

*Original Article*

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## Gastrointestinal complications associated with the treatment of patients with congenital cardiac disease: consensus definitions from the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Nancy S. Ghanayem,<sup>1</sup> Joseph A. Dearani,<sup>2</sup> Karl F. Welke,<sup>3</sup> Marie J. Béland,<sup>4</sup> Irving Shen,<sup>5</sup> Tjark Ebels<sup>6</sup>

<sup>1</sup>Department of Pediatrics, Division of Critical Care, Children's Hospital of Wisconsin and Medical College of Wisconsin, Milwaukee, Wisconsin, United States of America; <sup>2</sup>Division of Cardiovascular Surgery, Mayo Clinic College of Medicine, Rochester, Minnesota, United States of America; <sup>3</sup>Division of Cardiothoracic Surgery, Oregon Health and Science University, Portland, Oregon, United States of America; <sup>4</sup>Division of Paediatric Cardiology, The Montreal Children's Hospital of the McGill University Health Centre, Montreal, Quebec, Canada; <sup>5</sup>Inova Fairfax Hospital for Children, Falls Church, Virginia, United States of America; <sup>6</sup>Groningen University Medical Centre, Groningen, The Netherlands

**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 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.

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 endocrinal 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 the gastrointestinal system. 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.

Although serious gastrointestinal complications are relatively uncommon after congenital cardiac surgery, accurate estimates of the incidences of these complications are limited, in part due to lack of standardized reporting and the absence of universal nomenclature that defines organ-specific complications. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has prepared and defined a list of gastrointestinal complications that may be temporally associated with congenital cardiac surgery. 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; gastrointestinal tract

## Historical background

Serious abdominal complications after cardiac surgery are relatively uncommon and have been predominantly identified in adults. The average incidence of abdominal complications in adults is low, approximately 1.2%, with a range of 0.2 to 5.5%, but when incurred these complications are associated with a substantial increased risk of morbidity and mortality.<sup>1,2</sup> Similar gastrointestinal complications are seen in association with congenital cardiac surgery, but are less frequently reported in the literature.

Limitations in estimating the incidence and burden of organ-specific complications in congenital cardiac surgery are confounded by the absence of several elements:

- uniformly applied standardized reporting
- consistent reporting of outcomes beyond commonly used global performance measures such as mortality and length of stay in the hospital
- accurate identification of organ-specific morbidity including the temporal association with surgery, and
- universal nomenclature which defines specific gastrointestinal complications.

Further difficulty may arise when attributing causality, particularly in the sick infant with congenital anomalies.

Standardized nomenclature for gastrointestinal complications is limited, and potentially more challenging to define when temporally relating these complications to congenital cardiac surgery. Despite the differing nature of cardiac disease in adults compared to children, as well as different pre-existing morbidities, and social behaviours often unique to adults, clinicians and societal organizations have continued to extrapolate adult-focused diagnostic criteria for organ-specific complications, and extend these definitions to infants and children. Currently, consensus definitions for specific gastrointestinal complications following congenital and pediatric cardiac surgery are sparse. A working group representing the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease was convened to better identify and define organ-based complications. The objective of this manuscript is to provide the consensus-derived definitions of gastrointestinal complications associated with congenital cardiac surgery.

## Consensus definitions

In Part 4 of this Supplement, within each organ system, complications are presented and defined in alphabetical order. The process for creating this list of complications began in 1998 with initiation of the International Congenital Heart Surgery

Nomenclature and Database Project of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery.<sup>3</sup> In April of 2000, common database standards for congenital cardiac surgery were published and incorporated into the databases of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery. In addition, the Congenital Heart Surgery Databases of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery have used a common Complications Short List since 2000.<sup>4</sup> Starting with the Complications Short List of The Society of Thoracic Surgeons and The European Association for Cardiothoracic Surgery, a draft of a more complete Complications Long List was created. This effort led to the formation of the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease and its Risk Factors and Complications Subcommittees, with the task of reaching clear, specific and universally acceptable definitions of risks and complications. Members of this multidisciplinary taskforce formed organ-specific subcommittees that were charged with expanding the list of complications, when appropriate, as well as reaching consensus definitions within their organ-system subcommittee. Comprehensive definitions were obtained from existing professional organizations or consensus reports when available, and through consultation with organ specific experts. The list of complications and definitions were presented to the Multi-Societal Database Committee for final adjudication.

Gastrointestinal complications refer to complications associated with the organs that compose the gastrointestinal tract and those organs supplied by the celiac, superior mesenteric and inferior mesenteric arteries. These organs include the esophagus, stomach, small intestine, large intestine or colon, liver, gallbladder, spleen, and pancreas. These gastrointestinal complications are listed alphabetically in Table 1.

Organ-specific complications are further differentiated and defined by severity, which commonly reflects the need for intervention. For example, other than dysphagia, or the inability to eat, ischemic bowel likely represents one of the more common gastrointestinal complications. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease proposes the following consensus definition for ischemic bowel:

*“Ischemic bowel is defined as a reduction in the supply of oxygenated blood to the small intestine or large intestine, typically resulting in acidosis, abdominal distention, and feeding intolerance.”*

Necrotizing enterocolitis reflects a similar pathophysiologic process; however, the diagnosis of necrotizing enterocolitis requires additional criteria

Table 1. Gastrointestinal complications – Final List. Precise definitions for these complications are given in Part 4 of the Supplement.

*Complications with variable severity and variable need for intervention are shown in italics.*

1. Ascites
2. Ascites requiring drainage
3. Ascites requiring drainage, *With paracentesis*
4. Ascites requiring drainage, *With paracentesis and placement of peritoneal drain*
5. Ascites-modifier for type of ascites, *Chylous*
6. Ascites-modifier for type of ascites, *Serous*
7. Cholecystitis
8. Colitis
9. Complication requiring laparotomy
10. *Dysphagia and/or inability to eat*
11. *Dysphagia and/or inability to eat, Resolves without the need for feeding via gastrostomy or enterostomy or hospital discharge with tube feedings*
12. *Dysphagia and/or inability to eat, Resulting in feeding via gastrostomy or enterostomy*
13. *Dysphagia and/or inability to eat, Resulting in hospital discharge with tube feedings*
14. Enteritis
15. Esophagitis
16. Gastric perforation
17. Gastritis
18. *Gastroesophageal reflux disease (GERD)*
19. *Gastroesophageal reflux disease (GERD), Medically managed*
20. *Gastroesophageal reflux disease (GERD), Surgically managed*
21. *Gastrointestinal bleeding requiring transfusion*
22. *Gastrointestinal bleeding requiring transfusion, Bright red blood per rectum*
23. *Gastrointestinal bleeding requiring transfusion, Hematemesis*
24. *Gastrointestinal bleeding requiring transfusion, Lower gastrointestinal bleeding*
25. *Gastrointestinal bleeding requiring transfusion, Melena*
26. *Gastrointestinal bleeding requiring transfusion, Upper gastrointestinal bleeding*
27. Gastrointestinal complication
28. *Ileus*
29. *Ileus, Requires bowel rest and total parenteral nutrition (TPN)*
30. *Ileus, Resolves with bowel rest without total parenteral nutrition (TPN)*
31. Intrabdominal procedural injury
32. Ischemic bowel
33. Liver dysfunction
34. Liver failure
35. *Necrotizing enterocolitis (NEC)*
36. *Necrotizing enterocolitis (NEC), With intestinal perforation*
37. *Necrotizing enterocolitis (NEC), With intestinal perforation of large intestine*
38. *Necrotizing enterocolitis (NEC), With intestinal perforation of small intestine*
39. *Necrotizing enterocolitis (NEC), Without intestinal perforation*
40. Pancreatitis
41. Typhillitis

about the diagnosis and associated treatments. Specifically, the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease proposes the following consensus definition for necrotizing enterocolitis:

*“Necrotizing enterocolitis is defined as an acute reduction in the supply of oxygenated blood to the small intestine or large intestine, typically resulting in acidosis, abdominal distention,*

*pneumatosis, and/or intestinal perforation, that prompts initiation of antibiotics or exploratory laparotomy.”*

Necrotizing enterocolitis is further subclassified by location of involvement, that is either the small bowel or the large bowel. Similar differentiation and severity grading are also included for ascites, dysphagia, gastroesophageal reflux disease, gastrointestinal bleeding, and ileus, as shown in Table 1.

## Controversies

Unlike diagnoses such as sepsis, renal failure, or respiratory failure, complications associated with the gastrointestinal system are, at times, less well defined, and often subjected to interpretation as to whether certain gastrointestinal morbidities are true “complications” or expected findings after congenital cardiac surgery. This dilemma is particularly apparent when interpreting feeding difficulties. Gastrointestinal complications may reflect functional outcomes which are identified without confirmatory diagnostic tools or a specific cause-effect relationship. For example, Table 1 identifies “Dysphagia and/or inability to eat” as a gastrointestinal complication. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease proposes the following consensus definition for the complication of “Dysphagia and/or inability to eat”

*“Dysphagia and/or inability to eat is defined as difficulty in swallowing or the inability to eat that may result in the need for parenteral nutrition, tube feedings, or gastrostomy or enterostomy feedings.”*

This diagnosis is a relatively common gastrointestinal phenomenon after neonatal cardiac surgery, is often diagnosed through patient observation, and is subject to variable interpretation by the clinician. Further controversy arises when one attempts to relate the complication to a specific event, both as a cause-effect relationship and temporally. For example, inability to eat or difficulty swallowing may be due to multiple potentially contributory aetiologies:

- prolonged intubation
- neurologic injury incurred prior to surgery
- neurologic injury incurred during to surgery
- neurologic injury incurred after to surgery
- pre-existing abdominal pathology
- intestinal ischemia, or
- clinician preference not to feed due to a potential for aspiration in the presence of unilateral vocal cord paresis.

Similar discrepancies might also be present with the diagnosis of gastroesophageal reflux disease, which is often subjectively diagnosed without confirmatory diagnostics, and is an expected morbidity even in the healthy infant. These discrepancies may result in variable reporting of certain gastrointestinal complications and be prohibitive in identifying the incidence of specific complications and in future validation of the specific data about these complications.

## Gastrointestinal interactions with the cardiac system

Gastrointestinal complications are largely attributed to ischemia and perfusion abnormalities of the

splanchnic circulation and tissue dysoxia or shock. Shock-induced physiologic vulnerability is not limited to the intraoperative time, with or without the use cardiopulmonary bypass, but is also linked to events of ischemia and reperfusion which may occur during the preoperative and postoperative periods of time. Throughout the perioperative period, efficient delivery of oxygen to meet regional metabolic demands occurs through autoregulatory regional and global circulatory controls. Specifically, the regional flow of blood is determined by the interaction of neurohumoral factors related to inflammation and the sympathetic nervous system, and local factors related to autoregulation.<sup>1,5-7</sup> The sympathetic response to stress that evolved to deal with hypovolemic and septic shock<sup>8,9</sup> is activated in all states of shock to redistribute the flow of blood to the brain and heart.<sup>10</sup> The organs supplied by the splanchnic circulation are the first to suffer ischemic injury because sympathetic outflow and innervation is rich in these regions,<sup>11-13</sup> and because of the selective vasoconstriction effects of angiotensin.<sup>14,15</sup> The final common pathway seen with splanchnic ischemia includes the endogenous production of inflammatory mediators and the development of endotoxemia, which has been shown to instigate dysfunction of multiple organs and, potentially, death.<sup>16,17</sup>

## Conclusions

A need exists for the accurate identification and measurement of complications of surgical care. To address this need for patients with congenital cardiac disease, the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has worked to provide comprehensive standardized nomenclature for complications in this population.

The gastrointestinal system is prone to complication after surgery due to the interactions between the gastrointestinal and cardiovascular systems. However, the non-specific nature of many of the gastrointestinal complications, coupled with issues of correct identification and attribution of causality, creates ongoing challenges. The comprehensive list provided in this Supplement should be viewed as a starting point for ongoing efforts to increase the understanding of perioperative gastrointestinal complications.

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