Editorial
Fools rush in where angels fear to tread

Despite advances in medical therapies, surgery remains a key component of the treatment for many diseases. Each year, more than 300 million surgical procedures are performed worldwide, even though much of the global population is unable to access surgical treatments.[1,2] As the Lancet Commission on Global Surgery gains traction, we will see a substantial increase in the number of surgical procedures performed in low and middle income countries.[3,4] This improvement is undoubtedly welcome, yet as anaesthetists we can expect significant new challenges to result. In 2018, a seminal work by the African Surgical Outcomes Study group transformed our understanding of postoperative outcomes in African countries.[5] We now know that surgical patients in Africa are twice as likely to die after surgery even though they are younger, fitter and develop fewer complications. The new challenge is 'failure to rescue' or the undetected physiological deterioration of patients on the ward after surgery. As we succeed in extending access to surgical treatments in Africa, we must expect the absolute number of postoperative deaths to rise. The benefits of access to surgery cannot be fully realised unless these treatments are safe. In high income countries, this problem has been well described and tackled through various measures from staff education to support teams such as critical care outreach.[6] Similar strategies can and will allow us to resolve this problem in Africa, but research is urgently needed to determine the best approach for a resource poor context.

In this edition of the Southern African Journal of Anaesthesia and Analgesia, we report the results of the ASOS-2 Pilot Trial.[7] This was a pragmatic, international pilot study of 786 patients in 16 hospitals across eight African countries. Completing a pilot study of this size and complexity is itself a significant milestone for the group. Our aim was to test a new approach to preventing postoperative deaths through better postoperative surveillance. In particular, we wanted to understand the fidelity of the trial intervention (i.e. treatment compliance), the feasibility of the day to day trial tasks, and whether we were collecting all the data we needed. The main ASOS-2 trial will have a cluster randomised design which means entire hospitals will be allocated to the intervention or control groups. In the pilot, we only studied the proposed intervention arm of the trial as this is where the challenges in trial delivery will lie. Patients were risk stratified using the ASOS Surgical Risk Calculator,[8] and those at high risk of severe complications or death were allocated to a bundle of additional care to ensure increased postoperative surveillance. The four interventions, selected on the basis of simplicity and low cost, were admission to a higher care ward, more frequent vital signs monitoring by nursing staff, location in a bed visible from the nursing station, and allowing family members to remain with the patient whilst in hospital. Our findings suggest it is possible to achieve substantial improvements in postoperative surveillance, although we will need to improve intervention compliance in the main trial. In some cases, barriers such as poorly located nursing stations, will be impossible to solve. By recognising this early, we will be able to adjust the intervention to reduce the impact of these problems and improve the chances of reducing mortality.

The purpose of clinical effectiveness (or pragmatic) trials is to confirm the benefits of a treatment which has shown promise in smaller efficacy (or explanatory) trials in the 'real world' clinical environment. Explanatory trials are designed to answer the question 'can this treatment work?', whilst pragmatic trials answer the question 'does this treatment work?' and typically include widely generalisable populations in a large number of hospitals. It is very important that we don't progress to large pragmatic trials until we have a sound biological basis for our treatment strategy, in terms of dose, timing and patient population. In the context of ASOS-2, the pilot trial provides that explanatory learning which confirms a larger trial is worthwhile, and guides how this should be designed and run. Most readers will recognise the urgency to improve standards of care for patients in Africa. Some might cut corners with good scientific method to deliver a large trial quickly, but poor research will not help. The people of Africa deserve the highest standards of scientific rigour in the research which defines their healthcare. It is tempting to rush to perform what we hope will be a definitive major trial, but poorly designed trials may give incorrect answers to vital questions. Only with thoughtful pilot trials can we avoid this. The ASOS-2 Pilot Trial suggests that the proposed ASOS-2 Trial is both appropriate and feasible for Africa.[7] I look forward to working with the ASOS-2 group to deliver what we all hope will be learning which saves many lives.

Competing interests

RP holds research grants and has given lectures and/or performed consultancy work for Glaxo Smithkline, BBraun, Intersurgical and Edwards Lifesciences, and is a member of the Associate editorial boards of the British Journal of Anaesthesia, British Journal of Surgery and BMJ Quality & Safety.

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