

Accident Investigation Reference List

Medical Error and Patient Safety, Human Factors in Medical Error, Root Cause Analysis, and Medical Technology Accident Investigation

(128 citations)

Medical Error and Patient Safety

1. Abramson NS, Wald KS, Grenvik AN, Robinson D, Snyder JV. Adverse occurrences in intensive care units. JAMA 1980 Oct 3;244(14):1582-4.
2. American College of Clinical Engineering (ACCE). Enhancing patient safety: The role of clinical engineering [white paper]. 2001;
<http://www.accenet.org/downloads/ACCEPatientSafetyWhitePaper.pdf>.
3. Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, Siegler M. An alternative strategy for studying adverse events in medical care [see comments]. Lancet 1997 Feb 1;349(9048):309-13.
4. ASHP guidelines in the safe use of automated compounding devices for the preparation of parenteral nutrition admixtures. Am J Health-Syst Pharm 2000;57(Jul 15):1343-1348.
5. Bagian JP, Gosbee J, Lee CZ, Williams L, McKnight SD, Mannos DM. The Veterans Affairs root cause analysis system in action. Jt Comm J Qual Improv. 2002 Oct;28(10):531-45.
6. Bagian JP, Lee C, Gosbee J, DeRosier J, Stalhandske E, Eldridge N, Williams R, Burkhardt M. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. Jt Comm J Qual Improv. 2001 Oct;27(10):522-32.
7. Barach P, Small SD. Enhancing patient safety: beginning the dialogue in health services research. J Health Serv Res Policy. 2001 Apr;6(2):67-9.
8. Barach P, Small SD. How the NHS can improve safety and learning. By learning free lessons from near misses. BMJ. 2000 Jun 24;320(7251):1683-4.
9. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems BMJ. 2000 Mar 18;320(7237):759-63.
10. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. Qual Saf Health Care. 2003 Dec;12 Suppl 2:ii2-7.
11. Battles JB, Keyes MA. Technology and patient safety: a two-edged sword. Biomed Instrum Technol. 2002 Mar-Apr;36(2):84-8.

12. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001;76(2):125-33.
13. Battles JB, Kaplan HS, Van der Schaaf TW, Shea CE. The attributes of medical event-reporting systems: experience with a prototype medical event-reporting system for transfusion medicine. *Arch Pathol Lab Med*. 1998 Mar;122(3):231-8
14. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group [see comments]. *JAMA* 1995 Jul 5;274(1):29-34.
15. Bogner MS, ed. Human error in *medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.
16. Bogner MeDSuN. Stretching the search for the 'why' of error: the systems approach. *J Clin Eng* 2002;27(2):110-15.
17. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I [see comments]. *N Engl J Med* 1991 Feb 7;324(6):370-6.
18. Brennan TA, Hebert LE, Laird NM, et al. Hospital characteristics associated with adverse events and substandard care [see comments]. *JAMA* 1991 Jun 26;265(24):3265-9.
19. Burstin HR, Lipsitz SR, Udvarhelyi IS, Brennan TA. The effect of hospital financial characteristics on quality of care. *JAMA* 1993 Aug 18;270(7):845-9.
20. Connor M, Ponte PR, Conway J. Multidisciplinary approaches to reducing error and risk in a patient care setting. *Crit Care Nurs Clin North Am*. 2002 Dec;14(4):359-67, viii.
21. Clancy CM, Scully T. A call to excellence. *Health Aff (Millwood)*. 2003 Mar-Apr;22(2):113-5.
22. Clarifying JCAHO's alarm-safety goal. A conversation with Richard J. Croteau, MD. *Health Devices*. 2003 Mar;32(3):122-5.
23. Cohen MR, ed. *Medication errors*. Washington, DC: American Pharmaceutical Association; 1999.
24. Cook R, Woods D, Howie M, et al. Unintentional delivery of vasoactive drugs with and electromechanical infusion device. *J Cardiothorac Anesth* 1992;6:238-44.
25. Cook RI, Woods DD, Miller C. *A tale of two stories: Contrasting views on patient safety*. National Patient Safety Foundation: Chicago, IL, 1998 Apr (also available at <http://www.npsf.org>).
26. Cooper JB, Newbower RS, Long CD, et al. Preventable anesthesia mishaps: a study of human factors. *Anesthesiology* 1978 Dec;49(6):399-406.

27. Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. *Anesthesiology* 1984 Jan;60(1):34-42.
28. Cooper JB, Cullen DJ, Eichhorn JH, et al. Administrative guidelines for response to an adverse anesthesia event. The Risk Management Committee of the Harvard Medical School's Department of Anaesthesia [see comments]. *J Clin Anesth* 1993 Jan-Feb;5(1):79-84.
29. ECRI. Medication errors. *Healthcare Risk Control* 2000 Sept; 4: Pharmacy and Medications: 1.
30. ECRI. Sample medication error policies and forms. *Healthcare Risk Control* 2000 Sept; 4: Pharmacy and Medications: 1.2.
31. ECRI. Patient monitoring in the OR: Vigilance, monitoring, and the standard of care. *Healthcare Risk Control* 1996 Jan; 4: Surgery and Anesthesia: 4.
32. ECRI. Avoiding anesthesia mishaps through pre-use checks. *Health Devices* 1982;11:201-3.
33. Gaba DM. Human error in dynamic medical environments. In: Bogner MS, ed. *Human error in medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.
34. Gaba DM. Human error in anesthetic mishaps. *Int Anesthesiol Clin* 1989 Fall;27(3):137-47.
35. Gild WM. Risk management in cardiac anesthesia: the ASA Closed Claims Project perspective. *J Cardiothorac Vasc Anesth* 1994 Feb;8(1 Suppl 1):3-6.
36. Goode LD, Clancy CM, Kimball HR, Meyer G, Eisenberg JM. When is "good enough"? The role and responsibility of physicians to improve patient safety. *Acad Med*. 2002 Oct;77(10):947-52.
37. Heget JR, Bagian JP, Lee CZ, Gosbee JW. John M. Eisenberg Patient Safety Awards. System innovation: Veterans Health Administration National Center for Patient Safety. *Jt Comm J Qual Improv*. 2002 Dec;28(12):660-5.
38. Hill AG, Kurusz M. Perfusion standards and guidelines. *Perfusion* 1997 Jul;12(4):251-5.
39. Hyman WA. Errors in the use of medical equipment. In: Bogner MS, ed. *Human error in medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.
40. Institute for Safe Medication Practices. Over-reliance on pharmacy computer systems may place patients at great risk. *ISMP Med Saf Alert* 1999 Feb 10;4(3):1-2.
41. Institute of Medicine. *To err is human: building a safer health system*. Washington, DC: National Academy Press; 1999.

42. Johnson R, Coles BJ, Tribble DA. Accuracy of three automated compounding systems determined by end-product laboratory testing and comparison with manual preparation. *Am J Health Sys Pharm* 1998 Jul 15; 55:1503-1507.
43. Karcz A, Holbrook J, Burke MC, et al. Massachusetts emergency medicine closed malpractice claims: 1988-1990. *Ann Emerg Med* 1993 Mar;22(3):553-9.
44. Kroll DA, Caplan RA, Posner K, et al. Nerve injury associated with anesthesia. *Anesthesiology* 1990 Aug;73(2):202-7.
45. Kurusz M, Wheeldon DR. Risk containment during cardiopulmonary bypass. *Semin Thorac Cardiovasc Surg* 1990 Oct;2(4):400-9.
46. Kurusz M. Lessons from perfusion surveys. *Perfusion* 1997 Jul;12(4):221-7.
47. Leape LL. Error in medicine. *JAMA* 1994;272(23):1851-1857.
48. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. ADE Prevention Study Group [see comments]. *JAMA* 1995 Jul 5;274(1):35-43.
49. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991 Feb 7;324(6):377-84.
50. Lefevre F, Feinglass J, Potts S, et al. Iatrogenic complications in high-risk, elderly patients. *Arch Intern Med* 1992 Oct;152(10):2074-80.
51. Lilford RJ. Patient safety research: does it have legs? *Qual Saf Health Care*. 2002 Jun;11(2):113-4.
52. Maddox ME. Designing medical devices to minimize human error. *Med Dev Diag Indust* 1997;May: 166-178.
53. General Accounting Office medical device reporting. Improvements needed in FDA's system for monitoring problems with approved devices [report online]. 1997 Jan [cited 1998 Oct 14]. Available from Internet: <http://www.gao.gov>.
54. Napper C, Battles JB, Fargason C Jr. Pediatrics and patient safety. *J Pediatr*. 2003 Apr;142(4):359-60.
55. Newbower RS, Cooper JB, Long CD. Learning from anesthesia mishaps: analysis of critical incidents in anesthesia helps reduce patient risk. *QRB Qual Rev Bull* 1981 Mar;7(3):10-6.
56. O'Hara DA, Carson NJ. Reporting of adverse events in hospitals in Victoria, 1994-1995 [see comments]. *Med J Aust* 1997 May 5;166(9):460-3.

57. Ortiz E, Clancy CM; AHRQ. Use of information technology to improve the quality of health care in the United States. *Health Serv Res.* 2003 Apr;38(2):xi-xxii.
58. Runciman WB, Roughead EE, Semple SJ, Adams RJ. Adverse drug events and medication errors in Australia. *Int J Qual Health Care.* 2003 Dec;15 Suppl 1:i49-59.
59. Runciman WB, Merry AF, Tito F. Error, blame, and the law in health care--an antipodean perspective. *Ann Intern Med.* 2003 Jun 17;138(12):974-9.
60. Runciman WB. Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system-is this the right model? *Qual Saf Health Care.* 2002 Sep;11(3):246-51.
61. Runciman WB, Edmonds MJ, Pradhan M. Setting priorities for patient safety. *Qual Saf Health Care.* 2002 Sep;11(3):224-229.
62. Runciman WB, Helps SC, Sexton EJ, Malpass A. A classification for incidents and accidents in the health-care system. *J Qual Clin Pract.* 1998 Sep;18(3):199-211.
63. Samore MH, Evans RS, Lassen A, Gould P, Lloyd J, Gardner RM, Abouzelof R, Taylor C, Woodbury DA, Willy M, Bright RA. Surveillance of medical device-related hazards and adverse events in hospitalized patients. *JAMA.* 2004 Jan 21;291(3):325-34.
64. Senders JW. Medical devices, medical errors, and medical accidents. In: Bogner MS, ed. *Human error in medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.
65. Senders JW. Detecting, correcting and interrupting error. *J Intraven Nurs* 1995;18(1):28-32.
66. Shepherd M. Eliminating the culture of blame: A new challenge for clinical engineers and BMETs. *Biomed Instrum Technol* 2000;34:370-374.
67. Stanhope N, Vincent C, Taylor-Adams SE, et al. Applying human factors methods to clinical risk management in obstetrics. *Br J Obstet Gynaecol* 1997 Nov;104(11):1225-32.
68. Small SD. Medical device-associated safety and risk: surveillance and stratagems. *JAMA.* 2004 Jan 21;291(3):367-70.
69. Small SD, Barach P. Patient safety and health policy: a history and review. *Hematol Oncol Clin North Am.* 2002 Dec;16(6):1463-82.
70. Stalhandske E, Bagian JP, Gosbee J. Department of Veterans Affairs patient safety program. *Am J Infect Control.* 2002 Aug;30(5):296-302.
71. U.S. General Accounting Office (GAO). *Adverse drug events: the magnitude of health risk is uncertain because of limited incidence data*. GAO/HEHS-00-21. Washington, DC: GAO; 2000 Jan.

72. Wilson RM, Runciman WB, Gibberd RW, et al. The Quality in Australian Health Care Study. *Med J Aust* 1995 Nov 6;163(9):458-71.

Human Factors and Medical Errors

1. Bruley ME. Ergonomics and error—Who is responsible? In: *Proceedings of the First Symposium on Human Factors in Medical Devices*. Plymouth Meeting: ECRI, CITECH, Health Industry Manufacturers Association (HIMA), Ben Franklin Technology Center of S.E. Pennsylvania, and FDA; 1989 Dec:6-10.
2. Christoffersen K, Woods DD. How complex human-machine systems fail: Putting “human error” in context: In Karwowski W, Marras W, eds. *Handbook of occupational ergonomics*. CRC Press: 1999.
3. Cook RI, Woods DD. Operating at the ‘sharp end.’ The complexity of human error. In: Bogner MS, ed. *Human error in medicine*. Erlbaum; 1994.
4. Do It By Design: An Introduction to Human Factors in Medical Devices. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health. 1993. Available from Internet: <http://www.fda.gov/cdrh/humfac/doitpdf.pdf>
5. Gosbee J. Human factors engineering and patient safety. *Qual Saf Health Care*. 2002 Dec;11(4):352-4.
6. Gosbee J. Importance of human factors engineering in error-and-medicine education. *Acad Med*. 1999 Jul;74(7):748-9.
7. Guyton B. Human factors and medical devices: a clinical engineering perspective. *J Clin Eng* 2002; 27(2):116-22.
8. Hollnagel E, Mancini G, Woods DD, eds. *Intelligent decision support in process environments*. New York: Springer-Verlag; 1986.
9. Hollnagel E, Mancini G, Woods DD, eds. *Cognitive engineering in complex, dynamic worlds*. London: Academic Press, 1988.
10. Hyman WA, Cram N. A human factors checklist for equipment evaluation and use. *J Clin Eng* 2002; 27(2):131-3.
11. Kaye R, Crowley J. Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management - Identifying, Understanding, and Addressing Use-Related Hazards. 2000 July 18. [cited 2007 Aug 8]. Available from Internet: <http://www.fda.gov/cdrh/humfac/1497.pdf>

12. LT Kohn, JM Corrigan, MS Donaldson, eds: *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 1999.
13. Lilford RJ, Mohammed MA, Braunholtz D, Hofer TP. The measurement of active errors: methodological issues. *Qual Saf Health Care*. 2003 Dec;12 Suppl 2:ii8-12.
14. Reason J. *Human error*. Cambridge, England: Cambridge University Press; 1990.
15. Senders JW. In: Neville Moray, ed. *Human error: Cause, prediction and reduction*. Lawrence Erlbaum Associates; 1991.
16. Senders JW. Human errors: Their causes and reduction. In: Bogner MS, ed. *Human error in medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.
17. Taylor-Adams S, Vincent C, Stanhope N. Applying human factors methods to the investigation and analysis of clinical adverse events. *Safety Science* 1999;31:143-159.
18. Welch DL. Human error and human factors engineering in health care. *Biomed Instrum Tech* 1997;31(6):627-631.
19. Woods DD, Johannesen L, Cook RI, Sarter N. *Behind human error: Cognitive systems, computers and hindsight*. Dayton, OH: Crew Systems Ergonomic Information and Analysis Center, WPAFB; 1994.
20. Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health. 1993. Available from Internet: <http://www.fda.gov/cdrh/dsma/897.pdf>

Root Cause Analysis

1. Berry K, Krizek B. Root cause analysis in response to a “near miss.” *J Healthc Qual* 2000, 22(2):16-18.
2. Croteau RJ. Sentinel events, root cause analysis and the trustee. *Trustee*. 2003 Mar;56(3):33-4.
3. Boyer MM. Root cause analysis in perinatal care: health care professionals creating safer health care systems. *J Perinat Neonatal Nurs*. 2001 Jun;15(1):40-54.
4. ECRI. Systems analysis. *Healthcare Risk Control* 2000 Mar; 2: Risk and quality management strategies 14:1-17.
5. ECRI. Root cause analysis. *Healthcare Hazard Control* 2001 Oct; 1:Safety and behavior 2.2.1:1-8.

6. Gosbee J, Anderson T. Human factors engineering design demonstrations can enlighten your RCA team. *Qual Saf Health Care*. 2003 Apr;12(2):119-21.
7. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). *Root cause analysis in health care: Tools and techniques*. JCAHO: Oakbrook Terrace, IL; 2000.
8. Kazandjian VA. When you hear hoofs, think horses, not zebras: an evidence-based model of health care accountability. *J Eval Clin Pract*. 2002 May;8(2):205-13.
9. Neily J, Ogrinc G, Mills P, Williams R, Stalhandske E, Bagian J, Weeks WB. Using aggregate root cause analysis to improve patient safety. *Jt Comm J Qual Saf*. 2003 Aug;29(8):434-9, 381.
10. Root-cause software: look before you leap. *Hosp Peer Re* 2000 Mar;25(3):34-5.
11. The ASRS Celebrates Its 25th Anniversary. Callback 2001:Issue 260; http://asrs.arc.nasa.gov/callback_issues/cb_260.
12. VA National Center for Patient Safety. Root Cause Analysis. 2 April, 2001. <http://www.va.gov/ncps/rca.html> or <http://www.patientsafety.gov/toolsva.gov/ncps/rca.html>.

Medical Technology Accident Investigation

1. Bartlett RH, Harken DE. Instrumentation for cardiopulmonary bypass—past, present, and future. *Med Instrum* 1976 Mar-Apr;10(2):119-4.
2. Bruley ME. Accident and forensic investigation. In: van Gruting CW, ed. *Medical devices: International perspectives on health and safety*. Amsterdam: Elsevier, 1994.
3. Bruley ME. Forensic Engineering Analysis of Medical Device Accidents. NAFE J (accepted for publication 2007)
4. Cooper JB, Newbower RS, Long CD, McPeck B. Preventable anesthesia mishaps: a study of human factors. *Anesthesiology* 1978 Dec;49(6):399-406.
5. Cooper JB, Cullen DJ, Eichhorn JH, et al. Administrative guidelines for response to an adverse anesthesia event. The Risk Management Committee of the Harvard Medical School's Department of Anaesthesia [see comments]. *J Clin Anesth* 1993 Jan-Feb;5(1):79-84.
6. Dyro JF. Methods for analyzing home care medical device accidents. *J Clin Eng* 1998;23(5):359-368.
7. Dyro JF. Accident Investigation. In: Dyro JF, ed. *The Clinical engineering Handbook*. Burlington: Elsevier, 2004.

8. ECRI. Investigating device-related incidents. In: *Special Report: Medical device reporting under the Safe Medical Devices Act—A guide for healthcare facilities*. ECRI: Plymouth Meeting, PA; 1991:23-30.
9. ECRI. General purpose infusion pumps. *Healthcare Risk Control* 1997 Jul;3:Medical technology 16:1-5.
10. ECRI. Technology management. *Healthcare Risk Control* 1996 Jan;3:Medical technology 10:1-5.
11. ECRI. Safety during equipment inspections. *Healthcare Risk Control* 1996 Jan;3:Medical technology 1:1-7
12. ECRI. High risk equipment problems. *Healthcare Risk Control* 1996 Jan;3:Medical technology 11:1-4.
13. ECRI. Investigating device-related skin “burns.” *Healthcare Risk Control* 1996 Jan;2:Incident reporting and management 3:1-18.
14. ECRI. Ventilator disconnections. *Healthcare Risk Control* 1996 Jan;4:Critical care 4:1-3.
15. ECRI. Equipment-related injury: Design defect vs. user error. *Health Devices* 1983;12:253-256.
16. ECRI. Equipment problems in intensive care. *Health Devices* 1980;9:285-7.
17. ECRI. The clinical relevance of equipment related problems. *Health Devices* 1980;9:284.
18. ECRI. Inspection and preventive maintenance of cardiopulmonary perfusion equipment and an overview of problems. *Health Devices* 1980;9:70-80
19. Forsell RD. The clinical engineer’s role in incident investigation. *Biomed Instrum* 1993 Sep-Oct; 27(5): 378-83.
20. Gaba DM. Human error in anesthetic mishaps. *Int Anesthesiol Clin* 1989 Fall;27(3):137-147.
21. Geddes LA. *Medical device accidents: with illustrative cases*. Tucson, AZ: Lawyers & Judges Publishing; 2002.
22. Hyman WA. Errors in the use of medical equipment. In: Bogner MS, ed. *Human error in medicine*. Hillsdale, New Jersey: Lawrence Erlbaum Associates; 1994.
23. Hyman WA. A generic fault tree for medical device error. *J Clin Eng* 2002; 27(2) :134-40.
24. Investigating device-related burns [Guidance article]. *Health Devices* 1993; 22(7):334-352.
25. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Preventing ventilator-related deaths and injuries. *Sentinel Event Alert* 2002 Feb 26; 25:1ff.

26. Nobel JJ. Medical device failures and adverse effects. *Pediat Emerg Care* 1991;7:120-3.
27. Shepherd M, Painter FR, Dyro, JF, Baretich, MF. Identification of human errors during device related accident investigations. *IEEE Eng Med Biology* 2004 (May/Jun);23:66-72.
28. Shepherd M, Brown, R. Utilizing a systems approach to categorize device-related failures and define user and operator errors. *Biomed Instrum Tech* 1992;26(6):461-475.
29. Senders JW. Medical devices, medical errors, and medical accidents. In: Bogner MS, ed. *Human error in medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.
30. Spath PL. Using failure mode and effects analysis to improve patient safety. *AORN J*. 2003 Jul;78(1):16-37; quiz 41-4.
31. Spooner RB, Kirby RR. Equipment-related anesthetic incidents. *Int Anesthesiol Clin* 1984;22(2):133-147.
32. Stalhandske E, DeRosier J, Patail B, Gosbee J. How to make the most of failure mode and effect analysis. *Biomed Instrum Technol*. 2003 Mar-Apr;37(2):96-102.