

April 22, 2011

Joseph Martin
Executive Director
Pennsylvania Health Care Cost Containment Council
225 Market St., Suite 400
Harrisburg, PA 17101

Dear Mr. Martin:

On behalf of Pennsylvania Hospital, we would like to thank you for the opportunity to comment on the Cardiac Surgery 2008-2009 Report. We appreciate the time and effort involved in reporting information related to cost and outcomes of healthcare in Pennsylvania. After careful review of the report, we would like to provide these additional observations.

The patients who had heart valve repair and replacements in the cardiac surgery program at Pennsylvania Hospital included patients with complex medical conditions. Two of the patients included in the mortality report, who underwent isolated valve repair/replacement were high risk Jehovah's Witness patients, one in 2008 and another in 2009. One of these patients had chronic dialysis-dependent renal failure, diabetes, and multiple other significant medical problems including severe mitral regurgitation. She developed multisystem organ failure postoperatively, in part due to inadequate tissue oxygenation associated with anemia. Due to her religious beliefs, her anemia could not be corrected leading to a vicious cycle culminating in death. In spite of our request to have this patient excluded from the analysis her mortality is included in these results. If we excluded the two Jehovah's Witness patients from this analysis our mortality for isolated valve, total valve and valve/CABG would all be within the expected range.

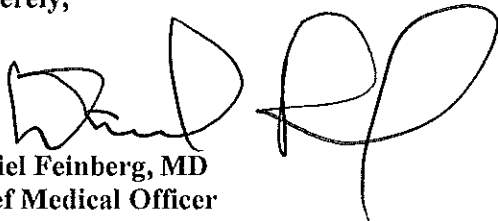
We receive patients for bloodless complex cardiac surgery from all over the country, primarily from our region. These patients have a religion-based refusal to accept blood or blood product transfusions. Most of these patients have been turned down by other cardiac surgeons and cardiac surgery programs because they are perceived to have a prohibitively high risk for cardiac surgery. In spite of the generally perceived high risk of these transfusion-free cases, we continue to have excellent overall results with these patients. At Pennsylvania Hospital using a transfusion-free approach, we have successfully performed 11 reoperations, including three in patients with patent internal mammary arteries, two Stanford Type A aortic dissections, reoperative complex aortic root replacements, hemiarch replacement using hypothermic circulatory arrest, combined aortic aneurysm/mitral valve repair, combined coronary artery bypass/ valve procedures, resection of cardiac tumors and adult congenital cardiac surgical procedures including septal defects and correction of anomalous pulmonary venous drainage. When published, ours will be the third largest series of cardiac surgery performed in Jehovah's Witness patients in the English literature, and of these series ours includes, arguably, the most complex collection of bloodless cardiac surgery procedures ever reported.

Although it is the consensus of expert opinion that the risk of performing these procedures without unrestricted access to blood product transfusions - when indicated - is higher than it would be otherwise, there is insufficient data to account for this increased risk. Given the absence of data to allow for an appropriate statistical risk-adjustment for these patients, they should be excluded when an analysis of their specific clinical course indicates that blood or blood product transfusion - were it available - would have potentially have been life-saving. Without a means for adjusting risk, the only statistically valid way to approach this problem is to exclude such patients from the analysis. Had we been able to exclude these two patients from the PHC4 analysis, our valve-related operative mortality would have been within the accepted range. We would strongly encourage PHC4 in the future, to exclude such patients from this analysis until an appropriate risk-adjustment can be made. Otherwise, these bloodless (transfusion-free) cardiac surgery patients will find it increasingly difficult to find highly skilled surgeons who will offer them potentially lifesaving surgical procedures in the future.

Several other high risk patients were included in our mortality date. These included one patient with leukemia and coagulation abnormalities and another who underwent double valve repair/replacement as well as a full Cox Maze III procedure. These multiple procedures are well known to carry higher risk than isolated valve replacement procedures due to the increased blood loss, the more severe systemic inflammatory response syndrome and associated organ dysfunction associated with the necessarily longer cardiopulmonary bypass times. These risks increase exponentially (rather than linearly) with increasing bypass time. In addition one of our patients was nearly 90 years of age and the analysis of our data also includes with other risk factors including chronic kidney disease, atrial fibrillation, chronic airway obstruction, acidosis and profound left ventricular dysfunction.

We continuously review the quality of patient care at Pennsylvania Hospital for improvement opportunities. Thank you for the inclusion of this information with the published report.

Sincerely,



Daniel Feinberg, MD
Chief Medical Officer