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

OCTOBER 2004

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State of Connecticut
Department of Public Health

Legislative Report to the General Assembly
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EXECUTIVE SUMMARY

Public Act 04-164 amended the Quality in Health Care program, effective July 1, 2004. It replaced the previous adverse event classification system with a list of reportable events identified by the National Quality Forum (NQF). Additionally, the law allows, and the Department of Public Health (DPH) added, six frequently occurring adverse events to supplement the NQF list.

The Department's Division of Health Systems Regulation presented in-service programs to hospitals and outpatient surgical facilities in July and August of 2004. The programs reviewed the provisions of P.A. 04-164, new reporting documents and instructions.

Since the beginning of adverse event reporting, the Department has significantly increased the number of investigations referred to the institutional and/or practitioner investigation units. Resources for part-time Department physician consultants were also allocated. Currently, physician consultants are available for the specialties of medicine, surgery, pediatrics, anesthesia, obstetrics and gynecology. The addition of these professionals has reduced timeframes for completion of the investigation process and, when necessary, expedited regulatory actions.

Of 36 events reported under the new definitions, 28% are NQF events and 72% are Connecticut-specific events. Medication errors and pressure ulcers have been the most commonly reported NQF events. The most common events of any type are two of the Connecticut-specific events: perforations during surgery and falls.

Using the new reporting form, 82% of reports have a box checked to indicate that the patient or an authorized representative was informed of the adverse event. The other 18% indicate either that the patient was not informed, or have neither (Yes/No) box checked. Overall, there appears to be a high rate of notification.

BACKGROUND

CGS §19a 127l

CGS §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, advises the program. The statute directs the commissioner to report on the Quality in Health Care program to the legislature by June 30, 2003 and annually thereafter.

P.A. 04-164

Public Act 04-164 (Appendix A) amended the Quality in Health Care program, effective July 1, 2004. It replaced the previous adverse event classification system with a list of reportable events identified by the National Quality Forum (NQF). Additionally, DPH added six adverse events to supplement the NQF list, as allowed by the law.

Emergent events include sudden or unusual occurrences which require immediate remedial action to protect the health and safety of the patient population. These events must be reported to the Department immediately. Otherwise, P.A. 04-164 extended to 7 days the period of time for reporting an adverse event and extended to 30 days the time for submitting a corrective action plan. It also modified disclosure of adverse event reports so that only those investigated by DPH would be disclosable.

The commissioner is directed to report annually to the legislature regarding the adverse events reporting program. P.A. 04-164 changed the date of this report from March 1 to October 1.

National Use of the NQF List of Serious Reportable Events

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 (Appendix B). Minnesota became the first state to adopt the list for use in statewide hospital reporting. Between July 2003 and June 2004, at least 74 events were reported to the Minnesota Hospital Association. Full implementation of the law will include reporting to the Minnesota Department of Public Health and will require funding for staff, event processing, analysis and feedback, dissemination and education, web maintenance, modifications, and security (MDH, 2004).

On April 27, 2004, New Jersey enacted a law for reporting "serious, preventable adverse events" to the state and family/guardians. The New Jersey Department of Health and Senior Services has adopted the NQF definition of a serious event and, with modifications, the NQF list of serious events. The NJ Department of Health and Senior Services is working toward implementation of its adverse events reporting law within several months.

Other states are considering use of the NQF list, and the NQF is interested in collaborating with states that have adopted the list (Appendix B).

IMPLEMENTATION OF LEGISLATION EFFECTIVE JULY 1, 2004

The Adverse Event Reporting working group of the Quality in Health Care Advisory Committee recommended the adoption of the NQF list of Serious Reportable Events in January, 2004 (Appendix C). These recommendations were derived from consideration of the following:

a. Implementation of PA 02-125 and collection of data from adverse events demonstrated that the current language did not provide clear, consistent definitions. Mandated formats were confusing and did not lend themselves to data analysis. The numerous classifications of adverse events led to inconsistent interpretations by the provider community.
b. Time frames for reporting and submission of corrective action plans failed to provide sufficient time for analysis of the event and development of a meaningful corrective action plan by the providers.
c. Desire to receive accurate and pertinent information that could be used to identify quality of care issues and ultimately improve patient care.
d. Weighing the public's right to information vs. institutional disclosure and confidentiality issues.

The NQF Serious Reportable Events list includes 27 serious events in six major categories that may occur in hospitals and outpatient surgical facilities. However, based on experience with PA 02-125, DPH deemed certain additional information critical to its efforts to enhance the safety of patients in Connecticut. Thus far the following six (6) Connecticut-specific events have been compiled and added to the NQF list:

1. Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability;
2. Falls resulting in serious disability while being cared for in a healthcare facility;
3. Obstetrical events resulting in death or serious disability to the neonate;
4. Significant medication reactions resulting in death or serious disability;
5. 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;
6. Nosocomial infections defined as reportable sentinel events by the Joint Commission On Accreditation of Healthcare Organizations.

The Department's Division of Health Systems Regulation presented in-service programs to hospitals and outpatient surgical facilities in July and August of 2004. The programs reviewed the provisions of P.A. 04-164, new reporting documents and instructions. A copy of the materials that were distributed at these in-service programs can be found in Appendices D & E of this report.

As a result of the data being provided by the reporting institutions since the initial implementation of adverse event reporting, the Department has significantly increased the number of investigations referred to the institutional and/or practitioner investigation units. For example, in 2003 the Department initiated 275 investigations as a result of complaints and an additional 259 as a result of adverse event reports. Additional staffing resources were allocated to address the substantially increased workload. Since many of the adverse events involved physician services, resources for part-time Department physician consultants were also allocated. Currently, physician consultants are available for the specialties of medicine, surgery, pediatrics, anesthesia, obstetrics and gynecology. The addition of these professionals has reduced timeframes for completion of the investigation process and, when necessary, expedited regulatory actions.

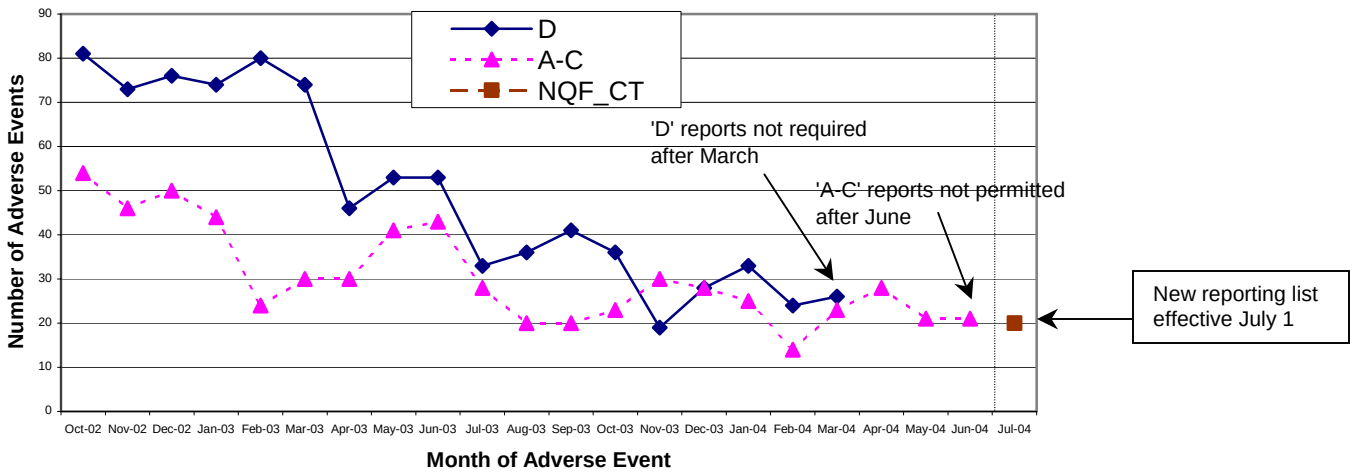
P.A. 04-164 provides the possibility that in the future, the Connecticut-specific adverse events list may be expanded or revised. However, as more states adopt legislation pertinent to adverse event reporting, it is hoped that they will also adopt the NQF list of serious reportable events, thus providing the opportunity to pool or compare data across states.

Currently, the Department is developing the mandated regulations for the reporting of adverse events. It is anticipated that draft regulations will be available within the next several months.

ADVERSE EVENT DATA

As of September 23, 2004, the DPH database contained 1,669 adverse event reports. Prior to July 1, 2004, adverse events were to be reported as class A, B, C, or D. Class A-C events were more serious than class D, and were required to be reported in writing within 72 hours of their discovery. Class D events were of lesser severity, were defined only as reportable events that did not fall into classes A-C, and were required to be reported quarterly. Beginning July 1, 2004 adverse events are reportable using the NQF list of 27 serious reportable events and six additional Connecticut-specific categories. These three groups, A-C, D, and the new Connecticut event definitions (NQF_CT), are identified in Figure 1.

Figure 1. Adverse Events by Class and Month of Occurrence



By June 2004 there had been a decline in the monthly number of adverse events reported to DPH, compared with October 2002 when reporting began. Under the old law, class D events occurring in April-June 2004 would have been reported to DPH in July 2004. However, because in July the new law would be in effect, class D events that occurred during this quarter were not submitted.

As shown in Figure 1, the number of reported events that occurred in July 2004 (20), under the new reporting definitions, was comparable to the number that had been reported as class A-C (21) during the previous month. As the new law requires adverse events to be reported within 7 days of discovery, eight additional events that occurred in June were reported, in July, using the NQF_CT list (not shown in figure).

Of 36 events reported under the new definitions (including some events that occurred in August), 28% (10) are NQF events and 72% (26) are Connecticut-specific additions. While numbers are too small for detailed comparison with Connecticut, Minnesota observed that the most common NQF-list events reported were surgical events and pressure ulcers (MDH, 2004). In Connecticut, medication errors and pressure ulcers have been the most commonly reported NQF events to date. The most common events of any type reported are two Connecticut-specific events: perforations during surgery and falls (Appendix F).

Based on the 9 NQF-event reports for the end of June and all of July 2004, the Department estimates that DPH will receive 50-100 such reports during one year. This would be roughly comparable with the "at least" 74 reports received by the Minnesota Hospital Association, in a state with a 44% larger population than Connecticut. Of interest, reporting in Minnesota increased over the course of the 2003-2004 year as more hospitals became aware of what, when, and how to report, and totaled 90-100 events by September 2004 (Dotseth, 2004).

The Department believes that the use of the NQF list of serious reportable events will lead to more reliable identification and reporting of such events, and that it will reduce incentives for underreporting. Of course, the number of events, awareness of such events, and willingness to report them all influence how many are ultimately reported. Nevertheless the use of the NQF list will minimize reporting variation due to these factors. Using the list, comparisons can identify common patterns that are likely to reflect true conditions, or identify puzzling differences and avenues for further investigation.

The March 2004 Adverse Events Report noted expert opinion that physicians and other health care providers have an ethical responsibility to inform patients when they have been harmed as a result of a medical error or unanticipated adverse event. The American Medical Association Council on Ethical and Judicial Affairs, American College of Physicians, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have disclosure standards. The Connecticut Hospital Association (CHA) presented a program to hospitals about disclosure in September 2001. All Connecticut hospitals have disclosure policies in place.

Using the new reporting form, 82% of reports received have a box checked to indicate that the patient or an authorized representative was informed of the adverse event. A further 18% indicate that the patient was not informed, or have neither the 'Yes' nor the 'No' box checked. It is possible that disclosure to patients of events that are reportable to DPH is even higher than indicated by self-report from hospitals and outpatient surgical centers; i.e. that some conversations took place but were not documented. DPH staff are following up with event reporters who omitted an answer to this question. Overall, there appears to be a high rate of notification.

Without additional information, we cannot determine why some patients may not have been notified. Some possible factors involve timing and lack of clarity over role responsibility. For example, a nurse may report the adverse event to DPH, a junior physician may manage most medical care, while a senior physician is expected to make the disclosure to the patient. Patients also vary in their preferences for receiving health information (Gallagher, 2004). Other issues that have been identified in the literature include malpractice concerns, damage to reputation, difficulty in identifying error, and socialization into an ideal of error-free medicine (Lamb et al, 2003; Mazor, Simon and Gurwitz, 2004; Hobgood et al, 2004; Mazor et al, 2004; Liebman and Hyman, 2004).

FUTURE PLANS

Electronic reporting

The Adverse Events Reporting working group will discuss the enhancement of the reporting process to support the direct electronic submission of adverse event data. The electronic system that is ultimately developed will cover all Connecticut's inpatient hospitals and outpatient surgical centers.

Patient Safety Organizations and Dissemination of Best Practices

Public Act 04-164 provides that the Department may designate as a patient safety organization (PSO) each applicant "whose primary activity is to improve patient safety and the quality of health care delivery for patients receiving care through the collection, aggregation, analysis or processing of medical or health care-related information submitted to it by health care providers" provided the applicant meets four (4) criteria specified in Section 2(b)(2) of the Public Act. The PSO is required to disseminate to health care providers, the Department, the Quality of Care Advisory Committee and the public, information or recommendations designed to improve patient safety and the quality of care.

The Department has received several applications for designation as a PSO and plans to make its first designation within the next several weeks.

P.A. 04-164 §3(c)(2) creates a standing subcommittee on best practices within the Quality of Care Advisory Committee. It states that this subcommittee "shall advise the department on effective methods for sharing with providers the quality improvement information learned from the department's review of reports and corrective action plans" and that "the department shall, at least quarterly, disseminate information regarding quality improvement practices, patient safety issues and preventative strategies to the subcommittee and hospitals."

It is anticipated that the Quality of Care Advisory Committee will appoint a best practices subcommittee at the next quarterly meeting, in November. The Department intends to distill lessons from the adverse events program and consult with the best practices subcommittee about disseminating this information more widely.

APPENDIX A

Substitute Senate Bill No. 566

Public Act No. 04-164

AN ACT CONCERNING THE QUALITY OF HEALTH CARE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 19a-127n of the general statutes, as amended by section 123 of public act 03-278, is repealed and the following is substituted in lieu thereof (*Effective July 1, 2004*):

(a) (1) For purposes of this section, an "adverse event" means **[**an injury that was caused by or is associated with medical management and that results in death or measurable disability. Such events shall also include those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations**]** any event that is identified on the National Quality Forum's List of Serious Reportable Events or on a list compiled by the Commissioner of Public Health and adopted as regulations pursuant to subsection (d) of this section; and "corrective action plan" means a plan that implements strategies that reduce the risk of similar adverse events occurring in the future, and measures the effectiveness of such strategies by addressing the implementation, oversight and time lines of such strategies.

(2) The commissioner shall review the list of adverse events periodically, but not less than annually, to ascertain whether any additions, deletions or modifications to the list are necessary.

[(b) Adverse events shall be classified into the following categories:

(1) "Class A adverse event" means an event that has resulted in or is associated with a patient's death or the immediate danger of death;

(2) "Class B adverse event" means an event that has resulted in or is associated with a patient's serious injury or disability or the immediate danger of serious injury or disability;

(3) "Class C adverse event" means an event that has resulted in or is associated with the physical or sexual abuse of a patient; and

(4) "Class D adverse event" means an adverse event that is not reported under subdivisions (1) to (3), inclusive, of this subsection.]

[(c)] (b) On and after October 1, 2002, a hospital or outpatient surgical facility shall report adverse events to the Department of Public Health [on Class A, B and C adverse events] as follows: (1) [A verbal report shall be made not later than twenty-four hours after the adverse event occurred; (2) a] A written report and the status of any corrective steps shall be submitted not later than [seventy-two hours] seven days after the adverse event occurred; and [(3)] (2) a corrective action plan shall be filed not later than [seven] thirty days after the adverse event occurred. Emergent reports, as defined in the regulations adopted pursuant to subsection (c) of this section, shall be made to the department immediately. Failure to implement a corrective action plan may result in disciplinary action by the Commissioner of Public Health, pursuant to section 19a-494.

[(d) A hospital or outpatient surgical facility shall report to the Department of Public Health on Class D adverse events on a quarterly basis. Such reports shall include corrective action plans. For purposes of this subsection and subsection (c) of this section, "corrective action plan" means a plan that implements strategies that reduce the risk of similar events occurring in the future. Said plan shall measure the effectiveness of such strategies by addressing the implementation, oversight and time lines of such strategies. Failure to implement a corrective action plan may result in disciplinary action by the Commissioner of Public Health, pursuant to section 19a-494.]

[(e)] (c) The Commissioner of Public Health shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section. Such regulations shall include, but shall not be limited to, a list of adverse events that are in addition to those contained in the National Quality Forum's List of Serious Reportable Events and a prescribed form for the reporting of adverse events pursuant to [subsections (c) and (d)] subsection (b) of this section. The commissioner may require the use of said form prior to the adoption of said regulations.

[(f)] (d) On or before [March] October first annually, the commissioner shall report, in accordance with the provisions of section 11-4a, on adverse event reporting, to the joint standing committee of the General Assembly having cognizance of matters relating to public health.

[(g)] (e) Information collected pursuant to this section shall not be [required to be] disclosed pursuant to subsection (a) of section 1-210, as amended, [for a period of six months from the date of submission of the written report required pursuant to subsection (c) of this section and] at any time, and information collected pursuant to this section shall not be subject to subpoena or discovery or introduced into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law. Nothing in this section shall be construed to limit access to or disclosure of investigative files, including any adverse event report contained in such files, maintained by the department as otherwise provided in section 19a-499.

(f) If the department determines that it will initiate an investigation of an adverse event that has been reported, such investigation may include review by one or more practitioners with clinical expertise of the type involved in the reported adverse event.

[(h)**]** (g) The Quality of Care Advisory Committee established pursuant to section 19a-127l shall establish methods for informing the public regarding access to the department's consumer and regulatory services.

Sec. 2. (NEW) (*Effective July 1, 2004*) (a) For purposes of this section:

(1) "Patient safety organization" means any public or private organization, or component of any such organization, whose primary activity is to improve patient safety and the quality of health care delivery for patients receiving care through the collection, aggregation, analysis or processing of medical or health care-related information submitted to it by health care providers;

(2) "Patient safety work product" means any information, documentation or communication, including, but not limited to, reports, records, memoranda, analyses, statements, root cause analyses, protocols or policies that (A) a health care provider prepares exclusively for the purpose of disclosing to a patient safety organization, (B) is created by a patient safety organization, or (C) contains the deliberations or analytical process of a patient safety organization or between a patient safety organization and health care providers participating in the evaluation of patient care; and

(3) "Health care provider" or "provider" means any person, corporation, limited liability company, facility or institution operated, owned or licensed by this state to provide health care or professional services, or an officer, employee or agent thereof acting in the course and scope of his or her employment.

(b) (1) Any private or public organization or a component of any private or public organization may apply to the Department of Public Health to be designated as a patient safety organization.

(2) The department may designate as a patient safety organization each applicant that (A) has a mission statement indicating its primary purpose is to conduct activities to improve patient safety, (B) has qualified staff and professionals capable of reviewing and producing patient safety work product, (C) is not a component of a health insurer or other entity that provides health insurance to individuals or group health plans, and (D) certifies that its mission does not create a conflict of interest with the health care providers who will submit patient safety work product to it. Each hospital or outpatient surgical facility shall seek to work with one or more patient safety organizations as they become available. The department shall assist hospitals and outpatient surgical facilities in developing working relationships with patient safety organizations.

(c) A health care provider shall enter into a written contract with each patient safety organization to which it sends patient safety work product. Each contract shall require the provider to maintain a document log itemizing the types of documents submitted to patient safety organizations without

indicating the content of such documents. Such document log shall be accessible to the department for the sole purpose of allowing the department to verify the type of information submitted to patient safety organizations. The department shall not have access to patient safety work product. Notwithstanding the provisions of sections 1-210, as amended, 1-211 and 1-213 of the general statutes, such document log shall not be subject to disclosure to, or use by, any person or entity, other than the patient safety organization and the provider with which it has contracted, and by the department for the sole purpose provided in this subsection.

(d) A patient safety organization shall, as appropriate, disseminate to health care providers, the department, the Quality of Care Advisory Committee, as established by 19a-127l of the general statutes, and the public, information or recommendations, including suggested policies, procedures or protocols, on best medical practices or potential system changes designed to improve patient safety and the overall quality of care.

(e) A patient safety organization shall have in place appropriate safeguards and security measures to ensure the technical integrity and physical safety of any patient safety work product. Patient safety work product shall be confidential, and shall not be subject to any discovery, access or use by any person or entity other than the patient safety organization and the provider with which the patient safety organization has contracted. Patient safety work product, if submitted to a public or governmental organization, shall not be subject to the provisions of section 1-210, as amended, 1-211 or 1-213 of the general statutes. Nothing in this subsection shall prohibit a patient safety organization from choosing to disclose patient safety work product, or portions of patient safety work product, in conformity with its mission and within its contractual obligations to the provider submitting the information. No patient safety organization may release protected health information or patient identifying information without meeting the requirements of state laws and the federal Health Insurance Portability and Accountability Act of 1996, as amended from time to time.

(f) A provider's disclosure of patient safety work product to a patient safety organization shall not modify, limit or waive any existing privilege or confidentiality protection.

Sec. 3. Subsection (c) of section 19a-127l of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2004*):

(c) (1) There is established a Quality of Care Advisory Committee which shall advise the Department of Public Health on the issues set forth in subdivisions (1) to (12), inclusive, of subsection (b) of this section. The advisory committee shall meet at least quarterly.

(2) Said committee shall create a standing subcommittee on best practices. The subcommittee shall advise the department on effective methods for sharing with providers the quality improvement information learned from the department's review of reports and corrective action plans, including quality improvement practices, patient safety issues and preventative strategies. The department shall, at least quarterly, disseminate information regarding quality improvement practices, patient safety issues and preventative strategies to the subcommittee and hospitals.

Sec. 4. (NEW) (*Effective July 1, 2004*) A hospital may administer influenza and pneumococcal polysaccharide vaccines to patients, after an assessment for contraindications, without a physician's order in accordance with a physician-approved hospital policy. The Commissioner of Public Health shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to carry out the provisions of this section.

APPENDIX B

Clearing the Confusion About Connecticut's New Adverse Event Reporting Law

Kenneth W. Kizer, MD, MPH

State lawmakers recently revised Connecticut's requirement for what adverse events hospitals must report to the state health department, adopting a nationally agreed upon list of events that should never occur. That list includes things like performing surgery on the wrong body part or wrong patient, discharging a baby to the wrong family, or the occurrence of an assault that causes significant injury or death of a patient or staff member on the grounds of a healthcare facility.

Connecticut's old adverse-events reporting law was broad but vague. The new law is a substantial improvement, in that it finally states, clearly and unambiguously, what hospitals must report. And while some legitimate criticism has been expressed because the law does not require public disclosure of what is reported, it remains that Connecticut has one of the nation's more comprehensive adverse event reporting laws.

Under the revised law, Connecticut hospitals must report whenever one of 27 so-called "*never events*" occurs. These events, taken from the National Quality Forum's *Serious Reportable Events in Healthcare* (2002), is a consensus list of harmful events that everyone agrees should never happen.

The objective of NQF's Serious Reportable Events project, which was undertaken at the request of the federal government, was to establish agreement among consumers, providers, purchasers, researchers and other healthcare stakeholders about those preventable adverse events that should never occur and to define them in a way that should they occur it would be clear what had to be reported to the authorities. The goal was to bring order to the chaos that typifies adverse event reporting in most of the relatively few states that have adverse event reporting laws.

Connecticut joins Minnesota in requiring reporting of the entire NQF list of Serious Reportable Events. A number of other states are considering doing the same thing. Our hope is that before long all states will collect and publicly report data on the occurrence of these events, forming a national system for tracking the worst kinds of medical mishaps.

Why these events in particular? This was the set of events about which a diverse array of healthcare stakeholders were able to achieve consensus that the evidence was clear that the occurrence of these things was under the control of the healthcare facilities and the events simply should never happen. This consensus is very important. Getting such disparate groups of people with their divergent interests to agree on anything is monumentally difficult. However, without that consensus there is not sufficient focus to get anything done. Indeed, that has been the experience of states having less clear reporting laws. To fix a problem there must be a common ground to which limited resources can be directed. The NQF list of *never events* provides that common ground.

> The events on this list are clearly identifiable and measurable events, and thus feasible to expect compliance with in a reporting system; and they are events for which the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility. The nature of these events is unambiguous, and they are usually preventable.

There is no question that lapses in patient safety are a major healthcare quality problem; that the occurrence of patient harm due to such lapses is too common; and that a large majority of these lapses are preventable. In the literature review, we learned that these lapses are rarely the result of professional misconduct or criminal acts, despite headlines that sometimes suggest the contrary. Instead, we found that the overwhelming majority of these lapses are unintended consequences of an exceedingly complex and imperfect healthcare delivery system.

The public expects healthcare professionals to go to great lengths to ensure that care is safe, and to the government and other oversight authorities to make sure that this is done. Part of providing oversight is collecting data and investigating serious adverse events. With the new law and its clearly defined list of adverse healthcare events, Connecticut's state government is now in position to provide more effective oversight and to make healthcare safer.

Kenneth W. Kizer, MD, MPH, is President and CEO of the National Quality Forum, Washington, DC.

APPENDIX C

JANUARY 2004 RECOMMENDATIONS OF THE ADVERSE EVENT REPORTING WORKING GROUP OF THE DPH QUALITY IN HEALTH CARE ADVISORY COMMITTEE

Recommendation: The working group recommends that the Connecticut legislature adopt the National Quality Forum (NQF) Serious Reportable Events as the list of adverse events that must be reported to the Department of Public Health.

Working group members discussed the variability in interpretation of reportable events and the impediment that variability creates to providing useful patient safety improvement data. The working group's concerns were confirmed by an October 2003 report, How States Report Medical Errors: Issues and Barriers, by the National Academy for State Health Policy, which noted that "The lack of clear, consistent definitions of adverse events thwarts efforts to compare and evaluate results."

Working group members extensively discussed the National Quality Forum list of 27 specific events, a copy of which is attached, as a replacement for the current adverse event reporting requirements. Consistent with the recommendation of the Institute of Medicine to report adverse events in a systematic manner, the federal government charged the National Quality Forum with "identifying a core list of preventable, serious adverse events." The NQF "encourages widespread adoption of this list of serious reportable events by states" and believes that use of the list "could lead to substantial improvements in patient care." Working group members discussed the use of the NQF serious reportable events in other state reporting systems such as Minnesota and the benefits of sharing lessons learned between states. The working group concluded that use of the NQF list could also have the benefit of facilitating analysis of reported adverse events, which has been challenging under the current definitions.

The working group discussed the possibility of adding to the NQF list a few additional events specific to Connecticut. DPH will review the events reported over the last year and determine whether additional events should be added at this time. The working group discussed the need to minimize the number of additional events, but also concurred that DPH should have a mechanism to update the list of events periodically to reflect changing patient safety priorities at the national and state level.

With respect to adverse events that are not captured in the NQF list, the working group concluded that those events could be reported to non-regulatory "patient safety organizations." The full Advisory Committee previously approved a recommendation that the Connecticut legislature facilitate the creation of patient safety organizations with which hospitals could share information about near misses and less serious adverse events. Patient safety organizations are public or private entities without regulatory oversight functions that have a mission of improving patient safety through effectively analyzing information and developing and disseminating recommendations to providers related to best practices for patient safety.

Recommendation: Protect the confidentiality of adverse event reports while maintaining the availability of the adverse event investigation results through the Freedom of Information (FOI) Act.

The working group discussed the absence of any evidence that public disclosure of individual adverse event reports and corrective action plans results in improved patient safety and also discussed findings in

much of the patient safety literature that confidentiality of adverse event reporting promotes more complete and consistent reporting of events. Working group members also discussed how reporting of raw numbers of adverse events could be misleading to consumers. The working group concluded that the value in reporting of adverse events comes not from the listing of individual events and corrective action plans but from the analysis of multiple events to identify causal factors and use the resulting information to develop patient safety improvements.

Working group members discussed the need to maintain accountability, while simultaneously protecting confidentiality of individual reports and corrective action plans. The working group concluded that public accountability is achieved by maintaining the availability of results of investigations conducted by the Department of Public Health related to adverse events.

The DPH working group members explained that review of adverse events is the same as for any other issue/complaint received by DPH. The issue/complaint/reported incident is reviewed by nurse supervisors/management for appropriate jurisdiction, and referrals are made to other federal/state entities, if applicable. Those issues that are identified as appropriate for institutional investigation are entered for investigation. 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. Additional DPH resources are utilized if issues identified fall within a licensed discipline (e.g. physician services, social work, recreation therapy). Should referrals of a licensed individual be appropriate the case may then be referred to the Practitioner Investigation Unit for additional review and action. DPH investigation results are available under the Freedom of Information Act, except for certain physician investigations as noted in CGS 20-13e (a).

Working group members also discussed the legislature's original concern that events were occurring without patients being informed. A proposal to require attestation by the organization that the patient was informed of the event in lieu of FOI of the adverse event report was raised, and the working group recommended that the adverse event form be modified to include a statement attesting to the fact that the patient has been informed of the adverse event.

REFERENCES

Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer health system. Washington: National Academy Press 2000.

Leape LL. Reporting of adverse events. New Engl J Med 2002; 347:1633-8.

Marchev M, Rosenthal J, Booth M. How states report medical errors to the public: issues and barriers. National Agency for State Health Policy October 2003. (http://www.nashp.org.)

National Quality Forum. Serious Reportable Events in Healthcare, 2002. www.qualityforum.org

Weeks WB, Bagian JP. Developing a culture of safety in the Veterans Health Administration. Effective Clinical Practice 2000.
(http://www.acponline.org/journals/ecp/novdec00/weeks.htm)

APPENDIX D

ADVERSE EVENT REPORTING FORM
(DIRECTIONS FOR USE)

On and after July 1, 2004, a hospital or outpatient surgical facility shall report to the Department of Public Health (DPH) adverse events as follows:

Monday through Friday, 8:30 AM – 4:30 PM

Emergent reports: Should the institution deem an event to be emergent in nature the reporter should immediately contact the department at (860) 509-7400 and request to speak to a supervisor or manager indicating that they are reporting an "Emergent Adverse Event".

Emergent reports include an unexpected situation or sudden occurrence of a serious and urgent nature which requires immediate remedial action on the part of the hospital to protect the health and safety of its patient population, or an event which is unusually serious in nature and has resulted in a patient's death or injury.

Emergent reports may include adverse events as defined in Section 19a-127-(a)(1).

Before 8:30 AM and after 4: 30 PM on weekdays and on weekends and holidays

Emergent reports: Should the institution deem the situation to be emergent in nature, the reporter should contact the Department's answering service at (860) 509-8000. The answering service should be advised that an "Emergent Adverse Event" has occurred, provide a brief summary of the situation and the name and phone number of the facility's contact person. A Department staff member will immediately contact the designated facility contact person.

- **Please remember to identify the institution, address, phone number and contact person**, the involved patient(s), utilizing identification number, and specify the number assigned to the adverse event report.

1. WRITTEN REPORTS

A written report shall be submitted on an approved form (AE#1) to the Department, within seven (7) days after the occurrence of any adverse events.

DIRECTIONS AND DEFINITIONS FOR USE OF FORM AE#1

Demographic Data-Page 1

a) Facility Information
   i) Type of facility: Check the applicable licensure level of the facility.
   ii) Facility name and address – self-explanatory.
   iii) License Number – The number as it appears on the current license. May also include letter designations for certain licensure levels.

b) Sequential Report Number:

All adverse events shall be identified on each page with a number as follows:

i) The number appearing on the facility license.
ii) The last two digits of the year.
iii) The sequential number assigned to the report for the calendar year.

Example: 0085-02-01
Breakdown: 0085-license number; 02-year; 01 – sequential number (first report)

Example: 21CD-02-03
Breakdown: 21CD-license number; 02-year; 03 – sequential number (third report)

c) Reporter's Name: The name of the person reporting the adverse event to the Department of Public Health.

d) Patient Information: The majority of information reported under this designation is self-explanatory.

e) Date and Time Event First Known: That point in time when the facility first became aware of the adverse event.

DEMOGRAPHICS: HOSPITALS ONLY PAGE 2

a) Hospital Based: Emergency Departments are included in the in-patient hospital based category.

b) Off Campus Satellite Sites: Health care and service delivery sites that would require a separate institutional license in accordance with Connecticut General Statutes 19a-490 but for the fact that these entities are incorporated within the hospital's single license.

c) Location of Occurrence: Check only the specific location where the event occurred.

NOTIFICATIONS: PAGE 2

Note: Separate reports should be submitted for a patient who experiences 2 or more discrete adverse events during their stay in the facility.

2. CORRECTIVE ACTION PLAN (CAP)

a) A CAP shall be filed for each adverse events not later than thirty (30) days after said occurrence. (see form AE#2).

b) Corrective Action Plan" means a plan that implements strategies that reduce the risk of similar events occurring in the future. Said plan shall measure the effectiveness of such strategies by addressing the implementation, oversight and time lines of such strategies.

Directions for use of form AE #2

i. Facility: Enter name, address of institution.
ii. Sequential Report Number for which the plan is being submitted: Enter the number which was assigned to the original notification to the Department for the event (e.g., number utilized on Form AE #1).
iii. Date of event: Enter the date that the event happened.

iv. Date CAP submitted: Enter the date CAP sent to the Department.
v. Unique Patient Identifier: Enter the patient billing number as utilized on the original adverse event reporting form AE #1.
vi. Event being addressed: Identify the adverse event.
vii. Findings: List outcome of facility investigation.
viii. Corrective Action Plan: The CAP must identify strategies/plans to reduce the occurrence of such events in the future inclusive of, but not limited to, implementation of policies/procedures, in-servicing of appropriate staff, monitoring, remediation, supervision, oversight and measures or mechanisms that shall be utilized to monitor the ongoing effectiveness of the plan.
ix. Time line for implementation: Identify the date that the components of the CAP are to be initiated.
x. Completion date for CAP: Identify the date that all components of the plan have been completed.
xi. Identification of staff member by title who has been designated the responsibility for monitoring the CAP: It is important that the institution identify a "position/title" rather than an individual name in this area as CAPs are an ongoing responsibility.
xii. Submitted by and date: Self-explanatory.

Written reports and corrective action plans shall be faxed to (860) 509-8369 or mailed to:

Department of Public Health
Division of Health Systems Regulation
Attention: Adverse Event
410 Capital Avenue – MS#12HSR
P.O. Box 340308
Hartford, CT 06134-0308

3. ADDITIONAL INFORMATION

a) Each hospital or outpatient surgical facility shall have a mechanism in place to provide the Department with the patient's name, physician(s) name and the name of any other healthcare provider or staff member involved in or with first-hand knowledge of this event. This information must be available to Department of Public Health representatives twenty-four (24) hours a day, seven (7) days a week.

b) Healthcare provider or staff person includes, but is not limited to, the individual who performed the surgery or procedure, administered the anesthesia, delivered the substance or was directly involved in the discrete event. In all cases please include the name of the patient's attending physician of record.

APPENDIX E

ADVERSE EVENT REPORTING FORM

DEMOGRAPHIC DATA – All Facilities

FACILITY INFORMATION:

Type of Facility: ☐ Children's Hospital ☐ Chronic Disease Hospital ☐ General Hospital	☐ Hospital for Mentally Ill Persons ☐ Hospital for the Care of Hospice Patients ☐ Maternity Hospital ☐ Outpatient Surgical Facility
Facility Name and Address:	License Number: Sequential Report Number:
Reporter's Name:	
Contact Person: Name:	Telephone Number:

PATIENT INFORMATION:

Medical Record Number:	Age	Date of Admission:
Patient's Billing Number:	Sex ☐M ☐F	Date and Time of Event: Date: Time:
Social Security Number:		Date and Time Event First Known: Date: Time:
Date of Patient Death (if applicable):		
Admission Diagnosis:		

Sequential Report Number _____

DEMOGRAPHICS – Hospitals Only

☐ Inpatient ☐ Hospital Based ☐ Off Campus Satellite Site Name:_____ Address_____	☐ Outpatient ☐ Hospital Based ☐ Off Campus Satellite Site Name:_____ Address_____
LOCATION OF OCCURENCE: ☐ Medical Intensive Care ☐ Neonatal Intensive Care ☐ Surgical Intensive Care Unit ☐ Adult Medical ☐ Adult Surgical ☐ Ambulatory Surgical ☐ Cardiac Cath Lab ☐ Cardiac Care ☐ Dialysis ☐ Emergency Department	☐ Obstetrical /Gynecological ☐ Operating Room ☐ Outpatient Services - Specify Type _____ ☐ Pediatrics ☐ Psychiatric ☐ Diagnostic Services – Specify Type: _____ ☐ Rehabilitative Services – Specify Type: _____ ☐ Other_____

NOTIFICATIONS:

PATIENT AND/OR AUTHORIZED REPRESENTATIVE NOTIFIED: Y ☐ Date notified _____ N ☐

DID THE PATIENT EXPIRE? Y ☐ N ☐

If yes:

MEDICAL EXAMINER NOTIFIED Y ☐ N ☐ CASE NUMBER (if applicable)	AUTOPSY PERFORMED (if applicable) Y ☐ N ☐ Unknown ☐ LOCATION:

At the time of this report, were any other entities known to have been notified of this event?

Check all that apply: ☐ Centers for Medicare/Medicaid Services ☐ Department of Children and Families ☐ Food and Drug Administration ☐ Joint Commission on the Accreditation of Health Care Organizations ☐ Product Manufacturer	☐ Local/State Police ☐ Office of Protection and Advocacy for Persons with Disabilities ☐ State Fire Marshal ☐ Department of Social Services, Protective Services ☐ Unknown to reporter at time of report

Sequential Report Number

_____

"CUT & PASTE" DESCRIPTION OF EVENT HERE FROM LIST

Facts of Event and Status of Patient Condition:

Immediate Plan of Action:

FOR DPH USE ONLY

Date Report Received- Emergent	
Date Report Received	
Date Corrective Action Plan Received	

CORRECTIVE ACTION PLAN (CAP)

Facility:	Sequential Report Number for which this plan is being submitted:
Patient Billing Number:	Date CAP Submitted:
Event being addressed: Findings:	
Corrective Action Plan to prevent reoccurrence: Does JCAHO require a root cause analysis for this event? Y ☐ N ☐	
Time line for implementation:	Completion date for CAP:
Identification of staff member, by title, who has been designated the responsibility for monitoring CAP implementation:	
Submitted by:	Date:

An **Adverse Event** means a discrete, auditable and clearly defined occurrence with a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.*
Serious describes an event that results in death or loss of a body part, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient facility.*
Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.*
(* as defined by the National Quality Forum, 2002)

EVENT	ADDITIONAL SPECIFICATIONS
1. SURGICAL EVENTS	
☐ 1A. Surgery performed on the wrong body part	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent**.**
☐ 1B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
☐ 1C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
☐ 1D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.

☐ 1E. Intraoperative or immediate post-operative death in an ASA (American Society of Anesthesiology) Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. PRODUCT OR DEVICE EVENTS	
☐ 2A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
☐ 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	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
☐ 2C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
3. PATIENT PROTECTION EVENTS	
☐ 3A. Infant discharged to the wrong person	
☐ 3B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
☐ 3C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.
4. CARE MANAGEMENT EVENTS	
☐ 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)	Excludes reasonable differences in clinical judgment on drug selection and dose.
☐ 4B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	

☐ 4C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
☐ 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	
☐ 4E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Hyperbilirubinemia is defined as bilirubin levels >30mg/dl. Neonates refers to the first 28 days of life.
☐ 4F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3, if Stage 2 was recognized upon admission.
☐ 4G. Patient death or serious disability due to spinal manipulative therapy	
5. ENVIRONMENTAL EVENTS	
☐ 5A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock.
☐ 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	
☐ 5C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	
☐ 5D. Patient death associated with a fall while being cared for in a healthcare facility	
☐ 5E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS	
☐ 6A. Any instance of care ordered by or provided by	

someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	
☐ 6B. Abduction of a patient of any age	
☐ 6C. Sexual assault on a patient within or on the grounds of a healthcare facility	
☐ 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	
7. CONNECTICUT SPECIFIC EVENTS	
☐ 7A. Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	Includes perforations which require resection.
☐ 7B. Falls resulting in serious disability while being cared for in a healthcare facility	Includes fractures and/or head injuries with intracranial hemorrhage.
☐ 7C. Obstetrical events resulting in death or serious disability to the neonate	
☐ 7D. Significant medication reactions resulting in death or serious disability	Includes medication reactions, anaphylaxis, or development of methemoglobinemia following use of anesthetic spray.
☐ 7E. Treatment in the emergency department resulting in death or serious disability due to incorrect or missed diagnosis	Includes laboratory or radiologic test results not reported to treating practitioner or reported incorrectly.
☐ 7F. Noscomial infections resulting in death or serious injury	Includes infections requiring return to the OR for treatment.

EMERGENT REPORT

Sequential Report Number:		
Facility Name and Address:		
Contact Person:	Telephone Number:	
Date reported to DPH: Time:	By:	
PATIENT INFORMATION (If Applicable)		
Patient's Billing Number:	Date of Event:	Time of Event:
BRIEF SUMMARY		

APPENDIX F

ADVERSE EVENTS REPORTED USING THE CATEGORIES EFFECTIVE JULY 1, 2004 NATIONAL QUALITY FORUM AND CONNECTICUT-SPECIFIC EVENTS LIST EVENTS THROUGH EARLY AUGUST 2004

Type of Event	Number of Events
*Perforation during surgery resulting in death or serious disability	14
*Fall resulting in serious disability while in a healthcare facility	12
Stage 3 or 4 pressure ulcer acquired after admission	4
Patient death or serious injury associated with a medication error	3
Retention of a foreign object in a patient after surgery	2
Assault of a staff member at a healthcare facility	1
Total Reports	36

*Connecticut-specific events list

APPENDIX G

REFERENCES

Dotseth M (2004). Email communication September 7, 2004.

Gallagher TH (2004). Content of medical error disclosures. Virtual Mentor: Ethics Journal of the American Medical Association 6(3). March.

Hobgood C, Hevia A, Hinchey P (2004). Profiles in patient safety: when an error occurs. Academic Emergency Medicine 11:766-70.

Institute of Medicine (2004). Patient safety: achieving a new standard for care. Washington, D.C.: National Academies Press.

Lamb RM, Studdert DM, Bohmer RMJ, Berwick DM, Brennan TA (2003). Hospital disclosure practices: results of a national survey. Health Affairs 22;2:73-83.

Liebman CB, Hyman CS (2004). A mediation skills model to manage disclosure of errors and adverse events to patients. Health Affairs 23;4: 22-32.

Mazor KM, Simon SR, Gurwitz JH (2004). Communicating with patients about medical errors. A review of the literature. Archives of Internal Medicine 164:1690-7.

Mazor KM, Simon SR, Yood RA, et al (2004). Health plan members' views about disclosure of medical errors. Annals of Internal Medicine 140:409-18.

Minnesota Department of Health (2004). Adverse events reporting system: first year milestones. www.health.state.mn.us/patientsafety/firstyear.html. Accessed August 4, 2004.