Family supplemented patient monitoring: An intervention to prevent failure to rescue after surgery in Ugandan hospitals

A thesis submitted in partial fulfilment of the requirements of the degree of Doctor of Philosophy

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Declaration

I, Adam Hewitt Smith, confirm that the research included within this thesis is my own work or that where it has been carried out in collaboration with, or supported by, others that this is duly acknowledged below, and my contribution indicated. Previously published material is also acknowledged below.

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Details of collaborations and publications

Hewitt Smith A, Bulamba F, Nanimambi J, Adong LR, Emacu B, Kabaleta M, Khanyalano J, Maiga AH, Mugume C, Nakibuule J, Nandyose L, Sejja M, Weere W, Stephens T, Pearse RM, Family supplemented patient monitoring after surgery (SMARTER): process evaluation of a complex intervention in Uganda. Submitted for publication. MedRxiv preprint. 2024 May 25; doi:2024.05.24.24307741

Written by Hewitt-Smith, with editorial advice from Stephens and Pearse; manuscript approved by all authors. Process evaluation run by Hewitt-Smith. Qualitative analysis guidance from Stephens.

Hewitt Smith A, Bulamba F, Patel A, Nanimambi J, Adong LR, Emacu B, Kabaleta M, Khanyalano J, Maiga AH, Mugume C, Nakibuule J, Nandyose L, Sejja M, Weere W, Stephens T, Pearse RM, Family supplemented patient monitoring after surgery (SMARTER): a pilot stepped-wedge cluster-randomised trial. British Journal of Anaesthesia 2024; 133(4), 846-852

Written by Hewitt-Smith, with editorial advice from Pearse; manuscript approved by all authors. Pilot trial run by Hewitt-Smith. Statistical advice from Patel and Pearse.

Hewitt-Smith A, Bulamba F, Olupot C, Musana F, Ochieng JP, Lipnick MS, Pearse RM. Surgical outcomes in eastern Uganda: a one-year cohort study. South Afr J Anaesth Analg. 2018; *24*(5), 122–127.

Written by Hewitt-Smith, with editorial advice from Pearse; manuscript approved by all authors. Data collected by data entrant under guidance of Hewitt-Smith. Analysis by Hewitt-Smith and Brennen Kahan with guidance from Pearse.

Publications not included in this thesis

Torborg A, et al. Outcomes after Surgery for Children in Africa a Fourteen-Day Prospective Observational Cohort Study (ASOS-Paeds). The Lancet. 2024 Apr 13;403(10435):1482-1492

National lead for Uganda

Bulamba F, Connelly S, Richards S, Lipnick MS, Gelb AW, Igaga EN, Nabukenya MT, Wabule A, **Hewitt-Smith A**. A Cross-Sectional Survey of Anesthetic Airway Equipment and Airway Management Practices in Uganda. Anesth Analg. 2023 Jul 1;137(1):191-199.

Kluyts HL, Bedwell GJ, Bedada AG, Fadalla T, **Hewitt-Smith A…..**Pearse R, Biccard BM. Determining the Minimum Dataset for Surgical Patients in Africa: A Delphi Study. *World J Surg* **47**, 581–592 (2023).

Bedwell GJ, Dias P, Hahnle L, Anaeli A, Baker T, Beane A, Biccard BM, Bulamba F, Delgado-Ramirez MB, Dullewe NP, Echeverri-Mallarino V, Haniffa R, **Hewitt-Smith A……**Stephens TJ. Barriers to Quality Perioperative Care Delivery in Low- and Middle-Income Countries: A Qualitative Rapid Appraisal Study. Anesth Analg. 2022 Dec 1;135(6):1217-1232.

ASOS-2 Investigators. Enhanced postoperative surveillance versus standard of care to reduce mortality among adult surgical patients in Africa (ASOS-2): a cluster-randomised controlled trial. Lancet Glob Health. 2021 Oct;9(10):e1391-e1401. **National lead for Uganda**

Law TJ, Subhedar S, Bulamba F, O'Hara NN, Nabukenya MT, Sendagire C, **Hewitt-Smith A**, Lipnick MS, Tumukunde J. Factors affecting job choice among physician anesthesia providers in Uganda: a survey of income composition, discrete choice experiment, and implications for the decision to work rurally. Hum Resour Health. 2021 Jul 28;19(1):93.

B.M. Biccard, **The African Peri-operative Research Group (APORG) working group.** Priorities for peri-operative research in Africa. Anaesthesia. 2020;75 (S1):e28-e33

Law T, Bulamba F, Ochieng JP, Edgcombe H, Thwaites V, **Hewitt-Smith A,…** Lipnick MS, Global Anesthesia Workforce Study Group. Anesthesia Provider Training and Practice Models: A Survey of Africa. *Anesth Analg*. 2019;129(3):839-846

Bishop D, Dyer RA, Maswime S…..**ASOS investigators.** Maternal and neonatal outcomes after caesarean delivery in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. *Lancet Glob Health.* 2019 Apr;7(4):e513-e522. **Hospital lead for original ASOS study.**

Bulamba F, Sendagire C, Kintu A, **Hewitt-Smith A**, Musana F, Lilaonitkul M, Ayebale E, Dubowitz G, Kituuka O, Lipnick MS. Feasibility of Simulation-Based Medical Education in a Low-Income Country: Challenges and Solutions from a 3-Year Pilot Program in Uganda. *Simul Healthc.* 2019 Apr;14(2):113-120.

Short abstract

Background: Patients who have surgery in Uganda are twice as likely to die compared the global average, despite being younger and fitter. Most deaths happen on the hospital wards after surgery following post-operative complications. There is limited evidence of ways to reduce this ‘failure to rescue’ in these settings. Interventions that utilise existing resources such as family members need to be developed and explored further.

Methods: This thesis includes a systematic review, one-year observational cohort study, stepped-wedge cluster randomised controlled trial, and concurrent mixed methods process evaluation which together describe the development and testing of a complex intervention to deliver family supplemented patient monitoring after surgery at the Mbale Regional Referral Hospital in Uganda. I compared the total number of sets of vital signs using an incident rate ratio and used logistic regression to analyse mortality after surgery. Qualitative data were analysed with a deductive approach using the consolidated framework for intervention research.

Results: 93/4773 (2.0%) patients having surgery died before hospital discharge. This rises to 68/304 (22.4%) for patients undergoing elective or emergency laparotomy. 73/83 (88.0%) of these deaths occur on the postoperative wards. During the SMARTER pilot trial of 1395 patients in four hospital wards, the median (IQR) number of sets of vital signs monitoring per three-day study period in the usual care group was 0 [0-1] compared with 3 [1-8] in the intervention group, where family members supplemented vital signs monitoring of patients after surgery (Incident rate ratio: 12.4 [8.8 to 17.5], p=<0.001). My process evaluation identified both positive factors influencing the intervention such as the ‘relative advantage’, and negative factors such as the ‘available resources’, ‘culture’ and ‘compatibility’.

Conclusions: Family supplemented patient monitoring results in significantly higher rates of vital signs monitoring for patients after surgery. This intervention was successfully implemented in a low-resource regional hospital in Uganda

Scientific summary

Background

Patients who have surgery in low-resource countries such as Uganda are twice as likely to die compared to those in high-resource settings, despite being younger and fitter, and despite similar rates of complications. In the majority of cases, ‘failure to rescue’ (death following a complication) happens on the postoperative wards. In this thesis, I describe available evidence for interventions to address failure to rescue in low- and middle-income countries (LMICs), outcomes after surgery at a regional hospital in eastern Uganda, the development of an intervention using family members to improve patient monitoring after surgery and its testing in a stepped wedge cluster randomised pilot trial with a concurrent process evaluation.

Interventions to reduce failure to rescue after surgery in LMICs: a systematic review

I conducted a systematic review of the literature following PRISMA guidelines to identify existing evidence using the search constructs [surgery] AND [LMIC] AND [failure to rescue]. A total of 99 articles were identified which after title, full text and abstract screening left four articles to be included in my qualitative synthesis. Articles were appraised for quality using the mixed methods appraisal tool (MMAT). A narrative synthesis was conducted to assimilate the identified evidence. Three of the four articles described the same trial to improve postoperative surveillance after surgery in Africa. This trial did not ultimately lead to improved outcomes. The fourth described the impact of enhanced critical care services on failure to rescue in Kenya.

Outcomes after surgery at Mbale Regional Referral Hospital

I conducted a one-year cohort study of all patients undergoing surgery between October 2016 and September 2017 at Mbale Regional Referral Hospital in eastern Uganda. Demographic data, details of surgical procedures and in-hospital outcomes censored at 30 days were captured using an electronic database. Additional details were captured for a subset of patients undergoing caesarean section and laparotomy over a three-month period. Data were summarised descriptively using mean (SD) or number (%) as appropriate. The association between four covariates (gender,

ASA score, surgical specialty, and urgency of surgery) and 30-day, in-hospital mortality using a multivariable logistic regression model was also assessed. 4773 patients underwent 4878 procedures. Patients missing hospital outcomes (8/4773, 0.2%) and re-operations were excluded from the final analysis. The commonest surgical procedure was caesarean section (2634, 55.3%) followed by laparotomy (304, 6.4%). A total of 93 (2.0%) patients died before hospital discharge, Children less than five years, patients with a higher ASA score and those undergoing emergency surgery were more likely to die. 73/83 (88%) of deaths happened after surgery on the postoperative wards.

Family supplemented patient monitoring after surgery (SMARTER): a stepped wedge cluster randomised pilot trial

I used an iterative approach to develop a complex intervention training family members to supplement patient monitoring after surgery. I then ran a stepped-wedge cluster randomised trial of an intervention training family members to support nursing staff to take and record patients' vital signs every four hours after surgery. Adult inpatients across four surgical wards (clusters) at Mbale Regional Referral Hospital were included. Clusters crossed from routine care to the SMARTER intervention at monthly intervals. Primary outcome was frequency of vital signs from arrival on the postoperative ward to the end of the third postoperative day. We enrolled 1395 patients between April and October 2021. Mean age was 28.2 (SD 12.8) years and 85.7% were female. The commonest surgical procedure was caesarean section (74.8%). Median (IQR) frequency of vital signs over the three-day period increased from 0 (0-1) in control wards to 3 (1-8) in intervention wards (incident rate ratio, 12.4; 95% confidence interval (CI), 8.8-17.5; p=<0.001). 6/718 (0.84%) patients died in the usual care group versus 12/677 (1.77%) in the intervention group (Odds ratio, 1.32; 95% CI, 0.1 – 14.7; p=0.821). There was no difference in length of hospital stay between the groups (usual care: 2 (2-3) days vs intervention: 2 (2-4) days (hazard ratio, 1.11; 95% CI, 0.84 - 1.47, p=0.44)).

A mixed methods process evaluation of the SMARTER pilot trial

I conducted a mixed methods process evaluation concurrent to the SMARTER pilot trial to provide contextual understanding of my intervention delivery. Data sources included field notes from a research team diary and focus group discussions. Deductive analysis used the consolidated framework for implementation research. Quantitative data evaluating the efficacy of family members recognising abnormal vital signs and reporting them to nursing staff were collected following a prespecified intervention review held after two months. Focus group discussions were conducted with 16 nurses and research assistants. Field notes included 88 episodes documented throughout the trial in a research team diary. Quantitative data were collected in the final 397 patients following ethics amendments. Intervention facilitators included: relative advantage, inner context factors including tension for change and relative priority, and individual characteristics centred around knowledge and beliefs. Available resources, culture, and compatibility were identified as important barriers, with a smaller negative influence from self-efficacy and intervention complexity. Family members recognised 91.3% (42/46) of abnormal sets of vital signs and communicated 100% (42/42) of these to a member of the nursing or medical team. The team responded 90.5% (38/42) of the time.

Summary

Outcomes in eastern Uganda suggest there are gaps in warded-based postoperative care leading to the higher mortality rates seen following surgical complications in this setting. Published evidence describing effective interventions to reduce failure to rescue in low-resource settings is currently very limited. Complex interventions implemented in healthcare environments need to take into context the positive and negative influences that may affect effectiveness. I have shown that family member supplemented vital signs monitoring substantially increased the frequency of vital signs after surgery and that novel interventions such as this involving family members, have the potential to positively impact patient care.

Plain English summary

Introduction

Research has shown us that patients who have surgery in hospitals in Africa are younger and fitter than equivalent patients in countries with more resources, but despite this, they are twice as likely to die. Almost all of the patients who die after surgery, do so on the wards following development of a complication after their operation. In my thesis, I describe the patients undergoing surgery at a regional hospital in eastern Uganda and how my idea to involve family members in the care of their patients after surgery developed. I then share the results from my study testing whether this idea works and factors affecting its success.

Do we already know how to reduce numbers of deaths after surgery in countries such as Uganda?

I ran a detailed search of articles that have previously been published in scientific journals to identify any known ways to reduce the number of deaths after surgery. Out of the 99 articles I first identified, only four included information that I was looking for and of these, three described the same research project in Africa. This told me that there is currently very little evidence to guide us how to reduce deaths after surgery in countries such as Uganda.

Outcomes after surgery at Mbale Regional Referral Hospital

Between October 2016 and September 2017, I conducted a study of all patients undergoing surgery at Mbale Regional Referral Hospital in eastern Uganda. I collected data that allowed me to describe who the patients undergoing surgery in this hospital are, and what happens to them afterwards. Out of the 4773 patients who had surgery, the commonest operation was caesarean section for pregnant mothers (2634, 55.3%), followed by surgery on the abdomen (304, 6.4%). A total of 93 (2.0%) patients died before they were sent home from hospital. When I looked at characteristics that were more common in patients who died after surgery, I found that children less than five years and those undergoing emergency surgery were more likely to die. Most 73/83 (88%) of the deaths happened on the wards after surgery.

Family supplemented patient monitoring after surgery (SMARTER): a stepped wedge cluster randomised pilot trial

I developed a project to train family members to supplement the patient monitoring after surgery that is usually done by nurses. I then tested this with adult patients across four surgical wards at Mbale Regional Referral Hospital. The study design meant I introduced family supplemented monitoring to one new ward each month. I was testing to see how many times vital signs were taken in the three days after surgery and whether this changed when family members supplemented the nurses' monitoring. We included 1395 patients between April and October 2021. The average age was 28.2 years and 85.7% were female. The commonest surgical procedure was caesarean section (74.8%). The number of vital signs over the three-day period increased from 0 in wards before family supplemented monitoring, to 3 when family members supplemented the nurses monitoring. This was 12 times higher following the introduction of my intervention. There was no significant difference in the number or deaths, or length of hospital stay between the two groups.

A mixed methods process evaluation of the SMARTER pilot trial

Hospitals are complicated places, and patient care can be influenced by very many different things. Things that affect patient care can also affect studies and so when an idea is tested, like we did with the SMARTER pilot trial, it is usual practice to run another study at the same time. This study is called a process evaluation, and it looks at all of the factors that have had an influence on the success or failure of the main idea to improve quality of care. My process evaluation used interviews with staff and observations of things that happened to understand these influences. When we looked at this information, we saw that there were things that had both positive and negative effects on family supplemented patient monitoring. Factors that had a negative influence included the available resources, including staff, cultural beliefs and how complicated the intervention was. Positive factors included the desire of healthcare staff to change for the better, the benefits of the intervention for both staff and the patients, and the knowledge and beliefs of people regarding how family supplemented monitoring could help them. The second part of my process evaluation checked to see whether family members and staff were doing what we

expected of them regarding checking their patients, identifying when they were deteriorating and notifying the nursing or medical teams. In the smaller group of patients that we check this, we found that family members were behaving as we needed them to.

Summary

I have identified and developed a way for family members to help the regular nursing staff to monitor their patients after surgery. I have done this using a robust process that is recommended for the development and testing of ideas such as this. After checking for existing evidence and understanding more about outcomes after surgery at Mbale Regional Referral Hospital, I developed a method with family members and healthcare workers that could be used on the wards. I tested this in a formal pilot study and found significantly higher rates of monitoring patients after surgery when family members were involved. I learnt a lot about factors that influenced my intervention both positively and negatively. These results and everything that I have learnt during this process can now be used to further develop my idea to improve the recognition of patients who develop complications after surgery. If we can recognise the patients who are deteriorating earlier, we should be able to treat them and reduce the number who die from preventable causes.

Statement of contribution

This thesis utilises several research methodologies to develop and test a complex intervention where family members supplement nursing staff vital signs monitoring of their patients after surgery. The thesis follows my research journey through this process, starting with an observational study looking at outcomes after surgery at Mbale Regional Referral hospital, through a literature review, development of the intervention and ending with the testing of that intervention in a single-centre stepped-wedge cluster randomised pilot trial and concurrent process evaluation.

I led each of these components of my PhD in Uganda with support from my supervisors and my team. My systematic review looking at existing evidence to support interventions to reduce failure to rescue after surgery followed. I developed the review methodology including the search strategy, conducted the literature review, screened and appraised the results. Ryan Ellis performed the role of second reviewer, screening identified articles and performing critical appraisal of the evidence in order to validate my work. I wrote the chapter for my PhD including analysis and discussion of the results. For my one-year cohort study looking at surgical volumes and outcomes at Mbale Regional Referral Hospital, I designed the study and data collection tools. I supervised a research assistant who was responsible for collecting data on a daily basis and I validated his data entry. Statistical analysis was performed by Brennan Kahan and I, under the supervision of Rupert Pearse. I wrote the manuscript which was reviewed and edited by all authors before being published.

I led all aspects of the development of my family supplemented patient monitoring after surgery intervention including audits to understand current vital signs monitoring on the wards and the iterative testing and revision of the intervention. I interacted directly with stakeholders, including family members and healthcare staff to further revise the process. Under the guidance of Rupert Pearse, I developed the trial protocol for the SMARTER pilot trial and applied for local and national ethics approvals in Uganda. I then ran the study as the local lead investigator with a team of research assistants. That team were responsible for the training intervention, data collection and data entry under my supervision. I validated the data entry. The statistical analysis plan was developed with guidance from Akshaykumar Patel and Rupert Pearse. I performed the statistical analysis which was checked by Akshay. I wrote the manuscript under Rupert's guidance which was reviewed and edited by all authors before publication.

The SMARTER pilot trial process evaluation methods were developed by myself with Tim Stephens, who kindly taught me how to perform qualitative research including analysis. To ensure the analysis of my qualitative data was performed in accordance with standard practice, both Tim and I coded the data independently and then came together to discuss and amalgamate our findings. I wrote up the results and drafted the manuscript under Tim's guidance which was reviewed by all authors before publishing as a pre-print. This has been submitted for publication.

Acknowledgements

My PhD has been a long journey that would have not been possible without the support of many people, my heartfelt thanks to all of you. It would not have been possible without my supervisors who have guided me over the years. To Rupert and Gareth, thank you for seeing my potential and taking me onto your team, supporting me to grow and develop over the years. Thank you for your time and for your continued advice and patience. You are both inspirational researchers and supervisors - it has been a real privilege to work with you. Rupert, I will be forever grateful for the time you have committed to supporting our work in Uganda and across low-resource settings around the world. Without your commitment to supporting me with multiple opportunities I would not have achieved everything that I have been able to achieve. Thank you for teaching me how to write and for the invaluable leadership and management guidance.

It has been a real pleasure working with teams of motivated and supportive friends and colleagues, both in the UK and in Uganda. In the UK, special thanks go to Tim who not only taught me how to conduct qualitative research but also provided sound guidance whenever I asked. Thank you Ryan, who contributed to my systematic review as the second reviewer, ensuring robust methodology validating my interpretations. Thank you to all the other members of the Critical Care and Perioperative Medicine Research Group at QMUL who have supported me during my PhD journey. Alex, Tom, Yize, John, PJ, Zudin and Priya, you all provided invaluable help and guidance when needed, thank you.

In Uganda, to our growing team in the Departments of Anaesthesia and Critical Care at Busitema University Faculty of Health Sciences and Mbale Regional Referral Hospital and the Elgon centre for Health Research and Innovation, thank you for your flexibility when I needed time to concentrate on my PhD. To Fred, my colleague and fellow PhD student, we shared a lot of learning experiences together and I am grateful for your support. Thank you to Herbert, John Paul, Justine and Joanne for the all the times when you have been there for me, no matter the reason.

Lastly, I would not have been able to complete this thesis without the love, support and patience of my wife, Kathy, my children, Eseld, Lowenna, Bryluen and Pip and my family and friends. Kathy, I appreciate the sacrifices you have made so I could undertake and complete this research. Thank you for your enduring patience, your encouragement and your belief in me.

The research described in this thesis was supported by grants from the Centre for Health Equity in Surgery and Anaesthesia at the University of California, San Francisco, the UK National Institute for Academic Anaesthesia (RCoA/BJA Project Grant) and the National Institute for Health Research (NIHR Global Health Group on Perioperative and Critical Care - NIHR133850).

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List of abbreviations

HIC	High-income country
HCIV	Health Centre IV
LIC	Low-income country
LMIC	Low and middle-income countries
PNFP	Private not for profit
RRH	Regional Referral Hospital

CHAPTER 1 INTRODUCTION

1.1 Global perioperative care

2015 was a pivotal year for global surgery and anaesthesia. The World Health Assembly resolution 68.15 recognised surgery and anaesthesia as essential components of universal health coverage,[1] one of the United Nation's Sustainable Development Goals. In the same year, the Lancet Commission on Global Surgery highlighted glaring disparities across the world with an estimated 5 billion people lacking access to safe surgery and anaesthesia care.[2] This focus has seen increasing efforts to document and understand the global burden of surgically treatable disease, but as access to accurate data is limited, this task should not be underestimated.

1.1.1 The global burden of surgical disease

Whilst efforts have been made to directly measure the surgical disease burden at a local level, with the prevalence of untreated surgical pathology as high as 25% in some countries,[3] the scale of the global challenge facing us has only recently become apparent. The Global Burden of Disease Study is commonly used to quantify disease burden and influence policy and research agendas. It began in 1990 and has seen multiple revisions over the years with an increasing breadth of coverage. Despite this, surgical conditions or diseases that are amenable to surgical treatment have not been grouped together, nor listed independently because focus is placed on disease causes and not management needs. This has led to them being hidden within other disease categories such as infectious diseases and chronic health conditions. In 2006, an expert opinion was published describing 11% of the overall global burden of disease to be treatable by surgery but this is likely to be a significant underrepresentation.[4] As part of the work by the Lancet Commission on Global

Surgery, surgeons, nurses, internists, anaesthesiologists and public health specialists were surveyed. 112/173 (64.8%) of the respondents worked full time or spent time working in low-income countries. Surgical conditions were estimated to account for 28-32% of the global burden of disease.[2,5]

1.1.2 Access to surgery and anaesthesia in LMICs

A significant proportion of this burden of surgical disease is not currently being managed. Five billion people around the world do not have access to safe, affordable, surgery and anaesthesia care and an additional 143 million procedures are required to address unmet need each year.[2] Access to surgery and anaesthesia care, when needed and with financial protection, is disproportionately limited in sub-Saharan Africa, (93% of the population do not have access) when compared to higher income regions (3.6%). The greatest unmet need exists in western (5625/100,000 population) and eastern (4935/100,000) sub-Saharan Africa. It is estimated an additional 17.5 million additional cases are needed per year in eastern sub-Saharan Africa to resolve the unmet need for surgical care, save lives and prevent disability.[2] Despite the large number, this may still be an underestimate. Global and regional estimations were calculated using surgical rates from New Zealand as a baseline. As New Zealand's healthcare population coverage is good, diseases are less likely to progress to the stage where they require surgical care. This is in comparison to countries with weaker healthcare systems where patients commonly present with advanced disease.

There is clear evidence that investing in systems to improve access to surgical care is cost effective.[6] This argument has been further strengthened by the COVID pandemic that started in late 2019, with correlation between strong surgical services and better pandemic response preparedness.[7] Disability adjusted life years (DALY) are commonly used to compare the economic benefit of interventions, including surgical procedures. One DALY is defined as the loss of the equivalent of 1 year of life at full health.[8] In low- and middle-income countries (LMICs), including in Africa, median cost effectiveness ratios of caesarean sections ($315.12 per DALY) and orthopaedic surgery ($381.15 per DALY) are more favourable than those of medical treatment for ischaemic heart disease ($500.41 - $706.54 per DALY) and HIV treatment with multidrug antiretroviral therapy ($453.74 – $648.20 per DALY).[6] Of course, cost effectiveness is not the only argument that supports the case for investment in surgical services. As we move towards 2030, the global target of Universal Health Coverage includes the provision of emergency and essential surgical interventions. Without these, equitable healthcare coverage is not possible. In settings where patients are forced to make catastrophic out of pocket expenditure, equitable access to affordable surgical and anaesthesia care cannot be achieved.[9]

Many countries have recognised the need to improve access to surgical and anaesthesia care. They have developed national surgical, obstetric and anaesthesia plans (NSOAP) with increased allocation of resources to implement improvements.[10] The first plans from countries such as Ethiopia and Tanzania have now been reviewed and important lessons integrated into revised plans.[11] Developing an NSOAP that is achievable and realistic requires a series of steps including a data driven situational analysis and baseline assessment.[12] Better epidemiological data describing current surgical activity and patient outcomes is urgently needed to support these processes. In particular, it is increasingly recognised that improving access to surgical care alone is not enough. Surgery is invasive and despite what may be good intentions, the potential absence of tools and resources for safe surgery in low- and middle-income countries can lead to preventable deaths.[13]

1.1.3 Surgical care in Uganda

Figure 1: Map of Uganda

Mbale located within red circle. GISGeography, 2024. https://gisgeography.com/uganda-map/#Physical-Map (Accessed 4 December 2024).

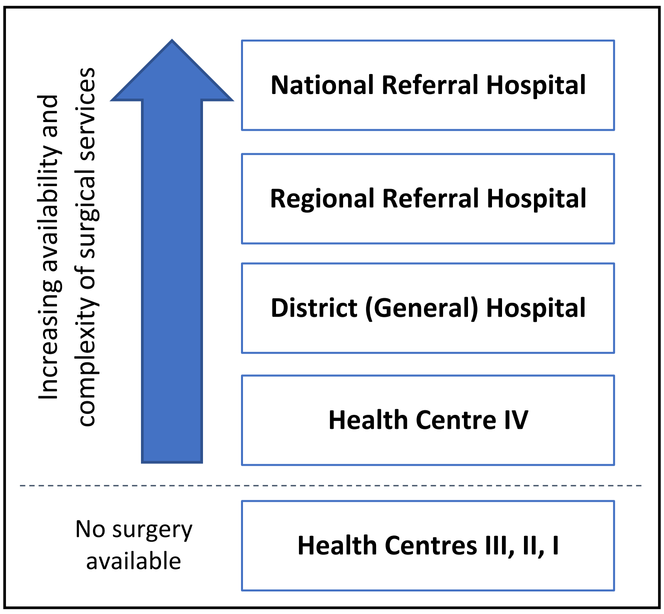
Uganda is located in eastern sub-Saharan Africa. It is a landlocked country bordered by Kenya to the east, South Sudan to the north, Tanzania, Rwanda and Lake Victoria to the south and the Democratic Republic of Congo to the west. Globally, countries are categorised into income levels by the World Bank[14] and a country's income level usually influences the availability of resources to spend on that country's healthcare system. Uganda is classified as a low-income country and spends $44 per capita per year on healthcare. This compares to $5035 per capita per year in the United Kingdom. Table 1 illustrates other

Table 1. Comparison between health metrics from the United Kingdom (high-income), Uganda (low-income), and other countries in east Africa including Rwanda (low-income) and Kenya (lower middle-income).

	United Kingdom	Uganda	Rwanda	Kenya
Current GDP per capita (2022, US$)	45,935.9	963.1	975,5	2,109.6
Current health expenditure per capita (2022, US$)	5,035.2	44.2	76.9	90.4
Current health expenditure (2022, % of GDP)	11.1	4.4	7.9	4.3
Maternal mortality ratio (per 100,000 live births)	13	189	234	155
Under-5 mortality rate (per 1000 live births)	5	41	41	41

healthcare system level differences between the UK, a high-income country, Uganda and two other countries in east Africa, using commonly measured and reported health metrics. Specific metrics of surgical care are not routinely available to allow comparison at a country level due to a paucity of reported data. However, comparisons have been described in the scientific literature in association with specific surgical procedures, for example oesphagectomy,[15] and entire surgical systems.[16] In Uganda, healthcare is provided by a combination of government, private-not-for-profit (PNFP) and private facilities of differing

Figure 2. Health facility levels in Uganda



levels (Figure 2). Surgical care is provided at Health Centre IVs (HCIV), District hospitals (DH) and Regional and National Referral Hospitals. Previous published data captured data for public hospitals serving 64% of Uganda's population and described an annual surgical volume of 144.5 cases per 100,000 people per year.[17] The global target for the sustainable development goals, to be achieved by 2030, is 5000 procedures per 100,000 people.[2] The volume of surgical procedures in the UK for comparison is >12,000 per 100,000 people per year.[18]

1.1.4 Mbale Regional Referral Hospital

Mbale is a city in eastern Uganda, approximately five hours drive away from the capital city Kampala (see Figure 1). The main government hospital in the city, Mbale Regional Referral Hospital, provides specialist care for a population of over 4.5 million people spread over three sub-regions - 16 districts and a city. The referral system sees the Regional Referral Hospital receiving patients from six district hospitals, 20 Health Centre IVs and many smaller health centres and private clinics.

Figure 3. Mbale Regional Referral Hospital

The Regional Referral Hospital has 470 inpatient beds with surgical, maternity, psychiatry, paediatric, neonatal and internal medicine inpatient units. It has 16 specialists (11% of the official staffing norms) and 164 nurses. The surgical specialists include four general surgeons, two orthopaedic surgeons, one ophthalmologist and five obstetrician/gynaecologists. Surgical wards consist of open 'nightingale style' wards separated for males and females (Figure 4).

Figure 4. General surgical ward at Mbale Regional Referral Hospital

Image redacted for confidentiality reasons

The limited human resources mean that it is not possible to access a surgical specialist for emergency surgical care 24/7. Anaesthesia care is provided largely by 5 employed non-physician anaesthesia providers, supplemented by recently graduated anaesthesia students who cover six operating rooms across four separate locations. The obstetric theatre (1 room,

Figure 5) is staffed 24/7 but the main operating theatres (3 rooms) have no anaesthesia cover overnight. Anaesthesia cover for the private wing and ophthalmology units are provided when needed and available. Intensive care services are now provided as part of a surgical high dependency unit by a volunteer anaesthesiologist and two anaesthesiologist lecturers from the twinned teaching university, Busitema University.

Figure 5. Obstetric operating theatre at Mbale Regional Referral Hospital

Institutional barriers to the provision of surgical care are often complex. At Mbale Regional Referral Hospital, the supply of oxygen is very variable. A mix of oxygen concentrators and oxygen cylinders meet some of the hospital’s needs, but the oxygen plant used to fill cylinders commonly breaks down requiring the hospital to find scarce resources to pay for transport to take 200 cylinders to the capital city six hours away for filling. Essential equipment required for safe surgical and anaesthesia care is either absent or commonly develops faults that require biomedical engineering support to repair. The single biomedical engineering workshop in the region does not have the budget for the spare parts that are required, resulting in equipment such as diathermy or patient monitors sitting unused in the corner of the operating rooms.

These limited resources exist throughout the hospital. In Mbale Regional Referral Hospital, perioperative care is provided on four main surgical wards. Two are dedicated to general and orthopaedic surgery and two are mixed obstetric and gynaecology wards. As we have seen, Figure 4 illustrates a typical inpatient ward in the hospital. Nursing staff number a maximum of two nurses on duty during the day and one at night resulting in a patient to nurse ratio as high as 40:1 on the surgical wards. In other wards for example the neonatal unit the patient to nurse ratio can be double this at 80:1. Care in the hospital is free but there are frequent stock outs of almost all consumables and medicines. Patients and their family members have to buy supplies that are out of stock from private pharmacies in the town. This can include everything from surgical gloves and sutures to antibiotics and iv fluids.

Figure 6. Main operating theatre, Mbale Regional Referral Hospital

1.2 Perioperative morbidity and mortality in Africa

Despite the Lancet Commission on Global Surgery recommendation to use perioperative mortality rates as an indicator to describe the state of a country's surgical system, routine reports detailing patient outcomes after surgery in low-income countries are limited in number. Globally, very few countries routinely report surgical volume and even less report mortality and complication rates.[19] This is compounded by a lack of a standardised approach for reporting outcomes after surgery. In most reports from LMICs, the commonest definition uses in-hospital deaths following surgery as the numerator and the number of operative patients as the denominator but there is huge heterogeneity.[20]

1.2.1 Complications after surgery in Africa

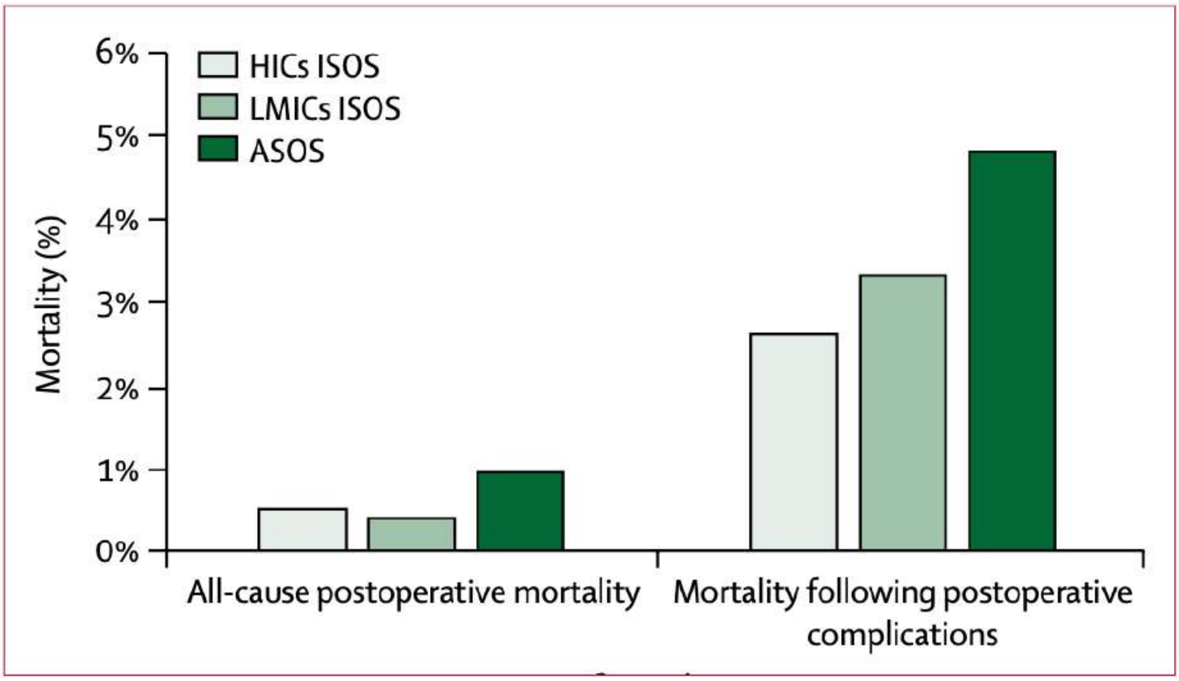
Complications after surgery can have catastrophic consequences leading to long-term morbidity and impacting on recovery times and length and cost of stay in hospital. Each year, 33 million individuals globally face catastrophic health expenditure due to payment for surgery and anaesthesia and the majority of these are from LMICs.[2] The role that complications play in defining outcomes after surgery in Africa is less clear. Their frequency varies, with differing rates described across the surgical disciplines and across country income groups. In the ASOS study, overall complication rates of 13.4% in African patients undergoing elective surgery were similar to those after surgery in a global cohort (International Surgical Outcomes Study in 27 low- middle- and high-income countries).[21] Other multi-centre, international cohort studies also report similar complication rates between HICs and LMICs.[22]

This may be explained in part by the distribution of complications. Surgical site infections after gastrointestinal surgery occurred at significantly higher rates in countries with low human development index in a Global Surg multicentre cohort study including 12,539 patients published in 2018.[23] This finding is replicated across multiple studies and literature reviews following neurosurgery, caesarean section and other surgical procedures.[24-27] Published literature on cardiovascular complications after surgery in Africa is very limited. In the ASOS cohort, they occurred in 1% of patients compared to 4% of patients in the global ISOS cohort.[21,28] As patients in Africa who undergo surgery are younger and fitter, it is not surprising that cardiovascular complication rates are lower.

1.2.2 Mortality after surgery in Africa

The African Surgical Outcomes Study (ASOS) describes mortality rates following all surgical procedures in centres across 25 African countries. In 11,193 patients undergoing surgery in this prospective observational study, the first of its size and kind in Africa, the mortality rate after surgery was 2.1% (Figure 7).[28]

Figure 7. Surgical mortality following elective surgery in HICs, LMICs and African countries



A pragmatic study design allowed participation from 247 hospitals with a practical numerator of in-hospital mortality, censored at 30 days. The ASOS study combines all surgery types to generate an overall mortality rate after surgery but in most literature reports, mortality rates after surgery in Africa are procedure specific and display significant disparities between countries. A systematic review of perioperative mortality rates in LMICs in 2018 found pooled, procedure specific mortality rates after surgery ranging from as low as 0.1% for appendicectomy and caesarean section to 20-27% for typhoid intestinal perforation.[29] In countries with a low human development index, including from Africa, overall 30-day mortality after intraperitoneal surgery was 8.6%. This increased to 17.3% for midline laparotomies.[30] The same group led a large prospective cohort study of patients undergoing surgery for primary breast, colon or gastric cancer in 2018 and 2019. In LMICs, their reported 30-day mortality rates were 0.4% for breast cancer, 7.0% for colorectal cancer and 10.1% for gastric cancer.[22] In a 14-day prospective observational cohort of paediatric surgical patients in South Africa, the in-hospital mortality rate was 1.1%.[31] In comparison, a multicentre, international prospective cohort study of patients younger than 16 years presenting with congenital gastrointestinal abnormalities in low-income countries (LICs) shows that mortality rates can be as high as 40%.[32]

The huge variability in mortality rates across different surgical disciplines makes direct comparison between countries and regions in the world difficult. Few published papers reporting surgical outcomes incorporate risk stratification into their analysis. Surgery in a neonate with gastroschisis, where mortality in LICs reaches 90%,[32] is a very different statistic to report compared with elective hernia repairs in older children. Mortality rates after surgery are reported to be significantly worse in sub-Saharan Africa compared to high-income settings, but until recently, there has been little published evidence to support these assumptions. We now know that patients in Africa who are undergoing surgery are younger and fitter than the global average, but despite this, they are twice as likely to die.[28] These disparities in mortality rates between LMICs and high income countries (HICs) have now become clear across all specialties. Mortality after colorectal cancer surgery is three times higher in LMICs compared to HICs.[22] In paediatric surgery, mortality rates can be as much as seven times higher but even this is dwarfed by mortality rates after caesarean section in Africa where mothers are fifty times as likely to die following surgery.[33]

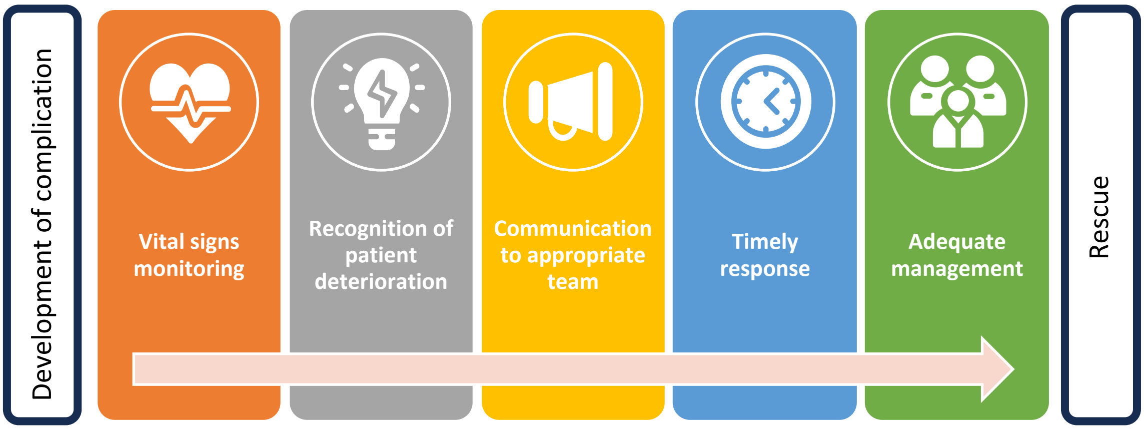
1.3 Failure to rescue

'Failure to Rescue' as a concept was first used by Silber and colleagues in 1992. They described an association between deaths in patients who developed postoperative complications and hospital characteristics, independently from the severity of a patient's illness.[34] This observation was reinforced by work looking at data from the American College of Surgeons National Surgical Quality Improvement Programme (NSQIP). In this cohort, rates of complications were similar in hospitals with both very high and very low mortality rates after general or vascular surgical procedures. In contrast, mortality after major postoperative complications was much higher in hospitals with higher mortality rates suggesting that failure to rescue has an important effect on overall mortality rates.[35] In the United States of America, failure to rescue is routinely used as a quality of care indicator and in the most dramatic examples, for example after pancreatectomy, rates of failure to rescue can vary from as low as 4.0% in the lowest mortality hospitals to 50.8% in the highest mortality hospitals.[36] In Africa, in the ASOS study, 95% of patient deaths following surgery occurred on the wards but it is unclear how failure to rescue contributes towards higher postoperative mortality rates in this setting.[28] With experience from HICs, and knowing that it is not possible to prevent all surgical complications, it may be that shifting focus in Africa away from the prevention of complications, towards how they are managed, may provide an alternative approach to improve surgical outcomes.[37,38]

1.4 What causes failure to rescue after surgery globally?

A recent systematic review has described, in detail, the literature from HICs surrounding the root causes that lead to failure to rescue a deteriorating patient.[39] A total of 52 studies were reported in the final qualitative analysis, with results grouped into three major stages that together, commonly lead to failure to rescue. These three critical steps in the pathway that may eventually lead to a patient's death include: a failure to identify the deteriorating patient (recognise), a failure to communicate information about the patient's deterioration (relay) and a failure to react in a timely way (react).[40-42] Figure 8 illustrates the 'chain of survival' involved in the failure to rescue pathway.

Figure 8. Failure to rescue 'chain of survival'.



The first two steps come under 'recognise' and the last two come under 'react'. Whilst describing failure to rescue in the context of these three stages could be considered a useful approach to identify areas for intervention development, when taken in isolation, these three steps seem to place the blame for failure to rescue on the shoulders of the healthcare providers who are caring for their patients. The reality of course, is much more complex and variation in failure to rescue rates is also linked to better hospital structure and quality processes, allowing prompt recognition and treatment of severe complications.[43]

In the following sections I describe factors that contribute to failure to rescue in more detail. These can be grouped into patient and hospital related factors. Most evidence comes from high-income countries but where possible I have applied this learning to an African context using my experience of working in Uganda.

1.4.1 Patient factors associated with failure to rescue

Age

Mortality, complication and failure to rescue rates are all higher in older patients.[44] It may be that older patients have a lower physiological reserve to deal with the traumatic nature of postoperative complications. Or that older patients also commonly have more co-morbidities than their younger cohort. But age alone cannot explain variations in failure to rescue rates seen across hospitals caring for older patients. Some hospitals seem to be much better at caring for elderly patients who develop complications.[44] In LMICs, patients undergoing surgery are younger than comparative populations in HICs and they generally have less co-morbidities.[21,28] If failure to rescue rates were directly and solely linked to age then we would expect to see less failure to rescue in LMICs.

Advanced nature of disease

Patients in LMICs tend to present to hospital with disease processes in their advanced stages. This is especially true for patients with cancer.[33,45] In the GlobalSurg study looking at outcomes after cancer surgery there was a strong positive correlation between cancer stage and poor outcomes, with higher mortality, complication and failure to rescue rates in this population.[22] Patients in more advanced stages of their disease are also more likely to present in an emergency and failure to rescue rates have been observed to be greater following emergency rather than elective surgery.[46]

Ability of a patient to pay for their medical care

There is correlation between patients in HICs who do not have health insurance and who are therefore unable to afford medical care, and patients in LMICs who are unable to access free or affordable health services. Patients from the USA who are uninsured are more likely to experience failure to rescue when compared with insured ones.[47,48] These socioeconomic disparities are exacerbated in LMICs where as many >31% of the population are likely to suffer catastrophic healthcare expenditure following a surgical admission.[49]

1.4.2 Hospital factors related to failure to rescue (capacity to rescue)

Healthcare worker to patient ratios

We know that failure to recognise a deteriorating patient is one of the contributing stages to failure to rescue. Patients who end up being admitted to ICU rarely deteriorate suddenly. Their decline occurs over hours and in some, over days.[50] The nursing and medical teams play a crucial role in detecting a patient who is developing a complication after surgery. In 2007, a systematic review of the literature was conducted to investigate the association between registered nurse staffing levels and patient outcomes. Looking at data from hospitals in the US, pooled analysis demonstrated consistent evidence that greater nurse to patient ratios reduce mortality rates in hospital.[51] Studies that were included varied in their design making direct association challenging, but the systematic review used statistical tests looking at sensitivity, heterogeneity and meta-regression to demonstrate consistency in the association they reported. In surgical patients in their cohort, the odds of failure to rescue were reduced by 16%. This means one additional registered nurse per patient registered day (this is the equivalent of an additional 8 hours of nursing time per patient day) would result in 26 avoided cases of failure to rescue per 1000 hospitalised patients. There is of course a cost implication with this increased staffing ratio and in the US from the same review, this was estimated at almost $200 extra per patient day.[51]

The correlation between nursing care and failure to rescue rates has led to failure to rescue bring proposed as a metric for the quality of nursing care.[52] The role that staffing levels of doctors play in failure to rescue rates has not been studied in as much detail. Hospital administrative data from the UK looking at the association of failure to rescue with staffing levels including both nurses and doctors.[53] Challenges with the way complications after surgery are coded in the UK make traditional analysis of mortality after complications difficult to do with routine UK hospital administrative data and so surrogates have been used.[54] A complication that is recognised late but that is then managed successfully will lead to extended lengths of stay (LOS) far outside the norm. Failure to rescue rates can therefore be calculated by using patients whose LOS exceeded the norm for their specific type of surgical case. In the UK, a larger healthcare workforce resulted in reduced failure to rescue rates using this surrogate measure.[53] When the role that the ratio of nurses to doctors play on failure to rescue were analysed, a high ratio (less doctors per nursing staff) correlated with higher failure to rescue rates suggesting that a skill mix with a higher number of doctors may play an important role in reducing failure to rescue rates.[53]

Hospital/surgical volume

The relationship with mortality rates and surgical volumes is well established although this relationship is unlikely to be simple and directly causal.[55,56] There is less data describing the relationship between failure to rescue rates and surgical volumes. In America, there is not much difference in complication rates between high- and low-volume hospitals but there are markedly higher failure to rescue rates in low-volume hospitals (30.3% vs 13.1%).[57] For example, patients undergoing pancreatectomy were 3.2 times more likely to die after developing a complication in low-volume hospitals when compared to very high-volume hospitals.[57] Vascular registry data from Australia, New Zealand, Hungary and the USA have shown that failure to rescue rates after intact abdominal aortic aneurysm repair are significantly associated with operative volume. Hospitals in the top operative quartile achieve the lowest failure to rescue rates.[58] This trend is also seen in multiple other surgical specialties including neurosurgery,[59] liver surgery[60] and gastric cancer surgery.[61]

Teaching hospital status

The impact of the long-standing recognition of failure to rescue in the US as a quality metric has led to a significant volume of scientific literature published from data in this region. Analysis of almost 2 million Medicare beneficiaries undergoing one of six high risk vascular or general operations from the US was conducted by Ghaferi and his colleagues with the specific aim of determining the effect of hospital characteristics on failure to rescue. There was a significant variation in failure to rescue rates between very high and very low mortality hospitals. Hospitals with teaching status were noted to result in lower failure to rescue rates.[44] This replicates findings by the same team when looking at failure to rescue rates after complications following pancreatectomy.[62] This factor has also been identified in other countries such as Sweden where university hospitals had lower failure to rescue rates compared with non-university hospitals[63] and the Netherlands.[64]

Intensive care

In the Netherlands, intensive care units are classified into levels depending on their staffing, capacity and resources. This makes it easy to analyse the impact of these different levels of critical care on failure to rescue rates after surgery. In a large study, Henneman et al looked at data derived from the Dutch Surgical Colorectal Audit, which prospectively collects a large number of variables as part of an ongoing national quality improvement project. This study, including more than 25,000 patients from 92 hospitals describes failure to rescue rates that were significantly higher in facilities with the lowest level of ICUs (19% vs 16%).[64] In his analysis of 2 million Medicare patients from the US, Ghaferi and colleagues showed hospitals with ICUs of <20 beds were associated with higher failure to rescue rates.[44] In LMICs, access to critical care facilities is often extremely limited.[65] The GloablSurg collaborative included consistent access to critical care services as a component of the postoperative care infrastructure that they used to compare rates of failure to rescue between income country groups.[22] They showed an association between these hospital level factors, including access to ICU, and failure to rescue.[22] Further evidence to support the role that access to ICU facilities plays in failure to rescue rates comes from a recent paper published from Kenya. Implementation of a critical care service in a rural hospital resulted in a reduction in failure to rescue rates despite an increase in patient complexity and the severity of critical illness.[66]

1.4.3 Workplace dynamics and their impact on recognise, relay and react

Most of the hospital level factors described so far would be considered as macro-level system factors that are often a direct result of the resources available to countries and healthcare systems. It is likely however that these factors do not account for all the differences in failure to rescue rates that are seen between countries and healthcare facilities. Patient factors will certainly play a role but there are also more subtle workplace environment dynamics that are likely to influence outcomes.

Recognise

I have previously described the three stages that contribute to the process of failure to rescue. The first, recognition of the deteriorating patient, is usually triggered in hospital by the identification of abnormal vital signs, and often using early warning scores based on these vital signs.[67] Other triggers have also been suggested such as ‘worried or concerned’ criteria that allow staff to escalate care even if a patient’s vital signs are normal.[68] It is commonly nursing staff who spend most of their time on the wards with patients who initially recognise a complication. There have been multiple qualitative descriptions of the factors that influence nurses’ detection of the deteriorating patient, including several reviews.[69-71] Massey et al describe factors influencing recognition of the deteriorating patient within four themes. These include patient assessment, knowledge of the patient, education and the environment.[69] Vital signs form an integral part of patient assessment and allow nursing staff to have an objective measure of the deteriorating patient.[72] Variability in a nurse’s level of training and patient assessment skills also played a role in influencing detection of deterioration.[70] Patient familiarity can result in staff recognising very subtle changes in patients. This 'sixth sense' or intuition helps nursing staff to recognise deterioration whilst not knowing a patient acts as a barrier.[72,73] Education has been identified as playing an important role in the detection of the deteriorating patient. Nurses who have completed four years of training were able to recognise patient deterioration significantly quicker than those from a 2-year training programme.[74] Ongoing clinical education and skills training also enabled nurses to recognise deterioration more quickly.[73] The influence of teamwork and microsystem factors such as workplace dynamics have been discussed above. Other environmental factors such as the availability of patient monitoring equipment is often described as an influencing factor, although whether this is in a positive or negative way is debated. Some feel that too much reliance on equipment can lead to a failure to carry out a holistic assessment of a patient and that staff are hindered by the presence of equipment they have not been trained on.[73] Chua et al also describe staff that can become overwhelmed with workload and fixate on specific parameters as reasons for deterioration instead of seeing the 'bigger picture'.[70]

Relay

For a health system to react to complications that occur, information must be relayed. This is traditionally from the nursing team to the medical team who are going to respond. Non-technical skills play an important role during this interaction. Staff with strong leadership abilities are more confident responding to the deteriorating patient,[75] and delays in communication can occur when ward nurses do not know other team members.[72] Negative emotional responses are one theme that influence how nurses respond to the deteriorating patient.[69] Fear of being reprimanded, looking stupid or having your credibility threatened can all lead to delayed escalation of care.[76] Effective communication relies on good working relationships with colleagues. The reality is that unequal relationships still exist within a healthcare setting where previously, diagnosis and prescribing was limited to the doctors alone and nurses were seen as subservient.[77] Several studies identify hierarchical barriers such as these as a leading cause of failure to communicate.[68,78] Access to support is also important. If junior nurses can seek help from their peers or senior colleagues easily, they are more likely to respond quickly.

Other reasons affecting the relay of information about deteriorating patients include difficulties reaching the intended recipient, for example a doctor on call who needs to be phoned in order to deliver the message. In Uganda there are rarely hospital telephone systems and hospital budgets for airtime for mobile phones is often very limited. Staff are forced to use their personal mobile phones and a commonly a lack of airtime leads to delays in making phone calls. Following effective communication, the third stage in the process is the response of the appropriate team. This needs to be both timely and effective. In African countries, where staffing levels are often very low, it is not uncommon for the senior doctor to be caught up in other clinical duties such as in the operating theatre or a clinic when their assistance on the ward is needed. This finding is also replicated in HICs such as the UK.[79]

React

Following the recognition and relay of information relating to the deteriorating patient, the response should be both timely and appropriate. The responding clinical team should include staff of appropriate experience and seniority, and the choice of management should be correct and implemented effectively within the constraints of the healthcare setting. A good example of this process would be the development of an infectious complication such as a surgical site infection. Appropriate selection of antibiotics and administration within specific time windows has been shown to significantly improve outcomes in patients like this who are septic.[80] In LMICs, all resources are usually constrained. This includes human resources. The Lancet Commission on Global Surgery recommend a density of 20 surgical, obstetric and anaesthesia specialists per 100,000 people in the public sector.[2] The reality in many countries is that specialist workforce densities are very far from this. In Uganda, in 2016, there were 0.3 per 100,000, just 1.5% of the recommended target.[17] From personal experience in eastern Uganda, this lack of specialist workforce leaves a large proportion of care delivery on the wards to very junior members of staff with either no or remote supervision. These gaps and a lack of leadership leads to a poor quality of care.[81] In Burke's review of failure to rescue, the capability of the team responding to a deteriorating patient was identified as a barrier to an appropriate response.[39]

1.5 Interventions to address failure to rescue in HICs

The literature currently available that describes failure to rescue in LMICs, does not address potential interventions to reduce failure to rescue rates. At best it describes some of the components that are likely to contribute such as patient factors and hospital factors (for example, limited postoperative care infrastructure - consistently available critical care services and access to a functional CT scanner).[22] Identifying potential interventions relies on personal experience and the extrapolation of interventions that have been implemented in HICs. In this next section I will describe some of these interventions with a focus on their applicability to LMICs. In the Globalsurg paper described above, that looked at global variation in postoperative mortality and complications after cancer surgery, it was estimated that patient factors contributed towards 60% of the excess mortality seen in LMICs.[22] These patient factors included variables such as age, sex, performance status, operative risk (ASA grade) and urgency of surgery. As these variables are often fixed or very difficult to change, I will not discuss them further. National healthcare systems that influence the availability of infrastructure resources (access to CT scanners for example) require huge amounts of investment to improve at scale. They also fall outside the scope of this review and will not be discussed further. Instead, I will focus on potential interventions that may be appropriate to help address the 3Rs.

1.5.1 Interventions to improve the recognition of the deteriorating patient

Complications that occur after surgery include infectious complications such as surgical site infections, pneumonia and urinary tract infections, cardiovascular complications such as myocardial infarctions or arrhythmias and other complications such as bleeding, acute kidney injury or anastomotic breakdown. Identifying these early, means they are usually more amenable to treatment and have not yet resulted in the severe physiological derangement that requires intensive care to correct. In LMICs, intensive care is commonly unavailable, especially at a district hospital level where a large proportion of emergency surgery occurs.[65] This means patients who develop complications that are in their advanced stages are often unable to access the resources they need to be treated. An example would be a patient developing an acute kidney injury who requires renal replacement therapy. In Uganda, renal replacement therapy is unavailable outside the capital Kampala.[82] For this reason, identifying complications early in these settings is extremely important. Early recognition often means before a complication is obviously visible to the untrained eye and it is for this reason that monitoring of vital signs should be routine for most patients in hospital, particularly in the early period after surgery. Vital signs include monitoring a patient's conscious level, respiratory rate, heart rate, blood pressure, oxygen saturations and temperature and in most healthcare settings it is the responsibility of the ward nursing team to regularly check, review and document these.[83] It is also considered a professional responsibility of a nurse to be able to understand the significance of the observations they have recorded and if necessary to escalate this.[83,84] Despite this, failure to monitor vital signs or failure to recognise the significance of these vital signs is one of the contributing factors to failure to rescue and may be caused by factors such as clinical inexperience, high workload or over confidence.[41,85,86]

There is some evidence that higher rates of nursing surveillance result in significantly reduced rates of failure to rescue. In California, increases in numbers of nursing staff, after implementation of minimum staffing legislation, led to reductions in failure to rescue rates.[87] Shever et al demonstrated reductions in failure to rescue rates when comparing high rates of surveillance (>12 times a day) and low rates of surveillance (<12 times a day).[88] This proposed level of surveillance however, is unrealistic in LMICs where critical gaps in the healthcare workforce exist. In 2014, it was estimated by the WHO that there was a global shortage of 9 million nurses and midwives, with this set to reduce only slightly by 2030 to 7.6 million.[89] This shortage is particularly apparent in public hospitals in LMICs where published patient to nurse ratios can be as high as 45:1.[90] From personal experience on paediatric and neonatal wards, this ratio can be much higher with a single nurse covering an overcrowded ward alone at night. High patient to nurse ratios inevitably leads to staff prioritising their workload. This means patients who need resuscitating come first followed by the delivery of regular medications and intravenous fluids. Routine surveillance or vital signs monitoring is often completely absent. One way to overcome this is to use remote monitoring systems.[91] In an LMIC setting however, outside a research project, the costs and associated necessary infrastructure to support this is likely to be prohibitive and so alternative approaches need to be explored. It may make sense to simply plan for an increase in the healthcare workforce but improvements in this direction have been very slow and significant changes are unlikely to happen within the next 5-10 years.[89] One alternative is to use someone else except the nursing staff to monitor vital signs on our patients and I discuss this in more detail below.

One of the commonest strategies to try and improve recognition of the deteriorating patient by nursing staff is the use of early warning scores (EWS). Evidence of clinical deterioration is often present for many hours before a serious adverse event such as a cardiac arrest or intensive care admission occurs.[92,93] The EWS concept was developed by Morgan et al in 1997 and is a simple scoring tool based on the vital signs, that can be utilised at the bedside.[94] In general, there has been a positive trend in patient outcomes following the introduction of EWS systems in hospital although the evidence is mixed. Studies looking at patient outcomes in this context have heterogeneous populations and there is conflicting evidence on the impact of EWS on cardiac arrests.[95] What is clear however is that all authors feel an EWS is an appropriate way to identify patients who are deteriorating. They acknowledge that, in addition to recognising the deteriorating patient, many other factors play a role in the ultimate patient outcome.[96,97] Since their original conception in 1997, EWS have been utilised in many different formats, including the Modified EWS (MEWS) and National EWS (NEWS). Disease process specific scores have also been proposed such as the qSOFA score in sepsis. Many comparisons of EWS have been undertaken to try and identify the best scoring system for predicting in hospital mortality but consensus has not yet been reached.[98-100] These comparisons have also been conducted in LMICs such as Rwanda. MEWS, qSOFA and a third EWS called the Universal Vital Assessment (UVA) score all showed a modest ability to predict mortality in a prospective study of inpatients with suspected infection at a Rwandan tertiary hospital.[101]

From as early as 2009, EWS have been proven to predict mortality in patients in Tanzania.[102] In this first evaluation of EWS in this setting, Rylance and his team also measured the predictive value of single abnormal vital signs. Hypotension, tachycardia and reduced conscious level were all strong prognosticators of mortality.[102] This concept was explored further, when a medical records observational study identified common, severely deranged vital signs but a lack of acute treatment modifications in the ICU.[103] The team went on to develop a vital sign directed therapy protocol and evaluate its implementation using a prospective before and after study design. The introduction of this vital signs directed therapy protocol resulted in improved acute treatment of abnormal vital signs in an ICU in a low-income country. In patients admitted with hypotension, mortality was lower post-implementation (69.2% vs 92.3%, p=0.02) but overall in-hospital mortality was unchanged.[104] There are two particularly interesting points that arise from this series of publications from Baker and his team. The first is the journey of understanding and improvement that is documented, confirming that an intervention from a high-income setting is relevant and applicable in a low-income setting. We can learn from this process. The second is that an early warning system is likely to play an important role in detecting deteriorating patients allowing us to trigger an appropriate response.

Other methods of implementing vital signs based EWS have also been studied. In an increasingly technological world, the use of information technology systems and even artificial intelligence have been proposed as ways to overcome the challenges of human error and shortfalls that inevitably occur.[105-107] In the Republic of Korea, an automated alert and activation of the emergency medical team led to reduced median time from patient deterioration to MET activation and decreased risk of death.[105] Implementation of a similar automated early warning scoring system in a surgical ward in the Netherlands resulted in large improvements in quality of MEWS reporting and adherence to the hospital MEWS protocol but in this study, did not result in improved clinical outcomes.[108] There is a paucity of literature relating to the use of automatic EWS in LMICs, this does not mean these systems will not be effective but is likely to reflect the lower availability of the resources required for such a system.

1.5.2 Interventions to improve information relay about a deteriorating patient

Relaying information about a deteriorating patient often involves interprofessional communication, for example between a nurse and doctor. Hierarchies still exist that can negatively influence the relay of potential concerns[68,78] but there are many proven strategies that can overcome these barriers. These include strategies that foster constructive conflict resolution, the maintenance of professional standards and the use of multidisciplinary rounds.[109] In the UK, a qualitative study was conducted with a diverse range of both senior and junior surgical team members. Despite reported proactive efforts by the senior team members to encourage escalation, the junior members of the teams still feared criticism, intimidation and humiliation.[40] This can be overcome with a flattened hierarchy[110] which can be achieved, to some extent by using standardised communication protocols.[111] Mackintosh et al describe an interesting concept. Traditionally the interface between nursing and medical teams has been seen as a barrier. With the implementation of standardised communication tools such as ‘SBAR’ (an acronym for Situation, Background, Assessment and Recommendation), the interface can instead be used to facilitate better communication.[111] SBAR as a tool can enable nursing staff to package information in a format colleagues are used hearing and interpreting. This improved delivery of information can enhance the experience of the interaction for both junior and senior members encouraging communication in the future.

1.5.3 Interventions to improve how teams react to the deteriorating patient

The third ‘R’ involves the response to the identification and communication of a deteriorating patient. The most described intervention to improve this reaction is the development of a specific rapid response system. These can be rapid response teams, medical emergency teams (MET) or critical care outreach teams. There are multiple single centre reports of the benefit of rapid response systems in terms of reduced length of hospital stay, reduced deaths and cardiac arrests.[112,113] Consensus from a panel of experts agreed that this evidence was probably enough to implement such a system in a hospital, provided implementation did not incur an excessive cost or face many barriers.[96] The differing names reflect the heterogeneity in makeup of the team members. Some are led by nurses, some by physicians and some by intensivists. When outcomes from teams led by nurses have been compared to teams led by physicians, no significant difference has been seen.[114] Williams and colleagues use an expert panel design to describe an approach to setting up a nurse let critical care outreach service.[115] They identify five key areas that should be considered to establish a successful service. These include 1) education and training 2) organisational engagement 3) approaches to service delivery 4) clinical governance and 5) monitoring and evaluation. In the real-world setting, interchangeable terms and multiple different models for rapid response systems make implementation difficult. This modified Delphi technique that combined clinical judgement, evidence and experience provides a practical guide to anyone who wishes to implement a successful critical care outreach service.[115]

In a low-income country such as Uganda, there is huge variety in clinical practice. Whilst national clinical guidelines exist, their guidance for the management of surgical conditions is not evidence based and would be considered harmful by many. An example is fluid management in a patient with suspected peritonitis. Their recommended fluid regime is '1L of crystalloid every 1-2 hours until their BP is normal, then 1L every 4-6 hours when the BP is normal' This would result in a stable patient receiving between 4-6 litres of iv fluids in 24 hours regardless of their overall fluid status.[116] With limitations in the specialist surgical, obstetric and anaesthesia workforce, junior clinicians are often left to provide hands on care to patients on the wards without supervision. We know that protocol driven care after surgery can improve outcomes. There are many examples of enhanced recovery after surgery protocols that have significantly reduced mortality rates.[117,118] Protocol driven care has also improved outcomes after surgery in LMICs. Examples include adoption of a care protocol for patients with gastroschisis in Mexico that resulted in survival rates increasing from 71% to 92.7%[119] and adoption of enhanced recovery after surgery protocols in Uganda leading to reduced lengths of hospital stay.[120] Protocol driven care has also seen improvements in outcomes across the medical spectrum. In intensive care, bundles of interventions are implemented in accordance with protocols ('care bundles') and have reduced the incidence and therefore associated morbidity of central venous line bloodstream infections and ventilator associated pneumonia.[121,122] In eastern Uganda, implementation of a protocol to drive improvements in care of neonates with tetanus resulted in a significant impact on mortality.[123]

Access to intensive care influences failure to rescue rates. In many LMICs, the majority of hospitals do not have established intensive care services despite Many et al demonstrating that implementation of a surgical critical care service in Kenya could result in reduced failure to rescue rates.[65,66] Critical care in HICs often requires advanced technology and very expensive resources however, in this setting, it's value for money in adults is comparable to

Figure 9. The single intensive care bed at Mbale Regional Referral Hospital

other commonly used health interventions.[124] It is not clear whether this is also true in an LMIC setting but traditionally strengthening critical care services has been low on the priority list of Ministries of Health.

A fairly new concept is now emerging that considers different levels of emergency and critical care. Essential emergency and critical care (EECC) is defined as 'care that all critically ill patients should receive in all hospitals in the world'.[125] There is significant crossover between the concepts that are required to implement EECC and those that are required to reduce failure to rescue. EECC is suggested as a unifying concept for initiatives that we have previously discussed including early warning scores, rapid response teams and treatment protocols.[125] EECC involves simple concepts and interventions that should be available to hospitals around the world regardless of their resources. Examples include administering oxygen in hypoxia and intravenous fluids in shock. A delphi panel with 269 experts reached consensus on 40 clinical processes and 67 requirements that should be enabled to implement EECC and it is likely that this package of care will form an integral part in any complex intervention designed to address failure to rescue in LMICs.[126]

1.6 Failure to rescue after surgery in Africa

In Africa, up to 18% of patients who undergo surgery are likely to develop a postoperative complication.[28] Some of those will undergo continued physiological deterioration and if unrecognised, this will eventually result in death. This failure to rescue has been proposed by Biccard and colleagues to play a significant role in the excess mortality after surgery that we see in LMICs when compared to HICs.[127] There seems to be a paucity of literature about failure to rescue in LMICs however the important role that it plays in safe surgical and anaesthesia care in these settings is increasingly recognised.[128] One of the first articles describing failure to rescue after surgery in LMICs was an international prospective cohort study looking at complications after elective surgery.[21] The ISOS study described 15,806 patients undergoing surgery in LMICs as part of a larger global cohort. 11.1% of those patients developed complications and of those patients, mortality was 3.3%. The authors highlighted the need for a more effective treatment response for those patients who develop complications after surgery.[21] Further analysis of this dataset was published in 2017 to assess the utility of using failure to rescue as a quality measure for perioperative care. Data from LMICs was incorporated into the analysis but hospitals were ranked into five groups depending on the volume of surgery they performed, not on the income status of the countries themselves. There was a greater than two-fold variation in failure to rescue rates between the best and worst performing hospitals, with lower failure to rescue rates in the highest volume hospitals.[129] Interestingly, hospitals with the highest complication rates did not have the highest failure to rescue rates suggesting that the ability of a hospital to identify and escalate care for patients who develop complications is not directly linked to their surgical volume.

Santhirapala and colleagues describe a global perspective on quality perioperative care and analyse the system contributors to the excess mortality rates seen in LMICs. Factors that impact on perioperative care were identified in the literature and added to the traditional three delays model that has been used successfully to describe avoidable maternal mortality.[130] Three additional phases in the pathway of perioperative care were identified when a healthcare system collectively 'fails to deliver quality care':

- Failure to provide timely access to surgical and anaesthesia services
- Failure to deliver safe anaesthesia and surgical care
- Failure to rescue patients who develop complications postoperatively

Using a modified delphi method, broad reaching strategies were developed to address areas within this 'critical failures model' including failure to rescue.[128]

In the last couple of years, a series of papers have been published that start to describe failure to rescue in LMICs in the context of specific diseases or surgical procedures. Cardiac surgery programmes in LMICs are generally poorly developed and in most low-income countries, capacity for this type of surgery has not yet been established.[131] Polivenok and colleagues work in one of the few LMICs in Europe and have described perioperative complications in their paediatric cardiac surgery programme that is set within a more general adult cardiac surgery service. When compared to HICs, overall complication rates were lower (24.7%), likely due to a patient cohort with lower complexity, but failure to rescue rates were more than twice as high (23.3%).[132] The African Surgical Outcomes Study led by Biccard and his team in South Africa which has been mentioned earlier does not specifically mention failure to rescue but the discussion provides some insight into the authors train of thought.[28] In their cohort of patients, 9.5% of those that developed a postoperative complication ended up dying. This failure to rescue rate is almost three times as high as failure to rescue in the global cohort of the ISOS study. They hypothesise that scarce workforce resources and poor early warning systems to detect physiological deterioration of patients who develop complications may be the contributing factors to this high mortality rate.[28] The ASOS study design was repeated in Nigeria and published a year later. Complications after elective surgery in 1425 patients across 79 hospitals were reported. The failure to rescue rate in this elective surgery cohort was 6.0% (compared to 4.8% in ASOS and 2.8% in ISOS) and the authors attribute this to better postoperative care but do not go into any details about the aspects of postoperative care that may be different.[133] An international prospective cohort study in 137 hospitals across 41 countries looked at 90-day mortality after oesophagectomy for oesophageal cancer, comparing outcomes between HICs and LMICs.[134] Patients in HICs were older with more comorbidities and tumours that were more advanced however, complication rates in this cohort, including anastamotic breakdown, were similar between HICs and LMICs. Despite this, mortality rates were three times higher in LMICs. The authors suggest this is likely to reflect a failure to rescue patients following a complication.[134] Interestingly this message is also identical to the comparison of complications and outcomes in postoperative patients in the original ASOS study.[28]

The Globalsurg collaborative network involves over 5000 clinicians across 100 countries. They have published several papers looking at outcomes after surgery including in adult patients undergoing surgery for primary gastric, breast or colorectal cancers. This prospective patient cohort included almost 16,000 patients from 428 hospitals in 82 countries.[33] They were able to show that 30-day postoperative mortality is four times higher in LMICs when compared to HICs despite patients experiencing similar major complication rates.[33] This study went further than some of the others to try and identify the reasons behind these excessive mortality rates in LMICs. Patients in LMICs presented with more advanced disease, probably due to reduced access to safe, affordable surgical services in a timely manner, however, this only partly explained the excess mortality seen. The team describe the capacity of health facilities to rescue their patients following the development of complications. They looked at the presence of infrastructure to support postoperative care in the health facilities. This included resources such as an available and working CT scanner, designated postoperative recovery areas and consistently available critical care services. The presence of postoperative care infrastructure was associated with fewer deaths suggesting that these components of the surgical healthcare system are essential if excess mortality after cancer surgery in LMICs is to be reduced.[33]

Excess mortality following surgery in LMICs is not only seen following complex operations such as cancer surgery. Acute appendicitis is an emergency condition requiring surgery worldwide yet outcomes following appendicectomy are poorly studied in LMICs.[135] Williams and colleagues describe a cohort of patients undergoing appendicectomy at Kamuzu Central Hospital in Malawi between 2013-2020.[136] The mortality rate of 5.6% is many times higher than a median global mortality rate of 0.4% reported by Weiser and colleagues in 2015.[137] The presence of a postoperative complication was the only independent predictor of mortality, and the authors suggest failure to rescue is a significant contributor to appendicitis related deaths in their hospital.[136] Emergency gastrointestinal conditions requiring surgery commonly present to hospitals across LMIC settings, including Africa. Mortality and complication rates in this group of patients is often very high.[30] In Malawi, Sincavage et al have described postoperative complications and the risk of mortality following laparotomy.[138] They describe intra-abdominal complication rates of 9.0% with a failure to rescue rate in those patients of 47.1%. Their almost three-fold increased risk of mortality in patients who developed an intraabdominal complication supports other literature that postoperative surveillance and management may be critical in determining patient outcomes. A second interesting point from their study is that most patients died without a confirmed diagnosis of the complication leading to their death. The authors suggest this reflects a failure to recognise deterioration and life-threatening complications in their patients and they suggest interventions to optimise postoperative care may be the most valuable investment to improve surgical outcomes in their setting.[138] In Kenya, a team at a tertiary teaching hospital also recognised the significant contribution of failure to rescue to their excess mortality rates following emergency gastrointestinal surgery. They describe a lack of data in this context in Africa and as part of a wider implementation project looking at the impact of critical care services on failure to rescue. failure to rescue rates in their hospital were as high as 36.8%.[66]

1.7 Evidence supporting interventions to address failure to rescue after surgery in Africa

During my scoping review looking at failure to rescue after surgery, I found virtually no articles that discussed interventions with evidence of implementation in Africa. Almost exclusively, the literature originates from HICs, and I have described this in section 1.4 above. This is, in itself, an important lesson and mirrors the global disparity where research from Africa is underrepresented in academic literature.[139] The reasons underlying this are outside the scope of this work but include a global research agenda that is largely set by HICs, and significant limitations in health research investments in Africa.[139] Whilst healthcare systems globally have many similarities, we know we cannot just automatically apply evidence from one setting to another without considering the context.[140] By their nature, healthcare systems are complex. Over time, we have increasingly learnt that developing and implementing an intervention to address gaps is not as simple as it sounds. There have been iterative efforts to provide guidance for teams that are looking to identify ways to improve healthcare systems and therefore reduce preventable mortality throughout the global context.[141-144] This guidance now provides a robust framework on which to base intervention development work and, if following carefully can lead to impactful results. If interventions to reduce failure to rescue rates after surgery in Africa are not widely described, this suggests there is a unique opportunity here for further exploration and scope for work that has potential for widespread impact.

1.8 Family involvement in patient care in LMICs

Involvement of patients and their family members in patient care is increasingly recognised as an important component of healthcare delivery and interventions that include family members are becoming more common.[145-148] In LMICs, especially the settings with the least healthcare workers, patient's families routinely accompany them to hospital and remain with their patient for the duration of their hospital stay. They provide all basic care needs such as feeding, bathing and helping with mobility. They are also the route through which patients can access supplies and medicines that are out of stock. Family members are given a 'shopping' list and take it to private pharmacies outside the hospital. When they return, the healthcare workers are able to administer the medication. Involvement of family members in

Figure 10. Family members involved in patient care in the neonatal ward at Mbale Regional Referral Hospital

Image redacted for confidentiality reasons this way tends to be informal and there is limited documentation of formal involvement of family members in healthcare delivery in LMICs.

A qualitative study looked at family involvement in care provision across five hospitals in Bangladesh, Indonesia and South Korea. There was an expectation from healthcare workers in these settings that a family carer would be present, but no formal training for them during the admission. Family members were involved in procedures such as nasogastric tube feeding, suctioning, wound dressing, and body fluid exposure activities.[149] In early 2023, Determeijer et al. published a systematic review assessing the effect and safety of family participation interventions in the case of hospitalised adults in resource limited settings. One of their aims was to try and assess whether this was a viable strategy to tackle shortages of healthcare workers in these settings. They included interventional studies only with six in their final analysis, four from Asia and two from Africa. Although the data was limited, they suggest that family participation can be safe and effective in specific contexts.[150] The two studies from Africa were both from Uganda. Alupo et al. describe a quality improvement effort to improve inpatient medication adherence. Efforts focused on attendant education and involvement and led to overall medication adherence increasing from 46.5% to 92%.[151] Wong et al. also used a quality improvement approach to attempt to standardise caregiver and nursing perioperative care on gynaecology oncology wards in the national women's specialised hospital. Although this report was for a very small group of patients (25 only), it demonstrates efforts to integrate caregivers as clinical care partners. More recently, and also in Uganda, Duby et al conducted a feasibility study looking at the adaption of family integrated care into a neonatal unit at Jinja Regional Referral Hospital in eastern Uganda.[152] Family integrated care had already been shown to be effective in improving infant and parent outcomes in HICs.[153] Duby et al were interested to know if it was feasible in a low-resource setting and were able to show that Ugandan mothers were able to collaborate in the medical care of their hospitalised infant.[152] Other, noninterventional work has also been previously published from Africa including in Malawi. Hoffman et al. describe family members who provide support to their patients. They were primarily female family members, involved in daily tasks of patient care including wound care and advocacy.[154]

1.9 Family involvement at Mbale Regional Referral Hospital

At Mbale Regional Referral Hospital, inspiration for involving family members in patient care was drawn from the neonatal unit where a 'mother centred model' of care is used. Mothers provide warmth through kangaroo mother care, they feed their babies via nasogastric tube and monitor them, notifying nurses if they are worried or if the baby stops breathing.[155] The neonatal unit also struggles with overwhelming nurse to patient ratios and relies on mothers to help with daily care tasks (Figure 11) and identify when their babies deteriorate. Family involvement in neonatal care is also routinely practiced in high resource settings.[156] Given

Figure 11. Family member involvement in patient care in the neonatal unit at Mbale Regional Referral Hospital.

the success of family member involvement in patient care both in Mbale Regional Referral Hospital and described in other settings, extrapolating this to other wards and specialties seemed an easy step to take.

1.10 Healthcare intervention development in complex environments

Previous experience attempting to introduce healthcare interventions to improve outcomes have highlighted important lessons about the complexity of such initiatives. Two examples in particular looking at outcomes after surgery include the EPOCH trial and the ASOS-2 trial. The Enhanced Peri-Operative Care for High-risk patients (EPOCH) trial was a stepped wedge cluster randomised trial of a quality improvement initiative programme to improve survival for patients having emergency abdominal surgery in 93 hospitals in the UK.[157] The ASOS-2 trial tested an enhanced post-operative surveillance programme to reduce postoperative mortality in hospitals across Africa.[127] Neither intervention resulted in improved outcomes as hypothesised. Process evaluations conducted concurrently demonstrated the likely reasons behind this lack of expected effect with many similarities between the two trials. In particular, investigators across all countries faced difficulty delivering the interventions as planned in challenging contexts.[158,159] Healthcare environments themselves are naturally complex due to multiple interacting systems, human factors and the high requirement for resources. The chances of a healthcare intervention being successful are significantly higher if an understanding of the context and its' complexity are factored into the intervention development process. The Medical Research Council have recently updated their guidelines for the development and evaluation of complex interventions, providing a roadmap that can help researchers and improvement scientists ensure their work is more effective.[142] It is this guidance that I have followed whilst developing my intervention to involve family members in patient monitoring after surgery.

1.11 Summary

In sub-Saharan Africa, it is estimated that 93% of the population are unable to access safe, affordable surgical services. Despite similar complication rates after surgery, mortality rates are double those in HICs, in a population that is younger and with less comorbidities. Healthcare environments are naturally complex, and this is compounded by inadequate resources in low-income countries such as Uganda. Higher rates of preventable mortality are the result of limited capacity to rescue patients when they develop complications, and human behaviours that are influenced by workplace dynamics.

Efforts to provide more surgical treatments to people across Africa are increasing in an attempt to address the current low surgical volumes across the continent. In Uganda, surgical volumes need to increase by 30 times to meet 2030 global targets. Studies looking at outcomes after surgery in Africa report outcomes that suggest surgical care is not as safe as it should be. There is a risk therefore that delivering higher surgical volumes will result in more preventable postoperative deaths. If we are to increase access to surgery and anaesthesia care, we must also ensure it is as safe as possible. This means developing concurrent improvements targeted at the surgical care pathway where there are the highest number of deaths.

Failure to rescue describes the death of a patient following development of a surgical complication. Using experience from failure to rescue after surgery in HICs, it is reasonable to expect that there will be similarities in the root causes in Africa, despite limited evidence. Whilst a proportion of these causes can be expected to result from limited access to higher levels of healthcare services (for example intensive care), factors influencing staff behaviours will also play a role. Examples include delayed recognition of deteriorating patients, delays in relay of this information and gaps in the response that is required. These are areas that are amenable to an appropriate and low-cost intervention with opportunity for high impact. It is important however that any intervention to reduce preventable postoperative mortality, that is also affordable and achievable in a low-resource setting, needs to be carefully developed within the complex system it is designed for. It needs to be formally evaluated, and this evidence used to guide further intervention development, change or scale up.

1.12 Research aims

- To identify existing literature describing interventions to reduce failure to rescue after surgery in low- and middle-income countries
- To investigate the current perioperative mortality rates at a regional referral hospital in eastern Uganda
- To develop a complex intervention involving family members to increase vital signs monitoring of patients after surgery
- To trial this complex intervention in a pragmatic pilot cluster randomised controlled trial in Uganda
- To investigate contextual factors influencing intervention delivery through a concurrent process evaluation

CHAPTER 2 FAILURE TO RESCUE AFTER SURGERY IN LMICS: A SYSTEMATIC REVIEW

2.1 Introduction

We know that mortality after surgery across the African continent is on average, twice that in high-income countries (HICs), despite patients being younger with a lower risk profile.[28] In some population groups, mortality rates can be as high as 22%.[160] Deaths after a surgical procedure usually follow development of one of several common complications that have previously been well described both in HICs and LMICs, for example sepsis, major bleeding or myocardial injury.[161,162] Death following development of a surgical complication is commonly described as ‘failure to rescue’ (Failure to rescue). As surgical complication rates are similar in both HICs and LMICs, the higher mortality rates in LMICs suggest higher rates of Failure to rescue.[22]

Three critical steps in the pathway that may eventually lead to a patient’s death have been regularly reported to contribute to Failure to rescue. They include a failure to identify the deteriorating patient (recognise), a failure to communicate information about the patient’s deterioration (relay) and a failure to react in a timely way (react).[40-42] When described in this way, Failure to rescue is often attributed to multiple failures that rest on the shoulders of the healthcare provider. The GlobalSurg collaborative described factors that contribute to failure to rescue in a different way, apportioning 40% to hospital or country level factors and 60% to patient factors.[22] Hospital factors might include healthcare worker to patient ratios, access to intensive care and hospital surgical volume. Patient factors can include age, the advanced nature of disease processes and the ability of the patient to pay for aspects of their care.[39,42] These differing descriptions serve to highlight the complexity of Failure to rescue.

Failure to rescue has been used as a metric to measure quality of patient care in HICs such as the United States of America and there are review articles published in peer reviewed journals describing interventions to address these challenges.[38,39] Identifying evidence based interventions that can be implemented to reduce failure to rescue in LMICs is much more difficult. Complex intervention research can be described as having four phases.[142] Although a research programme can begin at any of these, in our context, with a paucity of evidence surrounding Failure to rescue in LMICs, the first development or intervention identification stage is incredibly important. A robust understanding of any existing evidence, describing interventions to address Failure to rescue after surgery in the scientific literature, even if it is limited, is the logical next step. The aim of my systematic review is to identify known interventions to address failure to rescue after surgery in LMICs. By summarising the existing literature, we will be able to identify effective improvement strategies in this area and contribute to efforts to lower postoperative mortality rates.

2.1.1 PICO statement

I used the PICO framework to help formulate a well-focused research question for my literature search.[163] No comparator was used.

In surgical patients in LMICs (population) what interventions (intervention) reduce failure to rescue (outcome)

2.2 Objectives

1. To identify interventions described in the scientific literature that reduce failure to rescue in LMICs so that we can understand what evidence exists to support activities to reduce mortality after surgery in this setting.
2. To describe barriers and facilitators that influence implementation of these interventions in LMICs.

2.3 Methods

A systematic review and narrative evidence synthesis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and reported in accordance with PRISMA and synthesis without meta-analysis (SWiM) guidelines.[164,165]

2.3.1 Eligibility criteria

Inclusion criteria:

Types of studies: All study types that considered interventions to reduce failure to rescue in LMICs were included.

Types of participants: All patients in hospital

Outcome measure: Any outcome measure was accepted.

Setting: Hospital inpatients in an LMIC country.

Exclusion criteria:

Case reports, conference abstracts and narrative reviews were excluded. No exclusions were made based on outcomes or date.

2.3.2 Information sources

A search for articles was made using the following electronic databases: PubMed, EMBASE (OvidSP) and Global Indexus Medicus (GIM). To identify further relevant literature, reference lists and citations of the identified studies were reviewed, and any missed articles were included.

2.3.3 Search strategy

The search was undertaken on 5th April 2022 and repeated on 1st June 2023 using the following search terms.

Search constructs: [surgery] AND [LMIC] AND [failure to rescue]

Search terms:

Pubmed

("Surgical patients"[All Fields] OR surgery[All Fields])

AND

("Low* income countries"[All Fields] OR "Middle* income countries"[All Fields] OR "Developing countries"[All Fields] OR "LMICs"[All Fields] OR Africa* OR Asia* OR South America* OR Central America*)

AND

("failure to rescue"[All Fields] OR "failure to rescue, health care"[Mesh])

Global Indexus Medicus

("surgical patients" OR surgery)

AND

"failure to rescue"

Embase

('surgical patients' OR 'surgery'/exp OR surgery)

AND

('low* income countries' OR 'middle* income countries' OR 'developing countries'/exp OR 'developing countries' OR 'lmics' OR africa* OR asia* OR 'south america*' OR 'central america*')

AND

('failure to rescue'/exp OR 'failure to rescue' OR 'failure to rescue, health care'/exp OR 'failure to rescue, health care')

2.3.4 Data selection process

Selection: To manage the references through the different stages of the review process (title, abstract and full text reviews as appropriate), results from the search were imported into the Endnote reference manager. Endnote was used to identify and remove any duplicates. To reduce the risk of bias, I asked a second researcher to screen the records independently and record their inclusion decisions for comparison. The second researcher and I were blinded to each other's decisions until all the articles have been screened. Disagreements that arose were resolved by discussion between the two of us. A third researcher was identified to resolve any remaining disagreements but was not needed.

2.3.5 Data collection process

Data from included articles were exported directly into a table in Microsoft Word:

- author
- year of publication
- country(ies) of participating hospital(s)
- facility type (1st-/2nd-/3rd- level hospital)
- study design
- type of surgery, clinical problem or population that the failure to rescue intervention attempts to address
- brief description of the intervention
- outcome measures and effectiveness
- number of patients

2.3.6 Outcomes & measures

Main outcome

To identify interventions that can be used in LMICs to reduce failure to rescue after surgery.

Additional outcome

To identify barriers and facilitators during the implementation of interventions to reduce failure to rescue after surgery in LMICs.

2.3.7 Effect measures

Not applicable

2.3.8 Study risk of bias assessment

I used the Mixed Methods Appraisal Tool (MMAT, version 2018) to assess the quality of studies included in my review.[166] The assessment was repeated independently by a second researcher and any disagreements were resolved through discussion until a consensus was reached. A third researcher to resolve any ongoing disagreements was not needed.

2.3.9 Synthesis methods

A narrative synthesis and descriptive statistics were used to summarise the data identified during the systematic review. This included the design of interventions to address failure to rescue and the setting of the studies. Outcomes were categorised according to the COMET (Core Outcome Measures in Effectiveness Trials) Initiative taxonomy,[167] and strategies that were used to implement interventions were classified according to the ERIC (Expert Recommendations for Implementing Change) taxonomy.[168,169] The Consolidated Framework for Implementation Research (CFIR) will be used to synthesise any facilitators or barriers to implementation of the failure to rescue interventions identified.[170,171]

2.3.10 Report bias assessment and certainty assessment

Not applicable

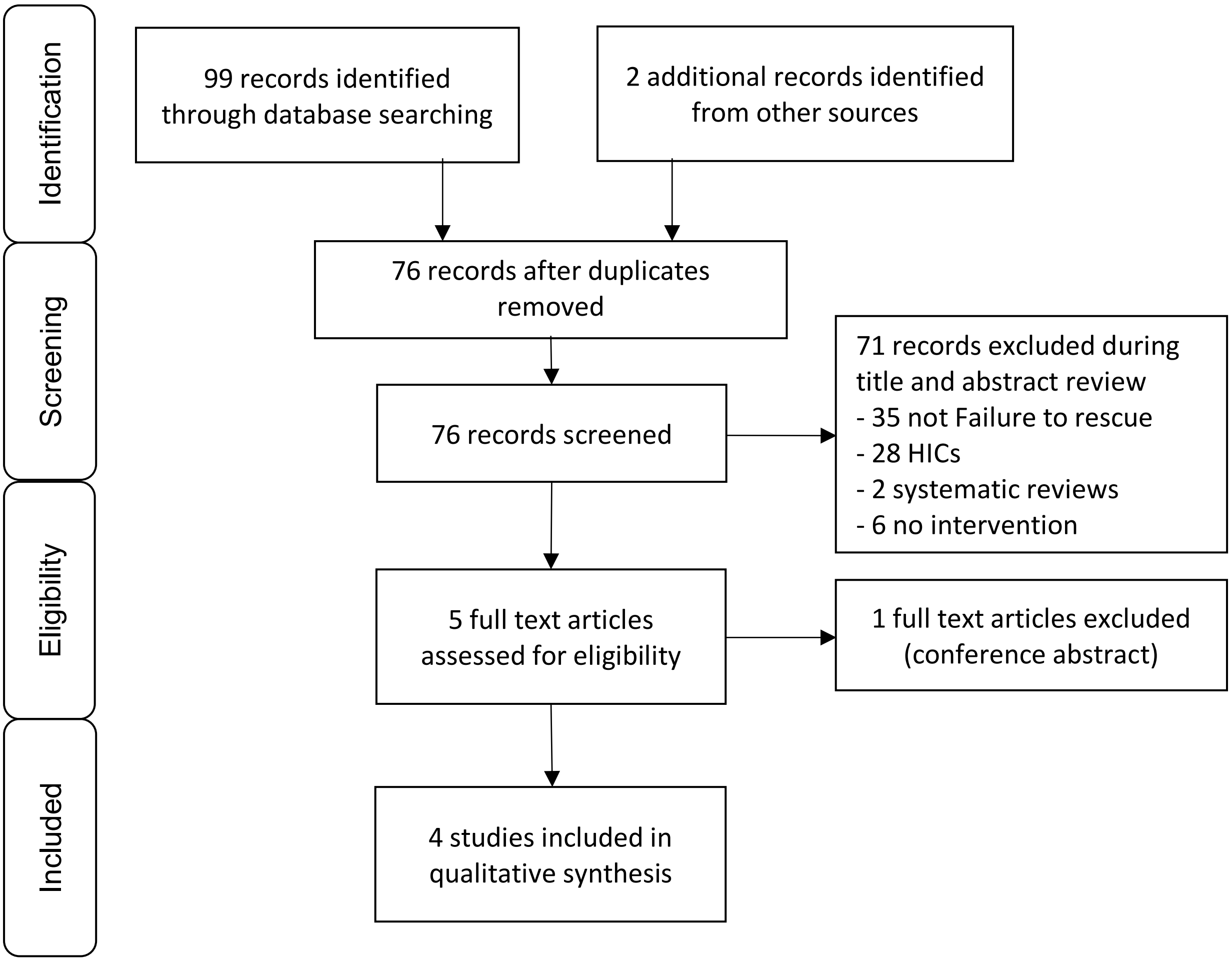
2.4 Results

99 articles were exported into Endnote where 25 duplicates were removed. After a review of titles and abstracts, articles were filtered according to the inclusion criteria, in particular, only those containing data from LMICs were included. Figure 12 illustrates the reasons articles were excluded at this stage, including 35 because they were not about failure to rescue, 28 that were from HICs, six that had no intervention and two that were systematic reviews. Five full-text articles were reviewed to assess suitability for inclusion and one article was excluded as it was a conference abstract. This left a total of four articles for inclusion in the literature review.

2.4.1 Characteristics of sources of evidence

Characteristics of the included studies are summarised in Table 2.

Figure 12 PRISMA flow diagram



2.4.2 Critical appraisal of sources of evidence

All four studies were appraised for quality using MMAT. Results are presented in full in Table 2. Two studies scored 100% (5/5). Du Toit et al. scored 80% (4/5), losing one mark because divergences and inconsistencies between quantitative and qualitative results could have been addressed in more detail. The ASOS Investigators scored 60% (3/5) losing marks for incomplete outcomes data (primary outcome missing in 2.4% (680/28,892) of participants, the study was also stopped early due to the COVID-19 pandemic with 28,892 of the planned sample size of 64,200 recruited) and gaps in adherence to the intended intervention.

Table 2. Characteristics of included studies and failure to rescue interventions

Source	Country	Facility type (number) b	Study design	Study population	Intervention	Outcome measure	Outcome effective?	Number of patients
Du Toit et al. 2019[172]	Benin, DRC, Kenya, Mali, Mauritius, Niger, Nigeria and South Africa	1st (1) 2nd (6) 3rd (9)	Mixed methods implementation pilot trial	Adults undergoing surgery	1. Risk identification 2. Increased postoperative surveillance	Data completeness Implementation fidelity Acceptability, feasibility of intervention of trial processes	Yes No Yes	803
ASOS Investigators 2021[127]	28 African countries a	1st (36) 2nd (59) 3rd (71)	Two arm, open label, cluster randomised trial	Adults undergoing surgery	1. Risk identification 2. Increased postoperative surveillance	In-hospital mortality	No	28,892
Vickery et al. 2021[158]	Sierra Leone, South Africa, Uganda	1st (2) 2nd (3) 3rd (3)	Mixed methods process evaluation	ASOS-2 study sites and study investigators	Not applicable	ASOS-2 intervention fidelity	Not applicable	22 interviews from 10 sites Field notes from 19 sites 96 questionnaires
Many et al. 2023[173]	Kenya	3rd	Before and after retrospective cohort study	Adults undergoing emergency gastrointestinal surgery	Implementation of surgical critical care service	Failure to rescue	Yes	484

a) The 28 African countries included: Angola, Benin, Burkina Faso, Burundi, Democratic Republic of the Congo, Djibouti, Egypt, Eswatini, Ethiopia, The Gambia, Ghana, Kenya, Libya, Malawi, Mali, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Sierra Leone, South Africa, Sudan, Tanzania, Togo, Uganda, and Zimbabwe. b) 1st = district hospital, 2nd = secondary or regional hospital, 3rd = tertiary hospital. Data from ASOS Investigators 2021 from 166 facilities, total facilities recruited = 332. c) Increased postoperative surveillance = provision of as many of the following package of interventions: admitting patient to higher care ward, increased frequency of postoperative observations, assigning patient to bed visible from nursing station, allowing family members to stay with patient, placing bedside guide next to bed.

Table 3. Mixed Methods Appraisal Tool (MMAT) quality ratings for each study

Source	MMAT Criteria (0, Can't tell or no; 1, Yes) a															Overall score
	1.1	1.2	1.3	1.4	1.5	3.1	3.2	3.3	3.4	3.5	5.1	5.2	5.3	5.4	5.5	
Du Toit et al. 2019[172]											1	1	1	0	1	* * * *
ASOS Investigators 2021[127]	1	1	0	1	0											* * *
Vickery et al. 2021[158]											1	1	1	1	1	* * * * *
Many et al. 2023[173]						1	1	1	1	1						* * * * *

a1. For quantitative randomized controlled trials
1.1. Is randomization appropriately performed?
1.2. Are the groups comparable at baseline?
1.3. Are there complete outcome data?
1.4. Are outcome assessors blinded to the intervention provided?
1.5. Did the participants adhere to the assigned intervention?
3. For quantitative non-randomized
3.1. Are the participants representative of the target population?
3.2. Are measurements appropriate regarding both the outcome and intervention (or exposure)?
3.3. Are there complete outcome data?
3.4. Are the confounders accounted for in the design and analysis?
3.5. During the study period, is the intervention administered (or exposure occurred) as intended?
5. For mixed methods
5.1. Is there an adequate rationale for using a mixed methods design to address the research question?
5.2. Are the different components of the study effectively integrated to answer the research question?
5.3. Are the outputs of the integration of qualitative and quantitative components adequately interpreted?
5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?
5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved

2.4.3 Interventions to reduce failure to rescue in LMICs

Three of the included studies describe the same intervention. A pilot trial,[172] a cluster-randomised controlled trial,[127] and a process evaluation,[158] test the effectiveness of an enhanced postoperative surveillance intervention among adult surgical patients in Africa. The studies hypothesise that failure to rescue was a major contributor to the high mortality rates seen in patients after surgery across the continent. In the African Surgical Outcomes Study, published in 2018, 95% of patients died on the wards after developing complications after surgery. We know that in LMICs, individual hospital capacities to rescue patients after they develop surgical complications is limited. The enhanced postoperative surveillance intervention was based on the premise that earlier identification of patients who develop complications would allow intervention before deterioration past the point of no return in this context. The intervention itself included two steps:

1. Identification of patients after surgery at high risk of deterioration, based on an established and validated, setting appropriate risk score. (ASOS Risk Score[174])
2. High risk (ASOS Risk Score >10) patients receiving increased postoperative surveillance, including the following five components:
    - admission to a higher care ward than had been planned prior to risk stratification
    - an increase in the frequency of postoperative nursing observations,
    - ensuring that the patient is placed in view of the nursing station, and not in a remote location in the ward,
    - allowing family members to stay with the patient in the ward
    - placing a postoperative surveillance guide in a visible position at the bedside.

Du Toit et al. piloted the intervention first, aiming to evaluate the adequacy of data produced, the fidelity of the intervention and understand the acceptability, appropriateness, and feasibility of the intervention. 803 patients were recruited from 16 hospitals across eight different African countries. Data from a post-trial survey showed that 73% of respondents felt they had provided increased postoperative surveillance to their high-risk patients during the trial, but intervention fidelity varied across the five components of the increased postoperative surveillance package. 60% of participants received increased nursing observations but all other components were achieved in less than 50% of participants. In some cases, this was down to unavailability of that component (for example access to a higher care ward) however failure to comply with available components ranged from 27.5% to 54.3%. Despite this poor intervention compliance, feedback from teams participating in the trial was overwhelmingly supportive of the intervention. Alongside efforts to improve intervention fidelity, the manuscript's conclusion was that this intervention was appropriate, acceptable and feasible in Africa.

The main cluster-randomised controlled trial (ASOS-2) included 28,892 participants across 332 hospitals in 28 African countries with a primary outcome of 30-day in-hospital mortality measured at the participant level. The intervention package, as delivered during the ASOS-2 trial did not lead to a reduction in postoperative mortality. In this main trial manuscript, there is some discussion about the reasons that may have led to the intervention not achieving the desired effect. Examples include the complexity of the intervention and its implementation, the need for behaviour change and involvement of multiple stakeholders, communication challenges and competing time pressures. The ASOS-2 process evaluation by Vickery et al. provides significantly more insight into these factors and is described in more detail below.

The fourth paper identified during this systematic review is by Many et al.[173] It describes a retrospective analysis of the impact of a dedicated surgical critical care service on the incidence of failure to rescue at a tertiary teaching hospital in Kenya. A total of 484 patients undergoing emergency gastrointestinal surgery were included and a significant reduction in failure to rescue was documented in the intervention group (36.8% to 21.8%, (odds ratio 0.48; 95% confidence interval: 0.24-0.96, p=0.037)). Critical care services already existed in the hospital. This intervention included enhancement of this care by providing an assigned critical care resident, dedicated critical care teaching and critical care attending surgeon oversight. The resident improved staffing levels leading to increased surveillance of high-risk patients. The level of training and education within the critical care unit increased and this may have led to changes around the culture of safety although this was not specifically measured.

2.4.4 Barriers and facilitators that influenced implementation of interventions to reduce failure to rescue in LMICs.

Papers by Du Toit et al. and Vickery et al. included specific process evaluation methodology that identified barriers that were encountered during the implementation of the bundled interventions to reduce failure to rescue. Du Toit et al. used a post-pilot trial electronic survey that included open questions to help them understand acceptability, appropriateness, and feasibility of their trial. Vickery et al. used site visits and interviews in addition to quantitative data from a post-trial questionnaire. There are common themes across the two papers that influenced intervention delivery and success. These factors can be described as facilitators or barriers depending on whether they are present or not. For this reason, I have described them as influences rather than solely describing their positive or negative impact. They can be summarised under the headings of resource constraints, stakeholder engagement, knowledge and beliefs about the intervention, and others.

Resource constraints identified as influences included the small numbers of ward nurses who may not have time to take on new responsibilities in addition to their usual workload, even if these are seemingly small. The additional burden of increasing the monitoring of high risk patients was a specific example and whilst one or two high risk patients may be manageable, three or more at a time represents a significant change to workload. Many et al. increased surveillance by increasing available human resources and this lead to a positive impact on failure to rescue rates. Bed capacity, particularly availability of higher care beds (for example high dependency or intensive care) where enhanced monitoring would be a routine part of care, access to monitoring equipment itself, and structural limitations in terms of the ward layout were also described as important factors that influenced the successful intervention delivery.

The important role that effective stakeholder engagement played was emphasised. Du Toit et al. list nursing management approval as a potential barrier and Vickery et al. saw that hospitals with effective leadership and management involvement in the ASOS-2 trial were more likely to have successful intervention delivery. Knowledge and beliefs about the intervention impacted delivery of the ASOS-2 trial. The ASOS risk calculator[174] was used to identify patients at high risk of postoperative complications however some clinicians felt that it was not always accurate. This mistrust in the tool may have led to a negative attitude that undermined nursing buy in on the wards. Influences such as this, that would likely have been addressed and corrected during a longer implementation trial were identified as potential barriers after ASOS-2 because of its short duration and design as a cluster-randomised trial.

2.5 Discussion

This review identified four papers that describe interventions to reduce failure to rescue in LMICs. All four papers were based in Africa and three of them describe the same package of interventions that were tested through a pilot trial and then a large cluster-randomised controlled trial (ASOS-2). The ASOS-2 trial did not show a reduction in mortality, and therefore failure to rescue, after surgery. Its' accompanying process evaluation provides valuable insights into the reasons that are likely to have led to the lack of observed benefit, despite an intervention that was expected to have a positive impact by clinical teams on the ground. The only successful intervention to reduce failure to rescue in LMICs that was described in the literature, improved critical care capacity by enhancing the human resource available with a dedicated surgery resident and improved training. They hypothesise that this is likely to have led to increased surveillance and therefore early recognition and management of deterioration.

The limited number of publications related to failure to rescue in LMICs is likely to be a result of several factors. Firstly, the volume of publications from LMICs is much lower than from higher income countries (HICs).[175] Whilst failure to rescue is a term that has been used to describe care processes in HICs for over 30 years,[34] its use to compare postoperative care globally, including in low-income settings, was first reported less than 10 years ago in 2016 in the International Surgical Outcomes Study.[21] Since then, the term has increasingly been used to describe the higher mortality rates observed in LMICs in patients who develop complications after surgery,[22,129,136,138] but the metric has not been utilised as an outcome measure in research or to benchmark quality of care across regions and countries. In order to identify evidence supporting interventions that reduce rates of failure to rescue, currently, we need to look to HICs. In 2022, Burke et al. published a systematic review of the root causes and improvement strategies for failure to rescue in adult patients.[39] Interventions were categorised into those that improve recognition of the deteriorating patient, those that improve the relay of this information to appropriate teams and those that improve the response. We know that earlier recognition of patients who are deteriorating, for example with conditions like sepsis, leads to better outcomes.[176] Adequate minimum staffing levels,[87,177,178] improved working environments for healthcare staff,[179] nursing staff with postgraduate training,[180] and the implementation of minimum review times all lead to improved recognition of deteriorating patients.[181] Other interventions with evidence include formal teaching on effective utilisation of early warning scores,[182] and the implementation of medical emergency or rapid response teams.[183] To improve the relay of information, the implementation of agreed escalation protocols and handover tools have evidence to support their use.[184] To improve the reaction and response to a deteriorating patient, evidence supports agreeing on response times that reflect the severity of the patient illness and the use of team-based training using simulation.[185]

The limitations of this systematic review include the small number of articles that are available in the published literature from LMICs. The inclusion of the term ‘failure to rescue’ may in itself have limited the identification of interventions that have potential to support improvements of care in this scenario. In order to address this limitation, I would recommend a second more inclusive literature review utilising terms from interventions that have been shown to be effective in HICs, for example ‘early warning score’ or ‘rapid response team’. The review by Burke et al. described above provides a list of improvement strategies that have some evidence to support their use in HICs. It is possible that evidence of their use exists in LMICs but has not been specifically described in connection with failure to rescue. The downside of using more inclusive search terms is that the search results are likely to end up including many thousands of results. However, having learnt that inclusion of the term ‘failure to rescue’ is likely to have limited valuable evidence, a more exhaustive literature review is needed to capture all existing evidence. Other limitations of our review process itself includes the search strategy we used to limit the geographical area and limit the patient population to surgical patients. We utilised general terms such as ‘low-income countries’ or ‘Africa’ but did not specifically include individual country names such as ‘Uganda’ that may fall into this group. A future search strategy could also include the individual names of all countries that fit the definition of an LMIC. Failure to rescue is also a concept that is commonly used in patient populations outside of surgery. Examples include recent publications recommending use of Failure to rescue as a quality measure for sepsis,[186] investigating nursing interventions to reduce rates of Failure to rescue across multiple general hospital wards,[187] and describe the association between nursing staffing levels and Failure to rescue in paediatric and neonatal acute and critical care wards.[188] In the United Kingdom, Martha’s rule now stipulates the right of all patients and their families to escalate care as a way to improve safety and reduce incidences where deterioration is unrecognised and Failure to rescue occurs.[189] It is appropriate to assume interventions to reduce Failure to rescue in one clinical area are likely to be effective in a difficult specialty in the same hospital or similar setting. In order to identify interventions to reduce Failure to rescue after surgery, the search net can be widened to include all inpatient populations.

Interventions are needed to reduce the high mortality rates after surgery in LMICs. To avoid duplication of effort and wastage of limited resources, it is important to identify existing interventions that can be implemented or adapted for a new context. This process is an important step in the development or evaluation of a complex intervention.[142] Our systematic review provides important information that will guide future strategies to address failure to rescue in LMICs. Firstly, given our limited results, we would recommend a repeat systematic review that encompasses wider search terms to identify evidence from LMICs for some of the individual interventions that have been shown to reduce failure to rescue in HICs. Proven interventions that are identified could then be combined into a package or care bundle that can be developed and tested robustly. The studies identified during this review contain valuable lessons regarding the challenges faced during implementation research in a low resource context. These lessons should be incorporated into any future intervention development processes. This review also demonstrates that there is need to invest in the systems and research capacity that generate evidence to improve perioperative care in LMICs.

2.6 Conclusions

There is limited published evidence from LMICs that provides guidance on effective interventions to be implemented to reduce failure to rescue after surgery in these settings. It is possible that my choice of search strategy, whilst technically correct, may have missed relevant literature, especially from across other inpatient disciplines, that can appropriately be applied to the surgical population. I would recommend the literature review is run a second time using a more comprehensive search strategy. This is currently being done by our research group. I have been involved in the development of the updated search terms which are included as appendix 1, screening of identified articles and assimilation of the results. Due to limitations in existing evidence describing interventions to reduce Failure to rescue after surgery, development of new interventions should be planned with appropriate resources that prioritise the generation of robust evidence. This can then be widely disseminated, and interventions scaled to maximise their impact in these regions.

CHAPTER 3 SURGICAL OUTCOMES IN EASTERN UGANDA: A ONE-YEAR OBSERVATIONAL COHORT STUDY

3.1 Introduction

Across sub-Saharan Africa, it is estimated that almost 900 million people (93% of the population) do not have access to safe, affordable, surgical and anaesthesia care.[190] However these estimates are based on mathematical models and, whilst useful at a global level, they do not describe country level variations in surgery and anaesthesia care. Accurate data describing current national surgical activity and patient outcomes should be used to ensure interventions are appropriate in that setting and not scaled blindly.[191] We need greater understanding of the factors contributing to the higher mortality rates after surgery in Africa before strategies to improve access to safe anaesthesia and surgical care are developed.

Despite the Lancet Commission on Global Surgery recommendation to use perioperative mortality as an indicator to describe the state of a country's surgical system, literature reports detailing patient outcomes after surgery in low-income countries, including across Africa, are limited in number.[2] There are also few national reporting systems in place in African countries that are able to track surgical volumes and outcomes despite the fact that these data are routinely documented in paper-based theatre and ward logbooks.[192] Mortality rates in this setting have been described between 0.2% and 6.5%, but significant heterogeneity also exists between the definitions of surgical outcomes used in these studies making interpretation between datasets difficult.[30,193-195] Pragmatic approaches to these definitions, for example in the ASOS study that used a 7-day cohort design, have resulted in limitations when generalising data to individual hospitals and countries.[28,196]

Uganda does not routinely report national surgical volume rates or surgical outcomes. Reports are limited to individual research efforts, often in single centres or specific patient populations. Examples include mortality after laparotomy in adults at Mulago National Referral Hospital reported to be 10.6%,[197] and postoperative mortality rates as high as 36% in a 5-year cohort of neonatal surgical patients and 34% in a cohort of non-traumatic gastroduodenal perforations at a regional hospital in western Uganda.[198,199] If we compare this to the 2% mortality reported in the ASOS study, it is obvious there is large variation across different patient populations. Of note in the three postoperative outcome papers I have described, none include caesarean sections which usually form the majority of surgeries in Uganda and have an associated lower risk of mortality compared to emergency laparotomies.[200,201]

Given the lack of overall surgical volumes and outcomes data across Uganda, I started by understanding and describing the surgical population at Mbale Regional Referral Hospital in eastern Uganda in detail. In this one-year cohort of patients undergoing surgical procedures, I describe the demographics and surgical outcomes. Data collection for the original ASOS study was conducted during this prospective one-year cohort and this allowed me to generate a comparison between the outcomes described.

3.2 Methods

This was a single centre, one-year observational cohort study at Mbale Regional Referral Hospital in eastern Uganda.

3.2.1 Setting

Mbale Regional Referral Hospital has been described in detail in the introduction (Chapter 1). It is a 470-bed hospital that serves 17 districts and a population of more than 4.5 million people in the east of Uganda. It is the busiest of Uganda's 17 regional referral hospitals. At the time of data collection for this study, there were close to 10,000 maternal deliveries and 55,000 in-patient admissions each year.[202] At that time, the hospital had one physician and nine non-physician anaesthesia providers, three obstetricians and three surgeons. It had four functioning operating theatres but no intensive care unit. Patients of any age undergoing either elective or emergency in-patient surgery at Mbale Regional Referral Hospital between 1st October 2016 and 30th September 2017 were eligible for inclusion. Patients undergoing surgery within the hospital's private wing were excluded. Ethics approval to conduct a prospective audit of in-hospital, post-operative outcomes was granted by the Mbale Regional Referral Hospital Research and Ethics Committee.

3.2.2 Data collection

Data describing all surgical procedures and ward admissions are routinely collected at Mbale Regional Referral Hospital using paper logbooks. Theatre logbooks contain demographic information, details of surgical procedures, anaesthesia type and staff involved in the patient's care. Ward logbooks duplicate basic demographic data and also contain information about patient outcomes (discharge, referral etc). We designed an electronic case report form that allowed us to collate data from logbooks using a simple spreadsheet (Numbers, Apple Inc.). Data were anonymised before exporting for further analysis. A single research assistant supported department staff in data collection. Additional data were collected for patients undergoing laparotomy and Caesarean section for shorter periods. This extended dataset was not collected for the entire duration of the study period during to the additional burden of data capture and limited human resources.

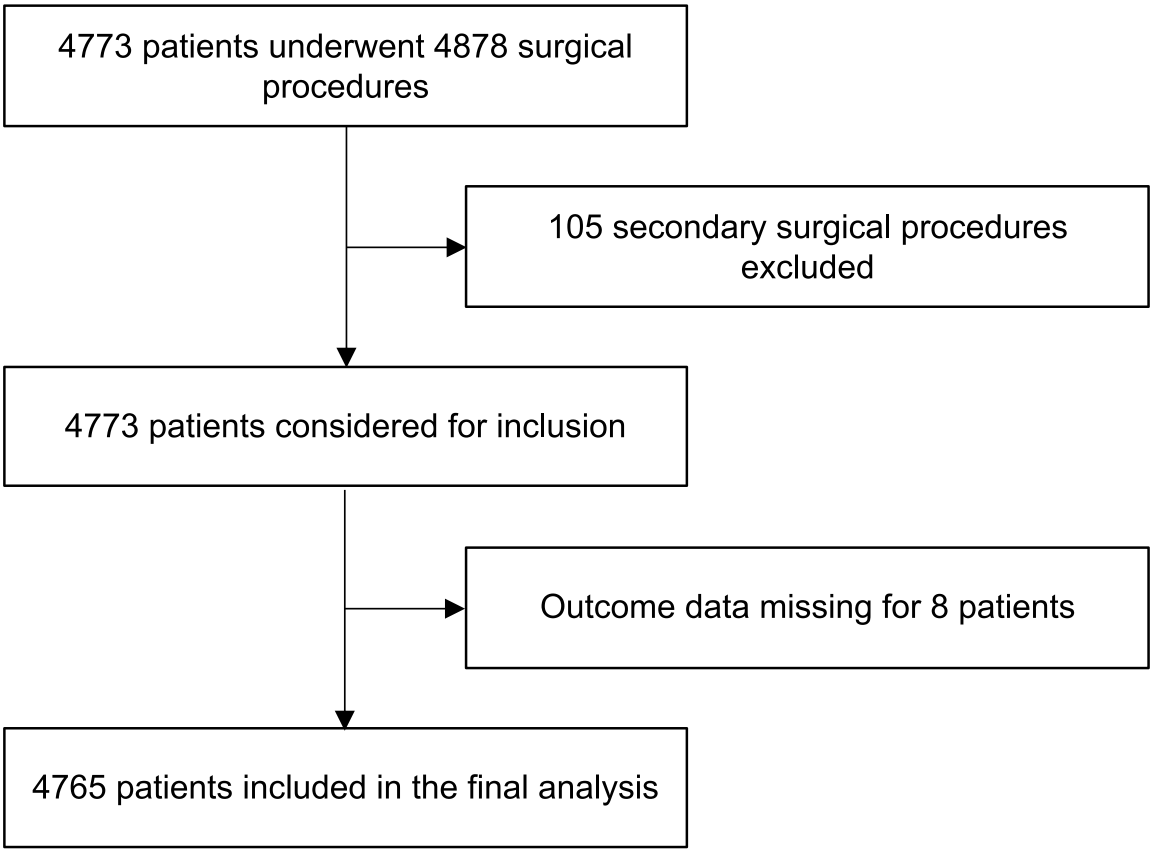
3.2.3 Outcome measures

The primary outcome measure was in-hospital mortality censored at 30 days for patients that remained in hospital. Secondary outcome measures were 30-day in-hospital, post-operative complications among patients undergoing laparotomies and Caesarean section during the supplemental data period.

3.2.4 Statistical analysis

We aimed to recruit all eligible patients over a one-year period. No formal sample size calculation was performed. Data were summarised descriptively using mean (SD) or number (%) as appropriate. The association between four covariates (sex, ASA score, surgical specialty, and urgency of surgery) and 30-day, in-hospital mortality using a multivariable logistic regression model was also assessed. These variables were chosen because of their routine availability in the patients' medical records. Other variables that are often included in surgical risk scoring systems such as P POSUM,[203] for example laboratory tests and physiological parameters, were not routinely available. Multiple imputations to account for missing data in the covariates were used. Patients with missing outcome data were excluded from the analysis. The imputation model included the four covariates, as well as the outcome (30 day in-hospital mortality). Imputations were performed using chained equations, and 10 imputations were used.[204] Results from each imputed dataset were combined using Rubin's Rules. These results are reported in Table 5 as adjusted odds ratio with associated p-values and 95% confidence intervals. In order to compare the impact of our multiple imputation model, a separate analysis was run excluding patients without a complete record. This comparison is presented in Table 8. My findings are presented in accordance with the STROBE guidelines for reporting of cohort studies.[205]

Figure 13. STROBE flow chart describing inclusion criteria



3.3 Results

3.3.1 Demographics

Data describing 4773 patients were collected at Mbale Regional Referral Hospital between October 2016 and September 2017. This represented 100% of surgical procedures conducted and recorded in theatre logbooks within the hospital's main operating theatres and obstetric theatre during the one-year study period. 3754 (79.0%) patients were women, and the mean (SD) age of all patients was 27.9 (15.3) years. 773 (16.2%) patients were children under 18 years of age, 266 (5.6%) were under five years of age and 24 (0.5%) were neonates. Three quarters of surgical procedures were emergency cases (3501, 73.8%) and the majority were ASA class I and II (4259, 89.4%). Demographic data is represented in Table 5.

3.3.2 Data completeness

8 (0.2%) patients were missing outcomes and were therefore excluded from the data analysis. The number of patients missing data for additional individual variables included in the main analysis ranged from 5 (0.1%, surgical procedure) to 97 (2.0%, ASA score) (see Table 4 below). To evaluate the impact of the multiple imputation approach, 110 patients with any missing variable were excluded from an analysis of complete cases. These results are available in Table 8. There was no difference in significance levels and variation of the reported odds ratios was minimal.

Table 4. Surgical outcomes cohort - missing data

	Missing data – n (%)
Gender	12 (0.25)
ASA Score	97 (2.04)
Surgical specialty	2 (0.04)
Urgency of surgery	20 (0.42)
Number of patients excluded from complete case analysis	110 (2.31)

3.3.3 Surgical procedures

A total of 4878 surgical procedures were conducted on 4773 patients, with an average of 397 per month (see Figure 14). The busiest department was obstetrics and gynaecology conducting 3158 surgeries (66.3%), followed by general surgery who conducted 1044 procedures (21.9%). The 10 commonest surgical procedures are described in Table 3. Caesarean section was the most common procedure (2634, 55.3%) followed by laparotomy (304, 6.4%) and hernia surgery (142, 3.0%).

3.3.4 Clinical outcomes

A total of 93 (2.0%) patients died before hospital discharge. Mortality was more common in children less than five years (7.1%) compared to older children (5 – 18 years, 0.8%) and adults (1.8%). Patients with an ASA score of IV were over 100 times more likely to die than ASA I patients but with such a small dataset, this estimate may be imprecise. (See Table 5). 12/1244 (1.0%) patients undergoing elective surgery died before hospital discharge compared to 81/3501 (2.3%) undergoing emergency surgery. In-hospital mortality for the commonest surgical procedures varied between 0.3% (caesarean section) and 22.4% (laparotomy). When I looked at hospital outcomes in more detail (Table 6), in addition to those that died, 4653 (95.5%) were discharged home alive, 14 (0.3%) patients were still alive in hospital at 30 days and 4 (0.1%) patients were referred to the national referral hospital in Kampala. 104 (2.1%) surgical procedures that took place were re-operations. Of the patients that died, 10 (12.0%) died in theatre and 73 (88.0%) died on the postoperative wards. A third of these (31.5%) occurred in the first 24 hours after surgery. 10 patients in this cohort were missing data on the timing of their death.

Table 5. Baseline patient characteristics and in-hospital 30-day mortality.

	No. of patients	Patients who survived	Patients who died
All patients	4765 (100.0)	4672/4765 (98.0)	93/4765 (2.0)
Age			
Age, years, mean (SD)	27.9 (15.3)	27.7 (15.0)	33.5 (25.6)
Age, years, median (range)	25.0 (0.0 – 96.0)	25.0 (0.0 – 96.0)	30.0 (0.0 – 92.0)
< 29 days	24 (0.5)	21 (87.5)	3 (12.5)
29 days – 5 years	242 (5.1)	226 (93.4)	16 (6.6)
5 – 18 years	507 (10.6)	503 (99.2)	4 (0.8)
Common surgical procedures			
Caesarean section	2634 (55.3)	2626 (99.7)	8 (0.3)
Laparotomy	304 (6.4)	236 (77.6)	68 (22.4)
Hernia operations	142 (3.0)	140 (98.6)	2 (1.4)
Open reduction & internal fixation	87 (1.8)	86 (98.9)	1 (1.1)
Hysterectomy	79 (1.7)	78 (98.7)	1 (1.3)
Incision and drainage	60 (1.3)	58 (96.7)	2 (3.3)
Salpingectomy	40 (0.8)	40 (100.0)	0 (0.0)
External fixation	40 (0.8)	40 (100.0)	0 (0.0)
Primary wound closure	39 (0.8)	39 (100.0)	0 (0.0)
Sequestrectomy	34 (0.7)	34 (100.0)	0 (0.0)

Data presented as n (%) unless otherwise stated. Patients with data incomplete for that category were excluded.

Table 6. Time of death after surgery and in-hospital outcomes.

	No. of patients n (%)
Time of death after surgery	
Died in theatre	10 (12.0)
Died on ward (<24 hours)	23 (27.7)
Died on ward (>24 hours)	50 (60.2)
Total deaths	83 (100.0)
Missing data	10/93 (10.8)
In-hospital outcomes	
Discharge	4652 (97.6)
Referral	4 (0.1)
Alive in-hospital at 30 days	14 (0.3)
Death	93 (2.0)
Total	4765 (100.0)
Surgical procedures that were re-operations	104/4878 (2.1)

Patients with missing data for time of death were excluded from that analysis

Figure 14. Trends in monthly surgical procedure rates and monthly mortality rates at Mbale Regional Referral Hospital. Dashed lines represent yearly average rates for procedure volume and mortality respectively.

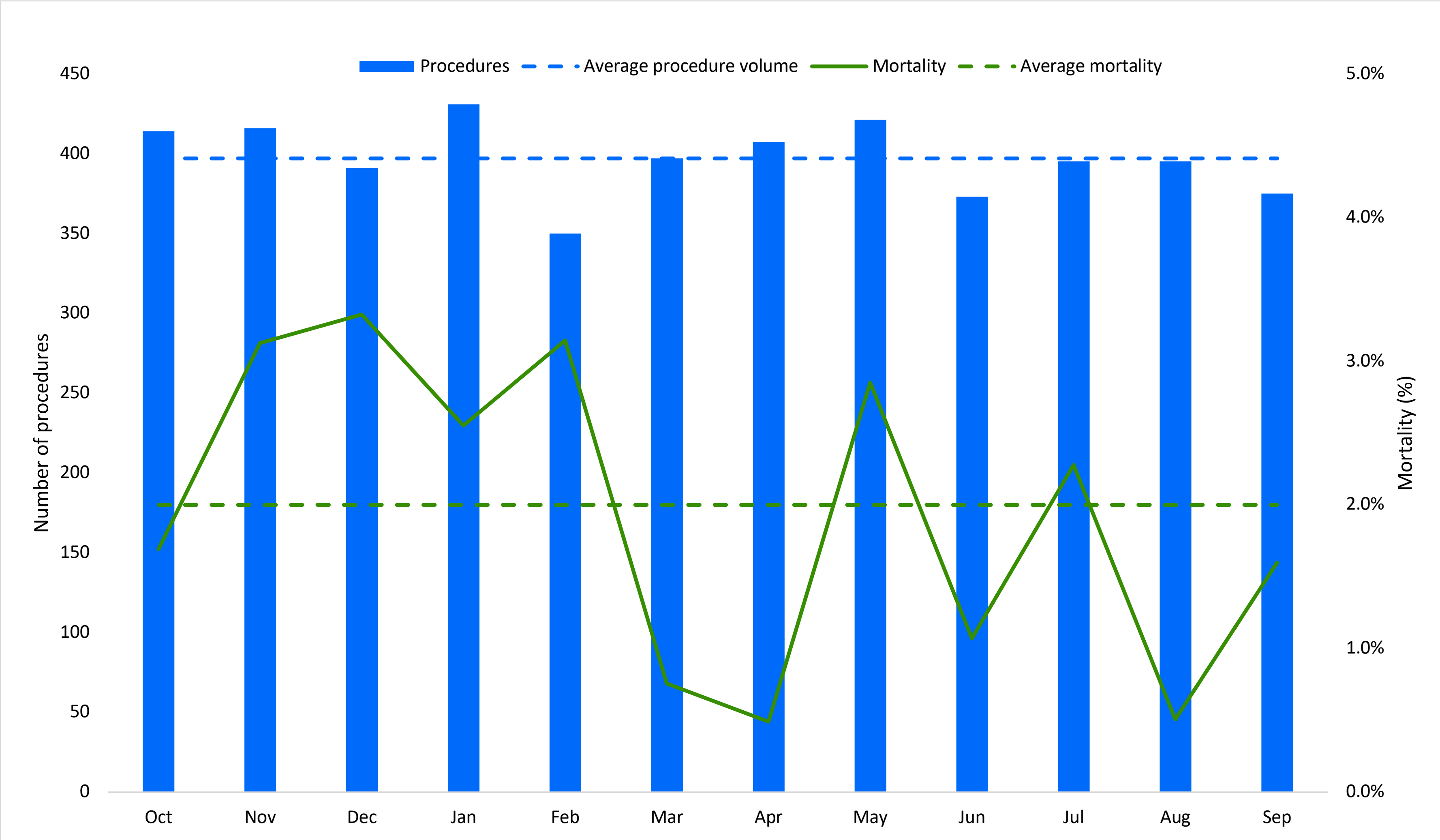


Figure 15. Comparison of in-hospital post-operative mortality data from Mbale Regional Referral Hospital with mortality following emergency and elective surgery across Africa. ASOS = African Surgical Outcomes Study.

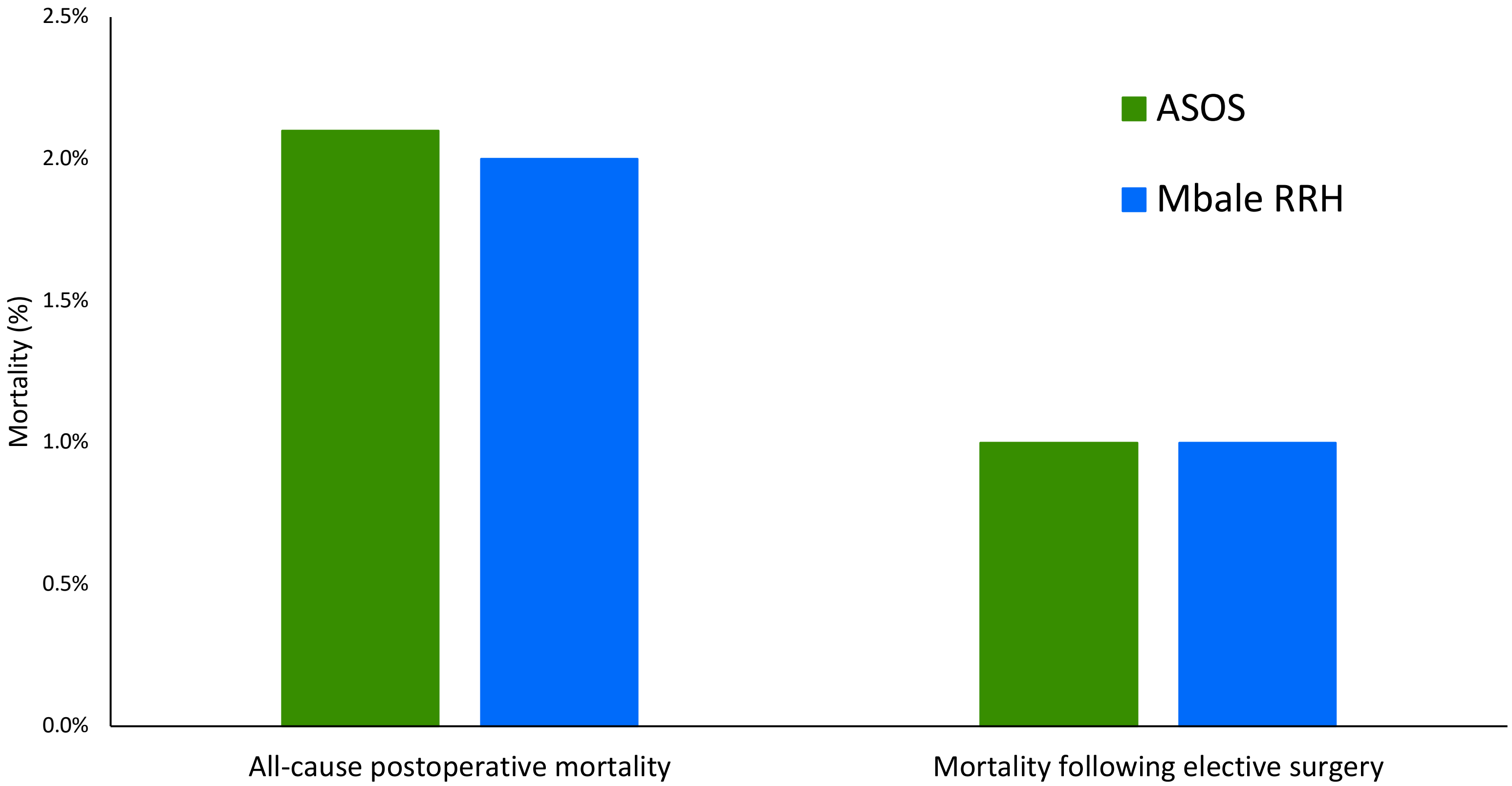


Table 7. Factors associated with 30-day, in-hospital mortality (multiple imputation model).

	Alive	Died	Odds ratio (95% CI)	p-value
Men	950/999 (95.10)	49/999 (4.90)	Reference	-
Women	3710/3754 (98.83)	44/3754 (1.17)	0.65 (0.36 to 1.18)	0.16
ASA score				
I	1918/1922 (99.79)	4/1922 (0.21)	Reference	-
II	2313/2337 (98.97)	24/2337 (1.03)	5.94 (2.02 to 17.50)	0.001
III	314/353 (88.95)	39/353 (11.05)	28.66 (9.72 to 84.57)	<0.001
IV	35/56 (62.50)	21/56 (37.50)	116.79 (35.60 to 383.16)	<0.001
Surgical specialty				
Obstetrics	2860/2878 (99.37)	18/2878 (0.63)	Reference	-
General	980/1044 (93.87)	64/1044 (6.13)	4.34 (2.02 to 9.30)	<0.001
ENT	140/141 (99.29)	1/141 (0.71)	0.61 (0.08 to 5.04)	0.65
Gynaecology	272/280 (97.14)	8/280 (2.86)	3.90 (1.51 to 10.04)	0.005
Orthopaedics	418/420 (99.52)	2/420 (0.48)	0.71 (0.14 to 3.49)	0.67
Urgency				
Elective	1232/1244 (99.04)	12/1244 (0.96)	Reference	-
Emergency	3420/3501 (97.69)	81/3501 (2.31)	1.52 (0.74 to 3.15)	0.26

ASA = American Society of Anesthesiologists; ENT = Ear, Nose and Throat. n/N (%) unless otherwise stated

Table 8. Surgical outcomes cohort - complete case and multiple imputation comparison

	Complete case		Multiple imputation	
	Odds ratio (95% CI)	**p-value**	**Odds ratio (95% CI)**	**p-value**
Women	0.62 (0.34 to 1.14)	0.13	0.65 (0.36 to 1.18)	0.16
ASA score				
II	6.26 (2.10 to 18.67)	0.001	5.94 (2.02 to 17.50)	0.001
III	28.57 (9.37 to 87.17)	<0.001	28.66 (9.72 to 84.57)	<0.001
IV	113.80 (33.62 to 385.27)	<0.001	116.79 (35.60 to 383.16)	<0.001
Surgical specialty				
General	5.48 (2.44 to 12.31)	<0.001	4.34 (2.02 to 9.30)	<0.001
ENT	0.80 (0.10 to 6.64)	0.84	0.61 (0.08 to 5.04)	0.65
Gynaecology	5.24 (1.97 to 13.91)	0.001	3.90 (1.51 to 10.04)	0.005
Orthopaedics	0.94 (0.19 to 4.71)	0.94	0.71 (0.14 to 3.49)	0.67
Emergency surgery	1.70 (0.80 to 3.58)	0.17	1.52 (0.74 to 3.15)	0.26

3.3.5 Complications following laparotomy

Complications data were collected over a period of three months for all patients undergoing laparotomies (n = 107). Data are presented in Table 7. The mean (SD) age of these patients undergoing laparotomy was 32.0 (18.6) years. 81.7% (58/71) of laparotomies were conducted by doctors without any specialist training in surgery. Anaesthesia for 90.2% (74/82) of these cases was provided by non-physician anaesthesia providers. 85/107 (79.4%) were conducted under general anaesthetic and the remainder under spinal anaesthesia. Antibiotics were given in theatre for 55/107 (51.4%) of cases and the surgical safety checklist was used during 19/107 (17.8%). A total of 18 (16.8%) patients undergoing laparotomy developed post-operative complications. There were 10 (9.4%) infectious complications and 10 (9.4%) cardiac arrests. Mortality following cardiac arrest was 100%.

3.3.6 Complications following Caesarean section

Complications data were collected over a period of two months for all patients undergoing caesarean section (n = 412). Data are presented in Table 9. The mean (SD) age of these patients undergoing caesarean section was 25.4 (6.3) years. 84.7% (349/412) of caesarean sections were conducted by doctors without any specialist training in surgery. Anaesthesia for 99.2% (359/362) of these cases was provided by non-physician anaesthesia providers. 391/412 (94.9%) were conducted under spinal anaesthesia and the remainder under general anaesthesia. Antibiotics were given in theatre for 138/412 (33.5%) of cases, and the surgical safety checklist was used during 150/412 (36.4%). A total of 24 (6.1%) patients undergoing caesarean section developed post-operative complications. There were 23 (5.6%) infectious complications and 2 (0.5%) cardiovascular complications (one pulmonary embolus and one cardiac arrest). Mortality following cardiac arrest was 100%.

Table 9. Additional baseline characteristics collected for subsets of patients following laparotomy and caesarean section and in-hospital postoperative complications.

	Laparotomy	Caesarean Section
Total patients	107/304 (35.2)	412/2634 (15.6)
Age, mean (SD)	31.96 (18.6)	25.43 (6.3)
Senior surgeon present		
Consultant	3/71 (4.2)	3/360 (0.8)
Medical Officer Special Grade	10/71 (14.1)	8/360 (2.2)
Medical Officer	52/71 (73.2)	41/360 (11.4)
Intern	6/71 (8.5)	308/360 (85.6)
Senior anaesthesia provider present		
Physician anaesthetist	8/82 (9.8)	3/362 (0.8)
Anaesthetic Officer (non-physician)	74/82 (90.2)	359/362 (99.2)
Anaesthetic technique		
General anaesthetic	85/107 (79.4)	21/412 (5.1)
Spinal anaesthetic	22/107 (20.6)	391/412 (94.9)
Endotracheal tube	67/67 (100.0)	4/21 (19.1)
Antibiotics given (Yes)	55/107 (51.4)	138/412 (33.5)
Surgical Checklist Used (Yes)	19/107 (17.8)	150/412 (36.4)
Complications		
Complications	18/107 (16.8)	24/412 (5.8)
Mortality	10/107 (9.4)	1/412 (0.2)
Death following a postoperative complication	10/18 (55.6)	1/24 (4.2)
Infectious complications		
Surgical site	5/107 (4.7)	19/412 (4.6)
Body cavity	3/107 (2.8)	2/412 (0.5)
Pneumonia	1/107 (0.9)	0/412 (0.0)
Blood	1/107 (0.9)	2/412 (0.5)
Total	10/107 (9.4)	23/412 (5.6)
Cardiovascular complications		
Pulmonary embolus	0/107 (0.0)	1/412 (0.2)
Cardiac arrest	10/107 (9.4)	1/412 (0.2)
Total	10/107 (9.4)	2/412 (0.5)
Other complications		
Unplanned return to theatre	2/107 (1.9)	0/412 (0.0)

Data presented as n (%) unless otherwise stated

3.4 Discussion

In this cohort of surgical patients treated at a regional hospital in eastern Uganda, overall in-hospital postoperative mortality was 2.0%. Mortality rates were more than three times higher among children under five. Patients with higher ASA scores were more likely to die and one-fifth of patients who underwent a laparotomy died. In patients undergoing laparotomy or caesarean section, the overall number of post-operative complications was small, however, mortality following cardiac arrest was 100%. Notably, almost 90% of patients who died, did so after surgery on the postoperative wards, suggesting that improvements in postoperative care may result in a significant reduction in the mortality associated with surgical procedures in this setting.

Mortality rates from this one-year cohort of patients are remarkably consistent with ASOS data, both in all patients and those undergoing elective surgery (Figure 15). Mbale Regional Referral Hospital contributed to ASOS, collecting data over seven days during the same study period. This cohort therefore serves to validate the reliability of the ASOS outcomes. We describe mortality in accordance with the recommendations of the Lancet Commission on Global Surgery, including all patients within our hospital who underwent a surgical procedure in an operating theatre. 60% of all our surgical procedures were obstetric. Although this is likely to be a representative statistic for many hospitals in low-income countries, it is higher than many published rates. A systematic review from 2023 describes an average of 30.1% of total surgeries being caesarean sections across 26 published articles.[206] However, this raises difficulty when directly comparing our postoperative mortality with published literature in other hospitals in similar settings. Postoperative mortality at a regional referral hospital in western Uganda has been reported as 2.4%. Although data collection there was limited to a four-week period, the overall figure is comparable.[192] A teaching hospital in Rwanda describes their perioperative mortality rate as 6.5%, three times higher than ours, but only included procedures involving surgical residents in their study.[194] If obstetric patients are excluded from our cohort, our mortality rate doubles to 4%. This is analogous to mortality rates following elective and emergency surgery in Europe (4%),[207] but less than a cohort of over 10,000 patients in 58 high, middle and low-income countries undergoing emergency abdominal surgery who had an overall mortality rate at 30 days of 5.4%.[30] In a population of 45,000 patients undergoing elective surgery in high, middle and low-income countries the in-hospital mortality rate was lower at 0.5%.[208] In comparison, following elective surgery in our hospital, patients are twice as likely to die despite, on average, being 30 years younger. This reinforces the recently published African Surgical Outcomes Study (ASOS) where patients in Africa were twice as likely to die after surgery when compared with the global average for postoperative deaths.[28] A major deficit exists in the specialist surgical workforce in many parts of the world.[209] At Mbale Regional Referral Hospital, seven obstetric, surgery and anaesthesia specialists cover a catchment population of 4.5 million. Over 84% of laparotomies and caesarean sections are conducted by doctors without specialist training in surgery and over 97% of anaesthetics were performed by non-physician anaesthesia providers. Although safe surgical and anaesthesia care has only recently come into focus at a global level, previous interventions aimed at improving outcomes have focused on making operative procedures safer.[210,211] Almost 90% of the postoperative deaths in our hospital occurred on the postoperative wards after surgery. In the African Surgical Outcomes Study, more than 95% of patients who died did so in the postoperative period.[28] It is known that poor patient outcomes commonly result from a failure to promptly recognise deteriorating patients on the wards.[212] It has also been suggested that failure to rescue patients following the development of postoperative complications may be a better measure of the quality of perioperative care within a health facility.[129] In our cohort, no patients survived following a cardiac arrest. In the International Surgical Outcomes Study, conducted mainly in high and middle-income countries, 40% of cardiac arrest patients survived.[213] This suggests that post-operative care in our setting, in particular ward care, should be a focus for future interventions. This data strengthens the case for interventions in this area to help reduce preventable mortality.

Patients given an ASA classification of III or IV in this cohort are more likely to die. 75% of the ASA IV patients underwent an emergency laparotomy and were given an ASA IV classification based on their acute illness rather than underlying chronic disease like the score is designed to be used. Whilst this is not strictly accurate, it may have served as a crude risk assessment tool. Since this period of data collection, the ASOS dataset has been used to generate a simple risk calculator that can now be used to more accurately identify patients who are at greater risk of post operative complications and mortality.[174] Following completion of this analysis, data was presented to hospital staff and has been used to inform interventions to improve patient care. One example is the establishment of a high dependency unit for surgical patients. The ASOS surgical risk score is used to identify high risk patients after surgery (ASOS Risk Score >10) and these patients are admitted to a separate ward that has a nurse-to-patient ratio of 1:5 and access to additional patient monitors and other equipment (for example oxygen concentrator and suction machine). There was a large monthly variation in our mortality rates. Figure 14 demonstrates on average, higher rates during the period November-February with a dramatic reduction during March and April. I did not set out to investigate seasonal variation in outcomes and am unable to clearly identify causal factors. More work would be needed to track this variation over time to see to see if this was natural variation or triggered by specific variables.

This dataset has several strengths and limitations. Its major strength is that it is the first description of surgical volumes and outcomes in Uganda that describes a cohort over a period of one year. Most other datasets described in the literature have short periods of data collection which are then extrapolated to give representative figures. I also describe the entire surgical cohort at Mbale Regional Referral Hospital and do not focus on one specialist patient area. This paints an accurate picture of the surgical capacity at the hospital and also the distribution of surgical categories that currently take place. There is a huge burden of untreated surgical disease in Uganda, and we suspect a significant number of these patients never reach theatre because of delays seeking care, delays travelling to health facilities and delays between presentation to hospital and reaching theatre.[213,214] One limitation is that looking at postoperative mortality alone has limited the data and means I was unable to measure these delays accessing care. I am likely to be missing a significant proportion of the mortality associated with overall surgical disease in this setting because we do not capture deaths that occur before the operating theatre. I also consider the low rates of postoperative complications in our cohort to be a limitation. In Mbale Regional Referral Hospital, like many low-income settings, documentation of postoperative reviews is often poor, complications are not sought after, and laboratory tests or radiology examinations are often unavailable to confirm complications when they are suspected. I have relied on data collection from logbooks and patient medical records. If I had conducted routine reviews of all postoperative patients, I may have identified additional complications. This was not feasible at the time due to resource limitations for this study. A previous study in Uganda has also shown only 94% of surgical related deaths to be recorded in logbooks.[192] It is possible that I may have missed some postoperative deaths. Paper based logbooks are routinely used in all health facilities in Uganda to help collate aggregate data to provide feedback to the Ministry of Health. This method of data collection is time consuming and places significant burden on staff who are already working in challenging conditions, for example nursing to patient ratios of 1:40 in the general surgical wards. It is also a barrier to the routine use of this data for quality improvement initiatives at health facility level. Although I successfully managed to collate this level of data for our patients, it was only with the assistance of a data assistant. A better alternative for future work would be to replace paper logbooks with an electronic registry. The often-reported challenges to this, of poor staff training, lack of regular power supply and inadequate infrastructure can all be overcome with appropriate and focused investment in time and suitable technology.[215-217]

3.5 Conclusion

I have successfully described a one-year cohort of patients undergoing surgery at Mbale Regional Referral Hospital, including in-hospital outcomes. These data are likely to be generalisable to similar health facilities in the region, and demonstrate that patients who die following surgery are more likely to do so on the hospital ward in the days following their operation, especially if they are higher risk (in this cohort, a higher ASA classification). I have demonstrated that, with the appropriate human resources, prospective longitudinal data collection is both feasible and provides useful data outputs that can be used to improve patient care. Mortality rates after surgery at Mbale Regional Referral Hospital are, like the ASOS study, twice that found in HICs despite a younger healthier population. This study provides important baseline data on which to base the development of an intervention to improve outcomes after surgery.

Future work following this cohort study should focus on two areas. The first is the routine collection and use of epidemiological data to understand trends over time. Such a registry should be electronic to improve access to data in near real time for clinicians on the front line. Electronic healthcare registries have previously been described as one solution to help improve quality of care in low-resource settings and I agree that this is an area that needs to be prioritised.[218] The second area to focus on next should be the iterative development of a complex intervention, developed in accordance with existing intervention research guidelines, to reduce postoperative mortality rates. Given the complexity of healthcare systems found in LMICs, including Uganda, it is likely the intervention development will need to be a multistage process with an opportunity to pilot any interventions before they are tested in a large multi-site effectiveness trial.

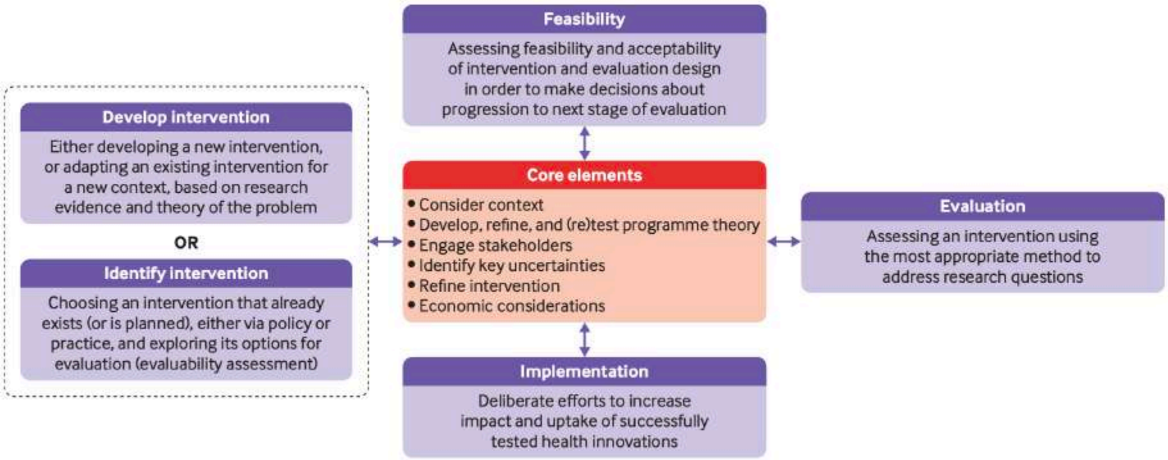
CHAPTER 4 DEVELOPMENT OF A COMPLEX INTERVENTION TO REDUCE FAILURE TO RESCUE IN HOSPITALS IN UGANDA

4.1 Introduction

Interventions can be described as complex for several reasons. The intervention itself may have multiple components or require a high level of knowledge or skill to implement. Alternatively, the setting that the intervention is being introduced into may involve multiple interacting components that rely on human factors, systems and other resources to function effectively. Health facilities are good examples of a complex environment where even the simplest of interventions may be difficult to successfully introduce. Human factors are perhaps the dominant reason that make healthcare settings so complex and interventions to improve patient care often focus on this area.[219] These human factors include human capabilities, needs and performance and they all affect patient care and outcomes. I have already described several in the context of failure to rescue, for example, the skill of recognising deteriorating vital signs, the communication of the deteriorating patient to the relevant teams and the workplace environment that can affect this, and an adequate and timely response.

In 2000, the UK Medical Research Council first published a framework for researchers on the development and evaluation of complex interventions and this has been revised several times since then, most recently in 2021.[141,142,144] The framework describes a common set of core elements illustrated in red in Figure 16 below. Regardless of the stage in the complex intervention research journey that one is in, incorporating these into the intervention development and evaluation will improve its effectiveness. I undertook a series of smaller research activities and tasks to inform the design of my complex intervention. In this chapter I describe each of these steps in turn, working through the design challenges in a sequential manner and incorporating this learning into my pilot trial.

Figure 16. Skivington's framework for developing and evaluating complex interventions



4.2 Postoperative patient monitoring at Mbale Regional Referral Hospital

'The patient changed condition'

This phrase is synonymous with the moments before patients deteriorate and die on the wards at many health facilities across Uganda. Personal experience from my time working in the surgical wards at Mbale Regional Referral Hospital saw both family members and healthcare workers using the same way to describe events that led to them losing their patients. Despite the apparent sudden nature of these deaths, we know that patients do not usually suddenly drop dead. Instead, we see a gradual deterioration over time, that if not recognised, leads to death.[220] Physiological deterioration is often not obviously visible and so vital signs monitoring of patients is a critical step in the early recognition of these deteriorating patients. In many countries around the world, like the UK, hospitals use early warning scores that are effective at detecting this physiological deterioration. These scores, like the National Early Warning Score (NEWS) allocate weighted points to individual vital signs depending on their level of derangement. These are then aggregated to give a score and the score used to trigger a response.[221]

Uganda has huge health workforce gaps manifesting at times in nurse-to-patient ratios of 1:50. There is often one single nurse on duty on the ward with responsibility for all duties. This includes administration of medications and treatment, admission of new patients, patient discharges, ward management duties for example ordering of stores and vital signs monitoring of patients. It does not take much imagination to realise this workload is overwhelming and therefore some aspects of care do not get completed.

4.2.1 A clinical audit of baseline vital signs monitoring

During our one-year cohort study of surgical patients, there were anecdotal reports of vital signs monitoring on the wards being rare. In order to understand whether this was a potential contributory factor to late recognition of deteriorating patients, I undertook a clinical audit of both rates of vital signs monitoring on the surgical and obstetric wards and staff to patient ratios during the different shifts.

Methods

The total number of inpatients on the four surgical wards at Mbale Regional Referral Hospital were documented for each shift (day, evening and night) by the nurses on duty. In addition, data on the number of nurses on duty for each shift was collated from the duty rota. For the rates of vital signs monitoring, a retrospective chart review was conducted for every patient who had surgery and was admitted to one of the postoperative wards during the data collection period (May 2018). Data was collected on the number of each of the vital signs (heart rate, blood pressure, respiratory rate, oxygen saturation, temperature and conscious level) that were taken and documented anywhere in the patients file during the first 48 hours after surgery. Data was recorded in an Excel spreadsheet and analysis conducted using R studio.

Results

A total of 244 patients were included in the clinical audit of which 86% (210/244) were female. The greatest proportion of patients were included from the postnatal ward following caesarean section.

Frequency of vital signs monitoring during the first 48 hours after surgery was generally poor. On the orthopaedic and ENT ward, no vital signs monitoring took place. Heart rate and blood pressure were documented most frequently but the median frequency was still only 2 documented vital signs on the gynaecology and postnatal wards. The other vital signs were rarely documented. Nurse to patient ratios ranged from 1:6 during the daytime on the gynaecology ward to 1:32 on the general surgery ward at night. The highest nurse to patient ratios were recorded on the general surgery ward with a ratio of 1:52. Table 10 shows the distribution of ratios across the inpatient surgical wards at Mbale Regional Referral Hospital.

Discussion

My audit of vital signs monitoring confirmed that there were significant gaps, in some instances, no vital signs monitoring took place. Following discussion with the nursing staff and documentation of the high nurse to patient ratios, the common reason for the lack of vital signs monitoring was the overwhelming workload. Of all the tasks the nursing staff had to do, vital signs monitoring was given the lowest priority. Ways to increase the frequency of vital signs monitoring were a priority for improvement so that deteriorating patients could be detected sooner.

Table 10. Baseline vital signs and staffing levels data at Mbale Regional Referral Hospital.

Ward	Orthopaedic & ENT	General Surgery	Gynaecology	Postnatal
Female n (%)	7/18 (39)	8/31 (26)	31/31 (100)	164/164 (100)
Age	27 (5-74)	35 (0.25-87)	29 (19-46)	24 (14-38)
Rates of vital signs monitoring				
Heart rate	0 (0-0)	0 (0-3)	2 (0-13)	3 (0-13)
Blood pressure	0 (0-0)	0 (0-5)	2 (0-17)	3 (0-13)
Respiratory rate	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-0)
Oxygen saturations	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-1)
Temperature	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-0)
Conscious level	0 (0-0)	0 (0-1)	0 (0-4)	0 (0-7)
Trained staff on duty				
Day	1 (1-2)	2 (1-4)	3 (1-5)	3 (1-4)
Evening	1 (1-1)	1 (0-2)	1 (1-2)	2 (1-2)
Night	1 (1-1)	1 (1-2)	1 (1-1)	1 (1-2)
Inpatients on ward				
Day	20 (14-30)	34 (19-50)	18 (9-28)	35 (18-52)
Evening	19 (15-30)	34 (21-50)	18 (9-28)	39 (19-54)
Night	21 (15-30)	33 (19-52)	18 (9-28)	48 (27-67)
Patient to staff ratio				
Day	18:1	16:1	6:1	12:1
Evening	20:1	31:1	12:1	23:1
Night	21:1	32:1	18:1	37:1

Data presented as median (range) frequency over 48-hour period unless otherwise indicated.

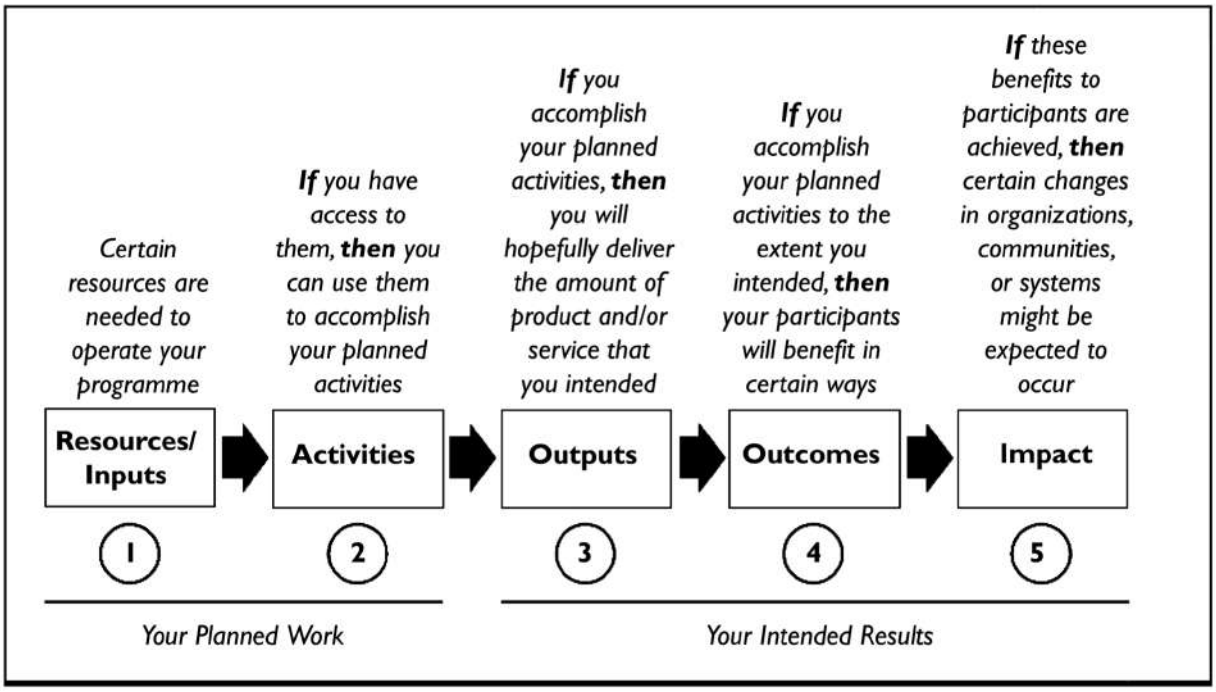
4.3 Family supplemented patient monitoring: programme theory

Following the decision to develop and test an intervention involving family members to improve rates of vital signs monitoring for patients after surgery, the next step involved the development of a robust programme theory. Programme theories are commonly used during the development and evaluation of healthcare interventions. They provide an overarching model or theory describing how the intervention is expected to work and allow comparison between expected and observed behaviours. Formal review of a programme theory following pilot studies can contribute to improved intervention design when tested at a larger scale.

In implementation science, understanding that the context will influence the implementation outcome is very important. Study to study variations in outcomes are often the result of contextual variations.[222-224] Across multiple implementation science frameworks and theories, several words are used interchangeably to describe this context. Alternatives to the word context include 'environment' and 'setting'.[225] The Consolidated Framework for Interventional Research (CFIR) was developed to provide a pragmatic structure for approaching interacting, multi-level constructs that combined and consolidated existing implementation theories that often overlapped but were not consistent in what they included.[171] This is the framework that I have used in my analysis of qualitative process evaluation data. The consolidated framework for interventional research uses the terms inner and outer setting. These are described alongside three other major domains that influence intervention effectiveness (intervention characteristics, characteristics of individuals and process).[171] The outer setting includes the economic, political and social context whereas the inner setting usually describes culture, readiness, communications and structural characteristics.[171] Whilst this framework differentiates between these two domains, in reality, the line between these two contexts is not always clear.

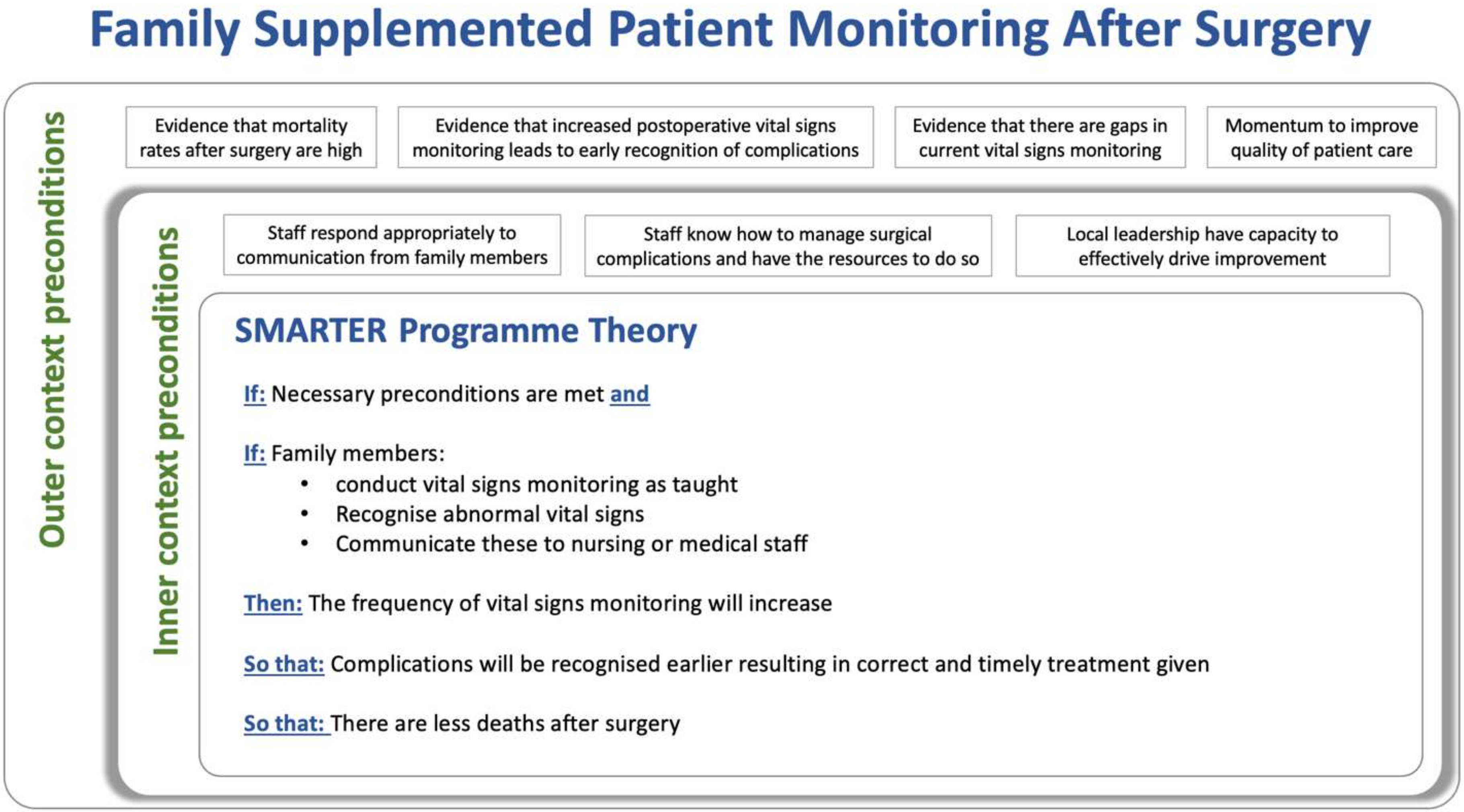
A programme theory explains how an intervention is understood to contribute to a chain of results that produce the intended or actual results. There are different processes that can be used to develop a programme theory. Many logic models used in programme theory show a single, causal path that is linear. These often focus on five categories. An example is the simple logic model that was published by the Kellog foundation in 2004 and is illustrated in Figure 17 below.[226] The challenge we face is that most processes in life are not simple and a programme theory that oversimplifies the reality on the ground is unlikely to be useful. For example, it is likely that for a simple logic model to work as expected, multiple other factors need to be in place first. Whilst these may be obvious, there may be huge heterogeneity across different settings, limiting the ability to extrapolate findings more generally or across countries and contexts.

Figure 17. A simple logic model (W.K. Kellog Foundation, 2004)



To address this, a programme theory can take into account some of the contextual factors that may influence the success of any individual intervention. One approach to this is to use articulating mental models. This involves talking with key informants, either individually or in groups, to identify how they understand an intervention may work. Key informants can include anyone within the context of the proposed intervention. In my case this included the research team, the healthcare workers and the patients and their family members. A set of leading questions can be used to draw out ideas. Funnell and Rogers describe some examples in their book 'Purposeful programme theory' that I have adapted to my intervention. These include: What are the current barriers to monitoring of patients on the wards? How would you see this programme overcoming these barriers? What else needs to happen? Who else needs to be involved and how?[227] Using this approach I developed my programme theory that is illustrated in Figure 18.

Figure 18. SMARTER programme theory



Provided conditions in the outer and inner contexts have been met and provided the family members we involved in the vital signs monitoring intervention do what we expect them to, then vital signs monitoring frequency should increase. This would then allow complications after surgery to be detected at an earlier stage and enable healthcare staff to intervene in a timely manner. This pathway would then result in a reduction in the number of deaths after surgery. Our outer context preconditions were based on our assumption that a robust evidence base was needed to influence change in a healthcare setting. We know that evidence-based practice leads to improved patient safety, quality of care and patient outcomes.[228] We also know that healthcare workers respond more positively if they understand the rational, and therefore value a proposed change.[229] Work by our colleagues across Africa and others provide the evidence to support our outer context preconditions,[28,230,231] with local audit work described earlier in this chapter showing gaps in vital signs monitoring with our study setting.

4.4 Intervention development, refinement and stakeholder engagement.

Quality improvement (QI) interventions can be seen has having a ‘hard core’, the clinical processes or practices that are the focus of improvement, and a ‘soft periphery’, the improvement methods that enable change to occur.[232] For implementation research to be most useful, it needs to take into account complexities from both the components of the intervention and how they interact with the surrounding settings. My intervention, to train family members to perform basic vital signs monitoring for their patient, identify when these are abnormal and communicate this to ward staff, grew out of the programme theory that family members were an underutilised resource in our hospital. It was however unknown whether family members would be willing and able to take and document simple vital signs.

The intervention was developed using an iterative process with stakeholder engagement from medical and nursing teams in the hospital and family members themselves. Although I did not have a formal community engagement and involvement strategy, this stakeholder engagement was an informal approach to ensure all relevant stakeholders could contribute to the development of the intervention. In particular, I met with nurses from the surgical wards, describing what I was planning to do and listened to their guidance and feedback, In the early stages I spoke with family members on the wards to see if they would be willing to assist with vital signs monitoring. Later during the intervention development, I also informally discussed use of the pulse oximeter with two groups of family members on the surgical high dependency ward to see whether they thought they would be able to use it and ask for feedback how best to train lay people in its use. Whilst healthcare workers undergo extensive training to enable them to take and make appropriate interpretations of vital signs such as blood pressure, heart rate and respiratory rate, in many countries auxiliary staff are employed to help with the increasing workloads of highly trained staff. Examples include nursing assistants in the UK. These staff have all the appropriate training to safely take patient vital signs but are empowered to ask for help from nursing staff to help interpret vital signs that are abnormal. Due to the large volumes of patients and high turnover, especially on wards such as the postnatal ward at Mbale Regional Referral Hospital, where the length of stay of patients is usually 1-2 days, during my intervention development I needed to be careful that the training component did not become an unnecessary and unmanageable burden.

Figure 19. Examples of a patient monitor (left) and vital signs monitor (right)

Globally, a standard set of vital signs includes six parameters (respiratory rate, oxygen saturation, heart rate, blood pressure, temperature and conscious level). It is routine to have access to a vital signs monitor, or a patient monitor to enable healthcare staff to be able to take this full set of vital signs (See Figure 19). However, teaching a family member who has no previous knowledge or previous healthcare experience to use a vital signs monitor safely would have been significant training burden and require lots of supervised practice. I needed to adopt a pragmatic approach that enabled a balance between the use of vital signs to detect early deterioration but that did not create an unmanageable training burden on the training team. Ultimately if successful, nursing staff who are already on the wards would be expected to take on this training responsibility.

I made the pragmatic decision to use only four vital signs that can be taken with minimal use of equipment. These were heart rate, respiratory rate, conscious level and arterial oxygen saturation (SpO_2). I excluded blood pressure, which is usually a late sign of deterioration, is slightly more complicated to take with the need to position the blood pressure cuff in the right position without causing harm to the patient. I also excluded temperature. Temperature probes are vulnerable to damage and easily lost and if not positioned well can lead to inaccurate readings. I felt that the use of a simple pulse oximeter would be feasible for family members, would give a reading for oxygen saturations and the heart rate and would be a pragmatic balance between training burden and

Figure 20. Pulse oximeter stand development and manufacture

benefit. Lifebox pulse oximeters (Model No. AH-M1; Acare Technology Co., Ltd, New Taipei City, Taiwan) were provided to all wards at the beginning of the study. As pulse oximeters are small and easily lost, they were fixed with their chargers to a mobile stand and a dedicated charging point on the wards identified with a sign. Detail during intervention development is important and the stands were custom designed for this trial. Pictures in Figure 20 show the stages of stand development. Design features included castors to enable easy movement around the wards, a smooth durable surface to enable easy cleaning, a tray for storage of the pulse oximeter probe and a stand with security attachment so that the pulse oximeter itself was easily visible and accessible but at the same time fixed and secure. Figure 21 shows the final product.

Figure 21. Lifebox pulse oximeter and mobile stand

4.4.1 Feedback from families: literacy and language barriers

In the intervention, family members were given practical training to assess the vital signs in accordance with standard operating procedures. Family members were taught to record they had taken the vital signs on a basic observation chart every 4 hours after surgery and how to interpret these results. Feedback from family members and patients during development of the intervention led to the identification of potential barriers to the implementation fidelity. Examples included language barriers and literacy rates. Mbale Regional Referral Hospital receives patients from a large geographical area with distinct cultural differences. Multiple languages are spoken that are distinct and not interchangeable. Some patients are unable to understand or read in the common languages of Luganda and English. In order to understand the language challenges more, a simple survey was undertaken at a single timepoint in September 2019. I asked all inpatients and their immediate family member present on inpatient surgical wards (general surgery and orthopaedic/ENT) at the time of the survey, what their first language was. We also asked whether they spoke a second or third language and whether they could read in their first or second languages.

Results

I interviewed 100 patients and family members. Two colleagues working with me provided local translation where needed. Three common first languages were described (Lugisu, Lugwere and Ateso) covering 82% of the patients and their family members. 37% were able to speak English and 44% were able to speak Luganda (one of the most widely spoken languages across Uganda). 32% were unable to read or write in any language. Table 11 summarises these findings.

This feedback was incorporated into the intervention by developing colour infographic guidelines that were simple to follow using pictures even if people could not easily read. My initial thoughts had been to develop a training guide that could be read and followed by family members however given the high rates of illiteracy I changed to a much simpler approach. Early versions of the poster also included text to explain each step for those family members who would be able to read but,

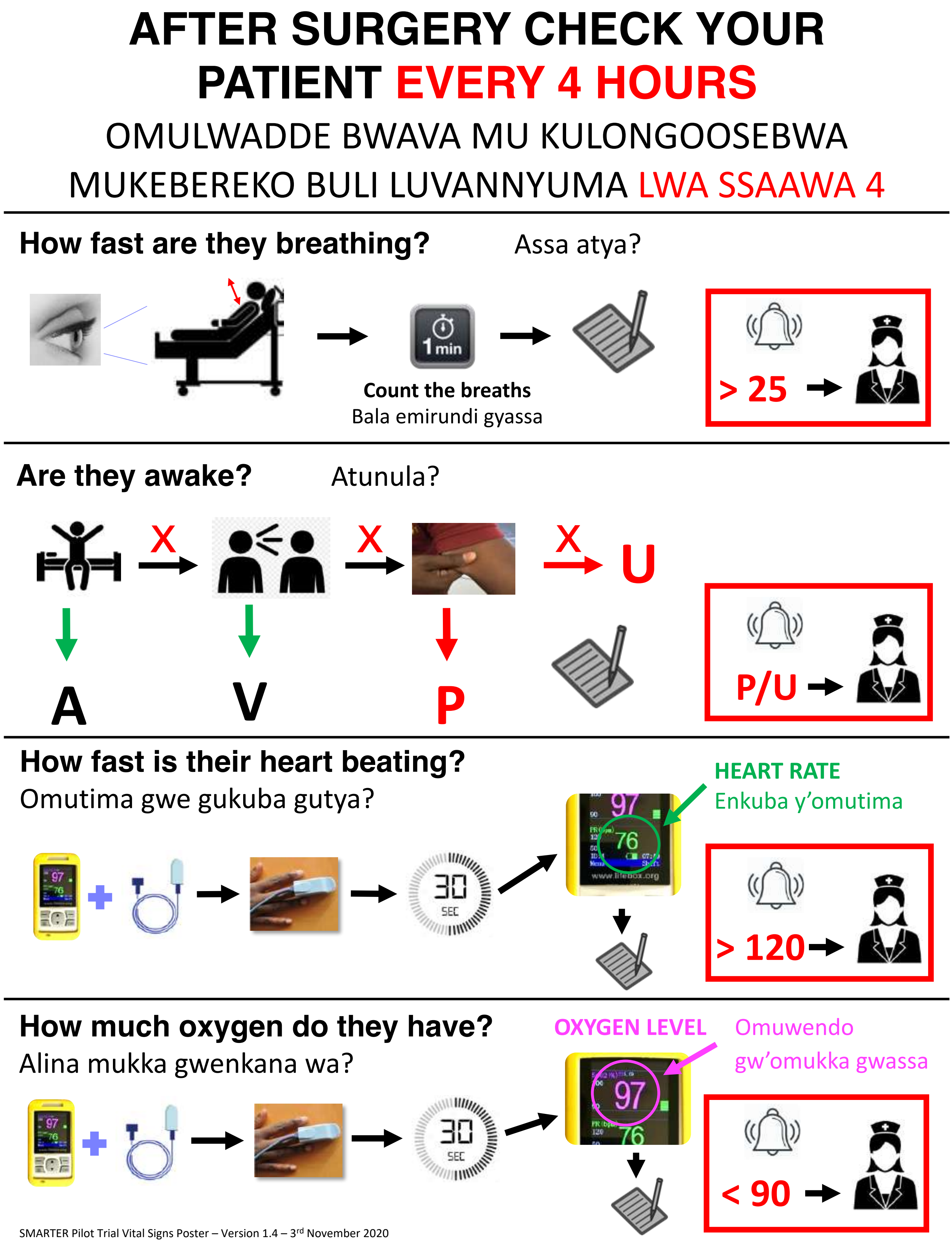
Table 11. Languages spoken and illiteracy rates at Mbale Regional Referral Hospital

	Number (%) n = 100
First language	
Ateso	17 (17)
Lugwere	19 (19)
Lugisu	46 (46)
Luganda	3 (3)
Other	15 (15)
Second or third language	
Luganda	44 (44)
English	37 (37)
Other or none	19 (19)
Able to read or write in any language	
Yes	68 (68)
No	32 (32)

given the need to translate all text into Luganda as well as English, the space for the visual components of the poster became very constrained. The end result was a poster that was as simple as possible in design but conveyed the key messages. Figure 22 illustrates the final version of the poster that I used. These posters were displayed throughout each ward during the trial intervention. For simplicity, a single pragmatic cut off for vital signs was used, allowing family members to decide whether the result they achieved was ok or needed attention from a medical worker. This approach has previously been used successfully by healthcare workers in an intensive care setting.[104]

Following stakeholder input from the nursing staff, they highlighted a concern about infection prevention and control. We therefore included a training component to ensure carers knew how to wash their hands before and after contact with their patients to reduce the risk of infection transmission. As further refinement of both the programme theory and the intervention may be needed during the testing of the intervention, an intentional specified time point was included in the process evaluation design to enable this to happen.

Figure 22 Infographic colour poster



4.5 Conclusion

In this chapter I have described the steps I took during the development of my intervention. This journey included describing current rates of postoperative vital signs monitoring, developing a programme theory, and a community engagement and involvement approach to ensure stakeholder input into the intervention. I developed a novel pulse oximeter stand to enable access and security for the small but user-friendly pulse oximeter available for use, and a poster that could be displayed clearly on the participating wards as a visual guide for family members to use when taking and identifying abnormal vital signs.

During stakeholder engagement, particularly with family members and patients, I was able to explore the diversity of cultures that exist in the region served by Mbale RRH. This diversity is exemplified by the large range of languages spoken on the wards. Over 40 languages are routinely spoken in Uganda. The challenge this presents to any intervention that is planned involving community and family members should not be underestimated. This is often compounded by poor literacy rates and the need for appropriate strategies to provide information to participants in a way they can understand. A qualitative study in Uganda explored this in more detail in a cohort of pregnant and lactating mothers, highlighting the need for simple and clear communication in participants' own languages.[233]

I opened this chapter by describing the complexity of health interventions, with their multiple interacting components that can influence intervention fidelity and effectiveness. Using the MRC guidance on intervention development and evaluation I have considered the core elements described in Figure 16 and explored them within the context of Mbale RRH. Where necessary I have used a data driven approach to understand the complexities in this specific setting in more detail. Following this intervention development, I am now ready to run a pilot trial to test the intervention. I have described this in chapter 5.

CHAPTER 5 FAMILY SUPPLEMENTED PATIENT MONITORING AFTER SURGERY (SMARTER): A PILOT TRIAL

5.1 Introduction

The African Surgical Outcomes Study (ASOS) provided, for the first time, robust surgical outcomes data from 25 nations across the continent. Compared to global averages, the typical surgical patient in Africa is twice as likely to die, despite being younger and with fewer comorbidities.[28] For some surgical procedures, for example caesarean section, mortality rates in Africa are 50 times higher than in high-income countries.[201] 94% of deaths occur on the hospital wards after surgery.[28] Other outcomes studies across Africa have also demonstrated that the majority of deaths occurring after surgery happen during the postoperative period.[160,234] These deaths therefore represent 'failure to rescue' i.e., death of a patient following unrecognised physiological deterioration caused by a complication of surgery or anaesthesia.[35,129]

As surgical complication rates are similar across low, middle and high-income settings, processes that lead to 'failure to rescue' are likely to be responsible for the higher mortality rates observed across Africa. The capacity of health facilities to rescue deteriorating patients is, in part, dependent on health system factors, for example access to critical care or advanced radiology services.[22] However, failure to appropriately monitor a patient, failure to recognise physiological deterioration, and failure to act when deterioration occurs also contribute to 'failure to rescue'.[235] Workforce shortages across Africa can result in patient to nurse ratios of up to 60:1 making close postoperative monitoring difficult to achieve.[236]

In many Ugandan hospitals, patients' family members provide much of the personal care that nurses deliver in high-income countries.[237] This practice is commonplace across Africa because of the critical shortage of nurses. In many cases, family members will sleep beside or under the patient's hospital bed throughout their in-patient stay. A few small studies have investigated how family members can contribute to other routine aspects of patient care. The involvement of trained family carers led to a two-fold increase in compliance with in-patient medication prescriptions at one hospital in Uganda.[151] At Mbale Regional Referral Hospital, mothers are trained to provide basic nursing care for newborn babies including temperature monitoring, daily weights and nasogastric feeding. Together with other simple interventions, this 'Mbale mother-centred model' halved neonatal mortality in just 18 months.[155] Given these successes, and the simplicity of vital signs monitoring, it seems likely that family carers could supplement the monitoring of patients by ward nurses, therefore contributing to post-operative surveillance and the prevention of deaths after surgery.

I developed an intervention to teach family carers to monitor and document patients' basic vital signs, in addition to the standard monitoring of patients by nursing staff, recognise when they are abnormal and communicate this to nursing staff. I hypothesised that if successful, this would contribute to improved post-operative surveillance, allowing early intervention when complications occur and the prevention of deaths after surgery. I tested this hypothesis in a stepped-wedge cluster randomised trial at Mbale Regional Referral Hospital.

5.2 Methods

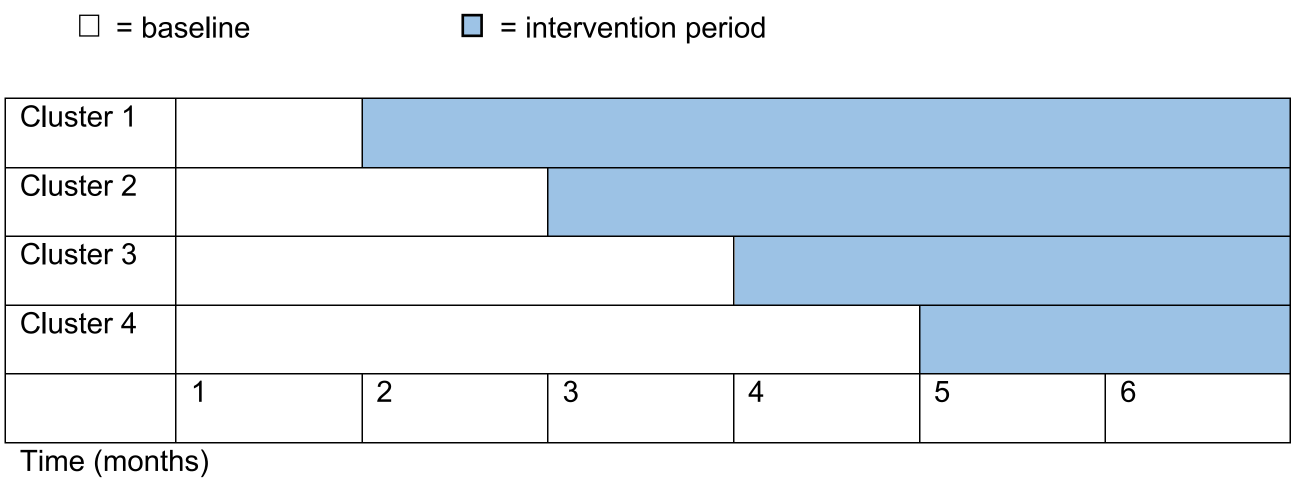
5.2.1 Setting

The trial took place at Mbale Regional Referral Hospital over six months in 2021. As described in the introduction, Mbale Regional Referral Hospital is a 470-bed teaching hospital in eastern Uganda serving a population of 4.5 million people. Four independent inpatient wards in the hospital provide care for patients after they have undergone surgery. Two wards providing postoperative care are dedicated surgical wards and two for mixed obstetric/gynaecology patients. Each ward contains between 20-40 beds. Patient to nurse ratios on the inpatient surgical wards can routinely reach 40:1. Surgical and maternity high dependency units provide care for the sickest patients. At the time of this trial the hospital did not have an intensive care unit and could not provide organ support (for example mechanical ventilation or renal dialysis). Medical and nursing teams provide care for patients on their wards only and movement of patients between wards is rare.

5.2.2 Trial design

SMARTER was a stepped-wedge cluster-randomised pilot trial. Each in-patient surgical ward in the hospital represented a cluster. The order in which the trial intervention was implemented through the clusters was determined by computer generated randomisation performed before the start of the trial, by an independent statistician at the Pragmatic Clinical Trials Unit at Queen Mary University of London. Only I, as the lead investigator in Uganda, knew the order of randomisation in advance. The study team and ward staff were informed two days before their transition to enable preparation. Each cluster had a usual care and intervention phase with the intervention being introduced into one cluster each month from months 2-5. (See Figure 23 below). Each cluster transitioned once from usual care to intervention at 8am on the first day of that month period. If the patient's date of surgery fell after this time, they were recruited into the intervention arm. A concurrent process evaluation of the intervention was undertaken by the study team. This is reported in the next chapter.

Figure 23. Intervention implementation timeline for clusters 1-4



5.2.3 The SMARTER trial intervention

In the SMARTER pilot trial, during the intervention period, in addition to the nurses' vital signs monitoring, family members were trained to perform basic vital signs monitoring for their patient and document the results. They were given clear guidance on when to alert staff to potential danger signs.[238] In this trial, the soft periphery was the training programme and resources designed to assist staff to rapidly and effectively train these skills combined with ongoing maintenance strategies to ensure the compliance with the intervention was maintained throughout the intervention period.

Family carers were given practical training by clinical research assistants to assess the following vital signs: heart rate, respiratory rate, level of consciousness (using the AVPU scale[239]) and arterial oxygen saturation (SpO_2). This included ensuring carers knew how to wash their hands before and after contact with their patients to reduce the risk of infection transmission. In order to reduce the risk from nosocomial infections, the study team worked with the hospital administration to ensure that handwashing facilities are always available on the ward for use. Family members were taught to record vital signs on a basic observation chart every four hours after surgery (Figure 24). They were taught how to interpret these results with the aid of colour posters displayed throughout each ward, as described in the previous chapter (Figure 22). For simplicity, a single pragmatic cut off for vital signs was used, allowing family members to decide whether the result they achieved was acceptable or needed attention from a medical worker. Family members had access to a simple pulse oximeter that was shared between all patients in their room of the ward during the trial. They also had access to analogue wall clocks, pens and clipboards throughout the trial. Training was conducted by the research team on a one-to-one basis or in small groups if multiple participants were recruited at the same time either before or immediately after their patient's surgical procedure. The intervention period lasted from arrival on the post-operative ward after surgery until the end of the third postoperative day, although family members were allowed to continue monitoring after this period if they wished. Each day started at 8am and ended at 8am the following day. The day of surgery was counted as day 0. Patients were followed up daily until discharge from hospital and if needed family members received refresher training during these follow up visits.

Nursing and medical teams looking after the patients on the wards retained full responsibility for patient care throughout all phases of the trial. The nursing team were provided with observation charts for all their ward patients at the beginning of the trial and were given training on how to use them and how to respond to deteriorating vital signs. During the intervention phase of the trial, when a carer identified an abnormal vital sign and informed the nursing team, the nurse was expected to repeat the observation and document their finds and actions in the patient's medical record in line with standard care. The set of observations taken by the nursing staff was regarded as the gold standard.

Figure 24.Family member vital signs chart

Patient Name: ______________________________ **Date of Surgery:** ____________ **IP Number:** ______________

		DAY OF SURGERY:						FIRST DAY AFTER SURGERY (DAY 1):					
Time		8 am	12 pm	4 pm	8 pm	12 am	4 am	8 am	12 pm	4 pm	8 pm	12 am	4 am
		Morning Kumakya	Breakfast Kyankya	Lunch Kyamisana	Evening Akawungeezi	Supper Ekyegulo	Night Ekiiro	Morning Kumakya	Breakfast Kyankya	Lunch Kyamisana	Evening Akawungeezi	Supper Ekyegulo	Night Ekiiro
Breathing rate	Above 25												
	9 - 25												
	Below 8												
Conscious level	A												
	V												
	P												
	U												
Oxygen Level	Above 90												
	Below 90												
Heart Rate	Above 120												
	40 - 120												
	Below 40												

SMARTER Pilot Trial Vital Signs Chart – Version 1.5 – 15th July 2021

1 of 2

SMARTER unique patient ID

Patient Name: ____________________________ **Date of Surgery:** ___________ **IP Number:** _____________

		SECOND DAY AFTER SURGERY (DAY 2):							THIRD DAY AFTER SURGERY (DAY 3):					
Time		8 am	12 pm	4 pm	8 pm	12 am	4 am		8 am	12 pm	4 pm	8 pm	12 am	4 am
		Morning Kumakya	Breakfast Kyankya	Lunch Kyamisana	Evening Akawungeezi	Supper Ekyegulo	Night Ekiiro		Morning Kumakya	Breakfast Kyankya	Lunch Kyamisana	Evening Akawungeezi	Supper Ekyegulo	Night Ekiiro
Breathing rate	Above 25													
	9 - 25													
	Below 8													
Conscious level	A													
	V													
	P													
	U													
Oxygen Level	Above 90													
	Below 90													
Heart Rate	Above 120													
	40 - 120													
	Below 40													

SMARTER unique patient ID

5.2.4 Participants

All patients who underwent surgery and were admitted to one of the four post-operative surgical wards during the trial period were screened for eligibility. Patients or a carer needed to speak one of five commonly used languages. Written informed consent was provided by patients during the usual care phase and, during the intervention phase, by both the patient and their family member acting as their main carer. Additional inclusion and exclusion criteria included the following:

Inclusion criteria

Patients:	Patients ≥5 years of age undergoing surgery at Mbale Regional Referral Hospital, who receive post-operative care in one of four main surgical wards, with a family carer prepared to participate in the trial intervention.
Carers:	All carers were included in the trial if they felt they were capable of performing and documenting the basic vital signs provided they agree to participate.
	The ability to speak English, Luganda, Lugisu, Ateso or Lugwere
	The ability to read a digital or analogue clock (to measure vital signs)
	the ability to read numbers from the pulse oximeter and the ability to document on an observation chart that the vital signs had been taken

Exclusion criteria

Patients:	Refusal of informed consent.
	Identification of potential participant >24hours after operative procedure has taken place
	Patients discharged on the same day as surgery
	Patients < 5 years of age
Carers:	Refusal of informed consent.

5.2.5 Recruitment and screening

Potential participants were screened by research staff having been identified from operating theatre lists and by communication with the relevant nursing and medical staff. Potential participants were identified and approached by a member of the research team either pre- or postoperatively. Wherever possible, the patient was approached at least 24 hours prior to surgery to allow time for any questions. However, by the nature of the inclusion criteria for this trial, many patients arrived in hospital on the day of surgery. Provided that all reasonable efforts have been made to identify a potential participant 24 hours in advance of surgery, they were still eligible for recruitment within this shorter time frame.

5.2.6 Informed consent

For patients receiving care on a ward during the baseline period, the research team took informed consent for data use only. For patients receiving care on a ward during the intervention period, informed consent was sought from both patients and their participating family member(s). Broadcasting signs were clearly displayed throughout wards participating in the trial intervention. Patients were visited on the ward by a member of the trial team to take consent. A trial information leaflet was provided at the beginning of each carer training session, and consent taken from carers at this point. Patient and carer participants were free to leave the trial at any point. All participant facing trial materials including posters were provided in Luganda and English. Information sheets and consent forms were available in English and translated into the local languages Luganda, Lumasaba and Ateso. Patients who were unable to read the patient information leaflets themselves had them read to them verbatim. Trial research assistants underwent training in the taking of consent before the trial began.

5.2.7 Outcome measures

Primary outcome measure

The primary outcome measure was the frequency of a completed set of vital signs performed per patient during the intervention period. A patient who arrived on the postoperative ward early on day 0 and who was monitored at the standard frequency (six sets of vital signs documented every 24-hour period) would have a total of 24 sets of vital signs during the intervention period. A set of vital signs was defined as three or more of the four vital signs: heart rate, respiratory rate, level of consciousness and arterial oxygen saturation.

Secondary outcome measures

- All cause in-hospital mortality, censored at 30 days after surgery
- Length of hospital stay
- All-cause mortality at 30-days
- Postoperative complications

5.2.8 Follow-up procedures

Participants were followed up until discharge from hospital. Medical records were reviewed to collect data on the secondary outcomes including length of hospital stay. Participants were also contacted by phone at 30 days after surgery if they are no longer in hospital, in order to determine 30-day mortality.

5.2.9 Blinding and procedures to minimise bias

Due to the nature of the intervention, it was not possible to blind patients, carers or hospital staff. Randomisation was performed by an independent statistician allowing data quality checks. Data monitoring was undertaken by an independent researcher from the UK who was blind to the intervention status of the wards. To ensure data capture on 100% of eligible patients, research staff screened operating theatre lists twice each day. Trial data was analysed on an intention to treat basis including all eligible patients.

5.2.10 Data collection

Data was collected on paper case record forms for all eligible patients who underwent surgery during the trial. Patients were followed up until hospital discharge. Paper records were stored in a locked filing cabinet in a locked office. Data were entered into a bespoke password protected online database by members of the research team. The online database was stored on secure servers at Queen Mary University of London in accordance with strict UK Data Protection Laws. The data we collected included the following variables (see Appendix 1 for full case report form):

Demographic data	Intra-operative data	Post-operative data
Age	Surgical procedure category	Number of postoperative observations
Gender	Start time of surgery	Number of vital signs recorded in each set
ASA physical status score	Urgency of surgery	Post-operative complications
Chronic co-morbid disease	Severity of surgery	Days in hospital after surgery
	Primary indication for surgery	Status at hospital discharge
	Duration of surgery	
	Grade of surgeon	
	Grade of anaesthetist	

5.2.11 Confidentiality

Information related to participants was kept confidential and managed in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR) (UK), NHS Caldecott Principles (UK), UK Policy Framework for Health and Social Care Research (UK), guidelines from the Uganda National Council for Science and Technology and the conditions of Research Ethics Committee Approval in Uganda. Personal data recorded on all documents was regarded as confidential. All patient related trial documents were confidential and were stored securely (e.g. patients' written consent forms). As the lead investigator in Uganda, I ensured the patient's confidentiality was maintained at all times.

5.2.12 Data ownership, sharing and storage

Data was transcribed on to the paper CRF prior to entry on to a secure SMARTER data entry web portal. Submitted data was reviewed by myself for completeness and consistency. Submitted data was stored securely against unauthorised manipulation and accidental loss. Only authorised users in Uganda, or at Queen Mary University of London had access. Desktop security was maintained through usernames and passwords. Data back-up procedures were in place. Storage and handling of confidential trial data and documents was in accordance with both the Data Protection Act 2018 and GDPR (UK) and the Data Protection and Privacy Act, March 2019 edition available at https://ulii.org/ug/legislation/act/2019/1 (Uganda). All source data and CRFs were kept securely in the Trial Master File, which was kept in a locked cabinet with restricted access in the Department of Anaesthesia & Critical Care at Busitema University Faculty of Health Sciences. A data ownership and transfer agreement between Busitema University and Queen Mary University of London was in place before the start of the trial.

Archiving

Paper CRFs are archived at the Department of Anaesthesia & Critical Care, Busitema University Faculty of Health Sciences. Electronic data is archived by Queen Mary University of London.

5.2.13 Statistical analysis

The trial was designed to provide greater than 90% power (two-sided p-value < 0.05) to detect a change in the rate of vital signs monitoring from 1 per patient per 24 hours to 3 per patient per 24 hours relative to a locally agreed standard of six sets of vital signs documented per patient per 24-hour period. Prior audit data had shown the current rates of vital signs monitoring on the surgical wards at Mbale Regional Referral Hospital to be as low as 0. Sample size calculations demonstrated that even a very small sample size of >20 would have provided adequate statistical power for the primary outcome. A time bound recruitment period of six months was therefore chosen to allow sequential activation of the four clusters, one new cluster per month.

Analyses followed the intention to treat principle including all patients with a recorded outcome, analysed according to the allocated intervention group. Missing data for baseline covariates that were included in the analysis model were accounted for using mean imputation for continuous variables and the missing indicator approach for missing data for categorical variables. Analysis was conducted using R Statistical Software (v4.1.2; R Core Team 2021)[240] and R Studio[241] and checked by Akshay Patel using STATA 17.[242] Primary outcome analysis used the number of documented sets of vital signs performed per patient from arrival on the post-operative ward to the end of the third post-operative day. A repeated measures negative binomial mixed effects model with a random intercept for patient was used. The model was adjusted for the intervention, period, cluster, surgical risk (calculated using the ASOS Risk Score[174]), and the number of days after surgery as fixed effects. The treatment effect is presented as an incidence rate ratio (95% CI).

The secondary outcome of all cause, in-hospital mortality censored at 30 days, was analysed using a logistic regression model. The duration of hospital stay was analysed using a cox proportional hazards model with fixed effects for period and cluster. A hazard ratio (95% CI) from this model would measure the relative probability of hospital discharge between treatment groups with a HR of >1 indicating a higher probability of hospital discharge after the introduction of the intervention. Postoperative complications were summarised for each treatment group by using number (%). Complications that were included are listed below:

Infectious	Cardiovascular	Others
Superficial surgical site	Myocardial infarction	Gastrointestinal bleed
Deep surgical site	Arrhythmia	Acute kidney injury
Body cavity	Pulmonary oedema	Postoperative bleed
Pneumonia	Pulmonary embolism	Acute respiratory distress syndrome
Urinary tract	Stroke	Anastomotic breakdown
Bloodstream	Cardiac arrest	Others

5.3 Results

Between 13th Apr 2021 and 12th Oct 2021, 1710 participants underwent surgery and were screened for eligibility with 1395 participants enrolled across four clusters (Figure 25). The commonest reasons for exclusion were literacy and children <5 years (Figure 25). 2.9% (49/1710) of patients who were screened declined to participate. There were 718 participants in the usual care group and 677 in the intervention group. The trial was conducted during the second wave of coronavirus disease 19 (COVID-19) in Uganda. This affected the patient population presenting to Mbale Regional Referral Hospital with the earlier, usual care phase seeing a larger proportion of maternity patients. As a result, control patients were younger and included more women (Table 12) The commonest surgical procedure by a long way was caesarean section (74.8%) with the second commonest being laparotomy (6.9%). 82.3% of surgical procedures were emergencies. Table 13 describes patient demographics by cluster. Patients in cluster 2, general surgery were older with a mean age of 42 years. This compares to cluster 3, postnatal, where the mean age of patients was 25 years. Demographic information on the family members who participated in the study were not collected. Patients in cluster 2, general surgery, were at the greatest risk of postoperative complications, including death with a median ASOS risk score of 11. Cluster 2, postnatal, had the lowest risk of postoperative complications with a median ASOS risk score of 5. There were no patients with missing primary or secondary outcome data.

The median (IQR) number of sets of vital signs monitoring per 3-day study period in the usual care group was 0 [0-1] compared with 3 [1-8] in the intervention group (Incident rate ratio: 12.4 [8.8 to 17.5], p=<0.001) (Figure 26 and Table 14). 6/718 (0.84%) patients died in-hospital in the usual care group versus 12/677 (1.77%) in the intervention group (Odds ratio: 1.32 [0.1 – 14.7], p=0.821) (Table 14). There was no difference between groups in length of hospital stay (usual care: 2 [2-3] days vs intervention: 2 [2-4] days. (Hazard ratio: 1.11 [0.84 - 1.47], p=0.44) (Table 14). Clusters 1 and 2 (orthopaedics/ENT and general surgery) saw the biggest increases in the number of sets of vital signs taken per 3-day study period from arrival on the surgical ward to the end of the third postoperative day (Table 16). The greatest number of deaths occurred in cluster 2 (general surgery) with the monthly mortality rate ranging from 3.0% to 15.4% (Table 15). Cluster 1 (orthopaedics/ENT) had the longest lengths of stay (Table 17).

Outcomes at 30 days after surgery in any location are reported as a sensitivity analysis. 30-day outcomes are available for 1,080 participants reflecting a 22.6% loss to follow up rate. 12/511 (2.3%) died in the usual care group versus 19/569 (3.3%) in the intervention group (Odds ratio: 0.79 [0.13 – 4.89], p=0.804, Table 14).

Although not a primary or secondary outcome, I also followed patient complications after surgery reported during the SMARTER pilot trial. These are reported in Table 18. The commonest causes were infectious in nature, with 79% (108/137) of these being surgical site infections. There were no reported cases of myocardial infarction, arrhythmias or gastrointestinal bleeds. Mortality after cardiac arrest was 100%.

Figure 25. Inclusion of patients in the SMARTER trial.

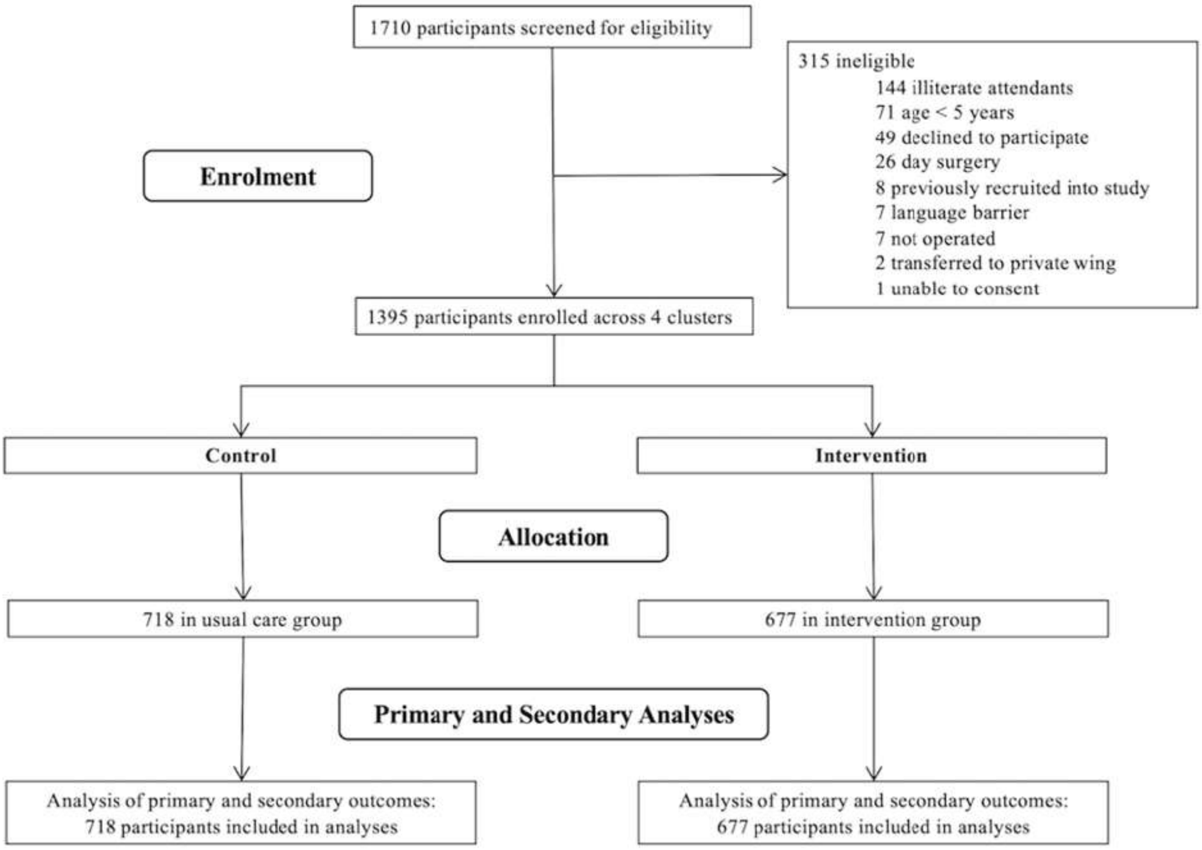


Table 12. SMARTER pilot trial - baseline patient characteristics.

	Overall n=1395	**Usual Care** n=718	**Intervention** n=677
Age, mean (SD)	28.2 (12.8)	26.8 (10.5)	29.7 (14.8)
Gender			
Male	200 (14.3)	55 (7.7)	145 (21.4)
Female	1195 (85.7)	663 (92.3)	532 (78.6)
Co-morbid disease			
Hypertension;	66 (4.7)	28 (3.9)	38 (5.6)
HIV/AIDS;	33 (2.4)	17 (2.4)	16 (2.4)
Diabetes mellitus;	27 (1.9)	10 (1.4)	17 (2.5)
ASA grade			
I	134 (9.6)	49 (6.8)	85 (12.6)
II	1171 (83.9)	629 (87.6)	542 (80.1)
III	81 (5.8)	36 (5.0)	45 (6.6)
IV	9 (0.6)	4 (0.6)	5 (0.7)
Surgical procedure category			
Caesarean Section	1043 (74.8)	610 (85.0)	433 (64.0)
Laparotomy	96 (6.9)	34 (4.7)	62 (9.2)
Orthopaedic	101 (7.2)	19 (2.6)	82 (12.1)
Hernia Repair	9 (0.6)	5 (0.7)	4 (0.6)
Gynaecology	20 (1.4)	14 (1.9)	6 (0.9)
Plastics/cutaneous	7 (0.5)	5 (0.7)	2 (0.3)
Ear, Nose & Throat	20 (1.4)	4 (0.6)	16 (2.4)
Neurosurgery	16 (1.1)	4 (0.6)	12 (1.8)
Other	83 (5.9)	23 (3.2)	60 (8.9)
Urgency of surgery			
Elective	134 (9.6)	49 (6.8)	85 (12.6)
Urgent	113 (8.1)	24 (3.3)	89 (13.1)
Emergency	1148 (82.3)	645 (89.8)	503 (74.3)
Severity of surgery			
Minor	6 (0.4)	4 (0.6)	2 (0.3)
Intermediate	1182 (84.7)	636 (88.6)	546 (80.7)
Major	207 (14.8)	78 (10.9)	129 (19.1)
Primary indication for surgery			
Infection	65 (4.7)	26 (3.6)	39 (5.8)
Non-communicable disease	168 (12.0)	56 (7.8)	112 (16.5)
Trauma	113 (8.1)	24 (3.3)	89 (13.1)
Caesarean Section	1049 (75.2)	612 (85.2)	437 (64.5)
ASOS Risk Score, median (IQR)	5 (5 - 6)	5 (5 - 6)	5 (5 - 8)

Data presented as n (%) unless otherwise stated. ASA - American Society of Anesthesiologists, ASOS - African Surgical Outcomes Study

Table 13. SMARTER pilot trial – baseline demographics by cluster

	Cluster 1		Cluster 2		Cluster 3		Cluster 4	
	Control N = 15	**Intervention N = 95**	**Control N = 71**	**Interventio n N = 134**	**Control N = 595**	**Intervention N = 426**	**Control N = 37**	**Intervention N = 22**
Age, mean (SD)	31.7 (20.3)	31.0 (21.3)	41.1 (20.1)	42.4 (20.2)	24.8 (6.2)	25.6 (6.9)	29.8 (11.5)	26.7 (6.9)
Gender								
Male	9 (60.0)	62 (65.3)	46 (64.8)	83 (61.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Female	6 (40.0)	33 (34.7)	25 (35.2)	51 (38.1)	595 (100.0)	426 (100.0)	37 (100.0)	22 (100.0)
Co-morbid disease:								
Hypertension;	0 (0.0)	8 (8.4)	4 (5.6)	17 (12.7)	21 (3.5)	13 (3.1)	3 (8.1)	0 (0.0)
HIV/AIDS;	0 (0.0)	2 (2.1)	3 (4.2)	4 (3.0)	14 (2.4)	10 (2.3)	0 (0.0)	0 (0.0)
Diabetes mellitus;	0 (0.0)	1 (1.1)	6 (8.5)	10 (7.5)	4 (0.7)	6 (1.4)	0 (0.0)	0 (0.0)
ASA grade								
I	8 (53.3)	50 (52.6)	30 (42.3)	26 (19.4)	10 (1.7)	8 (1.9)	1 (2.7)	1 (4.5)
II	6 (40.0)	40 (42.1)	25 (35.2)	66 (49.3)	568 (95.5)	415 (97.4)	30 (81.1)	21 (95.5)
III	1 (6.7)	5 (5.3)	13 (18.3)	37 (27.6)	16 (2.7)	3 (0.7)	6 (16.2)	0 (0.0)
IV	0 (0.0)	0 (0.0)	3 (4.2)	5 (3.7)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Surgical procedure category								
Caesarean Section								
Laparotomy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	594 (99.8)	420 (98.6)	16 (43.2)	13 (59.1)
Orthopaedic	0 (0.0)	1 (1.1)	26 (36.6)	56 (41.8)	1 (0.2)	1 (0.2)	7 (18.9)	4 (18.2)
Hernia Repair	13 (86.7)	77 (81.1)	6 (8.5)	5 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gynaecology	0 (0.0)	0 (0.0)	5 (7.0)	2 (1.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)
Plastics/cutaneous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	14 (37.8)	5 (22.7)
Ear, Nose & Throat	0 (0.0)	0 (0.0)	5 (7.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurosurgery	2 (13.3)	14 (14.7)	2 (2.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	4 (5.6)	12 (9.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

	0 (0.0)	3 (3.2)	23 (32.4)	55 (41.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)
Urgency of surgery								
Elective	7 (46.7)	31 (32.6)	31 (43.7)	34 (25.4)	6 (1.0)	17 (4.0)	5 (13.6)	3 (13.6)
Urgent	4 (26.7)	53 (55.8)	12 (16.9)	34 (25.4)	2 (0.3)	1 (0.2)	6 (16.2)	1 (4.5)
Emergency	4 (26.7)	11 (11.6)	28 (39.4)	66 (49.3)	587 (98.7)	408 (95.8)	26 (70.3)	18 (81.8)
Severity of surgery								
Minor	1 (6.7)	0 (0.0)	3 (4.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intermediate	8 (53.3)	40 (42.1)	23 (32.4)	59 (44.0)	583 (98.0)	426 (100.0)	22 (59.5)	21 (95.5)
Major	6 (40.0)	55 (57.9)	45 (63.4)	73 (54.5)	12 (2.0)	0 (0.0)	15 (40.5)	1 (4.5)
Primary indication for surgery								
Infection	6 (40.0)	8 (8.4)	17 (23.9)	30 (22.4)	0 (0.0)	0 (0.0)	3 (8.1)	1 (4.5)
Non-communicable disease	2 (13.3)	17 (17.9)	37 (52.1)	82 (61.2)	0 (0.0)	5 (1.2)	17 (45.9)	8 (36.4)
Trauma	7 (46.7)	70 (73.7)	17 (23.9)	19 (14.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Caesarean Section	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.2)	595 (100.0)	421 (98.8)	17 (45.9)	13 (59.1)
ASOS Risk Score, median (IQR)	8 (6.5 - 9.0)	8 (6.0 - 11.0)	10 (7.0 - 14.0)	12 (7.0 - 14.0)	5 (5.0 - 6.0)	5 (5.0 - 6.0)	7 (5.0 - 11.0)	6 (5.0 - 7.0)

Table 14. SMARTER pilot trial - primary and secondary outcomes.

	Number of patients with available data - no. (%)		Summary Measure		Treatment effect (95% CI)	p- value
	Control (N=718)	Intervention (N=677)	Control	Intervention		
Primary outcome: Median number of sets of vital signs	718 (100.0)	677 (100.0)	0 (0-1)	3 (1-8)	12·4 (8·8 - 17·5) *	<0·001
Secondary outcome: in-hospital mortality	718 (100.0)	677 (100.0)	6 (0.8)	12 (1.8)	1.32 (0.1 – 14.7) **	0.821
Secondary outcome: median duration of hospital stay (days)	718 (100.0)	677 (100.0)	2 (2 - 3)	2 (2 - 4)	1·1 (0·8 - 1·5) ***	0·440
Sensitivity analysis: mortality at 30 days after surgery (in any location)	511 (71.2)	569 (84.0)	12 (2.3)	19 (3.3)	0.79 (0.13 – 4.89)**	0.804

Data presented as n (%), mean (SD) or median (IQR) unless otherwise stated. * Incident rate ratio, ** Odds ratio, *** Hazard ratio, CI = confidence interval

Figure 26. Number of documented vital signs in usual care and intervention groups.

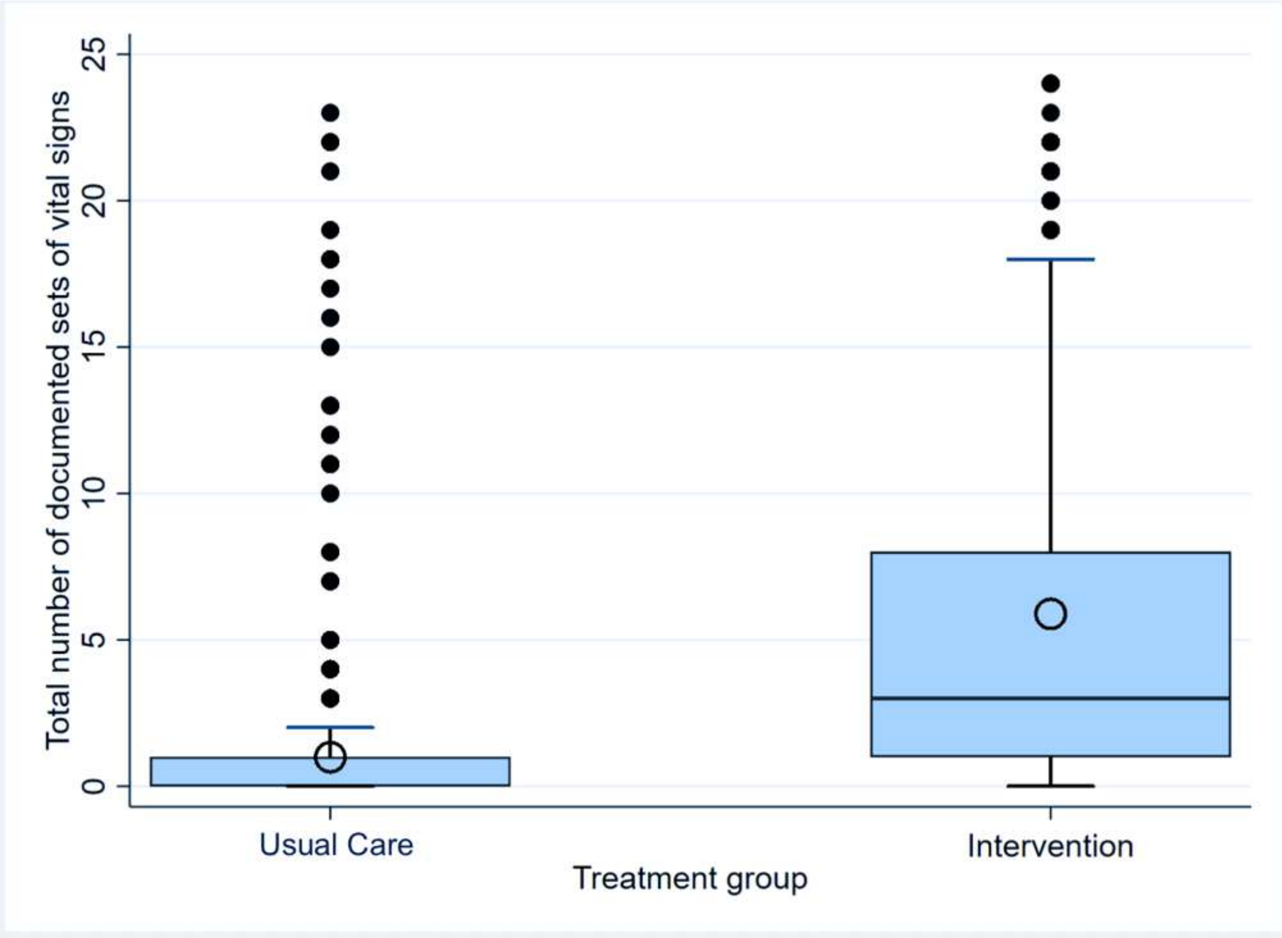


Table 16. SMARTER pilot trial - Mortality for each cluster in each period

	Mortality					
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Cluster 1 (Orthopaedics & ENT)	0/15 (0.0)	0/18 (0.0)	1/16 (6.3)	0/15 (0.0)	0/27 (0.0)	0/19 (0.0)
Cluster 2 (General Surgery)	2/39 (5.1)	2/32 (6.3)	3/33 (9.1)	4/26 (15.4)	2/42 (4.8)	1/33 (3.0)
Cluster 3 (Postnatal)	1/213 (0.5)	0/167 (0.0)	0/214 (0.0)	0/117 (0.0)	1/155 (0.6)	0/154 (0.0)
Cluster 4 (Gynaecology)	0/8 (0.0)	0/8 (0.0)	1/9 (11.1)	0/12 (0.0)	0/9 (0.0)	0/13 (0.0)

Intervention period shaded grey. n (%)

Table 15. SMARTER pilot trial - Number of documented sets of vital signs for each cluster in each period

	Number of documented sets of vital signs					
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Cluster 1 (Orthopaedics & ENT)	0 (0-1) [15]	8 (2-19) [18]	18 (13.5-21.5) [16]	16 (11-18) [15]	15 (6-18) [27]	6 (4-15) [19]
Cluster 2 (General Surgery)	1 (0-4) [39]	1 (0-2.5) [32]	13 (5-19) [33]	9.5 (6-18) [26]	7 (5-16) [42]	11 (5-17) [33]
Cluster 3 (Postnatal)	0 (0-1) [214]	0 (0-1) [167]	0 (0-0) [214]	3 (1-5) [117]	2 (1-4) [155]	2 (1-4) [154]
Cluster 4 (Gynaecology)	0 (0-0) [8]	0 (0-0.5) [8]	0 (0-0) [9]	0 (0-0) [12]	1 (1-2) [9]	1 (1-3) [13]

Number of documented vital signs per participant per postoperative monitoring period from time of arrival on the postoperative ward to hospital discharge or the end of the third postoperative day, whichever is sooner. Intervention period shaded grey. Median (IQR). [N] = number of participants in each group

Table 17. Duration of hospital (days) for each cluster in each period

	Duration of hospital stay (days)					
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Cluster 1 (Orthopaedics & ENT)	6 (3-11) [15]	4.5 (2-7) [18]	10 (4-15) [16]	5 (4-9) [15]	6 (4-14) [27]	6 (2-7) [19]
Cluster 2 (General Surgery)	5 (4-7) [39]	4 (2-6) [32]	6 (3-7) [33]	5.5 (3-13) [26]	5 (2-10) [42]	5 (2-7) [33]
Cluster 3 (Postnatal)	2 (2-3) [214]	2 (2-3) [167]	2 (2-3) [214]	2 (2-3) [117]	2 (2-3) [155]	2 (2-3) [154]
Cluster 4 (Gynaecology)	2 (2-2.5) [8]	2 (2-4) [8]	2 (2-2) [9]	2.5 (2-4) [12]	2 (2-3) [9]	3 (2-3) [13]

Intervention period shaded grey. Median (IQR). [N] = number of participants in each group

Table 18. Complications after surgery.

Complication – no. (%)	Complication severity						Number of deaths for all patients who developed complications	
	Mild		Moderate		Severe			
	Control N = 718	Intervention N = 677	Control N = 718	Intervention N = 677	Control N = 718	Intervention N = 677	Control	Intervention
Infectious complications								
Superficial surgical site	18 (2.5)	5 (0.7)	25 (3.5)	5 (0.7)	20 (2.8)	4 (0.6)	4/63 (6.3)	2/14 (14.3)
Deep surgical site	2 (0.3)	2 (0.3)	12 (1.7)	2 (0.3)	13 (1.8)	4 (0.6)	4/26 (15.4)	2/8 (25.0)
Body cavity	0 (0.0)	0 (0.0)	4 (0.6)	0 (0.0)	1 (0.1)	1 (0.1)	0/5 (0.0)	1/1 (100.0)
Pneumonia	0 (0.0)	1 (0.1)	1 (0.1)	0 (0.0)	2 (0.3)	6 (0.9)	1/3 (33.3)	6/7 (85.7)
Urinary tract	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)	1 (0.1)	0/2 (0.0)	1/1 (100.0)
Bloodstream	0 (0.0)	0 (0.0)	2 (0.3)	0 (0.0)	5 (0.7)	0 (0.0)	2/7 (28.6)	0/0 (0.0)
Total	20 (2.8)	8 (1.2)	44 (6.1)	7 (1.0)	42 (5.8)	16 (2.4)		
Cardiovascular complications								
Myocardial infarction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0/0 (0.0)	0/0 (0.0)
Arrhythmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0/0 (0.0)	0/0 (0.0)
Pulmonary oedema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)	1//1 (100.0)	0/0 (0.0)
Pulmonary embolism	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.3)	0 (0.0)	2/2 (100.0)	0/0 (0.0)
Stroke	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.3)	0/0 (0.0)	1/2 (50.0)
Cardiac arrest	-	-	-	-	12 (1.7)	19 (2.8)	12/12	19/19
Total	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (2.1)	21 (3.1)	(100.0)	(100.0)
Other complications								
Gastrointestinal bleed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0/0 (0.0)	0/0 (0.0)
Acute kidney injury	0 (0.0)	0 (0.0)	2 (0.3)	0 (0.0)	1 (0.1)	1 (0.1)	1/3 (33.3)	1/1 (100.0)
Postoperative bleed	-	-	6 (0.8)	0 (0.0)	9 (1.3)	5 (0.7)	2/14 (14.3)	1/5 (20.0)
ARDS	-	-	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)	1/2 (50.0)	0/0 (0.0)
Anastomotic breakdown	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	1 (0.1)	0/1 (0.0)	1/1 (100.0)
All others	1 (0.1)	0 (0.0)	4 (0.6)	2 (0.3)	4 (0.6)	3 (0.4)	2/7 (28.6)	2/5 (40.0)
Total	1 (0.1)	0 (0.0)	14 (1.9)	2 (0.3)	15 (2.1)	10 (1.5)		

5.4 Discussion

The principal finding of this pilot cluster trial is that training family members to assist in vital signs monitoring of patients on hospital wards after surgery is highly feasible, leading to a 12-fold increase in the rate of vital signs measurement. There was no significant difference in the number of patients dying in-hospital after surgery and no change in the length of hospital stay between the normal care and intervention groups. In terms of intervention fidelity, we achieved one set of vital signs per participant per day compared to the three sets of vital signs per participant per day we had aimed for. There was a trend towards reduced mortality rates in the intervention group at 30 days after surgery but there were high loss to follow rates. The findings from this trial add to the growing evidence base that family member involvement in patient care can effectively support the limited numbers of healthcare workers in low-resource settings. Our novel approach to postoperative monitoring is one that warrants further investigation.

There is increasing evidence in the published literature of efforts to involve family members in healthcare settings around the world.[146,147,150,153,189] The specific question, whether family participation can enhance care and tackle healthcare shortages in resource limited hospitals, was discussed in a systematic review, concluding was that in specific contexts, family participation can be safe and effective, although evidence was limited.[150] Family members are commonly present at the hospital bedside in low-income settings and are an underutilised resource. Multiple publications describe the ability of family members to recognise sick patients in the community, especially children with danger signs.[243-245] Despite family members wanting to be empowered to participate more actively, evidence to support their involvement in aspects of inpatient care that are traditionally reserved for healthcare staff is limited.[246,247] In some medical specialties such as neonatology, family members are increasingly involved in elements of patient care that have a direct impact on clinical outcomes, for example thermoregulation using kangaroo mother care.[155,248] In Uganda, other published examples of direct involvement of family members in inpatient care include the national referral cancer centre where almost half of family members interviewed reported being involved in providing direct patient care, including giving medication[249] and a quality improvement project on the internal medicine wards at the National Referral Hospital in Kampala that was able to double adherence to prescribed inpatient medications by involving family members.[151]

Interventions using family members to help monitor a patient's illness and identify when they are deteriorating are more novel. At the time, I was only able to identify one interventional study from Africa in the general paediatric wards of Kenyatta National Hospital, Kenya, where family member involvement in the recognition of clinical deterioration among acutely ill children in a low-resource setting was a feasible approach to help prioritise professional clinical assessment during hospitalisation.[250] This study taught caregivers to display colour coded severity of illness flags based on three perceived signs of clinical deterioration, including level of consciousness, capillary refill time and presence of chest retractions (the 'FASTER' tool). The FASTER intervention was anticipated to trigger an increased frequency of clinician reassessment. Although the study was not powered to detect the impact of the intervention on mortality, 82% of clinicians and 100% of caregivers agreed that the FASTER monitoring tool would improve the care of sick paediatric inpatients in their setting.[251] Since this there have been other publications recognising the role of family members in monitoring their patients to detect deterioration. In 2024, Mwale et al published some qualitative work looking at monitoring of critically ill children in their paediatric high dependency unit. One of their conclusions was to need to support caregivers to play a more formal role in escalation of care following deterioration.[252]

The numbers of reported complications after surgery in the SMARTER pilot trial were seemingly very low. The ability for healthcare teams to make formal diagnoses of complications at Mbale Regional Referral hospital is complicated by limited access to diagnostic tests. An example would be the lack of access to a CT scanner preventing the formal diagnosis of pulmonary embolism using CT Pulmonary angiography. During times of reagent and film stock outs, even access to seemingly simple investigations such as a chest x-ray to diagnose pneumonia or a blood test to support the diagnosis of an infection can be dependent on a patient or their family's ability for pay. The 100% mortality rate after cardiac arrest was unsurprising and likely a reflection of the healthcare system and resources available to respond in a timely manner. Like many other studies reporting surgical complications from similar settings, infectious complications were the commonest.[28,127 23] When compared to international cohort studies[129] that include more patients from HICs, the low rates of cardiovascular complications I saw is likely a reflection of the younger, healthier population (mean age 28.2 years vs 55.3 years).

The strengths of this trial include the iterative development of a pragmatic intervention to improve postoperative monitoring for surgical patients utilising available resources in a low-income setting and a carefully planned cluster randomised trial study design to avoid the risk of contamination. The step-wedge approach enabled the intervention to be introduced into an entire ward at the same time and therefore avoided the potential for confusion between intervention and usual care patients who may have been in adjacent beds under the care of the same nurse.

Limitations include those influenced by the COVID-19 pandemic, areas of intervention fidelity we did not test and limitations associated with the trial design itself. Uganda was affected by two waves of coronavirus disease 2019 (COVID-19), with the second wave in late April 2021, just after the trial started recruitment. Limited numbers of clinical COVID-19 cases and a strict lockdown across the country allowed us to continue recruitment into the trial during this period. However, it led to reduced access to healthcare services across the country. Priority was commonly given to maternal care resulting in higher proportions of females and caesarean sections during the usual care phases of the trial. The median total number of documented vital signs in these wards was much lower than the general surgical and orthopaedic wards and so it is possible this may have had an impact on our primary outcome. Our intervention was intentionally designed to be as simple as possible, for example by excluding blood pressure measurement from our family member vital signs. We also excluded family members who were unable to read numbers from the pulse oximeter (114, 7% of potential screened screened). We recognise these choices may have led to higher intervention fidelity, however our approach was a pragmatic balance between an intervention that 100% of family members could manage and one that included vital signs that have a higher chance of detecting deterioration.[253] We did not look at the accuracy of the individual vital signs that were taken by family members. We encountered challenges ensuring robust follow up of our patient's at 30 days after surgery. This is reflected in the >20% loss to follow up rates. This compares to in-hospital mortality rates where all study patients had an outcome. We followed up patients using phone calls but often found phones were switched off or no longer available. We improved our processes during the trial, ensuring we always had a minimum of two phone numbers, reducing our loss to follow up rates from 28.8% to 16%. Improving rates of follow up would require collection of additional phone numbers (for example for the local community leaders who would be able to connect the team with the patient and their family) or would require in person visits to the community. This latter approach, whilst highly effective, also requires significant financial resources for transport and staff time. I chose a cluster trial design because the SMARTER intervention is a local, system level intervention and cannot be implemented at a patient level without risk of contamination between patients in the same ward. There are however limitations with this approach. There is still a risk of contamination between the clusters. The effect of time on the analysis needs to be considered and when improvements are seen, it is always possible they may have been caused by confounders that have not been controlled for. Examples of these may include variability in implementation of the intervention between clusters because of differences in staffing or infrastructure and, as in my trial, with a small number of clusters, important co-variates may not be balanced evenly across clusters.

5.5 Conclusions

In the SMARTER pilot trial, family member supplemented monitoring for patients after surgery resulted in a rate of vital signs monitoring that was 12 times greater than usual care. Failure to rescue patients who develop complications after surgery is common in LMICs and innovative solutions to address this are needed in the short term to help reduce preventable deaths after surgery. We have demonstrated that family members can be involved in patient care to supplement the routine monitoring of patients on the postoperative wards. Two areas of work could follow on from this pilot trial. The first would be to evaluate the accuracy of family member supplemented vital signs and investigate the utility of each of the vital signs. I chose to exclude blood pressure and temperature but there may be some utility in understanding whether family members are also capable of accurately measuring these parameters and what the training burden would be. For us to understand the clinical effectiveness of family supplemented vital signs monitoring after surgery, the intervention needs testing on a larger scale. This would allow us to determine its impact on mortality outcomes or similar clinically relevant patient outcomes.

CHAPTER 6 FAMILY SUPPLEMENTED PATIENT MONITORING AFTER SURGERY (SMARTER): PROCESS EVALUATION OF A COMPLEX INTERVENTION IN UGANDA

6.1 Introduction

Family supplemented patient monitoring after surgery (SMARTER): a pilot trial

The SMARTER pilot trial was a single centre cluster randomised trial looking at the effect of family supplemented monitoring on the frequency of vital signs for patients who had undergone surgery. Conducted over a period of six months, there were twelve times more vital signs in patients whose family members supported the nursing staff to perform postoperative monitoring. The pilot trial was conducted at a regional hospital in eastern Uganda, a low-income country in sub-Saharan Africa. I developed the intervention using an iterative approach, following guidelines on the development and evaluation of complex interventions from the Medical Research Council.[142] Whilst the SMARTER pilot trial has demonstrated that family supplemented monitoring is feasible and results in increased vital signs, it doesn't provide enough detail about the implementation of the intervention or about the context in which it was tested. This chapter completes this picture and provides valuable information that can be used to inform further testing and development. The SMARTER pilot trial methods and results are described in detail in the previous chapter.

Healthcare settings are complex

Healthcare delivery, with its multiple interacting components is naturally complex. Patients depend on many people doing the right things at the right time. This system complexity is, amongst other things, due to: the variety of tasks involved in patient care, the diversity of healthcare workers and their patients, the natural dependency of healthcare providers on each other, variations in clinical environments, variability or lack of regulations, diversity of different care pathways across different institutions, the vulnerability of patients and the introduction of new technologies.[254-256] This is particularly true in low-income settings where resource constraints lead to unpredictable limitations in infrastructure, supplies and human resources. Interventions to improve healthcare delivery need to be tested and understood within the complex contexts into which they are being introduced.

Intervention effectiveness

A research trial that tests an intervention with a single primary outcome and demonstrates a significant difference (or no significant difference) may do so because of the intervention itself or because of multiple interacting components that contribute to the observed effect. These are often referred to as confounders. An intervention that is effective in one setting may fail to display similar results in another setting, because of differences in the way the intervention was delivered, differences in the targeted groups or differences in the wider context. For this reason, randomised controlled trials that are run in complex settings without an evaluation of the underlying processes that lead to an intervention working or not, can be easily criticised. Process evaluation data is key to enable effective translation of evidence generated from randomised trials into day-to-day clinical practice.

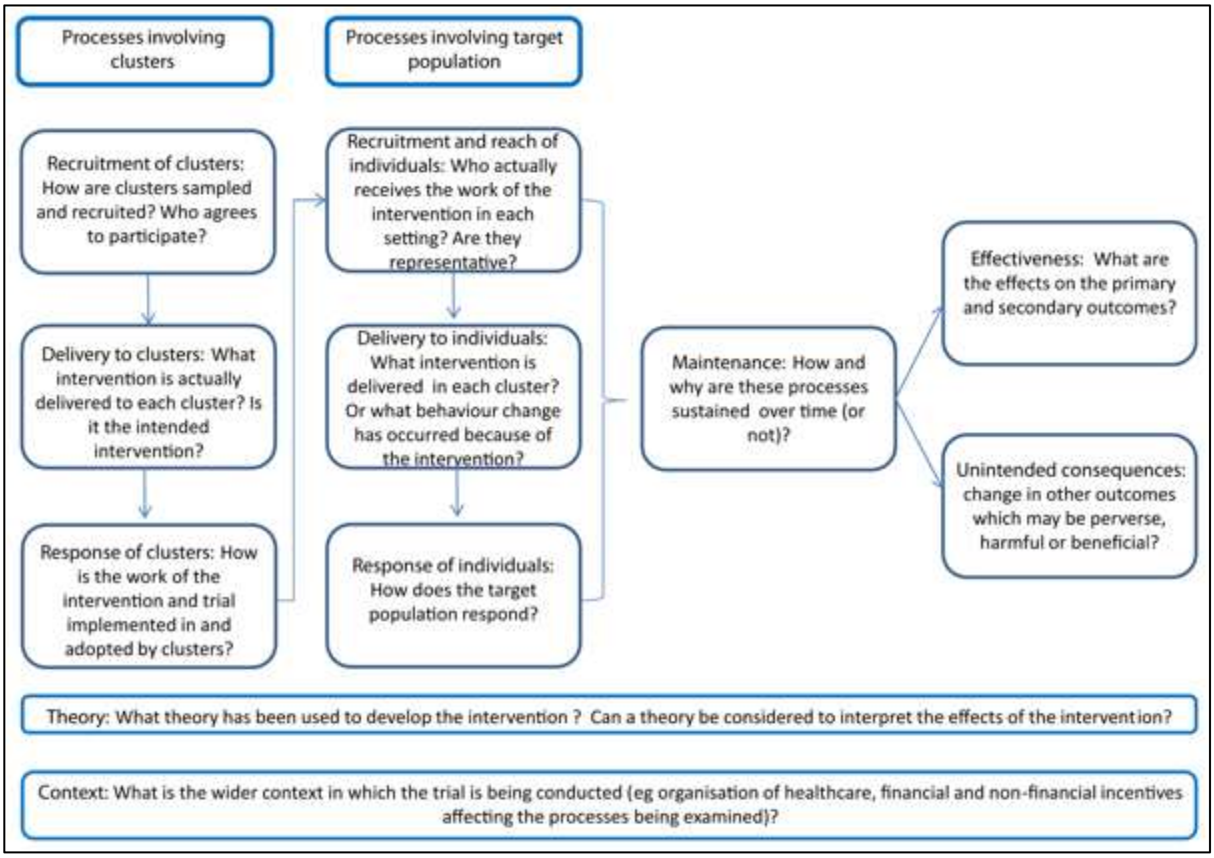
Complex intervention evaluations can provide useful information for decision making

A process evaluation is a study that runs alongside or after an intervention trial to help understand the processes underlying the intervention's impact. In comparison to previous UK Medical Research Council guidance, there are stronger recommendations that intervention evaluation needs to go beyond simply asking whether an intervention works (achieves its intended outcome). Evaluation must ask 'a broader range of questions including identifying what other impacts it has, theorising how it works, taking account of how it interacts with the context in which it is implemented, how it contributes to system change, and how the evidence can be used to support decision making in the real world'.[142] From the point of view of clinicians working in healthcare settings, whose overall goal is to develop and test interventions that will lead to improved quality of care and reductions in mortality rates, perhaps the most important shift in focus of this MRC guidance is the move from primarily focusing on obtaining estimates of effectiveness that are unbiased, to the prioritisation of information that is useful for decision making.[142] We can use the ASOS-2 trial as an example of this. An intervention to improve surveillance of high risk patients after surgery was designed and tested in a cluster randomised trial of hospitals across Africa but did not show any reduction in 30-day in-hospital mortality.[127] This result alone suggests that increased postoperative surveillance is not an effective strategy to reduce deaths after surgery in this population, contrary to other published reviews.[39,41] Importantly, the study team also undertook a concurrent evaluation to understand the process of intervention delivery.[158] The main finding was that poor intervention fidelity across the ASOS-2 sites was the likely cause of the lack of effect on mortality. This puts the lack of benefit into context and allows future work to think about the implementation science needed to introduce such an intervention effectively before testing its effect on outcomes.

Cluster randomised controlled trials are best evaluated using a mixed methods approach

A recognised framework (Figure 16) to be used both in the design of cluster randomised controlled trial process evaluations and their reporting was developed in 2013.[257] Previous literature describing evaluation approaches tended to focus on individual elements in-depth, which, while useful, did not provide a comprehensive framework for researchers to follow.[258,259] Whilst, naturally, there is a need to make choices about the research questions that are appropriate for an individual study, the framework allows teams to be clear about what they are (or aren't) evaluating. The focus of many process evaluations has traditionally been on the use of qualitative research methods,[260,261] but many of the elements described in this framework can be assessed using quantitative data. An example would be data on the recruitment of clusters or participants. This is often routinely reported in the main trial data using a flowchart following the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[262] In this case, it may not be considered a specific part of the process evaluation despite a deeper understanding of the recruitment processes being useful to inform trial generalisability. A mixed methods approach can enhance data quality through a better understanding of the context in which indicators have been used. The potential disadvantage of a mixed-methods approach to process evaluations is the need for greater planning and organisation (for example integration of process data points into the case report form, in addition to the data points needed for the main trial) but this is easily outweighed by the advantages.

Figure 27. Grant et al.'s framework model for designing process evaluations of cluster randomised controlled trials



The SMARTER Pilot Trial process evaluation

Innovative interventions are needed to reduce the high burden of mortality after surgery in low-income countries such as Uganda. In eastern Uganda, postoperative mortality rates mirror those of the wider original ASOS study.[160] A lack of monitoring on the postoperative wards, in part due to high patient to nurse ratios was identified as a significant contributing factor. The SMARTER Pilot Trial tested a complex intervention to train family members to perform basic vital signs monitoring of their patients after surgery. The objectives of this process evaluation were: a) to understand the contextual factors that influenced the frequency of family member supplemented vital signs monitoring in this low-resource setting and b) evaluate whether our programme theory accurately reflected the processes that occurred in the hospital.

6.2 Methods

6.2.1 Process evaluation

We undertook a process evaluation using the framework for the evaluation of complex interventions tested using cluster randomised trials.[257] A mixed-methods approach was used, including during and post intervention focus group discussions, analysis of field journals and evaluation of quantitative data from a subset of participants to assess intervention effectiveness. Process evaluation data collection was completed without knowledge of the trial results. The trial design included a predetermined point (two months into the trial) for a formal evaluation of the intervention.

6.2.2 Data sources and data collection

Qualitative and quantitative data were collected for the process evaluation from the following data sources: 1) field notes kept by the research team during the pilot trial, 2) transcripts of focus group discussions held with the research team and nursing staff from the wards, and 3) quantitative data on a subset of patients (described in more detail below).

Following the prespecified review of the intervention after two months, I realised that I was not collecting quantitative data to measure whether the intervention resulted in the anticipated effect (recognition of abnormal vital signs, notification of staff and a staff response). An amendment was made to the patient CRF and submitted for approval by the Mbale Regional Referral Hospital Research and Ethics Committee (see Figure 28). Following implementation of this data collection tool, during their routine daily follow up of the patients, the research team would review the previous 24 hours of the vital signs chart. If in the previous 24 hours an abnormal vital sign was documented, the research team asked the family member whether they had done anything about it. If the family member answered no, it was marked as ‘not recognised’ and the following two fields were marked as not applicable. If they recognised it, they were asked whether they had communicated it to a member of the nursing or medical team and if so if someone had responded. If multiple abnormal vital signs were noted in the previous 24 hours, the first abnormal set was used. Quantitative data were entered into REDCap electronic data capture tools hosted by the Association of Anesthesiologists of Uganda. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.[263,264]

Figure 28 Quantitative process evaluation case report form.

Process Evaluation				
	Were there abnormal vital signs?	Were they recognised by family member?	Were nursing or medical team notified?	Did the nursing or medical team respond?
Day of surgery (Day 0)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
First day after surgery (Day 1)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
Second day after surgery (Day 2)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
Third day after surgery (Day 3)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
Comments:				

6.2.3 Data analysis

Data from the field notes and focus group discussions was analysed by Tim Stephens (TS) and I using a framework approach.[265] This approach includes several well described steps that ensure rigor in the analysis process. Thematic coding was based upon the constructs defined in the Consolidated Framework for Implementation Research (CFIR).[171] The CFIR provides a mutual language that can be used across different complex environments to help organise and understand common constructs. It focuses on five areas, the inner and outer context, the implementation, individuals involved and the intervention itself. These constructs present a framework that can be used to understand the key influences on the implementation of the SMARTER intervention. Throughout the analysis process, manual coding of data was undertaken separately by TS and I using a deductive approach.[266] Data sources were initially read from start to finish to familiarise ourselves with the content as a whole. Data was then re-read to identify text that corresponded to identified constructs from within the CFIR. Regular meetings were held to discuss and agree on the coding decisions. Quantitative data were analysed using Microsoft Excel (Microsoft Corporation, 2018) and is presented using descriptive statistics.

6.3 Results

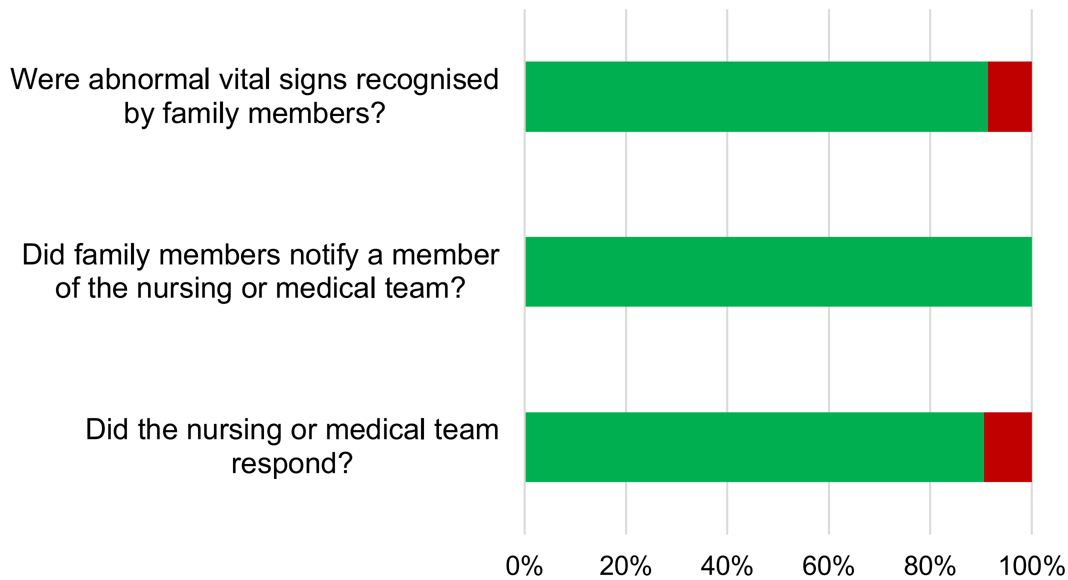
6.3.1 Process evaluation dataset

Two focus group discussions were held at the prespecified review point and at the end of the SMARTER intervention. A total of six research assistants and eight members of nursing staff were included in the focus group discussions. Field notes were collated from a diary filled on a daily basis by the research team and from comments documented on the process evaluation section within the pilot trial case report form.

6.3.2 Quantitative process evaluation results

Quantitative process evaluation data was collected for a total of 397 patients over 783 days. 46/783 (5.9%) abnormal sets of vital signs were documented during this time. Of these, 91.3% (42/46) were recognised by family members, 100% (42/42) were communicated to a member of the nursing or medical team and the team responded 90.5% (38/42) of the time (Figure 29).

Figure 29. Family member and staff response to abnormal vital signs during the SMARTER intervention.*



*Green = yes.

6.3.3 What were the factors that influenced the delivery of the intervention?

Delivery of the SMARTER intervention during the pilot trial was influenced by factors that can be categorised into two major groups, facilitators (those with a positive influence) and barriers (those with a negative influence). These factors, and the influence they had on the SMARTER intervention have been summarised under their corresponding CFIR constructs in Table 19.

6.3.3.1 Facilitators

Tension for change [inner setting] is a driving force that often leads to changes in practice. Healthcare settings in low-income countries commonly face significant human resource shortages. Nursing staff in hospital wards can be overwhelmed with competing pressures that force them to prioritise what they spend their time doing. This tension for change was evident during the SMARTER Pilot Trial where a single nurse on the postnatal ward had responsibility for helping with the ward round, delivering prescribed treatment, writing discharges for patients after vaginal deliveries, teaching mothers about post discharge care, collecting new admissions from labour suite theatre and monitoring patients after surgery.

"In all the charts they had written 'monitor vitals' [doctors' orders] - how can she monitor vitals for all those". [RA, FGD 1]

Staff on the wards know they need to monitor their patients closely after surgery but when they are alone there is simply not the time.

"When a patient has just come from theatre, we need to first take vitals, they have requested half hourly…..when you are alone on the ward with many patients, you will hardly meet that because you can't just be on one patient. Observing half hourly becomes somehow a

challenge, maybe they are calling you to pick another patient. Those first vitals …….are somehow a challenge." [Nurse, FGD 2]

'Relative advantage' [Characteristics of the Intervention] was the construct most commonly coded across all data sources. Healthcare workers, research staff, patients and their families shared the perception that the SMARTER intervention offered a significant advantage over the alternative of changing nothing. Nursing staff on the wards saw first-hand how the intervention helped to relieve them of some of their workload and at the same time contributed to improving the quality of care.

"I feel the programme has relieved us of some work, if the attendant is in position to come and tell you something has gone wrong, that means they have really helped you, than coming back in the morning after some rest and find when the patient is either deteriorated, you have to resuscitate or the patient has passed on." [Nurse, FGD 2]

This perception had a strong positive influence on how the nursing staff engaged with the intervention.

"…there was one girl there who was so keen but the attendants would chase her to go and do other things, to cook, so we had to stress to them that we want her there so that I know as a nurse I have someone there who can help me." [Nurse, FGD 2]

Table 19. Major CFIR constructs influencing the SMARTER intervention. Short descriptions taken from Damschroder et al's original publication.[171]

Category	Construct	Short description of construct
Facilitators (positive influences)		
Inner setting	Tension for change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
	Relative priority	Individuals' shared perception of the importance of the implementation within the organization
Characteristics of individuals	Knowledge and beliefs about the intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
	Other personal attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
Intervention characteristics	Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution
Barriers (negative influences)		
Inner setting	Available resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
	Culture	Norms, values, and basic assumptions of a given organization.
	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
Intervention characteristics	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement
Characteristics of individuals	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.

The nursing staff trusted the ability of the family members to monitor the vital signs and alert them when there was a problem.

"It actually improved, because now say for instance you are one nurse on the ward, when the caretaker is able to record the vitals and she knows when she or he [has to] come to the nurse, it gives me time to attend to other patients knowing that by the time the other attendant comes that means there is a problem there. And if I am to check you find they have already recorded." [Nurse, FGD 2]

Relative priority [inner setting] and individuals' knowledge and beliefs [characteristics of individuals] were the next most commonly coded constructs displaying a positive influence on the intervention. Patients and their family members in particular, recognised the importance of close monitoring.

A family member who had finished day 3 [of the] intervention the previous day requested to continue close monitoring on his patient since the results were so useful in the management of the patient. [Field notes]

At times during the trial, patients who did not meet the inclusion criteria also wanted to be closely monitored and made special requests to be trained.

One of the patients who was operated on was not recruited…today one of his attendants approached us and said he should be trained, consented, and included in the study. I explained to him why he could not be included in the study, but he still insisted. [Field notes]

One of the nurses reported "there was a time when they asked me to train the whole male side." [Nurse FGD 2]

The impact of an intervention that involves members of the family or community is often further reaching than initially expected. Increased positive community awareness of work in the hospital encourages patients to attend earlier and improves community engagement in their care.

"……there is some knowledge being spread in the community. I am sure those people who have learnt to do something on the ward, they are already telling others, when you go to hospital you do not only go to look after your patient but there is also some knowledge imparted in you by the nurses." [Nurse, FGD 2]

Variation in behaviours and attitudes of the general public in a hospital is expected. Patients and their families come from many different backgrounds. Even when some family members were hesitant to take on the extra responsibility of monitoring their patients closely, the patients themselves were enthusiastic.

"the perception of the patients is very good, very positive because this is a person who is very eager to know his physiology is running. The attendants whose duty it is to monitor, at times, they feel it is an added duty for them" [RA, FGD 1]

This idea of patients themselves supporting the intervention was also seen when their family members were illiterate and unable to participate.

On postnatal ward, some patients are requesting to be taught how to take vitals themselves, simply because the patient is learned and is able to understand everything taught efficiently yet the caretaker is unlearned and unwilling to even try. [Field notes]

Other personal attributes [characteristics of individuals] of family members facilitated use of the intervention in unexpected ways. Neighbouring patients and their families would assist others who were facing difficulty.

One patient had an illiterate attendant stay overnight. However, a neighbouring attendant had just finished [the] intervention for his patient so he was willing to help the attendant to do vitals for his patient. [Field notes]

Family members took pride in their ability to help with the responsibility of monitoring. This encouraged them to do what they were asked.

"…..they knew each other, so she was very proud, she said 'you hurry, I take your observations, hurry hurry position yourself.' She was saying 'now I am going home when I think I am now also a nurse' she was very proud" [Nurse, FGD 2]

6.3.3.2 Barriers

Self-efficacy [characteristics of individuals] describes an individual's belief in their own capabilities to perform the necessary actions to achieve the tasks set out in the intervention. Family members supporting their patients in hospital come from a large range of backgrounds. Some are educated with professional jobs and others are illiterate and unable to read and write. Almost half of the 315 participants excluded from the trial were due to illiteracy. The impact of this on the ability of family members to be involved was described clearly during the focus group discussions.

"…they fear they are going to do work they don't understand, some of them have never been to school so what they do is just ignore the pen…….i think the issue is about reading and understanding" [RA, FGD 1]

However, despite this, other family members demonstrated willingness to learn and be involved because they recognised the importance of monitoring their patients closely.

"I got one and she couldn't write, but she could interpret so was taught that if the oxygen levels are ok put a tick, if they are not ok put a cross. She was able to count the breathing but writing the real figure was a challenge." [RA, FGD 1]

A second identified barrier was the challenge presented by the available resources [inner setting]. In a low-income setting there are usually less staff available and less access to equipment and supplies within the hospital. Patients were deemed sick enough to require continuous monitoring, preventing use of the pulse oximeter by family members for routine monitoring of their postoperative patients.

Nursing staff were approached and asked to take the machine in the general ward but they refused giving a reason that they have a right to every equipment and the pulse oximeter should be on that patient for close observation [Field notes]

After identifying abnormal vital signs, family members were trained to notify a member of staff so that they can intervene however, limited human resources meant that at times there were no members of staff available on the wards. An example would be a single nurse on duty who may be required to carry out duties off the ward, for example collecting supplies from stores.

While taking vital signs, a caretaker recorded oxygen levels less than 40% so she tried to look for a nurse on duty but couldn't see her. She had to just look on to see what happened to her patient. [Field notes]

Nursing staff available to respond appropriately to communication from family members was an assumption that we made in our programme theory. Necessary absence from the ward was one example when this assumption failed. A second example were the cultural attitudes [inner setting] identified in some members of staff, patients and their family members. With low salary scales and poor remuneration for work, it is common for staff to work more than one job. Staff on duty at night routinely sleep and family members were reluctant to wake them.

The carers who identify abnormal vital signs at night do not alert the medical team because according to them 'we fear waking up the nurses at night to destroy their sleep'. [Field notes]

This potentially creates a barrier preventing family members from seeking help when they need to, however this was not identified within the quantitative data we have presented above.

Two or three times, the attendants have notified the nurses about abnormal signs and been told to wait "me I am tired, I am going to rest". [Field notes]

Other cultural norms within the context of the hospital site for the pilot trial were also noted to create barriers to use of the intervention. Research in Uganda is commonly associated with incentives for participants who are recruited. This has created a culture of expectation.

Family members who do the vital signs, think the organisation should give them 'something', probably cash or incentives for the work they are doing. [Field notes]

It is well known that the complexity [intervention characteristics] of an intervention plays a large role in its ease of implementation. During our iterative intervention design, we deliberately attempted to keep it as simple as possible. A pre-planned review at 2 months was incorporated into the pilot trial to enable further intervention refinement and adaption based on identified challenges (changes summarised in Table 20). We identified the respiratory rate as a specific vital sign that was challenging for family members to measure. Respiratory rate is the most sensitive sign of a patient condition and the best early predictor of patient deterioration but globally it is also the vital sign that is most frequently missed out.[267] Measuring a respiratory rate accurately requires several steps. Recognition of each individual breath a patient is taking, counting the number of breaths and simultaneously watching the clock. The identified challenges included difficulty coordinating both time keeping and counting at the same time and for those that chose to use their phones instead of the clock to keep time.

"….attendant complaining that they have to look at the clock and then also breathing…." [RA, FGD 1]

"for those who use the small phones, the button ones that have no stopwatch, its hard for them to count the breathing rate in one minute." [RA, FGD 1]

Feedback gained during our pre-planned review identified three areas of complexity that were able to be resolved through amendments and resubmission and approval by the local research and ethics committee. Differences in the order of documenting vital signs on the chart compared to the numbers visible on the pulse oximeter led to incorrect documentation of vital signs. (Figure 30)

[I] noted that our vital signs chart is giving some headache to our participants. Why? Because on the monitors, oxygen level comes first then heart rate yet on our vital signs sheet heart rate comes first the oxygen last. Therefore, you find that some patients may end up recording the oxygen level figures on the heart rate. [Field notes]

Table 20. Summary of changes made to the intervention following the pre-specified evaluation at two months.

Intervention area	Original intervention	Amended intervention	Reason for change
Training of family members	Training planned twice a day in groups	Training conducted when family members available, individually or in groups	Family members never available on the ward at the same time, scheduling for surgery at chaotic at times
Family member documentation of vital signs	Time of day listed as 12-hour clock using numbers only	Times of day as understood in local culture included (e.g. breakfast)	In the local culture, the day begins at 6am and so 8am ('8 hours after the beginning of the day') would equate to 2pm. Local language incorporated to avoid confusion
Family member documentation of vital signs	Use of > and < signs to mean greater or less than	Words used instead of symbols	Family members and patients did not understand the symbols
Family member documentation of vital signs	Choice of four ranges when documenting respiratory rate and heart rate	Simplified to three ranges, above the upper limit, below the lower limit and normal	No added benefit to two options within the specified 'normal range', additional options led to some confusion
Family member documentation of vital signs	Heart rate above respiratory rate in the observation chart	Order changed round to match the numbers visible on the pulse oximeter with respiratory rate above the heart rate	This simplification enabled more accurate differentiation between heart rate and respiratory rate

Figure 30. Images of the first version of the family member observation chart and the pulse oximeter used.

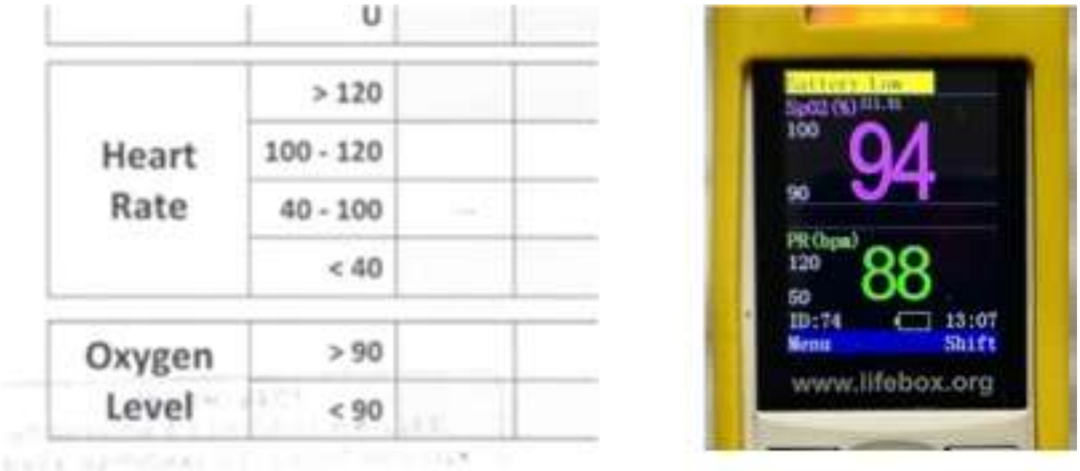


Figure illustrates the discrepancy between positioning of heart rate (bottom, in green on the pulse oximeter) and oxygen level (top, in pink on the pulse oximeter)

The second amendment involved the use of symbols instead of words (Figures 31 and 32).

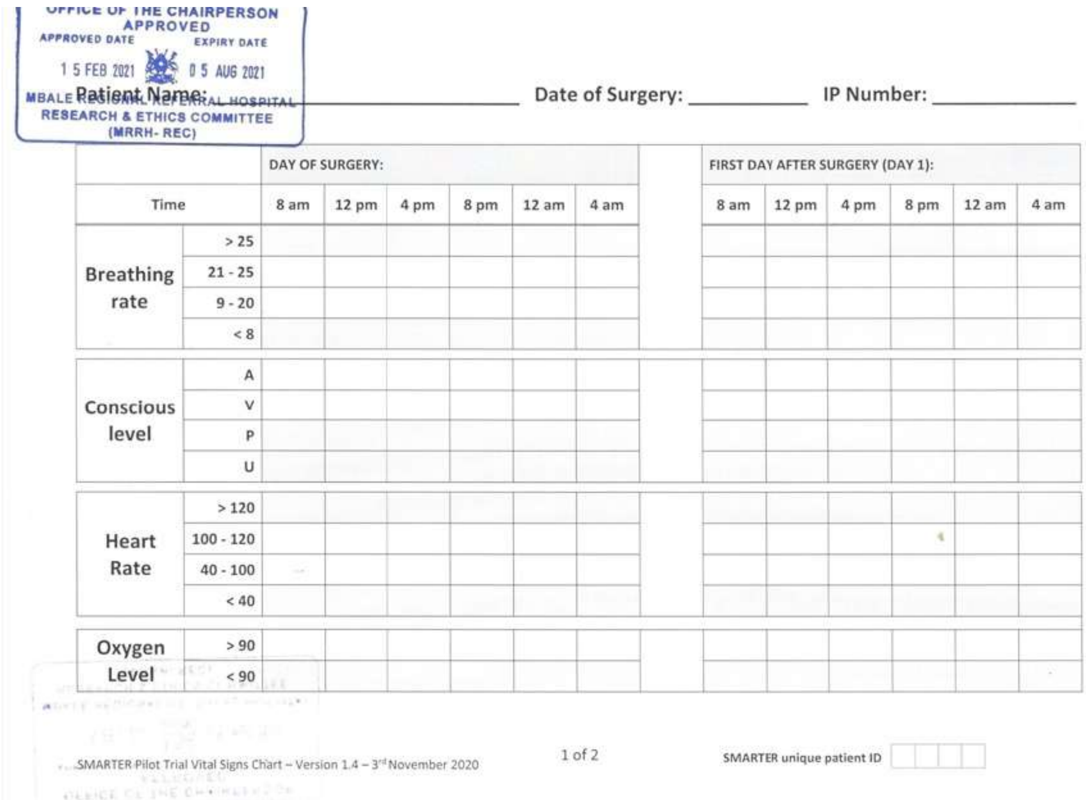
< and > signs are confusing some participants. (Maybe in future put 'less than' for < and 'greater than' for >). [Field notes]

Lastly in the local language the times of day are described differently. Version 1 of the observation chart listed the times of day using the 12-hour clock leading to confusion. The day locally begins at 6am. 11am in the 12-hour clock would be interpreted as 5pm in the local language. To overcome this, the times of day were described using common activities e.g. breakfast or lunch and the local translations of these times were used. (Figures 31 and 32)

"Here, if you say 8[am] they will think you mean 2pm. That's when you say the time in the local language…..there is one TV station that reads time in the local way, if it is 8am they will say 2 hours and many people watch that TV. If you count 1 [hour] it is 7am." [RA, FGD 1]

Other aspects of the routine workflow in the regional hospital where the SMARTER pilot trial was conducted commonly led to challenges in the intervention implementation. These barriers are coded under compatibility [inner setting]. Examples include exclusion of family members from the entire clinical areas to allow medical student examinations to take place.

Figure 31. Version 1.4 of the family member observation chart, before amendments were made.



OFFICE OF THE CHAIRPERSON
APPROVED
APPROVED DATE 15 FEB 2021 EXPIRY DATE 05 AUG 2021
MBALE REGIONAL REFERRAL HOSPITAL
RESEARCH & ETHICS COMMITTEE
(MRRH- REC)

Patient Name: ____________ Date of Surgery: __________ IP Number: ____________

		DAY OF SURGERY:						FIRST DAY AFTER SURGERY (DAY 1):					
Time		8 am	12 pm	4 pm	8 pm	12 am	4 am	8 am	12 pm	4 pm	8 pm	12 am	4 am
Breathing rate	> 25												
	21 - 25												
	9 - 20												
	< 8												
Conscious level	A												
	V												
	P												
	U												
Heart Rate	> 120												
	100 - 120												
	40 - 100												
	< 40												
Oxygen Level	> 90												
	< 90												

SMARTER Pilot Trial Vital Signs Chart – Version 1.4 – 3rd November 2020 1 of 2 SMARTER unique patient ID

Figure 32. Version 1.5 of the family member observation chart following the prespecified intervention review.

Patient Name: ______________________ Date of Surgery: __________ IP Number: ____________

OFFICE OF THE CHAIRPERSON APPROVED
APPROVED DATE 06 AUG 2021 EXPIRY DATE 06 AUG 2022
MBALE REGIONAL REFERRAL HOSPITAL RESEARCH & ETHICS COMMITTEE (MRRH-REC)

Time		DAY OF SURGERY:						FIRST DAY AFTER SURGERY (DAY 1):					
		8 am	12 pm	4 pm	8 pm	12 am	4 am	8 am	12 pm	4 pm	8 pm	12 am	4 am
		Morning Kumakya	Breakfast Kyankya	Lunch Kyamisana	Evening Akawungeezi	Supper Ekyegulo	Night Ekiiro	Morning Kumakya	Breakfast Kyankya	Lunch Kyamisana	Evening Akawungeezi	Supper Ekyegulo	Night Ekiiro
Breathing rate	Above 25												
	9 - 25												
	Below 8												
Conscious level	A												
	V												
	P												
	U												
Oxygen Level	Above 90												
	Below 90												
Heart Rate	Above 120												
	40 - 120												
	Below 40												

SMARTER Pilot Trial Vital Signs Chart – Version 1.5 – 15th July 2021 1 of 2 SMARTER unique patient ID

Changes incorporated include clarity on time of day, replacing < and > signs, and switching the oxygen level and heart rate to match the pulse oximeter

Attendants were asked to stay outside. They were unable to do vitals, and this also affected our training for new participants. [Field notes]

The flow of patients to theatre and back to the wards was also not always straightforward with patients unexpectedly going home despite being recruited and having family members trained.

Patients are meant to be discharged through the ward but after theatre recovery, they just leave for home. [Field notes]

In the obstetric department, particularly on the postnatal wards the high throughput of patients led to continuous movement around the ward disrupting the recording of vital signs.

When patients are so many on the ward, they are shifted to the side…so they have nowhere to keep the vital [signs] charts other than to put them in their bags. [Field notes]

There were also common changeovers of family members. Patients who undergo their operations at night often have different caretakers the following day. This was particularly true for the obstetric patients.

Some caretakers bring in their mothers or sisters to give birth, they are learned and willing to enrol in the study, so they consent. However, in the morning, the consented caretaker disappears and leaves [an] elderly grandmother or mother-in-law to take care of the patient. The grandma or mother-in-law can't write her name and…..only speaks a local language. [Field notes]

6.3.4 SMARTER programme theory

Our inner context preconditions were tested within the SMARTER process evaluation. In the majority of cases, staff responded appropriately to communications from family members. Formal assessment of staff knowledge and skills around the management of surgical complications and the capacity of local leadership to drive improvement was not conducted. However, during the SMARTER pilot trial, we saw active participation from both nursing, medical and administrative leadership suggesting that in our setting, the wider hospital team had the capacity to embrace improvement work and contributed to the success of the pilot trial. At the beginning of this chapter, we describe how the core SMARTER programme theory assumptions that we made have been tested and found to be largely accurate. We have not made changes to our programme theory following our pilot trial. During the process of evaluating the intervention, there are additional assumptions that we have made that would be relevant to test during a larger formal trial of the intervention. These include the accuracy of the individual vital signs that family members take in comparison to the experienced healthcare staff, and assumptions that staff possess the knowledge, skills and resources to respond appropriately to complications when they occur.

6.4 Discussion

I piloted an intervention to improve monitoring of patients after surgery by involving family members more directly in the process, supplementing the usual monitoring of patients by healthcare workers on the wards. At Mbale Regional Referral Hospital, there is a tension between the implementation climate, illustrated by the healthcare worker's recognition of gaps in postoperative monitoring and their desire to change; and the ability of the teams on the ground to put this into practice (implementation readiness). My mixed-methods process evaluation of the SMARTER Pilot Trial identified both facilitators and barriers influencing delivery of the family supplemented vital signs monitoring intervention. Positive influences included the clear 'relative advantage' of the intervention, factors within the inner context including 'tension for change' and 'relative priority', and individual characteristics centred around 'knowledge and beliefs'. Major constructs that had a negative influence sat largely within the inner context, including 'available resources', 'culture' and 'compatibility'. 'Self-efficacy' and 'complexity' also had a negative influence. Quantitative data provided evidence to support our original programme theory without major revisions.

The relative advantage of innovations to improve monitoring of patients has also been described in several other countries. In West Africa, clinicians recognised the added advantage of wearable sensor technology in paediatric patients, especially on wards where current levels of monitoring equipment were limited.[268] In HICs, improved postoperative monitoring using novel technology has shown benefit both in the community and before hospital discharge.[269,270] Implementing technology driven innovations in low resource settings in a sustainable way is however, much harder, facing significant challenges within the enabling environment, existing infrastructure and integration with existing systems.[271] Whilst the SMARTER Pilot Trial did not focus on the use of technology to improve postoperative monitoring, the barriers that affect implementation readiness for a new innovation cut across health system innovations. In 2020, a systematic review of barriers and facilitators to implementing health innovations in LMICs was published.[272] Although a different conceptual framework was used to assimilate the results from the systematic review (compared to the CFIR we have used) it is easy to identify cross-cutting themes that match those identified in our process evaluation and that contribute to a facility's implementation readiness. Examples include resource limitations (for example human, physical and time) and contextual factors such as socio-cultural influences.[272] Four main factors and ten sub-factors that contribute to an organisation's innovation readiness have been described.[273] Innovation readiness in this context can be considered synonymous with implementation readiness. Whilst these small differences in nomenclature exist, the overarching theme remains. A lack of facility or institution readiness for innovation will act as a barrier to implementation success.

The complexity of a healthcare system necessitates a formal process evaluation to run alongside any intervention research in this setting. One of the biggest strengths of our pilot trial has been the recognition of this complexity in the early stages of study conception, and the robust co-design of our formal process evaluation alongside the main pilot trial. We have followed established guidance for the evaluation of complex interventions and therefore provided robust context to support future efforts to test the SMARTER intervention on a larger scale. We have highlighted important themes that influence implementation work in low-resource environments that can be used by others during the design phases of their implementation development. Weaknesses of our process evaluation include limited stakeholder involvement in the design of the process evaluation itself. If we had the opportunity to start the whole process again from conception and design of the study idea, we would want to involve patients and their carers directly in the very early phases. Whilst we conducted useful engagement during the intervention design and testing phases, this did not fulfil the potential benefits of two-way involvement between our community and the research team. Patient researcher led focus group discussions with patients and their family members would be one way to address this gap in the future. Implementation research in a healthcare setting is also influenced by stakeholders at a policy level, for example in the Ministry of Health. Novel ideas are often avoided because they do not fit within the structures and systems policy makers are used to. Understanding these concerns and expectations can improve acceptability of any future scale up activities and so early engagement at this higher level is equally important. Although the research team have informally addressed this following the conduct of the SMARTER pilot trial, it was not a prespecified objective and is therefore a gap in our process evaluation strategy. The process evaluation was based on a relatively small pool of qualitative data. Although field notes were kept by the research team throughout the six-month duration of the trial, only two focus group discussions were held. The process evaluation and main pilot trial occurred during the COVID-19 pandemic and gatherings of groups of people was limited. Whilst we believe we reached thematic saturation by combining data from the field notes and focus group discussions there is a risk that this may not be the case.

6.5 Conclusions

My mixed-methods process evaluation of the SMARTER pilot trial has provided valuable insight into the context within which it was tested. I been able to validate my original intervention programme theory and make improvements to the intervention. I identified both positive and negative factors that influenced the success of the trial and it will be important to take these into consideration when deciding on the next steps. I am aware that each health facility and country has slightly different contexts and the success of family supplemented patient monitoring in Mbale Regional Referral Hospital may not necessarily mean it is successful across Uganda or Africa. One area of focus before implementing a new intervention is to prepare the ground for improvement. Does the right environment exist that will support changes in care and focus the team on patient centred outcomes. Developing an intervention itself is often the easier part. Understanding how to implement it within the complexity of health settings in low-resource countries is much more challenging. My SMARTER pilot trial process evaluation will provide crucial learning to support the development of a larger intervention, including the use of family members, to reduce preventable deaths after surgery and its testing in a larger trial across multiple settings in Africa.

CHAPTER 7 CONCLUSIONS AND FUTURE WORK

This thesis describes the development of an intervention that may help to reduce the high rates of failure to rescue, and therefore mortality after surgery, in Africa. The intervention was designed to improve vital signs monitoring of patients after surgery and was piloted at a regional referral hospital in eastern Uganda. A concurrent process evaluation provided a more detailed understanding of the context in which the intervention was piloted and identified important components of the implementation process that would need to be considered during future work. Now that the involvement of family members in patient care after surgery has been shown to be feasible, future work needs to focus on further development and testing of the intervention and how this can be integrated into routine workflows in different settings. In this chapter I provide an overview of my results and reflect on some of the strengths and weaknesses of my PhD. I also discuss family members supporting improvements in care, and integration of more frequent vital signs monitoring within the entire failure to rescue pathway (recognition of the deteriorating patient, relay of information and appropriate response).

7.1 Summary of results

Surgical care in Mbale Regional Referral Hospital is very different from the UK. It is the only government hospital with specialist surgical capabilities (e.g. orthopaedic surgery) serving a population of 4.5 million people in eastern Uganda. It is one of the busiest hospitals in the country in terms of annual surgical volume with almost 5000 operations per year but like many centres in low-income countries, where priority is often given to emergency obstetric care, the greatest proportion of surgical procedures are caesarean sections (55%), and 75% of all procedures are emergencies. Mortality rates after surgery in Mbale are double those in high income countries, mirroring mortality rates after surgery across the continent. In some subgroups, for example after laparotomy surgery, mortality rates were as high as 22%.

With the majority of post-surgical deaths happening on the wards after surgery following development of complications, and audits of vital signs monitoring demonstrating rates well below what would be expected, informal discussions with the nursing staff highlighted the overwhelming workload as the main causative factor resulting in this gap. With family members always present on the wards and already informally involved in patient care I developed an intervention to train family members to supplement the monitoring of patients on the surgical wards.

The centre of a complex intervention, usually the clinical processes or practices that are the focus of improvement, can be described as the core. The SMARTER core intervention involved family members taking, documenting and interpreting basic vital signs in order to supplement the work of the nursing staff, to monitor their patients after surgery. An intervention implementation also has a ‘soft periphery’, which describes the improvement methods that enable change to occur. In SMARTER, this was the training package that enabled the family members to perform the intervention, the change in practice by the nursing and medical staff who responded when receiving an alert from the family members, and the adoption of the intervention as a whole by the relevant departments. I tested the intervention during a cluster-randomised controlled trial using the hospital postoperative wards as the clusters, using a stepped wedge approach to introduce the intervention one ward at a time.

The SMARTER intervention resulted in more than 12 times as many sets of vital signs for participants enrolled in the intervention arm. There was no significant difference in the length of hospital stay for our patients nor the mortality rate. However, the study sample size was not powered for these outcomes and so this finding was not unexpected. Higher overall numbers of deaths in the intervention group likely reflected the different demographics of the usual care and intervention groups. Recruitment during the COVID pandemic led to a great proportion of obstetric patients in the usual care group. The group of surgical patients with the highest mortality rates fall in the general surgery category and the proportion of general surgery patients in the intervention group was higher.

I ran a process evaluation of the SMARTER trial intervention alongside the main step wedge pilot cluster randomised trial. The mixed methods process evaluation allowed me to answer questions beyond the effectiveness of the pilot trial. These included mechanisms of change, contextual influences and acceptability of the intervention. Following analysis of qualitative data from focus group discussions and field notes, I identified both facilitators and barriers influencing delivery of the SMARTER intervention. Coded in accordance with the consolidated framework for intervention research, positive influences I identified included the clear ‘relative advantage’ of the intervention, inner context factors including ‘tension for change’ and ‘relative priority’, and individual characteristics centred around ‘knowledge and beliefs’. Those factors that had a negative influence sat largely within the major constructs within the inner context. These included ‘available resources’, ‘culture’ and ‘compatibility’, although ‘self-efficacy’ and ‘complexity’ also resulted in a negative influence.

7.2 Strengths and weaknesses

Robust intervention development and testing can be challenging, especially within the added complexity of a resource limited setting such as Uganda. I have been able to develop and test an intervention that resulted in higher rates of vital signs monitoring for patients after surgery. I have done this using established and recognised guidance for the development of complex interventions published by the Medical Research Council and others. I have not presumed that I know the right intervention but have used an iterative approach with feedback from all relevant stakeholders, making adaptions as necessary along the way. This approach has resulted in an effective intervention that can be utilised in a low resource setting and that may have applicability within other healthcare systems globally. I have also used recognised and well described approaches for my systematic review and process evaluation. This ensures transparency, allows my findings to be interpreted by the reader within the context that the research has been conducted and provides robust evidence that can easily be replicated in the future if needed.

Another strength of this thesis is the first description of a year-long cohort of surgical patients in Uganda. Detailed data on surgical volumes and postoperative outcomes is limited from low resource settings. Many published works rely on small sample sizes that are often collected by visitors during short term trips and then extrapolated to give representative population data. In Uganda, examples include work by Anderson et al in western Uganda[192] and Albutt et al.[17]

Reflection following completion of my systematic review identified that the search strategy I had chosen to use may in itself have led to limitations in the evidence I was able to report. This is an important lesson, and to me, clear evidence of the powerful learning opportunities made available during my PhD pathway. Interventions used to detect deteriorating patients may have been published without explicitly mentioning failure to rescue. These interventions may also have been tested in non-surgical patient groups. Whilst my intervention focused on increasing rates of vital signs monitoring, learning suggests that for an intervention to be sustainable it is likely to need to include components that address each of the steps in the Failure to rescue pathway. For this reason, there is need to repeat the systematic review with a more inclusive search terminology. I have been involved in developing this new search strategy and have attached it as appendix 1. The strategy expands on the geographical limitations of my previous search terms by including all LMIC country names. It also includes more inclusive terms to capture any of the tools commonly used to address failure to rescue in HICs for example ‘early warning scores’ or ‘systems’. Although I am not leading the updated systematic review, my roles have also included screening some of the 38,340 studies identified papers and performing full text reviews to decide on eligibility of papers for inclusion.

The COVID-19 pandemic saw varied country responses around the world. Uganda was affected by two waves, the first during late 2020 and the second in late April 2021. Extremely strict lockdowns resulted in restricted movement of all people and patients, limiting movement across district boundaries and access to healthcare.[274] Although the direct impact of the lockdown on care at Mbale Regional Referral Hospital was not measured, increased surgical delays were seen at a nearby regional referral hospital,[275] there was a significant drop in patients accessing primary healthcare services in Masaka district in western Uganda,[276] and reports of difficulty accessing maternity services throughout the country[277] with increased risks for obstetric complications and immediate neonatal death.[278] Due to my timelines of approvals and funding, we continued with the planning and setup of the SMARTER pilot trial in early 2021 and started recruitment in mid-April. The second pandemic wage started unexpectedly at the end of the month. Due to low numbers of cases in Mbale and robust infection control practices in the hospital, the decision was made to continue recruitment. The trial used a stepped wedge cluster trial design meaning that the intervention was introduced to the clusters (wards) in a set wise manner. Patients recruited in the first half of the trial were largely included in the usual care arm whereas the majority of patients recruited during the second half were in the intervention arm. Differences in the demographics of the two patient populations reflect that, with usual care patients being younger, with more females and a higher proportion of obstetric patients. These differences can be considered a weakness of the trial, and the findings interpreted in light of these differences.

During qualitative research, it is often challenging to estimate the number of respondents that are needed to ensure all valuable data has been collected and to enable effective and meaningful analysis. A common approach is to analyse data as it is collected and when thematic saturation is reached, the study team can confidently agree their sample size is appropriate. The COVID pandemic affected my ability to bring groups of research staff and healthcare workers together to run focus group discussions. I utilised another technique to generate additional qualitative data, through the use of a field journal that was filled on a regular basis by the research team following their observations of family, patient or staff interactions. The small number of focus group discussions is a limitation in my process evaluation data.

I have previously described the chain of failure to rescue. It can be compared with the chain of survival following cardiac arrest that was first described in 1991.[279] There are multiple steps in a pathway that together, can result in a patients survival. The chain can be broken at any one of these stages with the same ultimate outcome that results in deterioration and death. In failure to rescue, the steps in the chain include recognition of the deteriorating patient, relay of that information to the right teams who can then respond in an appropriate manner, provided they have the resources they need. The SMARTER intervention considers gaps only in the first link in the chain, the early recognition of the deteriorating patient. This could also be considered as a weakness in the overall intervention. I have made assumptions that the remaining links in the chain will function correctly and that patients will be rescued. I discuss this in more detail in the section below as I describe my ideas for future work that builds on the SMARTER intervention.

7.3 Future work

The SMARTER pilot trial and process evaluation add to the growing body of evidence that family members can be used effectively to support safe, high quality healthcare delivery. I have utilised robust methodology to develop an intervention to address failure to rescue after surgery however, during my PhD journey I have also learnt a huge amount about implementing healthcare improvement, especially in a low-resource environment. I have also seen that there are many more similarities than one might think between improvement work in healthcare settings across different country income levels. Examples of this include the competing priorities for an individual's time and human factors affecting behaviour. Using this learning, I believe an intervention that addresses rates of vital signs monitoring alone is unlikely to lead to significant reductions in mortality. To improve outcomes after surgery, an integrated intervention is needed that includes components for each step in the chain of failure to rescue. Some of these potential components are outlined in Figure 33 below and, in addition to improved vital signs monitoring, include prioritisation of limited time to focus on the patients most at risk of complications, an early warning system for deteriorating patients, standardised responses to deterioration and a form of reflection.

Healthcare settings across Africa can be very varied. Uganda is a low-income country where resource limitations are at their most extreme. Many countries in Africa invest more in their health systems and as a result, whilst still resource limited, often have access to more human resource. In this scenario health facilities often limit access for family members to specific visiting times. There can be significant resistance to the idea of bringing family members into the hospital full time to support a task (monitoring) that is traditionally seen as one that should be done by a healthcare worker. If we are to scale an intervention that uses family members to support task sharing, these varied contexts need to be taken into account.

Figure 33. Proposed components of future ‘enhanced’ intervention to reduce failure to rescue after surgery

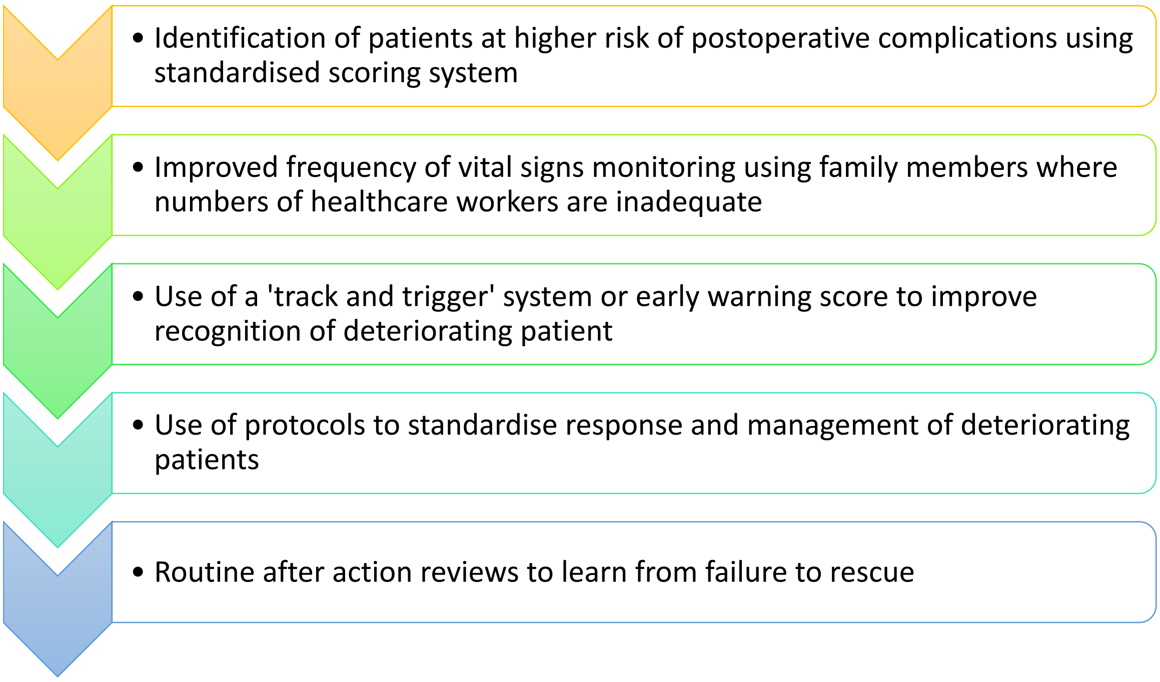


Figure 34. Proposed components of future ‘enhanced’ intervention to reduce failure to

In many low-resource settings, one of the biggest challenges facing health systems are the huge human resource gaps. Long term solutions at a national level are needed to address these gaps. In the meantime, strategies have to be adopted that allow the current healthcare staff to focus their valuable time where it is most needed. One solution that may allow this would be to identify patients who are at higher risk of deterioration and death after surgery and to focus any interventions on this patient group. My experience is that this often happens on an informal basis but is based on whether a patient looks ‘sick’ and ignores groups of patients who appear to be ok from the end of the bed but perhaps have underlying complications, for example acute kidney injury. There are multiple surgical risk scoring tools in routine use around the world, including P-POSSUM,[203] SORT[280] and ACS-NSQIP[281] however, they tend to be complicated and require variables such as laboratory test values that are often not routinely available in low-resource settings. Following the original ASOS study, a simple risk score was developed to identify adult patients in Africa who are more likely to develop complications, including death, after surgery. The ASOS surgical risk calculator[174] includes six variables that are commonly available before surgery. These include age, ASA physical status, surgery timing, surgery severity, indication for surgery and surgery type. A cut-off score of >10 is commonly used to describe patients who are at greater risk of postoperative complications, including death. We have used this score as a simple tool to guide admission to our surgical high dependency unit with good success. If implemented widely, this simple score would allow identification of high-risk patients and therefore allow prioritisation of available resources where they are likely to be most needed.

During the SMARTER pilot trial, I developed a simple ‘trigger’ system to enable family members to easily recognise when they needed to call for help. Systems like this, with varying degrees of complexity, have been utilised for many years in other settings. Examples range from composite early warning scores such as the National Early Warning Score used in the UK[221] to single vital signs triggers such as the Vital Signs Directed Therapy solution tested in intensive care in Tanzania.[104] They are effective at improving recognition of the deteriorating patient, rather than relying on an individual’s ability to recognise patterns from the observation chart. A broader failure to rescue intervention should include some kind of early warning or trigger system for both the healthcare workers and family members.

In hospitals in many low-resources settings, alongside shortages in permanent healthcare workers, it is common to find large numbers of training programmes. Although usually officially regulated, the net result is large numbers of junior staff providing the majority of care. Protocol driven care, whilst not without challenges, in general can lead to more consistent care, improve efficiency, reduce errors and lead to better resource utilisation and improved patient outcomes. Examples of improved outcomes include in sepsis management,[282] after surgery using enhanced recovery after surgery protocols,[283] and in the management of acute myocardial infarction.[284] It is reasonable to extrapolate this to the recognition and management of patients who develop complications after surgery. The use of standardised protocols to guide hospital systems, including their healthcare staff in this scenario is likely to lead to improvements in care and this component should be included in any intervention aimed at addressing failure to rescue after surgery.

Reflection is a tool that can be used by healthcare teams to turn unspoken, experience-based knowledge into explicit knowledge that can be shared with others. Systems for reflection, such as after-action reviews, are commonly used as a formal method to incorporate learning into health system improvements. Efforts to reduce maternal mortality are one area where this approach has been successful, including in Africa.[285] The benefits of after-action reviews include fostering open communication among team members and promotion of a culture of transparency and trust. They help break down silos within teams, leading to better collaboration and more cohesive team dynamics. They can also be used to learn from errors and if implemented effectively, can generate a culture of safety where lessons are learned, and mistakes are less likely to be repeated. Reflection or after-action reviews have been shown to be effective ways to improve patient outcomes and should form an important component of failure to rescue interventions.

Future work needs to consider each of these components in turn, identify whether evidence for their use already exists from low resource settings and if not decide whether evidence generation is needed for each component before they are put together into a complex intervention. A large component of any intervention is likely to be the implementation approach and the development of a local culture of positive learning and improvement. A good understanding of each context will be needed to enable successful implementation. Assumptions that all healthcare facilities are the same should not be made and where necessary, local adaptions to the intervention may be necessary.

CHAPTER 8 References

1. World Health Assembly. Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage. In: World Health Organisation, editor. 2015.

2. Meara JG, Leather AJ, Hagander L, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *Lancet*. Aug 8 2015;386(9993):569-624. doi:10.1016/s0140-6736(15)60160-x

3. Groen RS, Samai M, Stewart KA, et al. Untreated surgical conditions in Sierra Leone: a cluster randomised, cross-sectional, countrywide survey. *Lancet*. Sep 22 2012;380(9847):1082-7. doi:10.1016/S0140-6736(12)61081-2

4. Debas H, Gosselin R, McCord C. Disease control priorities in developing countries. *Surgery*. 01/01 2006:1245-1259.

5. Shrime MG, Bickler SW, Alkire BC, Mock C. Global burden of surgical disease: an estimation from the provider perspective. *Lancet Glob Health*. Apr 27 2015;3 Suppl 2:S8-9. doi:10.1016/s2214-109x(14)70384-5

6. Chao TE, Sharma K, Mandigo M, et al. Cost-effectiveness of surgery and its policy implications for global health: a systematic review and analysis. *Lancet Glob Health*. Jun 2014;2(6):e334-45. doi:10.1016/S2214-109X(14)70213-X

7. Bouchard ME, Sheneman N, Hey MT, Hoemeke L, Abdullah F. Investments in surgical systems contribute to pandemic readiness and health system resilience. *J Public Health Policy*. Sep 2021;42(3):493-500. doi:10.1057/s41271-021-00292-z

8. Murray CJ. Quantifying the burden of disease: the technical basis for disability-adjusted life years. *Bull World Health Organ*. 1994;72(3):429-45.

9. McQueen KA, Ozgediz D, Riviello R, et al. Essential surgery: Integral to the right to health. *Health Hum Rights*. Jun 15 2010;12(1):137-52.

10. Albutt K, Sonderman K, Citron I, et al. Healthcare Leaders Develop Strategies for Expanding National Surgical, Obstetric, and Anaesthesia Plans in WHO AFRO and EMRO Regions. *World J Surg*. Feb 2019;43(2):360-367. doi:10.1007/s00268-018-4819-z

11. Hellar AM, Akoko L, Jumbam DT, et al. An Assessment of Progress and Challenges in the Implementation of the National Surgical, Obstetric, and Anesthesia Plan (NSOAP) in Tanzania. *East and Central African Journal of Surgery*. 2024;29(2):15—22. doi:10.4314/ecajs.v29i2.4

12. Sonderman KA, Citron I, Mukhopadhyay S, et al. Framework for developing a national surgical, obstetric and anaesthesia plan. *BJS Open*. Oct 2019;3(5):722-732. doi:10.1002/bjs5.50190

13. Eyob B, Boeck MA, FaSiOen P, Cawich S, Kluger MD. Ensuring safe surgical care across resource settings via surgical outcomes data & quality improvement initiatives. *Int J Surg*. Dec 2019;72S:27-32. doi:10.1016/j.ijsu.2019.07.036

14. World Bank. World Bank Country and Lending Groups. Accessed 26 Jun 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

15. Oesophago-Gastric Anastomosis Study Group on behalf of the West Midlands Research C. International Variation in Surgical Practices in Units Performing Oesophagectomy for Oesophageal Cancer: A Unit Survey from the Oesophago-Gastric Anastomosis Audit (OGAA). *World J Surg*. Nov 2019;43(11):2874-2884. doi:10.1007/s00268-019-05080-1

16. NIHR Global Health Unit on Global Surgery, COVIDSurg Collaborative. Elective surgery system strengthening: development, measurement, and validation of the surgical preparedness index across 1632 hospitals in 119 countries. *Lancet*. Nov 5 2022;400(10363):1607-1617. doi:10.1016/S0140-6736(22)01846-3

17. Albutt K, Punchak M, Kayima P, Namanya DB, Anderson GA, Shrime MG. Access to Safe, Timely, and Affordable Surgical Care in Uganda: A Stratified Randomized Evaluation

of Nationwide Public Sector Surgical Capacity and Core Surgical Indicators. *World J Surg*. Aug 2018;42(8):2303-2313. doi:10.1007/s00268-018-4485-1

18. Abbott TEF, Fowler AJ, Dobbs TD, Harrison EM, Gillies MA, Pearse RM. Frequency of surgical treatment and related hospital procedures in the UK: a national ecological study using hospital episode statistics. *Br J Anaesth*. Aug 1 2017;119(2):249-257. doi:10.1093/bja/aex137

19. Weiser TG, Regenbogen SE, Thompson KD, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet*. Jul 12 2008;372(9633):139-144. doi:10.1016/S0140-6736(08)60878-8

20. Ng-Kamstra JS, Greenberg SL, Kotagal M, et al. Use and definitions of perioperative mortality rates in low-income and middle-income countries: a systematic review. *Lancet*. Apr 27 2015;385 Suppl 2:S29. doi:10.1016/S0140-6736(15)60824-8

21. Pearse RM, Clavien PA, Demartines N, et al. Global patient outcomes after elective surgery: Prospective cohort study in 27 low-, middle- and high-income countries. Article. *British Journal of Anaesthesia*. 2016;117(5):601-609. doi:10.1093/bja/aew316

22. GlobalSurg C, National Institute for Health Research Global Health Research Unit on Global S. Global variation in postoperative mortality and complications after cancer surgery: a multicentre, prospective cohort study in 82 countries. *Lancet*. Jan 30 2021;397(10272):387-397. doi:10.1016/S0140-6736(21)00001-5

23. GlobalSurg C. Surgical site infection after gastrointestinal surgery in high-income, middle-income, and low-income countries: a prospective, international, multicentre cohort study. *Lancet Infect Dis*. May 2018;18(5):516-525. doi:10.1016/S1473-3099(18)30101-4

24. Hussain MM, Bibi F, Shah S, et al. First American College of Surgeons National Surgical Quality Improvement Program Report from a Low-Middle-Income Country: A 1-Year Outcome Analysis of Neurosurgical Cases. *World Neurosurg*. Nov 2021;155:e156-e167. doi:10.1016/j.wneu.2021.08.026

25. Cooper L, Sneddon J, Afriyie DK, et al. Supporting global antimicrobial stewardship: antibiotic prophylaxis for the prevention of surgical site infection in low- and middle-income

countries (LMICs): a scoping review and meta-analysis. *JAC Antimicrob Resist*. Sep 2020;2(3):dlaa070. doi:10.1093/jacamr/dlaa070

26. Monahan M, Jowett S, Pinkney T, et al. Surgical site infection and costs in low- and middle-income countries: A systematic review of the economic burden. *PLoS One*. 2020;15(6):e0232960. doi:10.1371/journal.pone.0232960

27. Sway A, Nthumba P, Solomkin J, et al. Burden of surgical site infection following cesarean section in sub-Saharan Africa: a narrative review. *Int J Womens Health*. 2019;11:309-318. doi:10.2147/IJWH.S182362

28. Biccard BM, Madiba TE, Kluyts HL, et al. Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. *Lancet*. Apr 21 2018;391(10130):1589-1598. doi:10.1016/S0140-6736(18)30001-1

29. Ng-Kamstra JS, Arya S, Greenberg SLM, et al. Perioperative mortality rates in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Glob Health*. 2018;3(3):e000810. doi:10.1136/bmjgh-2018-000810

30. GlobalSurg C. Mortality of emergency abdominal surgery in high-, middle- and low-income countries. *Br J Surg*. Jul 2016;103(8):971-988. doi:10.1002/bjs.10151

31. Torborg A, Cronje L, Thomas J, et al. South African Paediatric Surgical Outcomes Study: a 14-day prospective, observational cohort study of paediatric surgical patients. *Br J Anaesth*. Feb 2019;122(2):224-232. doi:10.1016/j.bja.2018.11.015

32. Global PaedSurg Research C. Mortality from gastrointestinal congenital anomalies at 264 hospitals in 74 low-income, middle-income, and high-income countries: a multicentre, international, prospective cohort study. *Lancet*. Jul 24 2021;398(10297):325-339. doi:10.1016/S0140-6736(21)00767-4

33. Knight S, Weiser T, Pius R, Harrison E. Influence of hospital characteristics on patient outcomes following cancer surgery: An international, mixed methods study across 66 countries. Conference Abstract. *British Journal of Surgery*. 2021;108(SUPPL 6):vi18-vi19. doi:10.1093/bjs/znab258.069

34. Silber JH, Williams SV, Krakauer H, Schwartz JS. Hospital and patient characteristics associated with death after surgery. A study of adverse occurrence and failure to rescue. *Med Care*. Jul 1992;30(7):615-29. doi:10.1097/00005650-199207000-00004

35. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. *N Engl J Med*. Oct 1 2009;361(14):1368-75. doi:10.1056/NEJMsa0903048

36. Ghaferi AA, Birkmeyer JD, Dimick JB. Complications, failure to rescue, and mortality with major inpatient surgery in medicare patients. *Ann Surg*. Dec 2009;250(6):1029-34. doi:10.1097/sla.0b013e3181bef697

37. Bilimoria KY. Facilitating Quality Improvement: Pushing the Pendulum Back Toward Process Measures. *JAMA*. Oct 6 2015;314(13):1333-4. doi:10.1001/jama.2015.12470

38. Portuondo JI, Shah SR, Singh H, Massarweh NN. Failure to Rescue as a Surgical Quality Indicator: Current Concepts and Future Directions for Improving Surgical Outcomes. *Anesthesiology*. Aug 2019;131(2):426-437. doi:10.1097/ALN.0000000000002602

39. Burke JR, Downey C, Almoudaris AM. Failure to Rescue Deteriorating Patients: A Systematic Review of Root Causes and Improvement Strategies. *J Patient Saf*. Jan 1 2022;18(1):e140-e155. doi:10.1097/PTS.0000000000000720

40. Johnston M, Arora S, King D, Stroman L, Darzi A. Escalation of care and failure to rescue: a multicenter, multiprofessional qualitative study. *Surgery*. Jun 2014;155(6):989-94. doi:10.1016/j.surg.2014.01.016

41. Johnston MJ, Arora S, King D, et al. A systematic review to identify the factors that affect failure to rescue and escalation of care in surgery. *Surgery*. Apr 2015;157(4):752-63. doi:10.1016/j.surg.2014.10.017

42. Hatchimonji JS, Kaufman EJ, Sharoky CE, Ma L, Garcia Whitlock AE, Holena DN. Failure to rescue in surgical patients: A review for acute care surgeons. *J Trauma Acute Care Surg*. Sep 2019;87(3):699-706. doi:10.1097/TA.0000000000002365

43. Rosero EB, Romito BT, Joshi GP. Failure to rescue: A quality indicator for postoperative care. *Best Pract Res Clin Anaesthesiol*. Dec 2021;35(4):575-589. doi:10.1016/j.bpa.2020.09.003

44. Ghaferi AA, Dimick JB. Importance of teamwork, communication and culture on failure-to-rescue in the elderly. *Br J Surg*. Jan 2016;103(2):e47-51. doi:10.1002/bjs.10031

45. Swanson M, Ueda S, Chen LM, Huchko MJ, Nakisige C, Namugga J. Evidence-based improvisation: Facing the challenges of cervical cancer care in Uganda. *Gynecol Oncol Rep*. May 2018;24:30-35. doi:10.1016/j.gore.2017.12.005

46. Holena DN, Kaufman EJ, Delgado MK, et al. A metric of our own: Failure to rescue after trauma. *J Trauma Acute Care Surg*. Oct 2017;83(4):698-704. doi:10.1097/TA.0000000000001591

47. Metcalfe D, Castillo-Angeles M, Olufajo OA, et al. Failure to rescue and disparities in emergency general surgery. *J Surg Res*. Nov 2018;231:62-68. doi:10.1016/j.jss.2018.04.047

48. Bell TM, Zarzaur BL. Insurance status is a predictor of failure to rescue in trauma patients at both safety net and non-safety net hospitals. *J Trauma Acute Care Surg*. Oct 2013;75(4):728-33. doi:10.1097/TA.0b013e3182a53aaa

49. Anderson GA, Ilcisin L, Kayima P, et al. Out-of-pocket payment for surgery in Uganda: The rate of impoverishing and catastrophic expenditure at a government hospital. *PLoS One*. 2017;12(10):e0187293. doi:10.1371/journal.pone.0187293

50. Hillman KM, Bristow PJ, Chey T, et al. Duration of life-threatening antecedents prior to intensive care admission. *Intensive Care Med*. Nov 2002;28(11):1629-34. doi:10.1007/s00134-002-1496-y

51. Kane RL, Shamliyan TA, Mueller C, Duval S, Wilt TJ. The association of registered nurse staffing levels and patient outcomes: systematic review and meta-analysis. *Med Care*. Dec 2007;45(12):1195-204. doi:10.1097/MLR.0b013e3181468ca3

52. Mushta J, K LR, Andersen E. Failure to rescue as a nurse-sensitive indicator. *Nurs Forum*. Jan 2018;53(1):84-92. doi:10.1111/nuf.12215

53. Griffiths P, Jones S, Bottle A. Is "failure to rescue" derived from administrative data in England a nurse sensitive patient safety indicator for surgical care? Observational study. *Int J Nurs Stud*. Feb 2013;50(2):292-300. doi:10.1016/j.ijnurstu.2012.10.016

54. Rafferty AM, Clarke SP, Coles J, et al. Outcomes of variation in hospital nurse staffing in English hospitals: cross-sectional analysis of survey data and discharge records. *Int J Nurs Stud*. Feb 2007;44(2):175-82. doi:10.1016/j.ijnurstu.2006.08.003

55. Hendricks A, Diers J, Baum P, et al. Systematic review and meta-analysis on volume-outcome relationship of abdominal surgical procedures in Germany. *Int J Surg*. Feb 2021;86:24-31. doi:10.1016/j.ijsu.2020.12.010

56. Preston L, Turner J, Booth A, et al. Is there a relationship between surgical case volume and mortality in congenital heart disease services? A rapid evidence review. *BMJ Open*. Dec 18 2015;5(12):e009252. doi:10.1136/bmjopen-2015-009252

57. Ghaferi AA, Birkmeyer JD, Dimick JB. Hospital volume and failure to rescue with high-risk surgery. *Med Care*. Dec 2011;49(12):1076-81. doi:10.1097/MLR.0b013e3182329b97

58. D'Oria M, Scali S, Mao J, et al. Association Between Hospital Volume and Failure to Rescue After Open or Endovascular Repair of Intact Abdominal Aortic Aneurysms in the VASCUNET and International Consortium of Vascular Registries. *Ann Surg*. Nov 1 2021;274(5):e452-e459. doi:10.1097/SLA.0000000000005044

59. Malone H, Cloney M, Yang J, et al. Failure to Rescue and Mortality Following Resection of Intracranial Neoplasms. *Neurosurgery*. Aug 1 2018;83(2):263-269. doi:10.1093/neuros/nyx354

60. Chen Q, Olsen G, Bagante F, et al. Procedure-Specific Volume and Nurse-to-Patient Ratio: Implications for Failure to Rescue Patients Following Liver Surgery. *World J Surg*. Mar 2019;43(3):910-919. doi:10.1007/s00268-018-4859-4

61. Diers J, Baum P, Wagner JC, et al. Hospital volume following major surgery for gastric cancer determines in-hospital mortality rate and failure to rescue: a nation-wide study based on German billing data (2009-2017). *Gastric Cancer*. Jul 2021;24(4):959-969. doi:10.1007/s10120-021-01167-8

62. Ghaferi AA, Osborne NH, Birkmeyer JD, Dimick JB. Hospital characteristics associated with failure to rescue from complications after pancreatectomy. *J Am Coll Surg*. Sep 2010;211(3):325-30. doi:10.1016/j.jamcollsurg.2010.04.025

63. Lillie EM, Holmes CJ, O'Donohoe EA, et al. Avoidable perioperative mortality at the University Teaching Hospital, Lusaka, Zambia: a retrospective cohort study. *Can J Anaesth*. Dec 2015;62(12):1259-67. doi:10.1007/s12630-015-0483-z

64. Henneman D, van Leersum NJ, Ten Berge M, et al. Failure-to-rescue after colorectal cancer surgery and the association with three structural hospital factors. *Ann Surg Oncol*. Oct 2013;20(11):3370-6. doi:10.1245/s10434-013-3037-z

65. Atumanya P, Sendagire C, Wabule A, et al. Assessment of the current capacity of intensive care units in Uganda; A descriptive study. *J Crit Care*. Feb 2020;55:95-99. doi:10.1016/j.jcrc.2019.10.019

66. Many HR, Otoki K, Parker AS, Parker RK. Implementation of a Surgical Critical Care Service Reduces Failure to Rescue in Emergency Gastrointestinal Surgery in Rural Kenya: interrupted time-series analysis. *Ann Surg*. Sep 13 2021;doi:10.1097/SLA.0000000000005215

67. Gerry S, Bonnici T, Birks J, et al. Early warning scores for detecting deterioration in adult hospital patients: systematic review and critical appraisal of methodology. *BMJ*. May 20 2020;369:m1501. doi:10.1136/bmj.m1501

68. Jones D, Baldwin I, McIntyre T, et al. Nurses' attitudes to a medical emergency team service in a teaching hospital. *Qual Saf Health Care*. Dec 2006;15(6):427-32. doi:10.1136/qshc.2005.016956

69. Massey D, Chaboyer W, Anderson V. What factors influence ward nurses' recognition of and response to patient deterioration? An integrative review of the literature. *Nurs Open*. Jan 2017;4(1):6-23. doi:10.1002/nop2.53

70. Chua WL, Legido-Quigley H, Ng PY, McKenna L, Hassan NB, Liaw SY. Seeing the whole picture in enrolled and registered nurses' experiences in recognizing clinical

deterioration in general ward patients: A qualitative study. *Int J Nurs Stud*. Jul 2019;95:56-64. doi:10.1016/j.ijnurstu.2019.04.012

71. Mohammmed Iddrisu S, Hutchinson AF, Sungkar Y, Considine J. Nurses' role in recognising and responding to clinical deterioration in surgical patients. *J Clin Nurs*. May 2018;27(9-10):1920-1930. doi:10.1111/jocn.14331

72. Gazarian PK, Henneman EA, Chandler GE. Nurse decision making in the prearrest period. *Clin Nurs Res*. Feb 2010;19(1):21-37. doi:10.1177/1054773809353161

73. Cox H, James J, Hunt J. The experiences of trained nurses caring for critically ill patients within a general ward setting. *Intensive Crit Care Nurs*. Oct 2006;22(5):283-93. doi:10.1016/j.iccn.2006.02.003

74. Pantazopoulos I, Tsoni A, Kouskouni E, Papadimitriou L, Johnson EO, Xanthos T. Factors influencing nurses' decisions to activate medical emergency teams. *J Clin Nurs*. Sep 2012;21(17-18):2668-78. doi:10.1111/j.1365-2702.2012.04080.x

75. Hart PL, Spiva L, Baio P, et al. Medical-surgical nurses' perceived self-confidence and leadership abilities as first responders in acute patient deterioration events. *J Clin Nurs*. Oct 2014;23(19-20):2769-78. doi:10.1111/jocn.12523

76. Massey D, Chaboyer W, Aitken L. Nurses' perceptions of accessing a Medical Emergency Team: a qualitative study. *Aust Crit Care*. Aug 2014;27(3):133-8. doi:10.1016/j.aucc.2013.11.001

77. Gjerberg E, Kjolsrod L. The doctor-nurse relationship: how easy is it to be a female doctor co-operating with a female nurse? *Soc Sci Med*. Jan 2001;52(2):189-202. doi:10.1016/s0277-9536(00)00219-7

78. Endacott R, Kidd T, Chaboyer W, Edington J. Recognition and communication of patient deterioration in a regional hospital: a multi-methods study. *Aust Crit Care*. Aug 2007;20(3):100-5. doi:10.1016/j.aucc.2007.05.002

79. Donohue LA, Endacott R. Track, trigger and teamwork: communication of deterioration in acute medical and surgical wards. *Intensive Crit Care Nurs*. Feb 2010;26(1):10-7. doi:10.1016/j.iccn.2009.10.006

80. Kumar A, Roberts D, Wood KE, et al. Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. *Crit Care Med*. Jun 2006;34(6):1589-96. doi:10.1097/01.CCM.0000217961.75225.E9

81. Alidina S, Chatterjee P, Zanial N, et al. Improving surgical quality in low-income and middle-income countries: why do some health facilities perform better than others? *BMJ Qual Saf*. Dec 2021;30(12):937-949. doi:10.1136/bmjqs-2020-011795

82. Kalyesubula R, Brewster U, Kansiime G. Global Dialysis Perspective: Uganda. *Kidney360*. 2022;3(5):933. doi:10.34067/KID.0007002021

83. Kisiel M. Nursing observations: knowledge to help prevent critical illness. *Br J Nurs*. Oct 26-Nov 8 2006;15(19):1052-6. doi:10.12968/bjon.2006.15.19.22105

84. Hogan J. Why don't nurses monitor the respiratory rates of patients? *Br J Nurs*. May 11-24 2006;15(9):489-92. doi:10.12968/bjon.2006.15.9.21087

85. Cioffi J, Salter C, Wilkes L, Vonu-Boriceanu O, Scott J. Clinicians' responses to abnormal vital signs in an emergency department. *Aust Crit Care*. May 2006;19(2):66-72. doi:10.1016/s1036-7314(06)80011-1

86. Peebles E, Subbe CP, Hughes P, Gemmell L. Timing and teamwork--an observational pilot study of patients referred to a Rapid Response Team with the aim of identifying factors amenable to re-design of a Rapid Response System. *Resuscitation*. Jun 2012;83(6):782-7. doi:10.1016/j.resuscitation.2011.12.019

87. Mark BA, Harless DW, Spetz J, Reiter KL, Pink GH. California's minimum nurse staffing legislation: results from a natural experiment. *Health Serv Res*. Apr 2013;48(2 Pt 1):435-54. doi:10.1111/j.1475-6773.2012.01465.x

88. Shever LL. The impact of nursing surveillance on failure to rescue. *Res Theory Nurs Pract*. 2011;25(2):107-26. doi:10.1891/1541-6577.25.2.107

89. Drennan VM, Ross F. Global nurse shortages-the facts, the impact and action for change. *Br Med Bull*. Jun 19 2019;130(1):25-37. doi:10.1093/bmb/ldz014

90. Assaye AM, Wiechula R, Schultz TJ, Feo R. Nurse staffing models in medical-surgical units of acute care settings: A cross-sectional study. *Int J Nurs Pract*. Feb 2020;26(1):e12812. doi:10.1111/ijn.12812

91. Nangalia V, Prytherch DR, Smith GB. Health technology assessment review: remote monitoring of vital signs--current status and future challenges. *Crit Care*. 2010;14(5):233. doi:10.1186/cc9208

92. Hogan H, Healey F, Neale G, Thomson R, Vincent C, Black N. Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. *BMJ Qual Saf*. Sep 2012;21(9):737-45. doi:10.1136/bmjqs-2011-001159

93. Cei M, Bartolomei C, Mumoli N. In-hospital mortality and morbidity of elderly medical patients can be predicted at admission by the Modified Early Warning Score: a prospective study. *Int J Clin Pract*. Apr 2009;63(4):591-5. doi:10.1111/j.1742-1241.2008.01986.x

94. Morgan RJ, Lloyd-Williams F, Wright MM, Morgan-Warren R. An early warning scoring system for detecting developing critical illness. 1997:

95. Alam N, Hobbelink EL, van Tienhoven AJ, van de Ven PM, Jansma EP, Nanayakkara PW. The impact of the use of the Early Warning Score (EWS) on patient outcomes: a systematic review. *Resuscitation*. May 2014;85(5):587-94. doi:10.1016/j.resuscitation.2014.01.013

96. Devita MA, Bellomo R, Hillman K, et al. Findings of the first consensus conference on medical emergency teams. *Crit Care Med*. Sep 2006;34(9):2463-78. doi:10.1097/01.CCM.0000235743.38172.6E

97. Subbe CP, Davies RG, Williams E, Rutherford P, Gemmell L. Effect of introducing the Modified Early Warning score on clinical outcomes, cardio-pulmonary arrests and intensive care utilisation in acute medical admissions. *Anaesthesia*. Aug 2003;58(8):797-802. doi:10.1046/j.1365-2044.2003.03258.x

98. Liu VX, Lu Y, Carey KA, et al. Comparison of Early Warning Scoring Systems for Hospitalized Patients With and Without Infection at Risk for In-Hospital Mortality and

Transfer to the Intensive Care Unit. *JAMA Netw Open*. May 1 2020;3(5):e205191. doi:10.1001/jamanetworkopen.2020.5191

99. Lee SB, Kim DH, Kim T, et al. Emergency Department Triage Early Warning Score (TREWS) predicts in-hospital mortality in the emergency department. *Am J Emerg Med*. Feb 2020;38(2):203-210. doi:10.1016/j.ajem.2019.02.004

100. Pairattanakorn P, Angkasekwinai N, Sirijatuphat R, Wangchinda W, Tancharoen L, Thamlikitkul V. Diagnostic and Prognostic Utility Compared Among Different Sepsis Scoring Systems in Adult Patients With Sepsis in Thailand: A Prospective Cohort Study. *Open Forum Infect Dis*. Jan 2021;8(1):ofaa573. doi:10.1093/ofid/ofaa573

101. Klinger A, Mueller A, Sutherland T, et al. Predicting mortality in adults with suspected infection in a Rwandan hospital: an evaluation of the adapted MEWS, qSOFA and UVA scores. *BMJ Open*. Feb 10 2021;11(2):e040361. doi:10.1136/bmjopen-2020-040361

102. Rylance J, Baker T, Mushi E, Mashaga D. Use of an early warning score and ability to walk predicts mortality in medical patients admitted to hospitals in Tanzania. *Trans R Soc Trop Med Hyg*. Aug 2009;103(8):790-4. doi:10.1016/j.trstmh.2009.05.004

103. Schell CO, Castegren M, Lugazia E, et al. Severely deranged vital signs as triggers for acute treatment modifications on an intensive care unit in a low-income country. *BMC Res Notes*. Jul 25 2015;8:313. doi:10.1186/s13104-015-1275-9

104. Baker T, Schell CO, Lugazia E, et al. Vital Signs Directed Therapy: Improving Care in an Intensive Care Unit in a Low-Income Country. *PLoS One*. 2015;10(12):e0144801. doi:10.1371/journal.pone.0144801

105. Na SJ, Ko RE, Ko MG, Jeon K. Automated alert and activation of medical emergency team using early warning score. *J Intensive Care*. Dec 7 2021;9(1):73. doi:10.1186/s40560-021-00588-y

106. Cho KJ, Kwon O, Kwon JM, et al. Detecting Patient Deterioration Using Artificial Intelligence in a Rapid Response System. *Crit Care Med*. Apr 2020;48(4):e285-e289. doi:10.1097/CCM.0000000000004236

107. Kwon JM, Lee Y, Lee Y, Lee S, Park J. An Algorithm Based on Deep Learning for Predicting In-Hospital Cardiac Arrest. *J Am Heart Assoc*. Jun 26 2018;7(13)doi:10.1161/JAHA.118.008678

108. Mestrom E, De Bie A, Steeg MV, et al. Implementation of an automated early warning scoring system in a surgical ward: Practical use and effects on patient outcomes. *PLoS One*. 2019;14(5):e0213402. doi:10.1371/journal.pone.0213402

109. Schmalenberg C, Kramer M. Nurse-physician relationships in hospitals: 20,000 nurses tell their story. *Crit Care Nurse*. Feb 2009;29(1):74-83. doi:10.4037/ccn2009436

110. Reason J. Human error: models and management. *BMJ*. Mar 18 2000;320(7237):768-70. doi:10.1136/bmj.320.7237.768

111. Mackintosh N, Sandall J. Overcoming gendered and professional hierarchies in order to facilitate escalation of care in emergency situations: the role of standardised communication protocols. *Soc Sci Med*. Nov 2010;71(9):1683-6. doi:10.1016/j.socscimed.2010.07.037

112. Massey D, Aitken LM, Chaboyer W. The impact of a nurse led rapid response system on adverse, major adverse events and activation of the medical emergency team. *Intensive Crit Care Nurs*. Apr 2015;31(2):83-90. doi:10.1016/j.iccn.2014.11.005

113. Garry L, Rohan N, O'Connor T, Patton D, Moore Z. Do nurse-led critical care outreach services impact inpatient mortality rates? *Nurs Crit Care*. Jan 2019;24(1):40-46. doi:10.1111/nicc.12391

114. Lyons PG, Edelson DP, Churpek MM. Rapid response systems. *Resuscitation*. Jul 2018;128:191-197. doi:10.1016/j.resuscitation.2018.05.013

115. Williams G, Pirret A, Credland N, et al. A practical approach to establishing a critical care outreach service: An expert panel research design. *Aust Crit Care*. Mar 24 2022;doi:10.1016/j.aucc.2022.01.008

116. Ministry of Health U. *Uganda Clinical Guidelines*. 2016.

117. Ljungqvist O, Scott M, Fearon KC. Enhanced Recovery After Surgery: A Review. *JAMA Surg*. Mar 1 2017;152(3):292-298. doi:10.1001/jamasurg.2016.4952

118. Ljungqvist O, de Boer HD, Balfour A, et al. Opportunities and Challenges for the Next Phase of Enhanced Recovery After Surgery: A Review. *JAMA Surg*. Aug 1 2021;156(8):775-784. doi:10.1001/jamasurg.2021.0586

119. Escarcega-Fujigaki P, Hernandez-Peredo-Rezk G, Wright NJ, et al. Gastroschisis: A Successful, Prospectively Evaluated Treatment Model in a Middle-Income Country. *World J Surg*. Feb 2022;46(2):322-329. doi:10.1007/s00268-021-06357-0

120. Baluku M, Bajunirwe F, Ngonzi J, Kiwanuka J, Ttendo S. A Randomized Controlled Trial of Enhanced Recovery After Surgery Versus Standard of Care Recovery for Emergency Cesarean Deliveries at Mbarara Hospital, Uganda. *Anesth Analg*. Mar 2020;130(3):769-776. doi:10.1213/ANE.0000000000004495

121. Velasquez Reyes DC, Bloomer M, Morphet J. Prevention of central venous line associated bloodstream infections in adult intensive care units: A systematic review. *Intensive Crit Care Nurs*. Dec 2017;43:12-22. doi:10.1016/j.iccn.2017.05.006

122. de Neef M, Bakker L, Dijkstra S, Raymakers-Janssen P, Vileito A, Ista E. Effectiveness of a Ventilator Care Bundle to Prevent Ventilator-Associated Pneumonia at the PICU: A Systematic Review and Meta-Analysis. *Pediatr Crit Care Med*. May 2019;20(5):474-480. doi:10.1097/PCC.0000000000001862

123. Burgoine K, Egiru E, Ikiror J, Acom L, Akol S, Olupot-Olupot P. Neonatal tetanus in eastern Uganda: improved outcome following the implementation of a neonatal tetanus protocol. *Trop Doct*. Jan 2020;50(1):57-62. doi:10.1177/0049475519872860

124. Ridley S, Morris S. Cost effectiveness of adult intensive care in the UK. *Anaesthesia*. Jun 2007;62(6):547-54. doi:10.1111/j.1365-2044.2007.04997.x

125. Schell CO, Gerdin Warnberg M, Hvarfner A, et al. The global need for essential emergency and critical care. *Crit Care*. Oct 29 2018;22(1):284. doi:10.1186/s13054-018-2219-2

126. Schell CO, Khalid K, Wharton-Smith A, et al. Essential Emergency and Critical Care: a consensus among global clinical experts. *BMJ Glob Health*. Sep 2021;6(9)doi:10.1136/bmjgh-2021-006585

127. ASOS Investigators. Enhanced postoperative surveillance versus standard of care to reduce mortality among adult surgical patients in Africa (ASOS-2): a cluster-randomised controlled trial. *Lancet Glob Health*. Oct 2021;9(10):e1391-e1401. doi:10.1016/S2214-109X(21)00291-6

128. Santhirapala V, Peden CJ, Meara JG, et al. Towards high-quality peri-operative care: a global perspective. *Anaesthesia*. Jan 2020;75 Suppl 1:e18-e27. doi:10.1111/anae.14921

129. Ahmad T, Bouwman RA, Grigoras I, et al. Use of failure-to-rescue to identify international variation in postoperative care in low-, middle- and high-income countries: a 7-day cohort study of elective surgery. *Br J Anaesth*. Aug 1 2017;119(2):258-266. doi:10.1093/bja/aex185

130. Thaddeus S, Maine D. Too far to walk: maternal mortality in context. *Soc Sci Med*. Apr 1994;38(8):1091-110. doi:10.1016/0277-9536(94)90226-7

131. Nguyen N, Leon-Wyss J, Iyer KS, Pezzella AT. Paediatric cardiac surgery in low-income and middle-income countries: a continuing challenge. *Arch Dis Child*. Dec 2015;100(12):1156-9. doi:10.1136/archdischild-2015-308173

132. Polivenok IV, Novick WM, Pyetkov AV, Cardarelli M. Perioperative complications in a paediatric cardiac surgery program with limited systemic resources. *Cardiol Young*. Nov 2020;30(11):1659-1665. doi:10.1017/S1047951120002486

133. Osinaike B, Ayandipo O, Onyeka T, et al. Nigerian surgical outcomes - Report of a 7-day prospective cohort study and external validation of the African surgical outcomes study surgical risk calculator. *Int J Surg*. Aug 2019;68:148-156. doi:10.1016/j.ijsu.2019.06.003

134. Oesophago-Gastric Anastomotic Audit Collaborative: Writing C, Steering C, National L, Site L, Collaborators. Mortality from esophagectomy for esophageal cancer across low, middle, and high-income countries: An international cohort study. *Eur J Surg Oncol*. Jun 2021;47(6):1481-1488. doi:10.1016/j.ejso.2020.12.006

135. Kong VY, Sartorius B, Clarke DL. Acute appendicitis in the developing world is a morbid disease. *Ann R Coll Surg Engl*. Jul 2015;97(5):390-5. doi:10.1308/003588415X14181254790608

136. Williams BM, Purcell LN, Varela C, Gallaher J, Charles A. Appendicitis Mortality in a Resource-Limited Setting: Issues of Access and Failure to Rescue. *J Surg Res*. Mar 2021;259:320-325. doi:10.1016/j.jss.2020.09.030

137. Weiser TG, Uribe-Leitz T, Fu R, et al. Variability in mortality after caesarean delivery, appendectomy, and groin hernia repair in low-income and middle-income countries: implications for expanding surgical services. *Lancet*. Apr 27 2015;385 Suppl 2:S34. doi:10.1016/S0140-6736(15)60829-7

138. Sincavage J, Msosa VJ, Katete C, Purcell LN, Charles A. Postoperative Complications and Risk of Mortality after Laparotomy in a Resource-Limited Setting. *J Surg Res*. Apr 2021;260:428-435. doi:10.1016/j.jss.2020.11.017

139. Busse CE, Anderson EW, Endale T, et al. Strengthening research capacity: a systematic review of manuscript writing and publishing interventions for researchers in low-income and middle-income countries. *BMJ Glob Health*. Feb 2022;7(2)doi:10.1136/bmjgh-2021-008059

140. Parascandola M, Neta G, Salloum RG, Shelley D, Rositch AF. Role of Local Evidence in Transferring Evidence-Based Interventions to Low- and Middle-Income Country Settings: Application to Global Cancer Prevention and Control. *JCO Glob Oncol*. Aug 2022;8:e2200054. doi:10.1200/GO.22.00054

141. Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ*. Sep 16 2000;321(7262):694-6. doi:10.1136/bmj.321.7262.694

142. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. Sep 30 2021;374:n2061. doi:10.1136/bmj.n2061

143. Campbell NC, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ*. Mar 3 2007;334(7591):455-9. doi:10.1136/bmj.39108.379965.BE

144. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. Mar 19 2015;350:h1258. doi:10.1136/bmj.h1258

145. Strobel NA, Chamberlain C, Campbell SK, et al. Family-centred interventions for Indigenous early childhood well-being by primary healthcare services. *Cochrane Database Syst Rev*. Dec 13 2022;12(12):CD012463. doi:10.1002/14651858.CD012463.pub2

146. Matrook KA, Cowman S, Pertl M, Whitford D. Nurse-led family-based approach in primary health care for patients with type 2 diabetes mellitus: a qualitative study. *Int J Qual Stud Health Well-being*. Dec 2024;19(1):2323060. doi:10.1080/17482631.2024.2323060

147. Musters SCW, Kreca SM, van Dieren S, et al. Surgical outcomes in surgical oncology patients who participated in a family involvement program. *Surgery*. Jun 18 2024;doi:10.1016/j.surg.2024.05.004

148. Musters SC, Kreca S, van Dieren S, et al. Family caregiver outcomes after participating in a Hospital-based family involvement program after major gastrointestinal surgery: a subgroup analysis of a patient preferred cohort study. *Int J Surg*. Apr 15 2024;doi:10.1097/JS9.0000000000001473

149. Park JY, Pardosi JF, Islam MS, Respati T, Chowdhury K, Seale H. What does family involvement in care provision look like across hospital settings in Bangladesh, Indonesia, and South Korea? *BMC Health Serv Res*. Jul 16 2022;22(1):922. doi:10.1186/s12913-022-08278-7

150. Determeijer JJ, Leopold SJ, Spijker R, Agyemang C, van Vugt M. Family participation to enhance care and tackle health worker shortages in resource-limited hospitals: A systematic review. *J Glob Health*. Jan 20 2023;13:04005. doi:10.7189/13.04005

151. Alupo P, Ssekitoleko R, Rabin T, Kalyesubula R, Kimuli I, Bodnar BE. Improving inpatient medication adherence using attendant education in a tertiary care hospital in Uganda. *Int J Qual Health Care*. Aug 1 2017;29(4):587-592. doi:10.1093/intqhc/mzx075

152. Duby J, Kabajaasi O, Muteteri J, et al. Family Integrated Care in Uganda: a feasibility study. *Arch Dis Child*. Mar 2023;108(3):180-184. doi:10.1136/archdischild-2022-324638

153. O'Brien K, Robson K, Bracht M, et al. Effectiveness of Family Integrated Care in neonatal intensive care units on infant and parent outcomes: a multicentre, multinational, cluster-randomised controlled trial. *Lancet Child Adolesc Health*. Apr 2018;2(4):245-254. doi:10.1016/S2352-4642(18)30039-7

154. Hoffman M, Mofolo I, Salima C, et al. Utilization of family members to provide hospital care in Malawi: the role of Hospital Guardians. *Malawi Med J*. Dec 2012;24(4):74-8.

155. Burgoine K, Ikiror J, Akol S, et al. Staged implementation of a two-tiered hospital-based neonatal care package in a resource-limited setting in Eastern Uganda. *BMJ Glob Health*. 2018;3(1):e000586. doi:10.1136/bmjgh-2017-000586

156. Lee SK, O'Brien K. Parents as primary caregivers in the neonatal intensive care unit. *CMAJ*. Aug 5 2014;186(11):845-7. doi:10.1503/cmaj.130818

157. Peden CJ, Stephens T, Martin G, et al. Effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery (EPOCH): a stepped-wedge cluster-randomised trial. *Lancet*. Jun 1 2019;393(10187):2213-2221. doi:10.1016/S0140-6736(18)32521-2

158. Vickery N, Stephens T, du Toit L, et al. Understanding the performance of a pan-African intervention to reduce postoperative mortality: a mixed-methods process evaluation of the ASOS-2 trial. *Br J Anaesth*. Nov 2021;127(5):778-788. doi:10.1016/j.bja.2021.07.001

159. Stephens TJ, Peden CJ, Pearse RM, et al. Improving care at scale: process evaluation of a multi-component quality improvement intervention to reduce mortality after emergency abdominal surgery (EPOCH trial). *Implement Sci*. Nov 13 2018;13(1):142. doi:10.1186/s13012-018-0823-9

160. Hewitt-Smith A, Bulamba F, Olupot C, et al. Surgical outcomes in eastern Uganda: a one-year cohort study. *Southern African Journal of Anaesthesia and Analgesia*. 2018;24(5):122-127. doi:10.1080/22201181.2018.1517476

161. Vascular Events in Noncardiac Surgery Patients Cohort Evaluation Study I, Spence J, LeManach Y, et al. Association between complications and death within 30 days after noncardiac surgery. *CMAJ*. Jul 29 2019;191(30):E830-E837. doi:10.1503/cmaj.190221

162. Awuah WA, Ng JC, Nazir A, et al. Postoperative mortality in Africa: are there any improvements in the last decade? *Int J Surg*. May 1 2023;109(5):1080-1082. doi:10.1097/JS9.0000000000000125

163. Huang X, Lin J, Demner-Fushman D. Evaluation of PICO as a knowledge representation for clinical questions. *AMIA Annu Symp Proc*. 2006;2006:359-63.

164. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. Mar 29 2021;372:n71. doi:10.1136/bmj.n71

165. Campbell M, McKenzie JE, Sowden A, et al. Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline. *BMJ*. Jan 16 2020;368:l6890. doi:10.1136/bmj.l6890

166. Hong QN, Fàbregues S, Bartlett G, et al. The Mixed Methods Appraisal Tool (MMAT) version 2018 for information professionals and researchers. *Education for Information*. 2018;34:285-291. doi:10.3233/EFI-180221

167. Dodd S, Clarke M, Becker L, Mavergames C, Fish R, Williamson PR. A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. *J Clin Epidemiol*. Apr 2018;96:84-92. doi:10.1016/j.jclinepi.2017.12.020

168. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci*. Feb 12 2015;10:21. doi:10.1186/s13012-015-0209-1

169. Waltz TJ, Powell BJ, Matthieu MM, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. *Implement Sci*. Aug 7 2015;10:109. doi:10.1186/s13012-015-0295-0

170. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. *Implement Sci*. Oct 29 2022;17(1):75. doi:10.1186/s13012-022-01245-0

171. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. Aug 7 2009;4:50. doi:10.1186/1748-5908-4-50

172. Du Toit L, Kluyts HL, Gobin V, et al. The African Surgical OutcomeS-2 (ASOS-2) Pilot Trial, a mixed-methods implementation study. *South Afr j anaesth analg (Online)*. 2019/00 2019;25(1):14-31.

173. Many HR, Otoki K, Parker AS, Parker RK. Implementation of a Surgical Critical Care Service Reduces Failure to Rescue in Emergency Gastrointestinal Surgery in Rural Kenya. *Ann Surg*. Mar 1 2023;277(3):e719-e724. doi:10.1097/sla.0000000000005215

174. Kluyts HL, le Manach Y, Munlemvo DM, et al. The ASOS Surgical Risk Calculator: development and validation of a tool for identifying African surgical patients at risk of severe postoperative complications. *Br J Anaesth*. Dec 2018;121(6):1357-1363. doi:10.1016/j.bja.2018.08.005

175. Mahawar KK, Malviya A, Kumar G. Who publishes in leading general surgical journals? The divide between the developed and developing worlds. *Asian J Surg*. Jul 2006;29(3):140-4. doi:10.1016/S1015-9584(09)60073-7

176. Singer M, Deutschman CS, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. Feb 23 2016;315(8):801-10. doi:10.1001/jama.2016.0287

177. Blackburn LM, Harkless S, Garvey P. Using failure-to-rescue simulation to assess the performance of advanced practice professionals. *Clin J Oncol Nurs*. Jun 2014;18(3):301-6. doi:10.1188/14.CJON.301-306

178. Blegen MA, Goode CJ, Park SH, Vaughn T, Spetz J. Baccalaureate education in nursing and patient outcomes. *J Nurs Adm*. Feb 2013;43(2):89-94. doi:10.1097/NNA.0b013e31827f2028

179. Talsma A, Jones K, Guo Y, Wilson D, Campbell DA. The relationship between nurse staffing and failure to rescue: where does it matter most? *J Patient Saf*. Sep 2014;10(3):133-9. doi:10.1097/PTS.0b013e31829954e2

180. Park SH, Blegen MA, Spetz J, Chapman SA, De Groot H. Patient turnover and the relationship between nurse staffing and patient outcomes. *Res Nurs Health*. Jun 2012;35(3):277-88. doi:10.1002/nur.21474

181. Medicine Io. *Patient Safety: Achieving a New Standard for Care*. The National Academies Press; 2004:550.

182. Jarvis S, Kovacs C, Briggs J, et al. Aggregate National Early Warning Score (NEWS) values are more important than high scores for a single vital signs parameter for discriminating the risk of adverse outcomes. *Resuscitation*. Feb 2015;87:75-80. doi:10.1016/j.resuscitation.2014.11.014

183. Wakeam E, Asafu-Adjei D, Ashley SW, Cooper Z, Weissman JS. The association of intensivists with failure-to-rescue rates in outlier hospitals: results of a national survey of intensive care unit organizational characteristics. *J Crit Care*. Dec 2014;29(6):930-5. doi:10.1016/j.jcrc.2014.06.010

184. Parker CG. Decision-making models used by medical-surgical nurses to activate rapid response teams. *Medsurg Nurs*. May-Jun 2014;23(3):159-64.

185. Scalese RJ, Obeso VT, Issenberg SB. Simulation technology for skills training and competency assessment in medical education. *J Gen Intern Med*. Jan 2008;23 Suppl 1(Suppl 1):46-9. doi:10.1007/s11606-007-0283-4

186. Taylor SP, Kowalkowski M. Failure to Rescue as a Quality Measure in Sepsis. *JAMA*. Jul 2 2024;332(1):11-12. doi:10.1001/jama.2024.6771

187. Douglas C, Alexeev S, Middleton S, et al. Transforming nursing assessment in acute hospitals: A cluster randomised controlled trial of an evidence-based nursing core assessment (the ENCORE trial). *Int J Nurs Stud*. Mar 2024;151:104690. doi:10.1016/j.ijnurstu.2024.104690

188. Genna C, Thekkan KR, Raymakers-Janssen P, Gawronski O. Is nurse staffing associated with critical deterioration events on acute and critical care pediatric wards? A literature review. *Eur J Pediatr*. Apr 2023;182(4):1755-1770. doi:10.1007/s00431-022-04803-2

189. Subbe CP, Steinmo SH, Haskell H, Barach P. Martha's rule: applying a behaviour change framework to understand the potential of complementary roles of clinicians and patients in improving safety of patients deteriorating in hospital. *Br J Hosp Med (Lond)*. Feb 2 2024;85(2):1-6. doi:10.12968/hmed.2023.0422

190. Alkire BC, Raykar NP, Shrime MG, et al. Global access to surgical care: a modelling study. *Lancet Glob Health*. Jun 2015;3(6):e316-23. doi:10.1016/S2214-109X(15)70115-4

191. Meara JG, Hagander L, Leather AJM. Surgery and global health: a Lancet Commission. *Lancet*. Jan 4 2014;383(9911):12-13. doi:10.1016/S0140-6736(13)62345-4

192. Anderson GA, Ilcisin L, Abesiga L, et al. Surgical volume and postoperative mortality rate at a referral hospital in Western Uganda: Measuring the Lancet Commission on Global Surgery indicators in low-resource settings. *Surgery*. Jun 2017;161(6):1710-1719. doi:10.1016/j.surg.2017.01.009

193. Watters DA, Hollands MJ, Gruen RL, et al. Perioperative mortality rate (POMR): a global indicator of access to safe surgery and anaesthesia. *World J Surg*. Apr 2015;39(4):856-64. doi:10.1007/s00268-014-2638-4

194. Rickard JL, Ntakiyiruta G, Chu KM. Associations with Perioperative Mortality Rate at a Major Referral Hospital in Rwanda. *World J Surg*. Apr 2016;40(4):784-90. doi:10.1007/s00268-015-3308-x

195. Heywood AJ, Wilson IH, Sinclair JR. Perioperative mortality in Zambia. *Ann R Coll Surg Engl*. Nov 1989;71(6):354-8.

196. Dare AJ, Onajin-Obembe B, Makasa EM. A snapshot of surgical outcomes and needs in Africa. *Lancet*. Apr 21 2018;391(10130):1553-1554. doi:10.1016/S0140-6736(18)30002-3

197. Onen BC, Semulimi AW, Bongomin F, et al. Surgical Apgar score as a predictor of outcomes in patients following laparotomy at Mulago National Referral Hospital, Uganda: a prospective cohort study. *BMC Surg*. Dec 18 2022;22(1):433. doi:10.1186/s12893-022-01883-7

198. Ullrich SJ, Kakembo N, Grabski DF, et al. Burden and Outcomes of Neonatal Surgery in Uganda: Results of a Five-Year Prospective Study. *J Surg Res*. Feb 2020;246:93-99. doi:10.1016/j.jss.2019.08.015

199. Okidi R, Sambo VD, Ogwang MD, Mutiibwa D, Benitez NP, Bongomin F. Thirty-day postoperative outcome of patients with non-traumatic gastroduodenal perforations in southwestern Uganda. *Trop Doct*. Jan 2020;50(1):15-19. doi:10.1177/0049475519887654

200. Boeck MA, Ledesma Y, Motwani G, et al. Surgical Care in Eastern Uganda: Initial Results and Challenges of a Prospective Surgical Outcomes Registry in a Low-Income Country. *Journal of the American College of Surgeons*. 2019/10/01/ 2019;229(4, Supplement 1):S138-S139. doi:https://doi.org/10.1016/j.jamcollsurg.2019.08.307

201. Bishop D, Dyer RA, Maswime S, et al. Maternal and neonatal outcomes after caesarean delivery in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. *Lancet Glob Health*. Apr 2019;7(4):e513-e522. doi:10.1016/s2214-109x(19)30036-1

202. Ministry of Health U. Annual Health Sector Performance Report. 2016;

203. Prytherch DR, Whiteley MS, Higgins B, Weaver PC, Prout WG, Powell SJ. POSSUM and Portsmouth POSSUM for predicting mortality. Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity. *Br J Surg*. Sep 1998;85(9):1217-20. doi:10.1046/j.1365-2168.1998.00840.x

204. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med*. Feb 20 2011;30(4):377-99. doi:10.1002/sim.4067

205. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Bmj*. Oct 20 2007;335(7624):806-8. doi:10.1136/bmj.39335.541782.AD

206. Patil P, Nathani P, Bakker JM, et al. Are LMICs Achieving the Lancet Commission Global Benchmark for Surgical Volumes? A Systematic Review. *World J Surg*. Aug 2023;47(8):1930-1939. doi:10.1007/s00268-023-07029-x

207. Pearse RM, Moreno RP, Bauer P, et al. Mortality after surgery in Europe: a 7 day cohort study. *Lancet*. Sep 22 2012;380(9847):1059-65. doi:10.1016/S0140-6736(12)61148-9

208. International Surgical Outcomes Study g. Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries. *Br J Anaesth*. Oct 31 2016;117(5):601-609. doi:10.1093/bja/aew316

209. Kempthorne P, Morriss WW, Mellin-Olsen J, Gore-Booth J. The WFSA Global Anesthesia Workforce Survey. *Anesth Analg*. Sep 2017;125(3):981-990. doi:10.1213/ane.0000000000002258

210. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. Jan 29 2009;360(5):491-9. doi:10.1056/NEJMsa0810119

211. Scott DA, McDougall R. The effective introduction of Lifebox pulse oximetry to Malawi. *Anaesthesia*. Jun 2017;72(6):675-677. doi:10.1111/anae.13897

212. McGinley A, Pearse RM. A national early warning score for acutely ill patients. *BMJ*. Aug 8 2012;345:e5310. doi:10.1136/bmj.e5310

213. Tran TM, Fuller AT, Butler EK, et al. Burden of Surgical Conditions in Uganda: A Cross-sectional Nationwide Household Survey. *Ann Surg*. Aug 2017;266(2):389-399. doi:10.1097/SLA.0000000000001970

214. Butler EK, Tran TM, Fuller AT, et al. Pilot study of a population-based survey to assess the prevalence of surgical conditions in Uganda. *Surgery*. Sep 2015;158(3):764-72. doi:10.1016/j.surg.2015.05.011

215. Mehmood A, Razzak JA, Kabir S, Mackenzie EJ, Hyder AA. Development and pilot implementation of a locally developed Trauma Registry: lessons learnt in a low-income country. *BMC Emerg Med*. Mar 21 2013;13:4. doi:10.1186/1471-227X-13-4

216. Sileshi B, Newton MW, Kiptanui J, et al. Monitoring Anesthesia Care Delivery and Perioperative Mortality in Kenya Utilizing a Provider-driven Novel Data Collection Tool. *Anesthesiology*. Aug 2017;127(2):250-271. doi:10.1097/ALN.0000000000001713

217. Dasari M, Garbett M, Miller E, Machain GM, Puyana JC. Implementation of a Hospital Electronic Surgical Registry in a Lower-Middle-Income Country. *World J Surg*. Dec 2016;40(12):2840-2846. doi:10.1007/s00268-016-3654-3

218. Kluyts HL, Biccard BM. The role of peri-operative registries in improving the quality of care in low-resource environments. *Anaesthesia*. Jul 2021;76(7):888-891. doi:10.1111/anae.15445

219. Edwards Iii GF, Zagarese V, Tulk Jesso S, Jesso M, Harden SM, Parker SH. Designing healthcare for human use: Human factors and practical considerations for the translational process. *Front Health Serv*. 2022;2:981450. doi:10.3389/frhs.2022.981450

220. Al-Moteri M, Plummer V, Cooper S, Symmons M. Clinical deterioration of ward patients in the presence of antecedents: A systematic review and narrative synthesis. *Aust Crit Care*. Sep 2019;32(5):411-420. doi:10.1016/j.aucc.2018.06.004

221. Royal College of Physicians. National Early Warning Score 2 (NEWS2). Accessed 28 August 2024, https://www.rcp.ac.uk/improving-care/resources/national-early-warning-score-news-2/

222. Kaplan HC, Brady PW, Dritz MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. *Milbank Q*. Dec 2010;88(4):500-59. doi:10.1111/j.1468-0009.2010.00611.x

223. Taylor SL, Dy S, Foy R, et al. What context features might be important determinants of the effectiveness of patient safety practice interventions? *BMJ Qual Saf*. Jul 2011;20(7):611-7. doi:10.1136/bmjqs.2010.049379

224. Edwards N, Barker PM. The importance of context in implementation research. *J Acquir Immune Defic Syndr*. Nov 1 2014;67 Suppl 2:S157-62. doi:10.1097/QAI.0000000000000322

225. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. *BMC Health Serv Res*. Mar 25 2019;19(1):189. doi:10.1186/s12913-019-4015-3

226. Rogers PJ. Using Programme Theory to Evaluate Complicated and Complex Aspects of Interventions. *Evaluation*. 2008;14(1):29-48. doi:10.1177/1356389007084674

227. Rogers PJ, Funnell SC. *Purposeful Program Theory: Effective Use of Theories of Change and Logic Models*. Jossey-Bass; 2011.

228. Connor L, Dean J, McNett M, et al. Evidence-based practice improves patient outcomes and healthcare system return on investment: Findings from a scoping review. *Worldviews Evid Based Nurs*. Feb 2023;20(1):6-15. doi:10.1111/wvn.12621

229. Nilsen P, Seing I, Ericsson C, Birken SA, Schildmeijer K. Characteristics of successful changes in health care organizations: an interview study with physicians, registered nurses and assistant nurses. *BMC Health Serv Res*. Feb 27 2020;20(1):147. doi:10.1186/s12913-020-4999-8

230. Churpek MM, Adhikari R, Edelson DP. The value of vital sign trends for detecting clinical deterioration on the wards. *Resuscitation*. May 2016;102:1-5. doi:10.1016/j.resuscitation.2016.02.005

231. Kellett J, Murray A, Woodworth S, Huang W. Trends in weighted vital signs and the clinical course of 44,531 acutely ill medical patients while in hospital. *Acute Med*. 2015;14(1):3-9.

232. Langley A, Denis JL. Beyond evidence: the micropolitics of improvement. *BMJ Qual Saf*. Apr 2011;20 Suppl 1:i43-6. doi:10.1136/bmjqs.2010.046482

233. Twimukye A, Nabukenya S, Kawuma AN, et al. 'Some parts of the consent form are written using complex scientific language': community perspectives on informed consent for research with pregnant and lactating mothers in Uganda. *BMC Med Ethics*. Dec 21 2024;25(1):149. doi:10.1186/s12910-024-01147-4

234. GlobalSurg C. Determinants of morbidity and mortality following emergency abdominal surgery in children in low-income and middle-income countries. *BMJ Glob Health*. 2016;1(4):e000091. doi:10.1136/bmjgh-2016-000091

235. Kause J, Smith G, Prytherch D, et al. A comparison of antecedents to cardiac arrests, deaths and emergency intensive care admissions in Australia and New Zealand, and the United Kingdom--the ACADEMIA study. *Resuscitation*. Sep 2004;62(3):275-82. doi:10.1016/j.resuscitation.2004.05.016

236. Albutt K, Yorlets RR, Punchak M, et al. You pray to your God: A qualitative analysis of challenges in the provision of safe, timely, and affordable surgical care in Uganda. *PLoS One*. 2018;13(4):e0195986. doi:10.1371/journal.pone.0195986

237. Sadigh M, Nawagi F, Sadigh M. The Economic and Social Impact of Informal Caregivers at Mulago National Referral Hospital, Kampala, Uganda. *Ann Glob Health*. Sep - Oct 2016;82(5):866-874. doi:10.1016/j.aogh.2016.06.005

238. Ashengo T, Skeels A, Hurwitz EJH, Thuo E, Sanghvi H. Bridging the human resource gap in surgical and anesthesia care in low-resource countries: a review of the task sharing literature. *Hum Resour Health*. Nov 7 2017;15(1):77. doi:10.1186/s12960-017-0248-6

239. Romanelli D, Farrell MW. AVPU Score. Accessed 16 August 2023, https://www.statpearls.com/point-of-care/32812

240. R Core Team. R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing; 2022.

241. Posit team. RStudio: Integrated Development Environment for R. Posit Software, PBC; 2024.

242. *Stata Statistical Software: Release 18*. College Station, TX: StataCorp LLC; 2023.

243. Pagnoni F, Convelbo N, Tiendrebeogo J, Cousens S, Esposito F. A community-based programme to provide prompt and adequate treatment of presumptive malaria in children. *Trans R Soc Trop Med Hyg*. Sep-Oct 1997;91(5):512-7. doi:10.1016/s0035-9203(97)90006-7

244. Fujino Y, Sasaki S, Igarashi K, et al. Improvement in mothers' immediate care-seeking behaviors for children's danger signs through a community-based intervention in Lusaka, Zambia. *Tohoku J Exp Med*. Jan 2009;217(1):73-85. doi:10.1620/tjem.217.73

245. Campbell H, Byass P, Greenwood BM. Acute lower respiratory infections in Gambian children: maternal perception of illness. *Ann Trop Paediatr*. Mar 1990;10(1):45-51. doi:10.1080/02724936.1990.11747408

246. Lam LW, Chang AM, Morrissey J. Parents' experiences of participation in the care of hospitalised children: a qualitative study. *Int J Nurs Stud*. Jul 2006;43(5):535-45. doi:10.1016/j.ijnurstu.2005.07.009

247. Dijkstra BM, Felten-Barentsz KM, van der Valk MJM, et al. Family participation in essential care activities: Needs, perceptions, preferences, and capacities of intensive care unit patients, relatives, and healthcare providers-An integrative review. *Aust Crit Care*. May 2023;36(3):401-419. doi:10.1016/j.aucc.2022.02.003

248. North K, Whelan R, Folger LV, et al. Family Involvement in the Routine Care of Hospitalized Preterm or Low Birth Weight Infants: A Systematic Review and Meta-analysis. *Pediatrics*. Aug 1 2022;150(Suppl 1)doi:10.1542/peds.2022-057092O

249. Muliira JK, Kizza IB, Nakitende G. Roles of Family Caregivers and Perceived Burden When Caring for Hospitalized Adult Cancer Patients: Perspective From a Low-Income Country. *Cancer Nurs*. May/Jun 2019;42(3):208-217. doi:10.1097/NCC.0000000000000591

250. von Saint Andre-von Arnim AO, Kumar RK, Oron AP, et al. Feasibility of Family-Assisted Severity of Illness Monitoring for Hospitalized Children in Low-Income Settings. *Pediatr Crit Care Med*. Feb 1 2021;22(2):e115-e124. doi:10.1097/PCC.0000000000002582

251. von Saint Andre-von Arnim AO, Kumar RK, Clark JD, et al. Family-Assisted Severity of Illness Monitoring for Hospitalized Children in Low-Resource Settings-A Two-Arm Interventional Feasibility Study. *Front Pediatr*. 2022;10:804346. doi:10.3389/fped.2022.804346

252. Mwale D, Manda-Taylor L, Langton J, et al. The role of healthcare providers and caregivers in monitoring critically ill children: a qualitative study in a tertiary hospital,

southern Malawi. *BMC Health Serv Res*. May 7 2024;24(1):595. doi:10.1186/s12913-024-11050-8

253. Le Lagadec MD, Dwyer T, Browne M. Indicators of patient deterioration in poorly resourced private hospitals: Which vital sign to watch? A retrospective case-control study. *Aust Crit Care*. Jun 28 2023;doi:10.1016/j.aucc.2023.05.006

254. Melder A, Robinson T, McLoughlin I, Iedema R, Teede H. An overview of healthcare improvement: unpacking the complexity for clinicians and managers in a learning health system. *Intern Med J*. Oct 2020;50(10):1174-1184. doi:10.1111/imj.14876

255. Tien JM, Goldschmidt-Clermont PJ. Healthcare: A complex service system. *Journal of Systems Science and Systems Engineering*. 2009/09/01 2009;18(3):257-282. doi:10.1007/s11518-009-5108-z

256. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implementation Science*. 2016/10/19 2016;11(1):141. doi:10.1186/s13012-016-0506-3

257. Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*. Jan 12 2013;14:15. doi:10.1186/1745-6215-14-15

258. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology-the Journal of The British Sociological Association - SOCIOLOGY*. 06/15 2009;43:535-554. doi:10.1177/0038038509103208

259. Hardeman W, Sutton S, Griffin S, et al. A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health Educ Res*. Dec 2005;20(6):676-87. doi:10.1093/her/cyh022

260. Lewin S, Glenton C, Oxman AD. Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study. *BMJ*. Sep 10 2009;339:b3496. doi:10.1136/bmj.b3496

261. Oakley A, Strange V, Bonell C, Allen E, Stephenson J, Team RS. Process evaluation in randomised controlled trials of complex interventions. *BMJ*. Feb 18 2006;332(7538):413-6. doi:10.1136/bmj.332.7538.413

262. Hemming K, Taljaard M, McKenzie JE, et al. Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. *BMJ*. Nov 9 2018;363:k1614. doi:10.1136/bmj.k1614

263. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform*. Jul 2019;95:103208. doi:10.1016/j.jbi.2019.103208

264. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. Apr 2009;42(2):377-81. doi:10.1016/j.jbi.2008.08.010

265. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*. Sep 18 2013;13:117. doi:10.1186/1471-2288-13-117

266. Elo S, Kyngas H. The qualitative content analysis process. *J Adv Nurs*. Apr 2008;62(1):107-15. doi:10.1111/j.1365-2648.2007.04569.x

267. Cretikos MA, Bellomo R, Hillman K, Chen J, Finfer S, Flabouris A. Respiratory rate: the neglected vital sign. *Med J Aust*. Jun 2 2008;188(11):657-9. doi:10.5694/j.1326-5377.2008.tb01825.x

268. Ghomrawi HM, Many BT, Holl JL, et al. Clinicians' perspectives on wearable sensor technology as an alternative bedside monitoring tool in two West African countries. *Int J Med Inform*. Jul 2023;175:105046. doi:10.1016/j.ijmedinf.2023.105046

269. McLean KA, Sgro A, Brown LR, et al. Evaluation of remote digital postoperative wound monitoring in routine surgical practice. *NPJ Digit Med*. May 5 2023;6(1):85. doi:10.1038/s41746-023-00824-9

270. Amin T, Mobbs RJ, Mostafa N, Sy LW, Choy WJ. Wearable devices for patient monitoring in the early postoperative period: a literature review. *Mhealth*. 2021;7:50. doi:10.21037/mhealth-20-131

271. Ahmed Shuvo T, Islam R, Hossain S, et al. eHealth innovations in LMICs of Africa and Asia: a literature review exploring factors affecting implementation, scale-up, and sustainability. *Innovation and Entrepreneurship in Health*. 2015/10/30 2015;2(null):95-106. doi:10.2147/IEH.S88809

272. Leonard E, de Kock I, Bam W. Barriers and facilitators to implementing evidence-based health innovations in low- and middle-income countries: A systematic literature review. *Eval Program Plann*. Oct 2020;82:101832. doi:10.1016/j.evalprogplan.2020.101832

273. van den Hoed MW, Backhaus R, de Vries E, Hamers JPH, Daniels R. Factors contributing to innovation readiness in health care organizations: a scoping review. *BMC Health Serv Res*. Aug 5 2022;22(1):997. doi:10.1186/s12913-022-08185-x

274. Bose B, Alam SA, Portner CC. Impacts of the COVID-19 Lockdown on Healthcare Inaccessibility and Unaffordability in Uganda. *Am J Trop Med Hyg*. Sep 6 2023;109(3):527-535. doi:10.4269/ajtmh.23-0144

275. Starr S, Oke R, Okullu S, et al. Increased Surgical Delays Seen During the COVID-19 Pandemic in a Regional Referral Hospital in Soroti, Uganda: Perspective from a Low-Resource Setting. *World J Surg*. Jun 2023;47(6):1379-1386. doi:10.1007/s00268-023-06965-y

276. Kasonia K, Tindanbil D, Kitonsa J, et al. The impact of the COVID-19 pandemic on the provision & utilisation of primary health care services in Goma, Democratic Republic of the Congo, Kambia district, Sierra Leone & Masaka district, Uganda. *PLoS One*. 2023;18(6):e0286295. doi:10.1371/journal.pone.0286295

277. Kuria-Ndiritu S, Karanja S, Mubita B, et al. Impact of the COVID-19 pandemic and policy response on access to and utilization of reproductive, maternal, child and adolescent health services in Kenya, Uganda and Zambia. *PLOS Glob Public Health*. 2024;4(1):e0002740. doi:10.1371/journal.pgph.0002740

278. Ouma J, Hookham L, Akera LA, et al. Using electronic medical records to understand the impact of SARS-CoV-2 lockdown measures on maternal and neonatal outcomes in

Kampala, Uganda. *PLOS Glob Public Health*. 2023;3(12):e0002022.
doi:10.1371/journal.pgph.0002022

279. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the "chain of survival" concept. A statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the Emergency Cardiac Care Committee, American Heart Association. *Circulation*. May 1991;83(5):1832-47.
doi:10.1161/01.cir.83.5.1832

280. Protopapa KL, Simpson JC, Smith NC, Moonesinghe SR. Development and validation of the Surgical Outcome Risk Tool (SORT). *Br J Surg*. Dec 2014;101(13):1774-83.
doi:10.1002/bjs.9638

281. Bilimoria KY, Liu Y, Paruch JL, et al. Development and evaluation of the universal ACS NSQIP surgical risk calculator: a decision aid and informed consent tool for patients and surgeons. *J Am Coll Surg*. Nov 2013;217(5):833-42 e1-3.
doi:10.1016/j.jamcollsurg.2013.07.385

282. Levy MM, Dellinger RP, Townsend SR, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. *Intensive Care Med*. Feb 2010;36(2):222-31. doi:10.1007/s00134-009-1738-3

283. Kifle F, Kenna P, Daniel S, Maswime S, Biccard B. A scoping review of Enhanced Recovery After Surgery (ERAS), protocol implementation, and its impact on surgical outcomes and healthcare systems in Africa. *Perioper Med (Lond)*. Aug 2 2024;13(1):86.
doi:10.1186/s13741-024-00435-2

284. Eagle KA, Montoye CK, Riba AL, et al. Guideline-based standardized care is associated with substantially lower mortality in medicare patients with acute myocardial infarction: the American College of Cardiology's Guidelines Applied in Practice (GAP) Projects in Michigan. *J Am Coll Cardiol*. Oct 4 2005;46(7):1242-8.
doi:10.1016/j.jacc.2004.12.083

285. Dumont A, Fournier P, Abrahamowicz M, et al. Quality of care, risk management, and technology in obstetrics to reduce hospital-based maternal mortality in Senegal and Mali

(QUARITE): a cluster-randomised trial. *Lancet*. Jul 13 2013;382(9887):146-57.
doi:10.1016/S0140-6736(13)60593-0

Appendices

Appendix 1 – Extended search terms for failure to rescue literature review

1	((((((Hospital Rapid Response Team[MeSH Terms]) OR (postoperative care[MeSH Terms])) OR (Failure to Rescue, Health Care[MeSH Terms])) OR (early warning score[MeSH Terms])) OR (clinical deterioration[MeSH Terms])) OR (Postoperative Complications[MeSH Terms])) OR (Preceptorship[MeSH Terms])
2	("MEWS"[Title/Abstract] OR "hospital rapid response team"[Title/Abstract] OR "aggregate weighted track and trigger systems"[Title/Abstract] OR "single parameter track and trigger systems"[Title/Abstract] OR "post-operative monitoring"[Title/Abstract] OR "escalation of care"[Title/Abstract] OR "failure to rescue"[Title/Abstract] OR "rapid response"[Title/Abstract] OR "early warning score"[Title/Abstract] OR "critical care outreach"[Title/Abstract] OR "calling for help"[Title/Abstract] OR "patient deterioration"[Title/Abstract] OR "Clinical Deterioration"[Title/Abstract] OR "medical emergency team"[Title/Abstract] OR "postoperative care"[Title/Abstract] OR "postoperative mortality"[Title/Abstract] OR "failure to escalate"[Title/Abstract] OR "postoperative complication"[Title/Abstract] OR "resident supervision"[Title/Abstract] OR "clinical supervision"[Title/Abstract] OR "trainee supervision"[Title/Abstract] OR "requesting help"[Title/Abstract] OR "requesting support"[Title/Abstract])
3	#1 OR #2
4	("Deprived Countries"[Title/Abstract] OR "Developing Countries"[Title/Abstract] OR "Developing Country"[Title/Abstract] OR "Developing Economies"[Title/Abstract] OR "Developing Economy"[Title/Abstract] OR "Developing Nation"[Title/Abstract] OR "Developing Nations"[Title/Abstract] OR "Developing Population"[Title/Abstract] OR "Low Income Countries"[Title/Abstract] OR "Low Income Country"[Title/Abstract] OR "Low Income Economies"[Title/Abstract] OR "Low Income Economy"[Title/Abstract] OR "Low Income Nations"[Title/Abstract] OR "Low Income Population"[Title/Abstract] OR "Low Income Populations"[Title/Abstract] OR "Lower GDP"[Title/Abstract] OR "Lower Income Countries"[Title/Abstract] OR "Lower Income Country"[Title/Abstract] OR "Lower Income Nations"[Title/Abstract] OR "Lower Income Population"[Title/Abstract] OR "Lower Income Populations"[Title/Abstract] OR "Middle Income Countries"[Title/Abstract] OR "Middle Income Country"[Title/Abstract] OR "Middle Income Economies"[Title/Abstract] OR "Middle Income Nation"[Title/Abstract] OR "Middle Income Nations"[Title/Abstract] OR "Middle Income Population"[Title/Abstract] OR "Middle Income Populations"[Title/Abstract] OR "Poor Countries"[Title/Abstract] OR "Poor Country"[Title/Abstract] OR "Poor Economies"[Title/Abstract] OR "Poor Economy"[Title/Abstract] OR "Poor Nation"[Title/Abstract] OR "Poor Nations"[Title/Abstract] OR "Poor Population"[Title/Abstract] OR "Poor Populations"[Title/Abstract] OR "Third World"[Title/Abstract] OR "Transitional Countries"[Title/Abstract] OR "Transitional Country"[Title/Abstract] OR "Transitional Economies"[Title/Abstract] OR "Transitional Economy"[Title/Abstract] OR "Under Developed Countries"[Title/Abstract] OR "Under Developed Country"[Title/Abstract] OR "under developed nations"[Title/Abstract] OR "Underdeveloped Countries"[Title/Abstract] OR "Underdeveloped Country"[Title/Abstract] OR "underdeveloped economies"[Title/Abstract] OR "underdeveloped nations"[Title/Abstract] OR "underdeveloped population"[Title/Abstract] OR "Africa"[Title/Abstract] OR "Asia"[Title/Abstract] OR "South America"[Title/Abstract] OR "Central America"[Title/Abstract] OR "Afghanistan"[Title/Abstract] OR "Albania"[Title/Abstract] OR "Algeria"[Title/Abstract] OR "American Samoa"[Title/Abstract] OR "Angola"[Title/Abstract] OR "Armenia"[Title/Abstract] OR "Azerbaijan"[Title/Abstract] OR "Bangladesh"[Title/Abstract] OR "Belarus"[Title/Abstract] OR "Belarus"[Title/Abstract] OR "Belorussia"[Title/Abstract] OR "Belize"[Title/Abstract] OR "Benin"[Title/Abstract] OR

	"Bhutan"[Title/Abstract] OR "Bolivia"[Title/Abstract] OR "Bosnia"[Title/Abstract] OR "Botswana"[Title/Abstract] OR "Brazil"[Title/Abstract] OR "Bulgaria"[Title/Abstract] OR "Burma"[Title/Abstract] OR "Burkina Faso"[Title/Abstract] OR "Burundi"[Title/Abstract] OR "Cabo Verde"[Title/Abstract] OR "Cape Verde"[Title/Abstract] OR "Cambodia"[Title/Abstract] OR "Cameroon"[Title/Abstract] OR "Central African Republic"[Title/Abstract] OR "Chad"[Title/Abstract] OR "China"[Title/Abstract] OR "Colombia"[Title/Abstract] OR "Comoros"[Title/Abstract] OR "Comores"[Title/Abstract] OR "Comoro"[Title/Abstract] OR "Congo"[Title/Abstract] OR "Costa Rica"[Title/Abstract] OR "Côte d'Ivoire"[Title/Abstract] OR "Cuba"[Title/Abstract] OR "Djibouti"[Title/Abstract] OR "Dominica"[Title/Abstract] OR "Dominican Republic"[Title/Abstract] OR "Ecuador"[Title/Abstract] OR "Egypt"[Title/Abstract] OR "El Salvador"[Title/Abstract] OR "Equatorial Guinea"[Title/Abstract] OR "Eritrea"[Title/Abstract] OR "Ethiopia"[Title/Abstract] OR "Fiji"[Title/Abstract] OR "Gabon"[Title/Abstract] OR "Gambia"[Title/Abstract] OR "Gaza"[Title/Abstract] OR "Georgia"[Title/Abstract] OR "Georgia Republic"[Title/Abstract] OR "Ghana"[Title/Abstract] OR "Grenada"[Title/Abstract] OR "Grenadines"[Title/Abstract] OR "Guatemala"[Title/Abstract] OR "Guinea"[Title/Abstract] OR "Guinea-Bissau"[Title/Abstract] OR "Guyana"[Title/Abstract] OR "Haiti"[Title/Abstract] OR "Herzegovina"[Title/Abstract] OR "Hercegovina"[Title/Abstract] OR "Honduras"[Title/Abstract] OR "India"[Title/Abstract] OR "Indonesia"[Title/Abstract] OR "Iran"[Title/Abstract] OR "Iraq"[Title/Abstract] OR "Ivory Coast"[Title/Abstract] OR "Jamaica"[Title/Abstract] OR "Jordan"[Title/Abstract] OR "Kazakhstan"[Title/Abstract] OR "Kenya"[Title/Abstract] OR "Kiribati"[Title/Abstract] OR "Democratic People's Republic of Korea"[Title/Abstract] OR "Kosovo"[Title/Abstract] OR "Kyrgyz"[Title/Abstract] OR "Kirghizia"[Title/Abstract] OR "Kirghiz"[Title/Abstract] OR "Kyrgyzstan"[Title/Abstract] OR "Lao PDR"[Title/Abstract] OR "Laos"[Title/Abstract] OR "Lebanon"[Title/Abstract] OR "Lesotho"[Title/Abstract] OR "Liberia"[Title/Abstract] OR "Libya"[Title/Abstract] OR "Macedonia"[Title/Abstract] OR "Madagascar"[Title/Abstract] OR "Malawi"[Title/Abstract] OR "Malay"[Title/Abstract] OR "Malaya"[Title/Abstract] OR "Malaysia"[Title/Abstract] OR "Maldives"[Title/Abstract] OR "Mali"[Title/Abstract] OR "Marshall Islands"[Title/Abstract] OR "Mauritania"[Title/Abstract] OR "Mauritius"[Title/Abstract] OR "Mexico"[Title/Abstract] OR "Micronesia"[Title/Abstract] OR "Moldova"[Title/Abstract] OR "Mongolia"[Title/Abstract] OR "Montenegro"[Title/Abstract] OR "Morocco"[Title/Abstract] OR "Mozambique"[Title/Abstract] OR "Myanmar"[Title/Abstract] OR "Namibia"[Title/Abstract] OR "Nepal"[Title/Abstract] OR "Nicaragua"[Title/Abstract] OR "Niger"[Title/Abstract] OR "Nigeria"[Title/Abstract] OR "Pakistan"[Title/Abstract] OR "Palau"[Title/Abstract] OR "Papua New Guinea"[Title/Abstract] OR "Paraguay"[Title/Abstract] OR "Peru"[Title/Abstract] OR "Philippines"[Title/Abstract] OR "Principe"[Title/Abstract] OR "Romania"[Title/Abstract] OR "Ruanda"[Title/Abstract] OR "Rwanda"[Title/Abstract] OR "Samoa"[Title/Abstract] OR "Sao Tome"[Title/Abstract] OR "Senegal"[Title/Abstract] OR "Serbia"[Title/Abstract] OR "Sierra Leone"[Title/Abstract] OR "Solomon Islands"[Title/Abstract] OR "Somalia"[Title/Abstract] OR "South Africa"[Title/Abstract] OR "South Sudan"[Title/Abstract] OR "Sri Lanka"[Title/Abstract] OR "St Lucia"[Title/Abstract] OR "St Vincent"[Title/Abstract] OR "Sudan"[Title/Abstract] OR "Surinam"[Title/Abstract] OR "Suriname"[Title/Abstract] OR "Swaziland"[Title/Abstract] OR "Syria"[Title/Abstract] OR "Syrian Arab Republic"[Title/Abstract] OR "Tajikistan"[Title/Abstract] OR "Tadzhikistan"[Title/Abstract] OR "Tajikistan"[Title/Abstract] OR "Tanzania"[Title/Abstract] OR "Thailand"[Title/Abstract] OR "Timor"[Title/Abstract] OR "Togo"[Title/Abstract] OR "Tonga"[Title/Abstract] OR "Tunisia"[Title/Abstract] OR "Turkey"[Title/Abstract] OR "Turkmen"[Title/Abstract] OR "Turkmenistan"[Title/Abstract] OR "Tuvalu"[Title/Abstract] OR "Uganda"[Title/Abstract] OR "Ukraine"[Title/Abstract] OR "Uzbek"[Title/Abstract] OR "Uzbekistan"[Title/Abstract] OR "Vanuatu"[Title/Abstract] OR "Venezuela"[Title/Abstract] OR "Vietnam"[Title/Abstract] OR "West Bank"[Title/Abstract] OR "Yemen"[Title/Abstract] OR "Zambia"[Title/Abstract] OR "Zimbabwe"[Title/Abstract])
5	#3 AND #4 Filters: **English**

Appendix 2 – SMARTER Case Report Form

SMARTER Study Patient ID : SMARTER- ☐☐☐☐ Patient initials : ☐☐

Family Supplemented Patient Monitoring After Surgery: A Pilot Trial

Ward: ☐ 4 & 5 ☐ 6 & 7 ☐ Mat 1 ☐ Postnatal **Control:** ☐ **Intervention:** ☐

Age ☐☐ years **Gender** ☐ Male ☐ Female **ASA** ☐ I ☐ II ☐ III ☐ IV ☐ V

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

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

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

☐ Caesarean section ☐ Laparotomy ☐ Orthopaedic
☐ Hernia repair ☐ Gynaecology ☐ Plastics / cutaneous
☐ Ear, Nose & Throat ☐ Neurosurgery ☐ Other

Date of surgery: ☐☐ / ☐☐ / ☐☐☐☐

Start time of surgery: ☐ 06:00 - 12:00 ☐ 12:00 – 18:00 ☐ 18:00 – 00:00 ☐ 00:00 – 06:00

Urgency of surgery: ☐ Elective ☐ Urgent ☐ Emergency

Severity of surgery: ☐ Minor ☐ Intermediate ☐ Major

Primary indication for surgery: ☐ Infection ☐ Non-communicable disease ☐ Trauma ☐ Caesarean

Most senior anaesthetist present in operating room:

☐ Specialist ☐ Anaesthetic Officer ☐ Student ☐ No anaesthetist

Most senior surgeon present in operating room:

☐ Specialist ☐ Medical Officer ☐ Intern ☐ Student

Postoperative Follow Up

Day of surgery (Day 0)	8am	12pm	4pm	8pm	12am	4am
Breathing rate	☐	☐	☐	☐	☐	☐
Conscious level	☐	☐	☐	☐	☐	☐
Heart rate	☐	☐	☐	☐	☐	☐
Oxygen level	☐	☐	☐	☐	☐	☐

First day after surgery (Day 1)	8am	12pm	4pm	8pm	12am	4am
Breathing rate	☐	☐	☐	☐	☐	☐
Conscious level	☐	☐	☐	☐	☐	☐
Heart rate	☐	☐	☐	☐	☐	☐
Oxygen level	☐	☐	☐	☐	☐	☐

Second day after surgery (Day 2)	8am	12pm	4pm	8pm	12am	4am
Breathing rate	☐	☐	☐	☐	☐	☐
Conscious level	☐	☐	☐	☐	☐	☐
Heart rate	☐	☐	☐	☐	☐	☐
Oxygen level	☐	☐	☐	☐	☐	☐

Third day after surgery (Day 3)	8am	12pm	4pm	8pm	12am	4am
Breathing rate	☐	☐	☐	☐	☐	☐
Conscious level	☐	☐	☐	☐	☐	☐
Heart rate	☐	☐	☐	☐	☐	☐
Oxygen level	☐	☐	☐	☐	☐	☐

Patient ID : SMARTER- | | | | | Patient initials : | | |

Postoperative complications

Infection				
Superficial surgical site	☐ Mild	☐ Moderate	☐ Severe	☐ None
Deep surgical site	☐ Mild	☐ Moderate	☐ Severe	☐ None
Body cavity	☐ Mild	☐ Moderate	☐ Severe	☐ None
Pneumonia	☐ Mild	☐ Moderate	☐ Severe	☐ None
Urinary tract	☐ Mild	☐ Moderate	☐ Severe	☐ None
Bloodstream	☐ Mild	☐ Moderate	☐ Severe	☐ None
Cardiovascular				
Myocardial infarction	☐ Mild	☐ Moderate	☐ Severe	☐ None
Arrhythmia	☐ Mild	☐ Moderate	☐ Severe	☐ None
Pulmonary oedema	☐ Mild	☐ Moderate	☐ Severe	☐ None
Pulmonary embolism	☐ Mild	☐ Moderate	☐ Severe	☐ None
Stroke	☐ Mild	☐ Moderate	☐ Severe	☐ None
Cardiac arrest			☐ Severe	☐ None
Miscellaneous complications				
Gastro-intestinal bleed	☐ Mild	☐ Moderate	☐ Severe	☐ None
Acute kidney injury	☐ Mild	☐ Moderate	☐ Severe	☐ None
Postoperative bleed		☐ Moderate	☐ Severe	☐ None
ARDS		☐ Moderate	☐ Severe	☐ None
Anastomotic breakdown	☐ Mild	☐ Moderate	☐ Severe	☐ None
Other	☐ Mild	☐ Moderate	☐ Severe	☐ None

Days in hospital after surgery: | d | d | **Status at 30th postoperative day:** ☐ Alive ☐ Dead

If dead:
☐ Died **before** hospital discharge
☐ Died **after** hospital discharge **at home**
☐ Died **after** hospital discharge **in health facility**

Process Evaluation

	Were there abnormal vital signs?	Were they recognised by family member?	Were nursing or medical team notified?	Did the nursing or medical team respond?
Day of surgery (Day 0)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
First day after surgery (Day 1)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
Second day after surgery (Day 2)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐
Third day after surgery (Day 3)	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐	Y☐ N☐ N/A☐

Comments: