CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Keeping Connecticut Healthy

LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY
Adverse Event Reporting

General Statutes of Connecticut
Section 19a-127l-n

QUALITY OF CARE PROGRAM

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J. Robert Galvin, M.D., M.P.H., M.B.A., Commissioner
Norma Gyle, R.N., Ph.D., Deputy Commissioner

State of Connecticut
Department of Public Health
410 Capitol Avenue
P.O. Box 340308
Hartford, Connecticut 06134-0308

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EXECUTIVE SUMMARY

Under the current event definitions, the most common adverse events among 967 reports are: (1) falls resulting in serious disability or death, (2) perforations during open, laparoscopic, and/or endoscopic procedures, (3) stage 3-4 pressure ulcers acquired after admission to a healthcare facility, and (4) retention of foreign objects in patients after surgery. After screening an adverse event report, which includes a Corrective Action Plan, the Department of Public Health (DPH) determines whether to initiate an investigation. In addition to adverse event monitoring by DPH, Patient Safety Organizations disseminate information to improve patient care.

BACKGROUND

Connecticut General Statutes §19a 127l required the Department of Public Health (DPH) to establish a Quality in Health Care program for health care facilities. An Advisory Committee, chaired by the DPH Commissioner or designee, advises the program. Mandatory adverse event[1] reporting began October 1, 2002. After evaluating the program for more than a year, the Advisory Committee recommended adoption of the National Quality Forum (NQF) list of Serious Reportable Events, plus five or six Connecticut-specific events.

The Adverse Event reporting requirements were amended when CGS 19a-127n became effective July 1, 2004. The statute replaced the previous adverse event classification system with a list of reportable events identified by the NQF. Additionally, DPH added six Connecticut-specific adverse event definitions to supplement the NQF list, as allowed by the law. (The list appears in Appendix B). Items on the list are of concern to both the public and healthcare professionals, are clearly identifiable and measurable, and are often preventable. DPH has completed development of the mandated regulations for reporting of adverse events, and these became effective November 1, 2007.

In May 2007, hospitals and ambulatory surgical centers were provided with the updated NQF List of Serious Reportable Events and the revised list compiled by the Commissioner of Public Health. A new category was included in the NQF list related to fertility clinics (4H).[2] The NQF category "patient death associated with a fall" (5D) was expanded to include "serious injury associated with a fall." Reporting for this expanded category replaces the Connecticut-specific category (7B) that previously existed.

CGS Section 19a-127o identifies the primary activity of a Patient Safety Organization (PSO), which is to improve patient safety and the quality of care delivered to patients through the collection, aggregation, analysis, or processing of medical or health-related information submitted to the PSO by the health care provider. This "patient work product" may include reports, records, analyses, policies, procedures or root cause analyses prepared exclusively for the purpose of disclosure to the PSO. The patient safety work product is confidential and not subject to use or access except to the PSO and the health care provider. PSOs disseminate appropriate information or recommendations on best medical practices or potential system changes to improve patient care to the health care providers, DPH, the Quality of Care Advisory Committee and the public. DPH has designated three PSOs, including Qualidigm, the

[1] As discussed in Connecticut's March 2004 Adverse Events report, adverse events are not the same as medical errors. While there is overlap between the categories, some adverse events do not result from medical errors, and some medical errors do not result in adverse events. Adverse Events Reports are available at www.ct.gov/dph under "Health Care Quality."

[2] Category 4H is "Artificial insemination with the wrong donor sperm or wrong egg."

Connecticut Healthcare Research & Education Foundation (CHREF) and the Ambulatory Surgical Center Patient Safety Organization (ASC PSO) (see the June 30, 2006 and 2007 DPH reports on Connecticut's Quality of Care Program[3]).

ADVERSE EVENT DATA

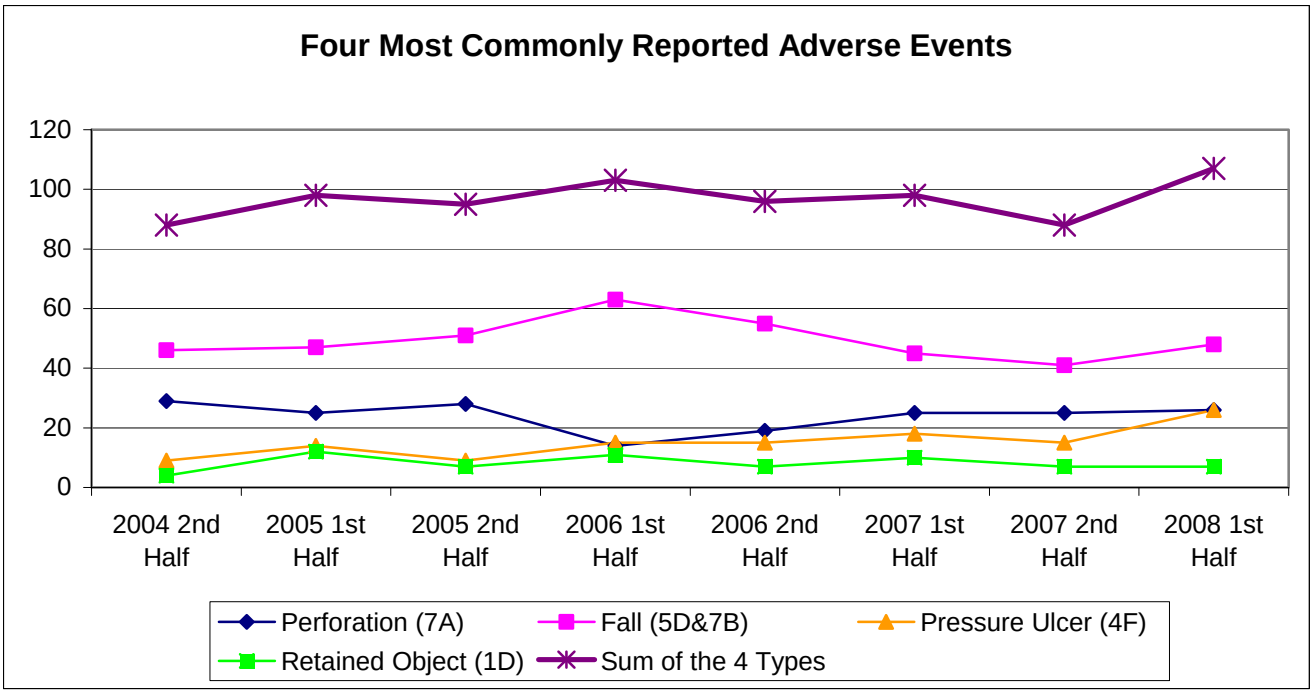
As of September 2, 2008, the DPH electronic database contained 967 reports received using the reporting system that came into effect on July 1, 2004. Demographic information is shown in Appendix A. This information reflects reporting, which is influenced by the varying rates of adverse events in various settings, which depend on the patient case mix, the quality of care, and other factors, as well as the number of patients served, willingness to report events, and the institutional system in place to convey information to the designated reporter. Some external factors may lead us to expect a higher number of reported events, even in facilities providing excellent health care. Consequently, clear conclusions cannot be derived from number of reports or fluctuations in the number of reports. For these reasons, no facility-level data are presented.

Acute care or children's hospitals submitted 833 (86%) of the 967 adverse event reports; chronic disease hospitals, 59; hospitals for the mentally ill, 46, and outpatient surgical facilities, 29. Forty-five percent of reported adverse events occurred in males and 55% in females. The majority of reports concerned patients over the age of 65 years. Reported events occurred at all hours of the day and night, though less so between 1 pm and midnight. The most common location of occurrence was reported to be the adult medical ward. Ninety-six deaths were reported in connection with an adverse event.

New to Appendix A is identification of the leading adverse event in the following categories: facility type, patient age, and location of event in the facility. The short adverse event identifiers in the right-most column of Appendix A correspond to the longer adverse event descriptions in Appendices B and C.

Appendix B presents the number of adverse events reported by calendar year half, according to the list of the NQF events (1A-6D) and Connecticut-specific events (7A-F). For some types of events, none have been reported. As shown in Appendix C, the most commonly reported events were falls that resulted in serious disability or death (5D & 7B). As noted above, the NQF expanded the fall definition for category 5D so that events formerly reportable under the Connecticut specific category 7B became reportable as category 5D in May 2007. The few reports in the second half of 2007 and all of 2008 of type 7B therefore should have been reported as 5D. Four hundred five falls comprised 42% of all 967 adverse events reported. The second most commonly reported events were perforations during open, laparoscopic, and/or endoscopic procedures, with 198 reports (21%). For more details about these adverse events, see the "Six Month Summary of Adverse Event Reports" (Appendix A of the June 30, 2005 DPH report on the Quality of Health Care Program). The third and fourth most commonly reported events overall in Connecticut were Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility, and retention of foreign objects in patients after surgery or other procedures. These four categories constitute 82% of reports overall. The number of reports in these four types and the proportion of all adverse events that they comprise have been fairly stable throughout four years of reporting.

[3] Quality of Health Care Reports are available at www.ct.gov/dph under "Health Care Quality".



CURRENT ACTIVITIES AND FUTURE PLANS

Investigation of Adverse Events

The first responsibility for investigation of an adverse event lies with the facility in which the event occurred. Under Connecticut's Adverse Event reporting law, facilities are required to submit a Corrective Action Plan to DPH for each reported Adverse Event.

An external investigation at a healthcare facility due to an adverse event may begin in several ways: (1) as a result of a complaint to DPH made by any person; (2) following a sentinel event report by the facility to the Joint Commission, a complaint to the Joint Commission by any person (see www.jointcommission.org), or an unannounced, onsite visit to a facility by the Joint Commission during which an adverse event comes to attention; or (3) as a consequence of an adverse event report sent by the healthcare facility to DPH. The last of these routes is discussed here.

After screening an adverse event report, which includes a Corrective Action Plan, the DPH Health Care Systems Branch determines whether to initiate an investigation. Screening to rule out medical error is based on clinical judgment and/or objective medical criteria. The screening team consists of a physician and nurse at DPH.

DPH conducts investigations regarding adverse event reports that may indicate a systems issue or issues related to inadequate standards of care. These investigations determine regulatory compliance versus noncompliance and provide additional information that may allow one to distinguish between events that have been due to a medical error and those that are not. Investigations involving adverse events follow the same process as issues received through the public complaint process. Information is gathered through onsite inspection, review of medical records, interviews with institutional staff and vested parties as appropriate. Beginning in the summer of 2004, resources for part-time DPH physician consultants have been allocated for the

specialties of medicine, surgery, pediatrics, anesthesia, obstetrics, gynecology, psychiatry, and orthopedics. The patient or family is contacted during and after completion of the investigation. The results of completed investigations are public, and may be obtained upon request, under the Freedom of Information Act.

Sharing of Lessons

Results from the adverse events program are shared with the Quality in Health Care Advisory Committee.

Connecticut General Statutes and national legislation encourage sharing of patient safety information between healthcare facilities and Patient Safety Organizations,[4] which are completely separate from regulatory entities. Through the Quality in Health Care Advisory Committee, DPH cooperates with PSOs to promote the adoption and development of best practices. The independence of the PSOs, and the confidentiality of their data, are ensured under the law.

Update on Adverse Event Reporting and Prevention Outside this Program

Falls are the largest single category of adverse event reported in the program. The Advisory Committee's subcommittee on Best Practices and Adverse Events has devoted special attention to fall prevention in past years. Recent studies differ about whether acute-care hospital fall prevention programs reduce the number of falls or fallers.[5] However, a study among primary care practices, outpatient rehabilitation, and senior centers in the greater Hartford area reported that rates of serious injury from falls decreased among the intervention group while remaining unchanged in a usual care comparison group.[6] The intervention included medication reduction and balance and gait training. This is relevant to hospitals because some of the same techniques for preventing falls in the community are applicable in hospitals also.

In October 2007 the Massachusetts Hospital Association began posting patient fall and fall with injury counts and rates for each hospital in that state (see www.patientsfirstma.org). The same site also lists event rates for another NQF event, pressure ulcers.

While the Connecticut PSOs address patient safety issues beyond those reportable to DPH, the following confluence may be noted. The Qualidigm PSO is partnering with the CHREF PSO in two statewide collaboratives: multi-drug resistant organisms (MDRO) and pressure ulcer prevention. The ASC PSO is also focused on infection control.

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[4] Other information about PSOs can be found in the June 30, 2006 and 2007 Quality of Health Care Reports to the General Assembly.

[5] Coussement et al. (Interventions for preventing falls in acute- and chronic-care hospitals: a systematic review and meta-analysis. J Am Geriatr Soc 2008;56:29-36) found a non-significant protective effect when combining several heterogeneous randomized controlled trials. Hendriks et al. (Lack of effectiveness of a multidisciplinary fall-prevention program in elderly people at risk: a randomized, controlled trial. J Am Geriatr Soc 2008 Jul 24 [Epub ahead of print]) reported no benefit. Oliver et al. (Strategies to prevent falls and fractures in hospitals and care homes and effects of cognitive impairment: Systematic review and meta-analysis. BMJ 2007;334:82-87) included large non-randomized before –and-after studies in their analysis and found a significant benefit for prevention programs on frequency of falling but not number of persons who fall.

[6] Tinetti et al., Effect of dissemination of evidence in reducing injuries from falls. N Engl J Med 2008 Jul 17;359:252-61.

The new mandatory Healthcare Associated Infections (HAI) reporting program goes beyond infections that are reportable under the adverse event program. In October 2008 the Department of Public Health's Healthcare Associated Infections Program will issue its first annual report.

A number of states besides Connecticut have either mandatory or voluntary adverse event reporting. As this Connecticut report was being drafted, the Oregon Patient Safety Commission released its Certification Report for 2007 on that state's activities.[7]

[7] Available at http://oregon.gov/DHS/ph/hsp/patientsafety/docs/PHOCertificationReport2007Final.pdf. Table 4 of the Oregon report compared adverse event reporting in Minnesota, Connecticut, New Jersey, Washington, and Oregon. The proportion of so-called "non-reporting" hospitals (whether non-participating or having no events occurring) in a state varied from 12%-72%, with Connecticut data for 2006/2007 shown as "not available." The table showed that definitions of reportable events differ, making straightforward comparison impossible. For example, a state which required reporting of the NQF list plus a list of state-specific adverse events would have at least as many events to report as a state that required only the NQF list. We offer the comment that in the four full years since Connecticut adopted the NQF definitions plus additional state-specific ones, all Connecticut hospitals have reported adverse events to the Department of Public Health; that is, the proportion of non-reporting hospitals is 0%. If a large institution was to never report any events, while comparably sized institutions reported many events, and the program had been in existence for a long time, one might suspect that the institution with no reports was not participating in the program. This is manifestly not the case for Connecticut, where all hospitals are participating. For comparison with the Oregon table, during any consecutive 12 month period in 2006-2007, variously 2-6 hospitals (6%-19% of hospitals, all small) in Connecticut did not report any adverse events. As discussed above, no clear conclusions can be drawn solely from the number of adverse events reported.

Appendix A. Demographic Data from 967 Adverse Event Reports in the Electronic Database, July 1, 2004-September 2, 2008

Measure	Frequency	Percent	Most Common Event
Facility Type (n=967)			Facility's Leading Event (n)
Acute Care or Children's Hospital	833	86.1	Fall (331)
Chronic Disease Hospital	59	6.1	Fall (48)
Hospital for Mentally Ill Persons	46	4.8	Fall (25)
Outpatient Surgical Facility	29	3.0	Perforation (21)
Patient Gender (n=957)			
Male	430	44.9	
Female	527	55.1	
Patient Age (n=967)			Age Group's Leading Event
0-14	44	4.6	Retained Object (8)
15-44	145	15.0	Perforation (31)
45-64	214	22.1	Fall (56)
65 and older	564	58.3	Fall (331)
Event Hour (n=933)			
Midnight-3:59 am	263	28.2	
4 am-7:59 am	160	17.2	
8 am-11:59 am	255	27.3	
12 noon-3:59 pm	145	15.5	
4 pm-7:59 pm	72	7.7	
8 pm-11:59 pm	38	4.1	
Location of Event (n=951)			Location's Leading Event
Adult Medical	254	26.7	Fall (194)
Adult Surgical	70	7.4	Fall (38)
Ambulatory Surgical	22	2.3	Perforation (12)
Cardiac Care	37	3.9	Fall (27)
Cardiac Cath Lab	6	0.6	--
Diagnostic Services	35	3.7	Perforation (24)
Dialysis	1	0.1	--
Emergency Department	37	3.9	Fall (21)
Medical ICU	57	6.0	Stage 3-4 Ulcer (39)
Neonatal ICU	1	0.1	--
Obstetrical/Gynecological	36	3.8	Obstetric Event (18)
Operating Room	98	10.3	Perforation (44)
Other	110	11.6	Perforation (53)
Outpatient Services	50	5.3	Perforation (38)
Pediatrics	3	0.3	--
Psychiatric	98	10.3	Fall (67)
Rehabilitative Services	14	1.5	Fall (11)
Surgical ICU	22	2.3	Stage 3-4 Ulcer (10)
Patient Expired (n=869)	96	11.1	

Appendix B. Connecticut Adverse Events Reports in Electronic Database September 2, 2008, by Event Code and Half Year of Occurrence NQF List (1A-6D) and Connecticut-Specific List (7A-7F)

Event Code	Description	Time - Period								Total
		2004	2005		2006		2007		2008	
		2nd half	1st half	2nd half	1st half	2nd half	1st half	2nd half	1st half	
1A	Surgery performed on the wrong body part	1	2	2	0	3	1	2	1	12
1B	Surgery performed on the wrong patient	0	0	0	0	1	2	0	0	3
1C	Wrong surgical procedure performed on a patient	0	1	1	0	0	2	2	1	7
1D	Retention of a foreign object in a patient after surgery or other procedure	4	12	7	11	7	10	7	7	65
1E	Intraoperative or immediate post-operative death in an ASA class I patient	0	0	0	0	0	0	1	0	1
2A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	0	1	0	0	0	0	0	1	2
2B	Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	2	4	3	3	1	2	0	1	16
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	0	2	1	0	0	0	0	1	4
3A	Infant discharged to the wrong person	0	0	0	0	0	0	0	0	0
3B	Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	0	0	0	0	0	0	0	0	0
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	0	2	1	1	2	2	2	1	11
4A	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	4	2	2	5	0	0	1	2	16

Appendix B continued

Event Code	Description	Time - Period								Total
		2004	2005		2006		2007		2008	
		2nd half	1st half	2nd half	1st half	2nd half	1st half	2nd half	1st half	
4B	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	0	0	0	0	0	0	0	0	0
4C	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	1	0	2	1	0	0	0	0	4
4D	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	0	1	0	0	1	2	0	0	4
4E	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	0	0	0	0	0	0	0	0	0
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	9	14	9	15	15	18	15	26	121
4G	Patient death or serious disability due to spinal manipulative therapy	0	1	0	0	0	0	0	0	1
4H	Artificial insemination with the wrong donor sperm or wrong egg							0	0	0
5A	Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	0	0	0	0	0	0	0	0	0
5B	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	0	0	0	0	0	1	0	0	1
5C	Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	0	0	0	1	2	1	0	0	4
5D & 7B	Patient death or serious injury associated with a fall while being cared for in a healthcare facility	46	47	51	63	55	45	41	48	396

Appendix B continued

Event Code	Description	Time - Period								Total
		2004	2005		2006		2007		2008	
		2nd half	1st half	2nd half	1st half	2nd half	1st half	2nd half	1st half	
5E	Patient death or serious disability associated with the use of restraints or bedrails while being	0	0	0	1	0	0	1	0	2
6A	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0	0	0	0	1	0	0	0	1
6B	Abduction of a patient of any age	0	0	0	0	0	0	0	0	0
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	2	3	2	7	5	5	2	4	30
6D	Death or significant injury of a patient or staff member resulting from a physical assault (i.e.battery) that occurs within or on the grounds of a healthcare facility	2	1	1	0	0	1	0	2	7
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	29	25	28	14	19	25	25	26	191
7B	See event code 5D & 7B*									
7C	Obstetrical events resulting in death or serious disability to the neonate	3	2	4	3	1	3	2	1	19
7D	Significant medication reactions resulting in death or serious disability	0	1	2	0	1	2	1	1	8
7E	Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department	0	0	0	0	1	0	0	0	1
7F	Nosocomial infections resulting in death or serious injury	3	1	1	2	1	1	2	3	14
Total		**106**	**122**	**117**	**127**	**116**	**123**	**104**	**126**	**941**

Adverse events reported using the older classification system, Oct 2002-June 2004 are not included.
Events reported using the NQF classification system but occurring prior to July 1, 2004 or after June 30, 2008 are not included. Totals in 2008 may rise with further entries into the database.
Category 4H was added to the list of reportable adverse events in May 2007.
*Prior to May 2007 category 5D included only death associated with a fall.
*Events formerly classified as 7B are reportable as 5D starting May 2007.

Appendix C. Connecticut Adverse Event Reports in Electronic Database September 2, 2008, by Frequency of Occurrence NQF List (1A-6D) and Connecticut-Specific List (7A-7F)

Event	Description	Frequency	Percent
5D & 7B*	Patient death or serious injury associated with a fall while being cared for in a healthcare facility	405	41.9%
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	198	20.5%
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	124	12.8%
1D	Retention of a foreign object in a patient after surgery or other procedure	68	7.0%
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	30	3.1%
7C	Obstetrical events resulting in death or serious disability to the neonate	19	2.0%
4A	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	17	1.8%
2B	Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	16	1.7%
7F	Nosocomial infections resulting in death or serious injury	14	1.4%
1A	Surgery performed on the wrong body part	13	1.3%
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	11	1.1%
6D	Death or significant injury of a patient or staff member resulting from a physical assault (i.e.battery) that occurs within or on the grounds of a healthcare facility	8	0.8%
7D	Significant medication reactions resulting in death or serious disability	8	0.8%
1C	Wrong surgical procedure performed on a patient	7	0.7%
4C	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	5	0.5%
4D	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	4	0.4%
5C	Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	4	0.4%
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	4	0.4%

Appendix C continued

Event	Description	Frequency	Percent
1B	Surgery performed on the wrong patient	3	0.3%
2A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	2	0.2%
5E	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	2	0.2%
4G	Patient death or serious disability due to spinal manipulative therapy	1	0.1%
5B	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	1	0.1%
6A	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	1	0.1%
7E	Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department	1	0.1%
1E	Intraoperative or immediate post-operative death in an ASA class I patient	1	0.1%
3A	Infant discharged to the wrong person	0	0.0%
3B	Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	0	0.0%
4B	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	0	0.0%
4E	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	0	0.0%
4H	Artificial insemination with the wrong donor sperm or wrong egg	0	0.0%
5A	Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	0	0.0%
6B	Abduction of a patient of any age	0	0.0%
Total		**967**	**100.0%**

*Prior to May 2007 category 5D included only death associated with a fall, while 7B included falls resulting in serious injury. Events formerly classified as 7B are reportable as 5D starting May 2007.