Original Article

Congenital cardiac surgical complications of the integument, vascular system, vascular-line(s), and wounds: consensus definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

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Abstract A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, 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. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has set forth a comprehensive list of complications associated with the treatment of patients with congenital cardiac disease, related to cardiac, pulmonary, renal, haematological, infectious, neurological, gastrointestinal, and endocrinial systems, as well as those related to the management of anaesthesia and perfusion, and the transplantation of thoracic organs. The objective of this manuscript is to examine the definitions of operative morbidity as they relate specifically to a collection of loosely related topics that include the following groups of complications: 1) Complications of the Integument, 2) Complications of the Vascular System, 3) Complications of the Vascular-Line(s), 4) Complications of Wounds. These specific definitions and terms will be used to track morbidity associated with surgical and transcatheter interventions and other forms of therapy in a common language across many separate databases.

As surgical survival in children with congenital cardiac disease has improved in recent years, focus has necessarily shifted to reducing the morbidity of congenital cardiac malformations and their treatment. A comprehensive list of complications is presented. This list is a component of a systems-based compendium of complications that will standardize terminology and thereby allow the study and quantification of morbidity in patients with congenital cardiac malformations. Clinicians caring for patients with congenital cardiac disease will be able to use this list for databases, initiatives to improve quality, reporting of complications, and comparing strategies of treatment.

Keywords: Congenital heart disease; quality improvement; patient safety; outcomes; registry; operative morbidity; paediatric; surgery; congenital abnormalities; cardiac surgical procedures; heart; catheter; skin; artery; vein
Background

This article discusses a collection of loosely related topics that include the following groups of complications:

- Complications of the Integument
- Complications of the Vascular System
- Complications of the Vascular-Line(s)
- Complications of Wounds.

Some general information about each group of complications is presented along with their proposed “root definitions”. In Part 4 of this Supplement, specific definitions are given for each of the 671 terms derived from these “root definitions”. In some cases, discussions of controversies surrounding these topics are included. Where it is appropriate to localize the complication, the body is divided into applicable regions such as the

- face
- head excluding the face
- neck
- right and left upper extremities
- right and left hands
- right and left lower extremities
- right and left feet, and
- the trunk or torso.

Integument

Introduction

The integument includes the following components:

- epidermis
- dermis
- subcutaneous tissue or superficial fascia
- along with its associated structures such as nails, hair follicles, sebaceous glands, sweat glands, blood vessels and nerve endings.

Studies examining altered integrity of the skin in hospitalized children document a prevalence of approximately 15% to 26% of pressure ulcers and other types of breakdown of the skin consisting of “tape burns”, “skin tears”, “diaper rash” and redness at the incision site. Complications of the integument, for the purposes of this project, are divided into six major categories:

- burns
- excoriations
- infiltrations – intravenous and intra-arterial
- lacerations
- alopecia – post-procedural and traumatic, and
- pressure sores.

Burns and pressure ulcers are discussed in more detail below.

Integument: Burns

Accidental burn injury during surgery may occur as a result of electrical current, thermal injury, chemical irritation, or mechanical stress during surgery resulting in temporary or permanent injury to the skin, muscle and nerves. The ROOT definition for the term “Burn” is presented below:

“A burn is defined as an injury to the integument caused by fire, heat, radiation, electricity, extreme cold, or caustic agent. The integument is defined as the epidermis, dermis and subcutaneous tissue (superficial fascia) along with its associated structures such as nails, hair follicles, sebaceous glands, sweat glands, blood vessels and nerve endings. Burns can be classified as first, second or third degree according to the depth of the injury. Burns can also involve the deep fascia, muscle and bone, though these structures are not traditionally considered to be a part of the integumentary system.”

Modifiers are listed to further define the depth and aetiology of the burn.

Though the incidence of burn injuries is low, these rare injuries can be catastrophic and traumatic for the patient and the surgical team and can cause a significant prolongation of the hospital course. Demir and colleagues reported a series of 19 patients who suffered intraoperative burn injuries, 15 of whom had undergone cardiac surgery. The average affected body surface area was 2.1% with 79% suffering superficial burns and the remaining 21% suffering deep dermal or full-thickness injuries. Forty-two percent of the patients required surgical intervention to treat the burn, whereas the remaining patients were treated with conservative measures. Sixty-eight percent of the patients had electrical injuries related to electrocautery devices. Twenty-six percent of the patients suffered chemical burns related to Betadine and in one patient, or 5 percent of the series, the cause of the burn was unclear. The authors conclude that attention to detail regarding the proper maintenance of intraoperative equipment, knowledge of the proper set-up and use of electrocautery devices, and knowledge of the chemical properties of and the proper application of sterilizing agents will avoid most intraoperative thermal injuries.

Integument: Pressure Sores or Pressure Ulcers

Pressure sores or pressure ulcers are localized areas of tissue destruction that develop when soft tissue is compressed between a bony prominence and an external surface for a prolonged period of time. The ROOT definition for the term “Pressure sore(s)” is presented below:

“A pressure sore is defined as a wound that occurs from tissue breakdown as a result of unrelieved pressure with
the pressure usually occurring over an underlying bony prominence. Pressure sores may be caused by a mechanical device or other factors.”

Pressure ulcers can be stratified according to the revised staging guidelines of the National Pressure Ulcer Advisory Panel6 adopted by the Agency for Healthcare Research and Quality as follows:

- **Stage I** – Observable pressure related alteration of intact skin whose indicators, as compared with the adjacent or opposite area on the body, may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue or purple hues.

- **Stage II** – This involves partial thickness loss of skin layers involving the epidermis and possibly penetrating into, but not through, the dermis. It may present as blistering with erythema and/or induration and with a moist and pink wound base that is painful and free of necrotic tissue.

- **Stage III** – This involves full-thickness tissue loss extending through the dermis to involve the subcutaneous tissue. It presents as a shallow crater unless covered by eschar. This may include necrotic tissue, undermining, sinus tracts formation, exudate, and/or infection. The wound base is usually not painful.

- **Stage IV** – This involves deep tissue destruction extending through the subcutaneous tissue to the fascia and may involve muscle layers, joint and/or bone. It may present as a deep crater and include necrotic tissue, undermining, sinus tracts formation, exudate, and/or infection. The wound base is usually not painful.

The same risk factors that predispose adults to the development of pressure ulcers, namely immobility and physiological instability, are active in the pediatric population, producing a similar increase in hospital morbidity and expense. Because relatively little specific research on the aetiology, prevention and management of pediatric pressure ulcers exists, extrapolations are frequently derived from the literature related to adults. However, the limited existing pediatric research has shown that the distribution of pediatric pressure ulcers is different from the adult population. Upper body lesions, specifically the head (occiput and ears) are more common in children because the head is proportionally the largest and heaviest bony structure in infants. Curley and colleagues performed a multi-institutional, prospective, cohort study of the incidence, location and factors associated with the development of pressure ulcers in a critically ill pediatric intensive care unit population. Along with other clinical variables, these authors studied the Braden Q Scale for Predicting Pediatric Pressure Ulcer Risk (Braden Q Scale)13 and found that mechanical ventilation, hypotension and a lower Braden Q Scale score were independent predictors for the development of pressure related ulcers. They also reported a 27% overall incidence of pressure ulcers which is similar to three other studies that reported a 17%,11 19%14 and 26%9 incidence of tissue breakdown in the pediatric intensive care unit setting. These authors12 found that a significant percentage of the pediatric pressure-related skin injury was created by medical devices such as pulse oximetry probes and artificial airways, including nasotracheal and orotracheal tubes, and BiPAP masks. Most of these studies document that pressure ulcers develop within the first two days stay in the pediatric intensive care unit, underscoring the importance of instituting early preventive measures at the time of admission to the pediatric intensive care unit. Evidence-based practices known to prevent pressure-related skin injury have been published by the Agency for Health Care Policy and Research, and include the following:

- the use of pressure reducing devices that redistribute weight over a larger surface area
- head-of-bed elevation consistent with the medical condition of the patient
- elevation of the heels off the bed, and
- implementation and documentation of an effective turning schedule.

**Vascular**

**Acute Limb Ischemia**

The ROOT definition for the term “Acute limb ischemia” is presented below:

“Acute limb ischemia is defined as an acute reduction in the supply of oxygenated blood to an extremity that is usually caused by vasoconstriction, thrombosis, embolism or dissection of the arterial vessels supplying the affected extremity. Physical signs can include diminished or absent pulses, coolness, pallor, paresis, paralysis, mottling, ulceration and gangrene. Limb ischemia caused by compartment syndrome is included in this complication. Limb ischemia caused by arterial and venous line complications is captured both in this “Acute limb ischemia” section and under “Vascular-Line(s)”.”

Several modifiers are listed for acute limb ischemia to specify the aetiology of the ischemia and whether surgical intervention was required for its treatment. Limb ischemia caused by arterial and venous line complications are captured both in this
Acute limb ischemia

Given the frequency with which arterial monitoring catheters are used in the surgical treatment of congenital heart disease, it is interesting to note that permanent ischemic complications are relatively rare (0.09%) compared to temporary occlusion of the cannulated vessel (20%).¹⁶ One study documents that ulnar arterial catheterization for hemodynamic monitoring in pediatric patients is relatively safe in terms of ischemic and infectious complications even when more traditional arterial cannulation sites have been previously exhausted.¹⁷

Aortic Dissection

An aortic dissection can occur anywhere in the thoracic or abdominal aorta and is rare in the pediatric population.¹⁸ The ROOT definition for the term “Dissection-Aortic dissection” is presented below:

“An aortic dissection can occur anywhere in the thoracic or abdominal aorta and is a tear in its intimal layer, followed by formation and propagation of a subintimal hematoma. The dissecting hematoma commonly occupies about half and occasionally the entire circumference of the aorta. This produces a false lumen or double-barreled aorta, which can reduce blood flow to the major arteries arising from the aorta. Aneurysmal dilation can also occur. If the dissection involves the pericardial space, cardiac tamponade may result.”

The Stanford classification¹⁹ divides aortic dissections into two types:

- A Stanford type A dissection is a proximal dissection that involves the ascending aorta
- A Stanford type B dissection is a distal dissection that involves aorta distal to left subclavian artery and does not involve the ascending aorta.

The DeBakey classification²⁰ divides aortic dissections into three types:

- A DeBakey type 1 dissection starts in the ascending aorta and involves the entire length of the aorta
- A DeBakey type 2 dissection is limited to the ascending aorta
- A DeBakey type 3 dissection is a distal dissection that involves aorta distal to left subclavian artery and spares the ascending aorta and the aortic arch.

In the database, aortic dissections are subdivided according to location and according to whether they are acute or chronic.

- Dissections that are acute are of sudden onset. Clinically, dissections seen within the first 2 weeks following onset of symptoms are considered acute.
- Dissections that are chronic are long standing conditions. Clinically, dissections beyond the first 2 weeks following onset of symptoms are considered chronic.

Modifiers further define the dissection by the systems of classification of Stanford and DeBakey, the extension of the dissection, the diameter of the aorta at the site of the dissection, and whether the dissection is calcific, ruptured or thrombosed. It is recommended that if a dissection of the aorta, iliac or femoral vessels produces acute lower extremity ischemia, one should also consider using any of the appropriate complications listed in the section titled “Acute limb ischemia”.

Arterial Thromboembolism

The ROOT definition for the term “Thromboembolism-Arterial thromboembolism” is presented below:

“Arterial thromboembolism is defined as ischemic changes caused by occlusion of an arterial blood vessel by a particle (clot, cholesterol crystals, atheroma, other) that breaks away from its site of origin/formation. This diagnosis can include ‘trash foot’ when debris or cholesterol crystals embolize down the leg. This diagnosis can include “blue toe syndrome” which is characterized by tissue ischemia secondary to cholesterol crystal or atherothrombotic embolization leading to the occlusion of small vessels.”

Arterial thromboemboli are subdivided according to the body location or internal organ in which their ischemic effects are clinically manifested.

Thrombosis (Arterial/Venous)

The ROOT definition for the term “Thrombosis-Arterial thrombosis” is presented below:

“Arterial thrombosis is defined as occlusion of an arterial blood vessel by clot, atheroma, tumors, external compression, trauma, hypercoagulable states, or other cause.”

The ROOT definition for the term “Thrombosis-Venous thrombosis” is presented below:

“Venous thrombosis is defined as a condition in which a blood clot (thrombus) forms in a vein. Tumors, external compression, trauma, hypercoagulable states or other etiologies can also be causal agents. This process can limit blood flow through the vein, causing swelling, venous congestion and pain. In its extreme form it can result in arterial insufficiency leading to tissue ischemia and necrosis.”

Intraluminal catheters are one of the most common aetiologies for the development of arterial and venous thromboses. In the intensive care setting, symptomatic thrombotic complications of
central venous catheters can present within four days of catheter insertion, with neonates having the highest rate of symptomatic venous thromboses. Children with acute life-threatening illnesses are likely at greatest risk for acute catheter-related thrombosis. Furthermore, the excessive thrombin production associated with patients in intensive care unit settings, who may have disseminated intravascular coagulation, hastens the development of thrombosis around intravascular catheters. Whether catheter-related or not, not all venous thrombosis is symptomatic. Nevertheless, the potential complications associated with venous thrombosis include recurrent thrombosis, loss of subsequent intravenous access, pulmonary embolism, post-thrombotic syndrome and death. One pediatric study documented that the prognosis after thrombosis of the inferior caval vein depends upon its extent, with persisting venous occlusion being absent after limited thrombosis and being frequent (80%) after extensive thrombosis. Persisting venous occlusion is frequently symptomatic with leg and abdominal pain as well as the development of varicose veins and post-thrombotic syndrome. Since most inferior caval vein thrombosis occurs after the indwelling line has been in place for over six days, some authors recommend routine replacement at six-day intervals or twice-weekly caval ultrasonds with prompt catheter removal if any evidence of thrombosis is discovered. Routine catheter replacement frequently may not be performed in children due to the difficulty in obtaining venous access and the lack of appropriate sites.

Renal vein thrombosis is a somewhat distinctive subset of venous thrombosis. The ROOT definition for the term “Thrombosis-Venous thrombosis, Renal vein” is presented below:

"Renal vein thrombosis is a condition in which a blood clot (thrombus) forms in one or both renal veins. Tumors, external compression, trauma, hypercoagulable states, or other etiologies causes can also be causal agents. This process can limit blood flow through the vein. Renal vein thrombosis involves acute or chronic occlusion of a renal vein by clot, emboli, dehydration, tumors, external compression, trauma, hypercoagulable states, systemic diseases (such as systemic lupus erythematosus) or other causes. Acute renal vein thrombosis is characterized by abrupt onset of flank pain, nausea, vomiting, and gross or microscopic hematuria. Physical findings may include a palpable kidney and hypertension. On occasion, acute renal vein thrombosis may be bilateral, resulting in oliguric acute renal failure and flank pain. The chronic presentation of renal vein thrombosis is observed more frequently than the acute form. In general, it is asymptomatic, although progressive nephrotic syndrome can be associated."

Vascular-Line(s) Complications

Complications related to vascular lines have been defined for four types of lines:

- Arterial line
- Central venous access
- Interosseous access
- Peripheral venous access.

The ROOT definition for the term “Arterial line complication” is presented below:

"An arterial line complication is any complication involving an arterial line at any site. These complications can include, but are not limited to documented or clinically suspected infection, insertion complications, and arterial thrombosis with or without signs of distal limb ischemia. Failure of insertion should be coded separately using the appropriate code. Line infections are divided into "Documented line infection" and "Clinically suspected line infection" and they also should be coded separately under these specific complications. Documented arterial line infection is defined as bacteremia/fungemia in a patient with an arterial line with at least one positive blood culture obtained from a peripheral vein, clinical manifestations of infection (fever, chills and/or hypotension etc.), and no apparent source for the infection except the arterial line catheter. One of the following should be present: a positive semiquantitative (greater than 15 colony forming units per catheter segment) culture whereby the same organism (species and antibiogram) is isolated from the arterial line catheter segment and peripheral blood; simultaneous quantitative blood cultures with a greater than 5:1 ratio of arterial line catheter versus peripheral blood growth; or differential period of arterial line drawn blood culture versus peripheral blood drawn blood culture positivity of greater than two hours. Clinically suspected arterial line infection is defined as clinical evidence of infection, without apparent alternative sources, with positive blood culture and/or arterial line culture and/or arterial line tip culture that improves with antibiotic treatment and possibly arterial line removal.

Arterial line – related complications that produce infiltration are documented under “integument”. Acute limb ischemic complications that involve an arterial line as the etiologic agent are documented both in this “Arterial line complication” section and also in the “Acute limb ischemia” section. Acute limb ischemic complications that do not involve a line as the etiologic agent are documented under “Acute limb ischemia”.

The ROOT definition for the term “Central venous access complication” is presented below:

“An arterial line complication is any complication involving a central venous line at any site. These complications can include, but are not limited to
infection, insertion complications, insertion failures and venous thrombosis (with or without signs of venous congestion). Failure of insertion should be coded separately using the appropriate code. Line infections are divided into “Documented line infection” and “Clinically suspected line infection” and they also should be coded separately under these specific complications. Documented central venous line infection is defined as bacteremia/fungemia in a patient with a central venous line with at least one positive blood culture obtained from a peripheral vein, clinical manifestations of infection (fever, chills and/or hypotension etc.), and no apparent source for the infection except the central venous catheter. One of the following should be present: a positive semiquantitative (greater than 15 colony forming units per catheter segment) culture whereby the same organism (species and antibiogram) is isolated from the central venous catheter segment and peripheral blood; simultaneous quantitative blood cultures with a greater than 5:1 ratio of central venous catheter versus peripheral blood growth; or differential period of central venous catheter drawn blood culture versus peripheral blood drawn blood culture positivity of greater than two hours. Clinically suspected central venous line infection is defined as clinical evidence of infection, without apparent alternative sources, with positive blood culture and/or central venous line culture and/or central venous line tip culture that improves with antibiotic treatment and possibly central venous line removal. Central venous line – related complications that produce infiltration are documented under “integument”. Acute limb ischemic complications that involve a central venous line as the primary etiologic agent are documented both in this “Central venous access complication” section and also in the “Acute limb ischemia” section. Acute limb ischemic complications that do not involve a line as the primary agent are documented under “Acute limb ischemia”. PICC lines (Peripherally Inserted Central Catheters), whose tips are central (internal jugular vein, subclavian vein, superior or inferior vena cava, femoral vein, atrium), are considered central venous lines for the purpose of recording their complications. PIC (Peripherally Inserted Catheters) lines, whose tips are not located in a central venous position (internal jugular vein, subclavian vein, superior or inferior vena cava, femoral vein, atrium), are considered peripheral venous lines."

The ROOT definition for the term “Interosseous access complication” is presented below:

"An interosseous access complication is any complication involving an interosseous line. These complications can include, but are not limited to infection, insertion complications, and thrombosis. Failure of insertion should be coded separately using the appropriate code."

The ROOT definition for the term “Peripheral venous access complication” is presented below:

“A peripheral venous access complication is any complication involving a peripheral venous line. These complications can include, but are not limited to infection, insertion complications, and venous thrombosis (with or without signs of venous congestion). Failure of insertion should be coded separately using the appropriate code. Line infections are divided into “Documented line infection” and “Clinically suspected line infection” and they also should be coded separately under these specific complications. Documented peripheral venous line infection is defined as bacteremia/fungemia in a patient with a peripheral venous line with at least one positive blood culture obtained from a peripheral vein at a different site, clinical manifestations of infection (fever, chills and/or hypotension etc.), and no apparent source for the infection except the peripheral venous catheter. One of the following should be present: a positive semiquantitative (greater than 15 colony forming units per catheter segment) culture whereby the same organism (species and antibiogram) is isolated from the peripheral venous catheter segment and peripheral blood from a different site; simultaneous quantitative blood cultures with a greater than 5:1 ratio of peripheral venous catheter versus peripheral blood growth from a different site; or differential period of peripheral venous catheter drawn blood culture versus peripheral blood drawn blood culture positivity (from a different site) of greater than two hours. Clinically suspected peripheral venous line infection is defined as clinical evidence of infection, without apparent alternative sources, with positive blood culture from a different site and/or peripheral venous line culture and/or peripheral venous line tip culture that improves with antibiotic treatment and possibly peripheral venous line removal. Peripheral venous line – related complications that produce infiltration are documented under “integument”. Acute limb ischemic complications that involve a peripheral venous line as the primary etiologic agent are documented both in this “Peripheral venous access complication” section and also in the “Acute limb ischemia” section. Acute limb ischemic complications that do not involve a line as the primary agent are documented under “Acute limb ischemia”. PIC (Peripherally Inserted Catheters) lines, whose tips are not located in a central venous position (internal jugular vein, subclavian vein, superior or inferior vena cava, femoral vein, atrium), are considered peripheral venous lines. PICC lines (Peripherally Inserted Central Catheters), whose tips are central (internal jugular vein, subclavian vein, superior or inferior vena cava, femoral vein, atrium), are considered central venous lines for the purpose of recording their complications.”

The term, “line complication”, has been defined to include, but not be limited to a documented or clinically suspected infection, insertion complications, and vessel thrombosis with or without signs
of limb ischemia. Peripherally inserted central venous catheters (PICC) that terminate in a central vein are considered central venous catheters, as consistent with national reporting standards for central line infections. Distinct codes have been created for clinically suspected line infection, documented line infection, and failure of insertion. The above definitions describe the difference between clinically suspected line infection and documented line infection. 

**Controversies surrounding Vascular Catheter Infections**

The Centers for Disease Control and Prevention of the United States of America sponsors the National Healthcare Safety Network. The National Healthcare Safety Network utilizes the terms “Catheter Related Bloodstream Infection” and “Catheter Associated Bloodstream Infection” to define healthcare acquired central vascular infections. In this manuscript, the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease uses the term “Documented line infection”, which closely parallels the term “Catheter Related Bloodstream Infection” and is a rigorous clinical definition that attempts to exclude other sources of bacteremia and/or fungemia. In this manuscript, the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease uses the term “Clinically suspected line infection”, which closely parallels the term “Catheter Associated Bloodstream Infection” and is a surveillance definition that overestimates the actually incidence of infections attributable to vascular catheters. 

Healthcare organizations report vascular catheter infections to the National Healthcare Safety Network as the rate of infections per 1000 catheter days utilizing the “clinically suspected line infection” definition. While the definition is clearly defined by the National Healthcare Safety Network, there continues to be wide variation in interpretation by infection control practitioners. In addition, as the terms “Clinically suspected line infection” and “Catheter Associated Bloodstream Infection” are surveillance definitions, their use will accordingly overestimate the “true” rate of infections that were a result of a vascular catheter. This overestimation can result in differing opinions regarding the veracity of a reported line infection, between the clinical team and the “infection control team”. This controversy has the capability to undermine the reporting process, causing clinicians to lose faith in the reported infection rate. Paradoxically, while some clinicians have lost faith in this rate, state and national oversight agencies are increasingly requiring public reporting of rates of healthcare acquired infection. It is and continues to be incumbent on clinicians to understand the limitations of these surveillance definitions and work to refine the national consensus definition, as required, to reflect clinical reality.

**Wound Complications**

Wound complications are divided into the following categories:

- sterile sternal instability (non-union)
- omental herniation
- sterile wound dehiscence
- foreign body
- hematoma
- superficial wound infection
- deep wound infections
- mediastinitis, and
- seroma.

These various subsets of wound complications are, where appropriate, further modified by the body location of the wound.

**Sterile Sternal Instability (non-union)**

The ROOT definition for the term “Sternal instability (sterile)” is presented below:

“Sternal instability (sterile)” is defined as non-union of the sternal edges, after median sternotomy. The superficial and deep layers of the incision remain intact. (If sterile separation of the superficial or deep layers of the incision coexists with the sternal non-union, then the term, “Wound dehiscence (sterile)” should be used to describe the complication.) This complication can be caused by ischemia, nutritional deficiencies, use of corticosteroids, vitamin C deficiency, trauma and others. Sternum instability secondary to mediastinitis is documented under “Wound infection, mediastinitis”.

While most cases of sternal instability after median sternotomy are caused by infection, non-union of the sternal edges can also be caused by other factors not related to infection such as ischemia, nutritional deficiencies, use of corticosteroids, vitamin C deficiency, trauma and others. This complication is reserved to describe isolated sterile sternal non-union. If sterile separation of the superficial or deep layers of the incision coexists with the sternal non-union, then the term, “Wound dehiscence (sterile)” should be used to describe the complication.

Little is written about sterile sternal non-union in both the pediatric and adult cardiac surgical literature. Multivariate analysis in an series of adult patients, in which this specific clinical condition was analyzed, determined that new York Heart Association class IV, obesity, and chronic
obstructive pulmonary disease were preoperative risk factors with an incidence of 0.39% and a mean interval between index operation and diagnosis of reoperation for sterile sternal non-union of 5.4 months. These risk factors have limited applicability to the pediatric population. Some partial cases of sterile sternal non-union are relatively minor and do not require operative intervention, whereas most, because of pain, instability, or aesthetic concerns, require reconstruction. Both of these possibilities are listed in the Long List of complications.

**Omental Herniation**

This relatively uncommon wound complication is defined as herniation of the omentum through a surgical incision or through a tube or catheter tract.

**Sterile Wound Dehiscence**

The ROOT definition for the term “Wound dehiscence (sterile)” is presented below:

“Wound dehiscence (sterile)” is defined as separation of the layers of a surgical wound. This separation can either be superficial or deep and can include the sternum in the case of a median sternotomy incision. When the sterile separation includes the skin and sternum, in the case of a median sternotomy incision, use this code (“Wound dehiscence (sterile)”). The code “Sternal instability (sterile)” should be used to record the complication when the superficial and deep layers of the incision remain intact but non-union of the sternal edges is present. Causes of wound dehiscence can include tissue ischemia, nutritional deficiencies, use of corticosteroids, vitamin C deficiency, and others. Wound dehiscence due to wound infection should be recorded as a wound infection.”

Separation of the superficial or deep layers of a surgical incision can rarely occur in the absence of an infection. Wound dehiscence due to wound infection should be recorded as a wound infection (see below). In the case of a median sternotomy incision, when the sterile separation includes the skin and sternum, use this code (“Wound dehiscence (sterile)”). As described above, the code “Sternal instability (sterile)” should be used to record the complication when the superficial and deep layers of the incision remain intact but non-union of the sternal edges is present.

**Wound Foreign Body**

The ROOT definition for the term “Wound foreign body” is presented below:

“Wound foreign body complications can include, but are not limited to, the following complications: 1) pain caused by prominent sternal wires necessitating sternal wire removal and 2) sinus tracts caused by foreign bodies such as sutures and sternal wires necessitating minor sinus tract excision with foreign body removal. Foreign bodies, such as pulse generators and permanent and retained temporary pacing wires can also be the source of more major infections and necessitate more major surgical interventions for their removal. Foreign body complications that result in a mediastinal infection should be documented under “Wound infection, Mediastinitis”.

**Wound Hematoma**

The ROOT definition for the term “Wound hematoma” is presented below:

“A wound hematoma is a localized collection of sterile extravasated blood that is confined within a space or a potential space within or adjacent to a surgical wound. Infected collections of blood located within a space or a potential space within or adjacent to a surgical wound should be listed as “Wound infection”.”

**Wound Infection (Deep/Superficial)**

Wound infections (otherwise known as surgical site infections) can be superficial or deep. The ROOT definition for the term “Wound infection-Superficial wound infection” is presented below:

“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.

The ROOT definition for the term “Wound infection-Deep wound infection” is presented below:

“A deep wound infection involves the deep soft tissues (e.g., fascial and muscle layers) of the incision AND the patient has at least ONE of the following numbered features:

1) Purulent drainage from the deep portion of the incision (but not from the organ/space component of the surgical site and no evidence of sternal osteomyelitis)
2) The deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has ONE of the following lettered signs or symptoms (unless the incision is culture negative):
   A) fever
   B) localized pain, or
   C) tenderness
3) An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination, or
4) A diagnosis of a deep wound infection by a surgeon or by an attending physician.

These definitions are adapted from those established by the Hospital Infection Control Practices Advisory Committee of The Centers for Disease Control and Prevention of the United States of America, in order to maintain uniformity with the definitions currently used by hospitals to track and report infections of surgical sites of all kinds.31 For a superficial wound infection, the definition of the Centers for Disease Control requires that the infection occurs within 30 days after the index operation. For a deep wound infection, the definition of the Centers for Disease Control definition requires that the infection occurs within 30 days after the index operation. For a deep wound infection, the definition of the Centers for Disease Control definition requires that the infection occurs within 30 days after the index operation if no implant is left in place. These timing requirements of the Centers for Disease Control are rejected in favor of the timing standard that is uniformly applied in this database of complications, as described below in the definition of the term “complication”

“A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breach in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, 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. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.”

If an implant is in place and a deep surgical site infection appears to be related to the index operation, the Centers for Disease Control definition arbitrarily extends the time interval from thirty days to one year. While this time interval extension is logical and reasonable, it is rejected in this database of complications for the sake of internal consistency. Many types of postoperative complications that are clearly related to the index operation can occur at varying time intervals postoperatively, some perhaps being diagnosed months after discharge from the hospital. This complications database adheres consistently to the time interval outlined above for both intraoperative and postoperative complications to promote consistency in the reporting of complications and to ensure the validity of comparisons of complication rates between institutions.

It should also be noted that, according to the definition of the Centers for Disease Control, the sternal wires within the base of a typical median sternotomy incision constitute a “foreign body” and would, therefore, theoretically extend the time interval during which a diagnosis of deep wound infection and/or mediastinitis could be made to one year after the index operation. Certainly, mediastinitis and deep wound infections can occur after the time interval of operative complications has expired; however, these late cases of mediastinitis and wound infections are classified as mediastinitis and/or wound infections, but they are not counted amongst the “operative complications”.

With the exception of these timing issues, the definitions of superficial and deep wound infection adopted by The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease are identical in substance to those promoted by the Centers for Disease Control.

It should be noted that younger age and longer duration of surgery, as well as the surrogate variable of cardiopulmonary bypass time, have been suggested as independent predictors of surgical site infections after pediatric cardiovascular surgery.32

**Mediastinitis**

The incidence of mediastinitis after pediatric open-heart surgery varies widely but is usually reported in the range of 0.2%33 to 1.4%.34 The median time from operation to diagnosis is usually 1134 to 1433 days. Two-thirds of patients will be infected with gram-positive organisms, whereas the remaining one-third will grow gram-negative organisms. The most commonly cultured organisms are Staphylococcus aureus (46%), coagulase-negative staphylococci (17%) and Pseudomonas aeruginosa (17%).34 One study documented concurrent bacteremia in 35%33 and another study in 53%.34

The definition for Deep Sternal Infection used by the Society of Thoracic Surgeons Adult Cardiac Database Version 2.61 is presented below:

“Indicate whether the patient, within 30 days postoperatively, had a deep sternal infection involving muscle, bone, and/or mediastinum REQUIRING OPERATIVE INTERVENTION.”
Must have ALL of the following conditions:

1. Wound opened with excision of tissue (incision and drainage) or re-exploration of mediastinum
2. Positive culture
3. Treatment with antibiotics.

The Centers for Disease Control states that 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
   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
   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
   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
   3) widening of the cardio-mediastinal silhouette.

This latter definition is more detailed than the Society of Thoracic Surgeons definition and also has the advantage of including more specific criteria for defining mediastinitis in infants. Since this definition of the Centers for Disease Control, though more complex, is essentially the same in core substance to that of the Society of Thoracic Surgeons, it is used by The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, with the presupposition that the maintenance of close conformity with established national standards, when they are scientifically accurate, is the best policy. Infections of the sternum (ster nal osteomyelitis) should be classified as mediastinitis. Sternal instability that is not associated with a wound infection or mediastinitis is documented as “Sternal instability.”

**Wound Seroma**

The ROOT definition for the term “Wound seroma” is presented below:

“A wound seroma is a localized collection of serum that is confined within a space or a potential space within or adjacent to a surgical wound. A seroma is distinguished from a hematoma by containing relatively few cellular elements, especially red blood cells. Infected collections of serum located within a space or a potential space within or adjacent to a surgical wound should be listed as “Wound infection.”

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**References**


