

ATLS® vs standard care trial – next steps

Notes 2023-11-22

We have planned to compare the effects of ATLS® training with standard care on outcomes in adult trauma patients, through a batched stepped-wedge cluster randomized trial in 30 hospitals across India.

We have been granted 5 million SEK out of the 11.7 million SEK required to conduct the trial as planned. We have full cost coverage during year 1 and about half of year 2, and then approximately 33% of costs are covered for subsequent years.

This means that we have two options going forward:

- adapt the study design to fit the granted amount; or
- continue as planned with an optimized design and apply for more funding.

The consensus was to move ahead with the second option, with the worst case scenario that we will need to reduce the number of hospitals in the later phases of the project and potentially delay the project.

We discussed what hospitals that we are most keen to include, and many felt that it would be important to include smaller hospitals where the initial resuscitation is happening, even if these centres do not provide neurosurgery.

This might however prove challenging, as following up patients who are transferred out is difficult. We would need to put in place a system for capturing contact details of these patients so that we can contact them or their relatives to get their outcome.

The next steps include finalizing the study protocol, ideally during December. Weekly meetings will be planned to achieve this. We will apply for regulatory approvals in India, specifically approval from the Health Ministry Screening Committee. We also need to identify the five hospitals to be included in the first batch and apply for ethical approval from there.

This will also be an opportunity for parallel and related projects and we should capture this opportunity to explore additional aspects related to trauma life support training.