

## Real-world implementation challenges in low-resource settings



Postoperative mortality is disproportionately high in low-income and middle-income countries (LMICs). In 2019, the African Surgical Outcomes Study (ASOS) collaborative prospectively followed 11 422 patients in 25 African countries and showed that postoperative mortality in this setting is twice as high as the global average.<sup>1</sup> As reported in *The Lancet Global Health*, ASOS-2, a cluster-randomised controlled trial, developed this earlier work to assess an intervention aimed at reducing postoperative mortality.<sup>2</sup> A package of five interventions were applied to patients at high risk on the basis of the clinical concept of failure to rescue—ie, that postoperative complications require active intervention and that hospitals with high rates of mortality fail to rescue deteriorating patients.<sup>3</sup> This package included admitting the patient to a higher care ward, increasing the frequency of postoperative nursing observations, assigning the patient to a bed in view of the nursing station, allowing family members to stay in the ward, and placing a postoperative surveillance guide in a visible position at the bedside.

Although the trial recruited 28 892 patients from 332 hospitals in 28 countries, it did not meet its target recruitment size. Additionally, the findings did not show a difference in 30-day in-hospital mortality between the intervention group (169 [1.3%] of 12 970) and control group (193 [1.3%] of 15 242). Most tellingly, the 160 hospitals allocated to the intervention group struggled to implement the package, with only 40.0% (64 hospitals) able to include the bedside surveillance guide plus one additional component, and only 59.4% (95 hospitals) able to implement two or more items in the package.

Despite the negative findings, the ASOS-2 study has made three major contributions. First, the trial shows that large-scale, multi-country, randomised controlled trials led by African investigators in surgical populations are feasible, but continue to be woefully underfinanced. Second, pragmatic clinical trials stress local health-care systems and providers. Although data collection was limited to 100 consecutive patients per hospital or a maximum of 4 weeks of collection, data forms were limited to one page to minimise their

clinical impact on constrained hospital resources, and intervention hospitals were asked to comply with a simple and resource-neutral intervention package, less than half of the initially recruited hospitals were able to enrol patients. A major reason for this observation was an inability to obtain ethical review or provide evidence of Good Clinical Practice (93 hospitals) and failed stakeholder engagement (49 hospitals). The third finding is the well known challenge of implementation. Even simple solutions, such as putting patients at high risk in close proximity to the nursing station and providing a surveillance guide at the bedside, could not be implemented uniformly, and less than a fifth hospitals allocated to the intervention group delivered all five components of the enhanced postoperative surveillance package to patients at high risk.

An implementation science approach is essential in resource-limited settings to leverage effective, novel solutions that work under resource variability. Implementation challenges tend to fall into five concrete categories: the specifics of the intervention; material, intellectual, and administrative support for implementation; the knowledge and behaviours required to enact change; the measurement, oversight, and feedback mechanisms to identify progress; and how interventions are systematised.<sup>4,5</sup> The ASOS-2 investigators acknowledge that a major trial limitation was the paucity of local input and co-ownership of the study design. Even though the intervention package was agreed on by a group of African experts, the evidence for some interventions, such as patients sleeping in close proximity to nursing stations, was not always strong. Did the enhanced postoperative surveillance not show a reduction in postoperative mortality because the interventions themselves were not effective or because the hospitals were not able to provide them? Were these five interventions comprising the package impactful, and would full implementation have reduced postoperative mortality? These questions are hard to answer given that implementation was incomplete. Nevertheless, this situation is not entirely surprising because implementation is a particular challenge in surgical systems: even in studies that focus on a select

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number of hospitals, full implementation across numerous settings is unlikely.<sup>6-8</sup>

Both the power of an intervention and its implementation strategy must be considered to effect improvements in patient care. Fixed budgets, overwhelmed resources, and weak engagement are particular challenges in LMIC settings. Despite these setbacks, there is an urgent need to identify effective real-world interventions in LMICs to improve the quality of surgical care. This study, powerful in its breadth and scope, should serve as a wakeup call for clinicians and investigators interested in improving surgical safety and quality. Collaborators are interested and the willingness is apparent; however, the resources are scarce and support is desperately inadequate.

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