Responding to the Global Injury Burden by Improving Access to Orthopaedic Medical Devices:
A qualitative case study of orthopaedic services in Uganda

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Abstract

The global burden of injury is severely underappreciated and disproportionately affects low-income countries. With timely, appropriate orthopaedic treatment disability and mortality can be prevented, yet appropriate health resources are seldom available. Without orthopaedic medical devices (OMDs), quality of orthopaedic care suffers and the burden of preventable injury is exacerbated. A qualitative case study of 45 key informant interviews was conducted in Uganda to explore accessibility of OMDs, such as plaster, external fixators and implants. Data analysis elicited four major themes as barriers preventing access to OMDs in Uganda: 1) Poor leadership in government and corruption; 2) inadequate human resources; 3) inefficient and insufficient health care infrastructure; and 4) high costs of OMDs and poverty. Potential solutions for improving access to orthopaedic care were categorized as policies prioritizing orthopaedic services, training more orthopaedic specialists and creating incentives for them to work in underserviced areas, and innovative strategies funding for orthopaedic services.
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List of Abbreviations

AAOS – American Academy of Orthopaedic Surgeons

AdvaMed – Advanced Medical Technology Association

AIDS – Acquired Immune Deficiency Syndrome

CAD – Canadian Dollars

DALY – Disability Adjusted Life Year

FDA – Food and Drug Administration

HIV – Human Immunodeficiency Virus

HSSIP – Health Sector Strategic and Implementation Plan

IMF – International Monetary Fund

MDG – Millennium Development Goals

MEDEC – Canada’s Medical Technology Companies

MSF – Médecins Sans Frontières

NMS – National Medical Stores

OMD – Orthopaedic medical device

SIGN – Surgical Implant Generation Network

TRIPS – Agreement on the Trade Related Aspects of Intellectual Property Rights
UNDP – United Nations Development Program

USD – United States Dollars

WHO – World Health Organization

WTO – World Trade Organization
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CHAPTER ONE
The need for appropriate access to orthopaedic medical devices to respond to the global injury burden

1.1 Thesis summary

The global injury burden is severely underappreciated by the international health and surgical communities. Orthopaedic injuries and disease account for 14% and 9% of the world’s morbidity and mortality, respectively (WHO, 2004). Ninety percent of injury deaths occur in low- and middle-income countries (Beveridge and Howard, 2004). Globally, injuries cause approximately as many deaths per year as HIV/AIDS, tuberculosis and malaria combined (Murray & Lopez, 1997). By 2020, road traffic crashes are expected to be the leading cause of Disability Adjusted Life Years (DALYs) worldwide (Murray & Lopez, 1997). By the year 2030, road traffic crashes, a major cause of orthopaedic injury, are predicted to be the third leading cause of long-term disability globally (WHO, 2008). This is an area that has not been a global health priority and demands immediate attention. Policy makers and health specialists need to educate the global community on the injury burden and develop mechanisms for alleviating it.

Untreated orthopaedic injuries can result in permanent disability and mortality and thus have a significant impact on human and economic development. In 2004, injuries accounted for 12% of the DALYs lost globally which was more than the DALYs lost to HIV/AIDS (3.9%), tuberculosis (2.2%), and malaria (2.8%) combined, and twice as much as the DALYs lost to diarrhea (6.0%) or cancer (5.6%) (WHO, 2004).

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1 Disability Adjusted Life Years (DALYs) are a measure of the combined impact of the morbidity and mortality of a condition, by adding the years of life lost because of premature mortality with the healthy years of life lost because of disability (WHO Global Burden of Disease, 2008).
Alleviating the burden of orthopaedic injuries in low-income countries will require timely access to appropriate orthopaedic care. As many orthopaedic procedures require an orthopaedic medical device, such as plaster, an external fixator or an implant (Canale and Beaty, 2002), accessibility and availability of these devices are essential. Untreated or maltreated orthopaedic injuries can result in preventable death, and disability due to infections, permanent deformities, chronic pain, or inability to ambulate (Canale and Beaty, 2002). In many low-income countries however, orthopaedic services and medical devices are generally inadequate or unavailable, as the required expertise, infrastructure and funding are often lacking.

Despite the negative health impact when orthopaedic medical devices are unavailable, this issue has received scant attention in global health, policy or orthopaedic forums. This may be a result of the little international aid and support diverted to trauma, or possibly from the lack of media attention on the rapid increase and impact of the burden of injuries. Research on the accessibility of orthopaedic medical devices in low-income countries is wanting, and may reveal policies and strategies for reducing the burden of injury.

The concept for this research was conceived from the student’s previous engagement in advocacy groups promoting the well-known issue of access to essential medicines in low-income countries, such as HIV/AIDS anti-retrovirals in Africa, and specifically how high costs and intellectual property policy can affect access to medicines. As this student is also an orthopaedic surgery resident, she began to question if inaccessibility to certain medicines, high costs of pharmaceuticals or other medical equipment, or intellectual property policies also impeded provision of orthopaedic care. While researching the question, it became clear that access to appropriate orthopaedic care requires improvements in many aspects of the current health care infrastructure in low-income countries. There are needs for improved availability of medicines, medical equipment and medical devices, and increased human resources and capital. Since very little research existed on the issue of access to orthopaedic medical devices, she decided to focus on this problem.

There is a shared assumption, by orthopaedic surgeons and allied health professionals, that orthopaedic medical devices are essential to providing optimal and appropriate treatment of orthopaedic conditions and injuries. Despite this, access to orthopaedic devices is limited
globally except in high-income countries. Investigation into why access to orthopaedic medical devices is limited, whether this affects patient care and outcomes, what can be done to improve access to orthopaedic care and medical devices, and what types of orthopaedic medical devices are appropriate in low-resource settings, is wanting. It will require multiple studies to answer each of those questions. This thesis therefore focuses the problem of access to orthopaedic medical devices. Based on the results of an original descriptive qualitative case study in Uganda, it reports on the barriers to accessibility of orthopaedic medical devices and offers potential solutions for improving access and availability to orthopaedic care and medical devices.

This case study elicited four major themes as barriers to orthopaedic medical devices: 1) Poor leadership in government and corruption, 2) inadequate human resources, 3) inefficient and insufficient health care infrastructure, and 4) high costs of orthopaedic medical devices and poverty. Potential solutions for improving access to orthopaedic care were categorized as policies for prioritization of orthopaedic services, training of more orthopaedic specialists and creating incentives for them to work in underserviced areas, and innovative strategies funding for orthopaedic services.

This thesis will provide background on the problem of access to orthopaedic care and medical devices based on an extensive literature search, and explore how it relates to the comparable problem of access to essential medicines. As medical devices and pharmaceuticals are both complex and lucrative health industries that are subject to stringent intellectual property laws, part of this chapter is dedicated to exploring whether these policies impede access to medical devices in the same ways they are known to prevent access to drugs. Moreover, the flexibilities in intellectual property laws that have enabled access to lower-cost drugs in low-income countries are investigated to determine if they could apply to medical devices as well.

The methodology of the case study is explained and justified based on examples from the literature in Chapter 1. Chapter 2 contains the raw results of the study and detailed outcomes of the data analysis. This thesis investigates in further detail the problem of corruption in Chapter 3. Corruption, as defined by Transparency International, is the “abuse of entrusted power for private gain” (Robinson, 2006, p.xvii). Corruption in medicine is not unique to low-income countries, and poses an ongoing challenge to the integrity of the medical enterprise and
profession as a whole. The unethical practices known to occur in the pharmaceutical and medical device industries are discussed. The impact of corruption on access to orthopaedic care and medical devices is still unknown, and is explored in this document based on findings from this case study.

Understanding and overcoming the barriers of access to orthopaedic medical devices is a crucial step in alleviating the global burden of preventable injury. The identified barriers are likely to be experienced in most low-resource health care settings, and could also be used to construct a framework that can be applied to identify, evaluate, and resolve other health problems in a broad range of disciplines globally. Discussion regarding this framework for problem solving in global health and concluding remarks will be included in Chapter 4.
1.2 The injured patient’s perspective of the problem of access to orthopaedic medical devices

“Adam” is a 35-year-old male teacher from Northwest Uganda. In April 2010, he was hit by a motorcycle. He had an open right femur fracture. After 6 months of non-operative treatment with traction in a public hospital, x-rays showed he also had a right hip dislocation and his fracture had not healed. In November 2010 he was transferred 4 hours away to a hospital with an orthopaedic surgeon. He had surgery for his femur that was fixed with a free, donated implant. His hip will require a second procedure that likely will not be free. They hope he can walk by the next summer.
“Beatrice” is a 45-year-old female “digger” or farmer, wife, and mother of eight from the bush in Northeast Uganda. While trying to break up a fight, she sustained fracture-dislocation of her forearm. Her injury requires surgery to prevent permanent disability. The implants for her procedure cost 400,000 Ugandan Shillings (175 US dollars). Her family is very poor and does not even have a goat to sell for the money. Without surgery, she will not be able to feed her family or work. She will be sent home untreated if she cannot pay.
“Carlos” is a 12-year-old male from Western Uganda near the Sudan. He has a 2-year history of osteomyelitis of his right tibia. Traditional healers and Western doctors have been unable to treat his infection. His bone has been sticking out of his skin for months. His family has decided to pay for care in a private hospital with an orthopaedic surgeon. The day after admission, his leg is treated surgically. He can walk and will return to school in a few weeks.

Clinical vignettes are derived from interviews with patients in Uganda. All identifying information has been removed. This researcher took all photographs while conducting this study in Uganda in 2010.
1.3 Background: The global injury burden and orthopaedic services in low-income countries

1.3.1 The global burden of injury and access to orthopaedic medical devices

Musculoskeletal injuries account for 14% of the world’s morbidity and mortality (WHO, 2004). There are over 5 million injury deaths annually, and 90% of them occur in low- and middle-income countries (Beveridge and Howard, 2004). Globally, injuries cause approximately as many deaths per year as HIV/AIDS, tuberculosis and malaria combined (Murray & Lopez, 1997). According to the World Health Organization, road traffic crashes, a common cause of musculoskeletal injury, were ranked the ninth leading cause of death and disability in the world in 2004 (WHO Factsheet, 2008). By the year 2030, road traffic crashes are projected to become the third leading cause of long-term disability globally, only after ischaemic heart disease and unipolar depressive disorders, respectively (WHO Global Burden of Disease, 2008). This is mostly due to a sharp rise in road traffic crashes in low-income countries, and in sub-Saharan Africa, southern Asia and South-East Asia particularly (WHO Global Burden of Disease, 2008). The term “crash” has replaced “accident” to clarify that road traffic crashes are non-random events and are therefore amenable to prevention strategies (Spiegel et al., 2008). Globally for both sexes, road traffic crashes are the third leading cause of disease burden in the 15-44 year age group (WHO, 2008). Injuries are an increasingly important global public health concern. Injuries have economic and social costs that impact individuals, communities and societies, and this is most pronounced in low-income countries where they exacerbate the vicious cycle of poverty because of the lack of social and health infrastructure (Gosselin et al., 2009).

Alleviating the burden of injury will require timely and appropriate orthopaedic surgical care in low- and middle-income countries, and yet such services are often inadequate or unavailable as the required expertise, infrastructure and funding are often lacking (Gosselin et al., 2009). As many orthopaedic procedures require an orthopaedic medical device, such as plaster, an external
A fixator or an implant (Canale and Beaty, 2002), accessibility and availability of these devices are essential. Untreated or maltreated orthopaedic injuries can result in preventable death, and disability due to infections, permanent deformities, chronic pain, or inability to ambulate (Canale and Beaty, 2002).

Despite the negative health impact when orthopaedic medical devices are unavailable, this issue has received scant attention in global health or orthopaedic forums. A literature review using medical and scholarly search engines and a variety of non-medical media from the internet revealed only six articles concerning the problem of access to medical equipment (Vossberg, 1985, Padhi & Padhi 2007, Nugent, 2008, Zirkle, 2008, Gupta et al., 2009, Gosselin et al., 2009), and a recent publication by the World Health Organization on the global accessibility and appropriateness of medical devices (WHO, 2010). The literature is limited and highlights only a few of the potential obstacles to access of orthopaedic care and medical devices. One barrier described in the American health care system is the high cost of orthopaedic medical devices (Nugent, 2008). In low-income countries, cost can be assumed an even larger obstacle to access, as patients must pay for the orthopaedic devices themselves (Zirkle, 2008). Cost renders medical devices, and often any kind surgical care, inaccessible to many patients. Inadequate human resources and limited training of orthopaedic specialists have also been reported as barriers to access of orthopaedic care, but this has not yet been related to availability of equipment (Speigel, 2008). There is also increasing awareness that corruption at the health care worker, hospital and government levels impedes access to health services (Kohler, 2010), and it is likely that orthopaedic services are similarly affected by corrupt activities.

Presently, the literature is devoid of research exploring the consequences of limited access to orthopaedic medical devices on the provision and quality of orthopaedic care, and on patient outcomes, nor does it offer analysis on how to improve access to these needed tools. If resources and research are not devoted to understanding impediments to orthopaedic care or the global injury burden, the number of injuries will only continue to rise and exacerbate the growing rates of mortality and long-term disability.
1.3.2 The orthopaedic medical device industry

Orthopaedics is the surgical specialty that concerns the musculoskeletal system, including the bones, joints, muscles and ligaments (Merriam-Webster Online Dictionary). Most orthopaedic procedures require an orthopaedic medical device or implant. For example, common procedures such as treatment of fractures, joint replacements, and correction of spine and limb deformities, are dependent on a variety of fixation medical devices from plaster, to external frames, to plates and screws, and joint prostheses (Canale and Beatty, 2002). Many of these devices, which in most cases are developed in industrialized countries, are patented (Annual Reports of Stryker Corporation and Zimmer Holdings, Inc., 2008 and 2009). The global orthopaedic medical device market was valued at 19.2 billion USD in 2008 and is expected to grow 42.9% to 27.4 billion USD in 2013 (Datamonitor Report, 2009). A review of the largest companies in the orthopaedic device industry using the European Patent Office (EPO) online database indicates that individual companies may hold as many as 7,491 patents each worldwide (EPO online database, 2010). In comparison to the pharmaceutical or electronics industries, that can hold more than 100,000 patents for a single company (EPO online database, 2010), this may not seem significant. However, the scope of users for orthopaedic devices is much smaller than for drugs or electronics (Acharya, 2008).

As reported by Cohen-Kohler (2007), advocates of intellectual property rights argue that patents are necessary to create incentive for companies to invest resources into the research and development of new therapies and products. There are five major competitors in the orthopaedic medical device business (Gelberman, 2010). The annual reports for the two orthopaedic device companies with the highest sales in 2008, Zimmer Holdings, Inc. and Stryker Corporation, were reviewed. One company, DePuy Orthopaedics, Inc., was omitted from the review as it is owned by Johnson & Johnson Company, and its annual report is not specific to orthopaedic sales (Johnson & Johnson Company Annual Report, 2008). The two other major orthopaedic device manufacturers are Smith & Nephew, Inc., and Synthes, Inc. (Gelberman, 2010). With regards to Zimmer Holdings, Inc. and Stryker Corporation, the reports show that annual profits from intangible assets from patents alone are over 104 and 87 million dollars, respectively (Annual Reports of Zimmer Holdings, Inc., 2009, and Stryker Corporation, 2008). This represents only 1
to 3% of the companies’ multibillion-dollar net profits (Annual Reports of Zimmer Holdings, Inc., 2009 and Stryker Corporation, 2008). However, patents allow the companies to maintain monopolies over their products, and so that prices of implants have remained high, thus helping to secure the industry’s multibillion-dollar profits (‘t Hoen, 2009).

Presently, the approximate cost for a standard trauma 10-hole plate and screw construct is 300 Canadian dollars (CAD), a femoral intramedullary rod is 900 CAD, a reusable external fixator frame is 1000 CAD, and a standard knee replacement prosthesis is 1700 CAD (Interview with Industry Representative, 2010). In high-income countries, the implant can represent up to one fifth of the cost of the entire surgical and anesthetic procedure (Interview with Industry Representative, 2010). In India, similar locally made and developed products can be purchased for a fraction of the Canadian price, such as a reusable external fixator frame for 50 US dollars (Padhi and Padhi, 2007). If hospitals in low-income countries used implants manufactured in the high-income countries, the device would often cost more than the entire hospital stay and surgical procedure (Gosselin et al., 2009).

There is very little published information regarding the orthopaedic medical device manufacturers in middle- and low-income countries and whether a generic orthopaedic device industry exists. A “Google” search for “orthopaedic device manufacturers” reveals multiple companies located in developing countries such as India, China, Pakistan, Thailand, and South Korea. Visiting the webpages of a number of these companies provides limited information. Most claim they have good quality products at low prices (GPC Medical Ltd., 2010; RHC Orthopaedics, 2010; Influx Medical Co., Ltd., 2010). Some report developing generic, off-patent, medical devices (Villoy Implants, 2010), while others report doing their own research and development (GPC Medical Ltd., 2010; RHC Orthopaedics, 2010; Influx Medical Device Co., Ltd., 2010; U&I Corporation, 2010). It is unclear why they can sell their products at significantly lower prices than the big five orthopaedic companies as no annual reports for these manufacturers were found online, but lower manufacturing, material and labour costs, less extensive marketing, and fewer patent applications and enforcements may be some of the reasons.
A review of the academic literature and available media articles on the medical device industry also fails to explain why generic manufacturers and orthopaedic device companies from lower income countries are not competitive with the big five manufacturers. One reason may be that in Europe and North America there is a tendency to move towards evidence-based medicine and there are strict requirements for licensing, marketing and distributing medical devices (FDA, 2009; Health Canada, 2011). These regulations may delay market entry and make surgeons hesitant to use generic implants or devices produced in lower income countries if they have not undergone rigorous studies proving the implant’s efficacy or quality (Schemitsch et al., 2010). Alternatively, the funds required to establish and operate a manufacturing plant are significant and often this investment cannot be recuperated in the first years of sales of the orthopaedic devices, causing most new companies to go out of business shortly after opening (Bhattacharyya, 2006). The possibility for purchasing lower priced orthopaedic medical devices from lower-income country manufacturers exists, yet most low-income countries are still unable to access and afford implants. Further research into the barriers of access to orthopaedic medical devices is a crucial step to improving orthopaedic care in low-income countries. Barriers to market entry for medical devices is an issue deserving of in-depth investigation, but one which will not be explored in this study.

1.3.3 Accessing and procuring orthopaedic medical devices

Access to orthopaedic medical devices is considered essential to the provision of proper orthopaedic care (Zirkle, 2008). Accessibility in this study is defined as affordability of medical devices such that patients and hospitals are able to purchase them when needed, as well as the physical availability of the devices when providing orthopaedic care (Obrist et al, 2007). In high-income countries, access to these types of devices is relatively simple. In Canada for example, there is a universal health care system where the government provides each hospital with a budget for its orthopaedic surgery department and part of this money is earmarked for purchasing medical devices (Ontario Ministry of Health and Long-Term Care, 2010). Patients can agree to any surgery or orthopaedic implant offered to them without incurring any costs. There is also a well-developed orthopaedic medical device market that enables health care providers to tender competitive contracts for the devices they need at the best possible price
In low-income countries however, the cost of an implant and frequently the surgery as well, are borne by the patient (Padhi and Padhi, 2007). This then means that in low-income countries, orthopaedics is generally limited to trauma surgery, as elective procedures are unaffordable and less critical to survival (Breena, 2009). Consequentially, patients presenting with traumatic injuries are forced to pay relatively large amounts for surgery, or opt for lower cost non-operative treatments of their condition even if well-accepted medical literature supports that surgery is the best option for decreasing the risk of long-term disability and mortality (Padhi and Padhi, 2007). For example, the total cost for treatment of a femur fracture in Cambodia with traction, a method requiring minimal tools and no surgery, is approximately 1107 US dollars (USD) per patient from hospital admission to discharge from follow-up in the clinic (Gosselin et al, 2009). To treat the same fracture with an interlocking femoral nail implant, a rod that is surgically placed inside the bone, would cost at least 2374 USD, where the implant represents anywhere from 38% to 71% of the cost (Detch and Zirkle, 2009, Gosselin et al, 2009).

Ensuring affordability and availability of orthopaedic medical devices is crucial. Morbidity and mortality of orthopaedic injuries have yet to be quantified on a global basis (Spiegel et al., 2008), however the World Health Organization’s Global Burden of Disease study has revealed that femur fractures, amputations, and spine injuries are among the most permanently disabling and fatal injuries (WHO, 2004; Begg and Tomijima, 2000). With affordable, timely and appropriate orthopaedic treatment, the negative sequelae of these disabling injuries could be avoided or minimized. An intramedullary nail for the treatment of tibia and femur fractures without the use of intra-operative x-ray, was developed by Dr. Lewis Zirkle of the Surgical Implant Generation Network (SIGN) and is provided in low-income countries at minimal or no cost by the organization (Zirkle, 2008). His invention has enabled studies on the feasibility, efficiency and cost-effectiveness of providing modern implantable orthopaedic medical devices in low-resources settings. In Cambodia, the average cost savings per patient with a femur fracture treated with a SIGN nail instead of traction was 219 USD or 20% of the cost of treating this injury (Gosselin et al, 2009). Unlike patients in traction who are bedridden for three to four months, SIGN nail recipients can walk within three days and return to work as soon as six weeks after surgery (Bouchard et al., Field Notes, 2010). The cost reductions shown by Zirkle (2008) when using a surgical implant instead of non-operative treatment methods illustrate that
although the implantable medical device may cost more than traction, the shorter length of hospital stay, shorter treatment time, and need for fewer human resources to manage this patient, can result in lower overall costs of treatment. Depending on the health care structure of a particular country, these cost savings may be to the hospital directly or to the patient, such as in private institutions where they must pay for all the costs incurred throughout their management.

From 1999 to 2008, over 18,000 SIGN nails have been implanted in over 49 countries (Gosselin et al, 2009). This suggests that with appropriate and affordable medical devices for the treatment for orthopaedic trauma, such as the SIGN nail, the injury burden may be alleviated. Availability of these devices, however, is dependent on the presence of a market for orthopaedic implants with options of low- as well as high-cost medical devices. It also requires that licensing and regulatory systems be implemented to ensure adequate quality of the medical equipment. Although some low-income countries already have this infrastructure, others do not, and this may pose as a significant barrier to accessing needed orthopaedic medical devices and managing the rising numbers of orthopaedic injuries.

A second reason for ensuring availability to affordable orthopaedic medical devices is that the high costs of treatment for musculoskeletal injuries often renders the procedures inaccessible to patients and public hospitals whose resources and funds are limited. A developing country is considered one with a low- or middle-income economy, and income groups are defined by the Gross National Income (GNI) per capita (World Bank, 2010). The GNI per capita for a low-income country is 975 USD or less, 976-11,905 USD for a middle-income country, and 11,906 USD or more for a high-income country (World Bank, 2010). When the cost of a medical device for the treatment of a femur fracture is more than the GNI per capita of a low-income country [900-1000USD] (Gosselin et al, 2009), there are clearly many patients who cannot afford treatment for their orthopaedic injuries.

Consequences of untreated or maltreated orthopaedic injuries can result in death, but more commonly in disability due to serious infections, permanent deformities, chronic pain, and inability to ambulate (Canale and Beaty, 2002). Long-term disabilities resulting from injury are significant as they affect a patient’s quality of life, ability to work, and what type of work can be performed. This has serious economic impacts for that person and their family (Gosselin et al.,
Road traffic crashes and other unintentional injuries disable and kill millions of people annually (WHO, 2008). Disability Adjusted Life Years (DALYs) are a measure of the combined impact of the morbidity and mortality of a condition by adding the years of life lost because of premature mortality with the healthy years of life lost because of disability (WHO Global Burden of Disease, 2008). One DALY is equal to the loss of one healthy year of life (WHO Global Burden of Disease, 2008). Road traffic crashes are predicted to be the leading cause of DALYs lost worldwide by 2020, and the second leading cause in low-income countries (WHO, 2004). In 2004, injuries accounted for 12% of the DALYs lost globally which was more than the DALYs lost to HIV/AIDS (3.9%), tuberculosis (2.2%), and malaria (2.8%) combined, and twice as much as the DALYs lost to diarrhea (6.0%) or cancer (5.6%) (WHO, 2004).

Globally for both sexes, road traffic crashes are the third leading cause of disease burden in the 15-44 year age group (WHO Global Burden of Disease, 2008). These are the prime years of a person’s economic productivity and this magnifies the economic impacts of the injury burden (Nantulya and Reich, 2003). Hardships also affect the individuals and family members attending the patient to care for and accommodate their short and long term disabilities resulting from the injury. In addition, road traffic crashes affect three times as many men than women (Nantulya and Reich, 2003). This is likely due to the increase access men have to vehicles, as well as gender based differences in risk taking. With men being disproportionately affected by injuries, the economic loss due to injury is exacerbated, as men tend to be the family member with jobs while women work at home, on the farm or in the fields (Nantulya and Reich, 2003). A woman sustaining a permanent disability will also incur significant consequences, as now the woman may be unable to care for or feed her family. Injuries therefore have a pivotal role in the vicious cycle of poverty by creating economic and social costs that affect individuals and communities (Gosselin et al., 2009).

The socioeconomic impact of injury-related disability is amplified in low-income countries. Trauma care and rehabilitation programs are poorly developed, and there is little or no social welfare infrastructure (Gosselin et al., 2009). The costs of treatment borne are by the patient and the resulting disability can prevent the patient from being able to provide for himself or his family (Gosselin et al., 2009). The estimated cost of road traffic injuries worldwide, over 500 billion USD annually, far exceeds the total global expenditures in developmental assistance.
(Gosselin et al., 2009). There is clearly a need for cost-effective solutions to the ever-growing problem of orthopaedic injuries in low-income countries. Improving access to affordable orthopaedic medical devices is one important way to begin reducing the injury burden and improving orthopaedic care globally.

This study explores potential strategies for improving accessibility of orthopaedic care and medical devices by conducting a qualitative case study of orthopaedic services in Uganda.

1.3.4 Uganda: The ideal site for a case study on orthopaedic services

Uganda is a low-income country situated in East Africa bordering the Sudan, Kenya, Tanzania, Rwanda and the Democratic Republic of the Congo (CIA World Fact Book, 2009). In 2008, it had a population of 31.7 million people with 13% of the population living in urban centers (World Bank, Uganda at a glance, 2008). Its Gross National Income (GNI) per capita was 450 USD in 2009, ranking 193rd of 213 countries (World Bank, GNI per capita, 2009). Uganda’s GNI per capita is similar to the average for low-income countries in 2008 which was 524 USD, but is considerably lower than the average for sub-Saharan Africa at 1082 USD (World Bank, Uganda at a glance, 2008). Life expectancy at birth in Uganda is 53 years, which is comparable to the average of 59 years for low-income countries and 52 years for sub-Saharan Africa (World Bank, Uganda at a glance, 2008). Infant mortality per 1000 live births is 85 in Uganda, 89 in sub-Saharan Africa and 78 in all low-income countries (World Bank, Uganda at a glance, 2008). Mortality rates in adults in sub-Saharan Africa range from 242 to 719 per 100,000 people, and Uganda is near the average with 411 deaths per 100,000 adults (World Bank, Data Bank, 2010). In 2004 deaths due to injury represented almost 10% of the mortality rate in low-income countries (WHO, Regional Estimates, 2009). Child malnutrition rates, literacy rates and access to clean water are slightly better in Uganda than the average for low-income and sub-Saharan African countries (World Bank, Uganda at a glance, 2008).

Health care expenditure in sub-Saharan African countries ranges from 2.1% of the GNI to 11.2% (World Bank, Data Bank, 2010). The higher overall spenders on health care are Liberia
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(10.2%) and Rwanda (10.3%), and the lower spenders include Mauritania and the Congo (World Bank, Data Bank, 2010). Canada spends 10% of its GNI on health expenditures (World Bank, Data Bank, 2010). In 2007, Uganda spent 6.3% of its total GNI on health care, two-thirds of which was dedicated to private health care (World Bank, Data Bank, 2010). The distribution of funds to public versus private health care varies from country to country, but Uganda’s higher expenditure on private services is not uncommon (World Bank, Data Bank, 2010). In 2004, Uganda had 0.7 hospital beds per 1000 people, which compared negatively to two of its neighboring countries, Rwanda and Kenya, which had 1.7 and 1.4 beds available, respectively (World Bank, Data Bank, 2010). Canada has 3 beds available per 1000 people (World Bank, Data Bank, 2010). The availability of nurses per 1000 people living in Uganda in 2004 is 0.6, which is considerably lower than other African countries, such as Gabon, and Canada where there are 4.6 and 10 nurses per 1000 patients, respectively (World Bank, Data Bank, 2010). The doctor-patient ratio in Uganda is 1:18,600. (Naddumba, 2008). As of 2008 there were 23 orthopaedic surgeons in Uganda, or 1 per 1.4 million people, and 18 of the surgeons worked in the capital city (Naddumba, 2008). Although there are more orthopaedic surgeons in Uganda than other African countries, such as Mozambique that has none, it has fewer than Sri Lanka (1:1 million people) (Fisher, 2008), and far fewer than Thailand (1:50,000) (Mahaisavariya, 2008) and Serbia (1:18,000) (Vukasinovic, Spasovski, & Zivkovic, 2008). In contrast, Canada has 3 doctors per 1000 people (World Bank, Data Bank, 2010), and an orthopaedic surgeon to patient ratio of approximately 1:31,000 (Comeau, 2004, World Bank, Data Bank, 2010).

Musculoskeletal injuries in Uganda occur mainly as a result of road traffic crashes. Predisposing factors include rapid urbanization, poor roads, a wide variety of vehicles on the road, poorly trained drivers, driving under the influence of alcohol, and lack of respect for traffic regulations (Naddumba, 2008). Two main district hospitals receive up to 67% of the trauma (Naddumba, 2008). Uganda has four levels of health care centers from level I primary care clinics rarely staffed by trained doctors to level IV district hospitals (Naddumba, 2008). Specialists are only available at the level III and IV hospitals, and surgery is performed only at level IV centers (Naddumba, 2008). Level IV district hospitals serve a population of 500,000 and have only 100 in-patient beds (Naddumba, 2008). Naddumba (2008), an orthopaedic surgeon in Kampala, does not expect an improvement in the underserviced orthopaedic care of Uganda until there is additional training and distribution of resources at all levels of health care countrywide. He also
calls for better health infrastructure and access to sustainable supply chains of essential medical equipment and pharmaceuticals.

Uganda has similarities in its demographic and epidemiologic profiles to many other low-income countries, and experiences many of the same economic constraints. Its health care infrastructure and health services may not be in the exact condition as those of other sub-Saharan African countries, yet Uganda’s experience is representative of the challenges low-income countries face when trying to respond to the burden of orthopaedic injuries. Since the researcher and her primary supervisor also have established professional relationships with surgeons in Uganda through international surgery meetings and previous research endeavors in the country, Uganda was an ideal and practical case study for exploring the barriers to access of orthopaedic care and medical devices.

1.3.5 A comparison of access to essential medicines and orthopaedic medical devices

In the global struggle against HIV/AIDS and other neglected tropical diseases, one of the main obstacles in providing treatment to infected patients is accessing life-saving medications. More research has been done on the barriers to access of medicines than on medical devices. Considering that pharmaceuticals and orthopaedic medical devices are complex medical technologies belonging to multi-billion dollar industries, it can be hypothesized that the access and availability of both technologies are similarly hindered.

Barriers to access of essential medicines are frequently described in the medical and policy literature. Inadequate human resources, from pharmacists to doctors, and poor health infrastructure are commonly cited impediments to access of pharmaceuticals (Gopal, 2001; Farmer et al, 2001). Limited markets and market failure, particularly for the generic industry, are other disincentives for distribution of pharmaceuticals in low-resource settings (Satyanarayana, 2007). In some countries, tariffs and taxes can hinder access by inflating the costs of medicines, or delaying and preventing their entry into the country (Bate et al., 2006). Corruption can affect access to medications in many ways. At the government level, there may be dubious spending
behaviours and misappropriation of funds intended for purchasing of medicines (Gopal, 2001). Within the production and supply chain of pharmaceuticals, corrupt activities can occur at many points including quality assurance, procurement and distribution. This can result as counterfeiting, bribes and kickbacks during the tendering process, theft, damage of stocks due to poor storage, and resale and loss of drugs to the black market (Kohler, 2010). An underlying reason for many of these barriers to medicines is their cost (Satyanarayana, 2007). Like medical devices, pharmaceuticals are lucrative and often priced out of reach of most patients and government health care budgets in low-income countries. One of the main drivers of cost of pharmaceuticals is stringent intellectual property regulation. By challenging some of these policies, and by using or threatening to use some of the public health safety measures in these trade agreements, some advocacy groups and governments have been successful in lowering the cost of pharmaceuticals and improving their accessibility in low-resource settings (Satyanarayana, 2007). The next section will explore if these strategies can be used to improve access to medical devices, as the latter are also subject to intellectual property laws.

1.3.5.1 International intellectual property policy: The WTO and the TRIPS Agreement

As with pharmaceuticals, intellectual property and trade rules likely impact access to orthopaedic medical devices. This section explores the potential lessons learned from the experiences with international trade agreements and access to essential medicines as they might apply to the access of orthopaedic medical devices.

Pharmaceuticals and medical devices are typically expensive components of medical care, whether the payer is the patient or the health care provider. The high prices of pharmaceuticals are linked to intellectual property policies that mandate the patenting of all technological inventions including health technologies (MSF, Access to Essential Medicines, 2010). A patent grants the patent owner exclusive marketing rights for their drug, which prevents competition between manufacturers resulting in higher drug prices (Elliot et al., 2003). Since some essential medicines are patented, low-income country governments and civil society organizations sought to find exceptions to patent laws to facilitate the purchasing of patented drugs at lower costs (MSF, Access to Essential Medicines, 2010). In a number of cases, both low- and high-income
countries, including Rwanda, Thailand, and Canada, have been successful at drawing attention to flexibilities in international patent legislation, such as a compulsory licenses, to obtain competitively priced pharmaceuticals (‘t Hoen, 2009).

Intellectual property legislation is adopted at a domestic level, however international agreements may dictate the policies countries must adhere to. One such agreement is the World Trade Organization’s (WTO) Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement is a set of minimum standards on trade and intellectual property rights, including patents, copyrights, trademarks and industrial designs, which all countries of the WTO must adopt in their domestic legislation as a condition of membership (Elliot et al., 2003; Cohen, 2006). The TRIPS Agreement obliges WTO member countries to maintain specific policies regarding the patenting of inventions in any field of technology, including medical devices and pharmaceuticals (TRIPS, 1994). Important policies which decrease the accessibility to health technologies, including pharmaceuticals, micro-organisms and medical devices, are patents that extend for up to 20 years, the disallowing of discrimination of patent rights for imported products, and the granting of exclusive marketing rights until patent expiry (Cohen-Kohler, 2007). Failure to comply with the TRIPS Agreement’s obligations could lead to trade sanctions (Helfer, 2004).

The goal of the TRIPS Agreement is to promote trade and innovation globally (TRIPS, 1994). These however, have not been the only effects of the TRIPS Agreement. Applying rigorous patent laws to health technologies is impeding access to health care, particularly in low- and middle-income countries, by promoting high prices for needed medicines and medical equipment (Elliot et al., 2003). The high prices of Pharmaceuticals have been linked to stringent patent protection (MSF, Access to Essential Medicines, 2010). Through exclusive marketing rights, patents prevent competition between manufacturers resulting in higher drug prices (Elliot et al., 2003). Elevated costs for technologies such as pharmaceuticals and orthopaedic medical devices often render them inaccessible to patients in low-income countries where patients, who often make less than 2 USD a day, must pay for these therapies themselves (Gosselin et al., 2009; MSF, Access to Essential Medicines, 2010). With the rising concern of the HIV/AIDS epidemic, the public health-impeding policies of the TRIPS Agreement became the target of much criticism from low-income countries and civil-society organizations (MSF, Access to
Essential Medicines, 2010). Exceptions to patent laws were sought to facilitate the purchasing of patented technologies at lower costs (MSF, Access to Essential Medicines, 2010).

The WTO responded to the growing global public concern around trade and intellectual property policies by calling a special meeting in Doha in 2001 (WHO Report on Intellectual Property Rights, 2006). A significant outcome was the Doha Declaration on the TRIPS Agreement and Public Health. Importantly, the Declaration recognizes that many grave public health emergencies exist and persist in low-income countries, and that the TRIPS Agreement should be part of the intervention to remedy these problems (Doha Declaration, 2001). The Declaration states that “[...] the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (Doha Declaration, Paragraph 2, 2001). This refers to the few articles in the TRIPS Agreement that justify a government’s right to prioritize health needs over trade goals. Article 7 encourages “a balance of rights and obligations [such that intellectually property rights should also encourage transfer of] technological knowledge in a manner conducive to social and economic welfare” (TRIPS, Article 7, 1994). Article 8 declares that WTO members must ensure that when adopting TRIPS measures they “protect public health and nutrition, and promote […] socio-economic and technological development […]” (TRIPS, Article 8 (1), 1994). Article 27 (2) (TRIPS, 1994) allows WTO members to exclude inventions from patentability when it is necessary to prevent commercial exploitation that would hinder human, animal or plant life or health.

The Doha Declaration (2001) also states that WTO member countries have the right to exercise certain flexibilities when implementing intellectual property policies. These policies are known as TRIPS flexibilities (‘t Hoen, 2009). One of the most important flexibilities, described in Article 31, allows the “use of [patented innovations] without authorization of the right holder” (TRIPS, subtitle Article 31, 1994) in specific pressing situations through a process called compulsory licensing. A compulsory license enables the use of a patented invention by a third-party or government agency without the consent of the patent holder (‘t Hoen, 2009), against a payment of adequate remuneration (TRIPS, 1994). A compulsory license lowers the cost of medicines by limiting the monopoly of the patent holder and creating greater competition (Canadian HIV/AIDS Legal Network, 2008). In a number of cases, both low- and high-income
countries, including Rwanda, Thailand, and Canada, have been successful at invoking compulsory licenses to obtain competitively priced pharmaceuticals (‘t Hoen, 2009). The Doha Declaration also reiterated that member countries have the freedom to determine for themselves the grounds upon which compulsory licenses are granted, and that this is not limited to states of public health emergencies (WHO Report on Intellectual Property Rights, 2006).

Despite the inclusion of public health-sensitive flexibilities in TRIPS Agreement, these policies are underused due to administrative, political, and knowledge barriers (Cohen, 2006). Research into how these flexibilities may be used as a mechanism for increasing access to patented orthopaedic medical devices in low-income countries is warranted. The successes of countries using compulsory licensing for accessing drugs are limited, but they have helped encourage competitive pricing of pharmaceuticals and have given millions of patients access to life-saving therapies (MSF, Access to Essential Medicines, 2010). If orthopaedic patients and surgical hospitals could be afforded the same opportunity to access lower cost medical devices, perhaps the global injury burden injury could be alleviated.

The barriers to orthopaedic medical devices elicited in this case study can be compared to the impediments to access of pharmaceuticals. Employing the strategies used to improve the availability of pharmaceuticals is discussed as a possible solution for expanding access to orthopaedic medical devices in Chapter 3.

1.3.5.2 Corruption within the pharmaceutical and orthopaedic medical device industries

Corruption, or the “abuse of entrusted power for private gain” (Robinson, 2006, p.xvii), is not simply a problem in low- and middle-income countries. It is a pervasive and ongoing challenge in medicine. Corruption is a threat to health care's core values and its capacity to ensure greater health systems and clinical practices, equitable access to these, and better patient outcomes. Unethical behaviors and practices within the pharmaceutical industry are a well-known source of corruption in health care. The orthopaedic industry is equally susceptible, and in recent years, corrupt activities between orthopaedic companies, hospitals and surgeons have been exposed to the media. Corruption in the biomedical industries can also impede access to health services and
clinical care. Strategies for managing corruption are an important step in ensuring access to medical care and technologies.

The pharmaceutical industry has been subjected to numerous government investigations, and civil and criminal lawsuits. Companies engage in aggressive marketing of their products and make attempts to prolong drug patent life to ensure sustained revenue (Angell, 2004). These efforts are well known and often considered unethical, but increasingly, they are also sometimes illegal. Fraud is defined in Duhaime’s Legal Dictionary (2011) as “deceitful conduct designed to manipulate another person to give something of value by (1) lying, (2) by repeating something that is or ought to have been known by the fraudulent party as false or suspect or (3) by concealing a fact from the other party which may have saved that party from being cheated.” Civil and criminal charges of fraud against the pharmaceutical industry include illegally overcharging government social insurance programs, kickbacks to doctors, anticompetitive practices, colluding with generic pharmaceutical companies to keep generic drugs off the market, illegally promoting drugs for unapproved uses, misleading direct to-consumer advertising, and covering up of evidence disfavoring the product (Angell, 2004). Some of the settlements have been significantly costly. For example, TAP Pharmaceuticals paid $875 million for Medicaid and Medicare fraud in the marketing of its prostate cancer drug, Lupron (Angell, 2004).

The orthopaedic medical device industry was relatively spared from public scrutiny until a recent investigation by the United States Attorney for the District of New Jersey. He alleged that orthopaedic companies were providing improper financial inducements to orthopaedic surgeons to use their products, such as consulting agreements for questionable work, royalty contracts without transfer of intellectual property, trips to luxury resorts for continuing medical education, expensive meals for medical lectures, inappropriate gifts, and payments to surgeons for using specific implants (Healy and Peterson, 2009). Since this index investigation of the five largest orthopaedic device companies, many other smaller orthopaedic device manufacturers, non-orthopaedic medical device companies, and pharmaceutical companies have been investigated for fraud and kickbacks (Healy and Peterson, 2009).

The State Attorney’s investigation of the orthopaedic industry and the general issue of industry-
physician financial relationships was widely reported in the medical and non-medical media. In response, the professional associations of pharmaceutical and medical device manufacturers and of medical professionals, the individual companies, hospitals and universities have developed or revised new public disclosure requirements, and ethical standards regarding relationships between medical companies and physicians (Healy and Peterson, 2009).

Although corruption is known to impede access to health care and corrupt practices in the pharmaceutical and medical device industries are well documented, the effects of corruption on access to orthopaedic care and medical devices in low-income countries have not yet been explored. The case study described in this thesis, elicited corruption as a major barrier to orthopaedic health services. This is an unexpected, but not an incidental finding. Corruption is pervasive in health care and there is a need to identify and address institutional challenges so as to minimize the possibility and effects of systemic corruption in medicine. Chapter 3 will explore the issue of corruption and access to orthopaedic medical devices in greater depth.
1.4 Methodology

1.4.1 Literature review

Exploring the issue of accessibility of orthopaedic medical devices in low-income countries requires an understanding of what orthopaedic care and equipment are presently available, and if any difficulties in providing this care are reported. Background research for this study consisted of reviewing the following topics: Orthopaedic services in low-resource settings, the orthopaedic medical device industry, accessibility of orthopaedic medical devices, the pharmaceutical industry and access to essential medicines, intellectual property rights of health technologies and flexibilities within these laws, corruption in the health sector, mechanisms for funding health care, and demographic and economic data on Uganda since the year 2000. A literature review was conducted using a variety of search engines including Scholars Portal, PubMed, and Google. Search terms included: “access to ortho*”, “medical device”, “implant”, “ortho* medical device”, “low-income country”, “developing country”, “access to essential medicines”, “WTO”, “TRIPS Agreement”, TRIPS flexibilities”, “corruption”, “innovative funding”, and “Uganda”. These searches produced relevant scholarly published articles from academic journals, special commissioned reports and publications, news articles, online books and book chapters, editorials and commentaries.

Websites of specific organizations and companies were also examined to review relevant global health, public health and trade policies, information on intellectual property rights and patent holders, current global health challenges and development goals, and detailed information on the operations, growth and value of the orthopaedic industry. Websites explored included: World Trade Organization, World Health Organization, Central Intelligence Agency, World Intellectual Property Organization, European Patent Office, United Nations, Médecins Sans Frontières, Partners in Health, Zimmer Holdings Inc, Stryker Corporation, Depuy Inc, Smith and Nephew, World Bank and International Monetary Fund. Printed textbooks were also consulted for references on methodology and orthopaedic care.
1.4.2 Methodology: Descriptive qualitative case study

The goal of this project was to explore and define barriers to access of orthopaedic medical devices and identify strategies for improving accessibility through the perspectives of key stakeholders involved in orthopaedic care in Uganda. An exploratory, descriptive qualitative case study addressing this problem was conducted in Uganda in November and December 2010.

Open-ended interviews were used to elicit the experiences of health care practitioners, patients, and industry and government representatives in accessing orthopaedic medical devices. Open-ended, semi-structured interviews enable participants to discuss their personal views were therefore an ideal technique for qualitative data collection (Hermanowicz, 2002). This format enabled participants to freely express their opinions and experiences, while ensuring all relevant information was elicited. Given the limited literature on the subject, this approach was useful for extracting information and investigating a phenomenon on which little is known (Keen & Packwood, 1995). Other methods of research, including quantitative surveys and grounded theory, were also considered. However, to obtain the least biased perspective on the issues of access of orthopaedic medical devices, the case study methodology was deemed most appropriate. Case studies are subject to less bias than other qualitative methodologies, as preconceived notions or theories from the literature are not imposed on the data (Sandelowski, 2000).

Case studies are particularly useful where “broad complex questions have to be addressed in complex circumstances” (Keen & Packwood, 1995) and when the goal is to study complex phenomena in their natural settings and contexts, such as the issue of access to orthopedic medical devices (Pope & Mays, 1995). A case study can involve a single case or multiple cases, and includes an object or a phenomenon to be studied, a research question, an aim for the research, collected data, and sampling strategies appropriate to the type of data (Heinz, as in Munhall, 2007). It can use data from a variety of sources such as documents, archival records, observation, interviews, and focus groups (Heinz, as in Munhall, 2007). The results of a case study can often be generalized across a larger group of similar phenomena (Heinz, as in Munhall, 2007). This method of inquiry is consistent with the standards set among scholars in
qualitative research where it has become a widely accepted method of inquiry, particularly useful for answering “How?” and “Why” questions (McGloin, 2008). Since the goal of this project is to explore the complex and context-dependent problem of access to orthopaedic medical devices with as few preconceived theories as possible, a descriptive qualitative case study with interviews of key informants is an ideal methodology.

1.4.3 Sampling

To collect the most information-rich data, purposive sampling and snowball sampling were employed. Miles and Huberman (1994, as in Curtis et al, 2000) published a checklist to ensure sampling yields rich and relevant data. They suggest that the “sampling strategy should be relevant to […] the research questions” (Miles and Huberman, 1994, as in Curtis et al, 2000, p. 1003). To obtain a wide array of perspectives, different groups of people with first-hand experience accessing orthopaedic medical devices in Uganda were included in the study sample.

The method of purposive sampling ensures participants have an understanding of the issues on access to orthopaedic devices. Purposive sampling occurs when researchers deliberately select their sample according to the participants’ experience with the studied phenomenon and their ability to effectively participate in an interview (Morse, as in Munhall, 2007). Based on the researcher’s personal history as an orthopaedic surgery resident in Canada and on discussions with orthopaedic surgeons from Uganda, four categories of participants were pre-selected: 1) health care workers; 2) health care administrators; 3) patients; and 4) medical device industry representatives. The first category of health care workers includes surgeons who perform orthopaedic procedures and other related health care professionals who manage orthopaedic patients, such as general surgeons, general practitioners, clinical or orthopaedic officers, orthopaedic technologists and nurses. The second group encompasses hospital administrators and government officials responsible for procuring orthopaedic medical devices. It was predicted that this group would be smaller, as there may not always be a formal procurement department and this duty would fall to the surgeon or patient. In the end, all hospital administrators interviewed were also doctors or health care workers and so were included in the first group of participants. The third group consisted of patients who have suffered orthopaedic
injuries. Patients were selected to differ in time since injury, degree of disability following the injury, and treatment received to highlight the different difficulties patients might experience due to an injury. The last group is of orthopaedic device industry representatives. Representatives from brand name and generic companies were sought.

Miles and Huberman (1994) also recommend sampling in a way to ensure generalizability of the findings (as in Curtis et al, 2000). Although the four participant categories allow for a range of perspectives on the issue of access to orthopaedic medical devices, it is also important to include informants from a range of hospital settings. Six subgroups of informants were developed to ensure the sample represented professionals and patients from a variety of healthcare settings: 1) those working or living in urban areas; 2) those working or living in rural areas; 3) those working or seeking care in academic hospitals; 4) those working or seeking care in non-university affiliated hospitals; 5) those working or seeking care in public hospitals; and 6) those working or seeking care in private hospitals.

Since not all participants could be identified prior to arriving in Uganda, snowball sampling was required. This occurs when one participant is asked to recommend another, and so on until enough participants have been recruited (Morse, as in Munhall, 2007). For example, prior to the beginning of the study, the researcher met an orthopaedic surgeon from Mulago University Hospital in Kampala, Uganda. Through him, she was placed in contact with two other senior orthopaedic surgeons at the same hospital who agreed to help her meet more contacts in their hospital and other hospitals throughout Uganda. Through these key informants, the researcher met more potential stakeholders who in turn referred her to other people they believed knowledgeable on the topic of access to orthopaedic medical devices. Selection of patients was also done with the snowball sampling technique. Doctors and nurses were asked to recommend specific patients for interview based on their injury and willingness to participate in the study.

The sample size was determined by the saturation principle, so that when ongoing analysis of the data, in this case transcribed interviews, reveals no new information and no new categories emerge sampling may cease (Morse, as in Munhall, 2007). Morse (as in Sandelowski, 2000) suggests that 6 to 20 interviews, with a minimum of 6 to 10 informants, will provide good data without generating so much information that it hinders analysis. This researcher conducted 45
interviews. Saturation was achieved after 32 interviews, but the opportunity to interview
government officials and surgeons working in other African countries arose late in the study and
could not be dismissed, as their experiences would likely hold valuable information.

1.4.4 Ethical considerations

As this research project requires human subjects to participate in an interview, Research Ethics
Board approval was obtained from the University of Toronto and Makerere University, home of
the largest academic hospital in Uganda. The project was considered “low-risk”. None of the
visited rural hospitals had formal ethics boards requiring authorization for conduction of the
study.

To comply with ethical standards, all informants provided written consent prior to participation,
and oral consent at the time of interview (please refer to the Appendices for consent forms).
Participants were told during the consent process and at the start of the interview that they could
ask to end the interview or withdraw from the study at any time without consequence. Should a
participant withdraw, the notes of their interview, their transcript, and any personal notes taken
by the researcher on this participant would be deleted. No identifying information on this
participant would be retained. Patient participants were reminded that participation would not
affect their orthopaedic care.

An assigned identification number was used to label study records, and all identifying
information was removed from the transcripts. Individuals that may use the interview data
include only the student investigator and the supervising investigators. These individuals may
release this information to the members of the student’s Masters’ Degree advisory committee,
the relevant Research Ethics Boards, and other regulatory agencies. The information released to
the above listed individuals will not contain names, or any other personal information.

There was no major risk to the participants by joining this study. Although focused on the
participant’s experience in accessing orthopaedic medical devices, instances may have occurred
in some interviews where patients discussed information in an interview they might have been
reluctant or hesitant to share. They may have disclosed personal information relating to their age, occupation, socioeconomic status, or social stigma concerning disabling or disfiguring orthopaedic injuries. Psychological and emotional risks related to the discussion of sensitive information were mitigated by first reassuring the participants that all identifying information is kept confidential. Secondly, participants were reminded that they may discontinue participation at any time, and once they withdraw from the study their information will be deleted. Third, prior to the beginning of the interview, the researcher conversed casually with each participant to introduce herself and give them time to become comfortable with her and ask any questions.

As there was no direct cost to the participants in participating in the study, no compensation was provided. The researcher traveled to see each participant in their place of work or at their doctor’s appointment, and incurred the charges for phone calls with participants. In recognition of the time the participants gave to the study, refreshments were available at the in-person interviews when the setting permitted.

There are no conflicts of interest with regards to funding, nor any restrictions with regards to access or distribution of information imposed upon the researchers. As the principal researcher is a Masters’ student, it is expected that her work will belong to her and her advisory committee has not imposed any restrictions on access to information. The two bodies which have provided funding for this student, the Bethune International Surgery Fellowship and the University of Toronto’s Surgeon Scientist Program, do not enforce any contracts regarding ownership, access to, or disclosure of information, nor do they have control over how and what research is conducted.

Another ethical consideration is that this student researcher is also an orthopaedic surgery resident. She was not in charge of providing orthopaedic care while in Uganda. She did assist or observe in the operating room, on the wards and in the clinics, but was always under supervision of a Ugandan physician. The involvement of the patient-participants in the study will not affect the care they receive in anyway, and this is reiterated in the consent form and to the patient.

The relationship between orthopaedic surgeon and orthopaedic industry representatives has been perceived as controversial in North America since the 2005 investigation by the United States
Department of Justice into excessive kickbacks from industry to surgeons for use their products (Healy and Peterson, 2009). For this project, although the researcher is an orthopaedic resident, her interactions with industry are as a researcher and not as doctor. She was not involved in decisions regarding the purchasing or recommendations of orthopaedic devices, nor was she making decisions on patient management.

1.4.5 Data collection

The researcher was in Uganda for 6 weeks in November and December 2010. Data collection occurred in clinics and major hospitals in multiple towns throughout Uganda. Kampala, the capital city, was used as a base and travel to other regions for interviews were reached from there. Kampala was a good starting point as that is where the pre-established key informants were located. Other towns she visited included Fort Portal and Kasese in the West, Mbarara and Masaka in the Southwestern region, and Arua and Gulu in the North. Participants from the Eastern region of Kumi were also interviewed, but while they were in Kampala for a conference. The conference was a meeting of the College of Surgeons of Eastern, Central and Southern Africa (COSECSA). Interviews lasted 20 to 45 minutes, and were conducted in the hospital of the informant with two exceptions. Participants from other countries were interviewed at the COSECSA meeting. One participant was interviewed over the phone as he/she was based in Western Canada. In this case, written consent was acquired over email, and oral consent was confirmed at the time of interview. The conversation was held in a private enclosed room at the University of Toronto.

All interviews were recorded with hand-written notes and transcribed by the student researcher. Although the original intent had been to digitally record the interviews, the interview settings were often noisy and informants were more forthcoming with information when the recorder was off. Note-taking therefore became the preferred method of recording. This is in keeping with experiences in other studies (Warren, as in Gubrium and Holstein, 2001). The interviews were generally transcribed the same day as the interview. The delay to transcription was never longer than a week. If there were any questions or ambiguities, participants were phoned or visited for clarification. A formal second interview was never required. Regular transcription of
the interviews enabled the researcher to assess the quality of data on an ongoing basis and determine whether saturation was being reached. Initial analysis of the data began once the first five interviews were transcribed. This process is described in the next section.

To contextualise the interview data, the author participated in clinical activities and kept a journal of her experiences as observational field notes. She participated in a clinical setting three to six days a week. Activities included assisting in the operating room, joining the residents on call, and observing ward rounds and clinics. Notes concerning the researcher’s impressions or reactions during each interview were also recorded. These notes were useful to deepen the researcher’s understanding of the participants’ comments, but they did not provide any information not already revealed in the interviews. The observational notes were not included in the data analysis, but were used as part of the reflexive process to be described in a later section.

The interview schedule and a list of the grand tour and secondary research questions are included in the Appendices.

**1.4.6 Data analysis**

The qualitative method of thematic analysis was used to analyze the data. This method identifies, analyses and describes patterns and themes within data (Braun and Clarke, 2006). Thematic analysis is ideal for this qualitative study as it employs direct coding of the text without the use of pre-constructed categories or codes (Hsieh and Shannon, 2005). This means participants responses will be analyzed and summarized based on their content alone, without trying to fit the data to theory or create a theory out of the data.

According to the methodology described by Fereday and Muir-Cochrane (2006), the first step of coding was to review the data. This involved transcribing the interviews, re-reading transcripts for accuracy, summarizing each interview, and tabulating the demographic statistics of the participants. The second step of creating initial codes of the data, and the third step of grouping codes into themes, were performed simultaneously. Coding requires the line-by-line reading of each transcript and the labeling of relevant pieces of information. Themes were then
created by sorting the hundreds of codes into groups of similar topics. Finally, themes were condensed into overarching categories that represented and accurately explained the data set.

“Nvivo 9” Software was used to create a database and organize, code and categorize the collected data from the interviews. All transcripts, interview summaries, and interview schedules were uploaded into program. Demographic data was also included so that each participant could be categorized if needed by gender, age, country of origin, town of origin, and profession. Codes and themes in this software take the shape of “nodes”. Data is organized in groups of parent nodes with respective child and grandchild nodes. At first all nodes may represent individual codes, but just as codes collapse into themes and categories, the nodes can also be amalgamated. Parent nodes tend to represent themes, and child and grandchild nodes consist of secondary and preliminary codes, respectively. See Figure 7.

Figure 7. Representation of hierarchy of codes, nodes and example with coded data
In this study, coding began by labeling each interview question and sub-question as a node. Each participant was also created as a node. “Nvivo 9” allows for special queries. For example, to get a sense of the most common data collected in the interviews a “word frequency” search was performed. This identifies the words most commonly appearing in the dataset. This guided the second set of searches for codes, “word queries” and “text searches”. Key words, such as “medical device”, “barrier”, or “cost”, could be highlighted in all texts in which they are contained. All responses would go under a node by the name of the queried word. The next step of coding involved the line-by-line reading of each transcript. Every word or sentence that held importance was labeled as a node. If two nodes were very similar, they could be collapsed into a single node. At the end of this process, the hundreds of resulting nodes are then condensed into a themes or “parent nodes”. These parent nodes are finally collapsed into overarching categories with major themes. These were illustrated with diagrams made in “Excel” and “PowerPoint”. Ultimately, the coded and themed data from the interviews was summarized into the various barriers to access of orthopaedic medical devices and the possible solutions for improving access to orthopaedic care.

1.4.7 Credibility

Lincoln and Guba (as in Hsieh and Shannon, 2005) suggest that “credibility [of the research methodology and data] can be established through activities such as peer debriefing, prolonged engagement, persistent observation, triangulation, negative case analysis, referential adequacy, and member checks” (Hsieh and Shannon, 2005, p. 1281). This study achieved credibility and validity in three ways. First, the method of triangulation was used. The data was triangulated with two different sources, observational field notes and published literature, to maximize comprehensiveness and diversity. Literature reviewed included academic publications, panel reports, reports of the WTO, WIPO, World Health Organization, World Bank, patent offices, relevant non-governmental organizations (NGO), and industry annual reports. Second, the researcher performed member checks. Here, the participant reviews their or another’s transcript for accuracy. This was done with at least one informant from each category.
Third, the researcher engaged in reflexivity. Wolf describes reflexivity as the “process by which researchers recognize that they are an integral part of the research and vice versa” (Wolf, as in Munhall, 2007, p.318). Reflexivity of the researcher can be based on their beliefs, biases, motives, preconceptions, as well as on the institutional, ontological and epistemological influences on the research (Mauthner and Doucet, 2003). To minimize bias, the researcher remained aware of how her social, emotional, academic and personal perspectives differed from and were similar to those of her informants, and avoided letting them inadvertently shape how she analyzed the data. The student researcher recognized that she is a Masters’ student, but also a fourth year orthopaedic surgery resident. Her relationships will vary with each category of interview subject. The most ubiquitous relationship between researcher and subjects in this study was the Canadian-Ugandan relationship. The researcher remained sensitive to the cultural, social and economic differences between herself and her participants. Her relationship with Ugandan surgeons was of a student-instructor nature, but also a relationship between high-income country surgeon and low-income country surgeon. The researcher was open-minded and sensitive to the differences in each other’s medical training and experience. A particularly sensitive relationship existed when interviewing patients, as the researcher was a Canadian doctor interviewing Ugandan patients. The researcher was not involved in providing orthopaedic care to these patients, and attempted to maintain her role as researcher over physician. Keeping a journal about her experiences in the operating room and during the interviews facilitated this reflexivity process.

The use of a descriptive, exploratory qualitative case study methodology with open-ended semi-structured interviews enabled the acquisition of rich data on the subject of accessibility of orthopaedic care and medical devices in Uganda. The method of thematic analysis to analyze the data revealed the details of each participant’s response and enabled an accurate summary of the entire dataset. The end result was the development of a framework of the common and important barriers a researcher could consider when exploring the problem of access to orthopaedic care and medical devices and developing strategies for responding to the growing global injury burden.
1.4.8 Limitations of the qualitative case study method

The methodology for this study was carefully selected for its ability and appropriateness in addressing the research question. Nonetheless, there are still weaknesses to the qualitative case study method. The rigor of qualitative research and of case studies has been a point of contention among critics of research methodologies. This is in part because historically researchers have not applied a sound methodical approach and as a result have been careless in conducting case studies. This led to the reputation of qualitative research being biased. However, there is now a renewed trust in the value of the well-designed case study for exploratory, descriptive and explanatory research (McGloin, 2008). In this study, bias was limited through careful design and execution of case studies methods, data collection procedures, and analytical methods, and by ensuring that the research question could appropriately be answered with this methodology.

A second main criticism of the case study method is the little evidence for generalizability of results. Although some advocates of qualitative methods agree that case study findings cannot readily be applied to broader populations, they support that findings can widely be applied for the generation of theories and hypotheses (McGloin, 2008). Therefore, although this study reports almost exclusively on orthopaedic care in Uganda, the resulting categories of barriers to access of care and equipment and of strategies for improving access are concepts that can safely be implied in other contexts. In addition, the policy recommendations suggested by this researcher are based on strong recurrent themes present across the entire case study data set.
1.5 Chapter summary

This thesis investigates the issue of limited access to orthopaedic medical devices in low-income countries and how this affects the global injury burden. As the number of people suffering from disabling and life-threatening injuries continues to rise globally, there is a need to ensure adequate access to orthopaedic care and equipment so that trauma patients may be offered a chance of recovery and return to normal function. Through a descriptive qualitative case study in Uganda, this research explores the socio-economic factors, inefficiencies in health care infrastructure, and policies that may impede effective access to orthopaedic medical devices. Orthopaedic surgeons, non-surgeon health care professionals practicing orthopaedic care, government officials involved in procuring orthopaedic medical devices, patients and industry representatives were interviewed about their experiences in accessing orthopaedic medical devices. Uganda was used for the case study, as it is a country that is representative of many low-income countries. It has similar health care resources, burden of orthopaedic injury, and availability of orthopaedic services. Based on the data collected from the interviews, a summary of the barriers to the access of orthopaedic medical devices was compiled, and from this information, policy recommendations on how to improve orthopaedic services and alleviate the injury burden are proposed.
2 CHAPTER TWO: Defining the barriers to access of orthopaedic medical devices: Results and discussion

2.1 Case study data

2.1.1 The study sample

A descriptive qualitative case study using semi-structured open-ended interviews was conducted in Uganda to explore the problem of access to orthopaedic medical devices. Interviews attempted to elicit the barriers to access of orthopaedic care and medical devices, and identify possible solutions to these barriers.

Forty-five interviews were conducted. Interviews took place in twelve health care centers across Uganda, at the Ministry of Health and at meeting of the College of Surgeons of Eastern, Central and Southern Africa (COSECSA) held in Kampala, Uganda. Two interviewees were met at restaurants, as they did not have offices or health care centers where they could be reached. One was reached over the phone.

Table 1 summarizes the study sample demographics. Participants fell into four categories: 1) health care workers; 2) health care administrators; 3) patients; and 4) medical device industry representatives. The health care worker participants included 16 orthopaedic surgeons and 13 health care professionals who are not orthopaedic surgeons. The latter group of health care professionals included general surgeons, interns, public health officials, orthopaedic clinical officers, orthopaedic technicians, and nurses. The health care administrator group ultimately included only 2 government officials from the Ministry of Health. All hospital administrators interviewed were also doctors or health care professionals, and therefore these administrators were included in the first group of participants as health care workers. There were 6 patients in
the third group, and 8 participants in the fourth group of orthopaedic medical device industry representatives.

Fifty-one percent of participants worked in or attended only public institutions, and 54% of the health care professionals worked in academic centers. Forty-seven percent of participants worked in or attended rural health care centers, and 49% had a part-time or full-time private practice. Seven participants practiced surgery in African countries other than Uganda. These interviews were conducted to ensure data from Ugandan participants were consistent with the experiences of accessing orthopaedic medical devices in other low-income countries. The age range of the 6 patients interviewed was from 22 to 47 years old, and 2 were female. This is representative of the cohort of patients admitted to hospital with orthopaedic injuries, as most are male and of working age (Bouchard et al, Observational Field Notes, 2010). Of the five industry representatives who were sales agents or distributors for orthopaedic implant companies, three sold brand name implants and two sold generic devices made by Indian companies. Two industry representatives were sales agents for a brand name pharmaceutical company that sells anti-coagulant medications for elective procedures to orthopaedic surgeons directly. The last industry participant coordinates freight shipments, and frequently organizes importation of orthopaedic medial devices, other medical equipment and pharmaceuticals. Only two government officials (4% of the total sample) were available for interview. This is a recognized potential limitation of the dataset.
<table>
<thead>
<tr>
<th>Sample Sub-Group</th>
<th>Number of Participants (% of Total Sample)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care workers</td>
<td>29 (65%)</td>
</tr>
<tr>
<td><strong>Orthopedic surgeons</strong></td>
<td><strong>16 (36%)</strong></td>
</tr>
<tr>
<td>Other health care workers</td>
<td>13 (29%)</td>
</tr>
<tr>
<td>Health care administrators</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Government officials</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Hospital administrators</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Patients</td>
<td>6 (13%)</td>
</tr>
<tr>
<td>Industry representatives</td>
<td>8 (18%)</td>
</tr>
<tr>
<td><strong>Public practice only</strong></td>
<td><strong>18 (51%)</strong></td>
</tr>
<tr>
<td>Private practice only</td>
<td>3 (9%)</td>
</tr>
<tr>
<td><strong>Public and private practice</strong></td>
<td><strong>14 (40%)</strong></td>
</tr>
<tr>
<td>Academic affiliation or institution</td>
<td>19 (54%)</td>
</tr>
<tr>
<td>No academic affiliation</td>
<td>16 (46%)</td>
</tr>
<tr>
<td>Urban practice location</td>
<td>24 (53%)</td>
</tr>
<tr>
<td><strong>Rural Practice location</strong></td>
<td><strong>21 (47%)</strong></td>
</tr>
<tr>
<td>Practice in Uganda</td>
<td>38 (84%)</td>
</tr>
<tr>
<td>Practice in other Africa country*</td>
<td>7 (16%)</td>
</tr>
</tbody>
</table>

*Kenya, Ethiopia, Malawi, and Rwanda

Table 1. Study sample participants

Saturation of data was reached after the thirty-second interview. This meant that the interviews no longer elicited new information regarding the problem of access to medical devices in Uganda. Each subsequent participant was listing the same barriers to access and strategies for improving care. This is an expected outcome in qualitative research, and in this case, it demonstrates that the researcher captured the entire scope of the problem, as the addition of more participants to the study did not yield any new information. However, opportunity to speak with surgeons working in other African countries and additional industry representatives arose later in the study. As their experience of orthopaedic care was in a different setting, these participants had the potential to provide more data and insight into the problem of access to
orthopaedic medical devices and were therefore included in the study. In the end, little significantly new data was obtained and interviewing ceased after the forty-fifth participant.

2.1.2 Preliminary codes

As the goal of the study was to broadly assess perceptions regarding the access of orthopaedic medical devices in low-income countries, the majority of data analysis was conducted by analyzing the entire dataset. Subset analysis of data was also performed to compare whether experiences differed between different groups of participants, for example Ugandan compared to non-Ugandan participants and industry representatives compared to health care professionals. These analyses are described later in this chapter. The following codes and themes represent the whole dataset.

Analysis of the interview transcripts and interview summaries resulted in the coding of hundreds of pieces of text. Codes were created in three ways. First, codes were developed by labeling the interview questions for each group of participants as nodes. Each node, as seen in Table 2, represents 2 to 33 excerpts of text. Second, word frequency and text queries were run with the “Nvivo 9” Software. The most commonly occurring or meaningful words are shown in Table 3. A source represents an interview transcript or interview summary. Third, nodes were identified through line-by-line coding of the sources. Codes could be an exact word, such as “corruption” or “poverty”, or could they summarize a concept. “Waiting for treatment” and “Health care infrastructure” are examples of the latter. See Table 4.
<table>
<thead>
<tr>
<th>Interview Questions as Preliminary Codes</th>
<th>No. of References in Coded Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1. Description of career</td>
<td>33</td>
</tr>
<tr>
<td>Q1. Self-description</td>
<td>6</td>
</tr>
<tr>
<td>Q2. Access to OMDs in participant’s practice</td>
<td>24</td>
</tr>
<tr>
<td>Q2. Experience as orthopaedic patient</td>
<td>6</td>
</tr>
<tr>
<td>Q2. Funding of orthopaedic and trauma services</td>
<td>2</td>
</tr>
<tr>
<td>Q2. How sales are conducted in participant’s territory</td>
<td>7</td>
</tr>
<tr>
<td>Q3. Barriers to access of OMDs</td>
<td>33</td>
</tr>
<tr>
<td>Q3. Status since injury</td>
<td>6</td>
</tr>
<tr>
<td>Q4. Government strategies for alleviating injury burden</td>
<td>2</td>
</tr>
<tr>
<td>Q4. How orthopaedic health care can be improved</td>
<td>6</td>
</tr>
<tr>
<td>Q4. Importance of availability of OMDs</td>
<td>23</td>
</tr>
<tr>
<td>Q5. Orthopaedic sales representatives</td>
<td>6</td>
</tr>
<tr>
<td>Q5. Suggestions for improving access to OMDs</td>
<td>32</td>
</tr>
<tr>
<td>Q6. Local manufacturing of OMDs</td>
<td>32</td>
</tr>
<tr>
<td>Q7. Orthopaedic sales representatives</td>
<td>23</td>
</tr>
<tr>
<td>Q8. Effect of appropriate access to OMDs on the provision of orthopaedic care</td>
<td>19</td>
</tr>
</tbody>
</table>

Table 2. Interview questions as preliminary codes

<table>
<thead>
<tr>
<th>Word Queried</th>
<th>Number of References within Coded Text</th>
<th>Number of Sources Coded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access</td>
<td>390</td>
<td>34</td>
</tr>
<tr>
<td>Government</td>
<td>365</td>
<td>35</td>
</tr>
<tr>
<td>Device</td>
<td>324</td>
<td>34</td>
</tr>
<tr>
<td>Implant</td>
<td>270</td>
<td>34</td>
</tr>
<tr>
<td>Equipment</td>
<td>190</td>
<td>36</td>
</tr>
<tr>
<td>Money</td>
<td>190</td>
<td>39</td>
</tr>
<tr>
<td>Availability</td>
<td>185</td>
<td>34</td>
</tr>
<tr>
<td>Cost</td>
<td>142</td>
<td>34</td>
</tr>
<tr>
<td>Tools</td>
<td>101</td>
<td>29</td>
</tr>
<tr>
<td>Affordability</td>
<td>99</td>
<td>30</td>
</tr>
<tr>
<td>Effects and Burden</td>
<td>86</td>
<td>26</td>
</tr>
<tr>
<td>Limited</td>
<td>63</td>
<td>24</td>
</tr>
<tr>
<td>Donations</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>Wait</td>
<td>34</td>
<td>17</td>
</tr>
<tr>
<td>Policy</td>
<td>29</td>
<td>18</td>
</tr>
<tr>
<td>Plaster</td>
<td>23</td>
<td>16</td>
</tr>
<tr>
<td>Disability</td>
<td>22</td>
<td>10</td>
</tr>
<tr>
<td>Budget</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Corruption</td>
<td>17</td>
<td>9</td>
</tr>
<tr>
<td>Tax</td>
<td>11</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 3. Preliminary codes resulting from word frequency and text search queries
<table>
<thead>
<tr>
<th>Line-by-line Codes</th>
<th>No. of References in Coded Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of OMDs</td>
<td>32</td>
</tr>
<tr>
<td>Local manufacturing</td>
<td>32</td>
</tr>
<tr>
<td>Patient or hospital buys from distributor</td>
<td>26</td>
</tr>
<tr>
<td>Government supply</td>
<td>24</td>
</tr>
<tr>
<td>Donations</td>
<td>23</td>
</tr>
<tr>
<td>Government budget</td>
<td>21</td>
</tr>
<tr>
<td>Poverty</td>
<td>21</td>
</tr>
<tr>
<td>Availability and Accessibillty of OMDs</td>
<td>19</td>
</tr>
<tr>
<td>Lack of health infrastructure</td>
<td>17</td>
</tr>
<tr>
<td>Procurement</td>
<td>17</td>
</tr>
<tr>
<td>Policies to prioritize ortho and trauma</td>
<td>14</td>
</tr>
<tr>
<td>Reallocation of health care dollars</td>
<td>13</td>
</tr>
<tr>
<td>Need more specialists</td>
<td>12</td>
</tr>
<tr>
<td>Policies and law enforcement</td>
<td>12</td>
</tr>
<tr>
<td>Brand versus generic</td>
<td>11</td>
</tr>
<tr>
<td>Corruption</td>
<td>11</td>
</tr>
<tr>
<td>Doctor-Industry relations</td>
<td>11</td>
</tr>
<tr>
<td>Family</td>
<td>11</td>
</tr>
<tr>
<td>Awareness and Education</td>
<td>10</td>
</tr>
<tr>
<td>Lack of interest/unawareness</td>
<td>10</td>
</tr>
<tr>
<td>Perceptions and utilizations of health care</td>
<td>10</td>
</tr>
<tr>
<td>Repairs and maintenance</td>
<td>10</td>
</tr>
<tr>
<td>Low-cost OMDs</td>
<td>9</td>
</tr>
<tr>
<td>Waiting for treatment</td>
<td>8</td>
</tr>
<tr>
<td>Appropriateness of OMD</td>
<td>7</td>
</tr>
<tr>
<td>Distance from capital city</td>
<td>6</td>
</tr>
<tr>
<td>Growth of OMD market</td>
<td>5</td>
</tr>
<tr>
<td>Inventory</td>
<td>4</td>
</tr>
<tr>
<td>Lack of health insurance plans</td>
<td>4</td>
</tr>
<tr>
<td>Road traffic control</td>
<td>4</td>
</tr>
<tr>
<td>Import tarrifs</td>
<td>3</td>
</tr>
<tr>
<td>OMD quality assessment and standards</td>
<td>3</td>
</tr>
<tr>
<td>Regulation of traditional healers</td>
<td>3</td>
</tr>
<tr>
<td>Non-government-run hospitals</td>
<td>2</td>
</tr>
<tr>
<td>Ortho care without an ortho surgeon</td>
<td>2</td>
</tr>
<tr>
<td>International involvement and funding</td>
<td>1</td>
</tr>
<tr>
<td>Motivations of health care professionals</td>
<td>1</td>
</tr>
<tr>
<td>Orthopaedics as its own hospital division</td>
<td>1</td>
</tr>
<tr>
<td>Research</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4. Preliminary codes resulting from line-by-line analysis
2.1.3 Themes and overarching categories: The data summarized

Subsequent data analysis produced dozens of themes. Themes were created by condensing codes into groups of similar topics. Themes must accurately represent each code within them. A second process of collapsing the themes in more broad, “major themes” was then performed. Ultimately, these were then condensed again to reveal two overarching categories. Table 5 displays the hierarchy of select codes, and all themes, major themes and overarching categories.
<table>
<thead>
<tr>
<th>Overarching Categories</th>
<th>Major Themes</th>
<th>Themes</th>
<th>Line-by-line Codes</th>
<th>No. of References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barriers to Access of OMDs</td>
<td>Poor leadership and corruption</td>
<td>Vulnerabilities</td>
<td>Patient hospital buys from distributor</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Government Supply</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Donations</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Procurement</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Policies and law enforcement</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Corruption</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Doctor-Industry relations</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Personal purchase</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Import tariffs</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>International involvement and funding</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Motivations of health professionals</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>High costs of OMDs and poverty</td>
<td>Barriers to Access of OMDs</td>
<td>Cost of OMDs</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Government budget</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Availability and accessibility of OMDs</td>
<td>19</td>
</tr>
<tr>
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<td>Growth of OMD market</td>
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Table 5. Hierarchical map of the dataset
The two overarching categories are represented in Figure 1: “Barriers to access of orthopaedic services and orthopaedic medical devices”, and “Improving access to orthopaedic care”. Four major themes were elicited as barriers: 1) Poor leadership in government and corruption; 2) high costs of orthopaedic medical devices and poverty; 3) inadequate human resources; and 4) inefficient and insufficient health care infrastructure. Condensed themes were also summarized as mechanisms for improving access to orthopaedic care. These included: 1) Policies for prioritization of orthopaedic services within health care; 2) training of more orthopaedic specialists and creating incentives for them to work in underserviced areas, such as rurally and in the public system; and 3) the adoption of innovative strategies for raising funds for orthopaedics. These seven major themes will be explored in greater detail in the following section.

Figure 8. Overarching categories and major themes from interview data
2.1.4 Subset data analyses

This study on the limited access of orthopaedic medical devices in Uganda incorporated the experiences of many different key informants to obtain a broad and complete understanding of the problem. Many important barriers to access were identified, and concrete innovative strategies were proposed as possible mechanisms for improving access to medical devices and health services. Although every elicited impediment and solution is important, it is interesting to explore if the four subgroups of participants, orthopaedic surgeons and other related health care professionals, government officials, patients, and orthopaedic industry representatives, expressed similar or differing views. To determine if the perspectives of the non-Ugandan participants contextualize the Ugandan descriptions of accessing orthopaedic medical devices in the broader low-income country experience, the subset of participants working in Uganda is compared to that of participants working in other African countries. Tables 6 through 9 summarize the number of references per code or theme identified in the transcripts of each participant subset.

When comparing the data collected from orthopaedic surgeons and health care professionals other than orthopaedic surgeons, there are a few concepts one group is more aware of than the other, as shown in Table 6. Codes reported solely by the orthopaedic surgeons, highlighted in bold text, include how orthopaedic medical devices at times must be purchased by the surgeons themselves, that choices must be made between brand or generic products, that international community funding and involvement are important, and that growth of the medical device market may improve access to orthopaedic equipment. Reliance on donations and lack of prioritization of orthopaedics and trauma are two other barriers to access that surgeons tend to identify more frequently than non-orthopaedic surgeon health care professionals. The latter group however, was more sensitive to the lack of human resources and training, and the need for better road traffic control. These are highlighted in italics in Table 6. Some of these differences can be attributed to the role of orthopaedic surgeon as the one health care worker who is knowledgeable enough to use and recommend these high-tech, expensive orthopaedic medical devices.
<table>
<thead>
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<td>3</td>
</tr>
<tr>
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<td>4</td>
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<td>Regulation of traditional healers</td>
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<td><strong>Road traffic control</strong></td>
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<tr>
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Table 6. Comparing responses of orthopaedic surgeons and non-orthopaedic surgeon health care professionals

Health care professionals and industry representatives are both aware of the multitude of issues that can affect access to orthopaedic medical devices. Health care professionals were more inclined to identify problems regarding government funding and infrastructure, dependence on
donated supplies, and inadequate human resources, as seen in bold in Table 7. Industry representatives were more apt to comment on the need for better quality control of orthopaedic devices, highlighted in italics, but they did not raise concerns about the appropriateness of medical devices, their cost, the need for surgeons themselves to purchase equipment, or problems with repair and maintenance. When asked how access to medical devices could be improved, most industry representatives felt that medical device access in Uganda was adequate as their companies could import any product within days to weeks as long as there was a buyer. They did not mention the need for improving the medical device market or economy, or advocacy for trauma, road traffic control, research or better infrastructure. This can likely be explained by the for-profit nature of the orthopaedic medical device industry. Since there are only a handful of orthopaedic device companies present in Uganda, they maintain a relative monopoly. Improving the market would take away from their business. Their lack of focus on trauma prevention and infrastructure is most likely because the only time they see a patient is when that patient or hospital has already agreed to purchase an implant. The industry representatives do not see the other patients who cannot afford medical devices, and therefore may not appreciate the large proportion of patients who are precluded from surgical management of their injuries. Also, most Ugandan medical device suppliers are companies based in India and therefore they may not feel invested toward improving domestic, systemic health care issues in Uganda.
### Codes and Themes

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Table 7. Comparing responses of health care professionals and industry representatives

Patients were primarily asked to describe their orthopaedic injury and the treatment they had received. There were also asked if they could identify any barriers to the access of orthopaedic
medical devices, and if they could suggest any mechanisms for improving access. The patient group mostly reported on difficulties or reluctance in seeking orthopaedic care, and their inability to pay for the needed instruments used in their treatment, as seen in Table 8. No patient proposed solutions for improving access to care. They felt the major barriers were poverty and the cost of the orthopaedic medical devices. They reported how their limited purchasing power delayed, and in some cases prevented, access to the orthopaedic equipment they needed.

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<td>Brand versus Generic</td>
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<td><strong>Patient or hospital buys from distributor</strong></td>
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<td><strong>Access to care</strong></td>
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<tr>
<td><strong>BARRIERS TO ACCESS OF OMDs</strong></td>
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<tr>
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</tr>
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<td>Lack of interest/unawareness</td>
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</tr>
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<td>Government supply</td>
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<td>Donations</td>
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<td>Trauma and ortho are not a priority</td>
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<td>OMD quality assessment and standards</td>
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<td>Local manufacturing</td>
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Table 8. Summary of the patient responses regarding access to orthopaedic medical devices
The participants who worked in African countries other than Uganda reported similar difficulties in accessing orthopaedic medical devices to the Ugandans. The differences between their experiences however, had more to do with the reliance on government supplies and a poor health care infrastructure described in Uganda. Only Uganda participants reported purchasing equipment themselves, having trouble with inventory, and needing better quality assessment of orthopaedic medical devices, as shown in bold in Table 9. These differences may be a result of Ugandans having enough access to devices that inventory systems and quality assurance protocols are required. Although the participants from outside Uganda were surgeons working in both urban and rural centers, Ugandans were also the only ones to mention distance from urban areas as a barrier to access of orthopaedic medical devices. It is unlikely that many African countries have sufficient orthopaedic care in rural areas, and so the omission of distance as barrier by non-Ugandan orthopaedic surgeons may be that they naturally assume such specialized surgery will only be offered in an urban center. Ugandan participants more commonly identified the appropriateness of orthopaedic medical devices, limited human resources and lacking health care infrastructure as barriers. Several non-Ugandan participants expressed that they were satisfied with non-operative methods of treating fractures and that more complex devices were not needed (Bouchard et al., Observational Field Notes, 2010). These surgeons however, tended to be the only orthopaedic-trained specialists in their country. There was therefore no medical device market or incentive for the government to consider increasing funding for their specialty, and this may force them to rely on non-operative strategies. Ethiopian participants reported problems with import tariffs, but this was not considered a barrier in any other country, in italics in Table 9. Importantly, one participant reported that East African countries are under the same customs legislation and this explains why none of the East African surgeons reported problems importing equipment. Lastly, Ugandans and non-Ugandans alike identified corruption as a major barrier to access of orthopaedic medical devices and orthopaedic care in their country.

The majority of barriers to access of orthopaedic medical devices, including corruption, from theft of supplies to embezzlement of donor funds, limited human resources and infrastructure, and cost of equipment, were identified by both Ugandan and non-Ugandan participants. Differences can be accounted for by the number of orthopaedic specialists present in different
low-income countries, as the more specialists there are the more incentive there is to procure medical devices and develop orthopaedic health services. Import tariffs and legislation will vary in each country and should be assessed on an individual basis.

<table>
<thead>
<tr>
<th>Codes and Themes</th>
<th>Ugandans (38)</th>
<th>Non-Ugandans (7)</th>
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Table 9. Comparing responses of Ugandan and non-Ugandan participants
2.2 Interpreting the case study data

2.2.1 Barriers to orthopaedic care and medical devices

The results of this study on the health services in Uganda expose significant systemic issues that prevent effective delivery of orthopaedic care and access to orthopaedic medical devices. The barriers elicited as impediments to access of orthopaedic medical devices are important to recognize and understand as they may similarly hinder access to other health care services and needs in Uganda, and in other countries worldwide.

2.2.1.1 Orthopaedic care is not a health priority

One of the biggest obstacles in providing appropriate care of injured patients is the lack of prioritization of orthopaedics and trauma in health care policy. This is related to government failure to recognize the gravity of the injury burden, and to the inadequate health care infrastructure, as there are few resources with which to provide orthopaedic care.

Key informants cited many instances in which orthopaedic services are neglected. Child and maternal health, and infectious diseases are consistently prioritized over trauma. Low-income countries often rely on donor funding to support their health care systems. Thirty-five percent of Uganda’s health care budget is from donor funds (Health Sector Strategic and Investment Plan, 2010). The Government of Uganda therefore is hesitant to prioritize a health burden that does not receive international attention, and trauma and surgical disease are not yet the focus of the international aid community. This is a very important finding as it demonstrates that external international community agendas are often imposed on local and national health care priority setting and ultimately on actual service delivery.
For example, the United Nation’s Millennium Development Goals (MDGs) are a blueprint for global development strategies, directing flow of aid to specific areas (UN Millennium Goals, 2011). The MDGs do not yet include reducing the injury burden; they support the more dominant international community health concerns such as HIV/AIDS, and maternal and child health (UN Millennium Goals, 2011). One informant noted:

“The problem is right from the top. When we talk Millennium Development Goals, our government implements them with international standards. So the focus is on maternal and child health, and they forget the other problems. Trauma is [not] recognized in the MDGs, and so countries act only on issues to which international money and funds are flowing to.”

Injuries and disabilities are however, included in Uganda’s Health Sector Strategic and Investment Plan (HSSIP), a published document of Uganda’s health care goals for the upcoming five years. Of note however, injuries are mentioned as one of many items under “Non-Communicable Diseases” (HSSIP, 2010), while maternal health and communicable diseases have their own sections. The strategies to alleviate the injury burden through prevention and rehabilitation, described on a single page, fail to mention surgical care (HSSIP, 2010). Study participants were aware of the disproportionately small attention given to orthopaedics, one of the largest disease burdens in the country.

“Money should not just go to primary health care. Trauma is emerging into an epidemic, and we need to change that.”

As orthopaedic services are not a health care priority, it follows that the purchase of orthopaedic medical devices is neglected as well. Pharmaceuticals treat many infectious, maternal and childhood diseases, and are therefore preferentially supplied. In the section on “Medicines and Other Health Supplies” of the HSSIP (p. 59), no medical supply other than pharmaceuticals is even discussed. Participants discussed how the high cost of orthopaedic medical devices relative to pharmaceuticals or consumable health supplies makes it difficult for hospitals to prioritize specialized orthopaedic equipment over items that are needed daily for all patients.
“Drugs are cheaper. So the hospital cannot spend all the money on one person for implants, drugs can be purchased and treat many people.

“We buy anti-malarials, antibiotics, gloves, diabetes drugs, anti-hypertensives, psychiatric drugs, fluids... With a small budget, orthopaedics is not a priority.”

Further research into the possibility of applying the flexibilities in international patent law to lower prices of health technologies, as was done for pharmaceuticals, is needed for orthopaedic medical devices. If prices of orthopaedic medical devices can be lowered, the likelihood of their purchase and use in the public health care system will be improved and can enable an adequate and appropriate management of the growing injury burden. This will be discussed in more detail in Chapter 3.

2.2.1.2 Inadequate human resources

Uganda, like most low-income countries, has a shortage of orthopaedic specialists, from surgeons to orthopaedic officers and nurses (Naddumba, 2008). There is an even greater scarcity of orthopaedic surgeons in rural areas (Naddumba, 2008). Presently, the government provides little incentive, such as higher wages or subsidies for costs of daily living, for health care professionals to work rurally or in the public system, and training is expensive. Participants remark that there is no support to encourage health care professionals to work in underserviced areas.

“Our salary is little. I [a surgeon] am not providing housing to live here [in a rural area].”

The government will not fund orthopaedic care or supply orthopaedic equipment to a hospital if there is no orthopaedic surgeon present, compounding the problem of inadequate orthopaedic health services in rural areas.

“There is a lack of specialists. If there is no orthopaedic surgeon, there is no motivation [from the government] to stock these tools.”
When hospitals or clinics lack knowledgeable health care workers, access to and quality of patient care is compromised in several ways. First, if medical professionals are unavailable or insufficiently trained, diagnoses might be missed or complex cases may be mismanaged. Second, in Uganda, the government insists on there be an appointed specialist to the hospital before they supply needed equipment to that center, even if general practitioners are or could be trained to use the same equipment. For example, as the participant above mentions, if there is no orthopaedic surgeon in a hospital, that hospital will not be eligible to receive tools such as drills and pins, or external fixators. Traction pin and external fixator application are simple, often life or limb-saving procedures that could be done by any physician with only minimal training. Despite this policy requiring presence of specialists, participants felt little was being done by the government to increase numbers of health professionals in underserviced areas.

Training programs, for specialists such as orthopaedic surgeons and orthopaedic officers, are considered too few in number and unable to produce enough trainees to account for the lack of needed specialists. Furthermore, many participants reported that there is little incentive provided by the government or hospitals for health professionals to work in underserviced areas. Participants felt that benefits such as accommodation, higher wages, or other forms of compensation should be provided to those who decide to work in rural or underserviced areas to justify the costs and inconvenience of relocating to often more remote or less desirable locations.

2.2.1.3 Insufficient and inefficient health care infrastructure

In Uganda’s universal health care system, the government attempts to supply all its hospitals with the necessary equipment and medicines. Hospitals can access what they need through the National Medical Stores, a centralized depot of medical supplies run by the government (National Medical Stores, 2011). The National Medical Stores however, do not regularly carry orthopaedic equipment other than plaster, forcing orthopaedic departments to rely on internationally donated supplies. Many other supplies and drugs are also frequently out of stock or cost more than hospitals or patients can afford.
“At the government hospital here, where I do spine surgery, I haven’t been provided with anything by the state. Everything is donated.”

Ugandan and non-Ugandan surgeons alike reported their dependence on donated implants in order to provide surgical care in the public system. Although this is a reasonable temporary solution for providing effective care to patients in need for free, it is not sustainable and long-term strategies for ensuring continued access to implants are needed.

2.2.1.4 Poor leadership in government and corruption

Participants also considered corruption within hospitals, clinics and governments to be another barrier of access to care and supplies. Corruption, as defined by Transparency International, is the “abuse of entrusted power for private gain” (Robinson, 2006, p.xvii). Corruption and its impact on the provision of orthopaedic services is an issue absent in the orthopaedic literature at this time. First, the failure of government and hospital leaders to recognize the need to prioritize trauma and injuries impedes any efforts at alleviating the injury burden. Participants reported instances where groups of health care professionals presented government officials with statistics and research demonstrating the persistent and significant increases in numbers of injured patients and the rates of morbidity and mortality these were causing. Despite meetings and conferences, interviewees did not feel their attempts to spread awareness of the impacts of trauma had any effect on the policy changes in health care or prioritization of trauma and orthopaedics. Participants also related lapses in leadership at government and hospital levels to the high frequently of theft and misuse of financial and capital resources.

“Money in the government is not always accounted for and doesn’t always make it to the hospitals.”

“[There is] theft of equipment in government hospitals by people who want to set up their own practice.”
Unaccounted for funds are assumed spent on luxuries, such as vehicles for the personal use of government officials or hospital management. Stolen implants, donated or purchased, are suspected of being taken from public hospitals and resold to patients in private hospitals. These problems deserve further investigation and are explored in Chapter 3.

### 2.2.2 Impacts of limited access to orthopaedic care

Gaps in funding and prioritization of orthopaedic care and orthopaedic medical devices lead to poor patient outcomes and higher risk of disability. As surgeons are scarce, funds are limited, patients are often poor, and costs of orthopaedic medical devices are high, most patients with orthopaedic injuries are treated non-operatively with casts or traction (Bouchard et al., Observational Field Notes, 2010; Gosselin et al., 2009). Plaster of Paris and traction are significantly cheaper methods of care and require lower cost instruments, and are therefore generally provided for free in the public health system. Traction requires bed rest for a minimum of 12 weeks while the injured limb is held out to length by a weight. This can lead to major complications and is not as effective as internal or external fixation devices in ensuring fracture healing (Della Rocca & Crist, 2006). Casting may also demand that a patient avoid weight bearing on the injured limb anywhere from 6 to 12 weeks. Known complications from bed rest and immobility associated with treatment in traction include prolonged hospitalization, increased risk of blood clots, bedsores and ulcers, pneumonia, muscle weakness and joint contractures, pin site infections, malunion, non-union and shortening of the bone (Canale and Beaty, 2002; Gosselin et al., 2009).

The study by Gosselin et al. (2009) explores the cost-effectiveness of treating femur fractures by internal fixation with the SIGN intramedullary nail compared to traction at the largest hospital in Cambodia. They found that treatment with internal fixation was significantly cheaper: 1,107USD in the traction group and 888USD in the SIGN group (p<0.01). Costs for hospital stay per diem (including nursing care, food, laundry and hospital cleaning), operating room time (including cost of medical and nursing staff, and infrastructure such as oxygen and water), equipment, use of blood products, physiotherapy, X-rays, and supplies such as drugs, dressings and orthotics, were less in the SIGN nail group than the traction group. Length of stay in
hospital was largely responsible for the cost difference per patient. The hospital per diem represented 88% of the total cost for the traction group, and 66% in the SIGN group. These costs are from the perspective of the payer/provider (hospital), as treatment was provided in a public hospital. It could therefore be extrapolated that in public hospitals in Uganda, similar cost savings could be achieved by using the SIGN nail or internal fixation over traction in femur fracture patients. A caveat however, is that only one Ugandan hospital has access to the SIGN nail, which is provided by the SIGN organization for free (Bouchard et al., Observational Field Notes, 2010). In the other institutions, public or private, patients must pay for their implant. Intra-medullary nails similar the SIGN nail cost as much as 900USD; this almost doubles the cost of the treatment with the added expense being the responsibility of the patient. Most Ugandans cannot afford 900USD implants and are therefore precluded from operative treatment and subjected to unnecessary risks of non-operative management.

The resulting disabilities and complications of these non-operative treatments are particularly devastating to the working age population and thus have a significant financial impact not only on the patient but also on the economic development of Uganda. Patients are unable to work during the minimum 12-week treatment period as they are in bed or cannot bear weight. In some cases, a poor treatment outcome results in permanent disability and the patient can never return to work. In hospital, as there is insufficient nursing staff, patients must have a family member or friend care for them at the bedside, and this renders that caregiver unable to work or tend to their family as well (Bouchard et al., Observational Field Notes, 2010).

2.2.3 Adapting Uganda’s health care system to respond to the injury burden

Analysis of the interview data enabled formulation of strategies for improving orthopaedic care and access to orthopaedic medical devices. This information could be translated into policies for managing the growing Ugandan and global injury burden.
2.2.3.1 Developing better infrastructure and improving human resources

There is a great need for more human resources to manage the orthopaedic patient volume. To increase numbers of health care professionals, more training programs for all specialists who manage trauma, including traditional bonesetters, are needed, as many participants reported.

“There is often no skilled personnel, and so if no one has the knowledge, no one uses them [orthopaedic medical devices].”

The government must also offer incentives for all health care professionals to work rurally and in the public system. Incentives can include financial support in the form of subsidies or higher wages, accommodations or allowances for costs of daily living. Informants felt little drive to work in underserviced areas.

“There is not much motivation to work because the salary is so little.”

“All the orthopaedic surgery in Uganda is concentrated at Mulago [the largest hospital in the country located in the capital city]. The doctors don’t want to go to the periphery and the government doesn’t insist they go.”

Alternatively, as some of the non-orthopaedic health care workers suggested, there should be more opportunities and encouragement for general practitioners and non-physician orthopaedic professionals to manage orthopaedic care. Since orthopaedic surgeons are scarce and rarely available in remote areas, having well trained clinical officers and orthopaedic officers manage straightforward orthopaedic injuries would improve access to patient care and alleviate the burden of patients referred for treatment at Level IV hospitals (hospitals with surgeon specialists) in the urban centers.

Efficient infrastructure is also needed to enable appropriate treatment, decrease length of hospital admissions, and improve patient outcomes. This includes having the appropriate pharmaceuticals, beds, imaging, operating rooms, personnel, as well as specialized orthopaedic equipment. There is also a need for more research and innovation of appropriate orthopaedic
medical devices and equipment for use in low-resource settings. The SIGN nail is an example of an implant that removes the need for expensive and highly technical intra-operative imaging (Zirkle, 2008). An Indian company, Jaipur Foot, developed an external foot prosthesis that is affordable, easy to fit and has functions better suited to the needs of the poor (Bhattacharyya et al., 2010). More low-resource setting appropriate medical devices such as these are needed. Options for manufacturing these devices locally might also decrease equipment costs and foster economic development.

2.2.3.2 Innovative funding strategies

With a limited health care budget, hospitals and the government could benefit from innovative strategies for funding orthopaedic care. Participants came up with a range of creative ideas to improve funding of orthopaedics. Several informants urged the government to reconsider “cost-sharing or public health insurance plans.” Such strategies could distribute the burden of health care costs between the government and health care users.

Others suggested the development of mechanisms for procuring medical devices at lower prices, since orthopaedic medical devices are a large portion of the cost of surgical care. As one participant said:

“The government [can] bring [in] equipment at the best cost. They could do this by excluding the sales tax on the medical devices, and by doing tenders and bulk purchasing for procurement.”

Another option for procuring lower priced medical devices would be to invoke the flexibilities in trade law, such as compulsory licensing as described in the TRIPS Agreement. Encouraging governments to consider their injury burden as public health emergencies could enable them to invoke compulsory licensing for importation of brand name orthopaedic implants at lower, competitive prices. This might be particularly useful in the countries where no domestic orthopaedic medical device market exists.
Some informants identified novel methods for funding orthopaedic services:

“We could put a levy on fuel and vehicles to put money directly into orthopaedics for implants and other [OMDs], for salaries to increase motivation and increase the working hours, and for improved call coverage to sustain a 24 hour operating theatre.”

“We can use profits from private surgeries to raise funds for the public care. Public hospitals can generate their own money through a private wing.”

A recent study by Bhattacharyya et al. (2010) examined the different innovative approaches used by the increasingly common private health organizations in low- and middle-income countries to improve the availability, affordability and quality of health care services. Effective strategies included social marketing, cross-subsidy, high-volume, low cost models, and process reengineering. Of the ten health service providers studied, many received support from partnerships with non-governmental organizations or foreign universities, government funding, grants and donations, and some recovered part of their costs from user fees. Funds were either generated for sustainability, or they redesigned cost structures in ways that allowed products and services to be more affordable to poor people. Significant cost savings were achieved with rigorous expense management, capital funding, and revenue-generating programs.

One example cited by Bhattacharyya et al. (2010) describes how simplifying medical services can lower operating costs. In this case, a company that provided vision screening, diagnosed farsightedness, and distributed reading glasses, trained and employed rural community members to provide this vision care. Engaging workers with lower skill levels can decrease costs and avoid the need for highly specialized personnel. This strategy is known to orthopaedics in Uganda. The Uganda Sustainable Clubfoot Care Project is a Canadian International Development Agency funded collaboration that aims to make the non-operative, gold standard treatment of clubfeet available to all affected infants in a safe, effective and sustainable manner (Staheli, 2008). This treatment uses only casts and is low-cost, but savings were also achieved by training non-orthopaedic surgeon health care workers to manage these patients. Nurses, clinical officers and orthopaedic officers in areas throughout the country were taught to perform clubfoot corrections
and follow-up patients. With this low-cost, low-tech treatment thousands of children have been saved from life-long disability (Staheli, 2008).

Unique revenue generating strategies, similar to the levy or tax concepts suggested by participants in this Ugandan case study, were also reported as successful tactics by Bhattacharyya et al. (2010). They describe how for-profit companies affiliated with a non-governmental organization in Thailand are mandated to put funds towards the organization to supplement operating costs. “Cabbages and Condoms” Restaurants located throughout the country serve condom-themed food and drink to help raise money for an organization while spreading information about safe-sex practices.

Process reengineering of health services, or employing novel strategies to render health care delivery more efficient and cost-effective, is another mechanism highlighted by Bhattacharyya et al. (2010). An Indian cataract surgery provider improved efficiency by reengineering their operating rooms to allow surgeons to work on two tables in alternation. While one surgery is in progress, support staff prepare the next patient and surgeons shift from table to table. The company also tracks surgical outcomes by surgeon and provides support to those in need, further improving quality of care. Similar reorganization of orthopaedic departments and operating rooms could be considered to improve efficiency. Performance incentives with feedback and support might also function to retain and engage orthopaedic health workers.

The innovative methods for health service delivery discussed in this chapter have the potential to better serve the health needs of the poor, support orthopaedic care providers, and respond to the growing injury burden. Informants also acknowledged that alleviating the injury burden requires developing education and awareness programs for patients on injury prevention and where to seek medical treatment. Many participants related the difficulties in funding and running orthopaedic programs with corruption at local, hospital and government levels. They expressed the need for anti-corruption measures and improved transparency in government. These strategies will be discussed in Chapter 3. Further investigation into the process of generating ideas for innovative funding, and into the usefulness and applicability of the funding strategies discussed in this section, are needed.
2.2.4 Study limitations

Like with any research methodology, there are some limitations of this study. First, this is a single exploratory qualitative case study examining only one country, although in great in depth. It cannot be confirmed that the information collected in this study will be applicable and accurate for all low-income countries, however the findings can more accurately be applied for the generation of broad theories and hypotheses on the problem of access to orthopaedic medical devices (McGloin, 2008). This is supported by the seven interviews conducted with doctors and industry representatives from other African countries. The responses of the non-Ugandan participants were well aligned with those from Uganda. Interview participants were also diversified and represented all of the key stakeholders involved in orthopaedic care, helping to ensure that the data collected was accurate in as many contexts as possible. In addition, the policy recommendations suggested by this researcher are based on the strong recurrent themes present across the entire case study data set.

Second, this data is reflective of the time period in which the study was conducted and it expresses the opinions of the summarized and coded interview data, and not necessarily any one individual, institution or nation. The study is meant to capture and understand the collective views of all participants. The data was collected over a six-week period in Uganda, and is therefore subject to the influence of the time and context of the country at time of interview.

Third, this research was conducted as part of a Master’s thesis, and the scope of the project had to be limited to a six week field study within a two-year academic process.

Fourth, as interviews were recorded with hand-written notes, it is possible that information or meaning were lost. Cross-cultural misinterpretation could also limit theme capture and identification of codes. Member checking and triangulation techniques however, minimize the possibility that participants’ responses were not captured, or were misinterpreted or misrepresented.
Finally, government officials are under-represented (4% of sample size) in this study and may represent a limitation of the dataset. Officials at the Ugandan Ministry of Health were difficult to schedule meetings with as few surgeons or health care workers were familiar enough with their government representatives to contact them or introduce them to the researcher.
2.3 Chapter summary

Poor leadership in government and corruption, limited human resources, inadequate health care infrastructure, and high costs of orthopaedic equipment prevent access to needed orthopaedic care and medical devices in Uganda. Without these medical devices, the quality of orthopaedic care suffers and the burden of preventable injury is exacerbated. Mechanisms to increase access to orthopaedic medical devices and orthopaedic care globally could include: 1) Hiring and training more orthopaedic specialists, and developing more standards to enable lower level health care centers with physicians in roles such as clinical officers to manage more simple aspects of orthopaedic care; 2) Creating policies prioritizing trauma and orthopaedics in health care; and 3) Developing innovative strategies for funding orthopaedic care. Further research into this global health challenge is needed. This study, although exploratory, aims to promote further scientific and policy inquiry into the issue of access to orthopaedic equipment globally as part of the response to alleviating the injury burden.
3 CHAPTER THREE: Corruption as a potential barrier to orthopaedic care and orthopaedic medical devices in low-income countries

3.1 Introduction

Given the wide range of findings illuminated in this qualitative study, the author has chosen to explore in detail the broad policy issue of corruption. The effect of corruption in the health sector, and in particular on orthopaedic care delivery is an area that deserves deeper attention. As the global injury burden continues to rise and disproportionately affect low-income countries, timely access to appropriate orthopaedic services must be ensured. The participants of the case study exploring the availability of orthopaedic medical devices described in the previous chapters perceived corruption as a major and consistent barrier to access of orthopaedic care and medical devices. The global governance and global health literature confirm that corruption is a major impediment to access of health care in low-income countries (Kohler, 2010). If corruption is affecting orthopaedic services, achieving adequate access to orthopaedic care and equipment will not be achieved without the implementation of strong anti-corruption measures. This chapter will explore how corruption hinders access to orthopaedic care and orthopaedic medical devices and exacerbates the global injury burden. It concludes that this broad policy issue is an area in need of future enquiry emerging from the work and learning of this thesis research.

3.2 Corruption in the health sector

Corruption, as defined by Transparency International, is the “abuse of entrusted power for private gain” (Robinson, 2006, p.xvii). With health care expenditures totaling 3 trillion US dollars globally, this sector is particularly vulnerable to corruption (Robinson, 2006). In health care, there is a significant diversity of services offered, and a large scale and expense associated with procurement (Vian, 2002). In addition, the nature of health care is such that the demand is not fully predictable and often exceeds supply (Vian, 2002). Health care systems also tend to
have weak or non-existent rules and regulations, lack of accountability, information and expertise imbalances between providers and patients and suppliers and providers, and low salaries for health care professionals and public officials (Kohler, 2010). These characteristics of the health sector make it susceptible to corruption.

A study by the International Monetary Fund shows corruption has negative effects on health indicators such as infant and child mortality, female education, health spending, and level of urbanization (Gupta et al, 2000). Furthermore, corruption disproportionately affects poor people as they are most susceptible when resources are wasted or stolen (Cohen, 2006), and unable to offer bribes or pay for private alternative services when corruption has depleted supplies in the public sector (Robinson, 2006). For example, low- and middle-income municipalities in the Philippines waited longer at public health clinics than rich communities (Robinson, 2006).

In the health sector, corruption can occur as embezzlement and theft, fraudulent activities in the procurement process of needed supplies, in the payment systems such as user fees, insurance or health care worker wages, in the pharmaceutical supply chain, and at the point of health service delivery where acts such as bribery and under-the-table payments are made (Robinson, 2006).

Common sources of corruption among health care providers are fraud and absenteeism. Fraud, defined as deceptive conduct designed to manipulate someone to give something of value (Duhaime, 2011), can include behaviours such as the acceptance of informal payments for better health care services and pocketing of user fees (Kohler, 2010). Absenteeism is often due to the lack of motivation, poor quality of health worker education, and lack of qualifications (Kohler, 2010). Absenteeism is also an effect of low or inadequate wages, which decreases motivation to attend formal work, and increases motivation to seek additional employment or alternative or informal means of payment. For similar reasons and because of a paucity of control and accountability mechanisms, health care providers are also known to steal drugs and medical supplies. Seventy-one percent of doctors and 83% of nurses in Costa Rica stated that equipment or supplies had been stolen from their hospital (Di Tella & Savedoff, 2001). A study in Uganda reported that the resale of pharmaceuticals is the greatest source of income for health care workers (Ferrinho & Van Lerberghe, 2002).
In many low-income countries, budget management systems and regulations are weak making effective monitoring of the health care budget difficult; essential data is often missing and information on expenditures may be inconsistent (Kohler, 2010). Accountability and transparency are therefore difficult to ensure, and budgets become vulnerable to corrupt practices. This is particularly common with funds received from international donors. In 2009, it was found that officials in the Ministry of Health and Social Welfare in Zambia had embezzled 1.4 million US dollars (Pereira, 2009). In 2005, the Global Fund for HIV/AIDS, Malaria and Tuberculosis suspended all donations to Uganda when over 1.6 million US dollars of grants went missing (Somali Press, 2009). To date, two Ugandan officials have been accused and sentenced for the embezzlement of Global Fund monies (Kelly, 2009).

3.2.1 Corruption in the pharmaceutical industry

Drugs are the second largest health care expenditure after salaries, representing up to half of most health care budgets (Vian, 2002). The global pharmaceutical industry was valued at over 808 billion US dollars in 2009, and is expected to rise to 1.14 trillion US dollars by the year 2014 (IMAP, 2010). By 2020, seven middle-income countries (Brazil, China, India, Indonesia, Mexico, Russia and Turkey) could represent up to one-fifth of global pharmaceutical sales, a 60 percent increase from 2004 (PricewaterhouseCoopers, 2007). Asia, Latin America and Africa account for 12% of the pharmaceutical market, but this is also expected to grow due to increasing disease burdens in low-income countries (World Bank, HNP Brief, 2005). Multiple studies have shown that the lucrative pharmaceutical supply chain is vulnerable to corruption at many points including selection, procurement, promotion, and distribution (Vian, 2002).

For example, if regulations are weak and there is a lack of transparency or accountability in the process of drug procurement, companies may pay-off government officials to register their drugs without the requisite information for procurement monitoring or quality control management (Kohler, 2010). Officials may also delay the registration process to solicit a bribe or to favour another company’s registration application (Kohler, 2010). This corruption in the procurement process can lead to higher drug prices, reduce competition, influence selection of products, and enable entry of lower quality or counterfeit drugs to the market (Klitgaard, 2000).
Theft, diversion and resale of drugs are other sources of corruption documented to occur at the distribution point of pharmaceutical supply chain (Vian, 2002). For example, there can be theft without falsification of inventory records, dispensing of drugs to patients who did not actually attend the pharmacy or clinic, recording of drugs as dispensed to legitimate patients but the patients do not receive them, and dispensing of drugs to patients who pay for them but the health care provider keeps the funds for themself (Vian, 2002). In Uganda, it is estimated that over two-thirds of drugs meant for free distribution in the public sector were lost due to theft or went unaccounted for, and that 68-77% of formal user charges were misappropriated or pocketed by workers (Mpake, 1999).

3.2.2 Corruption in the orthopaedic medical device industry

The orthopaedic medical device industry is another area where there are relatively large sums of money involved and thus a susceptibility to corruption (Vian, 2002). Corruption in orthopaedics was an uncommon topic in academic literature and non-medical media until the announcement of a large-scale lawsuit in the United States in 2005. The Department of Justice’s U.S. State Attorney for the District of New Jersey brought forth allegations against the five largest orthopaedic device manufacturers for illegal kickbacks to surgeons and false claims allegations. Physicians were allegedly awarded vacations, gifts and annual “consulting fees” as high as 200,000$ in return for physician endorsements of their implants or use of them in operations (Healy and Peterson, 2009). The false claims were concerning illegal promotions of off-label uses for a certain product. These five companies control 95% of the orthopaedic medical device market (Healy and Peterson, 2009). Four of those companies paid 311 million US dollars to settle the case (Healy and Peterson, 2009). Many of the individual orthopaedic surgeons are the subjects of investigations as well.

One example of a kickback program was Zimmer Inc’s “40 for 40” program. If a surgeon performed forty surgeries with the company’s hip implant, they would receive 40,000$ (Interview Anonymous Surgeon, 2011). This 1000$ per patient was intended as an honorarium
for following-up on the patient and reporting the results for the company’s records (Interview Anonymous Surgeon, 2011). The pharmaceutical industry also conducts similar arrangements with orthopaedic surgeons. For example, one company aiming to increase the use of their latest anti-coagulant offered surgeons 250 dollars per patient to whom the drug was prescribed, and a laptop for recording follow-up reports (Interview Anonymous Surgeon, 2011).

The proceedings of the US Department of Justice and the orthopaedic industry have completely changed today’s landscape of industry-doctor relations in North America. Policies and codes of conduct have been amended or developed to discourage corrupt behaviors, and there is increased oversight by government agencies (Healy and Peterson, 2009). Common examples of new regulations include (MEDEC, 2011; AdvaMed, 2009):

- Any gift over 100 dollars is now illegal and gifts must always be relevant to patient care.
- All grants from orthopaedic companies must be directly for education or patient care.
- All gifts, consulting fees or other forms of monetary or in-kind gifts must be disclosed on the companies’ websites.
- Consultation fees must be consistent with a fair market value and proportional to the expertise of the consultant.

As disclosure by both the company and physician is now required on an annual basis, as well as when research is presented or published, undisclosed financial interests and relationships are now an issue. A study from the New England Journal of Medicine by Okike et al (2009) compared the lists of disclosed gifts from each of the five big orthopaedic medical device companies in 2007 with the disclosures reported by physicians at the American Academy of Orthopaedic Surgeons’ (AAOS) Annual meeting in 2008. Surgeons who received funding from a company and presented at that meeting accurately disclosed their conflicts of interest only 71.2% of the time, despite it being a regulation of the AAOS to disclose any relevant conflict. Payments were found to be most likely to be disclosed if they exceeded 10,000$, were directed to an individual physician rather than a company or organization, or included an in-kind component. Reasons cited for nondisclosure included that payment was unrelated to the topic of the presentation, misunderstanding of the disclosure requirements, or that the disclosure had been reported but was mistakenly omitted from the program.
Fraudulent billing is another potential source of corruption in orthopaedic health care. This is not a widespread problem in Canada but it does occur (Interview Anonymous Surgeon, 2011). Fraudulent billing is commonly referred to as the act of a surgeon reporting to the government and seeking compensation for a procedure or consultation they did not actually perform or performed unnecessarily (Interview Anonymous Surgeon, 2011). This has obvious ethical implications for the physician, but it could also have devastating effects for the patient if procedures are being performed when they are not indicated or when the patient has not consented to them. Furthermore, should a complication arise from the procedure which was never needed in the first place, the physician will have committed serious harm and will potentially face legal action.

Although there are presently no studies to confirm this, corruption in the orthopaedic industry and among orthopaedic care providers in the form of kickbacks, unlawful contracts or inappropriate billing of procedures, may inflate the prices of equipment. Higher costs of orthopaedic devices potentially preclude many patients and certain providers from being able to afford them, especially in low-income countries. Limited access to orthopaedic medical devices could lower the quality of orthopaedic care, and exacerbate growing global injury burden. This case study conducted in Uganda identifies areas in which orthopaedic services are susceptible to corruption and how this affects patient care. The study data also suggest mechanisms that can be applied as anti-corruption measures. These findings are described in the next section.

### 3.3 Corruption and orthopaedic health services in Uganda

To explore the phenomenon of access to orthopaedic medical devices (OMDs) in low-income countries, this descriptive qualitative case study was undertaken in Uganda in November and December 2010. Open-ended interviews were used to elicit the experiences of key informants in accessing orthopaedic medical devices. Thematic analysis was used to analyze the data. Resulting codes and themes were condensed to reveal two overarching categories, as seen in
“Barriers to access of orthopaedic services and OMDs”, and “Mechanisms for improving access to orthopaedic care”. Of the four major themes that were elicited as barriers, “Poor leadership and corruption” was the most unexpected but significant finding. The three other themes were high costs of orthopaedic medical devices and poverty, inadequate human resources, and inefficient and insufficient health care infrastructure. The second category on improving access to orthopaedic care included three themes: 1) Policies for prioritizing orthopaedic services; 2) training of more orthopaedic specialists; and 3) the adoption of strategies for raising funds for orthopaedics. This chapter focuses on the theme of corruption and explores the participant-elicited policy recommendations and funding strategies that could serve as anti-corruption mechanisms in the orthopaedic sector.

Figure 9. Overarching categories from interview data: Focus on corruption

3.3.1 Barriers to orthopaedic care and medical devices

The results of this study of the health services in Uganda expose significant systemic issues that prevent effective delivery of orthopaedic and trauma care. The elicited barriers to orthopaedic medical devices may similarly hinder access to other health care services and needs in Uganda.
One of the largest reported obstacles in providing appropriate care to injured patients in this study was perceived corruption. In the process of delivering orthopaedic care, and procuring and distributing orthopaedic medical devices, there are many instances in which corruption is and could be occurring. Participants in this study, although never specifically asked to comment on their perceptions of corruption, easily identified as barriers to access of health services and medical equipment many of the corrupt practices common to the health care sector. The corrupt activities they described were those that led to personal gain at the expense of others’ well being. Examples of corruption reported included theft of equipment, misuse of health care dollars, and reckless driving leading to injuries. Many participants related the difficulties in funding and running orthopaedic programs with corruption at worker, hospital and government levels. This section will focus on the participants’ reports of misappropriation of funds, theft of equipment, resale of drugs and medical devices, absenteeism and fraudulent payments and billings. Study participants also expressed the need for anti-corruption measures and improved transparency in government, and these will subsequently be explored.

3.3.1.1 Misappropriation of funds

Participants interviewed frequently reported theft and misuse of resources both financial and material. Government funds and grants from donor agencies were often described by participants as often being lost or misappropriated.

"Money in the government is not always accounted for and doesn’t always make it to the hospitals."

"The government wastes a lot of their money. There is corruption. The government has the money [for health care], but they waste it on other things."

"When people are given money to purchase certain things, they don’t."

Unaccounted for funds are assumed spent on perceived luxuries, such as vehicles for the hospital, for the personal use by management or for government officials.
“There is a lot of corruption and wasted money in the government. For example, here there is a 60,000 US dollar vehicle for hospital use. It sits in the front of the hospital. It was bought by the government. I see it used maybe only once or twice a day for short periods. The problems probably come from higher up. Maybe they revoke proposals they don’t want to give money to, and use the money on luxuries.”

“The problem is that the people in power and in government are educated and should know what is right and wrong. Why can people afford to buy ‘4x4s’ but not pay for their health care? In the end, I think that all East African countries can afford [orthopaedic] implants if they use their public money properly. There is so much wasted money.”

Participants also identified a lack of transparency and accountability in government, particularly with regards to health budgets, in that reports on public spending are difficult to come by and poorly reported. A dominant theme identified was the lack of publicly disclosed oversight of government procurement procedures. Donated funds are typically associated with a higher degree of oversight and accountability. One participant suggested that donated funds for health care might encourage more transparency.

“We don’t know how the [government] money is spent. There is also foreign aid. This would not be a permanent solution but it could be a more reliable source of funds.”

Reports of misuse and loss of government and donated health care dollars were elicited by participants in this case study. Gaps in accountability and transparency in health care spending may be leading to misappropriation of funds for personal use or inappropriate hospital expenditures. Policies for improved reporting of health care spending are needed.

3.3.1.2 Theft and resale of drugs and medical equipment

In Uganda’s universal health care system, the government attempts to supply all its hospitals with the necessary equipment and medicines. Hospitals can access what they need through the
National Medical Stores (NMS), a centralized depot of medical supplies run and paid for by the government (National Medical Stores, 2011). The National Medical Stores however, do not regularly carry orthopaedic equipment other than plaster, forcing orthopaedic departments to rely on donated supplies. Many other supplies and drugs are also frequently out of stock or cost more than hospitals or patients can afford.

“At the government level, there is corruption. Policies are changing, now we have to get supplies at one location, the NMS, but they are not up to capacity. They only supply sundries and drugs. There is no equipment; that would be stretching it.”

“[There is] corruption. The health care budget has a budget for sutures, but when we ask for them they never come.”

Depleted stocks and high costs of some medical equipment and drugs often force hospitals, physicians and patients to buy from private pharmacies or commercial distributors (Bouchard et al., Observational Field Notes, 2010). This can also incite theft of equipment and pharmaceuticals. Stolen orthopaedic implants, donated, government supplied or purchased, are often suspected of being taken from public hospitals and resold to patients in private hospitals (Bouchard et al., Observational Field Notes, 2010). The lack of inventory systems, clear policies on how and where equipment should be accessed, price lists of medical supplies, and oversight mechanisms make the health care system vulnerable to corrupt practices.

“There is a lack of interest in noting when stocks are depleted and when to replenish them. Inventory is very poor.”

“The fear is that the staff will steal the implants [from public hospitals and] charge the patients in private hospitals for them. Cost of the implant is not the problem, it is the stealing.”

“There is theft of equipment in government hospitals by people who want to set up their own practice. Some stolen instruments are consumables but some are permanent fixtures.”
Interviews with orthopaedic industry representatives and orthopaedic surgeons who work in other low-income countries reveal the problems of theft and resale also exist outside Uganda. These non-Ugandan participants relate the problems of theft to the lack of suppliers of medical equipment, making medical devices difficult to come by in legitimate ways. Attempts at providing generic or cheaper implants are also difficult as these lower-cost products often end up on the black market, further deterring companies from setting up or distributing in low-income countries.

“Once in the 1970’s, Synthes [one of the big five orthopaedic medical device manufacturers] set up a plant in India. Everything they made in India was sent directly to Switzerland, so it could not be sold directly to the market. The labor was really cheap but the quality was the same. But they closed the plant because the manager in India started selling directly to the market. They tried to convince them to set up a plant in Kenya so Africans can have better access to implants, but they say ‘we don’t want to start a plant here’. They fear their products will end up on the black market.”

“In the private system in Ethiopia, you are supposed to buy equipment from the government or private suppliers. But we do not get the right suppliers because no suppliers are here. So you often buy on the black market.”

Absent or under-developed orthopaedic medical device markets, limited supply of orthopaedic equipment in government centralized stores, poor inventory systems, and desires for personal financial gain are some of the reasons driving theft and resale of orthopaedic medical devices in Uganda and other African countries. Strategies for stimulating the medical device market in low-income countries, improved methods of recording inventory, and appropriate compensation for health care workers may discourage theft and misuse of orthopaedic medical devices.

3.3.1.3 Absenteeism

Uganda, like most low-income countries, has a serious lack of orthopaedic specialists, from surgeons to orthopaedic officers and nurses (Naddumba, 2008). There is an even greater absence
of orthopaedic surgeons in rural areas (Naddumba, 2008). Presently, the government provides little incentive for health care professionals, such as higher wages or subsidies for living expenses, to work rurally or in public system, and training of specialists is expensive. Participants also report that the government will not fund orthopaedic care or supply orthopaedic equipment to a hospital if there is no orthopaedic surgeon present. This exacerbates the problem of access to orthopaedic services in Uganda, as even the general practitioners will not have access to equipment for managing orthopaedic injuries.

The low wages, lack of benefits, and poorly supplied hospitals do not motivate workers to dedicate themselves to the public health care system. Therefore they often work in the both the public and private systems, or the private system alone. Forty-nine percent of all medical professionals interviewed in Uganda worked at least part-time in the private system. Many participants reported needing the income from the private system to support their families (Bouchard et al., Observational Field Notes, 2010).

The involvement of many health professionals in the private system negatively affects the efficiency and availability of health services in the public system. The first author participated in clinical care and in the orthopedic operating room several times per week while in Uganda. In the larger cities where there were more private institutions, the operating room rarely started before 11AM as the nurse, anesthetist or surgeon was coming from an earlier case or clinic at a private hospital (Bouchard et al., Observational Field Notes, 2010). Other times, delays were simply because of lack of motivation from the staff. They preferred taking rest or a meal to performing operations, and since they were salaried it did not matter to them financially how many cases per day they achieved (Bouchard et al., Field Notes, 2010). The growing list of patients waiting for surgery did not seem to inspire the staff to work harder or longer. These findings are consistent with other studies on absenteeism and health worker motivation (Kohler, 2010).

A non-clinical consequence of absenteeism affects the procurement system for medical devices. As all procurement in Uganda must go through hospital management and the government, the process can be lengthy (Bouchard et al., Observational Field Notes, 2010). Absenteeism of physicians and government officials on the procurement committees renders this process even
longer, and often leads to annulment of the original tender and inability to procure the needed equipment.

“The supply procurement process is incredible. To prevent corruption, there are two to three committees at the district and hospital levels you have to submit your request to. The process takes 6 to 8 months. It always has to go through the government. It can happen that the committees don’t meet because people are away. This can create yearlong delays. When you finally get the tender, sometimes the supplier in the end is not able to supply, then you have to start all over again.”

Until there are more health care workers staffed in rural areas, better wages and benefits for health professionals, and improved infrastructure and supply of orthopaedic equipment in clinics and hospitals, health care worker absenteeism will be continue. Strategies for discouraging absenteeism will be discussed in the next section.

3.3.1.4 Fraudulent payments and billings

Health care professionals and government officials in many low-income countries are paid meager wages and are rarely rewarded for exceptional performance (Martinez and Martineau, 1998). Under these conditions, many workers engage in other economic activities during working hours or pursue opportunities for financial gain through public service (Vian, 2002). Unfortunately, these undertakings are frequently fraudulent, whereby there is intention to deceive or manipulate another person into giving something of value (Duhaime, 2011). Common examples include the acceptance of informal payments and fraudulent billing of care rendered. One study participant described that in Ethiopia, even private hospitals practice corrupt behaviors in order to make private gains. In this case, it is by overcharging patients for medical equipment.

“The private hospital will charge a patient the same whether they use an Indian [generic] or European [brand name] implant. Unless a patient specifies which one they want, the hospital will use the cheapest device, charge for the most expensive, and take the extra money.”
In Uganda, as hospital stocks are often depleted, patients are frequently asked to buy drugs or equipment from private distributors. Patients worry however, whether they are getting the best price for the medical equipment and drugs they need.

“Sometimes we tell patients to just go buy, but they don’t always trust us. Maybe the hospital is selling their equipment back to the open market, and now the patients are just going to buy the same equipment back from the market at a higher cost.”

High-income countries are not devoid of fraudulent activities even if though prices of orthopaedic medical devices are more tightly regulated and publicly disclosed. As mentioned in the previous section of this chapter, until the recent investigation by the United States Department of Justice, there were accounts of surgeons being paid inappropriately high honoraria for using certain companies implants, attending educational activities, or performing research on their behalf (Healy and Peterson, 2009). There are also known cases of surgeons fraudulently billing government or third party insurance payers for procedures either not actually performed or performed unnecessarily (Interview Anonymous Surgeon, 2011). It can be conceived that similar fraud is being committed in low-and middle-income countries as well.

Developing codes of conduct for companies and health professionals, and oversight mechanisms for health care worker billings may dissuade fraudulent activities such as overcharging of patients for care rendered, inappropriate billing of services, and unlawful kickbacks.

3.3.1.5 Law enforcement

Corruption in law enforcement is directly related to corrupt behavior in the health sector. Most cases of orthopaedic trauma are due to road traffic crashes and lack of regulation on the road.

“A major cause of trauma is road traffic accidents. Boda-bodas [motorcycles] are the cause of most of the accidents and cause the most amount of disability. We need more enforcement.”
There is little consequence for reckless or unsafe driving because the police rarely halt or prevent it, or alternatively because there is a lack of policy or legislation against a particular act of dangerous driving.

“Law enforcement here is not good. No traffic rules are enforced. Careless driving is performed by everyone here, rich or poor.”

For example, boda-bodas are the widely used motorcycle taxis in Uganda. A law exists that mandates drivers to wear helmets. Few drivers wear helmets, and yet the police rarely discipline the drivers (Bouchard et al., Observational field notes, 2010). There was an attempt to implement a law forcing passengers to also wear helmets, but this displeased Ugandans and since a presidential election approached, the legislation was dropped.

“Politicians are not controlling traffic. Restricting traffic and boda-bodas would not sell at election time. There is political interference. When the discussion of mandating helmets on a boda-boda came up, the original plan was to make it obligatory for driver and all passengers. When the time came, there was a lot of resistance, and so the government decided, only the driver would have to wear one. It was optional for the passenger.”

Participants hypothesized that similar to health care workers, police are too few in number, are poorly paid and inadequately rewarded for good performance. They may be unmotivated to properly perform their jobs and more likely to accept bribes or other forms of personal gain.

“Boda-boda drivers evade traffic areas which are commonly policed. The traffic police are overwhelmed by the work. [The police] are inadequate in terms of numbers, especially compared to the number of boda-bodas and taxis. The government recently increased the number of officers but they are still at less than 50% of the required numbers. There are also too many people to try, collect, and enforce. You should stop at the police station if you can, and see the line-ups of boda-boda drivers in to pay fines.”
“We need increased police enforcement, but I don’t know how to increase their interest. Maybe the police aren’t supervised well, they don’t have enough money or high enough salaries, and they don’t have enough knowledge.”

Many participants considered corruption in law enforcement as a barrier to access of orthopaedic care as the unpunished reckless driving consistently causes the disabling and fatal injuries that overload the emergency rooms, wards and operating rooms.

3.3.2 Adapting Uganda’s health care system to respond to the injury burden by reducing corruption

There is no one-size-fits-all solution to eradicating corruption (Kohler, 2010). A society is less vulnerable to corruption when there is rule of law, transparency, trust, and strong accountability mechanisms (Robinson, 2006). Anti-corruption measures must be tailored to each community and country’s needs, political context, and health care system (Robinson, 2006). Preventative measures against corruption can include procurement guidelines, inspection for quality of medical technologies and drugs, codes of conduct for individuals, institutions and industries, and transparency and monitoring procedures (Robinson, 2006).

Klitgaard (2000) describes three phases in overcoming corruption. First, raising awareness and consciousness about corruption and its devastating impacts through education of the public, and of decision and policy makers (Klitgaard, 2000). Second, conducting analyses to identify the different points in a system that are most vulnerable to corruption (Klitgaard, 2000). Last, determining what prevention strategies would be most effective at preventing corruption (Klitgaard, 2000). To prevent corruption within health care that hinders access to orthopaedic care and medical devices, several anti-corruption mechanisms would need to be developed.

3.3.2.1 Reducing corrupt practices committed by health care workers
Corrupt behaviors such as absenteeism, theft, fraudulent billing and payment schemes, and acceptance of bribes and kickbacks have been shown to decrease when health care professionals are paid decent wages proportional to their education, skills and training (Robinson, 2006). Governments can also reduce the occurrence of corruption by continuously monitoring payment schemes of employees, and by adopting codes of conducts in the workplace (Robinson, 2006).

A study in Peru found that absenteeism was less likely if health care professionals earned wages that were relatively higher than other opportunities for income, and if they were on temporary as opposed to permanent contracts, as the former encouraged more stringent accountability with the employer (Kohler, 2010; Savedoff, 2007).

Vian (2002) recommends strategies for decreasing worker level corruption, increasing accountability and improving incentives for good behavior. These include paying workers higher wages, development of performance-based management systems and provider payment systems, increasing the role of community committees and public scrutiny, and performing analyses of and providing report cards for public services.

There is a great need for more human resources to manage the orthopaedic patient volume. (See Figure 2.) Increasing the number of health care professionals, establishing more training programs for all specialists who manage trauma, and improving health care infrastructure and working environments will enable health care workers to provide better patient care and dissuade them from engaging in corrupt behaviors.

"There are often no skilled personnel. There is not much motivation to work because the salary is so little."

“All the orthopaedic surgery in Uganda is concentrated at Mulago [the largest hospital in the country located in the capital city]. The doctors don’t want to go to the periphery and the government doesn’t insist they go."

Increasing the number of skilled workers, their salaries and providing them with ethical incentives for working in underserviced areas could hopefully prevent many of the corrupt
activities such as pocketing of user fees, absenteeism and theft, as workers would be more satisfied with their workload and wages.

3.3.2.2 Anti-corruption strategies in the pharmaceutical and medical device industries

Although the medical device industry is not yet as pervasive or extensive in low-income countries as the pharmaceutical industry, it is likely susceptible to corruption in many of the same ways. The corruption literature identifies several strategies for preventing corrupt behaviors in the pharmaceutical sector. These could conceivably be applied to the medical device industry as well.

With regards to selecting drugs or medical devices for a sale on a domestic market, it is recommended that there are clear criteria for selection and pricing that are based on global standards as set out by international bodies, such as the World Health Organization (Cohen, 2002). Professional and public scrutiny of the proceedings of medical device and drug selection committees should be enabled and encouraged (Vian, 2002).

Procurement procedures must be transparent, follow formal written procedures, and use explicit criteria to award contracts (Cohen, 2002). Information on the tender process and results should be made available to all participants and published in the media (Cohen, 2002). Codes of conduct between industry and clients should be imposed, and unethical or corrupt acts sanctioned (Kohler, 2010). Pharmacies and medical device suppliers should be licensed and inspected (Cohen, 2002).

Of particular concern in Uganda is that all medical devices and drugs for the public health system must be procured and distributed through the government’s National Medical Stores. This system is vulnerable to corruption at several points. The government is the sole regulator and authority of the National Medical Stores, and depending on how this authority is maintained, overseen and granted can create incentives for corruption or discourage them. Presence or lack of regulations regarding transparency and enforcement of these policies can also be potential sources of corruption. Vian (2002) recommends that such centralized medical
stores ensure clarification of chains of authority and increase accountability and ethical business incentives.

As occurred when low-cost pharmaceuticals were unavailable due to overly aggressive implementation and prolongation of international patent laws and trade rules, flexibilities in intellectual property policy could be invoked to gain wider access to expensive orthopaedic medical devices. Pharmaceutical companies have a tendency to extend patent coverage as long as possible in order to maintain monopoly and enjoy continued profits from their patented drugs (‘t Hoen, 2009; Elliot et al., 2003). It is likely that orthopaedic device manufacturers also battle loss of revenue due to expiring patents and so similarly promote stringent intellectual property rules. Furthermore, there is no true generic industry within orthopaedics, and so there is little competitive drive to lower prices. Although loopholes in trade and intellectual property policies, such as the flexibilities in the TRIPS Agreement, are not by definition anti-corruption measures, they could allow for the purchase and import of lower cost orthopaedic medical devices when their prices remain high due to unjustified use of patent laws to maintain large profit margins.

3.3.2.3 Strategies for improving transparency

The literature on corruption in health care and participants of the Ugandan case study both call for effective mechanisms for improving accountability and transparency in the health sector. The “2006 Global Corruption Report” by Transparency International (2006) suggested several strategies. Transparency could be improved with regular publishing of information on health budgets and performance at the national, local and health care delivery center levels; independent audits of health funds, coordination of international donor support to the health sector with regular evaluations of their programs in terms of health outcomes, and not level or speed of disbursement (Robinson, 2006). There could also be mechanisms for implementing public oversight of government policies, practices and expenditures (Robinson, 2006). Study participants called for policies that would deter corrupt behaviors.
“We need to lobby the government to change the attitude towards theft [in the health care setting]. And if we can exclude theft [in the hospitals], we can then tell the government with certainty we used all [the supplies] we have, that it wasn’t enough, and we need more for legitimate reasons and not because staff is stealing.”

“We need policies to decrease corruption on the roads. We need to stop the circulation of unsafe cars and unlicensed drivers. This leads to many accidents and injuries.”

“Since there are low-cost implants from India and China, but also intermediate and high-tech implants [that cost more], we need to tell patients frankly which one is which, and let them make the choice of what they want.”

Improved transparency and accountability, in the forms of audits, monitoring of payment schemes, and mechanisms for public scrutiny and disclosure of government and institutional spending, will discourage embezzlement, theft of medical equipment, and fraud and bribery among government officials, law enforcement officers and health care workers. These strategies can help ensure that health care dollars are appropriately spent and prioritized, and that quality medical equipment is made available to all services, and in particular orthopaedic departments.

3.3.2.4 Strategies for creating and implementing codes of conduct

Codes of conduct for health care workers, government officials and industry are required to define what is appropriate practice in the health care sector, and to provide grounds upon which corrupt behavior can be deterred or punished. Codes of conduct should be implemented and promoted through continued training and enforcement (Robinson, 2006). These codes should make explicit reference to preventing corrupt practices and conflicts of interest (Robinson, 2006). Codes of conduct will be meaningless however, if health care workers are not disincentivized from engaging in corruption firstly and most importantly by being paid a fair wage for their work. Without this, a purely punitive strategy will fail. That said industry and government would need to muster the courage to enact and implement these policies to encourage ethical behavior, and punish firms and individuals for corrupt actions (Cohen, 2001).
3.3.2.5 Whistleblower protection

Governments should introduce whistleblower protection for individuals in procurement bodies, health authorities, health service providers and suppliers of medicines and equipment (Robinson, 2006). Pharmaceutical and medical device companies should do the same. Corrupt practices by individuals, government or industry should be punished, and where relevant these actors should be excluded from participation in future tendering processes with the government (Robinson, 2006). Conversely, good behavior should be rewarded and publicized (Kohler, 2010).

3.3.2.6 Reducing incentives for corruption through alternative funding of the health care budget

With a limited health care budget, hospitals and the governments are more susceptible to corruption, as is suggested by the reported occurrences of embezzled donor funds, misappropriated monies, and bribes and payoffs. Since this corruption diverts funds from needing orthopaedic and surgical departments, the participants’ suggestions of innovative strategies for funding orthopaedic care may provide new opportunities for financing health care that promote better transparency and accountability. Others suggested the development of more stringent and regulated mechanisms for procuring medical devices at lower prices, since orthopaedic medical devices are a large portion of the cost of surgical care. Vian (2002) also supports the allowance of private contracts within health care to encourage competition, lower costs and improve accountability. Alternatively, for example, the Columbian government set up a social control fund, whereby citizens monitor the donor funding for key sectors including health. It is estimated that as much as $5.4 million has been saved through these efforts (Kohler, 2010).

Lack of supplies, low wages, understaffing and poor infrastructure can all incite health care workers to engage in fraudulent behaviors for personal financial gain. These shortcomings in the health care system can also encourage hospitals to overlook the needs of orthopaedic services as orthopaedic care is particularly expensive to provide. Case study participants listed a number of
ways in which orthopaedic departments could raise funds independently of government or international donors. These included levies or user fees on vehicles, fuel or roads, tax rebates on orthopaedic medical devices, tendering contracts independently, and using profits from private health care providers to fund the provision of public health services. The innovative funding strategies elicited in this study may not in themselves prevent corruption, but if coupled with improved accountability and transparency, significant progress can be made as more money could be available to orthopaedics and additional oversight could dissuade unethical conduct.
3.4 Chapter Summary: Corruption and the injury burden

One of the major barriers to access elicited by this case study of orthopaedic services in Uganda was corruption and poor leadership in government concerning public spending and health care priority setting. This was the most unexpected but significant finding of the study. Corruption in the health care sector has repeatedly been shown to hinder access to needed health services. This is no exception for orthopaedic care. This study shows that one of the largest barriers to access of much needed orthopaedic and trauma care in low-income countries is corruption. Corrupt activities can occur at the worker, hospital and government levels in the form of misappropriation of funds, theft of equipment, resale of drugs and medical devices, absenteeism and fraudulent billing and payment schemes. Orthopaedic care is also affected by corruption within law enforcement. As the global burden of injury continues to grow, the need to manage corruption and ensure access to orthopaedic services and medical devices increases. Anti-corruption strategies such as improving transparency and accountability measures in policy, procurement, and payment schemes, codes of conduct, whistleblower protection, and higher wages and benefits for workers could be first steps in improving access orthopaedic care and managing the global injury burden.
CHAPTER FOUR: Responding to the growing global injury burden by improving access to orthopaedic medical devices: A framework for addressing global health challenges

This thesis investigates the problem of limited access to orthopaedic medical devices in low-income countries and how this affects the global injury burden. As the number of people suffering from disabling and life-threatening injuries continues to rise globally, there is a need to ensure adequate access to orthopaedic care and equipment so that trauma patients may be offered a chance of recovery and return to normal function. Through an exploratory qualitative case study in Uganda, this research explores the socio-economic factors, inefficiencies in health care infrastructure, and policies that may impede effective access to orthopaedic medical devices. Orthopaedic surgeons, non-surgeon health care professionals providing orthopaedic care, government officials involved in orthopaedic health services, patients and orthopaedic industry representatives were interviewed about their experiences in accessing orthopaedic medical devices. Uganda was selected for the case study, as it is a country that is representative of many low-income countries. It has similar health care resources, burden of orthopaedic injury, and availability of orthopaedic services. Based on the data collected from the interviews, a summary of the barriers to the access of orthopaedic medical devices was compiled, and from this information, policy recommendations on how to improve orthopaedic services and alleviate the injury burden are proposed.

Understanding and overcoming the barriers to orthopaedic medical devices is a first step in alleviating the global burden of preventable injury. This case study provides a broad and complete understanding of the problem of access to orthopaedic medical devices in a low-income country. Barriers to access can be summarized as: 1) Corruption and poor leadership in government resulting in deficiencies in transparency and accountability of public spending, inadequate prioritization of health care needs, and lapses in law enforcement; 2) inadequate human resources; 3) insufficient and inefficient health care infrastructure; and 4) high costs of orthopaedic medical devices and poverty.
Given the wide range of barriers to access of orthopaedic care and medical devices illuminated in this qualitative study, the author chose to explore in detail two broad policy issues. One, corruption and its impact on the injury burden, was germane to the immediate study results. Corruption as a barrier was an unexpected but significant finding of this study, as corruption is known to be a pervasive impediment to provision of medical care globally. Corrupt activities are also common to the lucrative orthopaedic and pharmaceutical industries, in high- and low-income countries alike, and these unethical behaviours can impact access to orthopaedic medical devices and medicines. The other issue relates to international trade and intellectual property regulations, such as the TRIPS Agreement, and their potential impact on access to orthopaedic medical devices. Potential lessons learned from the experience of TRIPS and access to essential medicines as they might apply to access to orthopaedic medical devices were examined. These two broad policy issues emerging from the work and learning of the thesis research are areas requiring future enquiry.

This case study produced a range of strategies that could be employed for improving access to orthopaedic care and medical devices. They fall under three major themes: 1) Policies for prioritizing orthopaedics within health care; 2) training more orthopaedic specialists and providing them with incentives to work in underserviced areas; and 3) developing innovative strategies for funding orthopaedics that are less reliant on government funding. Specific mechanisms that could potentially improve access to care include: Aligning international and domestic policies to recognize and fund injury and orthopaedic care, improving and expanding training programs of orthopaedic specialists, providing health care workers with better wages, encouraging general practitioners to perform more orthopaedic care in the absence of specialist surgeons, creating incentives for health professionals to work in underserviced areas, implementing codes of conduct at government, hospital, industry and health care worker levels, encouraging ethical behaviours and punishing corrupt behaviours, designing guidelines for improving accountability and transparency in health care spending, and developing innovative strategies for funding orthopaedic services, including levies on fuel and vehicles and the use of flexibilities in international trade agreements to import brand name medical devices at lower costs.
Although this study is based on orthopaedic health services provided in Uganda, the results may conceivably be applied to other low-income countries and other health care challenges. Uganda is similar in demographic and epidemiologic profile to many other sub-Saharan African countries, and experiences many of the same economic constraints. This study included interviews with seven participants who work as orthopaedic surgeons or in the orthopaedic medical device industry in four other countries, Kenya, Rwanda, Malawi, and Ethiopia. Their perspectives were aligned with the responses from Ugandan participants. The interviews with non-Ugandan participants serve to contextualize the Ugandan experience of accessing orthopaedic medical devices in the broader African experience, and suggest that the study findings may be relevant and applicable in most low-income countries.

The resulting sets of barriers to access of orthopaedic medical devices and proposed solutions for improving orthopaedic care may also be applicable to problems other than limited orthopaedic health services and the injury burden. Most global health challenges, from vaccinating against tropical diseases to maternal mortality, are impeded by similar barriers and are potentially resolved by similar kinds of mechanisms as the problem of poor access to orthopaedic medical devices. Attempts at alleviating any disease burden in a low-income country is likely to be affected by corruption, trade rules such as the TRIPS Agreement, a lack of human resources and expertise, poor health care infrastructure, and limited funds for specialised medical technologies and equipment.

Solving a global health challenge in a low-resource setting is a complex process due to the variety of factors contributing to the problem and hindering its resolution. Based on this study of orthopaedic services in Uganda, a basic preliminary framework could be proposed for evaluating systemic public health problems in any health care sector. Figure 10 contains a list of questions for approaching a health care problem. Health practitioners and policy makers could use this framework to help define and frame their health care challenge, identify the barriers to health care delivery, and develop a multi-disciplinary strategy for resolving the problem and directing related research. Multiple frameworks and checklists already exist for addressing specific global health concerns, however the questions in Figure 10 are intended more simply to guide an initial assessment of a lesser-known or researched health care problem.
Figure 10. Framework for addressing health care challenges in low-resource settings

A. What is the health care challenge?

1. Why does the problem exist? What exacerbates it?
2. Who is involved?
   a) Who is the patient population?
   b) Which health sectors and health care professionals?
   c) Which non-health sectors and non-health care professionals?
3. What international frameworks (ie. MDGs) influence priority setting and cultural aspects?

B. What are the barriers to ideal health care delivery?

1. Is the health care delivery system vulnerable to corruption (ie. Embezzlement, theft of supplies, informal payments)?
   a) At the health care worker level?
   b) At the hospital level?
   c) At the government level?
   d) What systems or activities are susceptible to corruption?
   e) In what forms are corrupt activities taking place?

2. Are there adequate human resources?
   a) Are there enough people to respond to the health challenge?
   b) Are they adequately trained?
   c) Is there a need for specialists who are not available in the area or setting?
   d) Are there adequate incentives for workers to go to affected areas?

3. Is there efficient and sufficient health care infrastructure?
   a) Are there enough clinics, hospitals or points of health care delivery?
   b) Are these centers properly equipped with consumable equipment, such as medical devices and medications?
   c) Are they equipped with adequate permanent infrastructure, such as water and electricity?
   d) Are these supplies well adapted to the low-resource setting in which they will be used?
   e) Is there adequate access to the health care delivery points, such as emergency medical services or proper roads?

4. Are the costs hindering to needed equipment and supplies for providing appropriate health care?
   a) Are the supplies priced so providers and patients can afford them?
   b) What is the purchasing power of the patient population?
   c) What is the purchasing power of the health provider?

B. What can be done to improve the response to the identified health care challenge?

1. Is this global health challenge recognized by the domestic government and the international community?
   a) Is this challenge a priority within domestic or international health care policies?
   b) Is there adequate awareness and advocacy surrounding this issue?

2. What mechanisms can be employed to build the human resource capacity?
   a) Is there adequate and accessible training at an affordable cost?
   b) Do new programs need to be established or do current programs need to be expanded?
   c) What incentives can be provided to health professionals to work in underserviced areas?

3. What innovative funding strategies can be used to support the health care service needed for responding the identified health care challenge?
   a) Can support or collaboration be sought from the government, a non-governmental organization or a private company?
   b) Can profits from a private endeavour be used to support a public service?
   c) Can new payment or fee structures be developed?
   d) Can levies or taxes be collected from a related service and used to fund health care?
   e) Are there adequate policies regarding transparency and accountability of funds?
This research highlighted many areas relating to the difficulties in providing equitable access to health care and orthopaedic care in particular. As the study was part of a Masters’ Degree, detailed investigations into every identified barrier to care or potential mechanism for improving health services could not be accomplished. Further research and policy inquiry are needed into the effects of corruption and stringent intellectual property laws on trauma and orthopaedic care delivery, innovative funding strategies of health services, methods for building human resource capacity, and the development of more appropriate medical devices for low-resource settings. There must also be stronger advocacy for accessible orthopaedic and trauma care to respond the growing injury burden, both globally and domestically. With better access to orthopaedic care or medical devices, the burden of preventable injury could be significantly improved.

This thesis represents a first and preliminary investigation into the problem of the global injury burden and limited access to orthopaedic care and medical devices in low-income countries. This study enabled the identification of the common barriers to access of orthopaedic health services and equipment, and proposes directions for future research and strategies that could address this important global health challenge. These findings can be translated into policies and mechanisms for improving access to health services and medical equipment, combatting corruption in the health sector, and urging management of the growing injury burden.
References


*Draft Declaration on the TRIPS Agreement and Public Health*, [Doha Declaration], Ministerial Conference, Fourth Session, Doha, 9-14 14 November 2001, WT/MIN(01)/DEC/W/2,


1. Research Questions

Grand Tour Question:
What are the socio-economic, political and health infrastructure barriers to the access of low-cost orthopaedic medical devices in low-income countries?

Subquestions:
Are the barriers different in urban and rural settings, public or private hospitals, and university affiliated versus non-academic hospitals?
What orthopaedic procedures are performed in low-income countries?
Who pays for orthopaedic medical devices?
Who orders the devices?
How are orthopaedic devices generally obtained and from where?
What are the costs of medical devices?
Is there access to locally produced devices?
How important is the infrastructure of the health system, hospital, operating room/surgery department?
What can industry do to help resolve this problem without negative consequences to their sales/revenues?
What are the perceived solutions to the problem of access to orthopaedic medical devices?
What role does intellectual property policy play in the access to medical devices?
Can flexibilities in the TRIPS Agreement offer mechanisms to improve the access to orthopaedic medical devices?
Does corruption affect accessibility to orthopaedic care or orthopaedic medical devices?
2. Interview schedule for health care professionals:

1. Please tell me about your career in health care. What is your profession? Please characterize your practice.
   
   Probes:
   How long have you been in this career?
   Where have you practiced? If in more than one place, please compare and contrast the different experiences.
   Do you work in different sectors, such as private and public?

2. Describe your experience in accessing orthopaedic medical devices in your hospital?
   
   Medical device here will represent orthopaedic implants, external fixators, screws, k-wires and pins, and orthopaedic tools such as drills, saws and plaster of Paris.

   Probes:
   Where do the devices you use come from? Are they donations? Do patients buy them?
   What is the official procedure for accessing orthopaedic medical devices?
   Is the official procedure adequate? If not, what other methods do you use to get orthopaedic medical devices?
   How easy or difficult is it to get access to medical devices?
   What factors affect the availability of medical devices?

3. How important is the availability of orthopaedic medical devices in the provision of orthopaedic care in your country? And in your practice?

4. If access to orthopaedic medical devices is not adequate in your hospital, how can access to orthopaedic medical devices be improved?

   Probes:
   What are steps that could be taken to improve access under ideal circumstances?

2 This question aims to uncover whether orthopaedic surgeons in developing countries truly are in need of better access to orthopaedic medical devices. It is possible that surgeons have learned to cope without orthopaedic medical devices in their practice, or it may be that other issues to providing care that are more important and pressing than the access to medical devices. If after a few interviews the participants unanimously believe access to orthopaedic implants is essential, I can omit this question.
Under the present circumstances?

5. How could provision of orthopaedic care be improved if there was ideal access to low-cost orthopaedic medical devices?

6. What is your experience working with orthopaedic medical device sales representatives?
   Probes:
   Where do you interact with industry representatives? In the operating room, at meetings?
   Do they interact with your patients?

7. What would be the pros and cons of industry establishing manufacturing plants in low-income countries?³

8. Is there any other important information about your experience as an orthopaedic health care professional you would like to mention that was not addressed by my questions?

³ It is possible that some surgeons or health care providers may not have an opinion on this question. In this case, the question will be omitted.
3. Interview schedule for patients:

1. Please tell me about yourself.
   Probes:
   How old are you? Where do you live? Do you have a family? Where do you work?

2. Please describe your experience as orthopaedic patient beginning with the reason you presented to the doctor.
   Probes:
   How did you sustain the injury? What was the nature of your injury?
   How soon did you receive medical care?
   Did you ever see an orthopaedic surgeon or were you attended by other health professionals?
   What care did you receive? What this the recommended care by the doctors?
   Did you need to pay for the health services? If so, how much and for what procedures?
   Did you have to pay for any implants or external frames for the treatment of your injury?
   Did you have to choose the type of care you received based on cost and what you could afford?
   Who paid for your care?

3. How have you been coping since your injury?
   Probes:
   What kind of follow-up and rehabilitation services are offered to you once you are discharged from hospital?
   Have you been left with any physical disability?
   Can you work? If so, what is your occupation? Is it the same as before the injury?
   Are you suffering from financial constraints as a result of the cost of your medical care or your inability to work?

4. Based on your experience with this orthopaedic injury, how can orthopaedic health care be improved?

5. During your time in hospital, did you ever meet a sales representative from the companies making implants for orthopaedic injuries? If so, please describe this experience.
   Probes:
Where did this person approach you? What did they discuss with you?
Did you feel forced to buy a particular product?
Was the surgeon involved in this discussion?
Was payment or cost discussed?
6. Is there any other important information about your experience as an orthopaedic patient you would like to mention that was not addressed by my questions?
4. Interview schedule for orthopaedic industry representatives:

1. Please tell me about your career in the orthopaedic medical device industry.
   Probes:
   - How long have you been in this career?
   - What are your roles and responsibilities?
   - Do you interact directly with doctors or patients?

2. How are orthopaedic medical device sales conducted in your territory?
   *Medical device here will represent orthopaedic implants, external fixators, screws, k-wires and pins, and orthopaedic tools such as drills, saws and plaster of Paris.*
   Probes:
   - Have you had experience in orthopaedic sales in other parts of the world? If so, can you please compare and contrast the experiences?
   - What is the official procedure for accessing orthopaedic medical devices? Is it the same every territory?
   - What factors affect the availability of medical devices?

3. For a company such as yours, what would be the pros and cons of establishing manufacturing plants in low-income countries?

4. How important is the availability of orthopaedic medical devices in the provision of orthopaedic care in your territory?

5. Do you believe there is adequate access to orthopaedic medical devices in your territory?
   If not, what are steps that could be taken to improve access?
   Probes:
   - What can your industry do to improve access to orthopaedic medical devices?

6. Is there any other important information about your career in the orthopaedic device industry in a low-income country you would like to mention that was not addressed by my questions?
5. Interview schedule for industry representative in imports/exports:

1. Please describe your career and responsibilities.
   Probes:
   How long have you been in this career?
   What are your roles and responsibilities?
   How does your career relate to the orthopaedic medical device industry?
2. As most orthopaedic equipment and implants in Uganda are imported, what is the process for bringing these devices into the country?
   Probes:
   Is the process similar in other African countries?
3. Is importing orthopaedic medical devices easier, similar or more difficult than other health technologies, such as drugs or other types of medical devices?
4. Doctors have a difficult time accessing orthopaedic medical devices in their practices.
   What do you think are the barriers to access of orthopaedic medical devices?
5. What do you think could be done to improve access to orthopaedic medical devices?
6. What would be the pros and cons of industry establishing manufacturing plants in low-income countries?
7. Is there any other important information about your career and how it relates to the orthopaedic device industry in a low-income country that you would like to discuss but was not addressed by my questions?
6. Interview schedule for government officials

1. Please describe your career, your role in the government and your responsibilities.
   Probes:
   How are you involved in orthopaedic health services?
2. How are orthopaedic and trauma care funded in the public health system?
3. How is orthopaedic care prioritized among other health care goals for Uganda?
   Probes:
   Are trauma and road traffic accidents a concern for the Ministry of Health?
4. Government hospitals seem to be having difficulty keeping up with the orthopaedic disease volume. They are also lacking the tools and equipment for treating these patients. Is the government aware of this, and if so, what is it doing to help rectify these problems?
5. What barriers do you think prevent adequate access to orthopaedic equipment and implants?
6. What do you think could be done to improve access to orthopaedic care and orthopaedic medical devices?
7. Does the government provide orthopaedic medical devices through the National Medical Stores (NMS)?
   Probes:
   How are these orthopaedic products procured?
   What happens if a patient needs a medical device not provided by the NMS or the government hospital?
   What happens when a patient cannot afford the orthopaedic care they are recommended?
8. What would be the pros and cons of industry establishing manufacturing plants in low-income countries?
9. Is there any other important information about access to orthopaedic care and medical devices you would like to discuss but was not addressed by my questions?
7. Consent form for health care professionals

Exploring the access to orthopaedic medical devices in developing countries: A case study of orthopaedic services in Uganda

PARTICIPANT CONSENT FORM – MEDICAL PROFESSIONAL
Version Date: 30NOV2010

Student Investigator: Dr. Maryse Bouchard
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Supervising Investigators:
Dr. Andrew Howard
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Dr. Jillian Clare Kohler
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INTRODUCTION:
You are being asked to take part in a research study coordinated by the Departments of Orthopaedic Surgery and Social and Administrative Pharmacy at University of Toronto in Canada. Taking part in this study is voluntary. You may withdraw from the study at any time without any negative consequences. Your name and responses will be kept confidential at all times. Should you leave the study at any point, your information will be discarded. The study is described below. This description tells you about the risks that you might experience. You should discuss any questions you have about this study with the person who explains it to you.

DESCRIPTION AND PURPOSE:
You are asked to participate in this research study because you play a role in providing orthopaedic services in a developing country and have access. We are trying to find out what doctors, health care workers, orthopaedic industry representatives, and patients think the barriers are that prevent access to orthopaedic medical devices in developing countries, and what they think may be possible solutions to this problem. With this information, we hope to direct future research into solutions for the problem of limited access to orthopaedic medical devices in developing countries.

PROCEDURE:
You will be asked to participate in an interview. It will be led by one person (the student investigator). In this interview, you will be asked questions about what you think of how orthopaedic services are provided where you work, if you think access to orthopaedic medical devices is a problem and why, and what you might think are ways of improving access. The interview will last approximately 30 to 60 minutes and will be recorded with an audio-recorder or by note-taking, and then typed. Whenever possible, we will attempt to schedule the interview while you are at work in the hospital and have spare time. If a meeting in a hospital is not possible, you may be asked to participate in a phone interview. In that case, the conversation will be recorded over a speakerphone. Your name or other identifying information will not be included when the recording is typed.
Your participation in this study will begin on the day of the interview. You may discontinue your participation in the study at anytime, even in the middle of the interview. Sometimes we have more questions to ask after we review the interview. You may be asked to participate in a second interview or to confirm what we understood in your interview. You are not required to participate in a second interview or to review the content of your interview, and so may decline without any negative consequences. Again, all identifying information and views will be kept confidential.

**RISKS:**
There are no risks to participation in the interviews that are part of this study. Identifying information and any responses you give will be kept confidential at all times.

**BENEFITS:**
You may or may not personally benefit from being in this study. By serving as a research subject, you will help us learn more about the issue of limited access to orthopaedic medical devices in developing countries and help us come up potential solutions to this problem.

**VOLUNTARY participation:**
Your participation in this study is voluntary. You may choose not to be in this study at anytime. If you do not participate in this study, it will not affect your relationship with the University of Toronto.

**CONFIDENTIALITY:**
The information that we gather as a result of your participation in this study will be kept in a secure area. Only an assigned study ID number will identify your study records, and your identity will be kept confidential. You will not be identified in any reports or publications of this research.

Individuals that may use your interview responses include only the student researcher and her supervisors. These individuals may release this information to the members of the student’s Masters’ Degree supervisory committee, the Research Ethics Board at the University of Toronto or other affiliated Ugandan hospitals or universities, and other regulatory agencies. The information released to the above listed individuals will not contain your name, or any other personal information.

**COMPENSATION:**
There is no compensation for participation in this study.

**COSTS:**
There are no costs associated with your participation in the research study.

**WHO TO CONTACT:**
If you need or wish to contact the study investigator concerning any questions or problems, please email Dr. Maryse Bouchard at maryse.bouchard@utoronto.ca or Dr. Andrew Howard at andrew.howard@sickkids.ca. If you wish to contact someone not involved with the project about any ethical issues related to this study, please feel free to contact the University of Toronto Research Ethics Board (email: ethics.review@utotonto.ca, phone: (001) 416-946-3273) or the
Faculty of Medicine Research and Ethics Committee at Makerere University (email: research@chs.mak.ac.ug, phone: (256) 414-533541).

**PARTICIPANT CONSENT**

I acknowledge that this research study has been explained to me and that any questions that I have asked have been answered to my satisfaction. I have been informed of my right not to participate in this study and of my right to withdraw at anytime, without any negative consequences. The potential risks have been explained to me and I also understand the benefits of participating in the research study.

I know that I may ask now, or in the future, any questions that I have about the study or the research procedures. I have been assured that records relating to my participation will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission. I have been given sufficient time to read and understand the above information.

I hereby consent to participate in an interview for this study and to be audio-recorded (when applicable). If I have any questions regarding this study, I can contact Dr. Maryse Bouchard or Dr. Andrew Howard at the University of Toronto, or the Research Ethics Committees at the University of Toronto or Makerere University.

________________________________________  _______________________
Participant Signature                       Printed Name

________________________________________  _______________________
Investigator Signature                      Printed Name

________________________________________  _______________________
Date

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8. Consent form for patients

Exploring the access to orthopaedic medical devices in developing countries: 
A case study of orthopaedic services in Uganda

PARTICPANT CONSENT FORM – PATIENT
Version Date: 30NOV2010

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Supervising Investigators:
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Dr. Jillian Clare Kohler
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INTRODUCTION:
You are being asked to take part in a research study conducted by the University of Toronto in Canada. Participation in this study is voluntary. You may leave the study at any time without any negative consequences. Your name and responses will be kept confidential at all times. Should you leave the study at any point, your information will be deleted. The study is described below. This description tells you about the possible risks. You should discuss any questions you have about this study with the person who explains it to you.

DESCRIPTION AND PURPOSE:
You are asked to participate in this research study because you have had orthopaedic surgery in Uganda. We are trying to find out what doctors, orthopaedic industry, and patients think the barriers are that prevent access to low-cost orthopaedic medical devices in developing countries, and what they think may be possible solutions to this problem.

With this information, we hope to direct future research into solutions for the problem of poor access to low-cost orthopaedic medical devices in developing countries.

PROCEDURE:
You will be asked to participate in an interview. It will be led by one person (the student researcher). In this interview, you will be asked questions about your injury, your experience in the hospital and your treatment, and if cost affected the treatment you received. The interview will last approximately 15 to 45 minutes and will be recorded with hand-written notes. We will schedule the interview while you are at the hospital and have spare time. If a meeting in a hospital is not possible, you may be asked to participate in a phone interview. In that case, the conversation will be recorded over a speakerphone.

The hand-written notes recording the interview will be typed. Your name or other identifying information will not be included when the recording is typed.

Your participation in this study begins on the day of the interview. You may end your participation in the study at anytime, even in the middle of the interview. Sometimes we have more questions to ask after we review the interview. You may be asked to do a second interview.
or to confirm what we understood in your interview is correct. You are not required to participate in a second interview or to review the content of your interview, and may decline without any negative consequences. Again, all identifying information and views will be kept confidential.

Approximately 15 to 20 doctors, industry representatives, and patients working or living in Uganda will take part in this study by the University of Toronto.

**RISKS:**
There are no risks to participation in the interviews that are part of this study. Identifying information and any responses you give will be kept confidential at all times. This study will not affect your orthopaedic care in any way.

**BENEFITS:**
You may or may not personally benefit from being in this study. By serving as a research subject, you will help us learn more about the poor access to orthopaedic medical devices in developing countries and help us come up potential solutions to this problem.

**VOLUNTARY PARTICIPATION:**
Your participation in this study is voluntary. You may choose not to be in this study at any time. If you do not participate in this study, it will not affect your relationship with the University of Toronto.

**CONFIDENTIALITY:**
The information that we gather as a result of your participation in this study will be kept in a secure area. Only an ID number will identify you, and your identity will be kept confidential. You will not be identified in any reports or publications of this research.

Individuals that may use your interview responses include only the student researcher and her supervisors, and the Research Ethics Boards at the University of Toronto and Makerere University. The information released to these people will not contain your name, or any other personal information.

**COMPENSATION:**
There is no compensation for participation in this study.

**COSTS:**
There are no costs associated with your participation in the research study.

**WHO TO CONTACT:**
If you want to contact the researchers for any questions or problems, please email Dr. Maryse Bouchard at maryse.bouchard@utoronto.ca or Dr. Andrew Howard at andrew.howard@sickkids.ca.

If you want to contact someone not involved with the project about any ethical issues related to this study, or your rights as a research participant, please feel free to contact the University of Toronto Research Ethics Board (email: ethics.review@utoronto.ca, phone: (001) 416-946-3273)
or the Faculty of Medicine Research and Ethics Committee at Makerere University (email: research@chs.mak.ac.ug, phone: (256) 414-533541).

**PARTICIPANT CONSENT**

I acknowledge that this research study has been explained to me and that any questions I have asked have been answered to my satisfaction. I have been informed of my right not to participate in this study and of my right to leave at anytime, without any negative consequences. The possible risks of participating in this study have been explained to me.

I know that I may ask now, or at any time, any questions that I have about the study. I know that records relating to my participation will be kept confidential. No information will be released or printed that would disclose my personal identity without my permission. I have been given enough time to read and understand the above information.

I hereby consent to participate in an interview for this study and to be audio-recorded, and I have been given a copy of this consent form. If I have any questions regarding this study, I can contact Dr. Maryse Bouchard or Dr. Andrew Howard at the University of Toronto, or the Research Ethics Committees at the University of Toronto or Makerere University.

____________________________  _______________________
Participant Signature              Printed Name

____________________________
Date

____________________________
Investigator Signature            Printed Name

____________________________
Date

Dr. Maryse Bouchard
Email: maryse.bouchard@utoronto.ca
Uganda Phone: 0791398396
Dr. Andrew Howard
Email: andrew.howard@sickkids.ca
University of Toronto Research Ethics Board
Email: ethics.review@utotonto.ca, Phone: (001) 416-946-3273
Faculty of Medicine Research and Ethics Committee at Makerere University
Email: research@chs.mak.ac.ug, Phone: (256) 414-533541)
9. Consent form for industry representatives

Exploring the access to orthopaedic medical devices in developing countries: A case study of orthopaedic services in Uganda

PARTICIPANT CONSENT FORM – INDUSTRY
Version Date: 30NOV2010

Student Investigator:          Supervising Investigators:
Dr. Maryse Bouchard          Dr. Andrew Howard
maryse.bouchard@utoronto.ca          andrew.howard@sickkids.ca
Dr. Jillian Clare Kohler
jillian.kohler@utoronto.ca

INTRODUCTION:
You are being asked to take part in a research study conducted by the University of Toronto in Canada. Participation in this study is voluntary. You may leave the study at any time without any negative consequences. Your name and responses will be kept confidential at all times. Should you leave the study at any point, your information will be deleted. The study is described below. This description tells you about the possible risks. You should discuss any questions you have about this study with the person who explains it to you.

DESCRIPTION AND PURPOSE:
You are asked to participate in this research study because you work in the orthopaedic surgery in Uganda. We are trying to find out what doctors, orthopaedic industry, and patients think the barriers are that prevent access to low-cost orthopaedic medical devices in developing countries, and what they think may be possible solutions to this problem.

With this information, we hope to direct future research into solutions for the problem of poor access to low-cost orthopaedic medical devices in developing countries.

PROCEDURE:
You will be asked to participate in an interview. It will be led by one person (the student researcher). In this interview, you will be asked questions about your injury, your experience in the hospital and your treatment, and if cost affected the treatment you received. The interview will last approximately 15 to 45 minutes and will be recorded with hand-written notes. We will schedule the interview while you are at the hospital and have spare time. If a meeting in a hospital is not possible, you may be asked to participate in a phone interview. In that case, the conversation will be recorded over a speakerphone.

The hand-written notes recording the interview will be typed. Your name or other identifying information will not be included when the recording is typed.
Your participation in this study begins on the day of the interview. You may end your participation in the study at anytime, even in the middle of the interview. Sometimes we have more questions to ask after we review the interview. You may be asked to do a second interview or to confirm what we understood in your interview is correct. You are not required to participate in a second interview or to review the content of your interview, and may decline without any negative consequences. Again, all identifying information and views will be kept confidential.

Approximately 15 to 20 doctors, industry representatives, and patients working or living in Uganda will take part in this study by the University of Toronto.

**RISKS:**
There are no risks to participation in the interviews that are part of this study. Identifying information and any responses you give will be kept confidential at all times. This study will not affect your orthopaedic care in any way.

**BENEFITS:**
You may or may not personally benefit from being in this study. By serving as a research subject, you will help us learn more about the poor access to orthopaedic medical devices in developing countries and help us come up potential solutions to this problem.

**VOLUNTARY PARTICIPATION:**
Your participation in this study is voluntary. You may choose not to be in this study at anytime. If you do not participate in this study, it will not affect your relationship with the University of Toronto.

**CONFIDENTIALITY:**
The information that we gather as a result of your participation in this study will be kept in a secure area. Only an ID number will identify you, and your identity will be kept confidential. You will not be identified in any reports or publications of this research.

Individuals that may use your interview responses include only the student researcher and her supervisors, and the Research Ethics Boards at the University of Toronto and Makerere University. The information released to these people will not contain your name, or any other personal information.

**COMPENSATION:**
There is no compensation for participation in this study.

**COSTS:**
There are no costs associated with your participation in the research study.

**WHO TO CONTACT:**
If you want to contact the researchers for any questions or problems, please email Dr. Maryse Bouchard at maryse.bouchard@utoronto.ca or Dr. Andrew Howard at andrew.howard@sickkids.ca.
If you want to contact someone not involved with the project about any ethical issues related to this study, or your rights as a research participant, please feel free to contact the University of Toronto Research Ethics Board (email: ethics.review@utoronto.ca, phone: (001) 416-946-3273) or the Faculty of Medicine Research and Ethics Committee at Makerere University (email: research@chs.mak.ac.ug, phone: (256) 414-533541).

**PARTICIPANT CONSENT**

I acknowledge that this research study has been explained to me and that any questions I have asked have been answered to my satisfaction. I have been informed of my right not to participate in this study and of my right to leave at anytime, without any negative consequences. The possible risks of participating in this study have been explained to me.

I know that I may ask now, or at any time, any questions that I have about the study. I know that records relating to my participation will be kept confidential. No information will be released or printed that would disclose my personal identity without my permission. I have been given enough time to read and understand the above information.

I hereby consent to participate in an interview for this study and to be audio-recorded, and I have been given a copy of this consent form. If I have any questions regarding this study, I can contact Dr. Maryse Bouchard or Dr. Andrew Howard at the University of Toronto, or the Research Ethics Committees at the University of Toronto or Makerere University.

____________________________  _____________________
Participant Signature        Printed Name

____________________________
Date

____________________________  _____________________
Investigator Signature        Printed Name

____________________________
Date

Dr. Maryse Bouchard
Email: maryse.bouchard@utoronto.ca
Uganda Phone: 0791398396

Dr. Andrew Howard
Email: andrew.howard@sickkids.ca

University of Toronto Research Ethics Board
Email: ethics.review@utoronto.ca, Phone: (001) 416-946-3273)

Faculty of Medicine Research and Ethics Committee at Makerere University
Email: research@chs.mak.ac.ug, Phone: (256) 414-533541)
10. Consent form for government officials

Exploring the access to orthopaedic medical devices in developing countries: A case study of orthopaedic services in Uganda

PARTICIPANT CONSENT FORM – GOVERNMENT OFFICIAL
Version Date: 30NOV2010

Student Investigator:  Supervising Investigators:
Dr. Maryse Bouchard  Dr. Andrew Howard
maryse.bouchard@utoronto.ca  andrew.howard@sickkids.ca
Dr. Jillian Clare Kohler  jillian.kohler@utoronto.ca

INTRODUCTION:
You are being asked to take part in a research study coordinated by the Departments of Orthopaedic Surgery and Social and Administrative Pharmacy at University of Toronto in Canada. Taking part in this study is voluntary. You may withdraw from the study at any time without any negative consequences. Your name and responses will be kept confidential at all times. Should you leave the study at any point, your information will be discarded. The study is described below. This description tells you about the risks that you might experience. You should discuss any questions you have about this study with the person who explains it to you.

DESCRIPTION AND PURPOSE:
You are asked to participate in this research study because you play a role in health policy in your country, or in the administration of health services. We are trying to find out what doctors, health care workers, policy makers, orthopaedic industry representatives, and patients think the barriers are that prevent access to orthopaedic medical devices in developing countries, and what they think may be possible solutions to this problem. With this information, we hope to direct future research into solutions for the problem of limited access to orthopaedic medical devices in developing countries.

PROCEDURE:
You will be asked to participate in an interview. It will be led by one person (the student investigator). In this interview, you will be asked questions about what you think of how orthopaedic services are provided in your country, if you think access to orthopaedic medical devices is a problem and why, and what you might think are ways of improving access. The interview will last approximately 15 to 45 minutes and will be recorded with an audio-recorder or by note-taking, and then typed. Whenever possible, we will attempt to schedule the interview while you are at work and have spare time. If a meeting in person is not possible, you may be asked to participate in a phone interview. In that case, the conversation will be recorded over a speakerphone. Your name or other identifying information will not be included when the recording is typed.
Your participation in this study will begin on the day of the interview. You may discontinue your participation in the study at anytime, even in the middle of the interview. Sometimes we have more questions to ask after we review the interview. You may be asked to participate in a second interview or to confirm what we understood in your interview. You are not required to participate in a second interview or to review the content of your interview, and so may decline without any negative consequences. Again, all identifying information and views will be kept confidential.

RISKS:
There are no risks to participation in the interviews that are part of this study. Identifying information and any responses you give will be kept confidential at all times.

BENEFITS:
You may or may not personally benefit from being in this study. By serving as a research subject, you will help us learn more about the issue of limited access to orthopaedic medical devices in developing countries and help us come up potential solutions to this problem.

VOLUNTARY PARTICIPATION:
Your participation in this study is voluntary. You may choose not to be in this study at anytime. If you do not participate in this study, it will not affect your relationship with the University of Toronto.

CONFIDENTIALITY:
The information that we gather as a result of your participation in this study will be kept in a secure area. Only an assigned study ID number will identify your study records, and your identity will be kept confidential. You will not be identified in any reports or publications of this research.

Individuals that may use your interview responses include only the student researcher and her supervisors. These individuals may release this information to the members of the student’s Masters’ Degree supervisory committee, the Research Ethics Board at the University of Toronto or other affiliated Ugandan hospitals or universities, and other regulatory agencies. The information released to the above listed individuals will not contain your name, or any other personal information.

COMPENSATION:
There is no compensation for participation in this study.

COSTS:
There are no costs associated with your participation in the research study.

WHO TO CONTACT:
If you need or wish to contact the study investigator concerning any questions or problems, please email Dr. Maryse Bouchard at maryse.bouchard@utoronto.ca or Dr. Andrew Howard at andrew.howard@sickkids.ca. If you wish to contact someone not involved with the project about any ethical issues related to this study, please feel free to contact the University of Toronto Research Ethics Board (email: ethics.review@utoronto.ca, phone: (001) 416-946-3273) or the
Faculty of Medicine Research and Ethics Committee at Makerere University (email: research@chs.mak.ac.ug, phone: (256) 414-533541).

PARTICIPANT CONSENT

I acknowledge that this research study has been explained to me and that any questions that I have asked have been answered to my satisfaction. I have been informed of my right not to participate in this study and of my right to withdraw at anytime, without any negative consequences. The potential risks have been explained to me and I also understand the benefits of participating in the research study.

I know that I may ask now, or in the future, any questions that I have about the study or the research procedures. I have been assured that records relating to my participation will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission. I have been given sufficient time to read and understand the above information.

I hereby consent to participate in an interview for this study and to be audio-recorded (when applicable). If I have any questions regarding this study, I can contact Dr. Maryse Bouchard or Dr. Andrew Howard at the University of Toronto, or the Research Ethics Committees at the University of Toronto or Makerere University.

____________________________  _______________________
Participant Signature        Printed Name

____________________________
Date

____________________________  _______________________
Investigator Signature        Printed Name

____________________________
Date

Dr. Maryse Bouchard
Email: maryse.bouchard@utoronto.ca
Uganda Phone: 0791398396
Dr. Andrew Howard
Email: andrew.howard@sickkids.ca
University of Toronto Research Ethics Board
Email: ethics.review@utoronto.ca, Phone: (001) 416-946-3273)
Faculty of Medicine Research and Ethics Committee at Makerere University
Email: research@chs.mak.ac.ug, Phone: (256) 414-533541)
11. Letter of invitation to participate in study from Dr. Beyeza

Makerere University Medical School
Department of Orthopaedics
PO Box 7051
Kampala, Uganda

September 23, 2010

CONSENT FORM

RE: Case study on access to orthopaedic fixation devices in low-income countries

Dear study participant,

You have been requested to participate in an interview for a study, which aims to learn the causes and effects of limited access to orthopaedic medical devices on orthopaedic care in Uganda. Dr. Maryse Bouchard, Dr. Andrew Howard, and Dr. Jillian Kohler from the University of Toronto in Canada are conducting this study in collaboration with Department of Orthopaedics, College of Health Sciences, and Makerere University.

You were personally invited to an interview because the research team believes your experience with orthopaedic health care in Uganda will provide important insight into the neglected problem of poor access to orthopaedic fixation devices. There is very little research available concerning this grave problem in orthopaedic care. I therefore request you to consent to this interview in order to help these researchers collect as much information as possible. Although you will need to give up to one hour of your time, there are no risks involved in your participation and your identity and responses will be kept confidential at all times.

Your participation in this study is important and will help develop future recommendations on possible solutions for remedying the lack of adequate access to orthopaedic fixation devices in Uganda and other low-income countries.

Warm regards,

Dr. Tito Beyeza
Head of Department of Orthopaedics
Makerere University
Mulago Hospital Complex.
On behalf of the Research Team
12. Letter of invitation for Maryse Bouchard from Dr. Beyeza

Makerere University Medical School
Department of Orthopaedics
PO Box 7051
Kampala, Uganda

September 23, 2010

RE: Dr. Maryse Bouchard - Invitation to conduct Master’s thesis research in Uganda

To whom it may concern,

In May 2010, Dr. Maryse Bouchard approached our department for support of her Master’s thesis research on the access of orthopaedic fixation devices in low-income countries. Her project is a case study which consists of interviewing surgeons, clinical officers, patients and industry representatives in Uganda to gain an understanding of the causes and effects of limited access to orthopaedic medical devices.

This study will explore an issue, which is very relevant to orthopaedic care in Uganda, considering the big problem we face from rise in road traffic accidents. We would be happy to receive Dr. Bouchard at our university so that she may conduct her interviews. We can also introduce her to orthopaedic care providers in other parts of the country and orthopaedic patients. Should she have the time, she would also be invited to attend in the operating theatre at Mulago Hospital for a more personal and contextual exposure to orthopaedics in Uganda. She will be under the supervision of one of our senior orthopaedic surgeons at all times.

We are look forward to receiving Dr. Bouchard at our university this fall and await the results of her work. Should you have any questions, please email me at beyeza1959@yahoo.com.

Sincerely,

Dr. Titus Beyeza
Head of Department of Orthopaedics
Makerere University
Mulago Hospital Complex.
13. University of Toronto Research Ethics Board approval letter

RESEARCH AND ETHICS COMMITTEE REVIEW AND ENDORSEMENT REQUIRED

Statement from the Institutional Ethical Review Board:
The REC will only accept for review and approval research proposals that have been found both scientifically and ethically acceptable in accordance with the Guidelines on Institutional Ethical Review Boards.

We, the Institutional Ethical Review Committee established by University of Toronto,

(Name of Institution conducting the research in which the research is to be conducted)

do certify that we have reviewed the research proposal titled

Examining the access of low-cost orthopaedic medical devices in low-income countries. A case study of orthopaedic services in Uganda

submitted by

Dr. J. William Kubler and Dr. Margo Bouchard

We attest to the scientific and ethical merit of this study and the competency of the investigator(s) to conduct the project and do hereby recommend the proposal to the UNCST for approval.

SIGNATURES

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<tr>
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<tbody>
<tr>
<td>Ethics Committee representative</td>
<td>13.04.2000</td>
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<tr>
<td>Name (Please Print)</td>
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<tr>
<td>Signature: Head of Ethics Committee</td>
<td>14.04.2000</td>
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<tr>
<td>(or other authorized signatory)</td>
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</table>

Contact Tel. Number: 416-978-5696
E-mail address: "jewen@utoronto.ca"

OFFICIAL STAMP OF INSTITUTION

*Institution includes Universities, Hospitals, Research Institutes or Companies.*