



Cardiovascular Standards

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Sec. 19a-638. (Formerly Sec. 19a-154). Certificate of need. When required and not required. Request for office determination. Policies, procedures and regulations. (a) A certificate of need issued by the office shall be required for:

(7) The establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery;

Definitions:

- **Elective** Percutaneous Coronary Intervention (**PCI**) or Coronary Angioplasty (PCA): Simply put, it's where a PCI is performed on a prescheduled basis (non-emergent).
- **Primary** Percutaneous Coronary Intervention (**PCI**) or Coronary Angioplasty (PCA): Basically performed on Emergency basis (non-scheduled).
- **Open-heart surgery (OHS)**: Surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (**CABG**), Valvuloplasty, and Valve Replacement.

Connecticut Cardiac Overview:

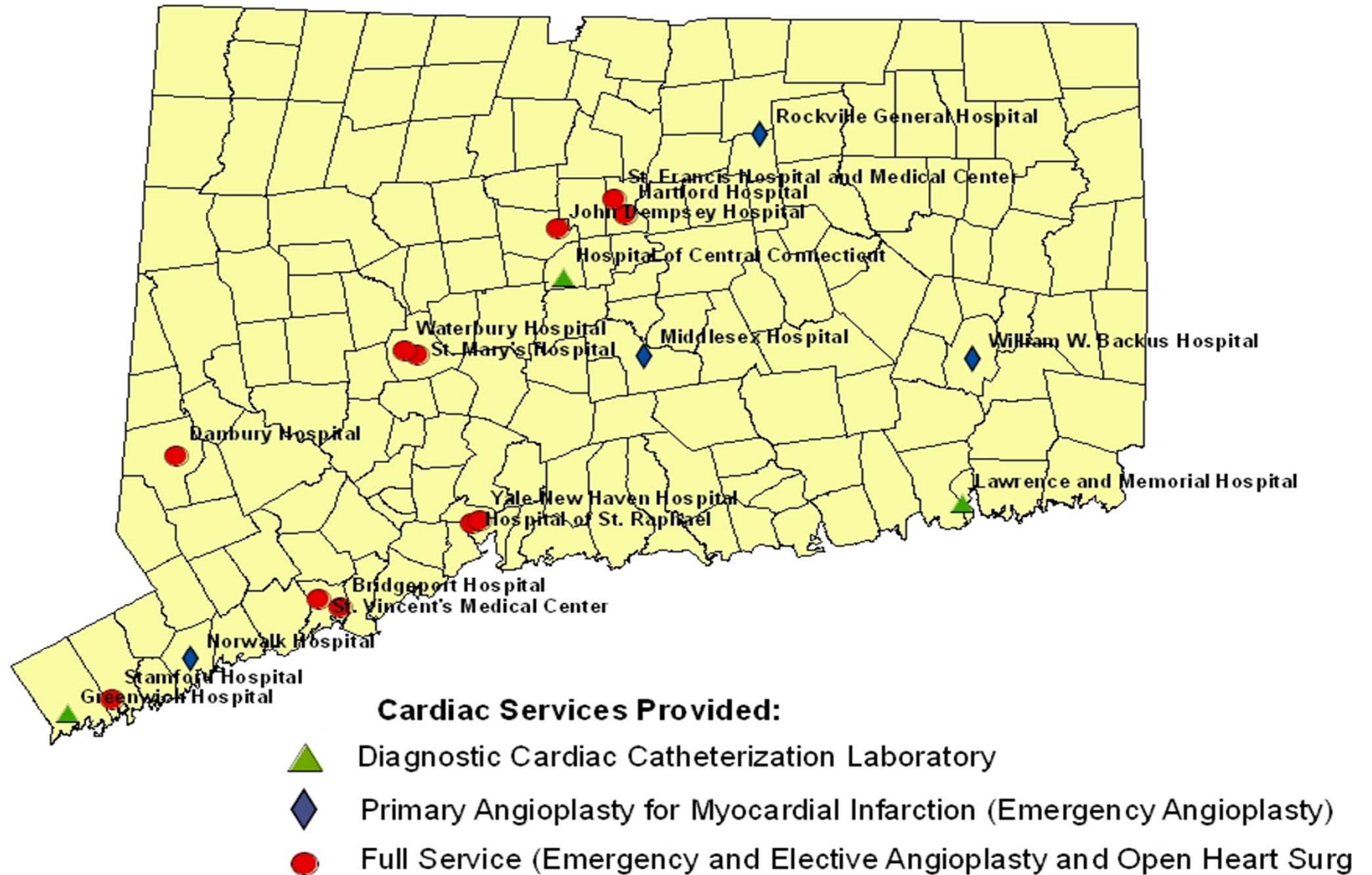
PCI:

- 14 Hospitals offer PCI service.
- Past 3 years statewide utilization:
 - FY 2008: 7,216
 - FY 2009: 7,185
 - FY 2010: 7,128
- 1% drop between FY '08-'10
- 9% drop between FY '06-'10

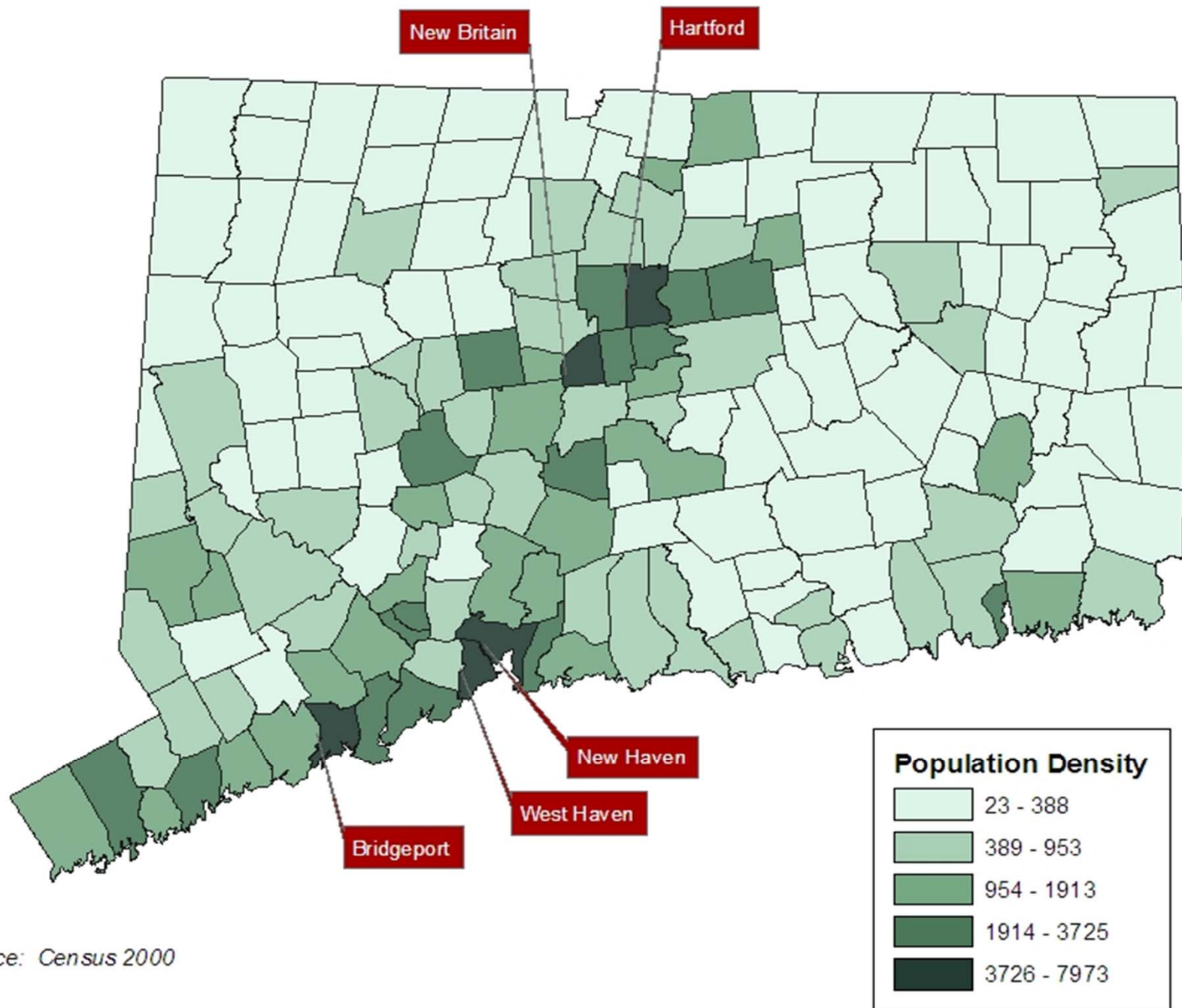
OHS:

- Currently there are 10 cardiac OHS programs at 11 Hospitals.
- Past 3 years statewide utilization:
 - FY 2008: 3,505
 - FY 2009: 3,309
 - FY 2010: 3,353
- 4% drop between FY '08-'10
- 6% drop between FY '06-'10

Cardiac Services in Connecticut January 2011



Connecticut Population Density (Persons/Square Mile)



Source: Census 2000

Past Practice:

- Certificate of Need applications (CON) were evaluated on a case-by-case basis.
- No standardized guidelines for cardiovascular services.
- OHCA utilized the American College of Cardiology/American Heart Association ("ACC/AHA") and Advisory Council for Cardiothoracic Surgery ("ACCS") Guidelines.

Proposed:

- Develop a set of standards that guide the evaluation of CON applications related to cardiovascular services, and also:
 - assess quality
 - determine unmet need
 - project future demand for additional cardiovascular services

Cardiovascular Standards Research:

OHCA examined a variety of health plans from various states for cardiovascular standards—

The following are the common elements utilized by other states:

- ACC/AHA& ACCS Guidelines
- Planning area
- Utilization of services
- Population demographics

ACC/AHA PCI Guidelines (2007):

- The 2007 ACC and AHA Guidelines for **PCI** recommend that PCI be performed by higher volume **operators (>75 cases/year)** with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional labs and experienced support staff. This setting will most often be in a high-volume institution (**>400 cases/year**) associated with an on-site cardiovascular surgical program.
- ACC/AHA are supportive of a posture of close monitoring of **institutions** that perform **<100** cases annually.

ACCS OHS Guidelines (2001):

- Annual volume of **at least 100 to 125** OHS per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures compared to those doing higher volumes.
- At least **200** procedures per year are necessary in order for a program to function efficiently.
- A team approach with a minimum of two (**2**) qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.

Sample of 3 Chosen States:

- OHCA staff reviewed various states that regulate cardiovascular services and address it in their state planning documents and chose the following three to illustrate different approaches:
 - South Carolina;
 - Illinois; and
 - Tennessee.

South Carolina Standards:

- **Primary PCI** at a hospital w/out an on-site comprehensive Cath lab and an OHS program requires a CON (otherwise **No CON**).
- Closely follow the ACC/AHA & ACCS guidelines.
- Comprehensive (Interventional) Cath labs shall only be located in hospitals that provide OHS.
- The capacity of OHS program is determined to be **500 OHS/yr** (Leapfrog) for the initial OHS unit and each additional OHS unit.
- Min. 200 **adult OHS** annually (w/in 3 yrs of start).

SC Cont.:

- New OHS units will only be approved if following conditions are met:
- Each existing provider in the service area (defined as w/in 60 minutes (in-state) one way auto travel) is performing annual min. of 350 OHS (per unit) (70% capacity).
- Applicant to provide epidemiological evidence of incidence and prevalence of conditions for which OHS is appropriate w/in the PSA, to include the number of potential candidates for these procedures.

SC Cont.:

- No new OHS programs shall be approved if the new program will cause the annual caseload of other programs w/in the proposed PSA to drop below 350 adult procedures.
- The OHS program will have the capability for emergency coronary artery surgery, including sufficient personnel and facilities available to conduct the coronary artery surgery on an immediate, emergency basis, 24 hours a day, 7 days a week.
- Many additional standards listed.

Illinois Standards:

- Pre-defined region (Health Planning Area)
- Adult- min. of 200 **OHS**/yr w/in 3 yrs of start
Child- min. of 75 **OHS**/yr w/in 3 yrs of start
- Need for additional **OHS** service is determined by at least 200 patients/year referred to other OHS providers following cardiac Caths at the applicant or a min. of 750 cardiac Caths performed/yr.

Tennessee:

- Has an actual formula for need for an OHS program:
- $N = U \times P$
 - N= number of procedures in a service area
 - U= latest available state rate (# procedures/1,000)
 - P= projection of population in the service area (in thousands)
- Min. 200 OHS per year.
- Existing program in the service area exceeds 350 OHS.

JAMA Study (Published May, 2011):

- Between 2001 & 2008, annual rate of CABG in US decreased by more than 30% but rates for PCI did not significantly change.
- Reasons: Innovations such as DES (drug-eluting stents), minimally invasive CABG surgeries and improved outcomes compared with older technologies and techniques.
- 15% decrease in annual rate of coronary revascularizations (2001-2002 to 2007-2008).
- 1/3rd fewer CABG surgeries performed in 2008 compared to 2001.
- CABG rate decreased from 1,742 to 1,081 per 1,000,000.

JAMA Study (Cont.):

Between 2001-2008:

- No. of hospitals providing nationwide CABG surgeries increased by 12% and PCI by 26%.
- CABG surgery caseload per hospital decreased by 28%.
- No. of CABG surgery hospitals providing fewer than 100 CABG surgeries increased from 23 (11%) to 62 (26%).

Moving Forward:

Issues in need of further discussion:

- Planning area
- Measuring Quality:
 - Institutional Volumes vs. Operator Volumes
- Elective PCI w/o onsite OHS backup
- Exceptions

DPH-OHCA staff are looking forward to working collaboratively with the advisory body to determine the most effective and appropriate standards for Connecticut's health care system.



Thank You!