



Supply chain of routine orthopaedic implants in Kampala, Uganda: public-private workarounds arising from poverty and scarcity

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Abstract

We examined how surgical implants were accessed by orthopaedic trauma patients in selected public and private hospitals in Kampala, Uganda. The study employed a series of interviews with professionals highly familiar with this circumstance: orthopaedic surgeons from Mulago National Referral Hospital (MNRH), and staff of the MNRH and Ministry of Health (MOH) procurement departments. We also interviewed patients who had received implants in MNRH. Surgeons were forthcoming in describing how implants were made available to their patients and offered several opinions on implant quality, regulation, and the importance of donations in orthopaedic care. The health care officers corroborated the implant procurement process described by the surgeons. We observed that the procurement process was comprised of three distinct pathways: two pathways through which patients purchased implants either directly or through intermediaries, and one donations pathway that provided Western implants through collaborative partnerships. These pathways have evolved to circumvent the mismatch between the high cost of orthopaedic trauma surgery and the overall poverty of the population. This qualitative study strongly supports expanding the capability of the Uganda National Medical Stores (NMS), the arm of the MOH that stores and distributes medicines and supplies to public hospitals, into a sustainable source of orthopaedic implants, inclusive of improved regulatory oversight and quality control for implants.

Keywords: orthopaedics; trauma; implant surgery; supply chain; Uganda; poverty

Introduction

Traumatic injury accounts for roughly a third of the world's Disability Adjusted Life Years (DALY) (Murray et al., 2012). Like many low and middle income countries (LMIC), Uganda is experiencing a growing burden of traumatic orthopaedic injuries (Kigera et al., 2010). It is also estimated that half of all traumatic injuries in Uganda are caused by road traffic collisions, as commuters more commonly use small motorcycle taxis or public buses on narrow, poorly maintained roads that are unsafe for both drivers and pedestrians (Nantulya & Reich, 2002). Femur and tibia fractures, a common injury in traffic accidents (Balikuddembe et al. 2017), account for over 15% of total hospital admissions at Mulago National Referral Hospital (MNRH) in the capital city of Kampala (Hsia et al., 2010). The significant lack of orthopaedic surgery supplies in MNRH drastically limits suitable treatment for such traumatic injuries, frequently resulting in long-term disability (O'Hara et al., 2014).

The routine treatment of fractured bones is plaster or fiberglass casting. In more severe cases, casting is accompanied with traction and/or surgical immobilization using orthopaedic bone fixation implants such as external fixators, pins, rods, plates, and screws (Ratner et al., 1997). Compared to traction, implant fixation of severe fractures results in significantly shorter hospital stays, lower financial costs, and better surgical outcomes (Ratner et al., 1997). Due to limited availability of orthopaedic implants, non-operative fracture management remains the current, albeit suboptimal, standard of care in Uganda. The prior reports from O'Hara et al. (2014) and Bouchard et al. (Bouchard, 2011, Bouchard et al., 2012) pointed to poor governmental leadership, corruption, an overburdened health care infrastructure, insufficiently trained personnel, and the high cost of surgical services and supplies as the primary factors that limit access to modern orthopaedic implants in Uganda.

The current study follows upon a previous report that assessed the use of biomedical materials in MNRH (Bakwatanisa et al., 2016) and was prompted by two confounding observations that arose from that report. First, although services in public healthcare institutions are ostensibly free of charge, this is almost never the case when surgery is involved. Second, was the ambiguous nature of the negotiations between patients, doctors, private vendors, donating entities, the government, and non-governmental organizations (NGOs) that determine access to medical implants.

We present orthopaedic surgeons' and procurement officers' perspectives of the Ugandan implant supply chain, supplemented with accounts by orthopaedic patients who have received implants at MNRH. LMIC lack the infrastructure for local implant fabrication

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and critical assessment of imported implants, relying largely on certification by the supplier. These factors effectively reduce the process in LMIC to implant selection, procurement and surgical implantation. The goal here was to understand how the high income country (HIC) vs LMIC healthcare gap plays itself out in Uganda in terms of patient access to routine orthopaedic implants, like screws, nails and bone plates. Specifically we sought to describe how patients gain access to routine orthopaedic implants in Uganda from the point of view of the crucial gatekeepers: orthopaedic surgeons and procurement officers. To our knowledge, the current study provides the first description of an orthopaedic implant procurement pathway in a low resource setting.

Methods

This was a cross-sectional study that used an exploratory case study approach to determine participants' perspectives on the orthopaedic implant quality and supply chain in both public and private hospitals around Kampala, the capital city of Uganda. Unlike the studies of O'Hara et al. (2014) that focused mainly on the patient and surgeon experience, this study focused on the process by which orthopaedic implants were selected and procured for use in trauma patients in Kampala, Uganda. According to Yin (2003), an exploratory case study is suitable for situations lacking "detailed preliminary research, or specifically formulated research questions or hypotheses". The case study approach also allows the examination of actual situations (Yin, 2003; Baxter & Jack, 2008). This approach was chosen because the LMIC orthopaedic implant pathway is a new area that has not been explored before and thus has limited contextual theoretical background (Kohn, 1997). This approach has the ability to facilitate in-depth exploration and collection of detailed data about a particular experience (Stjelja, 2013).

The study was approved by the Orthopaedic Surgery Department at MNRH and the Makerere University School of Biomedical Sciences Higher Degree Research Ethics Committee (SBS-HDREC: 331). Administrative clearance was obtained from Mulago Hospital Research Ethics Committee (MREC: 894). The manuscript derived from the study was approved for publication by the SBS-HDREC committee.

Participant Selection

Participants were recruited according to a purposive selection technique (Allen, 1971). The researchers obtained permission from the leadership of the Orthopaedic Department at MNRH to identify and interview surgeons who routinely perform implant surgery and were knowledgeable about the orthopaedic implant supply chain. The all-male surgeons were contacted by phone and informed about the study. Thirteen surgeons who routinely performed orthopaedic implant surgery (nine from MNRH, two from private not for profit, and two from private for profit hospitals) responded positively to the invitation. We also contacted one officer from the procurement and disposal of assets unit at MNRH, and one officer from the Ministry of Health (MOH) procurement department to verify the surgeons' account of the implant procurement process. Information requests were submitted to local and international suppliers of orthopaedic implants to obtain publically available price quotes to assess implant affordability.

A second set of 53 interviews was conducted with patients who had received orthopaedic implant surgery at MNRH. Of these patients, 16 were admitted to the hospital for post-surgery review, two of which had been living with implants for more than six months.

Interview Procedure

Written informed consent was obtained from all participants prior to enrolment into the study. To ensure privacy, interviews were conducted in closed offices in the respective hospitals and at the MNRH Orthopaedic Surgery Department. No compensation or incentives were provided and participant identities were not linked with individual names in order to maintain their anonymity and confidentiality.

All interviews were conducted between October 28, 2015 and December 21, 2015 in Kampala, Uganda by a team of five biomedical engineering undergraduates at Makerere University. Relationships between interviewers and interviewees were not established prior to the interview. For accurate data collection, all interviews were audio recorded to help later in data analysis. Interviews were semi-structured with a list of common guiding questions. The surgeons interviewed were designated by D1-D13. The patients interviewed was designated by P1-P53.

Data Analysis

Audio recordings of the interviews were transcribed by the authors, and independently checked by two investigators to confirm the accuracy of the verbatim transcription. Two senior authors (EM and ZS) reviewed the transcripts and identified themes and sub-themes to pursue in the analysis. Codes were then developed according to the themes identified. Data reduction and analysis were conducted through content analysis (Hsieh & Shannon, 2005) focusing primarily on understanding the path to orthopaedic implant procurement and quality. Outputs from the interviews were compared to identify patterns in the data. Key quotes from surgeons were selected to illuminate the main categories of interview findings.

Results

The researchers sought to understand surgeon preferences and criteria for selecting the types of implants, the quality of implants, how implant preference differed based on implant origin, and surgeon opinions on the impact of implant choice on patient outcomes. Interviews with surgeons and procurement officers primarily revealed three distinct implant supply pathways. In terms of tone, interviews with surgeons were largely frank and subjective. Several surgeons noted chronic under-procurement of orthopaedic surgery supplies, as well as rumored instances of chronic pilfering, and inadequate government support (Rwothungeyo, 2014). Surgeons also uniformly expressed preferences for donated implants from Western countries due to quality concerns over less

expensive implants from India and China. Interviews with procurement officers were less frank, but were confirmatory of the identified implant supply pathways described by surgeons. Information gleaned from implant suppliers was a straightforward response to a request for public information.

Orthopaedic Implant Procurement Pathways

Analysis of the interviews with surgeons and procurement officials at MNRH and MOH revealed three distinct procurement pathways as described below.

Pathway 1: Donations Model

The Orthopaedic Surgery Department at MNRH has established collaborations with foreign organisations and universities, for example, Duke University (USA), University of British Columbia (Canada), Fukui University (Japan) and Health Volunteers Overseas (USA). Visiting surgeons from mostly Western institutions often request implant donations from established overseas companies to be used on short-term medical missions. In most instances companies that donate orthopaedic implants for a medical mission expect the unused implants to be returned; however, it is often possible to negotiate for the unused implants to be stockpiled at the hospital. Through these collaborations MNRH has received significant donations for infrastructure development, human resource capacity building, and surgical supplies including orthopaedic implants and consumables.

When donations are received, they are usually cleared by Uganda Revenue Authority through the MNRH administration. On receipt, donated implants are entered into an inventory that is entrusted to the theatre area manager for safe custody (Figure 1). In consultation with the theatre area manager, practicing surgeons then decide which implants to use depending on the surgical indication and the available supply. Patients receive donated implants on a first come-first served basis depending on the availability of the type of implant that is needed. While highly desirable, surgeons noted that these donations are not a dependable source of implants.

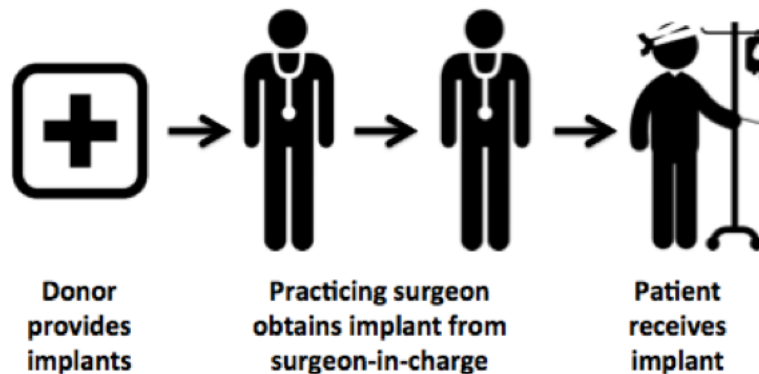


Figure 1. Donations model

Pathway 2: “Hawker” Negotiated Prescription Model at Public Hospitals

MNRH is the largest hospital in Uganda, and thus receives the highest number of orthopaedic trauma patients. The implant supply chain in MNRH operates largely on a patient prescription model where patients are required to purchase and supply their own implants through external suppliers (Figure 2). There are several private suppliers that sell surgical implants in Uganda with most of them having sales representatives, or “hawkers” on the MNRH premises. In fact, some of the hawkers are present on days when routine major ward rounds are held. Frequently it is during these rounds that decisions are made on the definitive treatment of orthopaedic conditions, particularly fractures. The suppliers have a Memorandum of Understanding with the hospital administration to supply implants and are usually given the opportunity to advertise themselves and promote their products in the weekly Orthopaedic Surgery departmental meetings. Usually when a patient is due for surgery, the surgeon provides a prescription for the required implant. The hospital plays no role in the purchase of implants by patients; rather the patients or a family member contacts these hawkers directly and agrees on the payment terms. In many cases surgeons will recommend a vendor to the patient depending on the type, biomaterial and country of manufacture. In extreme cases where surgery is the only option, and patient cannot afford to pay for implants, hospital social workers are requested to help secure sponsors.

Pathway 3: Hospital or Physician Mediated Procurement in Private Hospitals

The implant supply chain in the private institutions also passes through local suppliers and distributors (Figure 3); however, the patient plays no direct role in negotiating the purchase of implants. Some private hospitals procure and store implants from which the surgeon selects implants for their patients. In cases where an adequate stockpile is not available, the surgeon contacts the local suppliers and distributors, and negotiates the price and purchases the implant on behalf of the patient. When possible the surgeon consults with the patient or representative before initiating negotiations with suppliers. Of the three pathways identified in this study, this one most closely resembles the surgeon-centered implant procurement process seen in HIC, except that the patient is responsible for the entire cost of the implant and the surgical procedure.

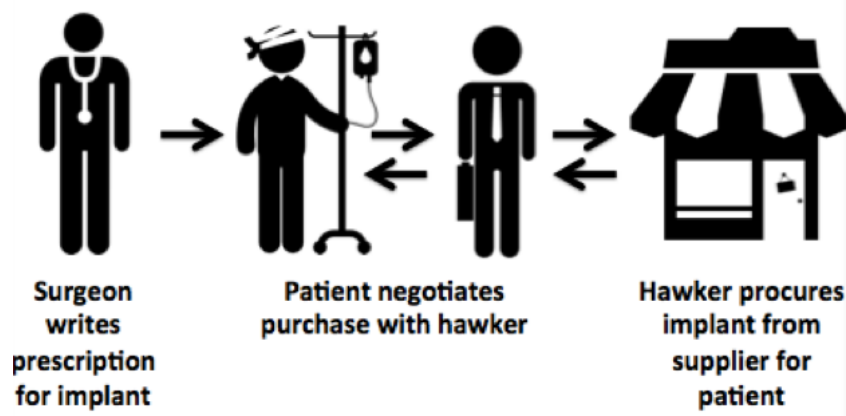


Figure 2. Hawker negotiated prescription medicine at public hospitals

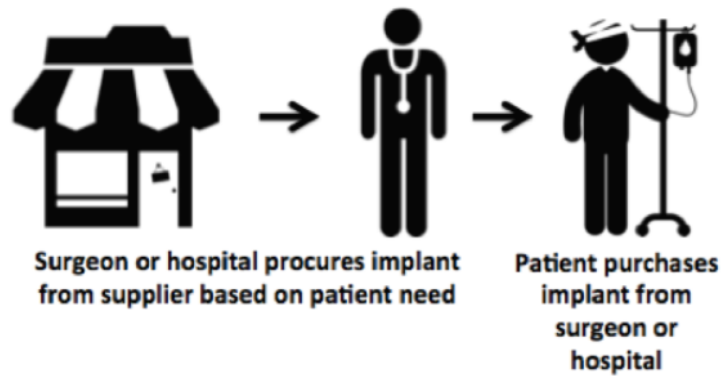


Figure 3. Hospital or physician mediated procurement model in private hospitals

Implant Affordability

Table 1 lists the prices of some commonly used orthopaedic implants as obtained from local suppliers via an information request. Typically, a patient in MNRH must pay for an implant unless it is donated. This cost is a negotiation between the patient and the supplier for which no specific formula was revealed, but is dependent on the implant price and the economic status of the patient. The choice of implant also depends on the economic status of the patient. Uganda does not have a national insurance scheme to defray medical costs, nor do any Uganda health insurance companies cover the cost of orthopaedic implants. In lieu of donations, patients undergoing orthopaedic surgery personally have to cover the entirety of costs.

TABLE 1. Example implant prices in USD as reported by suppliers at MNRH

Implant Type	Supplier1 (India)	Supplier 2 (India, China)	Supplier 3 (USA/Germany)
Upper Limb Narrow DCP 4.5mm (humerus)	\$24 - \$45	\$24 - \$45	-
Upper Limb Small DCP 3.5mm (radius, ulna)	\$22	\$24	-
Upper Limb Cortical Screw	\$2.75	\$2.40	-
Interlocking Nails, Locking Bolts (femur)	\$120	\$110	\$369
Intramedullary Rod and Nails	\$150	\$300	\$1000
Interlocking Nails, Locking Bolts (tibia)	\$120	-	\$294
Proximal Femur Locking Nail	\$239	-	\$359
Bipolar Hemi-arthroplasty	\$165	\$173	\$2000
Total Hip Replacement	-	\$2094	\$1300 - \$2500
Spine	\$900 - \$2400	-	\$1000 - \$3000
Total Knee Replacement	-	\$1,500	\$1800 - \$2500
Handplates and Screws	\$34	\$30	-

Surgeons' Opinions

The interviews with the surgeons were a rich source of information. The following, inclusive of representative quotes, provides insight into their experience vis-à-vis the access to, and use of, orthopedic implants in Kampala, Uganda.

Potential Role of Uganda National Medical Stores

Overall, surgeons concurred that government contribution was minimal, although they did not know the specifics of this shortfall. The Uganda National Medical Stores (NMS) is mandated by the MOH to provide medical supplies to all public health facilities in the country, but the NMS does not seem to have the capacity and/or willingness to effectively and reliably procure medical implants. The dilemma is that orthopaedic implants are expensive and the annual health budget in Uganda is limited; therefore, NMS seldom supplies these implants. When asked for their opinion on why NMS does not provide these much needed supplies for effective trauma management, most surgeons cited cost-effectiveness and equitable distribution of resources among the general population as the main factor.

... [the cost of] one implant may be the equivalent of supplies of a whole other department in term of costs. If you are to consider equitable distribution [of resources] I think it comes down to the economy, you would rather consider buying supplies to handle so many patients instead of just one implant.

Surgeon D4

Implant Quality

When asked about the quality of implants used in the fixation of fractures at MNRH surgeons opined that it was difficult to definitively comment on the quality of orthopaedic implants because the surgeons were not provided with implant quality assessment data. Regardless, all surgeons expressed a preference for implants from HIC primarily based on reputation.

The quality of implants from India is worse than that from China, South Africa, German[y] or USA. [Implants from the latter countries] are more durable and have a low failure rate. Some implants break prematurely and do not promote healing. However some are good.

Surgeon D5

Implant Regulation

The absence of well-streamlined procedures for verifying the quality of imported implants and the absence of locally fabricated implants seem to be major challenges in Uganda. Ideally the quality of these implants and their fitness for use on human beings should be verified by some combination of the MOH, Uganda National Bureau of Standards (UNBS), National Drug Authority (NDA) and Uganda Revenue Authority (URA); however the extent to which this occurs was not clear.

We assume that all imported implants are cleared by UNBS, NDA and URA. They should have mechanisms of verifying quality and differentiating genuine from fake products. They must have minimum acceptable standards. It is also assumed that donations from developed countries are approved, certified and of high quality.

Surgeon D6

Although the official from the MOH confirmed that the ministry scrutinizes donated equipment for usability, he also said there were no clear guidelines and policies on donated medical equipment.

You cannot really tell who is donating, what is being donated, and how recent[ly] the donation came in. Not all donations pass through [MOH], so we do not know what they donate. The MOH looks at particular things for instance, the relevance of the donations, the use of those donations, whether they are new or used. Particular care is taken on used donations.

MOH official

Donated Implants

All surgeons preferred donated implants from Western countries, but noted the cost difference.

There are some world renowned implant companies... but their products are more expensive. For instance a bipolar prosthesis from India costs about 450,000 shillings [~\$125] and the one from [German company] costs USD 2000.

Surgeon D9

However it was hard for surgeons to predict when these implants would become available.

There is no definite frequency for the replenishment of donations; they are not as regular to be a dependable source.

Surgeon D4

Implant Failure

Most surgeons asserted that the failure of an implant should not be squarely blamed on the quality of the biomaterial. However, surgeons were in agreement that the type of biomaterial is an important determining factor with regard to surgical outcomes. They observed that there was more failure with stainless implants; and this was attributed to wide use of affordable stainless steel implants as opposed to the more expensive titanium and other alloys.

But it all depends on the type of implant used. For example, I have seen more failures with stainless steel implants than with implants of titanium or those modified materials. It wouldn't be fair to compare it with the other materials because it [stainless steel] is the most abundant material. I wouldn't say that one implant is failing because it is inherently weaker or of poor quality. It is just because it is the most abundant therefore there are more chances of encountering it. The others are not as common.
Surgeon D4

Another factor noted that affects the success of implants in Uganda that was poor patient compliance to post-operative instructions.

Most of our patients are of low education level and patients do not always understand instructions especially with regard to implant loading and weight bearing.
Surgeon D4

Inadequate Local Implant Quality Assurance and Manufacturing Capability

Surgeons clearly understood the tradeoff between lower costs and presumably lower quality implants; however, there were no local facilities that confirmed whether the less expensive implants were indeed of lower quality.

We do not have laboratories to verify the quality of implant and quantity of metal.
Surgeon D7

Additionally, some surgeons suggested that one way of ensuring better availability of orthopaedic implants was the developing of capacity to manufacture them locally.

Biomedical engineers should design implants that are contextualized to our local setting basing on injury patterns and morphology. This will in the long run help in quality control.
Surgeon D5

Patients' Experience at MNRH

Table 2 summarizes the cohort of orthopaedic implant patients interviewed at MNRH. The patients interviewed were predominantly male (75%) with a mean age of 26.5 years. Eighty three percent of participants were working at the time of injury. The median daily income was 3000 Uganda shillings (< \$1 USD per day). Sixty four percent of the participants were injured in accidents involving motorcycle taxis (boda bodas). Fifty seven percent arrived at the hospital within 24 hours of their injury, but only 20% received treatment within two weeks. The time of medical intervention was largely dependent on the type and severity.

Patients with closed fractures had to wait about one day for transfer from the Accident and Emergency Unit to the wards; treatment was received after another three to four days. Patients with femur fractures did not undergo surgery for at least five days due to shortage of theater space and staffing. During this time, fractures were maintained under skin traction - a sustained pull on a fractured limb to maintain bone position. However, patients with open fractures were treated as emergency cases and received treatment within two to three days. Most injuries were of the femur and tibia bones that required the wide use of routine implants like bone plates, screws, and intramedullary nails. More advanced implants such as artificial hips and knees were not encountered in this cohort

Interviews with the patient cohort were more guarded and the information gleaned was largely factual in nature (Table 2). However, a few patients gave detailed accounts of their experience that included being told by the surgeon of their need for an implant, the interaction with the hawkers for the purchase of the implant, the wait time for receiving the implant and performance of surgical procedures, and the post-surgical experience. These accounts were confirmatory of the "Hawker" Negotiated Prescription Model at Public Hospitals (Figure 2), and the patient duress that this pathway can cause.

My relatives had to collect money [in addition to] the small money I had to pay for the implant. During ward rounds doctors usually move along with implant sales[men]. As soon as the implant sales[men] see [that] the doctor has finished prescribing they come to your bed and start the negotiation. These negotiations involved cost of the implant, if you can afford the money and when you can give them the money. As soon as I finished a successful negotiation with the salesman, my name then appeared on the list of those that are going to have surgery the following week. I was not operated on the next week because the hawkers informed me that the type of implant I required was not available in their stock.

Patient P1

Table 2. Characteristics of the patient study sample

Characteristic	Observation	Number	%
Sex	Male	40	75%
	Female	13	25%
Age	10 - 19 years	12	23%
	20 - 29 years	18	34%
	30 - 39 years	17	32%
	> 40 years	6	11%
Occupation	Body boda driver	20	39%
	Business/Service	18	34%
	Social worker	8	15%
	Laborer	4	7%
	Farmer	3	5%
Daily Income (USD)	< \$1	25	47%
	\$1 - \$1.50	15	28%
	\$3 - \$15	8	15%
	> \$15	5	10%
Mechanism of Injury	Body boda trauma	34	64%
	Multi-vehicle trauma	10	18%
	Pedestrian-vehicle trauma	4	8%
	Sports trauma	4	8%
	Fall from trees	1	2%
	Violence (non-gun)	1	2%
Time Injury to Admission	< 24 hours	30	57%
	24 - 48.hours	10	19%
	48 - 72 hours	10	19%
	More than 3 days	3	5%
Treatment Method	Internal Fixation	21	40%
	External Fixation	19	36%
	Conservative Method (includes traction)	13	24%
Injury Type	Tibia	20	38%
	Femur	20	38%
	Humerus	9	16%
	Spine	4	8%
Type of Fracture	Closed Fracture	28	60%
	Open Fracture	25	40%
Implant Access	Purchased (full price)	30	57%
	Purchased (half price)	19	35%
	Free	4	8%
Ward	General Ward	50	94%
	Private Ward	3	6%

Some men came to my bedside and told me that [the] doctors will require an implant plate for me to heal. I paid for the implant 300000 [UGX] but this implant failed after a year. I [came] back and this time I have paid 600000 [UGX]. The doctors said that the implant I brought last time was short and I had to buy a longer plate.

Patient P1

I have been at Mulago for months, got an accident when I was on the boda boda. When I got to Mulago I was told that I required an implant but had to buy it for myself at 750000 [UGX]. I am a poor woman I have no money at all. When the doctors told me to pay I told them that I do not have money. So that is the reason I have been in the hospital for long... The week the doctors accepted to give me a free implant but after asking them for long.

Patient P30

Discussion

The demand for the most routine variety of orthopaedic implants in Uganda, such as screws, nails and bone plates, far outweighs the supply. This is particularly true at MNRH, the largest hospital in Uganda. The number of trauma cases at MNRH is a variably reported figure ranging from 10 to 15 cases per day to 120 cases per day (Demyttenaere et al., 2009; Hsia et al., 2010; Kigera et al., 2010). However, interviews with surgeons put this figure at roughly 30 trauma cases per day. In a previous study on orthopaedic

trauma in MNRH, 40% of patients interviewed were transferred from another hospital, while 52% had direct admission to MNRH (O'Hara et al., 2014). This patient flow translates into 3000 to 4000 trauma cases per year, many of which are candidates for orthopaedic implants.

The Ugandan government claims to provide free healthcare services in public health facilities like MNRH, but it has not invested enough in the provision of implants for surgical care. In an effort to ease the distribution of medical supplies to public health facilities, the MOH established a central storage and distribution facility for all government medical supplies through the National Medical Stores Act of 1993. In Uganda NDA and UNBS are the government regulatory bodies responsible for ensuring the quality of medical equipment, devices and implants, guided by the Uganda National Medical Equipment Policy. The MOH also has a National Advisory Committee on Medical Equipment (NACME) that plays an advisory body on policy for the appropriate management of medical equipment. However, the ability of these government entities to properly regulate and adequately supply orthopaedic implants to Uganda is a work in progress.

Currently, the NMS is responsible for supplying over 2,800 Ugandan health facilities with free medicines and medical supplies that have seen an 11-fold increase in demand in the past five years (Rwothungeyo, 2014). Although the advent of the NMS was a dramatic improvement for a country with a substantial disease burden, it remains drastically underfunded and struggles to meet the demands for medicines and hospital supplies. The NMS now allows private institutions to directly purchase medicines and supplies through the public sector. Future plans to add electronic capabilities to monitor and analyze stocks in health care facilities will allow the NMS to become an active rather than reactive organization by sending supplies immediately as needed rather than upon request. Linking this system to suppliers will also eliminate the lag time in sending, waiting for, and receiving orders from suppliers. Inadequate funding dictates NMS spending priorities that do not include implants of virtually any kind.

The lack of funding for the NMS, and the absence of health insurance that reimburses the cost of medical implants, means that the three procurement pathways identified in this study will remain operational for the foreseeable future. The result is the creation of ad hoc workarounds that provide access to the minority of Ugandans who can afford the purchase price, or to the Ugandans fortunate to receive donated implants. These workarounds provide pay-as-you-go access to routine orthopaedic fracture fixation surgery in a severely resource limited healthcare marketplace.

Surgeons interviewed in the study consistently cited a preference for donated Western titanium implants over stainless steel implants from China and India, which they felt were more prone to imperfections, breakage and stiffness mismatch. Implants made of low cost materials or manufactured improperly also can corrode inside the body causing inflammation and infection (Ratner, 2013). Because the quality of implants may be not adequately verified at any point once received by the Ugandan authorities, there was strong consensus that introducing a regulatory body into the Uganda healthcare system would improve the assessment of implant quality. Surgeons also noted that higher quality implants could still fail if a surgeon's prescription for implant size and shape was inaccurate, if the implant vendor misinterpreted the surgeon's prescription, or where the surgeon's surgical skills were poor. The donations pathway was clearly the preferred route for both surgeons and patients because a superior implant can be obtained at no cost; however, according to patients interviewed during in this study, only 4% patients received free implants (Table 2), presumably via donations.

All of the patients in this study had received an implant, of which 76% purchased implants either via the "hawker" negotiated pathway if they are in public general ward (94%), or indirectly through the surgeon's supplier relationships in a private ward (6%). In both cases, surgeons had informed the patients of their options to purchase a Chinese or Indian implant compared to more expensive American or German devices. Unfortunately, few patients are able to afford even the inexpensive implants and may wait up to several months in the hospital while relatives collect funds, or when donated implants become available. In this scenario the patient is responsible for any outcome of the surgery tied to implant quality.

The hospital or physician mediated procurement in private hospitals (Figure 3) has the advantage of giving surgeons more direct control over procuring the implants most suited to the needed repair procedure. Private hospitals also have the advantage of attracting a more financially sound patient clientele that can better afford the cost of implants, surgery and hospital stay. This lends some preference for this pathway over the hawker-mediated pathway prevalent in public hospitals (Figure 2).

Most trauma patients in Uganda cannot afford the high cost of a private hospital stay and end up at a public hospital, mostly MNRH. In terms of total patient load, the hawker pathway (Figure 2) would appear to be the pathway most frequently encountered on a per capita basis. Patients in MNRH who cannot obtain the needed implants, either through donation or direct purchase, were treated by suboptimal conservative methods that left them bedridden for up to a month or more until they either came up with the funds or if donations become available. However, the current study did not follow patients that left MNRH without implants, nor did the study interview patients being treated at private hospitals. Thus we cannot definitively conclude that the majority of patients in Uganda actually receive implants through the hawker pathway, although the study appears to suggest that this is the case.

Instances of poor patient compliance were also noted by surgeons as leading to undesirable outcomes. Although this was attributed to misunderstanding of the surgeons' instructions for post-surgery care, it was also possible that the burden of the procedure on the family causes many patients to return home as soon as possible where suitable follow-up may not be possible.

Finally, while the orthopaedic implant conundrum in Uganda is fairly clear, the question arises "What might be a suitable path to improve orthopaedic implant access in Uganda?"

According to the procurement officer at MNRH, the Orthopaedics Department submits regular requisitions to the NMS for procurement of orthopaedic implants. Although the NMS is given a budget for implant procurement, the consignments of implants and supplies come infrequently and most surgeons interviewed could not recall the last time a consignment was delivered. In the rare instance when consignment delivery occurs, the order often does not contain the requested supplies. Surgeons interviewed believed that the NMS implant budget was spent on other supplies, such as drugs, that are deemed more necessary and cost effective

for the public at large. In the absence of NMS-provisioned implants, however, MNRH will remain entirely reliant on donations and patient-purchased implants.

Unlike in HIC, none of the private insurance companies in Uganda currently reimburse the cost of surgery involving implants (Bakwatanisa et al., 2016). This leaves the NMS as the best option for bolstering the orthopaedic implant supply chain were adequate (and realistic) funding to be identified, or if implant procurement were incorporated into the long-delayed comprehensive national healthcare scheme (Kisige, 2013). Establishing a fourth “Government Provision Pathway” could potentially replace the two patient-purchased pathways (Figures 1 and 2) as the largest source of orthopaedic implants, most profoundly impacting the impoverished patients at MNRH where the largest number of orthopaedic trauma surgeries are conducted (O'Hara et al., 2014). Even with more robust government provisioning, it is likely that donations from HIC would remain a significant source of routine orthopedic implants in Uganda given the cost and quality considerations.

Conclusions

The interviews conducted for this study resulted in three observations. First, donations are the preferred source of orthopaedic implants in Uganda due to high quality at no cost. However, there seems to be no proper procedure for sourcing and verifying the quality of donated equipment and implants. Second, the inconsistency of donations and burdensome healthcare expenditures for patients purchasing their own implants remain substantial barriers to adequate orthopaedic trauma care. Those unable to receive donated implants are subject to an ad hoc implant procurement system where orthopaedic implants are purchased from local suppliers by patients, few of whom can actually afford them without assistance. These two systems leave many orthopaedic trauma patients inadequately treated, causing significant long-term disability. Third, because the NMS was established to provision public hospitals with medical supplies, the only viable solution is one that requires the NMS to start providing medical implants. This could be accomplished by either by increasing the budget of the NMS directly, or possibly by incorporating the cost of implants into the yet-to-be-approved national health insurance scheme that the Uganda parliament has been debating for over a decade.

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References

- Allen, H. B., 1971. Principles of informant selection. *American Speech*, 46, 47-51.
- Bakwatanisa, B., Enywaku, A., Kiwanuka, M., Lamunu, C., Mbowa, N., Mukibi, D., Namayega, C., Ngabirano, B., Ntambi, H. & Reichert, W. 2016. Biomaterials use in Mulago National Referral Hospital in Kampala, Uganda: access and affordability. *Journal of Biomedical Materials Research Part A*, 104, 104-112. DOI: 10.1002/jbm.a.35542.
- Balikuddembe, J. K., Ardalan, A., Khorasani-Zavareh, D., Nejati, A., & Munanura, K. S. 2017. Road traffic incidents in Uganda: a systematic review study of five years trend. *Journal of Injury and Violence Research*, 9(1), 1. DOI: 10.5249/jivr.v9i1.796.
- Baxter, P. & Jack, S. 2008. Qualitative case study methodology: study design and implementation for novice researchers. *The Qualitative Report*, 13, 544-559. <http://www.nova.edu/ssss/QR/QR13-4/baxter.pdf>.
- Bouchard, M. 2011. *Responding to the global injury burden by improving access to orthopaedic medical devices: a qualitative case study of orthopaedic services in Uganda*. Master of Science. Clinical, Social and Administrative Pharmaceutical Sciences. University of Toronto. Canada.
- Bouchard, M., Kohler, J. C., Orbinski, J. & Howard, A. 2012. Corruption in the health care sector: a barrier to access of orthopaedic care and medical devices in Uganda. *BMC International Health and Human Rights*, 12, 5. DOI: 10.1186/1472-698X-12-5.
- Demyttenaere, S. V., Nansamba, C., Nganwa, A., Mutto, M., Lett, R. & Razek, T. 2009. Injury in Kampala, Uganda: 6 years later. *Canadian Journal of Surgery*, 52, E146.
- Hsia, R. Y., Ozgediz, D., Mutto, M., Jayaraman, S., Kyamanywa, P. & Kobusingye, O. C. 2010. Epidemiology of injuries presenting to the national hospital in Kampala, Uganda: implications for research and policy. *International Journal of Emergency Medicine*, 3, 165-172. DOI: 10.1007/s12245-010-0200-1.
- Hsieh, H.-F. & Shannon, S. E. 2005. Three approaches to qualitative content analysis. *Qualitative Health Research*, 15, 1277-1288. DOI: 10.1177/1049732305276687.
- Kigera, J., Nguku, L. & Naddumba, E. 2010. The impact of bodaboda motor crashes on the budget for clinical services at Mulago Hospital, Kampala. *East and Central African Journal of Surgery*, 15, 57-61. <http://www.bioline.org.br/request?js10009>.
- Kisige, A. 2013. *Control of Medicine Priced Needed – Experts*. Retrieved from: <http://www.newvision.co.ug/news/646862-control-of-medicine-prices-needed-experts.html>.
- Kohn, L. T. 1997. *Methods in case study analysis*. Center for Studying Health System Change. Technical Publication No. 2, June 1997.
- Murray, C. J., Vos, T., Lozano, R., Naghavi, M., Flaxman, A. D., Michaud, C., ... & Aboyans, V. 2012. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *The Lancet*, 380, 9859, 2197-2223. DOI: 10.1016/S0140-6736(12)61689-4.
- Nantulya, V. M. & Reich, M. R. 2002. The neglected epidemic: road traffic injuries in developing countries. *BMJ: British Medical Journal*, 324, 1139.
- O'Hara, N. N., Mugarura, R., Slobogean, G. P. & Bouchard, M. 2014. The orthopaedic trauma patient experience: a qualitative case study of orthopaedic trauma patients in Uganda. *PLoS One*, 9. DOI: 10.1371/journal.pone.0110940.
- Ratner, B. D., Hoffman, A. S., Schoen, F. J. & Lemons, J. E. 1997. *Biomaterials science: an introduction to materials in medicine*. London: Elsevier

Academic Press.

Rwothungeyo, B. 2014. *PPDA Law to promote efficiency, accountability*. Retrieved from: https://www.newvision.co.ug/new_vision/news/1338296/ppda-law-promote-efficiency-accountability.

Stjelja, M. 2013. *The case study approach: some theoretical, methodological and applied considerations*. Defence Science and Technology Organisation Edinburgh (Australia) Land Operations Div.

Yin, R. K. 2003. *Case study research: design and methods*. SAGE publications. Thousand Oaks.