

#### ORTHOPAEDIC TRAUMA ASSOCIATION

Education •• Research •• Service 9400 West Higgins Road, Rosemont, IL 60018-4976 Telephone (847) 698-1631 - FAX (847) 823-0536 Website: http://www.ota.org

#### **SECTION 1**

#### PROPOSAL RESEARCH GRANT APPLICATION

Total Amount Requested: \$30,000 DATE: 6/17/2019

This request is made by the undersigned, who also agree(s) to comply with the following:

- (1) Funds granted as a result of the request are to be expended for the purposes set forth herein.
- (2) All reports or original investigations supported by any grant made as a result of this request shall acknowledge support provided by the Orthopaedic Trauma Association.
- (3) Reports will be made as required and necessary records and accounts, including financial and property controls, will be maintained and made available to the Orthopaedic Trauma Association.

NAME	TITLE	DEPARTMENT	SIGNATURE
<b>Principal Investigator:</b> Billy Haonga, MD	Head of Orthopaedic Surgery	Orthopaedic Surgery at Muhimbili University of Health and Allied Sciences	Phone: +255- 22-215-1596 E-mail: bhaonga@gmail.com
Co-Principal Investigator: David Shearer, MD, MPH	Assistant Professor in Residence	Orthopaedic Surgery at University of California, San Francisco	Phone: 415-206-8812 E-mail: David.shearer@ucsf.edu
OTHER INVESTIGATOR	 	 TH_PR∩IECT:	
Co-investigator: Saam Morshed, MD	Associate Professor in Residence	Orthopaedic Surgery at University of California, San Francisco	La and
Co-investigator: Edmund Eliezer, MD	Senior Orthopaedic Surgeon	Orthopaedic Surgery at Muhimbili University of Health and Allied Sciences	sishin

#### **Institution Name and Address:**

Muhimbili University of Health and Allied Sciences

United Nations Rd, Dar es Salaam, Tanzania

#### ABSTRACT OF RESEARCH PLAN

# PROJECT TITLE:

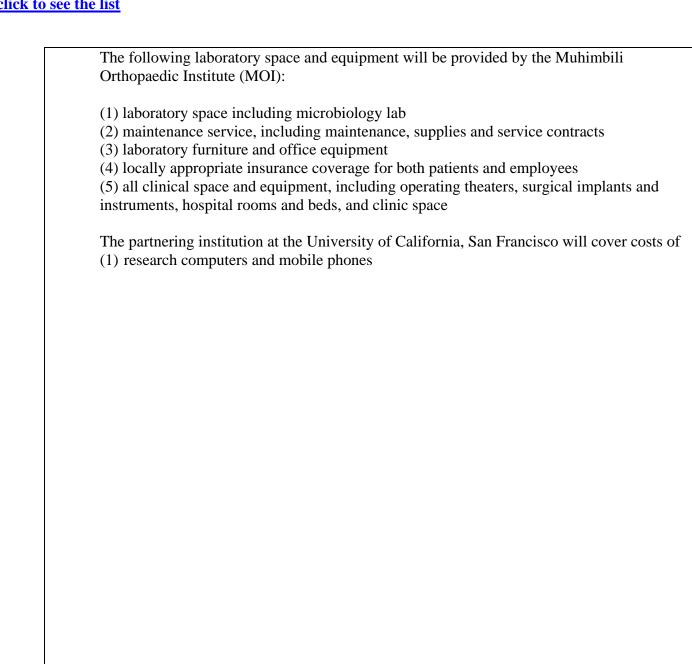
A Pilot Randomized Controlled Trial to Evaluate Local Antibiotics for Open Tibia Fracture in Tanzania

Abstract of research plan: Please provide an abstract of 250 words or less with 5 underlined phrases for a project summary. Please avoid summaries of past accomplishments and the use of the first person. The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

Tibial shaft fractures are the most common long-bone fracture. Deep infection remains a common, devastating complication of open injuries leading to lifelong impairment that disproportionately affects low- and middleincome countries (LMICs). Thorough surgical debridement, followed by fracture stabilization using internal or external fixation, is the mainstay of treatment. One proposed adjunctive measure is prophylactic local antibiotic delivery, which can achieve much higher antibiotic concentrations at the surgical site than can be achieved safely with systemic administration. There is a growing body of literature evaluating local antibiotic administration in both aqueous and powder form at the time of wound closure. While demonstrating potentially promising results, these studies are heterogeneous, of poor general methodologic quality, and none originate from LMICs where this technique would have the greatest potential benefits. Local gentamicin is particularly promising given the broad spectrum of activity against common pathogens in osteomyelitis (staphylococcus, gram-negative rods), wide availability, and low cost (<1\$ per 80mg vial). We propose a prospective, blinded, randomized controlled trial enrolling adult open tibial shaft fractures at the Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania. At the time of initial debridement, participants will be randomly assigned to receive aqueous gentamicin after closure or placebo saline injection. The primary outcome will be deep surgical site infection at 1 year. Secondary outcomes include health-related quality-of-life (HRQOL), modified Radiographic Union Scale for Tibial Fractures (mRUST), FIX-IT score for clinical healing, and cost of treatment using time-driven activity-based costing (TDABC) and survey methods.

# FACILITIES - Laboratory Space and Major Equipment

Please provide an accurate description of laboratory facilities and major equipment available at the grantee's institution that will support this project. Please recall the list of supplies and support that the grantee's institution, or grant funds other than those from the OTA, are expected to provide: click to see the list



#### RESEARCH PLAN

# **Click for Research Plan Instructions**

# A. SCIENTIFIC AIMS (not exceed 400 words)

**Deep infection remains a common, devastating complication of open fracture injuries leading to lifelong impairment** that disproportionately affects low- and middle-income countries (LMICs). Thorough surgical debridement, followed by fracture stabilization using internal or external fixation, is the mainstay of treatment. One proposed adjunctive measure is **prophylactic local antibiotic delivery, which can achieve much higher antibiotic concentrations at the surgical site** than can be achieved safely with systemic administration. There is a growing body of literature evaluating local antibiotic administration in both aqueous and powder form at the time of wound closure. While demonstrating potentially promising results, these studies are heterogeneous, of poor general methodologic quality, and none originate from LMICs where this technique would have the greatest potential benefits. **Local gentamicin is particularly promising** given the broad spectrum of activity against common pathogens in osteomyelitis (staphylococcus, gram-negative rods), availability, and low cost (<1\$ per 80mg vial).

We propose a prospective, blinded, randomized controlled trial enrolling adult open tibial shaft fractures at the Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania. At the time of initial debridement, participants will be **randomly assigned to receive aqueous gentamicin after closure or placebo saline injection**. The primary outcome will be deep surgical site infection at 1 year. Secondary outcomes include health-related quality-of-life (HRQOL) as measured by EQ-5D, modified Radiographic Union Scale for Tibial Fractures (mRUST), FIX-IT score for clinical healing, and the direct and indirect cost of treatment using time-driven activity-based costing (TDABC) and survey methods.

Our central hypothesis is that deep infection has significant clinical and economic impact on open tibial patients, and the risk of deep infection will be affected by prophylactic use of locally-administered antibiotics.

Specific Aim 1: To compare the rate of deep surgical site infection after intraoperative local gentamicin injection to debridement alone for open tibia fractures; and

**Specific Aim 2:** To quantify the direct and indirect cost of deep infection compared to an uncomplicated open tibial fracture

If efficacious, local antibiotics would be a highly cost-effective secondary prevention strategy in LMICs. Furthermore, although these findings will originate from an LMIC, results would be **applicable to populations** in both high <u>and</u> low-income countries. Therefore, a risk reduction on par with current literature could significantly reduce the global burden of open fractures. In the event that local antibiotics are not found to be effective, these prospective data will be highly impactful in establishing the economic burden of deep infection.

### B. BACKGROUND & SIGNIFICANCE (not to exceed 400 words)

The rate of musculoskeletal (MSK) trauma is 2-5 times higher than in high-income countries (HICs) (1). Among MSK injuries, open tibia fractures have arguably the greatest burden in LMICs (2). **Deep infection occurs in up to 40% of cases and frequently leads to lifelong pain and disability** that may require amputation (4–6). Given this morbidity, the Lancet Commission recently designated open fracture treatment as one of the "Bellwether Procedures" of essential surgical care in LMICs (7).

Intravenous antibiotics are standard of care for prophylaxis of infection after open fracture, but their dosage is limited by systemic toxicity. As an adjunctive measure, locally-administered antibiotics have been used to achieve higher concentrations (8,9). A recent systemic review and meta-analysis of observational studies demonstrated a 70% reduction in the odds of deep surgical site infection for open fractures treated with local antibiotics (10). However, conclusions were limited by heterogeneity of study designs, interventions, and the definition of deep infection. Specifically, the included studies utilized a variety of antibiotics with and without carriers, such as polymethylmethacrylate (PMMA) beads. While PMMA has demonstrated efficacy and offers prolonging of antibiotic elution, it requires a secondary surgery for removal and is cost-prohibitive for routine use in LMICs.

Direct application of antibiotic at wound closure, in the absence of a carrier, is a low-cost alternative to achieve high local antibiotic concentrations immediately. Limited data are available for open fractures treated using this technique, but a recent meta-analysis of powdered vancomycin prior to closure in spine surgery demonstrated a 60% reduction in the odds of infection (11). Similarly, the Vanco Study conducted by the Major Extremity Trauma Research Consortium (METRC) showed an approximately 50% relative risk reduction for infection with use of powdered vancomycin for high risk fractures (12). Limitations of local vancomycin include its relative high cost, narrow antimicrobial spectrum, and the potential of inducing resistance against second-line antibiotics available for drug-resistant organisms.

A promising alternative to local vancomycin is local gentamicin. Local gentamicin has demonstrated efficacy in reducing the rate of infection, both in an animal model and in a single retrospective cohort study of open tibia fractures, with a 50% reduction in relative risk of deep infection (10, 12). If proven to reduce the risk of infection, local gentamicin would be a highly cost-effective adjunctive treatment for open fractures that is likely generalizable in both high *and* low-income countries and promote care for injured patients.

#### C. PREVIOUS WORK DONE ON THE PROJECT (Not to exceed 400 words)

# RCT Comparing IM Nailing to External Fixation

We completed an RCT comparing the risk of reoperation due to deep infection or nonunion for intramedullary nailing (IMN) versus external fixation (EF) for open tibial fractures (13,14). Of 240 patients enrolled, 218 (90.8%) (110 IMN,108 EF) completed one-year follow-up and were included in the final analyses. There were 41 primary events: 28 deep surgical site infections (SSI) and 18 nonunions. **Primary events occurred in 17.3% and 20.4% of the IMN and EF groups**, respectively (Relative Risk [RR] 0.85, 95% CI 0.5 to 2.1, p=0.558). **Deep infection and nonunion were strongly associated with worse one-year quality-of-life** as measured by EQ-5D scores (0.81 vs.0.93, p<0.0001), which demonstrated persistent impairment at long-term follow-up (Figure 1). This study supports the *significance* of the proposed work and the *feasibility* of the study protocol.

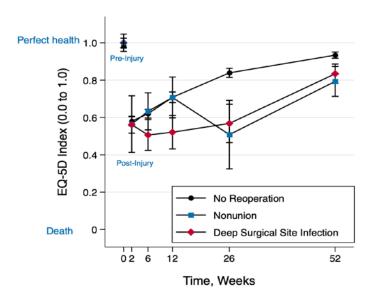


Figure 1: EQ-5D over time for patients with no complications, nonunion, and deep infection up to 1 year

# Qualitative Study Infected Nonunion

A subset of patients who developed deep infection and nonunion from the prior RCT was followed in a parallel cohort study. Patients underwent semi-structured interviews at 2.5 years post-injury to assess quality-of-life. **Patients reported very low EQ-5D scores at 1-year (0.756 \pm 0.1), and none had returned to per-injury work status.** The six patients that interviewed, reported ongoing medical complications (6), loss of employment (6), reduced income (5), difficulties with transportation (4), inability to support their family (4), difficulty with activities of daily living (4), loss of social network and support (4), significant ongoing pain (3), poor emotional/mental well-being (3), and significant loss of property (2) related to their injury. A representative quote is as follows:

"I lost all of my properties. My family now lives like beggars because I was the key of the family. I am supposed to do work to assist the family. But since the injury, I have not done anything to make money."

These data support the substantial impact of infection on quality of life in domains not adequately captured by EQ-5D score and fracture healing. These injuries primarily affect young, working age men in lower socioeconomic classes, which further perpetuates poverty for the patient and their family. This is the impetus for including more robust economic outcome instruments in the present proposal.

#### D. METHOD (not to exceed 1200 words and 4 pages)

This will be a **single-center**, **prospective randomized controlled trial conducted at the Muhimbili Orthopaedic Institute in Dar es Salaam**, **Tanzania**. All adults with open tibial shaft fractures presenting to the emergency department will be screened for enrollment, using the following eligibility criteria:

Inclusion Criteria	Exclusion Criteria
Age 18 or older	Wound requiring flap (Gustilo 3B)
Open tibial shaft fracture (OTA Type 42)	Vascular injury (Gustilo 3C)
	Aminoglycoside allergy

All participants who provide written informed consent will be treated with standard of care irrigation and debridement followed by bony stabilization at the discretion of the treating surgeon, typically intramedullary nailing (internal fixation) without the use of fluoroscopy. All patients will receive preoperative intravenous antibiotic prophylaxis using ceftriaxone. At the time of closure of the traumatic wound, participants will be randomly assigned to receive either the local antibiotic intervention or a normal saline placebo injection. The intervention consists of 80mg of liquid Gentamicin diluted in 40mL normal saline (2 mg/mL) injected immediately after wound closure at the open fracture site as described by Lawing et al (8). The local antibiotic solution will be

injected at the fracture site to infiltrate the fracture hematoma. The injection will continue until there is fluid extravasation from the wound up to a maximum of 40mL. The placebo group will receive an injection of 40mL of normal saline using an identical protocol. The randomization procedure will be performed electronically by a local study coordinator. **The patient, surgeon, research coordinators, and outcome assessors will be blinded to treatment group.** Only a research pharmacist at the local site, research coordinator based in San Francisco, and the Data Safety Monitoring Board will be un-blinded to treatment group. The study has received ethical approval from both the National Institute for Medical Research (NIMR) in Tanzania and the UCSF Institutional Review Board (IRB# 17-23950).

All subsequent postoperative care and rehabilitation will be equivalent for both groups. Follow up evaluations will occur at 2, 6, 12, 26 weeks post-operatively. Total duration of patient participation will be 6 months in the pilot trial. Data will be collected using Research Electronic Data Capture (REDCap)(15).

Both direct and indirect costs of treatment will be measured to achieve Aim 2. The direct costs will be estimated using a Time-driven Activity-based Costing (TDABC) methodology(20,21). TDABC requires estimation of the cost per unit time of a given resource (e.g. surgeon or nurse) and the time necessary to complete the activities in a given process. Process maps will be developed for each phase of care: pre-operative, operative, post-operative, and follow up. The personnel required for each process and time estimates will be directly observed by a study coordinator. The unit cost for each personnel will be calculated using the cost of capacity supplied divided by the practical capacity of resources supplied, assuming 80% practical capacity(20). The cost of capacity supplied will be obtained using monthly salary data provided by MOI. Use of consumable supplies (e.g. medications, surgical implants) will also be directly observed and recorded. Costs of permanent equipment (e.g. anesthesia machines, instrument sets) will be calculated using total cost and estimated lifespan of the equipment. Administrative overhead will be attributed to each patient using aggregate annual administrative costs using the patient-day-equivalent (PDE) method. Indirect costs will be assessed by administering the Work Productivity and Activity Impairment (WPAI) questionnaire, modified for lower extremity injury(22). The WPAI is a validated instrument to measure health-related work productivity loss that includes work time missed (absenteeism), reduced on-the-job effectiveness (presenteeism), and daily activity impairment. It will be administered to both patients and caregivers to quantify the indirect cost of injury and related complications.

#### **Outcome Measures**

The primary outcome measure for the definitive study will be the rate of reoperation for deep surgical site infection (SSI). A deep SSI will be defined as any patient with exposed bone, any wound drainage after 3 months, or infection involving the deep tissues requiring reoperation. All cases recommended for reoperation will be reviewed by an independent, blinded adjudication committee composed of experienced, non-treating orthopaedic trauma surgeons. The secondary clinical outcome measures will be clinical union, radiographic union, malunion, and EQ-5D. Clinical union will be assessed using the FIX-IT score, a validated survey instrument for tibia fractures that incorporates pain and ability to weight bear (18). Radiographic healing will be assessed by the modified Radiographic Union Scale for Tibial Fractures (mRUST) (17,19). Nonunion will be defined as a reoperation to promote healing or an mRUST score at final follow up of 10 or less (16,17). Malunion, or post-operative malalignment, will be defined as leg length discrepancy (>1 cm shortening), angular malalignment (>5 degrees sagittal or coronal angulation), or malrotation (>10 degrees, determined by Foot-Thigh Angle). Quality of life will be measured by EQ-5D. For the pilot trial we will additionally evaluate process metrics, including the rate of enrollment among screened patients, the effectiveness of the blinding and randomization procedures, the rate of follow up, and data quality.

#### Sample Size Considerations

Based on the previous RCT conducted at Muhimbili on open tibia fractures in the absence of local antibiotics, we estimated the rate of deep infection to be 12% (13,14). For a relative risk reduction of 50% in the rate of deep SSI with an Alpha (two-sided) of 0.05 and power of 0.80, the estimated sample size is 712 patients (356 per group). Assuming a loss to follow up of 20%, this study will need to enroll 890 patients to achieve the final sample size, which would require an enrollment period of 5 years based on past enrollment rates for a single center study. We anticipate enrollment of 180 patients or ~20% of the necessary sample size over 1 year for the pilot study.

#### Statistical Analysis

A Fischer's Exact test will be used to compare the rate of deep infection and other complications between groups. A multivariate logistic regression will be performed to identify predictors of the primary event. Continuous secondary outcomes, including the EQ-5D-3L index, FIX-IT score, EQ-VAS, and mRUST, will be assessed for between-group differences using a Student's t-test at one-year, and longitudinal linear mixed-effects regression models adjusting for putative baseline risk factors. Significance will be set at p < 0.05.

#### **Timeline**

This study will be a pilot randomized controlled trial enrolling for 1-year and collecting follow up for an additional 1 year. As such, the total necessary time to complete the trial will be 2 years.

Timeline for Proposed Research				
June 2019 to October 2019	- Training, refinement, and implementation of study protocol			
October 2019	- Begin pilot study enrollment			
October 2020	- End pilot study enrollment			
October 2021	- Complete follow up data collection			
October 2021 to January 2022	- Data analysis and manuscript preparation			

# E. REFERENCES (not to exceed 2 pages)

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- Collins, MSc; Yanjie Huang, MS; A Multicenter Randomized Trial Evaluating Intrawound Vancomycin Powder for Reducing Surgical Site Infection After Fracture Surgery. Orthop. Trauma Assoc. 2018 [Internet]. Abstract. Available from: https://ota.org/education/meetings-and-courses/abstracts/multicenterrandomized-trial-evaluating-intrawound
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#### **BIOGRAPHICAL SKETCH**

NAME	TITI	ITLE		BIRTHDATE (Mo., Day, Yr.)
	Trau	pecialist Orthopedic and rauma Surgeon, Muhimbili orthopaedic Institute		08/22/1971
Mbeya, Tanzania	citize	TIONALITY (If non-US zen indicate visa status) nzania		SEX (right click on the check in box/properties/default value/checked Male Female
EDUCATION (Begin with baccalaureate training a	and ii	nclude post	loctoral.)	
INSTITUTION AND LOCATION	Ι	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Warsaw Medical Academy, Poland		gree of edicine	2001	Medicine
Muhimbili University of Health and Allied Sciencies, Tanzania		ster of edicine	2009	Orthopaedic & Trauma Surgery
RELATIONSHIP TO PROPOSED PROJECT		MAJOR R	ESEARCH INTE	REST
Primary Investigator		Musculosk	eletal Disorders, O	Global Health, Orthopaedics
HONORS 1. OTA Humanitarian Award 2018	•			

#### OTHER RESEARCH SUPPORT

1. Orthopaedic Research and Education Foundation Young Investigator Grant \$30,000

Study Title: Titanium Elastic Nails versus K-wires for Pediatric Femoral Shaft Fractures in Tanzania

Period of Support: July 2017 to July 2019

PI: Patrick Curran Role: Co-Investigator

2. Foundation for Orthopaedic Trauma Research Grant \$20,000

Study Title: Titanium Elastic Nails versus K-wires for Pediatric Femoral Shaft Fractures in Tanzania

Period of Support: July 2017 to July 2019

PI: Patrick Curran Role: Co-investigator

RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)

#### PROFESSIONAL EXPERIENCE RELATED TO PROJECT:

1. 2015 - present Head of Orthopaedic and Trauma, Muhimbili University of Health and Allied

Sciences

2. 2008 - present SIGN Surgeon

3. 2009 - present Specialist Orthopedic and Trauma Surgeon, Muhimbili Orthopaedics Institute

4. 2014 – present OTA International Member

#### RESEARCH EXPERIENCE RELATED TO PROJECT:

- 1. Conway D, Albright P, Eliezer E, **Haonga B**, Morshed S, Shearer DW. The burden of femoral shaft fractures in Tanzania. Injury. 2019 Jun 3. pii: S0020-1383(19)30336-5. doi: 10.1016/j.injury.2019.06.005. [Epub ahead of print] PubMed PMID: 31196597.
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#### **BIOGRAPHICAL SKETCH**

NAME	TITLE		BIRTHDATE (Mo., Day, Yr.)	
David William Shearer	Assistant Professor in Residence, Orthopaedic Surgery		03/12/1982	
PLACE OF BIRTH (City, State. Country) Toppenish, Washington, USA	citizen indicate visa status)		SEX (right click on the check in box/properties/default value/checked Male	
EDUCATION (Begin with baccalaureate training	and include poste	doctoral.)		
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY	
Massachusetts Institute of Technology, Boston MA	BS	06/04	Mechanical Engineering	
University of Washington School of Medicine, Seattle WA	MD	06/08	Medicine	
Harvard School of Public Health, Boston MA	MPH	06/09	Quantitative Methods	
University of California, San Francisco CA	Resident	07/14	Orthopaedic Surgery, Residency	
University of Washington, Seattle WA	Fellow	08/15	Orthopaedic Trauma Surgery, Fellowship	
RELATIONSHIP TO PROPOSED PROJECT	MAJOR R	ESEARCH INTE	REST	
Co-Primary Investigator	Musculoskeletal injuries, cost-effective treatment, global orthopaedics			
HONORS  2011 UCSF Inman-Abbott Society Resi 2013 UCSF Inman-Abbott Conference 2014 UCSF Inman-Abbott Society Resi	Manning Award	for Best Resident	Research Presentation	

# 2019 UCSF James M. Morris Compassionate Physician Award OTHER RESEARCH SUPPORT

1. Orthopaedic Research and Education Foundation Young Investigator Grant \$20,000

Study Title: Titanium Elastic Nails versus K-wires for Pediatric Femoral Shaft Fractures in Tanzania

Journal of Orthopaedic Trauma Supplement Award on Global Partnership

Period of Support: July 2017 to July 2019

Role: Co-Investigator

2018

2. Foundation for Orthopaedic Trauma Research Grant \$30,000

Study Title: Titanium Elastic Nails versus K-wires for Pediatric Femoral Shaft Fractures in Tanzania

Period of Support: July 2017 to July 2019

Role: Co-investigator

1 2015 - present

#### RESEARCH AND/OR PROFESSIONAL EXPERIENCE

#### PROFESSIONAL EXPERIENCE RELATED TO PROJECT:

1.	2015 present	rissistant rioressor, Bept. or orthopaedic surgery, elest
2.	2012- present	Candidate Member, Orthopaedic Trauma Association
3.	2015 - present	Director, IGOT Global Research Initiative, University of California, San Francisco

Assistant Professor, Dept. of Orthonaedic Surgery, LICSE

4. 2018 – present Member, UCSF IGHS Faculty International Research Advisory group

#### RESEARCH EXPERIENCE RELATED TO PROJECT:

- 1. Wu HH, Liu M, Challa ST, Morshed S, Eliezer EN, Haonga BT, Zirkle L, **Shearer DW**. Development of Squatand-Smile Test as Proxy for Femoral Shaft Fracture-Healing in Patients in Dar es Salaam, Tanzania. J Bone Joint Surg Am. 2019 Feb 20;101(4):353-359. doi: 10.2106/JBJS.18.00387. PubMed PMID: 30801374.
- 2. Mustafa Diab M, **Shearer DW**, Kahn JG, Wu HH, Lau B, Morshed S, Chokotho L. The Cost of Intramedullary Nailing Versus Skeletal Traction for Treatment of Femoral Shaft Fractures in Malawi: A Prospective Economic Analysis. World J Surg. 2019 Jan;43(1):87-95. doi: 10.1007/s00268-018-4750-3. PubMed PMID: 30094638.
- 3. Ibrahim J, Liu M, Yusi K, Haonga B, Eliezer E, **Shearer DW**, Morshed S. Conducting a Randomized Controlled Trial in Tanzania: Institute for Global Orthopaedics and Traumatology and the Muhimbili Orthopaedic Institute. J Orthop Trauma. 2018 Oct;32 Suppl 7:S47-S51.. PubMed PMID: 30247401.
- 4. Challa S, Wu HH, Cunningham BP, Liu M, Patel K, **Shearer DW**, Morshed S, Miclau T. Orthopaedic Trauma in the Developing World: Where Are the Gaps in Research and What Can Be Done?. J Orthop Trauma. 2018 Oct;32 Suppl 7:S43-S46. doi: 10.1097/BOT.0000000000001293. PubMed PMID: 30247400.
- 5. Ibrahim JM, Conway D, Haonga BT, Eliezer EN, Morshed S, **Shearer DW**. Predictors of lower health-related quality of life after operative repair of diaphyseal femur fractures in a low-resource setting. Injury. 2018 May 23;. doi: 10.1016/j.injury.2018.05.021. [Epub ahead of print] PubMed PMID: 29866624.
- 6. Mustafa Diab M, Wu HH, Eliezer E, Haonga B, Morshed S, **Shearer DW**. The impact of antegrade intramedullary nailing start site using the SIGN nail in proximal femoral fractures: A prospective cohort study. Injury. 2018 Feb;49(2):323-327. doi: 10.1016/j.injury.2017.11.020. Epub 2017 Nov 16. PubMed PMID: 29162265.
- 7. Roth J, Goldman B, Zirkle L Jr, Schlechter J, Ibrahim J, **Shearer D**. Early clinical experience with the SIGN hip construct: a retrospective case series. SICOT J. 2018;4:55. doi: 10.1051/sicotj/2018050. Epub 2016 Nov 30. PubMed PMID: 30500327; PubMed Central PMCID: PMC6269155.
- 8. Eliezer EN, Haonga BT, Morshed S, **Shearer DW**. Predictors of Reoperation for Adult Femoral Shaft Fractures Managed Operatively in a Sub-Saharan Country. J Bone Joint Surg Am. 2017 Mar 1;99(5):388-395. doi: 10.2106/JBJS.16.00087. PubMed PMID: 28244909.
- 9. Kramer EJ, **Shearer DW**, Marseille E, Haonga B, Ngahyoma J, Eliezer E, Morshed S. The Cost of Intramedullary Nailing for Femoral Shaft Fractures in Dar es Salaam, Tanzania. World J Surg. 2016 Sep;40(9):2098-108. doi: 10.1007/s00268-016-3496-z. PubMed PMID: 26983603.
- 10. Kramer EJ, **Shearer D**, Morshed S. The use of traction for treating femoral shaft fractures in low- and middle-income countries: a systematic review. Int Orthop. 2016 May;40(5):875-83. doi: 10.1007/s00264-015-3081-3. Epub 2016 Jan 7. Review. PubMed PMID: 26744164.
- 11. Wu HH, Liu M, Patel KR, Turner W, Baltus L, Caldwell AM, Hahn JC, Coughlin RR, Morshed S, Miclau T, **Shearer DW**. Impact of academic collaboration and quality of clinical orthopaedic research conducted in low- and middle-income countries. SICOT J. 2017;3:6. doi: 10.1051/sicotj/2016042. Epub 2017 Jan 30. PubMed PMID: 28134090; PubMed Central PMCID: PMC5278648.
- 12. **Shearer DW**, Volberding PA, Schemitsch EH, Cook GE, Slobogean GP, Morshed S. Building Networks for Global Clinical Research: The Basics. J Orthop Trauma. 2015 Dec;29 Suppl 12:S15-8. doi: 10.1097/BOT.000000000000466. PubMed PMID: 26584260.
- 13. Chokotho L, Lau BC, Conway D, Wu HH, **Shearer D**, Hallan G, Gjertsen JE, Mkandawire N, Young S. Validation of Chichewa Short Musculoskeletal Function Assessment (SMFA) questionnaire: A cross-sectional study. Malawi Med J. 2019 Mar;31(1):65-70. doi: 10.4314/mmj.v31i1.11. PubMed PMID: 31143399; PubMed Central PMCID: PMC6526350.
- 14. Ibrahim JM, Liu M, Wu HH, Patel KR, Caldwell AM, Coughlin RR, Morshed S, **Shearer DW**. The extent of pediatric orthopaedic research in low- and middle-income countries and the impact of academic collaboration on research quality: a scoping review. Pediatr Surg Int. 2019 Mar;35(3):397-411. doi: 10.1007/s00383-018-4412-4. Epub 2018 Nov 9. Review. PubMed PMID: 30413920.
- 15. Lau BC, Wu HH, Mustafa M, Ibrahim J, Conway D, Agarwal-Harding K, **Shearer DW**, Chokotho L. Developing Research to Change Policy: Design of a Multicenter Cost-Effectiveness Analysis Comparing Intramedullary Nailing to Skeletal Traction in Malawi. J Orthop Trauma. 2018 Oct;32 Suppl 7:S52-S57. doi: 10.1097/BOT.00000000001299. PubMed PMID: 30247402.

#### Complete list of published work in My Bibliography:

https://www.ncbi.nlm.nih.gov/sites/myncbi/1nYfut\_zUE8kG/bibliography/40032457/public/?sort=date&direction=descending

	Bl	OG	RAPHICAL	SKETCH		
Edmund Ndalama Eliezer		Spe	TITLE Specialist Orthopaedic and Trauma Surgeon		BIRTHDATE (Mo., Day, Yr.) 10/21/1971	
PLACE OF BIRTH (City Dar es Saalam, Tanzania				,	SEX (right click on the check in box/properties/default value/checked Male	
EDUCATION (Begin wi	th baccalaureate train	ning	and include	postdoctoral.)		
INSTITUTION AN	ND LOCATION		DEGREE	YEAR CONFERRED	FIELD OF STUDY	
Peoples Friendship University of Iniversity-Moscow)	Russia- (LUMUMBA		Degree of Medicine	1999	Medicine	
Muhimbili University of Health at	nd Allied Sciences		Master of Medicine	2007	Orthopaedic & Trauma Surgery	
RELATIONSHIP TO PF Co-investigator	ROPOSED PROJECT	Γ		RESEARCH INT	EREST	
	rnational Surgical Skil International Paper Aw JPPORT		cholarship Re	cipient		
RESEARCH AND/OR F relevant to project. Inclu PROFESSIONAL EXPER  1. 2007- present 2. 2008 - present 3. 2003 - 2007 4. 2001-2003	de publications.)  IENCE RELATED TO  Specialist Orthopeo  SIGN Surgeon  Resident in Orthop	) PR lic a edic	OJECT: Ind Trauma S Ind Trauma	urgeon, Muhimbil , Muhimbili Ortho	position: list ALL experience i Orthopaedic Institute paedic Institute rthopaedic Institute	
	-				_	

#### RESEARCH EXPERIENCE RELATED TO PROJECT:

- 1. Kramer EJ, Shearer DW, Marseille E, Haonga B, Ngahyoma J, **Eliezer E**, Morshed S. The Cost of Intramedullary Nailing for Femoral Shaft Fractures in Dar es Salaam, Tanzania. World J Surg. 2016 Sep;40(9):2098-108. doi: 10.1007/s00268-016-3496-z. PubMed PMID: 26983603.
- 2. **Eliezer EN**, Haonga BT, Morshed S, Shearer DW. Predictors of Reoperation for Adult Femoral Shaft Fractures Managed Operatively in a Sub-Saharan Country. J Bone Joint Surg Am. 2017 Mar 1;99(5):388-395. doi: 10.2106/JBJS.16.00087. PubMed PMID: 28244909.
- 3. Mustafa Diab M, Wu HH, **Eliezer E**, Haonga B, Morshed S, Shearer DW. The impact of antegrade intramedullary nailing start site using the SIGN nail in proximal femoral fractures: A prospective cohort study. Injury. 2018 Feb;49(2):323-327. doi: 10.1016/j.injury.2017.11.020. Epub 2017 Nov 16. PubMed PMID: 29162265.
- 4. Ibrahim JM, Conway D, Haonga BT, **Eliezer EN**, Morshed S, Shearer DW. Predictors of lower health-related quality of life after operative repair of diaphyseal femur fractures in a low-resource setting. Injury. 2018 May 23. pii: S0020-1383(18)30260-2. doi: 10.1016/j.injury.2018.05.021. [Epub ahead of print] PubMed PMID: 29866624.
- 5. Ibrahim J, Liu M, Yusi K, Haonga B, **Eliezer E**, Shearer DW, Morshed S. Conducting a Randomized Controlled Trial in Tanzania: Institute for Global Orthopaedics and Traumatology and the Muhimbili Orthopaedic Institute. J Orthop Trauma. 2018 Oct;32 Suppl 7:S47-S51. doi: 10.1097/BOT.000000000001294. PubMed PMID: 30247401.
- 6. Wu HH, Liu M, Challa ST, Morshed S, **Eliezer EN**, Haonga BT, Zirkle L, Shearer DW. Development of Squatand-Smile Test as Proxy for Femoral Shaft Fracture-Healing in Patients in Dar es Salaam, Tanzania. J Bone Joint Surg Am. 2019 Feb 20;101(4):353-359. doi: 10.2106/JBJS.18.00387. PubMed PMID: 30801374.
- 7. Conway D, Albright P, **Eliezer E**, Haonga B, Morshed S, Shearer DW. The burden of femoral shaft fractures in Tanzania. Injury. 2019 Jun 3. pii: S0020-1383(19)30336-5. doi: 10.1016/j.injury.2019.06.005. [Epub ahead of print] PubMed PMID: 31196597.
- 8. Haonga, B. T., Mrita, F. S., **Eliezer EN,** & Makupa, J. E. (2015). Short-term outcome of patients with closed comminuted femoral shaft fracture treated with locking intramedullary sign nail at Muhimbili Orthopaedic Institute in Tanzania. Tanzania Journal of Health Research, 17(3).
- 9. **Eliezer, E. N.**, Haonga, B., Mrita, F. S., Liu, M. B., & Wu, H. (2016). Functional outcome and quality of life after surgical management of displaced acetabular fractures in Tanzania. East African Orthopaedic Journal, 10(1), 16-20.

#### **SECTION 5**

#### **BIOGRAPHICAL SKETCH**

			BIRTHDATE (Mo., Day, Yr.) 10/23/1974
Santa Monica, California, USA	citizen indicate visa status) USA		SEX (right click on the check in box/properties/default value/checked Male
EDUCATION (Begin with baccalaureate training at	nd include posto	doctoral.)	
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Harvard University, Cambridge, MA	B.A.	1996	Cum Laude
University of California, San Francisco	M.D.	2001	
University of California, San Francisco	Resident	2008	Resident in Orthopaedic Surgery
University of California, Berkeley	M.P.H.	2005	Epidemiology
University of California, Berkeley	Ph.D.	2010	Epidemiology
Harborview Medical Center, University of Washington, Seattle, WA	Fellow	2009	Orthopaedic Trauma Fellowship

RELATIONSHIP TO PROPOSED PROJECT	MAJOR R	ESEARCH INTERE	EST
Co-investigator	Musculosk	eletal disorders/care	, Clinical Epidemiology

#### HONORS

2005 Clinician Scientist Development Program, AAOS/OREF/ORS

Young Investigator Designee, NIH/AAOS Fracture Repair Symposium. Miami, FL 2007

Outstanding Chief Resident Award, UCSF, Orthopaedic Surgery Residency Training Program 2008

2018 Fellow, American Orthopaedic Association

#### OTHER RESEARCH SUPPORT

1. Foundation for Orthopaedic Trauma \$30,000

Study Title: Intramedullary kirschner wire versus flexible nail fixation for pediatric femur fractures

Period of Support: September 2016- September 2019

Role: PI

2. Canadian Institutes of Health Research

Study Title: Advancing the Care of Patients with Musculoskeletal Injuries Worldwide through Multi-National Research Initiatives

Period of Support: July 2016- June 2024

PI: Bhandari

Role: Co-investigator

3. AO North America

Study Title: Delta Well-Leg Compartment Pressure Validation study of new leg compartment measure comparing intracompartmental pressures from un-injured leg to that of legs with tibial fractures.

Period of Support: January 2018- December 2018

PI: El Naga

Role: Co-Investigator

RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position: list ALL experience relevant to project. Include publications.)

#### PROFESSIONAL EXPERIENCE RELATED TO PROJECT:

- 1. 2015-present Associate Professor in Residence, Orthopaedic Surgery, Epidemiology and Biostatistics, UCSF
- 2. 2009-2015 Assistant Professor in Residence, University of California, San Francisco
- 3. 2008-2009 Instructor, Orthopaedic Trauma, University of Washington
- 4. 2009-present Director, Clinical Research Center, San Francisco General Hospital and UCSF
- 5. 2010-present Chief, Orthopaedic Surgery, UCSF Medical Center, University Trauma Service
- 6. 2014-present Co-Director of Global Research Initiative, Institute for Global Orthopaedics and Traumatology, UCSF
- 7. 2016-present Co-Director, Orthopaedic Trauma Fellowship, UCSF/ZSFG
- 8. 2018-present Chair, Orthopaedic Trauma Association Strategic Research Initiatives Committee

#### RESEARCH EXPERIENCE RELATED TO PROJECT:

- 1. Ibrahim J, Liu M, Yusi K, Haonga B, Eliezer E, Shearer DW, **Morshed S**. Conducting a Randomized Controlled Trial in Tanzania: Institute for Global Orthopaedics and Traumatology and the Muhimbili Orthopaedic Institute. J Orthop Trauma. 2018 Oct;32 Suppl 7:S47-S51.. PubMed PMID: 30247401.
- 2. Eliezer EN, Haonga BT, **Morshed S**, Shearer DW. Predictors of Reoperation for Adult Femoral Shaft Fractures Managed Operatively in a Sub-Saharan Country. J Bone Joint Surg Am. 2017 Mar 01; 99(5):388-395. PMID: 28244909
- 3. Kramer EJ, Shearer DW, Marseille E, Haonga B, Ngahyoma J, Eliezer E, **Morshed S**. The Cost of Intramedullary Nailing for Femoral Shaft Fractures in Dar es Salaam, Tanzania. World J Surg. 2016 Mar 16. PMID: 26983603
- 4. **Morshed S**, Miclau T, Bembom O, Cohen M, Knudson MM, Colford JM. Delayed internal fixation of femoral shaft fracture reduces mortality among patients with multisystem trauma. J Bone Joint Surg Am. 2009 Jan; 91(1):3-13. PMID: 19122073. PMCID: PMC2663326
- 5. **Morshed S**, Corrales LA, Lin K, Miclau T. Femoral nailing during serum bicarbonate-defined hypo-perfusion predicts pulmonary organ dysfunction in multi-system trauma patients. Injury. 2011 Jul; 42(7):643-9. PMID: 20678765
- 6. **Morshed S**, Mikhail C, Miclau Iii T. Timing of Femoral Shaft Fracture Fixation Affects Length of Hospital Stay in Patients with Multiple Injuries. Open Orthop J. 2015; 9:324-31. PMID: 26312117. PMCID: PMC4541315
- 7. Wu HH, Liu M, Challa ST, **Morshed S**, Eliezer EN, Haonga BT, Zirkle L, Shearer DW. Development of Squat-and-Smile Test as Proxy for Femoral Shaft Fracture-Healing in Patients in Dar es Salaam, Tanzania. J Bone Joint Surg Am. 2019 Feb 20;101(4):353-359. doi: 10.2106/JBJS.18.00387. PubMed PMID: 30801374.
- 8. Mustafa Diab M, Shearer DW, Kahn JG, Wu HH, Lau B, **Morshed S**, Chokotho L. The Cost of Intramedullary Nailing Versus Skeletal Traction for Treatment of Femoral Shaft Fractures in Malawi: A Prospective Economic Analysis. World J Surg. 2019 Jan;43(1):87-95. doi: 10.1007/s00268-018-4750-3. PubMed PMID: 30094638.
- 9. Challa S, Wu HH, Cunningham BP, Liu M, Patel K, Shearer DW, **Morshed S**, Miclau T. Orthopaedic Trauma in the Developing World: Where Are the Gaps in Research and What Can Be Done?. J Orthop Trauma. 2018 Oct;32 Suppl 7:S43-S46. doi: 10.1097/BOT.000000000001293. PubMed PMID: 30247400.
- 10. Mustafa Diab M, Wu HH, Eliezer E, Haonga B, **Morshed S**, Shearer DW. The impact of antegrade intramedullary nailing start site using the SIGN nail in proximal femoral fractures: A prospective cohort study. Injury. 2018 Feb;49(2):323-327. doi: 10.1016/j.injury.2017.11.020. Epub 2017 Nov 16. PubMed PMID: 29162265.
- 11. Kramer EJ, Shearer D, **Morshed S**. The use of traction for treating femoral shaft fractures in low- and middle-income countries: a systematic review. Int Orthop. 2016 May;40(5):875-83. doi: 10.1007/s00264-015-3081-3. Epub 2016 Jan 7. Review. PubMed PMID: 26744164.
- Wu HH, Liu M, Patel KR, Turner W, Baltus L, Caldwell AM, Hahn JC, Coughlin RR, Morshed S, Miclau T, Shearer DW. Impact of academic collaboration and quality of clinical orthopaedic research conducted in low- and middle-income countries. SICOT J. 2017;3:6. doi: 10.1051/sicotj/2016042. Epub 2017 Jan 30. PubMed PMID: 28134090; PubMed Central PMCID: PMC5278648.
- 13. Shearer DW, Volberding PA, Schemitsch EH, Cook GE, Slobogean GP, **Morshed S**. Building Networks for Global Clinical Research: The Basics. J Orthop Trauma. 2015 Dec;29 Suppl 12:S15-8. doi: 10.1097/BOT.0000000000000466. PubMed PMID: 26584260.
- 14. Ibrahim JM, Liu M, Wu HH, Patel KR, Caldwell AM, Coughlin RR, **Morshed S**, Shearer DW. The extent of pediatric orthopaedic research in low- and middle-income countries and the impact of academic collaboration on research quality: a scoping review. Pediatr Surg Int. 2019 Mar;35(3):397-411. doi: 10.1007/s00383-018-4412-4. Epub 2018 Nov 9. Review. PubMed PMID: 30413920.
- 15. **Morshed S**, Shearer DW, Coughlin RR. Collaborative Partnerships and the Future of Global Orthopaedics. Clin Orthop Relat Res. 2013 Jul 25. PMID: 23884799

### Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/sites/myncbi/1xuMTnx6VsqQc/bibliography/48039075/public/?sort=date&direction=ascending

# **SECTION 6**

# RESEARCH SUPPORT, SUBMISSIONS

Please combine the information on this page for PI and Co-PI. Add additional lines and pages as needed, there is no word limit in this section.

Prior OTA Funding to Principal Investigator or Co-P.I.:				
SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF	
OTA Resident Research Grant	Nails versus Plates for Femoral Shaft Fractures in Tanzania	\$10,000	July 2012 to July 2014	

Research Support to Principal Investigator or Co-PI Relevant to THIS Project Past 5 Years (Include That from Own Institution):				
SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF	
UCSF Supernova	A Pilot Randomized Controlled Trial to Evaluate Local Antibiotics for Open Tibia Fracture in Tanzania	\$10,000	July 2019 to July 2020	
UCSF Hellman Fellows Fund	A Pilot Randomized Controlled Trial to Evaluate Local Antibiotics for Open Tibia Fracture in Tanzania	\$50,000	July 2019 to June 2021	
UCSF Seed Grant	Longitudinal comparison of outcomes and cost- effectiveness of intramedullary nailing versus external fixation for the treatment of open tibial fractures in Tanzania	\$25,000	July 2019 to July 2020	

Support to Principal Investigator or Co-PI for OTHER Research Projects:				
SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF	
Orthopaedic Research and Education Foundation	Intramedullary kirschner wire versus flexible nail fixation for pediatric femur fractures	\$20,000	July 2017 to July 2019	
Foundation for Orthopaedic Trauma	Intramedullary kirschner wire versus flexible nail fixation for pediatric femur fractures	\$30,000	July 2017 to July 2019	

Previous Research:				
SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF	
OREF Young Investigator Grant	Nails versus Plates for Femoral Shaft Fractures in Tanzania	\$50,000	May 2012 to October 2014	
Doris Duke Charitable Foundation	A randomized trial comparing intramedullary nailing to external fixation for open tibial fractures in Tanzania	\$30,000	July 2015 to July 2017	

Current Research:				
SOURCE OF SUPPORT	TITLE OF PROJECT	AMOUNT	PERIOD OF	

# Submissions of This or Similar Project to Other Agencies:

#### **SUBMITTED:**

None

# PLANNED:

- OREF Career Development Grant
- OTA Full Research Grants Directed Topic Grants (next cycle)