RESEARCH STANDARD OPERATING PROCEDURES

‘5Rs to Rescue’

A quality improvement initiative with a cluster trial evaluation and embedded process evaluation

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Introduction

Patients in Africa are twice as likely to die after surgery compared to the global average despite being younger and fitter. Most of these deaths occur on the postoperative wards following development of complications. These deaths are termed ‘failure to rescue’. As patient outcomes tend to improve when enhanced monitoring increases the identification and treatment of critically ill patients, we have co-produced a complex intervention with healthcare staff, community engagement and involvement (CEI) partners, and the Institute for Health Improvement (IHI) across four African countries (Ethiopia, South Africa, Tanzania and Uganda) to reduce rates of failure to rescue.

This complex quality improvement intervention focuses on improving five main areas of patient management following surgery: 1) Risk assessment, 2) Recognition of patient deterioration, 3) Response to patient deterioration, 4) Reassessment following intervention to manage deterioration, and 5) Reflection on care provided following a patient's death. The complex quality improvement (QI) intervention is known as '5 Rs to Rescue'.

Following our iterative intervention development, we are now testing whether implementation of ‘5Rs to Rescue’ increases surveillance for patients at risk of failure to rescue after surgery in hospitals in Africa. We are using a cluster trial design with baseline assessment and a mixed methods process evaluation across twenty facilities in Uganda, Ethiopia, Tanzania and Ethiopia.

Purpose

The purpose of this SOP is to describe how data related to the ‘5Rs to Rescue’ project should be collected and managed. It provides guidance on research data and improvement data and how the two data collection and management processes will support each other. It also provides guidance on the use of differing data platforms between countries to ensure high quality data outputs.

Applicability

This SOP applies to all research staff, improvement advisors and healthcare workers involved in the ‘5Rs to Rescue’ project.

This SOP must be followed in line with the International Conference of Harmonisation – Good Clinical Practice (ICH GCP) Research Governance Framework

Data types

Research data

We are using a cluster trial design to evaluate the ‘5Rs to Rescue’ intervention. This is described in the trial protocol. A research case record form (CRF) has been produced with a pragmatic dataset to minimise the data collection burden whilst providing an accurate and robust dataset to answer our research questions. Research data collection is continuous from the start of baseline data collection to the end of the sustainability phase (total 12 months).

Improvement data

APPRISE is working in collaboration with the Institute of Health Improvement. This improvement team are responsible for implementation of the improvement intervention. It is recognised that improvement work needs to be informed by data. These data are usually collected by the healthcare teams involved in the improvement work and is accessible in real time to inform change. These data are not continuous and will not be used in analysis of the pre-defined research questions. It will be shared across the improvement network involved in this project so that hospitals can learn from each other.

Procedures

Data collectors/entrants

Data collectors employed through the APPRISE network will prioritise screening log and CRF data collection and entry. In low volume sites where they have spare capacity, they may be requested by the hospital improvement teams to support collection and presentation of improvement data, but this must not compromise their primary role.

Screening log

Accurate tracking of the total number of eligible patients in each study site is essential to enable us to report missing data transparently. Sites must complete a daily screening log with the total number of eligible patients. Eligible patients meet all inclusion criteria and no exclusion criteria:

Inclusion criteria

- Adult (>18 years) patients
- Undergoing a *therapeutic* surgical procedure in an *operating room*
- Admitted for postoperative care on the participating ward
- Patient spends at least one night in hospital after surgery

Exclusion criteria

- Patients who opt out of data collection.
- Patients receiving end-of-life care (the decision to provide end of life care may be made before, during or immediately after surgery following intra-operative findings).
- Patients undergoing day-surgery even if they spend the night before surgery in hospital.

Data collection

One of two processes may be followed for data collection:

1. Data collectors will complete a paper CRF for each eligible participant. These will then be entered into the project's secure online REDCap database hosted in South Africa. Paper CRFs will be verified as complete before the REDCap form is marked as complete. Paper CRFs will be kept in secure locked storage with access limited to the data entry team and site lead.

2. Where countries have an existing perioperative registry platform (currently Uganda and Ethiopia) this will be used for data collection directly. These electronic registry platforms already adhere to strict data management regulations. The following points will apply:

    a. All data points on the CRF must be collected for every eligible patient.

b. A data validation process must be in place to ensure data accuracy and completeness.
c. Data must be made accessible to hospital improvement teams when needed to support their improvement work.

All fields on the CRF are mandatory and must be completed. Where a data point is not applicable (for example the patient is discharged on day 2) write NA.

Definitions

American Society of Anesthesiologists (ASA) score

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.

What are the definitions of the chronic co-morbid diseases?

We have not made any definitions for 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.

Surgical procedure category

Select the single most appropriate surgical procedure category from the list.

Indication for surgery

Tick the category that includes the reason for the surgical procedure. Non-communicable disease includes all indications that are not trauma, infection or caesarean section.

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 planned 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 e.g. arthroscopy without intervention, removal of small cutaneous tumour, diagnostic proctology, biopsy of small lesions, etc.

Intermediate procedures are more prolonged or complex that may pose the risk of significant complications or tissue injury. Examples include laparoscopic cholecystectomy, arthroscopy with intervention, bilateral varicose vein removal, tonsillectomy, inguinal hernia repair, breast lump resection, haemorrhoidectomy, appendicectomy, partial thyroidectomy, cataract surgery, uvuloplasty, minimally invasive repair of vaginal prolapse, vaginal hysterectomy, tendon repair of hand, fixation of mandibular fracture, etc.

Major surgical procedures are expected to last more than 90 minutes and include major gut resection, major joint replacement, mastectomy, extensive head and neck tumour resection, abdominal aortic aneurysm repair, major vascular bypass procedure, procedures involving free flap to repair tissue defect, amputation, total thyroidectomy, cystectomy, trans-urethral resection of prostate, resection of liver tumour, carotid endarterectomy, nephrectomy, total abdominal hysterectomy, spinal discectomy, etc.

Date of admission to postoperative ward

The date of admission to the postoperative ward. This may not be the same as the date of surgery if surgery happens late in the evening and the patient is transferred to the ward in the early hours of the next morning. If a patient is admitted to a different ward immediately after surgery (for example the Intensive Care Unit), they are still eligible for inclusion following arrival on the postoperative ward.

Time of admission to the postoperative ward

Time of admission to the '5Rs to Rescue' postoperative ward (use 24 hour clock)

High risk patients

All patients undergoing a surgical procedure should have a risk score calculated using the ASOS Surgical Risk Score. (see Appendix 1) Patients are identified as high risk by one of the following two methods:

1. A risk score >=10 calculated using the ASOS risk score
2. Patients with a risk score <10 who the surgical team identify as being high risk (for example following an intraoperative incident such as cardiac arrest).

All high-risk patients should be marked as high risk on the CRF and the postoperative follow up completed.

ASOS Surgical Risk Score documented and communicated to ward staff

The ASOS Surgical Risk Score should be documented in a prespecified location in the patient's records. This location will be defined by each hospital improvement team.

If the score is documented in this location it is considered to be documented and communicated to the ward staff.

If the score is not documented or documented in a different location, regardless of verbal communication, mark this data point as 'No'.

Number of completed EWS on patient chart

An early warning system (EWS) is any tool that highlights single or multiple vital sign parameters, that are out of normal range, to help healthcare teams identify patients who may be at risk of deteriorating or dying.

This may be an internationally recognised tool such as NEWS or VSDT but can also be a locally produced tool provided it meets the following criteria:

1. A chart that includes as a minimum documentation of the respiratory rate, oxygen saturation, heart rate, systolic blood pressure, conscious level and temperature.
2. A way to identify patient deterioration:
    a. an aggregate deterioration score for example NEWs) **and/or**
    b. colour coded (or grey scale equivalent) to allow identification of out-of-range vital signs.
3. Vital sign 'data points' are connected using line graphs

A completed EWS is defined as a set of vital signs documented on the chart that includes at least 5/6 vital signs. These must be joined to the previous vital signs by line graphs. (See Appendix 2)

Number of documented physician-patient encounters in patient notes/charts

A physician-patient encounter means any documented encounter between a doctor (of any grade) and the patient. If a junior doctor reviews the patient and documents in the patient's medical record and a short while later a senior doctor comes to review the patient and this encounter is documented separately, this would be counted as two encounters.

Care escalated to another ward or hospital following deterioration

If a high-risk patient deteriorates and is transferred to another ward or hospital for further care (for example an intensive care unit) mark 'yes' here.

Days in hospital after surgery

Total number of days in hospital after surgery. The day of surgery is day 0.

Status at hospital discharge or 30th postoperative in-hospital day:

The survival status of the patient at hospital discharge, or at the 30th in-hospital day (if the patient had not yet been discharged following surgery). The study is censored at the 30th in hospital postoperative day.

Patients who are referred or transferred to another hospital are recorded as 'discharged alive' on their day of transfer. Patients are not followed-up after they leave the health facility where they underwent their surgical procedure.

Appendix 1 – ASOS Surgical Risk Score

ASOS SURGICAL RISK SCORE

The ASOS Surgical Risk Score is used to identify high risk surgical patients

All patients undergoing a surgical procedure in the operating theatre should be assessed for surgical risk.

Patients who score ≥ 10 points are high risk and should be admitted after surgery to a dedicated area on the surgical ward that will allow increased frequency of vital signs monitoring.

Please make sure your postoperative ward knows about these high risk surgical patients before they leave theatre.

How to calculate the ASOS Surgical Risk Score:

1. Calculate score before surgery using the table to the right
2. ASOS Surgical Risk Score = Age (points) + ASA (points) + Surgery timing (points) + Surgery severity (points) + Indication for surgery (points) + Surgery type (points)

Additional ways to identify high risk surgical patients who need increased vital signs monitoring on the wards:

1. Patients who have an ASOS surgical risk score <10 but who the surgical and anaesthesia team feel are high risk. An example might include patients who have an intraoperative critical event (for example cardiac arrest in theatre).
2. Patients who develop a postoperative complication on the surgical wards. **These cases should be discussed with a senior member of the surgical team to decide on their required frequency of vital signs monitoring.**

Age	Points
18 - 29	**0**
30 - 69	**+1**
≥ 70	**+3**
ASA	
ASA 1	**0**
ASA 2	**+2**
ASA 3	**+5**
ASA 4 and more	**+8**
Surgery timing	
Elective surgery	**0**
Urgent surgery	**+3**
Emergent surgery	**+4**
Surgery severity	
Minor	**0**
Intermediate	**+2**
Major	**+4**
Indication for surgery	
Non-communicable disease	**0**
Caesarean section	**-2**
Trauma	**+1**
Infection	**+2**
Surgery type	
Gynaecology/ obstetrics	**-1**
Plastics and breast	**+1**
Urology	**+2**
Ear, nose and throat, gastro-intestinal, hepato-biliary, cardiothoracic, vascular	**+3**
Neurosurgery	**+4**
All other types of surgery	**0**

The ASOS Surgical Risk Calculator: development and validation of a tool for identifying African surgical patients at risk of severe postoperative complications. Kluyts H et al. British Journal of Anaesthesia, Volume 121, Issue 6, 1357 - 1363

ASOS AFRICAN SURGICAL OUTCOMES STUDY

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Appendix 2 – Example of complete EWS chart

