



STATE OF NEW YORK DEPARTMENT OF HEALTH

1 University Place Rensselaer, New York 12144

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

December 1, 2009

Dear Cath Lab Director:

I am writing to provide you with important information concerning an up-coming change in the Percutaneous Coronary Interventions Reporting System (PCIRS). Beginning January 1, 2010 and continuing for a period of at least 3 years, patients with documented pre-procedural acute MI, cardiac arrest and anoxic/hypoxic brain injury who expire under certain conditions subsequent to PCI will be excluded from Department of Health analysis and public reporting. This policy is the result of ongoing discussions with NYS providers, careful deliberations among the New York State Cardiac Advisory Committee (CAC) members, and feedback provided through the 2007 and 2008 annual cause of death surveys.

All PCI patients will continue to be reported to the PCIRS database. After quarterly reporting, the hospital will be provided the opportunity to indicate, through a written letter *and* medical record documentation, if any of the mortalities meet the criteria for death from anoxic brain injury. Information that could identify a hospital, physician, or patient will be removed from these materials by Cardiac Services Program staff and the materials will be reviewed by members of the CAC PCIRS subcommittee (cardiologists from inside and outside New York State). Hospitals will be notified regarding final determinations prior to publication of the annual report. Decisions of the CAC reviewers will be considered final.

Guidelines to assist you in determining when to request an exclusion for these circumstances have been developed and are attached. Any comments you wish to provide on the proposed guidelines or process for exclusion should be submitted to Ms. Kimberly Cozzens, by December 15th so that guidelines can be finalized and distributed prior to January 1, 2010. Ms. Cozzens can be reached by telephone at 518-402-1016, by email at ksc06@health.state.ny.us or by mail at:

Kimberly S. Cozzens, MA
Cardiac Initiatives Research Manager
Cardiac Services Program
New York State Department of Health
1 University Place, Suite 218
Rensselaer, New York 12144

Thank you in advance for your attention to this important matter.

Sincerely,

A handwritten signature in black ink that reads "Paula M. Waselauskas".

Paula M. Waselauskas, RN, MSN
Administrator, Cardiac Services Program
New York State Department of Health

cc: Data Coordinator
CAC Members

Guidelines for Requesting PCIRS Mortality Exclusion For Anoxic/Hypoxic Encephalopathy

A. Criteria present before the PCI is performed:

1. AMI: PCI is done for Acute Myocardial Infarction;
2. CARDIAC ARREST: Documented cardiac arrest has occurred as part of initial presentation for the AMI and before the patient is brought to the cardiac catheterization laboratory (typically out-of- hospital cardiac arrest);
3. COMA: The patient had normal consciousness before the cardiac arrest, but becomes comatose, broadly defined as the failure to exhibit adequate responsiveness to external stimuli with the understanding that early after cardiac arrest this can be due to multiple factors and not just prolonged hypoxia. There is no need to “prove” anoxic/hypoxic encephalopathy at this time and indeed it cannot be “proved”;

B. Criteria involving the procedure:

1. NO IN-LAB DEATH: The patient survives the procedure, even if emergency surgery is done.

C. Criteria present after the procedure:

1. RESPIRATOR DEPENDENT: The patient is dependent on mechanical respiratory support up to the time it is withdrawn. (This does not necessarily mean the ET tube is removed.)
2. CONSULTATION by Neurology or Critical Care (not a PCI physician) documenting the presence of anoxic/hypoxic encephalopathy:
 - a. the neurological status - physical findings consistent with Glasgow Score < 5 or wording generally to that effect (see Table 1);
 - b. tests supporting the consultant’s diagnosis of persistent anoxic/hypoxic encephalopathy such as EEG’s, apnea tests, etc.;
 - c. Specific language by the consultant stating that the neurological condition is due primarily to anoxic/hypoxic encephalopathy, indicating clearly that prognosis is poor for recovery from the coma, and that the consultant supports the withdrawal of care;
 - d. Documentation specifying the people involved in the decision to withdraw care (viz. physicians, family, proxies);
 - e. Documentation of the cardiac status as being hemodynamically stable (no shock or unstable hemodynamics, i.e. SPB> 90 mmHg), without reinfarction or repeat cardiac arrest while still being supported;
 - f. A timed and dated note in the chart to indicate that withdrawal is planned before it is actually carried out. This should be clearly written before the support is withdrawn. A reading of the chart which can be interpreted to indicate a planned withdrawal will be accepted if it is then seen to have been carried out only after appropriate consultation notes and documentation (see sections C.2.a-e above) are present. The specific cause of death is not important once withdrawal of support has occurred but it is encouraged to have the death certificate note anoxic/hypoxic encephalopathy or terms to that effect (“coma”, loosely “brain death”) as at least a contributing cause of death;

g. The patient has survived a minimum of 72 hours after the index PCI unless it can be documented that the diagnosis of anoxic/hypoxic encephalopathy is present (see C.2.a-f) and death was accelerated by renal failure that was not treated because of the anoxic/hypoxic encephalopathy.

The following features will make a case ineligible for exclusion:

- A. Before the procedure:
No cardiac arrest has occurred, regardless of the cause of coma.
- B. During the procedure:
In-lab death occurs for any reason.
- C. After the procedure:
Death before planned withdrawal of support as described above.

Table1.

Glasgow Coma Scale		<u>Points</u>
1. EYE OPENING		
Spontaneous		4
Response to verbal command		3
Response to pain		2
No eye opening		1
2. BEST VERBAL RESPONSE		
Oriented		5
Confused		4
Inappropriate words		3
Incomprehensible sounds		2
No verbal response		1
3. BEST MOTOR RESPONSE		
Obeys commands		6
Localizing response to pain		5
Withdrawal response to pain		4
Flexion to pain		3
Extension to pain		2
No motor response		1