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Surgical Quality in Haiti: The Development of a Quality Assessment
for the Emory University School of Medicine and Project Medishare Surgery Trip

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Abstract

Surgical Quality in Haiti: The Development of a Quality Assessment
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By Megan Elizabeth Quinn

Background: Surgical pathology comprises a large portion of the global burden of disease - disproportionately affecting low- and middle-income countries (LMICs). As LMICs currently lack the healthcare infrastructure, healthcare personnel, and training to handle this caseload, an unknown amount of surgery is performed by international organizations. Despite this, there is a paucity of data regarding the quality of care provided by these groups. The Emory University School of Medicine and Project Medishare (EUSOM-PM) surgery trip attempts to increase access to surgical services in the Central Plateau of Haiti, but has yet to establish a system to assess the quality of care provided to patients.

Objective: The goal of this thesis is to define indicators of surgical quality applicable to a low-resource setting and to establish reliable data collection techniques for the EUSOM-PM surgery trip.

Methods: Indicators of surgical quality validated in the United States that were transferable to a low-resource setting were included in a data collection instrument. The instrument was used to gather information regarding structural, process, and outcome elements of patient care

Results: Quantitative data collected using the data instrument had high response rates and provided complete information regarding patient demographics, processes of care, and outcomes.

Conclusions: A standardized data collection instrument results in more complete data regarding the patient population and the quality of care provided. However, the small quantity of data, particularly the low rates of adverse postoperative outcomes, limits any conclusions regarding the validity of indicators. Continued use of the data instrument will allow for the generation of a multi-year aggregated data set, providing information about shifts in patient demographics, reflect alterations in care processes, and potentially, the impact of these factors on patient outcomes.

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Table of Contents

List of Tables

Chapter 1: Introduction

1.1 Introduction

Surgical conditions, by conservative estimates, comprise 11% of the global burden of disease (Ozgediz, Jamison, Cherian, and McQueen, 2008). No consistent definition of what constitutes a surgical condition exists; but, the 2nd Edition of Disease Control Priorities in Developing Countries (DCP2) describes a surgical condition as "any condition in which the most potentially effective treatment is an intervention that requires suture, incision, excision, manipulation, or other invasive procedure that usually, but not always requires local, regional, or general anesthesia." (Jamison, et al., 2006) In practice, surgical conditions are largely injuries, malignancies, obstetric complications, congenital anomalies, cataracts, and glaucoma (Bellagio Work Group, 2007). Together, these conditions account for 15% of the disability-adjusted life years (DALYs) lost worldwide (Farmer and Kim, 2008). In absolute terms, each year 1.3 million people die due to road traffic accidents and more than 287,000 women die due to pregnancy-related complications (WHO, 2012). Despite the high prevalence of surgical conditions, access to surgical services in low- and middle-income (LMIC) countries is close to non-existent. As a point of contrast, in countries with high healthcare expenditures 11,110 major surgeries are performed per 100,000 people; in countries with low healthcare expenditures the rate is 295 per 100,000 people (Weiser, et al., 2008).

As LMICs currently the lack the health system infrastructure, medical personnel, and training to handle this caseload, an unknown amount of surgery is performed by international organizations (Ivers, et al., 2008). No homogeneity amongst organizations delivering surgical care exists – some deliver care via temporary platforms, while others utilize more permanent avenues. Despite

the large volume of surgery performed by international organizations, there is a paucity of outcomes data reported in the peer-reviewed literature.

1.2 Problem Statement

In low resource settings, a substantial burden of surgical disease remains unaddressed. To rectify this, the provision of surgical care has been classified as a primary care initiative by the World Health Organization (Bickler and Spiegel, 2010) and established as a cost-effective (Jamison, et al., 2006) priority for global funding. In response, many different platforms have been developed to provide surgical care in low- resource settings – among these, short-term surgical trips are becoming increasingly prevalent. However, little evidence exists regarding these interventions' impact on the volume of surgical disease they purport to reduce and the quality of care provided. The Emory University School of Medicine – Project Medishare (EUSOM-PM) Surgery Trip, a 3-week short-term surgical trip to rural Haiti, has been in place for 8 years. Despite a longitudinal commitment to provide care to the population of the Central Plateau of Haiti, the EUSOM-PM trip has not yet developed a formal plan to demonstrate that its actions lessen the burden of surgical disease, nor have they assessed the quality of the surgical care that is provided.

1.3 Purpose

The objectives of this project are to:

1. to define and field-test indicators of surgical quality applicable to low-resource settings, and
2. to establish reliable data collection techniques at HST that will generate complete and timely data regarding surgical outcomes in a low-resource setting.

1.4 Significance

Addressing the disparities in surgical care that exists between high-income and LMICs is a critical step in improving the health of significant portions of the world's population. Currently, no one intervention has been shown to be a cost-effective way to provide quality surgical care in low-resource settings. As the field of global surgery rapidly expands, more and more organizations will establish interventions in LMICs and it is important to define measures to ensure that the interventions that are instituted both provide quality care to the patients and that they are cost-effective and sustainable. The development of a quality assessment program for the EUSOM-PM surgical trip is a first step in developing such a system of oversight for short-term surgical trips. If the indicators used to measure the quality of surgical outcomes are deemed valid in a low-resource setting, they may be applied to other surgical delivery platforms, thus establishing a standard method of assessing global surgical quality.

Chapter 2: Literature Review

Surgically treatable conditions cause a significant burden of disease worldwide, yet access to safe and effective surgical services is limited, particularly in low- and middle-income countries (LMICs). The challenge of addressing the burden of surgical disease, particularly in rural and low-income settings revolves around three central issues: inadequate basic infrastructure, a shortage of adequately trained providers, and the lack of a consistent funding source (Ivers, et al. 2008). Recently, the World Health Organization has identified surgery as an essential component of comprehensive primary healthcare systems and integral to achieving the Millennium Development Goals (MDGs) (Kushner, et al. 2010). As the overlap between surgery and public health grows and the ways in which surgical interventions are public health becomes more prominent, it is likely that there will be a proliferation of surgical interventions in LMICs. Though all of these interventions are designed to address the global burden of surgical disease, the manner in which they attempt to do so are vastly different. Ranging from specialty care hospitals to more temporary platforms of delivery, each intervention has benefits and challenges. Underpinning the implementation of these interventions must be the development of a method to determine which interventions provide quality care to patients while remaining sustainable and cost-effective. Just as surgical procedures performed in the United States are increasingly evaluated by metrics of quality and cost-effectiveness, procedures performed in global, low-resource settings must be too. This project is an attempt to apply the tenets of healthcare quality assessments to a low-resource setting to better understand the actual impact of the EUSOM-PM surgical trip and ultimately, the practicality of measuring outcomes in a low-resource setting.

2.1. The Scope of the Problem

In evaluating the quality and effectiveness of global surgery interventions, it is necessary to first discuss the scope of the health problem and the lack of access to care that exists.

Surgery has long been absent from the public health discourse, having once been referred to as "the neglected stepchild of global health." (Farmer and Kim, 2008). Only in recent years has surgery been considered a component of global health. As the concept gains ground, it is necessary to define the scope of the problem to set objective, priorities, and strategies for both interventions and resources (Dare, et al., 2014). Further, as more countries undergo an epidemiologic shift toward higher prevalence of non-communicable diseases, the role of surgery in the health of populations will continue to increase.

Historically, the Global Burden of Disease Project did not include surgical conditions within its scope or reporting and few reliable statistics regarding the burden of surgical disease exist (Ozgediz, et al., 2008). However, by conservative estimates, 11% of the world's DALYs or 27 DALYs per 1,000 population are from conditions that require surgical intervention (Debas, et al. 2006). Of these, injuries account for 38% of estimated surgical DALYs, malignancies for 19%, congenital anomalies for 9%, and obstetric complications for 6% (Debas, et al., 2006). Despite the frequency with which these figures are cited, accurately estimating the true burden of disease is difficult for a variety of reasons.

There is no consistent definition of surgical conditions. The Global Burden of Disease Project was initiated in 2001 to "provide a unique framework to systematically assess national trends in age-specific and sex-specific all-cause mortality" (GBD, 2014) and is considered the major point of reference for data concerning the burden of disease affecting the world's population; but, it

does not accurately reflect the true burden of disease that could be alleviated by surgical expertise (Bickler, et al., 2010). Unlike other diseases, surgical conditions do not constitute a single entity with a well-defined diagnostic toolkit. Instead, surgical conditions are a heterogeneous collection of conditions for which surgery is one of any number of interventions. Estimates of burden differ if a surgical condition is defined as "any pathology for which an invasive procedure may provide treatment, palliation, or cure" (Ozgediz, et al., 2008) as the case in the initial GBD study, or when the definition is expanded in by the Disease Control Priorities Project to include "any condition in which the most potentially effective treatment is an intervention that requires suture, incision, excision, manipulation, or other invasive procedure that usually, but not always requires local, regional, or general anesthesia." (Jamison, et al. 2006) Though a collaboration of surgeons, anesthesiologists, emergency physicians, and public health experts have formed the Burden of Surgical Disease Working Group to refine the methodology used to generate these estimates, few groups have translated the theory in to action, and a critical and limiting amount of data persists.

Estimates regarding the global burden of surgical disease tell only half of the story. The other half, and perhaps more important half, is the volume of surgical disease that goes untreated and the disparity with which adequate surgical services are provided. In 2004, somewhere between 187.2 million and 281.2 million major surgeries were performed (Weiser, et al., 2008). According to the authors, this result translates to one operation for every 25 human beings. Yet, surgery disproportionately takes place in countries with high per capita healthcare expenditures: in countries with high healthcare expenditures 11,110 major surgeries are performed per 100,000 people; in countries with low healthcare expenditures the rate is 295 major surgeries per 100,000

people. (Weiser, et al., 2008) Though 34.8% of the world's populations reside in countries classified as poor-expenditure countries, only 3.5% of the volume of surgery takes place in these countries. As a consequence, diseases for which surgery is potentially the most effective treatment are neglected, and what could conditions which are easily cured through early surgical intervention develop in to lethal conditions.

Though more work is required to adequately define both the burden of surgical disease and the rates at which surgery is provided, the unmet need for surgical care is large and troublesome. Moving forward, data must be gathered to better define the true scope of the problem and a coordinated effort can be put forward to close the gap in access to surgical services.

2.2 Global Disparities in Surgical Services

Globally, disparities in health and its association with poverty have been documented by a number of individuals (Lynch, et al., 2004; Wilkinson and Pickett, 2006). In countries with poor or low rates of healthcare expenditures, fewer people have access to care and a smaller segment of the population receives appropriate and timely medical treatment (Farmer and Kim, 2008; WHO, 2014; IMF, 2014; UNDP, 2014). Disparities of health transcend specific classifications of disease, pathology, or medical interventions and are not unique to surgical conditions. However, the issue may be more starkly illustrated in surgery due to the comprehensive nature of the structures necessary for the provision of surgical care. As previously mentioned, there is a disproportionately low volume of surgery in low-income settings compared with high-income settings, which likely has a multifactorial etiology.

2.2.1 Lack of a Surgical Infrastructure

Surgery is a necessarily complex intervention. It requires not only a surgeon, but also an appropriate space, anesthesia, functioning anesthesia machines and gas supplies, sterilizing equipment, proper tools, sutures, drapes and other consumables, as well as a dependable blood supply and postoperative care (Myles and Haller, 2010; Ivers, et al., 2008; Kushner, et al., 2010). This complexity makes it difficult to isolate distinct causes for the disparities in surgical services and to fully represent the existing inequity between countries and regions. However, the lack of a surgical infrastructure in low-income regions when compared to high-income regions likely plays a significant role.

As the delivery of surgical services requires the integration of multiple medical disciplines, supply chains, and health facilities, defining what constitutes a surgical infrastructure proves difficult. One commonly used proxy is the availability of an operating room. At its most basic, the WHO defines an operating rooms as “a room specifically for use by the anesthesia and surgical teams that is not used for other purposes.” (WHO, 2015). While it has been estimated that there are an average of 6.2 functional and aseptic operating rooms per 100,000 people globally, there are wide ranges per geographic region: 25 per 100,000 in Eastern Europe, 14-15 in North America and Western Europe, 4-14 in Latin America, 4.7 in East Asia, 1.3 in South Asia and 1-1.2 in sub-Saharan Africa. (Funk, et al., 2010). Further, if these values are stratified into high-income subregions and low-income subregions, all high-income subregions have more than 14 operating rooms per 100,000 people while all LMICs have fewer than 2. (Myles and Haller, 2010)

However, the presence or absence of an operating room has no bearing on functionality. The WHO Global Initiative for Emergency and Essential Surgical Care (GIEESC), outlines the bare minimum requirements necessary to provide surgical care at a district level hospital, listing basics like running water, an electricity source or operational power generator, an oxygen cylinder with mask and tubing, and an area designated for postoperative care. (WHO, 2005) In a multi-country study of 132 health facilities in LMICs, no country had 100% of health facilities reporting a continuous supply of uninterrupted water, electricity, and oxygen and most reported less than 50% availability or supply (Kushner, et al., 2010). Beyond these basics infrastructure items, surgery requires a functioning anesthesia machine, a blood bank facility, a functioning pulse oximeter, and a steady supply of consumables. While no reliable data exist to determine the country- or region-specific availability of many of these items, one group has used the presence or absence of a pulse oximeter as an indicator of the availability of essential surgical resources and equipment. They estimate that 19% of operating rooms did not have pulse oximeters, which corresponds to about 77,700 operating rooms worldwide. When a similar income-based analysis is performed in low-income subregions, 23.6% of operating rooms in urban areas and 66.5% in rural areas lacked pulse oximetry. Conversely, high-income subregions had pulse oximeters in more than 99% of their operating rooms (Funk, et al., 2010).

As might be expected, deficiencies of infrastructure overlap with low volumes of surgical delivery and certainly play a causal role in the disparity of surgical volume. Despite this, the full benefit of well-equipped operating rooms cannot be achieved without properly trained healthcare workers (McQueen, et al., 2010).

2.2.2 Lack of Trained Healthcare Personnel

Central to improving access to surgical care in LMIC is the ultimate resource of health systems: health workers (Chen, et al., 2004). Worldwide, there is a shortage of healthcare workers, with 2.4 million too few physicians and nurses to provide essential care (WHO, 2008) that disproportionately affects LMICs. Sub-Saharan Africa has one tenth the nurses and doctors for its population that Europe has: Ethiopia has a fiftieth of the professionals for its population that Italy has (Chen, et al., 2004). These global workforce imbalances directly impact health, as health workers are a major determinant in the effectiveness of any healthcare intervention. Research shows that areas with higher worker density and work quality have improved population-based health and human survival. The converse is also true. Low worker density is associated with higher mortality rates (Chen, et al., 2004). Chronic underinvestment in human resources has led to poor salaries, poor working conditions, low morale, inadequate remuneration, absent opportunities for professional growth, and high rates of migration to high income countries among skilled health workers (Bellagio Work Group, 2007). Inequities also exist within countries, with greater numbers of providers concentrating in urban, wealthier areas (Anyangwe and Mtonga, 2007). Citing professional isolation, inadequate communication with peers and consultants in urban centers, and a lack of books, equipment and technology, (Bellagio Work Group, 2007) health care workers typically spend 1-2 years practicing in a rural setting before migrating out.

Similar trends affect surgical and anesthesia providers; the number of surgeons and anesthetists varies significantly by national income. The United States, the biggest spender on healthcare per capita, has 9.0 general surgeons per 100,000 people, compared with 1.6 per 100,000 in

Bangladesh and less than 1 per 100,000 in many African countries (Higashi, et al., 2015). A compilation of several single-nation analyses that encompasses 78 district-level facilities in LMIC demonstrates similar results. In each of four sub-Saharan African nations surveyed, physician surgeons and anesthesiologists were scarce, with fewer than 1 per 100,000 people and 1 per 1,000,000 people, respectively (LeBrun, et al., 2014). As a result, physician providers without surgical training or non-physician providers perform many surgical and anesthetic procedures. In Tanzania and Mozambique, non-physician providers perform 84% and 92% of caesarian sections, hysterectomies and laparotomies with low morbidity and mortality (Chu, Rosseel, Gielis, and Ford, 2009). Different cadres of healthcare workers can be trained to achieve more effective use of existing human resources and increase surgical access (Anyangwe and Mtonga, 2007; WHO, 2008). In response to increasingly frequent task-shifting, the WHO's Integrated Management Toolkit for Emergency and Essential Surgical Care (IMEESC) was developed to train healthcare workers of all levels of expertise in WHO minimum standards for emergency and essential surgical care. However, these programs require significant time and oversight to implement on a scale capable of diminishing the unmet burden of surgical disease.

2.2.3 Lack of Adequate Funding

In examining the difficulty of building surgical infrastructure or a surgical workforce, a commonly cited barrier is the lack of an adequate funding source. Referred to as the "neglected stepchild of global health," (Farmer and Kim, 2008) surgical capacity building has not been a funding priority for international organizations. Traditionally, the dominant trend in public health in LMICs has been to support low-cost, low-technology, preventive measures and primary healthcare (Ozgediz, et al., 2009) most often packaged as vertical initiatives targeted at infectious

diseases. Surgery has been perceived as a higher-cost, higher-technology, curative and individual intervention (Ozgediz, et al., 2009). Farmer and Kim (2008) point out "there is no surgical equivalent to a vaccination campaign or a mosquito net." Yet, without timely intervention, minor and easily treatable surgical conditions evolve into lethal ones that add to the massive burden of disease weighing on lives and productivity. The preferential funding of vertical programs may paradoxically weaken the provision of basic essential health services, including surgery, as donor projects often run in parallel to government systems with minimal spill over to local institutions (Angemi, Oyugi, Aziz, and Kyamukama, 2007). Similarly, infusions of donor support into research and training collaborations in fields focused on infectious diseases, draw medical students away from surgical training programs to the opportunities offered by careers in public health and research, pediatrics, medicine, and obstetrics and gynecology (Ozgediz, et al., 2008).

2.3 Surgery and Public Health

As recently as 2004, interventions to improve access to surgical care were largely absent from the public health discourse. However, in the 2008 World Health Report, the WHO classified the provision of surgical services as an integral part of a new primary health care initiative designed to strengthen healthcare systems. In this model, primary care is viewed as a hub of coordination within the health system with surgery as an essential component (Bickler and Spiegel, 2010). Rather than being viewed as a high-end intervention benefitting a specific subset of the population, basic surgical packages performed at district level hospitals can provide cost-effective care "at a cost per DALY that is on par with other well-accepted preventive procedures, such as immunization for measles and tetanus" (Jamison, et al., 2006). Further, because surgical services intersect with many other primary health programs such as maternal health, child health,

and a variety of non-communicable diseases (Ozgediz and Riviello, 2008), there is growing interest in the concept that the provision and maintenance of a robust surgical service can strengthen health systems overall (Bickler and Spiegel, 2010).

This revised attitude regarding the provision of essential surgical care is reflected not only by the WHO advocacy and programs to promote surgery at district hospitals, but an increasing presence in other major global health forums, most notably *Disease Control Priorities* (*DCP*). Funded by the Bill & Melinda Gates Foundation and published by the World Bank, *DCP* provides evidence regarding intervention efficacy and program effectiveness to guide regional and national level policy and priority setting for the leading causes of global disease burden. Though the massive burden of untreated surgical diseases was first noted as early as the mid-1980s (Brilliant, et al., 2005), the first edition of *DCP* had very little mention of surgical disease or any prioritization of funding for surgical services. As published accounts of the cost effectiveness of providing surgical care at first-level or district hospitals have become more prevalent, *DCP2*, published in 2006, devoted an entire chapter to essential surgical care. *DCP3*, currently in the process of publication, devotes an entire volume to essential surgery. From this increased awareness and the growing involvement of academic surgical institutions, global surgery is evolving from scattered interventions with little oversight towards developing methodologically rigorous studies to fill previously identified knowledge gaps and establishing global collaborative networks with the goal of universal access to surgical services.

2.4 Addressing the Gap: Platforms of Surgical Delivery

Access to surgical care in LMICs is limited by the global health workforce crisis, deficiencies in health system infrastructure, and absent funding resources. In light of this and the massive unmet surgical need, the provision of surgical care in many regions of the world has followed a trend in other realms of medicine – care is provided by private governmental organizations, nongovernmental organizations (NGOs), and private volunteer organizations. Though there are preliminary estimates of the volume of care provided by international health volunteers (Laleman, et al., 2007; Maki, et al., 2008), little data exist regarding their impact on the burden of disease, surgical or otherwise. One study estimates that annually relief organizations perform 25,000 operations in resource-poor countries (McQueen, et al., 2009); another survey of 46 organizations conducted in 2009 reports that these groups performed 223,425 cases (McQueen, et al., 2010). There is no homogeneity amongst organizations offering surgical interventions in LMICs – some are large, well-funded organizations capable of performing more than 1,000 surgeries per year, while others have a much lower case capacity (McQueen, et al., 2009). Some evidence suggest that these organizations preferentially impact the surgical need in LMIC where health resources are limited, health workers are in limited supply, and where the burden of surgical disease is the greatest (McQueen, et al., 2010). Though some interventions are vertically oriented, focusing on specific conditions and procedures, many perform a broad range of interventions. Due to this heterogeneity, it has been suggested that rather than focusing on disease-specific organizations, these groups should be classified and evaluated by their method of surgical delivery (Shrime, Sleemi, and Ravilla, 2015).

After excluding care provided by surgical outreach components of organizations who respond to humanitarian emergencies, this proposed framework suggests that charitable organizations provide deliver surgery in one of two ways: by establishing specialty surgical hospitals or through more temporary platforms (Shrime, Sleemi, and Ravilla, 2015). For further clarity, the following definitions are used:

> Specialty surgical hospitals: A platform of surgical delivery in which an NGO establishes an entire physical plant, either *de novo* or within an existing structure specifically for the treatment of one or a few related surgical conditions.
> Self-contained surgical platforms: A platform of surgical delivery in which the surgical infrastructure of the NGO is entirely self-contained and carried on ships, airplanes, or other modes of transportation. Typically these groups spend months to years in-country, but do not leave behind any physical structure.
> Short-term surgical trips: A platform of surgical delivery in which surgeons, anesthesiologists, nurses, and/or supporting staff operate in LMIC hospitals and clinics for short periods. Often these groups bring surgical instrumentation and technology with them and tend to perform a restricted set of surgeries.

2.4.1 Specialty Surgical Hospitals

In LMIC, specialty surgical hospitals are numerous and address a range of disease complexes – though each individual center only cares for patients with a certain type of pathology. Services offered at individual hospitals include ophthalmic disease, the repair of obstetric fistulas, and comprehensive cancer care (Shrime, Sleemi, and Ravilla, 2015). A nearly vertical surgical intervention, this model has advantages and disadvantages. Since a focus is placed on the treatment of a single disease or the provision of a single procedure, specialty hospitals are able to perform complex cases with, as some evidence suggests, similar outcomes to HICs (Muleta, 1997). Regardless of practice setting, surgeons who perform a high volume of a single procedure

have better outcomes and fewer complications than surgeons who perform a fewer number (Dudley, Johansen, Brand, Rennie, and Milstein, 2000). Specialty hospitals employ this tenet to their advantage, instituting narrowly focused educational and training programs, building particular physical structures, and developing reliable auxiliary services, like physical therapy or speech therapists, that district-level hospitals may not be able to provide or support. The longitudinal nature of this model provides these centers with a clear role in the education of local healthcare practitioners and the strengthening of the healthcare infrastructure. Though this narrow approach allows for a higher volume of a specific case to be performed and the reduction of a sub-segment of the burden of surgical disease, it does little to improve universal access to surgical services, nor it serve as the sole provider of surgical services in a region. Instead, specialty hospitals are best in conjunction with a district-level hospital, acting as a referral center, while the district-level hospital provides life-saving surgeries.

2.4.2 Temporary Surgical Platforms

2.4.2.1 Self-contained Surgical Platforms

Filling the “negative space” between the long-term specialty surgical hospitals and transient short-term surgical trips (to be discussed next) (Shrime, Sleemi, and Ravilla, 2005), self-contained surgical platforms may offer a quality and cost-effective interim model of surgical delivery. Though far rarer than either specialty hospitals or short-term trips, self-contained platforms have an entire, often mobile, infrastructure that allows for the provision of a range of services including ophthalmic, reconstructive, and orthopedic procedures, as well as obstetric fistulas (Cheng, McColl, and Parker, 2012). These platforms are often transported by ship as is the case with Mercy Ships or the floating hospitals employed by the US Navy. There have be

speculative reports of outcomes similar to those achieved in hospitals in high-income countries, though no studies to date regarding their cost-effectiveness have been established. However, because these platforms transport a specialized physical structure as well as a trained healthcare workforce to appropriately utilize that infrastructure, this model requires a large initial inlay of capital. At the same time, the existence of such an infrastructure allows for the training of local practitioners and potentially the conversion of the temporary infrastructure to a more permanent structure or intervention.

2.4.2.2 Short-term Surgical Trips

Short-term surgical trips are abundant and perhaps the most diverse platform of delivery of surgical services (Shrime, Sleemi, and Ravilla, 2005). They are also the most controversial in discussions of efficacy, cost-effectiveness, and sustainability. Trips may be oriented around particular disease processes or procedures such as cleft lips, hernias, or cataract surgery, and range in length from one to two weeks up to several months. Commonly, these trips carry their own equipment with them, return to the same region yearly, and attempt to create strong partnerships with local surgeons and ministries of health (Shrime, Sleemi, and Ravilla, 2005). Despite their variability in length and diseases treated, consistent among these trips is that surgeons from high income countries fly to an area in a LMIC deemed to have a high burden of surgical disease. As is the case with other platforms of surgical delivery, little methodologically rigorous data exists fully examining the efficacy of these trips. However, early reports indicate that these groups have higher mortality rates, particularly for more complex procedures. Though the difficulty of obtaining long-term follow-up severely limits any definitive conclusion regarding efficacy, the North American surgical literature, has established that outcomes

improve with an increased hospital volume of a certain procedure (Dudley, Johansen, Brand, Rennie, and Milstein, 2000). Shrime, Sleemi, and Ravilla (2015) argue that the very nature of short-term trips may support the validity of this trend and help to explain it. However, in areas where no surgical infrastructure or capacity exists, this platform of delivery may be a worthwhile endeavor until a more robust infrastructure can develop.

2.4.3 The Emory University School of Medicine – Project Medishare Short-Term Surgical Trip

The Emory University School of Medicine (EUSOM) and Project Medishare (PM) short-term surgical trip to Haiti very much fits this model. A needs assessment conducted in 2007 identified a high burden of untreated surgical disease in the Central Plateau of Haiti. In an effort to reduce this burden and provide specialized training in urologic procedures to local surgeons, the EUSOM-PM surgical trip was created. Since that time, teams of surgeons, anesthesiologists, students, and support staff from EUSOM, in conjunction with PM, have been conducting surgical missions to Hospital St. Therese (HST) in Hinche, Haiti (Chin-Quee, A, White, L, Leeds, I, MacLeod, J, & Master, VA, 2011; Leeds, et al., 2011). Between 2007 and 2012, teams spent one week at HST performing between 75-80 general surgical and urologic procedures annually. In 2012, the trip was expanded to a three-week surgical elective that included a dedicated postoperative follow-up clinic. All supplies and medications used for these procedures are transported from the United States. Yearly trips to HST have served to create a number of longitudinal relationships with local clinicians and healthcare providers.

Though each year, the trip is able to provide general surgery and urologic procedures to 75-80 patients and in some way address the local burden of surgical disease, many of the criticisms that are applied in general terms to short-term surgical trips may also be pertinent the EUSOM-PM trip. Initially, in an effort to reach as many patients as possible, operations at HST were performed during the entire time in country without a dedicated period for follow-up. As a result, immediate postoperative complications were captured, but the departing team relied upon local partners to report later postoperative complications. The departing team received a few reports on the status of patients, but largely proceeded under the assumption that complications were rare or handled by local physicians. To address this, a follow-up clinic initiated in 2012 allows for better postoperative complication surveillance and management: in two years, an aggregate of 24 postoperative complications were recorded. Though some of the complications were minor, 9 of 13 complications that occurred after hospital discharge required readmission for further hospital management.

The institution of a short-term follow-up clinic is a first step toward collecting outcomes data and the management of early postoperative complications, but it does not provide adequate information regarding the long-term quality of surgery performed, nor does it generate the data necessary to improve patient outcomes. Because of a lack reliable data, there is a need to develop a formalized framework to assess the quality of care provided by the EUSOM-PM short-term surgical trip and ultimately, one that can be applied to short-term humanitarian surgery missions working in low-resource settings. This need is much in keeping with the current trends regarding quality and outcomes that are being applied to most aspects of the United States healthcare system.

2.5 Theories of Healthcare Quality

The assessment of healthcare quality is not a new phenomenon. The concept has been present in the medical literature of the United States since the beginning of the 20th century, but was spurred on by the Institute of Medicine's (IOM) 2000 and 2001 publications of *To Err is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century*, respectively. In these reports, it was posited that at least 44,000 and as many as 98,000 people die in hospitals in the United States each year due to preventable medical errors, costing the healthcare system between $17 billion and $29 billion (IOM, 2000). Further, these costly errors were not usually due to mistakes committed by individual practitioners; but rather, a reflection of fragmented and broken systems and processes. The IOM called for an overhaul of healthcare systems, putting forward six specific aims – that healthcare be safe, effective, patient-centered, timely, efficient, and equitable – to be adopted on a national level and used as a framework for healthcare policymakers moving forward (IOM, 2001).

The foundation for the assessment of healthcare quality promoted by the IOM is a paper published in 1988 in the Journal of the American Medical Association (JAMA) by Donabedian, "The Quality of Care: How Can it be Assessed?" In this seminal work, Donabedian defines quality and dissects it into discrete, measureable, and in turn actionable elements. He posits that quality may be examined on multiple inter-related levels, gradually expanding from care provided by the healthcare practitioner outward to the care received by the community. At the core of quality assessments, the technical performance of the provider is a reflection of the knowledge and judgment of that individual and his or her skill in implementing the appropriate strategies of care (Donabedian, 1988). One level outward, quality may be affected by amenities,

or the attributes of the setting in which care is provided. As the scope of the evaluation expands, the quality of care must account for the portion of care implemented by the patient and finally, the care received by the community. At these levels, the assessment of quality shifts from the theoretical to the manner in which it is actually received, reflecting both the shared responsibility of the provider and the patient in healthcare quality as well as factors that influence the social distribution of care (Donabedian, 1988). Once quality is understood on multiple planes with a broad perspective, it can be more thoroughly evaluated.

Further, quality assessments must be multidimensional and include an examination of the elements of structure, process, and outcome. The structure of care is a general term to describe the attributes of the setting in which care takes place, including material resources like facilities, equipment, and money; human resources, or the numbers and qualifications of personnel; and organizational resources (Donabedian, 1988). Care processes consist of what is actually done to provide healthcare for the patient and focuses on both the decisions and activities of patients in seeking care and those of the practitioner in giving care. Finally, outcomes represent the effect of the care provided on the health status of patients and populations (Donabedian, 1988). These elements are intricately linked and must be examined in tandem rather than in isolation. This paradigm of quality assessments has been applied in a variety of different manners to a number of different healthcare fields. At each juncture, however, much debate exists regarding which metrics are the most appropriate to assess and the best method for translating the data generated into measureable improvements in healthcare quality.

2.5.1 Surgical Quality Assessments

As with other fields, quality metrics increasingly drive the provision of surgical care in the United States. A growing body of evidence indicates that surgical outcomes, like many other aspects of healthcare, vary between providers. In response, patients and insurers rightfully seek evidence of quality. To meet these interests, policy makers and health services researchers have begun to study and develop indicators of quality in each of the three domains of the Donabedian paradigm that may be applied to surgery (Birkmeyer, Dimick, and Birkmeyer, 2004). However, it is unclear which measures are the most appropriate to assess – structural, process, or outcomes measure. Given the established relationship between the procedure volume of a particular surgeon or a hospital and outcomes (Dudley, Johansen, Brand, Rennie, and Milstein, 2000), this is a common surrogate measure of structural quality. Structural measures, though easy and cheap to assess, do not clearly establish direct relationships between the structural variable and the outcome measure, nor are they immediately actionable (Birkmeyer, Dimick, and Birkmeyer, 2004). Further, structural indicators fall prey to the ecologic fallacy as they represent average results for large groups rather than individuals. Process measures, which are reflections of the actual care that patients receive and are in routine use in non-surgical specialties, allow for a closer examination of the associations between structural variables and outcomes measures and are often supported by evidence from randomized control trials. As they measure the actual care received, they are actionable and may link directly to quality improvement activities (Birkmeyer, Dimick, and Birkmeyer, 2004). Unfortunately, though much research has been done regarding process measures in non-surgical specialties, very little evidence about specific technical problems related to the surgical procedure exist. Most work that has been done is concentrated on the medical management of patients and may be difficult to extrapolate to the perioperative

population. Finally, the direct assessment of outcomes via the measurement of operative mortality rates, complication rates, postoperative length of stay, and other similar variables is not new to the surgical field. For this reason, there is often good buy-in from clinicians. In many instances, longitudinal measurement of these endpoints results in their improvement, generating improvements in care with limited effort (Birkmeyer, Dimick, and Birkmeyer, 2004). Fortunate for the patient, but unfortunate for the measurement of outcomes, for most procedures, few hospitals have sufficient adverse events or cases to allow for meaningful, procedure-specific measurement of morbidity and mortality. Arguably, the best quality assessments would incorporate elements of each domain – structure, process, and outcome – but with limited resources, this is not always possible. Instead, the procedure itself may dictate the best measures (Birkmeyer, Dimick, and Birkmeyer, 2004).

The application of these theories of quality to surgery at a national level began in the 1980s in response to high operative mortality rates in Veterans Affairs (VA) hospitals that were perceived as exceeding the national average (ACS, 2015). However, as no metrics detailing the average national mortality rate existed for comparison, the VA hospitals initiated a program to collect preoperative, intraoperative, and outcome variables on major operations, ultimately creating risk-adjusted models for operative morbidity and mortality. Monitoring of these outcomes resulted in a parallel improvement in outcomes – between 1991 and 2006, the VA hospitals recorded a 47 percent drop in postoperative mortality and a 43 percent reduction in postoperative morbidity (ACS, 2015). The American College of Surgeons (ACS) scaled these modeling schemes to create the National Surgical Quality Improvement Project (NSQIP), a “nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care across

surgical specialties. (ACS, 2015)" Aggregated outcomes data that is risk-adjusted for different patient populations compiles enough case outcomes and adverse events, paving the way for more precise measurements of procedure-specific morbidity and mortality (Birkmeyer, Dimick, and Birkmeyer, 2004). The application of NSQIP data collection and outcomes monitoring to hospitals throughout the United States has allowed for more targeted surveillance of outcomes and provides a basis for quality improvement programs to be built.

2.5.2 Quality Assessments in Global Surgery

The widespread implementation of healthcare outcomes monitoring and quality improvement projects has not been reflected in global surgery initiatives. It has been suggested that 7 million surgical complications occur each year, including 1 million deaths (Weiser, et al., 2009). Hampered by gaps in national data and a lack of standardized definitions for tracking surgical services, information regarding the frequency and safety of surgical care is severely limited (Weiser, et al., 2009). International organizations delivering surgical care in these settings demonstrate a similar lack of data collection and outcomes monitoring. According to a report from 2010, of the international organizations responding to a survey, 80% reported tracking surgical mortality rates and 82.5% reported tracking overall complications (McQueen, et al., 2010). Notably, only 46 of the 99 organizations contacted responded to the survey, creating the possibility that these rates may represent an overestimation due to higher survey response rates of international organizations that collect outcomes data (McQueen, et al., 2010). A similar lack of outcomes monitoring by foreign medical teams was reported following the sudden-onset disasters in Haiti, Indonesia, and Pakistan. Though in each instance foreign medical teams have called for a system to standardize data collection and reporting, few efforts have been made

towards implementation (Burkle, et al., 2012). Challenges mentioned include lack of patient follow-up, poor data collection flow, and limited provider buy-in. Amongst international groups providing care, certain platforms of surgical delivery are more conducive to the outcomes monitoring and the implementation of quality improvement projects. Specialty surgical hospitals, with their permanent infrastructure and longitudinal presence in a particular region, have a better foundation for data collection, but some organizations that deliver care via more temporary platforms have reported early success in the assessment of quality via the use of innovative electronic and remote methods to collect data (Bermudez, Carter, Magee, Sherman, and Ayala, 2012). Beyond the logistic issues of data collection, there is no consensus regarding what information should be collected and measured.

The Safe Surgery Saves Lives initiative, part of the WHO's Patient Safety Program, is one of the first groups to propose standardized metrics regarding global surgical surveillance. Comprised of international experts in the fields of epidemiology, global health, and surgical outcomes, the working group designed 6 measures that are applicable to a variety of resources settings and geographic regions, with the goal of improving oversight of surgical delivery systems and the surveillance of surgical volume and its effect on public health outcomes over time (Weiser, et al., 2009). Ultimately, the project aims to generate reliable data regarding the availability of surgical services with respect to personnel, infrastructure, quantity, and outcomes. All of the indicators chosen had to meet several criteria: simplicity, widely applicable, relevant to public health, and minimal unintended negative consequences (Weiser, et al., 2009). While underpinned by these principles, the measures assess structural elements through analysis of the number of operating rooms in a facility or country, the number of accredited surgeons, and the number of accredited

anesthesia providers; process elements via the volume of surgery provided; and outcomes through a 30-day postoperative death ratio (Weiser, et al., 2009). A pilot trial of data collection at eight sites worldwide has yielded promising results. According to the authors, the structure and process measures were simple to gather at the facility level, but the outcomes measures were more difficult due to variation in the methods and sources used to collect mortality data. Further, these data do not adjust for the case-mix or complexity of procedures performed, nor do they reflect the variability in patient demographics and conditions. This group concluded that while the structure and process measures can be used to examine resource allocation and access to care, it may be more difficult to draw any conclusions about the quality of care provided or make comparisons between facilities or countries (Weiser, et al., 2009). However, if data collection is consistent within a facility, it can provide critical information about the quality of care at that facility.

2.6 The Importance of Quality Assessment

The EUSOM-PM short-term surgical trip is an annual intervention to improve access to surgical services to an indigent population in Haiti's Central Plateau. Annually, 70-80 patients receive care from this organization. Without the EUSOM-PM intervention, many of the individuals treated may not have access to or be able to afford a surgical procedure; however, it is important to ensure that the care provided improves the health of patients. Since 2007, data regarding patient outcomes has been collected. Though complications from surgery are never intended, they do occur. With little national or group-specific historic data, it is difficult to interpret the rates of complications among patients treated by the EUSOM-PM intervention and to identify where in the provision of care improvements can be made. Preliminary data collection has

resulted in several adjustments to the care provided to patients; but, moving forward a systematic quality improvement program is necessary to determine which processes of care delivery are working and which are not and the impact that changes to these care processes may have on outcomes. The development of a standardized system of data collection and evaluation will allow EUSOM-PM to develop a historic database of outcomes data and fully evaluate the impact of changes in care processes.

Further, global surgery is an emerging field with increasing involvement from a variety of international organizations, delivering care via many different platforms. To date, there has not been a parallel development of systematic oversight of these interventions. If a simple and reliable system of data collection can be established for use in a range of settings and indicators of surgical quality can be shown to be easily collected and valid, it is possible that other similar groups can apply these measures to their own programs. By improving the ability of short-term surgical trips to assess the quality of the care they provide, the treated patient population will benefit and global surgery will take necessary steps toward the responsible care of patients.

Chapter 3: Methods

The EUSOM-PM short-term surgical trip acknowledges the importance of data collection to ensure that they are reaching the intended population and that the care provided to patients is high quality. Since 2007, trip participants have been collecting data regarding patient outcomes, but the current method of data collection and the quality of data is far from adequate. Though the current data collection instrument provides a basic record of patient care, it does not comprehensively document all the interactions between the clinical team and the patient – from initial preoperative assessment to postoperative follow-up – nor does it clearly enumerate the standardized data points to be collected. Because of prior involvement with this group, the researcher chose to work with EUSOM-PM to create this thesis project.

The main goals of this project are to:

1. to define and field-test indicators of surgical quality applicable to low-resource settings, and
2. to establish reliable data collection techniques at HST that will generate complete and timely data regarding surgical outcomes in a low-resource setting.

3.1 Sample Population

The EUSOM-PM short-term surgical trip provides general surgery and urology procedures to a rural population in the Central Plateau of Haiti. Patients are alerted of the availability of surgical services via radio announcements broadcast in the area or by clinician referral to a preoperative clinic that is conducted at Hospital St. Therese in Hinche, Haiti. During this clinic, presenting patients are evaluated for conditions requiring general surgery or urology intervention, screened

for medical conditions, and scheduled for an operative procedure or referred to a local provider for non-surgical medical services.

3.2 Research Design

Data collected during previous EUSOM-PM surgery trips was reviewed in depth and gaps in the data were identified. Informal interviews with past participants were conducted to: 1) determine the barriers to data collection, 2) identify the most clinically relevant data points, and 3) collect information needed to create standardized definitions of surgical quality metrics.

Short-term surgical trips are subject to little, if any, oversight and thus no evaluation criteria or standards have been established. However, the evaluation of healthcare quality, particularly as it pertains to the delivery of surgical care, is a rapidly growing field. The largest of these programs, the National Surgical Quality Improvement Program (NSQIP), details 66 preoperative variables that can be used to create risk-adjusted predictions for postoperative adverse events. Similarly, NSQIP defines a number of postoperative outcomes that may be collected by participating healthcare facilities. These variables have been validated for use in large hospitals in the United States and there is early evidence that the model is valid in smaller and rural hospitals (Anderson, Lassiter, Bickler, Talamini, and Chang, 2012).

For the purpose of this project, NSQIP variables were examined to determine if they were transferable to a low-resource setting and applicable to the patient population treated by the EUSOM-PM surgery trip. A full listing of NSQIP variables is included in Appendix 1. The NSQIP database includes 66 preoperative variables used to predict postoperative morbidity and

mortality, but it was not feasible to include them all in the data collection tool. To be included in the tool, variables needed to be easily obtainable and measured with the resources available at HST, have clinical bearing on the care of the individual patient, and for items that required self-report, be understandable by patients. Items that dealt with smoking status, a history of hypertension or diabetes were included; while many laboratory results were not, due to the limited capabilities of the HST laboratory. The primary surgeons involved in this project are faculty members at EUSOM and were intricately involved in selecting variables regarding the preoperative health status of patients, process variables, and outcome endpoints to collect and analyze.

The NSQIP database, despite being the largest quality improvement database in use, contains data from patients and major operations garnered primarily from large academic medical centers based in urban areas of the United States. Internal validation of the risk-adjustment models is based on a largely white, middle class population (Anderson, Lassiter, Bickler, Talamini, and Chang, 2012). The anticipated demographics of patients at HST are significantly different. In general, the population of the Central Plateau has limited access to many basic utilities, including clean water sources, toileting facilities, and electricity. Further, though many individuals are employed in farming, the variety and quantity of food available to many individuals is unclear. As the living environment and nutrition status of many of the patients at HST is vastly different from the patients included in the NSQIP database, it was necessary to include in the data collection tool variables that accounted for these differences.. In particular, a non-hygienic environment and baseline malnutrition have been shown to directly affect wound healing and postoperative infections (Haydock and Hill, 1986) – two outcomes variables that we were

specifically trying to measure. For this reason, variables that were intended to serve as proxies for socioeconomic status and overall health resources were included in the data collection instrument to allow for more appropriate risk-adjustments.

Following the selection of variables, a new data collection instrument (Appendix 2) was drafted to address the areas of data collection that were incomplete and to incorporate the measurement of metrics for indicators of surgical quality into the instrument. The NSQIP variables have very specific definitions associated with them and for consistency, both for potential comparison to US hospitals and for inter-recorder reliability, these definitions were applied to the data collection instrument (Appendix 3). As the data collection instrument was administered to every patient seen in the preoperative clinic at HST, it had to be simultaneously comprehensive, easy to use, and easy to analyze. Once a preliminary instrument was developed, it was distributed to key decision makers and clinical participants for revisions. Interviews were conducted with these individuals to determine the ease of use of the data collection instrument and the validity and reliability of the data it purports to measure.

3.3 Data Collection and Analysis

After the data collection instrument was finalized, medical student participants, who were the primary data recorders, were trained to use the instrument. All participating medical students underwent an hour-long training session in which they were introduced to the NSQIP definitions of variables and to resolve any inconsistent interpretation of data fields. Once at HST in Hinche, Haiti, a small pilot of the data collection instrument was conducted to identify any procedural inconsistencies and to allow for final revisions.

During the clinical phase of the project, trip participants used the data collection instrument to collect data on 150 patients from June 20 – July 10, 2014. Medical student participants utilized the data collection instrument to record all interactions with patients seen in preoperative clinic. For patients who were in seen in preoperative clinic, but not scheduled for surgery, only preoperative information was recorded during the initial clinic visit. For patients who were seen in preoperative clinic and scheduled for surgery, an extended data set collecting preoperative, intraoperative, postoperative, and follow-up data was recorded. A daily review of a sample of records was conducted to ensure the completeness and accuracy of data collection and that the use of the data collection instrument was consistent across participants.

Participants of the EUSOM-PM short-term surgery trip recorded all pertinent information on paper versions of the data collection instrument. Information was then entered into an electronic version of the data collection instrument on software provided by Adobe FormsCentral. Aggregate data was exported to Microsoft Excel and SAS 9.4 (SAS Institute Inc., Cary, NC) for analysis. Due to time constraints and a priority on providing clinical care, the clinical team involvement in data analysis was limited. Much of the analysis took place after the completion of clinical activities.

Cases were classified based on Accreditation Council for Graduate Medical Education (ACGME) category: (1) Genito-urinary – consisting of simple retropubic prostatectomies and hydrocelectomies; (2) Abdomen – Hernia; (3) Skin, Soft Tissue and Breast; (4) Pediatric; (5) Endocrine. Wounds were prospectively classified by the Center for Disease Control and

Prevention (CDC) surgical wound classifications: (1) Clean, (2) Clean-Contaminated, (3) Contaminated, and (4) Dirty-Infected.

Institutional Review Board approval and verbal patient consent were obtained for this study.

3.4 Limitations

This study has several limitations. First, medical students collected the data in a busy clinical setting. Though many of the preoperative variables were objective measures like blood pressure, a number required subjective assessment of a patient's functional status or overall health. Due to time constraints and a limited number of student participants, it was difficult to establish inter-rater reliability for these variables. Second, patients self-reported their medical and social history, making these variables prone to bias, particularly because few patients have access to primary care services for the diagnosis and management of diseases like hypertension or diabetes. Third, patient interviews were conducted in Haitian Creole through the use of an interpreter. Though medical student participants received training regarding the definitions of specific variables included in the data collection instrument, the interpreters did not. Therefore, it is difficult to assess whether the intended meaning of a question or data field was accurately relayed to a patient.

Though 150 patients were seen in the preoperative clinic, only 59 patients underwent operative procedures. This small sample size and correspondingly low volume of postoperative adverse events makes it difficult to draw conclusions regarding patient outcomes as a zero event rate may be either a reflection of quality care or due to chance alone. Finally, the NSQIP postoperative

outcomes variables are typically collected for a standard period of 30 days following the procedure. Given the setup of the short-term surgical trip and poor correspondence with local clinicians, it was not possible to collect outcomes for this entire period. Therefore, while early postoperative complications were captured, the current system for data collection does not allow for the surveillance and management of delayed and long-term postoperative complications.

Chapter 4: Results

The EUSOM-PM short-term surgery trip to Haiti is an attempt to improve access to surgical care for an underserved population in the Central Plateau of Haiti through the provision of safe elective general surgery and urology procedures. Though over 300 procedures have been provided to patients during the seven-year operative history of the trip, data regarding the patient population and the quality of care provided is limited. This study attempts to fill gaps in the existing data collection system through the design of a new data collection tool and to assess the utility of the data collected in the creation of future quality improvement projects.

4.1 Findings

4.1. Data Collection Tool – Ease of Use

The final data collection tool was divided into several sections to capture multiple longitudinal aspects of the patient encounter. At the preoperative clinic, medical student participants recorded basic demographic, social, and medical information about each patient. Variables that were intended for later use in quality assessments were integrated with standard data fields recorded in medical encounters like a chief complaint, a history of the present illness, and a physical exam. An extended data set containing intraoperative and postoperative information was collected for patients who underwent operative procedures. As one of the limiting factors of prior data analysis was missing and incomplete data on patients, the completeness of the data set will be a useful process indicator of the utility of this data collection instrument.

Student participants used the data collection instrument to record information for 150 patients in the preoperative clinic (Table 1). The highest response rates were for demographic information with some form of response recorded for the age, sex, and functional status of 99.3%, 100%, and 96% of patients, respectively. The instrument was used to record the access to bathroom facilities, electricity, and running water for 92.6 % of patients. Similarly, the education level of 92.6% of patients was recorded. An extended data set was recorded for 59 patients who underwent operative procedures. Operative data detailing the administration of preoperative antibiotic administration was recorded for 84.7% of patients, anesthesia type was recorded for 100%, and the procedure length was recorded for 96.6% of patients. Postoperatively, the tool was used to collect information for the 57 patients who returned to HST for a follow-up clinic appointment. Of the two patients who did not return for follow-up, one was transferred to a hospital in Mirebelais for a higher level of care and one was unable to make the journey to Hinche from Port-au-Prince due to financial constraints. He was contacted by phone. Student participants recorded data regarding the provision and utilization of postoperative wound education for 79.7% of patients and the use of postoperative antibiotic use for 57.6% of patients. A complete set of data for the 6 principle outcomes was recorded for 93.2% of patients.

4.1.2 Patient Demographics

During the period of June 20 – July 10, 2014 150 patients were seen in the preoperative clinic conducted by participants of the EUSOM-PM short-term surgery trip. Patient ages were evenly distributed (Table 2). Seventy two percent of patients were male. Several variables were collected as proxies for the socioeconomic status of patients, including access to certain utilities, the highest level of education achieved, and the employment status of patients. Only a small

portion (39%) of patients reported access to either an indoor or outdoor latrine. Similarly, approximately half of the patients reported having electricity in their home and just over 50% reported access to running water in their home. Seventy five percent of patients received only minimal education, with 26.5% reporting that they had no formal education and 49.7% reporting only completion of primary education (Table 2).

As a means of assessing baseline patient health status and the potential for adverse intraoperative and postoperative events, patients were asked about their medical history – specifically, if they had a history of diabetes, hypertension, shortness of breath, or smoking. Despite high response rates for these variables, in this cross-section, there is a low reported prevalence of all of these conditions, with only 1.3% of patients reporting a personal history of diabetes and 19.2% endorsing hypertension (Table 2). Further, in a global self-assessment of a patient's ability to complete their activities of daily living, 83.4% reported total independence and 11.3% reported partial dependence. Of the 17 patients reporting partial dependence, 10 were children below the age of 15. A final measure of an individual's overall health is the American Society of Anesthesia (ASA) classification. Student participants graded the impact of systemic disease on a patient's health from 1 to 4, with a score of 1 representing a healthy, normal patient and a score of 4 representing a patient afflicted by a severe disease that is a constant threat to life. Of the 150 patients evaluated in the preoperative clinic, the overwhelming majority of patients (90.7%) were assigned an ASA class of 1 or 2 (Table 2). Despite this, 86 patients (57.3%) reported that their surgical condition was severe enough to prevent the completion of daily activities.

4.1.3 Structures and Processes

The majority of the 59 cases performed were in the Genito-urinary, Abdominal-Hernia, or Skin/Soft tissue categories. Eighty three percent of these cases were classified as clean, while only 5% were classified as dirty or infected. The median case length was 75 minutes (IQR 46-120).Of the five types of anesthesia utilized, spinal anesthesia was performed 67.8% of the time.

The administration of preoperative antibiotics within 1 hour of a surgical incision, a standard procedure in major operations, was noted to have occurred for 40 cases (67.8%). Notably, antibiotics were not indicated for 11 cases (18.6%) and there is no record of preoperative antibiotic use for 19 cases (32.2 %). Though postoperative antibiotic use is not a standard of care in hospitals in the United States, Haitian Ministry of Health guidelines require that all patients undergoing surgical procedures complete a 5-day course of antibiotics. In compliance with this measure, patients who were hospitalized fewer than 5 days were discharged from the hospital with a course of oral antibiotics. Only 3.4% of patients did not receive the required course of antibiotics.

The median length of stay for operative patients was 1 day (IQR, 1-2 days). Beyond the provision of medications, the standard hospital discharge process for the EUSOM-PM surgery trip included an educational component and the scheduling of a follow-up clinic visit. It was intended that all patients watched a 5-minute video conducted in Haitian Creole detailing the care of a surgical incision – from boiling water for sterilization to dressing the incision with gauze. Fifty patients (84%) watched the educational video; while 93% of patients were provided with a specific day to return to HST for evaluation.

4.1.4 Outcomes

Early postoperative surgical outcomes were assessed during a dedicated follow-up clinic. Of the 59 patients to undergo a surgical procedure, 57 (96.6%) returned for a follow-up visit a mean of 7.28±2.71 days postoperatively. Of the two patients who did not return, one was transferred to L'hôpital Universitaire de Mirebalais for a higher level of care early in his postoperative care. The other patient could not return from Port-au-Prince due to financial constraints, but was contacted via cellular phone and felt he was in his normal state of health. Overall 3 patients experienced 5 complications. One gentleman who underwent the repair of a hydrocele experienced a wound dehiscence due to a superficial surgical site infection and required readmission for wound care. A second patient had a superficial disruption of a scrotal surgical incision that was managed on an outpatient basis. Finally, a third patient was readmitted to the hospital two days following a hernia repair for the management of pain and incisional swelling. There were no incidences of deep surgical site infections, sepsis, or unplanned reoperations.

Table 1: Encounter / Information Type	
Clinic (n=150)	Any Response, n (%)
Demographic	
Age	149 (99.3)
Sex	150 (100)
Functional Status	144 (96.0)
Social History	
Access to Utilities	139 (92.6)
Education Level	139 (92.6)
Physical Exam	
Blood Pressure Measurement	135 (90.0)
Documented Physical Exam	147 (98.0)
ASA Class	143 (95.3)
Operative (n=59)	
Preoperative Antibiotic Administration	50 (84.7)
Anesthesia Type	59 (100)
Procedure Length	57 (96.6)
Postoperative Follow-Up (n=57)	
Assessment of Wound Education	47 (79.7)
Assessment of Antibiotic Use	34 (57.6)
Set of 6 Outcome Variables	55 (93.2)

Table 2: Patient Demographics	(n=150)
Age	n (%)
< 15	21 (13.9)
15-29	39 (25.8)
30-44	29 (19.2)
45-59	27 (17.9)
60-75	28 (18.5)
>75	6 (4.0)
Missing	1 (0.6)
Sex	
Male	110 (72.8)
Access to Utilities	
Indoor Latrine	39 (25.8)
Outdoor Latrine	20 (13.2)
No Latrine	87 (57.6)
Electricity	70 (46.4)
Running Water	87 (57.6)
Education Status	
No Formal Education	40 (26.5)
Primary School	75 (49.7)
Secondary School	16 (10.6)
College or Higher	9 (6.0)
Missing	11 (7.3)
Employment	
Child	5 (3.3)
Professional / Student	55 (36.4)
Manual Labor	64 (42.4)
Unemployed	19 (12.6)
Other	3 (4.0)
Missing	5 (3.3)
Self-Reported Medical History	
Diabetes	2 (1.3)
Hypertension	29 (19.2)
Shortness of Breath	20 (13.2)
Smoker within 1 Year	17 (11.3)
Functional Status	
Independent	126 (83.4)
Partially Dependent	17 (11.3)
Totally Dependent	2 (1.3)

ASA Class	
1	101 (66.9)
2	35 (23.2)
3	7 (4.6)
4	1 (0.7)
Self-Reported Disease Severity: Surgical Condition Prevents Completion of Daily Activities	
Yes	86 (57.3)
No	56 (37.3)
Missing	8 (5.0)

Table 3: Operative Variables	(n=59)
ACGME Classification	n (%)
Abdomen – Hernia	20 (33.9)
Endocrine	1 (1.7)
Genito-Urinary	19 (32.2)
Pediatric	7 (11.9)
Skin/Soft Tissue	12 (20.3)
Wound Classification	
Clean	49 (83.1)
Clean/Contaminated	7 (11.9)
Contaminated	0 (0)
Dirty/Infected	3 (5.1)
Anesthesia Type	
Local	11 (18.6)
Regional	1 (1.7)
Spinal	40 (67.8)
MAC/IV Sedation	3 (5.1)
General	4 (6.8)

Table 4: Process Variables	(n=59)
Preoperative Antibiotics	n (%)
Yes	40 (67.8)
No	0 (0)
Not Indicated	11 (18.6)
Missing	19 (32.2)
Length of Case	
Median	75 min
Interquartile range	46-120 min
Length of Postoperative Hospital Stay	
Median	1 day
Interquartile range	1-2 days
Discharge Antibiotics	
Yes	49 (83.1)
No	2 (3.4)
Not Indicated	4 (6.8)
Missing	4 (6.8)
Discharge Surgical Wound Education	
Yes	50 (84.7)
No	0 (0)
Missing	9 (15.3)
Follow-up Appointment Scheduled at Hospital Discharge	
Yes	55 (93.2)
No	0 (0)
Missing	4 (6.8)

Table 5: Outcome Measures	
Follow-Up	(n=59)
Yes	57 (96.6)
No	1 (1.7)
Transferred	1 (1.7)
Length to Follow-Up	
Mean	7.28±2.71 Days
Selected Outcomes	(n=57)
Wound Dehiscence	2 (3.5)
Superficial Surgical Site Infection	1 (1.8)
Deep Surgical Site Infection	0 (0)
Sepsis	0 (0)
Unplanned Readmission	2 (1.8)
Unplanned Reoperation	0 (0)

Chapter 5: Discussion and Conclusions

5.1 Overview

The EUSOM-PM short-term surgical trip to Haiti provides surgical care at Hospital St. Therese in Hinche, Haiti on an annual basis. As a proto-typical example of a short-term surgical trip, evaluation of the quality of care provided by the EUSOM-PM trip may help establish a paradigm for the assessment of similar trips that take place in other low-resource settings. Quality assessments, under the Donabedian model, must consider structural, process, and outcomes measures in a coordinated fashion to better understand the care that is provided to patients within the broader context of a healthcare system. Through the collection of a standardized set of data related to each of these components, this project attempts to assess the process of data collection, report on the current state of care provided by the EUSOM-PM surgery trip, and to identify areas for potential improvement in the quality of care by future short-term surgical trips.

5.2 Principle Findings

5.2.1 Data Collection Tool

Regardless of setting, a major limitation of quality improvement projects is a lack of data. The EUSOM-PM surgery trip is no different. Past attempts to collect data regarding patient demographics and baseline risk, intraoperative and postoperative processes, and postoperative outcomes have been inconclusive due to gaps in the data set. The creation of a new data collection tool with pre-selected variables and standard definitions improved the amount and quality of data collected during the period of June 20 – July 10, 2014. For most variables included in the new data collection tool, there was a response rate of 80% or higher. As a point of comparison, during a similar period in June and July, 2012 and 2013, the EUSOM-PM

surgery trip provided surgery and collected data for an aggregate of 147 patients. The ASA class was reported on only 27 patients. With the new data collection tool, medical student participants reported ASA class for 143 of 150 patients. A strictly quantitative measure of data response rates does not reflect the accuracy of the data, but it is a first step toward filling gaps in knowledge.

Similarly, an examination of the different methods by which data was obtained also highlights several barriers to data collection. Despite the time constraints of collecting data in a busy clinical setting, data collected for the 150 patients seen in the preoperative clinic is more complete than the extended data set (which includes intraoperative and follow-up variables) collected for the 59 patients who underwent surgical procedures. The higher response rates for the preoperative variables may be due to the greater volume of data points collected for the 59 operative patients or it may be secondary to the need to collect data at several different time points in the patient's care. To complete the data on patients undergoing an operative procedure, a medical student participant had to record data in the preoperative clinic, from anesthesia records during the operation, and during the period of postoperative hospitalization and at follow-up clinic. Logistically, this multiple time point data set proved difficult to complete, due to the number of people involved and the need for prolonged patient participation.

Alternatively, the difference in data completeness may be due to the format of variables in the data collection instrument. Data points collected in the preoperative clinic were clearly listed on the data collection tool and simply required that data recorders select the appropriate response from a pre-populated list. In the extended data set, some variables of interest were not delineated in the data collection tool, but rather required that the data recorder remember to ask a specific

question of a patient and document a response. For the two variables with the lowest response rates, assessment of wound education and assessment of antibiotic use, with rates of 79.7% and 57.6%, respectively, this was the case.

5.2.2 Assessment of Quality Metrics

The EUSOM-PM short-term surgery trip treats patients across a wide range of ages, with the highest portion of patients falling between the age of 15 and 29. The majority of these patients are male, reflecting the specific type of surgical diseases that the project is equipped to treat. Despite previous assumptions that the population at HST had a higher baseline risk for surgery due to untreated or poorly managed medical comorbidities, very few patients reported that they had a history of diabetes, hypertension, or shortness of breath. This may however underestimate the true prevalence of disease in the patient population. Many patients may have these medical comorbidities, but due to limited access to healthcare services, lack a diagnosis of these disease states. Consequently, a high volume of disease may be undiagnosed, limiting the value of a self-reported medical history variable in this population. Interestingly, there is a high degree of agreement between self-reported health status and the overall health status of patients as evaluated by medical student participants - a high portion of the patient population had an ASA class of 1 or 2 and were able to accomplish activities of daily living with complete independence. However, it is unclear if the ASA class assigned to patients by medical student participants was biased by the self-reported health status of patients. . In this instance, a more objective measure of patient health status, like measured blood pressure or body mass index, might provide a better assessment of health risk.

Data regarding the socioeconomic status of patients is in direct conflict with data regarding the health status of patients. The majority of patients seen in the preoperative clinic had extremely limited access to basic utilities, like toileting facilities, clean water, or electricity. Further, many reported that they had no formal education or that they completed only primary school. The single most common type of employment among the population was manual labor, though a large portion reported professional or student status. In the original design of the data collection tool, these variables were included as proxy indicators of patient socioeconomic status. Given the well-established links between socioeconomic status and health outcomes, the limited access to utilities and the high portion of manual laborer in this population may allow for baseline risk adjustment regarding the success of operative procedures and the likelihood of postoperative adverse events.

Regardless of the health or socioeconomic status of patients, the EUSOM-PM surgery trip can optimize the care they provide through a thorough examination of both structural and process measures. Members of the working group of the Safe Surgery Saves Lives initiative have suggested that operative volume is a key structural indicator. As previously mentioned, for a given procedure, high volume surgeons and facilities have better outcomes and fewer complications than low volume surgeons and facilities. The two most commonly performed procedures categories were genito-urinary and abdomen – hernia. Within these categories, the single most common procedures were hydrocelectomies and inguinal hernia repairs, respectively. The CDC classifies both of these operations as clean operations, indicating a lower baseline risk of postoperative infection. Further steps by the EUSOM-PM surgery trip to reduce the risk of postoperative infection include the administration of preoperative antibiotics and an extended 5-

day course of postoperative antibiotics. Measurement of compliance with both of these processes allows for an assessment of their utility.

5.3 Strengths and Weaknesses

The implementation of a new data tool and standardized data collection techniques greatly improved the volume and quality of data for a short-term surgical trip. Whereas interpretation of prior data proved difficult due to missing data and inconsistent application of terminology, the use of the new tool assisted in the collection of a core set of data points on every patient seen in the preoperative clinic. As the data set is nearly complete for 150 patients, we may have a fair amount of confidence regarding conclusions drawn regarding patient demographics and socioeconomic status. Further, as a lack of time and funding are often cited as major barriers to data collection in low-resource settings, the ease with which this project was undertaken holds promise for translation to other similar settings.

Assessments of surgical quality have gained ground in the United States and other high healthcare expenditure countries, these principles have only minimally been applied in low-resource settings. Recently, members of the WHO Safe Surgery Saves Lives initiative have proposed a set of six standardized metrics for global surgical surveillance. Their project requires that each indicator be simple, widely applicable, relevant to public health, and have minimal unintended consequences (Weiser, et al., 2009). Ultimately, they concluded that the number of operating rooms in a facility or country, the number of accredited surgeons, the number of accredited anesthesia providers, the volume of surgery provided in a give facility or country, and a 30-day postoperative death ratio would meet all of their requirements while still providing a

comprehensive data set. Though the structural and process measures were fairly simple to gather, the group felt that the outcomes measure fell short due to a lack of adjustment for complexity of procedures performed or the variability in patient demographics (Weiser, et al., 2009). The data collected through the application of this tool meets the guidelines established by the WHO group and may provide potential opportunities for risk-adjustment. It has been suggested by several groups that a limited number of preoperative variables may be sufficient for adequate risk adjustment to measure surgical outcomes (Anderson, et al., 2012; Dimick, et al., 2012; Rubenfield, et al., 2010). In particular, they propose that a model including only ASA class, age, functional status, and wound class provides enough discrimination to measure surgical outcomes. All of these variables were included in this data collection tool and with further statistical analysis, may allow for preoperative risk stratification in a setting that would not otherwise have the means to do so.

This study has several limitations. Typically, outcomes measures are collected for a standard period of 30-days following a procedure. Though a somewhat arbitrary period of time, many reports of outcomes are based on this period. Due to the short-term nature of the trip, outcomes were collected for patients in the early postoperative period – but for a mean of 7.28 days – as compared to 30. High rates of patient follow-up allow for the conclusion that the EUSOM-PM group adequately captured and managed early postoperative complications, but does not provide any information regarding delayed or long-term complications. As such, there may be an underestimation of the true complication rates.

Similarly, the limited number of adverse events makes it difficult to draw any associations between preoperative risk factors, proxy indicators of socioeconomic status, intraoperative process measures and a poor postoperative outcome. Given that there is a low baseline risk associated with the procedures that are most commonly performed by the EUSOM-PM group, to detect a difference in complication rates associated with different risk factors or socioeconomic status, a far larger sample size would be required. As drawing any association between the included socioeconomic indicators and adverse events is so difficult, there is an unknown utility in collecting these variables. Similarly, very few conclusions can be made regarding direct effects that they may have on postoperative complications like surgical site infection or sepsis.

5.4 Implications of the Study

Despite its limitations, this project greatly improved the data collection processes for the EUSOM-PM short-term surgery trip. If the data collection instrument continues to be used in this setting, it will allow for the generation of a multi-year aggregated data set, providing information about shifts in patient demographics, reflect alterations in care processes, and potentially, the impact of these factors on patient outcomes. Currently, there is a lack of data regarding global surgical outcomes. As such, very few data sources exist to benchmark global surgical outcomes. The generation of a data set that is particular to the EUSOM-PM short term surgery trip will allow for the internal comparison of outcomes. Though comparing unadjusted outcomes between the EUSOM-PM trip and other short-term surgical trips has limited utility, the methods by which data is collected may be transferrable. Further, if it proves possible to use an abbreviated data set to perform risk-adjustment for outcomes in a low-resource setting, then it inter-group comparisons may be useful to ultimately establish baseline complication rates for global surgery.

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Appendix 1: NSQIP Variables for Calculating Probability of Mortality & Morbidity

1. Medical Record Number
2. Sex
3. Race
4. Principal Operative Procedure
5. Inpatient Status
6. Transfer Status
7. Date of Birth
8. Date of Operation
9. Surgical Specialty of Primary Surgeon
10. Elective or Scheduled Surgery
11. Height
12. Weight
13. Current Smoker
14. Alcohol Usage
15. Dyspnea (or shortness of breath – none, at rest, moderate exertion)
16. Do Not Resuscitate Status
17. Pre-surgery Functional Status (Independent, partially dependent, totally dependent)
18. Diabetes (No/Oral meds/Insulin)
19. Ventilator Dependent
20. History of Severe Chronic Obstructive Pulmonary Disease
21. Current Pneumonia
22. Current Ascites
23. Current Esophageal Varices
24. History of Congestive Heart Failure
25. History of Myocardial Infarction in Previous 6 Months
26. History of Percutaneous Coronary Intervention
27. Previous Cardiac Surgery
28. History of Angina within 1 Month Surgery
29. Hypertension Requiring Medication
30. History of Peripheral Vascular Disease
31. Rest Pain or Extremity Gangrene
32. Acute Renal Failure
33. Currently on Dialysis
34. Impaired Sensorium
35. Coma > 24 Hours
36. Hemiplegia
37. History of Transient Ischemic Attacks
38. Stroke with Neurologic Deficit
39. Stroke without Neurologic Deficit
40. Tumor Involving Central Nervous System
41. Paraplegia
42. Quadriplegia
43. Disseminate Cancer
44. Open Wound or Infection

45. Steroid Use for Chronic Condition
46. Weight Loss > than 10% of Body Weight
47. Bleeding Disorder
48. Preoperative Transfusion of > 1 Unit of Red Blood Cells
49. Chemotherapy for Malignancy
50. Radiotherapy for Malignancy
51. Systemic Sepsis
52. Sodium
53. Blood Urea Nitrogen
54. Creatinine
55. Albumin
56. Bilirubin
57. Aspartate Transaminase
58. Alkaline Phosphatase
59. White Blood Cell Count
60. Hematocrit
61. Platelet Count
62. Partial Thromboplastin Time
63. Prothrombin Time
64. Prior Operation within 30 Days
65. Emergency Surgery
66. American Society of Anesthesia Class (1/ 2/ 3/ 4)

Emory University Project Medishare for Haiti

Patient Name _____ Date _____

Contact Information _____

Source of Referral ◯ Radio ◯ Word of Mouth ◯ Other _____

Patient Age ◯ <15 years old ◯ 15-29 years ◯ 30-44 years ◯ 45-59 years ◯ 60-74 years ◯ >75 years old

Sex ◯ Male ◯ Female

CLINIC VISIT

Chief Complaint _____

HPI _____

Does your condition affect your ability to complete activities of daily living? ◯ Yes ◯ No

ROS _____

Past Medical History _____

Diabetes ◯ Yes ◯ No

HTN ◯ Yes ◯ No

Smoker within 1 year ◯ Yes ◯ No

Dyspnea ◯ At Rest ◯ Moderate Exertion ◯ No

If Smoker, # of Packs/Day _____

Functional Status ◯ Independent ◯ Partially Dependent ◯ Totally Dependent ◯ Unknown

Past Surgical History _____

Social History

☐ Access to Running Water ☐ Access to Electricity

☐ Access to Indoor Latrine ☐ # of Cohabitants _____

Cohabitants

Employment

◯ Professional / Student

◯ Manual Labor

◯ Unemployed

◯ Other

Education Level

◯ No Formal Education ◯ Completed Primary School

◯ Completed Secondary School ◯ College Education or Higher

Distance Traveled (time)

Method of Transportation

◯ On Foot ◯ Motorcycle ◯ Automobile

◯ Other

Body Temperature BP HR SaO2

ASA Class

◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5

Physical Exam

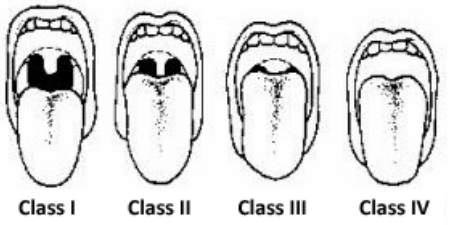
Mallampati Score

◯ 1

◯ 2

◯ 3

◯ 4



Thyromental Distance (finger breadths)

Neck Mobility

☐ Full Extension ☐ Full Flexion

☐ Other

Mouth Opening

◯ Full ◯ Restricted

Assessment

Plan

Operative Patient ◯ Yes ◯ No

Surgical Attending

Anesthesia Attending

Non-Operative Patients Only

- ☐ Non-surgical Disease
- ☐ Surgical Disease, too far advanced for surgery anywhere
- ☐ Surgical Disease, too far advanced for surgery at HST (answer next question)
- ☐ Surgical Disease, excluded for medical co-morbidities
- ☐ Surgical Disease, not within expertise of EUSOM surgical team

Why is surgical disease too far advanced for intervention at HST (select all that apply)

- ☐ Lack of proper surgical equipment
- ☐ Lack of proper anesthesia equipment
- ☐ Lack of postoperative care at facility

CONSENT TO PARTICIPATE IN RESEARCH

Entwodiksyon

Nap mandew si ou ta vle patisipe lan yon etid rechech. Avan ke ou aksepte si ou ta vle patisipe ou pa, tanpri koute enfomasyon ki sou papye sa. Patisipasyon ou se chwa paw. Si ou deside patisipe lan etid rechech la, ou ka chanje lidew pita oswa retire tet ou. Desizyon pou patisipe ou pa, pap few pedi privilej tretman ou. Si ou deside pou pa patisipe lan etid lan, Dokte ou ap kontinye trete ou.

Plan etid lan

Rezon nap fe etid lan se pou nou ka rasamble enfomasyon sou moun ke nap trete yo, e sou tretman ke nap bay yo. Sa ap ede nou amelyore jan ke nou trete malad nou yo e pou nou ka pi byen trete yo avan, pandan e apre operasyon yo.

Detay

Pou etid lan, nap posew kesyon pandan tretman an e repons ke ou bay yo ap lan yon dosye. Nap anrejistre kek enfomasyon sou tretman ou an tou.

Risk ak malez

Tout etid rechech gen posibilite pou risk oswa malez. Risk ki pi kouran lan etid sa se malez pandan enterogasyon an poutet kesyon sansib ke nou ka poze, plis pil tan sa ka pran pou reponn yo. Lan nenpot etid rechech, gen risk pou enfomasyon ou soti kotel pat ta dwe. Pou nou pwoteje enfomasyon ou, nou pap ekri non ou sou ni repons ke ou ba nou ni sou ranseyman ki gen rapo ak tretman ou. Tout enfomasyon ou ap lan yon dosye avek “mot de passe”.

Benefis

Pap gen okenn benefis pou ou pou patisipasyon ou lan etid lan. Etid sa se pou nou ka aprann plis bagay sou malad ke nap trete yo. Resilta yo ka edenn ak lot malad ke nou ka trete demen.

Peman

Ou pap resevwa lajan pou patisipasyon ou nan etid sa.

Pemisyon pou komanse

Eske nou ka komanse ak kesyon yo?

CONSENT FOR OPERATIVE PROCEDURE

Oumenm ak doktè ou te deside ke fè operasyon an se fason ki pi bon yo ranje pwoblèm medikal ou yo. Anvan ou fè operasyon an, li vrèman enpòtan pou ou konprann sa w ap gen pouw fè ak poukisa ou bezwen fè li. Si ou poko diskite sa a avèk doktè ou, asire w ke ou fèsa.

Nan jou wap fè operasyon an, ou ap resevwa yon IV (Sewòm) anvan ou ale nan sal operasyon an. Sa a se fason doktè a pral ba ou medikaman pandan operasyon ou a. Yon fwa ke ou nan sal operasyon an, yap mete ou sou operasyon epi yo pral ba ou anestezi ki pou anpeche santi doulè pandan operasyon an. Apre w fin pran anestezi a, doktè a ap ede ou pou ou abouje nan pozisyon ki pi bon pou operasyon an. Yo ap netwaye espas operasyon an ap fèt la ak yon savon espesyal ki ap touye mikwòb epi mete fèy papye ble alantou espas operasyon ou a ki pou anpeche li sal. Pandan operasyon an, ou ka santi yap rale ou oswa manyen ou pandan Medsen yo ap travay, men ou pa ta dwe santi doulè. Yon fwa ke operasyon an fini, yap mennen ou nan tounen nan espas chirijikal la kote ou ka repo ou ak reprann fòs ou. Pandan tout operasyon an, Doktè yo ap la avèk ou pou yo reponn nenpòt kesyon ou genyen sou sa k ap pase oswa ki pral fèt, yap voye je sou ou ak asire yo ke ou yo san danje.

Menm jan ak anyen nan medikaman, pa gen okenn risk pou operasyon an. Risk ki pi komen yo se doulè nan sit la operasyon an ak enfeksyon. Genyen yon ti posibilite ke pati nan kò a ki prè sit operasyon an ka domaje, epi ou ka senyen plis pase nivo nòmal la pandan oswa apre operasyon an, ou ka gen yon sikatris, oswa pwoblèm nan kè oubyen nan poumon . Si yon konplikasyon rive, doktè ou ap pran swen ou jiskaske pwoblèm-nan rezoud.

Si pandan operasyon an ou senyen twòp, doktè ou a ka deside ke ou bezwen san pou yon rezon ki medikal, epi li ap ba ou san.

Ou ka deside fè operasyon an pou ou korije (rezoud) pwoblèm ou an si ou santi ke risk operasyon yo twòp.

Nan kèk minit, yo pral ba w yon moso papye ki ap di ou menm bagay yo ki nan videyo sa a. Lè ou siyen li, li vle di ke ou konprann poukisa ou pral fè operasyon an. Sa vle di tou ke ou konprann risk ki gen nan operasyon an epi ou dakò ke ou ta renmen fè operasyon an. Si w gen nenpòt kesyon sou operasyon ou a, ou pral kapab mande Doktè a.

SURGERY SCHEDULE / DAT DE L'INTERVENTION

Patient Name / Nom	
Date of Operation/ Date de l'intervention	
Pre-Operative Diagnosis / Diagnostic preoperatorie	
Procedure / Type d'intervention	
Medical Student	
Surgeon / Chirugien	

PRE-OPERATIVE VITALS AND LABS:

Body Temperature | BP | HR | SaO2

Hemoglobin | HIV | RPR

INTRA-OPERATIVE DATA

Surgeon | Anesthesiologist

Medical Student

Date of Procedure

Procedure

Additional Procedure ◯ Yes ◯ No | Additional Procedure

Anesthesia Type
◯ General ◯ MAC/ IV sedation ◯ Epidural
◯ Spinal ◯ Regional ◯ Local
◯ None ◯ Other

Wound Classification
◯ Clean ◯ Clean/ Contaminated ◯ Contaminated
◯ Dirty/ Infected

Skin Prep

Method of Hair Removal
◯ Clipper ◯ Razor
◯ Other

Duration of Anesthesia

Total Operative Time

IVF (mL)

EBL (mL)

Brief Op-Note

DISCHARGE SUMMARY

Date

POD (LOS)

Hospital Course

Discharge Medications

Medication 1

Medication 2

Medication 3

Medication 4

Activity

Discharge Activities:

Discharge Packet ☐

Wound Care Video ☐

Follow-Up Appointment ☐

Follow-Up Date

Intent to Return to Follow Up Clinic ◯ Yes ◯ No

FOLLOW-UP SCHEDULE / DAT POUR RETOURNE

Patient Name / Nom

Appointment Date / Date appoitmen

Date of Operation / Date de l'intervention

Date of Discharge / Date de discharge

Procedure / Type d'intervention

Medical Student

Operative Surgeon / Chirugien

FOLLOW-UP DATA

Patient Name

Date POD

Subjective

Body Temperature BP HR SaO2

Objective

Assessment

Plan

Wound Dehiscence
- ◯ No Complication
- ◯ Superficial Wound Disruption
- ◯ Deep Wound Disruption

Superficial Incisional Surgical Site Infection ◯ Yes ◯ No

Deep Incisional Surgical Site Infection ◯ Yes ◯ No

Sepsis ◯ Sepsis ◯ No Complication

Unplanned Readmission ◯ Yes ◯ No Date of Readmission

Unplanned Reoperation ◯ Yes ◯ No Date of Reoperation

Appendix 3: Definitions of Variables

Does condition process affect activities of daily living?	Does the condition noted in the chief complaint affect the patient's ability to work, have sexual intercourse, etc.
Diabetes	Is the patient currently on medication for high blood sugar or have they ever been told by a doctor that they have diabetes of high blood sugar?
Hypertension	Is the patient on medication for high blood pressure or have they ever been told by a doctor that they have high blood pressure, or is their blood pressure at this visit greater than 140/90
Smoker within 1 year	Has the patient smoked in the last year
# of packs per day	On average, how much does the patient smoke? This may be in individual number of cigarettes each day.
Dyspnea	Does the patient have difficulty breathing or get short of breath while sitting and talking (Rest); or does the patient get short of breath while walking up stairs, working (Moderate Exertion)
Social History	At home, does the patient have access to running water or a well? Is there electricity in the primary place that the patient stays Is there an individual or shared latrine at the primary place the patient stays How many people share the same primary place of living with the patient
Employment	What is the patient’s primary source of employment
Education Level	List the highest level of education attained
Functional Status	The patient's ability to perform activities of daily living in the 30 days prior to surgery. Activities of daily living are activities that are normally performed in the course of a normal day (bathing, feeding, dressing, toileting, mobility). Independent: Does not require assistance from another person for any activities. A person is able to function without assistance from prosthetics, equipment, or devices. Partially dependent: Requires some assistance from another person for ADLs; Totally Dependent: Requires total assistance for all ADL; Unknown: Unable to ascertain
Additional Procedure	Additional operative procedure performed by the same surgical team under the anesthetic which is different from the principal operative procedure.

Anesthesia Type	Principal anesthesia technique used. General anesthesia takes precedence over other forms of anesthesia, then MAC, then epidural, then spinal, then regional, then local.
Wound Classification	Assign based on the primary principal procedure being performed. Clean: Uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. Typically primarily closed. Examples: mastectomy, exploratory laparotomy, hernia repair, thyroidectomy. Clean/Contaminated: Operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions - specifically, operations entering the biliary tract, appendix, vagina, and oropharynx. Example: cholecystectomy, colectomy, small bowel resection, TURP. Contaminated: Open, fresh, accidental wounds or operations with major breaks in sterile technique. Examples: appendectomy for inflamed appendicitis, bile spillage during cholecystectomy. Dirty/Infected: Old traumatic wounds with retained devitalized tissue and those involving existing clinical infection or perforated viscera. Examples: excision and drainage of abscess, perforated bowel, peritonitis, ruptured appendix.
Skin Preparation	Method of skin preparation. Example: chlorhexidine or betadine
Duration of Anesthesia	Total time of anesthesia administration in minutes, particularly for general. For epidural or spinal anesthesia, note time from initiation of spinal anesthesia until end of operative procedure.
Total Operative Time	Duration of operation in minutes from incision to final closure.
Postoperative Length of Stay	Total number of days spent in hospital. If patient is discharged on POD 0, then LOS is 0
Intent to Return to Follow-Up Clinic	Does the patient plan on returning for their scheduled follow up appointment
Wound Disruption	In the abdomen: a loss of the integrity of fascial closure; In other surgical sites: a total breakdown of the surgical closure compromising the integrity of the procedure
Superficial Incisional Surgical Site Infection	Infection occurs within 30 days of the operation and the infection involves only skin or subcutaneous tissue of the incision and at least one of the following: purulent drainage (with or without lab confirmation); OR at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat

	AND incision is deliberately opened by the surgeon; OR diagnosis of superficial incisional SSI by the surgeon. DO NOT REPORT: stitch abscesses, infected burn wound.
Deep Incisional Surgical Site Infection	Infection occurs within 30 days of the operation and the infection appears to be related to the operation and infection involved deep soft tissues (fascial and muscle layers) of the incision and at least one of the following: Purulent drainage from the deep incision but not from the organ/ space component of the surgical site; OR a deep incision spontaneously dehisces or is deliberately opened by a surgeion when the patient has at least one of the following signs and symptoms: fever (>38 C), localized pain, or tenderness; OR an abscess or other evidence of infection involving the deep incision is found on direct examination or during reoperation; OR diagnosis of a deep incision SSI by a surgeon
Sepsis	Intent of variable is to capture the patient whose physiology is compromised by ongoing infectious process after surgery. 1. Sepsis - 2 of the following clinical signs and symptoms of SIRS: Temp > 38 or < 36; HR>90 bpm; RR>20 breaths/min; WBC > 12,000 cell/mm3 AND EITHER A OR B. A: (One of the following: positive blood culture; clinical documentation of purulence or positive culture from any site for which there is documentation noting the site as the acute cause of sepsis) B: (One of the following findings during the principal operative procedure: purulence in the operative site; enteric contents in the operative site; positive intra-operative cultures.
Unplanned Readmission	Readmission to any facility for any reason within 30 days of the principal operative procedure
Unplanned Reoperation	Readmission to any facility for any reason within 30 days of the principal operative procedure