

# World Database for Pediatric and Congenital Heart Surgery

## Appendix H: Complications

### **Arrhythmia requiring drug therapy**

A condition in which the heart beats with an irregular or abnormal rhythm requiring drug therapy.

### **Arrhythmia requiring electrical cardioversion or defibrillation**

A condition in which the heart beats with an irregular or abnormal rhythm requiring electrical cardioversion or defibrillation

### **Arrhythmia requiring Permanent pacemaker**

Implantation and utilization of a permanent pacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block).

### **Bleeding, requiring reoperation**

Postoperative/postprocedural bleeding requiring reoperation

### **Cardiac dysfunction resulting in low cardiac output**

Low cardiac output state characterized by some of the following: tachycardia, oliguria, decreased skin perfusion, need for increased inotropic support (10% above baseline at admission), metabolic acidosis, widened Arterial - Venous oxygen saturation, need to open the chest, or need for mechanical support. If the cardiac dysfunction is of a severity that results in inotrope dependence, mechanical circulatory support, or listing for cardiac transplantation, please also code as "Cardiac failure (severe cardiac dysfunction)". A patient will be considered to have "inotrope dependence" if they cannot be weaned from inotropic support (10% above baseline at admission) after any period of 48 consecutive hours that occurs after the time of OR Exit Date and Time, and either (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation. If patient meets criteria for severe cardiac dysfunction, only code "severe".

### **Cardiac failure (severe cardiac dysfunction)**

Low cardiac output state characterized by some of the following: tachycardia, oliguria, decreased skin perfusion, need for increased inotropic support (10% above baseline at admission), metabolic acidosis, widened Arterial - Venous oxygen saturation, need to open the chest, or need for mechanical support. This complication should be selected if the cardiac dysfunction is of a severity that results in inotrope dependence, mechanical circulatory support, or listing for cardiac transplantation. A patient will be considered to have "inotrope dependence" if they cannot be weaned from inotropic support (10% above baseline at admission) after any period of 48 consecutive hours that occurs after the time of OR Exit Date and Time and either (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation. If patient meets criteria for severe cardiac dysfunction, only code "severe".

### **Chylothorax or pleural effusion, requiring drainage**

Presence of lymphatic fluid in the pleural space, commonly secondary to leakage from the thoracic duct or one of its main tributaries. Thoracocentesis is the gold standard for diagnosis and generally reveals a predominance of lymphocytes and/or a triglyceride level greater than 110 mg/dL

### **Endocarditis-postprocedural infective endocarditis**

Infective endocarditis in the setting of a heart which has been altered by surgery or intervention. Duke Criteria for the Diagnosis of Infective Endocarditis (IE): The definitive diagnosis of infective endocarditis requires one of the following four situations: 1) Histologic and/or microbiologic evidence of infection at surgery or autopsy such as positive valve culture or histology; 2) Two major criteria; 3) One major criterion and three minor criteria; 4) Five minor criteria. The two major criteria are: 1) Blood cultures positive for IE 2) Evidence of endocardial involvement. Blood cultures positive for IE requires: 1) Typical microorganism consistent with IE isolated from 2 separate blood cultures, as noted in number two below (viridans streptococci, Streptococcus bovis, Staphylococcus aureus, or HACEK group [HACEK, Haemophilus species {H. arophilus and H. paraaerophilus}, Actinobacillus actinoincetemcomitans, Cardiobacterium hominis, Eikenella corrodens, and Kingella kingae.]) or (Community-acquired enterococci in the absence of a primary focus); 2) Microorganisms consistent with IE isolated from persistently positive blood cultures defined as: (At least 2 positive cultures of blood samples obtained > 12 hours apart) or (All of 3 or a majority of 4 or more separate cultures of blood, the first and the last sample obtained > 1 hr apart); 3) Single blood culture positive for Coxiella burnetii or an antiphase I IgG antibody titer of >1 :800. Evidence of endocardial involvement requires 1) Positive results of echocardiography for IE defined as: (Oscillating intracardiac mass on the valve or supporting structures in the path of regurgitant jets or on implanted material in the absence of an alternative anatomic explanation) or (Abscess) or (New partial dehiscence of a valvular prosthesis) or 2) New valvular regurgitation (worsening or changing or preexisting murmur not sufficient). The six minor criteria are: 1) Predisposing heart disease or injection drug use (IVDA); 2) Temperature of > 38C; 3) Vascular phenomenon (major arterial emboli, septic pulmonary infarcts, mycotic aneurysm, intracranial or conjunctival hemorrhage, Janeway's lesions); 4) Immunologic phenomenon (glomerulonephritis, Osler's nodes, Roth's spots, rheumatoid factor); 5) Microbiologic evidence (a positive blood culture that does not meet a major criterion as noted above) or serologic evidence of active infection with an organism consistent with IE; 6) Echocardiographic findings that are consistent with IE but do not meet a major criterion as noted above.

### **Intraventricular hemorrhage (IVH) > grade 2**

An intraventricular hemorrhage involves bleeding into the brain's ventricular system, where the cerebrospinal fluid is produced and circulates towards the subarachnoid space. Grade I - bleeding occurs just in the germinal matrix; Grade II - bleeding also occurs inside the ventricles, but they are not enlarged; Grade III - ventricles are enlarged by the accumulated blood; Grade IV - bleeding extends into the brain tissue around the ventricles

### **Mechanical circulatory support (IABP, VAD, ECMO, or CPS)**

Utilization of postoperative/postprocedural mechanical support, of any type (IABP, VAD, ECMO, or CPS), for resuscitation/CPR or support, during the postoperative/postprocedural time period. Code this complication if it occurs (1) within 30 days after surgery or intervention regardless of the date of hospital discharge, or (2) after 30 days during the same hospitalization

### **Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS)**

Multi-System Organ Failure (MSOF) is a condition where more than one organ system has failed (for example, respiratory failure requiring mechanical ventilation combined with renal failure requiring dialysis). (MODS). Only code this complication if the patient has failure of two or more than two organs. Do not code MSOF if only failing organs are the heart and lungs.

**Neurological deficit diagnosed in the operating room, persisting at discharge or 91 days if patient is still in hospital.**

Newly recognized and/or newly acquired (diagnosed in the operating room) deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similar unaffected inpatient, with a persisting neurologic deficit present at hospital discharge or 91 days if patient is still in hospital.

**Neurological deficit diagnosed in the operating room, not present at discharge**

Newly recognized and/or newly acquired (in the operating room) deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similar unaffected inpatient, with no persisting neurologic deficit present at hospital discharge or 91 days if patient is still in hospital.

**Neurological deficit that occurred after the operating room visit, persisting at discharge**

Newly recognized and/or newly acquired (diagnosed after the operating room visit) deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similar unaffected inpatient, with a persisting neurologic deficit present at hospital discharge or 91 days if patient is still in hospital.

**Neurological deficit that occurred after the operating room visit, not present at discharge**

Newly recognized and/or newly acquired (diagnosed after the operating room visit) deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similar unaffected inpatient, with no persisting neurologic deficit present at hospital discharge or 91 days if patient is still in hospital.

**Paralyzed diaphragm (possible phrenic nerve injury), requiring surgical plication**

Presence of elevated hemi-diaphragm(s) on chest radiograph in conjunction with evidence of weak, immobile, or paradoxical movement assessed by ultrasound or fluoroscopy.

**Pericardial Effusion, requiring drainage**

Abnormal accumulation of fluid in the pericardial space, Requiring drainage, By any technique.

**Peripheral nerve injury persisting at discharge or 91 days if patient is still in hospital**

Newly acquired or newly recognized deficit of unilateral or bilateral peripheral nerve function indicated by physical exam findings, imaging studies, or both.

**Peripheral nerve injury not present at discharge or 91 days if patient is still in hospital**

Newly acquired or newly recognized deficit of unilateral or bilateral peripheral nerve function indicated by physical exam findings, imaging studies, or both.

**Pneumonia** (*Added April 24, 2018*)

Pneumonia is defined as a “respiratory disease characterized by inflammation of the lung parenchyma (including alveolar spaces and interstitial tissue), most commonly caused by infection”. Pneumonia is diagnosed by appropriate clinical findings (such as fever, leukopenia or leukocytosis, and new onset of purulent sputum) and one or more of the following: positive cultures (of sputum or pulmonary secretions) and / or pulmonary infiltrate on chest x-ray. An endotracheal tube culture may or may not be positive. Patients commonly demonstrate an evolving area of focal lung consolidation accompanied by fever (>38.5). Pneumonia (pneumonitis) may affect an entire lobe (lobar pneumonia), a segment of a lobe (segmental or lobular pneumonia), alveoli contiguous to bronchi (bronchopneumonia), or interstitial tissue (interstitial pneumonia). These distinctions are generally based on xray observations.

**Postoperative/Postprocedural respiratory insufficiency requiring mechanical ventilatory support > 7 days**

Respiratory insufficiency requiring mechanical ventilatory support from surgery or procedure to greater than 7 days postoperatively/postprocedurally. In other words, the inability of the patient to exchange oxygen and carbon dioxide in sufficient quantities to avoid unacceptable hypercarbia, hypoxemia, or both, without mechanical ventilatory support for greater than 7 days during the postoperative or postprocedural period. The patient therefore does utilize mechanical ventilatory support for greater than 7 days during the postoperative or post procedural period.

**Postoperative/Postprocedural respiratory insufficiency requiring reintubation**

Reintubation required after initial extubation. In other words, the need to reinstitute postoperative or postprocedural mechanical ventilation after a planned extubation and prior to discharge, or after a planned extubation and after discharge but within 30 days of surgery. The intent of this field is to capture Postoperative/Postprocedural respiratory insufficiency requiring reintubation. It is not intended to capture situations where a patient may undergo elective intubations for other additional operations or procedures (including percutaneous endoscopic gastrostomy [PEG], tube insertions, catheter placement, cardiac catheterizations, etc.). However, these elective intubations and extubations are included and counted when determining "Final Extubation Date and Time".

**Pulmonary vein obstruction**

Clinically significant stenosis or obstruction of pulmonary veins. Typically diagnosed by echocardiography or cardiac catheterization, this may present with or without symptoms. A "clinically significant" event or condition is an event or condition that necessitates a change in treatment

**Renal failure - acute renal failure, Acute renal failure requiring dialysis at the time of hospital discharge or 91 days if patient is still in hospital**

Acute renal failure is defined as new onset oliguria with sustained urine output < 0.5 cc/kg/hr for 24 hours and/or a rise in creatinine > 1.5 times upper limits of normal for age (or twice the most recent preoperative/preprocedural values if these are available), with eventual need for dialysis (including peritoneal dialysis and/or hemodialysis) or hemofiltration. Code this complication if the patient requires dialysis at the time of hospital discharge or death in the hospital.

**Renal failure - acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge or 91 days if patient is still in hospital**

Acute renal failure is defined as new onset oliguria with sustained urine output < 0.5 cc/kg/hr for 24 hours and/or a rise in creatinine > 1.5 times upper limits of normal for age (or twice the most recent preoperative/preprocedural values if these are available), with eventual need for dialysis (including peritoneal dialysis and/or hemodialysis) or hemofiltration. Code this complication if the patient does not require dialysis at the time of hospital discharge or death in the hospital.

**Renal failure - acute renal failure, Acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge or 91 days if patient is still in hospital**

Acute renal failure is defined as new onset oliguria with sustained urine output < 0.5 cc/kg/hr for 24 hours and/or a rise in creatinine > 1.5 times upper limits of normal for age (or twice the most recent preoperative/preprocedural values if these are available), with eventual need for dialysis (including peritoneal dialysis and/or hemodialysis) or hemofiltration. Code this complication if the patient does not require dialysis at the time of hospital discharge or death in the hospital. (This complication should be chosen only if the hemofiltration was associated with acute renal failure.)

**Respiratory failure, requiring tracheostomy**

Failure to wean from mechanical ventilation necessitating the creation of a surgical airway

**Seizure**

A seizure is defined as the clinical and/or electroencephalographic recognition of epileptiform activity.

**Sepsis**

Sepsis is defined as evidence of serious infection accompanied by a deleterious systemic response. In the time period of the first 48 postoperative or postprocedural hours, the diagnosis of sepsis requires the presence of a Systemic Inflammatory Response Syndrome (SIRS) resulting from a proven infection (such as bacteremia, fungemia or urinary tract infection). In the time period after the first 48 postoperative or postprocedural hours, sepsis may be diagnosed by the presence of a SIRS resulting from suspected or proven infection. During the first 48 hours, a SIRS may result from the stress associated with surgery and/or cardiopulmonary bypass. Thus, the clinical criteria for sepsis during this time period should be more stringent. A systemic inflammatory response syndrome (SIRS) is present when at least two of the following criteria are present: hypo- or hyperthermia (>38.5 or <36.0), tachycardia or bradycardia, tachypnea, leukocytosis or leukopenia, and thrombocytopenia.

**Sternum left open, unplanned**

Sternum was left open postoperatively without preoperative plans to leave the sternum open postoperatively (i.e., unplanned). The goal is for delayed sternotomy closure.

**Stroke: Ischemic**

A stroke is any confirmed neurological deficit of abrupt onset caused by a disturbance in blood flow to the brain, when the neurologic deficit does not resolve within 24 hours.

**Subdural Bleed**

Bleeding between the dura mater, and the brain. Usually resulting from tears in bridging veins which cross the subdural space, subdural hemorrhages may cause an increase in intracranial pressure (ICP), which can cause compression of and damage to delicate brain tissue. Subdural hematomas are often life-threatening when acute. Chronic subdural hematomas, however, have a better prognosis if properly managed

**Systemic vein obstruction**

Clinically significant stenosis or obstruction of any major systemic vein (e.g., superior vena cava, inferior vena cava, femoral veins, internal jugular veins, etc.). A "clinically significant" event or condition is an event or condition that necessitates a change in treatment

**Unplanned cardiac reoperation during the postoperative or postprocedural time period, exclusive of reoperation for bleeding**

Any additional unplanned cardiac operation occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. A cardiac operation is defined as any operation that is of the operation type of "CPB" or "No CPB Cardiovascular". The following operations will always be coded as "Planned Reoperation": (1) Delayed Sternal Closure, (2) ECMO Decannulation, (3) VAD Decannulation, (4) Removal of Broviac catheter. The following operations will always be coded as "Unplanned Reoperation": (1) Mediastinal exploration for infection, (2) Mediastinal exploration for hemodynamic instability, (3) Emergent mediastinal

exploration for initiation of ECMO or VAD, (4) Reoperation for residual or recurrent lesion. Mediastinal exploration for bleeding is always coded separately as "Bleeding, Requiring reoperation".

**Vocal cord dysfunction (possible recurrent laryngeal nerve injury)**

Presence of poor or no vocal cord movement assessed by endoscopy. Patient may or may not have stridor, hoarse voice or poor cry, in conjunction with endoscopic findings.

**Wound infection-Mediastinitis**

The diagnosis of Mediastinitis must meet one of the following criteria: Criterion 1: Patient has organisms cultured from mediastinal tissue or fluid that is obtained during a surgical operation or by needle aspiration. Criterion 2: Patient has evidence of mediastinitis by histopathologic examination or visual evidence of mediastinitis seen during a surgical operation. Criterion 3: Patient has at least ONE of the following numbered signs or symptoms with no other recognized cause: 1) fever, 2) chest pain, or 3) sternal instability AND at least one of the following numbered features: 1) purulent mediastinal drainage, 2) organisms cultured from mediastinal blood, drainage or tissue, or 3) widening of the cardio-mediastinal silhouette. Criterion 4: Patient ≤ 1 year of age has at least one of the following numbered signs or symptoms with no other recognized cause: 1) fever, 2) hypothermia, 3) apnea, 4) bradycardia, or 5) sternal instability AND at least one of the following numbered features: 1) purulent mediastinal discharge, 2) organisms cultured from mediastinal blood, drainage or tissue, or 3) widening of the cardio-mediastinal silhouette. Infections of the sternum (sternal osteomyelitis) should be classified as mediastinitis.

**Wound infection-Superficial wound infection**

A superficial wound infection must meet the following numbered criteria: 1) The infection involves only the skin and the subcutaneous tissue of the incision and 2) The patient has at least ONE of the following lettered features: A) purulent drainage from the superficial portion of the incision, B) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial portion of the incision, C) at least ONE of the following numbered signs or symptoms: [1] pain or tenderness, [2] localized swelling, redness, or heat, and [3] the superficial portion of the incision is deliberately opened by a surgeon, unless the incision is culture negative, or D) a diagnosis of superficial wound infection by the surgeon or by the attending physician.