

## **BACKGROUND**

The non-cardiac surgical population represents a major global public health burden with approximately 234 million major surgical procedures performed worldwide each year. In unselected non-cardiac surgical patients, reports of early postoperative mortality vary between 2 and 4%, with an annual global mortality of 5 to 10 million. Surgery is a cost-effective intervention, even in low to middle income countries and as such it is considered a core component of health. The Lancet Commission on Global Surgery was established to define safe surgery and develop strategies to ensure the adequate provision of safe surgery.

Recently, the African Surgical Outcomes Study (ASOS) demonstrated, that despite a patient low risk profile and low complication rates, patients in Africa were twice as likely to die following surgery when compared to the global average. ASOS provides the most comprehensive data on surgical outcomes in Africa, comprising 25 countries, 247 hospitals, and data from over 11 000 patients. Importantly, 95% of the deaths in ASOS occurred in the postoperative period, suggesting that many lives could be saved by effective surveillance for physiological deterioration amongst the patients who developed complications.

It is likely that a major contributor to the high mortality in ASOS was 'failure to rescue' partly due to an inadequacy of sufficient human resources necessary to identify postoperative surgical patients at risk. The solution to improving surgical outcomes in Africa is identification of the high-risk surgical patient prior to further physiological deterioration.

## STUDY OBJECTIVE

The objective of this trial is to assess whether increased postoperative surveillance decreases major morbidity and mortality in African surgical patients identified at high-risk of postoperative morbidity and mortality through the ASOS Surgical Risk Prediction calculator.

# STUDY DESIGN

ASOS-2 is an international African, multicentre, cluster randomised trial. The primary outcome is in-hospital mortality, censored at 30 days if the patient is still alive and in-hospital.

The intention is to provide a pragmatic solution to decreasing postoperative morbidity and mortality across Africa. This trial will run across at least 25 African countries in early 2019.

# PREPARATORY WORK

This study is built on the successful collaboration of the African Surgical Outcomes Study (ASOS) which ran across 25 African countries in 2016, recruiting nearly 11 500 patients, and including over 1000 African clinician investigators. The intervention is based on the signal from ASOS of the major driver for postoperative morbidity and mortality in Africa. This will be the first continental collaborative trial of surgical outcomes in Africa.

# IMPORTANCE OF THIS STUDY

Africa has a population of 1.2 billion people, yet 95% of these people do not have access to safe surgery. Surgery in Africa is currently associated with significant morbidity secondary to 'failure to rescue' in the postoperative period. It is hoped that this trial will make a significant contribution to improving the safety of surgery in Africa.

The trial design is sufficiently pragmatic to ensure that it the findings are implementable across Africa.