Introduction

In October 2009, Mass-DAC defined the exceptional risk criteria used to identify patient PCI procedures with characteristics not captured by the Mass-DAC compassionate use criteria or the ACC-NCDR data collection fields. These case studies were compiled as an educational tool based on scenarios that could be submitted as exceptional risk cases. The recommendation after each case study represents what the Exceptional Risk Committee could decide based on the submitted case information. The case studies are fictitious and do not represent any actual cases submitted to or reviewed by the committee.

Case Study 1

An 82 year old male with history of coronary artery disease, congestive heart failure, and chronic kidney disease slipped on the ice in driveway while shoveling snow, suffering extensive complex fracture of left femur. Upon presentation to emergency department, patient developed chest pain and shortness of breath, and was found to have suffered a NSTEMI. The patient was medically stabilized and evaluated for urgent complex orthopedic surgery. Given acute coronary syndrome and history of coronary disease, patient was taken for diagnostic catheterization which revealed complex 80% left main, 95% ramus and 95% RCA lesions with EF=40%. The patient was evaluated by cardiac surgery and deemed not a suitable surgical candidate due to the inability to participate in rehab following CABG (given orthopedic issues). After discussion with anesthesiology, orthopedic surgery and clinical cardiology, a consensus recommendation was made to proceed to high-risk PCI of LMCA and Ramus and RCA to allow progress toward necessary orthopedic repair of femur fracture.

The patient underwent technically successful PCI using bare metal stents to the LMCA, RCA and ramus branches which the patient tolerated well. Orthopedic surgery was scheduled for 7 days following LMCA intervention. On post-PCI day 4 the patient had increased leg pain, and a bedside traction pin was inserted to stabilize a bone fragment. Two days later the patient became delirious and was documented to have developed staph aureus bacteremia. The patient was treated aggressively with antibiotics, but definitive orthopedic surgery was delayed. Ultimately, the patient
became hypotensive, delirious and suffered multi-system organ failure from sepsis. After a family meeting, comfort measures were instituted and the patient expired on post-PCI day 12.

- Indication for procedure: Cardiac instability prior to major orthopedic surgery
- Unmeasured risk factors: Severe orthopedic injury ultimately leading to sepsis and death
- Alternative therapies considered: CABG

**Recommendation:** Class 2 (possible) – initial CABG would likely have been better strategy and there was no documentation that the recommendation of the original cardiac surgeon was appealed or discussed further.

**Case Study 2**

A 61 male with history of asymptomatic stable coronary artery disease and idiopathic pulmonary fibrosis underwent successful bilateral lung transplant complicated by persistent atelectasis and ultimately partial dehiscence of bronchial anastomosis and mediastinitis. Urgent repeat thoracic surgery was complicated by VF arrest and inferior STEMI for which the patient was taken emergently to coronary angiography. Cardiac catheterization demonstrated thrombotic occlusion of the RCA and high grade stenosis of the LAD. The infarct related artery was stented using a bare metal stent which was technically successful. The patient returned to the thoracic intensive care unit where, over the next three weeks the patient developed progressive renal insufficiency and ultimately developed sepsis and multi-system organ failure. The patient was ultimately made comfort measures only, and expired 20 days after the PCI procedure for STEMI.

- Indication for procedure: Emergent primary PCI for STEMI complicated by VF arrest
- Unmeasured risk factors: Recent lung transplantation, complicated by acute mediastinitis
- Alternative therapies considered: None

**Recommendation:** Class I (definite) – clinical instability and urgency of decision making mandated emergency PCI in the setting of a second life-threatening condition.
Case Study 3

An 83 year old male with history of severe COPD, ischemic cardiomyopathy, EF=25%, managed medically (due to patient’s expressed preference), developed progressive dyspnea and was found to have severe aortic stenosis with a echocardiographically estimated mean gradient of 40mmHg and a calculated aortic valve area of 0.8cm². The patient underwent elective coronary angiography which demonstrated complex calcified LAD and LCx disease. The patient was determined to be unsuitable for cardiac surgery, and was enrolled in a clinical trial for percutaneous aortic valve replacement, for which he was randomized to medical therapy arm (no percutaneous valve). Due to ongoing symptoms of dyspnea and class IV symptoms, the patient was referred for PCI and aortic valvuloplasty. The patient underwent technically successful PCI of the LAD and LCx with bare metal stents. In addition, the patient underwent palliative balloon valvuloplasty, which resulted in a modest improvement in hemodynamic parameters (with increase in calculated valve area to 1.5cm²), but also 2+ aortic insufficiency. Subsequently, the patient did well with daily improvements in ambulation and activity, but developed urosepsis on post-procedure day #6. Despite aggressive therapy, the patient developed renal insufficiency and ultimately declined dialysis, expiring on hospital day #14 after being made comfort measures only.

- Indication for procedure: Multi-vessel PCI for ischemic cardiomyopathy and class IV symptoms
- Unmeasured risk factor: Critical aortic stenosis
- Alternative therapies considered: CABG/AVR (determined not suitable by cardiac surgery)

**Recommendation:** Class 2 (possible) – It is not clear that PCI was required, nor that symptoms were attributable to severity of aortic stenosis. In general, non-emergent cases require no other viable therapeutic options to be considered “exceptional risk”.
Case Study 4

An 84 year old woman with O2 dependent COPD presented with dyspnea and atrial fibrillation to a community hospital, where attempts at placing a central venous access line (left subclavian) were complicated by chest hematoma. Ultimately, the patient developed severe pulmonary edema, and was found to have a NSTEMI and required intubation. The patient was transferred to PCI capable hospital, and attempts at extubation were unsuccessful. Therefore, the patient was referred to the cath lab where coronary angiography demonstrated complex left main and multivessel CAD. The patient and referring cardiologist declined CABG, and the patient underwent complex LMCA and multivessel CAD using drug eluting stents. Post procedure the patient remained intubated and developed ventilator associated pneumonia complicated by sepsis. Ultimately the patient developed multi-system organ failure and was made comfort measures only, after which she expired on post-PCI day #4.

- Indication for procedure: Multi-vessel PCI for NSTEMI and inability to wean from ventilator
- Unmeasured risk factor: Respiratory failure
- Alternative therapies considered: Family and patient declined consideration for CABG

**Recommendation:** Class 2 (possible) – It is not clear that inability to extubate was due to ischemia that would be effectively treated with PCI. In addition, patient/family preference to avoid CABG is not, in and of itself, support for class 1 exceptional risk.