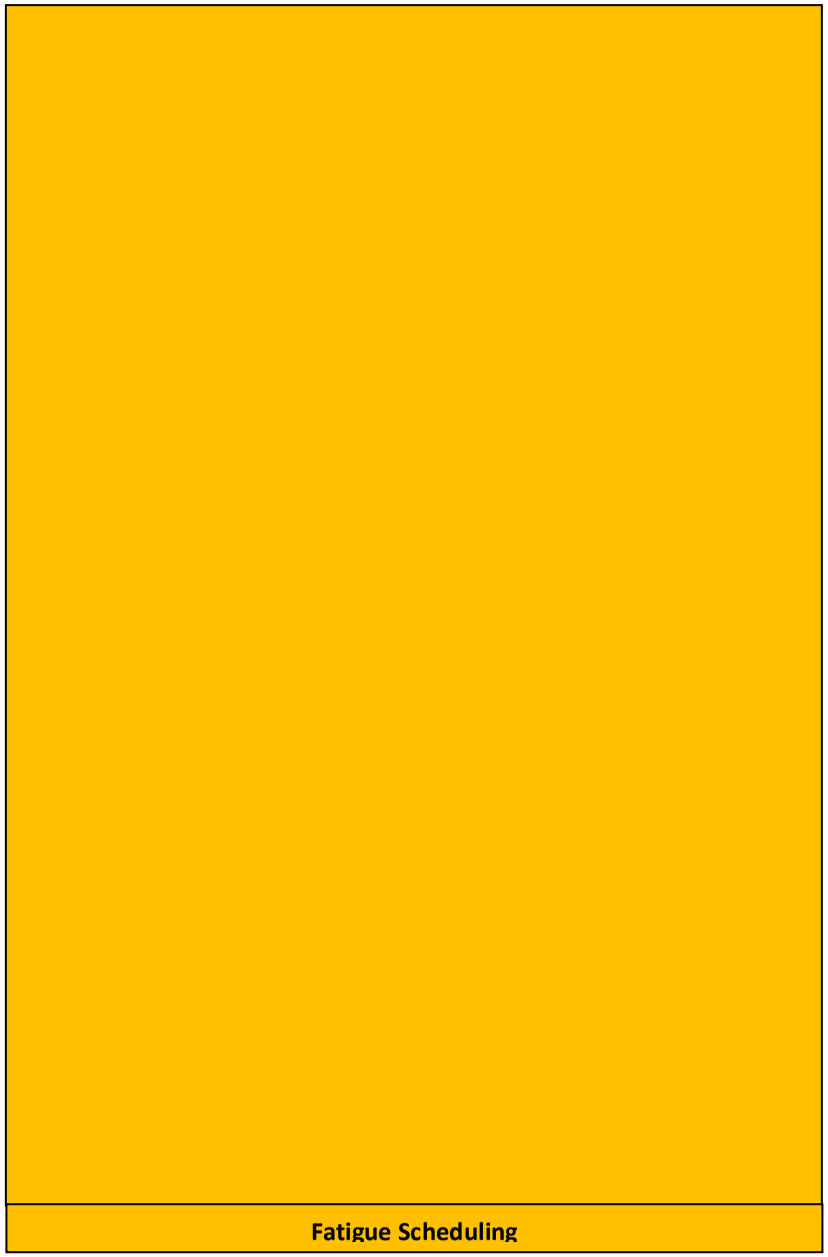
Training

Fatigue/Scheduling Questions

21. Were the levels of vibration, noise, or other environmental conditions appropriate?
22. If applicable, were environmental stressors properly anticipated?
23. Did personnel have adequate sleep?
24. Was fatigue properly anticipated?
25. Was the environment free of distractions?
26. Was there sufficient staff on-hand for the workload at the time? (i.e., Work-load too high, too low, or wrong mix of staff)
27. Was the level of automation appropriate? (i.e., neither too much nor not enough)

Fatigue/Scheduling


Training


Fatigue Scheduling

Environment/Equipment Questions (Page 1 of 4)

28. Was the work area/environment designed to support the function it was being used for?
29. Had there been an environmental risk assessment (i.e., safety audit) of the area?
30. Were the work environment stress levels (either physical or psychological) appropriate? (e.g., temperature, space, noise, intra-facility transfers, construction projects)
31. Had appropriate safety evaluations and disaster drills been conducted?
32. Did the work area/environment meet current codes, specifications, and regulations?
33. Was the equipment designed to properly accomplish its intended purpose?
34. Did the equipment work smoothly in the context of: staff needs and experience; existing procedures, requirements and workload; and physical space and location?
35. Did the equipment involved meet current codes, specifications and regulations?

Environment/Equipment

Environment/Equipment Questions (Page 3 of 4)

36. Were adequate time and resources allowed for physical plan and equipment upgrades, if problems were identified?
37. Was there adequate equipment to perform the work processes?
38. Were emergency provisions and back-up systems available in case of equipment failure?
39. Had this type of equipment worked correctly and been used appropriately in the past?
40. Was the equipment designed such that usage mistakes would be unlikely to happen?
41. Was the design specifications adhered to?
42. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?

Environment/Equipment

Environment/Equipment

Environment/Equipment Questions (Page 2 of 4)

43. Was there a documented safety review performed on the equipment involved? (If relevant, were recommendations for service/recall/maintenance, etc., completed in a timely manner?)
44. Was there a maintenance program in place to maintain the equipment involved?
45. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?
46. If previous inspections pointed to equipment problems, were corrective actions implemented effective?
47. Had equipment and procedures been reviewed to ensure that there was a good match between people and the equipment they used or people and the tasks they did?

Environment/Equipment

Environment/Equipment Questions (Page 4 of 4)

48. Were personnel trained appropriately to operate the equipment involved in the adverse event/close call?
49. Did the design of the equipment enable detection of problems and make them obvious to the operator in a timely manner?
50. Was the equipment designed so that corrective actions could be accomplished in a manner that minimized/eliminated any undesirable outcome?
51. Were equipment displays and controls working properly and interpreted correctly?
52. Was the medical equipment or device intended to be reused? (i.e., single use device not reused)
53. Was the medical equipment or device used in accordance with its design and manufacturer's instructions?

Rules/Policies/Procedure Questions (Page 1 of 2)

54. Was there an overall management plan for addressing risk and assigning responsibility?
55. Did management have an audit or quality control system to inform them how key processes related to the adverse event were functioning?
56. Had a previous investigation been done for a similar event, were the causes identified, and were effective interventions developed and implemented on a timely basis?
57. Would this problem have gone unidentified or uncorrected after an audit or review of the work process/equipment/area?
58. Was the required care for the patient within the scope of the facility's mission, staff expertise and availability, technical and support service resources?
59. Was the staff involved in the adverse event or close call properly qualified and trained to perform their function/duties?
60. Did the equipment involved meet current codes, specifications, and regulations?

Rules/Policies/Procedures

Barrier Questions (Page 1 of 2)

Barriers protect people and property from adverse events and can be physical or procedural. Negative/positive pressure rooms are an example of a physical barrier that controls the spread of bacteria/viruses. The pin indexing system used on medical gas cylinders is another example of a physical barrier that prevents gas misconnections. The surgical time out is an example of a procedural barrier that protects patients from wrong site, wrong patient, and wrong procedure surgeries.

61. What barriers and controls were involved in this adverse event or close call?
62. Were these barriers designed to protect patients, staff, equipment, or the environment?
63. Was patient risk considered when designing these barriers and controls?
64. Were these barriers and controls in place before the adverse event or close call occurred?
65. Had these barriers and controls been evaluated for reliability?
66. Were there other barriers and controls for work processes?
67. Was the concept of 'fault tolerance" applied in the system design? (A fault tolerant system can withstand the failure of one or more barriers without the patient being harmed.)

Barriers

Rules/Policies/Procedures

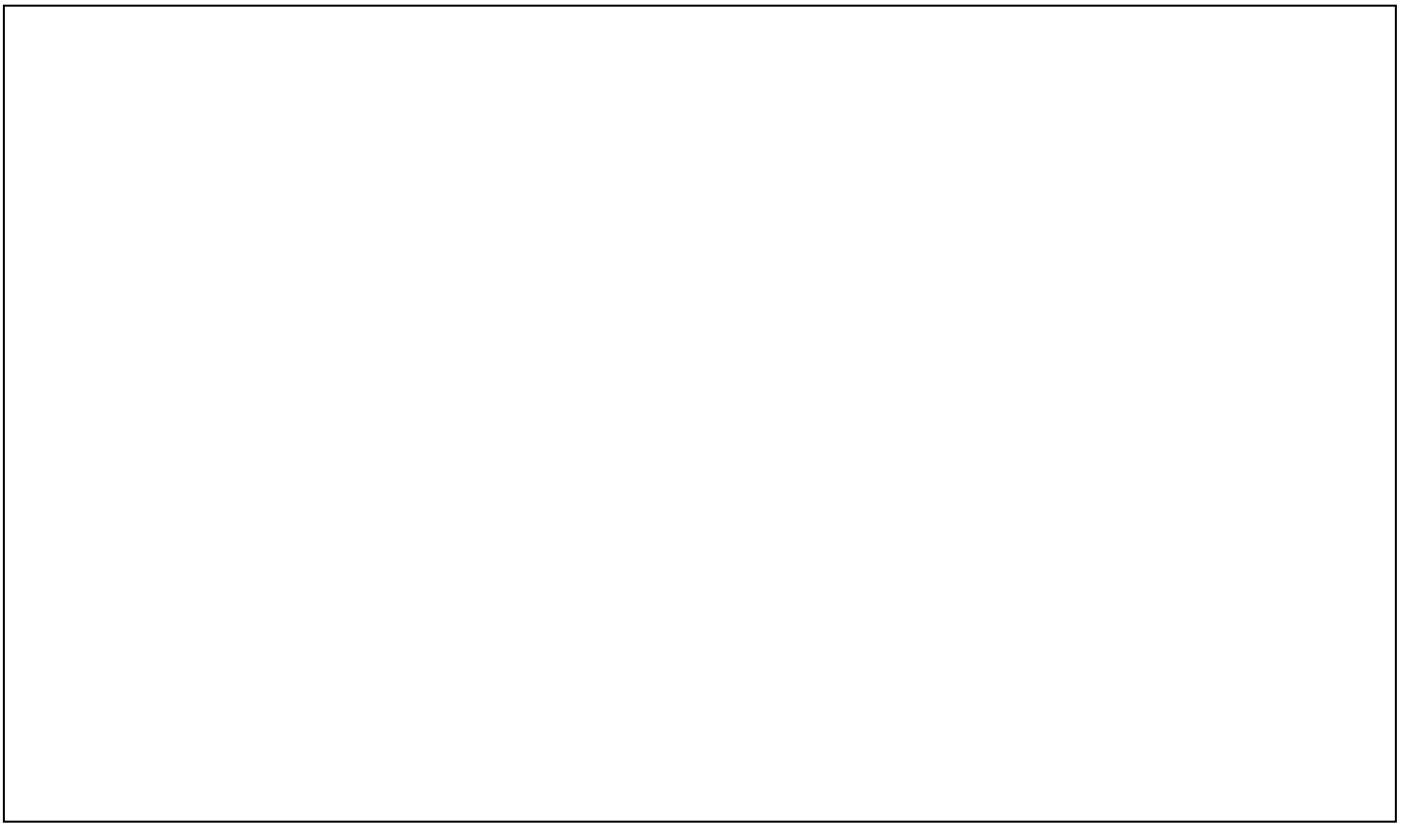
Rules/Policies/Procedure Questions (Page 2 of 2)

68. Were all the staff involved orientated to the job, department, and facility policies regarding: safety, security, hazardous material management, emergency preparedness, life safety management, medical equipment and utilities management?
69. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?
70. Were these policies/procedures consistent with relevant state and national guidance, regulatory agency requirements, and/or recommendations from professional societies/organizations?
71. Were relevant policies/procedures clear, understandable, and readily available to all staff?
72. Were the relevant policies actually used on a day-to-day basis?
73. If the policies and procedures were not used, what got in the way of their usefulness to staff?
74. If policies and procedures were not used, what positive and negative incentives were absent?

Barriers

Barrier Questions (Page 2 of 2)

75. Were relevant barriers and controls maintained and checked on a routine basis by designated staff?
76. Would the adverse event have been prevented if the existing barriers and controls had functioned correctly?
77. Were the systems or processes tested before they were implemented?
78. Did the audits/reviews related to barriers include evaluation of plans, designs, installation, maintenance, and process changes?
79. Did management have a method for identifying what the results of the system changes would be before implementation?



Event Investigation & Analysis

- Investigation
  - Chronological Timeline
  - Policy/Literature review
- Event debriefing
  - Review timeline
  - Tell “story” of what happened
  - Additional fact-finding opportunity
- Leadership Analysis/Action Plan
- Culpability & Accountability

Event Timeline/Chart Review

- Uses Chronological Timeline of Events template from toolkit
- Highlights relevant details that led up to the event the actual event and the outcome
- Use the comments/notes section to identify additional questions to ask or added information from interviews and findings not documented in the record.

Chronological Timeline of Events

Subsidiary:	**Dept.:**	**Event Date:**	**RCA Date:**
Event Title:			**RL File #:**
Patient Name:	**MRN:**	**DOB:**	

Case Background

Date/ Time	Clinician Role (RN, Physician, PCT, NP, RT, etc.)	Clinical Events	Vitals/Labs/Results/Response	Comments/Interviews

Chronological Timeline of Events

Policy/Procedure and Standards of Care Research

- Identify organizational policies and procedures that apply to the event to determine whether they were followed as intended
- Conduct a literature review, if applicable
  - Consider standards of care
  - Known complications
  - Search any literature for similar events, recommended practice, safety issues, sentinel alerts, etc.

RCA Event Debriefing Meeting

- If appropriate, conduct event debriefing meeting with all key players involved in event to review timeline of events, hear the story, find additional facts
- Triggering Questions Tool to prepare for event debriefing
- RCA SBAR Summary template
  - Complete SBA sections to pull all gathered information together prior to meeting
- Fishbone template, for complex multi-faceted events

RCA SBAR Summary

Subsidiary:	Dept.:	Event Date:	RCA Date:
Event Title:			RL File #:

(Except for names of action item owners, please do not use individual names in summary, indicate those involved be role: physician, PA, Nurse, Tech, PCT, etc.)

Situation: Description of event, approximately one or two sentences. (What happened? What was the outcome? How was the event discovered?)

Background: Provide some background information related to this problem or situation. Include pertinent medical information, patient diagnosis and/or violence potential. What is the frequency of the occurrence?

Assessment: What is your assessment of the current situation or problem? Focus on system processes positive and/or negative; what went well/what could have gone better. Consider the contributing factors list below.

Recommendations

Action Plan Item (SMART Goal)	Measure of Success (Data, %, numerator, denominator, audits, completion, etc.)	90 Day MOS Submission	Action Owner	Due Date	Notes	Action Item Strength (S, M, W)

RCA SBAR Summary

Action Item Strengths		
Strong (System Focused) Fail-safe mechanisms Forcing functions/Process Re-Design Automation and computerization	**Moderate** (System/Behavior Focused) Standardization Optimize Redundancy Reminders and checklists	**Weak** (Behavior Focused) Rules and Policies Training, Education and Information Suggestions to be more careful or vigilant, double checks

Contributing Factors *(Highlight)*		
Human factors Staffing Scheduling Orientation/training Competency assessment Supervision Qualification/requirements	**Equipment Factors** Preventive maintenance Equipment failure Equipment availability Defective equipment User error	**Environmental Factors** Physical Cultural Uncontrollable external Environmental risks Quality control Safety, security, utility, HAZMAT, emergency preparedness
Information Factors Accurate data Throughout and available data Unclear data/information Lack of Technology	**Communication Factors** Among staff/teamwork Between staff and patient or family Between physician and Staff Between physician and patient or family Between levels of care, units or external facilities	**Policy, Procedure and Practice Factors** Assessment, reassessment, monitoring Care planning Patient/family education Care /treatment protocols & practices Patient identification Patient observation

Best Practice/Policy Research

Lessons Learned *(Consider completing It Really Happened Here tool for education purposes)*

RCA SBAR Summary

Attendees *do not use individual names, indicate attendees by role, e.g. Physician, Nurse, PCT, RT, Tech, etc.)*

Additional Information
Presented to Claims Committee?
Copy of Summary to Nursing Council?
Further PI needed?
Copy of Summary given to MEC (Dr. Bates)?
Disclosure Made?
CERT Review?
Final Severity Classification:
Sent to Peer Review (PPEC/Nursing)?

Fishbone Diagram

Cause and Effect ("Fishbone") Diagram

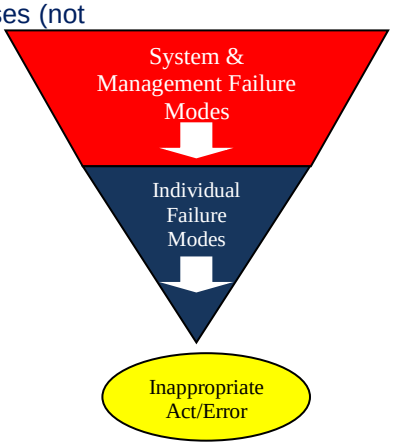
Definition/Purpose: Graphically displays potential causes of a problem. The layout shows cause and effect relationships between potential causes. Used in the Analysis phase.

Instructions: ***To use as a template, please save a copy by clicking on the save icon.***

1. Place the problem statement on the right side of the paper, half-way down; draw a horizontal line across the paper with an arrow pointing to the effect or problem statement.
2. Determine general, major categories for the causes; connect them to the horizontal line with the diagonal lines.
   a. Use contributing factors categories:
      - Human
      - Equipment
      - Environmental
      - Information
      - Communication
      - Policy/Procedure/Practice
3. Note the major causes (see examples in table below) and place them under the general categories. Use brainstorming techniques as needed. Add additional causes as needed.
4. List sub-causes and connect them to the main causes. To determine sub-causes, ask *why* five times.
5. Evaluate the diagram. Check that the branches on your cause and effect diagram are worded as possible causes and are arranged in a logical sequence.

Effective Use:

1. Have a narrowly defined problem to start.
2. Causes on the diagram must be verified to confirm that they are real causes (not assumptions).
3. Use this tool as an outline for action plan development.
4. Do not use this tool to list potential solution



Contributing Factors		
Human factors Staffing Scheduling Orientation/training Competency assessment Supervision/Leadership Qualification/requirements	**Equipment Factors** Preventive maintenance Equipment failure Equipment availability Defective equipment User error	**Environmental Factors** Physical Cultural Uncontrollable external Environmental risks Quality control Safety, security, utility, HAZMAT, emergency preparedness
Information Factors Accurate data Thorough and available data Unclear data/information Lack of Technology EMR/EPIC issues	**Communication Factors** Among staff Between staff and patient or family Between physician and Staff Between physician and patient or family Between levels of care, units or external Facilities	**Policy, Procedure and Practice Factors** Assessment, reassessment, monitoring Care planning Patient/family education Care /treatment protocols & practices Patient identification Patient observation

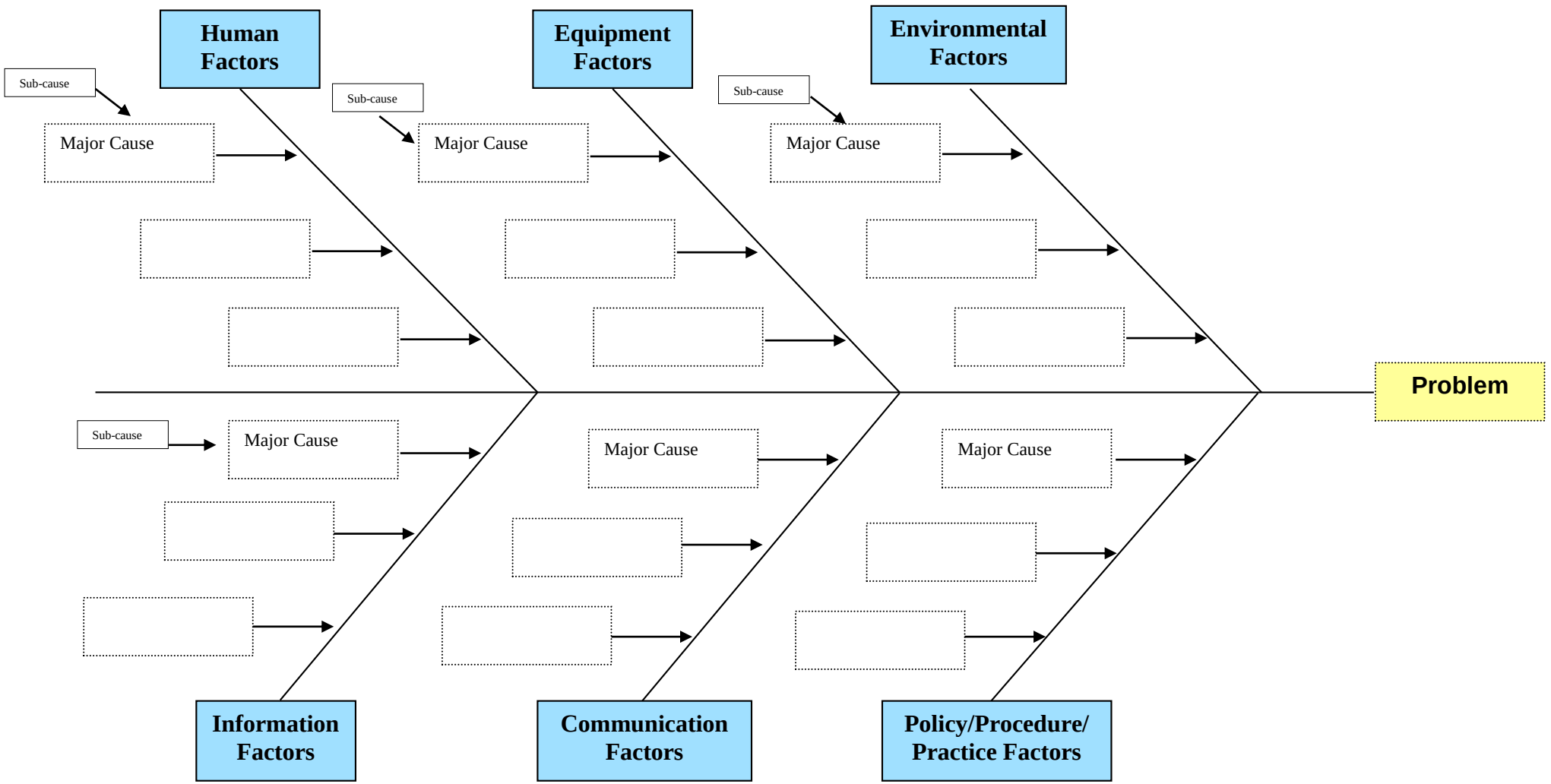
Fishbone Diagram

Individual Failure Modes				
Competency (Knowledge& Skills)	**Consciousness** (Attention)	**Communication** (Information & Processing)	**Critical Thinking** (Cognition)	**Compliance** (Motivation)
Unformed Skills/Habits (inability to do something well while possessing knowledge, lacks performance reliability gained through experience)	Inattention (preoccupied; rushing or hurrying; not paying attention)	Incorrect Assumption (assuming a thing to be true or correct that was in fact wrong)	Situational Awareness (unawareness or lacking knowledge of what is going on; failure to perceive that acts or conditions deviated from desired path)	Indifference (inadequate care or attention to people or things of responsibility; carelessness, informality, or casual attitude, yet with no deliberate intention to cause harm)
Normalized Deviance (conforming to an individual's standard, type, or custom, where behavior is sharply different from the generally accepted standard)	Distraction (divided or diverted attention)	Misinterpretation (forming an understanding that is not correct from something that is said or done)	Failure to Validate/Verify (failure to find or test the truth of something; failure in the cognitive process of establishing a valid proof)	Shortcut (deliberate, conscious act to take a quicker or more direct route - a route that deviates from the designated or optimal path)
Inadequate Knowledge (lacks fundamental knowledge-in-the-head of operating procedures or principles, or knowledge of available protocols)	Habit Intrusion or Reflex (act performed without conscious thought; a settled or regular tendency or practice)	Information Overload (overburdened with too much sensory or cognitive input or information)	Mindset (primed or biased by pattern or preconceived notion; a fixed mental attitude or disposition that predetermines a person's response to interpretations or situations)	Overconfident (excessively confident or presumptuous; failure to stop when questions arise; proceeding in the face of uncertainty)
	Spatial Disorientation (feeling lost or confused, especially with respect to direction or position; confused because of misleading information)		Tunnel Vision (the tendency to focus exclusively on a single or limited objective or view; overtly focused on details of task failure to see the big picture)	Reckless (acting without thought or care for the consequences of one's acts; acting overtly with full knowledge that an act could cause harm)
	Bored, Fatigues or Unfit for Duty (feeling weary; extreme tiredness because one is unoccupied; has no interest because of physical or mental activity or external influence)			
	Lapse (a momentary fault or failure in behavior; inadequate mental tracking; inadvertently forgot to complete something)			

Fishbone Diagram

System Failure Modes				
Structure	**Culture**	**Process**	**Policy & Procedure**	**Technology & Environment**
Structure Model (wrong model, incompatible missions)	Inadequate Mission or Vision (lacking or poorly executed mission)	Omitted Actions (key activity is missing or incomplete)	Lacking or Informal (no policy or protocol)	Input/Output (visual display, alarms, control configuration)
Inadequate Structure (span of control, levels of leadership, leveraging positions and experience)	Non-Collaboration Disruptive competition, defensiveness, poor teamwork, low morale)	Excessive Actions (contains low-value activities)	Usability (poor presentation or information depiction, low credibility, poor access)	Human Capability (symbols, codes, anthropometry, devices, Human control, physical work)
Inadequate Job Function (overlap or gaps in roles, responsibilities or expectations)	Operational Leadership (lacking or inadequate command, prioritization, or assignment in response to emergent or emerging situations)	Poorly Sequenced (poor flow, excessive branching or work process activities)	Understandability (difficult to comprehend because guidance details is lacking or inadequate for the knowledge and skill level of the user)	Arrangement (physical arrangement of work space, department, facility, or campus negatively impacting performance)
Resource Allocation (insufficient infrastructure, people, budget, equipment or other resources)	High Reliability Environment Setting does not incorporate error prevention expectations and focus including: **Competency** (knowledge, skills, practice habits) **Consciousness** (inattention, slips lapses) **Communication** (frequency, formality) **Critical Thinking** (situational awareness, judgment, decisions) **Compliance** (conformity to standards, conservatism)	Inadequate Interface (lack of poorly designed handoffs of information, resources or products)	Knowledge in Environment (inadequate or under-utilized job aids, forcing functions)	Environment (lighting, noise, climate, motion negatively impacting performance)
Collaboration Mechanisms (wrong or inadequate collaboration mechanisms)		Inadequate Checks (lack of poorly designed checks, inspections or reviews)		

Fishbone Diagram



Leadership Analysis and Action Planning

- Consensus and solutions meeting
  - Key leaders/stakeholders review & analyze findings & SBAR summary
    - Fishbone Diagram
    - 5 Whys
- Action Items identified (Recommendations section of SBAR)
- Counter Measures and action strength
- Measures of Success (MOS)
- Action Plan owner, monitoring and update cadence

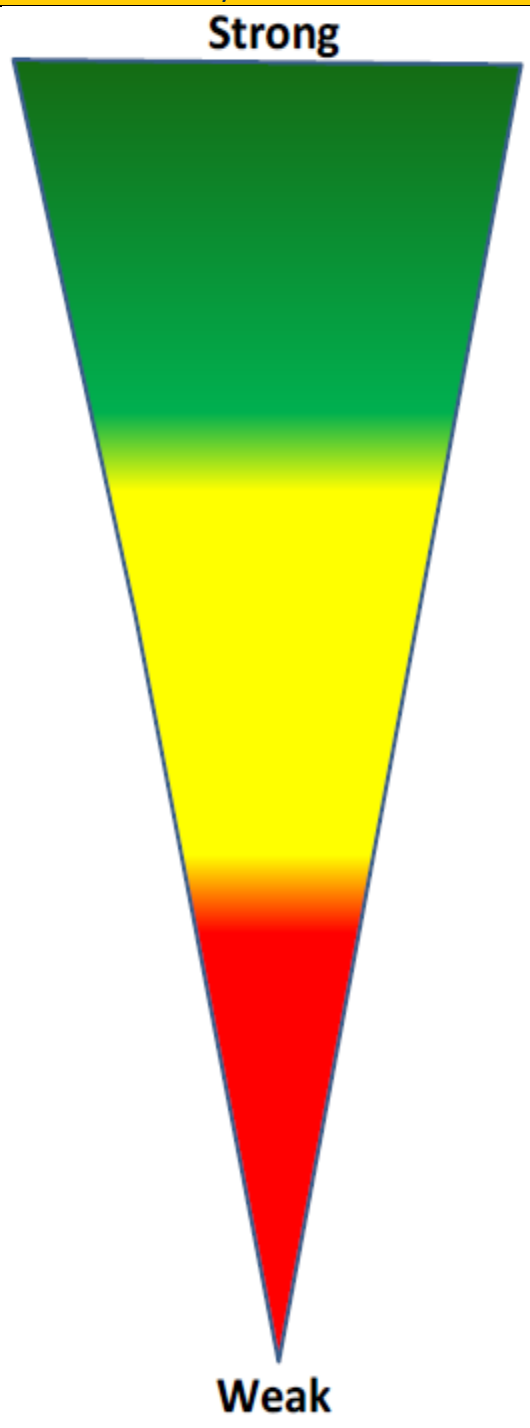
Consensus and Solutions Meeting

- Opportunity for the core team and event stakeholders to understand the event, why it occurred, and confirm contributing factors.
- Develop targeted solutions for the contributing factors to the event, to determine appropriate measurement strategies and measures of success.
- Identify action plan owner and counter measure owners
- Establish dates for action plan updates
  - 30 days, 60 and 90 days follow-up
  - Additional follow-up as needed

Action Plan/Accountability

- Each Root Cause must have at least one counter measure identified
- Counter measures must have a measure of success that may include metrics to gather during implementation
- Estimated due date of completion for each action
- Each action plan should have at least one moderate or strong counter measure. Evaluation of Effective Performance Improvement tool
- Owner for each action
- Owner for oversight of entire action plan to assure completion
- Shared learning across organization The More We Know

Evaluation of Effective Performance Improvement

	Strategies	Probability of Effectiveness
Strong System-Focused	Fail-safe Mechanisms	
	Forcing Functions/Process Re-Design	
	Automation and Computerization	
Moderate System/Behavior-Focused	Standardization	
	Optimize Redundancy	
	Reminders and Checklists	
Weak Behavior-Focused	Rules and Policies	
	Training, Education and Information	
	Suggestions to be more careful or vigilant, double checks	

The More We Know

Situation

Background

ZERO 24/7 HARM

Assessment

Recommendation

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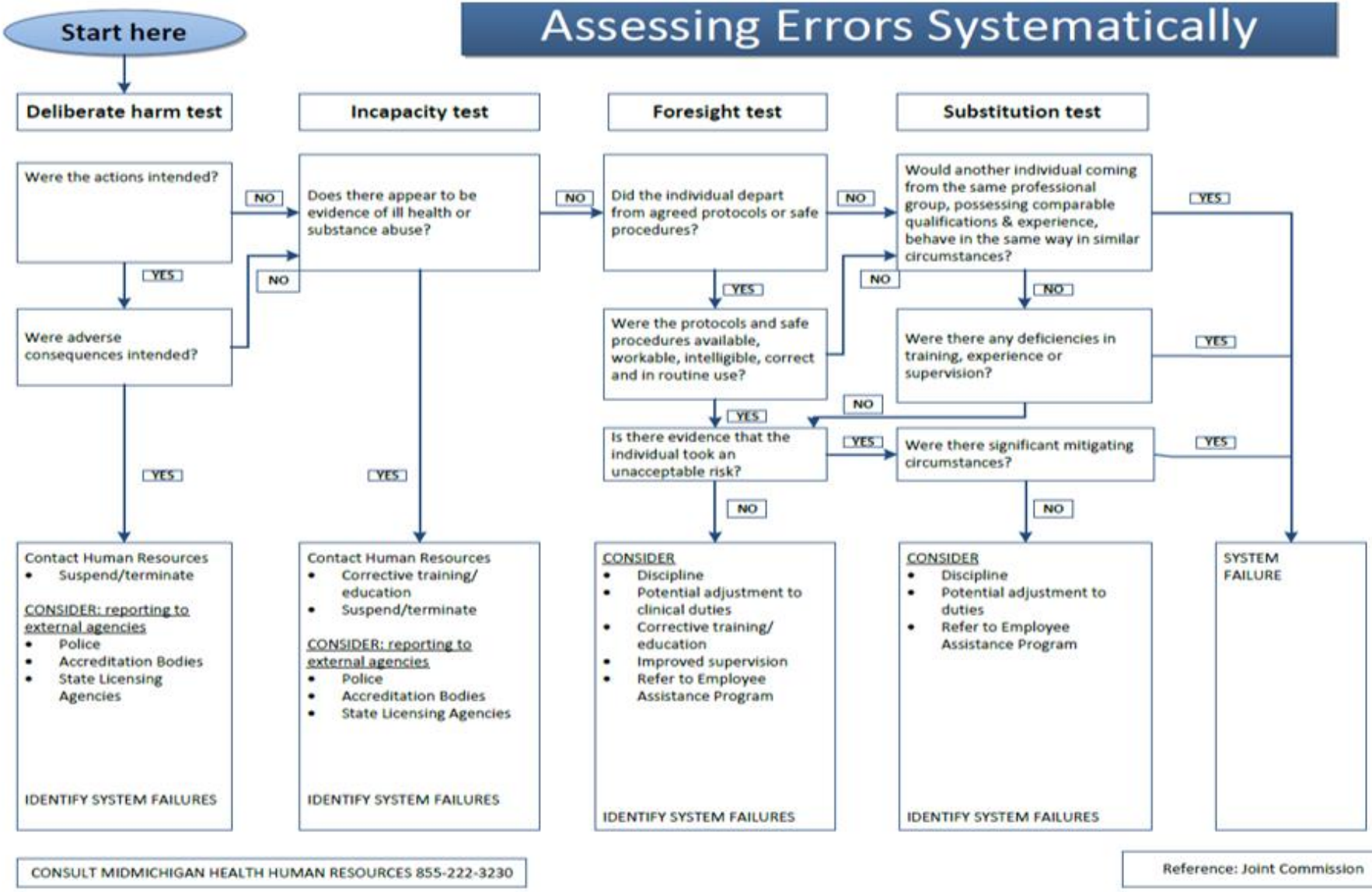
Culpability Tool

- Accountability is the acknowledgement and assumption of responsibility.
- Culpability is the degree of one's responsibility
- ***ALWAYS*** complete investigation/RCA process prior to assigning culpability
  - This is the last step of the process unless event was blatantly egregious
- System failures should not result in punishment of individuals involved. Console those involved.
- Include HR in events that lead to individuals needing coaching and/or discipline.

Assessing Errors Systematically



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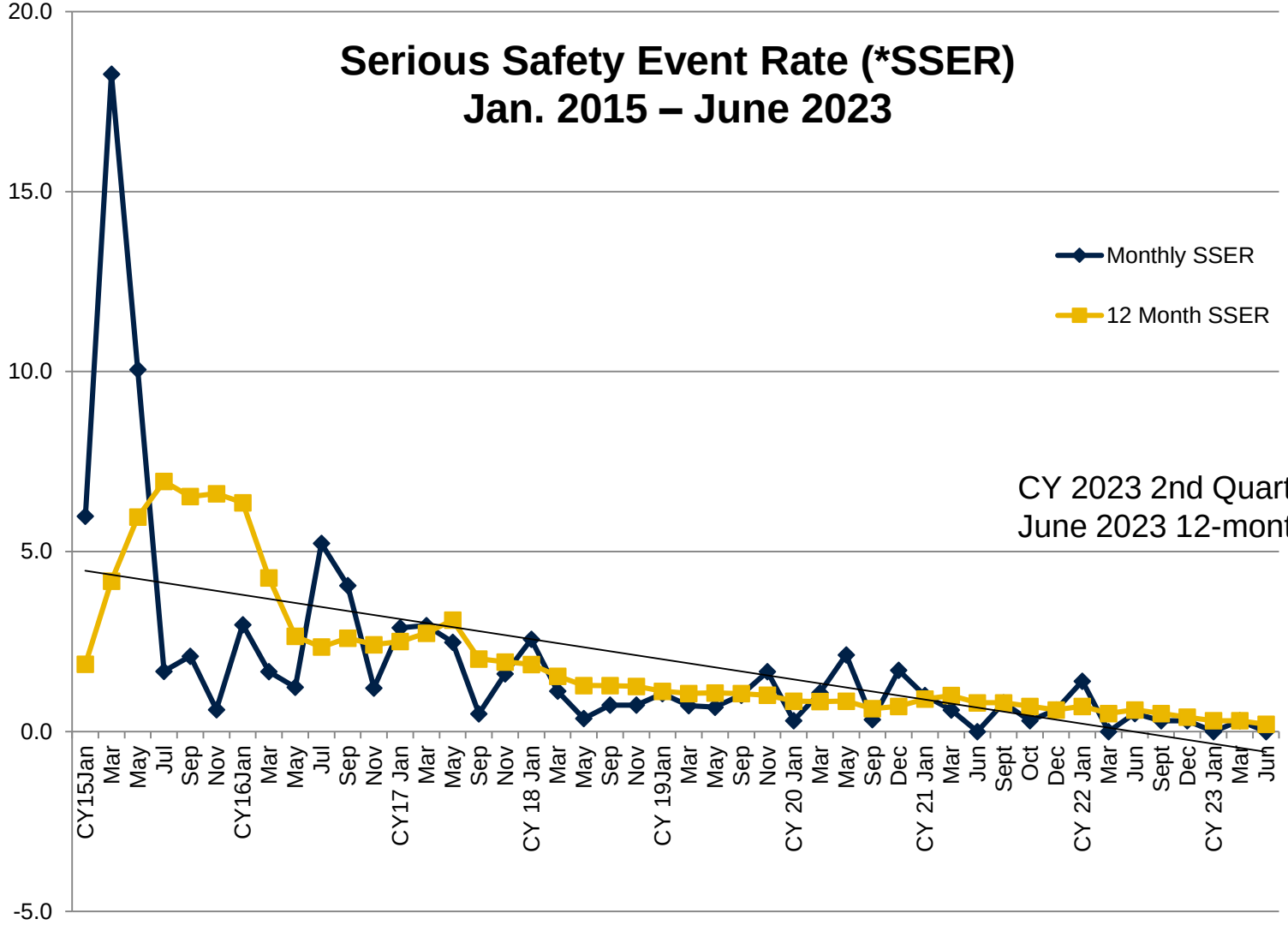
Reference: Joint Commission

Root Cause Analysis (RCA) Completed

Subsidiary	FY 19	FY 20	FY 21	FY 22	FY 23
Alpena	9	18	29	36	65
Clare	1	0	3	3	6
Gladwin	1	0	2	3	3
Alma	3	17	13	24	34
Midland	12	22	47	57	69
Sault	n/a	n/a	n/a	n/a	7
West Branch	6	9	7	11	6
Home Care	0	0	2	0	0
MMG	0	0	0	1	0
System Total	32	66	103	135	190

New RCA Process & Toolkit 2020-2021

Serious Safety Event Rate (*SSER)
Jan. 2015 – June 2023



*SSER Rate Calculation:
SSE volume last 12 months
Adjusted Patient Days x 10,000
Includes SSE 1 SSE 2 SE 3

CY 2023 2nd Quarter SSER = **0.00**
June 2023 12-month rolling SSER = **0.2**

Where We're Going

https://mmheadlines.org/2018/12/the-journey-to-high-reliability-continues/

"Excellence is never an accident; it is the result of high intention, sincere effort, intelligent direction, skillful execution and the vision to see obstacles as opportunities."

Anonymous