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CIRCULAR LETTER: DHCQ 06-8-465

TO: Chief Executive Officers
Acute Care Hospitals

FROM: Paul Dreyer, Associate Commissioner

DATE: August 21, 2006

SUBJ: **The MASS COMM Trial: Protocol, Community Hospital Eligibility, and Application Process for Participation** in the Randomized Trial to Compare Safety and Long Term Outcomes for Percutaneous Coronary Intervention between Massachusetts Hospitals with Cardiac Surgery-on-Site and Community Hospitals without Cardiac Surgery-on-Site

Introduction

Under the Massachusetts hospital licensure regulations governing cardiac catheterization services (105 CMR 130.900-.982), only hospitals with cardiac surgery services may routinely perform percutaneous coronary interventions (PCI).¹ This regulation is consistent with the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention², which recommends that "...elective PCI should not be performed in facilities without on-site cardiac surgery." Although complications of elective PCI have been reduced through developments in medications and technology, there remain some patients who will experience life-threatening complications that could be managed through on-site cardiac surgery availability, but not through urgent transfer to another facility.

The ACC/AHA/SCAI recommendation regarding on-site cardiac surgery may change based on clinical data and experience as it develops. In an effort to contribute to the assessment of the safety and efficacy of PCI at hospitals without cardiac surgery on-site, the Department of Public Health's

¹ Massachusetts conducts a separate special project that allows certain hospitals without cardiac surgery services to perform primary angioplasty in the treatment of acute myocardial infarction.

² Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: <http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf>.

(DPH/the Department) Invasive Cardiac Services Advisory Committee, with the advice of the Massachusetts Cardiac Care Quality Advisory Commission, voted in June 2005 to authorize a subcommittee of clinical experts to develop a trial to address the issue. Through the collaborative efforts of the Harvard Clinical Research Institute (HCRI), the MASS-DAC Data Coordinating Center (the data coordinating center in the Department of Health Care Policy at Harvard Medical School) and experts in the field of coronary interventions, the MASS COMM Trial, a prospective, multi-center, nested randomized controlled trial, was developed. The MASS COMM Trial protocol is available on the Division of Health Care Quality website at <http://www.mass.gov/dph/dhcq>.

Community Hospital Eligibility for Participation in the MASS COMM Trial

To be eligible to participate, the community hospital's cardiac catheterization service must have performed at least 300 diagnostic cardiac catheterization procedures in the year preceding the request to participate (as documented by the annual volume data submission to DPH).

In addition, the hospital must have participated for at least one year in the Department's special project that allows certain community hospitals to perform *primary* angioplasty in the treatment of acute myocardial infarction and have performed at least 36 primary angioplasty procedures during the most recent year (as documented by the monthly volume data submission to DPH). Primary angioplasty must be available at the community hospital 24 hours per day, seven days per week (24/7) within the first year of participation in the MASS COMM Trial. For each community hospital that does not provide primary angioplasty 24/7 during the first year of its participation in the MASS COMM Trial, primary angioplasty must be available at least 90% of the time, e.g., at least 151 hours per week, during that first year.

Physician Operator Requirements

Physicians performing elective angioplasty under this trial, at either the non-surgery-on-site (non-SOS) or the surgery-on-site (SOS) hospital, must be board certified in interventional cardiology, have performed 75 interventions in the past year, and continue to perform 75 PCI procedures per year. Interventionalists at the community hospitals must maintain credentials at the corresponding surgery-on-site hospital(s). The MASS COMM Trial Executive Operations Committee will review any requests for exceptions to the volume or board certification requirements.

Application Process for Community Hospitals

Eligible community hospitals interested in participating in the MASS COMM Trial must complete the attached application to request special project approval, under hospital licensure regulation 105 CMR 130.051 Special Projects, and return the completed form to the Department.

The application must be signed by the Chief Executive Officer, the Chief of Cardiology or Cardiovascular Services, and the hospital's Principal Investigator for the trial.

Each community hospital must establish a signed agreement (see attached Guidelines) with at least one hospital that provides cardiac surgery services (the corresponding or partnering SOS hospital) to outline terms to ensure:

- for those community hospitals that do not provide primary angioplasty 24 hours per day, seven days a week, provisions for management of any elective angioplasty patient's

complication by the interventional team until discharge the next day or 24 hours post-procedure, whichever is later.

- transport and/or efficient scheduling (in most cases on the same day as randomization, but no later than three days from randomization) of patients randomized to the SOS hospital for an elective angioplasty procedure.
- efficient and rapid transport for all elective angioplasty patients for whom a procedural complication warrants surgical intervention. This includes availability of ambulance transport at the non-SOS hospital within 30 minutes of a request by the cardiac catheterization service staff. Every effort must be made to ensure arrival of the patient at the partnering SOS hospital within 60 minutes of the decision to transport the patient.
- the partnering SOS hospital will maintain a contract with HCRI and provide the data, consistent with the protocol, to the non-SOS hospital (for submission to HCRI) on enrolled patients who are either randomized to the SOS hospital for treatment or transferred for emergency or urgent treatment at the SOS hospital.

Conditions

Written Department special project approval is required prior to any patient enrollment in the trial. The Department's approval may be withdrawn if the participant hospital fails to comply with the protocol, provide requested data, or provide timely payment. Hospitals are reminded that there must be a signed contract between each community hospital and HCRI as well as between the partnering surgery-on-site hospital(s) and HCRI prior to any patient enrollment. Hospitals must receive final written authorization from HCRI prior to enrolling any patient.

The Department may discontinue enrollment in the trial should early findings of the trial's Data Safety Monitoring Board indicate a quality of care or patient outcome problem with the study, if new studies clearly indicate a lack of safety in performing elective angioplasty in hospitals without surgery-on-site, or if the ACC/AHA/SCAI Guideline for PCI is revised to no longer recommend cardiac surgery on site be available for elective angioplasty procedures.

If you have any questions about the information in this letter, please contact Nancy Murphy in the Division of Health Care Quality at (617)753-8120 or Nancy.Murphy2@massmail.state.ma.us.

Attachments: DPH Application for Special Project Approval
DPH Guidelines for Agreement between non-SOS and SOS Hospital

cc Invasive Cardiac Services Advisory Committee
Cardiac Care Quality Advisory Commission
MASS COMM Trial Executive Operations Committee Members
Barbara Cox, HCRI
Linda Longo, HCRI