The South African Paediatric Surgical Outcomes Study (SAPSOS): A 14-day prospective, observational cohort study of paediatric surgical patients.

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South African Paediatric Surgical Outcomes Study (SAPSOS) definitions

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Definitions for preoperative and surgical data

American Society of Anesthesiologists (ASA) physical status score

Score	Description
I	A normal healthy patient
II	A patient with mild systemic disease which does not limit physical activity
III	A patient with severe systemic disease which limits physical activity
IV	A patient with severe systemic disease that is a constant threat to life
V	A patient who is not expected to survive for 24 hours without the operation

Addition of "E" denotes emergency surgery

Neurosurgery

Neurosurgical procedures are defined as involving the brain and cervical spine. Surgery on the thoracic and lumbar spine is defined as orthopaedic surgery in the CRF.

Chronic and acute co-morbid diseases

We have not made definitions for all these diseases. We simply want doctors to give what they believe are the most appropriate answers. If the patient probably has the disease, then tick the box. If they probably do not have the disease, then leave it blank.
We have defined the following:

- "**Current LRTI**" (lower respiratory tract infection): currently on treatment for or has active signs of a LRTI e.g., pneumonia, bronchitis, bronchopneumonia.
- "**Current URTI**" (upper respiratory tract infection): current signs of an active URTI infection, may or may not be on treatment
- "**Recent URTI**" (upper respiratory tract infection): history of an URTI infection within the past 6 weeks, not currently on treatment

Duration of surgery

Duration of surgery is calculated from 'anaesthetic induction time' until 'the end of surgery'. We realise that some patients will have regional techniques prior to general anaesthesia, and possibly in a 'block room' prior to transfer to the operating room. The 'anaesthetic induction start time' should be taken from the time of the first anaesthetic intervention i.e., if it is in a remote 'block room' then this is the anaesthetic start time. The 'end of surgery' is defined as the time at which the patient leaves the operating room.

Urgency of surgery

- **Elective**: Not immediately lifesaving; planned within months or weeks.
- **Urgent**: Planned surgery within hours or days of the decision to operate.
- **Emergency**: As soon as possible; no delay to plan care; ideally within 24 hours.

Severity of the surgery

This is the category of surgery which indicates a combination of complexity and amount of tissue injury.

- **Minor surgery** would include procedures lasting less than 30 minutes performed in a dedicated operating room which would often involve extremities or body surface or

brief diagnostic and therapeutic procedures. Examples include examination under anaesthesia, cystoscopy without intervention, removal of small cutaneous tumour, biopsy of small lesions, tenotomies, interventional radiology etc.

- **Intermediate procedures** are more prolonged or complex that may pose the risk of significant complications or tissue injury. Examples include insertion of k-wires, tonsillectomy, inguinal hernia repair, appendicectomy, tendon repair of hand, cleft lip and palate repair, ventriculoperitoneal shunts, strabismus surgery etc.
- **Major surgical procedures** are expected to last more than 90 minutes and include major abdominal surgery, cardiac surgery, thoracotomy, procedures involving free flap to repair tissue defect, amputation, craniofacial surgery, craniotomy, cystectomy, resection of liver lesions, nephrectomy, transplant surgery, spinal surgery, osteotomy etc.

Primary indication for surgery

This is the underlying initiating disease/ event which ultimately resulted in the need for surgery and may be 'non-communicable disease', 'trauma', 'infective' or congenital'. For example, should a patient present with a fractured humerus after a minor fall, but is found to have a malignant tumour at the fracture site, then the primary indication for surgery is 'non-communicable disease' i.e., cancer, and not 'traumatic injury' (i.e. 'trauma'), as the tumour preceded the fall. Another example is a patient presenting with an abscess for incision and drainage who is a diabetic. The underlying disease is diabetes and therefore the primary indication is "non-communicable".

Traumatic injury as the primary indication for surgery

Injury is defined as damage or harm to the body resulting in impairment of health whether unintentional or intentional. It can result from exposure to thermal, mechanical, electrical, or chemical energies. The World Health Organization defines 'Violence' as the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, which either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment, or deprivation (World Health Organization, 2002). Unintentional injuries may include near drowning, falls, burns, motor vehicle accidents, poisonings, sports injuries, and traumatic brain injury amongst others. Intentional injuries (or violence) may include assault, parasuicide, etc. Therefore 'traumatic injury' would include all intentional and unintentional injuries which were primarily responsible for surgery.

Anaesthesia and Surgical providers

We have decided to ask about the most senior staff member who is involved in the case and are present in the operating room. The most senior surgeon may not perform the operation themselves but watch a junior colleague do this. However, they are still the most senior surgeon in the operating room and could, for example, assist if something went wrong. The most senior surgeon may not be present in the operating room throughout the entire procedure. The same principles apply to anaesthetists.

- '**Specialist**' is a doctor who is registered as a specialist surgeon or anaesthesiologist.
- **'Resident'** (registrar) is a doctor who is in training to become a specialist anaesthesiologist or surgeon.

- '**Physician non specialist**' or '**medical officer**' is a doctor who performs the surgery or anaesthesia, but does not have specialist registration in the appropriate field i.e. surgery or anaesthesia. A medical officer in anaesthesia may have a Diploma in anaesthesia which is a 6-month post-graduate training course and qualification.
- '**Non physician or nurse anaesthetist**' is a person who is not a doctor, but is either performing the surgery or anaesthesia.

Level of Hospital

- **First-level**:
  - Hospitals with few specialties—mainly internal medicine, obstetrics and gynecology, pediatrics, and general surgery; often only one general practice physician or a nonphysician practitioner; limited laboratory services available for general but not specialized pathological analysis; from 50 to 250 beds.
  - Alternative names: 'District', 'Primary'.
- **Second-level**:
  - Hospitals with more differentiated by function with as many as 5 to 10 clinical specialties; from 200 to 800 beds.
  - Alternative name: 'Regional'.
- **Third-level**:
  - Hospitals with highly specialized staff and technical equipment—for example, cardiology, intensive care unit, and specialized imaging units; clinical services highly differentiated by function; could have teaching activities; from 300 to 1,500 beds.
  - Alternative names: 'Tertiary', 'Central' 'Academic teaching'.

Definitions of anaesthetic complications, severe anaesthetic-related incidents (SARCI)

The following definitions are provided for guidance where the nature of a possible complication following anaesthesia is uncertain. (SARCI are events where actual harm or physiological derangement occurred and exclude "near miss" events.)

Arrhythmia

Electrocardiograph (ECG) evidence of cardiac rhythm disturbance.

Aspiration

Regurgitation or vomiting of gastric contents which has passed through the larynx into the trachea or tracheobronchial tree.

Birth asphyxia

Defined as the failure to establish breathing at birth.

Bradycardia

Defined as heart rate below lowest normal value for age

AGE	Normal HR bpm
Newborn – 3 months	80 - 205
3 months – 2 years	75-190
2 - 10 years	60-140
>10 years	50-100

Bronchospasm

Bronchospasm is defined as an increased respiratory effort, especially during expiration, and wheeze on auscultation. If the patient is ventilated, bronchospasm may also be considered if a significant increase in peak inspiratory pressure (under volume-controlled ventilation) or significant decrease in tidal volume (under pressure-controlled ventilation) are observed. In all cases, any episode of airway constriction requiring the administration of a bronchodilator will be included. (ref)

Cardiac arrest

Cardiac arrest associated with the induction or maintenance of general anaesthesia, regional anaesthesia or airway manipulation.

Cardiac arrest is defined as the cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. ECG changes may corroborate the incidence of cardiac arrest.

Difficult BMV (Bag mask ventilation)

When it is not possible for the anaesthesiologist to provide adequate ventilation because of one or more of the following problems: inadequate mask seal, excessive gas leak, or excessive resistance to the ingress or egress of gas. (ASA)

Difficult intubation

Tracheal intubation that requires multiple attempts

Failed intubation

Failure to place the endotracheal tube after multiple intubation attempts.

Laryngospasm

Laryngospasm is defined either as complete airway obstruction associated with rigidity of the abdominal and chest walls and leading to unsuccessful ventilation of the patient, or glottic closure associated with chest movement but silent unsuccessful respiratory efforts and unsuccessful assisted ventilation of the patient, unrelieved in both situations with simple jaw thrust and CPAP manoeuvres and requiring the administration of medication (propofol, suxamethonium, lignocaine spray on vocal cords etc.) and/or tracheal intubation.

Low Glucose

Levels below the following blood glucose levels:

First 24 hours of life	<1.65 mmol/l
Neonates (>24hours old)	<2.5mmol/l
Infants and children	<3.6mmol/l

Severe hypoxia

Hypoxia with a peripheral saturation of <80% on pulse oximetry, or clinical impression of hypoxia in the absence of a pulse oximeter.

Severe hypotension

More than 30% below normal baseline for age

AGE	NORMAL SYSTOLIC PRESSURE	NORMAL DIASTOLIC PRESSURE
Neonate	67 - 84	35 - 53
1 - 12 months	72 - 104	37 - 56
1 – 2 years	86 - 106	42 - 63
3 - 5 years	89 - 112	46 - 72
6 - 9years	97 - 115	57 - 76
10 – 11 years	102 - 120	61 - 80
12 – 16 years	110 - 131	64 - 83

Definitions and grading of surgical complications

The following definitions and grading are provided for guidance where the nature and severity of a possible complication following surgery is uncertain. Specific definitions are also provided below.

The complications in SAPSOS are defined as mild, moderate and severe.

- The degrees of severity describe the degree of impact on the patient.
- The definitions are taken from the more complicated Clavien-Dindo (CD) classification and simplified into three categories for ease of data collection

"Mild" would be equivalent to grade I
"Moderate" would be equivalent to grade II
"Severe" would be equivalent to grades III to V
See table below for descriptors

SAPSOS GRADE	Equivalent to Clavien-Dindo Grade	Definition
"Mild"	I	**Any deviation from normal postoperative course** without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. **Allowed therapeutic regimens are:** drugs as anti-emetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Moderate	II	**Requiring pharmacological treatment** with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Severe	III	**Requiring surgical, endoscopic or radiological intervention** IIIa) intervention not under general anesthesia IIIb) intervention under general anesthesia
	IV	**Life-threatening complication** (including CNS complications) requiring IC/ICU-management IVa) **single organ** dysfunction (including dialysis) IVb) **multi organ** dysfunction
	V	**Death** of a patient

Acute Kidney Injury (AKI)

Acute Kidney Injury (AKI) Stage	AKIN	KDIGO
Mild (SAPSOS category)	Stage 1 Increase in creatinine of ≥50% or absolute increase in creatinine of 0.3mg/dl	Stage 1 Increase in creatinine of ≥50% or absolute increase in creatinine of 0.3mg/dl
Moderate (SAPSOS category)	Stage 2 Increase in creatinine of ≥100%	Stage 2 Increase in creatinine of ≥100%
Severe (SAPSOS category)	Stage 3 Increase in creatinine of ≥200%	Stage 3 Increase in creatinine of ≥200% or eGFR ≤35ml/min per 1.73m^2 (if age < 18 yr) or Renal Replacement Therapy

Guidance:

Estimate eGFR (estimated glomerular filtration rate) using the Schwartz method. (eGFR = 0.413 x (height/serum creatinine) if height is in cm)
Baseline serum creatinine should have been measured before surgery but an estimated value can be used if the patient does not have chronic kidney disease.

Severity grading
As per the table above.

Acute Respiratory Distress Syndrome (ARDS)

Age
Exclude patients with peri-natal related lung disease
Timing
Within 7 days of known clinical insult
Origins of oedema
Respiratory failure not fully explained by cardiac failure or fluid overload
Chest imaging
Chest imaging findings of new infiltrate(s) consistent with acute pulmonary parenchymal disease

Severity grading according to oxygenation:

Non-invasive ventilation:

- PARDS: Full face-mask bi-level ventilation or CPAP ≥ 5cmH2O PF ratio ≤300 SF ratio ≤ 264

Invasive ventilation:

- Mild: OI 4-8 OSI 5-7.5
- Moderate: OI 8-16 OSI 7.5 – 12.3
- Severe: OI ≥16 OSI ≥12.3

Special populations:

Cyanotic heart disease: standard criteria as above for age, timing, origin of oedema and chest imaging with an acute deterioration in oxygenation not explained by underlying cardiac disease.

Chronic lung disease: standard criteria as above for age, timing, and origin of oedema with chest imaging consistent with new infiltrate and acute deterioration in oxygenation from baseline which meet oxygen criteria above

Left ventricular dysfunction: standard criteria as above for age, timing, and origin of oedema with chest imaging changes consistent with new infiltrate and acute deterioration in oxygenation which meet criteria above not explained by left ventricular dysfunction

Guidance:

- OI = oxygenation index; OSI = oxygen saturation index.
- OI = (FiO_2 (%) x mean airway pressure (mmHg) x 100)/PaO_2 (mmHg)
- OSI = (FiO_2 (%) x mean airway pressure (mmHg) x 100)/SpO_2
- PF ratio = PaO_2/fiO_2
- SF ratio = SpO_2/fiO_2
- PEEP, positive end-expiratory pressure; CPAP, non-invasive continuous positive airways pressure

Anastomotic breakdown

Leak of luminal contents from a surgical connection between two hollow viscera. The luminal contents may emerge either through the wound or at the drain site, or they may collect near the anastomosis, causing fever, abscess, bacteraemia, metabolic disturbance and/or multiple-organ failure. The escape of luminal contents from the site of the anastomosis into an adjacent localised area, detected by imaging, in the absence of clinical symptoms and signs should be recorded as a sub-clinical leak.

SAPSOS Severity grading

See categories and definitions on page 4

Arrhythmia

Electrocardiograph (ECG) evidence of cardiac rhythm disturbance.

SAPSOS Severity grading

See categories and definitions on page 4

Cardiac arrest

The cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. ECG changes may corroborate the incidence of cardiac arrest.

SAPSOS Severity grading: None; tick Yes or No on CRF

(Cardiogenic) pulmonary oedema

Evidence of fluid accumulation in the alveoli due to poor cardiac function.

SAPSOS Severity grading
See categories and definitions on page 4

Gastro-intestinal bleed

Unambiguous clinical or endoscopic evidence of blood in the gastro-intestinal tract. Upper gastrointestinal bleeding is that originating from the oesophagus, stomach and duodenum. Lower gastro-intestinal bleeding originates from the small bowel and colon.

SAPSOS Severity grading
See categories and definitions on page 4

Bloodstream infection

An infection in the blood stream which may or may not be related to infection at another site and which meets at least one of the following criteria:

1. Patient has a recognised pathogen cultured from blood cultures which may or may not related to an infection at another site.

2. Patient has at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension and at least one of the following:

    a. common skin contaminant cultured from two or more blood cultures drawn on separate occasions
    b. common skin contaminant cultured from at least one blood culture from a patient with an intravascular line, and a physician starts antimicrobial therapy
    c. positive blood antigen test

SAPSOS Severity grading
See categories and definitions on page 4

Pneumonia

Child with a cough or difficulty breathing, coarse crackles, reduced breath sounds or bronchial breathing on auscultation, fever, lower chest wall indrawing, nasal flaring, grunting or head nodding.

Chest radiographs with new or progressive and persistent infiltrates, or consolidation, or cavitation, or clinical diagnosis with severity below:

Pneumonia Severity grading:

Pneumonia	Equivalent to earlier WHO staging	Definition
Mild (SAPSOS category)	Fast breathing pneumonia	• Fast breathing with a respiratory rate of ≥ 60 breaths/minute in children < 2months old; ≥ 50 breaths/minute in children 2- 11 months old; ≥40 breaths/minute in children 1- 5 years old; ≥35 breaths/minute in children 5-15 years old • Crackles, reduced breath sounds or bronchial breathing on auscultation.
Moderate (SAPSOS category)	Chest indrawing pneumonia	• Cough or difficulty breathing plus any one of the following: • Chest indrawing • Nasal flaring • Grunting (in young infants)
Severe (SAPSOS category)	General danger signs pneumonia	• Cough or difficulty breathing plus any one of the following: • Central cyanosis • Severe respiratory distress (head nodding) • Not being able to drink • Convulsions lethargy or unconsciousness

Postoperative bleed

Blood loss occurring within 72 hours after the end of surgery which would normally result in transfusion of blood according to your unit protocol. Gastro-intestinal bleeding is defined above.

SAPSOS Severity grading
See categories and definitions on page 4

Pulmonary embolism (PE)

A new blood clot or thrombus within the pulmonary arterial system.

Guidance: Appropriate diagnostic tests include scintigraphy and CT angiography. Plasma D-dimer measurement is not recommended as a diagnostic test in the first three weeks following surgery.
SAPSOS Severity grading
See categories and definitions on page 4

Surgical site infection (superficial)

Infection involving only superficial surgical incision which meets the following criteria:

1. Infection occurs within 30 days after surgery and
2. Involves only skin and subcutaneous tissues of the incision and
3. The patient has at least one of the following:

a. purulent drainage from the superficial incision
b. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision and at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, or superficial incision is deliberately opened by surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion.
c. diagnosis of an incisional surgical site infection by a surgeon or attending physician

SAPSOS Severity grading
See categories and definitions on page 4

Surgical site infection (deep)

An infection which involves both superficial and deep parts of surgical incision and meets the following criteria:

1. Infection occurs within 30 days after surgery if no surgical implant is left in place or one year if an implant is in place and
2. The infection appears to be related to the surgical procedure and involves deep soft tissues of the incision (e.g. fascial and muscle layers) and
3. The patient has at least one of the following:
    a. purulent drainage from the deep incision but not from the organ/space component of the surgical site
    b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or no cultures were taken whilst the patient has at least one of the following signs or symptoms of infection: fever (>38°C) or localized pain or tenderness. A culture-negative finding does not meet this criterion.
    c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during surgery, or by histopathologic or radiologic examination
    d. diagnosis of a deep incisional surgical site infection by a surgeon or attending physician

SAPSOS Severity grading
See categories and definitions on page 4

Surgical site infection (body cavity)

An infection which involves any part of the body excluding the fascia or muscle layers and meets the following criteria:

1. Infection occurs within 30 days after surgery and
2. The infection appears to be related to the surgical procedure and involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and
3. The patient has at least one of the following:

a. purulent drainage from a drain that is placed through a stab wound into the organ/space
b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/ space
c. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. diagnosis of an organ/space surgical site infection by a surgeon or attending physician

SAPSOS Severity grading
See categories and definitions on page 4

Urinary tract infection

An infection associated with at least one of the following signs or symptoms or strong strong clinician suspicion which should be identified within a 24-hour period:

- fever (>38 °C), urgency, frequency, dysuria, suprapubic tenderness, costovertebral angle pain or tenderness with no other recognised cause, and
- on urine microscopy >5 white cells per high powered field or leucocytes on urine dipstix or
- a positive urine culture of $\geq 10^5$ colony forming units/mL with no more than two species of microorganisms.

SAPSOS Severity grading
See categories and definitions on page 4

Hospital resource use after surgery

We will collect some basic data to describe the treatment resources patients received after surgery.

Critical Care

We have defined a critical care unit as a facility routinely capable of admitting patients who require single or multiple organ support such as invasive ventilation overnight.

Critical care immediately after surgery

These are patients who are transferred from the operating theatre straight to critical care or the intensive care unit.

Critical care admission to treat postoperative complications:

Postoperative complications requiring admission to critical care to treat the postoperative complications or provide critical care support necessitated by the severity of the postoperative complications.

Days in critical care after surgery: Total number of days in critical care within the first 30 days after surgery. May include multiple admissions and planned admission to critical care immediately after surgery.

Days in hospital after surgery: Total number of days in hospital from the day of surgery to the day the patient leaves your hospital. This will not be adjusted for delays relating to provision of social care

Status at hospital discharge or 30th postoperative in-hospital day: The survival status of the patient at hospital discharge, or at the 30 in-hospital day (if the patient had not yet been discharged following surgery). The study is censored at the 30th in hospital postoperative day. All patients are followed until hospital discharge or for thirty days after surgery whichever is the shortest.

SAPSOS Abbreviations List:

AIDS: Acquired Immunodeficiency Syndrome
ARDS: Acute Respiratory Distress Syndrome
ASA: American Society of Anaesthesiologists
ASA E: ASA Emergency
BMV: bag mask ventilation
BP: blood pressure
BUN: blood urea nitrogen
CC: Critical Care
CMO: cardiomyopathy
CVS: cardiovascular system
DKA: diabetic ketoacidosis
DOB: date of birth
ENT: Ear Nose and Throat
ETT: endotracheal tube
FiO_2: inspired fraction of oxygen
GCS: Glasgow Coma Scale
Gender: M = male, F = female
GIT: gastrointestinal system
HALO: Halothane
HIV: Human Immunodeficiency Virus
IAP: intraabdominal pressure
IV: intravenous
LMA: Laryngeal Mask Airway
LRTI: lower respiratory tract infection
MO: medical officer
NorAd: noradrenalin
NSAID: non-steroidal anti-inflammatory drug
N_2O: nitrous oxide
OSA: obstructive sleep apnoea
Paediatric GCS: E = eye, V = verbal, M = motor
PaO_2: partial pressure of oxygen
RRT: renal replacement therapy
SAPSOS: South African Paediatric Surgical Outcomes Study
SEVO: Sevoflurane
SGA: supraglottic airway
T: temperature
TPN: total parenteral nutrition
URTI: upper respiratory tract infection
WHO: World Health Organisation
Y: Yes N: No
^0C: degrees Celsius

References

Available on request