

Consensus definitions of complications for accurate recording and comparisons of surgical outcomes in pediatric neurosurgery

Clinical article

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Object. Monitoring and recording of complications in pediatric neurosurgery are important for quality assurance and in particular for improving outcomes. Lack of accurate or mutually agreed upon definitions hampers this process and makes comparisons between centers, which is an important method to improve outcomes, difficult. Therefore, the Canadian Pediatric Neurosurgery Study Group created definitions of complications in pediatric neurosurgery with consensus among 13 Canadian pediatric neurosurgical centers.

Methods. Definitions of complications were extracted from randomized trials, prospective data collection studies, and the medical literature. The definitions were presented at an annual meeting and were subsequently recirculated for anonymous comment and revision, assembled by a third party, and re-presented to the group for consensus.

Results. Widely used definitions of shunt failure were extracted from previous randomized trials and prospective studies. Definitions for wound infections were extracted from the definitions from the Centers for Disease Control and Prevention. Postoperative neurological deficits were based on the Pediatric Stroke Outcome Measure. Other definitions were created and modified by consensus. These definitions are now currently in use across the Canadian Pediatric Neurosurgery Study Group centers in Morbidity and Mortality data collection and for subsequent comparison studies.

Conclusions. Coming up with consensus definitions of complications in pediatric neurosurgery is a first step in improving the quality of outcomes. It is a dynamic process, and further refinements are anticipated. Center to center comparison will hopefully allow significant variations in outcomes to be identified and acted upon.

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KEY WORDS • pediatric neurosurgery • adverse event • complications

IMPROVING the quality of medical care has become integral to virtually every aspect of medicine, prompted by the recognition of the magnitude of complications and adverse events^{1,18} and the resulting morbidity and mortality, and costs. There have been several successful studies targeting specific common procedures (central lines) or common complications (ventilator-acquired pneumonia) that have become standard quality indicators.^{13,14,19} There is, however, a general lack of clearly defined and validated adverse event outcome measures.³ It has also been pointed out that the few criteria validated

for the adult population are not directly transferable to pediatric patients, and there is a need for pediatric-focused outcomes.²¹ Within surgery, particularly pediatric general surgery, specific common or serious complications have been monitored through large databases, and pediatric quality indicators have been developed by such organizations as the Agency for Healthcare Research and Quality.⁴ Pediatric neurological adverse outcomes have received some attention from the MultiSocietal Database Committee for Pediatric and Congenital Heart Disease for complications after cardiac surgery for congenital heart disease, including consensus definitions.² There are, however, no standardized or consensus-driven definitions for complications or adverse events in pediatric neurosurgery.

Abbreviations used in this paper: CDC = Centers for Disease Control and Prevention; CPNSG = Canadian Pediatric Neurosurgery Study Group; ICP = intracranial pressure.

We recently reported the incidence of complications from all surgical procedures in a single pediatric neurosurgical center prospectively over a 2-year period.¹² It became clear that broadening this approach to other centers would require standardized definitions to ensure accuracy and comparability. Therefore, we aimed to develop standardized definitions of complications through the CPNSG, an organization with representation from all of the 13 pediatric neurosurgery units across Canada. This is a first step in defining complications in pediatric neurosurgery, in what is imperatively an iterative process. It is our expectation that broad use of these definitions will lead to accurate data collection and comparison and to improved quality of care.

Methods

The conceptual model of standardized definitions of complications and outcome measures for pediatric neurosurgery was presented in 2008 and approved at the 2010 annual meeting of the CPNSG (*Appendix 1*). Existing standardized definitions were accepted if they had been integral to prospective studies or randomized trials in pediatric neurosurgery, or in widespread use as quality indicators developed by organizations such as the CDC. For definitions of other common complications, such as CSF leak, definitions were generated within what seemed like practical, objective, and easily applicable criteria. All of the definitions were then collated and circulated to the entire CPNSG membership for review and comment. All responses were rendered anonymous, collated, and integrated into the working definitions. Modified definitions were recirculated to the group for approval. The data collection form, previously used in a prospective study of pediatric neurosurgery complications,¹² was modified to reflect the new definitions and was then made available for common usage.

Results

A total of 10 members of the CPNSG, all practicing pediatric neurosurgeons, participated in the expert consensus process. The list of definitions appears in *Appendix 2*. The definitions are broken down into the following categories: shunt complications; other CSF-related complications; postoperative infections not shunt related; new neurological deficit, hemorrhage, and/or stroke; and seizures. The definitions of shunt complications were extracted from prospective randomized trials of CSF shunt design where shunt complications were the outcome of interest¹¹ and include shunt obstruction, overdrainage, loculated compartments, and infection. Other CSF-related complications include CSF leak, pseudomeningocele, postoperative hydrocephalus, and intracranial CSF collection. Other non-shunt related infections include wound infection, where the definitions were extracted from the CDC definitions,¹⁵ and meningitis. The severity of a posttreatment neurological deficit was graded based on the Pediatric Stroke Outcome Measure (PSOM), developed by de Veber and colleagues (*Appendix 3*).^{7,8,22,24} The severity score for cerebellar mutism was extracted

from 2 large prospective clinical trials in children with newly diagnosed medulloblastoma (Table 1).²³ Spinal cord injury was graded using the American Spinal Injury Association system.⁵ The modified data collection form is shown in Table 2.

Discussion

Much can be learned from complications or adverse events. Regarding pediatric neurosurgery, we have previously reported unusual complications of CSF shunt devices,⁶ unexpected delayed (and often fatal) rapid deterioration after endoscopic third ventriculostomy,⁹ fatal embolization of a sclerosing agent into an aneurysmal bone cyst,²⁰ and a near-miss injection of anesthetic agent into an external ventricular drain.¹⁰ These were rare and unexpected events but brought attention to their possible occurrence and suggested methods to prevent them.

Pediatric neurosurgery services provide care and surgical treatment for a wide variety of pathologies, and it was difficult to grasp the whole range and extent of complications in a specific surgical service. For that reason we reported the results of prospective surveillance of complications over a 2-year period¹² to try to identify complications that are common to the provision of care, rather than a particular procedure per se. In fact, a CSF leak was the most common complication across all proce-

TABLE 1: Cerebellar mutism syndrome survey*

cerebellar mutism syndrome (1 = yes; 2 = no; 9 = unknown)	---
if yes, code below:	
time of onset	---
1 = immediately postop	
2 = Days 1-2	
3 = Days 2-4	
4 = >Day 4	
mutism	---
1 = mild (mutism <1 wk)	
2 = moderate (mutism 1-4 wks)	
3 = severe (mutism >4 wks)	
ataxia	---
1 = mild (persists <1 wk)	
2 = moderate (persists 1-4 wks)	
3 = severe (persists >4 wks)	
hypotonia (quadriparesis)	---
1 = mild (can sit or stand by <1 wk)	
2 = moderate (can sit or stand, 1-4 wks)	
3 = severe (can't sit or stand, >4 wks)	
irritability	---
1 = mild (persists <1 wk)	
2 = moderate (persists 1-4 wks)	
3 = severe (persists >4 wks)	

* Reprinted with permission from Robertson et al: *J Neurosurg* 105 (6 Suppl):444-451, 2006.

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TABLE 2: Surgical morbidity data collection form*

CSF Circulation	
Shunt mechanical failure <30 days	----
Shunt infection	----
ETV failure <30 days	----
CSF leak	
minor	----
major	----
pseudomeningocele	
minor	----
major	----
intracranial CSF collection	----
postop hydrocephalus	----
Other Infection	
wound infection	----
meningitis	
septic	----
aseptic	----
Hemorrhage/Stroke/Deficit	
new neurological deficit - expected	----
new neurological deficit - unexpected - transient	----
new neurological deficit - unexpected - permanent - (PSOM___)	----
cerebellar mutism (score _____)	----
unexpected intraop hemorrhage	----
postop hemorrhage	
intraventricular	----
subdural	----
extradural	----
intraparenchymal	----
postop infarct/thrombosis	
arterial	----
venous	----
venous sinus thrombosis	----
postop brain edema	----
unexpected seizure	----
intraop death	----
unexpected postop death <30 days	----
other	----
Total	----

* ETV = endoscopic third ventriculostomy.

dures, and it appeared that it was potentially amenable to intervention. However, it became evident that to maintain consistency in surveillance from year to year and to allow other centers to collect and compare the same type of information, standardized definitions were required.

Most would agree, and we would strongly support the notion as stated by Bruce et al.:³ “The use of standardised, valid and reliable definitions is fundamental to the accurate measurement and monitoring of surgical adverse events.”

As these authors also pointed out, there is inconsistency in the quality of reporting of adverse events, thus limiting comparison over time and between institutions.³ Even less is known about the incidence of adverse surgical events in children. In one study using the Pediatric Health Information System database,²¹ the 30-day incidence of any adverse event in pediatric general surgery procedures was 10.3%, a figure not that different from what we observed in our prospective surveillance of complications in our own pediatric neurosurgical unit of 16.4%.

Standardized definitions of complications are often created in the setting of prospective clinical trials or registries. We took advantage of definitions of shunt failure created for a randomized trial,¹¹ which were subsequently used in another randomized trial,¹⁶ and a prospective study¹⁷ to the point that acceptance and consensus had been essentially achieved for these definitions. The PSOM was created as a similar device,⁷ as was the cerebellar mutism score.²³ We incorporated the CDC definitions of wound infection because they are also in widespread use. However, and highlighting the difficulty in standardizing definitions, a recent review found a total of 41 different definitions and 13 grading scales of surgical wound infection that were identified from 82 studies.³ For other definitions of complications not otherwise available, many of which were specific to neurosurgery, we created what seemed like reasonable and practical definitions and went through an iterative process to achieve agreement. The widespread adoption and use of such definitions will require ongoing collaboration,²¹ is fundamentally an iterative process, and may require certification by specialist organizations to gain widespread acceptance.

Conclusions

We anticipate that the definitions reported here will provide a basis for more accurate collection and reporting of complications in pediatric neurosurgery, particularly and initially within our CPNSG.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Drake, Kulkarni, DeVeber, Cochrane. Acquisition of data: Drake, Singhal, DeVeber, Cochrane. Analysis and interpretation of data: Drake, Singhal, Kulkarni, Cochrane. Drafting the article: Drake, Cochrane. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Drake. Study supervision: Drake.

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Appendix 2: General Definitions of Complications**A) Shunt Complications¹¹***Shunt Obstruction*

Shunt obstruction will be said to have occurred if a patient has at least 1 symptom or sign and at least 1 positive ancillary test
Symptoms: headache, nausea, vomiting, decreased level of

consciousness, irritability, decreased school performance, loss of developmental milestones

Signs: papilledema, bulging fontanel, nuchal rigidity, sixth cranial nerve paresis, loss of upward gaze, new seizures (or increased seizure frequency), increasing head circumference, fluid tracking along the shunt tubing, shunt reservoir depresses but does not refill, inability to depress the shunt reservoir

Fluid accumulation around the bur hole site in the early weeks following surgery will not be considered indicative of shunt failure unless it is extreme and progressive or results in leakage of CSF through the wound. Small fluid collections are common and normally resolve spontaneously.

Ancillary tests

a) CT scan, ultrasound, or MRI scan showing enlarged ventricles compared with the 3-month study or ventricles that have failed to decrease in size compared with the preoperative study (normalization of ventricle size is not a mandatory criterion for shunt function)

b) disruption or migration of the shunt system on plain radiographs

c) radionuclide or iodinated contrast study showing shunt obstruction

d) ICP monitoring showing persistent elevation of pressure with or without plateau waves

e) shunt tap in which fluid cannot be aspirated or high pressure is recorded or symptoms/signs of shunt obstruction are relieved

When there are no symptoms or signs of shunt obstruction but the ventricles are increased in size, shunt obstruction is said to have occurred if there is no clinical or radiographic suggestion that atrophy is the cause of the ventricular enlargement.

A CSF leak that does not resolve and requires a shunt revision is considered a shunt obstruction.

In the rare event of an emergency shunt revision without any ancillary tests or revision prior to the 3-month follow-up scan, obstruction will be judged to be present or absent using clinical information and operative findings.

Shunt Overdrainage

Shunt overdrainage is said to have occurred in the presence of the following:

a) subdural fluid collections: large subdural fluid collections associated with brain compression or symptoms and signs otherwise indicative of shunt obstruction

b) slit-ventricle syndrome: smaller than normal ventricles associated with postural headache, chronic headache, intermittent headache of an incapacitating nature and documentation of 1 of the following:

1) transient enlargement of the ventricles as seen on imaging
2) extreme negative pressure with associated headache in the upright position

3) sustained elevations of pressure above normal associated with headache

Loculated Compartments

The presence of a loculated portion of a ventricular system that is enlarged above normal and compressing surrounding brain and that requires reoperation will be considered evidence of shunt malfunction.

Shunt Infection

Shunt infection is said to have occurred in the presence of purulent discharge through the wound or erosion of the shunt material through the skin. Shunt infection will also be diagnosed in the presence of one of the following symptoms or signs with at least 1 of the following ancillary tests:

Symptoms and signs: fever, meningismus, wound erythema, abdominal pain and/or distention, abdominal mass or peritonitis

Ancillary tests: culture or identification of organisms on Gram

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stain of CSF taken from shunt lumen or abdominal fluid collection, if present, withdrawn under sterile conditions or from purulent material around the shunt. (Growth of organisms from the entire shunt material in broth culture in the absence of other positive culture results will not be considered an infection.) However, patients who have symptoms of shunt obstruction (as defined in protocol) and a positive test for shunt infection (as defined above) do meet the definition of shunt infection. An abdominal pseudocyst will be considered evidence of an abdominal shunt infection even in the absence of positive cultures.

B) Other CSF-Related Complications

Postoperative CSF Leak

Discharge of watery fluid consistent with CSF (normally clear or blood tinged) through surgical incision, CSF drainage catheter egress site or other surgical corridor.

Ancillary tests: targeting on gauze sponge, or fluid positive for Beta Transferrin. Imaging demonstrating CSF egress: contrast Omnipaque cisternogram, fluorescein dye study, or radionuclide study.

Minor: 1 or 2 episodes that stop spontaneously, or with simple maneuver, adjustment of drain level, tightening of circlage stitch, or simple sutures.

Major: persistent CSF drainage that requires return to operating room for resuturing/wound repair, reinsertion of CSF drain, or CSF diversion procedure.

Postoperative Pseudomeningocele

Collection of CSF beneath intact skin at surgical incision site that is easily visible clinically or radiologically, significantly distends surrounding soft tissues, and is under increased pressure when palpated.

Minor: Some discomfort, or easily palpable, or some threat to wound integrity. Responds to simple aspiration and/or wrapping.

Major: Significant discomfort, obvious skin deformation, significant threat to wound integrity. Requires repeated aspiration and/or wrapping, or additional surgical procedure (CSF diversion or reclosure of wound).

Postoperative Hydrocephalus

One symptom or sign of raised ICP, and 1 positive ancillary test

Symptoms: headache, nausea, vomiting, decreased level of consciousness, irritability, loss of developmental milestones

Signs: papilledema, bulging fontanelle, depressed level of consciousness sixth cranial nerve(s) paresis, loss of upward gaze, new seizures (or increased seizure frequency), increasing head circumference, CSF leak from incision or extraventricular drainage site, moderate to severe pseudomeningocele

Ancillary tests

(a) CT scan, ultrasound, or MRI scan showing enlarged ventricles compared with baseline or failure to decrease in size compared with the preoperative study

(b) ICP monitoring showing persistent elevation of pressure with or without plateau waves

OR

persistent requirement of external CSF drainage

Postoperative Intracranial CSF Collection

Subdural fluid, interhemispheric, posterior fossa collections that are large and associated with mass effect or symptoms and signs otherwise indicative of increased ICP and require treatment (drainage, repeat operation, or prolongation of hospital stay).

C) Non-Shunt Related Postoperative Infections

Wound Infection

One of erythema, discharge of purulent material, or separation

of wound edges to expose subcutaneous tissue, often with fever. Purulent collection in epidural, subdural, or intraparenchymal (abscess) locations. Classified according to CDC definitions as superficial, deep or organ space.¹⁵

Meningitis

One of fever, meningismus, altered level of consciousness, CSF leukocytosis, and presence of an organism on Gram stain, or growth of an organism from aseptically obtained CSF sample. Growth of skin commensals in broth only will not be considered a positive culture.

D) New Neurological Deficit, Hemorrhage, and/or Stroke

New Neurological Deficit

Significant loss of function of a cranial nerve, motor function, sensory function, autonomic function including bladder and bowel control, coordination, cognitive function. A new tremor or movement disorder is also a neurological deficit.

Mild: minimal or no neurological disability

Moderate: moderate neurological disability

Severe: severe neurological disability or impairment

PSOM Score⁸

Cerebellar Mutism

Cerebellar mutism following posterior fossa surgery is recorded and scored separately.²³

Postoperative Brain Edema

Swelling of the brain in the region of surgery that causes significant mass effect, and possibly produces symptoms and signs of decreased level of consciousness, or unexpected neurological deficit.

Postoperative Hemorrhage

Intraventricular: Significant blood clot within ventricular system that forms a cast and expands ventricle to some degree.

Parenchymal: A significant blood clot that expands the surgical bed, has mass effect on the surrounding brain, and/or possibly produces symptoms and signs of decreased level of consciousness, or unexpected neurological deficit.

Subdural: A significant subdural blood clot that has mass effect on the surrounding brain more than expected from the surgical procedure, and/or possibly produces symptoms and signs of decreased level of consciousness, or unexpected neurological deficit.

Extradural: A significant extradural blood clot that has mass effect on the surrounding brain more than expected from the surgical procedure, and/or possibly produces symptoms and signs of decreased level of consciousness, or unexpected neurological deficit.

Postoperative Cerebrovascular Accident

Ischemic²⁴

Arterial stroke: Arterial ischemic stroke is defined by both a neurological deficit of acute onset or, in neonates, seizures alone or other signs of neonatal encephalopathy, and radiological images (preferably MRI, CT if MRI was not available) showing parenchymal infarcts conforming to known arterial territory(ies) and corresponding to clinical manifestations. Of note is that a normal CT scan obtained within 48 hours of symptom onset does not rule out the diagnosis of arterial ischemic stroke.

Venous infarct: As in arterial stroke but consistent with venous occlusive distribution with or without evidence of venous thrombosis.

Venous sinus thrombosis: A clinical presentation characteristic of cerebral sinovenous thrombosis should be present. This includes the occurrence of headache, seizure, lethargy, or focal or generalized neurologic deficit. In addition, radiographic confirmation of the presence of thrombus is necessary and includes MRI, MR venography, CT venography, or cerebral angiography. The presence of thrombus

or flow interruption within cerebral veins or dural sinuses with or without venous infarction comprises radiographic proof of cerebral sinovenous thrombosis.

E) Seizures

Postoperative focal or general seizures are not characteristic of the patient’s underlying condition; single, multiple, or status epilepticus.

Appendix 3: Pediatric Stroke Outcome Measure

Summary of Impressions

After completing the PSOM-NE or equivalent detailed neurologic examination, summarize and grade your impressions about deficit severity in the following categories:

A. Sensorimotor Deficit (ANY motor or sensory abnormality including Cranial Nerve Deficits, Visual, and Hearing deficits)

	R side	L side
None	0	0
Mild but no impact on function	0.5	0.5
Moderate with some functional limitations	1	1
Severe or Profound with missing function	2	2

Select the Sensorimotor Deficits You Observed (select all that apply)

- Global developmental delay
- Global hypotonia or hypertonia Hemiparesis
- Hemifacial weakness
- Hemiataxia Dysarthria Other Motor deficit
- Hemisensory deficit Other Sensory deficit
- Difficulty with vision
- Difficulty with drinking, chewing or swallowing
- Other, describe: _____

B. Language Deficit – Production (*excluding* dysarthria)

None	0
Mild but no impact on function	0.5
Moderate with some functional limitations	1
Severe or Profound with missing function	2

Describe the Language Production Deficits You Observed Here:

C. Language Deficit - Comprehension

None	0
Mild but no impact on function	0.5
Moderate with some functional limitations	1
Severe or Profound with missing function	2

Describe The Language Comprehension You Observed Here:

D. Cognitive or Behavioural Deficit (specify which)

	Cognitive	Behavioural
None	0	0
Mild but no impact on function	0.5	0.5
Moderate with some functional limitations	1	1
Severe or Profound with missing function	2	2

Describe the Cognitive or Behavioural Deficits You Observed Here:

TOTAL SCORING: _____/10 – Are all the neurologic deficits completely attributable to stroke? Yes No

If no, please specify which deficits are not and state responsible diagnosis _____

E. Was the event an AIS/CSVT/Primary hemorrhagic stroke?

- 1. Definitely yes 2. Probably yes 3. Unclear
- 4. Probably not 5. Definitely not

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