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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EXECUTIVE SUMMARY

During 2007, hospitals and ambulatory care centers were provided with the updated National Quality Forum's List of Serious Reportable Events. Items on the list are of concern to both the public and healthcare professionals, are clearly identifiable and measurable, and are often preventable. Under the current adverse event definitions, the most common adverse events 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. These four categories constitute 81% of reports. 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 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 5-6 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. We expect to submit these regulations to the Legislative Review Committee in October 2007.

In May 2007, hospitals and ambulatory surgical centers were provided with the updated National Quality Forum's List of Serious Reportable Events and the revised list compiled by the Commissioner of Public Health. A new category was included in the National Quality Forum's list related to fertility clinics (4H). Notably, the National Quality Forum's category "falls resulting in death" (5D) was expanded to include death or "fall resulting in serious injury." This expansion was attributed to the information gathered in Connecticut through the list of events compiled by the Commissioner of Public Health. Since mandatory adverse event reporting was initiated in 2002, Connecticut has required reporting of serious injuries related to falls. Since May 2007, events formerly reported as the Connecticut-specific falls category (7B) are now reportable as category 5D.

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 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[1]).

ADVERSE EVENT DATA

As of September 24, 2007, the DPH electronic database contained 2,374 adverse event reports, of which 722 reports were received using the reporting system that came into effect on July 1, 2004. In contrast to the period from October 2002 through June 2004, during which the monthly number of reports declined, the monthly number of reports since July 2004 has remained at the same level. Assigning causes for the earlier reporting decrease remains speculative, and so reasons for the halt in that decline also remain speculative. However, the change in pattern coincided with introduction of the new reporting system.

Due to the differences between the previous and present adverse event reporting systems, and because previous legislative reports summarized data received under the earlier system, this document focuses on the data submitted using the NQF and Connecticut-specific lists of reportable adverse events beginning 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, no clear conclusions can be derived from number of reports alone. For these reasons, no facility-level data are presented. Also, as discussed in Connecticut's March 2004 Adverse Event report, adverse events are not identical with 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.

Acute Care or Children's Hospitals submitted 623 (86%) of the 722 adverse event reports; Chronic Disease Hospitals, 42; Hospitals for the Mentally Ill, 36, and Outpatient Surgical Facilities, 21. Forty-four percent of reported adverse events occurred in males and 56% 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. Seventy three deaths were reported in connection with an adverse event.

Appendix B presents the number of adverse events reported by calendar year quarter, 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 National Quality Forum expanded the fall definition for

[1] Adverse Events and Quality of Health Care Reports are available at www.ct.gov/dph (formerly www.dph.state.ct.us) under "Health Care Quality".

category 5D so that events formerly reportable under the Connecticut specific category 7B became reportable as category 5D in May 2007. Three hundred eight falls comprised 43% of all 722 adverse events reported. The second most commonly reported events were perforations during open, laparoscopic, and/or endoscopic procedures, with 147 reports (20%). 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 81% of reports.

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 for each reported Adverse Event.

An external investigation at a healthcare facility due to an adverse event may begin in one of three 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 (formerly known as the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO), 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 may 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 completing 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,[2] 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.

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

Appendix A. Demographic Data from 722 Adverse Event Reports in the Electronic Database, July 1, 2004-September 24, 2007

Measure	Frequency	Percent
Facility Type (n=722)		
Acute Care or Children's Hospital	623	86.3
Chronic Disease Hospital	42	5.8
Hospital for Mentally Ill Persons	36	5.0
Outpatient Surgical Facility	21	2.9
Patient Gender (n=714)		
Male	316	44.3
Female	398	55.7
Patient Age (n=722)		
0-14	38	5.3
15-44	111	15.4
45-64	163	22.6
65 and older	410	56.8
Event Hour (n=688)		
Midnight-3:59 am	195	28.3
4 am-7:59 am	115	16.7
8 am-11:59 am	187	27.2
12 noon-3:59 pm	103	15.0
4 pm-7:59 pm	61	8.9
8 pm-11:59 pm	27	3.9
Location of Event (n=710)		
Adult Medical	194	27.3
Adult Surgical	41	5.8
Ambulatory Surgical	12	1.7
Cardiac Care	30	4.2
Cardiac Cath Lab	6	0.9
Diagnostic Services	28	4.0
Dialysis	1	0.1
Emergency Department	30	4.2
Medical ICU	39	5.5
Neonatal IC	1	0.1
Obstetrical/Gynecological	28	3.9
Operating Room	84	11.8
Other	83	11.7
Outpatient Services	32	4.5
Pediatrics	2	0.3
Psychiatric	71	10.0
Rehabilitative Services	11	1.6
Surgical ICU	17	2.4
Patient Expired (n=645)	73	11.3

Appendix B. Connecticut Adverse Events Reports in Electronic Database
September 24, 2007, by Event Code and Date of Occurrence
NQF List (1A-6D) and Connecticut-Specific List (7A-7F)

Event Code	Description	3Q 2004	4Q 2004	1Q 2005	2Q 2005	3Q 2005	4Q 2005	1Q 2006	2Q 2006	3Q 2006	4Q 2006	1Q 2007	2Q 2007	Total
1A	Surgery performed on the wrong body part	0	1	0	2	0	2	0	0	1	2	0	1	9
1B	Surgery performed on the wrong patient	0	0	0	0	0	0	0	0	0	1	1	1	3
1C	Wrong surgical procedure performed on a patient	0	0	0	1	0	1	0	0	0	0	0	2	4
1D	Retention of a foreign object in a patient after surgery or other procedure	1	3	8	4	5	2	4	6	5	2	4	6	50
1E	Intraoperative or immediate post-operative death in an ASA class I patient	0	0	0	0	0	0	0	0	0	0	0	0	0
2A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	0	0	1	0	0	0	0	0	0	0	0	0	1
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	1	1	2	2	1	2	2	1	1	0	1	1	15
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	0	0	0	2	0	1	0	0	0	0	0	0	3
3A	Infant discharged to the wrong person	0	0	0	0	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	0	0	0	0
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	0	0	1	1	0	1	1	0	1	1	0	2	8

Event Code	Description	3Q 2004	4Q 2004	1Q 2005	2Q 2005	3Q 2005	4Q 2005	1Q 2006	2Q 2006	3Q 2006	4Q 2006	1Q 2007	2Q 2007	Total
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)	3	1	1	1	0	2	2	3	0	0	0	0	13
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	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	0	1	0	0	0	2	1	0	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	0	1	0	0	0	0	0	0	1	1	1	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	0	0	0	0
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	3	6	6	8	3	6	7	8	3	12	5	10	77
4G	Patient death or serious disability due to spinal manipulative therapy	0	0	0	1	0	0	0	0	0	0	0	0	1
4H	Artificial insemination with the wrong donor sperm or wrong egg												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	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	0	0	0	0	0	0	1	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	0	0	0	1	0	1	1	0	1	4
5D	Patient death associated with a fall while being cared for in a healthcare facility	0	0	1	0	0	0	1	0	0	2	1	7	12

Event Code	Description	3Q 2004	4Q 2004	1Q 2005	2Q 2005	3Q 2005	4Q 2005	1Q 2006	2Q 2006	3Q 2006	4Q 2006	1Q 2007	2Q 2007	Total
5E	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	0	0	0	0	0	0	0	1	0	0	0	0	1
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	0	0	0	0	0	1	0	0	1
6B	Abduction of a patient of any age	0	0	0	0	0	0	0	0	0	0	0	0	0
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	0	2	1	2	1	1	3	4	3	2	0	5	24
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	1	1	0	1	1	0	0	0	0	0	0	1	5
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	16	13	14	11	19	9	6	8	6	12	10	15	139
7B	Falls resulting in serious disability while being cared for in a healthcare facility	23	23	27	19	25	26	25	37	21	31	23	9	289
7C	Obstetrical events resulting in death or serious disability to the neonate	2	1	2	0	2	2	1	2	1	0	1	2	16
7D	Significant medication reactions resulting in death or serious disability	0	0	0	1	1	1	0	0	1	0	0	1	5
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	0	0	0	0	0	1	0	0	1
7F	Nosocomial infections resulting in death or serious injury	1	2	1	0	0	1	0	2	1	0	1	0	9
Total		**51**	**55**	**66**	**56**	**58**	**59**	**54**	**72**	**45**	**69**	**48**	**66**	**699**

Adverse events reported using the older classification system, Oct 2002-June 2004 are not included.
Also, 23 events reported using the new classification system but occurring prior to July 1, 2004
or after June 30, 2007 are not included. Totals in 2007 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 falls resulting in deaths.
Events formerly classified as 7B are reportable as 5D starting May 2007. Q=quarter.

Appendix C. Connecticut Adverse Event Reports in Electronic Database September 24, 2007, 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	308	42.7%
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	147	20.4%
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	79	10.9%
1D	Retention of a foreign object in a patient after surgery or other procedure	52	7.2%
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	24	3.3%
7C	Obstetrical events resulting in death or serious disability to the neonate	16	2.2%
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	15	2.1%
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)	14	1.9%
1A	Surgery performed on the wrong body part	10	1.4%
7F	Nosocomial infections resulting in death or serious injury	9	1.2%
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	9	1.2%
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	6	0.8%
7D	Significant medication reactions resulting in death or serious disability	5	0.7%
1C	Wrong surgical procedure performed on a patient	4	0.6%
4C	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	4	0.6%
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	0.6%
5C	Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	4	0.6%
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	3	0.4%
1B	Surgery performed on the wrong patient	3	0.4%
2A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	1	0.1%
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%
5E	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	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	0	0.0%
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		**722**	**100.0%**

Prior to May 2007 category 5D included only falls resulting in deaths, while 7B included falls resulting in serious injury. Events formerly classified as 7B are reportable as 5D starting May 2007.