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‘5 Rs to Rescue’: a study protocol of a multi-centre, stepped-wedged cluster trial in four African countries with a mixed methods process evaluation

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Study protocol

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Abstract

Background

Post-operative physiological deterioration that is not promptly treated, leading to a preventable death, is described as ‘failure to rescue’. In many resource-poor African hospitals, systems to prevent ‘failure to rescue’ are generally absent. This protocol outlines the methods for a stepped-wedge cluster trial that aims to determine the efficacy of a co-produced complex intervention, known as ‘5 Rs to Rescue’, in improving rescue capacity.

Methods

A multicentre stepped-wedged cluster trial will be conducted to evaluate the efficacy of ‘5 Rs to Rescue’ in four African countries. All consecutive elective and non-elective surgical patients aged ≥18 years admitted to participating hospital wards will be included. Five care processes will be implemented: risk assessment, recognition of deterioration, response to deterioration, reassessment, and reflection on the care provided. A three-month set-up phase will provide baseline data, followed by a six-month adaptation phase and a three-month sustainability phase. Comparison will be made between baseline and sustainability phases to determine whether the ‘5Rs to Rescue’ intervention increases surveillance for patients at risk of failure to rescue after surgery.

A mixed-methods, theory-informed process evaluation will be conducted alongside the trial. This evaluation will combine small-group interviews, structured observations of care, and an end-of-study questionnaire. We will conduct deductive thematic analysis, mapped to the domains and constructs of the Consolidated Framework for Implementation Research.

Discussion

Given the unmet surgical need in Africa and projected increases in procedure volume, it is vitally important that interventional investigations continue for surgical patients. The outcomes of this study will inform the efficacy of the ‘5Rs to Rescue’ implementation. The intention is to then conduct a cluster randomised trial to demonstrate that the ‘5 Rs to Rescue’ intervention can decrease ‘failure to rescue’ and improve postoperative survival.

Trial Registration: clinicaltrials.gov ID NCT06997328

Background

The physiological deterioration accompanying a postoperative complication, such as haemorrhage or infection, is usually identified by monitoring the patient's basic “vital signs,” including pulse rate, respiratory rate, oxygen saturation, blood pressure, and level of consciousness. However, if physiological deterioration is not identified and treated promptly, it will progress and lead to organ failure and, in turn,

to cardio-respiratory arrest and the death of the patient. The preventable death of a patient following complications and deterioration after surgery is described as ‘failure to rescue’.

‘Failure to rescue’ can serve as a key concept for delivering safe and effective perioperative care and as a general healthcare quality metric. The first African Surgical Outcomes Study (ASOS) showed that ‘failure to rescue’ is the mode of death in 19 out of 20 deaths following surgery across Africa.[1] Using early warning systems to monitor patients after surgery can trigger care escalation for critically ill patients and ensure prompt treatment. However, these systems are not widely available in many resource-poor African hospitals, and nurse-to-patient ratios can be as high as 1:35, which significantly limits capacity to rescue. This contributes to the high postoperative mortality seen in Africa, which is double the rate in high-income countries[1].

The ‘5 Rs to Rescue’ intervention

As patient outcomes tend to improve when enhanced monitoring increases the identification and timely treatment of critically ill patients,[2-4] we co-produced a complex intervention with healthcare staff, community engagement and involvement (CEI) partners, and the Institute for Healthcare Improvement (IHI) across four African countries (Ethiopia, South Africa, Tanzania and Uganda) to improve the capacity of health facility teams to rescue deteriorating patients. This complex quality improvement intervention focuses on improving five principal 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 deterioration or death. The complex quality improvement (QI) intervention is known as ‘5 Rs to Rescue’. This protocol outlines the methods for a stepped-wedge cluster trial to assess the intervention's efficacy in improving postoperative surveillance rates. The trial will also include an embedded process evaluation to identify factors that positively or negatively affect the process.

Methods

This will be a multicentre stepped-wedged cluster trial with a baseline assessment to evaluate the efficacy of the ‘5 Rs to Rescue’ quality improvement intervention. Usual postoperative care will serve as a comparator to reflect real-world practice and to enable evaluation of the effectiveness of the ‘5 Rs to Rescue’ intervention when implemented alongside existing care processes. A mixed-methods, theory-informed process evaluation will run alongside the trial of our complex intervention. The process evaluation will provide insight into how the trial results were achieved and how the intervention mechanisms did or did not work in practice. The cluster trial and process evaluation will be described separately below.

Cluster Trial

Study setting and patient population

The study will be conducted in the participating surgical wards of 20 hospitals in four African countries (Ethiopia, South Africa, Tanzania, and Uganda). All consecutive adult patients aged 18 years or older admitted to participating hospital wards who are undergoing elective or non-elective surgery will be included in the trial. 'Broadcasting' through appropriate hospital notices and signage will inform the patients and the public that the hospital is participating in the complex quality improvement intervention study. The inclusion and exclusion criteria for both hospital and patient-level recruitment are described below:

Hospital inclusion criteria

- Sufficient volume of high-risk patients (ASOS Surgical Risk Calculator Score ≥10) having surgery: defined as ≥seven high-risk patients having surgery per week
- Confirmed engagement with the surgical and nursing teams on target surgical wards

Hospital exclusion criteria

- Insufficient participation in similar improvement programmes within the previous 12 months (Ward level only exclusion criteria)

Patient inclusion criteria

- Patients aged 18 years or older undergoing any surgery who receive postoperative care in a participating ward

Patient exclusion criteria

- Patients who opt out of trial participation
- Patients receiving end-of-life care

Study design

The '5 Rs to Rescue' clinical intervention is a complex intervention which comprises five key postoperative care processes designed to reduce 'failure to rescue':

1. Risk assessment: Use the ASOS Surgical Risk Calculator Score (Additional File 2) for all surgical patients.

For those patients deemed high risk by the ASOS Surgical Risk Calculator Score (≥10) or where the clinical team deems the patient high-risk, the following processes will be applied:

2. Recognition of patient deterioration: regular, protocolised vital signs (Additional File 3) monitoring with or without use of an Early Warning Score (EWS) (Additional File 4).

3. Response to deterioration: protocolised escalation based upon EWS plus protocolised care pathways for common complications (e.g. hypoxia, hypovolaemia, sepsis).

4. Reassessment following deterioration: protocolised re-assessment based upon the EWS.

5. Reflection on care provided using structured review tools for daily ward ‘huddles’ and regularly scheduled ‘reflection meetings’ to discuss patients who deteriorate and/ or die.

This trial intervention will commence with a three-month ‘Set-up Phase’ that will serve as the control period, providing baseline data and preparing for quality-improvement changes. This will be followed by a six-month ‘Adaptation Phase’ where local clinical teams will receive education and training to implement the ‘5 Rs to Rescue’ quality improvement intervention. This will be supported by Improvement Advisors from the Institute for Healthcare Improvement (IHI). Data will be collected during this period; however, these data will not be used to assess the intervention's efficacy. The trial will conclude with a three-month ‘Sustainability Phase’ to build a learning system to adopt and sustain the ‘5 Rs to Rescue’ quality improvement intervention and provide efficacy outcomes data. Further adaptations to the complex intervention by the quality improvement teams are permissible during this phase, and any adaptations will be described as part of the embedded process evaluation. Clusters need not commence the trial on the same date.

Objectives and outcome measures

Primary objective

To evaluate whether implementation of the ‘5 Rs to Rescue’ quality improvement intervention increases surveillance for patients at risk of ‘failure to rescue’ after surgery in hospitals in Africa.

Secondary objectives

To evaluate the effect of the trial intervention on:

1. 30-day in-hospital mortality.

2. Duration of hospital stay.

Co-primary outcome measures

1. The number of ASOS Surgical Risk Calculator Scores documented.

2. The number of completed episodes of documented sets of vital signs or EWS within the first 72 hours after surgery.

3. The number of physician-patient encounters within the first 72 hours after surgery.

Secondary outcome measures

1. All-cause in-hospital mortality within 30 days of surgery.

2. Duration of hospital stay (number of days from the day of surgery until hospital discharge).

Sample Size

The sample size for the cluster trial will be determined by the number of participating hospitals and the durations of the baseline, intervention, and sustainability periods. Based on experience from the previously completed intervention development phase, we estimate a total recruitment period of 12 months. The baseline phase over the first three months would allow all facilities to embed the intervention. The next six months would enable system learning. The final 3 months, 'a sustainability phase', would allow us to evaluate the sustained impact. Separate sample size calculations were performed for each primary outcome to ensure sufficient recruitment during the 12-month period, given that four countries will contribute five hospitals each to the study.

This is a stepped-wedge cluster trial in which hospitals (clusters) will transition from control (usual care) to the '5 Rs to Rescue' intervention according to a pre-specified rollout sequence. The random allocation sequence determining the order of cluster crossover will be generated centrally by an independent statistician using a restricted randomisation procedure stratified by country. Details of any restrictions used to reduce predictability will be retained by the statistician and will not be accessible to personnel involved in hospital recruitment, data collection, or intervention delivery.

Allocation will be centrally implemented by the coordinating team, and clusters will be informed of their scheduled crossover timing after completion of baseline procedures. Personnel responsible for enrolling participants and collecting outcome data will not have access to the full random allocation sequence.

Given the nature of the quality improvement intervention, blinding of hospitals, clinical teams, and implementation staff is not feasible. Where feasible, data analysts will be blinded to allocation during primary analyses by coding trial phases until the analysis is complete. Formal unblinding procedures are not applicable.

Analysis plan

Analysis and reporting of this stepped-wedge cluster trial will be conducted in accordance with the CONSORT extension for stepped-wedge cluster randomised trials (CONSORT-SW-CRT)[6] to ensure transparent, complete, and reproducible reporting of the design, conduct, and analysis. The results of this study will be disseminated through peer-reviewed publications, presentations at national and international scientific meetings, reporting in relevant trial registries, and feedback to participating hospitals, healthcare professionals, and local stakeholders in accessible summary formats.

Patterns of missing data will be examined by cluster and period, analyses will include all available data, and sensitivity analyses will be performed to evaluate the impact of missing data on study conclusions.

Patient recruitment and description will be presented as follows:

- A flow diagram will be produced, reporting:
    - numbers of clusters and participants by sequence and period,
    - eligibility, inclusion, and exclusions at both cluster and individual levels,
    - losses to follow-up and missing observations, with reasons.
- Dates of each step, intervention initiation, and deviations from the planned rollout will be reported.

- The number of participating hospitals, hospital characteristics and patients at each hospital level will be reported in a table. Detailed hospital characteristics will be provided in a Supplementary Table.

- The patient characteristics of the cohort will be presented in the table.

Outcomes will be presented for the whole cohort, including a comparison between the baseline and sustainability phases. Categorical variables will be described as the number (n/N) and proportions, and will be compared using chi-square tests. We will describe continuous variables using either the mean and standard deviation or the median and interquartile range (IQR), depending on the distribution of the data. Comparisons of continuous variables between groups will be performed using t-tests, one-way ANOVA or equivalent non-parametric tests as appropriate. Basic statistical analyses will be performed using the Statistical Package for the Social Sciences (SPSS) version 28.0.1.1 (SPSS Inc., Chicago, IL, USA) and R statistical software: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing (2024) using Studio: Integrated Development Environment for R. Boston, MA: RStudio, Inc. (2024).

No Data Monitoring Committee was convened because this is a low-risk quality improvement intervention using routinely collected clinical data, with no investigational medicinal product and no participant-level treatment allocation. No interim analyses are planned, and no formal stopping guidelines have been specified, as the study evaluates a ward-level implementation package across fixed baseline, adaptation, and sustainability phases. Trial conduct and implementation fidelity will be monitored through routine review of study metrics and regular contact between site teams, country coordinators, and IHI Improvement Advisors, with deviations from the planned rollout documented in the process evaluation

Process Evaluation

Study design

This evaluation will be a mixed-methods study combining small-group interviews, structured observations of care, and an end-of-study online questionnaire for staff.

We will purposively sample eight study sites across the four participating countries, ensuring a mix of hospital service levels (primary, secondary, and tertiary).

Qualitative data collection will include site visits by research assistants (with structured field notes) and up to three small-group interviews with key actors (nurses, doctors, and managers) at each participating site (two to five staff per interview). Data collection and analysis will occur concurrently, and sampling will cease when thematic saturation is reached (or at the stated maximum).

One small-group interview with the quality improvement project's main delivery team (from the Institute for Healthcare Improvement) will also be conducted online. Questionnaire data will be collected online, and healthcare workers will provide informed consent to participate.

Healthcare staff inclusion criteria

- Nurses and doctors who work on participating surgical wards and in management roles within participating hospitals

Healthcare staff exclusion criteria

- Refusal of written informed consent

Objectives and outcome measures

To understand the influence of contextual and socio-dynamic factors on the effectiveness of the implementation of the '5 Rs to Rescue' complex intervention, including: how the QI programme was delivered to hospital staff, how hospital staff perceived the QI programme, including its relative value and usability; the contextual enablers of and barriers to improvement, including structural and cultural influences, and how individual staff in study sites responded to and enacted the guidance offered by the QI programme.

Data analysis

Deductive thematic analysis, mapped to the domains and constructs of the Consolidated Framework for Implementation Research (CFIR), will be usedto answer the study objectives listed above. Questionnaire responses will be reported using descriptive statistics.

Data Management

Individual patient data provided by participating hospitals remains the property of the respective institution once the study report has been published. Once each local coordinator has confirmed that the data provided by their hospital is complete and accurate, they will receive a spreadsheet containing their hospital's raw (uncleaned) data. In the study report, only summary data will be presented publicly, and all national, institutional, and patient-level data will be strictly anonymised.

Discussion

Failure to rescue is an important post-surgical quality improvement indicator that has demonstrated differences in outcomes[7,8,9], which partly explain the increased mortality following surgery in Africa.[1] However, the ASOS-2 study could not demonstrate that enhanced post-operative surveillance reduces mortality following surgery in Africa.[2] The process evaluation[10] for the ASOS-2 study found that the lack of effect on mortality was related to poor intervention fidelity, insufficient time to improve care processes, and a recognition that improved surveillance may be necessary but not sufficient. The evaluation identified that future interventions should address monitoring, escalation, and management of deteriorating surgical patients. Due to resource constraints, it was noted that further intervention studies should focus solely on surgical patients at high risk.

Given the unmet surgical need in sub-Saharan Africa and estimates of increased procedure volume,[11] it is vitally important that interventional investigations continue for surgical patients with physiological deterioration. The ASOS-2 trial yielded two conclusions supporting further study. Firstly, the trial demonstrated that despite the multiple challenges, high-quality, large-scale interventional studies can be coordinated across Africa. Secondly, the trial demonstrated that diverting human resources to high-risk patients did not increase morbidity or mortality among patients not designated as high risk. This absence of harm to low-risk patients supports the design of a quality improvement programme with implementation focused on a high-risk population.

The above considerations provide several reasons to support this proposed study to reduce ‘failure to rescue’ and improve surgical outcomes in sub-Saharan Africa. The need to formulate strategies to reduce surgical mortality remains, and it is likely to increase with an expected rise in surgical volume. The ‘5 Rs to Rescue’ intervention package incorporates lessons from previous work and will focus on high-risk surgical populations via the use of the ASOS surgical risk calculator, and has points of focus on enhanced monitoring and escalation, response, and continued review. Each participating country in this study has a dedicated team to ensure a sound understanding of the working environment and to formulate strategies to enhance the intervention's fidelity. The embedded process evaluation and the local quality improvement teams' ability to adapt interventions in practice will help produce programmes that are appropriate and acceptable to the context. The embedded process evaluation will also help identify any potential, currently unidentified factors within the complex intervention.

Conclusion

The stepped-wedged cluster trial and process evaluation outcomes will inform the efficacy of the ‘5 Rs to Rescue’ implementation. The intention is then to conduct a larger randomised trial of the ‘5 Rs to Rescue’ intervention across several African nations, comparing patient-important outcomes for patients undergoing major surgery between intervention and usual-care hospitals. Ultimately, the aim will be to demonstrate that the ‘5 Rs to Rescue’ intervention can decrease ‘failure to rescue’ in Africa and, in turn, improve postoperative survival.

Abbreviations

ASOS – African Surgical Outcomes Study

CEI – Community Engagement and Involvement

CFIR – Consolidated Framework for Implementation Research

EuSOS – European Surgical Outcomes Study

EWS – Early Warning Score

IHI - Institute for Healthcare Improvement

QI – Quality Improvement

VSDT – Vital Signs Directed Therapy

Declarations

Ethical approval and consent to participate

The study will be conducted in accordance with the ethical principles of the Declaration of Helsinki and the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines. Ethical approval will be obtained from the national ethical committee of each participating country and from each institution's local regulatory authority. Each country coordinator will be responsible for clarifying the need for ethical and regulatory approvals and ensuring that they are in place before data collection.

Each participating country will request a waiver of informed consent on the basis that this is an evaluation of a large-scale quality improvement project. The dataset will only include variables documented as part of routine clinical care, and identifiable patient data will not leave the treating hospital. The sponsoring institution, the University of Cape Town in South Africa, has granted an informed consent waiver. Additional reasons justifying this waiver request are outlined as follows. Firstly, more than 50% of surgeries in Africa are urgent or emergent, and urgent or emergent surgery is a strong independent predictor of postoperative mortality in Africa.[1] Attempts to obtain traditional consent in the preoperative period for predominantly urgent and emergent surgery, which may include patients with reduced consciousness, may result in non-consecutive patient enrolment in the evaluation. This would likely lead to a biased sample with artificially low estimates of adverse outcomes in African surgical patients and data following the study, which are not generalisable to most African surgical patients. Secondly, for these reasons, a waiver of consent is increasingly common worldwide in both interventional and observational research involving time-sensitive procedures, such as surgery, and has

been accepted previously in a similar trial across Africa.[2] Thirdly, generating biased and poorly generalisable data would not address the research question, would dishonour the contributions of the other included patients, and would be wasteful research in a resource-limited environment. Fourthly, we believe that our quality improvement intervention is low risk. Finally, we will use 'broadcasting' signage informing patients and families that the site is a participating surgical site. A precedent for this approach was set internationally with the EuSOS and ASOS studies. In EuSOS[5], consent was waived in 27 of the 28 participating European countries,[5] and in the ASOS-1[1] and ASOS-2[2] trials, consent was waived in most hospitals across the African continent.

The interviews conducted during the process evaluation will be transcribed, and the output will not identify any individual or hospital. Participating hospitals will not be permitted to record data unless they have confirmed that the necessary ethical and regulatory approvals are in place.

Consent for publication

Informed consent for participation will be obtained from all interview participants, including consent to the use of anonymised quotations in publications. All quotes will be de-identified and will not contain information that could reasonably identify individuals.

Availability of data and materials

The datasets generated and/or analysed during the study will not be publicly available due to the risk of compromising the confidentiality of participants, hospitals, and countries. De-identified data may be made available upon reasonable request to the corresponding author, subject to approval of the proposed use by the study steering committee and completion of a signed data access agreement.

Trial Registration: Registered with clinicaltrials.gov, ID NCT06997328, registered 21/8/2024. Study Details | NCT06997328 | '5 Rs to Rescue' A Cluster Trial With an Embedded Process Evaluation | ClinicalTrials.gov

Protocol and Statistical Analysis Plan: Can be accessed via clinicaltrials.gov using the ID NCT06997328

Competing interests

The authors declare that they have no competing interests

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