Mass-DAC Exceptional Risk Case Definitions
Adjudication Protocol – October 2010

Summary: This memorandum provides the definition and application of the exceptional risk designation for the Mass-DAC angioplasty registry. These proposed changes are based on the recommendation of

Definition: An exceptional use case will be considered for review if the operator or institution believes that the case in question meets the following criteria:

1. Extremely high risk features not captured by current risk adjustment covariates.
2. PCI was the “best” or only option for improving chance for survival.

The intent of the exceptional risk designation is to categorize rare uniquely high risk cases, with high potential patient benefit, in which the predictors of risk are not included in the current Mass-DAC risk adjustment model. The risk of in-hospital mortality can be based on anatomical or clinical considerations, but will typically involve a second, acutely life-threatening condition for which PCI is urgently required in order to allow continued treatment. It is expected that nearly all exceptional risk cases will involve severe time pressure in order to make a therapeutic decision (such as the need to treat STEMI in a patient with a second severe medical co morbidity) and that elective/urgent cases will rarely qualify for exceptional risk designation. Of note, a case being declined by cardiac surgery or by patient preference is not sufficient to warrant exceptional risk designation. Refractory ischemic instability may not, in and of itself, qualify for exceptional risk designation unless all reasonable medical options have been exhausted. Finally, it is important to note that a non-cardiac cause of death is not, in and of itself, justification for exceptional risk designation.

An example of exceptional risk case could include a patient presenting with simultaneous life-threatening medical condition such as a STEMI as well as impending rupture of an abdominal aortic aneurysm. In such cases, there may not be an opportunity to attempt to stabilize the patient from the second medical condition before treating the acute coronary syndrome. Treating the STEMI with PCI is a prerequisite to safe treatment of the second life-threatening condition (such as a rupturing abdominal aortic aneurysm).

The review committee will require a detailed letter explaining the circumstances, background and justification for categorization of exceptional risk. The letter needs to include the components listed here:

1. The first paragraph of the letter must clearly and concisely summarize the clinical presentation and hospital course, the unusual circumstances and extreme risk of the procedure, as well as the justification for performing the procedure in terms of potential benefit for the patient.
2. The second paragraph should provide a detailed summary of the clinical presentation and hospital course with justification for
appropriateness of intervention based on established clinical guidelines or evidence in the medical literature.

3. Throughout the letter, there should be specific references (which are attached) of the particular elements of the medical record where the additional objective risk factors are documented.

4. Clear documentation and supporting evidence for high risk features for the case. These clinical features must not be currently included in the Mass-DAC risk adjustment covariates and may not be included in the current ACC-NCDR instrument.

5. Documentation of consideration of alternative treatments (medical therapy, surgical therapy) and why PCI was selected. References to clinical notes from consultants and other caregivers will be important. The source clinical records referenced in the letter will be required during the review process.

Explanations of Terms and Intent: The exceptional risk definition is purposefully broad, so as to allow a wide range of possible case submissions. In general, the intent of the exceptional risk designation is to categorize uniquely high risk cases, with high potential benefit, in which the predictors of risk are not included in the current Mass-DAC risk adjustment model. The predictors of risk for such exceptional risk cases may derive from cardiac or non-cardiac causes, and should not include risk factors qualifying the case for compassionate use designation. While the definition is broad, the threshold for adjudication as exceptional risk is extremely high, and determination of exceptional risk requires compelling justification from the petitioning hospital and physician. While the strong preference of the adjudicating committee would be to receive cases that both survived to discharge and died before discharge; the committee will review all cases submitted regardless of vital status at discharge.

Adjudication Procedure:
Cases submitted for review as potential exceptional risk cases will be submitted to Mass-DAC through existing mechanisms and must include the following information:

1. A letter, signed by the interventionalist on their professional letterhead, reviewing the clinical presentation of the case, justification of appropriateness of intervention, clear explanation of all accompanying support documents, and justification for designation as exceptional risk as noted above. The preferred letter format is provided at the end of this document.

2. A digital copy of all angiograms performed during the hospitalization.

3. A copy of the full medical record, if possible. If the entire medical record is too large to send, please send the part of the medical record that would substantiate and document the case as exceptional use.
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The Exceptional Risk Adjudication Committee (ERAC) will meet to review specific cases twice per year. Non-interventional members of the ERAC will include a non-interventional physician (clinical cardiologist and/or cardiac surgeon) and a medical ethics representative as recommended by DPH.

The ERAC will meet at Mass-DAC to review the submitted exceptional risk cases. At the time of the full ERAC meeting, each case will be comprehensively reviewed by a primary reviewer and then presented to the full committee. ERAC members will then be able to ask questions of each presenter, and a vote, by secret ballot, will be taken. At each meeting, the voting members of ERAC will be reminded of the process for determining exceptional risk by reviewing the definition. In addition, the ERAC will specifically consider those factors which would favor supporting designation as exceptional risk including:

1. Clinical evidence or expert opinion that the cited risk factors leading to dramatically increased peri-procedural risk are valid/supported **AND** that the specific risks are not adequately captured in the existing risk adjustment models.

2. Evidence of appropriateness for performance of the procedure, as supported by generally accepted clinical practice guidelines (e.g., ACC/AHA) or substantial support for performance of procedure by multiple physicians with written documentation in the clinical record.

3. Evidence that PCI at the time performed was the only, or clearly best, option to avoid major morbidity or death from coexistent medical problems.

The ERAC committee will then vote to determine the classification of the case being reviewed. The three classes for exceptional risk are:

- **Class I** – requires unanimous consent of ERAC that the procedure meets the criteria for exceptional risk.
- **Class 2** – requires majority, but non-unanimous, vote of ERAC.
- **Class 3** – all cases not achieving majority vote.

Only Class 1 designated cases will be excluded from the analysis of the Mass-DAC risk adjusted mortality analyses, both for the institution physician operator. Class 2 exceptional risk cases will be utilized, on a periodic basis, to refine the risk adjustment and adjudication process, but will remain included in the overall case volume used for determination of risk-adjusted mortality estimates. Class 3 designated cases will not be used for modifying or adjusting the analysis and will not help inform changes in the risk-adjustment policies. De-identified summaries of the deliberation of each case will be retained by Mass-DAC and may be used in later processes, including but not limited to,
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physician specific quality review efforts. Mass-DAC will send a brief summary of the findings of the committee to the submitting hospital.

Specific case reviewers must recuse themselves if the case assigned involves their medical center, a physician in practice with the reviewer, or a physician involved in a competing practice. Likewise, a member of ERAC must recuse themselves from voting on any case that involves their medical center, a member of their practice or a member of a competing practice. The absence of conflict of interest of each ERAC presenter and voter will be recorded in the archived deliberations of the ERAC review.
Exceptional Risk Letter Template

Section 1: Introduction
A one paragraph brief overview of the clinical circumstances of the case, the general nature of the unusual risk features. Examples might include simultaneous infectious, neurologic, oncologic, surgical or other medical co-morbidity. Also, the first paragraph should include an overview of the therapeutic options that were considered, whether additional consultants (from which specialties) were involved in the decision to proceed with treatment.

Section 2: Clinical Course
This section should provide a detailed clinical review that is temporal in nature, from time of initial presentation through time of discharge or death. All references to critical information including procedure notes, consultant notes, attending physician’s notes, etc. should be attached to the letter. All alternative treatments that were considered and documented in the medical record should be noted and referenced, along with the rationale to proceed to PCI given the circumstances of the case. A detailed description of the preparation for the procedure, contingency planning, patient consent process as well as a detailed review of the procedure itself should be provided.

Section 3: Unique Risk Factor Discussion
This section should be dedicated to presenting the rationale as to why the risks faced by the patient treated were unique and portended extremely high risk of mortality during the hospitalization, and are not adequately accounted for in the existing Mass-DAC risk adjustment algorithm. Specific references should be made to the medical literature, with direct quotations if possible. This section is essential to demonstrating that the risks faced by the patient warrant consideration as an exceptional risk case.

Section 4: Evidence for Probable Benefit from Procedure
The next section of the petition letter should provide the review committee with the rationale as to why PCI was the preferred treatment for the patient; and that the planned PCI procedure was likely to provide meaningful clinical benefit to the patient. References to medical literature and especially to current clinical guidelines will provide the best means of justification for a choice of therapy.

Section 5: Summary and Conclusion
Please note: It would be helpful if the submitting organization clearly labeled every piece of information in the records they are providing so that the reviewers may easily find the confirmatory evidence. Page numbers stamped on the submitted documents and then referred to in the letter would make reviewing the records that much easier.