



# Reflection

Hannah Graham Memorial Award 2016

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*Disclaimer: any time that I use “I” in this paper, I am most likely referring to a much larger group. Whether thanks to my mentors, (Dr. Martin and Dr. Schroen), my roommates (Eliza, Alice, and Emily), Rwandan medical students (Zeta and Kelly) or Human Resources for Health personnel (such as Dr. Costas), I was never alone during this process. I send so much gratitude and love for all of the guidance and friendship.*

## **Living in Kigali**

While preparing for my adventure in Rwanda, I focused on two things in addition to research preparation: language and cultural studies. My semester in Geneva prepared me incredibly well for the French that I would be using in Rwanda. I find that African French speakers are significantly easier to communicate with than their European counterparts. Their words aren't quite as slurred together, and they're far more patient when I'm searching for my words (after all, French is often their second language as well!). Delegates at the UN also tend to repeat the same statements over and over again, which allowed me to slowly stray away from the crutch of the translation earpiece: the WHO became *OMS (organisation mondiale de la santé)*, development became *développement*, and excuse me became *pardon*. Although Rwanda recently changed the language of education from French to English and the country as a whole is becoming increasingly anglophile, being able to communicate in French was extremely helpful. French is still very present in the culture of Kigali. The public hospital is called *say-ash-u-kuh*. One may think that is a Kinyarwanda (the language of the vast majority of less educated and rural Rwandans) term, but it's actually the French pronunciation of the hospital's acronym CHUK. My favorite coffee shop was called *Shokola*, presumably an adaptation of the French *chocolat*. Ordering at restaurants and directing cabs was done almost entirely in French.

Unfortunately for the medical students and residents, the language switch came towards the end of their educational careers. I sometimes helped the medical students to find their words

when presenting to the Ugandan professors who didn't know any French. I also helped a resident translate his thesis presentation. I was able to give greetings and words of comfort to visitors to the surgery clinic, though most only spoke Kinyarwanda fluently. Although there are many Americans who are extremely effective healthcare providers communicating only in English, they work entirely through translation by their Rwandan medical colleagues. This necessity for translation definitely serves as a capacity building tool for the Rwandan doctors because care cannot be given without their help.

My second focus while preparing for this experience was to understand the history and culture of the country. In Rwanda, one event prevails in the minds of historians, politicians, and civilians: the genocide. The Rwandan genocide, formally referred to as "The Genocide against the Tutsi", raged from April 7 to mid-July 1994. Between 800,000 and 1 million people were killed. For the people I met in Rwanda, The Genocide wasn't some colossal historical event or war, but instead a real-life nightmare that they remember vividly. A few of our younger friends, especially the brothers at Niyo Cultural Center, told us their story of escaping to neighboring Congo with their mother. Such open conversation regarding the genocide was extremely rare—other than Rwandans who work with tourists, few people discuss the genocide. Aside from historical plaques and banners posted for the 100 days between April and July, the only recognition or public mourning of The Genocide occurs during the annual remembrance week starting April 7th. This is how the country collectively chooses to cope with the memories.

While in Geneva, I took a seminar on genocide studies co-taught by an American scholar, an Armenian author, and a Norwegian photographer who specialized in genocide remembrance (Kristian Skeie judged our Center for Global Health photography competition this year!).

Because all three of my professors had worked in Rwanda, I was able to mentally prepare for how to approach the genocide. They taught me to be a silent observer—never asking questions but maintaining careful awareness of how the history of the space around me affects its workings today. I was first able to apply this practice with the help of my professors during our class trip to Bosnia and Herzegovina.

Both the genocides in Rwanda and in Bosnia and Herzegovina occurred in the mid-1990s, but their respective remembrances today couldn't be more different. We happened to be visiting the memorial at Srebrenica the day that the International Criminal Court released a “not guilty” verdict for a man who was a leader in the genocidal regime. Trucks drove back and forth in front of the memorial cemetery waving Serbian flags and blasting the Serbian national anthem while the drivers yelled slurs at the Hijabi students on the trip. This sort of polarized attitude and harsh disrespect would *never* occur in Rwanda.

After the Bosnian genocide, the Treaty of Dayton created a system of government that combined the 3 fighting groups—Serbs, Croats, and Bosnians—into a rather disjointed government. Each group takes turns with their own leader in power. All children attend the same public schools, but they are split into groups during religion and history classes based on their reported association. Clearly, this continued separation has allowed bigotry and hate to thrive. Following the genocide in Rwanda, a single leader took power, and dissolved the dichotomy of Hutu or Tutsi (in fact, it is illegal to claim association to Hutus or Tutsis). The current leader Paul Kagame is so beloved by his people for uniting the country that he will likely serve as president until his death. As an American who was raised with democratic ideals, I often felt

uncomfortable living in the semi-police state of Rwanda. Despite this, I had extreme respect for Kagame's approach after witnessing the alternative in Bosnia and Herzegovina.



The view of downtown Kigali from the Genocide Memorial

One activity born out of the Genocide that sets Rwanda apart from other communities is Umuganda. On the last Saturday of each month, all adults are required to complete service work together and attend a community meeting. Local leaders run the event, and 100% attendance is expected. My roommate, Eliza, and I were fortunate enough to attend our unit's June meeting with our friend, Cyusa. Although we came prepared to work, we quickly found ourselves useless. Although cutting the grass on the roadside with a machete required special skill that the locals assumed we did not possess, we enjoyed the quick lesson and demonstration they gave us. At the

community meeting, Cyusa translated our introduction to the entire group, and the meeting began. Because few people read the newspaper or own televisions, the federal government has found that the best way to reach their populace is Umuganda. The local leaders read announcements regarding taxes, trash disposal, school fees, etc., then entertain community input on each and every item. Neighbors might bring up issues such as barking dogs or litter. Our favorite part was the presentation by a Community Health Worker who discussed the nutritional value of vegetables and payment for Mutuelle de Santé—the federal health plan. I had read about Umuganda during my studies as being one of the world’s most effective systems for building community trust and communication between leaders and the populace. Actually taking part in the ritual, I developed a profound respect for the personal features of this endeavor. The last Saturday of every month, all business shuts down and all adults get a chance to be *heard* by their government—that is truly a remarkable thing.

Clearly, Rwanda is a beautiful country with a rich culture and history. I would not have been able to develop such an appreciation for Rwanda without the outstanding people, Rwandese, American, and others, who were by my side each day.

Eliza Campbell is a 4th year student in the Frank Batten School of Leadership and Public Policy who received a Center for Global Health Award this summer for her internship with Dr. Agnes Binagwaho, the Rwandan Minister of Health. The Honorable Minister is a pop-star in the world of global health, and Eliza and I could talk about her for hours. Through finding a house, trudging through Kigali construction sites in heels to get to meetings on time, Wednesday night yoga, immigration stress, and much more, Eliza and I quickly became friends. Once CGH Scholars Alice Burgess and Emily Romano arrived a few weeks into the adventure, our little



family started even longer nightly chats about research projects, lives at UVA, and medical school applications. We stayed at the home of the Gaskills, a missionary family home in North Carolina for the summer. Their house staff—Margaret, Sam, and Jack—took great care of us. Margaret made authentic rice, potatoes, and bananas all the time, and Sam picked fresh avocados from the tree in our front yard. Jack, our night guard, was a martial artist. Although he didn't speak much English, we worked out together a few times (I have a black belt in Taekwondo) and bonded. Dr. Durieux's dear friends and trusted drivers, Emmy and Jeanne-Paul, ensured our safe travel around the country. They were by our side in minutes if we ever had a concern.

We also became very active in the Kigali art scene. Inema Arts Centre hosts yoga, gallery openings, and other social events, and we befriended the brothers who run it. Niyo Arts Gallery was just down the street from our home. They hosted a dance troupe made up of children from our neighborhood whose school fees were paid for by the art sold in the gallery. Eliza became very involved there, working on an inventory of the pieces. We both spent free time watching dance practice with the artists and bonding with the children. Niyo was our method for immersion in Rwandan friendships and culture, an unplanned addition that truly completed our experience.



Dance practice at Niyo Cultural Center with neighbors Pacifique and Cyusa

We spent the weekends exploring all of the beauty that Rwanda has to offer. Our major trips were to Akagera, Nyungwe Forest, and Volcanoes National Parks. At Akagera, we saw nearly every African animal aside from lions and leopards. The park doesn't host a massive tourist industry like most other sub-Saharan game parks, so the rules were much less strict. We were able to get out of the car and picnic on the savannah about 100 meters away from 4 grazing giraffes! Dr. Martin joined our trip to Nyungwe rainforest and the most intense four- turned seven-hour hike of our lives. I will never forget that day trudging up and down mountains on the waterfall trail behind our ridiculously speedy guide. Eliza and I visited Volcanoes National Park with her uncle, who works at the University for Global Health Equity in Rwanda, and his family. We toured Butaro hospital and the new University site on the way up and slept at the Team Africa Rising cycling center the night before our trek. In the park, we completed the famed

gorilla trek, machete-ing our way through the jungle to spend over an hour with the Umubano mountain gorilla family in their natural habitat. This physically demanding tourism was unlike anything that I have ever done before, and I plan to seek similarly thrilling adventures in the future.



Nyungwe National Forest with Dr. Martin and Eliza

## **Shadowing**

During the week, if I was not working on one of the research projects, I was probably shadowing at Rwanda Military Hospital (RMH) or CHUK. Throughout the 6 weeks, I spent time in the ER, general and plastic surgery, and pediatrics. Dr. Costas, an investigator on all three of the projects, always welcomed me into surgery and clinic. Perhaps the most interesting surgery that I was able to shadow was a mastectomy, as it related to the work we were doing with breast prostheses. When I returned to the US, I was also able to shadow a mastectomy completed by Dr. Schroen at UVA Hospital. Comparing and contrasting the two surgeries was an extremely

important lesson in global health. Although the stages, settings, personnel, and prognosis were different, the cutting of tissue itself was the same. The anesthesia was also very different, as anesthetists in Rwanda normally have certificates rather than medical degrees. Dr. Durieux and I have discussed how professional organizations in the US have cut their donations to places like Rwanda because of extreme lobbying efforts against mid-level care providers in any form. These links between care provision and politics were a vital part of my unofficial curriculum developed during shadowing.

My fondest memories of shadowing in Rwanda come from pediatrics. Because it was summer holidays, there were medical faculty members from the US working in Rwanda that I would only dream of meeting back home. My first day of shadowing pediatrics brought about a major realization regarding my future career. A pediatric nephrologist from Yale University was rounding at CHUK; he was called to a child who was suffering from suspected kidney disease, but thus far it had been impossible to diagnose him with the resources available. The visiting nephrologist quickly took a urine sample from the child, ran it to the lab, spun it down, and put it under a microscope. Sure enough, he was able to diagnose an extremely rare kidney disease within a few minutes.

Through this experience, I learned that there are two different types of doctors in the aid arena. First are those so experienced in the low resource setting that they are pros at utilizing what is available to provide competent care for the greatest number of people. Second are the specialists who, though they are used to working with more advanced technologies, know a finite set of maladies so well that they could diagnose and cure them with a microscope and a glorified

first aid kit. I'm not sure which of those doctors I will be, but it was extremely beneficial to learn that each of those skillsets are needed and wanted.



I hold a child while their mother is examined at the breast clinic

## **Scientific work**

Epidemiological and Cultural Understanding for the Prevention of Gastric Cancer in Rwanda  
(Appendix A)

The Institutional Review Board (IRB) approval for *Epidemiological and Cultural Understanding for the Prevention of Gastric Cancer in Rwanda* took far longer than expected. We met barriers relating to a lack of trust from the leaders at Rwanda Military Hospital (RMH)

and confusion regarding the ever-changing complexities of the application process both for RMH and for the larger IRB body that makes decisions for the major teaching hospitals in the country. Instead of learning how to administer a lengthy survey to a large foreign population, I was able to learn (by watching Dr. Martin and sometimes through trial and error) the fine art of building communication, understanding, and trust. Rather than spend my summer in one clinic at one hospital, I was able to shadow in multiple departments at RMH and CHUK (the public hospital in Kigali) and travel to Butare (in the Southern Province). At Butare, we found a very welcoming atmosphere and two enthusiastic co-investigators, Dr. Christian and Dr. Ahmed. Thanks to them, Dr. Martin was able to open the study and gather the first ~100 responses at Butare. Since that time, the study has been approved and started at RMH as well. The study will not be closed (and the overall results will not be officially analyzed) until we reach 100 respondents at RMH (expected in early Spring 2017). It is important to note that we struck the portion of the study that involves calling patients on the gastric cancer registry due to logistical restraints.

In order to show a poster at the Center for Global Health Annual Symposium in early October, I completed a preliminary analysis of the responses from Butare (Appendix A). This analysis was also submitted and accepted to the Unite for Sight Global Health and Innovation Conference at Yale University; I'll travel there in April in order to present a poster.

Although we will not know the actual outcomes of the study for months, one very interesting piece of data is already apparent: 125 people have been willing to complete the 100+ question survey. All members of our team were concerned that the survey was so long that no one would take it. Whether it's due to clinic waiting lines being extremely long or to people's

kindness and willingness to help others, Dr. Martin and the medical student translators have been received with welcome.

A Mixed Methods Study Measuring Perceived Patient Benefit of Locally-made Breast Prostheses in Rwanda (Appendix B)

As I was waiting for the IRB for the gastric cancer study to go through, I built a relationship with Dr. Costas and Dr. Pacifique (leaders at RMH); I spent many days in the breast cancer clinic with them. This clinic, established as a partnership between the two doctors, was the first of its kind in the country. Women from all around Rwanda come to RMH in Kigali in order to be seen by an oncologist (Dr. Pacifique) and a general surgeon (Dr. Costas). These women are referred by doctors in their district, missionaries, and other small private health agencies. Some have learned about self-checks and breast lumps from friends, family, or public service announcements and are self-referred. Many are sent by the oncology center run by Partners in Health in Butaro, which provides chemotherapy but limited surgical care.

In my public health classes at UVA, we often discuss Community-Based Participatory Research (CPBR). Very popular among researchers today, CPBR attempts to work with the community in question at all levels of research: establishing a question, building a protocol, ethical approval, data gathering and analysis, and communication. When I first received the Hannah Graham Memorial Award, I was trying to model CPBR without having learned what it was. Dr. Martin helped me to establish email communication with in-country healthcare providers in order to clarify the research questions, build the survey, and organize administration. But only once I was actually in clinic with absolutely no research question did I learn the true meaning of a community-based approach. I recognized themes in the conversation between Dr. Pacifique, Dr. Costas, and the patients that they examined. There are a large number of projects



that the two would love to undertake but simply never had the time to. Since Dr. Martin and I were actively looking for projects at the time, we decided to offer our help.

The first project hoped to measure the emotional and social effects of giving culturally relevant breast prostheses to women post-mastectomy. The idea of cultural relevance is important because in the past, prostheses have been donated to Rwandan cancer patients by various European groups; however, these donated items are often thought to be too hot or uncomfortable and are rarely worn. The production of the traditional silicone-based products is also unsustainable in-country. I have attached the most recent version of the project overview in the appendix. I helped Dr. Martin to write the initial drafts; the protocol has now been edited by all of the co-investigators. I was most involved with the creation and focus-group testing of the first prostheses.

My mom taught me how to sew when I was young (she's a pro—she even made her own wedding dress!), but I never thought that this skill would have any impact on my future in public health. Surprisingly, my sewing abilities allowed me to take part in creating the first breast prostheses made in Rwanda! I printed a pattern and directions online, then went to an appointment at Nyamirambo Women's Center (NWC) with Dr. Martin and Dr. Grace Kansayisa (a Rwandan surgery resident and co-investigator). "NWC's mission today is to provide education and training to disadvantaged women so that they can gain better opportunities for employment." The women in the NWC workshop create everything from clothing to bags to stuffed animals (one of the women was able to improvise the nipple on the first piece with a technique used to make stuffed animal eyes). Since my co-seamstress spoke Kinyarwanda, we communicated using our hands. As we drew, measured, and cut, I was reminded of working at the elbow of my mom.

After our meeting, NWC agreed to partner for the entirety of the project, and they have made multiple iterations of the prostheses since.

Dr. Martin and I took a variety of sizes of the first prototype prostheses to a breast cancer support group meeting in Butaro. Here are the key points that we learned from the focus group:

Ten of the fourteen women present had undergone mastectomy. Three of these ten had stuffed something into their clothing to give the appearance of a breast. One was wearing a prosthesis that had been donated to Butaro (but she and the other women who had received one didn't wear it and complained that it was too hot).

The rest of the women said they would wear a prosthesis if they had one that they liked. One commented that she felt nervous being in public without a breast, and Albert Ndayisaba (the support group facilitator) said that this issue is commonly discussed in the group.

The women liked the Kitenge fabric (traditional fabric worn by many urban and most rural women). They said that it was not too hot, something that they were used to wearing, and easier to clean than white fabric.

The women were very engaged the entire time, especially when we asked them to touch the prostheses. Many immediately tried them on. They commented that the breast itself should be more circular and have more projection.

The most important outcome of the meeting was the realization that none of the fourteen women regularly wore bras. We introduced the idea of a camisole or t-shirt with a pocket for the prosthesis, and all women were in favor of this idea.

This information was shared with the co-investigators and used to develop the study protocol and the next iteration of the prostheses. The protocol was recently approved by the University of Rwanda College of Medicine and Health Sciences IRB. Although I will not be in-country to conduct research, I hope that I will be helpful in data analysis or transcript drafting.



The first iteration of the prostheses

An Epidemiological Survey and Case Series of Military Women Presenting with Breast Abscesses at the Rwanda Military Hospital (RMH) (Appendix C)

Based on my status as an active young woman/future epidemiologist, the 3<sup>rd</sup> project was probably the most interesting to me. During my few days in clinic, four female military trainees were diagnosed with breast abscesses. This was a classic case for epidemiology: we needed to connect the dots and find the culprit. It is likely that a chart review of the previous months would have revealed additional cases. Dr. Costas invited me to do some background research to see what I could come up with, and it turns out that there is an extensive body of literature dedicated to avoiding breast infection in military women. I contacted Captain Laura Byrnes, a member of the US Army charged with integrating the first female students at the Virginia Military Institute. She referred me to multiple manuals that detailed the wearing and hand-washing of sports bras, the use of towelettes when showers were unavailable, and the application of baby powder multiple times each day.

The literature as a whole suggested a wide range of possible causes of such abscesses. We hoped to complete a chart review and interview the women to learn about their hygiene and exercise practices in order to understand this outbreak of infection. Of course, such interviews

would be extremely personal and possibly even embarrassing for these women. Kelly Kaneza, a University of Rwanda medical student from Burundi, joined the project to help examine these barriers.

Attached is the IRB application that was given to Dr. Pacifique, the head of the RMH ethics committee (and the same person from the breast clinic discussed earlier), for his consideration. As a high-ranking army official, Dr. Pacifique was well aware of the many challenges involved with researching a military institution or military personnel. He politely explained that although the project was valuable (he had suggested the idea himself), it would likely never happen. After a few weeks went by with multiple check-ins but no news, we assumed that the project would not be approved. Though I am still upset by this refusal, this probably would have happened in any country. If there is one thing that I learned on this trip, it is that no science (especially not medicine) is unaffected by politics. When trying to make people healthier, we cannot avoid the environment where they live and work.

## **The World Cancer Congress**

The ideal close to my experience over the past year was attending the World Cancer Congress (WCC) in Paris, France. Dr. Martin was presenting her research about gastric cancer inequities in Virginia, and I was thrilled to be there as a student and friend. But rehearsing and editing the presentation was just a small portion of our week. We were also able to catch up with mentors from the U.S., Rwanda, and Geneva.

These mentors included Dr. Shannon Barkley and her husband, Dr. André Ilbawi. They met their first year of medical school and now work in Geneva at the WHO headquarters; her specialty is primary care and his is non-communicable diseases. Dr. Ilbawi met with me at the WHO last Spring to look over the project and offer advice. It was quite obvious that he had both an incredible mind and an incredible heart. In Paris, while he and Dr. Martin discussed additional Rwanda projects, I was finally able to meet Dr. Barkley. She was about to give a talk on the importance of the primary care physician in ensuring quality cancer care. I had been thinking about this topic a lot; although my project was focused on cancer, I don't plan on becoming an oncologist. I am more interested in seeing how a cancer or other major disease fits into the person as a whole, and how we can improve the life of them and their families even when a "cure" is not possible. Dr. Barkley so eloquently stated that this was also her mission and gave me many tips and resources for the years ahead.

We also saw Albert Ndayisaba, the director of the Butaro Breast Cancer Support Group and an investigator on the breast prostheses project, and many other leaders from the Butaro cancer center. Their joint presentation about partnerships between developed and developing countries was well attended, and I was thrilled with the realization that I had studied in a health

system that is the model for many other places. I also overheard some conversations with rock-stars like faculty of the Harvard School of Public Health and surgeon Peter Kingham. Throughout the experience, Dr. Martin was a role model for how to act at professional conferences. Shaking hands with leaders in your field can be quite intimidating, and she showed me how to do this in a polite manner even though I'm at the bottom of the metaphorical medical ladder.

The presentations themselves were phenomenal. Speakers ranged from President François Hollande of France, to Princess Dina of Jordan, to American Cancer Society CEO Gary Reed. After attending the WHO Executive Board meeting last January, where non-communicable diseases were postponed to a one-hour conversation on the final afternoon, it was exhilarating to see so much excitement to push cancer to the forefront from so many different disciplines, both public and private. I also learned much more about global health research by seeing presentations on the methodology and outcomes of studies that seemed most valuable in the eyes of the WCC. I completed reflections on two of my favorite presentations for my public health ethics course, and I've included them in Appendix D.

It was also a blast to explore Paris with Dr. Martin. We wandered, shopped, ate amazing food, and spent a very late final night at the Musée D'Orsay followed by a ride up the Eiffel Tower. We were guided for a few hours by my foreign exchange brother, Valentin. Perhaps my favorite place we visited was the Musée des Arts Forains, the site of the WCC final celebration. In this museum dedicated to the Belle Époque era, we played games and rode carnival rides with some of the world's leading cancer fighters.



WCC reception at the Musée des Arts Forains

## **In Closing**

The past year as the Hannah Graham Memorial Award Scholar has been a time of extreme trial and growth for me. I am only starting to see all of the rewards that I will reap as a result of the hard work I've put in and the extreme generosity of my mentors and the Grahams. I have developed skills relating to health policy, research design and publication, cultural humility, medical communication, and independence; these will be immeasurably valuable in my future career. I also look forward to sharing my stories with others and inspiring them to pursue similar growth experiences. I can't wait to see what the Hannah Graham Memorial Award will allow Nadjad, Golda, and Jessie to accomplish. I look forward to providing mentorship whenever possible.

**Appendix A: Epidemiological and Cultural Understanding for the Prevention of Gastric  
Cancer in Rwanda**



IRB Proposal

**Epidemiological and Cultural Understanding for the Prevention of Gastric Cancer in Rwanda: A Clinical Survey**

**Principal Investigator (Rwanda):** Pacifique Mugenzi, MD, Oncologist

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### Proposal Summary/Synopsis

Gastric cancer is among the leading causes of cancer in Rwanda, although epidemiological data is lacking. Understanding the contemporary etiology of gastric disease in a representative population of this country may inform healthcare priorities in a resource-poor setting in order to better allocate healthcare resources among patients with gastric disease and gastric cancer.

This study will involve prospective collection of survey data related to gastric illnesses, cancer risk factors, and health literacy among patients with and without gastric cancer who receive treatment at three main referral hospitals in Rwanda. Survey response data will be analyzed to identify relevant environmental exposures or personal behaviors that differ between patients with and without the disease of interest. We will utilize descriptive statistics and univariate analysis as the primary statistical analysis.

### 1. Background

Although recent reports from the World Health Organization (WHO) indicate overall reduction in cancer-related mortality, there are communities with a disproportionate burden of surgically curable malignancy. East Africans suffer the highest rates of gastric cancer and higher rates of *Helicobacter pylori* colonization among regions of Africa, however this relationship has yet to be fully determined.

Known risk factors for gastric cancer include *H. pylori* infection, dietary factors, smoking, gender, and family cancer history, among other risk factors. Poor diagnostic capacity, limited screening, and low treatment rates for persons positive for *H. pylori* are among the potential causative factors that further accentuate high gastric cancer rates in East Africa. Examining the relationship between socioeconomic factors, healthcare access, geography and cancer outcomes for African patients with gastric cancer is critical to ultimately developing interventions aimed at reducing the cancer disease burden in this population.

There is a paucity of cancer and epidemiologic data related to non-communicable diseases (NCDs) in sub-Saharan African. Global health has traditionally focused on infectious, communicable disease. NCDs are emerging as a leading cause of mortality in the developing world. Cancer has been identified as the second leading cause of NCD-related mortality and nearly two-thirds of all cancer diagnoses come from low- and middle-income countries (LMICs) [9]. The Global Burden of Disease Study 2013 reiterated that while age-standardized cancer mortality rate is decreasing, the overall number of cancer-related deaths is increasing. This is multifactorial and can be attributed to environmental factors, lifestyle factors, such as like smoking and obesity, as well as to increasing average age of persons in LMICs [16].

At present, gastric cancer is the 12th most common cancer in Africa [1], but this is likely an underestimate for East Africa. Rates are highest in Eastern African countries, including Rwanda, which has an estimated incidence and mortality of 8.3 per 100,000 and 8 per 100,000 [1]. These are the best available statistics related to gastric cancer rates in Africa, however they are very

likely to underestimate the actual problem—a representation bias likely exists because of multiple factors, including differential availability of country-specific cancer registries, access to care, and screening modalities, such as endoscopy [1]. Understanding possible explanations for this disproportionate disease burden is essential to reducing health disparities in gastric cancer.

As healthcare priorities transition to a focus on chronic disease, it is important to understand patient-specific risk factors for different types of cancer. In 2012, the Human Resources for Health (HRH) partnership was announced between the Rwandan Ministry of Health (MOH), the US government, and multiple professional schools, including the University of Virginia School of Medicine (UVA SOM). The MOH is actively involved in improving care and management of NCDs, including a renewed focus on cancer care and collection of epidemiologic data.

UVA has an ongoing relationship for education research and local faculty members in an academic partnership between the UVA Global Surgery Initiative and the Rwandan MOH.

## 2. Aims and objectives

2.1 The primary aim of this study is to describe the health experience (i.e., symptom pattern, treatment regimen) of study patients with and without cancer in Rwanda.

2.2. Secondary objectives are to characterize the burden of gastric diseases, including gastric cancer in the following manner:

1. To report prevalence of gastric complaints among the study population
2. To describe environmental contacts and associations identified by individuals with gastric cancer who take the survey
3. To assess health literacy of Rwandan patients regarding their understanding of cancer

## 3. Methods

### *3.1.1 Study Description*

This is a case comparison study that will involve prospective collection of survey data pertaining to gastric disease, gastric cancer, and cancer literacy.

### *3.1.2 Study Design*

We will survey patients with and without gastric cancer. Survey takers who do not report gastric disease or gastric cancer will serve as a comparison group. The survey will be administered during interviews by researchers in the preferred language of the patient (i.e., English or Kinyarwanda). Surveys will also be administered via telephone to include patients in the gastric cancer registry previously created by Dr. Costas-Chavarri and colleagues. The data will be collected on iPad devices using the online survey tool QuestionPro (<https://www.questionpro.com>). Please see attached documents for surveys in both languages.

### *3.1.3 Study Site*

The study will include patients from Rwanda Military Hospital (RMH), Centre Hospitalier Universitaire de Butare (CHUB), and Butaro District Hospital (BDH). RMH is a tertiary care referral hospital in Kigali that provides health care services to both civilian and military patients, 80% and 20%, respectively. It has a bed capacity between 350-400 beds. CHUB is also a tertiary care referral hospital located in the Southern Province/Huye District with a 500 bed capacity. BDH is a 150-bed facility in the Northern Province/Burera District.

### *3.1.43 Study Population*

The study will include patients presenting to University of Rwanda referral hospitals for an outpatient appointment during the proposed study period and gastric cancer patients listed on the registry provided by Dr. Costas-Chavarri.

### *3.1.5 Proposed Intervention*

This study does not have a true intervention, however the study instrument is the survey (please see attached document).

### *3.1.6 Main Exposures and/or confounders and/or outcomes to be measured*

The survey includes questions about the following:

- Demographic information
- Symptoms of dyspepsia and treatment of these symptoms
- Access to and utilization of medical care
- Water and food sources, availability, and consumption
- Smoking and alcohol consumption
- Health literacy

## 4. Selection of study population

### *4.1 Inclusion Criteria*

Any patient  $\geq 18$  years of age presenting to University of Rwanda referral hospitals for an outpatient appointment are eligible for enrollment. All patients  $\geq 18$  years of age previously identified as having gastric cancer will also be eligible to complete the study via telephone interview.

### *4.2 Exclusion Criteria*

Patients  $< 18$  years of age and those with cognitive impairment severe enough to prohibit them from providing informed verbal consent will be excluded from the study.

### *4.3 and 4.4 Sampling/Randomization*

This study does not involve sampling or randomization.

## 5. Study procedures

### *5.1 Procedures at enrollment*

*IN PERSON PROCEDURES: For non-gastric cancer patients*

Prospective participants will be approached while waiting for their outpatient appointments at one of the University of Rwanda referral hospitals. They will be asked to participate. The preferred language will be identified. Verbal informed consent will be sought before surveying can begin.

*OVER THE TELEPHONE PROCEDURES: For gastric cancer patients*

The names and contact information for patients with gastric cancer will be obtained from Dr. Costas, who is affiliated with University of Rwanda Ministry of Health and is an unaffiliated investigator for this project. These patients will be contacted and, if they provide verbal consent, will be administered the same survey over the telephone. An IRB –approved telephone contact script with verbal consent language will be used during this contact (please see attached documentation for telephone interviews).

*5.3 Measures of exposures and confounders*

*IN PERSON PROCEDURES: For non-gastric cancer patients*

Using a tablet device, survey responses will then be entered into the online survey tool, QuestionPro (<https://www.questionpro.com>) if Internet is available. If internet is not available or nonfunctional, responses will be collected via paper/pencil survey and then entered when Internet becomes available.

*OVER THE TELEPHONE PROCEDURES: For gastric cancer patients*

The interview will occur according to the IRB-approved telephone script. Answers will be entered into QuestionPro software in real time by the researcher completing the interview.

We will collect the following information on each patient regardless of method of recruitment:

- 1.Age
- 2.Sex
- 3.District/Province/Sector
- 4.Employment/Occupation
- 5.Source of income
- 6.Health insurance coverage/status
- 7.Reason for visiting the hospital (if applicable)
- 8.Source of transportation to the hospital (if applicable)
- 9.Travel time to hospital (if applicable)
- 10.Prior trips to district health centers/hospitals
- 11.Past medical history (i.e., gastritis, GERD, HIV)
- 12.Presenting signs/symptoms
- 13.Use of traditional healers/medicines
- 14.Water sources
- 15.Dietary information
- 16.Social history (i.e., tobacco/alcohol consumption)
- 17.Cancer knowledge
- 18.Health-related behaviors (i.e., hand washing, seatbelts)

*5.5 Measurement of outcomes*

The primary outcome we will measure will be prevalence of gastric complaints and prevalence of gastric cancer among the study population. Secondary outcomes we will measure include reporting of most common behavioral risk factors that might result in gastric problems or gastric cancer, barriers to accessing health care services, and report of prevalence of cancer literacy (measured by knowledge of cancer and other health-related behaviors).

### *5.6 Sample Size*

The accrual goal for this study is 200 patients with a maximum enrollment of 500.

### *5.7 Data Management*

Only investigators for this study and clinicians caring for the patient will have access to the data. They will each use a unique login ID and password that will keep confidential. Information will not be shared with those not on the study team or those who do not have a need to know. The data will be password-protected. Hard copies will be physically locked and secured at all times if not directly supervised.

### *5.8 Proposed Analysis*

Data will be analyzed using STATA 14 Software. Descriptive statistics will be computed for characteristics of participants using Student t-test and chi-squared test, when appropriate.

**ANALYSIS OF PRIMARY OBJECTIVE:** To describe the health experience of individuals with and without gastric disease or cancer (i.e., symptom pattern, treatment regimen) we will utilize answers to questions regarding barriers to transportation, difficulty paying for medications, use of traditional healers etc. and report descriptive statistics.

**ANALYSIS OF SECONDARY OBJECTIVES:** In order to report prevalence of gastric complaints among the study population we will utilize answers to questions asking about symptoms of dyspepsia and treatment of these symptoms and report descriptive statistics. To describe personal health behavior and environmental risk factors that might result in gastric problems or gastric cancer we will report descriptive statistics of answers to questions regarding water sources, food availability, and personal behaviors, such as smoking or drinking alcohol. To assess health literacy of Rwandan patients regarding their understanding of cancer we will report descriptive statistics of responses to questions regarding understanding of the concept of cancer. We will look at the global responses to the entire survey and utilize descriptive statistics to determine areas of improvement in the management of gastric disease and gastric cancer patients presenting at hospitals in Rwanda and provide guidelines and plans for improvement of the identification and treatment of these patients at the different hospital levels.

## 6. Ethical considerations

### *6.1 Confidentiality*

Any identifying information collected in this study will be demographic in nature (age, gender, district, etc.). Names of in-person survey participants will not be recorded. Names and telephone

numbers of telephone participants will not be stored with or connected to their survey data. Non-personally identifiable survey data will be stored under a secured server on the QuestionPro website, which has multiple firewalls in place. In order to ensure confidentiality, the iPad device holding all survey data will be configured according to HIPAA regulations as follows:

1. with a password to "open" the device that is unique and difficult to guess.
2. to auto-lock after no more than 10 minutes of inactivity
3. be kept up-to-date with security and operating system (OS) patches
4. have remote wipe enabled
5. have auto-wipe after a maximum of 10 failed login attempts

### *Informed Consent*

Participants must give verbal consent in order to be surveyed. To ensure informed consent, participants will be read a scripted description of the survey that includes possible risks and benefits.

### *Ethical Approval*

Minimal risk is involved due to participation in this study. The study may cause the participant to reflect on their personal health status or health problems. However, the results of this study may help researchers to create preventative measures for gastric cancer in the future. Furthermore, if a patient reports concerns about their own health status before, during, or after survey administration, the research team will be able to refer them for additional health evaluation if desired.

Ethical approval has been sought and granted from the University of Virginia Institutional Review Board (Please see attached US/UVA IRB approval letter). Additional approval is being sought through the University of Rwanda College of Medicine and Health Sciences (for Rwanda Military Hospital (RMH) and Centre Hospitalier Universitaire de Butare (CHUB)) and through the Butaro District Hospital (BDH).

## 7. Logistics

### *7.1 Distribution of responsibilities*

Dr. Pacifique Mugenzi and Dr. Ainhoa Costas-Chavarri will provide training, supervision, and support in Rwanda for the project. Claire Romaine, Alice Burgess, and Emily Romano will complete in-person and telephone interviews in English. Alphonse Zeta Mutabazi will complete all interviews in Kinyarwanda. Dr. Pacifique Mugenzi and Mr. Alphonse Zeta Mutabazi have and will provide guidance for any questions regarding Rwandan eating habits, cultural practices, etc. as they related to the Rwandan context. Dr. Allison Martin and Dr. Anneke Schroen will oversee the project from the United States throughout preparation, execution, and analysis. Allison Martin and Claire Romaine will complete statistical analysis and publishing after returning to the United States.

### *7.2 Timetable*

March 2016 – May 2016: Review and approval by Rwanda and Virginia IRBs  
 June 2016 – August 2016: Data collection and analysis  
 August 2016 – December 2016: Manuscript drafting, revision and submission

### 7.3 Budget

Translation Services	\$400
Data collection staff salary	\$400
Computer software	\$200
Tablets/iPad	\$240
Transportation to and from hospital sites	\$800
University of Rwanda College of Medicine and Health Sciences IRB	\$500
<b>Total</b>	<b>\$2540</b>

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# Epidemiological and cultural understanding for the prevention of gastric cancer in Rwanda: a clinical survey

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<sup>1</sup>University of Virginia, <sup>2</sup>University of Virginia school of Medicine, <sup>3</sup>University of Rwanda College of Medicine and Health Sciences, <sup>4</sup>Boston Children's Hospital



## Background

There is a paucity of epidemiologic data related to non-communicable diseases (NCDs) in sub-Saharan African. Global health has traditionally focused on infectious, communicable disease. NCDs are emerging as a leading cause of mortality in the developing world. Cancer has been identified as the second leading cause of NCD-related mortality and nearly two-thirds of all cancer diagnoses come from low- and middle-income countries (LMICs)[1].

Gastric cancer (GC) is the 12th most common cancer in Africa[2]. Rates are highest in Eastern African countries, including Rwanda, which has an estimated incidence and mortality of 8.3 per 100,000 and 8 per 100,000[2], though these statistics severely underrepresent the problem.

Since the 1994 genocide, Rwanda has rebuilt its healthcare system to be among the most well-respected in the region, particularly for cancer care[3].



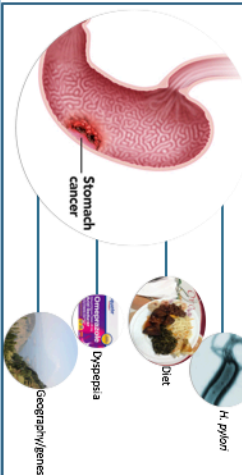
The USA researchers in Nyungwe Forest, near Bwira



U Rwanda cancer campus in Bwira

## Introduction

Understanding the contemporary etiology of gastric disease may inform healthcare priorities in a resource-poor setting in order to better allocate healthcare resources among patients with gastric cancer. Although identification of GC is improving in Rwanda, identifying a large population of cases was difficult. Instead, we sought to characterize the prevalence, risk factors, and preliminary illness narrative of gastric disease in a representative population by examining the risk factors displayed below [4,5].



## Methods and Materials

This survey study was completed using a 100-question survey tool developed by the researchers.

Participants were identified and interviewed in the waiting room of a surgery clinic at Bwira hospital, a tertiary care referral hospital located in Rwanda's Southern Province. A native Kinyarwanda speaker administered the survey while a co-investigator organized all survey administration and recorded responses into Excel. 93 people responded, and 3 were excluded from analysis (1 was a prisoner and 2 were unable to complete the survey).

Results were stratified as having dyspepsia (reporting symptoms ≥ 2 times per week for ≥ 1 month) versus not. Descriptive statistics were computed in R using odds ratios and 2-tailed t-tests.

## Results

Of the 90 respondents, 81% were farmers and 90% were from the Southern Province. Dyspepsia symptoms were not associated with age ( $T=0.299$ ,  $p=0.766$ ) or sex (for males,  $OR=0.699$ ,  $p=0.399$ ).

52% of respondents described chronic or ongoing dyspepsia and reported symptom frequency of 3 times weekly for 9 years, on average. Among dyspeptic respondents, 47% sought care from a healthcare provider, while 13% visited a traditional healer (see Table 1).

62% of dyspeptic respondents reported seeking medication for treatment but facing financial barriers.

Neither the *H. pylori* nor the GC risk factor behaviors showed any significant association with dyspepsia symptoms (see Table 2). However, 92% of dyspeptic respondents attributed worsening symptoms to starchy foods. The most commonly listed food was potatoes, followed by cassava then beans.

Table 1. Most commonly reported dyspepsia therapies.

	Suggested by Doctor	Suggested by Traditional Healer	Suggested by Family
Most common	Omeprazole (N=4)	Herbal medicines (N=5)	Drinking sour milk (N=2)
2 <sup>nd</sup> most common	Carbamates (N=1)	Drinking sour milk (N=2)	Herbal medicines (N=5)
3 <sup>rd</sup> Most Common	*Artisanal/ethnic (N=1)	Water and fluids (N=1)	Hydrated water (N=2)
4 <sup>th</sup> Most Common	Carbamates (N=1)	N/A	Asa (N=1)
5 <sup>th</sup> Most Common	*Tigey (N=1)	N/A	Citrus fruits (N=1)
6 <sup>th</sup> Most Common	N/A	N/A	Laying with belly on ground (N=1)

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Table 2. Association of *H. pylori* and GC risk factors with dyspepsia symptoms.

Exposure	Risk Factor for...	Odds Ratio	2-tailed Test
Home crowding	<i>H. pylori</i> infection	N/A	$T=0.551$ , $p=0.583$
Work with soil	<i>H. pylori</i> infection	$OR=1.59$ , $p=0.294$	N/A
Never boil drinking water	<i>H. pylori</i> infection	$OR=1.23$ , $p=0.631$	N/A
Consume citrus fruits	GC	$OR=0.70$ , $p=0.417$	$T=0.080$ , $p=0.932$
Consume few non-citrus fruits	GC	$OR=2.09$ , $p=0.087$	$T=-1.82$ , $p=0.072$
Consume few vegetables	GC	$OR=1.15$ , $p=0.923$	$T=0.218$ , $p=0.828$
Consume fried meat	Dyspepsia	$OR=1.29$ , $p=0.553$	N/A

## Outcomes

High prevalence of dyspepsia symptoms and lack of access to medications exist, suggesting significant disease burden among adults in Rwanda's Southern province. High dyspepsia rates may be associated with incidence of other gastric diseases in this population.

Future directions include plans to expand survey administration to referral hospitals in the Central and Northern districts to capture varying lifestyle and diet. This study could be made stronger with the addition of *H. pylori* testing for respondents and surveying of known GC patients.

Although reliable statistical data is lacking and detection is insufficient, global health researchers should continue to expand knowledge of NCDs through creative methods.

## Personal Statement

I cannot claim to have even scratched the surface of coming to understand the complicated culture, people, or history of Rwanda. Throughout my summer there, I was constantly being surprised by yet another act of kindness or confused by yet another unwritten rule. Even in my confusion, there always seemed to be a very kind Rwandan standing just outside the door ready to answer my questions or calm my concerns.

Although working in Rwanda presented me with many barriers, it was a great introduction to global health. I learned to never make assumptions, rush, or give up. I learned to always make connections, seek guidance, and take notes. I also realized that it's not all about the work—legal was a stunning place where I got to eat pizza and play trivia with professionals who I wouldn't even dream of meeting in the US. Thanks to Dr. Allison Martin and Eliza Campbell for being with me every step of the way.

IR3 Number: UVA-IR3-IR3-18035, UR CMHS-4983

## Acknowledgements:

Dr. Allison Martin, UVA/Rwanda mentor  
 Dr. Annette Schonek, UVA mentor  
 UVA/Centre for Global Health  
 The Hannah Graham Memorial Award, research sponsor  
 John and Sue Graham

Unite for Sight Abstract (Yale University)

**Epidemiological and cultural understanding for the prevention of gastric cancer in Rwanda: a clinical survey**

**Claire M. Romaine; Allison N. Martin, MD, MPH; Zeta Mutabazi; Christian Ngarambe, Mmed; Ahmed Kiswezi, Mmed; Pacifique Mugenzi, MD; Ainhoa Costas-Chavarri, MD, MPH; Anneke T. Schroen, MD, MPH**

**Preferred method of presentation:** Oral presentation

**Design and methodology:** According to GLOBOCAN, estimated gastric cancer (GC) incidence in Rwanda is 8.2 per 100,000. Severe gastrointestinal disease may be a marker for infection with *Helicobacter pylori*, a known risk factor for GC. This study utilized a survey of people visiting surgery clinics at a major referral hospital in Butare, Rwanda to characterize the prevalence, risk factors, and preliminary illness narrative of dyspepsia. Results were stratified as having dyspepsia (reporting symptoms  $\geq 2$  times per week for  $\geq 1$  month) versus not.

**Original data and results:** Of 90 respondents, 52% described chronic or ongoing dyspepsia and reported symptom frequency of 3 times weekly for 9 years, on average. Among dyspeptic respondents, 47% sought care from a healthcare provider, while 13% visited a traditional healer. 62% of dyspeptic respondents reported seeking medication for treatment but facing financial barriers. Accepted risk factors for *H. pylori* infection, including working with soil (OR=1.59, p=0.29) and not boiling water before drinking (OR=1.23, p=0.63) were not associated with dyspeptic symptoms. Neither was consumption of foods typically associated with dyspepsia including fried meats (OR=1.60, p=0.36). However, 92% of dyspeptic respondents attributed worsening symptoms to starchy foods.

**Conclusion:** High prevalence of dyspepsia symptoms and lack of access to medications exists, suggesting significant disease burden among adults in Rwanda's Southern province. High dyspepsia rates may be associated with incidence of other gastric diseases in this population. Future directions include plans to expand survey administration to referral hospitals in the Central and Northern districts to capture varying lifestyle and diet.

**Appendix B: A mixed methods study measuring perceived patient benefit of locally-made breast prostheses in Rwanda**

## IRB proposal

### **A Mixed Methods Study Measuring Perceived Patient Benefit of Locally-Made Breast Prostheses in Rwanda**

PI: Dr. Ainhoa Costas-Chavarri

Other investigators:

Dr. Pacifique Mugenzi

Dr. Allison Martin

Dr. Grace Kansayisa

Dr. Paul Park

Dr. Lydia Pace

Claire Romaine

Sojung Yi

Dr. Jacob Stephanus Dreyer

Mr. Albert Ndayisaba (PIH)

Mr. Vedaste Hategekimana (MOH)

Alexandra Fehr

### **Project Summary**

The purpose of this study is to utilize a mixed methods approach to assess the post-surgery experience of Rwandan women who have been diagnosed with breast cancer and have undergone a mastectomy for removal of one or more breasts. Specifically, we will evaluate their experience with the health care system, body image, quality of life, and wearing a locally-made breast prosthesis. The women will be randomized into an intervention group that receives a breast prosthesis at the beginning of the study and a control group, which will initially receive no prosthesis, but will be provided with one at the conclusion of the study. We will judge their experience using a combination of measures, including the Body Image After Breast Cancer questionnaire, the EORTC BR23, and a semi-structured interview. The interview will be analyzed utilizing an approach based in grounded theory. We hypothesize that women who receive the locally-made prosthesis will report improved self-perception and quality of life compared to the women who do not receive the prosthesis.

### **Background**

The incidence of breast cancer in Rwanda is 12.1%, a statistic that is extrapolated using Globocan data from surrounding countries given a paucity of local data. [1] Elsewhere in East Africa, age-standardized incidence for breast cancer is estimated at rates 30.4 per 100,000 women. [1] Approximately 76% of breast cancers are initially diagnosed at a late stage. [2] Currently, the available modalities for the management of breast cancer in Rwanda include endocrine therapy, chemotherapy (neoadjuvant, adjuvant and palliative), and surgery but not radiation. While the mastectomy rate in Rwanda is unknown, the lack of radiation therapy in the country effectively precludes providers from offering conservative surgery; women with surgically resectable disease are offered and managed with mastectomy.

Breast reconstruction is an important component of comprehensive care of breast cancer patients. Patients who have undergone reconstruction post-mastectomy have been shown to have higher quality of life outcomes than those who have not, [3] but surgical reconstruction is currently unavailable in Rwanda. Breast prostheses have also been used to improve self-image post-mastectomy. [4] Fitted silicone prostheses, which most closely mimic the feeling of breast tissue and can be adhered to the surgical site without a bra, are currently unavailable in this setting. Cloth bra inserts, made from African Kitenge fabric and other available materials by local women's sewing cooperatives, are a potential low-cost alternative. Commercially-made, silicone breast prostheses are expensive, costing on average around \$400 with costs as high as \$5000 for a custom-made prosthesis. [5] Alternatively, the locally-made, Kitenge cloth and foam prosthesis costs approximately \$2.45.

Multiple factors, including weight, appearance, and fit, have been associated with a woman's belief that her breast prosthesis is a quality product. [6] It is possible that the introduction of quality prostheses can enhance survivors' quality of life following breast cancer, as dissatisfaction with appearance when dressed and self-consciousness about appearance have both been associated with less contentment and lower quality of life. [7] Quality of life, level of psychological stress, and sexual functioning for breast cancer patients have even shown to be predictive of survival time. [8] The purpose of this study is to develop a breast prosthesis from local Kitenge fabric and evaluate its impact on the quality of life of Rwandan women with breast cancer who have undergone mastectomy.

## **Aims and Objectives**

### *Aim*

To measure the effects of locally-made, Kitenge fabric breast prostheses on perceived quality of life among a sample of women who have undergone mastectomy in Rwanda.

### *Specific Objectives*

1. To assess differences in quality of life and body image perception between post-mastectomy women with and without prostheses using the Body Image After Breast Cancer Questionnaire and the EORTC QLQ-BR23
2. To use qualitative interviews to describe the unique experiences of female breast cancer survivors in Rwanda in regard to breast cancer treatment, including breast loss due to mastectomy

## **Methods**

### *Study description*

This will be a prospective, mixed methods study using breast cancer body image questionnaires for quantitative evaluation and a qualitative semi-structured interview component.

### *Study population*

Participants will be drawn from women active in two local breast cancer survivor groups: BCCOE in Butaro, Rwanda and Conquer Breast Cancer Association (CBCA), a local non-governmental organization (NGO) in Kigali, Rwanda. We aim to recruit a total of 30 women: 15 to comprise the intervention group and 15 women for the control group. This sample size has been selected based on the number of members in these participant groups and also based on previous similar studies that have applied mixed methods to evaluate quality of life amongst survivor groups in the African context. We will enroll women who have undergone a mastectomy, but who have never undergone surgical reconstruction. All participants will provide written informed consent prior to participation.

### *Study design*

Study participants will be identified and randomly selected from the two survivor groups. After selection and consent, participants who are to receive prostheses will undergo measurement by the study investigators during or after a regular session of their respective survivors group. These measurements will be collected and communicated to the sewing cooperative by the study investigators; appropriately sized prostheses will then be created for the participants. Fifteen women will be given Kitenge breast prostheses, fifteen will not be provided with prostheses (N = 30). All women will interact with the study personnel on three separate occasions for administration of questionnaires: 1) at the start of the study; 2) two weeks following initial visit; 3) six weeks following initial questionnaire/interview administration. The reasoning for repeat administration of the questionnaires is to evaluate the change in score(s) from initial presentation (no prosthesis) and after a period of time has elapsed since following receipt of the prosthesis. The third administration evaluates whether the scores will return to baseline after a period time has elapsed following surgery or initiation of wearing the prosthesis. The semi-structured interview will be conducted at the time of the final questionnaire administration. The study team will visit the support groups during their regular meetings times to administer the questionnaires/interview at the specified intervals in order to minimize any additional cost or travel burden on the part of study participants. At the conclusion, women who did not initially receive a prosthesis will be provided with one free of cost. The study team will remain available for questions and to provide information about prostheses repairs or replacements.

Each visit will consist of the following questionnaires administered in the local language of the study participants by a member of the research team, who is a native speaker of Kinyarwanda. Each instrument will be translated into Kinyarwanda by a member of the study team (Dr. Kansayisa).

1. The Body Image After Breast Cancer Questionnaire (BIBCQ) [9]

- a. 5 minute to administer on average
2. The EORTC QLQ-BR23 [10, 11]
  - a. 5 minutes to administer on average
3. A semi-structured interview that will provide a quantitative perspective on women's experience after mastectomy in Rwanda. For the test group, the interview will also address women's opinions on the prostheses themselves. All interviews will be audio recorded for later analysis.
  - a. Administered one time at the same time as the third (6-week) questionnaire administration
  - b. 30 minutes to administer on average

*Study site (primary site of study investigators)*

1. Rwanda Military Hospital (RMH), a referral-level military hospital in Kigali, Rwanda
2. Butaro Cancer Center of Excellence

*Proposed intervention*

The intervention group will be given a breast prosthesis made from Kitenge fabric by a local women's cooperative. They will be asked to utilize them on a regular basis throughout the study period. The control group will not be given prostheses until after the study is completed.

*Main outcomes to be measured*

1. Body image as measured by the BIBCQ
2. Quality of life as measured by the EORTC QLQ-BR23
3. Experience with breast prosthesis as assessed through semi-structured interviews

**Selection of study population**

*Inclusion criteria*

Female patients who have undergone mastectomy and who participate in a breast cancer survivors group.

*Exclusion criteria*

- Patients under age 21
- Patients who have undergone surgical reconstruction
- Patients who are currently using breast prostheses or have used them in the past
- Patients who refuse informed consent
- Male patients

**Randomization**

Potential study subjects will be approached for enrollment in the study. Study procedures will be explained in detail and informed consent will be obtained for interested individuals. Study personnel will randomly open an envelope containing the arm of the trial that the participant will be enrolled in: control versus intervention.



## **Study Procedures**

### *Sample size*

The sample size of this study is limited by the number of women who are currently participating in survivor's groups within the country of Rwanda. Therefore, the sample size takes into account the approximate sizes of each group and makes a reasonable estimate as to the number of women who will be willing and able to participate in the study.

Expected enrollment:

Control group = 15

Intervention group = 15

Total participants = 30

### *Data management*

Survey results, interview recordings, and transcripts will be de-identified and kept in a password protected file on an encrypted laptop.

### *Proposed analysis*

Each participant's responses to the Body Image After Breast Cancer Questionnaire and the EORTC QLQ-BR23 will be scored according to the guide from the respective tool. Scoring of the Body Image After Breast Cancer Questionnaire will result in scores from three subsections (body stigma, transparency, body concerns).[9] Scoring of the EORTC QLQ-BR23 will result in four functional scores (body image, sexual functioning, sexual enjoyment, and future perspective) and four symptom scores (systematic therapy side effects, breast symptoms, arm symptoms, and upset by hair loss). Differences in the 14 total scores will be tested using ANOVA, Fisher's exact test, or chi-squared analysis, where appropriate.

Patients will also undergo a semi-structured interview that utilizes pre-written, focused open-ended questions. The semi-structured nature of the interview will allow for the interview to respond to new concepts that arise during the course of the interview, thus allowing for individualization of each interview. The interviews will be audio recorded and transcribed in whole (and translated back to English). Interviews will be conducted and transcribed by study personnel (Dr. Kansayisa). For analysis of the interviews, we will utilize a multi-level coding strategy based in grounded theory.[12]

### *Limitations*

1. Participants may be nervous or hesitant to share their entire experience in a live interview format
2. Tools have not been validated in the Rwanda context
3. Unknown confounders

## **Ethical considerations**

### *Confidentiality*

In order to ensure confidentiality of study data, each study participant will be assigned a number. The survey results, interview recordings, and transcripts will be labeled with these numbers, but

never with patient names. Identifying information associating participants with their numbers will be stored in a separate password-protected file. All study-related materials will be kept on an encrypted laptop. Upon completion of transcription and study analysis, all audio recordings will be destroyed securely.

#### *Informed consent*

All participants will have the study explained to them in detail before enrollment. They will be given the opportunity to ask any questions and have them answered by a member of the research team. Participants will sign a consent form prior to enrollment.

#### *Ethical approval*

This protocol, translated surveys and translated template informed consent forms contained in Appendix I will be reviewed and approved by the College of Medicine and Health Sciences (CMHS) Institutional Review Board (IRB) with respect to scientific content and compliance with applicable research and human subjects regulations. Additional approval will be sought through the BCCOE and the RMH institutional IRBs, and the Boston Children's Hospital Institutional Review Board (employer of PI A.C.C.). The protocol, site-specific informed consent forms (translated into Kinyarwanda), and questionnaire/interview materials will be reviewed and approved by the relevant IRBs. Subsequent to study initiation, the responsible above listed IRBs will review the protocols and provide approval or request modifications.

#### *Risk to patients*

This study may place patients at risk of psychological stress, but there is minimal to no risk of physical harm. Any participant who reports or appears to be experiencing emotional distress will be referred for psychological assessment and potential counseling. Information gathered and conclusions formed may help guide the future care of patients with breast cancer post-mastectomy.

### **Logistics**

#### *Distribution of responsibilities*

Dr. Ainhoa Costas-Chavarri will provide training, supervision, and support in Rwanda for the project. Dr. Grace Kansayisa will complete in-person and telephone interviews in Kinyarwanda and Claire Romaine will complete in-person and telephone interviews in French. Dr. Martin will complete statistical analysis. All investigators will be involved in preparing manuscripts for publication.

#### *Timetable*

September– October 2016: Review and approval by CMHS, BCCOE, RMH, and BCH IRBs

November– March 2016: Data collection and analysis

March– May 2016: Manuscript drafting, revision and submission

#### *Budget*

Translation Services	\$200
Breast prostheses (RWF 2000 each x 30)	\$75
Data collection staff salary	\$400
Handheld recording device	\$50
Research staff transportation to and from hospital sites	\$800
<b>Total</b>	<b>\$1450</b>

## **Informed Consent Agreement**

**Please read this consent agreement carefully before you decide to participate in the study.**

**Purpose of the research study:** The purpose of the study is to better understand the post-surgery experience among women who have been diagnosed with breast cancer and have undergone mastectomy. You will be asked questions about your self-confidence, self-image, quality of life, and experience wearing a breast prosthesis.

**What you will do in the study:** All participants will be randomized to a control or intervention group. The intervention group will be provided with a Kitenge breast prosthesis. All women will complete two questionnaires on three separate occasions (at randomization, 2 weeks after randomization, 6 weeks after randomization). All women will complete a semi-structured interview. The surveys will allow us to evaluate the post-surgery experience of women with breast cancer and to assess the impact of the Kitenge breast prosthesis. You may skip any questions that make you uncomfortable. You may also elect to discontinue your participation in this study at any time.

**Time required:** The study will require about approximately 60 minutes of your time (10 minutes for each of 3 questionnaire administrations and 30 minutes for the semi-structured interview). I

**Risks: Minimal risk is involved in this study. The study may cause you to reflect on your experiences related to breast cancer diagnosis, surgery, and how this has affected your life.**

**Benefits:** You will be provided with one Kitenge breast prosthesis as part of your participation in this research study. You will not otherwise be compensated for your participation. The study may help us understand if locally-made prostheses are beneficial for Rwandan women who have mastectomies. It may also help us understand how to better educate Rwandan general practitioners in the postoperative management of women who undergo mastectomy.

**Confidentiality:**

**Data linked with identifying information:**

The information that you give in the study will be handled confidentially. Your information will be assigned a code number. The list connecting your name to this code will be kept in a locked file. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report.

**Anonymous data:**

The information that you give in the study will be handled confidentially. Your data will be anonymous which means that your name will not be collected or linked to the data. Because of the nature of the data, it may be possible to deduce your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you.

**Voluntary participation:** Your participation in the study is completely voluntary.

**Right to withdraw from the study:** You have the right to withdraw from the study at any time without penalty.

**How to withdraw from the study:** If you want to withdraw from the study, please contact the study coordinator by phone or email. There is no penalty for withdrawing.

**Payment:** You will receive no payment for participating in the study.

**If you have questions about the study, contact:**

Dr. Ainhoa Costas-Chavarri  
Rwanda Military Hospital, University of Rwanda  
Telephone: +250 0789528584  
noabelles@gmail.com

Dr. Grace Kansayisa  
University of Rwanda, Postgraduate Trainee in Surgery  
Telephone: +250 788 503 841  
gracekansayisa@gmail.com

**If you have questions about your rights in the study, contact:**

Ms Kaligirwa Nadine, Research Assistant

Rwanda Biomedical Center

Medical Research Center Division

Phone: +250788302495

**Agreement:**

I agree to participate in the research study described above.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

You will receive a copy of this form for your records.

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**Appendix C: An Epidemiological Survey and Case Series of Military Women Presenting  
with Breast Abscesses at the Rwanda Military Hospital (RMH)**

IRB proposal

**An epidemiological survey and case series of military women presenting with breast abscesses at the Rwanda Military Hospital (RMH)**

**Principal Investigator (Rwanda):** Ainhoa Costas Chavarri, MD, MPH, FACS, University of Rwanda/Human Resources for Health, Rwanda Military Hospital, Kigali, Rwanda; Boston Children's Hospital, Boston, Massachusetts, USA

Other investigators:

Dr. Pacifique Mugenzi, MD, Oncologist, University of Rwanda, Rwanda Military Hospital/King Faisal Hospital, Kigali, Rwanda

Kelly Kaneza, Medical Student, University of Rwanda

Claire M. Romaine, Undergraduate Student, University of Virginia

Dr. Allison Martin, MD, MPH, General Surgery Resident, Department of Surgery, University of Virginia



## Background:

With more focused attention towards non-communicable diseases (NCDs) in low resource settings/LMICs, specifically breast cancer, the establishment of early detection and screening programs, has led to the increased recognition and diagnosis of benign breast diseases as well. Despite this elevated awareness, the literature contains few descriptions of breast abscesses in immunocompetent, non-lactating women in sub-Saharan Africa (SSA). In Kenya, in a study evaluating 390 breast lesions diagnosed in both male and female patients, 24.1% were found to be non-neoplastic, and only 2.6% (n=9) of the total lesions were abscesses.<sup>1</sup> A 25-year histopathologic review of 1864 benign breast lesions in Nigerian men and women identified only 77 cases of breast abscess or chronic, granulomatous, periductal, or acute mastitis.<sup>2</sup> Neither study specified whether or not the women had been lactating. The population groups that have been most commonly described to suffer from breast abscesses in SSA include those with TB of the breast (a subset of granulomatous mastitis) and HIV-infected women.<sup>3,4</sup>

In the high-resource settings, the organisms that most commonly cause breast infections are *S. aureus*, *Enterococcus*, anaerobic *Streptococcus*, and *Bacteroides* spp.<sup>5</sup> Trauma, as well as factitial disease of the breast, have both been implicated as a possible causes of breast abscesses.<sup>5</sup> Risk factors for mastitis include breast feeding, smoking, nipple piercing, and eczema.<sup>6</sup> To our knowledge, no studies correlating breast abscess to a specific vocation or pattern of exercise, including involvement in the military, are published and available at this time.

In Rwanda, there is only one combined breast clinic, located in the capital city of Kigali at the Rwanda Military Hospital (RMH). This multidisciplinary clinic is managed by a general surgeon and an oncologist working together and is open to both women and men with either benign or malignant breast disease. The clinic sees approximately 30 patients every week. While breast abscesses comprise only 2.89% of clinical diagnoses seen in the clinic during its 2 year duration, a disproportionate number of cases have been found to be in military women. The cause of these abscesses is currently unknown. The epidemiology of breast abscesses in military women has not been adequately addressed in the literature, though the United States (US) army has published official recommendations related to breast hygiene in enlisted women. These include advice on wearing breathable sports bras, using a washcloth to clean the area under the breasts when showers are unavailable, and utilizing a moisture absorbent powder on the skin under the breasts.<sup>7,8</sup> At the present time the Rwandan Ministry of Defense does not have specific guidelines regarding breast care for women enlisted in the military.

## Aims and Objectives:

*Aim:* To identify the etiology of the breast abscesses in this specialized patient population and develop best practices for maintaining breast health in military women in Rwanda

*Objectives:*

- Present a descriptive case series of HIV negative, non-lactating military women who have presented with breast abscesses to the combined breast clinic at RMH, a referral hospital in Kigali, Rwanda

- Administer an epidemiological survey interview to all women in the case series to determine possible etiologies and risk factors for breast abscess in this population
- Develop recommendations for breast health based on study findings and a review of the literature

Hypothesis:

We hypothesize that breast abscesses in military women in Rwanda are related to changes in living conditions or specific physical activities related to their military service.

Methods:

*Study Description:*

Using medical records from the breast clinic, the general surgery clinic, and the general surgery wards at RMH, we will identify all female military patients who have presented with breast abscesses since April 2014 (when the multidisciplinary breast clinic opened). A retrospective chart review of these cases will be completed. Participants will also participate in an epidemiological survey interview in order to collect information related to behavioral and/or environmental risk factors to identify possible causes of breast abscess that would not be recorded/captured in the medical charts.

*Study Design:*

- Retrospective and prospective case series chart review of breast abscess cases in military women at the Rwandan Military Hospital
- Interviews of study participants that will explore etiology and risk factors.

*Study Site:*

Rwanda Military Hospital is a tertiary care referral hospital in Kigali that provides health care services to both civilian and military patients, 80% and 20%, respectively. It has a bed capacity between 350-400 beds.

*Study Population:*

The study will include military women presenting with breast abscesses between April 2014 and August 2016.

*Main exposures and/or confounders to be measured:*

The retrospective chart review will collect the following data for each case:

- date of presentation
- time between onset of symptoms and presentation to clinic
- laterality/location of the breast abscess
- any other medical comorbidities (diabetes, hypertension, HIV, etc) noted by the doctor during initial presentation to clinic
- treatment completed
- microbiology/culture data
- pregnancy/breast feeding status

The interview will collect the following data for each participant (see attached Interview document):

- type and duration of physical activities engaged in during military service
- environmental exposures
- dietary patterns
- patterns of behavior including smoking
- living conditions, including hygiene patterns

### Selection of a study population:

#### *Inclusion criteria*

- Military women presenting to RMH with a clinically confirmed diagnosis of breast abscess between April 2014 and August 2016.

#### *Exclusion criteria*

- Any woman who has presented with a breast abscess but is not in the military
- Male patients

### Study Procedures:

#### *Procedures at enrollment*

Informed consent will be necessary for all enrolled in the study, as both a chart review and an interview are necessary for complete data collection. Once possible participants are identified, they will be contacted over the phone to schedule an interview. The research team will explain the purpose of the study and provide the patient with the choice to give written voluntarily consent to participate in the study (see attached Informed Consent document).

#### *Measurement of exposures and confounders*

Primary data collection will occur during the retrospective chart review. Additional data collection will occur during the interview.

#### *Measurement of outcomes*

The primary outcome of interest is to identify patterns of exposures and behavior related to military service that may be causing an increased number of breast abscesses. This will be evaluated using both the chart review and the interview.

#### *Sample Size*

We expect to enroll between 5 to 7 cases.

#### *Data management*

Data from the chart review and interview transcripts will be de-identified and kept in a password protected file on an encrypted laptop.

#### *Proposed analysis*

Case profiles will be created using data collected from both the retrospective chart review and the interviews.

The epidemiological survey will consist of structured interviews which will be audio recorded, and then later transcribed. The qualitative data contained in the interview transcripts will be analyzed with grounded theory. This process will allow us to code and group concepts that are repeated in the interviews, thereby identifying thereby identifying possible risk factors and other issues that may currently be unknown (and it has proven successful in studies with East African participants).<sup>9</sup> Three researchers will read each manuscript in order to create and assign these concept codes. This odd number of readers will allow for extended discussion and comparison among perspectives. Once important concepts are identified and described with this method, qualitative data from the experimental and control groups will be compared and reported using a narrative.

#### *Limitations*

- Inadequate or missing patient documentation for the study population
- Low sample size may result in study that is descriptively interesting but not statistically significant

#### Ethical considerations:

##### *Confidentiality*

Patient name and phone number will be recorded and only accessed by the research team in order to schedule interviews. A de-identified database will be created in Microsoft excel. De-identified data will be stored in a password protected and encrypted laptop. Data will be kept in the possession of the PI of the study and only the research team will have direct access to patient name or phone number if required.

##### *Informed consent*

Written consent will be obtained from all study participants before their interview begins. The study will be thoroughly explained, and participants will be allowed to ask researchers any remaining questions.

##### *Ethical approval*

This study imposes no more than minimal risk to participants. Ethical approval will be sought from RMH.

#### Logistics:

##### *Distribution of responsibilities:*

Dr. Costas and Dr. Mugenzi will provide guidance and oversee the project. Retrospective chart review will primarily be performed by Ms. Romaine. Interviews will primarily be performed by Kelly Kaneza. Dr. Martin will complete statistical analysis. All researchers will be involved in manuscript drafting, revision, and submission.

##### *Timetable:*

July 2016: Review and approval by RMH IRB.

August 2016–September 2016: Data collection and analysis

October 2016: Manuscript drafting, revision, and submission

*Budget:*

Data collection staff: \$200

Voice recording device: \$50

References:

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**Appendix D: World Cancer Congress reflection papers**

Strengthening health systems for Cancer and NCD comorbidities: successful approaches for integrated care

At the World Cancer Congress, this panel argued that cancer care must be linked into other fields (primary care, cardiology, etc.), in order to deliver better and more affordable care. The most inspiring speaker was Dr. Shannon Barkley, a primary care physician and WHO Technical Officer.

The primary ethical issue that arises when considering an integrated approach to cancer care is resource allocation. Why invest even more into curing cancer when it is already so expensive? First, cancer and other NCDs constitute an overwhelming majority of the global burden of disease. Second, a short-term investment in strengthening health systems should cause long-term savings. Here, the presentation's strongest argument stated that when healthcare systems are properly managed and integrated, all members of the team perform to their highest level of training. This improves efficiency in personnel education costs. Countries have also minimized costs by redirecting wasted or outdated human and monetary resources towards integrated care. In China, health workers previously responsible for enforcing the one-child policy have been retrained to create NCD risk factor awareness and referral networks. The US Department of Veteran's Affairs has shared its universal patient chart technology with healthcare management companies such as Kaiser Permanente.

Expanding cancer care into a systems-based approach also provokes a possible breach of confidentiality. As discussed in class, tumor registries are a source of ethical concern because entry of patient data is the default. Depending on the state, approval may not be required for entry into the registry. Even if "consent" is sought, true informed consent is difficult to achieve for matters that may seem trivial in comparison with patient treatment. This confidentiality breach is greater still for tumor boards, where patient information is discussed with a group of practitioners. I would argue that, from a communitarian perspective, adding a primary care physician, cardiologist, or diabetes specialist to a tumor board constitutes an overall social good. Input from these fields improves the integrated medical perspective of all present, therefore leading to overall improved patient care. This triumph would overrule the miniscule confidentiality concerns of adding one more person to the room, especially a licensed practitioner who is HIPAA-trained. Of course, this argument could be overshadowed by a research perspective, wherein the safety of the individual must be protected over larger societal gain.

## The global impact of cancer on women: healthy women, healthy economies

At the World Cancer Congress, this panel focused on aspects of cancer that are gender-unique. It portrayed views from both the developed and developing world, important because the roles of women are so different in those respective societies. Princess Dina, the most notable panelist, has been an advocate for cancer care in the developing world ever since her son traveled all the way to Boston for treatment in the late 1990s. Her statements were both powerful and powerfully spoken.

While addressing breast cancer, Princess Dina stated that breast reconstruction is treatment, not cosmetic surgery. This is a serious claim, especially for the developing world, where actual tumor removal surgery is scarce and reconstructive surgery is almost nonexistent (the one patient that I met while working in Rwanda this summer who had undergone reconstruction had traveled to Saudi Arabia for the surgery). She based her claim on the fact that so much social stigma exists over altered feminine physical structure that many patients experience serious psychological problems post-mastectomy. In order to make a resource allocation argument for breast reconstruction, one would have to (1) establish that the psychological health of breast cancer patients is worthy of resources and (2) argue that reconstruction is the cheapest and most effective method for maintaining psychological health. This decision would be based on the specific situation in a given country. Does stigma exist to the extent that patients may lose their families or livelihood? What is the availability of surgical and psychological services? Would prostheses be a better option in this context? Though these and many other questions must be considered, I agree with Princess Dina's statement that appearance-altering services should not always be associated with vanity.

Princess Dina also said that she hates the word "lifestyle" because health behaviors are rarely based on individual choice. Myself and anyone who has studied the social determinants of health would agree with her belief that health, especially when it comes to noncommunicable diseases, is the result of an ecological model. We can establish that the blame is communal, but the ethical problem comes when we ask if the responsibility is communal. If the responsibility is communal, does the government have the ability to guide or limit unhealthy choice? Countries such as Mexico, which recently adopted a sugar tax, would argue the affirmative. Princess Dina's country of Jordan is fighting its own battles on this front, most notably regarding the regulation of tobacco and shisha (hookah).