CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Keeping Connecticut Healthy

ANNUAL LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY
Adverse Event Reporting

General Statutes of Connecticut
Section 19a-127l-n
QUALITY OF CARE PROGRAM

MARCH 2004

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EXECUTIVE SUMMARY

CGS 19a 127l-n requires the Department of Public Health (DPH) to establish a quality of care program for health care facilities. The Quality in Health Care Advisory Committee, chaired by the DPH commissioner, advises the program. Consistent with this legislation, the following four categories are used for reporting adverse events to DPH:

> Class A: An adverse event resulting in or associated with a patient's death or immediate danger of death.
> Class B: An adverse event resulting in or associated with a patient's serious injury or disability or immediate danger of such.
> Class C: An adverse event resulting in or associated with a patient's physical or sexual abuse.
> Class D: An adverse event not reported in Class A through C above.

Adverse event reporting began October 1, 2002. As of March 8, 2004 the DPH database contained 1359 adverse event reports. The percentage of reports by event class were: A (6.1%), B (32.0%), C (2.6%), D (56.1%), and unclassified (3.1%). Unclassified reports represent those in which the event class was noted on the verbal report, but no event was entered into the electronic database because the event class was not legible on the faxed written report. These data entry errors are being corrected. Not all adverse events are caused by medical errors, so the role of follow-up investigations is critical to understanding the nature of the event. These investigations are undertaken for about 50% of reported events. They evaluate regulatory compliance and provide information that may allow one to distinguish between events due to a medical error and those that are not.

There was a decline in reporting over the first 12 months of the program, which appears to have stabilized at less than half the original number of monthly events. There are three possible explanations for the decline: 1) decrease in the number of adverse events; 2) decrease in the erroneous submission of reports when no reportable event took place, due to clarification of definitions; 3) decrease in the reporting of adverse events without a change in the occurrence of reportable adverse events.

Under-reporting of adverse events is widely recognized in the professional literature. Potential barriers to reporting include fear of malpractice litigation, fear of adverse publicity, inability to identify incidents, reporting burden, lack of perceived usefulness, and unclear adverse event definitions, among others. While some of these reasons may be more influential than others, their relationship to Connecticut's experience remains speculative.

The Adverse Event working group was created as part of the Quality in Health Care Advisory Committee. The working group identified problems with the existing reporting form, and the associated event definitions, and proposed ways to improve reporting that were adopted by the Quality in Health Care Advisory Committee. The Adverse Events working group and Advisory Committee have recommended the following:

- that Connecticut adopt the National Quality Forum (NQF) list of serious reportable events. This will address possible under-reporting or misreporting caused by unclear definitions. Extension from 72 hours to 7 days, of the time within which what are presently A, B, and C written reports must be submitted, allows for more accurate reporting.
- adding 5-6 Connecticut-specific events to the reporting requirement.
- that a check box be added to the report form attesting that the patient had been informed of the adverse event.
- creation of a Patient Safety Organization separate from regulatory oversight, to collect near miss and other patient safety information.
- that the confidentiality of adverse event reports be protected, while maintaining the availability of the adverse event investigation results through the Freedom of Information Act. This measure would

ameliorate possible under-reporting that can be caused by fear of unfavorable publicity or of lawsuits, while achieving public accountability.

If modifications to CGS 19a 127l-n are made in the current legislative session, DPH will implement them. This would include revising the adverse event reporting form. Contingent upon the implementation of revisions, DPH plans to implement electronic, web-based adverse event reporting.

INTRODUCTION

CGS 19a 127l-n

CGS 19a 127l-n (Appendix A) requires the Department of Public Health (DPH) to establish a quality of care program for health care facilities. DPH must develop a health care quality performance measurement and reporting system, initially applicable to the state's hospitals and outpatient surgical facilities. Other health care facilities become part of the quality program in later years as it develops. An advisory committee, chaired by the DPH commissioner, advises the program.

The statute directs the Commissioner to report on the quality of care program on or before June 30, 2003. The statute directs DPH to produce a report that compares the state's hospitals based on quality performance measures. The statute requires all hospitals to implement performance improvement plans. These plans must be submitted annually to DPH as a condition of licensure, beginning June 30, 2003. On or before March first and annually thereafter the Commissioner shall report on adverse event reporting to the General Assembly. The following is the second report submitted to the General Assembly on adverse event reporting.

Reporting on Adverse Events

An "adverse event" is an injury caused by or associated with medical management that results in death or measurable disability. It includes those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), an independent, not-for-profit organization that evaluates and accredits health care organizations, including hospitals, in the United States. A "sentinel event," according to JCAHO, is an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof.

The following four categories are used for reporting adverse events to DPH:

Class A: An adverse event resulting in or associated with a patient's death or immediate danger of death.
Class B: An adverse event resulting in or associated with a patient's serious injury or disability or immediate danger of such.
Class C: An adverse event resulting in or associated with a patient's physical or sexual abuse.
Class D: An adverse event not reported in Class A through C above.

As of October 1, 2002, hospitals and outpatient surgical facilities were required to report adverse events classified as A through C to the Department of Public Health as they occurred. These facilities must also report, on a quarterly basis, Class D adverse events along with a corrective action plan.

BACKGROUND/ NATIONAL TRENDS

According to the Institute of Medicine (IOM, 2000), mandatory adverse event reporting systems, like the system recently introduced in Connecticut, serve three purposes. The first is to protect the public by assuring that serious errors are reported and will be investigated. Second, they provide an incentive to health care facilities to improve quality of care, because facilities want to avoid the negative consequences associated with adverse events. Last, they require that all health care facilities devote additional efforts to patient safety.

Several other states have mandatory adverse event reporting systems (OHCQ, 2002; NASHP, 2002). According to the Health Policy Tracking Service, National Conference of State Legislatures, as of 9/27/02, sixteen states had mandatory reporting systems, and another five had voluntary systems. Reporting formats vary by state – some states have a specific reporting form like Connecticut, others have different forms for different types of events, and some have no forms. The reporting format varies as to which events are

reportable, ranging from vague, general requirements to highly specific definitions. States with well-defined reportable events approach the reporting of events in either of two ways: by outcome or by the mechanism of death or injury. CGS 127n calls for an outcomes-based reporting system. Reportable events are stipulated as those injuries that result in, are associated with, or present an immediate danger of, certain outcomes: death, serious injury, measurable disability, or are associated with physical or sexual abuse.

IMPLEMENTATION

The Department of Public Health (DPH) initiated preparations for the October 1, 2002 implementation of Adverse Event reporting in July 2002.

Hospitals

Currently, Connecticut licenses forty-four (44) hospitals consisting of thirty (30) general hospitals, one (1) children's hospital, six (6) chronic disease hospitals, one (1) hospice facility, five (5) psychiatric hospitals and one (1) maternity hospital.

A working group consisting of representatives from the Connecticut Hospital Association (CHA), the DPH, and other stakeholders was convened in July 2002, and functions as a subcommittee of the Quality of Health Care Advisory Committee, created in response to CGS 19a 127l-n. This group met on a regular basis to discuss the implementation of Adverse Event reporting to the DPH. CHA was provided with the opportunity to share the views of the hospital providers, review and comment on the reporting tool, related forms and DPH's proposed processes. Three formal presentations in 2002 were provided to the hospital community by DPH. All three forums were well attended by various levels of hospital personnel, such as administrators, physicians, nurses and risk managers. During 2003 the Adverse Events working group has met several times and has reported at the quarterly meetings of the Advisory Committee.

Outpatient Surgical Facilities

Currently, Connecticut licenses 20 outpatient surgical facilities. The outpatient surgical facilities that are affiliated with hospitals provided comments through the DPH/CHA workgroup and one other meeting was held to receive additional comments. One formal presentation was provided to outpatient surgical facilities.

General Information

A reporting mechanism was established at DPH to enable hospitals and outpatient surgical facilities to report Adverse Events on a twenty-four hour basis, seven days a week. DPH staff is also accessible via the Department's after hours emergency answering service (860) 509-8000.

Hospitals and outpatient surgical facilities are required to use the following standardized documents:

- Adverse Event Reporting Form: This form requires the reporting of demographic data in addition to discreet adverse event information. In order to ensure consistent reporting across facilities, directions for completing the form are also provided. (Appendix B)

- Corrective Action Plans: Forms were designed for providers to document strategies that reduce the risk of similar events. There are two corrective action plans, one for Class A, B and C events; the other for Class D events. (Appendix C)

Hospitals and outpatient surgical facilities may also use the Decision Making Model to assist them in their reporting: This document is a flow chart designed to assist the providers in determining what situations were required to be reported to the Department. (Appendix D)

The Adverse Event reporting requirements were implemented on October 1, 2002, as required by CGS 19a 127l-n.

The Distinction Between Medical Errors and Adverse Events

Not all adverse events are caused by medical errors, and not all medical errors result in adverse events. For example, if a patient with no known allergies developed an allergic reaction to a drug, it would be an adverse event but not a medical error. If a patient with a documented allergy to a drug had an allergic reaction in response to the drug, that would be an adverse event caused by a medical error. If a patient with a documented allergy to a drug was prescribed the drug, but the pharmacist detected the error and alerted the prescribing physician, who then changed the prescription, there was a medical error but no adverse event. By focusing on the National Quality Forum (NQF) list of serious reportable events, those reported are more likely to be preventable (NQF, 2002).

Unfortunately, the information routinely obtained under Connecticut's current adverse event reporting system often does not contain enough information to make this determination. The role of follow-up investigations made by Bureau of Health Care Systems staff is a critical part of the review process. Furthermore, we anticipate that some degree of medical review for reported events will always be required.

Unanticipated outcomes of medical care cannot be entirely eliminated due to our limited human knowledge and skills. With the advance of knowledge and skills, what once were considered acceptable risks and side-effects of treatment may to a later generation be considered avoidable risks and side-effects, or even errors in care. Errors considered in one generation as due to carelessness may in a later generation with more knowledge be considered reckless behavior. This progress is to be welcomed.

Status of Adverse Event Data Reporting

The adverse event data collection system is being developed in two phases, the first of which is complete. The first phase included development of a data repository and data entry tool, allowing Department of Public Health (DPH) staff to process paper reports submitted by facilities. To facilitate linkage with appropriate facility information, for reporting and analysis, the adverse event data is incorporated into tables within the DPH facility licensure system.

Concurrent with the development of this data storage system, the Connecticut Hospital Association (CHA) created a local database system that could be deployed in a hospital environment. This allows hospitals to maintain a local database of information, if desired, for their own reporting and analysis purposes. Entry of submitted reports, into the central system, is currently being performed, after review at DPH to determine whether to investigate further. Currently there is no entry backlog for Class A, B and C events, but some backlog for class D event reports (which are received shortly after the end of each quarter).

Phase two of the project addresses the desire for an automated interface between the hospital systems and the central data store at DPH. The interface will eliminate double data entry and minimize the chance for data entry errors. Initial consideration was for a World Wide Web (Web) based data entry screen allowing direct input by hospitals into the central repository. Since, however, hospitals still would like to maintain a local copy, this

solution failed to eliminate double data entry. The current design will utilize the Web as the interface but will provide a file transfer page, allowing hospitals to upload a local extract file to the central DPH repository.

Several hardware components of the solution are in place, including the mechanism for transporting data from the Web into the licensure system at DPH. Current efforts are focusing on establishing the remaining architectural components and development of the Web based file transfer page. Deployment of the new solution will likely be timed with the release of a major form revision, if one is needed. This will minimize the impact and timing of modifications to both hospital and central systems associated with file structure changes.

As with any new information system, there are some issues affecting the quality of the data set. In July 2003, a field was added to the computer database to indicate whether DPH had initiated an investigation in response to the relevant adverse event report. The backlog of D event reports is a consequence of their arrival quarterly in batches, and the fact that reports are not entered into the database until DPH has decided whether to begin an investigation.

Recommendations of the Adverse Events Working Group

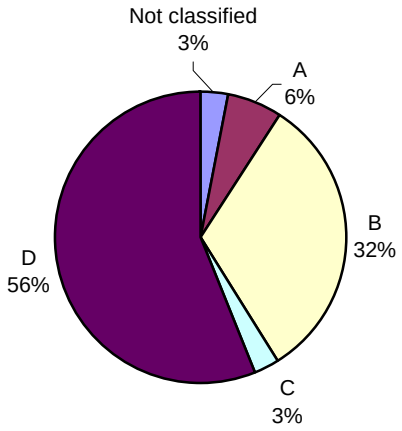
Over the last year a consensus developed among members of the Adverse Events working group that the current reporting schema was unnecessarily complicated and had ambiguous wording that was likely to reduce the reliability and comparability of adverse event reporting. Discussion in the Adverse Events working group led to recommendations that were ultimately accepted by the Quality in Health Care Advisory Committee. The details of these recommendations for simplifying and standardizing the reporting requirements are provided in Appendix E. Recently proposed legislation (SB 566) reflects these recommendations.

ADVERSE EVENT DATA

As of March 8, 2004 the DPH database contained 1359 adverse event reports. The facility types represented, by number of reports, were: general hospital (75%), outpatient surgical facility (11%), hospital for mentally ill persons (8%), chronic disease hospital (5%), and children's hospital (2%). 82% of all reports came from hospital-based facilities, and 18% from off campus satellite facilities. About 25% of patients who experienced a reported adverse event were less than 40 years of age, 25% were between 40-59, 29% were between 60-79, and 21% were 80 and older.

Class A, B, and C events are the most serious, and must be reported in writing to DPH within 72 hours. Class D events are of lesser severity and must be reported quarterly. The number and percentage of reports by event class were: A (83, 6.1%), B (435, 32.0%), C (36, 2.6%), D (763, 56.1%), and unclassified (42, 3.1%) (Figure 1). Unclassified reports represent those in which the event class was noted on the verbal report, but no event class was entered into the electronic database because the event class was not legible on the faxed written report. These data entry errors are being corrected. About half of reports with unclassified event were received during the early months, and none for events after September 2003. Upon review, the class under which an event was reported was not always correct, and a few reports did not actually concern a reportable adverse event. DPH has regularly worked to educate reporting facilities about the definitions of adverse event classes. Note that some patient sexual abuse (Class C) adverse event reports, which would seem to always be preventable, were submitted along with commentary indicating that DPH had been contacted and had determined that no reportable event occurred (e.g., because the facility was reporting abuse that occurred prior to the patient's interaction with the facility). Other reports reflected duplicate reporting of a single event. In addition, some "wrong surgery" reports indicated that the surgical procedure was modified on the operating table due to the surgeon's clinical judgment--certainly not an adverse event.

Figure 1. Adverse Event Reports by Event Class
October 1, 2002-March 8, 2004



The reported number of adverse events that occur each month, although stable over the four-month period from October, 2002, to January, 2003 (as noted in the 2003 report), experienced a decline during the following 8 months (Figure 2). Based on the DPH database as of March 8, 2004, between October 1, 2002 and September 30, 2003 dates of occurrence, the number of reported adverse events declined 54% for class D events and 63% for class A-C events. Both trends were statistically significant. The overall decline in reporting was 56%--from 136 in October 2002 to 60 in September 2003. Class D reports for the fourth quarter of 2003 arrived at DPH around January 15, 2004. They are excluded from this analysis because not all had been reviewed or entered into the database as of March 8. The number of class A-C event reports during October through December was similar to July through September 2003. Thus there was a decline in reporting over the first 12 months of the program, which appears to have stabilized at less than half the original number of monthly events.

Figure 2. Adverse Event Reports by Event Class and Month of Occurrence

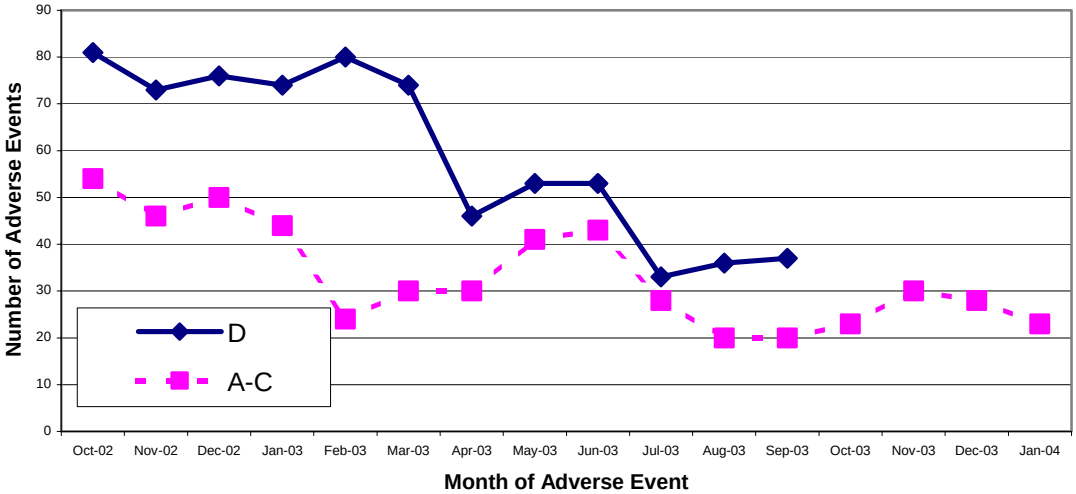


Figure 2 note: Class D events occurring between October and December 2003, reported in January 2004, are first reviewed at the Department of Public Health, and had not all been entered into the database as of March 8, 2004.

There are three possible explanations for the overall decline:

1) Decrease in the number of adverse events. This would mean that hospitals were becoming safer places for patients.
2) Decrease in the erroneous submission of reports when no reportable event took place, due to clarification of definitions. DPH believes this explanation accounts for at least some of the decline.
3) Decrease in the reporting of adverse events without a change in the occurrence of reportable adverse events. This would mean that hospitals are becoming less willing to report events that are reportable.

Under-reporting of adverse events is widely recognized in the professional literature. Barriers include fear of malpractice litigation, fear of adverse publicity, inability to identify incidents, reporting burden, lack of perceived usefulness, and unclear adverse event definitions, among others (NASHP, 2003a). While some of these reasons may be more influential than others, their relationship to Connecticut's experience remains speculative. It is possible that initial reporting in Connecticut was less than complete, and declined further. Public confusion may have occurred over the distinction between adverse events and medical errors, and between mandatory reporting systems for accountability and voluntary reporting systems for learning.

RESPONSE OF THE DEPARTMENT OF PUBLIC HEALTH

Response to Adverse Event Reports

The Department of Public Health determines, after screening an adverse event report, 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. Investigations are initiated in about half the class A-C event reports received, and a smaller percentage of class D events. 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. This is a critical phase in the process since it can identify events that were due to medical error, and because the results of these investigations are available to the public, upon request, under the Freedom of Information Act. The patient or family is contacted during and after completing the investigation. If later contact by family or patient brings a new issue to light, the case may be reopened.

Response to Recommendations of the Adverse Events Working Group

The DPH and its partners are taking steps to improve adverse event reporting and reduce medical errors. In 2003 the Adverse Events working group of Connecticut's Quality in Healthcare Advisory Committee made eight recommendations (see Appendix E), of which seven were adopted by the Advisory Committee, while the recommendation concerning the confidentiality of reports was later reworked to the satisfaction of the Committee (see below).

The National Quality Forum (NQF) released a list of Serious Reportable Events, to promote standardized reporting across states. Events on the list were selected because they were more likely to be preventable. The Adverse Events working group and Advisory Committee have recommended that Connecticut adopt the NQF list (Appendix E). Adoption of the NQF list will address possible under-reporting or misreporting caused by

unclear definitions. Extension from 72 hours to 7 days, of the time within which what are presently A, B, and C written reports must be submitted, allows for more accurate reporting.

The working group and Advisory Committee recommended adding 5-6 Connecticut-specific events to the reporting requirement, to capture events of significance and frequent reporting in the first year of Connecticut's experience. This dovetails with the National Academy for State Health Policy observation (NASHP, 2003b) that the NGF list is not all encompassing, but will be useful for cross-state comparisons. The Advisory Committee also accepted the recommendation that a check box be added to the report form to attest to the fact that the patient had been informed of the adverse event, in order to ensure accountability.

The Advisory Committee approved a recommendation for the creation of a Patient Safety Organization separate from regulatory oversight, to collect near miss and other patient safety information.

After meeting in January 2004, the Adverse Events working group and Advisory Committee recommended that the confidentiality of adverse event reports be protected, while maintaining the availability of the adverse event investigation results through the Freedom of Information Act. This measure would ameliorate possible under-reporting that can be caused by fear of unfavorable publicity or of lawsuits, while achieving public accountability.

Participation in Patient Safety Improvement Corps

A Patient Safety Improvement Corps consisting of four DPH and Connecticut Hospital Association (CHA) members is participating in training conducted by the Veterans Administration National Center for Patient Safety (VA NCPS) and AHRQ. As part of this training the Connecticut team is seeking ways to improve the adverse event reporting process. On March 12, 2004, CHA and Qualidigm sponsored a Patient Safety Summit for Connecticut's healthcare leaders, which included speakers from the VA NCPS.

EXTERNAL FACTORS AFFECTING ADVERSE EVENT REPORTING

A number of external factors affect the volume and quality of adverse event reporting. A detailed discussion of these factors is beyond the scope of this report. Nevertheless, identifying some of them helps to place current DPH activities in a larger context. External factors include: improving the patient safety culture in hospitals; the role of confidentiality protection in adverse event reporting; finding optimal methods for disclosing adverse events to patients; and barriers to making the business case for safety.

Improving the Patient Safety Culture in Hospitals

In the opinion of patient safety expert Dr. Lucian Leape, the greatest impediment to error prevention is that we punish people for making mistakes. As a result, only a small percentage of major errors are thought to be reported through US hospital reporting systems (Marx, 2001).

The AHRQ report on its Patient Safety Initiative (AHRQ, 2003) notes that the predominant patient safety culture in US hospitals does not adequately reconcile the demand for professional accountability and the need to create a safe environment to report medical errors. The report also suggests that improvements in adverse event reporting could be obtained with a shift toward a more just patient safety culture in which disciplinary action is reserved for errors resulting from reckless behavior. In the aviation industry for example, there have been large increases in error reporting, and corresponding safety gains, through creating climates in which mistakes can be reported without penalty.

Adverse Events, Medical Errors, and Confidential Reporting

The IOM report To Err is Human (IOM, 2000) recommends that information about errors not associated with serious harm be protected from all uses not connected with safety improvement, including uses requiring access to information by such methods as subpoena, legal discovery, and the Freedom of Information Act. The recommended protection of information about "lesser harms" is consistent with recent recommendations made by the Adverse Events working group for handling the less serious class-D events. The workgroup recommended that the NQF list of serious adverse events plus a short list of CT-specific events be reportable to the state, while events of lesser harm be reportable to a Patient Safety Organization. This would have the effect of making confidential what are currently some class D events, and near misses not now reported, unless separate requirements exist to report them to DPH. The proposed confidential reporting of class D events is intended to improve the reporting of these events, and in turn allow providers to identify more opportunities to improve patient safety.

Adverse Event and Medical Error Disclosure to Patients

As detailed in the Best Practices working group report, Recommendations for Best Practices of Medical Care in Connecticut Hospitals (DPH, 2003), many national and state organizations now require hospitals to take steps to improve patient safety and avoid adverse events. Physicians and other providers have an ethical responsibility to inform patients when they have been harmed as a result of a medical error or due to an unanticipated adverse event (Sharpe, 2003). However, information is limited about how to disclose errors to patients. The circumstances of such disclosure may be complicated in some cases. For example, the physician caring for a patient may not know of the error, but may be expected by other members of the health care team to make the disclosure (Hobgood et al, 2004). This presents a challenge for hospitals in developing policies regarding adverse event disclosures to patients. A medical errors disclosure bibliography is posted on the JCAHO website (www.jcaho.org).

Making the Business Case for Safety

Adverse events related to medical care may lead to additional length of stay and costs in hospitals, lost productivity among the injured, as well as preventable deaths. In a few instances, the business case for safety can be made under present payment schemes. For example, the use of adjunctive devices to confirm the placement of tracheal intubations has been shown to save money in the VA healthcare system, where there is a 6.5% rate of unanticipated esophageal intubation (the tube intended to lead to the lungs mistakenly leads to the stomach). Mistaken tube placement increases medical costs by $25,000 per incident, and the VA system pays $427,000 on related tort claims annually. The adjunctive device costs $10 per one-time use. A savings of $4.55 would be realized for every $1.00 spent on adjunctive devices (VA 2004).

More often, the financial costs to improve safety fall upon those rendering care, while the financial savings accrue to insurers. For example, if a patient develops an infection while hospitalized for another condition, the hospital will be paid to treat the infection. However, if the hospital spends more on equipment by switching to single-use IV flush vials, decreasing its hospital-acquired infection rate, hospital revenue will decrease and the savings will go to insurance companies. This barrier appears to slow implementation of cost-effective patient safety improvements. Removal of this barrier requires a realignment of payments to reward those who make improvements, or at least afford them equal compensation (Leatherman, 2003). The Institute for Healthcare Improvement (Gosfield and Reinertsen, 2003) offers tips on improving the business case for quality.

FUTURE PLANS

1. If modifications to CGS 19a 127l-n are made in the current legislative session, DPH will implement them. This would include revising the adverse event reporting form.

2. Contingent upon the implementation of #1, DPH plans to implement electronic, web-based adverse event reporting.

APPENDICES

APPENDIX A
CGS 19a-127l-n

CGS 19a-127l-n

AN ACT CREATING A PROGRAM FOR QUALITY IN HEALTH CARE.

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

Section 1. (a) There is established a quality of care program within the Department of Public Health. The department shall develop for the purposes of said program (1) a standardized data set to measure the clinical performance of health care facilities, as defined in section 19a-630 of the general statutes, and require such data to be collected and reported periodically to the department, including, but not limited to, data for the measurement of comparable patient satisfaction, and (2) methods to provide public accountability for health care delivery systems by such facilities. The department shall develop such set and methods for hospitals during the fiscal year ending June 30, 2003, and the committee established pursuant to subsection (c) of this section shall consider and may recommend to the joint standing committee of the General Assembly having cognizance of matters relating to public health the inclusion of other health care facilities in each subsequent year.

(b) In carrying out its responsibilities under subsection (a) of this section, the department shall develop the following for the quality of care program:

(1) Comparable performance measures to be reported;

(2) Selection of patient satisfaction survey measures and instruments;

(3) Methods and format of standardized data collection;

(4) Format for a public quality performance measurement report;

(5) Human resources and quality measurements;

(6) Medical error reduction methods;

(7) Systems for sharing and implementing universally accepted best practices;

(8) Systems for reporting outcome data;

(9) Systems for continuum of care;

(10) Recommendations concerning the use of an ISO 9000 quality auditing program;

(11) Recommendations concerning the types of statutory protection needed prior to collecting any data or information under this act; and

(12) Any other issues that the department deems appropriate.

(c) 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.

(d) The advisory committee shall consist of (1) four members who represent and shall be appointed by the Connecticut Hospital Association, including three members who represent three separate hospitals that are not affiliated of which one such hospital is an academic medical center; (2) one member who represents and shall be appointed by the Connecticut Nursing Association; (3) two members who represent and shall be appointed by the Connecticut Medical Society, including one member who is an active medical care provider; (4) two members who represent and shall be appointed by the Connecticut Business and Industry Association, including one member who represents a large business and one member who represents a small business; (5) one member who represents and shall be appointed by the Home Health Care Association; (6) one member who represents and shall be appointed by the Connecticut Association of Health Care Facilities; (7) one member who represents and shall be appointed by the Connecticut Association of Not-For-Profit Providers for the Aging; (8) two members who represent and shall be appointed by the AFL-CIO; (9) one member who represents consumers of health care services and who shall be appointed by the Commissioner of Public Health; (10) one member who represents a school of public health and who shall be appointed by the Commissioner of Public Health; (11) one member who represents and shall be appointed by the Office of Health Care Access; (12) the Commissioner of Public Health or said commissioner's designee; (13) the Commissioner of Social Services or said commissioner's designee; (14) the Secretary of the Office of Policy and Management or said secretary's designee; (15) two members who represent licensed health plans and shall be appointed by the Connecticut Association of Health Care Plans; (16) one member who represents and shall be appointed by the federally designated state peer review organization; and (17) one member who represents and shall be appointed by the Connecticut Pharmaceutical Association. The chairperson of

the advisory committee shall be the Commissioner of Public Health or said commissioner's designee. The chairperson of the committee, with a vote of the majority of the members present, may appoint ex-officio nonvoting members in specialties not represented among voting members. Vacancies shall be filled by the person who makes the appointment under this subsection.

(e) The chairperson of the advisory committee may designate one or more working groups to address specific issues and shall appoint the members of each working group. Each working group shall report its findings and recommendations to the full advisory committee.

(f) The Commissioner of Public Health shall report on the quality of care program on or before June 30, 2003, and annually thereafter, in accordance with section 11a-4 of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health and to the Governor. Each report on said program shall include activities of the program during the prior year and a plan of activities for the following year.

(g) On or before April 1, 2004, the Commissioner of Public Health shall prepare a report, available to the public, that compares all licensed hospitals in the state based on the quality performance measures developed under the quality of care program.

(h) The Department of Public Health may seek out funding for the purpose of implementing the provisions of this section. Said provisions shall be implemented upon receipt of said funding.

Sec. 2. All hospitals, licensed pursuant to provisions of the general statutes, shall be required to implement performance improvement plans. Such plans shall be submitted on or before June 30, 2003, and annually thereafter by each hospital to the Department of Public Health as a condition of licensure.

Sec. 3. (a) 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.

(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 subdivision.

(c) On and after October 1, 2002, a hospital or outpatient surgical facility shall report 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 written report not later than seventy-two hours after the adverse event occurred; and (3) a corrective action plan shall be filed not later than seven days after the adverse event occurred.

(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 of the general statutes.

(e) The Commissioner of Public Health shall adopt regulations, in accordance with chapter 54 of the general statutes, to carry out the provisions of this section. Such regulations shall include, but shall not be limited to, a prescribed form for the reporting of adverse events pursuant to subsections (c) and (d) of this section. The commissioner may require the use of said form prior to the adoption of said regulations.

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

(g) Information collected pursuant to this section shall not be required to be disclosed pursuant to subsection (a) of section 1-210 of the general statutes, for a period of six months from the date of submission of the written report required pursuant to subsection (c) of this section and 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.

APPENDIX B
Part I - Adverse Event Reporting Form (Directions for Use)

Part II - Adverse Events Reporting Form

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITALS/OUTPATIENT SURGICAL FACILITIES
DIRECTIONS FOR USE

On and after October 1, 2002, a hospital or outpatient surgical facility shall report to the Department of Public Health (DPH) on all Class A, B and C and D adverse events as follows:

1. VERBAL REPORTS:

Verbal reports shall be made to DPH not later than twenty-four (24) hours after a Class A, B or C adverse event occurred. (Note: Class D reports do not require a verbal report).

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

Emergent reports: Should the institution deem the situation to be emergent in nature the reporter should 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.

Non-emergent reports: Events may be reported directly on the DPH Adverse Event Reporting line: (888) 519-2400 (toll free line). This line has voice mail capacity. Department staff will retrieve these verbal reports throughout the day.

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.

Non-emergent reports: Events may be reported directly on the Department's Adverse Event Reporting line: (888) 519-2400 (toll free line). This line has voice mail capacity. Department staff will retrieve these verbal reports on a regular basis.

2. CONTENT OF VERBAL REPORTS

Verbal reports recorded on the adverse event reporting line shall contain the following information:

i) Facility name and address.
ii) Sequential report number.
iii) Contact person and telephone number where said person can be reached for additional information, if necessary.
iv) Date and time verbal report is being recorded.
v) Patient's billing number.
vi) Date and time event occurred.
vii) Notification of the Medical Examiner's Office, if applicable.
viii) Brief summary of the event and patient's condition.
ix) Class of adverse event (i.e., A, B, or C).

The contents of the verbal reports are highlighted on the adverse event reporting form.

3. WRITTEN REPORTS

A written report shall be submitted on an approved form to the Department, within seventy-two (72) hours after the occurrence of any adverse events classified as an A, B and C. (see form AE #1).

DIRECTIONS AND DEFINITIONS FOR USE OF FORM AE#1

a) "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 include sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations.

b) "Disabilities" means any weakening, impairment or destruction of a patient's physical, mental or cognitive status which was not a foreseeable effect of the patient's planned treatment regime or was not related to the natural course of the patient's illness or underlying condition(s).

c) "Foreseeable effect" means an expected or anticipated outcome due to an individual patient's clinical presentation and/or underlying condition(s).

d) "Immediate Danger" means an adverse event has the potential to directly and in the near future, place a patient at risk for death, serious injury or disability.

e) "Medical Management" means to assess, direct, provide, control, or supervise the care and services provided to a patient, either directly or indirectly.

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) Verbal Report to DPH: Date, time and name of individual that filed the verbal class A, B, or C report.

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

f) 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 and 3

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.

d) Adverse Event: Check one classification only (A, B, C, or D).

Medical/General and Surgical/Anesthesia Events Pages 4-7

Check all the boxes that apply to the discrete event.
Example: A patient is administered chemotherapeutics in a higher dose than that ordered by the physician due to an infusion pump malfunctioning. The form would indicate the following:

Infusion Pump	Substance Administration Events	Event Associated with:
☒ Equipment malfunction	Product	☐ Omission
☐ Programming Error	☒ Chemotherapeutic	☒ Dose/quantity
☐ Component incompatibility	☐ Dietary	☐ Patient identification
☐	☐ Electrolytes	☐ Preparation
Other_____	☐ Fluids	☐ Product
	☐ Medical Gases	☐ Rate of administration
	☐ Medications	☐ Route of administration___
	☐ Treatments	☐ Time of administration___
	☐ Other_____	☐ Other_____

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

This report is to include all Adverse Events and is not limited to the categories noted in this reporting tool. Categories labeled "other" have been included for this purpose.

4. CORRECTIVE ACTION PLAN (CAP)

a) A CAP shall be filed for each Class A, B, and C adverse event not later than seven (7) 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 timelines 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. 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.
viii. Time line for implementation: Identify the date that the components of the CAP are to be initiated.
ix. Completion date for CAP: Identify the date that all components of the plan have been completed.
x. 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.
xi. 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

5. CLASS D EVENTS

a) All Class D adverse events shall be forwarded to the Department on a quarterly basis, on the form approved by the Department. Each event shall be accompanied by a corrective action plan. One corrective action plan may address multiple adverse events of a similar nature (e.g. medication administration).

b) Class D adverse reporting quarters are as follows:
- ✓ January, February, March
- ✓ April, May, June
- ✓ July, August, September
- ✓ October, November, December

c) Reports are to be submitted 10 working days following the closure of each quarter.

6. 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 means, 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.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM

DEMOGRAPHIC DATA

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:		

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number _____

DEMOGRAPHICS – Hospitals Only

☐ In Patient ☐ Hospital Based ☐ Off Campus Satellite Site Name:_____ Address_____	☐ Out Patient ☐ Hospital Based ☐ Off Campus Satellite Site Name:_____ Address_____
LOCATION OF OCCURENCE: ☐ Acute Intensive Care ☐ Medical Intensive Care ☐ Neonatal Intensive Care ☐ Surgical Intensive Care Unit ☐ Other _____ ☐ Adult Medical ☐ Adult Surgical ☐ Ambulatory Surgical ☐ Cardiac Cath Lab ☐ Cardiac Care ☐ Dialysis ☐ Emergency Department ☐ Neurological Services ☐ Neurosurgical ☐ Nursery	☐ Obstetrical /Gynecological ☐ Oncology Care ☐ Operating Room ☐ Orthopedics ☐ Outpatient Services - Specify Type _____ ☐ Palliative Care ☐ Pediatrics ☐ Psychiatric ☐ Diagnostic Services – Specify Type: _____ ☐ Rehabilitative Services – Specify Type: _____ ☐ Respiratory ☐ Other_____

NOTIFICATIONS:

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: ☐ Center for Medicare/Medicaid Services ☐ Department of Children and Families ☐ Food and Drug Administration ☐ Joint Commission on the Accreditation of Health Care Organizations	☐ 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

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number
_____

Following the adverse event:

1. Was the patient's anticipated stay extended? Y ☐ N ☐ Not Determined ☐
2. Was the patient transferred to another health care facility for treatment? Y ☐ N ☐
3. Was the hospitalized patient transferred to a more intensive level of care within the hospital? Y ☐ N ☐

Was the patient discharged prior to identification of the event? Y ☐ N ☐

If yes, did the patient return for treatment? Y ☐ N ☐ Date :_____

Facts of Event and Status of Patient Condition: _____

FOR DPH USE ONLY

Date Report Received- Verbal	
Date Report Received- Written	
Date Corrective Action Plan Received:	

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number
_____

CLASSIFICATION DATA

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

Please check applicable class of event:

☐ Class A: An event that has resulted in or is associated with a patient's death or the immediate danger of death

☐ Class B: 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

☐ Class C: An event that has resulted in or is associated with the physical or sexual abuse of a patient.

Class A, B, & C events require a verbal report to DPH no later than twenty-four (24) hours after the event occurred and a written report within seventy two (72) hours after its occurred.

☐ Class D: An event that is not class A, B, or C. Class D events are reported on a quarterly basis only.
Note: Verbal reports are not required for Class D Events

MEDICAL/GENERAL EVENT

Event associated with:

- ☐ Diagnosis
- ☐ Lack of treatment
- ☐ Hemorrhage (over 15% of circulating blood volume loss)
- ☐ Obstetrical event
- ☐ Restraints
- ☐ Seclusion
- ☐ Nosocomial Malnutrition
- ☐ Nosocomial Dehydration
- ☐ Nosocomial Infections
- ☐ Other_____

Organism
_____

Location of Infection
_____

Is this a surgical site: ☐Y ☐N

Device/Equipment Event

- ☐ Equipment Type:
  _____
- ☐ Patient Implant Type:
  _____
  - ☐ Internal
  - ☐ External
- ☐ Other_____

Alarm

- ☐ Malfunction
- ☐ Disconnected
- ☐ Not audible to staff
- ☐ Other _____

Infusion Pump

- ☐ Equipment malfunction
- ☐ Programming Error
- ☐ Component incompatibility
- ☐ Other_____

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number
_____

MEDICAL/GENERAL EVENT

Substance Administration Events
Product
- ☐ Chemotherapeutic
- ☐ Dietary
- ☐ Electrolytes
- ☐ Fluids
- ☐ Medical Gases
- ☐ Medications
- ☐ Treatments
- ☐ Other_____

Event Associated with:
- ☐ Omission
- ☐ Dose/quantity
- ☐ Patient identification
- ☐ Preparation
- ☐ Product
- ☐ Rate of administration
- ☐ Route of administration_____
- ☐ Time of administration_____
- ☐ Other_____

Adverse Drug/Biological Reaction
- ☐ Anaphylactic Shock
- ☐ Allergic response
- ☐ Other_____

Poisoning
- ☐ Drug
- ☐ Food
- ☐ Chemicals
- ☐ Other _____

Physical Accidents
- ☐ Observed by staff
- ☐ Unobserved by staff
- ☐ Other_____

Burn
- ☐ 1st degree; _____% of body surface area
- ☐ 2nd degree; _____% of body surface area
- ☐ 3rd degree; _____% of body surface area

☐ Patient neglect (circumstance not documented under another category)

☐ Suicide while in the facility

☐ Attempted Suicide while in the facility

Use of Substances/Products:
- ☐ Contaminated/Infected
- ☐ Related to storage or maintenance
- ☐ Outdated
- ☐ Other_____

Types:
- ☐ Blood
- ☐ Biologic
- ☐ Drugs
- ☐ Device
- ☐ Fluids
- ☐ Gases
- ☐ Other_____

☐ Administration of ABO-incompatible blood or blood products

☐ Electric Shock

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number
_____

MEDICAL/GENERAL EVENT

Intra-Vascular Embolism ☐ Air ☐ Blood ☐ Fat ☐ Foreign body ☐ Other_____ Decubitus Developed after admission: ☐ Stage II ☐ Stage III ☐ Stage IV Laboratory test event associated with ☐ Omission ☐ Results ☐ Patient identification ☐ Mislabeled specimen ☐ Other_____ ☐ Elopement	Patient Abuse ☐ Sexual molestation ☐ Rape ☐ Physical Assault ☐ Sexual relations involving two patients one of which is 15 years old or younger ☐ Other_____ ☐ Abduction of a patient of any age ☐ Discharge of an infant to the wrong guardian/parent ☐ Infant given to wrong guardian/parent within hospital ☐ Other:_____

SURGICAL/ANESTHESIA EVENT

Identify procedure that was performed (e.g. appendectomy): _____ Length of time in Surgery _____hours _____minutes Surgical procedure associated with ☐ Patient identification ☐ Site on a patient ☐ Surgical procedure ☐ Unexpected retention of a foreign object in a patient post closure ☐ Implantation of wrong device ☐ Other_____	Open Surgical Procedures ☐ Perforation ☐ Trauma ☐ Hemorrhage (over 15% of circulating blood volume loss) ☐ Dehiscence ☐ Laceration ☐ Other_____ Anesthesia procedure ☐ Endotracheal tube placement ☐ Airway obstruction ☐ Aspiration ☐ Other_____

DEPARTMENT OF PUBLIC HEALTH
ADVERSE EVENT REPORTING FORM
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number
_____

SURGICAL/ANESTHESIA EVENT

☐ Cardiac or respiratory arrest - Patient requiring resuscitation during a procedure or within 24 hours of a procedure

Resuscitation Procedures
- ☐ Fractures
- ☐ Burns
- ☐ Trauma/Injury
- ☐ Other_____

Endoscopic Procedures
- ☐ Perforation
- ☐ Trauma
- ☐ Hemorrhage (over 15% of circulating blood volume loss)
- ☐ Unplanned conversion to an open procedure
- ☐ Other_____

Biopsy Procedures
- ☐ Perforation
- ☐ Trauma
- ☐ Hemorrhage (over 15% of circulating blood volume loss)
- ☐ Other_____

Type of Anesthesia
- ☐ General
- ☐ Spinal
- ☐ Regional
- ☐ Local
- ☐ Sedation
- ☐ Other_____

Anesthesia Event Associated with:
- ☐ Dose
- ☐ Preparation
- ☐ Product
- ☐ Rate
- ☐ Route of administration
- ☐ Patient identification
- ☐ Other_____

☐ Other_____

APPENDIX C
Corrective Action Plans

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
Hospital and Outpatient Surgical Facility
Corrective Action Plan (CAP)
Adverse Event

Facility:	Sequential Report Number for which this plan is being submitted:
	Date of Event
Patient Billing Number:	Date CAP Submitted
Events being addressed:	
Corrective Action Plan to prevent reoccurrence: Attach additional information if necessary	
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:

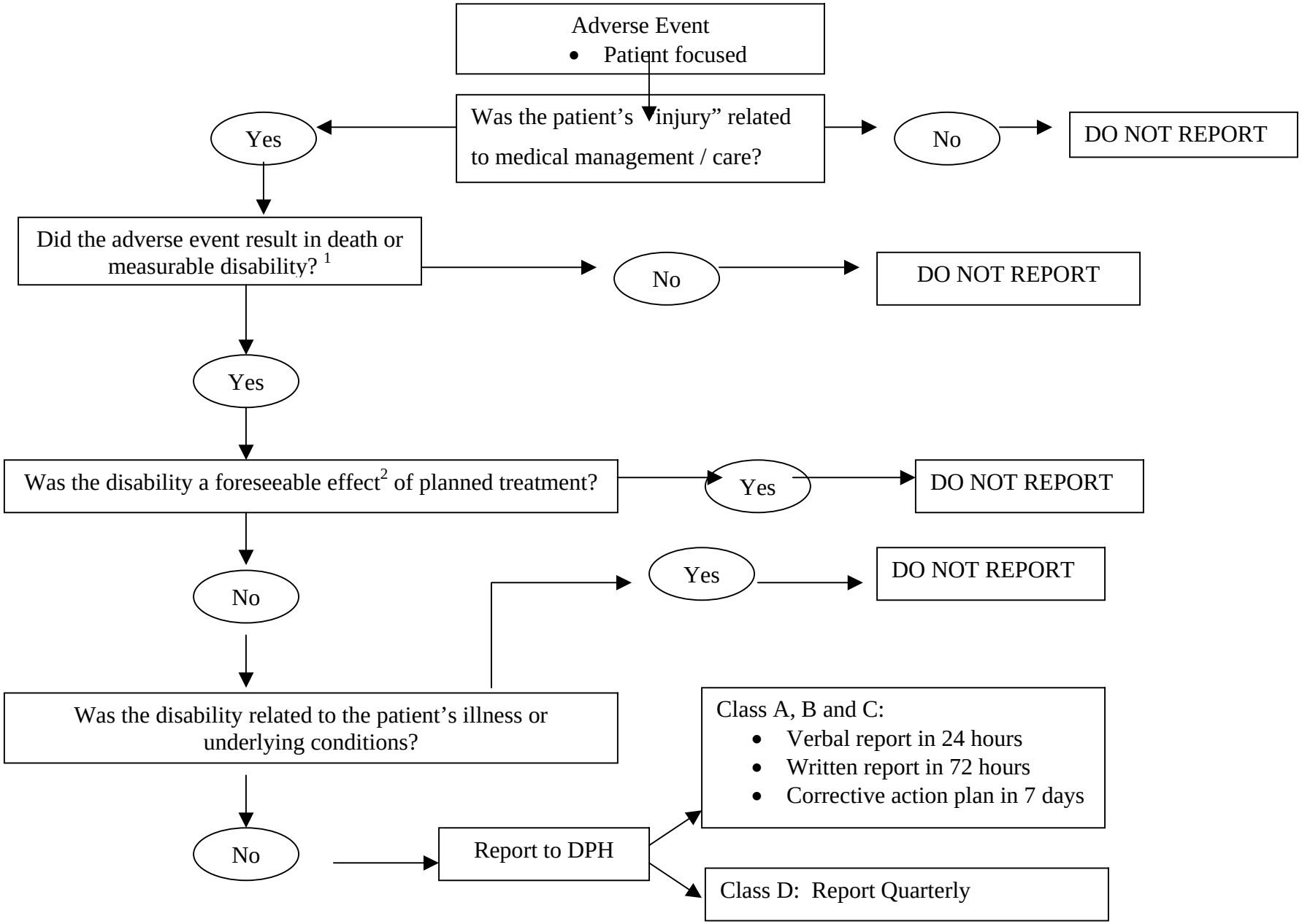
STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
Hospital and Outpatient Surgical Facility
Corrective Action Plan (CAP)
Class "D" Adverse Events

<table>
<tr><td>Facility:</td><td rowspan="3">Sequential Report Number(s) for which this plan is being submitted:</td></tr>
<tr><td>Quarter _____
Year _____</td></tr>
<tr><td>Date CAP Submitted</td></tr>
<tr><td colspan="2">Events being addressed:</td></tr>
<tr><td colspan="2">Corrective Action Plan to prevent reoccurrence:

Attach additional information if necessary</td></tr>
<tr><td>Time line for implementation:</td><td>Completion date for CAP:</td></tr>
<tr><td colspan="2">Identification of staff member, by title, who has been designated the responsibility for monitoring CAP implementation:</td></tr>
<tr><td>Submitted by:</td><td>Date:</td></tr>
</table>

APPENDIX D
Decision Making Model Chart



[1] Disability means any weakening, impairment or destruction of a patient's physical, mental or cognitive status (may be brief or lengthy)
[2] Foreseeable effect means an expected or anticipated outcome due to an individual patient's clinical presentation and/or underlying condition(s).

APPENDIX E

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

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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

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(http://www.acponline.org/journals/ecp/novdec00/weeks.htm)

2002 National Quality Forum Report

"Serious Reportable Events in Healthcare"

EVENT	ADDITIONAL SPECIFICATIONS
1. SURGICAL EVENTS A. 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.** Surgery includes endoscopies and other invasive procedures.
B. 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.
C. 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.
D. 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.
E.Intraoperative or immediately post-operative death in an ASA 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 A. 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.
B. 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.
C. 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 A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. 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 A. 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.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	

C. 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.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinimia in neonates	Hyperbilirubinimia is defined as bilirubin levels >30mg/dl. Neonates refers to the first 28 days of life.
F. 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.
G. Patient death or serious disability due to spinal manipulative therapy	
5. ENVIRONMENTAL EVENTS A. 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.
B. 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	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	
D. Patient death associated with a fall while being cared for in a healthcare facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of a healthcare facility	
D. 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	

APPENDIX F
Draft of Proposed Regulations

STATE OF CONNECTICUT
REGULATION
OF
Department of Public Health
Name of Agency

Concerning
Adverse Event Reporting for Hospitals and Outpatient Surgical Facilities
SUBJECT MATTER OF REGULATION

SECTION ____

The Regulations of Connecticut State Agencies are amended by adding section 19a-XXX-1 as follows:

(NEW) Section 19a-XXX-1. Definitions. As used in section 19a-XXX-1 to section 19a-XXX-X-2, inclusive of the Regulations of the Connecticut State Agencies:

(1) "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 include sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations;

(2) "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;

(3) "Disabilities" means any weakening, impairment or destruction of a patient's physical, mental or cognitive status which was not a foreseeable effect of the patient's planned treatment regime or was not related to the natural course of the patient's illness or underlying condition;

(4) "Foreseeable effect" means an expected or anticipated outcome due to an individual patient's clinical presentation or underlying condition;

(5) "Healthcare provider or staff person" means, 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;

(6) "Immediate Danger" means an adverse event has the potential to directly and in the near future, place a patient at risk for death or serious injury or disability;

(7) "Medical Management" means to assess, direct, provide, control, or supervise the care and services provided to a patient, either directly or indirectly;

(8) "Commissioner" means the Commissioner of Public Health;

(9) "Department" means the department of public health;

(10) "Health Care Facility" means any hospital or outpatient surgical facility licensed pursuant to section 19a-490 of the Connecticut General Statutes;

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

(12) "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;

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

(14) "Class D adverse event" means an adverse event that is not reported as a class A, B or C adverse event.

(NEW) Section 19a-XXX-2. Procedures for adverse event reporting.

(a) Adverse events and corrective action plans shall be documented and submitted in the format prescribed by the Commissioner.

(b) All documentation of adverse events shall be maintained for not less than five (5) years and shall be made accessible to the department upon request.

(c) Class A, B, and C adverse events shall be reported by a health care facility to the department as follows:
(1) A verbal report shall be made not later than twenty-four (24) hours after the adverse event has occurred or immediately if the event is discovered more than twenty-four (24) hours after its occurrence;
(2) A written report shall be made not later than seventy-two hours after the adverse event occurred;
(3) A corrective action plan shall be filed not later than seven days after the adverse event occurred.

(d) Class D adverse events shall be reported by a health care facility to the department as follows:
(1) Written reports shall be submitted quarterly by the tenth (10^{th}) working day in the months of January, April, July and October;
(2) Such reports shall include corrective action plans. One corrective action plan may address multiple class D adverse events of a similar nature.

(e) Each facility shall have a mechanism in place to provide the department with the patient's name, physician's name, including the attending physician of record and the name of any other healthcare provider or staff member involved in or with first-hand knowledge of each event. This information shall be available to department representatives twenty-four (24) hours a day, seven (7) days a week.

(f) Numbering. Each report shall be identified on each page with a number as follows:
(1) the number appearing on the facility license; and
(2) the last two digits of the year and the sequential number of the report during each calendar year.

(g) Subsequent reports. Subsequent reports relevant to any adverse event shall be submitted as often as is necessary to inform the department of significant changes in the status of affected individuals or changes in material facts originally reported. Such reports shall be attached to a photocopy of the original adverse event report.

Statement of Purpose: To enact Section 3 (e) of Public Act 02-125 which requires the Commissioner to codify an adverse event reporting form and system in regulations.

APPENDIX G
References

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