January 20, 2009

Paul Dreyer, Director
Health Care Safety and Quality
Massachusetts Department of Public Health
99 Chauncy Street
Boston, MA 02111

Dear Dr. Dreyer:

We are responding to your telephone call of Jan. 16, 2009, regarding percutaneous coronary intervention (PCI) mortality at Massachusetts General Hospital in fiscal year 2007. We understand that in the most recent Mass-DAC analysis, MGH has been identified as a statistically high mortality outlier institution. We appreciate the serious nature of the observations and have prepared the following report in response. We would like to emphasize four elements of our report in summary:

1. **We monitor PCI outcomes closely and have been aware of this issue since early 2008.** Our routine surveillance of our aggregate outcomes data brought this trend to light both via the ACC-NCDR reports and via the preliminary 2007 Mass-DAC report, which we received in May 2008. In all prior years, our outcomes had been within state norms.

2. **At that time, we analyzed our PCI data, reviewing every 2007 death. As a result of this process, we changed our practices significantly and saw improvement in the subsequent interval.** Our conclusion at the time, explained in more detail in this report, was that we were performing PCI in an excess number of patients with little hope of survival and that we needed to modify our practices. Interventional and non-interventional cardiologists at MGH agreed to a "second opinion" approach to this issue and to collectively review high-risk cases. Data for the rest of 2008 show a progressive reduction in mortality, reflecting this new approach. In one particular area – cardiac support with a new external device for shock patients and patients with high-risk coronary anatomy – we reassessed our approach after a suboptimal initial experience and instituted improvements that led to better outcomes.

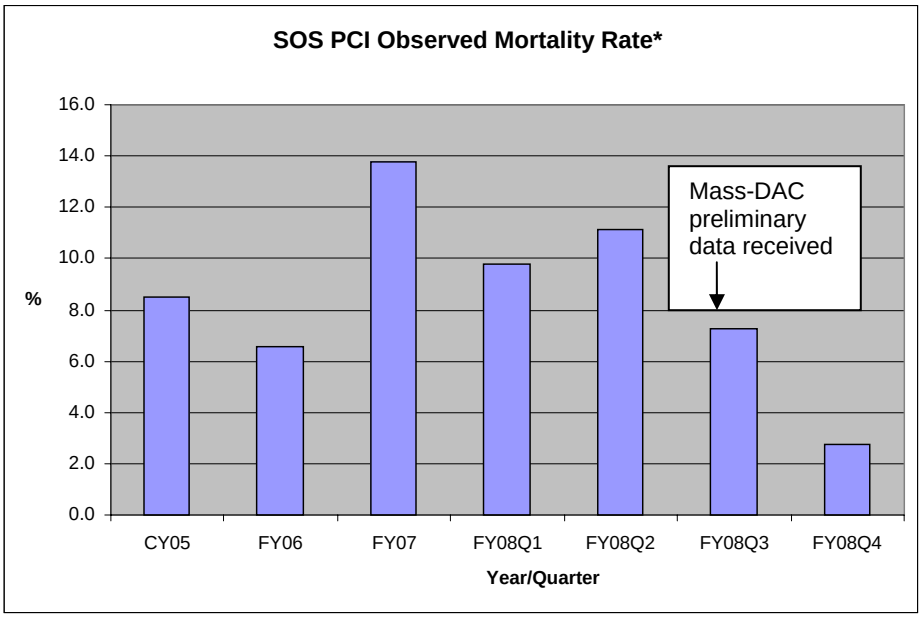
3. **Subsequent to your phone call, we re-reviewed our deaths from 2007 and brought in an outside expert to render an independent assessment.** Of the 43 PCI deaths, our opinion was that 31 were not procedure-related but rather a direct consequence of the medical condition of the patients undergoing the procedure. These assessments involved patients in both the SOS and non-SOS categories**.** Our outside expert, Alice Jacobs, MD, Director, Cardiac Catheterization Laboratory and Interventional Cardiology at Boston Medical Center and former president of the American Heart Association, reviewed these cases and in her exit interview confirmed her agreement with this assessment. She will speak to you separately and will independently document her views in a separate report.

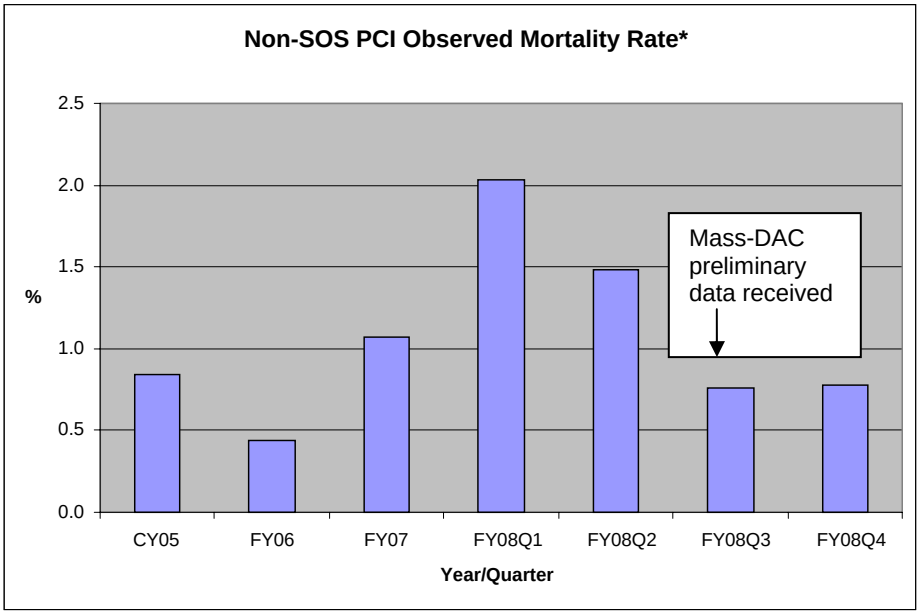
4. **We will continue to monitor outcomes both internally and with independent external monitoring until the DPH considers the concern to have been adequately addressed.** We will also continue to aggressively seek opportunities to improve our practices in the cath lab and periprocedural management to ensure the best possible outcomes for our patients.

The Data

MGH mortality

Below are tables showing our unadjusted mortality rates for each category for the years 2005 through 2007 followed by quarterly results from 2008. As you know, PCI patients are categorized into two groups: patients who have shock and/or ST elevation myocardial infarction (STEMI) are classified as SOS; all other patients undergoing PCI are classified as non-SOS. These tables demonstrate the decrease in mortality after our revised policies were instituted in mid-2008.





*** We do not have access to Mass-DAC data for 2008, so these tables represent unadjusted data from our databases. Also, we do not know precisely how patients were put into SOS and non-SOS categories, so our categories may not conform exactly to Mass-DAC criteria.**

It is important to note that the SOS cohort aggregates two subgroups of patients that sometimes overlap in severity, but in other instances (e.g., shock vs. STEMI without shock) have very different expected outcomes. For example, the national average mortality rate for PCI in patients with uncomplicated AMI is under 10%, whereas post-PCI mortality rate for patients in cardiogenic shock is at least 50% in most studies. In this context, it should be noted that the prevalence of cardiogenic shock within our SOS group is approximately twice that of the state average (16% vs. 8.36%).

Individual operator mortality

Mass-DAC reports to institutions when they identify individual operators whose mortality is excessive compared with state norms. The MGH has not had any individual outliers, either this year or any other year. On Jan. 18, 2009, we re-reviewed internal data looking at individual mortality and complication rates for all 15 interventional cardiologists (we had already performed this review earlier in the month) and found no mortality outliers.

Review of deaths from FY 2007

On Jan. 17, 2009, we re-reviewed all 43 PCI deaths from FY 2007. For each patient, we used a structured review form (Appendix 1), incorporating parameters determined by Mass-DAC to predict outcomes for SOS or non-SOS PCIs, but which also permitted us to record comorbidities not included in the ACC-NCDR registry that forms the basis of the Mass-DAC risk models. Based upon this review of all post-PCI deaths, our categorization of the causes of death was:

Procedure-related	12
Cardiac, unrelated to procedure	18
Noncardiac, unrelated to procedure	11
Indeterminate cardiac/noncardiac, unrelated to procedure	2

- Examples of procedure-related deaths include:
    - right ventricular infarction associated with occlusion of a right ventricular marginal branch during right coronary artery stenting
    - bleeding from a cannulation site used for a peripheral circulatory support device in the femoral artery

- Examples of cardiac deaths unrelated to the procedure include:
    - papillary muscle rupture after myocardial infarction
    - asystolic cardiac arrest six days post-PCI in patient on three antiarrhythmic drugs

- Examples of noncardiac deaths not related to the procedure include:
    - respiratory arrest 37 days after PCI
    - pre-existing cirrhosis with intractable ascites

- Other examples of non-procedure-related deaths, include:
    - PCI in four patients with pre-procedural STEMI, arrhythmic arrest and coma, to enhance the probability of cardiac salvage in the event that there was neurologic recovery; these patients never recovered neurologically and died in spite of a successful cardiac result.

Many of the patients who died had serious comorbidities not captured by the risk-adjustment model – including severe aortic stenosis, recent cardiac or vascular surgery or recent unsuccessful PCI at another hospital. Of the deaths in the second and fourth quarters of FY 2007 (selected because these quarters had the highest non-SOS mortality rates) we identified important comorbidities not captured in the risk-adjustment model in 9 of the 24 patients. For the group of 43 deaths, the breakdown of patients is as follows:

Transferred patients*		25
From PCI-capable hospitals*	10	
From PCI-capable hospitals after PCI*	3	
Renal failure		8
EF< 30		14
Significant aortic stenosis*		4
Surgical or other major procedure on same admission prior to PCI*		4
Cardiac surgical refusal prior to PCI*		7
Metastatic cancer*		2

** – Not in model*

On Jan. 18, 2009, Alice Jacobs, MD, Director of the Cardiac Catheterization Laboratory and Interventional Cardiology at Boston Medical Center, and her colleague Zoran Nedeljkovic, MD, an interventional cardiologist, reviewed all 43 PCI deaths from FY 2007. At their exit interview, they indicated verbal agreement with our findings. Drs. Jacobs and Nedeljkovic will file an independent report.

Quality Improvement and Assurance Activities in MGH Interventional Cardiology

Background information

PCIs at MGH are performed by seven full-time MGH staff interventional cardiologists and eight part-time community interventional cardiologists. Each interventional cardiologist is assisted by an interventional cardiology fellow. Each procedure is staffed by three additional people, a combination of nurses and technicians. Primary PCIs for STEMIs are staffed by four additional people, a combination of nurses and technicians. Pre- and post-procedure order sets are available on-line as a component of the MGH Provider Order Entry System. Guidelines for post-procedure sheath management are continually updated by a task force of physicians and nurses.

Ongoing quality program

The following measures are part of routine quality control for all PCIs performed at MGH:

- The Cardiac Catheterization Laboratory retains Robert C. Leinbach, MD, a former interventional cardiologist who is no longer in active clinical practice, to review performance of all procedures in the laboratory.

- Dr. Leinbach leads Mortality and Morbidity rounds every two months. All deaths and other complications are tabulated. We review in detail all cases with significant clinical or

educational content. Minutes of these meetings, including case presentations, discussion, conclusions and recommendations, are on file.

- Our multidisciplinary, interdepartmental STEMI Committee reviews in detail the care of each patient referred to the Cath Lab for STEMI. Co-chairs are Kenneth Rosenfield, MD, of Interventional Cardiology, and David Brown, MD, of Emergency Medicine.

- For each invasive cardiologist, we track volume, mortality and morbidity (stroke, cardiac perforation, access site complications) rates for both diagnostic and interventional procedures. We examine quarterly and rolling two-year average complication rates. Complication rates above established thresholds prompt an internal review.

- A committee undertakes periodic reviews of all PCI deaths. This committee consists of G. William Dec, MD, Chief of the MGH Cardiology Division; Michael A. Fifer, MD, Medical Director of the Cath Lab; Dr. Leinbach; James McFarland, MD, noninvasive cardiologist; Igor Palacios, MD, Director of Interventional Cardiology; Eugene Pomerantsev, MD, Manager of Cath Lab Information Systems and a nonpracticing cardiologist; and Dr. Rosenfield. Minutes are on file.

Consultation program for high-risk PCIs

Since June 2008, interventional cardiologists asked to perform high-risk PCIs are to consult a second cardiologist prior to deciding whether to perform the requested procedure. This step was implemented as a result of our review of FY 2007 data in May 2008. At that time and again in recent days, we observed that the majority of the deaths after PCIs were related to patient selection. Documentation of these consultations is on file.

Quality control for new circulatory support device

In April 2007, we instituted a program involving a new device that temporarily supports circulation in patients with failing hearts, particularly those with cardiogenic shock or those undergoing very high-risk PCI. Between April and July 2007, we placed these devices in six patients, and three of these patients subsequently died. In response to high mortality and morbidity rates in the critically ill patients undergoing placement of the device, we temporarily halted the program in July 2007. Under the auspices of Christopher Coley, MD, Assistant Chief of Medicine for Quality Assurance, we formed a multidisciplinary task force to review the protocols and procedures related to the use of this device. As a result of the task force analysis, we revised our procedures (Appendix 2), including the criteria for patient selection, and restarted the program in May 2008. Since then, we have placed these devices in three patients, all of whom underwent high-risk PCI with no mortality.

Proposed Next Steps

The data provided by Mass-DAC affords us the opportunity to rigorously evaluate our PCI program. Such comparative data enables us to examine our practice with regard to case selection, PCI performance and overall clinical care. As a result of this most recent comprehensive review, we are committed to reinforcing the changes we have made in case selection and to redoubling our efforts to

maintain technical excellence and superb, compassionate care of our patients. Going forward, we propose the following measures:

- Interventional cardiologists will continue the second opinion process for prospectively defined high-risk PCIs, closely reviewing controversial cases to be sure that we are consistent and appropriate in providing procedures to those patients who are most likely to benefit from them.

- We will continue to assess every PCI death at Morbidity and Mortality Rounds, which we will hold on a monthly basis.

- We are committed to having outside review of Cath Lab outcomes at MGH in a manner, frequency and duration acceptable to the DPH.

In addition to these measures, we remain open to any further suggestions or recommendations that will enhance our program. Our goal remains to provide the highest quality, safest program for the patients and families we serve.

Thank you for the opportunity to respond.

Sincerely,

G. William Dec, MD
Chief, MGH Cardiology Division

Michael A. Fifer, MD
Medical Director, MGH Catheterization Laboratory

Igor Palacios, MD
Director, MGH Interventional Cardiology

Appendix 1

Name:

Medical Record Number:

Reviewer:
Review Date:
Agree with Coding:

Transfer from OSH:

Operator:

Would Case be Done after Practice Change: Yes No

Comorbid Conditions / Status

Renal Failure:	Yes	No	
EF < 30%:	Yes	No	Value:
Status:	Urgent	Emergent	Salvage
LAD > 70%:	Yes	No	%:
Cardiogenic Shock:	Yes	No	
STEMI:	Yes	No	

Compassionate Use:	Yes	No
Refractory VF:	Yes	No
Use of PVAD/CPB:	Yes	No
CPR at start of PCI:	Yes	No
Coma on Presentation:	Yes	No

Other Comorbid Conditions:

Complications:

MI	Yes	No
Cardiogenic Shock	Yes	No
CVA/Stroke	Yes	No
Tamponade	Yes	No
Renal Failure	Yes	No
Emergency PCI	Yes	No
Bleeding	Yes	No
Unplanned CABG	Yes	No

DNR: Yes No

DNR status assigned due to PCI Outcome

Review of Cause of Death:

Comments

Appendix 2

New Circulatory Support Device Program

Implementation of Team Recommendations

Pre-procedure:

- Limit patient selection to high-risk PCI support during standard business hours. (After 6-10 cases have been completed the program will be re-evaluated to include shock patients with device insertion coverage 24/7.)
- Developed interventional cardiologist insertion protocol and training requirements.
- Continued with ongoing cath lab and ICU staff training.
- Developed relative contraindications for device placement.
- Created evaluation team with representatives from Interventional Cardiology, Cardiac Surgery VAD Team, Heart Failure Team and Vascular Surgery.

Post-procedure:

- Patients admitted to single unit (CSICU) post-device placement under the same standard as all VAD patients.
- MD coverage provided by the CSICU intensivist, Cardiac Surgery ICU Team and the Cardiac Surgery VAD attending on call.
- Post-procedure order template developed in collaboration with Cardiac Surgery.
- Tracking of patient outcomes through existing cardiology database.