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
Public Act 04-164
QUALITY OF CARE PROGRAM

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EXECUTIVE SUMMARY

Public Act 04-164 amended the Quality in Health Care program, effective July 1, 2004. Under the new adverse event definitions, the most common adverse events are those identified using Connecticut-specific definitions: falls resulting in serious disabilities and perforations during open, laparoscopic, and/or endoscopic procedures. The rate of reported adverse events that are on the list of the National Quality Forum (NQF), and the leading types of events from this list (retention of a foreign object in a patient after surgery, stage 3-4 pressure ulcer acquired after admission to a healthcare facility), are roughly comparable to those in Minnesota, the other state using this national list.

BACKGROUND

CGS §19a 127l and P.A. 04-164

Connecticut General Statutes §19a 127l requires 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. 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, and other changes, from considerations detailed in the March 2004 and October 2004 Adverse Events reports.

Public Act 04-164 amended the Quality in Health Care program, effective July 1, 2004. The act 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). DPH has almost completed development of the mandated regulations for reporting of adverse events. They will be submitted to the Attorney General's Office for formal review, and then to the Legislative Regulations Review Committee.

P.A. 04-164 allowed DPH to designate Patient Safety Organizations (PSOs). The primary activity of a PSO 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. Patient safety work product is confidential and not subject to use or access except to the PSO and the health care provider. The PSO will 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), and this work has begun (see the June 30, 2005 DPH report on Connecticut's Quality of Care Program[1]).

[1] Adverse Events and Quality of Health Care Reports are available at www.dph.state.ct.us under "Heath Care Quality".

Selected National Developments

The NQF list of 27 serious reportable events was developed at the request of the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) in order to establish agreement about the types and definitions of usually preventable adverse events (see Appendix B of Connecticut's October 2004 Adverse Event report). Minnesota became the first state to adopt the NQF list for use in statewide hospital reporting and in January 2005, released its first annual report, "Adverse Health Events in Minnesota Hospitals" (www.minnesotahealthinfo.org). Connecticut's adverse event reporting program predates Minnesota's, and with the legislation enacted July 1, 2004, Connecticut became the second state to adopt the NQF list. More recently, New Jersey, Illinois, and Indiana have adopted the NQF list for reporting of adverse events, and other states are considering adopting it.

The Patient Safety and Quality Improvement Act of 2005 (S. 544) allows for confidential and voluntary reporting of medical errors to PSOs. It intends to safeguard existing patient rights, while ensuring that information disclosed to PSOs will be used for quality improvement and patient safety, but cannot be used in lawsuits.

ADVERSE EVENT DATA

As of September 14, 2005, the DPH electronic database contained 1,889 adverse event reports, of which 239 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, there has been no trend toward either increase or decrease in the number of monthly reports since July 2004. A decrease in the number of reports could be due to a decrease in the number of adverse events, a decrease in the erroneous submission of reports when no reportable event took place, a decrease in reporting without a change in the occurrence of reportable events, or a combination of reasons. 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 Hospitals submitted 206 (86%) of the 239 adverse event reports; Chronic Disease Hospitals, 14; Hospitals for Mentally Ill Persons, 11; and Outpatient Surgical Facilities, 8. 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 4 pm and midnight. The most common place of occurrence was reported to be the Adult Medical Ward. Twenty-five deaths were reported in connection with an adverse event.

Appendix B presents the numbers of adverse event reports according to the ordered 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 event was a fall that resulted in serious disability (7B). The 98 such fall reports comprised 41% of all 239 adverse event reports. One additional fall was reported under the NQF definition of a death associated with a fall (5D). The second most commonly reported event was perforation during open, laparoscopic, and/or endoscopic procedures, with 59 reports (25%). 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, and the most commonly reported NQF events, were

- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility, and
- Retention of a foreign object in a patient after surgery or other procedure.

These two NQF event categories were also the most commonly reported events under Minnesota's system.

Overall, 72, or 30% of 239 reports in Connecticut using the current reporting system were NQF-defined events, while the remaining 167 (70%) were Connecticut-specific events. The rate of reporting NQF-defined events in Connecticut was very roughly the same as in Minnesota.[2]

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 outside 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 on Accreditation of Healthcare Organizations (JCAHO), a complaint to JCAHO by any

[2] Excluding outpatient surgical facilities (which did not report in Minnesota prior to December 2004), Connecticut's 64 NQF-list reports in 12 months is a 16% higher rate than Minnesota's 99 reports in 15 months, after accounting for Minnesota's 44% larger population. This small rate difference might change if based upon comparisons of hospital beds rather than population. Reporting in Minnesota increased over the course of the 2003-2004 year as more hospitals became aware of what, when, and how to report. Adverse event reporting in Minnesota is web-based. The most recent months were not included in estimating Connecticut's rate, as paper reports are not entered into the electronic database until DPH has made a determination whether to investigate further. The percentage of NQF-defined events that were fatal was similar in Minnesota (20/99=20.2%) and Connecticut (12/61=19.7%; the vital status check box was left blank for 11 of the 72 Connecticut adverse event reports from the NQF list).

person (see www.jcaho.org), or an unannounced, onsite visit to a facility by JCAHO 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.

The DPH Health Care Systems Branch determines, after screening an adverse event report, including its Corrective Action Plan, 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 investigated 80 out of 284 reported adverse events from July 1, 2004 to September 14, 2005.

DPH conducts formal investigations on adverse event reports that may indicate a systems issue or inadequate standard 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 and gynecology. The patient or family is contacted during and after completing the investigation. The results of completed investigations may be made public, upon request, under the Freedom of Information Act.

Sharing of Lessons

Connecticut's experience with adverse event reporting is an important contribution to the national effort. DPH has been invited by the NQF to share its knowledge with other states that have adopted the NQF adverse events list at a meeting scheduled for the fall of 2005.

Results from the adverse events programs are periodically shared with the Quality in Health Care Advisory Committee. The subcommittee on Best Practices and Adverse Events is using these data in preparing guidelines on prevention of falls.

As noted above, P.A. 04-164 and national legislation encourage sharing of patient safety information between healthcare facilities and Patient Safety Organizations, which are completely separate from regulatory functions. Through the Quality in Health Care Advisory Committee, DPH cooperates with these PSOs to promote the adoption and spread of best practices, while the independence of the PSOs, and the confidentiality of their data from DPH, are maintained.

Appendix A. Demographic Data from 239 Adverse Events Reports in the Electronic Database, July 1, 2004-September 14, 2005

Measure	Frequency	Percent
Facility Type (n=239)		
Acute Care Hospital	206	86.2
Chronic Disease Hospital	14	5.9
Hospital for Mentally Ill Persons	11	4.6
Outpatient Surgical Facility	8	3.4
Patient Gender (n=239)		
Male	108	45.2
Female	131	54.8
Patient Age (n=239)		
0-14	11	4.6
15-44	31	13.0
45-64	55	23.0
65 and older	142	59.4
Event Hour (n=221)		
Midnight-3:59 am	49	22.2
4 am-7:59 am	37	16.7
8 am-11:59 am	68	30.8
12 noon-3:59 pm	41	18.6
4 pm-7:59 pm	18	8.1
8 pm-11:59 pm	8	3.6
Location of Event (n=234)		
Adult Medical	73	31.2
Adult Surgical	13	5.6
Ambulatory Surgical	2	0.9
Cardiac Care	10	4.3
Cardiac Cath Lab	1	0.4
Diagnostic Services	10	4.3
Emergency Department	12	5.1
Medical ICU	9	3.9
Neonatal IC	1	0.4
Obstetrical/Gynecological	8	3.4
Operating Room	33	14.1
Other	29	12.4
Outpatient Services	7	3.0
Pediatrics	1	0.4
Psychiatric	20	8.6
Rehabilitative Services	1	0.4
Surgical ICU	4	1.7
Patient Expired (n=207)	25	12.1

Appendix B. Adverse Events Reports in Electronic Database, July 1, 2004- September 14, 2005, by Event Code

Event Code	Description	Frequency
1A	Surgery performed on the wrong body part	3
1B	Surgery performed on the wrong patient	0
1C	Wrong surgical procedure performed on a patient	1
1D	Retention of a foreign object in a patient after surgery or other procedure	17
1E	Intraoperative or immediate post-operative death in an ASA class I patient	0
2A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	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	7
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	1
3A	Infant discharged to the wrong person	0
3B	Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	0
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	2
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)	7
4B	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	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
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	1
4E	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	0
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	21
4G	Patient death or serious disability due to spinal manipulative therapy	0
5A	Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	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

5C	Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	0
5D	Patient death associated with a fall while being cared for in a healthcare facility	1
5E	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	0
6A	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0
6B	Abduction of a patient of any age	0
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	4
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	5
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	59
7B	Falls resulting in serious disability while being cared for in a healthcare facility	98
7C	Obstetrical events resulting in death or serious disability to the neonate	6
7D	Significant medication reactions resulting in death or serious disability	1
7E	Treatment in an emergency department resulting in death or serious disability due to incorrect or missed diagnosis	0
7F	Nosocomial infections resulting in death or serious injury	3
total		239

Appendix C. Adverse Events Reports in Electronic Database, July 1, 2004-September 14, 2005, by Frequency

Event Code	Description	Frequency	Percentage
7B	Falls resulting in serious disability while being cared for in a healthcare facility	98	41.0%
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	59	24.7%
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	21	8.8%
1D	Retention of a foreign object in a patient after surgery or other procedure	17	7.1%
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	7	2.9%
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)	7	2.9%
7C	Obstetrical events resulting in death or serious disability to the neonate	6	2.5%
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	5	2.1%
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	4	1.7%
1A	Surgery performed on the wrong body part	3	1.3%
7F	Nosocomial infections resulting in death or serious injury	3	1.3%
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	2	0.8%
1C	Wrong surgical procedure performed on a patient	1	0.4%
2A	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	1	0.4%
2C	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	1	0.4%
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	0.4%

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	1	0.4%
5D	Patient death associated with a fall while being cared for in a healthcare facility	1	0.4%
7D	Significant medication reactions resulting in death or serious disability	1	0.4%
1B	Surgery performed on the wrong patient	0	0.0%
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%
4G	Patient death or serious disability due to spinal manipulative therapy	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%
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%
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%
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%
6A	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0	0.0%
6B	Abduction of a patient of any age	0	0.0%
7E	Treatment in an emergency department resulting in death or serious disability due to incorrect or missed diagnosis	0	0.0%
total		239	100.0%