Cover Page

Official Title of the Study: P-KIDs CARE: An Intervention to Address Health Systems Delays to Care for Injured Children in Tanzania

NCT number: Not yet assigned

Date: September 18, 2023

RESEARCH STRATEGY

SIGNIFICANCE

Every day, 1900 children die from an injury, and more than 95% of these deaths occur in low-and-middle-income countries (LMICs).[18-20] Thus, the burden of pediatric injuries in LMICs is a significant public health problem that deserves urgent attention.[18, 21] Yet, there remains a lack of data on strategies to improve the care and outcomes of injured children in LMICs.[15, 22]

Scientific Premise for Aim 1: Pediatric injury morbidity and mortality can be improved with prompt arrival to definitive care. Research suggests that delaying arrival to definitive care in children is associated with higher mortality risk.[23-29] One program in two LMICs decreased the time to definitive care for injured adults and children and lowered mortality from 40% to 9%.[30] In my preliminary work at the tertiary zonal referral hospital Kilimanjaro Christian Medical Centre (KCMC) in Northern Tanzania, I found that 81% of injured children went to at least one health facility before presentation. The median time from injury to presentation was 8 hours [IQR 3.8, 39.1],[17] which is drastically longer than the optimal trauma "golden hour." [25] My qualitative data identified significant delays in reaching definitive care at KCMC from the level of first medical contact, including a complex referral system (**Fig 1**) and shortcomings in healthcare provider knowledge of when and how to refer injured patients directly to KCMC.[31-35] Formal prehospital care is not currently established in this region. Moreover, the first medical contact for injured children is a health center or district hospital, where healthcare providers do not have the capability to care for seriously ill children. Thus, there is an opportunity to streamline the healthcare system with an intervention at the first medical contact to get injured children to definitive care sooner.

Figure 1. Preliminary data from my Fogarty Fellowship showing the pathway to care for child X demonstrating the complex referral system in Northern Tanzania with location of proposed intervention. Child X's time from injury to arrival at KCMC was 26 hours.

Streamlining the healthcare system requires intervention strategies rooted in implementation science. Implementation science frameworks, such as the Consolidated Framework for Implementation Research (CFIR), are helpful to develop or adapt interventions to improve care and outcomes. CFIR has been successfully used in many LMIC settings.[36-46] A CFIR-guided mixed methods evaluation of pediatric injury care at the first medical contact can identify barriers to guide intervention development. Including the perspectives of family members and clinical stakeholders at the first medical contact will make an intervention more acceptable, feasible, and locally relevant.

Scientific Premise for Aim 2: Evidence-based interventions to improve the triage of injury patients exist, but implementation science methods are needed to adapt these to a local healthcare system. When a patient presents to medical care, they undergo a triage process that includes assessment, stabilization, and through to disposition. I propose to develop an intervention to streamline the triage process at the first medical contact. The intervention will include adapting the World Health Organization *Basic Emergency Care Course* on patient assessment and stabilization to the local context.[47] Next, the provider must judge the patient's injury severity and risk of poor outcome to decide whether or not to refer the patient to a higher level of care. To help with this decision, we will create a decision support tool by adapting measures of risk assessment, such as the *Pediatric Resuscitation and Trauma Outcome (PRESTO)* model[48] and the *Field Triage Decision Scheme*.[49] In high-income countries, the CDC and American College of Surgeons developed the *Field Triage Decision Scheme* to assist with referral decisions in injured patients.[49] The literature on this tool mainly derives from adult trauma populations in high-income countries,[50] and only a few pediatric studies exist.[50-52] While these tools have the potential to assist with referral decisions in LMICs, they require local adaptation to be relevant to the skills and resources of the providers and patient population.[52] This intervention could be a model for translation to other contexts.

Local stakeholders co-designing a health systems intervention to solve challenges in their community can demonstrate best effect. We will have local stakeholders involved in developing the intervention and adaptation of the tools. Studies have demonstrated that stakeholder co-design can provide innovative solutions to implementation to make interventions more readily adopted.[53-57]

Scientific Premise for Aim 3: A health systems intervention to improve the triage of injured children at the first medical contact is necessarily complex given the many potential barriers. Given the intervention's potential complexity, a pilot to identify potential challenges before full implementation can lead to improvements to increase the likelihood of success and lay a foundation for a future efficacy trial.

Preliminary Data: I conducted a mixed methods study at KCMC during my Fogarty Fellowship. We established a pediatric injury registry, enrolling 365 children in 12 months. The mortality rate of injured children in our cohort was high (8.2%),[16] compared to other similar studies (0.3-7.0%).[21, 58-61] We also validated the PRESTO model in our population as a risk assessment.[48] We found that 81% of injured children went to at least one health facility prior to presentation, and the median time from injury to presentation was 8 hours [IQR 3.8, 39.1].[17] We investigated the causes of delay in an exploratory qualitative study,[62] showing delays in care from the perspective of family members of injured children at KCMC. Identified delays in reaching KCMC at the first medical contact included a complex referral system (**Fig 1**) that requires families to seek care at a health center or district hospital first and then be referred stepwise to higher levels of care. This system causes logistical challenges leading to delayed care and, for severely injured children or those needing specialist care, it causes unnecessary and deadly delays. We also found that healthcare providers at these health facilities often do not know when and how to refer injured children directly to KCMC, and instead refer these patients to secondary facilities unable to address their injuries.[31-35] Such barriers could inform intervention development.

This proposal is significant because it introduces to Northern Tanzania a healthcare system intervention, P-KIDs CARE, that will streamline the triage process from patient assessment and stabilization through disposition. The goal is to decrease time to definitive care and improve the outcomes of injured children. It aligns with NIH's strategic goals by focusing on advancing emergency care research, such as trauma in LMICs, and NICHD's Strategic Plan, which lists traumatic injury in children as a scientific priority to advance public health.[63-69] It responds to calls to action by the WHO and the Lancet Global Health Commission for increased research on access to quality healthcare for the injured in LMICs.[70, 71]

INNOVATION

This proposal is innovative in four ways. **1] Creating upstream solutions for improved outcomes:** Most trauma systems research in LMICs focuses on tertiary referral hospitals. Our work showed that most delays within the health system occur between the first medical contact and definitive care. By innovatively focusing on the first medical contact, we are more likely to improve trauma outcomes across the whole health system. **2] Focusing on the patient care continuum:** Most pediatric trauma registries in LMICs are established at tertiary referral hospitals. This study establishes a data collection system from first medical contact to the referral hospital, which innovatively spans the patient continuum through the health system. **3] P-KIDs CARE optimizes resources with a process improvement:** Health systems in LMICs work with limited resources. This study uses community-based participatory research to develop a health systems intervention optimizing limited resources, a generalizable solution for other low-resource settings. **4] Capacity building to address pediatric trauma challenges.** This award will combine skills in PEM and Global Health, implementation science, intervention development, and global clinical trials to advance pediatric injury care and outcomes in Sub-Saharan Africa (SSA). The collaborations and networks developed through this award will advance the global pediatric injury research field and build my capacity as an independent researcher.

APPROACH

Study Design & Timeline: We will use the CFIR across aims to inform intervention development and ensure it is ready for implementation (**Table 3**). In Aim 1, we will use a sequential mixed methods design involving 1) quantitative pediatric injury registry data and health facility capacity assessments to identify barriers to pediatric injury care and 2) qualitative in-depth interviews (IDIs) with family members and focus group discussions (FGDs) with healthcare providers to explore barriers. Aim 2 is a participatory design involving an intervention development workshop with the interdisciplinary study team to develop P-KIDs CARE and refinement after feedback from stakeholders. Aim 3 is an intervention pilot with healthcare providers of up to 24 injured children, with an implementation-focused formative evaluation to finalize the intervention and prepare for a clinical trial.

Table 3. Timeline of research activities during the award

Activities		Y1		Y2		Y3		Y4		Y5	
Preparation	Planning/Training/IRB approvals										
Aim 1: Barriers at first medical contact	Pediatric registry establishment and Capacity assessments										
	FGDs and IDIs										
	Data analysis + Publications										
	Develop P-KIDs CARE intervention										

Aim 2: P-KIDs CARE development	Pre-implementation assessment and refinement of intervention					■					
	Data analysis + Publications					■	■				
Aim 3: P-KIDs CARE pilot	Pilot P-KIDs CARE							■	■		
	Formative Evaluation of P-KIDs CARE							■	■		
	Data analysis + Publications								■	■	
Preparation for the Future	R01 Protocol and Grant Development								■	■	■
	R01 Submission										■

Setting & Sample Size: Our study setting is the KCMC referral system. We are choosing two health facilities that are common first medical contacts for injured children: Hai District Hospital and Pasua Health Center (see **Letters of Support**). These were chosen for proximity, logistic ease, representativeness, and number of injured children referring to KCMC (**Table 4**). The two sites differ in level and distance from KCMC to improve the generalizability of the results. Our preliminary data show that 49 injured children were transferred to KCMC from these two facilities over 12 months (November 2020-October 2021). Local healthcare providers estimate that approximately 40% are transferred, meaning that an additional 74 could be enrolled that were not transferred. Based on these estimates, we could potentially evaluate the care for 123 pediatric patients annually in this health system care process, so we estimate a conservative sample size of 100.

Table 4. Preliminary data from the study facilities

Health facility	Level	Setting	Approx driving distance from KCMC (min)	Median time from injury to arrival at KCMC (min)	Injured children transferred to KCMC from Nov 2020-Oct 2021 (N)	Potential number of injured children for enrollment (N)
Hai District Hospital	Government District Hospital	Semi-urban	35	480	41	103
Pasua Health Center	Government Health Centre	Urban	20	180	8	20

Project Team: Dr. Keating will lead the interdisciplinary study team (**Fig 2**). A community-engaged panel (CEP) will include 2-3 family members of injured children that have been through this healthcare system, 2 senior advisors from the community, and 2 community health workers (CHWs) to ensure the context of recipients and systems are well understood. We will identify CEP participants in Aim 1, purposively select family members from Aim 1 participants, and identify senior advisors and CHWs in consultation with KCMC community health department contacts and health facility leadership. We will convene CEP in FGDs in Aim 2. Due to ethical concerns about the power dynamic, we will ensure that the interdisciplinary study team and CEP meet separately for project discussions.

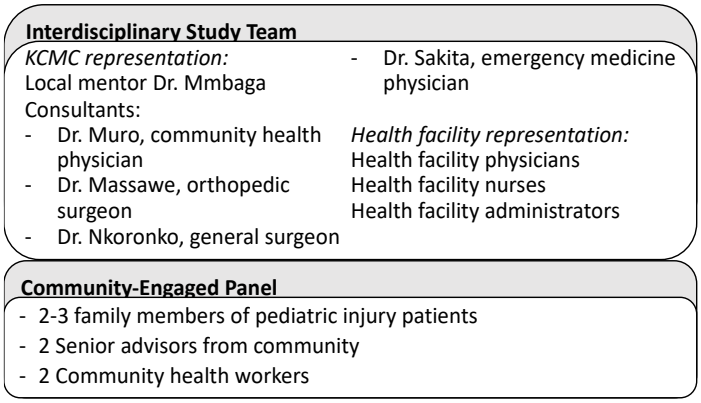

Figure 2. Project team.

Overview of CFIR: CFIR provides a structured approach to assess barriers to implementing interventions across five domains: outer setting, inner setting, characteristics of individuals, intervention characteristics, and implementation process.[72] We will apply the CFIR framework and community-based participatory research across study aims to inform the development of an intervention that considers local contexts, the actors in these contexts (i.e., family members and healthcare workers), and the processes that must occur to improve pediatric injury care, triage, and referral (**Fig 3**). In Aim 1, we will apply **outer setting**, **inner setting**, and **characteristics of individuals**. In Aim 2, we will apply **intervention characteristics pre-intervention** and **implementation process**. In Aim 3, we will apply **process** and **intervention characteristics post-implementation**.

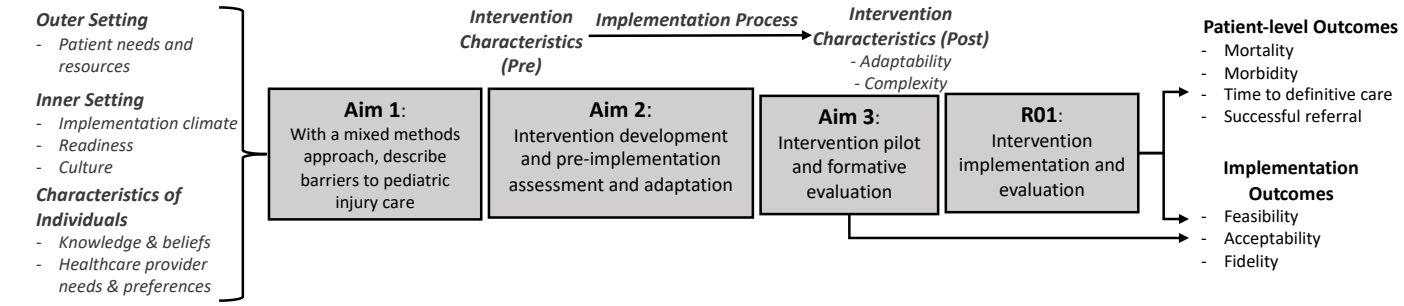

Figure 3. CFIR framework mapped to our aims with outcomes.

Specific Aim 1: With a mixed methods approach, describe the barriers to pediatric injury care at the first medical contact.

Research Design: We will conduct a sequential mixed methods study of pediatric injury care at two study facilities (**Fig 4**). We will use quantitative methods to 1) identify the patient-level data and priorities by implementing a pediatric injury registry (CFIR outer setting), and 2) identify institutional-level barriers in pediatric injury care by performing capacity assessments with the HEAT tool (CFIR inner setting). We will then use qualitative methods to explore and describe the context of the barriers identified and find potential solutions with IDIs and FGDs with key stakeholders (CFIR outer setting, inner setting, and characteristics of individuals).

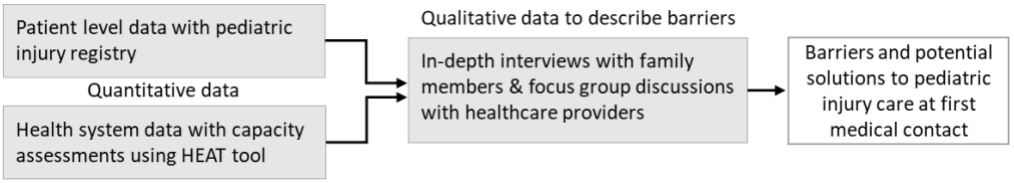

Figure 4. Sequential mixed methods study to describe barriers to pediatric injury care at the first medical contact

Quantitative Methodology: Registry Data Collection: We will implement a pediatric injury registry at the two study facilities to collect baseline data over 12 months. It will mirror the pediatric injury registry we implemented at KCMC, creating a data collection system that spans the KCMC referral system.[16] Pediatric patients who present to a study facility with WHO-defined injuries will be enrolled in the registry by trained Tanzanian research assistants (RAs). Patients and caregivers will be informed at enrollment that they will be contacted for follow-up. If a patient is referred to KCMC, their data (**Table 5**) will be continued in the KCMC pediatric injury registry. Post-discharge data will be collected from patients' caregivers by phone call at 2 weeks and 3 months. Data will be recorded on tablets in REDCap,[73] and the PI will review the quality of all entries.

Table 5. Variables Collected in Pediatric Injury Registry during Health Facility Stay and at Disposition

Data Collected – Health Facility and Disposition	
Acute Presentation	Mechanism of injury
	Mode of transportation to health center
	Patient demographics
	Timing of injury and arrival to first medical contact
Health facility-based care	Patient education
	Treatment, procedures, and complications
	Length of stay
Outcomes	Disposition – referral or no referral
	Mortality
	Morbidity: GOS-E Peds[74] and PSFS[75]
Data Collected – Post-Discharge at 2 weeks and 3 months	
Outcomes	Disposition - did patient make it to disposition location?
	Mortality
	Morbidity: GOS-E Peds and PSFS

Registry Variables: Outcomes will be recorded, including disposition, mortality, and morbidity. Two morbidity instruments will be used as they represent different ways of measuring morbidity: the Glasgow Outcome Scale-Extended Pediatrics (GOS-E Peds),[74] as an external assessment of capacity, and the Patient Specific Functional Scale (PSFS),[75] which is a personalized assessment of return to function.

Health Emergency Unit Assessment Tool (HEAT) Data Collection & Variables: Concurrently, we will perform capacity assessments of the study facilities using an adapted validated WHO HEAT.[76-79] We have experience using this tool in this region.[80] HEAT is a tool designed to evaluate the vital functions of an emergency unit for acutely injured patients. It includes availability rating questions used to assess the ability to perform vital functions in the emergency care time frame. The availability rating responses are 1-generally unavailable, 2-somewhat available, or 3-adequate. Our team will complete the assessments with input from administrators and healthcare providers. Findings will be used to identify systems gaps to target in our intervention.

Qualitative Methodology: FGDs: Two FGDs will be conducted with 10-15 healthcare providers (nurses and physicians) at each of the 2 study facilities. FGDs will assess barriers and facilitators to care and referral of injured children, including patient assessment, patient stabilization, and timely disposition, as well as key elements needed in an intervention to improve pediatric care and referral. The FGD guide will explore CFIR constructs in the inner setting, such as culture, implementation climate, and readiness for implementation, as well as characteristics of individuals, such as knowledge and beliefs and healthcare provider needs.

IDIs: We will conduct IDIs with 15 family members of injured children who were referred and made it to KCMC and 15 who were referred but did not make it to KCMC. Interview guides will aim to understand: the reasons for the choice of first medical contact, delays to care, barriers to care and referral to KCMC, and proposed solutions for a successful intervention. Interviews will explore CFIR constructs in the outer setting, such as patient needs and resources. Participants will be selected through purposive sampling to include children of

different ages, injury types, injury severity, and those who are and are not referred to KCMC. Participants will undergo a consent process approved by the Tanzanian and University of Utah ethics committees before joining the FGD or IDI. Participants will be >18 years of age and fluent in Kiswahili. Face-to-face FGDs and IDIs will be conducted in Kiswahili by our research team, with previous experience conducting interviews in Tanzania.[17] Interviews will be recorded, transcribed, and translated into English for analysis.

Analytical Approach: Data from the quantitative and qualitative analyses will be triangulated to describe barriers to pediatric injury care and referral at the study facilities and to identify potential solutions.

Quantitative Analysis: Based on Dr. Keating's Fogarty preliminary data, we anticipate a sample size of 100 patients in the pediatric injury registry in the 12-month enrollment period (see **Setting & Sample Size**). Pediatric injury registry data will identify priorities for intervention development by describing the differences between patients referred to KCMC and those not referred. The primary outcome will be in-hospital mortality. Secondary outcomes will include time from first medical contact to definitive care at KCMC, disposition (discharge to home, referral to KCMC, referral to other health facilities, or admission), and morbidity. We will summarize data using descriptive statistics for all patients and assess differences by sex, age, injury type, sociodemographic features, mechanism of injury, and injury severity. We will assess differences in the aforementioned descriptive statistics by disposition using analysis of variance (ANOVA) or Chi-squared tests in SAS (Version 9.4). The registry will collect baseline data we will compare with data collected after intervention implementation (Aim 3). We will analyze data with descriptive analysis using SAS (Version 9.4) for the HEAT results. For the availability ratings of less than 3 (less than adequate), we will identify reasons for the rating.

Qualitative Analysis: In qualitative methods, a sufficient sample size relies on saturation, or the point at which no additional themes are identified with subsequent data points.[81] Work with IDI data found that thematic saturation was present after twelve interviews,[82, 83] which is below our current estimated sample sizes for our IDIs and FGDs. Our data analysis will be iterative to assess for thematic saturation, with additional data collection added as needed. Thematic analysis will be conducted using Dedoose. De-identified data will be coded through a team-based approach informed by applied thematic analysis.[84] The CFIR framework will inform an a-priori, deductive code list, and we will identify emerging, inductive themes under each construct. All transcripts will be coded by two independent coders, and discrepancies will be resolved by consensus. Coded data will be retrieved and synthesized in analytic memos, with robust comparisons of themes that emerge across the groups. Our team has used a similar approach in prior qualitative studies in Tanzania.[17]

Potential Challenges & Alternative Approaches: One potential limitation is that our estimates for enrollment into the pediatric injury registry are potentially optimistic. To address this, we have built-in flexibility to increase our enrollment period for Aim 1 from 12 to 15 months if enrollment is insufficient. If this does not adequately increase enrollment, we have identified a third facility, Same District Hospital, where we can collect data (see **Letter of Support**). Another possible limitation is loss to follow-up of registry patients. We will collect all patient phone numbers to prevent this and emphasize follow-up importance. Using identical protocols in our preliminary study, we achieved a follow-up rate of 97.5%. A further challenge is potential difficulties with data quality, given that we will have 24-hour enrollment in a registry with limited personnel performing quantitative and qualitative work simultaneously. To combat this challenge, we will ensure each study facility has a RA who will work with local facility staff to ensure they are alerted when a pediatric injured patient presents for care so that no patients are missed. However, if we cannot enroll simultaneously at both sites with the proposed team, we will have time to collect data at each health facility sequentially. Another potential limitation is being unable to recruit healthcare providers or family members for FGDs or IDIs. We do not anticipate this being a major barrier since we have performed a similar methodology in our preliminary studies.[17] However, we can collect data at our third facility if necessary. An additional possible challenge is the need for Aim 1 before completion of Aim 2. We developed our aims to be informative rather than interdependent so that we can accurately include findings of Aim 1, if pertinent, in informing system plan changes in Aim 2 intervention development.

Expected Outcomes: Includes 3 manuscripts: 1) differences between injured children who are referred to KCMC and those who are not; 2) systems-level barriers in pediatric injury care assessed by WHO HEAT capacity assessments; and 3) barriers and facilitators to pediatric injury care and transfer at health facilities from healthcare provider and family member perspectives.

Specific Aim 2: Iteratively develop the P-KIDs CARE intervention using a nominal group technique and conduct a pre-implementation assessment and refinement.

Research Design: Guided by CFIR evaluation strategies,[85] we will synthesize the barriers and facilitators identified from our preliminary data and Aim 1 and identify potential strategies to address them. This information will form the foundation of a 2-day intervention development workshop where the interdisciplinary study team (see **Project Team**) will use a nominal group technique (NGT) to refine the identified strategies for local context and review the existing tools that could be adapted for the local context. The workshop outcome will be a template for the P-KIDs CARE intervention. The workshop will be NGT-guided to ensure that consensus is reached on the appropriate intervention design to solve the barriers. After the workshop, we will perform a pre-implementation assessment and refinement of the intervention by convening two FGDs using a modified NGT with 1) healthcare providers and 2) the CEP (**Fig 5**). The pre-implementation assessment aims to obtain feedback on the intervention to enhance its likelihood of success and ensure it is locally relevant and perceived as acceptable and feasible.

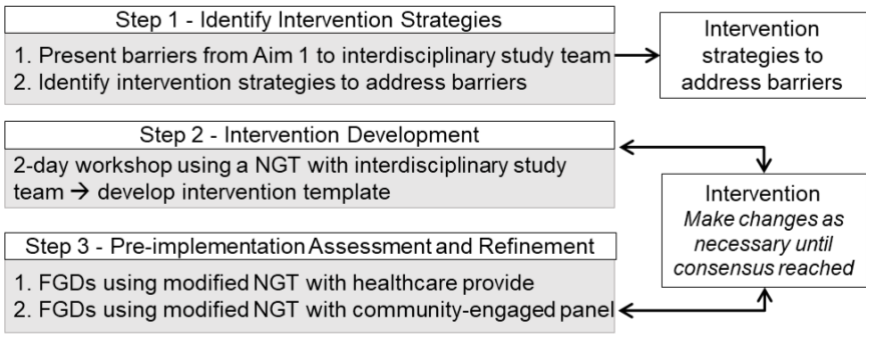

Figure 5. Development process for the P-KIDs CARE intervention

Step 1 - Identify Intervention Strategies: We will convene the study team to discuss the barriers and facilitators identified from preliminary data and Aim 1 and select intervention strategies to address them.

Intervention Framework: Based on our prior research, we anticipate that the intervention will streamline the triage process (**Fig 6**). P-KIDs CARE will include two components: 1) the WHO *Basic Emergency Care Course*[47] for training on patient assessment and stabilization, and 2) a decision support tool that integrates adaptation of two evidence-based tools: a) the *PRESTO* model for mortality risk assessment[21, 48] and b) the *Field Triage Decision Scheme*.[49] The decision support tool will be online and adapted for use in Northern Tanzania, with attention to contextual and cultural factors.

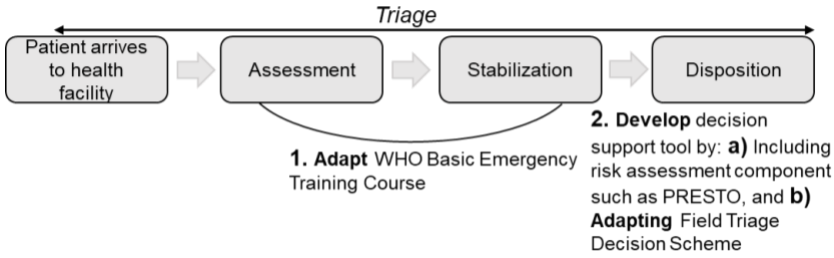

Figure 6. Proposed P-KIDs CARE Intervention with intervention components

Step 2 - Intervention Development: In a 2-day workshop using an NGT, we will develop the locally-relevant intervention by adapting or creating the components (**Fig 7**). We selected the NGT process as it is a structured method for group brainstorming that encourages contributions and facilitates quick agreement on the relative importance of barriers. First, the intervention components will be introduced and reviewed on the morning of the first day. Then, we will convene small groups to answer key questions: 1) *What is the actual degree of less-than-best practice of the current care of injured children?*, 2) *What about the existing tools could work in Tanzania?*, 3) *What about the existing tools will not work in Tanzania?*, 4) *What are the necessary adaptations for Tanzania?*, and 5) *What are the organizational conditions necessary for it to work?* The large group will come together and an expert facilitator (PI) will lead a guided discussion of answers to the key questions regarding each core intervention component. At the end of the first day, preliminary voting will occur on the appropriateness of each intervention component. On the second day, the large group will discuss the preliminary voting results, and final voting with determination of consensus will occur. Consensus will be defined as 75% agreement that the intervention design is appropriate to solve the barriers.

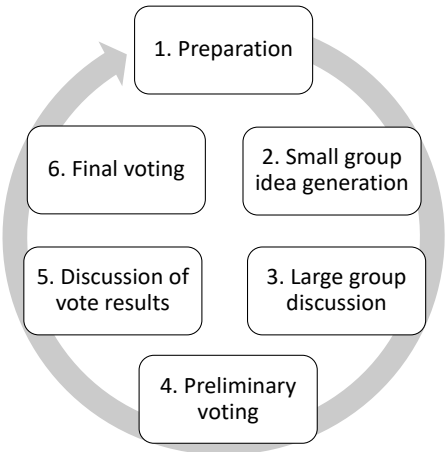

Figure 7. Nominal group technique used in Steps 2 and 3 for each intervention component.

Step 3 - Pre-implementation Assessment & Refinement: Once the intervention is developed, we will conduct a pre-implementation assessment and refinement to obtain preliminary feedback to enhance its likelihood of success and ensure it is perceived as acceptable and feasible. This will be done by convening FGDs using a modified NGT with only steps 1, 3, and 6 (**Fig 7**) with 2 groups: 1) healthcare providers at the study facilities who are not interdisciplinary study team members but could have participated in Aim 1, and 2) the CEP (see **Project Team**). During the FGD, a facilitator (PI) will present each intervention component

developed during the workshop to the group. The facilitator will ask questions on the potential barriers and facilitators to the implementation of the intervention and the perceived acceptability and feasibility of the intervention. Based on feedback, the interdisciplinary study team will refine the intervention as necessary until consensus is reached. Consensus will be defined as a 75% agreement that this is the final intervention. After finalization, the intervention will be translated into Kiswahili.

Potential Challenges & Alternative Approaches: There are three potential limitations. First, if Aim 1 identifies different barriers than we have anticipated, we will change strategies as appropriate and be flexible and responsive to changes. Second, the inability to recruit healthcare providers or family members for the FGDs. We have recruited healthcare providers for FGDs in our preliminary study[17] and do not anticipate this being a problem. If it is, we could recruit from our third study facility, Same District Hospital. Finally, the inability to reach a consensus in the NGT. We will continue to discuss and edit the intervention until we reach 75% consensus. If there is a disagreement between groups, we will defer to the healthcare providers as these individuals will use the intervention.

Expected Outcomes: Includes the P-KIDs CARE intervention and 2 manuscripts: 1) intervention strategies to address barriers and improve pediatric care and referral, and 2) P-KIDs CARE development process.

Specific Aim 3: Pilot P-KIDs CARE and perform an implementation-focused formative evaluation .

Research Design: We will pilot P-KIDs CARE with healthcare providers at the study facilities over 12 months to 1) improve and finalize the intervention and 2) prepare for a clinical trial (**Fig 8**). We will perform a formative evaluation with exit interviews with healthcare providers and family members of injured children and revise until our intervention is final.

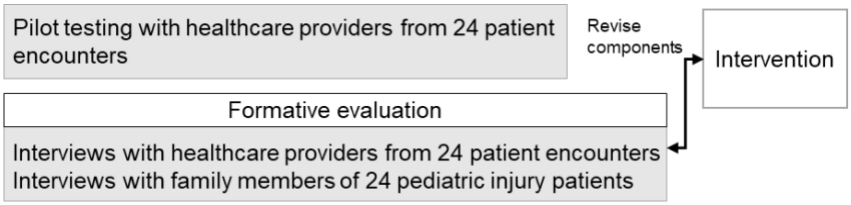

Figure 8. Pilot testing and formative evaluation of P-KIDs CARE

Early Implementation/Training: The first 3 months of implementation, the PI will train healthcare providers at the study facilities on P-KIDs CARE, including pediatric assessment and stabilization using the WHO *Basic Emergency Care Course* and use of the decision support tool. Healthcare providers will receive *Basic Emergency Care Workbooks*.[47] All injured children will be enrolled in the registry developed in Aim 1.

Ongoing Implementation: From months 3-12, we will implement the decision support tool component of the intervention. We will encourage all healthcare providers at the study facilities to use the decision support tool when caring for a pediatric injury patient over this time.

From months 3-12, we will evaluate P-KIDs CARE with an *implementation-focused formative evaluation*. We will purposively select 12 injured children who are seen at the study facilities and referred to KCMC for definitive care and 12 injured children who are seen and not referred to KCMC for definitive care. We will perform the formative evaluation with the healthcare provider who cared for each of these 24 patients. If one provider sees more than one patient, they will participate in multiple interviews. The RA at each study facility will alert the PI when an injured child is seen and check the decision support tool online for each patient to record if it was used. If it was not used, we will follow up with the healthcare provider to see why it was not used. If it was used, the RA would contact the healthcare provider of that patient to have them complete a survey and exit interview. The interview guide will include questions on healthcare provider experience with the intervention, components of the intervention that were or were not implemented, and ways to improve the intervention. The RA will contact the family member of each of the 24 pediatric injury patients and consent them to complete an IDI. The interview guide will include questions on family member experience with the intervention and satisfaction with the disposition decision. Data collection and analysis will be similar to Aim 1. During this formative evaluation period, we will iteratively identify challenges and refine components of the intervention to move progressively toward the best intervention.

Outcomes & Sample Size: We anticipate that 100 injured children will be seen at the 2 study facilities to pilot the intervention, and at least 24 will undergo the entire intervention, with 12 referred to KCMC and 12 not referred. Based on preliminary estimates from local healthcare providers, over 100 patients are seen at the study facilities in a 12-month period and 40% are transferred to KCMC. Our possible enrollment of 24 patients is a conservative estimate and should be easily attainable.

Sample Size: We anticipate following 24 patients through their entire health system journey will be sufficient to provide qualitative saturation in barriers during the transfer process for those sent to KCMC and satisfaction with the disposition decision for the entire cohort. We anticipate enrolling 81% (100 out of 123) of the eligible injured children during the pilot study; the 95% exact interval for the enrollment rate is (72.9%, 87.5%) of eligible patients. Thus, with 95% confidence the expected number of enrollments in a similarly designed trial with 600 eligible patients would be between 440 and 527. We will use enrollment and outcomes estimates from this pilot to adequately power a future clinical trial of our intervention.

Implementation Outcomes: With 24 patients, we will collect implementation outcomes (feasibility, acceptability, and fidelity) that will help us to refine the intervention (**Table 6**).

Potential Trial Outcomes: With 100 patients we will collect patient-level, potential trial outcomes to prepare for a fully powered clinical trial (**Table 6**). We are evaluating four potential trial outcomes to determine the most feasible primary outcome for our trial. While not powered to determine an effect size, we hope that preliminary analysis will suggest a signal of difference between groups in the pre- and post-intervention periods.[86, 87]

Table 6. Outcomes for Implementation and Planned Trial

Implementation outcomes		How we will measure
Feasibility		- Exit interview with healthcare providers after treatment of eligible patient. - Asking providers how feasible the intervention was when piloting it on injured children.
Acceptability		- Surveys to healthcare providers that pilot the intervention to assess acceptability. - In exit interviews, asking their perception of how it impacted patient triage and referral. - Interviews with family members to assess satisfaction with intervention and disposition decision.
Fidelity		- By assessing protocol deviations via decision support tool forms online to determine what components of the intervention were completed for each patient.
Potential Trial Outcomes		
Primary	*Mortality*	Pediatric injury registry
Secondary	*Time to KCMC*	Pediatric injury registry
	Successful referral	
	Morbidity	

Analytical Approach: We will conduct a quantitative analysis of the pediatric injury registry similar to Aim 1 and compare data to determine preliminary impact. We will analyze qualitative data using Dedoose software and quantitative survey data using SAS (Version 9.4). We anticipate recruiting up to 10 healthcare providers that used the intervention with up to 24 patients. The data generated from this pilot and evaluation will finalize P-KIDs CARE for future evaluation with a clinical trial.

Potential Challenges & Alternative Approaches: It is possible that we may have challenges motivating healthcare providers to use the intervention, especially if time-consuming. We will combat this by including healthcare providers in the development of P-KIDs CARE, so that it will be perceived as acceptable at origin. An additional potential limitation is if we do not enroll 24 injured children to perform the formative evaluation. However, we do not anticipate this being a problem given preliminary data that shows that over a 12 month period the 2 study facilities transferred more than 24 injured children to KCMC (Table 4). It is likely that a sample size of 24 for the formative evaluation will not give us a great assessment of patient-level outcomes. Thus, we will focus on implementation outcomes that will enable us to refine and finalize the intervention.

Expected Outcomes: Includes R01 grant application, *P-KIDs CARE Evaluation through a Clinical Trial in Northern Tanzania*, and 2 manuscripts: 1) preliminary impact of P-KIDs CARE measured with feasibility, acceptability, fidelity, and intervention effectiveness, and 2) process of piloting and formatively evaluating P-KIDs CARE.

Rigor & Reproducibility: We are using a rigorous design with a solid scientific premise. We will use validated tools, including the WHO *Basic Emergency Care Course*,[47] the *PRESTO* model that has been validated in our population,[21, 48] and the *Field Triage Decision Scheme*.[49] We will use framework guided processes, translated and validated tools, and will report all trial methods. To ensure rigorous data, intensive quality assurance processes and audits are planned. We have considered potential sources of biologic variability in our study including sex and age. In our preliminary study, 65.8% of our pediatric injury population was male.[48] We will enroll all injured children <18 years that present to the two study facilities regardless of sex, and analyze data by sex to address sex differences and by age to address any potential differences.

FUTURE DIRECTIONS:

P-KIDs CARE has the potential to improve care of injured children in SSA and reduce time from first medical contact to definitive care. In year 5, we will submit an R01 proposal to evaluate P-KIDs CARE in additional

health centers in Northern Tanzania in a clinical trial. By focusing on reducing time to definitive care, P-KIDs CARE will be a crucial first step towards improving care and outcomes of injured children in Northern Tanzania. We will seek additional grant support to address other aspects along the pediatric injury care continuum such as primary injury prevention, family member care-seeking, transportation barriers, communication between health facilities, and family member communication barriers. This grant is the first step in building a comprehensive research program focused on improving morbidity and mortality in injured children in Northern Tanzania.