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TITLE: Far-Forward, Fluid First, (4F) Enteral Resuscitation (EnteroResus) for Moderate-Size Burns (20%-40% TBSA): A Hybrid Type I Effectiveness-Implementation Study

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14. ABSTRACT Short- and long-term outcomes of soldiers and civilians with burn injuries are greatly impacted by the care provided in the first hours and days after injury, particularly fluid resuscitation.(1-3)Profound inflammation-induced capillary leak syndrome (CLS) is a hallmark of moderate and severe burn injury.(4) If un- or under-treated, CLS results in dehydration, hypovolemic shock, wound progression, organ failure and death. Patients with burn injuries ≥10-20% total body surface area (TBSA) are typically resuscitated with intravenous (IV) fluids to prevent these sequelae. However, in austere settings, patients often present to medics, health posts, and first-level hospitals that do not have the resources to provide goal-directed IV fluid resuscitation.(5) To address the complexity of goal-directed IV fluid resuscitation while acknowledging resource constraints in LMICs, burn care experts have recommended implementation of enteral resuscitation-based protocols.(6-11) burn injured soldiers and civilians around the world. We plan to perform a hybrid effectiveness-implementation cluster-randomized controlled trial of enteral resuscitation to IV resuscitation in Ghana. The first and second years has been focused on developing materials (e.g., study protocol revisions, resuscitation protocols, documentation, educational/training materials, DSMB documents), navigating the labyrinth of US and Ghanaian regulatory bodies with conflicting priorities/perspectives (e.g., eligibility of children, safety of enteral resuscitation, role of IV fluids in the intervention clusters), establishing agreements and infrastructure to facilitate the project (e.g., sub-contracts, financial sharing platform), and bringing co-investigators and sites to speed on research operations. Within the last month and after significant back and forth we have received approvals from the major IRBs in Ghana (i.e., Kwame Nkrumah University of Science and Technology, Ghana Health Service representing all district and regional hospitals, and two major burn centers – Tamale Teaching Hospital and 37 Military Hospital). We have UW IRB approval and once OHRO gives final approval we can begin. In the meantime, we are planning supply procurement, training and onboarding for hospitals, and hiring staff. We are very much looking forward to enrolling this year.					
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1. INTRODUCTION:

Burn-injured warfighters, like most people injured in the world, often lack access to timely resuscitation due to logistical and security challenges, operational stresses, limited burn care expertise, and low-resources. This is particularly the case in prolonged field care scenarios, multiple casualty incidents, shipboard incidents, in low- and middle-income countries (where 90% of the world's burn injuries occur), and even in rural America. When burn-injured patients do not receive timely and appropriate resuscitation, they are markedly more likely to experience acute kidney injury (renal failure), wound progression, sepsis and multiple organ dysfunction, and death. Therefore, there is an urgent need for simple, operationally advantageous, safe, and effective resuscitation strategy tailored for low-resource settings.

One such proposed strategy is enteral resuscitation, or the administration of oral rehydration solution via drinking or an nasogastric tube. Although remote case series and small controlled studies have demonstrated the safety and efficacy of enteral resuscitation for burn injuries, there has not been a large effectiveness trial or study of its implementation to inform guidelines. Therefore, we aim to: i) compare the effectiveness of an enteral resuscitation bundle (4F EnteroResus) to enhanced standard of care (IV resuscitation) for patients with moderate burns (10-60% TBSA) at first-level (district) hospitals in Ghana; and ii) identify the challenges and facilitators to enteral and IV resuscitation protocol implementation, compliance and sustainability.

2. KEYWORDS:

Burn injury, low-resource settings, resuscitation, enteral resuscitation, oral rehydration solution

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. Establish a research network that includes first-level hospitals within the catchment of major burn centers (i.e., referral hospitals) in Ghana to participate in the study.
 - a. Coordinate central and local protocol submissions, approvals and agreements and develop SOPs/training materials to harmonize care across participating centers.
 - b. Organize a network of first-level and referral hospitals that commonly care for burn injuries to maximize enrollment.
 - c. Establish local advisory groups and DSMB to inform protocol, monitor the study, and facilitate dissemination.
 - d. Prepare processes and sites for enrollment, data collection, and data transfer.
2. Randomize participating first-level hospitals to provide 'Far-Forward, Fluid First,' (4F) Enteral Resuscitation (EnteroResus) bundle vs enhanced standard of care bundle (i.e., organized IV resuscitation) for patients with moderate burn injuries (10-60% TBSA).
 - a. Compare the 4F EnteroResus with enhanced standard of care with regard to successful resuscitations, acute kidney injuries, shock, electrolyte disturbances and over-resuscitations; and
 - b. Compare the 4F EnteroResus with enhanced standard of care with regard to gastrointestinal intolerance, aspiration, pneumonia, sepsis and death.

What was accomplished under these goals?

We have built a strong community of collaborators ready to participate in the trial, including Ghanaians with experience in cluster-randomized and implementation trials, burn care experts from the largest four burn care facilities in Ghana, and clinical leads at first-level hospitals identified by the burn care experts as being district hospitals with high incidence of burn injury referrals. We met bi-weekly in the first few months of the year and monthly since to refine the protocol consistent with the capabilities of each center and the burn care standards in Ghana. Additionally, we have organized a DSMB and a burn advisory group to help us navigate the complexities and asks of the regulatory agencies.

The latter has been quite complex and has led to significant delays. There is no central IRB in Ghana, therefore, we have had to submit our application, respond to reviews, and resubmit our application to: Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics, Ghana Health Service Ethical Review Board, and each of the participating referral hospitals (namely Komfo Anokye Teaching Hospital, Tamale Teaching Hospital, 37 Military Hospital, Eastern Regional Hospital, Cape Coast Hospital). During this process, we were confronted with several unexpected challenges. The first was the need to include children, who were deemed by the IRBs as key stakeholders in burn injury and the likely key beneficiaries of the intervention should it be effective. This required major revisions and resubmissions that led to additional questions regarding safety, monitoring, and oversight. These additional changes then led us to change our approach from a parallel submission approach to each of the Ghanaian IRBs to a serial approach to avoid complex revisions while other regulatory agencies are reviewing a now outdated draft. This has come at the expense of significant delay in our anticipated enrollment but will ensure that we meet all regulatory requirements and build trust in the research ethics community in Ghana. The second unexpected challenge was the requirement to have the protocol reviewed by the Ghanaian FDA. This was requested by the Ghana Health Service and Komfo Anokye Teaching Hospital IRB because we are using WHO ORS, which is considered a drug. The application for this has been completed and is being submitted this coming week. The third unexpected challenge was the mandate for us to purchase an insurance plan for the liability of the investigators and damages and care for study patients. While this is somewhat common for trials in many high-income countries, this is not common in Ghana. After consultation with multiple insurance companies and estimating rates of adverse events based on prior observational studies and burn care generally in Ghana with the help of our advisory group, we were able to identify company and create a plan/premium that were agreeable by all parties. The insurance coverage was approved by Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics. Another challenge encountered was the ask by two review bodies for building capacity for remote enrollment. This was not part of our design initially, but we created a plan and the documents required to do remote enrollment in a hub-spoke model to accommodate the multiple languages of patients across the country/sites. These and other regulatory challenges led us to hiring an international multicenter trial and regulatory expert from the Institute for Translational Health Sciences. She and her team have and continue to help us reduce delays as we navigate the web of ethical and regulatory approvals. Currently, Tamale Teaching Hospital and 37 Military Hospital have given approvals in addition to KNUST, GHS, and University of Washington. Komfo Anokye Teaching Hospital and Cape Coast Hospital have not given approvals in large part for political complexities beyond our control. We have elected to begin with these two hubs

while we continue to work toward bringing these other hubs online in time.

Another more complex challenge that we encountered was the development and operationalization of the sub-contract between University of Washington and Kwame Nkrumah University of Science and Technology. The sub-contract was primarily required to pay the IRB submission fees ahead of any other research or personnel expenses. While our intuitions have worked together for years, there has not been a formal sub-contract of this size. It took several months of work involving our respective accounting and grants offices but was completed. We were able to process some IRB fees through bringing money with me during field visits. However, larger monies were required to be processed through the sub-contract system (e.g., fee for the Ghanaian FDA submission). The shared invoicing platform between our institutions has been created and the money should be available for invoicing and payment starting the first week of September.

Despite the delays, we have received approvals from Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics, Ghana Health Service (all district and regional hospitals in Ghana) and the University of Washington IRB. We have undergone preliminary review by ORHO and addressed concerns. With the recent approval from the GHS and two main hubs we will work with ORHO to gain approval to begin the study.

Additionally, the delays have given us time to develop research documentation tools, SOPs, communication tools, and REDCap database. Further, one of the reviews from Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics was related to the poor palatability of ORS, which might prevent its successful use for patients cared for in the intervention arm. In addition to sharing data from a US Military study on this exact topic, we were able to complete a single-blind, age-stratified study of oral rehydration drinks' palatability in comparison to one another (and to the findings from the US Military study) to identify a formulation that would be most acceptable for use in Ghana as well as by others in low-resource settings. This rapid study was appreciated by the review board and has since been [published](#). This work has gained lots of excited from the burn community and has sparked a single center feasibility study in Nepal supported by the NIH, which informed the design of the current study/IRB applications, and other summative work for Surgical Clinics and World Health Organization.

We have visited and held mock resuscitations and enrollments with participating referral hospital partners and staff. Additionally, we have been able to use lessons learned from a smaller pilot trial of enteral resuscitation for burn injuries in Nepal to identify and raise potential problems with our protocol with our Ghanaian partners and adapt the protocol for success. During these visits and with consultation of the Ghana Health Services Deputy Director General, we have identified the target first-level hospitals for randomization once we have full approval from ORHO.

What opportunities for training and professional development has the project provided?

Training has been focused on:

1. Education of research partners regarding burn resuscitation standards,

enteral resuscitation, and study protocols.

2. Research ethics, standards and integrity using the CITI training modules for new researchers involved in the study (all but Ghanaian co-investigator, Dr. Adam Gyedu).
3. Global health research and leadership offered by University of Washington Department of Global Health for affiliated researchers.
4. Harborview Injury Prevention and Research Center Works in Progress meetings to highlight research protocol development, data analysis and interpretation, dissemination strategies.
5. Study leaders (Dr. Adam Gyedu and myself) regarding regulatory complexities by way of UW Institute of Translational Health Sciences consultations.
6. Building research capacity within our staff (Hilary Baidoo, Dorcas Addo, Mohammed Abdullah) with completion of the palatability study.

How were the results disseminated to communities of interest?

While we have been keeping our research partners and regulatory bodies up to date, there we have not yet been able to enroll participants and there are no results to disseminate. However, we have formed our burn advisory group in Ghana comprised of burn care providers, pediatrician and pediatric surgeon, experienced researchers, local professional society leaders. These individuals will help us with a dissemination strategy when we are ready to develop one ahead of enrollment.

We did disseminate the results of the palatability study to this group and the Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics. Additionally, this has been published.

We have shared our experience and current data regarding enteral resuscitation from our pilot project in Nepal and the palatability study at conferences (e.g., 2022 and 2023 American Burn Association, 2022 and 2023 International Society for Burn Injuries, 2022 Schilling Lecture Series, 2022 Military Health Research Symposium, 2022 African Federation of Emergency Medicine in Ghana). We will use these and other platforms for additional results dissemination once we are able to begin enrollment.

What do you plan to do during the next reporting period to accomplish the goals?

We now have a clear path to enrollment given the above approvals. Additionally, we have gained a lot of insight into trial performance and regulatory management due to: i) pre-consultations with each body that has provided us with very useful feedback that has shaped all of our submissions; ii) multiple IRB revisions that has yielded a very strong and detailed protocol; iii) additional trial infrastructure including grant management services, insurance for study participants, and hub-spoke collaborations; iv) and understanding of the

labyrinth of reporting required. We are wholly focused in the near-term on approval from ORHO so that we can begin onboarding sites and enrolling participants.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

What was the impact on other disciplines? What was the impact on technology transfer? What was the impact on society beyond science and technology?

We are yet to generate findings that will make an impact, although we anticipate the potential for enteral resuscitation significantly augment burn care in low-resource settings and be more easily implemented as a direct result of the protocol, findings, and lessons learned from this project.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

The challenges and changes encountered are detailed above and listed below:

1. Timeline as a result of the regulatory delays we are navigating. We did not anticipate the complexity of the regulatory environment in Ghana.
 - a. In response, we hired regulatory expertise from Institute of Translational Health Sciences to assist us with more rapidly achieving approvals and initiating enrollment.
2. Inclusion of children
 - a. Our initial plan was to focus on adults. However, Ghanaian IRBs requested that we include children since they would be the primary beneficiaries of such an intervention in Ghana (large proportion of people who are burn injured and do not have IV access). We have gotten this approved by University of Washington and discussed this with OHRO ahead of final submission. Now that we have received necessary approvals in Ghana we will seek final approval from OHRO
 - b. We have updated our protocols and documentation to reflect differences in pediatric and adult burn care and documentation.
3. Evaluation of palatability/acceptability of oral rehydration drinks
 - a. The Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics was concerned about the acceptability of plain ORS as a resuscitation drink.
 - b. We designed, had approved, completed, and published a single-blind study of the palatability of different oral rehydration drinks to ensure that we used the most acceptable formulation for Ghanaians. The findings were consistent from those generated at the Institute of Surgical Research among US Military personnel, which suggests generalizability in the use of citrus flavored ORS formulations.
4. Creating a process for remote enrollment
 - a. We initially expected that this cluster-randomized study would be an Exception to Informed Consent (EFIC) trial. However, this mechanism is

not available in Ghana. Therefore, we created a plan for site-specific enrollment by trained staff at each first-level hospital.

- b. Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics also asked that we change from a site-specific enrollment to centralized remote enrollment to ensure consistency and integrity in the enrollment process.
 - c. We created a process for this, which has been conditionally approved by Kwame Nkrumah University of Science and Technology Committee for Human Research and Publication Ethics. We will rehearse and conduct many mock enrollments to work out all kinks in the process once all approvals are achieved.
5. Expanding eligibility to patients with full-thickness injuries $\geq 10\%$ and total injury size $< 60\%$ total body surface area (TBSA)
- a. The study was originally designed to include only individuals with 20-40% TBSA burn injuries. However, since patients with 10% full-thickness (at least 3rd degree) injuries, particularly children, usually require some resuscitation and prior studies have shown that enteral resuscitation can be performed safely for patients with up to 60% TBSA injuries, we expanded our inclusion criteria on the recommendation of our Ghanaian burn advisory group.
 - b. In addition to providing more generalizable results, this will also increase the rate of enrollment given that a larger number of people will be eligible.

Actual or anticipated problems or delays and actions or plans to resolve them

Actual and anticipated problems and delays have been outlined above. We have returned to biweekly meetings and ad hoc communication via WhatsApp now that we have a path to regulatory approval to facilitate preparations for site onboarding, staff training and enrollment practice ahead of full approval and actual enrollment. We have hired a regulatory consultant to help us more deftly navigate the complex regulatory environment in Ghana and between the US and Ghana and HRPO specifically. We have established working relationships between this trial group in Ghana and our project in Nepal to help share lessons learned with novice trialists and enteral resuscitation specifically. We anticipate that these working relationships and the ideas generated among them will assist this Ghanaian project in avoiding some of the clinical pitfalls we have encountered in Nepal.

Changes that had a significant impact on expenditures

We have done all possible to reduce/limit/restrict expenditures until enrollment. We have all agreed that we will do the work necessary to achieve approvals without salary in order to save the money available for research expenses, our added time during enrollment, and potentially a no-cost extension should we need one. Therefore, we have spent marked less this year than predicted, and will continue to do so until approvals have been achieved.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Human subjects

Significant changes in use or care of human subjects

We were asked by our Ghanaian burn advisory group and Kwame Nkrumah University of

Science and Technology Committee for Human Research and Publication Ethics to include children in the protocol. We made adjustments to the protocol and have had these reviewed by a pre-consultation with HRPO to ensure that we meet all US federal regulations regarding the inclusion of children (including direct benefit). Resubmissions to KNUST, GHS, and UW have been successful. We will now submit to OHRO for final approval ahead of enrollment.

Significant changes in use or care of vertebrate animals

None

Significant changes in use of biohazards and/or select agents

None

6. PRODUCTS:

- **Publications, conference papers, and presentations.**

The following are related to this work and build expertise and opportunities for dissemination of the planned trial, but were not funded by this contract directly:

1. 2022 American Burn Association (Presentation) – Development and implementation of enteral resuscitation in a low-resource setting.
2. 2022 International Society for Burn Injuries (Presentation) – Results from an implementation trial of enteral resuscitation in Nepal,
3. 2022 Schilling Lecture Series (Presentation) – Resuscitation in Austere Settings: the role and study of enteral resuscitation,
4. 2022 Military Health Research Symposium (Presentation) - Pilot randomized, controlled trial of enteral resuscitation for major burn injuries in Nepal,
5. 2022 African Federation of Emergency Medicine (Presentation) – State of the art burn resuscitation and care.
6. 2023 American Burn Association (Presentation) – Feasibility trial results of enteral resuscitation for burn injuries in Nepal (informing larger trial design)
7. 2024 American Burn Association (Presentation) – Implementation of an enteral resuscitation trial for burn injuries in Nepal (informing larger trial design)

- **Journal publications (these are related to this work, not funded by this work; all of these inform the design of or add to the dissemination to the current grant, however.)**

Gyedu A, Mehta K, Baidoo H, Addo D, Abdullah M, Mesic A, Samosorn A, Cancio LC, Nakarmi K, Stewart BT. Preferences for oral rehydration drinks among healthy individuals in Ghana: A single-blind, cross-sectional survey to inform implementation of an enterally based resuscitation protocol for burn injury. *Burns*. 2022 May 20:S0305-4179(22)00124-3. doi: 10.1016/j.burns.2022.05.016. Epub ahead of print. PMID: 35715342.

Stewart BT, Nsafu K, Allorto N, Man Rai S. Burn Care in Low-Resource and Austere

Settings. Surg Clin North Am. 2023 Jun;103(3):551-563

Gyedu A, Stewart BT, Nakua E, Donkor P. A standardized trauma intake form with clinical decision support prompts improves care and reduces mortality for seriously injured patients in non-tertiary hospitals in Ghana: stepped-wedge cluster randomized trial. Br J Surg. 2023 Aug 24:znad253.

- **Books or other non-periodical, one-time publications.**
- **Other publications, conference papers and presentations.**
- **Website(s) or other Internet site(s).**
- **Technologies or techniques.**

Enteral resuscitation protocol (this has not been published or presented before). We are going to turn this into a technique manuscript for submission as well.

- **Inventions, patent applications, and/or licenses.**
- **Other Products.**

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS What individuals have worked on the project?

Name: Barclay Stewart

Project Role: PI

Nearest person month worked: 2

Contributions (no change): Overall strategy and coordination, regulatory decision-making, drafting and final reviews of materials ahead of submission, meetings with all involved, meetings with regulatory bodies

Name: Charles Mock

Project Role: Co-Investigator

Nearest person month worked: .5

Contributions (no change): Mentorship for Drs Stewart and Gyedu

Name: Adam Gyedu

Project Role: Site PI - Ghana (KNUST)

Nearest person month worked: 3

Contributions (no change): Development and execution of strategy in Ghana, supporting regulatory decision-making, drafting and final reviews of materials ahead of submission, meetings with all involved, meetings with regulatory bodies

Name: Etuh Ighohwo

Project Role: Co-Investigator – Ghana (Tamale Teaching Hospital)

Nearest person month worked: 1

Contributions (no change): Participating in burn advisory group meetings, participating in study meetings, reviewing protocols and SOPs, identifying and coordinating with first-level hospitals, identifying study staff for hiring once approved

Name: Paa Ekow

Project Role: Co-Investigator – Ghana (Komfo Anokye Teaching Hospital)

Nearest person month worked: 1

Contributions (no change): Participating in burn advisory group meetings, participating in study meetings, reviewing protocols and SOPs, identifying and coordinating with first-level hospitals, identifying study staff for hiring once approved

Name: CMD Kwesi Nsaful

Project Role: Co-Investigator – Ghana (37 Military Hospital)

Nearest person month worked: 1

Contributions (no change): Participating in burn advisory group meetings, participating in study meetings, reviewing protocols and SOPs, identifying and coordinating with first-level hospitals, identifying study staff for hiring once approved

Name: Forster Amponsah

Project Role: Co-Investigator – Ghana (Eastern Regional Hospital)

Nearest person month worked: 1

Contributions (no change): Participating in burn advisory group meetings, participating in study meetings, reviewing protocols and SOPs, identifying and coordinating with first-level hospitals, identifying study staff for hiring once approved

Name: Kajal Mehta

Project Role: Research fellow

Nearest person month worked: 3

Contributions (no change): Drafting protocols, refining protocols and SOPs given ongoing work and experience from sister study in Nepal, building REDCap database

Name: Aldina Mesic

Project Role: Research fellow

Nearest person month worked: 3

Contributions (no change): Drafting protocols, providing implementation science guidance, developing and testing interview guides and qualitative analysis plan

Name: Jane Edelson

Project Role: Research coordinator and regulatory consultant

Nearest person month worked: 1.5

Contributions (addition): Coordinating regulatory efforts, meeting with regulatory bodies, providing insights and expertise on international multicenter trials

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No

What other organizations were involved as partners?

As detailed above, we have connected our Ghanaian and Nepali research partners working on similar projects about enteral resuscitation to generate synergy and avoid shared pitfalls that slow research progress and reduce clinical effectiveness. The partners in this case are Dr. Shankar Man Rai, Dr. Kiran Nakarmi, Dr. Raslina Shresthsa, pfect NEPAL, Nepal Cleft and Burn Center at Kirtipur Hospital.

These partners have provided only in-kind intellectual support and are all located in Nepal.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: None