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Table A1 - CEC Sub-classification of Cardiovascular Procedure Deaths

| | Treatment | | |
|--|-------------------------------------|----------------------------------|------------------------|
| Mortality Distribution (% of Patients, % of Deaths) | CABG (N=610, 218) ^{1,2} | MED (N=602, 244) ³ | Total (N=1212, 462) |
| Total Procedure deaths | 28 (4.6, 12.8) | 9 (1.5, 3.7) | 37 (3.1, 8.0) |
| CABG | 28 (4.6, 12.8) | 7 (1.2, 2.9) | 35 (2.9, 7.6) |
| CABG alone | 25 (4.1, 11.5) | 2 (0.3, 0.8) | 27 (2.2, 5.8) |
| CABG + MVR | 1 (0.2, 0.5) | 2 (0.3, 0.8) | 3 (0.2, 0.6) |
| CABG + MVR + TVR | 0 | 1 (0.2, 0.4) | 1 (0.1, 0.2) |
| CABG + TVR | 1 (0.2, 0.5) | 0 | 1 (0.1, 0.2) |
| CABG + SVR | 1 (0.2, 0.5) | 2 (0.3, 0.8) | 3 (0.2, 0.6) |
| Transplant | 0 | 2 (0.3, 0.8) | 2 (0.2, 0.4) |

^{1.} These are total number of patients and total number of deaths.

^{2.} All events in the surgical cohort occurred after the initial procedure.

^{3. 7} deaths occurred in the medical therapy cohort after a CABG-related crossover procedure; 2 post transplant

STICH- Mode of Death definitions

Event Definitions

Death:

All deaths will be adjudicated.

The STICH CEC will categorize the cause of death as follows:

Cardiovascular Death:

- Sudden death VT/ VF, Brady arrhythmia, or Unknown
- Fatal pump failure
- Fatal MI
- Fatal CVA
- Other cardiovascular

I. Cardiovascular procedure related death

- PCI
- CABG
- Surgical ventricular restoration and CABG
- ICD/ Bi-ventricular pacemaker
- Other cardiovascular procedure related

II. Vascular death

- Peripheral vascular disease
- Vascular complication
- Peripheral emboli
- Venous thrombosis
- Other

Non-Cardiovascular Death

- Infection
- Neurologic
- Pulmonary
- Renal
- Malignancy
- Other

Unknown

Definitions in Detail:

I. Cardiovascular Death - Death will be considered to be of cardiovascular etiology unless there is an obvious non-cardiac cause.

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Sudden death:

Defined as death that occurred suddenly and unexpectedly in which the time of death is known.

Witnessed Death due to:

- An identified arrhythmia (ECG or at least monitor recording, or monitor witnessed arrhythmia either by a medic or a paramedic).
- Cardiac arrest or cardiovascular collapse in absence of premonitory heart failure or myocardial infarction or other modes of death.
- Patients resuscitated from a sudden cardiac arrest who later die of the sequelae of the event or similar patients who die during an attempted resuscitation.

Or

 Death that occurred in which the time of death is unknown. In this case, the interval between the time the patient was last seen and the time the death became known will be recorded.

Fatal pump failure:

• Death occurring after new or worsening symptoms and/or signs of heart failure. Patients who are being treated for heart failure and who have a sudden death as the terminal event will be classified as having a pump failure related death.

Classified as:

- 1. Heart failure with secondary arrhythmic death.
- 2. Heart failure without secondary arrhythmic death.

Fatal myocardial infarction:

Fatal myocardial infarction may be adjudicated in any one of the following three scenarios:

• Death occurring after a documented myocardial infarction in which there is not conclusive evidence of another cause of death.

Patients who are being treated for myocardial infarction and who have a sudden death as the terminal event related to the MI will be classified as having a myocardial infarction related death.

- Autopsy evidence of a recent infarct with no other conclusive evidence of another cause of death.
- A Fatal Myocardial Infarction may be adjudicated for an abrupt death that has suggestive criteria for an infarct but does not meet the strict definition of a myocardial infarction. The suggestive criteria is as follows:
 - Presentation of chest pain AND

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- One of the following:
 - ECG changes indicative of a myocardial injury or
 - Abnormal markers without evolutional changes (i.e., patient died before a subsequent draw) or
- other evidence of wall motion abnormality

CVA Related Death:

• Death occurring after a documented CVA.

Cardiovascular procedure related death:

• Death occurring during a cardiovascular procedure (CABG, SVR, PTCA, other) or when the events leading to death are related to the procedure. The type of procedure will be specified.

(Example: A patient who had a CABG up to 15 days ago, who developed a subsequent myocardial infarction and who later died will still be classified as procedural related death.)

Other Cardiac Death:

• Death must be due to a fully documented cardiovascular cause not included above.

II Non-Cardiovascular Death – documented non-cardiovascular cause

III Unknown – deaths without available information