‘5 Rs to Rescue’

A cluster trial with an embedded process evaluation

Protocol version 1.0

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Contents

LIST OF 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 scores
ICC	intra-cluster correlation
IHI	Institute for Health Improvement
QI	quality improvement
SSSA	Safe Surgery South Africa

SUMMARY

Title	**'5 Rs to Rescue': A cluster trial with an embedded process evaluation**
Project Office	Department of Anaesthesia and Perioperative Medicine, Groote Schuur Hospital, University of Cape Town, South Africa.
Trial Size	20 centres in 4 countries – Ethiopia, South Africa, Tanzania, and Uganda.
Trial Design	Multi-centre, cluster trial with a baseline assessment to evaluate the efficacy of the '5 Rs to Rescue' quality improvement intervention. The trial will incorporate a mixed-methods process evaluation of the trial intervention.
Primary Objectives	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	1. 30 day in-hospital mortality 2. Duration of hospital stay
Inclusion Criteria	Hospitals: Sufficient volume of high-risk patients (ASOS score >10) having surgery, defined as ≥7 high risk patients having surgery per week. Patients: Patients aged 18 years and older undergoing any surgery, who receive postoperative care on a participating ward.
Exclusion Criteria	Hospitals: 1. Insufficient volume of high-risk patients having surgery. 2. No confirmed engagement with surgical and nursing teams. 3. (Ward level only) Participation in similar improvement programmes within previous 12 months Patients: 1. Patients that opt out of the trial will be excluded. Patients receiving end of life care.
Recruitment	Twenty facilities in Ethiopia, South Africa, Tanzania and Uganda
Trial intervention	Three-month 'Set-up Phase' which will serve as the control period providing baseline data and preparation for change associated with quality improvement. Six -month 'Adaptation Phase' will provide local clinical teams with education and training to implement the '5 Rs to Rescue' quality improvement intervention. Three-month 'Sustainability Phase' to build a learning system for adoption and sustainability of the '5 Rs to Rescue' quality improvement intervention. This Phase will provide efficacy outcomes data. The '5 Rs to Rescue' includes: 1. Risk assessment using the ASOS risk score for all surgical patients, 2. Recognition of patient deterioration by regular, protocolised vital signs monitoring plus use of an Early Warning Score (EWS) system, 3. Response to deterioration by protocolised escalation based upon EWS plus protocolised care pathways for common complications (hypoxia, hypovolaemia, sepsis), 4. Reassessment following deterioration by protocolised re-assessment based upon EWS, and 5. Reflection on care provided following a patient's deterioration or death using a structured review tool at regular reflection meetings
Trial duration	Twelve months

INTRODUCTION

'Failure to rescue' describes the preventable death of a patient following a complication after surgery. Patients who develop complications after surgery, such as haemorrhage or infection, begin to deteriorate physiologically and become acutely unwell. This is usually identified by careful monitoring of the patient's basic 'vital signs' which include pulse rate, respiratory rate, oxygen saturation, blood pressure and consciousness level. However, if physiological deterioration is not identified and treated in a timely manner, it will progress and lead to organ dysfunction and then organ failure. This will ultimately lead to cardio-respiratory arrest and the death of the patient.

'Failure to rescue' can be used as a key concept in delivering safe and effective perioperative care as well as a healthcare quality metric in general. The first African Surgical Outcomes Study (ASOS-1) showed that 'failure to rescue' is the mode of death in 19 out of 20 deaths following surgery across Africa.[1] Hospitals in high-income countries use early warning systems to monitor patients after surgery and trigger the escalation of care for patients who are critically ill to ensure prompt treatment. However, these systems do not exist in many resource-poor African hospitals where nurse: patient ratios can be as high as 1:35 and limit capacity-to-rescue within the system. Furthermore, in many African hospitals they do not use early warning systems to monitor patients following surgery. These factors contribute to the higher mortality post-surgery in Africa compared to high-income countries.

As patient outcomes tend to improve when enhanced monitoring increases the identification and treatment of critically ill patients,[2-4] 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 improve the capacity-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'. Ultimately, we intend to conduct a large international cluster randomised trial of the '5 Rs to Rescue' intervention comparing patient important outcomes for patients undergoing major surgery between intervention and usual care hospitals. We hope to demonstrate that the '5 Rs to Rescue' intervention can decrease 'failure to rescue' in Africa, and improve postoperative survival.

However, to inform the large international cluster randomised trial, we need to i) determine the efficacy of the intervention in demonstrating positive change to clinical management and ii) understand the factors which are either positively or negative impacting on the processes involved in the delivery of the quality improvement intervention. We will therefore undertake a pilot cluster trial to assess intervention efficacy with an embedded process evaluation.

CLUSTER TRIAL

Trial design

Multi-centre, cluster trial with a baseline assessment to evaluate the efficacy of the '5 Rs to Rescue' quality improvement intervention. The trial will incorporate a mixed-methods process evaluation of the trial intervention.

Objectives

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.

Outcome measures

Co-primary outcome measures

1. The number of ASOS Surgical Risk Calculator Scores documented.
2. The number of completed Early Warning Scores (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 day of surgery until hospital discharge).

A list of definitions is available in the 'Definitions document' in Appendix 1.

Trial setting

Surgical wards of participating hospitals in four African countries (Ethiopia, South Africa, Tanzania, Uganda). It is anticipated that in some hospitals not every surgical ward will participate.

Eligibility criteria

Hospital inclusion criteria

- Sufficient volume of high-risk patients (ASOS Surgical Risk Calculator Score >10) having surgery, defined as ≥7 high risk patients having surgery per week
- Confirmed engagement with the surgical and nursing teams on target surgical wards

Hospital exclusion criteria

- Insufficient volume of high-risk patients having surgery.
- No confirmed engagement with surgical and nursing teams.
- Participation in similar improvement programmes within previous 12 months (Ward level only exclusion criteria).

Patient inclusion criteria

Patients aged 18 years and older undergoing any surgery, who receive postoperative care on a participating ward.

Patient exclusion criteria

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

Recruitment and screening

We expect all consecutive adult patients aged 18 years and older admitted to participating hospital wards undergoing elective and non-elective surgery to 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.

Ethical considerations, informed consent and study participation

The study will be carried out in accordance with the ethical principles in the International Conference on Harmonisation and Good Clinical Practice. Ethical approval will be obtained from the University of Cape Town with additional approvals in each country as required by national ethical committees, and from each institution as required by local regulatory requirements. The Country Coordinators will be responsible for clarifying the need for ethical and regulatory approvals and for ensuring these are in place prior to data collection. Participating hospitals will not be permitted to record data without providing confirmation that the necessary ethical and regulatory approvals are in place.

The requirement for patient consent may vary according to national regulations. We anticipate that patient consent will not be required by most, or even all, nations on the basis that the study is, in effect, 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. Therefore, we will apply to all ethics committees for a waiver of consent for participating sites for the following reasons. Firstly, more than 50% of surgery in Africa is 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 in predominantly urgent and emergent surgery, which may include patients with a decreased level of consciousness may lead to non-consecutive patient enrolment in the study. It is likely that this would 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 the majority of African surgical patients. Secondly, for these reasons, a waiver of consent is increasingly common around the world in both interventional and observational research involving time-sensitive procedures, such as surgery, and has been accepted previously in a similar trial by our group across Africa.[2] Thirdly, generating biased and poorly generalizable data would not address the research question, and thus would dishonour the contributions of the other included patients, and would be wasteful research, in a resource-limited environment. Fourthly, we believe that the trial intervention is low risk, as it is a complex quality improvement intervention. Finally, we will use 'broadcasting' signage informing patients and families that the site is a participating surgical trial site, through appropriate signage (Appendix 2) and a patient information sheet (Appendix 3). A precedent for this approach was set internationally with the EuSOS and ASOS studies. In EuSOS, consent was waived in 27 of the 28 European countries participating,[5] and in ASOS-1[1] and the ASOS-2[2] trial consent was waived in the majority of hospitals participating across the African continent.

Trial intervention

The trial will commence with a three-month 'Set-up Phase' which will serve as the control period providing baseline data and preparation for change associated with quality improvement. 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 Health Improvement. We will collect data during this period, but this will not be used to describe intervention efficacy. The trial will conclude with a three-month 'Sustainability Phase' to build a learning system for adoption and sustainability of the '5 Rs to Rescue' quality improvement intervention. The 'Sustainability Phase' will provide efficacy outcomes

data. Further adaptations to the complex intervention by the quality improvement teams are permissible during this phase. It is not essential for all clusters to commence the trial on the same date.

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 of the ASOS Surgical Risk Calculator Score (see Appendix 4) 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:

2. Recognition of patient deterioration: regular, protocolised vital signs monitoring plus use of an Early Warning Score (EWS) system (Appendix 5).
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 regular scheduled 'reflection meetings' to discuss patients who deteriorate and/ or died.

Further adaptations to the complex intervention by the quality improvement teams are permissible during the trial. Any adaptions will be described as part of the embedded process evaluation.

The case record form (CRF) is shown in Appendix 6.

Statistical analysis

Sample size calculation

The sample size determination is based on four countries contributing approximately five hospitals each to the study.

One-level clustering has been assumed, not accounting for clustering by countries separately. As no intra-cluster correlations (ICC) estimates are available, a high within cluster ICC is assumed (being conservative).

All sample size calculations are for a one-sample proportion tests, testing against a fixed value and accounting for clustering. The fixed values are based on baseline estimates, however, choosing target values might be preferable. System optimisation step rates assumed not used in analyses.

1. Documentation of the ASOS Surgical Risk Calculator Score postoperatively.

Calculation based on i) a control rate from the pilot study of 25%, with ii) a post intervention (a 'Sustainability Phase') compliance of 90%.

alpha	power	K	M	N	delta	p0	pa	rho	CV_cluster
.05	.9	20	.15	3	.65	.25	.9	.1	1.5
.05	.9	20	.1	2	.65	.25	.9	.2	1.5
.05	.9	20	.1	2	.65	.25	.9	.3	1.5
.05	.9	20	.1	2	.65	.25	.9	.4	1.5
.05	.9	20	.1	2	.65	.25	.9	.5	1.5

2. The number of completed early warning scores (EWS) within the first 72 hours postoperatively (high-risk patients only).

Calculation based on a post intervention (a 'Sustainability Phase') compliance of 80% of patients across all sites.

alpha	power	K	M	N	delta	p0	pa	rho	CV_cluster
.05	.9	20	8.3	166	.2	.6	.8	.1	1.5
.05	.9	20	11.45	229	.2	.6	.8	.2	1.5
.05	.9	20	14.55	291	.2	.6	.8	.3	1.5
.05	.9	20	26.95	539	.2	.6	.8	.4	1.5
.05	.9	20	.	.	.2	.6	.8	.5	1.5

3. The number of patients who have documented physician patient encounters within the first 72 hours postoperatively (all postoperative patients).

Calculation will be based on i) control rate of number of physician encounters per patient over 72 hours (1 physician encounter per day), and ii) a post intervention (a 'Sustainability Phase') physician encounter increase of 30% from the baseline rate over 72 postoperative hours.

PROCESS EVALUATION

Mixed methods process evaluation

Theory-informed process evaluations alongside trials of complex interventions are now standard. The process evaluation will provide an understanding of how the trial results were achieved and how the intervention mechanisms did, or did not, work in practice**.**

Objectives

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 quality improvement (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.

Methods

Mixed-methods study combining small group interviews, structured observations of care and an end of study on-line questionnaire for staff.

Sampling and Data collection

We will purposefully sample eight study sites from across the four participating countries ensuring a mixture of hospital service level (primary, secondary, tertiary).

Qualitative data collection will include site visits by research assistants (with structured fieldnotes taken) and up to 3 small group interviews with key actors (nurses, doctors and managers) per participating site (2-5 staff per interview). Data collection and analysis will occur concurrently, and sampling will cease when theoretical saturation is reached (or up to maximum number stated).

One small group interview with the quality improvement project main delivery team (from the Institute of Healthcare Improvement) will also be conducted online. Questionnaire data collection will be online. Healthcare workers will provide informed consent to participate (Appendix 7).

Healthcare staff inclusion criteria

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

Healthcare staff exclusion criteria

- Refusal of written informed consent.

Data collection

A structured topic guide template will be used by the research assistants visiting the study sites (Appendix 8). The template will be completed following each visit to the site and will be emailed to the process evaluation team for analysis. The research assistants will be instructed in the methods for case study visits, field notes and interviews by a process evaluation expert who will oversee the qualitative analysis of the case study data. The small group interviews will be recorded on the research assistant's cell phone and the audio files emailed to the process evaluation team for analysis directly from audio. The small group interview with the main quality improvement delivery team will be conducted and recorded using MS Teams. Interviews will not be transcribed. The post-trial questionnaire will be based in REDCap. Individual hospital lead investigators (one per hospital) will be invited in person to participate. Output will not identify any individual or hospital.

Data analysis

Deductive thematic analysis, mapped to the domains and constructs of Consolidated Framework for Implementation Research (CFIR)[6] to answer the study objectives listed above. Analysis will be led by Tim Stephens, who will support other investigators in the theming process. Questionnaire responses will be reported using descriptive statistics.

SECTIONS PERTAINING TO BOTH COMPONENTS OF THE STUDY

Data Handling and Management

The papers containing identifiable patient data for the follow-up of clinical outcomes will be stored within a locked office in each hospital or institution. Data will be pseudo-anonymised by generation of a unique numeric code and transcribed by local investigators onto an internet based electronic case-record file (e-CRF).

Each patient will only be identified on the e-CRF by their numeric code; thus the central co-ordinating study team cannot trace data back to an individual patient. A participant list will be used in each hospital/site to match identifier codes in the database to individual patients in order to record clinical outcomes and supply any missing data points. This participant list will be stored on a password-protected computer. Access to the data entry system will be based on the principle of least privilege and will be protected by username and password delivered during the registration process for individual local investigators.

All electronic data transfer between participating hospitals and the co-ordinating institution will be encrypted using a secure protocol (HTTPS/SSL 3.0 or better). Data will be anonymised during the transcription process using the Research Electronic Data Capture (REDCap) tools hosted by Safe Surgery South Africa (SSSA) who will act as the data custodian. REDCap is a secure, web-based application designed to support databases and data capturing for research studies. Soft limits will be set for data entry, prompting investigators when data were entered outside these limits. In countries with poor internet access, paper case record forms may be forwarded to SSSA, for entry by SSSA. Pseudo-anonymised (coded) data may also be sent by encrypted e-mail to the coordinating institution if necessary. Each institution will maintain a secure trial file including a protocol, local investigator delegation log, ethics approval documentation, the participant list, etc. Copies of the relevant protocols, approvals and investigator lists will also be kept securely in an internal drive by SSSA. A final summary of included patients with aggregated data of patients, and outcomes will be produced for each hospital together with final data submission to double check for completeness and accuracy.

Individual patient data provided by participating hospitals remain the property of the respective institution, once the study report has been published. Once each local co-ordinator has confirmed the data provided from their hospital are both complete and accurate, they will be provided with a spreadsheet of the raw (un-cleaned) data for their hospital. In the study report, only summary data

will be presented publicly, and all national, institutional and patient level data will be strictly anonymised.

Safety considerations

There are no safety considerations relating to the study, as this is a quality improvement intervention. There is no risk of harm to either patients or investigators.

Monitoring and Auditing

Study documents may be selected by the Sponsor to ensure study activities are conducted according to the protocol, the Sponsor's standard operating procedures, Good Clinical Practice and the applicable regulatory requirements. In participating hospitals, local study documents may also be selected for audit on a local basis. The trial team will not routinely monitor data collection in individual hospitals or conduct source data verification.

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APPENDICES

Appendix 1: Definitions

1. 72 hours after surgery: 72 hours from the patient's arrival on the ward postoperatively

2. Documented African Surgical Outcomes Study (ASOS) Score: ASOS score written in an appropriately visible location on the patients notes / ward charts

3. Completed Early Warning Scores (EWS): This is dependent on the EWS chart chosen.

   Each score requires a set of measured and documented vital signs that includes all the following:

   - Conscious level (AVPU Scale)
   - Respiratory rate per minute
   - Oxygen saturation (%)
   - Heart rate per minute
   - Systolic blood pressure (mmHg)
   - Plus documentation of the aggregate score (e.g. for NEWS) or documentation of any out-of-range vital signs (e.g. for the VSDT)

4. Physician encounters: any documented reviews of a patient by a physician

5. Hospital population: all adult patients aged 18 years or over who have been admitted for inpatient care in any department or ward in participating hospitals on the day of data collection

6. In-hospital mortality: Death in-hospital within 30 days of surgery. Patients discharged alive are not followed-up at home.

Appendix 2: Broadcasting document

IMPORTANT PATIENT INFORMATION

A research study is being conducted at ……..Hospital.

The research study is being done by Dr ……. from the Department of ……..

Why is this research study being done?

We have attempted to change the way we care for our patients after an operation by using a new system called "5R's to Rescue."

The "5R's to Rescue" project aims to improve how we categorise patients into high and low risk patients groups, how we recognise who are developing complications earlier after surgery, how respond with earlier care, and how we learn from each case.

Through this study we aim to understand whether this project will improve how our patients recover after surgery.

Why are we telling you about this research study?

All surgical patients in this hospital are part of the research study. It is a requirement that some details of your clinical care will entered into a research study folder. All information will be used anonymously to understand how surgical patients respond to the increased care given in the study.

Will this research study affect my care while I am in hospital?

Yes. We have set early warning systems to alert the doctors and nurses if you are very ill, and given advice on how to provide more care while you are in hospital.

Will my name or any personal details be kept by this research study?

No. Your name and personal details will not be kept as part of this research study. All information from the study will be kept strictly confidential.

Are there any risks or benefits associated with this project?

No. There are no risks or direct benefits associated with this research study.

Who should I contact if I have any questions or concerns?

Please contact Dr …… on telephone……

If you have questions about your rights or welfare as a participant, please contact the UCT Faculty of Health Sciences Human Research Ethics Committee on +27 (0)21 406 6338.

Appendix 3: Patient information sheet

Patient Information Sheet

(To be read to all surgical patients)

A research study is being conducted at ……..Hospital.

The research study is being done by Dr ……. from the Department of …….

We hope to improve the care of patients after an operation by using a new system called “5R’s to Rescue”.

The “5R’s to Rescue” system aims to help us recognise patients early, who may be developing complications after surgery, and then how we respond to provide increased care where it is needed.

We are studying all our surgical cases to understand whether the “5R’s to Rescue” system improves how our patients recover after surgery.

Some of the details of your clinical care will be entered into a research study folder. Information from this folder will be used anonymously to understand how surgical patients respond to the increased care given in the study.

Your name and personal details will not be kept as part of this research study. All information from the notes will be kept strictly confidential.

There are no risks or direct benefits associated with this research study.

Appendix 4: ASOS Surgical Risk Calculator Score

The ASOS Surgical Risk Calculator for preoperative risk prediction of severe postoperative complications and mortality

Age	
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**
Other	**0**

ASA American Society of Anesthesiologists; A single point represents a standard increase in risk, defined as a 0·25 increase in the logistic regression coefficient, equivalent to a 30% increase in the risk of the outcome being present. Total score possible: -3 to 25

Appendix 5: Standard operating procedures manuals

1. NEWS scoring system[7]

PHYSIOLOGICAL PARAMETERS	3	2	1	0	1	2	3
Respiration Rate	≤8		9 - 11	12 - 20		21 - 24	≥25
Oxygen Saturations	≤91	92 - 93	94 - 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35.0		35.1 - 36.0	36.1 - 38.0	38.1 - 39.0	≥39.1	
Systolic BP	≤90	91 - 100	101 - 110	111 - 219			≥220
Heart Rate	≤40		41 - 50	51 - 90	91 - 110	111 - 130	≥131
Level of Consciousness				A			V, P, or U

2. Vital Signs Directed Therapy (VSDT) system[8]

VSDT Vital Signs Directed Therapy Protocol To be used for *all patients* over 16years

Name ..... Hospital Number ..... Date .....

1. If a **Danger Sign** is present give the treatment indicated ***immediately***
2. **Recheck** vital signs and repeat treatment if necessary until Danger Sign is no longer present
3. All patients with a Danger Sign must have their vital signs rechecked ***at least every 30 minutes***
4. **Call doctor** ***if you are concerned for any reason*** or if the Danger Sign persists

The protocol can be modified by the attending physician
The protocol is a complement to the usual medical management

			Danger (Red)	Abnormal (Yellow)	Normal (Green)	Abnormal (Yellow)	Danger (Red)		Treatment if Danger Sign	Physician's modifications to protocol
A	Airway	Conscious Level (Glasgow Coma Scale = GCS)	3-8	9-14	15			A	PROTECT AIRWAY Lateral position Chin lift / jaw thrust Oro-pharyngeal airway Suction	•..... •.....
		Airway sounds			Normal airway sounds		Abnormal airway sounds eg. gurgling/ snoring / stridor			
B	Breathing	Respiratory Rate / minute	<8	8-11	12-18	19-30	>30	B	HYPOXIA? Sit patient up (if no shock) Increase Oxygen	•..... •.....
		Inspired Oxygen			Air	<80% or ≤10L/min	80-100% Or >10L/min			
		Oxygen Saturation (%)	<90	90-94	95-100					
C	Circulation	Heart Rate / minute	<40	40-59	60-100	101-130	>130	C	SHOCK? Tip bed head-down IV RL/NS 500ml in 30mins Recheck & repeat 500ml in 30min as long as Danger Sign persists If >2 litres given in 2hrs: Call doctor	•..... •..... •.....
		Systolic Blood Pressure (mmHg)	<90	90-99	100-180	>180				

Other treatments to consider
- Bag & Mask Ventilation
- Intubation
- Modify Ventilator settings
- Adrenaline
- Atropine
- Dextrose (IV 10% 5ml/kg)
- Naloxone
- Pain relief (Morphine)
- Paracetamol
- Salbutamol

ICU Muhimbili National Hospital 2014

Appendix 6: Case record form (CRF)

APPRISE African Partnership for Perioperative and CRitical Care ReSEarch

'5 Rs to Rescue' unique ID: ☐☐☐ – ☐☐☐☐

APORG AFRICAN PERIOPERATIVE RESEARCH GROUP

'5 Rs to Rescue' Trial: Case Record Form (CRF) v1.0

Age: ☐☐☐ years **Sex** ☐ Male ☐ Female

ASA ☐ I ☐ II ☐ III ☐ IV ☐ V

Chronic co-morbid disease (tick all that apply):

☐ Hypertension ☐ HIV/AIDS ☐ Diabetes ☐ Asthma/COPD ☐ Other

Surgical procedure category (select *single* most appropriate):

☐ Gynaecology ☐ Obstetrics ☐ Orthopaedic ☐ Ear, Nose and Throat ☐ Plastics or breast

☐ Urology ☐ Neurosurgery ☐ Gastro-intestinal or hepato-biliary ☐ Cardiothoracic/vascular ☐ Other

Indication for surgery:

☐ Non-communicable disease ☐ Trauma ☐ Infection ☐ Caesarean SectionI

Urgency of surgery: ☐ Elective ☐ Urgent ☐ Emergency

Severity of surgery: ☐ Minor ☐ Intermediate ☐ Major

Date of postoperative admission to the ward: d d / m m / y y y y

Time of postoperative admission to the ward (24 hr): h h : m m

ASOS Surgical Risk Score: ☐ < 10 (Not high-risk patient) ☐ ≥ 10 (High-risk patient)

Post-operative follow-up for HIGH RISK patients only *(ASOS Surgical Risk Score ≥ 10 or clinical decision made for high risk)*

Post-op measures	0-24hrs	25-48hrs	49-72hrs
ASOS Surgical Risk Score documented & communicated to ward staff:	☐ Yes ☐ No		
Number of completed EWS on patient chart:			
Number of documented physician-patient encounters in patient notes / chart:			

Days in hospital after surgery: ☐☐ days

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

☐ Alive & discharged ☐ Alive & in-hospital ☐ Dead

CRF completed by: .....

CRF verified by: ..... CRF verified on ..... / ..... / .....

Patient name: _____ DOB: ..... / ..... / .....

Patient hospital number: _____

5Rs to Rescue CRF v1.0

Appendix 7: Participant Information Sheet for the process evaluation

A mixed-methods process evaluation of the '5 Rs to Rescue' complex quality improvement intervention.

Introduction

This Participant Information Sheet explains the research study and what taking part will mean. Knowing what is involved will help you decide if you want to take part in the study.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary and it is your choice to agree to be a part of the study or not. If you do not wish to take part, you do not have to. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent (agree) to take part in the research project
- Consent to the research that is described

You will be given a copy of this Participant Information and Consent Form to keep.

Background and purpose of this study

You are invited to take part in this research project because you work at a hospital participating in the '5 Rs to Rescue' project. You are a critically important voice in understanding the current status of post-surgical care at the hospital, what is required for post-surgical service improvement and capacity building, and the potential implications of this for yourself, your colleagues, and patients based on your experiences participating in '5 Rs to Rescue'.

Surgery is an important part of healthcare and worldwide; approximately 40% of illnesses, which can't be spread from person to person, require surgery. Over the past 10 years, there has been an increase in research into how to make surgery safe, affordable, and effective.

Research is a very important part of surgery and the healthcare system, and it includes a varied group of people. These people include patients, policymakers (all people involved in making decisions on how healthcare is provided to patients), allied services (such as laboratories, pharmacy, biotechnology), and healthcare workers and administrators like you.

The ultimate goal of our research is to improve post-surgical services for the communities living in the African region. The '5 Rs to Rescue' study seeks to hear your perspective to inform how to adjust the initiative as we prepare to scale it to additional hospitals across Africa. Through talking about your experiences and exploring aspects of surgical capacity building at your hospital, we hope to understand some of the facilitators and barriers to improving surgical care and make the intervention more successful and easier to adopt.

This research is designed to directly benefit the patients of your hospital and wider community, but also to potentially provide a model for other African hospitals to improve their post-surgical services. In addition, taking part in this study could be important in helping the community to be more involved in healthcare and surgical delivery, for the benefit of the community in the future.

What would taking part involve?

One of the researchers will explain the study process to you and if you agree, to sign a consent form. You will then be asked a set of questions which will be audio-recorded and transcribed (copied word-by-word). The interview will either be done in person at your workplace, or if preferred, by video call (such as ZOOM), or over the telephone. You will be asked a set of questions in a conversation with a member of the research team.

You will first be asked questions about your demographics, role and length of service. Further questions will be focused on your opinion of the current post-surgical service delivered at your hospital, and your perspective and recommendation of what might be required to improve, extend, and sustain these services. You will be asked to consider both positive and negative implications and to give us reasons for your answers. The interview will be conducted in English.

Time commitment

The time commitment will be 30-45 minutes. We will also ask you if you are interested in the research process, and if we can contact you in the future. This is entirely voluntary.

Information to be collected, and stored confidentially

The audio recordings and their transcripts will be stored securely. Any responses will be completely confidential; you will not be able to be identified from any research outputs.

Who is organizing and funding the research?

This research study has been conceived by the University of Cape Town's Department of Anaesthesia and Perioperative Medicine. The research is funded by the National Institute of Health Research (NIHR).

Will I get paid to take part in this study?

There is no reimbursement for this study.

Consent

It is up to you whether you decide to join the study. If you agree to take part, we will ask you to sign a consent form. You are free to leave the study at any time, without giving a reason. Whether or not you take part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study, you should ask to speak to your local lead researchers who will do their best to answer your questions (contact details are at the bottom of this form).

The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant in this research study.

Contact details

For any further information you may require, please contact Prof Bruce Biccard (021 404 5001).

Topic guide – Healthcare staff interviews for "5Rs to Rescue"

Summary of topics

1. Short summaries of site experience
2. Specifics about the "5Rs to Rescue" components
3. Specifics about the quality improvement (QI) programme
4. Specifics about key actors
5. Reflections on what you might do differently (and anything you would definitely do the same)

Topics guide

1. Obtain a short overall summary
   "How did the "5Rs to Rescue" initiative unfold from your perspective?"

   (aiming for a bit of a narrative description of the story of the initiative at this site) - 5 mins (if short of time, can ask each person for 1 or 2 words to describe the overall experience with a brief description of why they chose those words)

2. The components of 5Rs – 15 mins

   "For each R component, we are going to discuss what worked and what didn't"

   - ASOS Surgical Risk Score – what worked / what was difficult?
   - Early warning score (EWS) – what worked / what was difficult?
   - Response protocols - what worked / what was difficult?
   - Reassess - what worked / what was difficult?
   - Reflect - what worked / what was difficult?

3. Discuss about the quality improvement (QI) support (including learning sessions, calls, visits)
   "Can you tell us about the quality improvement support of the project"
   - What worked well?
   - What was difficult?

4. Discuss the improvement process
   "Can you describe or tell us"
   - Who or what in your sites was / were the biggest facilitators of change?
   - What would you do differently if you could do this again?

5. Reflections on what you might do differently (and anything you would definitely do the same)
   "Can you tell us what you might do differently, or is there anything you would definitely do the same?"