IMPROVING INITIAL MANAGEMENT OF THE INJURED AT GHANAIAN DISTRICT AND REGIONAL HOSPITALS WITH A TRAUMA INTAKE FORM

- **Protocol and Statistical Analysis Plan**

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STUDY PROTOCOL

We propose a pragmatic randomized clinical trial to be carried out at 8 district and regional hospitals in Ghana. The intervention to be tested is the Trauma Intake Form (TIF) to be used in recording information about injured patients during their initial assessment and care and which is designed to serve as a memory prompt (built-in checklist) to decrease omission of critical steps in care and so to improve care and to improve record keeping. The unit of randomization will be hospitals and a stepped-wedge design will be used to select which hospitals will start use of the TIF at what time.

Overall Strategy and Methods.

Methods for specific aims 1 and 2.
Specific aim 1. *To determine the effectiveness of a model Trauma Intake Form (TIF) to function as a checklist for increasing the appropriate use of key performance indicators (KPIs) (e.g. airway maintenance, tests to exclude internal bleeding, examination of distal pulses, pulse oximeter placed) during care of the injured in emergency units in district and regional hospitals in Ghana, as assessed by independent observers.*
Specific aim 2. *To determine the percent of injured patients with adequate data on initial assessment before vs. after introduction of the TIF in emergency units in district and regional hospitals in Ghana.*

The effectiveness of the TIF will be assessed at the 8 study hospitals by measuring the use of KPIs during initial care of the injured before vs. after introduction of the TIF. Data on the KPIs will be obtained from *observations* by research assistants (RAs) of care provided by EHSPs and by *data from medical records*.

Data gathering. We will station 2 RAs in the emergency units of recruited hospitals to observe EHSP practices regarding initial care of the injured. To adequately capture EHSP practices across the entire work day, RAs will be stationed at each hospital's emergency unit in rotating 8-hour shifts. In the period before TIF introduction, RAs will use an observation form (derived from the TIF) to record the implementation (or lack thereof) of KPIs as they observe EHSPs assess and manage each injured patient. They will fill the form without interaction with EHSP or the patient. For any components of the assessment and management that they are unable to directly observe, they will obtain information from the patient records to complete the observation form before the patient leaves the emergency unit.

Additional data from medical records. They will complete the observation form with information from patient records (in the period before TIF introduction) and/or from the EHSP-filled TIF (during TIF use). Both before and after introduction of the TIF, RAs will review the medical records of all patients observed for additional details (as above) and for additional safety-related data, including occurrence of complications (e.g. infections) or death.

Methods for introducing the TIF. We will employ a stepped-wedge design in sequentially introducing the TIF to the 8 selected hospitals. We will consider two nearby hospitals as a group, thereby getting four groups of hospitals. First, following 14 weeks of initial observation of EHSP practices at all 8 selected hospitals, we will conduct a training workshop for EHSPs of the first randomly-selected group of hospitals on use of the TIF. Following the workshop, the EHSPs will be encouraged to begin use of the TIF at their hospitals. After another 14 weeks, we will conduct the training workshop for the next group of randomly selected hospitals, after which use of the TIF will begin at those hospitals. We will continue this sequential conduct of training workshops followed by use of TIF every 14 weeks until all 8 hospitals have been exhausted. The RAs will continue to observe EHSP practices for a further 14 weeks during which the TIF will be in use at all 8 hospitals. The total duration of observation of EHSP practices will be 70 weeks.

***Data management and quality control*.** Data will be sent from the hospital sites to the Open Data Kit cloud repository, which employs end-to-end encryption and strict user credentials to ensure data security. A data manager will review new data from each site daily for the first week of data collection, then weekly during the first month and then monthly for the entire duration of the study. Additionally, the PI will engage the coordinator at each hospital by monthly phone calls for the first 9 months, and every 2 months for the next 9 months, to discuss study progress and address any concerns.

Sample size calculations

Statistical design and power.

Specific aim 1: We expect to enroll 25 patients per site per month and so, over the 17.5 months recruitment period at the 8 sites, a total of 3,500 patients. Assuming an alpha of 0.05 and the likely baseline values (Pre-

TIF) in Table 1, we have 80% power to detect (at a minimum) the post-TIF values indicated. We consider a range of coefficients of variation. Examples of several KPIs are shown for all injured patients and for a subset of seriously injured (referred or admitted ≥24 hours) patients, for whom additional KPIs apply. Based on pilot data, we anticipate 40% (n=1,400) of patients will be seriously injured.

Table 1. Sample size considerations

	Percent of patients		
	Pre-TIF	Post-TIF	Range
For all injured patients			
Blood pressure recorded on arrival	70*	77.6	77.4-77.6
Heart rate recorded on arrival	60*	68.2	67.9-68.2
Consciousness level checked on arrival	50*	58.5	58.1-58.6
For seriously injured patients (referred out or admitted ≥24 hours)			
Chest auscultated	85**	93.4	93.3-93.5
Internal bleeding ruled out by clinical exam, US, CT, DPL, or X-Ray	27**	39.0	38.0-39.5
Distal pulses in all 4 extremities examined	54**	67.1	66.7-67.3

Post-TIF values based on mid-range coefficient of variation (COV) of 0.25. Range is for COV of 0.15 to 0.40; *Baseline values from consensus of PI and investigators from multiple Ghanaian hospitals; **Baseline values from TCC study (3). US – Ultrasonogram, CT – Computer Tomography, DPL – Diagnostic Peritoneal Lavage

Specific Aim 2: The above patient numbers, alpha and power levels, and COV range apply. We are powered to detect an increase in the documentation of important clinical data (including *all* of: time of injury, mechanism of injury, respiratory rate, heart rate, blood pressure, consciousness level, temperature, and time of disposition) by at least 5% (10% to 15%).

Statistical Analyses for Specific Aims 1 and 2

We will perform descriptive statistics (e.g. percents, means) to describe characteristics of injured patients, including age, gender, mechanism of injury and initial diagnosis. For Spec Aim 1, we will create binary variables describing whether each of the KPIs of care (as specified by the TIF) were performed. Similarly, for Spec Aim 2, we will create a binary variable describing whether adequate data (*all* of the following: time of injury, mechanism of injury, respiratory rate, heart rate, blood pressure, consciousness level, temperature, and time of disposition) have been recorded for each patient. Differences in performance of KPIs or adequate data recorded will be estimated using generalized linear mixed models, adjusted for TIF introduction and time periods as fixed effects and hospitals and time periods as random effects. We will use STATA version 17 (College Station, TX) for all analyses. Data will be analyzed on an intention-to-treat basis.