CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Keeping Connecticut Healthy

# LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY
# Adverse Event Reporting

**General Statutes of Connecticut**
**Public Act 04-164**
**Section 19a-127l-n**
**QUALITY OF CARE PROGRAM**

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# State of Connecticut
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## 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 current 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 two leading types of events from the National Quality Forum list of serious reportable events were retention of a foreign object in a patient after surgery and stage 3-4 pressure ulcer acquired after admission to a healthcare facility.

## 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 completed development of the mandated regulations for reporting of adverse events. They have been 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, 2006 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 "Health Care Quality".

## ADVERSE EVENT DATA

As of September 15, 2006, the DPH electronic database contained 2,132 adverse event reports, of which 485 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 or Children's Hospitals submitted 417 (86%) of the 485 adverse event reports; Chronic Disease Hospitals, 28; Hospitals for the Mentally Ill, 28, and Outpatient Surgical Facilities, 12. 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 place of occurrence was reported to be the Adult Medical Ward. Fifty-one deaths were reported in connection with an adverse event.

Appendix B presents the numbers of adverse event reports by calendar year quarter 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 209 such fall reports comprised 43% of all 485 adverse event reports. Two additional falls were 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 100 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, 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. Overall, 154, or 32% of 485 reports in Connecticut using the current reporting system were NQF-defined events, while the remaining 331 (68%) were Connecticut-specific events.

## 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 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 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*

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,[2] 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.

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

## Appendix A. Demographic Data from 485 Adverse Event Reports in the Electronic Database, July 1, 2004-September 15, 2006

| Measure | Frequency | Percent |
|---|---|---|
| Facility Type (n=485) | | |
| Acute Care or Children's Hospital | 417 | 86.0 |
| Chronic Disease Hospital | 28 | 5.8 |
| Hospital for Mentally Ill Persons | 28 | 5.8 |
| Outpatient Surgical Facility | 12 | 2.5 |
| Patient Gender (n=484) | | |
| Male | 214 | 44.2 |
| Female | 270 | 55.8 |
| Patient Age (n=485) | | |
| 0-14 | 25 | 5.2 |
| 15-44 | 68 | 14.0 |
| 45-64 | 110 | 22.7 |
| 65 and older | 282 | 58.1 |
| Event Hour (n=453) | | |
| Midnight-3:59 am | 109 | 24.1 |
| 4 am-7:59 am | 81 | 17.9 |
| 8 am-11:59 am | 133 | 29.4 |
| 12 noon-3:59 pm | 69 | 15.2 |
| 4 pm-7:59 pm | 41 | 9.1 |
| 8 pm-11:59 pm | 20 | 4.4 |
| Location of Event (n=480) | | |
| Adult Medical | 145 | 30.2 |
| Adult Surgical | 24 | 5.0 |
| Ambulatory Surgical | 10 | 2.1 |
| Cardiac Care | 17 | 3.5 |
| Cardiac Cath Lab | 5 | 1.0 |
| Diagnostic Services | 19 | 4.0 |
| Dialysis | 1 | 0.2 |
| Emergency Department | 22 | 4.6 |
| Medical ICU | 20 | 4.2 |
| Neonatal IC | 1 | 0.2 |
| Obstetrical/Gynecological | 20 | 4.2 |
| Operating Room | 56 | 11.7 |
| Other | 58 | 12.1 |
| Outpatient Services | 21 | 4.4 |
| Pediatrics | 1 | 0.2 |
| Psychiatric | 43 | 9.0 |
| Rehabilitative Services | 6 | 1.3 |
| Surgical ICU | 11 | 2.3 |
| Patient Expired (n=430) | 51 | 11.9 |

# Appendix B. Connecticut Adverse Event Reports in Electronic Database September 15, 2006, 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 | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| 1A | Surgery performed on the wrong body part | 0 | 1 | 0 | 2 | 0 | 2 | 0 | 0 | 5 |
| 1B | Surgery performed on the wrong patient | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1C | Wrong surgical procedure performed on a patient | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 2 |
| 1D | Retention of a foreign object in a patient after surgery or other procedure | 1 | 3 | 8 | 4 | 5 | 2 | 3 | 6 | 32 |
| 1E | Intraoperative or immediate post-operative death in an ASA class I patient | 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 | 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 | 12 |
| 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 | 3 |
| 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 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 4 |

| Event Code | Description | 3Q 2004 | 4Q 2004 | 1Q 2005 | 2Q 2005 | 3Q 2005 | 4Q 2005 | 1Q 2006 | 2Q 2006 | 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 | 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 |
| 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 | 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 | 1 |
| 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 | 3 | 6 | 6 | 8 | 3 | 6 | 6 | 8 | 46 |
| 4G | Patient death or serious disability due to spinal manipulative therapy | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| 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 | 0 | 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 | 0 | 0 | 0 | 1 | 0 | 1 |
| 5D | Patient death associated with a fall while being cared for in a healthcare facility | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 2 |

| Event Code | Description | 3Q 2004 | 4Q 2004 | 1Q 2005 | 2Q 2005 | 3Q 2005 | 4Q 2005 | 1Q 2006 | 2Q 2006 | 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 | 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 |
| 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 | 0 | 2 | 1 | 2 | 1 | 1 | 3 | 4 | 14 |
| 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 | 4 |
| 7A | Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability | 16 | 13 | 14 | 11 | 19 | 9 | 6 | 8 | 96 |
| 7B | Falls resulting in serious disability while being cared for in a healthcare facility | 23 | 23 | 27 | 19 | 25 | 26 | 25 | 36 | 204 |
| 7C | Obstetrical events resulting in death or serious disability to the neonate | 2 | 1 | 2 | 0 | 2 | 2 | 1 | 2 | 12 |
| 7D | Significant medication reactions resulting in death or serious disability | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 3 |
| 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 |
| 7F | Nosocomial infections resulting in death or serious injury | 1 | 2 | 0 | 0 | 0 | 1 | 0 | 2 | 6 |
| **Total** | | **51** | **55** | **65** | **56** | **58** | **59** | **52** | **71** | **467** |

Adverse events using the older classification system with classes A-D, Oct 2002-June 2004 are not included, nor are 18 events using the new classification system but occurring prior to July 1, 2004 or after June 30, 2006. Totals in 2006 may rise with further entries into the electronic database. Q=quarter.

## Appendix C. Connecticut Adverse Event Reports in Electronic Database September 15, 2006, by Frequency of Occurrence NQF List (1A-6D) and Connecticut-Specific List (7A-7F)

| Event Code | Description | Frequency | Percent |
|---|---|---|---|
| 7B | Falls resulting in serious disability while being cared for in a healthcare facility | 209 | 43.1% |
| 7A | Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability | 100 | 20.6% |
| 4F | Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility | 48 | 9.9% |
| 1D | Retention of a foreign object in a patient after surgery or other procedure | 34 | 7.0% |
| 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) | 14 | 2.9% |
| 6C | Sexual assault on a patient within or on the grounds of a healthcare facility | 14 | 2.9% |
| 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 | 12 | 2.5% |
| 7C | Obstetrical events resulting in death or serious disability to the neonate | 12 | 2.5% |
| 7F | Nosocomial infections resulting in death or serious injury | 7 | 1.4% |
| 1A | Surgery performed on the wrong body part | 6 | 1.2% |
| 3C | Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility | 5 | 1.0% |
| 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 | 1.0% |
| 4C | Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility | 4 | 0.8% |
| 2C | Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility | 3 | 0.6% |
| 7D | Significant medication reactions resulting in death or serious disability | 3 | 0.6% |
| 1C | Wrong surgical procedure performed on a patient | 2 | 0.4% |
| 5D | Patient death associated with a fall while being cared for in a healthcare facility | 2 | 0.4% |
| 2A | Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility | 1 | 0.2% |

| | | | |
|---|---|---|---|
| 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 | 0.2% |
| 4G | Patient death or serious disability due to spinal manipulative therapy | 1 | 0.2% |
| 5C | Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility | 1 | 0.2% |
| 5E | Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility | 1 | 0.2% |
| 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% |
| 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% |
| 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 | Laboratory or radiologic test results not reported to the treating practitioner or reported incorrrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department | 0 | 0.0% |
| **total** | | **485** | **100.0%** |