This cognitive aid is adapted from the work of James P. Bagian, M.D., P.E.; Joseph M. DeRosier, P.E., C.S.P.; John W. Gosbee, M.D., M.S.; Caryl Z. Lee, R.N., M.S.N.; and David Marx, J.D. published by the U.S. Department of Veterans Affairs National Center for Patient Safety, October 2001.

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Instructions

1. After reviewing the initial flow diagram identify and document all questions team members have about the adverse event.

2. Review the Triggering Questions as a team with the goal of identifying questions that are applicable to the adverse event being investigated.

3. Combine the Triggering Questions to the team questions and identify where the answers may be obtained. This may include: interviewing staff, reviewing documentation (e.g., policies, procedures, the medical record, equipment maintenance records), regulatory requirements (e.g., The Joint Commission, CMS, State of Michigan), guidelines (e.g., AORN, ISMP, ECRI Institute), publications, and codes & standards.

4. As the investigation progresses additional questions may be identified that will need to be answered.

5. By the end of the investigation the RCA team should be able to identify which Triggering Questions are not applicable and know the answers to the remaining questions.
Communication Questions

1. Was the patient correctly identified?

2. Was information from various patient assessments shared and used by 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 patient’s response to treatment? (e.g., Assessments, consultations, orders, progress notes, medication administration record, x-ray, labs)

4. Was communication between management/supervisors and front line staff adequate? (i.e., Accurate, complete, unambiguous, using standard vocabulary and no jargon)

5. Was communication between front line team members adequate?

6. Were policies and procedures communicated adequately?

7. Was the correct technical information adequately communicated 24 hours/day to the people who needed it?

8. Were there methods for monitoring the adequacy of staff communications? (e.g., Read back, repeat back, confirmation messages, debriefs)

9. Was the communication of potential risk factors free from obstacles?

10. 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?

11. If relevant, were the patient and their family/significant others actively included in the assessment and treatment planning?

12. Did management establish adequate methods to provide information to employees who needed it in a timely manner that was easy to access and use?

13. Did the overall culture of the department/work area encourage or welcome observations, suggestions, or “early warnings” from staff about risky situations and risk reduction? (Also, if this has happened before what was done to prevent it from happening again?)

14. Did adequate communication across organizational boundaries occur?
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?

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., Workload too high, too low, or wrong mix of staff)

27. Was the level of automation appropriate? (i.e., Neither too much nor not enough)
Environment/Equipment Questions (page 1 of 2)

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?

36. 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?)

37. Was there a maintenance program in place to maintain the equipment involved?

38. If there was a maintenance program, did the most recent previous inspections indicate that the equipment was working properly?

39. If previous inspections pointed to equipment problems, were the corrective actions that were implemented effective?

40. 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?

41. Were adequate time and resources allowed for physical plant and equipment upgrades, if problems were identified?

42. Was there adequate equipment to perform the work processes?

43. Were emergency provisions and back-up systems available in case of equipment failure?

44. Had this type of equipment worked correctly and been used appropriately in the past?

45. Was the equipment designed such that usage mistakes would be unlikely to happen?

46. Was the design specification adhered to?

47. Was the equipment produced to specifications and operated in a manner that the design was intended to satisfy?
**Environment/Equipment Questions (continued)**

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 manufacturers’ instructions?


**Rules/Policies/Procedure Questions**

54. Was there an overall management plan for addressing risk and assigning responsibility for risk?

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 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?

61. Were all 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?

62. Were there written up-to-date policies and procedures that addressed the work processes related to the adverse event or close call?

63. Were these policies/procedures consistent with relevant state and national guidance, regulatory agency requirements, and/or recommendations from professional societies/organizations?

64. Were relevant policies/procedures clear, understandable, and readily available to all staff?

65. Were the relevant policies and procedures actually used on a day-to-day basis?

66. If the policies and procedures were not used, what got in the way of their usefulness to staff?

67. If policies and procedures were not used, what positive and negative incentives were absent?
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, wrong procedure surgeries.

68. What barriers and controls were involved in this adverse event or close call?

69. Were these barriers designed to protect patients, staff, equipment, or the environment?

70. Was patient risk considered when designing these barriers and controls?

71. Were these barriers and controls in place before the adverse event or close call occurred?

72. Had these barriers and controls been evaluated for reliability?

73. Were there other barriers and controls for work processes?

74. 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.)

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 system 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?