The Low Dose CT Scan Lung Screening Study

The Low Dose CT scan Lung Screening Study was approved by the IRB on October 22, 2013. The study was approved to be conducted across HHC system (except for William Backus Hospital) at Hartford Hospital, MidState Hospital, Windham Hospital and the Hospital of Central Connecticut. William Backus Hospital joined HHC after the initiation of the IRB application and had already developed a separate lung cancer-screening program.

This is a prospective study of subjects, at high risk for lung cancer, who meet enrollment criteria. There is sample size of 500 subjects or as many as can be recruited in one year with additional follow-up studies being obtained as needed including recommendations for subsequent annual screening exams. All subjects need an order from a primary care physician in order to be considered for the program and to be eligible for the study. We recruited subjects through our community outreach program and our primary care providers. For subjects who do not have a primary care provider, a PCP from our hospital medical staff and clinic would be identified.

The goals of the study were:

• Determine the feasibility of establishing a low dose lung cancer-screening program based on established NCCN guidelines for high-risk subjects utilizing a primary care provider based system of referral.
• Determine the feasibility of reaching underserved (as determined by Medicaid or no insurance) populations in our community with this intervention.
• Benchmark abnormal findings to published studies to determine those findings in our study population-i.e. 27% positive findings, 7% significant findings and 1% incidence of cancer in patients screened with low-dose CT compared to chest x-ray as shown in the previous National Lung Screening Trial (NLST).
• Implement a system of standardized reporting and link findings with standardized NCCN recommendations for treatment and follow-up to ensure that patients are receiving the highest standard of care as outlined in the mission, vision and values of the HHC System.
• Analyze lung cancer staging rates of participants in the study in comparison to data collected through the Cancer Registry for the Helen & Harry Gray Cancer Center to
evaluate whether low dose lung cancer screening is finding cancer at earlier and more treatable stages.

- Describe smoking cessation outcomes of participants in the lung cancer-screening program to evaluate whether lung cancer screening provides a “teachable” moment to motivate smokers to quit smoking.
- Use the data and analysis of this pilot program to configure additional research questions that might result in seeking outside funding, and to advocate for continued appropriate support.

Subjects were screened for entry into the study according to the following eligibility criteria based on the NCCN Guidelines for High Risk Groups. The criteria are:

- Participants 55-74 years old
- Are currently a smoker or have quit within the past 15 years
- Have smoked at least a pack of cigarettes a day for 30+ years

Or:

- Participants 50-74 years old
- Have smoked at least a pack of cigarettes a day for 20+ years
- Have one additional lung cancer risk factor, not to include secondhand smoke exposure, including:
  1. Personal cancer history such as lung, lymphoma and other smoking related cancer
  2. Family history of lung cancer 1st degree relative
  3. Chronic lung disease such as emphysema. COPD, Chronic bronchitis or pulmonary fibrosis
  4. Carcinogen exposure such as arsenic, asbestos, cadmium, chromium, diesel fumes, nickel, radon and silica

Exclusion criteria will include:

1. Patients who have current symptoms of a lung condition, such as a new cough, hemoptysis or shortness of breath.
2. Treatment for lung cancer or other malignancy within the last 5 years.
3. Chest CT in the past 18 months
4. Unable to lie on back with arms over head

Board-certified radiologists with expertise in thoracic imaging read the study. Standardized, structured reporting is used to facilitate strict adherence to guidelines for follow-up and treatment as well as statistical analysis of outcomes. Studies are identified as positive or negative based on NCCN lung cancer screening guidelines.
The study is expected to run until September 2015 or until there is CMS reimbursement for lung screenings.

As of January 27, 2014, the sites reported the following:

HOCC: 14 patients screened, 10 in queue
HH: 27 patients screened, 13 in queue
MidState: 134 patients screened, 22 in queue
Windham: 23 patients screened

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