

### The Lancet Commission on Global Surgery Teaching Case

**Entrepreneurial Leader Collection** 

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# NSQIP-LITE: MEASURING SURGICAL OUTCOMES IN MOZAMBIQUE

On a Tuesday morning in the fall of 2014, the Medical Education Partnership Initiative (MEPI) Working Group assembled at an oval table in a conference room at the offices of Universidade Eduardo Mondlane (UEM) in Maputo, Mozambique.¹ The fan overhead provided a welcome breeze against the early-morning humidity. The group was preparing to review the most recent findings from its much-anticipated NSQIP-Lite research. NSQIP-Lite is a shorter version of the National Surgical Quality Improvement Program (NSQIP), a program widely used in United States hospitals to measure risk-adjusted surgical outcomes and to improve the quality of surgical care. Conversation was light and collegial as the participants greeted one another. Through their commitment to a shared vision, the team members, who hailed from Mondlane University, University of California, San Diego School of Medicine (UCSD), and Mozambique's Ministry of Health, had developed not only professional ties during the preceeding years, but also close personal bonds. Their aim was to define surgical needs in rural areas of Mozambique and, ultimately, improve surgical delivery.

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<sup>&</sup>lt;sup>1</sup> Information about the Medical Education Partnership Initiative (MEPI) can be found at http://www.fic.nih.gov/programs/Pages/medical-education-africa.aspx. The website for Universidade Eduardo Mondlane (UEM) is http://www.uem.mz. Both websites accessed January 2015.

The team took a few moments to reflect on how far the work had advanced over the past 36 months. Prior to initiating the NSQIP-Lite program, which sought to establish a 'risk-adjusted' approach to monitoring surgical outcomes in Mozambique, work of this kind was uncommon in the developing world. To advance its surgical outcomes research, the MEPI Working Group selected three pilot hospitals in geographically dispersed regions of Mozambique. The group systematically gathered approximately 1,000 patient records, data it believed necessary to better understand and predict surgical outcomes.

A simple example represented, on a basic level, the reasoning behind risk-adjustment. Dr. John Rose, a UCSD surgery resident, offered a hypothetical, "If my 88 year-old grandmother with heart failure and pneumonia goes to a hospital and has her appendix taken out, she is very different from my 12 year-old nephew who [had his appendix removed and] is otherwise completely healthy." Without risk adjustment, statements relating to morbidity and/or mortality of these two patients would carry very little statistical weight or comparable clinical information. "Mortality statistics alone do not allow us to make conclusions about what's really happening in health care," Dr. Rose said.

A number of technical research questions had animated the minds of the MEPI Working Group throughout the preceding months; a great deal of time, thought, and care had gone into developing and implementing optimal research protocols. However, with 1,000 patient records now gathered, a set of related administrative and strategic issues began to come into focus. The group considered how it could make the best use of the data to advance its goal of improving surgical delivery in Mozambique.

For months, the team had been discussing potential applications of the data. Some advocated for a focus on Quality of Care improvements at the pilot sites, while others suggested applying generalizable strategies and system-related improvements, generally called Implementation Science, across the country. Still others wondered whether, and to what extent, the new data might be beneficial to bolster fundraising efforts. Would organizations such as the Gates Foundation or World Health Organization (WHO) be interested in these findings?

#### The MEPI Working Group: Profiles and Perspectives

Composed of closely-affiliated and committed researchers, the MEPI Working Group was deeply collegial. Individual members tended to be self-effacing, habitually sharing credit or deflecting attention from any one individual's contributions to the group. However, the MEPI Working Group did see its research as foundational to the broader surgery research efforts in Mozambique, in other African countries, and around the world.

Four key actors constituted the core of the MEPI Working Group:

**Dr. Emilia V. Noormahomed** Educated in Spain and holding both an MD and PhD in parasitology, Dr. Noormahomed acknowledged that she "understands a little bit about surgery." As the MEPI Principal Investigator (PI), she oversaw not only research related to NSQIP-Lite, but also other Mozambique-focused research streams for which UEM had received \$11 million in funding from the U.S. government.

A former UEM dean, Dr. Noormahomed commented, "Apart from infectious disease, I have a special interest in medical education." She was instrumental in deepening the relationships with researchers from UCSD, which grew, as she said, "from a previous small research project" to "thinking about other ways of cooperating," and culminated in the MEPI partnership.

One of Dr. Noormahomed's chief priorities was to ensure the sustainability of the group's work. She explained, "even after a program or initiative is complete, we have to find ways of sustaining it into the future." To that end, Dr. Noormahomed and her counterparts in other African countries created a "Council of Principal Investigators" representing public health leaders in Sub-Saharan Africa. They met every six months to discuss and advance ways to reach the elusive goal of creating sustainable health care systems within their respective countries.

**Dr. Stephen W. Bickler** A professor of surgery and pediatrics at UCSD, Dr. Bickler had made many trips to Africa during his career, including working in The Gambia as a pediatric surgeon for two-and-a-half years. An experienced researcher, Dr. Bickler was involved with MEPI from the start. He oversaw the research fellows carrying out work in Mozambique,

including Dr. Rose. As a "senior person at UCSD," Dr. Bickler looked to "provide opportunities" and guidance to other researchers. He believed that it was important to allow appropriate freedom to learn through experience and meet the many inevitable challenges that global research presented, "My job [in overseeing Dr. Rose and other research fellows] is to sit back and watch things a little bit, okay, which can be frustrating. But one of the things I learned as a pediatric surgeon working in The Gambia was how much you learn from kind of struggling sometimes."

Dr. Bickler was passionate about advancing awareness, status, and funding relating to global surgery. He commented,

You look at the NGOs in Mozambique, you look at the level of funding provided. For HIV, the budget is over \$200 million a year. And what does surgery get? Nada. I hope it's going to change. I've spent a good part of my career trying to collect data and make logical arguments that surgery actually needs to be better represented, and I was fortunate to be put in charge of the Global Burden of Disease part of the Disease Control Priorities (DCP3). And when you do all of the analysis, the burden turns out to be about one-and-a-half times the burden relating to turberculosis, HIV, and malaria. It's massive, just massive.

**Dr. John Rose** A UCSD surgery resident, Dr. Rose noted that his relationship with Dr. Bickler at UCSD and an interest in "public health, or population health research" drew him to the work in Mozambique. Work on the NSQIP-Lite research involved periodic visits from his home in California to pilot sites in Mozambique approximately every two to three months. Dr. Rose noted that his site visits, lasting three to four months each, involved "getting things to the next step of implementation" and then "taking a step back and letting people on site go on their own for a while."

Dr. Rose, age 34, maintained a strong belief that once a rigorous approach to capturing risk-adjusted outcomes was implemented in Mozambique, the implications for patient health and well-being would be substantial. In keeping with the expectations for young surgeons conducting important research in the field, he expected to publish papers about the MEPI research through traditional academic outlets.

Dr. Rose, who learned Portuguese to prepare for his role, spent much of his time during implementation of the project working closely with site data on his encrypted laptop, bringing innovative ideas to surgeons and staff at the pilot sites, educating stakeholders about the goals and progress of the project, and connecting with other MEPI Working Group members to make mid-stream course corrections.

**Dr. Carlos Funzamo** An epidemiologist by training, Dr. Funzamo provided a direct link to the Mozambique Ministry of Health, where he had worked for 14 years. Dr. Funzamo attended most pilot site visits with Dr. Rose, often providing introductions to key stakeholders, helping with logistics and travel, and serving as a sounding board to advance the work of MEPI.

Dr. Funzamo saw the Ministry of Health as "very open in terms of new proposals—they want to improve our health system." He acknowledged the inherent lack of funding available for new projects, while remaining optimistic about the effect NSQIP-Lite would have. "This is very exciting, something new," he said, "We've never conducted such a study in Mozambique." He indicated that the results of the study "might help us come up with new policy" and placed importance on "understanding the real figures" and "finding out something that we don't know yet." One specific aspiration Dr. Funzamo mentioned in connection with the MEPI research was to increase the number of qualified surgeons serving Mozambique.

#### **Country Context: Mozambique Past and Present**

"It is necessary to know what happened in this country during the colonial time, the war, and the time just after independence," said Dr. Fernando Vaz, "if you are to understand anything about our present experience." In addition to being an active surgeon in Mozambique for 25 years, Dr. Vaz also served as director of Central Hospital of Maputo for 10 years. He was the Mininster of Health in the 1980s and 1990s.

War for independence began in September 1964 and ended more than a decade later, when full independence from Portugal was achieved in 1975. The transition to life as an independent state was anything but smooth. The country encountered a number of barriers to

proper development, including "large-scale emigration, economic dependence on South Africa, severe drought, and a prolonged civil war." The civil war, which spanned from 1975 to 1992, succeeded in separating people from each other, while also impairing critical economic development and compromising the country's basic infrastructure. A U.N.-negotiated peace agreement between the Frelimo and Renamo warring factions ended the war.

By the conclusion of Mozambique's civil war, the vast majority of educated professionals, including physicians, had left for Portugal. For those who remained, a commitment to rebuild Mozambique out of the ashes of war became paramount. "It was about a dream to create a new country out of ruin," Dr. Vaz explained. "It would be very easy to look back now and feel bad that I could have fled to Portugal and had a 'perfect life' without all this war-torn stuff," he said. "But even now I don't look back and regret it."

#### Meeting the Demand for Surgical Care: The Shortage of Surgeons

The history of depleted human resources in Mozambique extends far beyond the twentieth century. Dr. Peter Bendix, Fogarty Clinical Research Fellow at Dartmouth-Hitchcock Medical Center, offered the following summary:

There are structural issues in Mozambique that are 500 years old, and a colonial history that set up a system of separation that provided zero education to the majority of its population for 450 years. Then you have a period where nearly all the educated people in the country left. These were the same people who had gained so much benefit from the country in which they lived. And then you're trying to rebuild a health system in 40 years to go from zero to something that has taken 150 years in America. The fact that Mozambique has come this far under these circumstances is pretty damn amazing.

The number of physician surgeons practicing in Mozambique remained extremely low. Most estimates placed the number between 20 and 25, serving a population of about 25 million. Dr.

<sup>&</sup>lt;sup>2</sup> World Factbook, Mozambique Background, https://www.cia.gov/library/publications/the-world-factbook/geos/print/country/countrypdf\_mz.pdf. Site accessed January 2015.

Noormahomed noted that one of the biggest challenges facing Mozambique's health care system was a "shortage of human resources—a shortage of surgeons." She explained,

Surgeons are very few in this country, and of course very, very busy. So when you are a medical doctor in the hospital, the first thing asked of you is to take care of the patients, first and foremost. And then if you have time left, you will think on research, you will think on teaching. Since our doctors are so overwhelmed with work and patient care, there is little time afforded them to do research and teaching. So, yes, the challenge is to have many more people trained to become physicians in Mozambique.

An estimated 35% of Mozambique's population had either a current or previous surgical issue.<sup>3</sup> As of 2014, Mozambique maintained 56 rural hospitals, eight provincial hospitals, and three central hospitals, situated in a country whose land mass was about twice the size of California. Compounding its surgeon shortage was the fact that many Mozambican patients faced challenging, often prohibitive, circumstances in travelling back and forth to hospitals. Dr. Funzamo explained,

It's a challenge because first of all, the majority of our patients live far from our hospitals. They go to surgery, they're discharged, and they go home. Sometimes it's difficult to come back, to come just for follow-up. For those who live close it's much easier. But for the vast majority, they live very far away. They certainly live far from the biggest hospitals.

In 2012, the Mozambican government allotted approximately \$40 per capita for health expenditures, compared with the regional average of about \$1,000 per capita. Respectively, only 0.4 physicians and 4.1 nurses and midwives per 10,000 citizens served Mozambique. (See **Exhibits 1A** and **1B** for additional WHO health data on Mozambique.) Some seasoned doctors feared that the strain of working in the resource-constrained public system forced doctors to find part-time positions in private clinics in an effort to supplement their incomes. Dr. Bendix pointed out that while some Western surgeons enjoyed the luxury of insisting on

<sup>&</sup>lt;sup>3</sup> Estimate provided during case interview with Dr. Stephen Bickler.

using only their favorite suture in the operating room, or choosing among needles of fine size gradations, Mozambican surgeons typically made do with only a perfunctory kit of medical supplies. "They've got one suture for a hernia repair at many of the district hospitals," he said. "No one individual should be faulted for having poor [surgical] outcomes in many of the country's facilities."

#### Cultivating a Research Environment

Despite the country's dramatic need for increased healthcare infrastructure and spending, Dr. Rose viewed the medical research environment in Mozambique as relatively "progressive" and particularly well-suited to a project like NSQIP-Lite. Dr. Rose described the data-centric culture that existed in Mozambique,

Five or six years ago, the Ministry of Health started holding meetings every other year to review surgical statistics. In terms of research infrastructure, Mozambique has a National Institute of Health, which collects reports from each province, with the provinces consisting of many districts. And so the director of each province will present their health report from the surgical perspective every two years. In my mind, this is something that is very progressive, as many countries don't operate this way.

Given the culture of data collection and the existence of a nationalized healthcare system, Dr. Rose believed that some aspects of NSQIP-Lite would be easier to implement in Mozambique than they might be in the United States:

I find the process of collecting data much easier than in the United States, because clinicians in Mozambique are accustomed to having their work evaluated. When someone in the US says "we want you to collect data or fill out a form", you get a lot of hems and haws from the surgical department. But in the Mozambican context, after seeking consent of the local health authorities, there is a nationalized healthcare system where order and structure come down from the top, so dissemination is more streamlined.

#### Promoting Surgery: A Global Health Agenda

Public funding for surgery-related resources was historically limited in Mozambique. Researchers, clinicians, and policy makers with a strong interest in improving surgical delivery on a global scale often lamented the relatively low level of funding and attention given to improving the treatment of surgical disease in low- and middle-resource countries, whether drawn from governmental, non-governmental, or philanthropic sources. Dr. Bickler noted a recent primary health care project in Northern Mozambique, funded at about \$70 million, "that didn't even mention surgery—so surgery got no attention." He continued, "Until there's a concept that surgery is a component of health systems, then it is never going to change. You know, surgery is always going to be forgotten."

A common explanation for sub-standard funding of surgery-related research, supplies, and other initiatives rested on a kind of zero-sum game for health funding; prevalent infectious diseases such as HIV/AIDS, tuberculosis, and others tend to draw the largest share of the funding. Of Mozambique's \$1 billion annual budget, an estimated one third was spent on health, of which 80% was directed towards HIV/AIDS.<sup>4</sup>

Important global players also appeared drawn to funding the treatment of high-profile, dangerous infectious disease, with the U.S. government allocating \$6 billion to HIV/AIDS outside the United States in 2014.<sup>5</sup> Few questioned the wisdom of funding these prominent global diseases, and much progress had been made in recent years to stem infection and mortality rates of HIV/AIDS worldwide. Dr. Bendix stated, "Bilateral donors and large funding agencies like the World Bank and WHO are focused on things that are considered to be causing the most morbidity and mortality." He continued, "The idea is 'We've got to choose just a couple of problems to focus on – let's pick these." Because HIV and malaria were the leading causes of death in Mozambique (see **Exhibit 2** for the Top Ten Causes of Death in Mozambique), funders appeared to be following a "get the most bang for the buck" strategy.

<sup>&</sup>lt;sup>4</sup> Estimate drawn from case interview with Dr. Peter Bendix.

<sup>&</sup>lt;sup>5</sup> Kaiser Family Foundation, "U.S. Federal Funding for HIV/AIDS," http://kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hivaids-the-presidents-fy-2015-budget-request/. Site accessed January 2015.

## NSQIP-Lite: Measuring Surgical Outcomes in Mozambique BAB300 / MARCH 2015

However, although these diseases were the top ten causes of death, these rankings fail to include surgery, which impacted the mortality and quality of life of patients.

However, some global health professionals questioned the rationale of dedicating such a high percentage of aid dollars to a relatively small number of infectious diseases. In recent years, there had been increasing criticism of disease-specific or "vertical" approaches and a push for interventions that focused more on developing health systems and capacity building, often called "horizontal" or "diagonal" approaches, such as the MEPI working group. An upcoming 2015 Lancet Commission Report on Global Surgery might also help to raise awareness of global surgery needs, but as of yet, there had been no major changes in funding.

Furthermore, others argued that some of the common metrics used to define the costs and patient outcomes of specific health problems were overly simplisitic and failed to capture the broader needs of the population. For example, Dr. Bickler indicated that mortality rates relating to surgical disease were grossly understated in Mozambique. "Mortality rates at district hospitals in Mozambique are pretty low," he stated. "It might be one percent. In the U.S., it might be way below 0.1 percent. But in Mozambique, nobody wants to go to the hospital to get a surgery (they don't trust) and die from it. So people don't go. Mortality is then a very misleading number."

#### Medical Education Partnership Initiative (MEPI): Moving in the Right Direction

Launched in 2008, MEPI was a partnership between UEM and UCSD, with the support of Mozambique's Ministry of Health. One key feature of the partnership, which received funding through the U.S. Department of State,<sup>6</sup> was that it was a Mozambican-driven program that sought to fulfill a Mozambican research agenda. Dr. Rose commented,

I would be very quick to point out that I am a member of the team and not the head of the team. The head of the team is Mozambique and has always been Mozambique. The team is based at the University Eduardo Mondlane, and it is led by a partnership because that is the way the grant is set up. This partnership

<sup>&</sup>lt;sup>6</sup> The U.S. Department of State disbursed \$130 million in MEPI funding, \$11 million of which went to Mozambique. Source: Case interview with Dr. Noormahomed.

mechanism is designed to give power to the African institution. So the money actually goes to the African institution, to the researchers within that institution. And then they decide who they are going to partner with, with a requirement that they partner with a U.S. institution.

#### Creating MEPI Leadership and Vision

In putting many research programs in place under the MEPI umbrella, Dr. Noormahomed worked with great care to assemble a committed team of Mozambican researchers. She explained,

We created a core group of researchers, Mozambican researchers, and we work together with our partners from UCSD. We identified young people, junior residents interested in doing research. We organized courses, writing grants, writing manuscripts, writing research methodolgies—to provide them all the tools they need to be future researchers. We identified mentors for the different ideas they have for research, and they developed their research proposals. We believe that over time we will be able to scale up the number of researchers in the country.

The NSQIP-Lite project fit well with the research interests of UCSD's Dr. Rose and his mentor, Dr. Bickler, who observed, "The main thing is to have a specific question you want to answer. As a researcher, what drives me is, I want to know how I can improve global surgery. We have an important question, a question we want to answer, a problem we want to solve."

#### Researching Surgical Outcomes

The specific aim of the NSQIP-Lite research was to develop and implement a data-gathering protocol to monitor surgical outcomes in resource-poor hospital settings in Mozambique. Hospitals in the country already maintained standard logbooks that captured important clinical variables, including basic patient profiles. It was not clear, however, if this data could be used in a systematic way to monitor and improve surgical delivery in the future. Specifically, there was no mechanism in place to compare outcomes across patients, across

hospitals, or across systems of care. If, for example, mortality rates resulting from Caesarean deliveries varied greatly between Hospital A and Hospital B, it was difficult to draw statistically-supported conclusions about what factors accounted for these differences. Did the patients themselves differ in terms of age, health status, or some other critical variable? Did one hospital have relatively inferior medical supplies and infrastructure, such as a blood bank? Was there an important difference in the training and expertise of surgeons responsible for patient care?

Understanding the relative risk profiles across patients could be difficult. Dr. Rose commented,

Suppose you've got two women who come in pregnant. One of them is bleeding, and she's lost a liter of blood, and the other has a dead fetus inside of her uterus. Which one has more risk for post-operative infection? That's actually really difficult to understand, the discrete difference between the two cases. What we've done in the United States, we've created a kind of gold standard system to risk-adjust for surgical outcomes, so we know that if there are two hospitals that have different mortality rates, or any other metric, I'm just picking on mortality in this case. If they have variation in mortality rates, we need to account for the case mix that presents itself to that hospital. So for example, does an academic center see much more difficult cases because it is an academic center, or does a private hospital seek only certain case types because they can refuse or defer care to other people, or does a county hospital see certain cases because it's a county hospital, and they can't refuse care because it's a public institution? So accounting for the patient population is a huge part of evaluating surgical services.

#### Working from Precedent

The "gold standard" approach to risk-adjustment was known as the National Surgical Quality Improvement Program, or NSQIP. It was well-established in the United States and followed a rigorous data-gathering protocol involving 135 distinct variables for each patient, cutting

across pre-operative, intra-operative, and post-operative complications. Administratively, this required hiring a full-time nurse for the explicit purpose of verifying the variables.

While the depth and rigor of NSQIP was laudable and provided statistically relevant findings when administered in the United States, carrying out NSQIP in its full form was impractical to the point of being prohibitive in low-resource countries such as Mozambique. Still, the MEPI Working Group believed that a customized version of NSQIP, referred to as "NSQIP-Lite" among team members, could provide valuable evidence-based insight that might otherwise never materialize.

In conceiving its research strategy and project plan, the MEPI Working Group divided their activities into four broad areas: 1) planning, 2) developing messages and materials, 3) implementation, and 4) assessing effectiveness and making refinements.

#### Planning and Strategy Development

One decision that the project team needed to make was determining which hospitals would serve as pilot locations for the research. The MEPI Working Group decided on three rural hospitals located in geographically disperse locations of Mozambique: Chokwe (southern), Nhamatanda (central), and Ribaue (northern). (See **Exhibit 3** for Map of Mozambique showing location of the three pilot sites.) Dr. Funzamo, who would eventually accompany Dr. Rose on site visits, indicated that finding sites in different regions of Mozambique was important, as was finding sites with a sufficiently high population; each hospital's catchment area was composed of approximately 250,000 people. The pilot sites needed to represent regional differences and be significant in size to ensure a large data sample. Additionally, some members of the MEPI Working Group had already developed relationships with physicians and staff at hospitals in Chokwe, Nhamatanda, and Ribaue as a result of a prior research project. These existing relationships, the team believed, would help to pave the way for deeper involvement and collaboration.

Before visiting any of the sites to begin implementation, the MEPI Working Group determined which variables they believed would predict surgical outcomes in Mozambique. Dr. Rose and his colleagues expected the number of variables could be greatly reduced while

still maintaining a high level of statistical significance. This initial hypothesis proved correct. Dr. Rose explained, "We took the entire NSQIP database, and we ran multiple regression to find out how many variables you need, and in what sequence, before you see diminishing returns on the discriminatory value for post-operative complications and mortality." Focusing on so-called in-hospital outcomes was another adaption the team made to its low-resource setting. The practical difficulties of obtaining follow-up data from patients who, on average, faced difficulties returning to the hospital for post-surgery follow-up drove this adaptation.

The team determined that only four variables were required to achieve a C-Statistic of 0.93.7 In fact, the researchers found that a single variable actually accounted for about 70% of variation. The crucial variable used to predict mortality and morbidity outcomes was called the ASA score, a score on a scale of one to six based on the patient's Physical Status, given prior to surgery by the attending anesthesiologist (See **Exhibit 4** for the ASA Physical Status Scale.) "It mattered more than any lab value, more than any vital sign," Dr. Rose explained. "In a way it's bizarre, because we like to think that our technology and labs and testing are so very important. And yet across the board, across multiple types of surgery, ASA was the one thing that really mattered most."

#### Developing Messages, Materials, and Approach

In the months leading up to the first site visit in 2011, the MEPI Working Group developed a computer-based platform for gathering patient data. From the outset, there was a strong interest in developing a simple, user-friendly approach to gathering and recording data, one that would not overly tax the clinicians and hospital staff.

The MEPI Working Group recognized that it would be impractical to hire a full-time person devoted to data gathering and verification, as was the practice in resource-rich U.S. hospitals carrying out the full-scale NSQIP model. Nonetheless, the team believed that assigning and training one person at each pilot hospital to serve as the Surgical Quality Champion was

<sup>7</sup> C-Statistic was defined as the probability that predicting the outcome is better than chance. Values for this measure range from 0.5 to 1.0. A value of 0.5 indicates that the model is no better fit than chance at making a prediction of membership in a group and a value of 1.0 indicates that the model perfectly identifies those within a group and those not. (From Manitoba Centre for Health Policy).

important. In the words of Dr. Rose, the team expected the Surgical Quality Champions to "be the ones who are ultimately responsible for data collection," and to serve as a link for the hospital, the Ministry of Health, and the MEPI Working Group.

The MEPI Working Group followed an approach to research collaboration based on Frederick Murphy's "Community Engagement, Organization, and Development for Public Health Practice." This included identifying local customs and surgical practice, assessing available resources and assets, and identifying community gatekeepers to accommodate formal and informal leadership roles. For example, the Surgical Quality Champions became important leaders for the group's work and local surgeons' opinions were critical for deciding which variables to use in NSQIP-Lite. This approach squared more generally with Dr. Bickler's summary of his work in a variety of settings in Africa, "I think I learned a long time ago from my work in Africa that relationships are everything. And so our job is to be as supportive as possible, to move things along, but at the same time to let others lead things."

#### Learning from Initial Implementation

Following many months of preliminary planning and data work, including selecting the three pilot sites, developing a statistically-supported sub-set of pre-operative variables which were most critical for predicting post-operative outcomes, as well as developing a computer-based platform for building the new database registry, it was time for the MEPI Working Group to move on-site. The plan was for Drs. Rose and Funzamo to begin the implementation period by visiting Chockwe. Located just three hours by car from the capital city of Maputo, Chockwe was the most logical site because of its proximity to the research team at UEM. Once the Chockwe site was set up, the plan was for Dr. Rose and Dr. Funzamo to visit all of the sites on a rotating schedule, at a rate of one site every two months.

The first visit to Chockwe in the summer of 2012 proved to be, in Dr. Rose's words, "a flop." One of the early challenges included the fact that the iPad designated for collecting data "disappeared in a week," leaving the researchers with no way to begin developing the registry. In addition to this technology problem, it was clear that the research team and the on-site clinicians and staff at the hospital in Chockwe lacked a shared understanding of the methods

and goals of the project. The research team had underestimated the challenges of seemingly simple activities, such as reviewing patient logs, which were often incomplete and inaccurate. Given that even initial data collection proved more problematic and labor-intensive than they had anticipated, the research team realized that they needed to provide additional education and some basic monetary incentives before moving on to more complex indicators such as ASA class and functional status. While the additional training inevitably slowed progress in Chokwe, the experiences at the pilot site proved instrumental when the team moved on to set up the other two sites. Comprehensive training became a key component of implementing NSQIP-Lite and helped develop a sense of collaboration and shared goals between the research team and on-site personnel.

In early 2013, the MEPI Working Group returned to Chockwe with a more refined approach. Dr. Rose spent many weeks on site, devoting much time and effort to training the Surgical Quality Champion, whom he described as "super sharp, right on top of things, right with us every step of the way." As a result, the hospital uploaded the first data to the MEPI Working Group's computer-based platform. All patient data was de-identified in keeping with patient confidentiality. To the dismay of the research team, however, the Surgical Quality Champion left his position at the hospital, having found a higher-paying job in another province of Mozambique. According to Dr. Rose, the Surgical Quality Champion's departure represented a "huge set back." Not only would Dr. Rose need to train a new person during a subsequent site visit, but the new hire would also need to learn even higher-order skills to make sure that the data regarding patients' ASA functional status was accurate.

#### Revising Approach: Pilots Continue

Site visits to the three selected hospitals progressed, with the MEPI Working Group incorporating lessons learned at the Chockwe site into subsequent visits in Nhamatanda and Ribaue. Throughout 2013 and 2014, Dr. Rose and Dr. Funzamo maintained regular contact with other members of the MEPI Working Group to report on how things were going on site and to solicit thoughts from the research team. Some of these meetings took place in person at UEM in Maputo, while others were carried out over Skype, thereby connecting researchers in Maputo with Dr. Bickler and others in the United States. Dr. Bickler praised the research

team's ability to take the full-form NSQIP approach and "distill things down to what is useable." As a rule, the team benefited from the small, closely connected network of physicians and surgeons in Mozambique.

Collaborating with this network, the MEPI Working Group developed two important tools to facilitate the on-site data gathering and reporting. The first was an on-site data sheet to be completed for each patient, with data captured at the pre-operative, peri-operative, and post-operative stages. The creation of this tool revealed some issues regarding the research methodology. Specifically, the MEPI Working Group had determined in advance of the initial trip to Chockwe that 10 variables would be used to capture data for the study. However, in discussions with Chockwe's surgical technicians and nursing staff, during which the MEPI Working Group indicated that they only needed 10 variables before diminishing returns ensued, the Mozambican surgical staff advocated strongly for including 30-35 variables instead, to cover maternity patients who are not caputured in the U.S. NSQIP dataset. (See **Exhibit 5** for Excerpted Datasheet.)

Commenting on the design and content of the data sheet, Dr. Rose found it to be "too complicated, too busy." He added, "If this were up to me, it would have been 10 variables and that's it. But it's their datasheet. If the Mozambican staff tells you 'We think these variables are important,' you need to account for that. They are the ones who are actually gathering the data. They're the ones who actually have to take five extra minutes to fill out a little form."

The second important data-gathering tool developed by the MEPI Working Group was a mobile device platform that could save inputted research data on a cloud-based server. Because of this, data could be entered at a pilot site via smartphone provided by the MEPI team for this purpose. Data could then be reviewed by the MEPI Working Group in Maputo, San Diego, or any other remote location. Creating this mobile-based platform, which was developed in Open Data Kit (ODK), was an important technological advance from the prior approach, as it provided both mobility for the medical team collecting the data and remote access via the cloud for MEPI members to view the data. (See **Exhibit 6** for Mobile Device Platform – Screen Shots.)

As the on-site work continued, with each hospital beginning to make the process their own, the research team realized that while collecting data was the easy part, the research team would need to remain vigilant to ensure proper data verification. One challenging task was to ensure that attending anesthesiologists evaluated all patients at a given site, and across all sites, in the same way regarding the highly important ASA Physical Status score. To address this issue, the MEPI Working Group provided ongoing education and discussion with Surgical Data Champions. The research team also worked in collaboration with Boston's Brigham and Women's Hospital, which provided test cases for external validation to ensure that Mozambique's scoring was consistent with the international standard.

#### **MEPI Meeting: Assessment & Next Steps**

Since the initial data was now available, the MEPI Working Group began to determine how to make the best use of what the team had learned and how to share their findings with various constituents. There were a variety of decisions that needed to be made in the meeting.

#### Considering How to Use the Data

One important decision was whether to place initial focus on Quality of Care improvement or Implementation Science. The former places data in the hands of clinicians and hospital administrators to enact local change, while the latter places data in the hands of the Ministry of Health to enact broad changes to the healthcare system's fundamental infrastructure. Dr. Rose explained,

Quality [of care] improvement traditionally is where we're going to take a centralized database and give you your hospital's results, but only to you. So you are going to know where you are in relation to your peers, but no one else knows where you are and you don't know where anyone else is. All we need everyone else for is to risk adjust your outcomes, and then it is up to local staff to affect change.

In the United States, for instance, if it were discovered that one hospital's urinary tract infection rate following surgery was three times the national average, after adjusting for patient risks, then it would be clear that the practices at the hospital were problematic. Were

catheters being removed soon enough? Were patients encouraged to get on their feet and urinate on their own appropriately? Were patient complaints and early symptoms being addressed aggressively? In the United States, where most hospitals have access to similar resources, it is practical to compare risk-adjusted outcomes and consider the local practices and procedures that might be improving health. However, when hospital resources and patient access to hospitals differ greatly in ways that are systematic at the level of the healthcare system, additional information must be obtained to make fair comparisions and eventually improve care.

Some MEPI Working Group members, including Dr. Rose, believed that Implementation Science was the best first use for the data. The goal would be to idenify strategies for provision and use of effective health services. Dr. Rose commented,

For example, if I say, 'Wow, your hospital's maternal mortality rate is three times as high as your neighbor's,' one might follow by saying, 'Wow, your quality of care is not that great.' But they can point out that it's because the hospital lacks a blood bank that women are bleeding to death. They might say: 'It's not anything I can control at my hospital. I can't go buy a blood bank. That's a very central problem to the Ministry of Health and to the system-wide planning.'

The views of the physicians and staff from each of the three participating pilot sites were another factor for the research team to consider. Although the pilot sites did not have representatives in the MEPI Working Group, they had a vested interest in how the research team used the findings. Although the research team did not set a timetable for improving clinical care, the project goals made clear that the findings would be used to help improve day-to-day care of patients in Mozambique, while the project itself simultaneously deepened the country's research capacity. In addition, the Health Ministry's involvement in the research network raised the stakes for everyone involved. More specifically, a number of thorny political issues were closely tied to how the Ministry of Health elected to use data relative to individual sites. The MEPI team considered a number of issues. Would the jobs of some physicians and staff be jeapardized by the poor performance of individual sites,

notwithstanding the country's widespread structural challenges? Given this, what incentives were individual sites operating under as they gathered and collected data?

Owing to the novelty and complexity of NSQIP-Lite research, the question of using the data for local improvements or for system-wide efforts had not been fully resolved at the outset of the project, although there was a shared understanding that either or both of these approaches were possible. Dr. Noormahomed's focus on sustainable solutions framed much of the discussion within the MEPI Working Group. She also held a strong interest in sharing the findings of the research beyond the borders of Mozambique, commenting,

In terms of communication, I think once we have the results we can organize a workshop where we invite scientists, researchers, and policymakers and present the results in a scientific mode, perhaps creating questions to provoke discussion, because the ultimate goal is to improve the health care delivered.

#### Drawing Funds for Global Surgery

Another important discussion area which emerged in the MEPI Working Group during the project was how to use the data to draw funds from the international philanthropic community. Dr. Bickler expressed his concern that the NSQIP-Lite research might not be adequately understood by key constituencies (pilot site medicial professionals, external funders, etc.) at the time the results were coming in, thus providing a potential barrier to gaining funding. "I keep telling [Dr. Rose] that I don't think people completely appreciate where all this is going and how significant this is; and I think that's the key," he said. This raised the question of how the MEPI Working Group could overcome the current approach by international funders and draw more funds for surgical care.

As part of its strategy for using the data, the research team also understood that the Ministry of Health may be, in effect, limited by the interests of its funding partners. "If you look at the Ministry of Health, it is dominated by infectious disease projects, it is dominated by vaccination campaigns," explained Dr. Rose. "If you look at the funding behind most of those projects, most of it comes internationally." (See **Exhibit 7** for Mozambican Indicators Relating to Total Health Expenditure.)

#### Communicating with Diverse Stakeholders

Given the diverse range of constituents who might be interested in the findings, the MEPI Working Group needed to think carefully about its communication strategy for the research. "Now that we have results from the research, we have to think about how best to pass them on," said Dr. Noormahomed. She continued, "You know, which messages we need to pass to politicians, which to health providers. We cannot pass the same messages to all groups. I think it's a matter of communication."

The meeting of the MEPI Working Group had a full agenda. The research team planned to begin by discussing the NSQIP-Lite pilot implementation and identifing the key lessons. They also needed to discuss the analysis and possible uses of the data, as well how to leverage their results to gain the attention of potential international funders. These topics were pivotal for the project's success, and each was complicated. The meeting began.

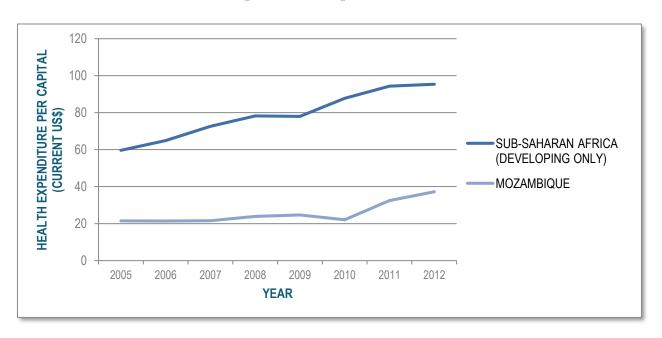
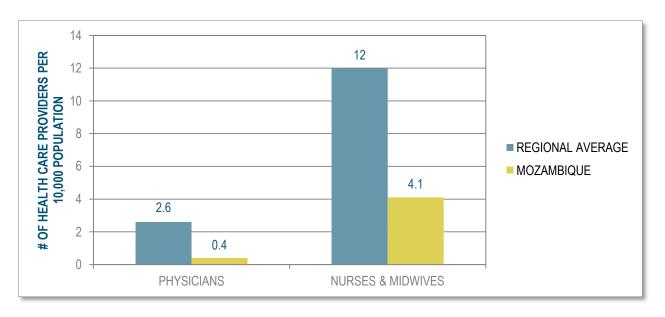


EXHIBIT 1A: WHO - Mozambique Health Expenditure

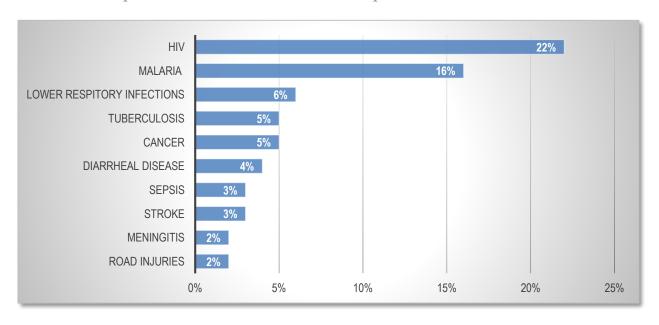
 $Source:\ World\ Health\ Organization\ Website, Country\ Data:\ Mozambique,\\ http://data.worldbank.org/indicator/SH.XPD.PCAP/countries/ZF-MZ?display=graph,\ accessed\ January\ 2015.$ 

EXHIBIT 1B: WHO – Mozambique Health Workforce Data



Source: World Health Organization Website, Country Data: Mozambique, http://www.who.int/gho/countries/moz.pdf?ua=1. Site accessed January 2015.

EXHIBIT 2: Top Ten Causes of Death in Mozambique in 2010



Source: Center for Disease Control and Prevention, http://www.cdc.gov/globalhealth/countries/mozambique/ Site accessed January 2015.

EXHIBIT 3: Map of Mozambique Showing Three (3) Pilot Site Locations



Source: Anderson JE, Erickson A, Funzamo C, Bendix P, Assane A, Rose J, Vaz F, Noormahomed EV, Bickler SW. Surgical conditions account for the majority of admissions to three primary referral hospitals in rural Mozambique. World J Surg. 2014; 38(4):823-9. PMID 24346631. Used with permission.

#### EXHIBIT 4: ASA PHYSICAL STATUS SCALE

ASA Physical Status 1	A normal healthy patient
ASA Physical Status 2	A patient with mild systemic disease
ASA Physical Status 3	A patient with severe systemic disease
ASA Physical Status 4	A patient with severe systemic disease that is a constant threat to life
ASA Physical Status 5	A moribund patient who is not expected to survive without the operation.
ASA Physical Status 6	A declared brain-dead patient whose organs are being removed for donor purposes

 $Source: American\ Society\ for\ An esthesiologists.$ 

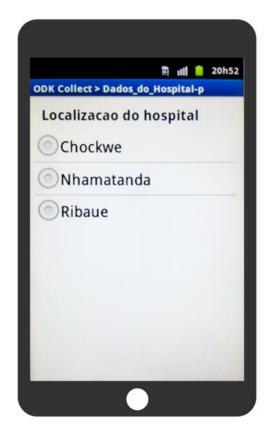
https://www.asahq.org/clinical/physicalstatus.htm. Accessed January 2015.

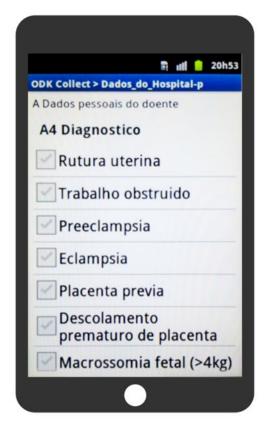
#### EXHIBIT 5: Excerpted Datasheet

<u>Pre-operative Data</u> Name:		NID:	
Sex: Male	Female	_	Age:
Diagnosis:			
Date arrived at hospital:			
Is this a trauma patient?			If maternity, also complete the following:
No			
Vehicle or car accident			Number of previous births:
Burn			Prior Caesarian sections: Y N
Other:			Duration of labor prior to Caesarian: (hours)
	=		Use of labor induction(Oxytocin, Misoprostol): Y N
ASA classification			Use of instrumentation (succao, forceps, etc.): Y N
Normal healthy patient			Was the patient bleeding prior to Caesarian section?
Mild systemic disease			Y N
Severe systemic disease			If yes: 0-500mL
Severe disease, constant the	nreat to life		500-1000mL
Not expected to survive			>1000mL
Sepsis status			If yes, did the patient receive a blood transfusion?
None			Y N
SIRS			
Sepsis			Diagnoses:
Septic shock			Uterine rupture Placental abnormality
Functional status prior to surgery			Obstructed labor Uterine/vaginal infection
Independent			Atony Fetal macrosomia (>4 kg)
Partially dependent			Pre-eclampsia Eclampsia (convulseos)
Totally dependent			Other:
Is the patient HIV positive?	Pos	Nog	
		Neg	
Is the patient pregnant?	Υ	N	
Preoperative laboratory values:			
Weight:	Height:	-	
Temperature:	Pulse:		Blood pressure: Respiratory Rate:
Hematocrit:	WBC:	_	Platelet count:
Urea:	Albumin:	_	
Date of surgery:		 N	Cesariana Herniorraphy Exploratory laparotomy Bowel resection Salpingectomy (ectopic) Hysterectomy Split-thickness skin graft Wound debridement and primary closure Appendectomy Hydrocelectomy Limb amputation Other:
None Duration of Operation: Duration of Anesthesia: Operative Wound Classification: Clean, uninfected wound Clean contaminated			

Source: MEPI Working Group Materials. Used with Permission.

**EXHIBIT 6:** Mobile Device Platform – Screen Shots





Source: MEPI Working Group Materials. Used with Permission.

#### **EXHIBIT 7:** Mozambican Indicators Relating to Total Health Expenditure

	2005	2006	2007	2008	2009	2010
Gross Domestic Product/ per capita (GDP, US\$)	334.5	362.8	393.6	468.9	439.2	422.8
Total Health Expenditure (THE) (million US\$)	381,9	409,6	418.9	507.0	594.1	574.0
External resources on health as % of THE	53	58	59.9	73.7	65.7	na
General government expenditure on heath (GGHE) as % THE	74.2	72.6	75.1	77.3	75.5	na
Out of pocket expenditure as % of THE	25.8	27.4	24.9	22.7	24.5	24
Total expenditure on Health/capita at exchange rate	19.6	20.6	19	23	23	21
Total health expenditure as % of GDP	6	5	5	4	5	5

Source: WHO Global Health Expenditure Database,

 $http://www.afro.who.int/index.php?option=com\_content\&view=article\&id=3131\&Itemid=2857.$ 

Site accessed January 2015.