

Keeping Connecticut Healthy

REPORT TO THE GENERAL ASSEMBLY

AN ACT CREATING A PROGRAM FOR QUALITY IN HEALTH CARE

JUNE 2006

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Report to the General Assembly June 30, 2006

An Act Creating a Program for Quality in Health Care

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ANNUAL REPORT

JUNE 30, 2006

I. INTRODUCTION and BACKGROUND

Connecticut General Statutes section 19a-127l-n requires the Department of Public Health (DPH) to establish a quality of care program for health care facilities. This legislation also directs DPH to develop a health care quality performance measurement and reporting system initially applicable to the state's hospitals. Other health care facilities may be included in the quality program in later years as it develops. An advisory committee, chaired by the DPH commissioner or designee, advises the program.

Responsibility for the quality of care program within DPH lies with the Health Care Systems Branch and, in the Planning Branch, with the Health Care Quality, Statistics, Analysis, and Reporting (HCQSAR) section.

In compliance with the reporting requirement in the statute, the current report describes the activities of the quality of care program over the past year, as of June 30, 2006. In addition to this report, DPH submitted the fourth adverse event report to the General Assembly (dated October 2005), and second hospital performance comparisons report (dated February 2006).

Public Act 05-167 amended CGS §19a-127l(c)(2) in 2005 to require the Quality in Health Care Advisory Committee to examine and evaluate possible approaches that would aid in the utilization of an existing data collection system for cardiac outcomes, and the potential for statewide use of a data collection system for cardiac outcomes, for the purpose of continuing the delivery of quality cardiac services in the state. To meet this requirement, in the fall of 2005 the Advisory Committee created a subcommittee on cardiac care. The subcommittee and working groups as of June 30, 2006 are:

Sub-Committee

- 1. Health Promotion and Illness Prevention
- 2. Physician Profiles
- 3. Continuum of Care
- 4. Regulations
- 5. Settlement Agreements/Tort Reform
- 6. Promotion of Quality and Safe Practices

Working Group I Hospital Performance Comparisons Working Group II Patient Satisfaction Survey

- 7. Best Practices and Adverse Events
- 8. Legislative
- 9. Cardiac Care

DPH staff members were assigned to co-chair the numerous subcommittees and working groups. The continuum of care, legislative, and tort reform subcommittees have not met this year and are therefore not discussed in this report.

Recent Connecticut Legislation

Public Act 05-167, *An Act Concerning the Improvement of Cardiac Care*, passed the Connecticut General Assembly and was signed into law by the governor on July 1, 2005 (Appendix B of the June 2005 Quality in Health Care report). This act directs the Quality in Health Care Advisory Committee to examine and evaluate possible approaches that would aid in the utilization of an existing data collection system for cardiac outcomes, and the potential for statewide use of a data collection system for cardiac outcomes, for the purpose of continuing the delivery of quality cardiac services in the state. The bill became effective October 1, 2005 and requires the Advisory Committee to submit a report by December 1, 2007.

Public Act 05-272, An Act Concerning Revisions to Department of Public Health Statutes, passed the General Assembly and was signed into law on July 13, 2005. At section 30 (Appendix C of the June 2005 Quality in Health Care report), the act amended subsection (c) of section 19a-127l of the Connecticut General Statutes, to require the standing committee on best practices, to: (B) not later than January 1, 2006, review and make recommendations concerning best practices with respect to when breast cancer screening should be conducted using comprehensive ultrasound screening or mammogram examinations.

II. Quality in Health Care Advisory Committee and Subcommittee Activities

Advisory Committee

The Quality in Health Care Advisory Committee (QHCAC) held four meetings this past year in July 2005, October 2005, January 2006, and April 2006. Much of the work was divided among several subcommittees and working groups. A synopsis of current year activities and plans for next year is provided below for each of the subcommittees.

Subcommittee on Health Promotion and Illness Prevention

During the 2006 legislative session, continuing education requirements were mandated as a condition of license renewal for two additional professions, respiratory care practitioner and radiological technologists.

The subcommittee continues to research current restraint practices used on pediatric patients and the issue of informed consent in the use of restraints. The subcommittee is completing research for a survey of dentists licensed in Connecticut regarding restraint practices currently used on pediatric patients and how they address the issues of informed consent in the use of restraints.

Subcommittee on Physician Profiles

Discussions concerning the implementation of Public Act 05-275, An Act Concerning Medical Malpractice, continued over the past year. In light of the many changes to the physician profile reporting requirements that were included in P.A. 05-275 and a subsequent decision that no other changes should be made to physician profiles at this time, the focus of this subcommittee has shifted toward addressing issues related to physician competence.

Assuring the ongoing competence of physicians has been identified as a major challenge at the national level, and as a result, there are several national initiatives related to physician accountability and competence. This subcommittee will continue to monitor these initiatives to determine the impact any resulting recommendations will have on physicians in Connecticut.

The Department of Public Health and the Connecticut Medical Examining Board have developed penalty guidelines for use in the physician disciplinary process. The guidelines provide a standardized mechanism for considering the scope and severity of a violation as well as mitigating or other factors in determining an appropriate sanction.

Mandatory continuing education requirements and the need for specific educational offerings, for example programs aimed at coordinating services and strengthening communication among providers of health care services to special needs clients, continue to be discussed.

Subcommittee on Regulations

The Department in conjunction with representatives from the Connecticut Hospital Association (CHA) has reviewed the recommendations of the hospital community and drafted revisions to the regulations governing hospitals. The Department believes that the revisions were necessary and reflect current standards for acute care settings that will benefit the consumers of health care services. A public hearing was held on February 22, 2006 in response to infection control practitioners who voiced opinions regarding the proposed changes in the area of infection control. The Department has revised the regulations to reflect many of the concerns expressed and will submit the proposed changes for regulatory review. The Adverse Event Regulations and Influenza and Pneumoccocal Polysaccharide Vaccine Regulations required by P.A. 04-164 have also been approved.

Subcommittee on Promotion of Quality and Safe Practices

Working Group I: Hospital Performance Comparisons

Working Group I met in April 2006 to discuss public reporting for quality of care in Connecticut subsequent to the release of the second Hospital Performance Comparisons Report produced by DPH in February 2006. The Group reviewed DPH's current data collection efforts and the additional clinical measures being collected on a voluntary basis at the national level as part of the Hospital Quality Alliance. The Group recommended that DPH continue to collect data on the 10 clinical measures on which they currently report. Because additional clinical measures

are only voluntarily reported at the national level, the Group did not recommend mandating them to be collected in Connecticut at this time.

These recommendations have been taken under advisement by DPH in their quality of care program activities.

Subcommittee on Promotion of Quality and Safe Practices

Working Group II: Patient Satisfaction Survey

In 2004 this working group submitted recommendations for: 1) data collection strategies, 2) data analysis strategies, and 3) public reporting formats for the patient survey. DPH staff members have developed an estimate of funds needed to conduct a comparative hospital patient survey in consultation with the University of Connecticut Center for Survey Research and Analysis. The estimate ranges from \$68,000 (mailed survey, analysis, and report with a sample size of 9,000 medical patients) to \$105,000 (mailed survey, analysis, and report with a sample size of 18,000 medical, surgical, and obstetric patients). However, staff agreed to postpone further meetings of this work group until external sources of funding could be identified for use in implementing the recommendations.

CGS §19a-127l-m notes that conducting the patient satisfaction survey is contingent upon additional funding. The final paragraph reads:

(i) 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.

Working group II will be reconvened if a source of funding is identified.

At the national level there has been progress toward implementing a voluntary HCAHPS program. The Centers for Medicare and Medicaid Services (CMS) partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop a 66-item version of HCAHPS, a hospital survey of patient satisfaction. The HCAHPS instrument was pilot-tested in three states and Connecticut. In May 2005, the National Quality Forum (NQF) endorsed the now 27-item HCAHPS instrument. In October 2005, Abt Associates, at the request of CMS, released a report on HCAHPS costs and benefits

(http://www.cms.hhs.gov/hospitalqualityinits/30_hospitalHCAHPS.asp).

The 27-item HCAHPS instrument consists of questions in seven domains: (1) nurse communication, (2) responsiveness of staff, (3) doctor communication, (4) cleanliness and quiet of the physical environment, (5) pain control, (6) communication about medications, and (7) discharge information. According to the HCAHPS website (www.hcahpsonline.org, accessed June 2, 2006), training for national implementation of HCAHPS has been completed, a "dry-run" has been extended through June 2006, and full voluntary national implementation is to begin in October. Hospitals will survey a random sample of live discharges aged 18 years and older at admission who had a non-psychiatric diagnosis and an inpatient overnight stay. Hospitals may

implement HCAHPS either alone or as part of an existing survey. The survey may be implemented in any of four modes: telephone only, mail only, mail with telephone follow-up, or active Interactive Voice Response (IVR). Hospitals may collect data themselves or use an approved vendor. Results using eligible discharges during the period October 2006-June 2007 will be posted on the Hospital Compare website of CMS (www.hospitalcompare.hhs.gov) in late 2007.

Subcommittee on Best Practices and Adverse Events

The subcommittee on Best Practices and Adverse Events met in July, September, October, and December 2005 and January, February, and April 2006.

A plan to initiate a fall prevention program was postponed and will be addressed in September 2006. Public Act 05-272 (P.A. 272), Section 30, charged the subcommittee with reviewing and making recommendations to the Department of Public Health "with respect to when breast cancer screening should be conducted using comprehensive ultrasound screening or mammogram examinations." Following extensive research and a teleconference between the subcommittee and a representative of the Radiology Society of Connecticut, the subcommittee presented the "Report to the Commissioner of the Department of Public Health – Breast Cancer Screening" in January 2006 (appendix B here). The report reflected the subcommittee's findings and recommendations.

The subcommittee has focused on a "health messaging" campaign to concentrate on providing educational information to consumers including medication reconciliation and hand hygiene. (Medication reconciliation implies that anyone prescribing or dispensing medication knows all other medications that the patient is concurrently receiving.) A wallet sized "medicard" used to list each person's medications was designed by the subcommittee and distributed at the April meeting of the full Advisory Committee and is available on the Department's website.

Subcommittee on Cardiac Care Data

"An Act Concerning the Improvement of Cardiac Care" (Appendix B of the June 2005 report) requires the Quality of Health Care Advisory Committee to examine and evaluate possible approaches that would aid in the utilization of an existing data collection system for cardiac outcomes, and the potential for state-wide use of data collection system for cardiac outcomes, for the purpose of continuing the delivery of quality cardiac care services in the state. The Act further requires the advisory committee to submit a report of the results of the examination along with any recommendations to the Governor and the Legislature by December 1, 2007.

The Cardiac Care Data Committee conducted its first meeting on April 25, 2006. The Office of Health Care Access distributed the current data elements submitted for the Connecticut Cardiac Data Registry and identified the seven acute care providers that submit data, which is currently for certificate of need compliance only. These acute care providers report on 73 data elements on a quarterly basis and the data were described as risk-adjusted. The Committee members discussed data collection by other states and identified potential pitfalls in data collection related

to not reporting the data timely due to lengthy audit of data sets, the data itself, the need to consider the cost to the state and usefulness of the information to the public. The fifteen acute care providers that provide cardiac services in Connecticut were invited to the Cardiac Care Committee's second meeting on May 25, 2006. Overviews of the data sets collected from each of the hospitals represented were discussed with possible benefits and pitfalls of each. The Committee plans to review the national data registries and will develop recommendations for use of the harvested data. The recommendations will include data elements to be collected, hospital participation, audit parameters, distribution of costs, risk adjusted analysis, and data to be reported to the public.

III. RECENT AND FUTURE PLANNED DPH PROGRAM AND PATIENT SAFETY ORGANIZATION ACTIVITIES

Implementation of P.A. 04-164

List of Adverse Events

In May of 2004, Public Act 04-164 (P.A. 04-164) amended section 19a-127n of the Connecticut General Statutes and defined an adverse event as "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." P.A. 04-164 also directed the Commissioner of Public Health to review the list periodically and to annually determine whether any changes need to be made. No changes have been made to the list of Connecticut events to date.

Patient Safety Organizations

P.A. 04-164 allowed DPH to designate "Patient Safety Organizations" (PSOs). The primary activity of a PSO is to improve patient safety and the quality of care delivered to patients through the collection, aggregation, analysis or processing of medical or health care related information submitted to the PSO by the health care provider. This "patient safety work product" may include reports, records, analyses, policies, procedures, or root cause analyses prepared exclusively for the purpose of disclosure to the PSO. The patient safety work product is confidential and not subject to use or access except to the PSO and the health care provider. The PSO will disseminate appropriate information or recommendations on best medical practices or potential system changes to improve patient care to the health care providers, DPH, the Quality of Health Care Advisory Committee, and the public. DPH has designated three PSOs, including the Qualidigm Patient Safety Organization, the Connecticut Healthcare Research and Education Foundation Patient Safety Organization (CHREF PSO), and the Ambulatory Surgical Center Patient Safety Organization (ASC PSO). The Qualidigm PSO and CHREF PSO, along with Hartford Hospital and the Department of Public Health, sponsored the third annual Patient Safety Summit in March 2006, featuring national experts in various aspects of patient safety. PSO activities from the previous year are described in the June 2005 Quality in Health Care report.

This year the Qualidigm PSO is offering monthly electronic News Flashes focused on timely sharing of patient safety information, resources and tools; on-site and Webex interactive education sessions exploring best practices on a variety of patient safety topics; and telephonic discussions of de-identified case studies submitted by member facilities.

The education sessions this year have included a two-day workshop on Human Factors and Root Cause Analysis; a session on Medication Reconciliation including tools and sharing of best practices; and an interactive educational session on Patient Falls involving participants in the assessment process, development of tools and interventions, and effective evaluation.

The Qualidigm Patient Safety Organization believes that while most safety and quality issues in health care are national concerns, most of the solutions need to be "local". With that in mind, Qualidigm's aim is to offer ways successful approaches that can be adapted to best meet the members' unique organizational environments.

All 30 of Connecticut's not-for-profit hospitals continue to participate in the CHREF PSO, which has a mission of promoting patient safety by identifying and disseminating reliable information that can be used to reduce adverse events and enhance the quality of healthcare provided in Connecticut. During the past year, the CHREF PSO has engaged in a variety of activities to support its mission including developing a data collection and reporting system to allow hospitals to share information about potential patient safety hazards, as well as practical operational strategies for improving patient safety, coordinating statewide patient safety initiatives, and providing patient safety education.

The three statewide patient safety improvement projects initiated by the CHREF PSO this year related to medication reconciliation, patient safety literacy, and just culture. The medication reconciliation initiative was focused on improving the process for reconciling patient medications in hospitals, as well as across the continuum of care. CHREF PSO participants met several times to share strategies related to medication reconciliation, and also recommended creation of a wallet medication card for patients, which the CHREF PSO developed in conjunction with partners including DPH and Qualidigm. The development of the wallet medication card was the beginning of a larger patient safety literacy initiative focused on using targeted public health messages to educate and empower consumers to take a more active role in their healthcare. The CHREF PSO, as well as DPH, Qualidigm, the Connecticut Hospital Association, and Southern Connecticut State University are participating in this initiative. The Just Culture project is a collaborative effort between the CHREF PSO and DPH to examine the behaviors that contribute to errors as well as the appropriate responses to those behaviors, and develop an oversight system that reinforces patient safety.

The CHREF PSO also developed and implemented a four-part patient safety tools curriculum to provide frontline staff members with expert training in patient safety tools and techniques. The curriculum focused on conducting root cause analyses, using human factors engineering to advance patient safety, conducting prospective risk assessments, and using statistical methods to analyze patient safety data. More than 175 professionals attended one or more of the curriculum programs and can now more effectively promote patient safety in their hospitals by proactively identifying risks and developing processes to reduce those risks.

The state's third patient safety organization, the ASC PSO, was approved by the Department of Public Health in the summer of 2005. The ASC PSO, LLC recently completed an anesthesia safety initiative and on May 2, 2006 rolled out its findings from a survey of facilities at a mandatory interactive workshop. Findings were presented by Dr. Henry Dove, a noted academician in the health care field, and Jeffrey Wagner, MD, a Diplomate of the American Board of Anesthesia and the National Board of Medical Examiners and an instructor in Advanced Cardiac Life Support for the American Heart Association.

The ASC PSO team provided an in-depth analysis of the survey and identified four areas to focus on during the presentation. Individualized reports were provided to each facility, with specific recommendations relative to each respondent. The report also included the Accreditation Association for Ambulatory Health Care's (AAAHC's) requirements relative to anesthesia safety for accredited facilities, pain management policies, and the complete database broken down by facility type for comparative purposes. No facility-specific information was publicly provided, however, each facility was aware of their identification and able to reference their responses relative to other facilities within their specialty. Following the presentation, facilities were able to ask questions on specific issues raised during the workshop.

With the anesthesia safety initiative complete, the ASC PSO, LLC is moving on to its next study, which will address issues related to informed consent.

Standing Orders for Vaccinations

P.A 04-164 allowed a hospital to administer influenza and pneumococcal polysaccharide vaccines to patients in accordance with physician-approved hospital protocols. The Act required DPH to adopt implementing regulations. The Influenza and Pneumococcal Polysaccharide Vaccine Regulations have been approved. The changes reflect studies showing that standing hospital policies ("standing orders") are effective in achieving high levels of vaccination.

Quality of Care Information on the DPH Web Site

Descriptions of the activities of the Health Care Systems Branch are listed under *Health Care Quality* in the Quick Links section of the DPH website (www.dph.state.ct.us). Descriptions for the activities of HCQSAR are listed under *Quality of Care* in the Publications section of the DPH website, and are also linked through the *Health Care Quality* page under "Health Care Quality Program Reports". Annual Adverse Event reports, the Hospital Performance Comparisons report, and annual reports to the legislature about the Quality of Care Program are also posted on the website.

Hospital Clinical Performance Measures

In February 2006, DPH produced its second hospital performance comparisons report, which is available on the DPH website (see also Appendix C here). Data were collected from all 30 adult acute care hospitals in Connecticut on patients with a diagnosis of heart attack, heart failure, or pneumonia, who were discharged between January 1, 2004 and December 31, 2004. Performance rates are provided for 10 clinical process measures.

There were two main differences between the first report produced in April 2004 and the February 2006 report:

- (1) The second report was based upon four quarters of data (CY 2004) whereas the first report was based on only one quarter of data (CY 2003, Quarter 3). Using a larger number of cases significantly reduced the number of unreliable performance measures. Therefore, only 8% of the 300 measures had to be suppressed due to insufficient data, whereas 23% were unable to be displayed in the first report.
- (2) The second report shows trend data between 2003 and 2004. On average, Connecticut improved significantly on 8 of the 10 clinical measures reported. The other two measures were already at a high performance level.

Future DPH program activities include ongoing data collection for the 10 clinical measures presented in the April 2004 and February 2006 reports; participating in the ongoing Advisory Committee and Subcommittee activities; and monitoring public reporting efforts on hospital clinical performance measures at the national level.

Adverse Events

Pursuant to the changes to adverse event reporting made by P.A. 04-164, regulations for adverse event reporting were submitted for review with passage pending.

DPH revised the data collection form and provided training for hospitals and outpatient surgical centers in adverse event reporting under the new law.

Utilization of the National Quality Forum's List of Serious reportable Events and events on the list compiled by the Commissioner of Public Health has resulted in consistent information submitted by hospitals and ambulatory surgical center. DPH released its fourth Adverse Events report dated October 2005 (www.dph.state.ct.us). More recent data from the fourth quarter of 2005 through the (incomplete) second quarter of 2006 extend established patterns in both the type and volume of reports. Falls resulting in serious disability and perforations during open, laparoscopic and/or endoscopic procedures are the most commonly reported events and are included in the list compiled by the Commissioner of Public Health (see Appendix A here).

Appendix A. Connecticut Adverse Event Reports in Electronic Database June 30, 2006, by Event Code and Date of Occurrence NQF List (1A-6D) and Connecticut-Specific List (7A-7F)

Event	Description	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	Total
Code	0 0 1 1	2004	2004	2005	2005	2005	2005	2006	2006	
1A	Surgery performed on the wrong body part	0	1	0	2	0	2	0	0	5
	Surgery performed on the									
1B	wrong patient	0	0	0	0	0	0	0	0	0
1C	Wrong surgical procedure performed on a patient	0	0	0	1	0	1	0	0	2
	Retention of a foreign object in a patient after surgery or									
1D	other procedure	1	3	8	4	5	2	3	4	30
15	Intraoperative or immediate post-operative death in an	0	0	0	0	0	0	0		0
1E	ASA class I patient Patient death or serious	0	0	0	0	0	0	0	0	0
	disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare									
2A	facility	0	0	1	0	0	O	O	0	1
2B	Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	1	1	2.	2	1	2.	2.	0	11
2.13	Patient death or serious	1	1			1			U	11
	disability associated with intravascular air embolism that occurs while being cared for in a healthcare									
2C	facility	0	0	0	2	0	1	0	0	3
3 1	Infant discharged to the	0	0	0	0	0	0	0	0	0
3A 3B	wrong person Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	0	0	0	0	0	0	0	0	0
3C	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	0	0	1	1	0	1	1	0	4

Event	Description	3Q	4Q	1Q	2Q		4Q	1Q	2Q	Total
Code		2004	2004	2005	2005	2005	2005	2006	2006	
4A	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	3	1	1	1	0	2	2	1	11
4B	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	0	0	O	0	0	0	O	0	0
4C	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	0	1	0	0	0	2	1	0	4
4D	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	0	0	1	0	0	0	0	0	1
4E	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	0	0	0	0	0	0	0	0	0
4F	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	3	6	6	8	3	6	6	3	41
4G	Patient death or serious disability due to spinal manipulative therapy	0	0	0	1	0	0	0	0	1
5A	Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	0	0	0	0	0	0	0	0	0
5B	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	0	0	0	0	0	0	0	0	0
5C	Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	0	0	0	0	0	0	1	0	1

Event Code	Description	3Q 2004	4Q 2004	1Q 2005	2Q 2005	3Q 2005	4Q 2005	1Q 2006	2Q 2006	Total
5D	Patient death associated with a fall while being cared for in a healthcare facility	0	0	2003	2003	2003	0	2000	2000	2
50	Patient death or serious disability associated with the use of restraints or bedrails while being	U	U	1	0	O	U	1	J	
5E	cared for in a healthcare facility	0	0	0	0	0	0	0	1	1
6A	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0	0	0	0	0	0	0	0	0
6B	Abduction of a patient of any age	0	0	0	0	0	0	0	0	0
6C	Sexual assault on a patient within or on the grounds of a healthcare facility	0	2	1	2	1	1	3	3	13
6D	Death or significant injury of a patient or staff member resulting from a physical assault (i.e.battery) that occurs within or on the grounds of a healthcare facility	1	1	O	1	1	O	0	0	4
7A	Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability	16	13	14	11	19	9	6	4	92
7B	Falls resulting in serious disability while being cared for in a healthcare facility	23	23	27	19	25	26	25	17	185
7C	Obstetrical events resulting in death or serious disability to the neonate	2	1	2	0	2	2	1	2	12
7D	Significant medication reactions resulting in death or serious disability	0	0	0	1	1	1	0	0	3
	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									
7E	the emergency department Nosocomial infections resulting	0	0	0	0	0	0	0	0	0
7F	in death or serious injury	1	2	0	0	0	1	0	1	5
Total		51	55	65	56	58	59	52	36	432

Adverse events using the older classification system with classes A-D, Oct 2002 –June 2004 are not included. Also, 12 events reported using the new classification system but occurring prior to July 1, 2004 are not included. Totals in 2006 may rise with further entries into the electronic database. Q= Quarter

APPENDIX B

REPORT TO THE COMMISSIONER of the DEPARTMENT OF PUBLIC HEALTH

Breast Cancer Screening

Quality of Health Care Advisory Committee

Subcommittee on Best Practices and Adverse Events

January 2006

I. PURPOSE:

To ensure compliance with Public Act 05-272, Section 30 which charges the best practices subcommittee to review and develop recommendations to the Department of Public Health "with respect to when breast cancer screening should be conducted using comprehensive ultrasound screening or mammogram examinations."

II. BACKGROUND

Screening for Breast Cancer

When the Susan G. Komen Breast Cancer Foundation was founded in 1982, few individuals were willing to speak publicly about breast cancer. Former First Ladies Betty Ford and Nancy Reagan raised public awareness through their own experiences of breast cancer. In the early 1980s, public health advocates established screening guidelines, encouraging women to do breast self-examinations and have regular mammograms and clinical breast examinations.

Screening mammography is used to detect suspicious breast tumors that may prove cancerous, and which may require further investigation and possibly treatment. For women of certain ages, screening mammography results in decreased time to detection of breast cancer and longer survival. Additional screening tools for breast cancer are continually being developed and investigated.

On February 17, 2005 Nancy and Joseph Cappello testified at the State of CT legislative hearing concerning Senate Bill #434. Ms. Cappello described her experience with a missed diagnosis when a mammogram failed to identify a tumor because she had "dense breasts". Mr. Cappello testified regarding studies performed which suggested that the use of ultrasound or Magnetic Resonance Imaging (MRI) screening to augment mammography should be used for women with dense breasts. Letters that appeared in <u>Radiology</u> 2003 were presented to the committee. These letters referenced studies performed by Dr. Thomas Kolb that described dense breasts and a recommendation for the use of ultrasound as an adjunct to mammography for breast cancer screening. The letters also discussed the cost to the patient for ultrasound. (See appendix)

Connecticut Legislation Regarding Screening Mammography

An Act Concerning Health Insurance Coverage for Breast Cancer Screening requires that, effective October 1, 2001, health insurance policies in Connecticut provide coverage for baseline screening mammography for any woman who is thirty-five to thirty-nine years of age, inclusive, and annual screening mammography for any woman who is forty years of age or older. The Act was amended (Public Act. 05-69) effective October 1, 2005 to provide "additional benefits for comprehensive ultrasound screening of an entire breast or breasts if such screening is recommended by her physician for a woman classified as a category 2,3,4, or 5 under the Breast Imaging Reporting and Data System established by the American College of Radiology."

An Act Concerning Revisions to Department of Public Health Statues (P.A. 05-272) amended Connecticut General Statutes section 19a-127l at section 30, effective October 1, 2005, to require that the standing subcommittee on best practices "review and make recommendations concerning best practices with respect to when breast cancer screening should be conducted using comprehensive ultrasound screening or mammogram examinations."

Quality of Health Care Advisory Committee Activity

Members of the Subcommittee on Best Practices and Adverse Events (hereafter, 'the Subcommittee') gathered and distributed to the others information on breast cancer screening provided by Dr. Ed Cronin via Dr. Andrew Salner, both physicians at Hartford Hospital. This included (1) "Screening Breast Sonography in Dense Breasts," a position statement from the Society of Breast Imaging, (2) the American College of Radiology "Practice Guidelines for the Performance of a Breast Ultrasound Examination," (3) an American College of Radiology Imaging Network article entitled "What is the Supplemental Benefit of Screening Breast Ultrasound After Mammography?" An article in the September 17, 2005 Hartford Courant on digital breast cancer tests was also distributed.

On October 20, 2005 the Subcommittee heard a presentation from Ms. Nancy Capello, a breast cancer survivor and constituent of Senator Hartley, and discussed the above material. Ms. Cappello urged the Subcommittee to include education for women about the problems that dense breast tissue may cause for reliable screening and that women need to take charge of their own health. David Boomer of the Kowalski Group, representing the Connecticut Society of Radiologists, was also present. Subsequently a literature review was conducted (see appendix) and a glossary and the section on "Dense Breast Evaluation" from www.densebreast.org were distributed. An important point is that mammography is less effective in women with dense breast tissue.

On October 25 Subcommittee co-chair Wendy Furniss of the Department of Public Health summarized activities to the Advisory Committee. She noted that there does not appear to be a clear best practice regarding screening in women with dense breasts that the Subcommittee could point to. Deputy Commissioner Dr. Norma Gyle volunteered to speak with members of the legislature about the appropriateness of the Subcommittee attempting to deal with such complex clinical care issues.

On December 6, the Subcommittee spoke at length via teleconference with Dr. Steven Cohen, Chair of the Department of Radiology at Stamford Hospital, President of the Radiology Society of CT and as counsel for the Radiology Society of America. Among other things, Dr. Cohen noted that ultrasound is appropriate when a mammogram is negative but a lesion is palpable. However, unlike mammography, ultrasound does not detect microcalcifications. MRI can show the extent of disease when cancer is known to be present. A paper was distributed entitled "ACR Remains Committed to Mammography and Supports Study of Screening Modality Options." The Subcommittee agreed to produce an outline for a report to the Commissioner at its January meeting.

III. WHAT ARE "DENSE BREASTS"?

"Dense breasts" is a term used for breasts that are composed of more fibroglandular tissue than fatty tissue. Fibroglandular breast tissue appears white in a mammogram. Fatty tissue appears dark gray to black on the film. A mammogram may identify a dense pattern when the radiologist sees more white than gray on the mammogram. The mammography report will describe the breast related to the amount of fatty and dense tissue.

IV. CLASSIFICATION SYSTEM

Breast Imaging Reporting and Data System (BIRADS) – BIRADS is a system that utilizes scales to describe breast tissue related to density and to categorize the findings on the mammogram. The BIRADS system was designed by the American College of Radiology (ACR) as a quality assurance tool designed to standardize mammography reporting, reduce confusion in breast imaging interpretations, and facilitate outcome monitoring.

- A. BIRAD scale for categorizing breast density
- 1 Having no areas of tissue that could obscure cancer (the breast is almost entirely fat)
- 2 Having at least one area of tissue that could obscure cancer (there are scattered fibroglandular densities)
- 3 Having tissue that can obscure cancer in 50% to 75% of the breast (the breast is heterogeneously dense)
- 4 Having tissue that can obscure cancer in greater than 75% of the breast (the breast tissue is extremely dense)
- B. BIRAD scale to categorize findings on a mammogram
- 0 Additional imaging necessary
- 1 Negative
- 2 Benign finding
- 3 Probably benign finding short interval follow-up suggested
- 4 Suspicious abnormality biopsy should be considered
- 5 Highly suggestive of malignancy appropriate action should be taken

V. BREAST CANCER SCREENING METHODS

A. Mammography – Mammography is an x-ray of the breast. A traditional mammogram consists of four views that are left and right, top to bottom and breastbone to armpit. (Densebreast.org) According to the American College of Radiology "mammography remains the most useful and best demonstrated screening modality for the detection of breast cancer available to patients today".

- B. Breast Ultrasound Ultrasound uses "high frequency sound waves to get an image of the breast and helps determine if a lump is a cyst or a solid mass". (Lippincott Manual of Nursing Practice, 2006) According to the American College of Radiology, breast ultrasound is indicated for but not limited to identification and characterization of palpable and nonpalpable abnormalities, further evaluation of clinical and mammography findings and guidance of interventional procedures.
- C. Magnetic Resonance Imaging (MRI) MRI is an imaging procedure that uses "powerful magnetic field and radio frequency waves to create an image" (Lippincott Manual of Nursing Practice, 2006). According to the American College of Radiology, MRI is a useful tool "for the detection and characterization of breast disease, assessment of the local extent of disease, evaluation of treatment response, and guidance for biopsy."

VI. USE OF MAMMOGRAM VS. ULTRASOUND VS. MRI

Dense breast tissue appears white on the mammogram. Tumors also appear white on a mammogram. Therefore a cancerous tumor may not appear on the mammogram. According to Dr. Thomas Kolb, a radiologist in New York, in ultrasound, unlike the mammogram, "dense breast tissue appears white, while the cancer is dark".

The American Cancer Society News Center reported that a study performed by Dr. Kolb showed that a "combination of mammography and ultrasound was the most effective in detecting breast cancer among women with dense breasts."

According to Dr. Steven Cohen, President of the Connecticut Radiology Society, breast ultrasound is a powerful adjunct to mammography as it picks up many cancers not seen on mammography. However ultrasound should not be used as a single screening method as it misses the microcalcifications that can be identified on mammograms. According to Dr. Cohen, MRI is the best method for accurate screening for breast cancer however it should be used after other screening tests have been completed.

VII. <u>SUBCOMMITTEE'S RECOMMENDATIONS</u>

A. FOR THE PUBLIC

- Utilization of the Department of Public Health website to post multiple "best practice" references, other sites dedicated to patient safety, quality organizations such as Qualidigm, physician specialty organizations and/or links to their site, media links such as CT NOW and consumer messaging.
- Inform the public of the requirements for payment for breast screening in legislation.

B. FOR THE CLINICIANS

- Development of a patient education brochure by the Department of Public Health to be available for distribution to medical/nursing associations, hospital associations, pharmacy associations, physicians' offices, radiology centers, etc. that is culturally sensitive and literacy appropriate.
- Encourage participation by the Breast and Cervical Cancer Section of the Department of Public Health in development of the brochure and/or distribution.
- Work with medical societies and associations to educate primary care physicians, medical/surgical specialists and all others involved in the patient's care regarding informing patients whether they have dense breasts, and how this could influence the interpretation of mammography, or the need for additional testing.

C. FOR THE PAYORS

• Inform payors of the requirements for payment for breast screening in legislation, the value of various screening modalities and/or to distribute DPH brochures or other health messages to their constituents.

APPENDIX

- A. Insurance Committee Hearing Transcript for 2/17/05 [omitted]
- B. Glossary of Terms [omitted]
- C. Literature Review: Breast Cancer Screening
 - 1. Results
 - According to a recent review article, "Mammography is the best tool available for screening for breast cancer. Although the data supporting clinical breast examination are not as strong, this procedure continues to be widely used in the United States. To maximize accuracy of results, women who undergo screening during their premenopausal years should attempt to schedule mammography during the follicular phase of the menstrual cycle [days 1-14, when breast density is lower]. All women should be educated about the benefits and the harms of screening, including the risk of being called back for further testing." (1)
 - North American recommendations for routine mammographic screening of women at average risk, from 5 government sponsored and private groups, 6 medical societies, and 3 advocacy groups were compared in 2003 (2). Recommendations from selected organizations from that list (3) when checked in October 2005 had not changed. With few exceptions, screening is recommended every year or every 1-2 years starting at age 40 and continuing until upwards of age 70.
 - All women aged 40 and older should have clinical breast examination annually as part of a periodic health exam. Breast self-examination (BSE) has no proven benefits but may be recommended, although it is acceptable for a woman to choose not to do BSE (4). Magnetic

resonance imaging is not recommended for breast cancer screening in the general population; it is an adjunct to mammography, clinical breast exam, and ultrasonography in women at high risk of breast cancer based on family history or the presence of Breast Cancer Gene 1 (BRCA-1) or Breast Cancer Gene 2 (BRCA-2). (5).

- About 40% of women undergoing screening have dense breasts, although breast density can change over time (6). Screening film mammography is less accurate in dense breast tissue than in fatty breast tissue. Sonography is capable of detecting cancers in dense breasts that cannot be detected by film mammography. A recent reviewer considered ultrasonography the most effective detection tool in dense breasts (7). However, the Society of Breast Imaging considers that the benefit of screening sonography has not been established and that screening sonography is not the standard of care (8).
- The overall screening accuracy of digital and film mammography are similar, but digital mammography is more accurate in women under age 50, women with radiographically dense breasts, and premenopausal or perimenopausal women. Palpable findings and symptoms that develop after screening should be evaluated even if a woman has negative findings on mammography (9).
- Other promising modalities include computer-aided detection (CAD), nuclear medicine including positron emission tomography (PET), electrical impedance imaging, thermography, optical imaging, optacoustic tomography, tomosynthesis, MR lyphangiography, ductogram, and microwave imaging. None of these have been shown in randomized trials to decrease mortality (10).

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- 6. Digital vs. Film Mammography in the Digital Mammographic Screening Trial (DMIST): Questions and Answers. www.acrin.org
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For Further Information

American Cancer Society (www.cancer.org)
American College of Obstetricians and Gynecologists (www.acog.org)
American College of Radiology (www.acr.org; acrin.org)
American Medical Association (www.ama-assn.org)
National Cancer Institute (cancernet.nci.nih.gov)
Society of Breast Imaging (www.sbi-online.org)

It is important for health care consumers to be knowledgeable about their own health status, so that they can participate with their physicians in planning appropriate health care. Women should always discuss their concerns and questions about breast cancer screening methods with their physician. Women may want to bring information from the sources noted here or others when discussing their health with their personal physician. The public should remember that guidelines change over time and should be rechecked periodically. The sharing of this information between the physician and patient will result in a "best decision" for the patient and the physician.

^{*} This report was written at the Department of Public Health at the direction of the Subcommittee and was reviewed, revised and approved by the Subcommittee.

APPENDIX C

HOSPITAL PERFORMANCE COMPARISONS, 2004

Table of Contents & Executive Summary

The full report is at http://www.dph.state.ct.us/hcquality/Quality/qcr.htm



Keeping Connecticut Healthy

Hospital Performance Comparisons, 2004

A REPORT ON QUALITY OF CARE IN CONNECTICUT HOSPITALS

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Health Care Quality, Statistics, Analysis, and Reporting Unit

February 2006

State of Connecticut Department of Public Health

Hospital Performance Comparisons, 2004

A REPORT ON QUALITY OF CARE IN CONNECTICUT HOSPITALS

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- A. Definitions of Measures
- B. Tables

2003 Heart Attack, Heart Failure, and Pneumonia Performance Rates 2004 Heart Attack, Heart Failure, and Pneumonia Performance Rates Performance Rates with Significant Differences from 2003 to 2004

Executive Summary

Increasing attention is being focused on evaluating and improving health care quality at both the state and national levels. Efforts are being made to provide standardized, useful and valid information to the public about hospital quality of care and also to promote quality improvement efforts within hospitals. The incentives are clear-- high quality care leads to fewer repeat hospitalizations, medical procedures, and medical errors, thereby reducing costs. Results presented in this report constitute the first step in this ongoing process to evaluate and report on health care quality in Connecticut hospitals.

Connecticut's initiative began with the passage of legislation (Sections 19a-127 l-n of the Connecticut General Statutes) during the spring of 2002 that created a quality of care program within the Department of Public Health (DPH). Under that program, hospitals are required to collect and report quality of care information to the DPH in order to produce a public report that compares all licensed hospitals in the state. Connecticut has aligned its efforts with national quality initiatives aimed at collecting similar information.

Included in this report are comparisons among adult general acute-care hospitals in Connecticut about how often they provide the recommended care to patients who have been diagnosed with a heart attack, heart failure, or pneumonia, which are three common and costly medical conditions for which people go to the hospital. Hospital performance rates are provided for ten clinical measures that focus on treatments that are well established and generally accepted recommended care based on medical evidence.

Based upon 2004 hospitalization data, Connecticut's hospitals are doing better on average than those in the U.S. on all ten of the clinical measures, yet they still fall short of the goal of 100% on most of the measures. That is, performance gaps still exist between the care that could be given and the care that is being delivered.

Performance rates are improving, however. Between 2003 and 2004, Connecticut hospitals' performances rates improved significantly for eight of the ten measures.

Connecticut's Performance Compared to the U.S. Performance, 2004

Condition	Measure	Average Connecticut Rate	Average National Rate*
Heart Attack	Aspirin at Arrival	96%	91%
	Aspirin at Discharge	97%	86%
	ACEI for LVSD at Discharge	83%	75%
	Beta-Blocker at Discharge	95%	85%
	Beta-Blocker at Arrival	94%	84%
Heart Failure	LVF Assessment	93%	78%
	ACEI for LVSD at Discharge	79%	74%
Pneumonia	Oxygenation Assessment	100%	98%
	Pneumococcal Vaccination	58%	46%
	Timely Antibiotic	75%	73%

^{*} Source: <u>www.hospitalcompare.hhs.gov</u> for hospitals participating in the Hospital Quality Alliance initiative.

Data are based upon patients hospitalized from 1/1/04 - 12/31/04.

Connecticut's I	Performance fr	rom 2003 to	2004
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Condition	Measure	2003 Q3-Q4	2004 Q1-Q4
Heart Attack	Aspirin at Arrival	95%	96%
	Aspirin at Discharge	95%	97%*
	ACEI for LVSD at Discharge	76%	83%*
	Beta-Blocker at Discharge	92%	95%*
	Beta-Blocker at Arrival	92%	94%*
Heart Failure	LVF Assessment	90%	93%*
	ACEI for LVSD at Discharge	71%	79%*
Pneumonia	Oxygenation Assessment	100%	100%
	Pneumococcal Vaccination	43%	58%*
	Timely Antibiotic	68%	75%*

^{*} Difference is significant at the 0.05 level.

Consumers should view this information as a starting point for educating themselves about hospital quality, for talking to their doctors about choosing a hospital for medical care, and for asking questions while receiving care in the hospital. This information should also be used by the medical community to heighten their awareness of the opportunity that exists to improve the care that they currently deliver.