

Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

Clinical Trial Protocol
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ATLS® vs Standard Care in Adult Trauma Patients

Clinical Trials Registry-India ID:

ClinicalTrials.gov ID:

Coordinator:

Sponsor:

1 Synopsis

Title Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

Rationale Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Among these programmes, Advanced Trauma Life Support® (ATLS®) is the most popular, having trained over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes. Multiple systematic reviews emphasise the need for such trials.

Aim To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Primary Outcome All-cause mortality within 30 days of arrival at the emergency department.

Trial Design Batched stepped-wedge cluster randomised trial in India.

Trial Population Adult trauma patients presenting to the emergency department of a participating hospital.

Sample Size 30 clusters and 4320 patients.

Eligibility Criteria

Hospitals are secondary or tertiary hospitals in India that admit or refer/transfer for admission at least 400 patients with trauma per year.

Clusters are one or more units of physicians providing initial trauma care in the emergency department of tertiary hospitals in India.

Patients participants are adult trauma patients who presents to the emergency department of participating hospitals and are admitted or transferred for admission.

Intervention The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India.

Ethical Considerations We will use an opt-out consent approach, in which consent is presumed unless actively declined. Note that consent here refers to consent to data collection, as it will not be possible for patients to opt out from being subjected to the intervention. This approach is justified because the trial can be considered to involve only minimal risk and the data collection is non-invasive and mostly involve extracting routinely collected data from medical records. Patient participants will be informed about the study and their right to opt out once they are admitted or telephonically if they are transferred. Patients will be

informed that they can withdraw their data from the trial at any time before final analysis of the data.

Trial Period October 1, 2024, to September 30, 2029

2 Background and rationale

Each year, 4.3 million people die from trauma¹. Among people aged 10-24 and 25-49 years trauma is the largest cause of disability adjusted life years². Most deaths from trauma occur within the first 24-48 hours³. Traumatic brain injury and exsanguination are the most common causes of trauma deaths^{4,5}. Most preventable trauma deaths are caused by clinical judgement errors during initial resuscitation or early care including airway management and haemorrhage control, even though the deaths occur later during the hospital stay^{4,6}.

Several trauma life support training programmes have been developed to improve the early management of patients in the hospital by providing a structured framework for assessment and treatment⁷⁻¹⁰. The proprietary Advanced Trauma Life Support® (ATLS®) is the most established trauma life support training programme and more than one million physicians in over 80 countries have been trained in the programme since the first course in 1978¹¹. In the US and many other countries training in ATLS® is virtually mandatory for trauma care physicians¹². Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs⁹.

There are three randomised controlled studies showing that ATLS® improves knowledge and clinical skills¹³⁻¹⁵, but there are no randomised controlled trials or high-quality quasi-experimental trials indicating that ATLS® improves patient outcomes^{7,8,10}. We conducted an updated systematic review for project (unpublished), and estimated a pooled risk ratio of 0.82 (95% CI 0.60; 1.11) from ten heterogeneous (I^2 0.91) retrospective or small studies on the effect of ATLS on mortality (see Figure 1)¹⁶⁻²⁵. No study assessed functional outcomes.

We conducted a pilot cluster randomised controlled trial (ClinicalTrials.gov NCT05417243) that we conducted between April 2022 and February 2023 as part of our network grant to assess the feasibility of a full scale trial. We published the protocol for this pilot study²⁶. Our pilot study enrolled 376 patients from seven hospitals across India (unpublished data) and shows that it is feasible to conduct the proposed trial with a high percentage of patients consenting to out of hospital follow up (78%), low loss to follow-up rate (1%), and low missingness in key variables (mean 0.8%).

To involve patients and the public in the planning of this trial we conducted 19 semi-structured interviews with trauma patients, caregivers, and community representatives (unpublished data). The aim of these interviews was to understand their views on the trial and important outcomes and the interviews showed high acceptability of our research and emphasised the importance of better recovery before discharge and functional outcomes at and after discharge, including pain, mobility and self-care activities. The interviews also highlighted return to work as an important outcome.

2.1 Updated systematic review

We performed a systematic literature search in the Medline, Embase, Cochrane, Web of Science, CINAHL and Google Scholar databases (PROSPERO ID CRD42022373977). The last search was conducted on November 11, 2022. We developed the search strategy in Medline (Ovid) in collaboration with librarians at the Karolinska Institutet University Library. We limited the search to English language articles, searched all databases from inception, and screened a total of 7896 records. We used a random effects model to pool estimates across studies.

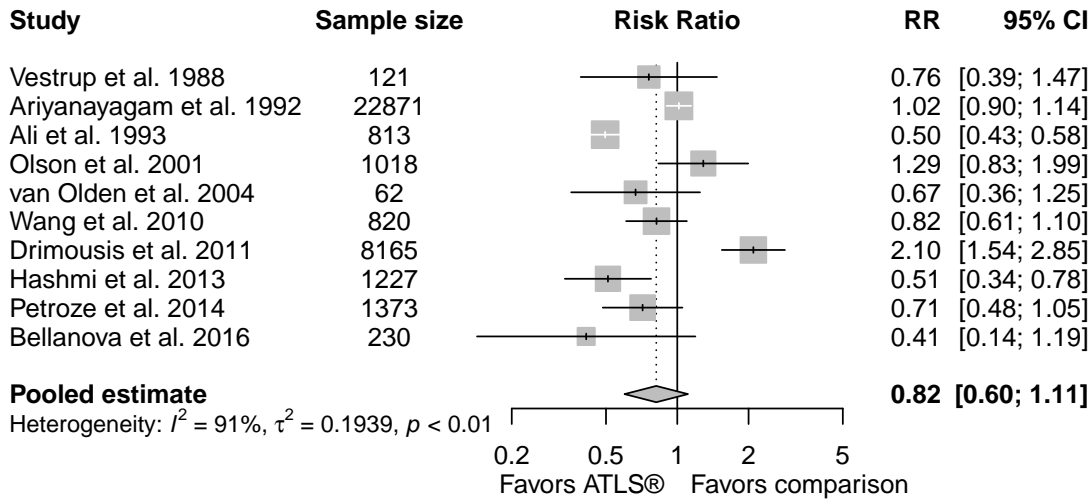


Figure 1: Summary of the updated system review. The forest plot shows the effect of ATLS on mortality. Abbreviations: RR, risk ratio; CI, confidence interval; ATLS, Advanced Trauma Life Support; I^2 , heterogeneity.

3 Benefit-risk evaluation

The direct risks includes integrity violations and data leakage. We will mitigate these risks by employing rigorous data collection and storage mechanisms. The procedures that we will use to collect data will be direct observation of care, routine physical examinations, questionnaires, and extraction of already collected data from patient records, which are often seen as involving only minimal risk.

The long-term risks of the research and the risk that the research will be used in detrimental ways are minimal. Our trial will assess the effect of Advanced Trauma Life Support® (ATLS®)

on patient outcomes. Training in ATLS® is standard in many health care systems and it is unlikely that training physicians in this programme induces any harm to participants.

We consider these risks weighed up by the potential direct benefit for the participants in the intervention phase, if ATLS® is found to improve patient outcomes, and by the potential for improved care for the trauma patient population.

4 Trial aim

To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

5 Regulatory approvals and trial registration

We will submit this trial to the Health Ministry Screening Committee at the Indian Council for Medical Research for their approval. We will apply for ethical approvals from each participating hospital, The George Institute for Global Health in India and the Swedish Ethical Review Authority. We will register this trial with Clinical Trials Registry-India and ClinicalTrials.gov.

6 Trial design and procedures

6.1 Overall trial design

We will conduct a batched stepped-wedge cluster randomised controlled trial (see Figure 2). The stepped-wedge trial is a uni-directional cross-over trial but the time point when clusters cross-over from standard care to the intervention is randomised²⁷. Each cluster will be at least one unit of physicians performing initial resuscitation of trauma patients in the emergency department of tertiary hospitals in India. The number of units that we will train in each hospital will depend on the sizes of these units and the volumes of patients that they see. If more than one unit is trained in the same hospital these units will be considered one unit for the purpose of randomization. We choose this approach for two reasons: 1) it will not be logistically or financially feasible to train all physician in a given hospital; and 2) we need to balance cluster size with the number of clusters. We will conduct this trial in India because physicians providing initial trauma care in India are so far not routinely trained in ATLS® or similar programmes.

We will roll out the interventions to 30 clusters over six batches, so there will be five clusters in each batch. The clusters in each batch will be randomised to one of five implementation

sequences, with one hospital randomised to each implementation sequence. All clusters will transition through three phases, first a standard care phase, then a one month transition phase during which the training is delivered, and finally an intervention phase, for a total of 13 months. The implementation sequence determines how long the phases of standard care and intervention are. Patient participants will be followed up for a total of three months.

6.2 Design justification

We use the cluster randomised design because the intervention cannot be randomised at the individual patient level. We use the stepped-wedge design for two reasons. First, this design is statistically more efficient than the parallel cluster design when the number of clusters is limited²⁸. In this trial, the number of clusters is limited because of the costs associated with ATLS[®] training and the available slots for ATLS[®] training in India. Second, the stepped-wedge design is likely to enhance participation and engagement because all clusters receive the intervention. The batched stepped-wedge design further improves feasibility as it does not require all clusters to start at the same time, and it is robust to potential delays in cluster recruitment²⁹.

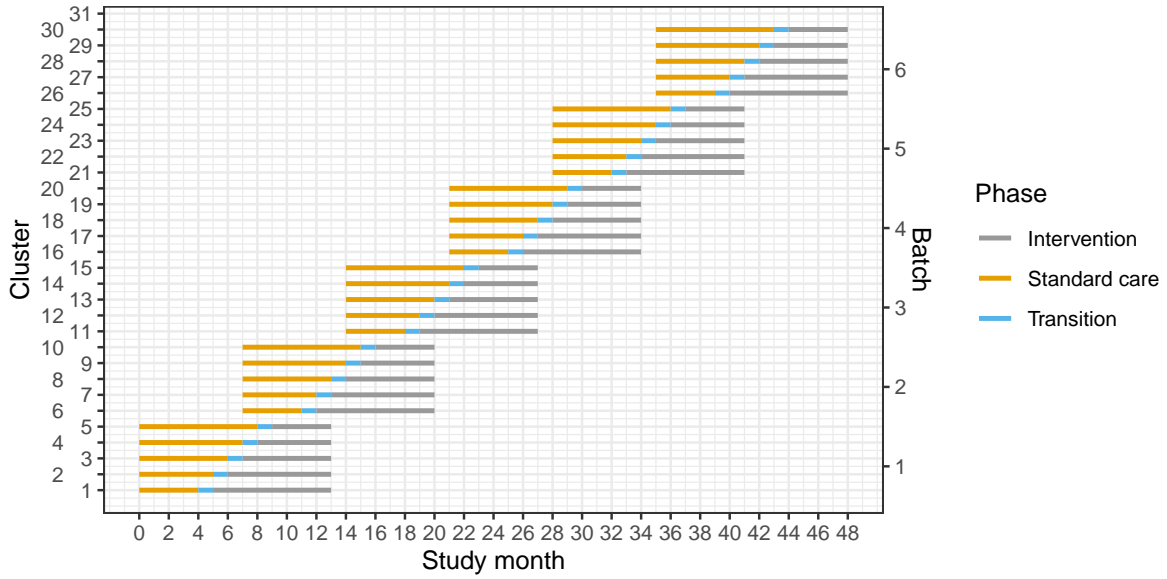


Figure 2: Trial design. Lines represent the duration of patient enrolment across clusters and phases. Clusters will be sequentially allocated to a batch based on when they enter the study. Within each batch clusters will then be randomised to an intervention implementation sequence.

6.3 Eligibility criteria

Our trial include eligibility criteria on three levels: hospitals, clusters and patient participants. We include eligibility on both the hospital and cluster level to facilitate the screening process.

6.4 Hospital selection

Hospitals will be secondary or tertiary hospitals providing trauma care in India.

6.4.1 Inclusions criteria

Hospitals must meet the following criteria:

- admit or refer/transfer for admission at least 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months;
- provide surgical and orthopaedic emergency services around the clock; and
- have at most 25% of physicians providing initial trauma care trained in a formalised trauma life support training programme, like ATLS® or Primary Trauma Care (PTC).

6.4.2 Exclusion criteria

Hospitals are excluded if they meet any of the following criteria:

- the hospital of the cluster implements a formalised trauma life support training programme ¹ during the trial period; or
- the hospital of the cluster plan to implement or implements other major interventions² that affects trauma care during the trial period.

6.5 Cluster selection

Clusters are one or more units of physicians providing initial trauma care in the emergency department of secondary or tertiary hospitals in India.

¹These include but are not limited to the National Emergency Life Support (NELS) programme, the Basic Trauma Life Support (BTLS) programme, the Pre-Hospital Trauma Life Support (PHTLS) programme, the Trauma Nursing Core Course (TNCC) and the Advanced Trauma Care for Nurses (ATCN) programme.

²These include but are not limited to implementing of a trauma team approach, opening a trauma centre and implementing a trauma quality improvement programme.

6.5.1 Inclusion criteria

Clusters must meet the following criteria:

- admits or refers/transfers for admission at least 12 patients with trauma per month for at least the last six months, meaning that the hospital of the cluster should admit or refer for admission 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months;
- the hospital of the cluster provides surgical and orthopaedic emergency services around the clock; and
- no more than 25% of physicians providing initial trauma care trained in a formalised trauma life support training programme.

6.5.2 Screening

The trial management group will compile a list of hospitals with potentially eligible clusters and reach out to them to assess their interest in participating in the trial. We will then screen hospitals for eligibility based on the criteria above. The data sources for screening will be hospital records and interviews with hospital staff. The screening will be standardised using a cluster screening instrument (see Appendix Section 17.1) in REDCap and logged in the associated REDCap database.

We will strive to include hospitals that to a large extent conducts primary resuscitation of trauma patients, rather than hospitals that primarily receives transferred patients from other hospitals, but this is difficult to formalise in the eligibility criteria. We will therefore discuss each eligible centre individually in the trial management group before deciding whether to include it in the trial. To avoid excluding centres we will also discuss plans to implement other potentially competing interventions during the trial period, and take these plans into account when assigning clusters to batches. For example, we are aware of the ongoing implementation of the National Emergency Life Support (NELS) programme in India, and will therefore not include hospitals that plan to implement this programme during the trial period.

6.6 Patient participants selection

Patient participants are adult trauma patients who presents to the emergency department of participating hospitals and are admitted or transferred for admission.

6.6.1 Inclusion criteria

Patients participants must meet the following criteria:

- age of at least 15 years;

- present to the emergency department of participating hospitals, with a history of trauma defined as having any of the reasons listed in the International Classification of Diseases chapter XX as the reason for presenting;
- admitted or died between arrival at the hospital and admission, or referred/transferred from the emergency department of a participating hospital to another hospital for admission; and
- trauma occurred less than 48 hours before arrival at the hospital.

6.6.2 Exclusion criteria

Patients participants are excluded if they meet the following criteria:

- present with isolated limb injuries; or
- are directly admitted to a ward without being seen by a physician in the emergency department.

6.6.3 Screening

Clinical research coordinators will screen patient participants either as they arrive to the emergency department or using emergency department registers. Once the patient is admitted, the clinical research coordinators will approach eligible patients or their representatives to provide study information and inform participants that they can opt out from the study at any time before final analysis. Patients who are transferred before they have had an opportunity to be informed about the study will be contacted by phone. Phone numbers will be extracted from the emergency department registers, and will be securely held only by the clinical research coordinators at each sites

6.6.4 Withdrawal criteria

Patient participants can choose to withdraw their consent at any time before the final analysis. If they withdraw their consent the clinical research coordinator will not contact them for additional follow ups. They can also choose to have the data collected about them removed from the trial at any time before final analysis of the data. Withdrawal of consent or removal of data from the trial will not affect their care in any way. If the patient participant withdraws consent, follow-up of this participant will be performed according to the participating hospitals routine.

6.7 Procedures

Table 1 shows an overview of trial procedures. Clinical research coordinators will follow up patients daily until discharge to capture injury information. They will also follow up patients at 24 hours, 30 days and 90 days after arrival to the emergency department to capture mortality outcomes, and at 30 days and 90 days after arrival to the emergency department to capture functional outcomes and return to work. If patient participants are discharged before any of these follow-up time points, clinical research coordinators will follow up patients by phone.

Table 1: Overview of trial procedures

Procedure	Screening	Follow up				
		Daily	24 hours	Discharge	Within 7 days of discharge	30
Eligibility criteria	✓					
Study information ¹	✓					
Informed consent for follow up ¹	✓					
Baseline data collection	✓					
Injury data collection	✓	✓				
Assessment of safety events		✓				
Mortality data collection ²	✓	✓	✓	✓		✓
EQ-5D/WHODAS					✓	✓
Return to work						✓
End of Trial						

¹Clinical research coordinators will inform patient participants about the study, including that they are free to withdraw their data from the study at any time, and approach them for informed consent for follow up either in person or telephonically.

²Mortality data will be collected from the hospital records and from the patient participants or their caregivers by telephone.

6.8 Biological sampling procedures

This trial does not include biological sampling.

6.9 End of Trial

The trial ends when the last patient participant has completed the last follow-up. The trial may be prematurely terminated if it is necessary for safety reasons affecting the risk-benefit

balance or if the recruitment of subjects cannot be met within reasonable time limits. If the trial is prematurely terminated or suspended, the investigator should immediately inform the subjects about this and ensure appropriate treatment and follow-up. Decisions on premature termination are taken by the Trial Steering Committee and Trial Management Group.

6.10 Intervention and control treatment

The intervention will be ATLS® training. The control will be standard care, meaning no formal trauma life support training. We will train the physicians that initially resuscitate and provide trauma care during the first hour after patient arrival at the emergency department. These physicians can be casualty medical officers, surgical residents, or emergency medicine residents, depending on the setup at each participating centre. The training will occur during the transition phase in each cluster. Our experience from our pilot study is that study sites adhere to the training slot allotted to them through the trial, so we judge the risk of clusters implementing ATLS® before their randomised implementation sequence as very low.

We will train the number units of physicians needed to reach the required patient sample size, but estimate that this will require training an average of ten physicians per hospital, which on average should be mean that we can train one to two units per hospital. This is possible because many hospitals in India organise physicians staffing their emergency departments in units, and the physicians in the same unit work together in the emergency department on the same days of the week. We will therefore collect data only on the days when these units work. The units selected to constitute a cluster from each hospital will be a convenience sample out of all eligible units in those hospitals.

Advanced Trauma Life Support® (ATLS®)¹¹ is a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. The programme was developed by the Committee of Trauma of the American College of Surgeons. The course includes initial treatment and resuscitation, triage and interfacility transfers. Learning is based on practical scenario-driven skill stations, lectures and includes a final performance proficiency evaluation. Physicians will be trained in an accredited ATLS® training facility in India.

Standard care varies across hospitals in India, but trauma patients are initially managed by casualty medical officers, surgical residents, or emergency medicine residents. They are mainly first- or second-year residents who resuscitate patients, perform interventions and refer patients for imaging or other investigations. Compared with other settings where a trauma team approach is adopted, nurses and other healthcare professionals are only involved to a limited extent during the initial management.

6.10.1 Description of investigational medicinal products

This trial does not include any investigational medicinal products.

6.10.2 Auxiliary medicinal products

This trial does not include any auxiliary medicinal products.

6.10.3 Concomitant use of other medications or treatments

Other than implementing another formalised trauma life support training programme or other major interventions to change the care of trauma patients as specified in the exclusion criteria, concomitant use of other medications and treatments may be provided at the discretion of the investigators and will not be considered an exclusion criterion.

6.11 Randomization

We will assign clusters to batches as they are found to be eligible and receive ethical approval. Batches will include clusters from hospitals in different regions to optimize trial logistics. We will randomize the clusters allotted to each batch to the different intervention implementation sequences within that batch³. We will balance the randomization within each batch on cluster size, defined as monthly volume of eligible patient participants, using covariate constrained randomization. We will conceal the randomization order for as long as it is logistically possible, considering that arrangements for sending physicians to ATLS® training need to be made in advance.

6.12 Blinding

It is not possible to blind a stepped-wedge trial, because all clusters receive the intervention.

6.13 Treatment after trial end

When the trial ends, the intervention will have been implemented in all clusters.

6.14 Outcomes

6.14.1 Primary outcome

The primary outcome will be all-cause mortality within 30 days of arrival at the emergency department. Clinical research coordinators will extract information on death from patient hospital records, by calling the patient or a patient representative, or if the patient has been transferred to another hospital by contacting the hospital to which the patient was transferred.

³Randomization will be done using bespoke code from previous trials.

Data on this outcome will be collected continuously during the trial. We chose this outcome as the primary outcome because it is an outcome of clinical and patient importance with very low missing data rates (1%) in our pilot study. We will also be able to compare our findings with previous research.

6.14.2 Secondary outcomes

- All cause mortality within 24 hours and three months of arrival at the emergency department. Data on this outcome will be collected in the same way as for the primary outcome.
- In-hospital mortality within 30 days of arrival at the emergency department. Data on this outcome will be collected in the same way as for the primary outcome.
- Quality of life within seven days of discharge, and at 30 days and three months of arrival at the emergency department, measured by the official and validated translations of the EQ5D3L. Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. We will collect this data from a stratified random sample (site and period) of patient participants. The sampling will be designed so that it maximises statistical efficiency.
- Disability within seven days of discharge, and at 30 days and three months of arrival at the emergency department, assessed using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0). Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. This data will also be collected from a stratified random sample of participants.
- Return to work at 30 days and three months after arrival at the emergency department. Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged.
- Length of emergency department stay. Data on this outcome will be collected from patient hospital records.
- Length of hospital stay. Data on this outcome will be collected from patient hospital records.
- Intensive care unit admission. Data on this outcome will be collected from patient hospital records.
- Length of intensive care unit stay. Data on this outcome will be collected from patient hospital records.

6.15 Handling of Adverse and Safety Events

6.15.1 Definitions

6.15.1.1 Adverse Event

Any untoward medical occurrence in a clinical trial subject and, which does not necessarily have a causal relationship with the treatment, can be an unfavorable and unintended sign (including an abnormal laboratory discovery), symptom or disease temporally associated with the inclusion in the trial, whether or not related to the trial.

6.15.1.2 Serious Adverse Event

Any untoward medical occurrence in a trial participant that:

- leads to death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability or incapacity
- results in a congenital anomaly/malformation

6.15.1.3 Safety Event

Any unexpected serious complication that might occur as a consequence of the trial and that are not part of the natural history of trauma.

6.15.2 Reporting and Assessment of Adverse and Safety Events

In alignment with other current trials including critically ill patients³⁰, we will not collect adverse events or serious adverse events, because many of these events are expected in this patient population and we already collect many of these events, for example mortality, as part of our outcomes.

We will only report safety events, if they are life-threatening, prolong hospitalisation or result in meaningful harm to the participant. We cannot pre-define a comprehensive list of events that can be considered safety events, but will actively assess the presence of the following safety events:

- Prolonged mechanical ventilation (> 7 days)
- Initiation of renal replacement therapy
- Prolonged (> 2 days) or renewed (restart after at least 2 days without) use of vasopressors such as norepinephrine or vasopressin

These events are considered safety events because they suggest pulmonary, renal, septic or bleeding complications and an increase in their occurrence following ATLS® training could indicate that the intervention is harmful. These events therefore need to be tracked during the standard care phase as well as the intervention phase, but will only be considered indicative of harm related to the intervention if they occur more often during the intervention phase than during the standard care phase.

We will also report any other safety events that we identify during the trial, and the reporting of such will have to be based on the intuition of the clinical research coordinators and local investigators. Examples of such safety events could include missed injuries or missed investigations, which could be suspected if certain injuries or investigations were identified or conducted more often during the standard care phase than during the intervention phase.

All safety events will be recorded in the CRF and reported to the trial management team within 24 hours of its occurrence. The trial management team will then assess if the event can be considered related to the trial or the intervention within 24 hours of it being reported. Events that are considered probably related will be reported immediately to the Data Safety Monitoring Board.

6.15.3 Follow up of Safety Events

All safety events should be followed up by the local investigator until they are fully evaluated.

6.16 Independent Data Safety Monitoring Committee

An independent Data Safety Monitoring Committee, comprising four external members, will review trial data for each batch, assessing data quality, completeness, cluster performance in recruitment and loss to follow-up rates, and external factors affecting trial validity, safety, or ethics. They will also review the results of interim analysis of outcomes and review safety events reported by the trial management group. The Data Safety Monitoring Committee can at any time, based on its reviews, recommend to terminate the trial.⁴

6.17 Statistics

6.17.1 General principles

We will conduct all analysis by modified intention to treat. Clusters and observations within clusters will be considered exposed to the intervention after the date at which the cluster was scheduled to transition. All data will be included with the exception of the transition phases. We will not adjust for multiplicity of analyses because none of the secondary outcomes will be singularly more important. However, all secondary outcomes will be interpreted with due consideration for how all are affected by the intervention without putting any undue emphasis on a single outcome that might be statistically significant but where all others appear to have remained unchanged.

We will use a two-sided significance level of 5% and estimate 95% confidence intervals. The primary subgroup analyses will be based on geographical region because demonstrating the

⁴**TODO** Identify four members of the independent Data Safety Monitoring committee.

consistency of any effect across multiple regions will enhance the generalisability of the results⁵. Additional subgroup analyses will include age across the groups older adolescents (15-19 years), young adults (20-24 years), adults (25-59 years), and older adults (60 years and older)³¹; sex; and the clinical cohorts blunt multisystem trauma, penetrating trauma, and severe isolated traumatic brain injury.

6.17.2 Analysis models

There are a number of requirements for the analysis model. Firstly, all analysis will consider the clustered nature of the design. Secondly, as the trial has only 30 clusters, it will be essential that the model allows for a correction due to the small number of clusters. Thirdly, as the design is a stepped-wedge study, we will adjust for temporal confounding using categorical effects for period of the study (month). Full details on how each of these will be undertaken, with justification is provided below³².

For binary outcomes, a mixed effects binomial regression with a logit link will be used to estimate the odds ratio; and a binomial model with identity link used to estimate the risk difference. These models will be fitted using residual pseudo-likelihood estimation based on linearization with subject-specific expansion (RSPL). If the binomial model with the identity link does not converge then only a odds ratio will be reported.

We will include fixed effects for period and a fixed effect for intervention exposure. The primary analysis will allow for clustering by as a random cluster and random cluster by period effect. To correct the potential inflation of the type I error rate due to small number of clusters, the Kenward and Roger small sample correction will be used. In a sensitivity analysis we will explore if models with more complicated correlation structures are a better fit to the data. These models are not being used as our primary analysis models as there is limited understanding as to when such models will converge and how to choose between the various different correlation structures which might be plausible.

To this end we will additionally fit generalised linear mixed models (with same link functions and fixed effects as described above) to include a discrete time decay correlation structure including a random cluster effect with auto-regressive structure (AR(1)). To allow for the randomisation by batches, a different secular trend will be included for each batch (interaction between batch and period). For continuous, count and prevalence outcomes similar model-based approaches will be used but with appropriate links and distribution functions, using transformations where appropriate.

⁵**Note:** Batches will not be based on regions because it will be logistically more feasible to include clusters from different regions in each batch.

6.17.3 Additional sensitivity analyses

To additionally explore if the fixed period effect is both parsimonious and adequate to represent the extent of any underlying secular trend, we will model the time effect using a spline function. Models will also be extended to include random cluster by intervention effects (with a non-zero covariance term) to examine if results are sensitive to the assumption of no intervention by cluster interaction. Models will also be extended to include an interaction between treatment and number of periods since first treated, to examine if there is any indication of a relationship between duration of exposure to the intervention and outcomes.

This will allow us to different lag effects (whereby it takes time for the intervention to become embedded within the culture before its impact can properly start to be realised); as well as waning effects (whereby the effect of the intervention starts to decrease – or fade). This type of analysis attempts to disentangle how some clusters end up having a long exposure to the intervention and others have a much shorter exposure time. A fully adjusted covariate analysis will additionally adjust for a set of pre-specified individual-level covariates of known prognostic importance.

6.17.4 Estimation and reporting of within cluster correlations

We will report time adjusted within-cluster correlations for all outcomes with 95% confidence intervals. We will report correlations from the different assumed correlation structures (so we will report intra-cluster correlations (ICC); within and between-period correlations; and within-period correlations and exponential decay). As well as reporting correlations we will additionally report all variance components. For all outcomes we will report correlations on the latent scale (i.e. proportions scale for binary outcomes) as is appropriate to inform future sample size calculations.

6.17.5 Sample size calculations

With 30 clusters and a total sample size of 4320 our study has ~90% power across different combinations of cluster autocorrelations (CAC) and intra-cluster correlations (ICC) to detect a reduction in the primary outcome from 20% under standard care to 15% after ATLS[®] training (see Figure 3). This effect is a conservative estimate and the reduction equals a risk ratio of 0.75, which would be clinically important while also being consistent with our pilot study and updated systematic review. We allowed for the clustered design and assumed an ICC of 0.02, but considered sensitivity across the range 0.01-0.05^{33,34}, and a CAC of 0.9 but considered sensitivity across the range 0.8-1.0, based on our pilot study and current guidance³⁵⁻³⁷. We included the CAC to allow for variation in clustering over time. We assume that each cluster will contribute approximately 12 observations per month to the analysis, based on our previous work.

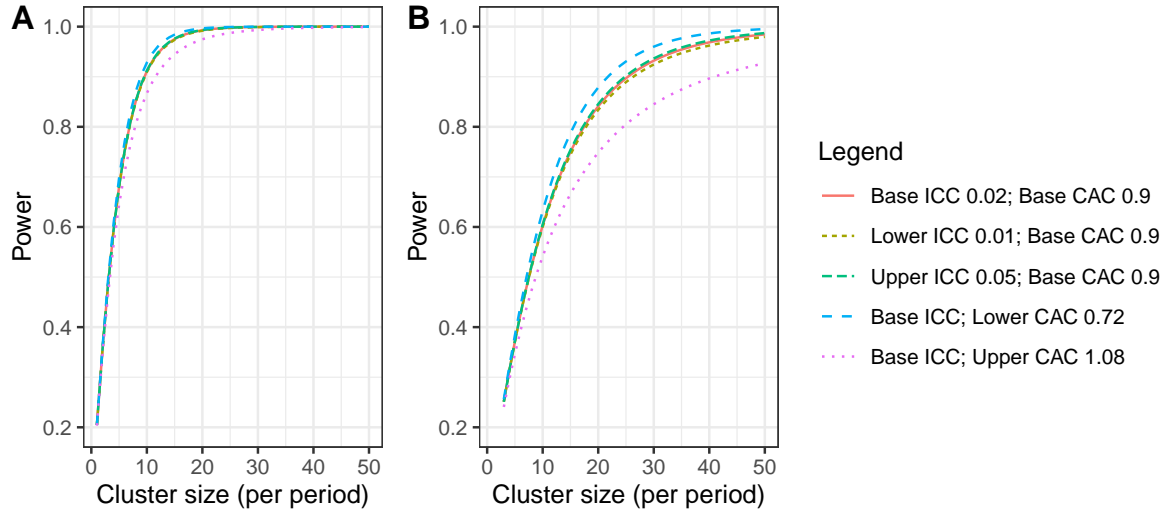


Figure 3: Power curves for different combinations of cluster autocorrelations (CAC) and intra-cluster correlations (ICC). **A)** Shows power curves assuming a reduction in the primary outcome from 20% under standard care to 15% after ATLS[®] training. **B)** Shows power curves assuming a reduction in the primary outcome from 10% under standard care to 7.5% after ATLS[®] training. Under this scenario, we would need to increase the sample size per month to around 30 observations to achieve 90% power under most combinations of CAC and ICC.

6.17.6 Interim analysis

There will be one interim analyses after half of the batches have completed the trial. The first purpose of this interim analysis will be to assess the trial's feasibility and recommend stopping the trial if the trial is not feasible, for example if clusters fail to adhere to the randomisation schedule or if there are substantial missing data in outcomes. The second purpose of the interim analysis will be to assess if sample size calculations should be revised, primarily by increasing the number of clusters to be included. The interim analyses will be assessed by the independent Data Safety Monitoring committee.

6.18 Quality Control and Quality Assurance

The George Institute for Global Health - India will ensure proper conduct of the trial through quality control measures including on-site training of personnel, standard operating procedures, ongoing quality metrics assessment, review of missing data and outliers, and round-the-clock availability of coordinating center personnel and Principal Investigators. The trial will strictly follow ICH GCP principles, Indian regulations, and George Institute procedures. The trial operations staff from the George Institute India will train local investigators, and trial site staff, before the trial, with continuous documentation in the site master file. All documentation will be stored securely and retained according to regulatory requirements.

6.19 Quality Assurance and Sponsor oversight

The Trial Management Group and Trial Team, comprising key project leaders and managers, will play a pivotal role in ensuring the highest standards of quality assurance and effective sponsor oversight throughout the trial. These groups will be responsible for facilitating consistent communication, maintaining fidelity in study implementation, and overseeing the quality of data collection.

To achieve these objectives, the groups will implement a comprehensive communication plan and provide extensive training to site personnel. The training will cover not only the study protocol but also practical aspects of various systems, supplemented by both written and electronic materials designed to educate study and clinical emergency staff.

The trial's quality assurance systems will be meticulously designed based on a thorough risk analysis. A key component of our quality assurance strategy will include the development and implementation of detailed operational manuals and regular meetings. These tools and interactions will ensure that all trial personnel will be used to uphold the trial's quality standards.

Central to our oversight approach will be a comprehensive monitoring and auditing plan. This plan will be tailored based on the identified risks associated with the trial. Through these comprehensive measures, the trial management group, in conjunction with the hospital staff,

will ensure that the trial is conducted with the utmost rigor, adhering to the highest standards of quality assurance and effective sponsor oversight.

6.20 Monitoring

We will implement a multi-tiered monitoring strategy, including centralized data consistency checks, statistical monitoring, and selective on-site evaluations. Key integrity measures include source data verification, data entry validation, and regular audits. Any protocol deviations will be thoroughly documented, with serious breaches promptly addressed to ensure data integrity.

Monitors from coordinating centres will assist investigators in maintaining high ethical, scientific, technical, and regulatory quality. Monitoring visits will review protocol adherence, participant recruitment, adverse event reporting, compliance with study procedures, and regulatory adherence. Regular remote monitoring of the web-based database will be conducted to ensure data integrity, using validation and consistency rules and regular data cleaning.

7 Deviations, serious breaches and other reporting obligations

The responsible investigator shall, without delay, report to the sponsor any serious breaches and deviations from the trial protocol, ICH-GCP and other regulations that significantly and directly affect, or with high likelihood could affect, the subjects' safety and integrity or the reliability and robustness of the data generated in the trial. The sponsor should assess the suspected serious breach and the consequences of deviations that have occurred. Minor deviations that do not affect subjects' integrity or safety, nor significantly affect the trial's scientific value, are documented in the trial documentation of the principal investigator and the sponsor and appropriate measures shall be taken. The deviations must be recorded in the clinical trial report.

8 Audits and inspections

Authorized representatives for the sponsor and Competent Authorities (CA) may carry out audits or inspections at the trial site, including source data verification. The investigator must ensure that all source documents are available for audits and inspections. The purpose of an audit or inspection is to systematically and independently review all trial-related activities and documents, to determine whether these activities were performed, registered, analyzed and reported correctly according to protocol, ICH- GCP and applicable regulations.

9 Ethics

9.1 Compliance to the protocol, ICH-GCP and regulations

The trial will be performed in compliance with this clinical trial protocol, the Declaration of Helsinki, ICH-GCP (Good Clinical Practice), and current national regulations governing this clinical trial. This is to ensure the safety and integrity of the trial subjects as well as the quality of the data collected.

9.2 Ethical review of the trial

The final protocol will be submitted for ethical review at all participating hospitals, where possible, as well as the The George Institute for Global Health in India and Swedish Ethical Review Atuhortiy.

9.3 Procedure for obtaining consent

We will use an opt-out consent approach, in which consent is presumed unless actively declined. Note that the consent here refers to consent for data collection, because it will not be possible for patients to opt out from being subjected to the intervention, as the intervention is delivered at the cluster level and involves training physicians in trauma life support, and these physicians cannot be expected to temporarily forget their training.

This approach is justified because the trial can be considered minimal risk and because data collection will be non-invasive and mostly rely on extraction of routinely collected data from medical records. Clinical research coordinators will inform patient participants about the study and they will be given the opportunity have their data deleted before final data analysis.

The clinical research coordinators will approach patients or patient representatives to provide this information in person after admission. If a patient is transferred to another hospital before the patient has had an opportunity to receive the study information, then the clinical research coordinators will contact the patient or patient representative by phone.

9.4 Data protection

We will ensure that appropriate agreements and/or other appropriate protective measures are taken to ensure that the data processing is performed in accordance with the provisions of the relevant legislation, before any data transfer takes place.

In the study information provided to patient participants, they will be fully informed about how their trial data will be collected, used and disclosed. The study information will explain how

trial data are stored to maintain confidentiality in accordance with national data legislation⁶. All information processed by the sponsor will be pseudonymized.

The study information will also explain that for verification of the data, representatives delegated by the sponsor, as well as relevant authorities, may require access to parts of medical records or trial records that are relevant to the trial, including the patient participant’s medical history.

10 Insurances

*Here it should be explained how subjects are insured throughout the trial.*⁷

11 Substantial changes to the trial

Substantial changes to the signed clinical trial protocol are only possible through approved protocol amendments and by agreement between the sponsor and the principal investigator.

12 Collection, handling, and archiving of data

Clinical research coordinators will collect data using a paper based Case Record Form (CRF)⁸, which is then transferred to an electronic CRF (eCRF). Paper-based CRFs will be securely stored on-site and archived for as long as required by local regulations, but at least 10 years. Access to the eCRF is provided using a Virtual Private Network with two-factor authentication⁹. Access is granted by the project PI or authorized delegates. Metadata will be publicly accessible via a persistent DOI, and anonymised data will be released upon project completion. The data management plan is published (<https://doi.org/10.5281/zenodo.7748764>).

12.1 Source data

The source data for each variable is given in Section 12.2. Whenever medical records are the source data, this includes imaging and lab reports. Whenever an interview is given as the source, the CRF will constitute the source data, as this is where the responses to questions will be recorded.

⁶**TODO:** Describe data protection mechanisms, or cross-reference the section on “Collection, handling and archiving of data”

⁷**TODO TGI:** Please add information about insurance.

⁸**TODO:** Create a CRF template and attach.

⁹**TODO TGI:** Please check that this is correct.

The local investigator must keep source documents for each patient participant in the trial. A document describing what has been classified as source data in the trial (source data reference document) should be included in the Investigator Site File (ISF)¹⁰. The investigator must ensure that all source documents are accessible for monitoring and other quality control activities.

Source data is further defined before trial start at each individual site and can, in cases where source data is not registered in another document, consist of the CRF. This should be decided in consultation with the monitor and clearly stated in the source data reference document.

Access to trial-related documentation, such as patient participants' medical records, CRFs, other source data and other trial documentation will be provided for monitoring and auditing purposes. Access to patient participants' medical records will require a confidentiality agreement to be signed by the person in charge of the medical records at the trial site and by the monitor and auditor, if applicable. Access will also be granted in the context of regulatory inspections.¹¹

12.2 Variables

If we want to be able to do a cost-effectiveness analysis, then we also need to collect data on who does what for how long, capture changes in expensive procedures and investigations, capture health care utilisation after discharge, in-formal care (who does the caring, when and for how long), and productivity losses. There may be instruments for this already, or we can adapt existing instruments. To capture potential equity aspects we also need socioeconomic information on the patients

12.2.1 Baseline

- **Inclusion and exclusion criteria**, *Source*: Medical records
- **Age in years**, *Source*: Medical records/interview
- **Sex**, *Source*: Medical records/interview
- **Mechanism of injury** (Coded using the external causes codes in Chapter XX (20) of International Classification of Diseases - 10th Revision (ICD-10)), *Source*: Medical records/interview
- **Comorbidities** (Coded using Charlson Comorbidity Index), *Source*: Medical records/interview
- **Phone numbers to patient and patient representative**, *Source*: Medical records/interview

¹⁰**TODO**: Create an ISF template.

¹¹**TODO TGI**: Please check that this applies.

12.2.2 Pre-Hospital Data

- **Date and time of injury**, *Source:* Medical records/interview
- **Mode of transport to the participating centre**, *Source:* Medical records/interview
- **Referred to the participating centre from another centre**, *Source:* Medical records/interview

12.2.3 Emergency Department Data

- **Date and time of arrival to emergency department at the participating centre**, *Source:* Medical records/interview
- **First recorded systolic blood pressure**, *Source:* Medical records
- **First recorded diastolic blood pressure**, *Source:* Medical records
- **First recorded heart rate**, *Source:* Medical records
- **First recorded respiratory rate**, *Source:* Medical records
- **First recorded Glasgow Coma Scale score**, *Source:* Medical records
- **First recorded temperature**, *Source:* Medical records
- **First recorded oxygen saturation**, *Source:* Medical records
- **First creatinine**, *Source:* Medical records
- **Emergency department disposition**, *Source:* Medical records
- **Date and time of discharge from emergency department at the participating centre**, *Source:* Medical records/interview
- **Date and time of referral or transfer for admission at a higher level centre**, *Source:* Medical records/interview

12.2.4 Hospital Data

- **Date and time of admission to the participating centre**, *Source:* Medical records/interview
- **Type of admitting ward**, *Source:* Medical records
- **Date, time and type of any surgical procedure** (A surgical procedure is defined as any procedure performed in the operating room, interventional radiology suite, or at the bedside, requiring general or regional anesthesia, coded using), *Source:* Medical records
- **Date and time of any transfusion, type of blood product, and number of units transfused**, *Source:* Medical records
- **Date and time of intensive care unit admission and discharge**, *Source:* Medical records
- **Date and time of discharge from the participating centre, and the discharge destination**, *Source:* Medical records

12.2.5 Injury Data

- **Injury, the modality used to diagnose the injury, and the date and time when the injury was first registered** (Coded using the International Classification of Diseases - 10th Revision (ICD-10)), *Source:* Medical records

12.2.6 Outcomes

- **Date and time of death**, *Source:* Medical records/interview
- **Quality of life** (The EuroQol 5 Dimensions 3 Levels (EQ-5D-3L) questionnaire will be used to assess quality of life within 7 days of discharge, and at 30 and 90 days after arrival to the participating centre), *Source:* Interview
- **Disability** (The World Health Organization Disability Assessment Schedule 2.0 (WHO-DAS 2.0) questionnaire will be used to assess disability within 7 days of discharge, and at 30 and 90 days after arrival to the participating centre), *Source:* Interview
- **Return to work** (Assessed at 30 and 90 days after arrival to the participating centre), *Source:* Interview

12.2.7 Safety Events

- **Prolonged mechanical ventilation (> 7 days)** (Assessed during hospital stay), *Source:* Medical records
- **Initiation of renal replacement therapy** (Assessed during hospital stay), *Source:* Medical records
- **Prolonged (> 2 days) or renewed (restart after at least 2 days without) use of vasopressors such as norepinephrine or vasopressin** (Assessed during hospital stay), *Source:* Medical records

13 Trial Organization

More information will be added here

14 Funding

- Swedish Research Council (reg. no. 2023-03128)

15 Notification of trial completion, reporting, and publication

More information will be added here

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17 Appendices

17.1 Cluster screening instrument

Screening call

Page 1

This form is for screening potentially eligible clusters for the ATLS vs standard care trial. Please fill it in while talking to the hospital representative. Thank you so much for helping with this task!

Please complete the questions below.

Synopsis Title Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

Rationale Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Advanced Trauma Life Support® (ATLS®) is the most popular of these programmes and have been used to train over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes. Multiple systematic reviews emphasise the need for such trials.

Aim To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Primary Outcome In-hospital mortality within 30 days of arrival at the emergency department.

Trial Design Batched stepped-wedge cluster randomised trial in India.

Trial Population Adult trauma patients presenting to the emergency department of a participating hospital.

Sample Size 30 clusters and 4320 patients.

Eligibility Criteria

Cluster will be hospitals with a baseline admission rate of at least 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months, that provide emergency surgical and orthopaedic services around the clock, and where no more than 25% of initial trauma care providers trained in a formalised trauma life support training programme.

Patients will be at least 15 years old, who present to the emergency department of participating hospitals with a history of trauma occurring less than 48 hours before arrival, and who are admitted or die between and admission, or who are transferred from the emergency department of a participating hospital to another hospital for admission.

Intervention The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India.

Ethical Considerations In-hospital data collection will be conducted under a waiver of informed consent. Patients will be informed about the trial and their right to opt out of data collection. Patients will be informed that they can withdraw their data from the trial at any time.

Trial Period 2024-10-01 to 2029-10-01

Hospital details

Hospital name and address

Eligibility assessment

Does the hospital admit trauma patients?

- ☐ Yes
☐ No

Is the hospital representative interested in potentially participating?

- ☐ Yes
☐ No
 (Comment: _____)

If the hospital representative is not interested in participating then you can go ahead and submit the form.

How many trauma patients aged 15 years or older, excluding patients with isolated limb injuries, are admitted each month?

- ☐ < 30
☐ 30-60
☐ > 60
☐ Not sure
 (Comment: _____)

Does the hospital provide emergency surgery and orthopaedic services around the clock?

- ☐ Yes
☐ No
 (Comment: _____)

Out of the physicians involved in the initial resuscitation of trauma patients, are less than 25% trained in a formalised trauma life support training programme like ATLS or Primary Trauma Care?

- ☐ Yes
☐ No
 (Comment (like name of other training programme): _____)

Unfortunately, the hospital does not fulfil the eligibility criteria and you may go ahead and submit the form.

The hospital fulfills the cluster eligibility criteria. Please enter the hospital representative's contact details:

Name E-mail Phone number

Before you can proceed to fill in descriptive information about the potential cluster, please confirm that the contact details are complete:

Cluster descriptive information

Out of the patients with trauma who present to the emergency department, what percentage are referrals or transfers from other hospitals?

- ☐ < 20%
☐ 20-50%
☐ 51-80%
☐ > 80%
☐ Not sure
 (Comment: _____)

Out of the patients with trauma who are admitted, what percentage are transferred to other hospitals?

- ☐ < 10%
☐ 10-20%
☐ 21-30%
☐ > 30%
☐ Not sure
 (Comment: _____)

Who performs the initial resuscitation of trauma patients as they arrive to the hospital?	<input type="checkbox"/> Casualty medical officers <input type="checkbox"/> Emergency medicine residents <input type="checkbox"/> Surgical residents <input type="checkbox"/> Not sure (Comment: _____)
How many CMOs work in the emergency department?	<input type="radio"/> < 10 <input type="radio"/> 10-20 <input type="radio"/> 21-30 <input type="radio"/> > 30 <input type="radio"/> Not sure (Comment: _____)
This question is here to help us estimate the number of people we will need to train.	
How many emergency medicine/general surgery residents are admitted each year?	<input type="radio"/> < 10 <input type="radio"/> 10-20 <input type="radio"/> 21-30 <input type="radio"/> > 30 <input type="radio"/> Not sure (Comment: _____)
This question is here to help us estimate the number of people we will need to train.	
What specialities are available around the clock to care for trauma patients?	<input type="checkbox"/> General surgery <input type="checkbox"/> Orthopaedics <input type="checkbox"/> Neurosurgery <input type="checkbox"/> Vascular surgery <input type="checkbox"/> Interventional radiology <input type="checkbox"/> Emergency medicine <input type="checkbox"/> Not sure (Comment: _____)
What facilities are available around the clock?	<input type="checkbox"/> X-ray <input type="checkbox"/> Ultrasound/FAST <input type="checkbox"/> CT <input type="checkbox"/> MRI <input type="checkbox"/> Blood bank <input type="checkbox"/> Not sure (Comment: _____)
How many beds does the hospital have?	<input type="radio"/> < 250 <input type="radio"/> 250-500 <input type="radio"/> 501-750 <input type="radio"/> 751-1000 <input type="radio"/> >1000 <input type="radio"/> Not sure (Comment: _____)
How many ICU beds does the hospital have?	<input type="radio"/> No ICU beds <input type="radio"/> 1-10 <input type="radio"/> 11-20 <input type="radio"/> 21-30 <input type="radio"/> > 30 <input type="radio"/> Not sure (Comment: _____)
How many dedicated trauma beds does the hospital have?	<input type="radio"/> No dedicated trauma beds <input type="radio"/> 1-10 <input type="radio"/> 11-20 <input type="radio"/> 21-30 <input type="radio"/> > 30 <input type="radio"/> Not sure (Comment: _____)

Please submit the form once you have completed all questions above.