The ethical development and sustainability of trauma registries in low- and middle-income

countries

by

Chantalle Lauren Grant

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ABSTRACT

Trauma registries are an anonymized, systematic, prospective data banks for trauma patients that may include details on demographics, injury details, hospital processes, and outcomes. They are an important component of trauma care systems and a tool for improving outcomes in trauma. Given the high rates of morbidity and mortality from trauma in low- and middle-income countries (LMICs), the implementation of trauma registries in LMICs is a growing area of interest; however, while many pilot trauma registries have been demonstrated to be feasible in LMICs, very few are sustainable in the long term. In this thesis, a trauma registry established in 2017 in Mbarara Regional Referral Hospital (MRRH), Uganda is examined. Since the establishment of this registry, data for over 3000 trauma patients has been collected, however, the registry faces questions of how to achieve long-term viability without the financial support of external partnerships. The aim of this thesis is therefore to evaluate several aspects of sustainability of trauma registries for low-income settings.

First, the ethical importance of sustainability in global surgery was established through a scoping review on the literature on the ethics of global surgery. A grounded theory content analysis was completed to identify themes and gaps in the existing literature. Four major ethical domains in global surgery were identified: clinical care and delivery; education and exchange of trainees; research, monitoring, and evaluation; and engagement in collaborations and partnerships. While the literature on ethics in global surgery was sparse, mostly in the form of commentaries or editorials, and largely published by authors in high-income countries (HICs), the importance of including LMIC authors in the conversation on ethics in global surgery and the value of building sustainable collaborations and partnerships were key findings of this scoping review.

Next, a literature review of considerations for the implementation of ethical and sustainable trauma registries in LMICs was completed. A number of practical challenges were identified for the development of trauma registries in LMICs and included funding sources, personnel requirements, technology access, and quality assurance mechanisms. Ethical considerations for trauma registry development were also identified, and included concerns of patient confidentiality, informed consent, and sustaining the registry. Strategies for these ethical and practical considerations for trauma registry development in LMICs are discussed, and opportunities for future research opportunities are explored.

The widespread nature and accessibility of mobile phones in most low- and middle-income countries, including Uganda, makes the use of mobile phone technology in health a potential avenue for inexpensive health care innovation. A mobile application trauma registry was designed and implemented to minimize workload and contribute to sustainability of the registry. Healthcare workers involved in trauma then completed a validated questionnaire known as the Unified Theory of Acceptance and Use of Technology (UTAUT) for evaluating the usability of the mobile application trauma registry and predicting future use behaviours. Healthcare workers scored the mobile application highly, indicating a high potential for ongoing use. The UTAUT was also identified as a method for other trauma registries to predict future use and opportunities for sustainability.

Finally, a potential means of financial self-sustainability for trauma registries in low-income countries was evaluated. In many public hospitals in low-income settings, government funding for

patients seen is dependent on documentation of those patients. This study evaluated the improvements to patient documentation following the implementation of a trauma registry and concurrent patient registration system at MRRH. A significant improvement in patient documentation was found, with a 20-fold increase in trauma patients documented following the implementation of patient registration and a trauma registry. This more accurate documentation could then be used to apply for increased government funding for trauma patients and for sustaining the trauma registry in the long-term. The concurrent implementation of a patient registration system with a trauma registry therefore could be an avenue for financial viability for other trauma registries in low-income contexts.

Taken together, these studies represent a compelling picture for the ethical imperative to develop sustainable trauma registries in LMICs and some of the strategies that may be undertaken to achieve this. By combining these techniques, we hope to achieve a sustainable, long-term trauma registry at MRRH that can serve as a model for other trauma registries in LMICs going forward.

PREFACE:

This thesis is an original work by Chantalle L. Grant. Research ethics board approvals were obtained from the University of Alberta for the work contained in Chapters 4 and 5, project names "Development and analysis of a sustainable trauma registry in a resource-limited setting in East Africa" and "Introduction of a trauma registry mobile application and assessment of usability amongst health care providers at Mbarara Regional Referral Hospital in Uganda" (Research Ethics Board Pro00083961 and Pro00088012). Research Ethics Committee approval was also received from Mbarara University of Science and Technology (Research Ethics Committee No 20/08-16).

Identification and design of the research was done in collaboration with Dr. Abdullah Saleh, Dr. David Bigam, Dr. Dean Eurich, and Dr. Martin Situma. Dr. Martin Situma served as regional contact and local principal investigator in Mbarara, Uganda. The initial implementation of the Mbarara trauma registry in 2016 was initiated by Dr. Abdullah Saleh in conjunction with Dr. Brian Cameron from McMaster University.

Chapter 2 of this thesis has been published as: "Ethical considerations in global surgery: A scoping review" in BMJ Global Health 2020,5:e002319. doi:10.1136/bmjgh-2020-002319. For this study, CG was responsible for the data extraction, analysis, and completion of the manuscript. AS, CM, TR, AA, and RG all contributed significantly to study conceptualization and manuscript editing. AA, CM, and TR performed the literature screen; AA and CM contributed to data analysis, and TR created the search strategy.

Chapter 3 of this thesis is in preparation for submission as: "Sustainable and ethical development of trauma registries in low- and middle-income countries". CG, AS, and DB were responsible for the conceptualization, writing, and editing of the manuscript.

Chapter 4 of this thesis is in preparation for submission as: "Developing and evaluating a trauma registry mobile application for use in low- and middle-income countries".
CG conceptualized the study, designed and administered the survey, extracted data and performed the statistical analysis, and was responsible for manuscript composition. Additional surveys were administered by AMA, FO, and MS. Implementation and design of the trauma registry was performed in conjunction by BC, TR, MS, and AS. AS, DB, and DE all contributed to study design and manuscript composition.

Chapter 5 of this thesis is in preparation for submission at this time: "Change in trauma patient volume following the implementation of a trauma registry and patient registration system: a means of sustainability for a trauma registry at a district hospital in Uganda". CG extracted data from the trauma registry, performed the statistical analysis, composed the manuscript, and was involved in study conceptualization with AS. CT and CS collected the data from the Mbarara Trauma registry. TR also assisted in extracting data from the trauma registry and ensuring data quality. AS, MS, DE, and DB were involved in study design and manuscript composition. DE also participated in performing the statistical analysis.

ACKNOWLEDGEMENTS

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ABBREVIATIONS

LMIC(s): Low- and middle-income country/countries

MRRH: Mbarara Regional Referral Hospital

HIC(s): High-income country/countries

UTAUT: Unified Theory of Acceptance and Use of Technology

USD: United States Dollars

MUST: Mbarara University of Science and Technology

A&E: Accidents and Emergencies Department

ICChange: Innovative Canadians for Change

ACGME: Accreditation Council for Graduate Medical Education

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

USA: United States of America

UK: United Kingdom

EHR: Electronic Health Records

MADD: Mothers Against Drunk Driving

CDC: Centers for Disease Control and Prevention

ISS: Injury Severity Score

KTS: Kampala Trauma Score

e-Health: Electronic health technologies

m-Health: mobile health technologies

SMS: Short Message Services

RADAR: Relevance, Authority, Date, Appearance, Reason for writing

CRAAP-O: Currency, Relevance, Authority, Accuracy, purpose, and O-assessment

NMEDAPP: Novel, Potential of benefit versus risk, Medically sound, Ease of use, Developer, Audience, Price, Platform

REDCap: Research Electronic Data Capture tool

MUST-REC: Mbarara University of Science and Technology Research Ethics Committee

IR: Incident Rate

IRR: Incident Rate Ratio

SD: Standard Deviation

CHAPTER 1: INTRODUCTION

1.1 Statement of the Problem

1.1.1 The Burden of Surgical Disease in Low- and Middle-Income Countries

Worldwide, there are an estimated 5 billion people who lack timely access to safe and affordable surgical care, and 143 million surgical procedures are required to make up this shortfall[1]. The most significant need for surgical care falls upon low- and middle-income countries (LMICs), defined by the World Bank as countries with a per capita gross national income of less than $12,055 United States Dollars (USD)[1,2]. Approximately 90% of the population in LMICs are unable to access necessary surgical care[1]. Traditionally, the majority of public health efforts in LMICs have focused on communicable diseases or disease prevention, with limited attention paid to surgery, leading some to call it the "neglected stepchild of global health"[3,4]. This may have been attributable in part to the perception that surgical interventions are too expensive or complex for resource-limited settings. However, recent analyses have highlighted the heavy economic burden constituted by untreated surgical diseases and demonstrated that provision of surgical care is, in fact, a cost-effective intervention in LMICs[5,6]. Therefore, there are both compassionate and economic motivators to providing surgical care in under-resourced contexts.

The term 'global surgery' has grown from a recognition of these unmet needs, and can been applied to describe this multidisciplinary field of "study, research, practice, and advocacy that seeks to improve health outcomes and achieve health equity for all people who require surgical care, with a special emphasis on underserved populations and populations and crisis"[7]. Global surgery encompasses a breadth of specialties involved in provision of surgical care, and may

include multiple surgical specialties, obstetrics, anesthesia, nursing, radiology, and pathology[8]. Most definitions of global surgery do not limit its application to only LMICs, and further include under-resourced settings and vulnerable populations within high-income countries (HICs) as well. As well, global surgery is not restricted to the provision of individual surgical care; instead, it includes population-based strategies and international collaborations at a health systems level[7 8]. With a rising awareness of the substantial need for global surgery, the Lancet Commission on Global Surgery highlighted surgical diseases and concerns as priorities, increasing international efforts to improve the provision of surgical and anesthetic care in under-resourced settings[3]. The growing involvement of the international community in global surgery in recent years creates a timely opportunity to develop initiatives and strengthen health systems to meet the surgical needs of populations.

1.1.2 The Importance of Sustainability in Global Surgical Initiatives

The rapid growth of the field of global surgery has given rise to a number of practical and ethical concerns on how best to address inequitable access to care and build capacity to meet surgical needs. While global surgery traditionally is understood as healthcare professionals from high-income regions travelling to low-income regions to perform surgeries on a short-term basis, there is a lack of quality evidence to support the effectiveness of such initiatives[9-11]. While some studies claim to demonstrate cost-effectiveness of short-term surgical trips, these studies compared these surgical missions to no surgery; when compared instead to alternate platforms of delivery, short-term missions are much less likely to perform favourably from a cost-effectiveness standpoint[9]. In addition, short-term surgical trips are associated with unsatisfactory outcomes for complex

surgeries, negative impacts on patients' health-seeking behaviours, detriments to local healthcare infrastructure, and a failure to reach the patients at greatest need[9].

Instead, modern global surgery partnerships are increasingly placing an emphasis on sustainability, capacity-building, and long-term surgical delivery planning[12]. Rather than representing solely the provision of surgery by an individual surgeon, global surgery has come to represent a synthesis of both "population-based [and] individual surgical care" that takes place through "collaborative, cross-sectoral, and transnational approaches"[7]. The Lancet Commission on Global Surgery, the United Nations Sustainable Development Goals, and World Health Association Resolutions all recognize this need for population-based strategies and health systems strengthening, and advocate these as means to meet the significant surgical needs worldwide[1 13-15]. The development of sustainable health systems development is a necessity for progressing the field of global surgery.

1.1.3 The Significant Burden of Surgical Disease from Trauma

One of the most significant contributors to the burden of surgical disease worldwide is traumatic injury. An estimated 5.8 million people are killed by traumatic injuries annually, accounting for approximately 10% of global deaths[16 17]. This burden is disproportionately shouldered by LMICs where over 90% of the world's injury deaths occur[17]. Trauma also accounts for significant morbidity and economic costs. The worldwide cumulative GDP loss from traumatic injuries is estimated at $7.86 trillion USD, or approximately 37.9% of the GDP loss from all surgical diseases[5]. When disability-adjusted life years are considered, traumatic injury accounts for 17% of the global burden of disease, and rates of trauma are only predicted to continue to grow[16].

1.1.4 Sustainability of Trauma Registries in LMICs

As trauma represents a significant proportion of the global surgical disease burden, it is an area in which health systems strengthening and sustainability must be addressed in order to create lasting improvements[16]. One crucial means for bringing about quality and process improvement for trauma care systems in LMICs is through the development of trauma registries, or databases of anonymized trauma patient demographics, injury patterns, and outcomes[18]. Though many studies have demonstrated the feasibility of trauma registries at LMIC institutions, few have been able to sustain them long-term[19]. Yet in order to build capacity into local trauma care systems, creating trauma registries that can be self-sustained and implemented long-term should be a priority. The intent of this thesis is to examine the barriers to sustainability for trauma registries in low- and middle-income countries, and potential strategies for overcoming these barriers.

1.1.5 Trauma and Trauma Care Systems in Uganda

Uganda, a low-income country in East-Central Africa, was home to one of the first ever trauma registries in a LMIC which was established in 1999 in Kampala, Uganda[20]. Data from that trauma registry revealed that road traffic collisions were the largest source of injury morbidity and mortality in Kampala; other country-wide studies also identified road-traffic injuries as among the top ten causes of death in the country[20-22]. Over 18,000 road traffic collisions are reported by the Uganda Police each year, and this is considered likely to be an underestimate. The majority of these collisions involve are boda-bodas (motorcycles), commonly used because of their affordability[23 24]. Mortality from road traffic incidents is reported at 28.9 per 100,000 population in Uganda, far above the average African and global mortality rates[22]. In addition to high rates of

morbidity and mortality, trauma also has profound effects on economic health and quality of life in Uganda, such as an average 12-month income loss of 88% following an orthopedic injury[25].

A number of specific issues exist with trauma care in Uganda. To begin with, pre-hospital care is minimal, due to inadequate resources and unskilled first responders[22][26]. No formal pre-hospital emergency medical transport system exists, and patients are brought to hospital most commonly by police or by family members of bystanders by car, motorcycle, taxi, or on foot. Arrival at the hospital is often delayed for a significant proportion of patients, which can result in significantly decreased survival after injury[26]. A number of injured patients may not reach the hospital at all, given trauma registry data showing as many as 90% of patients arriving in hospital are only mildly injured, suggesting that more severely injured patients never access emergency care[20]. Once trauma patients arrive at hospital, a number of challenges for care delivery exist, including lack of space, patient overloading, scarcity of qualified health care professionals, and inadequate equipment[27]. One common issue identified is the lack of surgical repair for major orthopedic injuries; non-surgical healing results in a significantly longer length of stay, which drives up costs, further highlighting the need for better access to surgical care in this setting[25][27]. Ugandan government health facilities do not technically charge user fees, and instead rely on government allocation based on utilization; however, some health care providers surveyed found that government funding was inadequate to provide care to surgical patients and collaboration with international partners was necessary for provision of surgical care and education[27].

The development of sustainable trauma registries in Uganda represents a possible means for improving trauma care systems, as hospital-based trauma registries can provide valuable data for

trauma care improvement initiatives and track outcomes of care both in and out of hospital[28][29].

The studies in this thesis are based on a trauma registry at Mbarara Regional Referral Hospital

(MRRH) in Mbarara, a city of an estimated 200,000 people in Western Uganda. As district referral

hospital for the districts of Mbarara, Bushenyi, Ntungamo, Kiruhura, Ibanda, and Isingiro, MRRH

officially serves a population of approximately 2.25 million people[30]. It is a government-funded

public hospital with an official capacity of 600 beds, and is one of 15 internship hospitals in

Uganda, affiliated with the medical school at Mbarara University of Science and Technology

(MUST). A pilot trauma registry was first implemented here in 2016 in conjunction with

researchers from McMaster University in Canada, and data collection is still ongoing[31]. Two part-

time nurse data collectors were employed to collect data on all trauma patients seen at MRRH

(pediatric and adult) within 14 days of injury, and so far, data have been collected on over 3000

trauma patients (2016-2020). Data were initially collected on a two-page paper trauma registry

form (Figure 1.1) and then inputted at regular intervals by the nurse data collectors into a secure,

password encrypted server that is physically present in a locked office at MRRH. Data collectors

followed up with patients in the Accidents and Emergencies Department (A&E) as well as on the

surgical ward to identify patients who were seen or admitted overnight, and to complete 14-day

follow-up data for patients.

While the MRRH trauma registry has demonstrated initial successes, a number of barriers exist for

the sustainability of the registry going forward. The need for ongoing funding and local ownership

of the registry is the most pressing concern, as the trauma registry is currently supported by a mix

of international research grants and the support of a Canadian not-for-profit organization,

Innovative Canadians for Change (ICChange), but these funding sources are not likely to be

sustainable in the long term. This thesis will examine strategies for sustainability for the MRRH

trauma registry, creating solutions which can be applied to other trauma registries in LMICs and other low-income settings.

1.2 Summary

The growth of interest in global surgery necessitates a deeper understanding of ethical practice of global surgery and the development of sustainable, long-term initiatives. Trauma is a surgical disease of particular concern in LMICs due to its increasing prevalence and high rates of morbidity and mortality. The implementation of sustainable trauma registries in LMICs is an important first step of developing trauma care systems and improving outcomes for trauma patients in LMICs, though a number of barriers exist for maintaining these registries beyond the pilot phase. The development of trauma registries that build capacity into local trauma systems, grow out of equitable partnerships with LMIC institutions, and that can be sustained long-term for ongoing trauma care improvement in LMICs should be an ethical priority. This thesis aims to address challenges for sustainability of a local trauma registry in Mbarara, Uganda and can form a roadmap for sustainability and ethical development for other trauma registries in LMICs going forward.

1.3 Objectives

1) Gain insight into ethical considerations in the field of global surgery, and to identify gaps in the existing knowledge.

2) Review existing knowledge on the methods and processes for developing trauma registries in LMICs, including areas of controversy or uncertainty.

3) Utilize strategies for sustainability of trauma registries and incorporate feedback from local stakeholders to develop and evaluate a mobile application trauma registry; to demonstrate a means of evaluation for ease of usability for mobile application registries.

4) Demonstrate a means of financial self-sustainability for the Mbarara trauma registry by assessing the impact of linking a patient registration system with trauma registry implementation.

The first objective was met through a scoping review of ethical considerations in global surgery and identified domains and themes of important ethical considerations for participating in global surgical initiatives in the literature (Chapter 2). The second objective was met through a literature review of trauma registries in LMICs, including the practical and ethical considerations for establishing trauma registries and barriers for sustainability previously identified (Chapter 3). The third objective involved the introduction of a mobile application trauma registry at MRRH and the evaluation of the mobile application using a Unified Theory of Acceptance and Use of Technology questionnaire (UTAUT) (Chapter 4). The final objective was addressed through an interrupted time series study comparing the number of patients documented prior to the implementation of a trauma registry and patient registration system at MRRH to the number of patients documented following implementation (Chapter 5).

1.4 Figures

Trauma Registry Pilot – Mbarara Regional Referral Hospital

Study ID: _____

Hospital identification number: _____

Name: _____

Phone number: _____

District: _____

Village/town/city of residence: _____

Patient activity / event during time of injury:

Sex   ❑ Male   ❑ Female

Occupation

❑ Peasant farmer
❑ Housewife
❑ Civil servant / private employee
❑ Driver / conductor
❑ Casual laborer
❑ Large business owner

❑ Small business owner
❑ Student
❑ Child / baby
❑ Unemployed
❑ Other: _____

Place where injury occurred

District: _____

Village/town/city: _____

❑ Home
❑ Farm
❑ Industry
❑ Sport / recreation
❑ Road / street

❑ Public building
❑ School
❑ Other: _____

Time Sequence

Injury Date: _____ / _____ / _____
        Time: _____ am / pm

Patient's arrival date: _____ / _____ / _____
        Time: _____ am / pm

Healthcare provider arrival date: _____ / _____ / _____
        Time: _____ am / pm

Cause of injury

❑ Traffic accident
  ❑ Pedestrian
  ❑ Bicyclist
     Helmet: yes / no
  ❑ Motorcycle
     Helmet: yes / no
  ❑ Driver
     Restrained: yes / no
  ❑ Passenger
     Restrained: yes / no

❑ Unintentional fall
❑ Burn
❑ Gunshot
❑ Stab / cut
❑ Blunt injury
❑ Poisoning
❑ Animal bite
❑ Other: _____

Intent

❑ Intentional
  ❑ Self-inflicted
  ❑ Assault

❑ Unintentional
❑ Undetermined

Alcohol   ❑ Yes   ❑ No   ❑ Unknown

Other substances   ❑ Yes   ❑ No   ❑ Unknown

KTS

1. Age: _____ | KTS Total: _____
❑ 5-55 years   (2) | (Add points from items 1-5)
❑ <5 or >55 years (1)

2. Systolic pressure on admission
❑ >89 mmHg   (4)
❑ 50-89 mmHg   (3)
❑ 1-49 mmHg   (2)
❑ Undetectable   (1)

3. Neurological status
❑ Alert   (4)
❑ Responsive -verbal stimuli   (3)
❑ Responsive -painful stimuli   (2)
❑ Unresponsive   (1)

4. Respiratory rate on admission
❑ 10-29 / minute   (3)
❑ > 29 / minute   (2)
❑ < 10 / minute   (1)

5. Number of serious injuries
❑ Nil   (3)
❑ Single   (2)
❑ Multiple   (1)

Body areas with serious injuries
❑ Nil
❑ Head / neck / face
❑ Chest
❑ Spinal cord injury
❑ Abdomen / pelvis / peritoneum
❑ Bony pelvis and extremities

Pulse on admission
❑ Undetectable
❑ < 50 / min
❑ 51-120 / min
❑ 121-140 / min
❑ 141-160 / min
❑ >160 / min

Patient disposition
❑ Treated and sent home
❑ Admitted
❑ Died in casualty department
❑ Transferred to higher level facility
❑ Dead on arrival (DOA)

Had operation   ❑ Yes   ❑ No   ❑ Unknown

Two-week follow-up period
Please indicate for each day whether the patient: (1) was discharged, (2) died, (3) was still in the hospital, or (4) had run away.

Day 1:	Day 5:	Day 9:	Day 13:
Day 2:	Day 6:	Day 10:	Day 14:
Day 3:	Day 7:	Day 11:	
Day 4:	Day 8:	Day 12:	

Figure 1.1 Mbarara Regional Referral Hospital (MRRH) pilot trauma registry data collection forms. Initial pilot trauma registry data was collected on paper forms by two nurse researchers and then inputted to an online, data-encrypted, password-protected server.

CHAPTER 2: ETHICAL CONSIDERATIONS IN GLOBAL SURGERY: A SCOPING REVIEW

2.1 Introduction

Global surgery, the "enterprise of providing improved and equitable surgical care to the world's population", has garnered increasing attention over the last two decades[8]. A number of academic and policy developments, most significantly the Lancet Commission on Global Surgery, have drawn attention to the staggering burden of surgical disease harboured by low- and middle-income countries (LMICs). An estimated 5 billion people worldwide lack timely access to safe and affordable surgical care, and 143 million surgical procedures worldwide are required to make up this shortfall[1]. The international academic community has responded to this health care crisis with increasing participation in global surgical initiatives and collaborations, as evidenced by an increasing number of publications on the topic[32], the development of academic positions in global surgery[33], the growth of formalized education programs in international surgery[34], and the recognition of international surgical electives by the Accreditation Council for Graduate Medical Education (ACGME)[35]. Despite this growing attention to the field of global surgery, little has been published to critique or guide the ethics of global surgical endeavours.

While history has shown a preponderance of short-term medical service trips for participants from high-income countries to travel to low-income countries, there is a lack of quality evidence to

support the effectiveness of these initiatives[10]. Furthermore, global health has been moving instead towards a focus on sustainability through bilateral educational exchanges, reciprocal partnerships, and systems-level interventions[11]. It follows then, that global surgery should also be evaluated and conducted in a manner that ensures sustainability and an appropriate transfer of knowledge and skill. However, little is known about the ethics of transnational global surgical endeavours and whether they differ significantly from ethical considerations in a broader global health discourse. Part of this evaluation includes understanding and addressing the ethical challenges that may be unique to global surgery. The overall aim of this scoping review is to synthesize the existing literature related to ethical challenges and considerations in global surgical partnerships involving high-income countries (HICs) and LMICs. The literature has been analyzed for its thematic content and gaps in the literature identified. This analysis provides insights into the ethical issues that may be encountered in global surgical partnerships and may serve as a springboard for the future development of an ethical framework to guide the field of global surgery as it matures.

2.2 Methods

The framework for scoping reviews developed by Arksey and O'Malley[36] was used to conduct this review. This framework consists of five stages: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) data charting, and (5) collating, summarizing, and reporting the results. This method was chosen because it allows for a broad assessment of the available literature, easy replication of the search strategy, transparency through the process, and good reliability of the study findings. Each step is described in further detail below.

2.2.1 Identifying the Research Question

This scoping review focussed on mapping the available literature that pertains to ethical principles in global surgery. The study question was: What are the ethical considerations reported in the current literature to guide the practice of global surgery?

2.2.2 Identifying Relevant Studies

To identify relevant studies, a systematic search of the following databases was conducted: PubMed, MEDLINE, Embase, CINAHL, Web of Science, and the Cochrane Library. No restrictions were placed on date, but studies were restricted to the English language. A wide definition of key words was used to identify a broad range of articles for potential inclusion. Medical Subject Headings (Mesh) used were: Ethics, Morals, Specialties Surgical, Developing Country, and Global Health. Mesh terms used varied slightly depending on the database being queried. Keywords used included: 'global surger*', 'global health', 'low and middle income countr*', 'lmic', 'ethic*', 'moral*', and 'developing countr*'. A hand search of the reference lists of identified articles was also undertaken. No restrictions were placed on publication type. A full example of the search strategy is available in Supplementary File 1.

2.2.3 Study Selection

A total of 4865 references were identified from the six databases searched in November 2018. After the removal of duplicates (1542), 3353 studies were screened. Screening was completed in two stages: (1) screening by title and/or abstract and (2) full-text screening. Two reviewers screened records at each stage, with a third resolving conflicts. Studies describing general medical ethics without a surgical context, lacking a global perspective, and those focusing on strictly

military or humanitarian crisis medicine were excluded. Studies were also excluded if they focused on advanced reproductive technologies, female genital mutilation, abortion, and transplant tourism. Articles were included if they addressed one or more ethical considerations within the context of global surgery. When deciding which articles to exclude, an effort was made to focus on ethical issues pertaining to the practice of global surgery itself. The exclusion list does contain major issues of ethical concern, but the ethical considerations involved are much broader than the practice of global surgery and would require a level of ethical analysis that is outside the scope of this project. A repeat search was run in August 2019 to include studies published between October 2018 and August 2019 prior to manuscript submission, which identified an additional 512 studies. After removal of duplicates of this repeat search, 265 studies were added to screening for a total of 3618 studies screened.

2.2.4 Charting the Data

A standard set of information was then collected from each of the studies identified for inclusion using a data charting form created for this review in Microsoft Excel (Microsoft, Santa Rosa, CA, USA; 2016). The country of study origin and type of publication were recorded. Information pertaining to ethical considerations and issues in global surgery was extracted from the studies.

2.2.5 Collating, Summarizing, and Reporting the Results

After data extraction, results were summarized and are reported in Section 3. The grounded theory approach reported by Strauss and Corbin was used to analyze the ethical content of all included studies[37]. Open coding was used to identify abstract concepts reported in the literature and attempts made to group them first into emerging themes and then into categories and sub-

categories. As this was a non-linear analysis process, articles were then re-examined to confirm that no codes or themes initially identified were missed and that saturation was achieved. The results of the content analysis have been represented in tables and charts.

2.2.6 Patient and Public Involvement

As this research represents a review of previously published literature rather than clinical research, patients were not directly involved in the design, conduct, assessment, or dissemination of this study.

2.3 Results

2.3.1 Descriptive Analysis

The search yielded 5407 studies. After the removal of duplicates and screening the titles and abstracts for relevance, a total of 238 full-text articles were reviewed for inclusion. Of those, 55 were included in the final analysis. This is summarised in the PRISMA chart (Figure 2.1)[38]. Included articles were published between 2005 and 2019 (Table 2.1).

Of the 55 articles included, the vast majority (70.9%) were published by authors affiliated with academic institutions in the United States of America (USA), followed by Canada (12.7%) and countries of the United Kingdom (UK) (9.1%). When assessed by country income level as defined by the World Bank, 80% of publications were published exclusively by authors from HICs. There were 4 studies with exclusively LMIC authorship listed, and 7 collaborations between HIC and LMIC authors (Figure 2.2). Most articles were commentaries or editorials (38, or 69.1%) and only seven (12.7%) were original research studies (Figure 2.3). The majority of studies (34, or 61.8%)

did not specify which LMIC country the study took place in or which LMIC partners were involved, or they reflected only hypothetical case studies.

2.3.2 Emerging Domains

Content analysis identified four major domains in the literature on the ethics of global surgery: 1) the ethics of clinical care and delivery; 2) ethics of education, exchange of trainees, and certification; 3) ethics of research, monitoring, and evaluation; and 4) ethics of engagement and collaboration in partnerships. Most of the literature framed these topics with considerations that related primarily to a visiting surgical team or practitioner (typically from a HIC) and those that related to a hosting surgical team or practitioner (typically from an LMIC). The four domains are described below in greater detail and summarized in Table 2.2.

2.3.2.1 Clinical Care and Delivery

One of the most prominently reported domains identified in the literature involved the ethics of delivering clinical care in global surgery (n=49 papers). This term was used to describe ethical considerations relating directly to patient care in global surgery.

The domain of clinical care and delivery predominantly identified the issues of cultural awareness, disclosure, and informed consent as ethical concerns[33 39-70]. Authors reported that language barriers, cultural differences, or disparate interpretations of patient autonomy could lead to ethical distress over informed consent and ethical disclosure for surgical practitioners in unfamiliar environments. Another frequently identified theme in the included articles was variations in standard of care in different locations and the preparedness of global surgical practitioners to practice in low-resource

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settings[39-44 46 47 49 50 53-55 59 60 64 66-76]. This theme included considerations on whether or not it was ethical to accept a perceived lower standard of care due to resource limitations, the problems caused by visiting teams being unprepared to perform surgery in resource-limited settings, and questions of whether or not to perform procedures outside of a visiting surgical practitioner's usual scope of practice when considering patients' limited access to care.

In the literature, global surgical initiatives also created ethical conflicts by exhausting local resources, typically by focusing on or prioritizing a single type of operation or specialty at the expense of other types of surgeries happening in that hospital[40 44 45 47 49-52 68 72 77-80]. Ethical concerns were also identified in the setting of short-term surgical trips failing to plan for adequate post-operative care and follow-up care for patients[39 41 42 44-47 51 52 54 56 57 59-64 66-70 72 75 78 81-84]. Finally, the ethical and equitable distribution of limited resources in regards to selection of patients, procedures, or hosting communities was also commonly reported as an area of moral distress in global surgery[40 44-47 50-54 58-60 63 64 67 68 75 79-81 84-86].

2.3.2.2 Education, Exchange of Trainees, and Certification

The next domain identified in the literature on the ethics of global surgery was that of education, exchange of trainees, and issues relating to certification (n=32). The literature emphasized the value of teaching and transferring knowledge to LMIC communities, with ethical standards not being met when global surgical endeavours failed to prioritize education and knowledge transfer [33 39 40 43 44 46 47 52-54 57 59 60 64 66 68 76 78-83]. In some cases, educational initiatives were attempted, but knowledge and skills passed on were not relevant for LMIC settings (for example, if the resources required to

perform a procedure were not readily available, then educating on such a procedure was futile)[46 47 50 52 57 77 86].

Other ethical issues in education focused on the exchange of medical students or surgical trainees. This typically focused on visiting trainees from HICs travelling to LMICs for electives or observerships in global surgery. The adequacy of preparation of these visiting surgical trainees was an important ethical consideration identified, including a lack of familiarity with medical conditions frequently encountered in their host community, as well as the social, cultural, and linguistic challenges that trainees encountered in these unfamiliar environments[33 39 44 47 54 62 74 76 87-89]. The level of supervision of visiting trainees may have differed relative to their home training environment, resulting in moral distress for the visiting surgical trainee over the safe care of patients[39 42 44 54 55 59 62 74 76 85 87-89]. Furthermore, the literature identified that trainees from HICs travelling to LMICs may impact local education programs by taking away surgical experience from local trainees whose education would be more likely to benefit the local community[44 47 57 77 85]. There were also concerns of equity in global surgical training exchanges: while overseas training opportunities may be easily available for surgical trainees from HICs, reciprocal opportunities for trainees from LMICs are rarely available[40 47 57 78 85]. Finally, the ethics of exchange of trainees is further complicated by the issue of human capital flight, or the "brain drain" effect. The emigration of surgical trainees away from LMICs can further deplete resources in already resource-limited settings[40 44 47 57 62 81 86 90].

2.3.2.3 Research, Monitoring, and Evaluation

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The third domain identified, the ethics of research, monitoring, and evaluation in global surgery, was relatively underreported domain in the literature (n=17). This domain was used to describe all literature pertaining to surgical research initiatives in or concerning LMICs, surgical innovation, monitoring of outcomes, and formal evaluation processes for global surgical endeavours. The literature that did discuss this topic placed an emphasis on the necessity for equitable research partnerships between host and visiting communities, including equal opportunities for authorship [33] [44 46 47 49 57 59 62 77]. The literature also recommended that efforts should be made to obtain formal research ethics approval from all involved partner institutions prior to embarking upon surgical research[44 46 49 66 69 91 92]. Some suggested that if formal ethics review boards did not exist at the planned site of research, efforts should be made to help create an ethics review board and develop research capacity for that institution; if this could not be accomplished, the research should not be undertaken[44 66 91].

Ethical concerns were also identified with the potential for surgical research to exploit vulnerable populations and a failure to obtain adequate informed consent in light of these vulnerabilities[47 66 69] [91 92]. The available published literature also suggested that ethical global surgical research needed to be relevant and likely to benefit to the host communities to further protect against ethical violations[33 77 91 92].

A deficiency in monitoring and evaluation of surgical outcomes was identified by several articles. It was noted, however, that monitoring of surgical outcomes should be made "mandatory in order to prevent inadvertent harm [and] the exploitation of patients for goals other than their own

welfare"[68]. Monitoring was viewed as necessary for the process and quality improvement required to improve global surgical care in resource-limited settings[44 46 47 49 59 61 64-66 70].

2.3.2.4 Engagement in Collaboration and Partnerships

The engagement of global surgery practitioners and institutions in the creation of long-term sustainable partnerships and collaborations was seen as a priority by several of the articles referenced (n=30). Details on how to best accomplish ethical collaborations, however, were often sparse. The literature reviewed proposed that successful partnerships should be equitable, reciprocal, and long-term, with the intent of creating sustainability so an eventual transition of care back to the host institution can take place. Yet a lack of capacity building and failure to plan for long-term sustainability was referenced by several articles as an ethical concern with many global surgical initiatives[33 39-42 44-47 50 52 54 57-59 64-66 69 71 76 82 90]. Even when partnerships were created with the intent of introducing sustainability, there was often a failure to adequately consult and include LMIC communities and institutions in collaborations[44 47 57 58]. The literature was not specific enough to evaluate whether the examples of partnerships discussed reflected singular short-term missions, recurrent occurrences, or long-term collaborations.

Ethical considerations also arose regarding the donation of materials, supplies, and funding[40 44-47 49-53 58 62 77 78 84]. In some cases, concerns were identified with material and financial donations that were expired, inappropriate, unhelpful, or not cost-effective for the setting to which they were donated. Other articles discussed conflicts of interest or corruption that influenced how, when, and where donations are made. Finally, concerns were raised that donations to LMIC institutions could

contribute to a reliance on external aid sources and undermine local supply chains, acting as a hindrance to capacity-building and sustainability in the long run[39 49 59 64 90].

2.4 Discussion

The goal of this scoping review was to provide an understanding of the current ethical landscape associated with global surgery. Four discrete domains were identified as important pillars of global surgical activity requiring ethical consideration. These were: clinical care and delivery; education, exchange of trainees, and certification; research, monitoring, and evaluation; and engagement in partnerships and collaborations. Our review demonstrated that the domain of clinical care and delivery was over-represented relative to the other domains, with the majority of the literature focused on the clinical ethics of individual patient-doctor relationships. There was also a dearth of original research (most of the literature was in the form of commentaries or editorials), and a reporting bias from HICs, specifically the United States. The literature tended to disclose its own issues of bias and recommended increased reporting from the perspective from LMICs.

The focus on direct patient care in global surgery ethics comes as no surprise. The majority of global surgery initiatives still take the form of short-term surgical missions, with the primary goal of delivering surgical service, and most of the literature reflected this. Additionally, physicians and surgeons are well-oriented to the supreme importance of the doctor-patient relationship and have a firm grasp of classic biomedical ethics principles of autonomy, beneficence, non-maleficence, and justice that affect particularly the domain of clinical care and delivery. Unfortunately, in the complex arena of global surgery, focusing on individual patient care at the

expense of system level change and limiting ethical discussion to a single ethical framework will likely fall short in producing a sustainable ethical solution.

All four domains identified in the literature need to be addressed when considering global surgical initiatives, with collaboration and partnership forming the foundation. The reporting bias from HICs betrays a lack of collaboration and true partnership with LMIC institutions reflected in many initiatives. This neglect of equitable and sustainable partnerships has echoes of neo-colonialism that must be abandoned if we are to achieve an ethical solution that respects and upholds the unique cultures, beliefs, and priorities of LMIC partners. Once an equitable partnership is established, all other domains can be incorporated into a long-term sustainable plan that is consistently informed by ongoing monitoring and evaluation.

It is also likely that additional domains exist that are not recognised in the current literature. Potential domains identified independently by the authors include the ethics of the impact of global surgery on the local economy and on the environment. In the literature reviewed, only Fenton *et al*, 2019[79] identified environmental concerns as a potential ethical issue in global surgery. With a more balanced discussion including input from LMIC partners, it is likely that further domains would be uncovered and emphasized. The authors would purport that these domains, though not directly related to patient care, are essential to consider as potential bystander casualties in global surgical initiatives. This speaks to the importance of widening the ethical framework from biomedical ethics alone to the addition of relational, business, and environmental ethics.

2.5 Limitations and Future Directions

The use of grounded theory as a method for analyzing data is not without controversy. While a comprehensive explication of the method is not possible within the confines of this scoping review, it is important to highlight some of concerns associated with this approach. Theorized as a purely inductive approach at its inception[93], some grounded theorists argue for a truly emergent process of category construction from the data. In this more idealist approach, the standpoint of the researcher is not influenced by preconceived notions of the conceptual structure that will evolve. One can argue that this neutral perspective is not only difficult to achieve; it is also perhaps not even the most desirable because it would seem to require that new knowledge emerges in isolation from the broader conceptual network it is in fact grounded in[94][95]. It is important to understand that isolationism is unlikely to be realized and thus, it is critical to address the perspectives that are present and missing in a grounded theory approach.

These considerations are of particular importance to a scoping review such as the one undertaken by these authors; the data and the domains that emerge are derived largely from the perspective of HICs. The interpretation of the data and the thematic analysis was also undertaken by researchers situated within a HIC, some of whom are also engaged in the practice of global surgery. This perspectivism does not necessarily entail that the results are false, but rather that they should be interpreted with both caution and an openness to being interrogated for their veracity. The authors of this study recognize the limitations inherent in this grounded theory approach to the extant literature.

The results of this scoping review highlight these significant gaps in the literature. In an attempt to mitigate these weaknesses and build on the strengths, the results of this scoping review should be used to inform a broader ethical framework of global surgery. The creation of an ethical framework will require a more extensive, iterative process, involving multinational stakeholders, with the specific aim of addressing the perspectives of LMIC partners to assess the internal and external validity of these identified domains. Given the identified gaps, it is anticipated that the identified domains will evolve and that new domains may emerge through this process.

In recognizing that international collaborations can bring differing worldviews together, future work will need to be undertaken to inform the ethical foundations of global surgery. Currently, the discourse itself is heavily influenced by HIC ethical principles. This influence may not capture and pay adequate respect to the diversity of values that can inform ethical obligations and the principles that are meant to express them. For example, traditional medical ethics dominated by European and North American discourse typically emphasizes autonomy and the individual, and this may not necessarily be sufficient for practice in low-resource settings, where an emphasis on the common good or community-focused public health ethics may predominate[96]. Even apparent similarities in how these ethical principles are expressed need to be explored for the meanings that underlie them. Future work needs to consider the importance of building a dialogue that explores and discovers shared values and meanings; work that will seek a common moral grounding for interactions with patients, between teams, and within the broader community of stakeholders who are impacted by global surgery.

2.6 Conclusion

As the arena of global surgery continues to mature it must also become self-reflective. This literature review demonstrates that the academic surgical community has identified the importance of ethics in global surgery and concedes that the best ethical standards and practices are not always realized. In this setting, ethical practice extends beyond individual patient care to encompass education, partnership and collaboration, and research. A notable gap in the literature was found in the paucity of reporting from LMIC institutions. This perhaps illustrates the crux of the issue with ethics: ethical and equitable solutions cannot be achieved unless and until all stakeholders are present at the table. Given that LMICs are frequently the recipients of global surgical initiatives, the relative absence of their voice in the literature reviewed is a substantive deficiency that requires urgent attention. Any attempt to address the ethical considerations that arise in these collaborations must take into account the perspectives and experiences of the LMIC participants. The lack of original research is a concern, not because ethical principles are empirically derived, but because global surgical ethics should be informed by the experiences of the patients, families, and communities that these surgical missions are meant to serve. Similarly, because addressing the disparity in access to the benefits of surgery worldwide requires sustainable, collaborative partnerships to be established, the limited attention in the literature to the ethics of these partnerships in the delivery of surgical care is another gap that requires focused attention. Without meaningful stakeholder input into the current ethical discourse it is likely that domains of concern, and the broader range of perspectives required to inform them, are missing. The authors hope that this literature review will stimulate more primary research in this field of study with more equitable representation from LMIC partners.

2.7 Tables

Table 2.1. Summary of literature included in scoping review and domains identified in each article

FIRST AUTHOR, YEAR [REFERENCE NUMBER]	COUNTRIES	TYPE OF PUBLICATION	DOMAINS REFERENCED IN EACH ARTICLE (bullet point [•] indicates a theme identified in that article)			
			Clinical Care & Delivery	Education, Exchange of Trainees, & Certification	Research, Monitoring, & Evaluation	Engagement in Collaborations & Partnerships
Ahmed, 2017[39]	United Kingdom (UK)	Commentary/editorial	•	•		•
Aliu, 2014[71]	United States of America (USA)	Original Research	•			•
Almeida, 2018[40]	Canada Spain	Original Research	•	•		•
American College of Obstetricians and Gynecologists (ACOG), 2010[41]	USA	Committee Opinion	•	•		•
ACOG, 2018[42]	USA	Committee Opinion	•	•		•
Berkley, 2019[85]	USA	Commentary/editorial	•	•		
Bernstein, 2004[43]	Canada	Commentary/editorial	•	•		
Butler, 2016[44]	USA	Suggested Guidelines with Commentary	•	•	•	•
Coors, 2015[45]	USA	Original Research	•			•
Cordes, 2018[46]	USA	Commentary/editorial	•	•	•	•
Cunningham/, 2019[47]	Nigeria USA	Commentary/editorial	•	•	•	•
Dunin De Skyrzzno, 2018[48]	Burundi UK	Commentary/editorial	•			
Elobu, 2014[77]	Uganda	Original Research	•	•	•	•
Erickson, 2013[78]	USA	Commentary/editorial	•	•		•
Eyal 2014[86]	USA	Commentary/editorial	•	•		
Fallah, 2018[72]	Canada USA	Original Research	•			
Fenton, 2019[79]	USA	Commentary/editorial	•			
Ferrada, 2017[73]	USA	Commentary/editorial	•			
Gishen, 2015[87]	USA	Commentary/editorial		•		
Hardcastle, 2008[88]	South Africa	Commentary/editorial		•		
Harris, 2019[49]	USA	Commentary/editorial	•		•	•
Howe, 2014[80]	USA	Commentary/editorial	•	•		
Howe, 2013[50]	Canada Nigeria	Commentary/editorial	•	•		•
Hughes, 2013[51]	USA	Commentary/editorial	•			•
Ibrahim, 2015[52]	Canada	Commentary/editorial	•	•		•
Isaacson, 2010[53]	USA	Commentary/editorial	•	•		•
Jesus, 2010[54]	USA	Commentary/editorial	•	•		•
Kingham, 2009[55]	USA	Commentary/editorial	•	•		•
Klar, 2018[90]	Canada	Commentary/editorial		•		•
Krishnaswami, 2018[33]	USA	Commentary/editorial	•	•	•	•
Martin, 2014[56]	USA	Original Research	•			
Mock, 2018[57]	USA	Commentary/editorial	•	•	•	•
Mohan, 2018[74]	UK	Committee Opinion	•	•		
Nguah, 2014[81]	Ghana	Commentary/editorial	•			
Nouvet, 2018[82]	UK	Original Research	•			•

Ott, 2011[58]	USA	Commentary/editorial	•			•
Pean, 2019[59]	Haiti USA	Commentary and Suggested Guidelines	•	•	•	•
Precious, 2014[60]	USA	Commentary/editorial	•	•		
Ramsey, 2007[89]	Canada	Commentary/editorial		•		
Sahuquillo, 2014[91]	Spain Uruguay	Commentary/editorial			•	
Selim, 2014[83]	USA	Commentary/editorial	•	•		
Sheth, 2015[61]	USA	Commentary/editorial	•		•	
Small, 2014[75]	USA	Commentary/editorial	•			
Steyn, 2019[62]	South Africa	Commentary/editorial	•	•	•	•
Swendseid, 2019[84]	Haiti USA	Commentary/editorial	•			•
Thiagarajan, 2014[63]	USA	Commentary/editorial	•			
Wall, 2014[64]	USA	Commentary/editorial	•	•	•	•
Wall, 2013[92]	USA	Commentary/Editorial and Case study			•	
Wall, 2005[70]	USA	Commentary/Editorial	•		•	•
Wall, 2007[69]	USA	Commentary/Editorial	•	•	•	•
Wall, 2011[65]	USA	Commentary/Editorial	•			
Wall, 2008[68]	USA	Case Study	•			
Wall, 2006[67]	Ghana USA	Commentary and Suggested Guidelines	•		•	•
Wall, 2008[66]	Kenya Nigeria USA	Suggested Guidelines	•		•	
Wright et al, 2018[76]	UK	Symposium	•	•		•
Total number of articles referencing each domain:			**49**	**32**	**17**	**30**

Table 2.2. Summary of domains and themes identified in the ethics of global surgery

DOMAIN 1: CLINICAL CARE AND DELIVERY
Potential exhaustion of local resources: Local resources (human and material) may be diverted from more dire basic needs to less urgent, surgical missions[40 44 45 47 49-52 68 72 77-80]
Continuity of care and follow-up: Long-term follow-up plans for patient care should be accounted for in global surgical undertakings [39 41 42 44-47 51 52 54 56 57 59-64 66-70 72 75 78 81-84].
Patient, procedure, and location selection: Opportunities for access to surgical missions are not always equitable; patient and procedure selection can be ethically fraught in light of limited resources[40 44-47 50-54 58-60 63 64 67 68 75 79-81 84-86].
Variations in standard of care and preparedness of global surgical practitioners: Global surgical procedures may be performed outside of scope of training and can result in compromised quality of patient care; limited resources available to manage complex surgical diseases can lead to variations in standards of care[39-44 46 47 49 50 53-55 59 60 64 66-76]
Cultural awareness, disclosure, and informed consent

Visiting practitioners may be unaccustomed to cultural, social, religious, and linguistic differences of the hosting community; challenges with ethical informed consent and disclosure may exist in unfamiliar environments [33 39-70]

DOMAIN 2: EDUCATION, EXCHANGE OF TRAINEES, AND CERTIFICATION

Non-transference of knowledge:

Global surgical endeavours may fail to include an educational component for transferring knowledge (clinical, structural, or otherwise) or skills to LMIC communities [33 39 40 43 44 46 47 52-54 57 59 60 64 66 68 76 78-83]

Relevance of educational activities:

Knowledge or skills taught may be not relevant to host communities or require resources not readily available rendering them futile [46 47 50 52 57 77 86]

Level of visiting trainee supervision:

Visiting surgical trainees may be requested to work in settings of limited supervision which may be inappropriate for their skill level [39 42 44 54 55 59 62 74 76 85 87-89]

Preparedness of trainees to work in host communities:

Visiting trainees may be unfamiliar with surgical diseases or presentations in hosting communities and their added complexity; visiting trainees may lack insight or preparedness to deal with cultural and linguistic challenges in unfamiliar environments [33 39 44 47 54 62 74 76 87-89]

Impact of visiting trainees on local educational programs:

The presence of visiting global surgical trainees may detract from learning opportunities for local trainees [44 47 57 77 85]

Reciprocity of global surgical training programs:

Overseas training opportunities may be frequently available for HIC surgical trainees, but bidirectional exchanges or similar opportunities for LMIC trainees are not as frequently available [40 47 57 78 85]

Human capital flight:

Emigration of trainees away from LMICs may result in "brain drain" and a loss of healthcare providers in those regions [40 44 47 57 62 81 86 90]

DOMAIN 3: RESEARCH, MONITORING, AND EVALUATION

Involving and crediting researchers from LMICs in collaborative research:

Global surgical research activities may neglect to involve researchers from local communities where research occurs; or researchers from LMIC may not be adequately credited or involved in publication in global surgical research partnerships [33 44 46 47 49 57 59 62 77]

Obligations for institutional ethics review:

Formal research ethics approval from both host and visitor's institutions should be obtained for global surgical research; if institutional ethics review boards are not available in an LMIC setting, consideration should be given to helping develop research capacity [44 46 49 66 69 91 92]

Relevance of research activities:

Research performed in LMICs may be done for the benefit of another external population and may be unlikely to benefit local populations [33 77 91 92]

Protection of vulnerable populations in research:

Global surgical research may involve vulnerable populations that are susceptible to exploitation for personal, financial, or academic gain; research activities in LMICs present with challenges to informed consent and disclosure as patients may be vulnerable or lack viable alternatives to care[47 66 69 91 92]

Monitoring of surgical outcomes:

Global surgical endeavours may fail to monitor and study post-operative complications and surgical outcomes for ongoing quality and process improvement[44 46 47 49 59 61 64-66 70]

DOMAIN 4: ENGAGEMENT IN COLLABORATIONS AND PARTNERSHIPS

Sustainability in global surgical collaborations:

Global surgical collaborations and partnerships may lack capacity building or fail to plan for sustainability and long-term results[33 39-42 44-47 50 52 54 57-59 64-66 69 71 76 82 90]

Involvement of local communities in collaborative partnerships:

Partnerships may fail to adequately involve the hosting institution in planning and coordinating for collaborative efforts[44 47 57 58]

Donation of funds and materials:

Donated funds/materials may be inappropriate, unhelpful, expired, or not cost-effective. Conflicts of interest or corruption may influence the donation of funds or materials[40 44-47 49-53 58 62 77 78 84]

Potential dependence on external donations:

Donations of material or financial aid may undermine local supply chains or result in dependence on external aid sources[39 49 59 64 90]

2.8 Figures
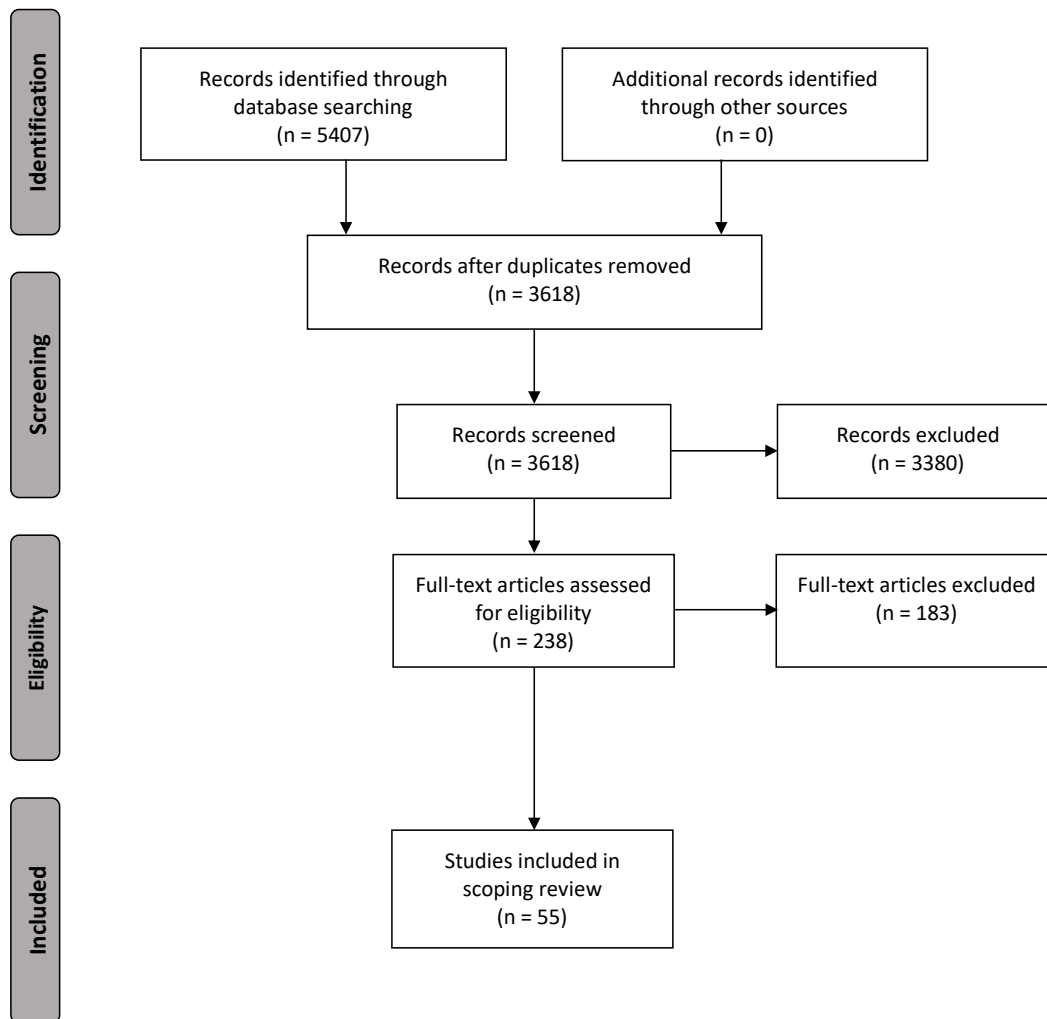
Figure 2.1. PRISMA 2009 flow diagram[38]
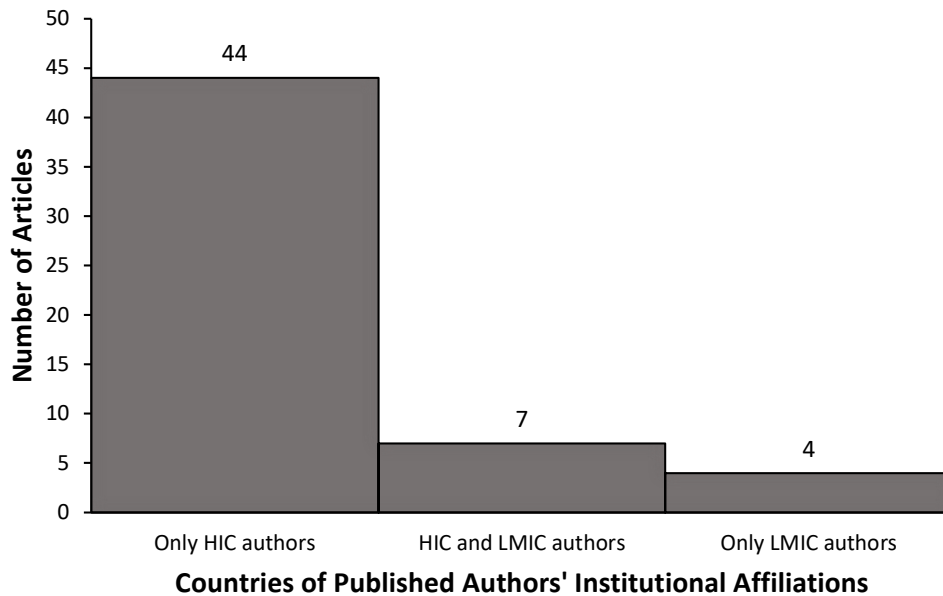
Figure 2.2. Number of articles per country of published author's institutional affiliations, organized by income level as defined by the World Bank Atlas Method (HIC, high-income country; LMIC, low-income and middle-income country)
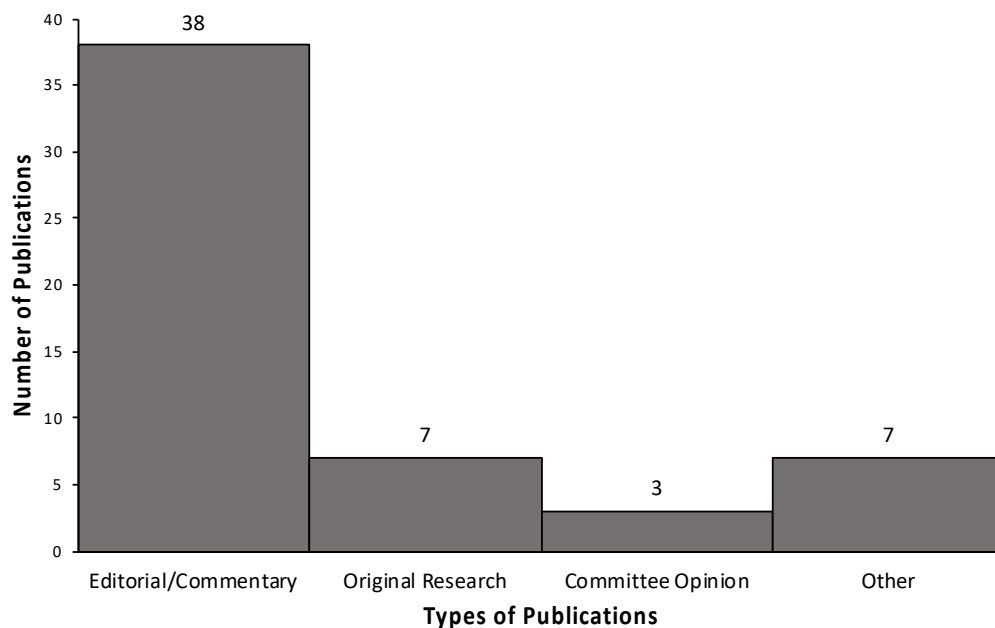
Figure 2.3. Number of each type of publication identified in this scoping review on ethical considerations in global surgery.

CHAPTER 3: SUSTAINABLE AND ETHICAL DEVELOPMENT OF TRAUMA REGISTRIES IN LOW- AND MIDDLE-INCOME COUNTRIES

In preparation for submission as: Grant CL, Bigam D, Saleh A. Sustainable and ethical development of trauma registries in low- and middle-income countries.

3.1 Background

3.1.1 The Burden of Traumatic Injury in Low- and Middle-Income Countries

Trauma is a surgical disease that comprises a significant source of global morbidity and mortality. Worldwide, 5.8 million people annually die of traumatic injuries, accounting for 10% of global deaths[16][17]. LMICs shoulder a disproportionate burden of mortality from trauma: over 90% of the world's injury deaths occur in an LMIC[17]. For adults with life-threatening but potentially survivable injuries, mortality in low-income settings is 36%, compared to only 6% in their high-income counterparts[97]. Trauma also accounts for significant morbidity and economic costs, accounting for 17% of the global burden of disease when disability-adjusted life years are considered, and estimated annual costs of $7.86 trillion USD worldwide[5][16]. This burden of traumatic injury is predicted to continue to grow[16]. Road traffic crashes, in particular, are a major public health concern, resulting in more than 1.3 million deaths and 50 million people disabled annually[98]. Over 90% of road traffic injuries occur in LMICs, despite LMICs only accounting for 54% of the world's motor vehicle ownership[98]. As motor vehicle ownership continues to increase in LMICs, road traffic injuries are also projected to increase, and are estimated to be the fifth leading cause of death worldwide by 2030[16]. Road traffic injuries also account for a significant economic cost, estimated at $518 billion United States Dollars (USD) globally and up to 5% of the gross national product in some LMICs[16]. The significant economic burden of trauma and the

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detriments to health and well-being that it poses to injury victims, their families, and their communities is a serious public health concern.

3.1.2 Trauma Care Systems and Trauma Registries as Public Health Priorities for Improving Trauma Care in Low- and Middle-Income Countries

Though primary prevention of injuries is a critical priority worldwide, it is also important to examine the disparities in outcomes between high-income countries (HICs) and LMICs once injuries have occurred. One important contributor to the disparity in outcomes between HICs and LMICs that has been identified is the lack of well-developed trauma care systems in LMICs[99]. Trauma care systems are organizational structures within a defined geographic area that encompass trauma prevention, response, and treatment and integration into the local health system. Trauma care systems have well-documented benefits: severely injured patients treated at designated trauma centres within organized trauma care systems have demonstrated estimated mortality reductions of 15-25% compared to patients who were not treated in organized trauma care systems[100-103]. Notably, these improvements in outcomes from improved trauma care systems may not be seen until 10-16 years after enactment[97]. Mature trauma systems are typically found in HICs but are absent in most LMICs[104]. In addition to improved mortality, effective trauma care systems with quality improvement initiatives have been shown to contribute to improved morbidity, reduced time to interventions, decreased length of stay, and a cost savings of more than $4,000 USD per patient in developed countries[28,105]. Implementation of trauma care systems is therefore an area of focus for improving trauma care worldwide and helping mitigate disparity in outcomes between high and low-income countries; it has been estimated that the implementation of trauma care systems worldwide could prevent about one-third of injury deaths[17,97].

An essential first step for developing the capacity of trauma systems in LMIC is the systematic collection and evaluation of injury data through the means of a trauma registry[106]. Trauma registries are repositories of prospectively collected and anonymized trauma patient data used for quality improvement, including epidemiologic, process, and outcome data[18]. However, there is great variability in structure and implementation of trauma registries, even in highly developed countries. The purpose of a registry differs from that of electronic health records (EHRs), which exist to collect clinical health care data for an individual. However, it is also possible to create electronic systems where EHRs and registries are interoperable[107]. Typically, trauma registries collect data that is not routinely available from hospital admissions or emergency department data collections, and they can include anonymized information on patient demographics, types of injuries, injury mechanism and severity, and patient outcomes[108 109]. Datasets vary between trauma registries and must be carefully selected and validated: too little information and the data loses value, too much information and the collection of data becomes too time-consuming and expensive. Varying inclusion and exclusion criteria between trauma registries may lead to significant differences in reported outcomes[29]. Trauma registries may also differ in regards to funding sources (government-funded or hospital-funded among the most common), methods of data collection and storage (paper-based or electronic), population sizes and registry sizes, administration and governance, data collectors (for example, dedicated trauma registry staff or other clinical personnel), injury severity scoring measures, and whether they incorporate data from single-sites or multiple sites[18 110]. In general, the requirements for implementing a trauma registry included adequate and dependable funding, software and physical resources, trained personnel, well-defined inclusion and exclusion criteria, and processes for data collection, reporting, and validation[29 111].

As a critical component of established trauma care systems, trauma registries provide invaluable information for hospital quality improvement and assurance, research, education, and resource allocation[17]. Though it can be difficult to directly demonstrate mortality benefits of trauma registries, a study by Hashmi *et al* demonstrated an 80% reduction in odds of death and 62% reduction in odds of complications for trauma patients following the implementation of a trauma registry in a LMIC hospital and subsequent quality improvement initiatives[28]. Evidence for improved mortality with trauma registries has also been documented indirectly in HICs, though it is difficult to distinguish the effects of a trauma registry itself on outcomes from the effects of trauma care systems as a whole[99 103 112].

Trauma registries have uses beyond in-hospital trauma care improvement; some track geographic distributions of injury, causes of injury, and factors contributing to injury outcomes, and in some cases they can capture the results of trauma care system interventions made out of hospital[29]. Data from trauma registries has been used to help prevent injury and improve pre-hospital care—including, for example, public health initiatives by Mothers Against Drunk Driving (MADD) and the validation of the concept of the rapid transport of injury victims in trauma care, known as "scoop and run"[99]. Trauma registries have an important role to play in research for generating new hypotheses or monitoring effectiveness of public health interventions in trauma, and successful trauma registries help institutions to grow their datasets for publication and clinical care guidelines[99 113]. For example, a Canadian trauma registry has helped to inform safety standards and legislation on numerous topics including bicycle helmets, baby walkers, and off-highway recreational vehicles[114]. The validation of several injury severity scoring systems is also owed to the implementation of trauma registries[20 99]. Finally, if trauma registries are expanded to a regional

level, they can be used to compare care between hospitals and look for outliers in outcomes, and could eventually grow to the level of a population-based registry, which captures all trauma cases within a defined population and serves as a comprehensive source of epidemiologic data in trauma[110].

3.1.3 Current State of Trauma Registries Worldwide

Trauma registries have existed since the late 1960s in HICs when the first trauma registry was developed at Cook County Hospital in Chicago, United States of America (USA). Despite this, development of trauma registries in LMICs has been much slower to take off, with very few trauma registries in LMICs identified prior to the year 2000[108]. One scoping review identified a total of 293 trauma registries worldwide, but the vast majority (82%) of publications came from trauma registries in very highly developed countries, and less than 1% from the least developed countries[115]. There were only 34 distinct LMIC trauma registries identified at the time of this review[115]. With regards to multi-site regional trauma registries, none were identified in LMICs in a 2012 review; however, a subsequent review by O'Reilly *et al* found publications on multi-site regional trauma registries in Ethiopia, South Africa, Uganda, Jamaica, Mexico, Iran, and Thailand[108 110]. By 2018, St-Louis *et al* identified the existence of at least nine multi-site trauma registries in LMICs[19]. While this represents a growth of regional trauma registries in LMICs, the majority today still remain single-institution registries[19 108]. Furthermore, while the earliest LMIC trauma registries were reported over two decades ago, most trauma registries in LMICs remain limited to short-term pilot studies, with very few trauma registries documented that persist long-term beyond the pilot study phase[19 20].

3.2 Practical Considerations for Implementing Trauma Registries in Low- and Middle-Income Countries

3.2.1 Costs and Challenges of Funding Trauma Registries

The lack of funding available is the first and most pressing concern for developing a trauma registry in an LMIC. Inadequate funding was highlighted as a concern in every manuscript included in a comprehensive 2018 review on the challenges faced by trauma registries in LMICs[109]. As one trauma registry custodian from a developing country stated, "…[a trauma registry] requires personnel and it requires money. In a place like [this], where money is at a premium, there are other priorities"[116]. In HICs, the cost of running a trauma registry was estimated at approximately $68 USD per patient: a cost that is most likely prohibitively high for the majority of LMIC institutions[117]. Typically, the majority of costs for operating trauma registries are taken up by human, technological, and physical resources. Physical resources required may include office space, telephones, computers, internet access, printers, paper, reliable electricity sources and generators, among others, many of which may be lacking in LMIC institutions[18]. There are additional technology costs associated with electronic-based registries, including the costs of developing or obtaining rights to software, maintaining technological support, and ongoing licensing. Personnel resources include the costs of hiring dedicated staff to run a trauma registry, training staff, or the relative costs to the system of requiring clinical staff to take time to complete trauma registry data collection. While utilizing different techniques for management of human, technological, or physical resources may result in immediate cost savings, this must be balanced with the potential for shifting costs and the inadvertent creation of higher expenses in other areas instead.

For example, the use of electronic trauma registries may help with efficiency of analyzing and collecting data, however, this can create significant up-front costs to develop or obtain the rights to a trauma registry software. Commercially available trauma registry software used in LMICs may cost up to $7500 to $10,000 USD for initial licensing, $2500 USD per year for ongoing licensing, and approximately $2400 USD per month for other computer and employee costs[118][119]. An alternative is to instead develop software locally, a technique that some trauma registries in LMICs have utilized, as locally-developed software may be better adapted to better fit local requirements and potentially result in further cost savings[118]. However, locally-developed software may still expensive and may be cost-prohibitive: in Pakistan, a locally developed trauma registry software cost $9600 USD to develop and implement (not including expenditures for ongoing maintenance), and an electronic trauma registry developed in South Africa was estimated to have start-up costs of $7000 USD with $10,000 to $15,000 USD maintenance costs annually[118][120]. To help with the up-front technological costs for electronic trauma registries, many LMIC institutions find financing from research grants or partnerships with high-income country institutions or governments. However, the ongoing costs of running a trauma registry in a low-income setting remain challenging to finance[19].

An alternative to electronic trauma registries is a paper-based registry or a hybrid approach (where data is initially collected on paper and then inputted into a computer database) to save on up-front software development costs. However, these methods can also be time-consuming, inefficient, and labour-intensive. The use of a paper registry may actually be less economical due to the additional personnel costs associated with the time required to organize and analyze data[19][113][120]. Furthermore, data recorded in paper-based registries lags behind real-time and may lose value as a

quality improvement and assurance mechanism[120]. Most trauma registries in LMICs report utilizing computer software at some point in the process for either primary data collection or backup, with only 17% utilizing paper-only approach[19].

Additional strategies for affordability that have been proposed include the development of open-source electronic health technologies that can be freely used by other institutions, the development of low-cost and low-maintenance electronic trauma registries, and the use of mobile applications to help reduce the costs associated with electronic collection of data[121-123]. There are also free software programs available for creating forms for data collection and data processing, such as Epi Info ™ from the Centers for Disease Control and Prevention (CDC)[124]. As trauma registries in LMICs become more commonplace, access to these open-source technologies and mobile applications may be innovative avenues explored to reduce costs and improve maintainability of trauma registries for low-resource settings.

Regardless of whether paper-based or electronic-based modalities are used, personnel requirements represent a significant cost of operating trauma registries in LMICs. The majority of trauma registries reported the costs of employing staff to track data to be a major expense, particularly with high patient volumes seen in LMICs and the need for 24-hour staffing to consistently recruit all eligible patients[19 108 109]. It has been estimated that, for every 1000 trauma patients inputted into a trauma registry per year, at least one full-time, dedicated trauma registry employee is necessary[125]. In HICs, the most common data collectors are nurses with no concurrent clinical duties or dedicated health information managers. In contrast, most trauma registries in LMICs use front-line clinical staff to collect data and save on costs of hiring an additional

employee[18]. However, this can lead to poor data quality and completeness, and can increase heavy workloads for healthcare workers in locations that are already understaffed and resource-limited[19]. As well, only 23% of trauma registries in LMICs described any specialized training for data collectors, despite the importance of training to ensure high data quality[19][111]. The cost of staffing and training either dedicated data personnel or health care workers who will participate in data collection is a necessary expense that must be accounted for in the development of a trauma registry, both in terms of time and financial resources required.

The importance of securing an ongoing source of funding to maintain trauma registries is a crucial, though often neglected component of planning for trauma registries in LMICs. In an interview of trauma registry custodians in LMICs, one participant described how the initial finances for trauma registry development came from research project grants, but "because the initial funding of the registry was a research project, rather than a continuous registry… the funding stopped… [and] we didn't have any more money to stretch it out"[116]. As the effects of trauma care system improvements may not be seen until after 10-16 years of implementation, it is also crucial to plan for the long-term success of the registry[97]. In order to achieve ongoing improvements to quality of trauma care and contribute to capacity building in LMICs, solutions for financial sustainability must be identified. In some cases, this may include the recruitment of private corporate sponsorship, or partnerships with high-income countries or government[126][127]. It is also possible that trauma registries can self-contribute to cost-savings through ongoing quality improvement, however, this can be difficult to enact. Some regions have therefore mandated ongoing data submission to regulatory centres in order to receive ongoing funding, and in some settings, resource allocation for trauma care is tied to data collection and documentation of trauma

patients[128 129]. The notion that improved documentation and data collection of trauma patients can result in increased funding that could be used to sustain a trauma registry is intriguing. Regardless of the source of initial funding, a reliable source of continued funding must be established before the initiation of a trauma registry in order to ensure its long-term success.

3.2.2 Other Challenges for Trauma Registries

Data integrity and quality assurance within trauma registries themselves is also a major concern for trauma registries in LMICs[19 109]. Some of these issues are inherent to trauma registries themselves: for example, underreporting of injury data occurs as trauma patients who do not present to hospital (including those who seek care elsewhere, do not seek care at all, and those who die before reaching hospital) are typically not captured by any hospital-based data repositories[109]; however, trauma registries have still been found to be more comprehensive than alternative data sources in LMICs including police reports and newspaper reports[130 131]. Variations in inclusion and exclusion criteria and parameters recorded can also lead to information bias and inability to make inter-registry comparisons[29 99 113 132]. The use of regional trauma registries and standardized data sets to facilitate inter-hospital comparisons may overcome this, but also creates increased complexity and requires coordination of trauma registries which may not be possible in all LMIC settings[109 110]. While many registries included data on five core categories (demographics, injury event, processes of care, diagnosis/severity, and outcome), the exact data points may vary significantly between registries[108 113]. The ideal number of data points and best data points to include are not known and may in fact vary by institution (though this of course limits comparability); however, smaller datasets that require less completion time have the benefit of less missing data[113 133]. A diversity of injury scoring systems are also utilized by different

trauma registries, including the Injury Severity Score (ISS), (the most common scale used in high-income countries), and the Kampala Trauma Score (KTS), (developed in Uganda, and used by 18% of LMIC trauma registries studied)[19]. The wide range of potential variables for trauma registries in LMICs makes the development of an ideal minimum data set a worthwhile avenue for future research.

Data quality problems in trauma registries may also arise within the collection of data itself, and may be attributed to lack of training, limited human resources or heavy workload, unclear data definitions or coding, overemphasis on speed of completion, or technology interface concerns[111]. To solve these problems, it has been proposed that every registry have a dedicated data quality personnel assigned to tracking completeness and quality of data[19 128 134]. With electronic modalities of data collection, software that is user-friendly and utilizes efficient drop-down menus was also recommended to improve data quality[120]. Point-of-care collection, with data collected at the patient bedside rather than retrospectively from chart data, was found to be more reliable in ensuring data completeness and quality[119 134]. Finally, adequate training of data collectors was emphasized as a need for trauma registries by numerous study authors, regardless of whether these were dedicated trauma registry staff, clinical staff, or trainees[28 118 119 127 129 131 135]. Data quality assurance should therefore be integrated into LMIC trauma registries. With built-in data quality assessments, well-trained dedicated registry personnel, and simplification and optimization of the systems and technology, trauma registries in LMICs can continue to improve the quality of data they produce[19].

Other barriers faced by trauma registries in LMICs may be due to deficiencies in the trauma care systems themselves. Several studies identified the lack of pre-hospital care, transport services, and transfer of care, and a lack of data available on same, as issues with trauma systems in LMICs that affected data quality of trauma registries[19 29 109]. Another challenge for trauma registries in under-resourced settings is the poor availability of equipment for measuring clinical data, meaning physiologic data points may go uncollected regardless of training and data quality assurance. One respondent in a survey of trauma registry custodians described it as follows: "So, blood pressure, for instance, if there are no blood pressure cuffs, it doesn't actually get collected. Not because they don't want to collect it, but because nobody actually takes the blood pressure in the hospital"[116]. Another example identified by a survey participant was the lack of access to CT scanning, which hindered the ability to generate accurate documentation of internal injuries and led to unreliability of injury severity scoring systems typically utilized in high-income settings[116]. For this reason, the KTS injury scoring system may be more appropriate for LMIC settings, as it is more resource-efficient and was found to perform better at discriminating in-hospital mortality than the ISS in low-income settings[20 136]. Further issues with trauma care systems that can complicate the development of trauma registries in LMICs include the overall high trauma volumes and the lack of government policies and systems in place to standardize, strategize, and coordinate trauma care[19 29 109]. However, while solving these larger systemic issues is not easy, these concerns should be identified and anticipated before establishing a trauma registry through a needs assessment, so that potential solutions can be found. Ideally, these concerns with trauma systems as a whole can be detected by trauma registries and used to promote quality improvement for the trauma system[19 29 109].

Importantly, other challenges with trauma registries exist that are institution and registry-specific, necessitating flexibility and locally appropriate solutions built into trauma registries. For example, in the development of one Kenyan trauma registry, there were patients being admitted directly to the ward that were not being captured by the trauma registry. In response to this, a structure for collecting data on inpatients was developed to capture these missed patients[135]. In settings where Wi-Fi internet connectivity was unreliable, investigators found success by designing a Wi-Fi-independent version of an electronic trauma registry where data could be stored locally until internet access was re-established[122 137]. Every trauma registry may face possible challenges unique to its site, and therefore both an *a priori* needs assessment and a system of ongoing feedback and response to unanticipated concerns should be built into novel trauma registries. It is also imperative that solutions involve local staff and are culturally sensitive and tailored to that site's needs. One survey respondent noted "you can't go into a low or middle income country or anyone's country and say this is what we do in the United States, we're going to do it here – yeah, right… it has to be culturally sensitive and based on what they need"[138]. A formal needs assessment should be created prior to establishing a trauma registry in a low-resource setting, and a feedback-response system that is locally managed and culturally appropriate should be built in to respond to unanticipated challenges that should arise.

3.3 The Ethical Considerations for Trauma Registry Development in Low- and Middle-Income Countries

3.3.1 Sustainability of Trauma Registries in LMICs

While the barriers faced in establishing trauma registries in LMICs may appear to represent primarily practical concerns, these challenges also reflect ethical concerns and the responsibilities

of partnering institutions and researchers. The strengthening of trauma care systems is a life-saving intervention, and it is vital to create a system of feedback, quality improvement, process improvement, and outcomes monitoring in the form of a trauma registry in order to implement these improvements. The importance of monitoring patient outcomes in order to improve surgical care in resource-limited settings should be viewed as "mandatory in order to prevent inadvertent harm" and was identified as a recurring theme in a scoping review of the literature on the ethics of global surgery[70][139].This highlights the importance of trauma registries as a means of monitoring outcomes and improving trauma care.

The most common concern addressed in the practical challenges of establishing a registry in an LMIC is that of affordability: both in the short-term and for long-term sustainability. The planning of a trauma registry in a low-income setting therefore carries the responsibility of maximizing cost-effectiveness. Other important steps that should be taken prior to implementation of a trauma registry include the recruitment of a "local champion", often a local healthcare provider or administrator, to advocate for the implementation and ongoing success of the trauma registry[137][138]. From an ethical standpoint, if external partners from HICs are to be involved in the implementation of a trauma registry in an LMIC, their partnerships should unequivocally include the significant contributions and consultations of local stakeholders. These partnerships must be built with equity and respect: the local stakeholders' viewpoints should be prioritized, and ultimately, the ownership of the trauma registry and its data should belong to the local community[139]. Furthermore, publications and research outputs from the trauma registry should involve and credit the researchers from the local institution[44]. Finally, the importance of performing a needs assessment – to anticipate and learn from the needs of the community, rather

than imposing a pre-formed idea of what a trauma registry should look like in that setting – should also precede implementation of the registry[44 116].

3.3.2 Ethics of Registry Data Collection

Other ethical considerations for trauma registries overlap with those of research ethics, where the protection of vulnerable populations is a priority[67]. Trauma patients from low-resource settings frequently fit this definition of a vulnerable population; and in order to ensure their protection, trauma registries should be submitted to local institutional ethics review boards. If an ethical review board does not exist at that institution, consideration should be given to help develop that capacity, rather than proceeding without local institutional ethics approval[67]. While participation in a trauma registry does not involve interventions or changes to clinical care, risks do exist and are primarily related to the collection of sensitive health data and the potential for confidentiality breach. Institutional ethics review board approval should note how data will be stored, who will access the data, and how long the data will be stored. Most trauma registries are anonymized, or often "pseudonymized" with a 'key' file linking the anonymized patient registry data to patient identifiers in case of the need to update clinical information. If this technique is utilized, the 'key' file also needs to be stored separately from registry data, with appropriate storage protections to prevent backwards identification of patients[140]. Any presentation of data from registries should also be sufficiently large-scale to prevent identification of individual patients from indirectly identifying information.

The issue of informed consent and the inclusion of patient data in registry-based research is a matter of controversy, and actual practice varies between different registries even within highly

developed countries. Expectations of informed consent and how it is collected may also differ between cultures and geographies. In the administration of registries, some do not consider informed consent to be necessary, particularly as registry data anonymized or pseudonymized, collection of data does not interfere with clinical care, and, in many cases, collecting data for registries does not even require direct contact with patients[140][141]. Collecting formal informed consent for individual registry participants also creates pragmatic challenges, especially when the registry is large or in other cases where collecting consent is impractical (for example, seriously ill patients or those with altered levels of consciousness, both of which are common in trauma registries)[140]. Necessitating individual informed consent therefore reduces participation, which can result in a reduction of the scientific validity of the data[141]. The time and personnel required to collect informed consent also may increase costs, which is especially concerning for registries located in low-income settings[140]. In some countries, data are collected without consent with the expectation that it represents the most common good, as incomplete data comes with greater risks to public health than the individual risks of participating in registry. As well, some jurisdictions consider consent to be implied based on patient participation in a publicly funded healthcare system[140-142]. However, it has also been contended that a lack of informed consent for data collection for research weakens the trust that must be present in healthcare relationships and undermines patient rights[143][144]. In cases where serious patient illnesses make it difficult to collect consent, a solution is to obtain patient consent after data collection but prior to disclosing or utilizing any data[145]. As well, the nature of trauma as a potentially sensitive and stigmatizing health issue creates added vulnerability for trauma patients, compounded by poverty and the limited access to healthcare in many LMICs. A tension therefore exists between the practical and ethical considerations for informed consent in registry data collection. In reality, many disease

registries in LMICs waive informed consent, and there is with limited published experience on any practical solutions for collecting informed consent in these settings[146]. Local legal and organizational standards will also play a role in informing practice in this area. However, the issue of informed consent for registries in LMICs should be explored further by inviting the perspectives of stakeholders from LMICs to inform future practice.

3.4 Conclusion

There are high burdens of injury from trauma in LMICs and trauma registries represent an important means of improving trauma care in these settings. Practical considerations that must be addressed prior to establishing a trauma registry include sources of financial support, personnel requirements, data parameters collected, local needs and challenges, and a plan for data quality assessments. A greater emphasis on the sustainability and investigation into the best ethical practices for trauma registries in LMICs must be priorities moving forward.

CHAPTER 4: DEVELOPMENT AND EVALUATION OF A MOBILE APPLICATION

TRAUMA REGISTRY

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4.1 Introduction

Trauma is a significant source of global morbidity and mortality, and this burden is shouldered disproportionately by low and middle-income countries (LMICs), with 90% of trauma deaths occurring in LMICs[16]. An essential first step for developing trauma care systems and improving care in LMICs is the collection and evaluation of injury data through the means of a trauma registry, or a database of trauma patient data used for quality improvement[28 106 108]. A number of trauma registries have previously been established in LMICs, however, significant challenges exist for sustaining trauma registries in this setting, including a lack of funding and lack of human resources[19 108 109].

The use of electronic health technologies (known as e-Health) and, in particular, mobile health technologies (or m-Health), have been proposed as potential tools to help overcome these barriers and advance data collection in LMICs. Mobile devices are a relatively low-cost technology, with continually improving functionality and widespread accessibility in many LMICs[147]. In Uganda, where this study is based, there are an estimated 25 million mobile phone subscriptions for a country of 37.7 million; in all developing countries, there are an estimated 103.8 mobile cellular subscriptions per 100 persons worldwide[148 149]. In fact, due to the relative prevalence of mobile phones compared to personal computers, mHealth is considered likely to leapfrog ahead of other

electronic health technologies in LMICs[150]. While most mHealth technologies in LMICs utilize short-message services (SMS), a growing number of mobile phone applications are also being used for health purposes and data collection in LMIC[151]. These technologies have also previously been demonstrated to be feasible tool for the implementation of trauma registries, as demonstrated by Zargaran *et al* with the creation of a tablet-based application for use in a South African trauma centre[120]. Mobile applications are a practical and affordable means of health data collection and trauma registries in LMICs.

Despite the implementation of e-Health and m-Health technologies in LMICs, there remains only limited evidence on evaluating these technologies in this setting[152]. While there are methods of evaluation that have been developed for other electronic health devices and mobile applications, no specific evaluation systems exist for electronic trauma registries. A scoping review identified two mnemonic systems used for evaluating health information on the internet, and these were deemed reasonable for evaluating medical mobile applications as well: "RADAR" (Relevance, Authority, Date, Appearance, Reason for writing) and CRAAP-O (Currency, Relevance, Authority, Accuracy, Purpose, and O-assessment: referring to whether the app was easy to use, fun, or interesting). The only system identified specifically for evaluating medical mobile applications was the NMEDAPP mnemonic (Novel, Potential of benefit versus risk, Medically sound, Ease of use, Developer, Audience, Price, Platform)[152]. With regard to trauma registries, there are a few qualitative evaluation systems proposed, but these are not specific to electronic or mobile application trauma registries. One such trauma registry evaluation framework assesses registries on general criteria (including usability, security, maintainability, and interoperability) and on specific criteria (including data submission and entry, reporting, quality control, and decision and research support)[153]. Another example of a qualitative evaluation system for trauma

registries, the Trauma Registry Assessment Tool, assesses the key components of the trauma registry in terms of physical resources (infrastructure and equipment), human resources (staffing and training), and processes (including administration and organization, which is further broken down into inclusion criteria, variables, data capture, scores, and analyses)[108]. However, these qualitative models of evaluation are descriptive rather than predictive.

Beyond these proposed evaluation models for medical mobile applications and trauma registries, the most broadly published and well-validated studies are technology evaluation models, several of which are quantitative. Among the best-validated and quantitative analyses for technology evaluation and prediction of future use is the Unified Theory of Acceptance and Use of Technology questionnaire[154] [155]. The UTAUT formulates a unified model that incorporates data from eight other information technology acceptance models and was found to predict approximately 70% of variance in an individual's intention to use a specific technology[154]. The UTAUT evaluates behavioural intention to use through three major constructs: Performance Expectancy ("the degree to which an individual believes that using the system will help him or her attain gains in job performance"), Effort Expectancy ("the degree of ease associated with use of the system"), and Social Influence ("the degree to which an individual believes that important others believe he or she should use the new system"). It also incorporates two direct determinants of usage behavior: Facilitating Conditions ("the degree to which an individual believes that an organizational and technical infrastructure exists to support use of the system"), and Behavioural Intention to Use. Indirect constructs including Attitude toward Technology, Self-Efficacy, and Anxiety are also incorporated into the original UTAUT model but are generally nonsignificant as they are captured by the other major constructs. All constructs are then modified by four contingencies: age, gender, experience, and voluntariness[154].

The UTAUT has been specifically validated in health-care technology, however, in this context, the model can be simplified as age becomes the only important modifier, with a younger user age significantly correlated to intention to use (Figure 4.1)[156]. The use of UTAUT in healthcare contexts in LMICs has also been demonstrated, however, the exact significance of major constructs can differ, and the degree of predictive performance has been shown to vary; it has also been utilized in African settings specifically[157-159]. Despite some variations in performance in different contexts, this study remains the best validated for evaluating technology in healthcare environments and was identified as a relevant means of quantitative evaluation for implementing a mobile application trauma registry at Mbarara Regional Referral Hospital (MRRH) in Uganda, along with open-ended, qualitative feedback from healthcare professionals at MRRH.

4.2 Methods

4.2.1 Process of Developing a Mobile Application Trauma Registry

A paper-based pilot trauma registry utilizing a minimal data set was initially developed, validated, and implemented at MRRH in Uganda in conjunction with McMaster University (Canada), University of Alberta (Canada), and the not-for-profit organization Innovative Canadians for Change (ICChange). A literature review, needs assessment, and workflow assessment at MRRH was completed to initially develop the paper-based data collection tool, and it was then validated with a retrospective chart review. Data was collected from 2017-2019 by two part-time nurse data collectors for over 3000 trauma patients, pediatric and adult, seen within 14 days of injury at MRRH. Data was later inputted into a secure, data-encrypted, password-protected data server located at MRRH[31].

Through consultation with local stakeholders, the introduction of an electronic modality to facilitate ease of data collection and analysis was identified as a priority to avoid duplication of workload to help sustain and expand the Mbarara trauma registry. However, they also identified a lack of computer infrastructure as a concern for implementing electronic health technologies for use with the trauma registry and recognized a mobile phone application as a more accessible means of accessing and inputting data into the trauma registry due to high mobile phone ownership and utilization by healthcare providers at MRRH. With the assistance of a software engineer, an open-source, android-based mobile application was created to upload trauma patient data to the same local data server, encompassing the same minimal data set as the paper-based trauma registry[31] (Figure 4.2; full contents of mobile application trauma registry available in Supplemental File 1).

A number of steps were taken prior to development of the mobile application in order to optimize functionality based on the needs of local stakeholders. A lack of reliable internet access was identified as another concern by local stakeholders and is echoed in the literature as a barrier to e-health in many developing countries[121]. Therefore, the ability to store data locally in the application when used in an off-line mode was incorporated into the design of the mobile application (data can then be uploaded to a server at a later time when connectivity is re-established). To reduce future implementation costs for other health care organizations wishing to adopt this technology, the mobile application was developed to be open-sourced. Privacy concerns were addressed by password-protecting, encrypting, and de-identifying data in the mobile application as well as the data server and reviewing with all affiliated local and international ethics boards. The data server was stored onsite at MRRH with the intention of promoting local

ownership of data. Finally, in order to promote sustainability of use of the mobile application, feedback on the mobile application from local healthcare providers was sought.

4.2.2 Evaluation of a Mobile Application Trauma Registry

In order to evaluate the mobile application trauma registry, a population of healthcare providers involved in the initial care of trauma patients at MRRH was identified, as this was the population most likely to be involved in completing trauma registry patient data. This included resident physicians, interns, and trauma nurses. Informed consent was obtained, and healthcare providers were then given a 15-minute tutorial on the use of the trauma registry mobile application and then trialed inputting mock patient data into the mobile application. A mixed methods design was employed, with participants completing a modified UTAUT questionnaire of technology acceptance was completed by participants, as well as open-ended qualitative feedback (Supplemental File 2). UTAUT responses were reported on a Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree) and analyzed using descriptive statistics and logistic regression. Differences between demographic groups including age, occupation, and sex were also explored. Multivariate logistic regression modelling was performed to determine factors predicting a behavioural intention to use the mobile application in <6 months; variables assessed included all UTAUT major and minor constructs (performance expectancy, effort expectancy, social influence, facilitating conditions, self-efficacy, and anxiety), as well as demographic factors (age, occupation, and sex). From univariate analyses, all variables with a p<0.2 were considered for a multivariate model. Qualitative feedback was analyzed by thematic analysis as described by Vaismoradi *et al*, 2013[160].

4.2.3. Ethics Approvals

Research ethics approval was obtained through the Mbarara University of Science and Technology Research Ethics Committee (MUST-REC) in Mbarara, Uganda and the University of Alberta Research Ethics Board in Edmonton, Canada. The original implementation of the trauma registry also obtained ethics approval from MUST-REC and McMaster University.

4.3 Results

4.3.1 Participant Demographics

A total of 17 out of 24 health care providers (70.9%) involved directly in trauma patient care completed the mobile app tutorial and questionnaire. The average age of participants was 29.06 years old (SD ± 3.89) and 53.9% were residents (9 of 17), 35.3% intern doctors (6 of 17), and 11.8% were nurses involved in trauma care (2/17). 88.2% of participants were male and 11.8% female (Table 4.1).

4.3.2 UTAUT scores

UTAUT scores were reported on a Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). Scores were high for the three major constructs (performance expectancy, effort expectancy, and social influence). For performance expectancy, 92.65% of responses were scored as 5 or higher (somewhat agree to strongly agree; mean 6.41, SD ± 1.43); for effort expectancy, 94.12% of scores were 5 or higher (mean 6.25, SD ± 1.41); and for social influence, 84.37% of scores ranked as 5 or higher (mean 5.44, SD ± 1.27). 70.59% of responses in the 'facilitating conditions' category of responses were scored as a 5 or higher (mean 5.32, SD ± 1.99), and 86.67% of participants reported a behavioural intention to use in under 6 months (mean 2.6

months, SD ± 1.64). For the indirect UTAUT constructs, 92.06% scored 5 or higher for attitude towards technology (mean 6.05 ± 1.43) and 83.13% scored 5 or higher for self-efficacy (mean 5.94 ± 1.44). Anxiety, which is scored inversely on the UTAUT, had only 35.94% of scores scoring 5 or higher, with 50% of responses slightly to strongly disagreeing on experiencing anxiety with use of the application (mean 2.60 ± 1.64) (Figure 4.3; See Supplemental File 3 for complete UTAUT responses).

The only significant difference in scores between males and females was in the social influence category, where female respondents had an average Likert-scale score of 6.63 (SD ± 0.52) compared to males with a mean score of 5.66 (SD ± 1.27) (p=0.04). However, there was no significant difference in behavioural intention to use within 6 months or less between any of the demographic groups.

With respect to predictors of behavioural intention to use <6 months, the only statistically significant factor identified was facilitating conditions (p = 0.01). All other UTAUT variables measured, as well as age, sex, and occupation, were not statistically significant predictors of behavioural intention to use category and therefore a multivariate logistic regression could not be performed. Overall behavioural intention to use was high, with 86.7% of participants indicating that they intended to use the application within 6 months' time if available.

4.3.3 Qualitative analysis

Qualitative themes identified in participant responses included ease of use, the benefits of large databases for future research and clinical work, efficiency of the mobile application, and data

comprehensiveness. Privacy and security concerns and type of platform were also identified as major themes from the qualitative feedback using the application (Table 4.2).

4.4 Discussion

This study represents the implementation, development, and evaluation of a mobile application trauma registry for use in a low- and middle-income setting. The analysis of this trauma registry application was done by means of a modified UTAUT questionnaire which can be used to predict future usage behaviours. Overall, scores on the UTAUT survey were high, with the majority of participants responding positively to each construct on the validated questionnaire. The major constructs of performance expectancy, effort expectancy, social influence, and facilitating conditions had mean Likert scores of 6.41, 6.25, 5.44, and 5.32, respectively. A young average user age (29.1 years) was also found in this study. Overall, high scores on UTAUT constructs and a young major user age have been previously found to predict higher likelihood of usage behaviours in previous UTAUT studies in healthcare contexts and specifically in LMIC healthcare contexts[156 157 158].

Facilitating Conditions refers to the infrastructural support that exists to support the use of a technology (including physical infrastructure, access to information technology support services, and the time cost of using the technology)[161]. In our study, facilitating conditions was the only major construct found to be significant predicting the healthcare provider's intention to use the trauma registry mobile technology, and is consistent with previous studies[157]. Furthermore, this significance was supported by the qualitative responses from participants: time to use the application and type of mobile phone platforms required for use were widely cited as factors

influencing the participants opinions of the mobile application. Although scores were still overall found to be positive for facilitating conditions with a mean Likert score of 5.32 and 70.59% of responses scored as a 5 or higher, this construct had relatively lower scores compared to other constructs and is therefore one potential area of focus for improvements to the application.

This study did not find a significant association between Performance Expectancy, Effort Expectancy, Social Influence, Self-Efficacy, Anxiety, age, or other demographic factors with future use behaviours. This is surprising, given many previous studies confirm a positive relationship between the UTAUT major constructs and intention to use in technology adoption[156] [157]. A significant difference in social influence scores did exist between males and females, however, this did not affect future intention to use the application. This lack of significance of individual factors meant that a multivariate logistic regression model could not be created. The reasons for the lack of significant association may reflect the limitations of a cross-sectional study with a small sample size and overall high scores reported with little variability reported, as the vast majority of participants reported high scores in all of these categories, as well as high future use intentions. However, it was important to maintain internal validity of the study by surveying only trauma care providers at MRRH who would be likely to utilize this technology in the future, and therefore only healthcare providers involved in the direct and initial care of trauma patients were included in this survey.

Another potential limitation to this study may include non-response bias, as only 17 healthcare providers completed the survey out of a population of 24 healthcare providers identified as a possible study population, for a response rate of 70.9%. However, though it is possible this could

have led to differential misclassification if those who did not respond to the survey were more or less likely to have positive or negative responses to the application than those who did complete the survey, the reasons that responses were unable to be obtained were instead due to unavailability of healthcare providers due to rotation and shift scheduling, which is unlikely to be related to factors of information technology acceptance. Another potential limitation of this type of study is social desirability bias, however, to mitigate the potential impact of this, local resident physicians and interns were recruited to administer surveys to their peers, surveys responses were kept anonymous with only indirectly identifying information collected, and an option to opt-out was provided discreetly on the response forms.

The results of the qualitative analysis found, in general, that healthcare providers found the application easy to use and efficient. The potential use for future research or clinical care was highlighted as a positive finding on several occasions, and suggestions were made for expanding the data points collected to improve its functionality for these purposes. Several adaptations have already been made for use in a low-resource setting, including a function which allows data to be stored locally in the application when internet connection is lost and uploaded at a later time. Privacy and security concerns were brought up by a few participants ("data entry involves and includes patient names" and "[what happens] when the phone gets stolen?"), however, we note that some of these concerns are addressed in the development of the application by utilizing password protection and data encryption, as well as de-identification of patient data in the server. To address these concerns of healthcare providers, a better description of privacy precautions should be provided to healthcare workers and built into tutorials for using the mobile application.

Challenges remain for use of mobile application trauma registries in low-income settings. In order to improve upon future user satisfaction, we have embarked upon creating changes to the application based on the feedback received. This includes expanding use of the mobile application to be functional on multiple technology platforms (including personal computers and non-android mobile devices) and the hiring of a local employee to provide information technology and electronic health records support onsite. The next steps to full implementation of the mobile application trauma registry includes improved training for employees, the recruitment of additional local champions for use of the application, early adoption in clinical care and research, and developing a means for financial sustainability of the trauma registry so that it no longer depends on external research funding. Finally, a follow-up survey on actual patterns of use and quality assessments of data completeness should take place.

4.5 Conclusion:

This study demonstrates the process of developing and evaluating a mobile application trauma registry for use in low and middle-income countries through the use of the UTAUT questionnaire. The UTAUT represents a potential analysis method for information technology in healthcare settings and its use reflects the importance of consulting local stakeholders and front-line users of healthcare technology in LMICs.

4.6 Tables

Table 4.1: Demographics of respondents

	Mean (SD)
Age	29.06 (±3.90) years
	Frequency (%)
Occupation	
Nurses	2 (11.76%)
Interns	6 (35.29%)
Residents	9 (52.94%)
Total	*17 (100%)*
Sex	
Female	2 (11.76%)
Male	15 (88.24%)
Prefer Not to Say	0 (0%)
Total	*17 (100%)*

Table 4.2: Qualitative feedback on usability of mobile application trauma registry and thematic

analysis of feedback received

Themes identified	**Examples of feedback**
Ease of use	"easy to use and understand"
Speed/efficiency	"it makes data collection and entry fast as it is all done by the bedside" "it might take a lot of time entering the data"
Future research/clinical use of data	"makes work and research easy" "better storage of data for future use"
Comprehensiveness of data	"[I liked] the comprehensiveness of the amount of data captured about the patient, even preceding trauma examination, and [including] followup" "Does not include parameters in trauma assessment like GCS"
Type of technology/platform	"Developer should increase its ability to function on iOS devices"
Privacy/Security	"[What happens] when the phone gets stolen?"

4.7 Figures
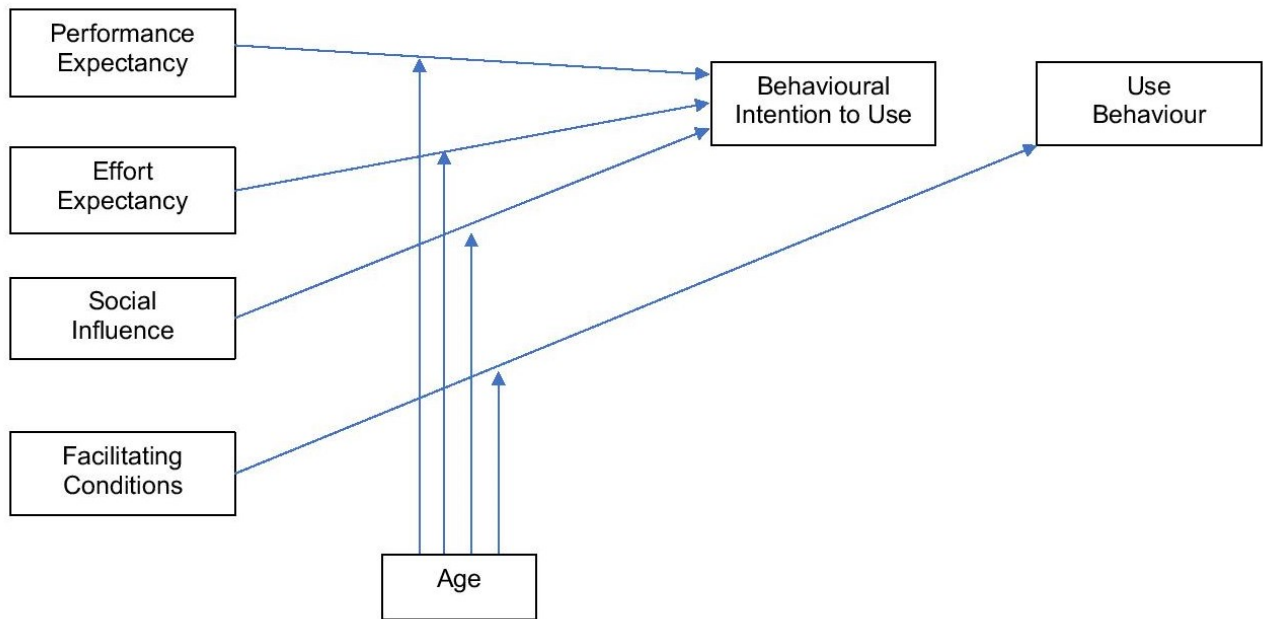
Figure 4.1: Modified UTAUT for use by physicians (adapted from Venkatesh et al, 2011)

Figure 4.2: Screenshots from the MRRH mobile application trauma registry demonstrating the

Kampala Trauma Score section with drop-down menus for age category.
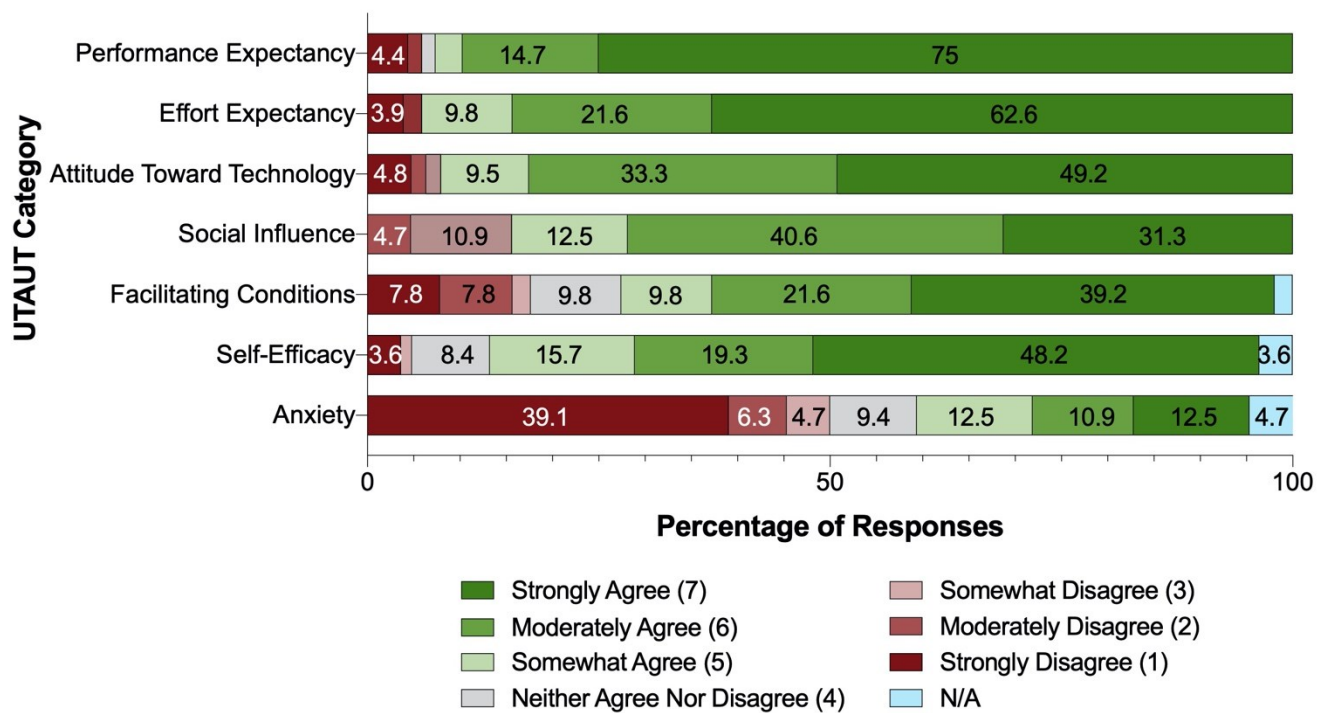
Figure 4.3. UTAUT Survey Results by Category. Numerical values for responses that represented

less than 3% of responses for that category are excluded from this figure for size constraints.

CHAPTER 5: A SUSTAINABILITY ANALYSIS OF A TRAUMA REGISTRY IN A LOW-INCOME COUNTRY

In preparation for submission as: Grant CL, Robinson T, Tumuhimbise C, Siima C, Eurich D, Bigam D, Situma M, Saleh A. Change in trauma patient volume following the implementation of a trauma registry and patient registration system: a means of sustainability for a trauma registry at a district hospital in Uganda.

5.1 Introduction

Trauma in low- and middle-income countries (LMICs) is a significant cause of global morbidity and mortality, and trauma care in these settings is often hindered by a lack of trauma care systems[16][97]. As trauma care systems have been shown to reduce trauma mortality, they are therefore an area of focus for mitigating the disparity in trauma outcomes between high- and low-income countries[101]. One important component for the advancement of trauma care systems and quality improvement in trauma is the trauma registry: a database of epidemiologic, process, and outcome data of trauma patients seeking medical care[115].

Although several pilot trauma registries have been successfully established in low-income settings, few have been able to maintain their operability in the long-term[19][109]. A few strategies have been identified for maximizing the potential for long-term sustainability, and include obtaining buy-in from local stakeholders to act as 'champions' for the trauma registry, and eliciting the support of local hospital administration and management[116][118][135]. However, securing a sustainable funding source for a trauma registry in a low-income setting remains an ongoing issue. While research grant funding or external partnerships with high-income countries can be

used to support the development of a pilot trauma registry, trauma registries in LMICs are rarely able to rely on external support for the long term[116]. Estimated maintenance costs of trauma registries in LMICs may be as high as $2,500 to $15,000 USD annually, and personnel requirements for operating trauma registries can also incur significant costs[113 118-120]. Ideally, the most ethical approach should be to develop a sustainable funding source built into local institutions in LMICs, in order to build capacity into local trauma systems, decrease reliance on external partnerships, and transition ownership of trauma registries to local partners (as discussed in Chapter 1)[139].

It is possible that trauma registries can contribute to cost-savings in LMIC hospitals through ongoing quality improvement, however, this can be difficult to quantify and enact. Some regions have therefore mandated ongoing data submission to regulatory centres in order to receive ongoing funding; in many settings, resource allocation for trauma care is tied to data collection and documentation of trauma patients[128 129]. Patient records in many low-income settings are often of poor quality, difficult to access, and may be missing altogether as a consequence of severe systematic limitations and overburdened clinical staff[162]. For many publicly funded hospital institutions in LMICs, improved patient documentation could result in increased government funding to the institution. By pairing trauma registry data collection with the implementation of an electronic patient registration system, improved documentation of trauma patients and increased funding could result. This increased funding to the institution could potentially be used to sustain a trauma registry and patient registration in the long-term, as well as fund other improvements in patient care. This study aims to address barriers to the long-term viability of trauma registries in

LMICs by demonstrating a potential means of financing a trauma registry through more accurate documentation.

5.2 Methods

5.2.1 Establishing a pilot trauma registry and needs assessment

A pilot trauma registry was established at the government-funded Mbarara Regional Referral Hospital (MRRH) in Mbarara, Uganda, in February 2017 in collaboration with the Mbarara University of Science and Technology (MUST, Mbarara, Uganda), the University of Alberta (Edmonton, Canada), McMaster University (Hamilton, Canada), and the non-profit organization Innovative Canadians for Change (ICChange; Edmonton, Canada).

Hospital patient records were identified as a concern during the initial needs and workflow assessment of the hospital, as patient data was documented using paper-based charting. In most cases, new patient charts were created for each visit and not linked to existing patient records. Documentation was noted to be incomplete and difficult to locate within the records department; a previous study done on surgical patients at the same institution found admissions and discharge data to be missing on 41.3% of patients who underwent an operation[163]. It was estimated by hospital staff that as many as 50% of patients seen in the Accidents and Emergencies (A&E) Department were trauma patients, however, this was not able to be quantified due to poor record keeping. A needs assessment prior to implementation of the trauma registry was performed, and through this to also improve documentation at the hospital concurrently to the establishment of the trauma registry. An electronic patient registration system with dedicated personnel was established at the hospital entrance to assign each patient a unique record number that could be linked to

previous records, while an anonymized paper-based trauma registry was also developed, with a confidential 'key' file linking the anonymized trauma registry to patient registration numbers stored securely. This initiative gained the support of hospital administration as both a potential means of improving trauma care through a trauma registry, while also creating a registration system that could be utilized by all hospital patients.

5.2.2 Data Collection

A retrospective chart review of completed trauma patient charts prior to implementation of the trauma registry was completed. Dates and numbers of monthly admissions were recorded from January 2015 until July 2016. Two part-time nurse data collectors, available seven days a week, were then hired to collect data for all trauma patients (pediatric and adult) seen within 14 days of injury at MRRH. Trauma patient data, collected after implementation of the trauma registry from February 2017-December 2019, was included in the present study. Patient data was managed using REDCap (Research Electronic Data Capture) tool— a secure, web-based software platform designed to support data capture for research studies[164].

5.2.3 Statistical Analysis

The number of monthly trauma admissions were compiled retrospectively for the period of time prior to implementation of the trauma registry and electronic patient registration system (January 2015-July 2016), and prospectively for the data collection period after implementation of the trauma registry and patient registration system (February 2017-December 2019). The incident rate (IR) of documented trauma admissions pre-implementation of the trauma registry and patient registration system was compared to post-implementation incident rate with a negative binomial

regression analysis, adjusting for month and year. A negative binomial regression analysis

comparing pre-implementation years to each other (2015 to 2016) and post-implementation years

to each other (2017 to 2018 to 2019) was also performed to determine if any major secular trends

occured. Statistical analyses were performed using Stata Statistics/Data Analysis software version

13.0 from StataCorp.

5.2.4 Ethics Approvals

The secondary analysis of trauma registry data for this study was obtained through the Mbarara

University of Science and Technology Research Ethics Committee (MUST-REC) in Mbarara,

Uganda and the University of Alberta Research Ethics Board in Edmonton, Canada. The original

implementation of the trauma registry also obtained ethics approval from MUST-REC and

McMaster University in Hamilton, Canada.

5.3 Results

The number of completed documented trauma records that could be identified from paper charts

available in MRRH's hospital record department prior to implementation of the trauma registry

and patient registration system (2015-2016), ranged from 1 to 18 trauma patients per month, with

a mean of 5.16 per month (standard deviation ±4.39). Following the implementation of the trauma

registry and patient registration system, prospectively completed documented trauma records

ranged from 39 to 163 trauma patients per month, with a mean of 103.36 trauma patients per

month (standard deviation ±32.03). Monthly changes are visualized in Figure 5.1. A total of 3617

trauma patients were enrolled into the trauma registry from January 2017 until December 2019,

and data collection is ongoing.

Using negative binomial regression analysis, significantly more trauma admissions were

documented following registry implementation with an incident rate ratio (IRR) of 20.86 (95% CI

15.74-27.64, p<0.001) (Figure 5.2). There were no significant effects of monthly or yearly

variation on the analysis, and no statistically significant difference within the pre-implementation

years (2015 and 2016; p=0.212) or within post-implementation years 2017, 2018, or 2019;

p=0.668). In the retrospective period, 31 patient admissions records (31.3%) were for pediatric

patients (under the age of 18), and 68 for adults, and in the prospective data collection period, 769

records were for pediatric patients (21.5%) and 2,848 were for adults, but this difference was not

statistically significant using negative binomial regression.

5.4 Discussion

While the feasibility of developing pilot trauma registries in LMICs has been demonstrated in the

short-term, strategies for sustainability need to be a key consideration going forward. In this study

of a pilot trauma registry in Uganda, we demonstrate a potential means of self-sustainability for a

trauma registry in a low-income country. By considering the implementation of the trauma

registry as an opportunity to improve overall trauma patient registration and documentation for

hospitals this could in turn be used to apply for an increase in funding for the hospital. In this case

study in a public hospital in a low-income country, trauma patient registrations were poorly

documented and difficult to identify in a paper-based charting system. Following the

implementation of a trauma registry and concurrent electronic patient registration system, we were

able to demonstrate an increase of 20.86 times in completed trauma patient documentations that

could be identified. As government funding for trauma care at MRRH is dependent upon

documentation of number of patients seen and treated, this significant improvement in patient

documentation and registration following the implementation of a trauma registry could result in

an increase in funding for trauma patients. This funding could then be used to justify and support

the ongoing existence of a locally run trauma registry. A similar strategy could be considered for

the implementation of trauma registries in other low-income settings where funding is contingent

on number of patients seen and documented. In addition to providing a sustainable source of

funding for the trauma registry at MRRH, the implementation of a patient registration system

created unique patient identifiers for all patients seen in the A&E Department of the hospital

(including non-trauma patients). By creating identifiers for all patients, it provided an opportunity

to improve care for all patients at the hospital by reducing duplication of patient records and

improving accessibility of patient records by providing reliable means of linking records from

repeated visits[165]. The inclusion of a patient registration system with a trauma registry was an

additional motivator for hospital administration to participate in a partnership to develop a trauma

registry.

There are a number of limitations to this study. The most significant limitation is that trauma

documentations could have increased as a result of an actual increase in number of traumas

occurring in the district that were seen at the hospital. Unfortunately, there were no police records

available to us to demonstrate the number of traumas encountered in the district, nor is there any

census information available after 2014 in Uganda to assess whether or not these changes are due

to an increase in population in the district. However, given such a dramatic increase in patient

records (an average increase of 98 patients per month from the pre-registry period in 2015-2016 to

post-registry period in 2017-2019), it is unlikely that actual rates of trauma increased by such a

substantial amount. Also, as we found no statistically significant difference between trauma

records documented between the pre-registry years (2015 and 2016) or between the post-registry

years (2017, 2018, and 2019), any change in trauma rates would have had to reflected a dramatic

shift between August 2016 and February 2017 while the registry was being implemented, which is

highly unlikely given no significant event was noted by hospital staff. While it is probable that

neither data set represents a fully accurate picture of all trauma that occurred in Mbarara district

from 2015-2019 (and this is, in fact, a recognized limitation of all hospital trauma registries), it

remains most feasible that an improvement in documentation is responsible for the changes, rather

than a sudden increase in trauma patients seen by the hospital.

Another potential limitation is that the pre-registry trauma admissions represent the completed

trauma patient files that investigators were able to identify retrospectively in the hospital records

department from January 2015 onwards. It is possible that further trauma records existed at the

hospital pre-registry that could not be identified by study investigators due to the structural and

organizational challenges inherent in the record keeping system. Regardless, the inability to

identify further records indicates that it is unlikely they are being used in the most efficient

manner to demonstrate an accurate number of trauma patients actually being seen at the hospital.

The results of this analysis demonstrate a potential means of financial sustainability for a trauma

registry in LMICs. By demonstrating improved documentation of trauma patients at Mbarara

Hospital with the implementation of a trauma registry and a patient registration system, the

hospital may be eligible to apply for more governmental funding for trauma patients at this

institution. While currently the MRRH trauma registry is paper-based, the electronic patient

registration software is undergoing upgrading to incorporate an electronic version of the trauma

registry within the same computer program. As the initial startup costs of the trauma registry and

registration system have been covered by research funding from an external partnership, the

ongoing maintenance costs of the trauma registry and registration system could be funded going

forward by a portion of the increased funds from the improved documentation. The hospital also

benefits from the implementation of a patient registration system. These findings could also

provide motivation for government funding agencies to prioritize funding for trauma registries,

patient registration systems, and electronic health records in LMICs, as improved documentation

allows the government to more accurately collect information for resource allocation while

improving trauma care systems and outcomes in the region[99][166]. Moving forward, the utilization

of this strategy to more sustainable funding for trauma registries in LMICs can be incorporated

with lessons learned from other studies to promote the long-term maintenance of registries,

including *a priori* needs assessments, identification of a local champion to advocate for the

ongoing use of the registry, involvement of local hospital healthcare workers and administration,

and responsiveness to feedback[19][116].

5.5 Conclusion:

The development of trauma registries is an important consideration for improving trauma care in

low-income settings. While several pilot trauma registries have demonstrated feasibility, there are

few studies demonstrating long-term success of trauma registries in LMICs, and most are limited

by financial constraints. This study demonstrates a potential source of long-term funding for

trauma registries in LMICs by linking the establishment of a trauma registry with an electronic

health record, resulting in significant improvements to documentation of trauma patients. This

improved documentation can allow hospital institutions to apply for increased funding for trauma

patients, funding which can be used to support and sustain a trauma registry and health records

system moving forward.

5.6 Figures
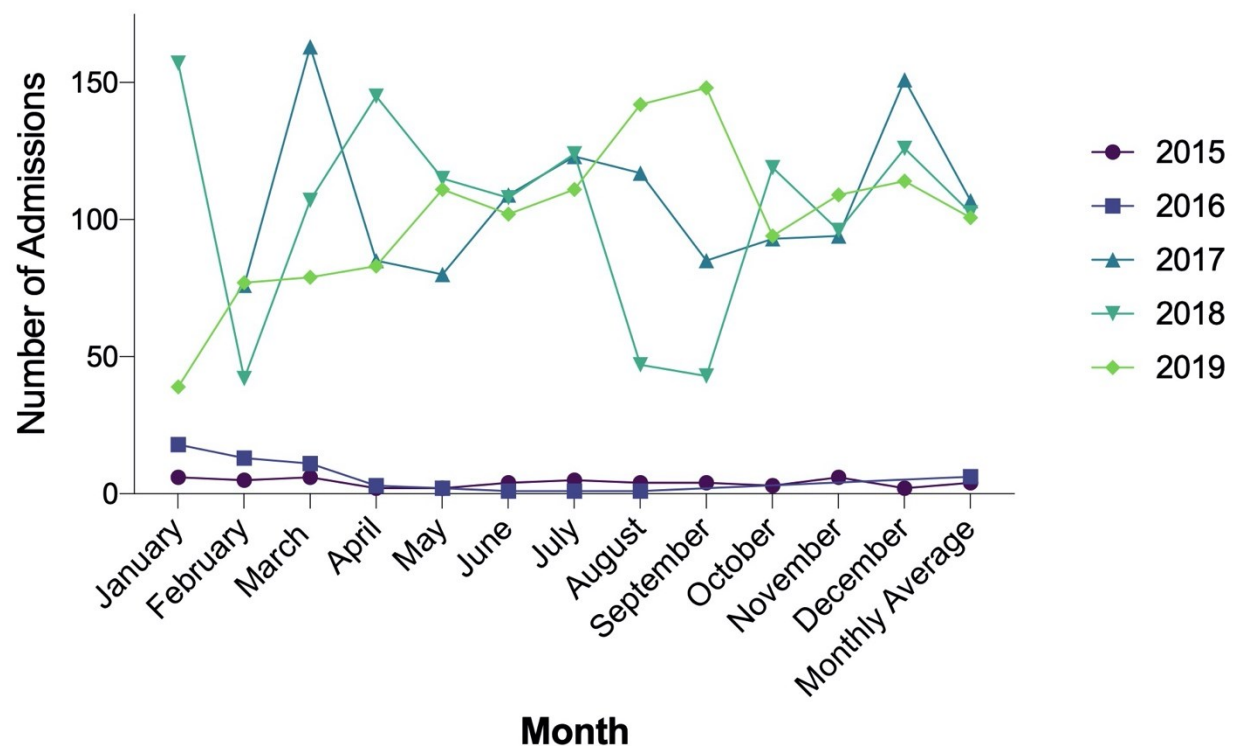
Figure 5.1: Number of monthly documented trauma admissions at Mbarara Regional Referral

Hospital by year. Data prior to the implementation of a trauma registry and electronic patient

registration system were collected from January 2015-July 2016. Data following the

implementation of the trauma registry and patient registration system were collected from

February 2017-December 2019.
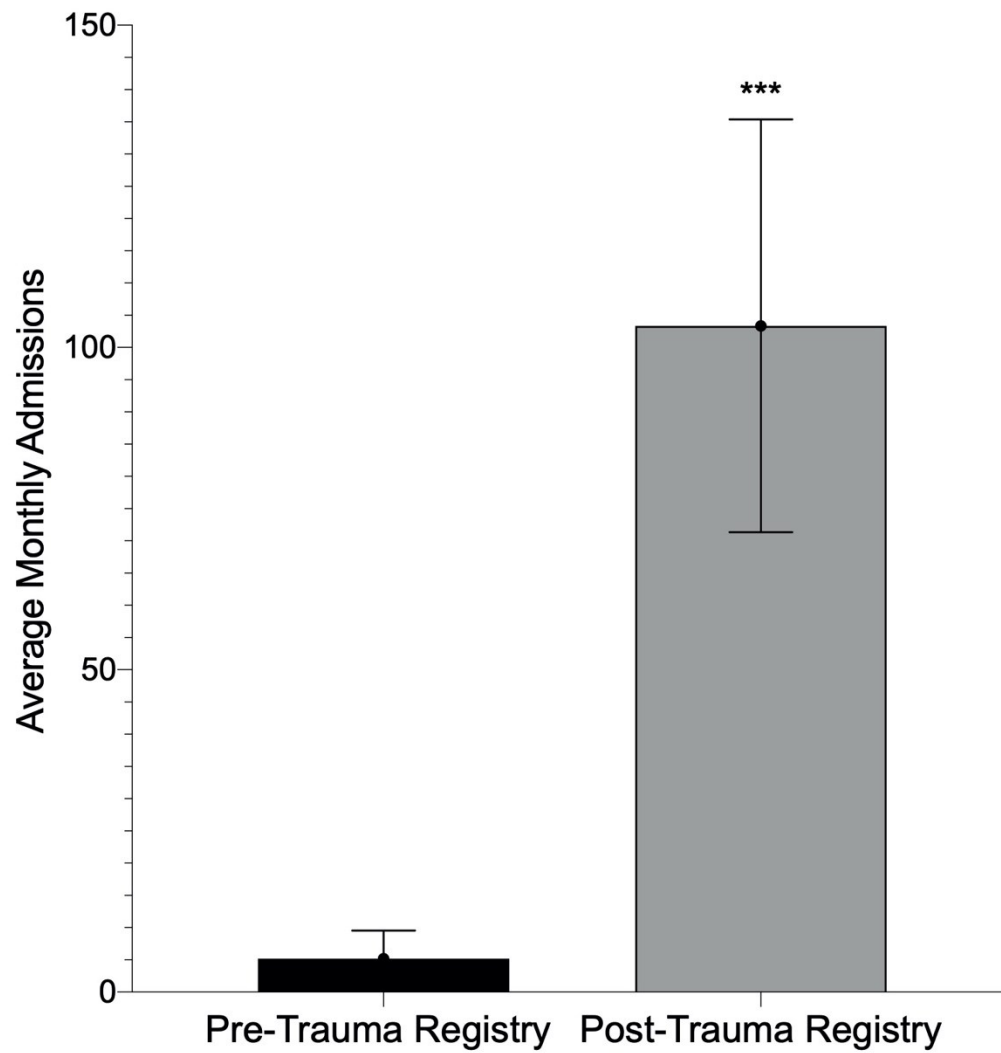
Figure 5.2. Average documented number of monthly trauma admissions at MRRH prior to implementation of the trauma registry and patient registration system (5.16, standard deviation [SD]±4.39) compared to after implementation of the trauma registry and patient registration system (103.36, SD ±32.03), IRR=20.86 (95% CI 15.74-27.64, p<0.001)

CHAPTER 6: CONCLUSION

6.1 Previous Work on Sustainability of Trauma Registries in Low- and Middle-Income Countries

The rapid growth of the field of global surgery has given rise to a number of practical and ethical concerns on how best to address inequitable access to surgical care. As short-term surgical service delivery missions lack quality evidence to support their practice, there is a movement instead towards capacity-building and long-term health systems planning[9][12]. The growth of health systems for surgical care in LMICs includes the establishment of trauma registries, which can act as a means of improving quality and delivery of trauma care in LMICs[29]. However, while several trauma registries have been demonstrated to be feasible in LMICs, few have been able to be sustained long-term[19]. In order to build capacity and improve trauma care, trauma registries in LMICs must develop strategies to ensure sustainability.

6.2 Summary of Findings

This thesis work has studied the ethics of global surgery and the importance of sustainable partnerships (Chapter 2) and reviewed the ethical and practical challenges of creating trauma registries in LMICs (Chapter 3). The creation and evaluation of a mobile application trauma registry to help with ease of usability of the registry was then discussed (Chapter 4), followed by an assessment of a potential means of financial viability for a trauma registry in a LMIC (Chapter 5).

6.2.1. Summary of Chapter 2— Ethical Considerations in Global Surgery: A Scoping Review

Participation in global surgical activities, including the development of trauma registries, should require the deliberate contemplation of the ethical principles and practical implications of participating in such endeavors. In order to identify relevant ethical concerns in global surgery, a scoping review of the literature on ethics of global surgery was completed. Four major ethical domains were identified, including clinical care and delivery; education and exchange of trainees; research, monitoring, and evaluation; and collaborations and partnerships. Within these domains, a number of themes were identified that are relevant to the establishment of trauma registries. These included the need for monitoring patient outcomes in global surgery, which highlights the importance of establishing trauma registries for this purpose, and the importance of involving and crediting researchers from LMICs, which is necessary if establishing or publishing findings from a trauma registry in an LMIC. The literature in this review also emphasized the need for protecting vulnerable populations for research or quality improvement projects in LMICs, and the need for local institutional ethics approvals when conducting research in these settings. Finally, the literature highlighted the importance of sustainability in global surgical collaborations, and the need to extensively involve local communities in planning and coordinating these collaborative efforts.

Several limitations were found in the literature on this topic. First, the majority of the literature focused on themes of clinical care and delivery, or ethical concerns that pertained specifically to the individual doctor-patient relationship. While this is a critical concern, it is also important to consider the larger context of global surgery and the need for developing ethical partnerships and

health systems planning to meet the vast global surgical needs of low-resource settings. While many papers did stress the importance of developing sustainable collaborations, there was a lack of details for how to achieve such sustainability or what sustainable collaborations could look like. There was also a dearth of original research, and most of the literature included was in the form of an editorial or commentary: though this is not unexpected when examining ethics literature, additional original research would help to provide a balanced and evidence-based perspective to the field of study. Furthermore, most of the literature was published by authors from HICs, and the LMIC perspective was sorely lacking on the literature on this topic. The involvement of LMIC authors should help to inform the development of an ethics framework to guide sustainable development of global surgery moving forward.

6.2.2: Summary of Chapter 3— Sustainable and Ethical Development of Trauma Registries in Low- and Middle-Income Countries

A literature review was completed discussing the role of trauma registries in improving trauma care systems and trauma outcomes, and practical considerations for developing a trauma registry in a LMIC. A number of challenges currently exist for the successful implementation of trauma registries in LMICs: most pressingly, the need for ongoing funding and cost savings. A number of strategies for cost savings were explored, including the implementation of electronic or hybrid registries, the use of novel technologies like mobile or tablet applications, and the availability of free or open-source software. While personnel costs were also a major concern for most registries, the optimal approach for lowering the cost of human resources for low-income trauma registries was unclear. The employment of dedicated data collectors or registry staff avoids overburdening clinical personnel and may improve data quality, however, there are less direct costs to having

healthcare workers collect data in addition to their clinical duties. Regardless of type of staff employed, the importance of training to ensure data quality was stressed. Other strategies for improving data quality to ensure sustainability of the registry were also reviewed, including simple data collection forms, point-of-care collection, and ongoing data quality assessments.

The ongoing quality improvement and monitoring of patient outcomes through trauma registries should be viewed as an ethical imperative in low-income settings. Strategies for long-term sustainability were discussed and included the possibility of trauma registries self-funding through the cost savings of ongoing quality improvement, or through partnerships with industry, high-income country academic institutions, or governments. Other ethical considerations that must be addressed prior to the development of trauma registries in LMICs include the need for institutional ethics approval, the imperative for protecting confidentiality, and the question of whether or not to obtain individual informed consent for each trauma registry patients. These ethical concerns over informed consent should be explored further by inviting LMIC stakeholder perspectives, and an emphasis on sustainability of trauma registries should inform future practice.

6.2.3: *Summary of Chapter 4— Development and Evaluation of a Mobile Application Trauma Registry*

One potential technique for improving sustainability of trauma registries is the use of mobile applications. Mobile phone technology is widespread in LMICs, simple to use, and inexpensive to maintain, and therefore represents one form of e-Health that may be more sustainable than computer-based registries in LMICs[120][150]. The need for an electronic version of a trauma registry at MRRH in Uganda was identified to avoid duplication of work efforts, and local stakeholders

expressed that a mobile application may be the best platform of delivery for the electronic trauma registry based on availability and ease of use of this technology. We therefore designed a mobile application trauma registry for use at MRRH and described potential evaluation methods for mobile health software. The UTAUT, a validated questionnaire for evaluating usability of electronic health technology, was used in this situation to evaluate the usability of a mobile trauma registry application in a LMIC context. A population of healthcare providers involved in trauma care at MRRH trialed the application and completed a UTAUT questionnaire. Overall scores on the UTAUT were high, predicting a high potential for future use by healthcare providers. Qualitative feedback from survey respondents has also helped to inform future iterations of the mobile application according to the needs of the relevant stakeholders at MRRH.

Though a mobile application trauma registry represents a promising avenue for improving the Mbarara trauma registry and achieving sustainability, challenges remain for achieving its full implementation in the long term. Ideally, the use of the mobile application should be expanded for functionality on multiple platforms, including non-android mobile devices and personal computers, and should be linked to the hospital's patient registration system. Addressing the facilitating conditions for use of the mobile application, particularly technological support, is an important consideration moving forward, as well as an improved training program to support the early use and adoption of the mobile application are also evidence-based approaches for sustainability that should be implemented. A plan for long-term financial sustainability also needs to be identified and adopted by hospital administration moving forward. And finally, a follow-up survey on actual patterns of use and assessment of data completeness should take place following full implementation of the mobile application trauma registry.

6.2.4. Summary of Chapter 5— Sustainability Analysis of Trauma Registry in a Low-Income Country

While improving the ease of use of trauma registries through strategies like the use of mobile health technology is important for sustainability, the most critical concern remains finding a means for financing trauma registries in LMICs apart from short-term research grants or one-time involvement of external partners. This thesis demonstrated that the linking the establishment of a trauma registry and an electronic patient registration system at the hospital resulted in significant improvements to the documentation of trauma patients which could be used to advocate and apply for increasing funding for trauma patients and fund the registry itself. In this study, the implementation of a concurrent trauma registry and patient registration system resulted in nearly a 20-fold increase in completed trauma patient documentation. As government funding for trauma care is contingent upon the number of trauma patients treated at the hospital, this significant increase in documentation following the implementation of a trauma registry could result in an increase in funding for trauma patients, as well as improve the documentation for all patients admitted to the hospital through the implementation of a patient registration system. The increased funding from improved documentation could both justify and support the ongoing use of a local trauma registry and equip the registry for long-term sustainability.

This study represents a theoretical basis for sustaining a trauma registry in an LMIC, however, future avenues of research should involve the recruitment of hospital administration to create a financial analysis plan and support the ongoing existence of the trauma registry. As this study was also limited by its inability to control for confounding, this study should also be replicated in a

location where a better knowledge of actual trauma rates from police reports and population data from a census could be used to help control for confounding. While there are limitations from the data in this study, it still remains the most feasible explanation that the sudden increase in trauma patient documentations is due to improved documentation from the trauma registry and patient registration, rather than from a sudden increase in trauma patients seen at the hospital.

6.3 Limitations and Future Directions

While a number of barriers to sustainability of the MRRH trauma registry have already been addressed, further challenges remain. Ongoing feedback with local trauma registry staff, hospital administration, and clinical staff was maintained since the initial establishment of the trauma registry, allowing responses to needs as they were identified. Through this feedback, the development of a concurrent patient registration system and a mobile phone trauma registry application were identified as priorities by local stakeholders. While the successful implementation of an electronic patient registration system in the Accidents and Emergencies (A&E) Department at MRRH was completed, and a preliminary mobile application version of the trauma registry was developed, both have since run into financial challenges with ongoing funding for technological and logistical support. At this current time, the trauma registry is supported by a mix of international research grants and the involvement of a Canadian not-for-profit organization, Innovative Canadians for Change (ICChange), which do not represent sustainable funding sources for the future. We hope, on the basis of the presentation of the improved documentation of trauma patients at MRRH in Chapter 5, that the local hospital administration will choose to financially support the trauma registry moving forward, however acknowledge that a number of competing priorities exist at this publicly funded institution in a low-income setting.

Furthermore, in order for the trauma registry at MRRH to achieve sustainability, a transition of ownership of the registry must take place. Currently, the majority of organisational, funding, and research aspects of the trauma registry are being administered by researchers in Canada. This results in a number of logistical challenges, but more importantly, compromises the ethical standards we wish to achieve with this trauma registry. The goal of partnerships and collaborations in global surgery should be equitable, cooperative relationships, with the end goal of transferring ownership of the program over to the local clinical and research staff. In order for the MRRH trauma registry to find continued success, the recruitment of local champions and the use of the trauma registry for research and quality improvement by the staff at MRRH must occur. The MRRH trauma registry should not belong to external partners from a high-income country, but rather to the local healthcare staff, administration, and patients in Mbarara.

6.4 Conclusion

This thesis has examined the ethical and practical considerations of developing trauma registries in LMICs, drawing upon lessons learned in the broader fields of hospital-based disease registries and global surgery. Strategies for achieving sustainability that have been implemented at MRRH including responding to local challenges, attaining the support of hospital administration, and developing a mobile application trauma registry which ranks highly for usability by healthcare providers. An approach for achieving the long-term financial viability of the MRRH trauma registry was demonstrated, through the improved documentation of number of patients following implementation of a trauma registry and concurrent patient registration system. While ongoing challenges remain for the MRRH trauma registry, the findings of this thesis research can provide a

groundwork to overcome barriers to sustainability at MRRH and inform the creation of sustainable

trauma registries in low-income settings around the world.

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SUPPLEMENTAL FILE 1 (CHAPTER 4):

MOBILE APPLICATION TRAUMA REGISTRY SCREENSHOTS OF USER

INTERFACE
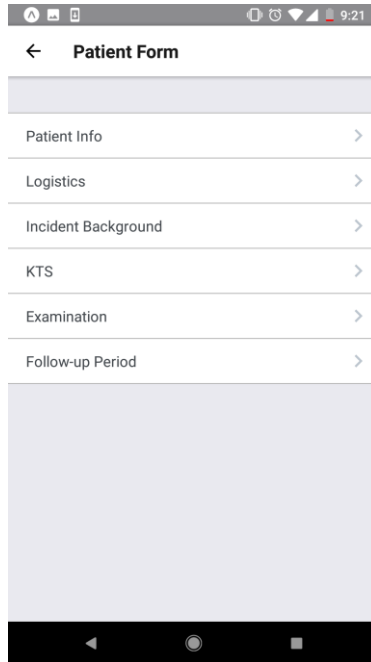
Figure 4.3(Suppl): Mobile application screenshot of home screen
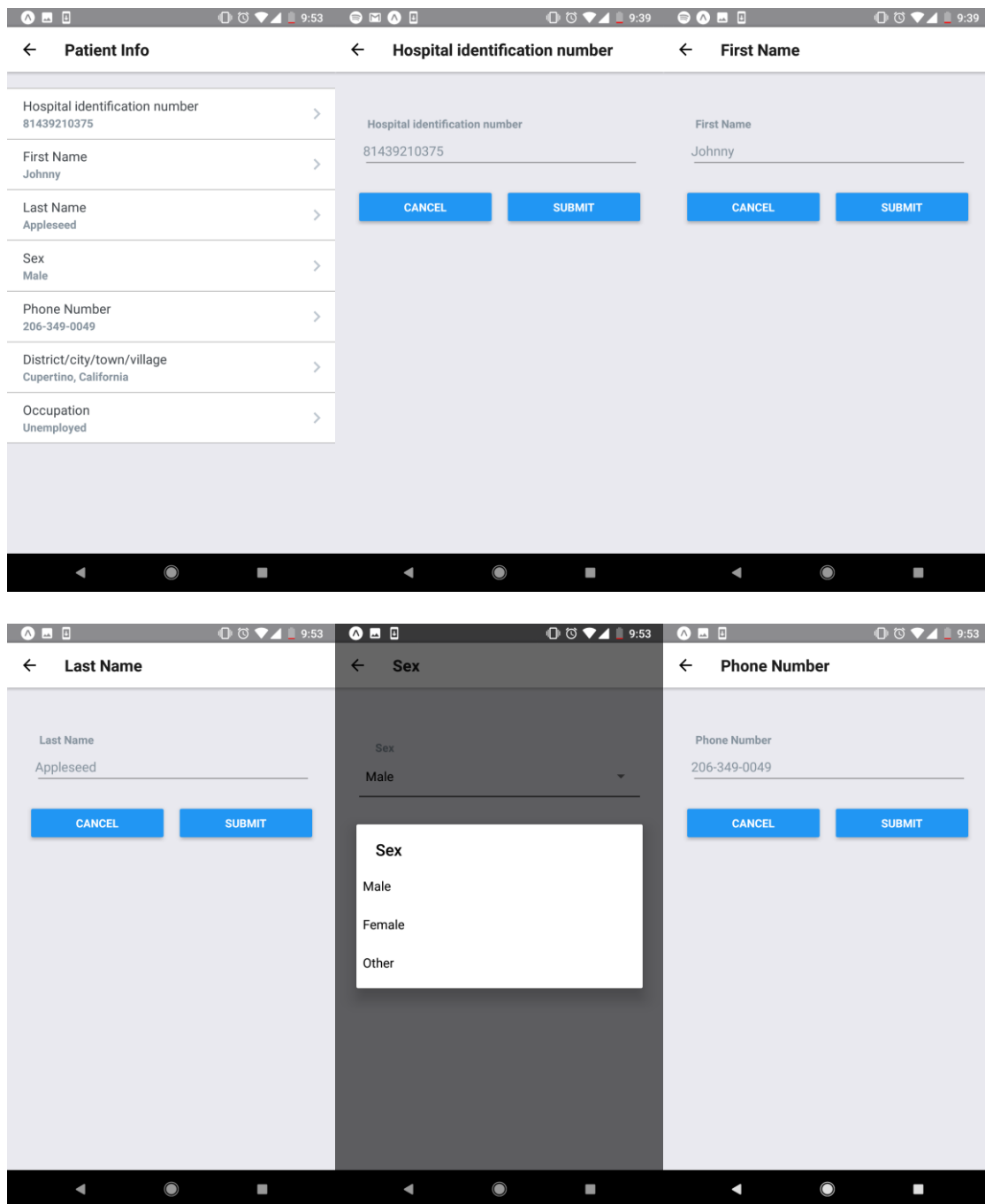
Figure 4.4a(Suppl): Mobile Application Screenshots for Section 1 "Patient Info" completed with mock patient data
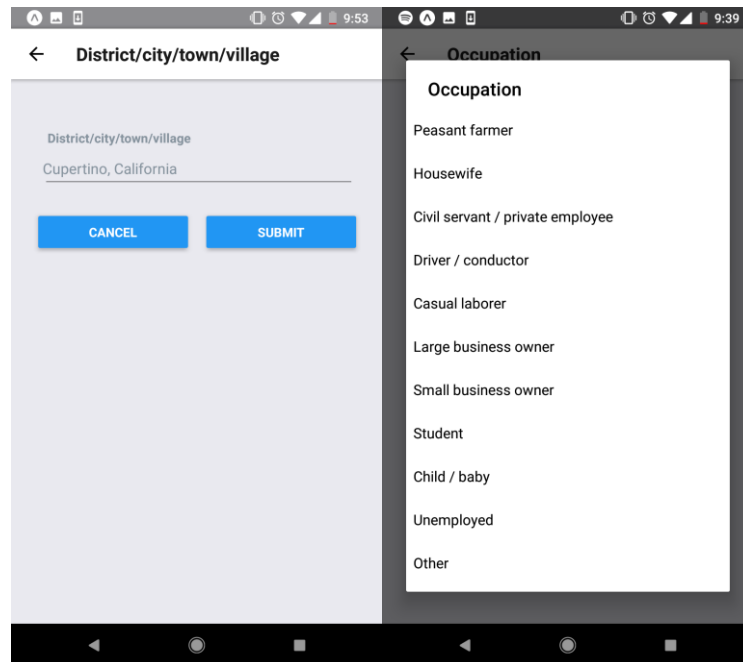
Figure 4.4b(Suppl): Mobile Application Screenshots for Section 1 "Patient Info" completed with mock patient data
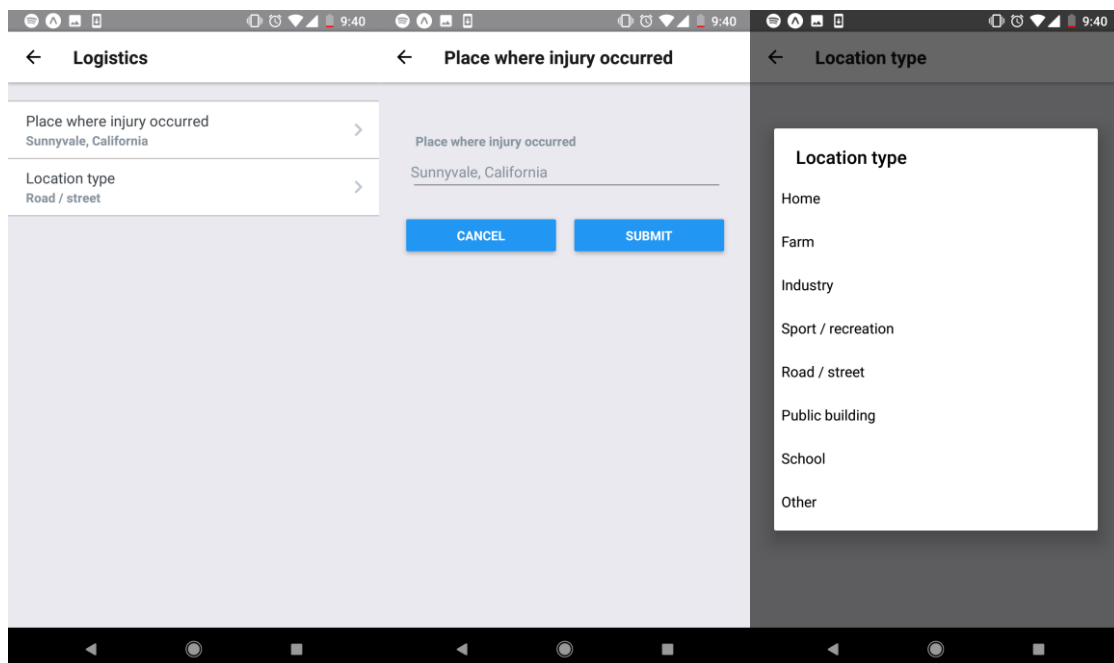
Figure 4.5(Suppl): Mobile application screenshots for Section 2 "Logistics" completed with mock patient data
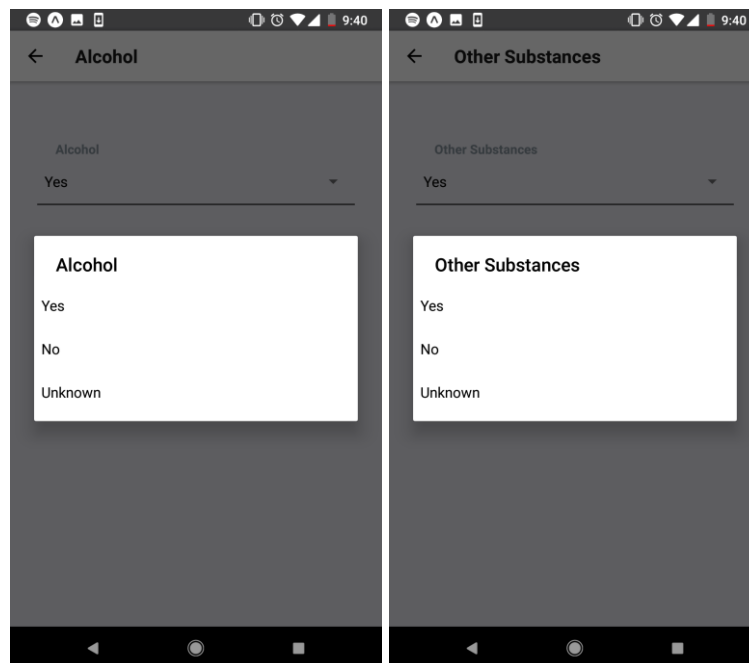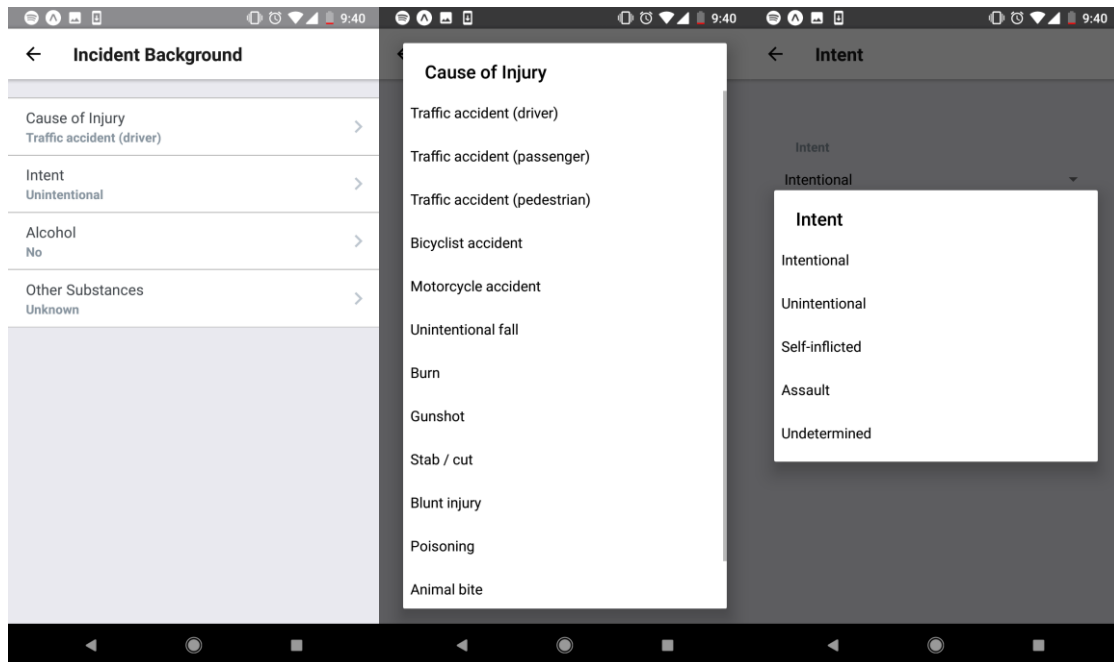
Figure 4.6(Suppl): Mobile application screenshots for Section 3 "Incident Background" completed with mock patient data
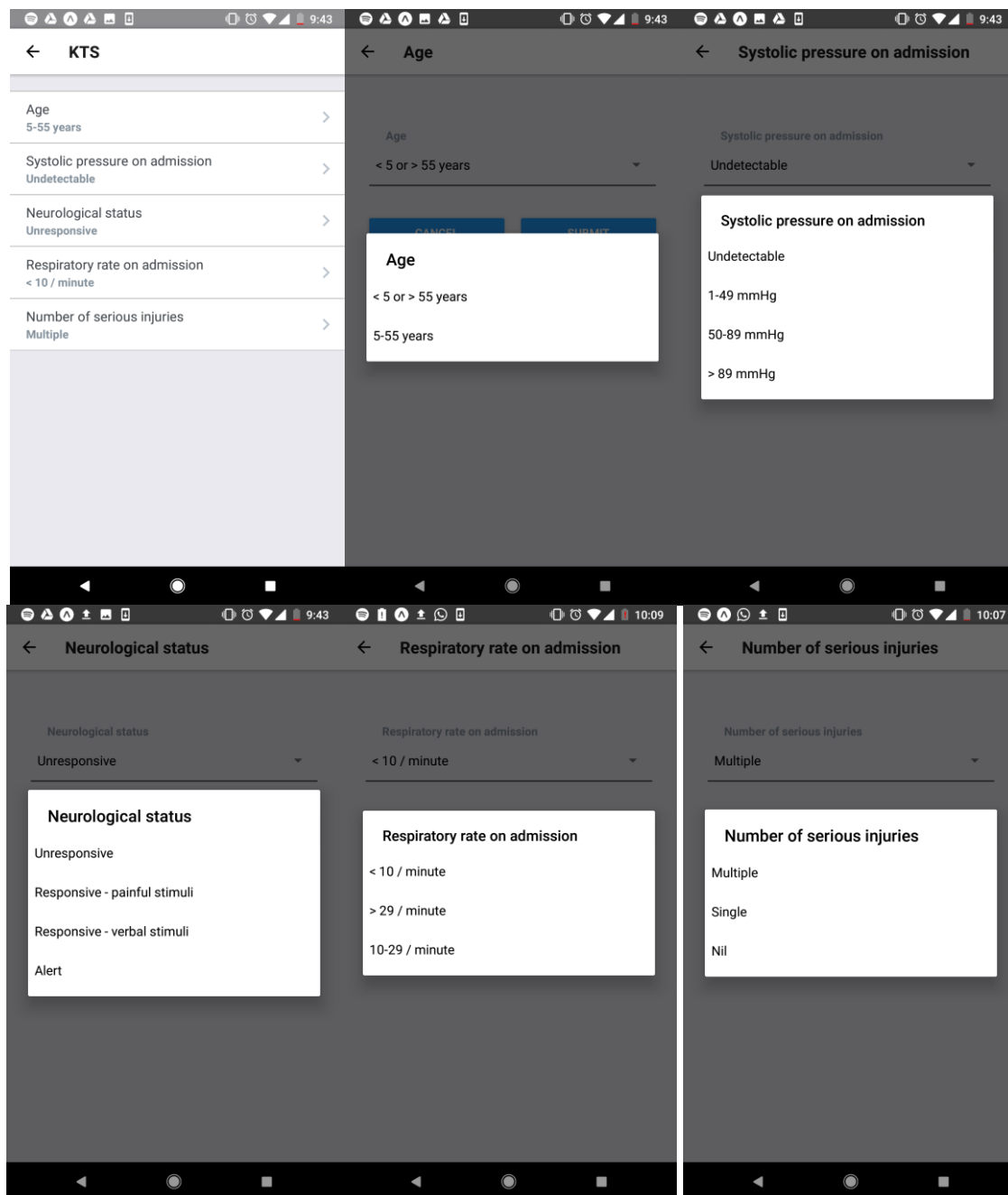
Figure 4.7(Suppl): Mobile application screenshots for Section 4 "Kampala Trauma Score (KTS)" completed with mock patient data
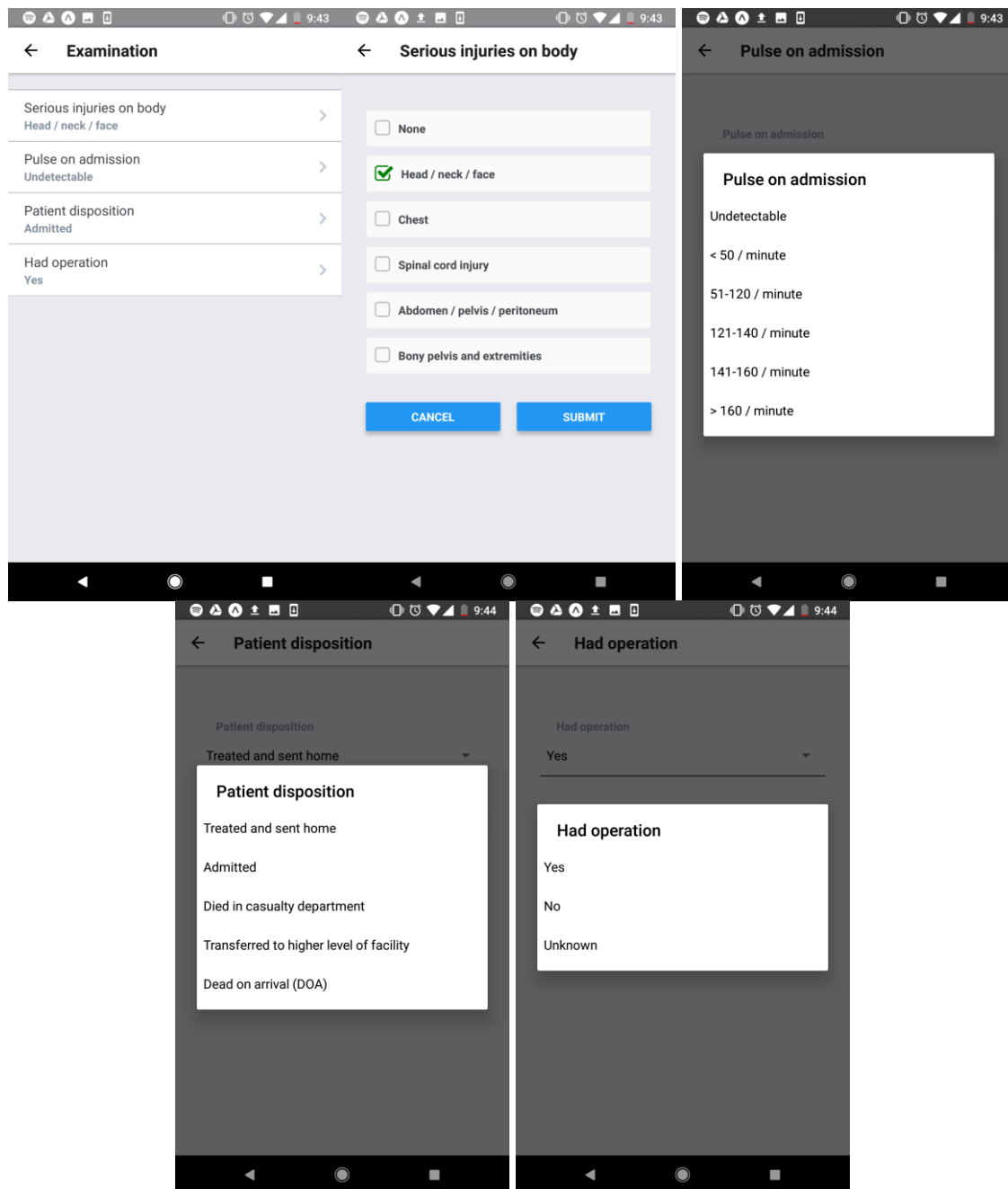
Figure 4.8(Suppl): Mobile application screenshots for Section 5 "Examination" completed with mock patient data
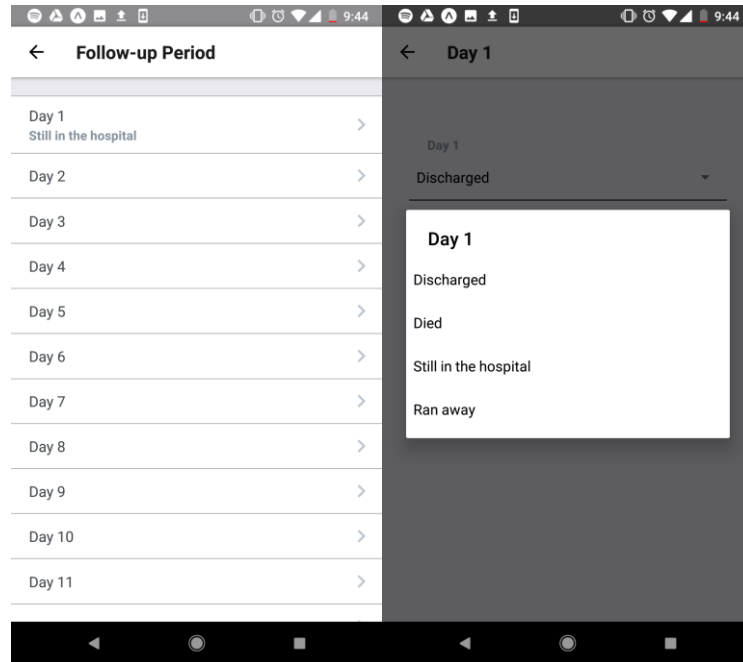
Figure 4.9(Suppl): Mobile Application Screenshots for Section 5: "Follow-Up Period" completed with mock patient data

UTAUT AND SURVEY QUESTIONNAIRE RESPONSES

Table 4.3(Suppl): UTAUT construct scores by sex

	Sex (female)	Sex (male)	Overall	p-value
Performance Expectancy (PE)				
Mean score (SD)	6.88 (± 0.35)	6.35 (±1.51)	6.41 (± 1.43)	0.33
Percentage (%) of responses scoring ≥5	87.50	91.66	92.65	
Effort Expectancy (EE)				
Mean score (SD)	7.00 (±0)	6.16 (± 1.48)	6.25 (± 1.41)	0.17
Percentage (%) of responses scoring ≥5	100.00	93.33	94.12	
Attitude Towards Technology (AT)				
Mean score (SD)	7.00 (±0)	5.93 (±1.54)	6.05 (± 1.43)	0.07
Percentage (%) of responses scoring ≥5	100.00	91.07		
Social Influence (SI)				
Mean score	6.625 (±0.52)	5.66 (±1.30)	5.44 ± 1.27	*0.04*
Percentage (%) of responses scoring ≥5	100.00	82.15		

Facilitating Conditions (FC)				
Mean score (SD)	6.00 (±0.52)	5.24 (±1.98)	5.32 ± 1.99	0.43
Percentage (%) of responses scoring ≥5	80.00	71.11	70.59	
Self-Efficacy (SE)				
Mean score (SD)	6.29 (±0.95)	5.90 (±1.48)	5.94 (± 1.44)	0.51
Percentage (%) of responses scoring ≥5	100.00	84.94		
Anxiety (AN)				
Mean score (SD)	2.20 (±1.64)	3.45 (±2.37)	3.34 (± 2.33)	0.52
Percentage (%) of responses scoring ≥5	20.00	39.29		
Behavioural Intention to Use (BIU)				
Percentage (%) indicating intention to use within 6 months or less	83.33	87.18	86.67	0.80

Table 4.4(Suppl): UTAUT construct scores by age category

	Age (<30)	Age (≥30)	Overall	p-value
Performance Expectancy (PE)				
Mean score (SD)	6.53 (± 0.76)	6.31 (± 1.83)	6.41 (± 1.43)	0.52
Percentage (%) of responses scoring ≥5	96.87	88.89	92.65	
Effort Expectancy (EE)				
Mean score (SD)	6.54 (±0.66)	6.00 (±1.82)	6.25 (± 1.41)	0.17
Percentage (%) of responses scoring ≥5	100.00	88.88	94.12	
Attitude Towards Technology (AT)				
Mean score (SD)	6.04 (±0.96)	6.05 (± 1.81)	6.05 (± 1.43)	0.96
Percentage (%) of responses scoring ≥5	96.43	88.57		
Social Influence (SI)				
Mean score	5.46 (±1.00)	6.03 (±1.40)	5.44 ± 1.27	0.08
Percentage (%) of responses scoring ≥5	78.58	88.89		
Facilitating Conditions (FC)				
Mean score (SD)	5.21 (±2.08)	5.42 (±1.94)	5.32 ± 1.99	0.71

Percentage (%) of responses scoring ≥5	79.17	76.92	70.59	0.42
Self-Efficacy (SE)				
Mean score (SD)	5.70 (±1.67)	6.18 (±1.15)	5.94 (± 1.44)	0.14
Percentage (%) of responses scoring ≥5	82.50	90.00		
Anxiety (AN)				
Mean score (SD)	3.38 (±2.41)	3.31 (±2.29)	3.34 (± 2.33)	0.78
Percentage (%) of responses scoring ≥5	50.00	37.92		
Behavioural Intention to Use (BIU)				
Percentage (%) indicating intention to use within 6 months or less	86.36	86.96	86.67	0.15

Table 4.5(Suppl): UTAUT by occupation type

	Occupation (resident)	Occupation (intern)	Occupation (nurse)	Total	p-value
Performance Expectancy (PE)					
Mean score (SD)	6.22 (±1.87)	6.54 (±0.66)	6.88 (± 0.35)	6.41 (± 1.43)	0.44
Percentage (%) of responses scoring ≥5	86.12	100.00	87.50	92.65	
Effort Expectancy (EE)					
Mean score (SD)	5.85 (±1.79)	6.61 (±0.61)	7.00 (±0)	6.25 (± 1.41)	0.08
Percentage (%) of responses scoring ≥5	88.88	100.00	100.00	94.12	
Attitude Towards Technology (AT)					
Mean score (SD)	5.92 (±1.76)	5.95 (±1.05)	7.00 (±0)	6.05 (± 1.43)	0.20
Percentage (%) of responses scoring ≥5	88.89	95.00	100.00		
Social Influence (SI)					
Mean score	5.75 (±1.40)	5.50 (±1.10)	6.63 (±0.52)	5.44 (± 1.27)	0.10
Percentage (%) of responses scoring ≥5	86.11	75.00	100.00		

Facilitating Conditions (FC)					
Mean score (SD)	5.07 (±2.00)	5.50 (±1.98)	6.00 (±0.52)	5.32 (± 1.99)	0.58
Percentage (%) of responses scoring ≥5	66.67	77.77	80.00	70.59	
Self-Efficacy (SE)					
Mean score (SD)	6.05 (±1.17)	5.70 (±1.84)	6.29 (±0.95)	5.94 (± 1.44)	0.49
Percentage (%) of responses scoring ≥5	86.04	83.33	100.00		
Anxiety (AN)					
Mean score (SD)	3.56 (±2.33)	3.29 (±2.46)	2.20 (±1.64)	3.34 (± 2.33)	0.48
Percentage (%) of responses scoring ≥5	40.62	37.50	20.00		
Behavioural Intention to Use (BIU)					
Percentage (%) indicating intention to use within 6 months or less	78.26	100	83.33	86.67	0.15

Table 4.6: Qualitative responses and coding

Response (What Did You Like About Using This Mobile Application?)	Theme(s) Identified
• It hastens the data entry problem and increases efficiency in follow-up • It shortens the process of obtaining information and data entry. Better storage of data for future use. • Easy to use and detailed • I liked most using this app- especially (unintelligible)/ choosing the KTS easily • Easy flow in scrolling down, rather than flipping page for each section • Easy to use and understand • It makes data collection and entry fast as it is all done by the bedside • Easy to use interphace (sic) • User friendly • It is simple and clean. It needs short inputs (at a click) • (unintelligible) if patient's (unintelligible) and medical information can be obtained from the app • The comprehensiveness of the amount of data captured about the patient, even preceding trauma examination and followup • A tool that captures almost all the information about the patient in a short time • Its fast + it helps store patient information in one place where one could check it out later • Having database • It's easy to learn using it. Doesn't take long to fill in details • This quickens and makes work and research easy	• Speed/efficiency • Speed/efficiency, future research or clinical use of data • Ease of use • Ease of use • Ease of use • Ease of use • Speed/efficiency • Ease of use • Ease of use • Ease of use • (none) • Comprehensiveness of Data • Comprehensiveness of data, speed/efficiency • Speed/efficiency, future research or clinical use of data • Future research or clinical use of data • Ease of use, speed/efficiency • Speed/efficiency, future research or clinical use of data
Responses (What Did You Not Like About Using This Mobile Application?)	
• Needs a smart phone. Needs skills to operate and enter data • Nothing	• Type of technology/platform, ease of use • (none)

• It might take a lot of time entering the data. Might not be compatible installing in some electronic gadgets	• Speed/efficiency, type of technology/platform
• Conditions do not allow photo-taking	• Comprehensiveness of data
• Requires a smart phone	• Type of technology/platform
• Nothing	• (none)
• Data entry involves and includes patient names	• Privacy/security
• Requires an Android phone	• Type of technology/platform
• May be cumbersome if patients are many	• Speed/efficiency
• It is not possible to scroll on a simple page?	• Ease of use
• Misses out on investigations, interventions, and management plan of patients	• Comprehensiveness of data
• Has no management plan	• Comprehensiveness of data
• Its time consuming especially where there are few medical staff as compared to the influx of patients	• Speed/efficiency
• Hard walk-through	• Ease of use
• Does not include parameters in trauma assessment like GCS in adults and matched GCS in kids	• Comprehensiveness of data
• I don't know whether its applicable for all phones including apple	• Type of technology/platform
Suggestions to Make the App Easier to Use	
• Maybe to be a mobile application (unintelligible)	• (none)
• None	• (none)
• Reduce the content in particular (very many parameters for particular)	• Speed/efficiency
• This is so nice, I don't have suggestions but am saying keep on make	• (none)
• It could allow saving data to be completed later in case one initiates and is caught up in other duties	• Ease of use
• Need bigger mobile phones	• Type of platform
• Include in all fields available in the questions	• Comprehensiveness of data
• Include picture section. Include scoring system	• Comprehensiveness of data
• Training of postgraduates who will be immediate people to apply this app	• (other)
• Include investigations and management plan	• Comprehensiveness of data
• Please include the management plan	• Comprehensiveness of data
• Developer should increase its ability to function on iOS devices	• Type of technology/platform
• Easier walkthrough	• Ease of use
• Increasing awareness of this app to other health workers	• (other)
• None	• (none)

Other Comments/Questions/Concerns	
• Why does it refuse to work in some (unintelligible)	• (none)
• A good app that will help us in daily research because of data studied	• Future research or clinical use of data
• What I am wondering - is it always when you are using this app needs internet or not?	• Type of platform/technology
• If connected to the internet, does data go directly into the Redcap? (server)	• Type of platform/technology
• If one doesn't have a smartphone what happens? Or when the phone gets stolen?	• Type of platform/technology, Privacy/Security
• From which time shall we start effecting the use of this app?	• (none)
• It's a wonderful innovation, can't wait to use it	• (none)

UTAUT Survey Questionnaire

Survey Questionnaire:	
Usability of a trauma registry mobile application amongst health care providers in Uganda	

Section 1: Participant Demographics
Please circle one of the following answers or write in the correct information

1. Sex
   a. Male
   b. Female
   c. Prefer not to say

2. Occupation:
   a. Nurse
   b. Resident
   c. Medical Officer / Clinical Officer
   d. Attending Physician
   e. Other: _____

3. Age: _____

Section 2:
Please answer the following questions on a scale of 1 through 7. An answer of 1 means "strongly disagree" and an answer of 7 means "strongly agree". Put an X in the box that represents your answer. If the answer does not apply to you, select "not applicable".

Example:

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	Moderately Disagree	Mildly Disagree	Neither agree nor disagree	Mildly Agree	Moderately Agree	Strongly Agree	Not Applicable
A triangle has three sides							**X**	

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
Using this mobile app would be useful in my job								
Using this mobile app would help me to input more patient data into a trauma registry								
Using this mobile app would help me to input data into the trauma registry more quickly								
If I use this system, I will have more chances to perform research and quality improvement								

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
My interaction with the mobile app was clear and understandable								
It would be easy for me to become skillful at using this app								
Learning to operate this app is easy for me								

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
Using this mobile app for a trauma registry is a good idea								
I like working with this mobile app								
Working with this mobile app makes work more interesting								
This mobile app is enjoyable to use								

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
My supervisors at work would want me to use this mobile app at my job								
My coworkers would want me to use this mobile app at my job								
Management at the hospital would be supportive of my use of this app								

	In general, the hospital supports the use of this mobile app for a trauma registry							

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
I have the resources necessary to use this mobile app								
I have the knowledge necessary to use this mobile app								
This mobile app is not compatible with other systems that I use								

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
If I needed help using the mobile app, I would have access to a specific person or group of people who could assist with difficulties in using it								
I could complete entry of patient data into the mobile app if no one was around to tell me what to do								

I could complete patient data entry into the app if I could call someone for help if I got stuck							
I could complete patient data entry into the app if I had a lot of time available							
I could complete patient data entry into the app if the only assistance I had was what is currently built into the app							

	1	2	3	4	5	6	7	N/A
	Strongly Disagree	**Moderately Disagree**	**Mildly Disagree**	**Neither agree nor disagree**	**Mildly Agree**	**Moderately Agree**	**Strongly Agree**	**Not Applicable**
I feel apprehensive about using this mobile app								
It scares me to think I could lose information by pressing the wrong button								
I hesitate to use this mobile app for fear of making mistakes I can't change afterwards								
This mobile app is somewhat intimidating for me to use								

Section 3.
Please circle Yes or No

1. If this app were immediately available, I would intend to use this app in the next 6 months   **Yes**
   No

2. If this app were immediately available, I would plan to use this app in the next 6 months   **Yes**
   No

3. I predict I would use this app in the next 6 months (if available)   **Yes**   **No**

Section 4. Please write in your answers or feedback to the questions below

1. What I liked about using this app:

   _____

   _____

   _____

   _____

   _____

2. What I did not like about using this app:

   _____

   _____

   _____

   _____

   _____

3. Suggestions to make this app easier to use:

   _____

_____

_____

_____

_____

4. Other questions, comments, or concerns about this app:

_____

_____

_____

_____

_____

Check this box here if you do not want your responses included in the study results: ☐