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Supplementary appendix 4

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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b

Effect of enhanced postoperative surveillance on mortality amongst adult surgical patients in Africa: A cluster randomised trial.

The ASOS-2 Investigators

Supplementary material

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Lassana Cissé

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Munawwara Makoon
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Hôpital Ibn Sina CHU Rabat
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Hôpital militaire d'instruction Rabat
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Houssam Rebahi
Hajar Chichou
Safae Zarouf
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Adamu Isa

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Provincial leaders:
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Gauteng North: Motselisi Mbeki
Western Cape: Estie Cloete
Northern Cape: Philip Anderson.
KwaZulu Natal: Alexandra Torborg
Eastern Cape: Busi Mrara
Northwest: Annemarie Steyn.
Limpopo: Tsakani Mhlari.
Mpumalanga:. Nic Proctor, Caroline Robertson
Free State: Gillian Lamacraft.

Addington Hospital
Sebenzile Sikhakhane
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Akanimo Akpakan

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Sarwat Ikram-Hameed*
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Vivesh Rughubar
Rishan Bipath
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Priyadeshni Singh
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Potchefstroom Hospital
Bianka Bester
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Abrar Widatalla

Ribat Teaching Hospital
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Lina Aljeally
Mohammed Dirar

Wad Medani Teaching Hospital
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Port Sudan Maternity Hospital
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Titus Kihwili
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Suzana Kajeri
Jacquiline Mchilla

Muhimbili National Hospital - Mloganzila
Julieth Magandi*
Deogratius Manyama
Redempta Matindi
Adam Moshi
Daudi Kitwana
Merida Makia
Philip Muhochi
Miriam Herman
Clauda Miombo

Mbeya Zonal Referral Hospital
Bernard Mbwele
Mpoki Ulisubisya
Lazaro Mboma*

Deocles Donatus
Hazina Maduhu
Tumaini Mariro
Given Massasi
Moshi Moshi Shabani
Braison Cholela
Marco Mgeleka
Yohatinus Mbilinyi

Dodoma Regional Referral Hospital
Ernest Ibenzi*
Peter Mbelle*
Kato Peleus
Enid Chiwanga
Nillah Richard
Shoo Leonard
Paulo Sanka
Subira Mushi

Nyakahanga Hospital
Furaha Kahindo*
Langtone Kishebuka

Muhimbili National Hospital
Faraja Chiwanga*
Bilton Exavery
Caspar Haule
Samson Ndile
Sirili Harya

Shree Hindu Mandal Hospital
Ludovick Rukeha*
Tareeq Mohamed
Nabila Fuad
Winifrida Halinga

Bukumbi Mission Hospital
Phinius Makubi*
Frank Manumbu*
Suzan Mlingwa

Selian Lutheran Hospital
Elibariki Lucumay*
Robert Maise
Amon Marti
Beatrice Mahundi

Arusha Lutheran Medical Centre
Paul Kisanga*
Emmanuel Lema*
Benson Lyimo

Temeke Regional Referral Hospital
Hussein Msuma*
Eva Shang'a
Stella Ibrahim

Jakaya Kikwete Cardiac Institute
Bashir Nyangasa*
Mohamed Janabi
Naizihijwa Majani
Pedro Palangyo
Evarist Nyawawa
William Ramadhan
Faraj Lydenge

Benjamin Mkapa Hospital
Mohamed Binde*
Alphonce Chandika*
Salim Salim

Sylvia Jumbe

Tanga Regional Hospital / Bombo Regional Referral Hospital
Naima Yusuf*
Rashid Saleh
Rashid Inoja

Kilimanjaro Christian Medical Centre
Ansbert Ndebea*
Gileard Gabriel Masenga
Sakina Rashid
Mubashir Jusabani

Togo. National Leader: Hamza D Sama
CHU Kara
Talkana Adja*
Edem Gueouguede

Centre Hospitalier Universitaire Sylvanus Olympio de Lomé
Hafoudhoi Oussene Seddoh
Saliou Adam
Pilakimwe Egbohou
Mawunyo Ahomagnon
Olivier Kadjossou
Abdul-Bassiti Boukari

Uganda. National Leader: Adam Hewitt-Smith, Janat Tumukunde
International Hospital Kampala
Peter Kaahwa Agaba*
Daphne Kabatoro
Joseph Kayongo
Margaret Naggujja
Nabasiige Rehema

Uganda Heart Institute
Rita Nkwine*

Mengo Hospital
Gorret Nampiina*

Jinja Regional Referral Hospital
Daniel Kavuma
Aggrey Lubikire
Phiona Nansubuga*
Hope Bisilikirwa
Godfrey Ssebaggala

Masaka Regional Referral Hospital
Emmanuel Muwema*
Humble Joan Agaba
John Kiconco
Nicholas Wataaka
Bonet Chan
Mary Juliet Nampawu

St. Mary's Hospital Lacor
Peter Kayima*
Jacob Eyul
Erick Odwar

Mbale Regional Referral Hospital
Fred Bulamba*
Emmanuel Bua
Christine Mugala
Caroline Nyakato
John Paul Ochieng
Linda Kyomuhendo Jovia

Uganda Martyrs' Hospital Lubaga
Elizabeth Nabakka
Christine Namata*
Denis Kakaire

Mbarara Regional Referral Hospital
Rachel Alum
George Kateregga*
Lazia Najjuma

Nakasero Hospital Limited
Andrew Kintu*
Joshua Sempiira
Luzige Simon

China-Uganda Friendship Hospital
Ruth Muhindo
Mary T Nabukenya*
Peter Waswa

Zimbabwe. National Leader: Pisirai Ndarukwa
Gwanda Provincial Hospital
Elton Ndhlovu*
Zanele Mangwangwa
Nombulelo Dube

Parirenyatwa Hospital
Dennis Mazingi*
Chenesa Mbanje
Busisiwe Mlambo

Mpilo Central Hospital
Crispin Ntoto*
Derek Matsika

Marondera Provincial Hospital
Celestino Dhege*
Juliet Hungwa
Hemish Jasi

Mutare Provincial Hospital
Brightson Mutseyekwa*
Joseph Zimbovoora
Beaulah Gudyanga

Gweru Provincial Hospital
Velda Mushangwe-Mtisi*
Erisha Munhamo

Chitugwiza Central Hospital
Pisirai Ndarukwa*
Michael Chiwanga

Harare Central Hospital
Harunavamwe N Chifamba*

PSMI Westend Hospital
Sarudzai Zhou*
Esta Hove*
Shamiso Dende
Beauty Manjengwa
Penias Kapisa

The Avenues Clinic
Caritas Chiura
Locadia Katsukunya*
Godfrey Muguti
Doreen Mashava

Supplementary Material S1. ASOS-3 Protocol amendments

Protocol v2
Protocol v2 was the first approved ASOS-2 protocol by the UCT Human Research Ethics Committee (HREC)

v2 to v3 amendment
1. Page 2. Steering Committee: This has been changed to include essential local and international collaborators who have helped further refine the sample size and statistical analysis, and the trial processes.
2. Page 2. Funders of ASOS-2 have now been added to the protocol.
3. Page 6, 10, 14. Sample size amendment. Based on the coefficient of covariance of ASOS-1 we have increased the sample size to a more conservative number. This has required an increase in the recruitment period of potentially up to four weeks (in low recruiting sites). We have increased the recruitment period to four weeks at low surgical volume sites, as this decreases the coefficient of variance, which limits the sample size.
4. Page 18. Monitoring and auditing. Based on the increase in the sample size, and the potential increase in the duration of recruitment for some sites, we have added an independent international advisor (a world leading perioperative clinical trialist) who will advise on whether; i) hospital recruitment can continue after the planned recruitment window, and ii) whether an interim analysis would be required prior to continuing recruitment, if recruitment is slower than expected.
5. Page 11. Intervention arm. Based on the findings of the ASOS-2 Pilot Trial, we have made the following amendments; i) changed the definition of proximity to the nurses station, as a bed assigned to within view of the nurses' station, and ii) have added the 'Postoperative surveillance bedside guide' for all high-risk patients.
5. Page 18. Training of investigators. We have added 'remote electronic site initiation', as we believe it will be impossible for the national leaders to visit every site prior to the trial.
6. Page 6 and 20. We have increased the potential recruitment window to 4 months, as we believe that the sites will not all be ready to recruit within the same starting month.
7. The amended CRF's are attached. They also include capturing 'source data' of in-hospital mortality, which is the primary outcome.
8. There are minor grammatical changes in the protocol, to clarify (or correct the text) where questions have arisen from National Leaders, and other ASOS-2 investigators.

v3 to v4 amendment
Revision 1. Page 11. Section 6.3

i. Old wording:

Participating sites will be randomised to normal postoperative care or increased postoperative surveillance. Randomisation will be stratified according to the level of the surgical facility and the expected weekly surgical case-load.

ii. New wording:

Participating sites will be randomised to normal postoperative care ("SOC"), or increased postoperative surveillance ("Intervention") in four recruitment blocks (calendar time blocks). Randomisation in each block will be stratified by country and by level of the surgical facility with a fixed block size of 2. The randomisation algorithm will seek to balance randomisation arms by simulating randomisations with an automated filter to screen out poorly balanced randomisations. In the second and subsequent recruitment blocks, the randomisation algorithm will use knowledge of the previous randomisations and a similar simulation and filtering approach to ensure reasonable balance across arms and across level of surgical facility. This approach was developed on the basis of a simulation model for the randomisation that was used to evaluate the probability of overall balance of randomisation arms and balance within level of care strata if randomising recruitment phases in waves. Results of 10,000 simulation runs indicated that a balanced simulation within the bounds described below would be obtained >50% of the time without the filtering step.

The algorithm is described briefly here:
For recruitment phase 1:
Simulate stratified block randomisation within country and level of facility
Check that simulated randomisation has percent SOC between [48% - 52%]
If NO, then repeat steps 1 and 2. If YES then use this randomisation.
For all other recruitment phases:
Simulate stratified block randomisation for this phase within country and level of facility
Combine this simulation with prior actual randomisations
Check that combined randomisation has percent SOC between [48% - 52%]

If NO, then repeat steps 1-3. If YES proceed to next check.
Check that combined randomisation has balance within level of care between [45% - 55%]
If NO, then repeat steps 1-5. If YES then use this randomisation.

iii. Detailed rationale/ justification/ explanation:

The randomisation procedure was incompletely described in the previous protocol. The updated description of the randomisation procedure was tested through simulation and describes the procedure more comprehensively.

Revision 2. Pages 15-17. Section 7.5

i. Old wording:

Not applicable

ii. New wording:

7.5. Process evaluation

During the conduct of the ASOS-2 Trial we will perform a concurrent 'process evaluation' to gain insight into the implementation process. The process evaluation aims to:

1. Measure protocol compliance (fidelity of implementation),
2. Identify factors that influence success of implementation,
3. Verify specified process steps that form part of the implementation of the protocol and logical framework of the trial, and
4. Generate contextual information about the trial setting.

The questions asked by the process evaluation are:

1. Which factors determined fidelity of implementation at the local hospital level?
2. How did implementation of the intervention affect patient care?
3. Why does the intervention produce (or fail to produce) a change in patient morbidity and mortality?

The measurement tools used for the process evaluation are:

1. The post-education, REDCap online test,
2. The individual participant case record form (CRF),
3. An online database, called the screening log, which is a REDCap application for participating hospitals to record the number of eligible patients daily,
4. Research fellows will perform selected site visits in order to verify specified process steps and perform structured interviews with a sample of stakeholders,
5. Telephonic structured interviews with a sample of stakeholders that cannot be reached by the two research fellows, and
6. A post-trial, semi-quantitative, REDCap based, online questionnaire built around the key components identified in the structured interviews and the pilot trial.

Each member of the local hospital investigator team will be asked to complete the post-education online test prior to patient recruitment. The online test comprises eight short multiple-choice questions which test the comprehension of the key points from the education material.
The individual participant CRF (Appendix 3) captures information that allows checking accuracy of risk stratification, fidelity of implementation, and differences in patient experience between non-high risk patients in the two arms.
The research fellows will visit specific sites during the trial on appointed days agreed upon by the local hospital investigators. They will visit sites during the initiation phase, the recruitment phase, and the follow-up phase of the trial. They will use standard site visit checklists to identify non-compliance, barriers and facilitators of implementation. During the follow-up phase they will interview a sample of stakeholders who indicate willingness to participate in a qualitative interview about their personal experience of the trial. Verbal consent will be obtained and recorded for each interviewee who agrees to participate. No personal identifying information will be recorded for interviewees. Interviews will be recorded. A semi-structured script will be used for the interviews. Recordings will be stored on a password protected cloud based drive. Interviews will be analysed deductively by independent investigators using the Consolidated Framework for Implementation Research (CFIR) as a guide. The recordings will be destroyed following analysis.

The post-trial questionnaire will be anonymous. At the start of the questionnaire respondents will be informed about its content and intent. Respondents will be given the opportunity to opt out, or to give consent prior to continuing to the questions. Questions will test the CFIR constructs that were highlighted in the structured stakeholder interviews.

ii. Detailed rationale/ justification/ explanation:
The previous protocol did not describe any process evaluation. Various experienced international trialists urged the steering committee to describe a formal process evaluation as part of the trial. The process evaluation is essential for translation of the findings of the trial to subsequent clinical practice. I will allow improved understanding of the trial context which influences implementation and effectiveness of the intervention.

Revision 3. Page 19. Section 10

i. Old wording:
Not applicable

ii. New wording:
He [referring to the independent international advisor] will also check the event rate in the control arm of the study when at least 80% of all recruited patients have been captured on REDCap. If the event rate of the control arm is lower than predicted, the independent international advisor will use the event rate in the control arm to decide whether recruitment of further hospitals is required beyond the original sample size of 664 hospitals, in order to maintain 80% power for the primary outcome. This specified interim analysis of data will not lead to adjustment of the prespecified alpha of 0.05.

iii. Detailed rationale/ justification/ explanation:
Event rate driven recruitment is an established method to ensure that a trial does not conclude with a sample that is underpowered for the outcome(s) of interest. Such an outcome would waste the considerable time, effort and resources that have been invested by thousands of researchers across Africa. Testing the event rate does not test any of the outcomes of the trial and does therefore not incur any penalty for repeated testing.

Revision 4. Pages 37-38. Appendix C (case record forms)

i. Old wording:
Status at hospital discharge or 30th postoperative in-hospital day:
☐ Alive & still in hospital ☐ Dead ☐ Alive & discharged

ii. New wording:
Status at hospital discharge or 30th postoperative in-hospital day: ☐ Alive & still in hospital ☐ Dead
☐ Alive & discharged → if alive and discharged, was patient transferred to another facility for higher care? ☐ Yes ☐ No

iii. Detailed rationale/ justification/ explanation:
The same amendment is made to both the control and intervention case report forms. This amendment to the case report forms allows us to distinguish between patients who have been discharged home or to a convalescent facility (i.e. experienced a favourable outcome) compared to patients who were transferred to another hospital for higher level of care (i.e. lost to follow-up).

v4 to v5 amendment

Revision 1. Page 2.

iv. Old wording:
None

v. New wording:
6. Patrice Forget MD, PhD, Professor, Clinical Chair in Anaesthesia, Institute of Applied Health Sciences, School of Medicine, Medical Sciences and Nutrition, University of Aberdeen, United Kingdom. Honorary Consultant, NHS Grampian, Aberdeen, United Kingdom
7. Tim Stephens BA (Hons), MSc Global Health and Development, Critical Care and Peri-operative Medicine Research Group WHRI, Queen Mary University of London, E1 1BB, United Kingdom

vi. Detailed rationale/ justification/ explanation:
Two steering committee members added. Patrice Forget is a crucial member of the trial team and will be the only Francophone steering committee member. Tim Stephens is a crucial member of the process evaluation team bringing expertise in this area to the steering committee.

Revision 2. Pages 15. Section 7.1

iii. Old wording:
The inter-cluster correlation coefficient (ICC) in ASOS was 0.01.

iv. New wording:
The intra-cluster correlation coefficient (ICC) in ASOS was 0.01.

v. Detailed rationale/ justification/ explanation:
The correct term is intra-cluster correlation coefficient. This was a spelling mistake.

Revision 3. Pages 15. Section 7.1

i. Old wording:
Based on a relative risk reduction of 25% in the intervention arm, the power for the secondary outcome, based on the sample sizes for the primary outcome are shown in Table 1.

ii. New wording:
Based on a relative risk reduction of 25% in the intervention arm, the sample sizes for the primary outcome are shown in Table 1.

iii. Detailed rationale/ justification/ explanation:
The sample size refers to the primary outcome, not the secondary outcome.

v5 to v6 amendment

Revision 1. Page 7. Section 2.

vii. Old wording:
To determine whether increased postoperative surveillance reduces in-hospital mortality in high-risk adult surgical patients aged 18 years and over in Africa.

viii. New wording:
To determine whether increased postoperative surveillance in high-risk adult surgical patients reduces overall in-hospital mortality in surgical patients aged 18 years and over in Africa.

ix. Detailed rationale/ justification/ explanation:
The sentence structure of the outcome definition was corrected as it became apparent that the former version suggests we are only interested in the outcome of high-risk patients, whereas, we are principally interested in the outcome of all patients in the trial.

Revision 2. Page 7. Section 2.

vi. Old wording:
Recruitment end date August 2019

vii. New wording:
Recruitment end date March 2020

viii. Detailed rationale/ justification/ explanation:
At the end of August we had not reached our recruitment target. The progress of the trial was evaluated by our external auditor, Professor Paul Myles, Monash University, who advised that the trial continue. We plan to provide a next progress report to Professor Paul Myles during January 2020.

Revision 3. Page 9. Section 4.

iv. Old wording:
To determine whether increased postoperative surveillance reduces in-hospital mortality in high-risk adult surgical patients aged 18 years and over in Africa.

v. New wording:
To determine whether increased postoperative surveillance in high-risk adult surgical patients reduces overall in-hospital mortality in adult surgical patients aged 18 years and over in Africa.

vi. Detailed rationale/ justification/ explanation:
Duplication of revision 1.

Revision 4. Page 9. Section 4.

i. Old wording:
To determine whether increased postoperative surveillance reduces the incidence of the composite of severe in-hospital complications and mortality in high-risk adult surgical patients aged 18 years and over in Africa.

ii. New wording:
To determine whether increased postoperative surveillance in high-risk adult surgical patients reduces the overall incidence of the composite of severe in-hospital complications and mortality in adult surgical patients aged 18 years and over in Africa.

iii. Detailed rationale/ justification/ explanation:
Duplication of revision 1.

Revision 5. Pages 10. Section 5.

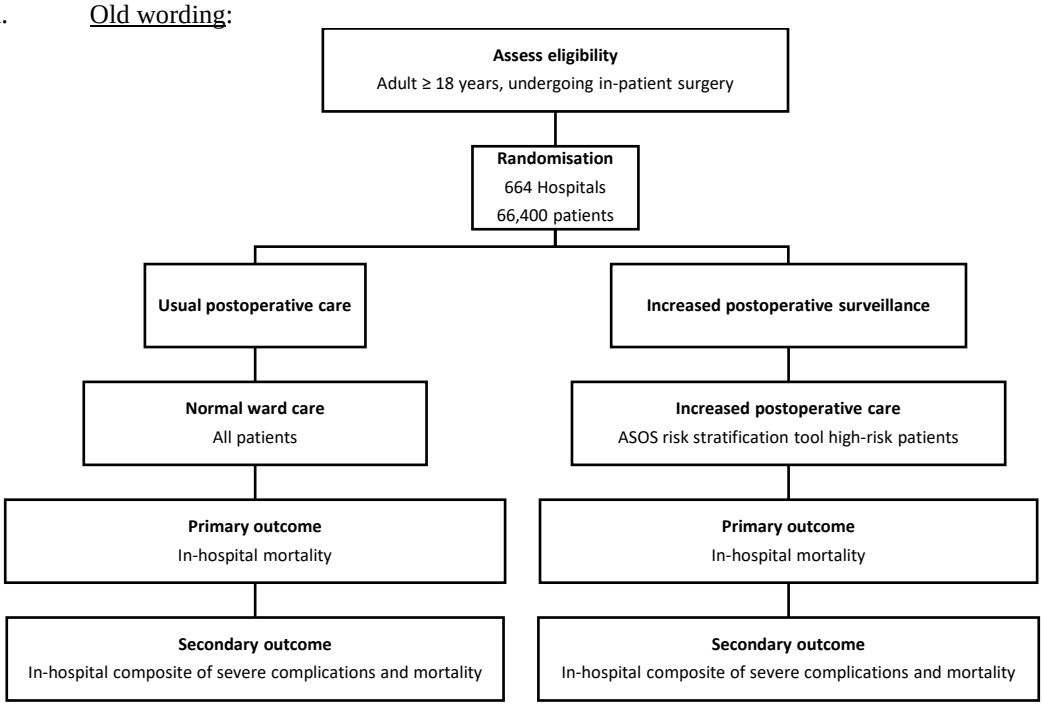
i. Old wording:
Recruitment will run in 2019.

ii. New wording:
Recruitment will run until March 2020.

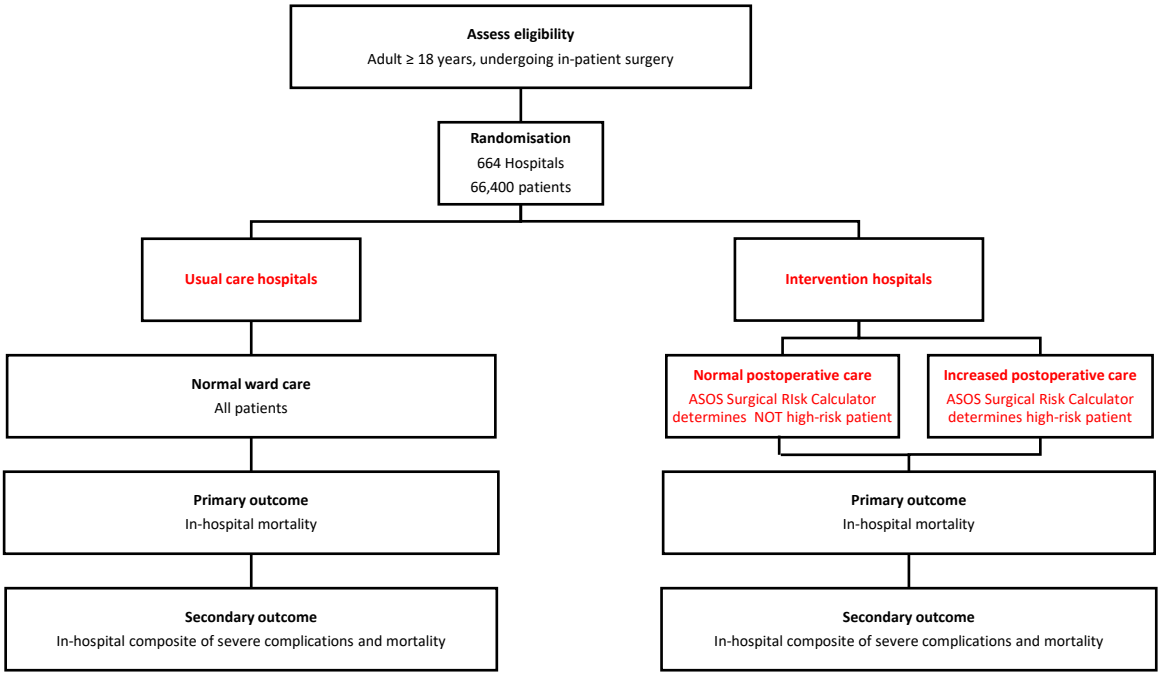
iii. Detailed rationale/ justification/ explanation:
Duplication of revision 2.

Revision 6. Page 10. Section 5.

i. Old wording:



ii. New wording:



iii. Detailed rationale/ justification/ explanation:

The flow diagram was updated to make it clear that the hospital is the unit of randomisation in this trial and that within intervention hospitals it is only the subset of high-risk patients who should receive increased postoperative surveillance.

v6 to v7 amendment

The statistical analysis plan was added to version 6.

Supplementary Material S2. Broadcasting document

This hospital is participating in a surgical trial

This hospital is participating in a surgical trial, known as the African Surgical OutcomeS-2 (ASOS-2) Trial. The ASOS-2 Trial will determine whether increased postoperative surveillance reduces in-hospital death in high-risk adult surgical patients across Africa. Hospitals are randomised to provide usual care, or increased surveillance of high-risk patients. All adult patients aged 18 years and over who have surgery in this hospital are included in this trial. All patients in this hospital will receive similar postoperative surgical management, based on which arm of the trial that this hospital has been randomised to.

Potential harm to participants: We do not believe that this trial provides any potential harms to participants. You may not benefit directly from participation in this trial, however the results of this trial may help us to provide better care to future surgical patients in Africa.

Confidentiality: The study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. This information includes:

- Your name, gender and date of birth
- Information about your surgery, and test results before your surgery and while you are in hospital after the surgery
- Information about your health status and health outcomes

The information that is collected for the study will be kept in a locked and secure area by the study doctor. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital. The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- The study lead investigator(s) or his/her representatives
- Representatives of the University of Cape Town Research Ethics Board

Some of your health information will be sent outside of the hospital to the trial lead investigators and stored at a secure research database hosted by Safe Surgery South Africa, of the South African Society of Anaesthesiologists. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

Treatment Options: If you choose not to be in this study you will still get the best available treatment and be managed according to standard international guidelines. If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

Publication of Results: The results of this study may be presented at conferences or seminars and may be published in a medical journal. All information during presentations will be anonymous. Study results will be available from the study investigators once the study is complete and the data is analysed.

Potential Costs of Participation and Reimbursement to the Participant: There is no cost to participate in this study. You will not be reimbursed for your participation.

Compensation for Injury: If you suffer a physical injury from participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. Participation in this trial does not waive your legal rights nor release the study doctors, the hospital from their legal and professional responsibilities. Reasonable medical expenses incurred through research-related injuries will be covered by the University of Cape Town's no-fault insurance cover.

Participation and Withdrawal: Participation in any research study is voluntary. If you choose not to participate, you and your family will continue to have access to surgical care at this hospital. If you decide to participate in this study, you can change your mind without giving a reason, and you may withdraw from the study at any time without any effect on the care you and your family will receive any Hospital.

New Information: If the trial investigators learn new information that affects your participation, you will be informed in a timely manner.

Research Ethics Board Contact: If you have any questions regarding your rights as a research participant, you may contact Administrator, Human Research Ethics Committee during business hours.
Contact: E 53 Room 46, Old Main Building, Groote Schuur Hospital, Observatory, Cape Town
Telephone: 27 21 406 6492
Email: nosi.tsama@uct.ac.za or shuretta.thomas@uct.ac.za

The study protocol and consent form have been reviewed by a committee called the Human Research Ethics Committee at University of Cape Town. The Human Research Ethics Committee is a group of scientists, medical staff, and individuals from other backgrounds (including law and ethics) as well as members from the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant, as well as the potential benefit to society.

This committee is also required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Human Research Ethics Committee to discuss your experience in the research study.

Study Contacts: If you require any further information or have any concerns, please feel free to contact the investigators or study coordinator: _____

Supplementary Material S3. Randomisation algorithm

The randomisation algorithm is described briefly here:
For recruitment phase 1:

1. Simulate stratified block randomisation within country and level of facility.
2. Check that simulated randomisation has percent ‘standard of care’ between [48% - 52%].
3. If NO, then repeat steps 1 and 2. If YES then use this randomisation.

For all other recruitment phases:

1. Simulate stratified block randomisation for this phase within country and level of facility.
2. Combine this simulation with prior actual randomisations.
3. Check that combined randomisation has percent ‘standard of care’ between [48% - 52%].
4. If NO, then repeat steps 1-3. If YES proceed to next check.
5. Check that combined randomisation has balance within level of care between [45% - 55%].
6. If NO, then repeat steps 1-5. If YES then use this randomisation.

Supplementary Material S4. Postoperative surveillance bedside guide

'Increased postoperative surveillance' bedside guide

This is a 'high-risk' surgical patient

This patient requires 'increased postoperative surveillance' and is most likely to experience one of these complications postoperatively

'High-risk' patients most commonly experience the following complications.

Most common complications	Consider the following management
Cardiac arrest	**Ensure staff know where the emergency drugs and defibrillator are stored**
Surgical site infections	**Swab wound for microbiology, and consider antibiotics**
Bloodstream infections	**Consider early blood cultures, and consider antibiotics**
Pneumonia	**Physiotherapy, mobilise early, sputum & blood cultures, & consider antibiotics**
Acute kidney injury	**Ensure adequate hydration, monitor the serum creatinine**
Postoperative bleed	**Look for signs of hypotension, and decreasing haemoglobin**

If for any reason you are concerned about the patient's condition postoperatively,

then please look for these complications

Supplementary Material S5. Case record form: Control arm

ASOS-2
African Surgical OutcomeS-2 Trial

Age ☐☐☐ years Sex ☐ M ☐ F

ASA ☐ I ☐ II ☐ III ☐ IV ☐ V

Chronic co-morbid disease (tick all that apply): ☐ Hypertension ☐ HIV / AIDS ☐ Diabetes mellitus ☐ COPD / Asthma

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

☐ Gynaecology ☐ Obstetrics ☐ Orthopaedic ☐ Ear, nose and throat ☐ Plastics or breast

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

Indication for surgery:

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

Urgency of surgery: ☐ Elective ☐ Urgent ☐ Emergency

Severity of surgery: ☐ Minor ☐ Intermediate ☐ Major

Start of surgery time (24h) & date: h h : m m d d m m 2 0 1 9

Postoperative Follow Up

Indicate postoperative care given:

Higher care ward ☐ No ☐ Yes

Increased nursing observations ☐ No ☐ Yes

Assigned a bed in view of nurses' station ☐ No ☐ Yes

Family with patient in ward ☐ No ☐ Yes

Severe complications (tick *all* that apply): Superficial or deep surgical site, or body cavity infection ☐ N ☐ Y Postop day ☐☐

Bloodstream infection or ARDS ☐ N ☐ Y Postop day ☐☐ Pneumonia ☐ N ☐ Y Postop day ☐☐

Urinary tract or AKI ☐ N ☐ Y Postop day ☐☐ Postoperative bleed ☐ N ☐ Y Postop day ☐☐

Cardiac arrest ☐ N ☐ Y Postop day ☐☐ Other severe complication ☐ N ☐ Y Postop day ☐☐

Days in hospital after surgery ☐☐

Status at hospital discharge or 30th postoperative in-hospital day: ☐ Alive & still in hospital ☐ Dead

☐ Alive & discharged → if alive and discharged, was patient transferred to another facility for higher care? ☐ Yes ☐ No

If deceased, photo of clinical note of death uploaded: ☐ Yes CRF completed and verified by................ on dd/mm/2019

ASOS-2 unique patient ID ☐☐☐☐☐☐☐☐☐☐ ASOS-2 Trial CRF v4 (Control arm)

✂- -

Patient name: ___________________________________ DOB d d m m y y y y

Patient hospital number : __________________ ASOS-2 unique patient ID ☐☐☐☐☐☐☐☐☐☐

Supplementary Material S6. Case record form: Intervention arm

ASOS-2
African Surgical OutcomeS-2 Trial

Age ☐☐☐ years (<30 points; 0 points/ 30-69 years; 1 point/ ≥70 years; 3 points) Sex ☐ M ☐ F

ASA ☐ I (0 points) ☐ II (2 points) ☐ III (5 points) ☐ IV (8 points) ☐ V (8 points)

Chronic co-morbid disease (tick all that apply): ☐ Hypertension ☐ HIV / AIDS ☐ Diabetes mellitus ☐ COPD / Asthma

Surgical procedure category (select *single* most appropriate): ☐ Gynaecology (minus 1 point) ☐ Obstetrics (minus 1 point)

☐ Orthopaedic (0 points) ☐ Ear, nose and throat (3 points) ☐ Plastics or breast (1 point) ☐ Urology (2 points)

☐ Neurosurgery(4 points) ☐ Gastro-intestinal or Hepato-biliary(3 points) ☐ Cardiothoracic/ vascular(3 points) ☐ Other(0 points)

Indication for surgery:

☐ Non-communicable disease (0 points) ☐ Caesarean section (minus 2 points) ☐ Trauma (1 point) ☐ Infection (2 points)

Urgency of surgery: ☐ Elective (0 points) ☐ Urgent (3 points) ☐ Emergency (4 points)

Severity of surgery: ☐ Minor (0 points) ☐ Intermediate (2 points) ☐ Major (4 points)

Start of surgery time (24h) & date: h h : m m   d d m m 2 0 1 9

ASOS Surgical Risk Score points per risk factor:

☐ Age + ☐ ASA + ☐ Surgical procedure category + ☐ Indication for surgery + ☐ Urgency surgery + ☐ Severity surgery = ☐☐ points

Time that the ASOS Surgical Risk Score was calculated: ☐ Pre-op ☐ Intra-op ☐ Immediately post-op

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

Postoperative Follow Up

☐ Not high-risk patient: (*Indicate postoperative care given*): Higher care ward ☐ No ☐ Yes Increased nursing observations ☐ No ☐ Yes

Assigned a bed in view of nurses' station ☐ No ☐ Yes Family with patient in ward ☐ No ☐ Yes

☐ High-risk patient: *(Indicate all postop surveillance)*	Day 0	Day 1	Day 2	Day 3	Day 4+
Higher care ward	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
Increased nursing observations	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
Assigned a bed in view of nurses' station	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
Family with patient in ward	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
'Postoperative surveillance bedside guide' at the patient's bedside?	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes

Severe complications (tick *all* that apply): Superficial or deep surgical site, or body cavity infection ☐ N ☐ Y Postop day ☐☐

Bloodstream infection or ARDS ☐ N ☐ Y Postop day ☐☐ Pneumonia ☐ N ☐ Y Postop day ☐☐

Urinary tract or AKI ☐ N ☐ Y Postop day ☐☐ Postoperative bleed ☐ N ☐ Y Postop day ☐☐

Cardiac arrest ☐ N ☐ Y Postop day ☐☐ Other severe complication ☐ N ☐ Y Postop day ☐☐

Days in hospital after surgery ☐☐

Status at hospital discharge or 30th postoperative in-hospital day: ☐ Alive & still in hospital ☐ Dead

☐ Alive & discharged → if alive and discharged, was patient transferred to another facility for higher care? ☐ Yes ☐ No

If deceased, photo of clinical note of death uploaded ☐ Yes CRF completed and verified by................ on dd/mm/2019

ASOS-2 unique patient ID ☐☐☐☐☐☐☐☐☐☐☐ ASOS-2 Trial CRF v4 (Intervention arm)

✂- -

Patient name: ________________________________ DOB d d m m y y y y

Patient hospital number : ________________ ASOS-2 unique patient ID ☐☐☐☐☐☐☐☐☐☐☐

Supplementary Material S7. Site initiation checklists

ASOS-2 HOSPITAL LEADER CHECKLIST (CONTROL ARM)	☑
Site initiation educational material attached	☑
Upload ethics approval	☐
Upload Hospital Leader GCP certificate	☐
Weeks three and two before recruitment begins Identify local ASOS-2 team of at least two people, ideally three or more	☐
Hospital Leader to educate Local ASOS-2 team with site initiation educational material	☐
Local ASOS-2 team to complete site initiation online questionnaire after completing educational material	☐
Local ASOS-2 team decides who will perform each task (data collection, follow up)	☐
Local ASOS-2 team members to educate all involved departments e.g. surgery department etc., about the trial	☐
One week before recruitment begins Placement of trial advisory ('broadcasting') posters in patient care areas	☐
Monday of start of recruitment Trial begins	☐
Trial recruitment ends at i) the end of the week when the total recruited patients exceeds 100 patients, or ii) after 4 weeks recruitment	☐
Hospital Leader or designee uploads physical CRFs into electronic database	☐

ASOS-2 HOSPITAL LEADER CHECKLIST (INTERVENTION ARM)	☑
Site initiation educational material attached	☑
Upload ethics approval	☐
Upload Hospital Leader GCP certificate	☐
Weeks three and two before recruitment begins Identify local ASOS-2 team of at least two people, ideally three or more	☐
Hospital Leader to educate Local ASOS-2 team with site initiation educational material	☐
Local ASOS-2 team to complete site initiation online questionnaire after completing educational material	☐
Local ASOS-2 team decides who will perform each task (risk calculation, interventions, follow up)	☐
Local team decides how interventions will be instituted in the hospital	☐
Local ASOS-2 team members to educate all involved departments e.g. surgery department etc., about the trial and the intervention procedures	☐
Local ASOS-2 team members to educate anaesthetists or designees about how to use the ASOS Surgical Risk Calculator and identify high-risk patients	☐
One week before recruitment begins Placement of trial advisory ('broadcasting') posters in patient care areas	☐
Two-day ASOS-2 Trial test run to identify barriers to providing 'increased postoperative surveillance'	☐
Determine solutions to barriers identified in the test run	☐
Monday of start of recruitment Trial begins	☐
Trial recruitment ends at i) the end of the week when the total recruited patients exceeds 100 patients, or ii) after 4 weeks recruitment	☐
Hospital Leader or designee uploads physical CRFs into electronic database	☐

Supplementary Material S8. Definitions of the components of the secondary outcome 'severe complications'

These definitions are based on the 'Standards for definitions and use of outcome measures for clinical effectiveness research in perioperative medicine: European Perioperative Clinical Outcome (EPCO) definitions: a statement from the ESA-ESICM joint taskforce on perioperative outcome measures'.[1]
A severe complication is one that results in significant prolongation of hospital stay and/or permanent functional limitation or death. Almost always requires clinical treatment. The following are considered severe complications in the ASOS-2 trial:

I. Surgical site infection (superficial)

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

a. Infection occurs within 30 days after surgery and
b. Involves only skin and subcutaneous tissues of the incision and
c. The patient has at least one of the following:
    i. purulent drainage from the superficial incision
    ii. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision and at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, or superficial incision is deliberately opened by surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion.
    iii. diagnosis of an incisional surgical site infection by a surgeon or attending physician

II. Surgical site infection (deep)

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

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

III. Surgical site infection (organ/space)

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

a. Infection occurs within 30 days after surgery and
b. The infection appears to be related to the surgical procedure and involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and
c. The patient has at least one of the following:
    i. purulent drainage from a drain that is placed through a stab wound into the organ/space
    ii. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/ space
    iii. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
    iv. diagnosis of an organ/space surgical site infection by a surgeon or attending physician

IV. Bloodstream infection

An infection which is not related to infection at another site and which meets at least one of the following criteria:

a. Patient has a recognised pathogen cultured from blood cultures which is not related to an infection at another site
b. Patient has at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension and at least one of the following:
    i. common skin contaminant cultured from two or more blood cultures drawn on separate occasions
    ii. common skin contaminant cultured from at least one blood culture from a patient with an intravascular line, and a physician starts antimicrobial therapy
    iii. positive blood antigen test

V. Acute Respiratory Distress Syndrome (ARDS)

Respiratory failure, or new or worsening respiratory symptoms, commencing within one week of surgery; and a chest radiograph or computed tomography scan which demonstrates bilateral opacities not fully explained by effusions, lobar/lung collapse, or nodules; and respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic oedema if no risk factor is present.
Severity grading:
Severe: $PaO_2:FiO_2 \leq 100$ mmHg with PEEP ≥ 5 cmH_2O
Guidance:
If altitude is higher than 1000 m, a correction factor should be calculated as follows: ($PaO_2:FiO_2$ x [barometric pressure/760 mmHg]). PEEP, positive end-expiratory pressure; CPAP, non-invasive continuous positive airways pressure

VI. Pneumonia

Chest radiographs with new or progressive and persistent infiltrates, or consolidation, or cavitation, and at least one of the following:

a. fever (>38°C) with no other recognized cause
b. leucopaenia (<4,000 white blood cells/mm3) or leucocytosis (>12,000 white blood cells/mm3)
c. for adults >70 years old, altered mental status with no other recognised cause;
d. and at least two of the following:
    i. new onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements
    ii. new onset or worsening cough, or dyspnoea, or tachypnoea
    iii. rales or bronchial breath sounds
    iv. worsening gas exchange (hypoxaemia, increased oxygen requirement or increased ventilator demand)

Guidance: Two radiographs are required for patients with underlying pulmonary or cardiac disease. The definition may be used to identify ventilator associated pneumonia.

VII. Urinary tract infection

An infection associated with at least one of the following signs or symptoms which should be identified within a 24 hour period; fever (>38 °C), urgency, frequency, dysuria, suprapubic tenderness, costovertebral angle pain or tenderness with no other recognised cause, and a positive urine culture of ≥105 colony forming units/mL with no more than two species of microorganisms.

VIII. Acute Kidney Injury (AKI)

Acute Kidney Injury (AKI) Stage	Serum creatinine	Urine output
Severe	Increase of 3.0 times baseline within 7 days or increase in serum creatinine to ≥4.0 mg/dL (≥354 μmol/L) with an acute rise of >0.5 mg/dL (>44 μmol/L) or initiation of renal replacement therapy	≤0.3 ml/kg/h for 24 hours or Anuria for 12 hours

Guidance: Baseline serum creatinine must be measured before surgery but an estimated value can be used if the patient does not have chronic kidney disease.

IX. Postoperative haemorrhage

Blood loss occurring within 72 hours after the end of surgery which would normally result in transfusion of blood.

X. Cardiac arrest

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

XI. Other severe complications

If any of the following complications result in a significant prolongation of hospital stay and/or permanent functional limitation or death, then mark ‘Other severe complication’ as ‘Yes’. Note that they will almost always requires clinical treatment.

a. Anastomotic breakdown

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

b. Arrhythmia

Electrocardiograph (ECG) evidence of cardiac rhythm disturbance.

c. (Cardiogenic) pulmonary oedema

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

d. Gastro-intestinal bleed

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

e. Myocardial infarction

Increase in serum cardiac biomarker values (preferably cardiac troponin) with at least one value above the 99th percentile upper reference limit and at least one of the following criteria:

i. Symptoms of ischaemia
ii. New or presumed new ST-segment or T-wave ECG changes or new left bundle branch block
iii. Development of pathological Q-waves on ECG

iv. Radiological or echocardiographic evidence of new loss of viable myocardium or new regional wall motion abnormality
v. Identification of an intra-coronary thrombus at angiography or autopsy

f. Pulmonary embolism (PE)

A new blood clot or thrombus within the pulmonary arterial system.
Guidance: Appropriate diagnostic tests include scintigraphy and CT angiography. Plasma D-dimer measurement is not recommended as a diagnostic test in the first three weeks following surgery.

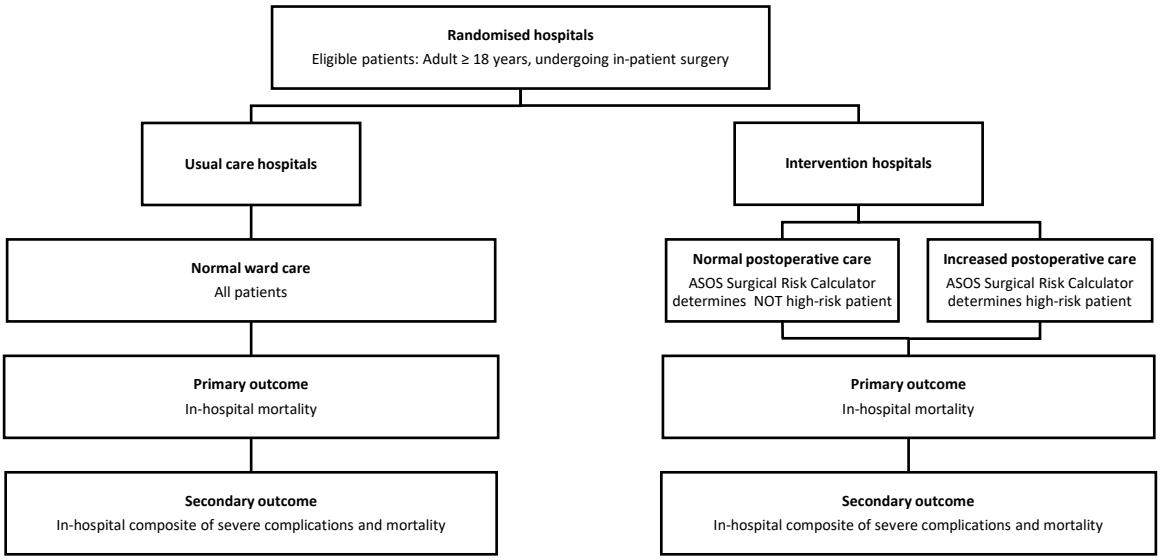
I. Stroke

Embolic, thrombotic, or haemorrhagic cerebral event with persistent residual motor, sensory, or cognitive dysfunction (e.g. hemiplegia, hemiparesis, aphasia, sensory deficit, impaired memory).

Reference

1. Jammer I, Wickboldt N, Sander M, et al. Standards for definitions and use of outcome measures for clinical effectiveness research in perioperative medicine: European Perioperative Clinical Outcome (EPCO) definitions: a statement from the ESA-ESICM joint taskforce on perioperative outcome measures. Eur J Anaesthesiol 2015;32(2):88-105. doi: 10.1097/EJA.0000000000000118

Supplementary Material S9. The ASOS-2 trial design



Supplementary Material S10: Sample size calculations for the ASOS-2 Trial based on a power of 80%, 2-sided α = 0.05 and a mean cluster size of 100 patients

Primary outcome (in-hospital all-cause mortality)					
Control event rate	**Intervention arm**	**Relative risk**	**Intra-cluster correlation coefficient (ICC)**	**Coefficient of variance (CV)**	**Total clusters**
2.0%	1.5%	0.75	0.015	0	536
2.0%	1.5%	0.75	0.015	0.63	664
2.0%	1.6%	0.80	0.015	0.63	1068

Supplementary Material S11. Prespecified sensitivity and subgroup analyses

Other prespecified sensitivity and subgroup analyses on the effectiveness outcomes were also conducted; i) the potential impact of unobserved outcomes on the primary and secondary effectiveness estimates, ii) subgroups treated as stratification variables; including hospital level, recruitment wave, and income category of country, and iii) analysis stratified by individual patient and surgical characteristics that form part of the ASOS Surgical Risk Calculator. The full prespecified additional secondary analyses are shown below.

The following prespecified sensitivity and subgroup analyses on the effectiveness outcomes were also conducted.
1. Sensitivity analyses investigated the potential impact of unobserved outcomes (transfer out or lost to follow up) on the primary and secondary effectiveness estimates, where individuals with unobserved outcomes were alternately assumed to be alive at discharge (censored at thirty days) or to have died in-hospital within 30 days.
2. Primary endpoints were also analysed under the same model as the primary analysis for the following subgroups treated as stratification variables: i) hospital level (primary, secondary, tertiary), iii) recruitment wave, and iii) income category of country (low or middle, according to the World Bank classification in 2020).
3. The relative risk of experiencing the primary and secondary outcome by exposure to the intervention (defined below) was estimated in stratified models for the following individual characteristics: i) age (years), ii) American Society of Anesthesiologists (ASA) status (1-5), iii) surgical procedure category (gynaecologic, obstetric, neurosurgery, ear nose and throat (ENT), orthopaedic, plastics and breast, urology, gastrointestinal and hepatobiliary, cardio-thoracics, and other), iv) indication for surgery (non-communicable disease, caesarean section, trauma, infection), v) urgency of surgery (elective, urgent, emergent), and vi) severity of surgery (minor, intermediate, major).
(Secondary analyses included two analytic approaches to two per protocol populations, based on implementation fidelity. In the first per protocol analysis, we compared all patients from hospitals with data in the standard of care arm to all patients from hospitals with data in the intervention arm where the intervention hospital provided the intervention with fidelity to at least 80% of high-risk patients. Patients from hospitals in the intervention arm where the hospital delivered the intervention with fidelity to fewer than 80% of patients will be excluded from this analysis. In the second per protocol analysis, we compared all patients from hospitals with data in the standard of care arm to all patients from hospitals in the top two tertiles of implementation fidelity. Patients from intervention hospitals in the bottom tertile of implementation fidelity were excluded from this analysis. At the hospital level we report implementation fidelity as the proportion of high-risk patients who received the intervention with fidelity. We used two definitions for implementation fidelity; i) provision of at least the high-risk bedside guide plus one additional component of the intervention on days 0 and 1 postoperatively and ii) provision of at least 2 components of the intervention on days 0 and days 1 postoperatively, regardless whether the high-risk beside guide is one of the components.)

Supplementary Table S1. Hospitals and participants recruited per randomisation wave in the trial

Randomisation wave	Hospitals (n=332)	Patients (n=28855)
Wave 1	63 (19·0%)	6479 (22·5%)
Wave 2	39 (11·7%)	2269 (7·9%)
Wave 3	35 (10·5%)	985 (3·4%)
Wave 4	55 (16·6%)	7025 (24·3%)
Wave 5	66 (19·9%)	5964 (20·7%)
Wave 6	13 (3·9%)	1047 (3·6%)
Wave 7	10 (3·0%)	984 (3·4%)
Wave 8	6 (1·8%)	597 (2·1%)
Wave 9	4 (1·2%)	320 (1·1%)
Wave 10	19 (5·7%)	1238 (4·3%)
Wave 11	22 (6·6%)	1947 (6·7%)

Supplementary Table S2. Hospitals recruited in the trial

	All patients (n=28892)	Increased postoperative surveillance group (n=13275)	Standard of care group (n=15617)
Primary	3846 (13·3%)	1977 (14·9%)	1869 (12·0%)
Secondary	10094 (35·0%)	4442 (33·5%)	5652 (36·3%)
Tertiary	14952 (51·8%)	6856 (51·6%)	8096 (51·8%)

Supplementary Table S3. Physician surgeons, anaesthesiologists and obstetricians, and the number of operating theatres in hospitals recruited in the trial

	All hospitals (n=169)	Increased postoperative surveillance group (n=76)	Standard of care group (n=93)	p-value
Primary hospitals	n=36	n=14	n=22	
Physician surgeon	1 (0-4)	2 (0-3)	1 (0-6)	0.74
Physician anaesthesiologist	2 (0-5)	3 (2-7)	1 (0-5)	0.10
Physician obstetrician	2 (0-4)	3 (0-4)	1 (0-5)	0.58
Secondary hospitals	n=60	n=27	n=33	
Physician surgeon	4 (1-9)	4 (1-7)	4 (0-10)	0.81
Physician anaesthesiologist	4 (0-8)	5 (0-9)	2 (0-9)	0.54
Physician obstetrician	4 (1-8)	4 (1-8)	3 (0-9)	0.71
Tertiary hospitals	n=73	n=35	n=38	
Physician surgeon	8 (2-25)	8 (3-25)	8 (1-24)	0.49
Physician anaesthesiologist	8 (2-16)	8 (2-18)	7 (1-15)	0.34
Physician obstetrician	9 (3-20)	8 (2-20)	10 (1-19)	0.94

Supplementary Table S4. ASOS Surgical Risk Calculator Scores in participating patients

	All patients (n=28892)	Enhanced postoperative surveillance group (n=13275)	Standard of care group (n=15617)
Missing	936	261	675
-3	141 (0·5%)	100 (0·8%)	41 (0·3%)
-2	58 (0·2%)	23 (0·2%)	35 (0·2%)
-1	373 (1·3%)	176 (1·4%)	197 (1·3%)
0	653 (2·3%)	275 (2·1%)	378 (2·5%)
1	931 (3·3%)	438 (3·4%)	493 (3·3%)
2	2302 (8·2%)	970 (7·5%)	1332 (8·9%)
3	2537 (9·1%)	1176 (9·0%)	1361 (9·1%)
4	2643 (9·5%)	1289 (9·9%)	1354 (9·1%)
5	3813(13·6%)	1737 (13·1%)	2076 (13·9%)
6	3093(11·1%)	1499 (11·5%)	1594 (10·2%)
7	2292 (8·2%)	1110 (8·5%)	1182 (7·9%)
8	2214 (7·9%)	1028 (7·9%)	1186 (7·9%)
9	1336 (4·8%)	648 (5·0%)	688 (4·6%)
10	1186 (4·2%)	527 (4·0%)	659 (4·4%)
11	1118 (4·0%)	513 (3·9%)	605 (4·0%)
12	752 (2·7%)	358 (2·8%)	394 (2·6%)
13	694 (2·5%)	322 (2·5%)	372 (2·5%)
14	489 (1·7%)	225 (1·7%)	264 (1·8%)
15	311 (1·1%)	149 (1·1%)	162 (1·1%)
16	302 (1·1%)	117 (0·9%)	185 (1·2%)
17	199 (0·7%)	104 (0·8%)	95 (0·6%)
18	178 (0·6%)	85 (0·7%)	93 (0·6%)
19	125 (0·4%)	65 (0·5%)	60 (0·4%)
20	87 (0·3%)	28 (0·2%)	59 (0·4%)
21	78 (0·3%)	34 (0·3%)	44 (0·3%)
22	44 (0·2%)	14 (0·1%)	30 (0·2%)
23	3 (0·0%)	3 (0·0%)	0 (0·0%)
24	4 (0·0%)	1 (0·0%)	3 (0·0%)

Supplementary Table S5. Number of postoperative surveillance interventions provided to high-risk patients

	Day 0	Day 1
No intervention	66 (2·6%)	123 (4·8%)
One intervention	244 (9·6%)	319 (12·5%)
Two interventions	345 (13·5%)	402 (15·8%)
Three interventions	603 (23·7%)	554 (21·7%)
Four interventions	879 (34·5%)	814 (31·9%)
Five interventions	411 (16·1%)	336 (13·2%)

Supplementary Table S6. Sensitivity analyses of the potential impact of unobserved outcomes on the primary and secondary effectiveness estimates, where individuals with unobserved outcomes were alternately assumed to be alive at discharge (censored at thirty days) or to have died in-hospital within 30 days

Sensitivity analysis	Relative risk	2.5% confidence interval	97.5% confidence interval	p-value
Primary outcome				
Unobserved outcomes assumed alive	0·96	0·69	1·32	0·79
Unobserved outcomes assumed dead	1·13	0·67	1·91	0·65
Secondary outcome				
Unobserved outcomes assumed alive	0·92	0·73	1·17	0·50
Unobserved outcomes assumed dead	1·07	0·82	1·38	0·63

Supplementary Table S7. Per protocol analyses of enhanced postoperative surveillance implementation fidelity to decrease in-hospital mortality.

	Fidelity definition 1: (High-risk individuals exposed to the bedside guide plus at least 1 additional component of the intervention)	Fidelity definition 2: (High-risk individuals exposed to at least any 2 components of the intervention)
Per protocol population 1: (Intervention hospitals where >= 80% of high-risk patients received the intervention with fidelity)	RR 1·20, 95% CI 0·76-1·88 p-value 0·44	RR 1·12, 95% CI 0·75-1·67 p-value 0·58
Per protocol population 2: (Top two tertiles of intervention hospitals ranked according to proportion of patients receiving the intervention with fidelity)	RR 1·07, 95% CI 0·75-1·53 p-value 0·69	RR 1·17, 95% CI: 0·82-1·67 p-value 0·38

RR relative risk, CI confidence interval

Supplementary Table S8. Per protocol analyses of enhanced postoperative surveillance implementation fidelity to decrease in-hospital severe complications and death

	Fidelity definition 1: (High-risk individuals exposed to the bedside guide plus at least 1 additional component of the intervention)	Fidelity definition 2: (High-risk individuals exposed to at least any 2 components of the intervention)
Per protocol population 1: (Intervention hospitals where >= 80% of high-risk patients received the intervention with fidelity)	RR 1·16, 95% CI 0·88-1·53) p-value 0·30	RR 1·10, 95% CI 0·85-1·43 p-value 0·46
Per protocol population 2: (Top two tertiles of intervention hospitals ranked according to proportion of patients receiving the intervention with fidelity)	RR 1·07, 95% CI 0·84-1·36 p-value 0·58	RR 1·06, 95% CI 0·83-1·35 p-value 0·66

RR relative risk, CI confidence interval

Supplementary Table S9. Stratified models for primary effectiveness outcome associated with enhanced postoperative surveillance

Strata	Relative risk	2.5% confidence interval	97.5% confidence interval	p-value
Hospital level				
Primary	1·68	0·53	5·32	0·38
Secondary	0·98	0·52	1·84	0·96
Tertiary	0·86	0·59	1·26	0·44
Randomisation wave				
Wave 1	1·24	0·56	2·77	0·60
Wave 2	2·41	0·57	10·30	0·23
Wave 3	0·25	0·04	1·49	0·13
Wave 4	2·12	0·68	6·60	0·19
Wave 5	0·35	0·07	1·70	0·19
Wave 6	1·18	0·60	2·34	0·63
Wave 7	1·89	0·79	4·51	0·15
Wave 8	0·86	0·46	1·60	0·63
Wave 9	0·72	0·20	2·60	0·62
Wave 10	0·44	0·14	1·43	0·17
Wave 11	0·66	0·11	4·10	0·66
Country income category				
Low	1·04	0·69	1·58	0·84
Middle	0·56	0·23	1·39	0·21
High	0·91	0·50	1·66	0·76

Supplementary Table S10. Sensitivity analyses for primary effectiveness outcome associated with enhanced postoperative surveillance

Model	Strata	Relative risk	2.5% confidence interval	97.5% confidence interval	p-value
Per protocol definition 1 Fidelity definition 1					
Age					
	18-29	1·60	0·76	3·36	0·22
	30-69	1·10	0·70	1·72	0·69
	≥70	1·17	0·51	2·68	0·72
ASA category					
	ASA-all	1·16	0·76	1·75	0·49
	ASA 1	1·71	0·58	5·10	0·33
	ASA 2	1·85	0·86	4·02	0·12
	ASA 3	1·41	0·88	2·27	0·16
	ASA 4	0·47	0·19	1·14	0·10
	ASA 5	1·83	0·46	7·25	0·39
Grade of surgery					
	Severity-all	1·16	0·76	1·75	0·49
	Minor	2·48	0·47	13·09	0·28
	Intermediate	1·28	0·63	2·63	0·50
	Severe	0·99	0·63	1·56	0·97
Urgency of surgery					
	Urgency-all	1·16	0·76	1·75	0·49
	Elective	2·87	1·15	7·13	0·02
	Urgent	1·12	0·56	2·22	0·75
	Emergency	0·87	0·53	1·43	0·59
Surgical speciality					
	Gynaecology	3·33	0·80	13·85	0·10
	Obstetrics	0·69	0·23	2·02	0·49
	Orthopaedic	1·06	0·35	3·24	0·92
	Ear· nose and throat	3·41	0·63	18·37	0·15
	Plastics and Breast	2·02	0·21	19·77	0·55
	Neurosurgery	1·92	0·61	6·06	0·27
	Gastro-intestinal or Hepato-biliary	1·14	0·66	1·97	0·64
	Cardiothoracic or Vascular	0·26	0·03	2·07	0·20
	Other	0·47	0·06	3·76	0·48
Indication for surgery					
	Non-communicable disease	1·49	0·81	2·76	0·20
	Caesarean section	0·59	0·17	2·08	0·41
	Trauma	0·73	0·31	1·70	0·46
	Infection	1·00	0·53	1·89	1·00
Per protocol definition 1 Fidelity definition 2					
Age					

	18-29	1·35	0·67	2·74	0·40
	30-69	1·16	0·78	1·70	0·46
	≥70	1·03	0·49	2·19	0·94
ASA category					
	ASA-all	1·12	0·78	1·61	0·53
	ASA 1	1·64	0·60	4·47	0·33
	ASA 2	1·58	0·77	3·26	0·21
	ASA 3	1·38	0·89	2·15	0·15
	ASA 4	0·60	0·31	1·19	0·14
	ASA 5	1·20	0·25	5·76	0·82
Grade of surgery					
	Severity-all	1·12	0·78	1·61	0·53
	Minor	2·81	0·68	11·57	0·15
	Intermediate	1·21	0·64	2·29	0·55
	Severe	0·98	0·65	1·46	0·92
Urgency of surgery					
	Urgency-all	1·12	0·78	1·61	0·54
	Elective	2·44	1·07	5·59	0·03
	Urgent	1·12	0·61	2·07	0·71
	Emergency	0·88	0·57	1·38	0·59
Surgical speciality					
	Gynaecology	2·53	0·63	10·06	0·19
	Obstetrics	0·62	0·22	1·74	0·36
	Orthopaedic	0·98	0·36	2·68	0·97
	Ear· nose and throat	3·37	0·67	16·92	0·14
	Plastics and Breast	1·52	0·15	14·91	0·72
	Neurosurgery	1·85	0·67	5·08	0·23
	Gastro-intestinal or Hepato-biliary	1·08	0·66	1·77	0·76
	Cardiothoracic or Vascular	0·42	0·09	1·88	0·26
	Other	0·95	0·27	3·30	0·94
Indication for surgery					
	Non-communicable disease	1·40	0·82	2·41	0·22
	Caesarean section	0·46	0·13	1·63	0·23
	Trauma	0·82	0·38	1·78	0·62
	Infection	1·02	0·60	1·74	0·94
Per protocol definition 2 *Fidelity definition 1*					
Age	18-29	1·49	0·79	2·80	0·22
	30-69	1·05	0·74	1·49	0·78
	≥70	1·05	0·56	1·96	0·88
ASA category					
	ASA-all	1·07	0·78	1·48	0·66
	ASA 1	1·32	0·50	3·47	0·58

	ASA 2	1·61	0·88	2·95	0·12
	ASA 3	1·22	0·81	1·82	0·34
	ASA 4	0·68	0·38	1·21	0·19
	ASA 5	1·33	0·43	4·15	0·62
Grade of surgery					
	Severity-all	1·07	0·78	1·48	0·66
	Minor	1·44	0·38	5·47	0·59
	Intermediate	1·15	0·67	2·00	0·61
	Severe	1·03	0·72	1·48	0·87
Urgency of surgery					
	Urgency-all	1·07	0·78	1·48	0·66
	Elective	1·92	0·88	4·19	0·10
	Urgent	1·05	0·62	1·79	0·85
	Emergency	0·97	0·64	1·47	0·90
Surgical speciality					
	Gynaecology	2·10	0·52	8·49	0·30
	Obstetrics	0·53	0·18	1·55	0·25
	Orthopaedic	0·67	0·25	1·80	0·43
	Ear· nose and throat	2·58	0·58	11·50	0·22
	Plastics and Breast	1·54	0·26	9·15	0·63
	Urology	0·38	0·08	1·78	0·22
	Neurosurgery	1·30	0·48	3·51	0·61
	Gastro-intestinal or Hepato-biliary	1·16	0·76	1·76	0·49
	Cardiothoracic or Vascular	0·64	0·29	1·40	0·26
	Other	1·06	0·36	3·13	0·92
Indication for surgery					
	Non-communicable disease	1·40	0·87	2·27	0·17
	Caesarean section	0·40	0·11	1·47	0·17
	Trauma	0·65	0·33	1·28	0·21
	Infection	1·02	0·65	1·62	0·92
Per protocol definition 2 *Fidelity definition 2*					
Age					
	18-29	1·54	0·82	2·90	0·18
	30-69	1·19	0·85	1·68	0·31
	≥70	1·03	0·53	1·99	0·93
ASA category					
	ASA-all	1·17	0·85	1·61	0·35
	ASA 1	1·34	0·49	3·71	0·57
	ASA 2	1·63	0·87	3·06	0·13
	ASA 3	1·33	0·89	2·00	0·17
	ASA 4	0·91	0·53	1·54	0·71
	ASA 5	1·67	0·53	5·20	0·38
Grade of surgery					

	Severity-all	1·17	0·85	1·61	0·35
	Minor	1·81	0·48	6·84	0·38
	Intermediate	1·28	0·72	2·25	0·40
	Severe	1·09	0·76	1·57	0·65
Urgency of surgery					
	Urgency-all	1·17	0·85	1·61	0·35
	Elective	2·10	0·96	4·55	0·06
	Urgent	1·11	0·65	1·93	0·70
	Emergency	1·06	0·70	1·60	0·79
Surgical speciality					
	Gynaecology	2·48	0·64	9·54	0·19
	Obstetrics	0·68	0·25	1·83	0·45
	Orthopaedic	0·87	0·34	2·18	0·76
	Ear· nose and throat	2·49	0·56	11·16	0·23
	Plastics and Breast	1·84	0·31	10·80	0·50
	Urology	0·40	0·08	1·90	0·25
	Neurosurgery	1·50	0·57	3·97	0·41
	Gastro-intestinal or Hepato-biliary	1·21	0·79	1·86	0·39
	Cardiothoracic or Vascular	0·55	0·22	1·36	0·19
	Other	1·35	0·45	4·03	0·59
Indication for surgery					
	Non-communicable disease	1·41	0·86	2·31	0·17
	Caesarean section	0·43	0·12	1·55	0·20
	Trauma	0·94	0·51	1·77	0·86
	Infection	1·09	0·68	1·74	0·73

Per protocol definition 1; where the intervention hospital provided the intervention with fidelity to at least 80% of high-risk patients
Per protocol definition 2; hospitals in the top two tertiles of implementation fidelity
Fidelity definition 1; provision of at least the high-risk bedside guide plus one additional component of the intervention on days 0 and 1 postoperatively
Fidelity definition 2; provision of at least any two components of the intervention on days 0 and days 1 postoperatively, which did not necessarily have to include the high-risk beside guide as one of the components
ASA=American Society of Anesthesiologists

Supplementary Table S11. Sensitivity analyses for primary effectiveness outcome associated with enhanced postoperative surveillance for high-risk patients

Model stratification	Strata	Relative risk	2.5% confidence interval	97.5% confidence interval	p-value
Age					
	18-29	1·34	0·73	2·47	0·35
	30-69	1·14	0·82	1·56	0·44
	≥70	0·97	0·54	1·76	0·93
ASA category					
	ASA-all	1·09	0·81	1·47	0·59
	ASA 1	1·19	0·47	3·02	0·71
	ASA 2	1·59	0·91	2·78	0·10
	ASA 3	1·24	0·84	1·83	0·27
	ASA 4	0·69	0·41	1·15	0·16
	ASA 5	1·62	0·56	4·66	0·37
Grade of surgery					
	Severity-all	1·09	0·81	1·47	0·59
	Minor	1·40	0·40	4·90	0·60
	Intermediate	1·25	0·75	2·09	0·39
	Severe	1·04	0·74	1·46	0·83
Urgency of surgery					
	Urgency-all	1·09	0·81	1·47	0·59
	Elective	1·74	0·83	3·65	0·15
	Urgent	0·98	0·59	1·62	0·94
	Emergency	1·08	0·74	1·58	0·69
Surgical speciality					
	Gynaecology	1·94	0·50	7·59	0·34
	Obstetrics	0·51	0·18	1·40	0·19
	Orthopaedic	0·62	0·25	1·58	0·32
	Ear, nose and throat	2·38	0·54	10·54	0·25
	Plastics and Breast	1·21	0·20	7·26	0·83
	Urology	0·32	0·07	1·50	0·15
	Neurosurgery	1·33	0·54	3·28	0·53
	Gastro-intestinal or Hepato-biliary	1·25	0·85	1·82	0·26
	Cardiothoracic or Vascular	0·57	0·26	1·26	0·17
	Other	0·99	0·36	2·69	0·98
Indication for surgery					
	Non-communicable disease	1·39	0·88	2·18	0·16
	Caesarean section	0·33	0·09	1·20	0·09
	Trauma	0·86	0·48	1·56	0·63
	Infection	1·00	0·65	1·54	0·99

ASA=American Society of Anesthesiologists

Supplementary Figure 1. The African Surgical OutcomeS-2 (ASOS-2) trial results