Embodiment of a laparoscopic tower for the Kenyan healthcare context

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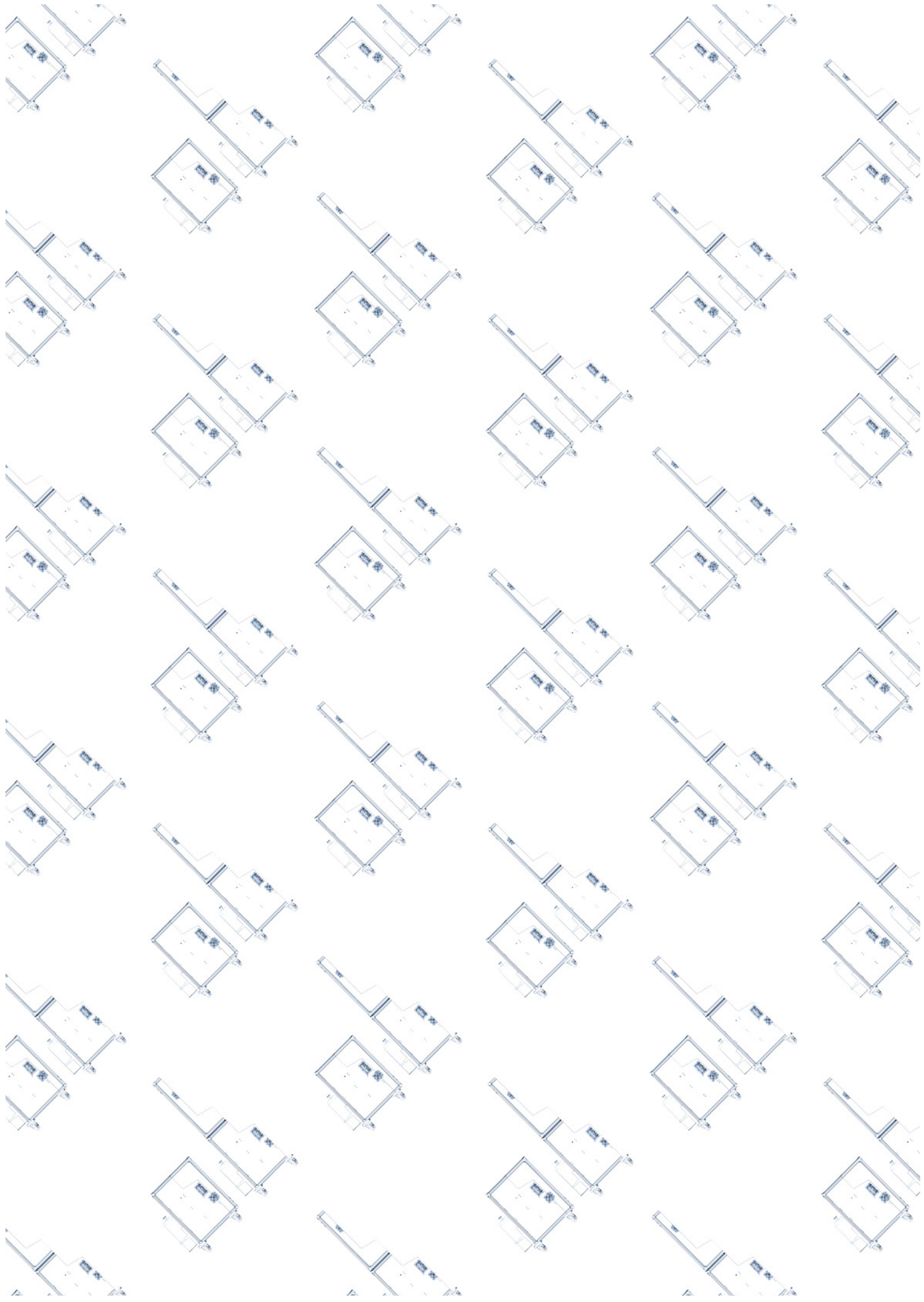

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Glossary

Bellwether procedures

Any surgical procedure involving laparotomy, cesarean section, or treatment of open long bone fractureand then classified as emergent or elective.

Biomedical engineers

Stakeholders in hospitals applying engineering principles, practices, and technologies to the fields of medicine and biology especially in solving problems and improving care

Diathermy

device generating heat in tissue by electric currents for medical or surgical purposes, electrosurgical unit

ENT

ear, nose, and throat, specialization focused on medical conditions of the ear, nose, throat

Global surgery

field that aims to improve health and health equity for all who are affected by surgical conditions or have a need for surgical care, with a particular focus on underserved populations in countries of all income levels, as well as populations in crisis, such as those experiencing conflict, displacement, and disaster.

Insufflator

Medical device used for the introduction of a flow of gas into a body cavity

Laparoscopy:

A surgical procedure performed through small incisions in the abdomen using a laparoscope, a thin, long tube with a camera and light attached to it.

Laparatomy

a surgical incision into the abdominal cavity, for diagnosis or in preparation for major surgery

Low and Middle-Income Countries (LMICs):

Countries with economies and incomes considered to be low or middle-range according to World Bank classifications, often facing specific healthcare challenges due to limited resources.

Trocar

a surgical instrument with a three-sided cutting point enclosed in a tube, used for withdrawing fluid from a body cavity.

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1. Introduction & background

This chapter introduces the project background and scope, executive summary and describes the approach taken to accomplish the goal of the project

1.1 Executive summary

Problem
Limited access to surgical care in low- and middle-income countries has resulted in **the loss of approximately 16.9 million lives annually, accounting for 32% of global deaths**. This is more than tuberculosis, malaria and HIV combined.

Several factors contribute to this disparity, including the scarcity of surgical equipment. Despite the limited availability of equipment, a staggering **40% of donated equipment in sub-Saharan Africa is ultimately discarded in landfills due to its short lifecycle.**

This is attributed to the **lack of consideration for the local use context in the design of medical devices.** For example, medical devices are not robust enough, can not be repaired locally due to lack of access to spare parts and might not function because of the harsh working environment. (i.e. fluctuations in the electricity grid).

District hospitals act as the primary point of care for many communities, making them an **ideal location to improve access to surgical care**. Implementing laparoscopy - a form of minimally invasive surgery - in district hospitals, can address many issues currently faced by these hospitals, such as limited patient beds and high infections rates.

Laparoscopy offers much shorter recovery times and reduces risks of infection, thus improving clinical outcomes and allowing individuals to return quickly, thus enhancing the livelihoods of families that might rely on a single source of income.

Solution
Recognising that equipment availability is an issue in hospitals, **I designed EasyTower - a practical and cost effective design.** EasyTower integrates an outer casing to securely store the devices required for laparoscopy, such as the diathermy, ENT drill, and insufflator. Seamless connectivity to an uninterruptible power supply ensures continuous operation through power outages.

The tower includes a laptop holder and a drawer for accessories. **Instead of using the typical laparoscopic stack, costs are drastically reduced by using a laptop to replace the light source, screen and image processing, thus eliminating the need for expensive equipment,** by connecting to a scope that works with a standard laptop or tablet.

EasyTower is **designed to be mobile, thus ensuring equipment can be moved and utilised in various hospital settings as needed.** It can easily be opened up and used directly.

To reduce the risk of damaging the medical equipment, Easy tower folds into a safe, lockable storage space (like a flightcase), protecting equipment from frequent impacts with e.g. patient beds, thus **ensuring a longer life span.**

Produced from off-the-shelf components which can be easily procured in Africa, **EasyTower can be produced locally and spare parts can be easily sourced, making it easy to repair locally.**

The introduction of laparoscopy in district hospitals brings surgical care closer to local communities, ensuring patients save on transportation costs, stay connected to their families while receiving treatment, and can quickly return to their communities due to shorter recovery times.

Easy tower reduces equipment needs and protects equipment from breaking, either due to impacts or due to electrical problems. **In this way equipment can have a longer lifespan, thus preventing the equipment from ending-up in the landfill, contributing to a more accessible and sustainable healthcare system.**

1.2 Project introduction, brief and background

More people die from treatable surgical conditions than from tuberculosis, malaria and HIV put together (Oosting, 2019) . Access to life-saving surgical treatment is still limited in low- and middle-income countries (LMICs). This is partly due to a mismatch between how medical devices are currently designed (e.g., for the context of the global north) and the healthcare context in which they need to function. Challenges include sterilization, maintenance, and compatibility with existing infrastructure. This project is focused on designing for the Kenyan healthcare system.

This project is focused on laparoscopic surgery, which is a type of minimally invasive surgery in which a camera and surgical instruments are inserted into the patient's abdomen through small incisions. The key equipment is the laparoscope, which is connected to the laparoscopic tower for power, image processing capabilities and image display. This has many advantages, including reduced risk of infection and quicker recovery time. Disadvantages include, need for expensive equipment and highly trained practitioners.

1. Client: MISIT Tu Delft
The Minimally Invasive Surgery and Intervention Techniques is part of the department of Biomechanical Engineering at Delft University of Technology. Their goal is to improve minimally invasive surgery techniques, with a focus on designing new instruments. One of their focus areas is designing medical equipment for low- and middle-income countries, which this project is part of.

2. Problem
While minimally invasive surgery techniques have evolved tremendously during the last 30 years, the laparoscopic tower has kept its structure and form since the 1980s (Kelley 2008). Designed with the western context in mind, developments in laparoscopic technology have become increasingly complex and expensive. To address this issue, frugal alternatives to the current laparoscope have been developed, by incorporating most of the tower's functionality within the scope, therefore significantly minimizing the need for expensive equipment. While this is an important step for facilitating access, the connection between the scope and the operating theater has been overlooked.

In Kenya, the disconnect between the scope and operating theater is even more pronounced (as compared to the western context) due to infrastructural barriers such as operating in makeshift operating rooms, frequently moving equipment between operating theaters, or between hospitals and limited personal. Therefore, there is a need for re-designing the laparoscopic tower to facilitate the connection between the laparoscope, operating theater, and local infrastructure.

3. Stakeholders
Kenyan healthcare providers (level 4 and above): the Kenyan healthcare system is divided in 6 levels. Levels 4 and above provide surgery. Healthcare providers have a high incentive to purchase equipment that is suitable for the context, as it has the potential to lower costs.

Surgeons/surgical assistants: Surgeons are responsible for the clinical outcome and rely on equipment to achieve good results.

Biomedical Equipment Technicians (BMET): BMETs are responsible for ensuring that medical equipment functions accordingly and is ready to use. This includes maintenance, configuration and ensuring surgical equipment is ready for the next surgery. BMETs will therefore, interact on a daily basis with the equipment designed during this project.

Scrub nurses: Nurses are assisting the surgeon through the surgery. However, due to staff shortage they must take over the responsibilities of BMETs, therefore nurses will frequently interact with the equipment designed during this project.

4. Project scope
Embodiment of a laparoscopic tower, that is affordable, ergonomic, and compatible with local needs and infrastructure. The laparoscopic tower will be designed to be compatible with a laparoscope (currently being developed at the MISIT lab) that doesn't require an external light source and will process images on a laptop or tablet.

Three project phases are distinguished: the exploration phase, design phase and validation phase.

Exploration phase
Literature, interviews with experts and relevant stakeholders, and previous graduation projects provide an extensive theoretic foundation, which will be used to define the requirements for the laparoscopic tower. The focus of this exploration is to understand the most important contextual factors and what is the minimum functionality required to create a low-cost, high-quality solution.

Design phase
After the exploration phase, the laparoscopic tower will be designed and embodied in an iterative approach. This includes prototyping and extensive collaboration with healthcare professionals and other relevant stakeholders. This will result in a minimum viable product that will be prototyped and later validated within the Kenyan healthcare context

Validation phase
For the validation phase, the prototype of the minimum viable product will be taken to Kenya and validated by interviewing local stakeholders and observing how it can be integrated within the surgical workflow

Outcome
The outcome of this project is the embodiment of a medical product that addresses the challenges of providing surgical care in low- and middle-income countries.

1.3 Approach

To design a context driven laparoscopic tower, the “Roadmap for designing surgical equipment for safe surgery worldwide” (Oosting R. , 2018) was chosen as an approach. The approach consists of four steps: the first step is to establish the need for a specific equipment, followed by ensuring a proper understanding of the context of global surgery. The third step is to determine the implementation strategy and design requirements, while the last stage is to develop the new equipment.

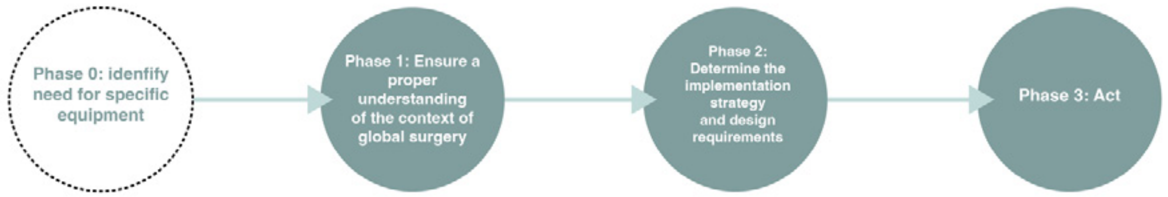


Figure 1 - Roadmap for designing of surgical equipment for safe surgery worldwide

As the need for designing a new laparoscopic tower was already established this project is focused on developing a good understanding of the context of global surgery, determining the requirements and implementation strategy, and finally designing a new laparoscopic tower. This project is focused on the context of the Kenyan healthcare system.

Phase 1: ensure a proper understanding of the context of global surgery

To ensure a proper understanding of the context of global surgery, it’s important to understand the barriers patients encounter to reach surgical care, understand the structure of the healthcare system, and understand the surgical structure – including the operating theatre process, the team offering surgery, the available devices and the types of surgery performed. The following questions are used as a guide to understand the context of surgery within the Kenyan healthcare system:

- What barriers are encountered by patients seeking surgical care?
- What type of health care facilities are targeted?
- What surgical procedures are performed?
- Is anesthesia, sterilization and maintenance provided and how is it organized?
- Who is involved during procurement and usage of equipment?
- Who is part of the team providing surgery and how are they trained?
- Is infrastructure working properly? (Water, electricity etc.)
- What equipment is available and used? If unavailable, why is equipment unavailable?

Phase 2: determine the implementation strategy and design requirements

Based on the information gathered in the previous phase, a list of design requirements is gathered to ensure a sustainable implementation in the Kenyan healthcare system. This is done by compiling design requirements typical for medical equipment in low- and middle-income countries and specific to the laparoscopic tower, based on the insights gathered from phase one.

Phase 3: act

The last phase of the approach is to iteratively develop a solution in collaboration with local stakeholders that fulfils the requirements defined in the previous phase.

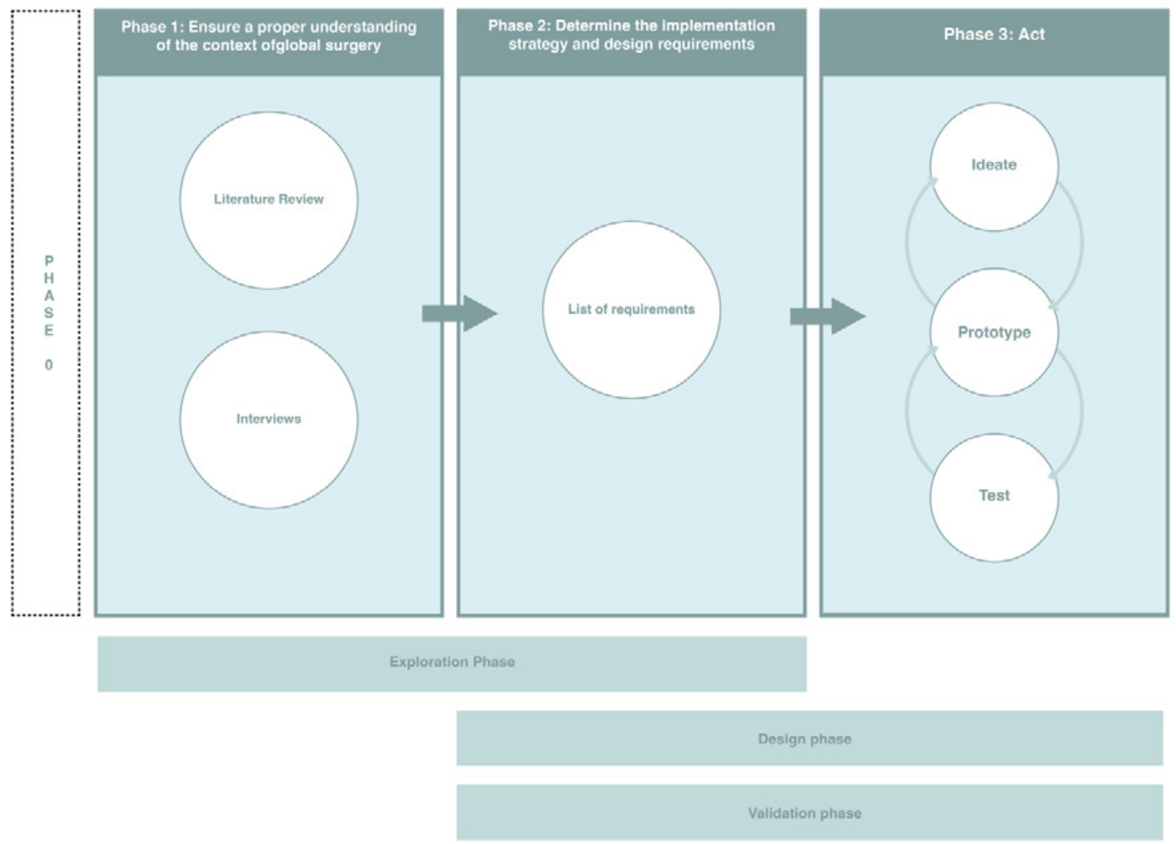


Figure 2 - Method applied through the project phases

This report presents the findings in a linear fashion, through three distinct project phases: the exploration phase, design phase and validation phase. The exploration phase is aimed at ensuring a proper understanding of the context of global surgery (phase 1) and results in an extensive list of requirements for implementation (phase 2). The design phase and validation phase coincide with the act phase (phase 3), where an iterative approach of ideating, prototyping, and testing (Interaction Design Foundation , retrieved 2023) is taken, and the design is validated with end users. Lastly, the results and final design are presented.

2. Exploration phase

This chapter is focused on providing an extensive exploration of the surgical context within the Kenyan healthcare system. Combining literature reviews and expert interviews, this chapter explains how surgical care is offered in Kenya. The exploration phase examines both the challenges patients face in accessing surgical care and the critical surgical resources required for providing surgical care – with a focus on the implementation of laparoscopy.

2.1 Introduction

Surgical care is widely unavailable in low- and middle-income countries (LMICs). A 2010 estimate that 16.9 million lives (or 32.9% of deaths worldwide) have been lost due to conditions needing surgical care (Meara, 2015). This is greater than deaths from HIV/AIDS, tuberculosis and Malaria combined. The Lancet commission estimates 77.2 million DALYs could be adverted by basic lifesaving surgical skills (Meara, 2015). The need for surgery is tremendous in LMICs.

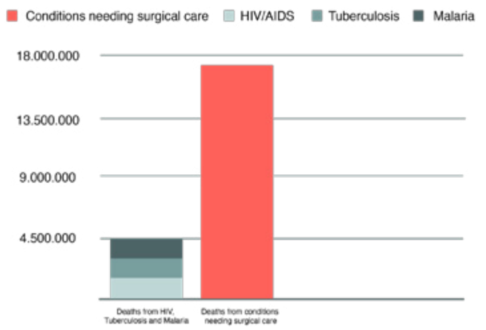


Figure 3: deaths from different conditions

Several factors influence access to surgery. From limited equipment unavailability (Oosting R. W., 2019), to limited trained staff (Oosting R. W., 2019), all the way to systematic and infrastructural challenges, such as barriers encountered by patients to reach the first line of care (Oosting R. W., 2019) or limited availability of electricity and running water (Oosting R. W., 2019).

“Global surgery refers to all groups facing inequitable or inadequate surgical care delivery, weather they are chronically underserved populations, or those in acute crisis, conflict or disaster settings” (Meara, 2015)

This chapter aims to provide an extensive understanding of the context of global surgery, with a focus on the Kenyan healthcare system. Based on previous literature, using the “Roadmap for designing surgical equipment for safe surgery worldwide”, this chapter aims to answer the following questions (Oosting R. W., 2019):

• What barriers are encountered by patients seeking surgical care?

• What type of health care facilities are targeted?

• What surgical procedures are performed?

• Is anesthesia, sterilization and maintenance provided and how is it organized?

• Who is involved during procurement and usage of equipment?

• Who is part of the team providing surgery and how are they trained?

• Is infrastructure working properly? (water, electricity etc.)

• What equipment is available and used?
If unavailable, why is equipment unavailable?

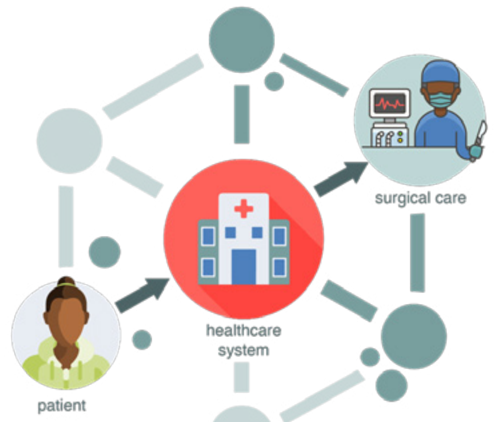
To address those questions, two distinct phases are distinguished:

1. Phase 1: This stage delves into the intricacies of the Kenyan healthcare system, exploring the healthcare facilities providing surgical services, the barriers patients face when navigating the healthcare system to receive surgical care, and the type of procedures that are offered.

2. Phase 2: In this stage, the focus is on understanding the surgical infrastructure, encompassing the essential requirements for delivering surgical care and the distinctive needs for implementing laparoscopy

2.2 Phase 1 – Understanding the Kenyan Healthcare System and Surgical Care Access Challenge

This phase is focused on the intricacies of the Kenyan healthcare system, its relationship with surgical care and the challenges patients encounters while seeking surgical care.



The following questions will be answered:

• What barriers are encountered by patients seeking surgical care?

• What type of health care facilities are targeted?

• What surgical procedures are performed?

The Kenyan healthcare system
To gain a better understanding of what healthcare facilities to target, it’s important to understand the structure of the Kenyan healthcare system. Kenya is a sub-Saharan country with a population of 53,005,614 (World bank, 2021). The country is divided in 8 provinces with a total of 70 districts. The Kenyan healthcare system is divided in 6 levels (Dr. Richard Muga, 2005).

Level	Type	Number	Goal
Level 1.	Community	7011	First line contact: provision of preventative healthcare services.
Level 2.	Dispensaries	9944	First line contact: provision of preventative healthcare services.
Level 3.	Health centers	2364	Ambulatory health services adapted to local needs.
Level 4.	Primary referral facilities (district hospitals)	852	Delivery of health services: including surgical care and lab diagnostics
Level 5.	Secondary referral facilities (provincial hospitals)	22	Delivery of health services: including sophisticated surgical care and diagnostics
Level 6.	Tertiary referral facilities (national hospitals)	6	Apex of the healthcare system

Hospitals providing surgical care

Figure 4 - Overview of Kenyan healthcare system based on - https://www.ghspjournal.org/content/10/1/e2100500, Larissa thesis and - https://dhsprogram.com/pubs/pdf/spa8/02chapter2.pdf (Shirley, 2022)

A patient's community (level 1) and Dispensaries (level 2) are the first contact patients have with the healthcare system. Dispensaries are staffed with nurses and provide basic outpatient care and treatments for pregnant women (Dr. Richard Muga, 2005). Health centers provide basic curative and preventative services, including minor surgeries such as incisions or drainage. Level 4 is represented by district hospitals (primary referral facilities). Those are the facilities for clinical care at district level and provide a wide range of health services: from advanced diagnostic techniques to surgery. At the 5th level, provincial hospitals provide specialized and more sophisticated care. Finally, the highest level of care at level 6 represented by national hospitals. Kenya has 6 national hospitals, 22 provincial hospitals and 852 district hospitals (WHO and Minsitry of Health, 2016). Figure 5 (Noor, 2016) shows an overview of the distribution of Kenya's health facilities.

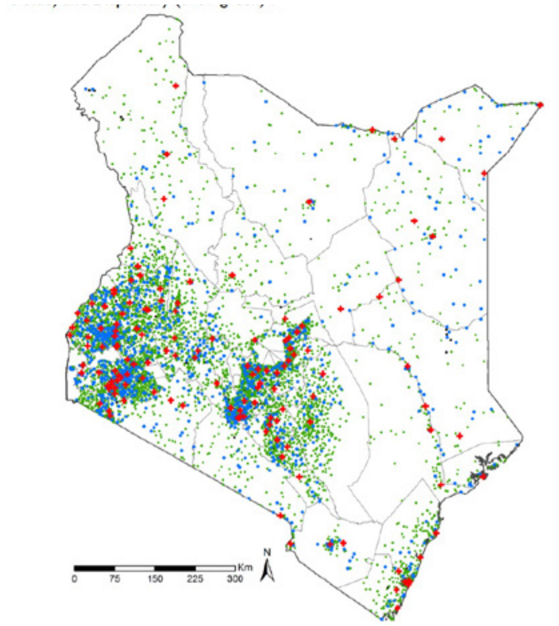


Figure 5: overview of facilities

Journey to access surgical care
Access to surgery is impacted by many factors, both in terms of workforce and infrastructure, but also by the patient's ability to obtain surgical care in a safe, timely and affordable way (Meara, 2015).).

In the Kenyan healthcare context, there are three layers to receiving surgical care. The first level is the community health worker network which connects the patient to the broader healthcare system (Meara, 2015). This first layer is well connected to primary health centers, which is connected to the district hospitals. District hospitals are the first point in which patients can receive surgical care (Meara, 2015). It is therefore detrimental, to ensure district hospital can provide adequate care, thus avoiding overcrowding of secondary and tertiary hospitals and minimizing the time needed for patients to reach care (Meara, 2015).

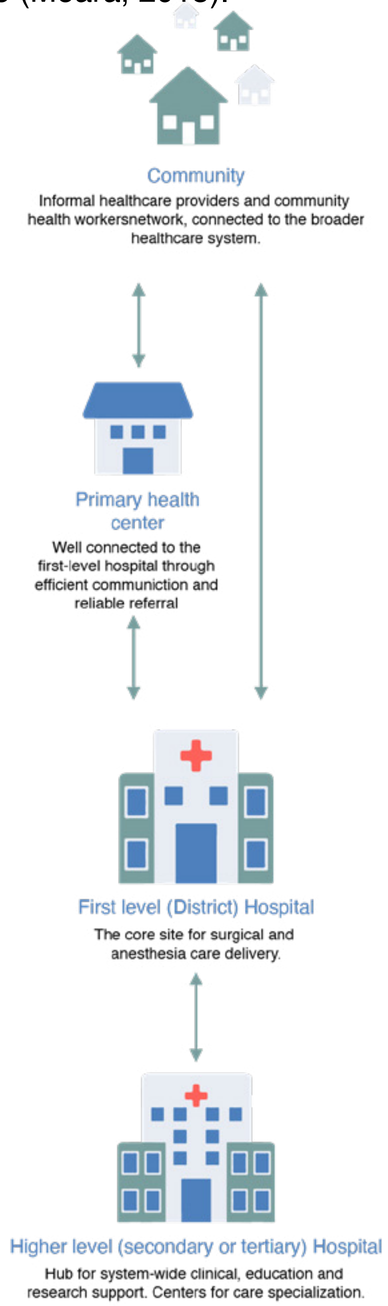


Figure 6: referral structure (Meara, 2015)

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To understand what barriers patients might face when accessing surgical care, the three-delay framework is used. The first delay refers to delay in patients seeking care. Reasons may include living far away from a health facility, financial barriers or stigma around receiving care (Shirley, 2022). Many patients in LIMCs face catastrophic expenditure because of accessing surgical care (Meara, 2015), in Kenya this is around 36% of people (Shirley, 2022). The second delay refers to delay in patient reaching care – this is due to patients needing to travel far away to acquire surgical care and is exacerbated by poor public infrastructure and ambulance services unable to meet population demands. The third delay refers to the delay in receiving care once they have reached the hospital. While 90% of Kenya's population lives 2h away from a hospital, only 50% of those facilities offer the Bellwether procedures (Shirley, 2022), meaning significant delay in receiving care is happening.

"District hospital level was identified as one of the top 30 mechanisms for advancement of global welfare" (Meara, 2015)

Delay	Causes
First delay (seeking care)	Cost of impatient care (Dr. Richard Muga, 2005) (Meara, 2015) Cost of out-of-pocket expenses (Dr. Richard Muga, 2005) (Meara, 2015) Low awareness of available services or low confidence in those services (Meara, 2015) Stigma around receiving surgery (Ouweltjes, 2018)
Second delay (reaching care)	Road infrastructure (Dr. Richard Muga, 2005) Access to ambulance or motored vehicle access (Dr. Richard Muga, 2005) Distance to adequate facilities (Dr. Richard Muga, 2005) Availability of diagnostic equipment (Shirley, 2022)
Third delay (receiving care)	Surgical work capacity (Dr. Richard Muga, 2005) Limited availability of emergency services (Dr. Richard Muga, 2005), (Meara, 2015) Blood supply infrastructure (Dr. Richard Muga, 2005) Availability of equipment (Dr. Richard Muga, 2005) Limited availability of anesthesia (Dr. Richard Muga, 2005) -Limited infrastructure: oxygen, electricity, water (Meara, 2015) Limited infrastructure for postoperative care (Meara, 2015)

Figure 7 - Overview of delays and causes

Figure 8 gives an overview of the delays patients might face during seeking, reaching, and receiving care. Seeking care starts with contacting an informal healthcare provider and receiving referral to a first level hospital.

Upon receiving referral, the patient must consider whether to seek care. Concerns might include high costs associated with care, needing to skip work and low trust in the healthcare system. If the patient decides to seek care, there are many logistical considerations needed to ensure the patient can reach care – such as road infrastructure to diagnostic facilities and access to motorized vehicles.

As diagnostic equipment is scarcely available, further delays can occur during the diagnostics process. Once the patient receives a diagnosis, the patient needs to further consider the logistics. Once reaching the surgical facilities, delays can occur as the surgical capacity – including staff and resources – are limited, which can further delay the patient's surgery.

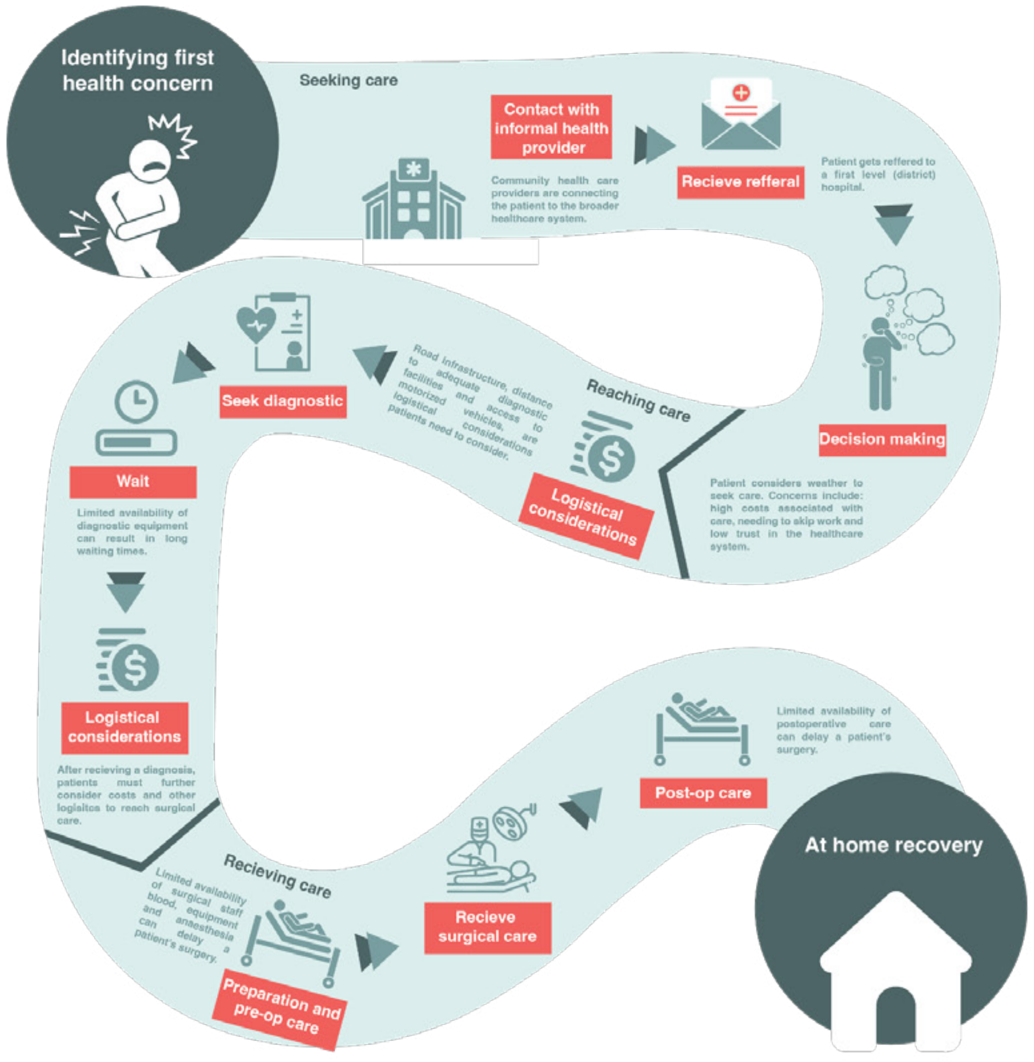

Figure 8: delays during seeking, reaching and recieving care

While 90% of Kenya's population lives within two hours of a health care facility (Shirley, 2022), several barriers are still encountered when it comes to receiving adequate surgical care. From patients not seeking care because of financial reasons, to transportation infrastructure and limited availability of diagnostic equipment, all the way to limited capacity due to shortage of staff and limited blood supply infrastructure.
District hospitals are the first point of receiving surgical care. Integrating surgical care in the district hospitals enables the whole healthcare system to function properly. When first level hospitals cannot meet demand for care, the burden of care falls on tertiary hospitals (Meara, 2015), which can further impede patients from accessing care – and doesn't allow tertiary hospitals to develop capabilities for more complex procedures. This project will therefore focus on developing a laparoscopic tower for district hospitals in Kenya.

The District Hospital
Kenya has 852 district hospitals that offer both surgical care and more complex diagnostics services. District hospitals are the first point at which patients can receive surgical care. District hospitals must be able to provide the Bellwether procedures: laparotomy, caesarean delivery, and treatment for open fractures (Meara, 2015). District hospitals should also be able to offer planned surgery, including procedures such as Hernia repairs, Tumor resections and Mastectomies (Meara, 2015).

While district hospitals must provide the Bellwether procedures and should be able to perform a wide variety of planned surgeries, there are high discrepancies between hospitals (Grimes, 2012). Despite high incidence of bowel obstructions and trauma, few procedures are executed in district hospitals (Shirley, 2022) (Grimes, 2012)

Must do	Should do	Can do
Acute, high-value procedures that need consistency through local structures; and less complex, urgent procedures that can be delivered through these same structures. Acute, high-value procedures inlcude: Laparotomy caesarean delivery Treatment of open fracture Lesser complex, urgent procedures include: Wound debridement Dilation and currettage Closed fracture reduction	High-priority, high-volume procedures for planned surgery at the first-level hospital. Lower-risk procedures include: Hernia repair Contracture release Superficial soft tissue tumour resection Gastroscopy Medium-risk procedures include Cholecystectomy Intracranial haematoma evacuation Thyroidectomy Mastectomy	Important procedures potentially needing specialist support. Ideally, higher-risk procedures should be done at first-level hospitals with the assistance of visiting super-specialist teams. Examples include: Thoracic surgery Transurethral resection of prostate Uretro-renoscopy Vesicovaginal fistula Basic skin flaps Rectal prolapse repair Cataract Cleft lip and palate repair

Figure 9 - procedures in district hospitals (Shirley, 20222)

District hospitals play a unique role in the healthcare system. Their role in providing healthcare services is detrimental, being the first point of care for patients. This makes them a unique intersection point for different communities seeking health, therefore having a high involvement in community health (WHO, 2003). District hospitals are generally smaller than regional and national hospitals and can vary a lot in size and capacity: from smaller hospitals having 20 beds, to over 300 beds in the larger hospitals. Located in rural or semi-urban areas, district hospitals make care more accessible to local communities. However, this also means that they are often loosely connected to the supply chain (Interview3)

Type of procedure	Procedure	Number of papers
General surgery	Hernia repair	26
	Laparotomy	21
	Appendicectomy	10
	Abscess	7
	Hydrocele repair	7
	Thyroid surgery	5
	Colectomy	4
	Chest tube insertion	4
	Hernia repair	4
	Prostatectomy	4
	Cricothyroidotomy	3
	Colostomy	2
	Lipoma	2
	Tracheostomy	2
	Fibroma	1
	Urethrotomy	4
	Vascular repair	3
	Bladder stone surgery	2
Obstretics and gynecology	Caesarean section	30
	Salpingectomy (ectopic pregnancy)	10
	Hysterectomy	9
	Evacuation of retained products of conception	7

Type of procedure	Procedure	Number of papers
Obstretics and gynecology	Tubal ligation	5
	Fistula repair	3
	Cervical tear repair	2
	Breast surgery	1
Orthopedics	Amputation	10
	Open fracture repair	8
	Closed fracture repair	5
	Arthrotomy	3
	Osteotomy	2
	Total hip replacement	4
	Bipolar hemiarthroplasty	4
Neurosurgery	Major neurosurgery	1
	Burr holes	2
Plastics	Skin grafting	7
	Debridement	5
	Burn	4
	Cleft lip/palate surgery	3
	Contracture release	21
	Escharotomy	1

Most common procedures

While a wide variety of surgeries are performed in district hospitals, many complications still arise, such as surgical site infection and high mortality from causes such as sepsis, hemorrhage, and anesthesia complications (Bentounsi Z, 2021). Lack of operating theater space, hospital beds and high patient volume can lead to frequent delays and cancellation (Bentounsi Z, 2021).

A wide array of procedures are performed in district hospitals, yet assessing their availability can be quite challenging due to the significant disparities among hospitals. It's worth noting that a majority of these procedures are open procedures. However, if hospitals are equipped to perform procedures such as uroscopy and ENT (Ear, Nose, and Throat) procedures, it paves the way for the potential implementation of laparoscopy for simple procedures.

2.3 Phase 2 – Understanding the surgical infrastructure required for laparoscopy

Phase one covered the intricacies of the Kenyan healthcare system, its relationship with surgical care and the challenges patients encounters while seeking surgical care. The second phase is focused on understanding the surgical infrastructure – including equipment, surgical staff, and anesthesia. The goal is to understand the required infrastructure for implementing laparoscopy.

The following questions will be answered:

• Is anesthesia, sterilization and maintenance provided and how is it organized?
• Who is involved during procurement and usage of equipment?

• Who is part of the team providing surgery and how are they trained?

• Is infrastructure working properly? (Water, electricity etc.)

• What equipment is available and used? If unavailable, why is equipment unavailable?

Understanding laparoscopic surgery

To understand how laparoscopy is performed, it's important to understand the differences between laparoscopy and open surgery.

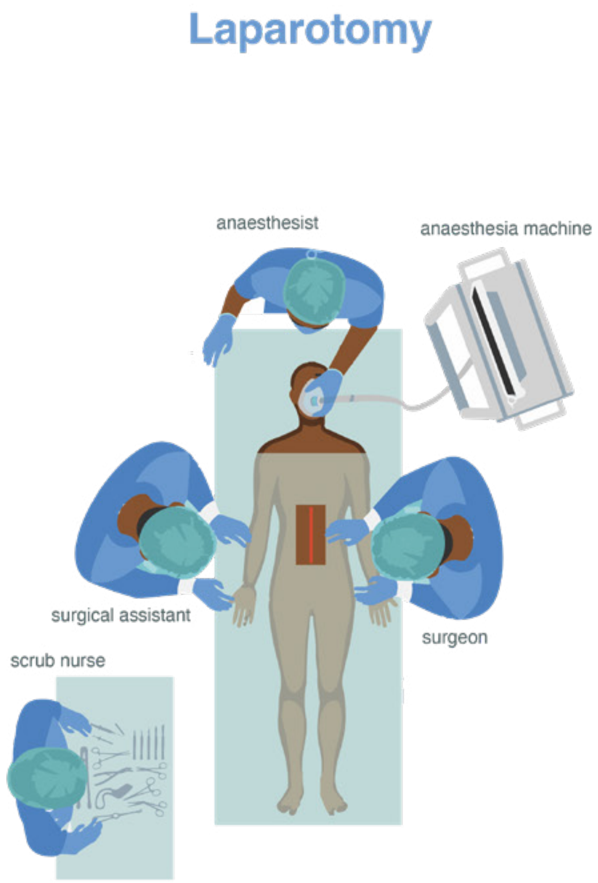

Figure 10: laparotomy

Laparotomy is an open surgical procedure in which the surgeon creates a long incision to gain access into the patient's abdomen (Cleaveland clinic, retrieved 2023). Laparotomy is commonly performed in district hospitals and commonly used to diagnose and treat abdominal pain.

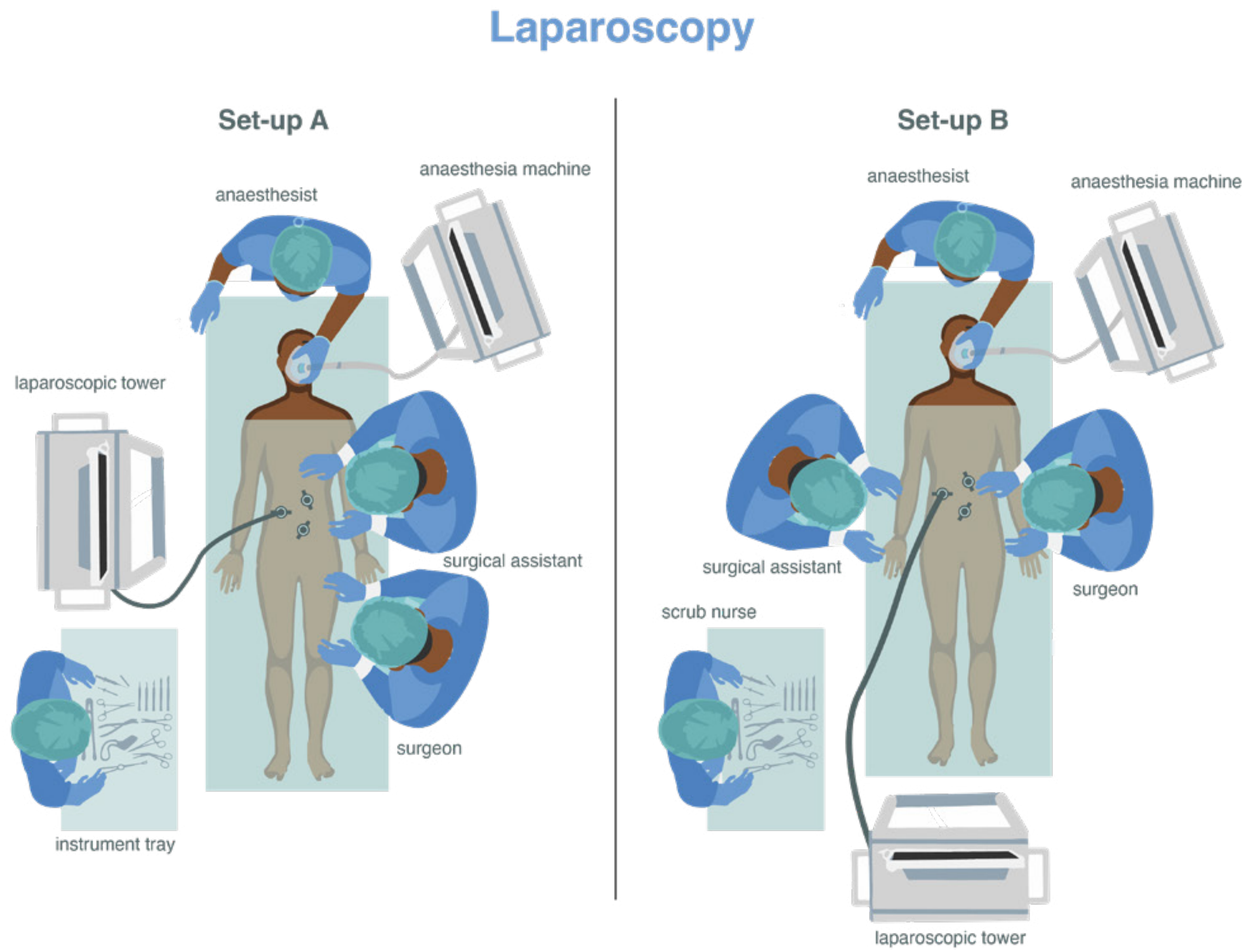

Figure 11: laparascopy set-up

Laparoscopy is an alternative to open surgery used for exploring the abdominal area. Laparoscopic surgery is a type of minimally invasive surgery, where the surgeon accesses the abdomen through small incisions, through which instruments are inserted. The surgeon can see in the abdomen by using a laparoscope. A laparoscope is a small tube, consisting of a light source and camera, that relays the images from inside the abdomen to an external display (NHS, retrieved 2023). Main advantages of laparoscopy over traditional open surgery include shorter hospital stay, less pain and bleeding after the operation and less scar tissue (NHS, retrieved 2023). Laparoscopy is commonly applied for gynecology, gastroenterology, and urology (NHS, retrieved 2023).

When performing laparoscopic surgery, it is of utmost importance that both the surgeon and the surgical assistant have an excellent view of the operating field on the screen. It's important that the surgeon is in a comfortable position through the surgery. This either means that the laparoscopic screen is either directly in front of the surgeon or between the patient's legs. The scrub nurse should also be able to see the screen, enabling anticipation of the next instrument required (Clinical Gate, retrieved 2023)

Equipment
To provide surgical care, a lot of equipment is required. The following equipment is considered essential for providing surgical care and anesthesia (Oosting R. W., 2019):

- Oxygen concentrator
- Anaesthesia machine
- Pulse oximeter
- Suction pump
- Blood pressure measurement equipment
- Sterilizer
- Theatre light
- Electrosurgical unit
- Endoscope
- Electrocardiogram monitor
- Infusion pump
- Defibrillator
- Laryngoscope

In public district hospitals, essential surgical equipment tends to be less available than in public referral and private hospitals (Oosting., 2019). Endoscopes, defibrillators, infusion pumps and oxygen concentrators are limited within public district hospitals.

“With district hospitals price is often most important. This is because district hospitals are harder to reach, therefore they need to pay more to source the equipment” (Interview3)

“Surgeries are often performed in makeshift rooms that lack the necessary space. “ (Interview2)

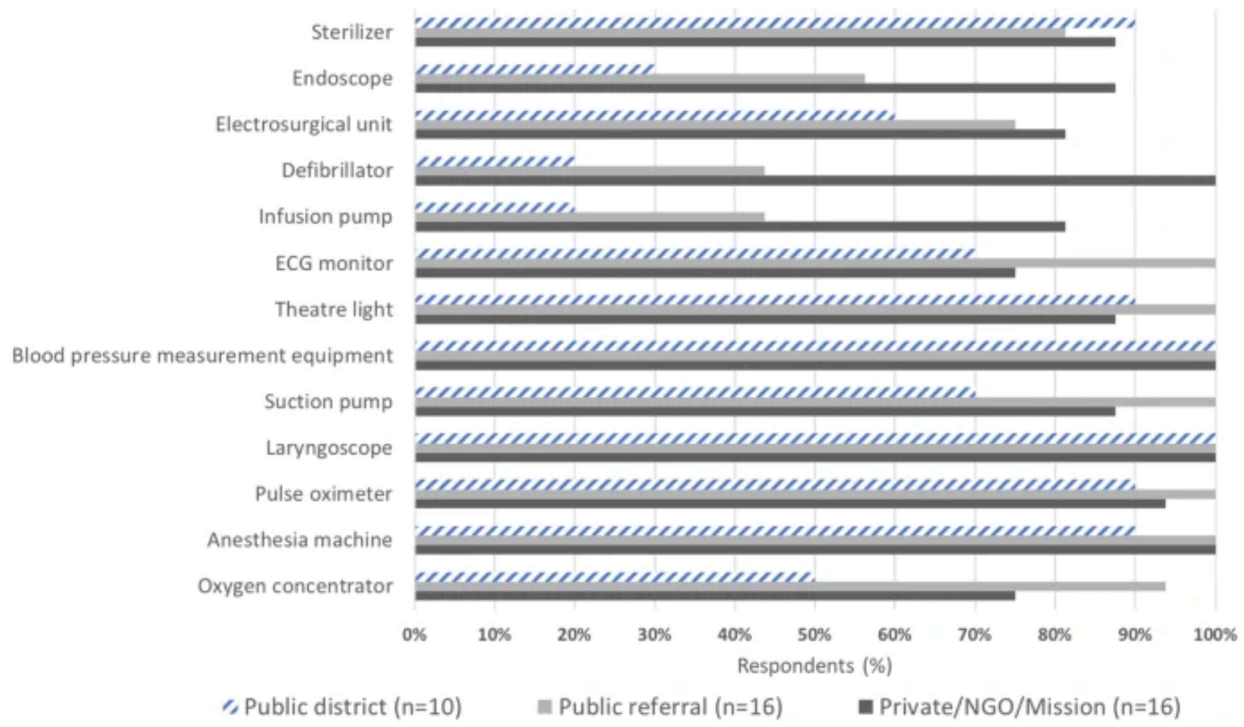

Figure 12: availability of fundamental equipment (Oosting R., 2019)

When performing laparoscopy, the laparoscope and various instruments are inserted within the patient’s body through small incision. To enable visualization inside the abdomen, the laparoscope needs to be connected to the laparoscopic tower or stack for power, image processing capabilities and display.

Next to this, the abdomen also needs to be inflated with CO2 so that surgeons get good visualization and have space to move within the abdominal cavity.

To enable this, the following equipment is required for laparoscopic surgery required (Clinical Gate, retrieved 2023):

- Trocars
- Laparoscopes
- Light source and lead
- Camera system
- Recording equipment
- Television monitor
- Insufflator
- Operating instruments

The laparoscopic tower typically holds the light source and connects it to the camera through the light lead. The camera system is where the imaging happens, and the monitor is on the stand. The laparoscopic stack also holds the insufflator and the Co2 supply.

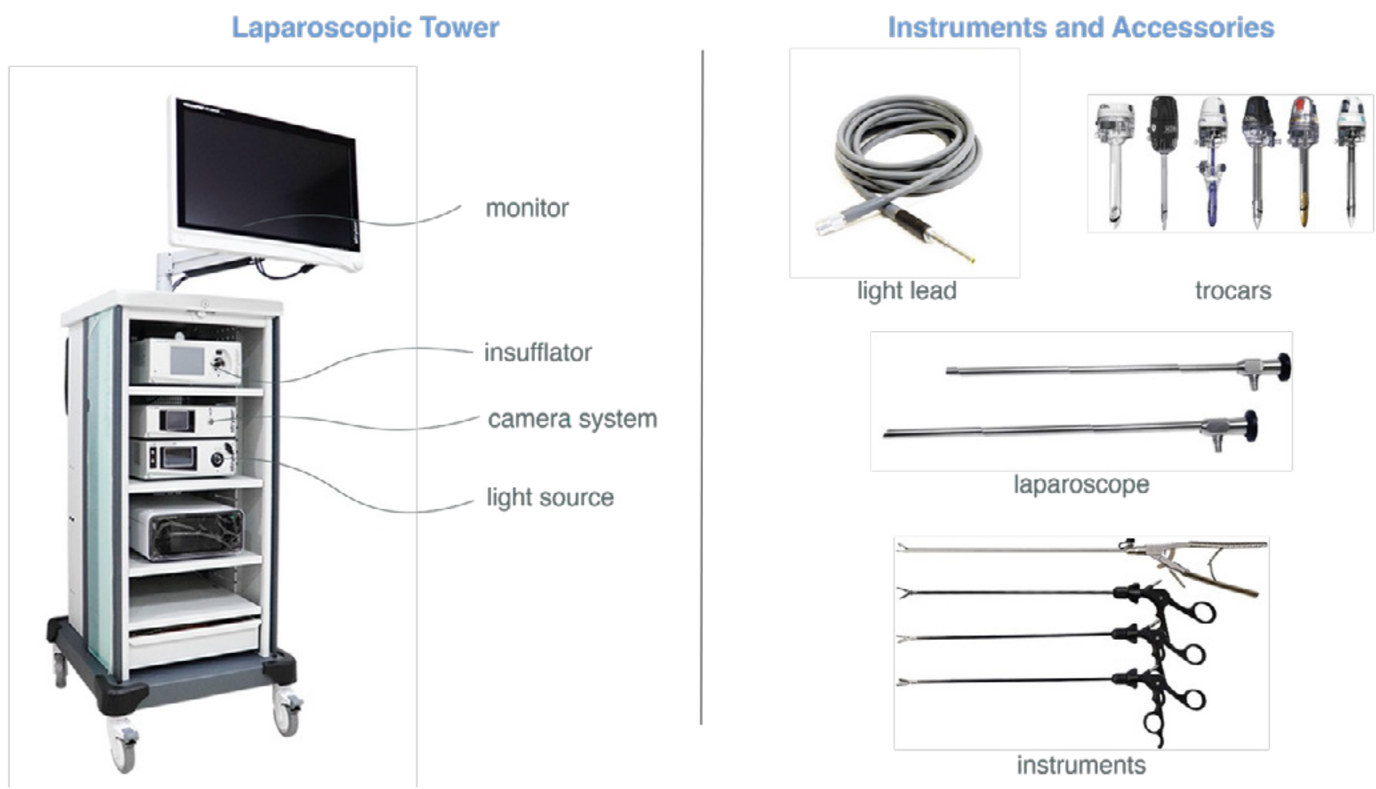

Figure 13: laparoscopic equipment

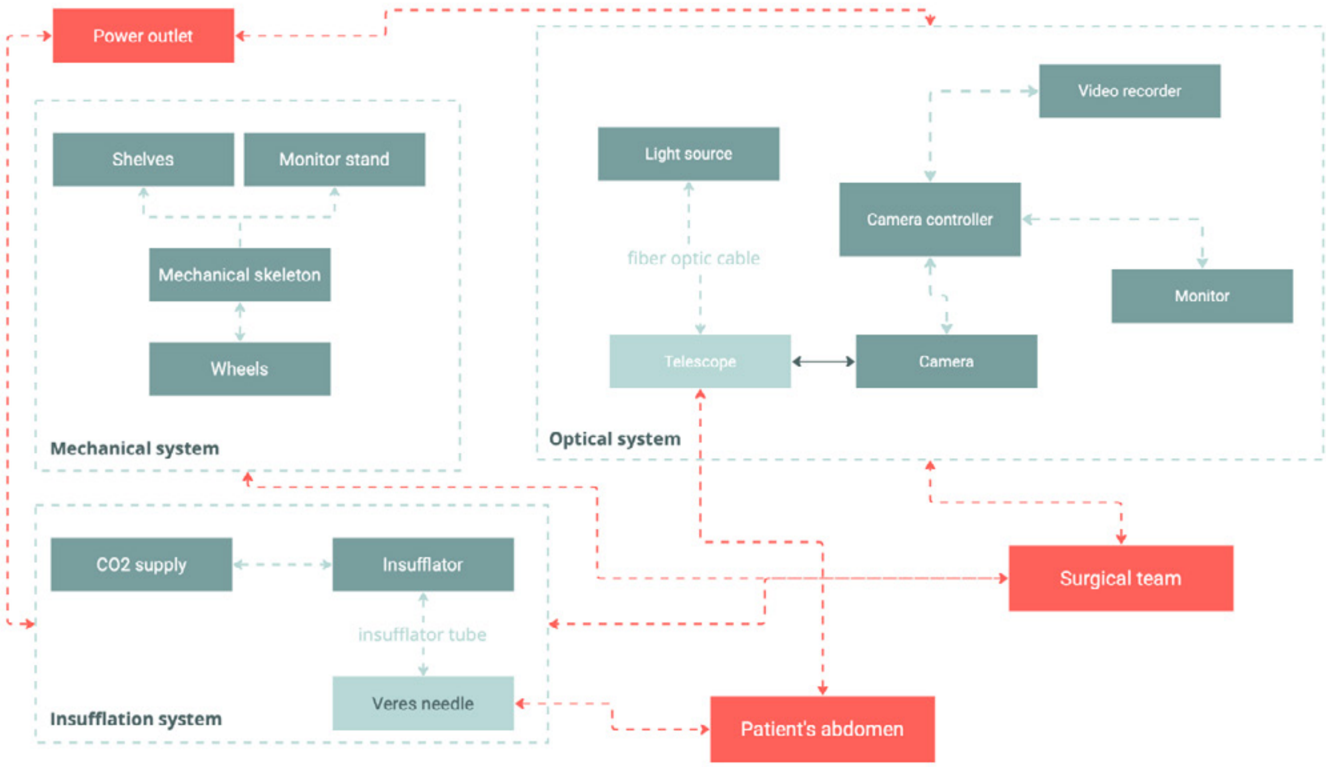

Figure 14: systematic overview, current solution

Three subsystems are defined: the mechanical system keeping all elements together, the optical system allowing for imaging and the insufflation system. Each element has important interfaces with the surgical team. For instance, the light source in the optical system, connects with the scope and allows for different light intensities. The insufflator has different settings for and cues for achieving the right gas flow and pressure inside the patient's abdomen (Department of Surgical Research and Techniques, retrieved 2023)

Laparoscopic surgery, while commonplace in the global North, can be challenging to implement in Kenyan district hospitals due to the extensive equipment requirements beyond those needed for open surgery. Sourcing, maintaining, and disinfecting this additional equipment may pose significant difficulties.

Surgical staff and anesthesia

In district hospitals, surgical providers vary from specialist surgeons to medical officers and non-physician clinicians. (Bentounsi Z, 2021). To provide surgery in LMICs extensive knowledge and skills are required, as there is no such thing as routine surgery (Ouweltjes, 2018). Anesthesia is often provided by trained non-physician clinicians or anesthetists. (Bentounsi Z, 2021).

While many stakeholders are involved in offering surgical care, three main users have most interactions with the laparoscopic tower: the surgeon, the scrub nurse, and the biomedical equipment technician. To better understand each user's needs, a persona is made for each.

"Operating rooms can be crowded and it's often unclear who is responsible for what." (Interview2)

Surgical providers	Number of publications
Specialist surgeon/obstetrician	5
Specialist surgeon/obstetrician & medical offficers	9
Medical officers	8
Medical officers and non-physician clinicians	4
Specialist surgeon/obstreltician and non-physician clinicians	1
Non-physician clinicians	6
Specialists and medical officers and non-physician clinicians	6

Figure 15: surgical providers (Bentounsi Z, 2021)

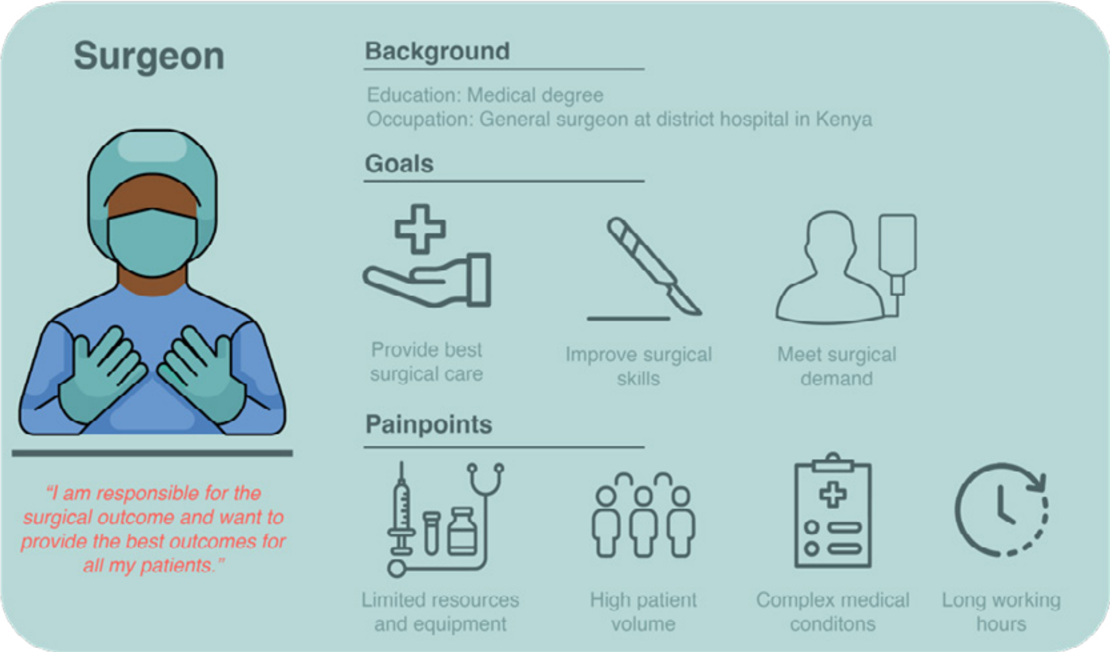

Figure 16: persona for surgeon

Surgeon
The surgeon is the leader of the surgical team and is responsible for the clinical outcomes. The surgeon is also the main user of most surgical tools (Ouweltjes, 2018). The surgeon works in close collaboration with the surgical assistant which provides the necessary tools and partly performs the surgery (Ouweltjes, 2018). In the case of laparoscopic surgery, the assistant is often responsible for holding the scope. Non-medical professionals are often trained to provide surgery in the context of LMICs (Ouweltjes, 2018). Surgeons often have limited training which is passed down from older generations (Interview2) , (Ouweltjes, 2018)

Surgeons are motivated to provide the best possible surgical care, meet local demand, and improve their surgical skills. Potential pain points include limited resources and equipment, challenges to meet demands, needing to offer a wide range of procedures and long working hours.

"The knowledge surgeons have is very experienced based, meaning that it gets old very quickly, as it's being passed down from older generations" - (Interview2)

Biomedical Engineering Technicians (BMET)
BMETs are responsible for checking machines before surgeries and operating the machinery (Hesselink, 2019). However, this is often not possible as there are often not enough BMETs to ensure this is done before each surgery (Hesselink, 2019). BMETs want to ensure that equipment is regularly maintained and repair, meet the repair demand on time and improve their skills. Potential pain points include limited resources and equipment, dealing with tight budgets when it comes to procurement, maintenance and repair and long working hours due to staff shortages.

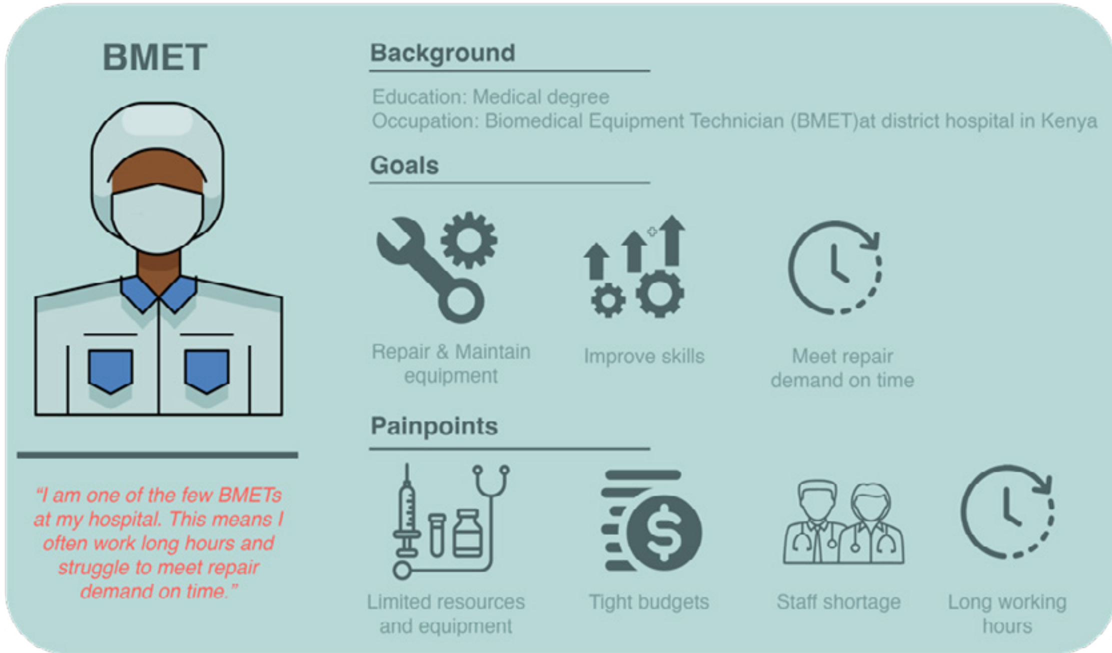

Figure 17: persona for BMET

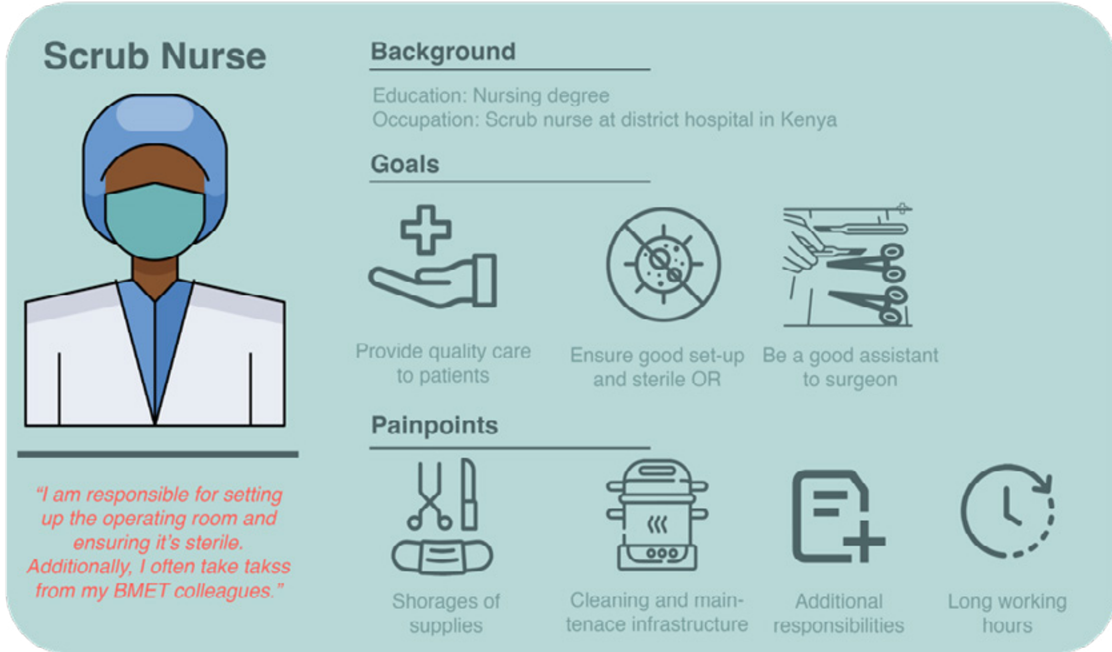

Figure 18: persona for scrub nurse

Scrub nurses
Scrub nurses are responsible for setting the operating room and ensuring adequate sterility. Their workload is often very high due to staff shortages (Hesselink, 2019). When BMETs are unavailable, scrub nurses often must pick up various tasks from BMETs (Hesselink, 2019). their skills. Potential pain points include limited resources and equipment, dealing with tight budgets when it comes to procurement, maintenance and repair and long working hours due to staff shortages.

Implementing laparoscopy in low- and middle-income countries (LMICs)

In LMIC, laparoscopy can be very advantageous. Smaller incisions, minimize the risk of infection due to poor sanitation within the operating room. Shorter recovery times are beneficial both for the patient and for the hospital: on the one hand patients recover quicker, thus lowering the hospitalization bill, while on the other hand hospitals can accommodate more patients. Additionally, laparoscopic surgery in LMICs can provide a low-cost alternative to diagnostics, thus shortening waiting times (Chao TE, 2016). While there are several advantages, implementing laparoscopy in LMICs comes with its challenges. The associated starting cost with implementation is often high and donation dependent, additionally trained laparoscopic surgeons are not always available (Oosting R. W., 2019) (Chao TE, 2016). Figure 19 gives an overview of the clinical, economical, and systemic advantages and challenges of implementing laparoscopic surgery in LMICs.

Category	Advantages	Challanges
Clinical	Shortened hospital stay, decreased pain, fater return to work Improved clinical outcomes, mainly: 1. Smaller wound 2. Fewer infections 3. Fewer long-term complications 4. Less immunosuppression 5. Less abdominal drainage Fewer unnecessary appendectomies When imaging is limited, it can be used for diagnostic purposes	High rate of conversion to open Higher incidence of major complication Absence of safe guidelines Increased time to perform laparoscopic operations Trained laparoscopic surgeon not always available
Economical	Equipment cost ratio for laporascopy/ultrasound/ct/mri is 1:500:2500:4500 More cost effective for hospitals than open surgery due to 1. Minimal use of analgesics, antibiotics, medical supplies 2. Early discharge Better for patients due to lower hospital bill, quicker return to work, particularly important for single income households	Cost prohibitive given hospital billing procedures, absence of health insurance, insurance that only pays for open surgery High start-up costs often necessitate donated equipment Similar costs to open operations Higher anesthesia costs due to increased OR time Economic benefit might only apply to high income patient
Systemic	Beds in short supply are made available due to quicker discharge, therefore elective surgery wait time decreases Laparoscopic training facilitates courses for basic and emergency surgical services Gives surgeons a sense of professional accomplishment and motivation.	Limited availability of trained staff and high-quality training opportunities leads to inability to handle complications Limited resources, equipment, and maintenance availability Patients might mistrust the "new" and not perceive the benefits due to lack of education and nonscientific beliefs

Figure 19: advantages and disadvanages of implementing laparoscopy in LMIC

Despite the challenges, implementing laparoscopy in LMICs has shown improved outcomes for patients (Oosting R. W., 2019). Several frugal alternatives to laparoscopes making use of mobile technology decrease the cost and significantly reduce the number of devices required for laparoscopic surgery (Oosting R. W., 2019). Figure 20 (Butter, 2023) shows an overview of the different frugal laparoscope solutions found in literature. Those solutions significantly minimize the need for equipment, as processing is done with a laptop or phone, and the light source and camera are often integrated within the scopes.

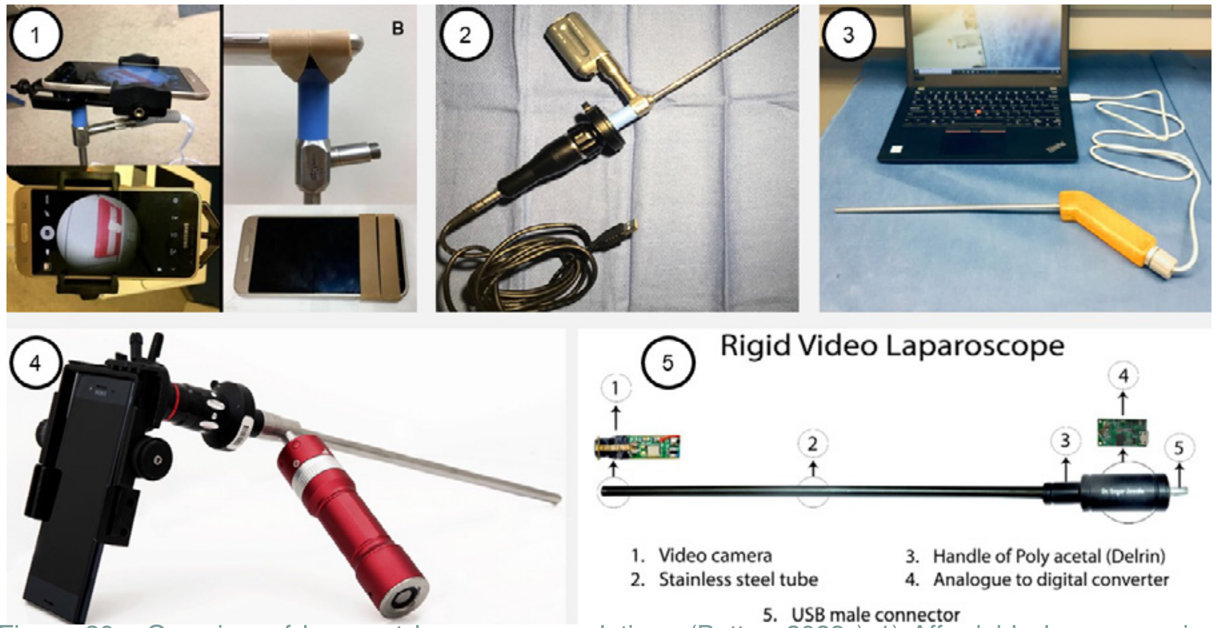

Figure 20 - Overview of low cost laparoscope solutions (Butter, 2023) 1) Affordable Laparoscopic Camera System (ALCS) consisting of a Stryker telescope and a Samsung Galaxy J (Gheza, 2018) 2) A low cost rapidly deployable minimally invasive surgical system (RDMIS) that uses a USB-compatible camera (Ellis-Davy, 2022) 3) The ReadyView laparoscope, consisting of an integrated camera and LED light source compatible with any laptop 4) Laparoscope created by coupling a 0□ 10-mm telescope via a commercially available adapter with an Apple iPhone 6s (Chatzipapas, 2018) 5) Rigid video laparoscope combining the telescope, light source and camera into one low-cost device (Mueller, 2021)

While those solutions are an important first step for a sustainable implementation in LMICs, the connection between the scope and the operating room has been overlooked. To create a sustainable solution that can be used on the long term in an ergonomic way, it is necessary to re-think how the scope relates to the wider setting of the OR and the hospital at large. Therefore, there's a need to develop a new laparoscopic tower that is compatible with different frugal scope solutions. Figure 21 shows how the system would change with the implementation of a frugal scope solution.

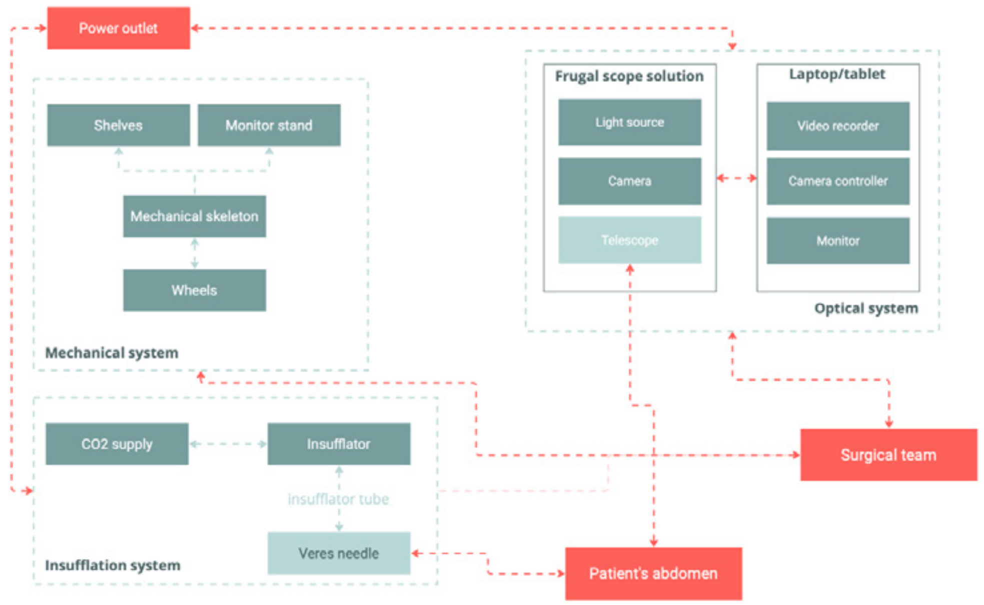

Figure 21: systematic overview, new solution

2.4 Conclusion

The goal of the exploration phase is to develop a good understanding of how surgical care is offered in the Kenyan healthcare system. The exploration phase delves into the intricacies of the Kenyan healthcare system, the barriers patients face to receive surgical care and the type of procedures that are offered. This phase ensures a good understanding of the surgical infrastructure, including the essential requirements for delivering surgical care and the additional requirements for implementing laparoscopic surgery, by answering the following questions:

- What barriers are encountered by patients seeking surgical care?
- What type of health care facilities are targeted?
- What surgical procedures are performed?
- Is anesthesia, sterilization and maintenance provided and how is it organized?
- Who is involved during procurement and usage of equipment?
- Who is part of the team providing surgery and how are they trained?
- Is infrastructure working properly? (Water, electricity etc.)
- What equipment is available and used? If unavailable, why is equipment unavailable?

The Kenyan healthcare system is divided in 6 distinctive layers. The 4th layer, represented by district hospitals, is the first layer at which surgical care is offered – and often the most accessible to patients. When seeking surgical care, patients encounter numerous challenges – including barriers to seek care (e.g., high costs, low awareness of treatment possibilities), reach care (e.g., poor road infrastructure, high transportation costs) and receive care (e.g., limited diagnostic infrastructure, limited surgical capacity). As district hospitals are the first point at which patients can receive surgical care, those facilities will be targeted. A wide array of procedures is offered at district hospitals, however there are big discrepancies between facilities.

To provide surgical care, working equipment, anesthesia and trained surgical staff is required. Fundamental equipment for providing surgical care, is less available in district hospitals as compared to higher level hospitals. While laparoscopy requires additional equipment, implementation in district hospitals can tackle other challenges district hospitals face – such as limited patient beds and high infection rates. Many different stakeholders are involved in providing surgical care. The stakeholders that would have the most interactions with the laparoscopic stack are the surgeon, the scrub nurse, and the biomedical equipment technicians.

Requirements
Based on the information gathered, a list of design requirements is defined to design a laparoscopic tower that is suitable for the Kenyan healthcare system. The list of requirements is created by compiling design requirements typical for medical equipment in low- and middle-income countries and requirements specific to the laparoscopic tower.

The list of requirements states the most important characteristics the new laparoscopic tower must have over different categories. This is done iteratively, by defining as many requirements as possible and then eliminating requirements that are too similar (Boeijen , van Daalhuizen , Schoor , & van der Schoor, 2014).

Based on this the following list of requirements was developed based on the Delft Design guide method (Boeijen , van Daalhuizen , Schoor , & van der Schoor, 2014)

Type of requirement	Requirment	Test
Performance	The cost of ownership over time should be minimised, including maintenance cost, running costs and initial cost (Piaggio, 2021).	Calculate the total cost of ownership, including initial purchase, maintenance, and expected lifespan, and ensure it is 50% below the industry average.
	The tower should be robust and be able to withstand regular use within a clinical setting.	Conduct stress tests to ensure the tower can withstand clinical use without structural failure
	The tower must exhibit robustness against environmental factors (e.g., temperature, humidity, dust)	
	The tower must be user-friendly.	Conduct user testing
	The tower must be manufactured locally	Verify that at least 80% of the components are locally available in Kenya
	The tower must be user-friendly.	Conduct user testing
	The the laparoscopic tower should be easily moved by one person between operating rooms within the healthcare facility	Conduct user testing
	The laparoscopic tower should protect equipment while stored in informal storage areas	
Life in service	The tower must be able to securely hold a laptop/tablet during operation	Conduct user testing to verify that the screen remains securely in place under normal operating conditions
	The tower must support different sized insufflators weighing around 10 kilograms.	
	The tower must have a Lifetime longer than 5 years (Oosting R.M., 2019)v	

Type of requirement	Requirment	Test
Environment	The tower must be resistant against high ambient dust levels.	
	The tower must function within a temperature range of 10-45 degrees Celsius.	
	The tower must operate in relative humidity ranging from 0% to 90%	
	The shower must be able to withstand power fluctuations (surges and dips) without compromising functionality.	
	The tower should protect equipment from impacts during storage and moving.	
Size and weight	The tower must be designed to fit in most surgical rooms, including makes shift surgical rooms (Interview2).	Measure the dimensions of the tower and compare them to the average dimensions of surgical rooms. Ensure that the system can be accommodated in the majority of surgical environments.
	The tower must be lightweight, allowing a single person to move and set up the equipment easily.	Conduct user tests to confirm ease of handling.
Maintenance and reliability	The tower must be designed for easy, local maintenance.	Evaluate the tools, parts and time required for maintenance and ensure they are locally available
	Maintenance tasks must be completed in a short period of time.	Evaluate the tools, parts and time required for maintenance and ensure they are locally available
Aesthetic, appearance and finish	The tower must have a finish that is clean and easy to maintain.	
	The tower must have a durable finish, resistant to wear and tear.	

Type of requirement	Requirment	Test
Materials	The tower must be constructed from 100% non-absorbent material (RoosThesis5, 2019).	Confirm with material data in CES Edupack that the material is entirely non-absorbent and does not retain moisture.
	The material must be resistant to cleaning with heavy chemicals (e.g., Cidex) (Oosting R.M., 2019) (Hesselink, 2019) (Ouweltjes, 2018).	Confirm with material data in CES Edupack that the material can withstand cleaning with heavy chemicals, including Cidex, and ensure it withstands the cleaning process.
Ergonomics	The tower must have a clear interface (Oosting R.M., 2019)	Conduct user testing to ensure that participants find the interface intuitive and easy to navigate..
	The tower must be easy to use (Oosting R.M., 2019)..	Conduct user testing to ensure that the system is easy to use
	The tower must be suitable for users with minimal training (Oosting R.M., 2019)	Conduct user testing with novice users
	The tower must be suitable for users with minimal training (Oosting R.M., 2019)	Conduct user testing with novice users
Safety	The tower must ensure electric safety, safeguarding against electrical hazards.	Evaluate the tools, parts and time required for maintenance and ensure they are locally available
	The tower must minimise the risk of sharp injuries during use.	Evaluate the design and components to ensure that all component don't have sharp edges or are appropriately covered
	The tower must be properly secured during use	Verify that the tower includes secure fastenings or locking mechanisms to prevent any unintended movements during use

After developing a good understanding of the context of surgical care within the Kenyan healthcare system, the initial brief is re-defined as follows:

“Design a cost-effective, durable, and easily movable laparoscopic tower that meets the needs of district hospitals in Kenya. The tower should be designed for compatibility with laptop-connected scopes and must prioritize easy storage, local manufacturability, and repairability.”

The most important drivers are:

1. **Portability**: the laparoscopic tower should be easily moved between operating rooms within the healthcare facility

2. **Durability**: the laparoscopic tower should be robust and be able to withstand regular use within a clinical setting

3. **Low purchasing cost**: the design should be cost-effective and aim to minimize initial purchasing cost

4. **Low lifetime cost**: the tower should have a low life-time cost, ensuring repair and maintenance costs stay low

5. **Storage**: the laparoscopic tower should be suitable for storing in informal storage areas

6. **Local manufacturability and repairability**: the design should use parts and materials available in Kenya to ensure it is locally repairable and manufacturable

3. Design phase

This chapter is focused on explaining the process of how the final design was reached, including ideation and all the relevant iterations.

3.1 Introduction

The exploration phase has resulted in a good understanding of surgical care in the Kenyan healthcare context, together with an extensive list of requirements needed to create a cheap, portable, and robust alternative to the current laparoscopic tower.

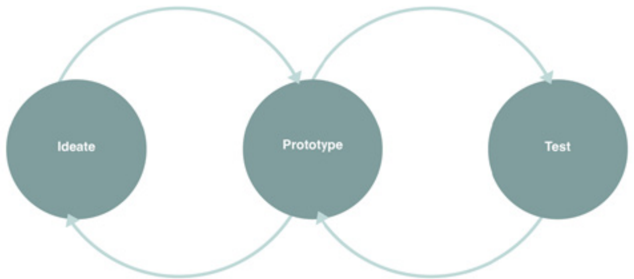

Figure 22 - design process

To design a new laparoscopic tower, that is suitable for the Kenyan healthcare context an iterative approach is taken (Interaction Design Foundation , retrieved 2023). First, ideas are generated to develop novel solutions. Then, low-cost prototypes are made to investigate the feasibility of some of the solutions generated during the ideation phase. Afterwards, those solutions are analyzed and tested to gain a better understanding of how the tower will be used and potentially uncover new requirements.

Once ideas were generated, two very different concept directions were chosen. The first concept is a mobile solution, designed to be moved around and protect the equipment. The other concept consists of a simple solution fixed to the hospital bed. The first concept was chosen for further development, and an iterative approach was taken. Rapid prototypes were made to test the concept out and develop it. Figure 23 shows an overview of how the design evolved from the initial idea, towards a final concept.

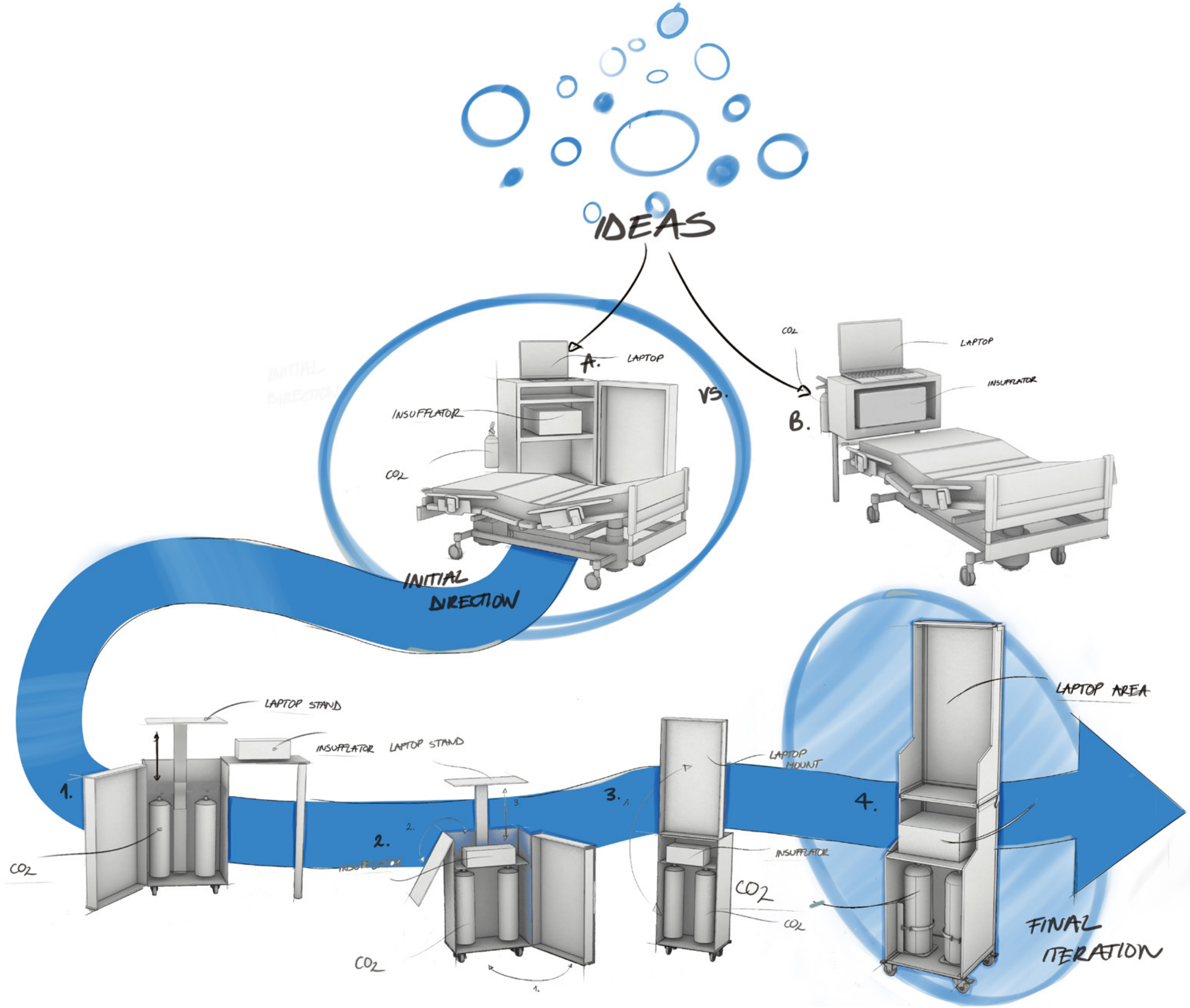

Figure 23 - design evolution

3.2 Ideation and initial direction

To generate ideas, different solutions were developed individually through sketching and a brainstorming session was held together with students with an interest in medical design. The session centered around the tension between mobility and robustness, which are both important requirements for the new tower. Lego serious play (Lego serious play, retrieved 2023) was used to explore associations with "mobility" and "robustness", and those associations were then integrated into new concepts for the laparoscopic tower. The session resulted in over 40 Lego metaphorical models and over 10 concept directions.

Once the session was completed and a discussion with the client, two different concept directions were chosen. The first concept consists of a very simple bed-side solution that would be static in each operating room (figure 24) , while the other one consisted of a flight case that would be able to house all the necessary equipment and be moved around easily (figure 25).

A survey was made to gain input from differentstakeholders at a surgical conference in Mombasa and shared on LinkedIn to gain a better understanding which direction would be preferred. Due to limited participation, the survey was not conclusive, however preference for the second concept was indicated due to its mobility.

The fixed concept would require enough available equipment so that each operating room would have one, therefore the mobile concept would be more cost effective. Additionally different set-ups might be needed for laparoscopy, meaning a fixed concept might get in the surgical team's way during operating and set up. With those considerations in mind, the second concept was chosen for further development.

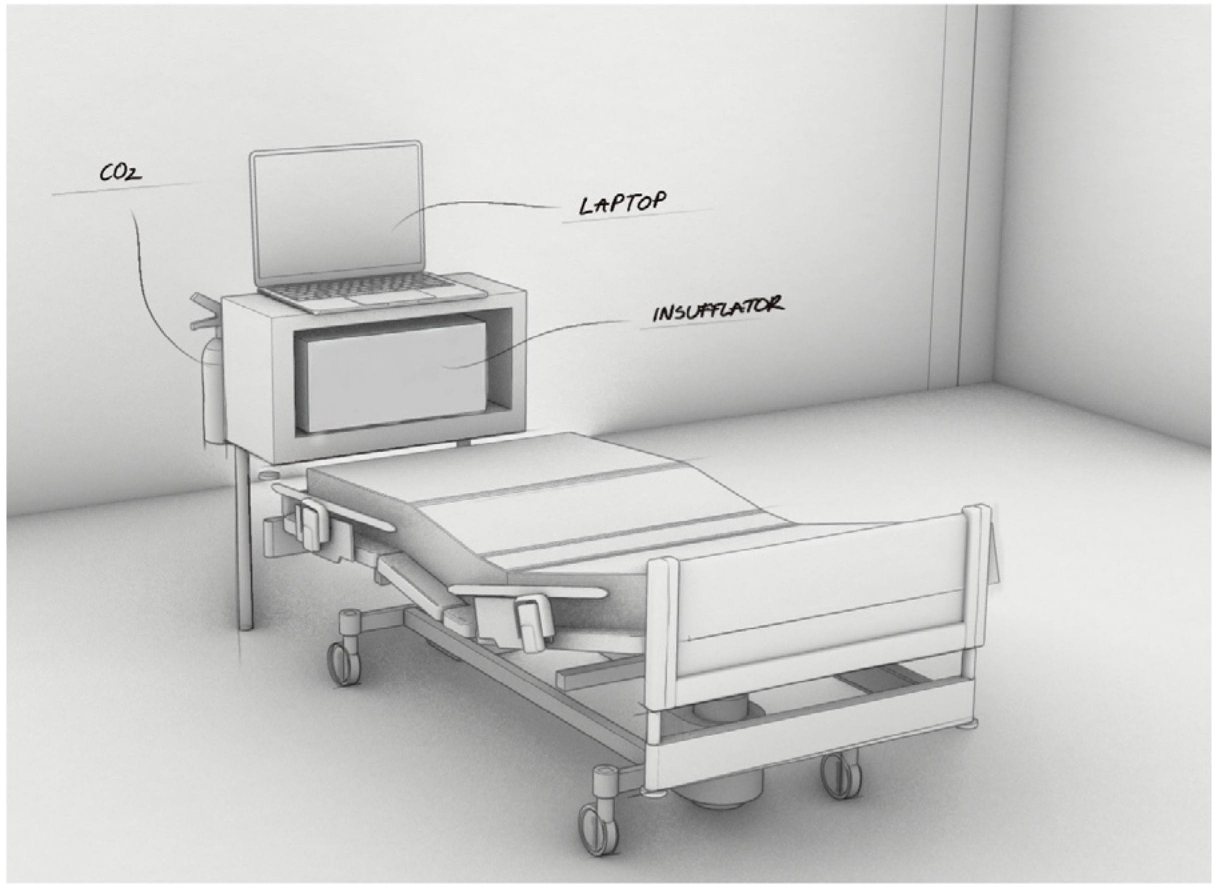

Figure 24 - initial concept direction

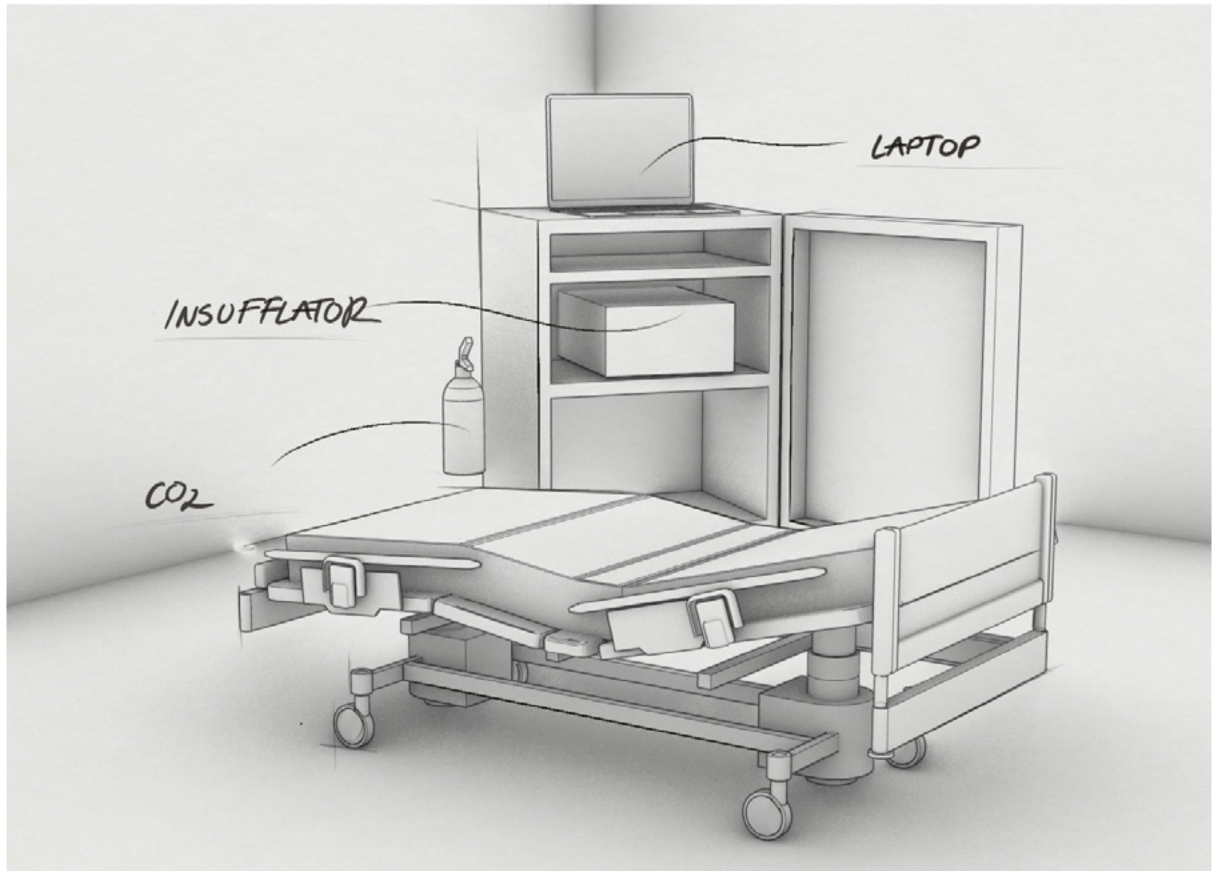

Figure 25- initial concept direction

3.3 Developing the flight case concept

First iteration

The next iteration was focused on raising the screen to eye height without unnecessarily increasing the size of the flight case. The top of the case can be easily opened and transformed into a table, by attaching a screw on leg, thus making space to hold the insufflator during procedures. Clear visualization is very important during laparoscopic surgery; therefore, the tower features an adjustable beam as support for a laptop, allowing surgeons to adjust the screen at a comfortable height.

This led towards my next iteration (figure 26), where the screen/laptop is placed on the adjustable beam, and the insufflator is put on the side. A survey was made to gain input from differentstakeholders at a surgical conference in Mombasa and shared on LinkedIn to gain a better understanding which direction would be preferred. Due to limited participation, the survey was not conclusive, however preference for the second concept was indicated due to its mobility.

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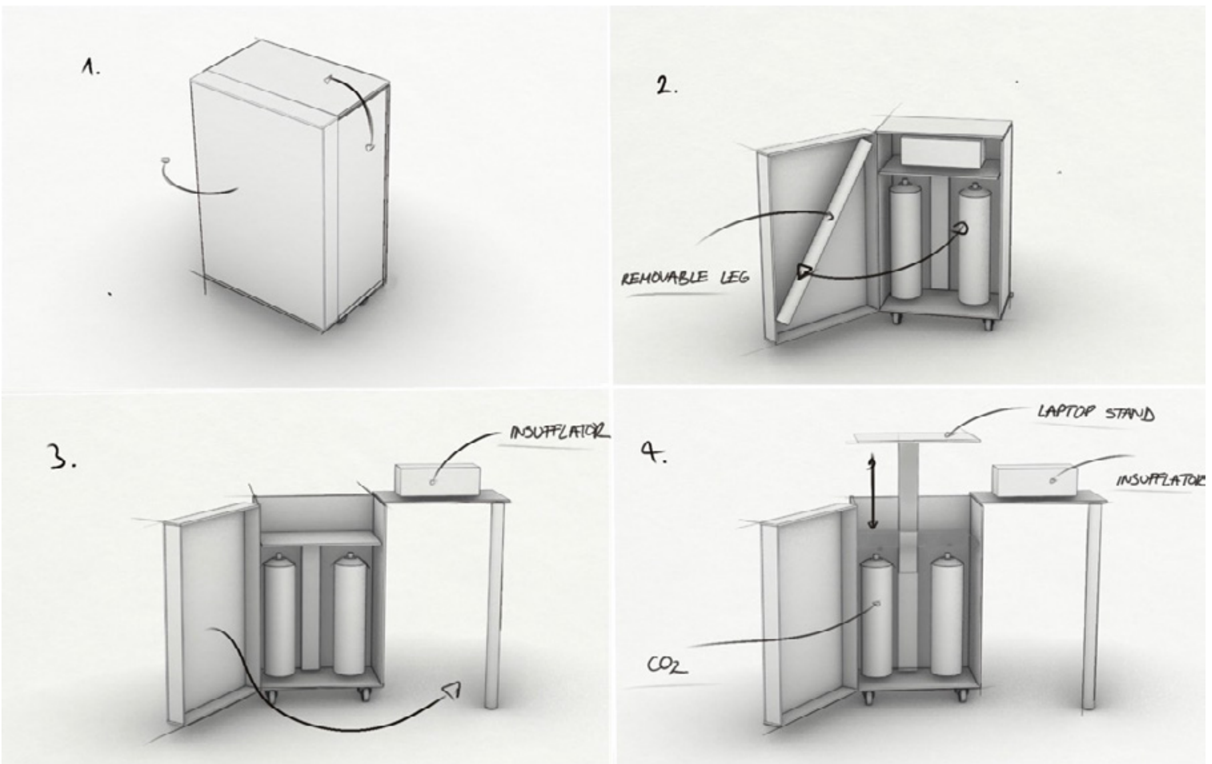


Figure 26 – first iteration

The first iteration was shown to Dr. Odula over a teams call. He liked that the concept was mobile and easy to move from one operating room to the other. He stressed the importance of ensuring a good balance between robustness and portability:

"If it's portable you need to make sure that it can't easily break. You might focus on making it nice and light, but once you put it together something breaks or slips and than you can't use it"

Additionally, he mentioned the importance of ensuring that parts are not easily lost:

"these parts need to be literally connected to each other so that people do not lose them"

While the concept is both mobile and robust and ensures the laptop can be moved at the right height, it also has some disadvantages. The main disadvantage is that too many steps are needed, which could lead to parts being lost. As the leg needs to be connected and re-connected, there is a high risk of losing it. Similarly, the insufflator needs to be moved and out which could create issues with cabling.

Advantages	Disadvantages
Screen is easy to adjust	Loose parts, such as the leg can be easily lost
Good balance between mobility and robustness	There are a lot of steps required to get the tower ready for use
	Might be unstable as only one leg is used
	Cabling might prove to be difficult

Figure 27 - Advantages and disadvantages

Second iteration
To improve on the first iteration, the number of steps is reduced. Instead of unfolding into a table, the top opens allowing for a mechanism to unfold with the goal to reach the right eye height and the insufflator is kept on a shelf. A true to size prototype was made to test stability with open doors (figure 28).

The challenge with this concept was to keep the insufflator in a fixed position inside the case, while ensuring the screen can be moved to reach eye height. Benchmarking (figure 29) was used to research existing solutions.

While testing the prototype, it became apparent that the device becomes quite big when the doors are open, making it difficult to walk around. While the number of steps was minimized and the stability is improved, this iteration showed challenges with achieving the desired height and compactness during use.


Figure 28 - First prototype


Figure 29 - benchmarking solutions for screen

Advantages	Disadvantages
Good balance between mobility and robustness	Difficulty reaching eye height
Reduced number of steps	Increase in size with open doors
Improved stability	

Figure 30 - Advantages and disadvantages

Third Iteration

To improve on the previous iteration, I thought of using the length of the door to reach the required eye height and ensure the door is not in the way. Using a hinge to secure the door at the top instead of on the side, allowed for a solution where the door folds out to reach the right height, at which a laptop stand can be mounted. This further reduced the number of steps: instead of opening two doors and adjusting the beam, only one door needs to be opened. Disadvantages are that the door is not secured when open, risking tipping over. Additionally, the door does not perfectly align when being closed.


Figure 31 - First prototype

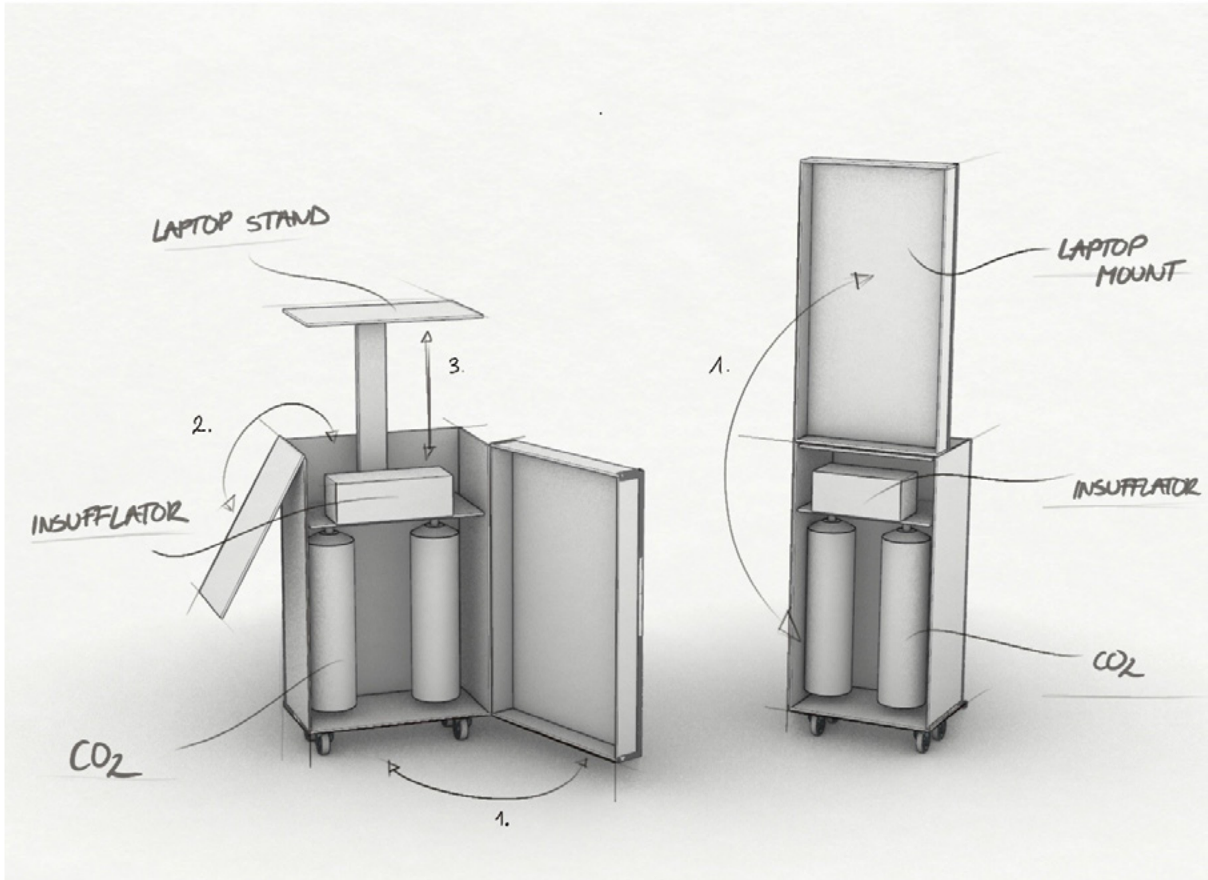


Figure 32 - third iteration

Advantages	Disadvantages
Good balance between mobility and robustness	Door is not secured, risk of falling shut
Further reduced number of steps	Door is not perfectly aligning when closed
Improved stability	
Easy to reach eye height	
Decrease of size when in use	

Figure 33 - advantages and disadvantages

Fourth Iteration

To counter the issues in the previous iteration, the form was adjusted to ensure the top door can align and be fixed at the bottom, thus improving stability. This ensures there is no risk of the door falling when open, ensuring the laptop is safe. The new shape also ensures there is more weight at the bottom than at the top, making it easier to open and secure in place.

The new tower can be used in three simple steps. The box is opened and then secured into place using the lock at the back. The last step is to open the laptop holder and secure the laptop in place. A simple, foldable, off the shelf laptop holder was chosen, as to minimize the number of parts and create a minimum viable product. The CO_2 supply is held in place with straps that are secured on the inside with a metal plate.

Figure 34 - Final prototype

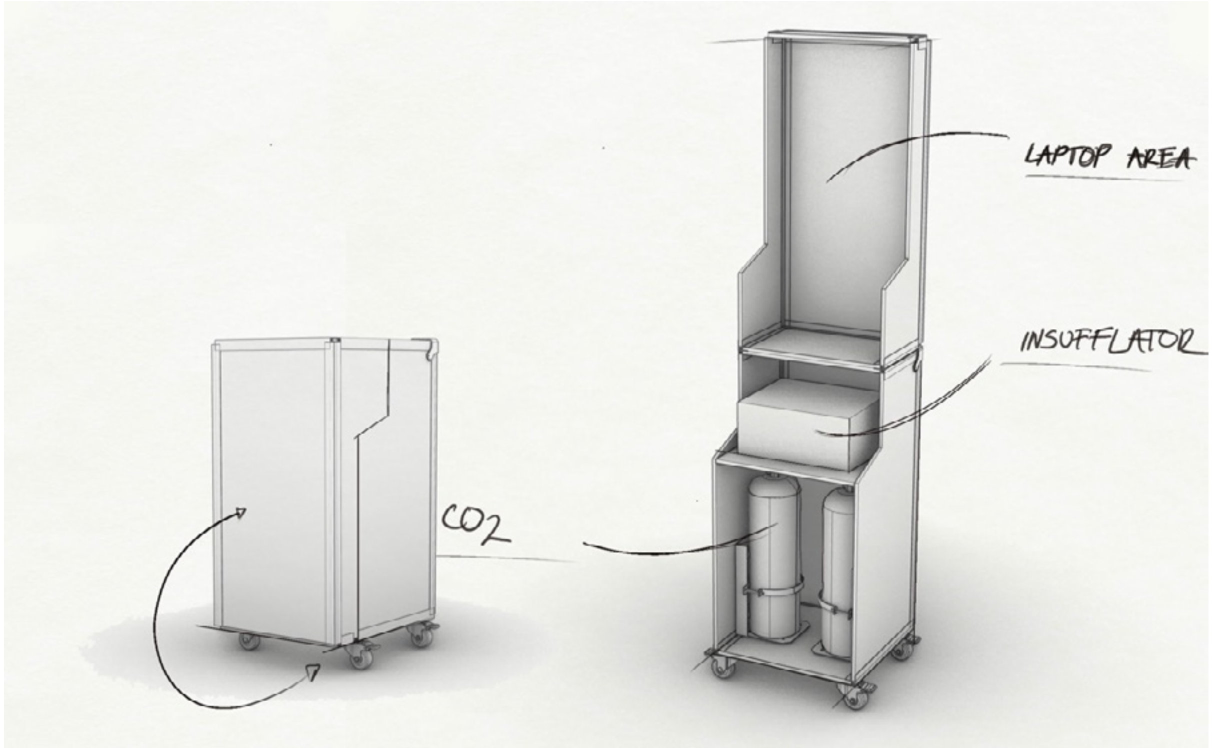


Figure 35 - final concept

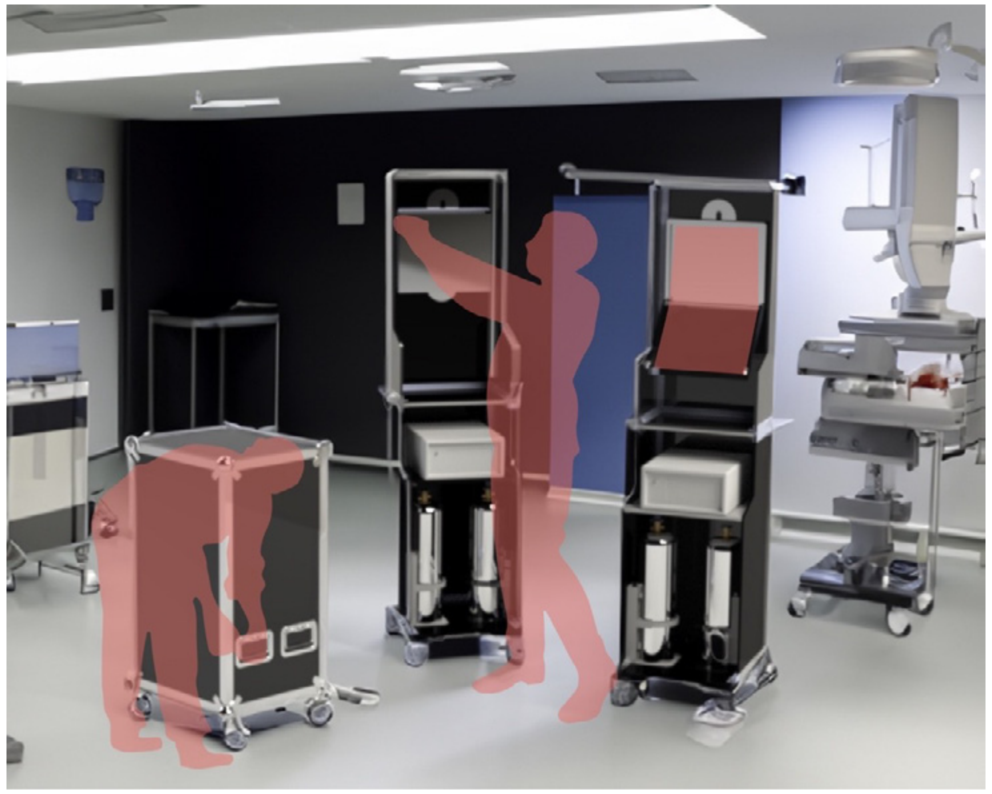


Figure 36 -interaction

2.4 Conclusion

In this phase, a new laparoscopic tower was designed for the Kenyan healthcare context, by taking an iterative approach. Three different prototypes were made to investigate the feasibility of the solution and gain a better understanding of how the tower will be used and uncover new requirements.

This resulted in a final design that balances the need for mobility and robustness, is easy to set-up and has good stability and alignment. The final design makes use of standard parts that can easily be purchased and replaced in Kenya, allowing for local manufacturing and repair.

4. Validation phase

This chapter is focused on validating the design in the local context through contextual insights and surveys with relevant stakeholders.

4.1 Methods

In the previous phase a minimum viable product for a laparoscopic tower was designed for the Kenyan healthcare system, and a prototype was built. In the validation phase the design will be validated with local users and stakeholders, with the goal find and understand any requirements that might have been missed and uncover wrong assumptions.

To achieve this, end users will be asked to give their initial reaction to the prototype and fill in a survey detailing upon the current challenges of implementing laparoscopy. The survey consists of questions to evaluate the prototype on usability in a clinical setup, robustness, storage, and ergonomics. To augment the data from the survey with users, the surgical workflow will be observed from pre-operative set-up to post-operative sterilization.

To guide the process the following research questions are defined:

1. What are the current challenges of implementing laparoscopic surgery in Kenya and what impact does this have on the design of the new laparoscopic tower?

2. How does the current surgical workflow look like from pre-operative set-up to post-operative sterilization and how can the laparoscopic tower be improved to integrate into the existing workflow?
a.What are the current bottlenecks and inefficiencies in the surgical workflow?
b.What are the strong points of the new design when it comes to working within the current surgical workflow? How can it be improved to better integrate within the surgical workflow?

3.How can the laparoscopic tower be improved to better meet the needs of use in a clinical set-up, including robustness, storage and use ergonomics?

Answering those questions will help uncover new requirements and challenge the assumptions made during the exploration part of the project. Observing surgeries will help further develop my understanding of the surgical workflow and better understand how the laparoscopic tower is used in the day-to-day surgical practice. Feedback from end-users will allow me to understand what areas the tower must be improved and give clarity on why certain steps are taken.

To answer the research questions, three types of data is collected: observational data, survey data and reactions to the prototype from the end users. The use of the existing laparoscopic tower was observed in the day-to-day workflow, while end-users were given a short explanation and observed while interacting with the prototype. When possible, end-users were asked to fill in a survey to give detailed feedback on how the tower can be improved, and when time was limited, end-users were asked to give their initial reaction after interacting with the prototype.

Figure 37 - types of data collected

To interpret the data, triangulation was used (Alicia O'Cathain, 2010). The input from the survey was compared to the observational data and reactions from end-users, by explicitly looking for disagreements (Alicia O'Cathain, 2010). In this way the findings can be better understood to gain a richer picture of the context of surgical care in Kenya.

4.2 Results

In the observational phase of the study, data was collected by viewing surgical procedures. A total of 24 procedures were observed, out of which 40% of the procedures used the laparoscopic tower, one procedure being laparoscopy. Figure 38 gives an overview of the procedures observed together with the equipment used during the procedure.

Type of surgery	Procedure	Number of procedures observed	Equipment used
Uroscopy	Stent insertion Stent removal Uroscopy (unknown) Uroscopy (unknown)	4	Laparoscopic tower Diathermy
ENT	ENT (unknown) ENT (unknown) ENT (unknown) ENT nasal biopsy ENT bone surgery	5	Laparoscopic tower Diathermy Drill Microscope
Orthopedic	Femoral fracture Femoral fracture Femoral fracture	3	X-Ray
Open surgery	Nephrectomy Cystectomy Open heart surgery Laparotomy (tumor removal) Laparotomy (tumor removal) Laparotomy (prostate removal) C-section C-section	5	Diathermy Bypass machine
Laparoscopy	Diagnostic laparoscopy (ob-gyn)	1	Laparoscopic tower
Other	Maxillofacial surgery Neurosurgery Penis amputation	3	Diathermy Neuro microscope X-ray

Figure 38 - overview of procedures observed

Next to the observational data, a survey was shared with 13 end-users at the hospital, figure 39 gives an overview of the participant demographics:

Professional background		Experience with laparoscopy or using laparoscopic equipment	
Biomedical Engineering	7	Beginner	5
Anesthesia	5	Intermediate	5
General surgery	1	Advanced	3

Figure 39 - participant demographics

The survey covered questions in four different areas: challenges of implementing laparoscopy in the hospital, first impression and reactions, usability and use aspects, and critical parts and improvement. The most important themes are presented for each of the four areas.

Challenges implementing laparoscopy
Participants were asked to rank the challenges encountered with the implementation of laparoscopy in the hospital, on a scale from 1 - low barrier to 5 – high barrier. The highest barriers to implementing laparoscopy are difficulties sourcing spare parts and high costs associated with purchasing laparoscopic equipment, followed by the costs associated with consumables and maintenance. The lowest barriers are skepticism/reluctance from patients to undergo laparoscopic surgery and difficulties using laparoscopic equipment Figure 40 shows an overview of the challenges ranked from high barrier to low barrier.

Type of procedure	Number of papers
Difficulty sourcing spare parts	4.07
High costs associated with purchasing laparoscopic equipment	4
Costs associated with consumables	3.83
Costs associated with maintenance	3.69
Limited opportunities to learn and practice laparoscopy skills	3.33
Time required to set-up and perform laparoscopic surgery	3.08
Difficulties with preparing room for laparoscopic surgery	2.84
Availability of laparoscopic equipment	2.76
Cleaning infrastructure for laparoscopic equipment	2.61
Difficulty using laparoscopic equipment	2.46
Scepticism/reluctance from patients to undergo laparoscopic surgery	1.66

Figure 40 - challenges implementing laparoscopy ranked high to low

First reaction
Next, participants were asked to describe what they think about the new design at first glance and rank the usability of the design after interacting with it. Additionally, 10 different first impressions were communicated verbally from end users. The professional background of the end-users giving reactions are shown in Figure 41

Professional background (verbal reactions)	
Biomedical Engineering	3
General surgery	3
Ob-gyn surgery	1
ENT surgery	1
Nursing	1
Anesthesia	1

Figure 41 - professional background, verbal reactions

Based on the survey questions and the reactions the following themes emerged as first impressions to the prototype:

Good solution
At first glance, the tower was seen as a good solution, which is appropriate for the purpose it's been designed for.

Practicality and simplicity
The design was appreciated for its practicality and simplicity, which was mentioned 6 times. The tower was described as "handy", "convenient" and "not cumbersome".

"It's nice to see a solution that simplifies things. Right now a lot is coming in and technology is advancing very quickly. It's challenging to keep up and too expensive to pay for training for different equipment all the time"

– Biomedical engineer

"Nice compact solution"

– Biomedical engineer

Moveability
Another theme was mobility, end-users indicated mobility was a plus point which was mentioned 3 times.

"I like that it's not cumbersome and mobile. It can easily be moved around the hospital. Can also be very useful for arthroscopy."

– Anesthesiologist

Good for low low-level hospitals
The tower was described as a great solution for lower-level hospitals that might have limited resources. Potential training application was also mentioned.

"This is a great solution for hospitals with less resources. Many doctors come to MOI, train with the best equipment, and then go to hospitals where they don't have much opportunity to practice"

– Ob-gyn surgeon

"It's a good solution for remote areas"

– Nurse manager

"It's portable, could be great for training purposes as well"

– Biomedical engineer

Storage
At first glance, end-users also noticed that the tower is easy to store, which was mentioned 2 times

Looks
Users mentioned that the tower looks “basic” and resembles a suitcase.

Usability
Next, the participants were asked to rank the usability score of the prototype on a scale from 1 – difficult to use to 5 – easy to use. The mean score for usability was a 4.07 out of 5

General usability score	4.07

Figure 42 - mean usability score

Users were then asked to indicate what the easiest and most challenges use aspects were based on their interaction with the prototype. The following themes emerged when it comes to the best aspects of the design

Easy to open
Mentioned 5 times, end-users believe that the tower was easy to open and close.

“Opening, transportation around the hospital because it’s easy to fold and has wheels for easy movement”

– Anesthesiologist

Moveability and transportability
Mentioned 3 times, end-users liked the transportability of the tower, as it’s easy to “transport around the hospital” and “moveable because of its size”

Practicality
End-users mentioned some practical advantages, such as “having one equipment in one place” and “safety” as advantages.

“Having the equipment in one place, safe and moveable because of its size”

– Biomedical engineer

Use of a laptop instead of a monitor
End-users indicated that replacing the monitor with a laptop is a good solution.

When it comes to points of improvement, the following themes emerged:

Laptop stand and connection to scope
End-users indicated that the laptop stand needs further improvement, especially when it comes to adjustability and safety. Visualization during surgery was also mentioned as an aspect that needs improvement.

“A longer cable from the camera to the laptop and possibly finding a solution for a bigger screen - some details might be difficult to see during a surgery, especially if you’re working in a bigger team.”

– General surgeon

Wheels and base
Improving the wheels was mentioned three times, including making the base wider as to improve stability.

“The base should be wider and have a larger surface area due to its size and weight in order to increase the stability.”
– Biomedical engineer

CO2 cylinders
The CO2 storage was also mentioned as needing improvement.

“Create a mounting area for bigger CO2 cylinders”

– Anesthesiologist

Finally, the participants were asked to evaluate the prototype on different aspects such as suitability for use in a clinical setting, long term storage, mobility, and the tower’s ability to withstand impacts. Suitability for regular use in a clinical sue scored highest, followed by suitability for long term storage. The design scored lowest on ability to withstand impacts and accidents without getting broken. Participants had to rank each aspect on a scale from 1 – not suitable to 5 – very suitable. Figure 43 shows the ranking of different usability aspects from high to low:

Useability scores

- Is the tower suitable for regular use in a clinical setting?
- Is the tower suitable for long term storage?
- Is the tower suitable for moving equipment around across the hospital?
- Is the tower suitable to withstand impacts and accidents without getting broken?

Figure 43 - usability aspects, ranked from high to low

Improvements and critical parts
Participants were asked to identify parts that might break and need frequent replacement and how they would improve the prototype for transportation and storage. The following themes emerged:

Wheels
The wheels were mentioned 11 times as a point of improvement. Participants stressed the need to use more robust wheels, increase the size and ensure the wheels are resistant to corrosive agents and dirt.

“Castors need replacement since it is moving too many parts of the hospital and the floor is not clean.”

– Biomedical engineer

“The wheels to made of duroplastic that can withstand corrosive agents used in cleaning theatre.”
– Biomedical engineer

Materials
Improving the materials was mentioned 5 times, participants stressed the importance of using moisture proof materials and potentially using more lightweight materials to reduce the weight.

“it should be made out of strong plastics to reduce heaviness”

– Biomedical engineer

Laptop stand
The laptop stand was mentioned 3 times as a point of improvement. Participants highlighted the need to better secure the laptop and ensure the laptop stand can withstand more weight.

The final question was an open question, allowing participants to share any other thoughts they might have about the new tower design. One participant mentioned it was important the tower should hold the diathermy, while another expressed concern for the safety of the instruments inside.

Finally, by combing the observational data on surgical workflow with the survey responses, a comprehensive view was gained on what the challenge of implementing laparoscopy is and what is required to improve the design for the laparoscopic tower for the Kenyan healthcare system.

4.3 Discussion

What are the current challenges of implementing laparoscopic surgery in Kenya and what impact does this have on the design of the new laparoscopic tower?
Looking at the challenges of implementing laparoscopic surgery in Kenya, costs of laparoscopic equipment is the biggest challenge, followed by sourcing spare parts and costs associated with consumables and maintenance. This is in line with previous findings (Piaggio, 2021), (Oosting R. W., 2019).

Patient skepticism is the lowest barrier towards implementation, followed by difficulty using the equipment and the cleaning infrastructure. Availability of equipment is not seen as a big challenge as compared to sourcing of spare parts, however only one functional tower was available in the hospital, and there is no knowledge or infrastructure to repair and source spare parts.

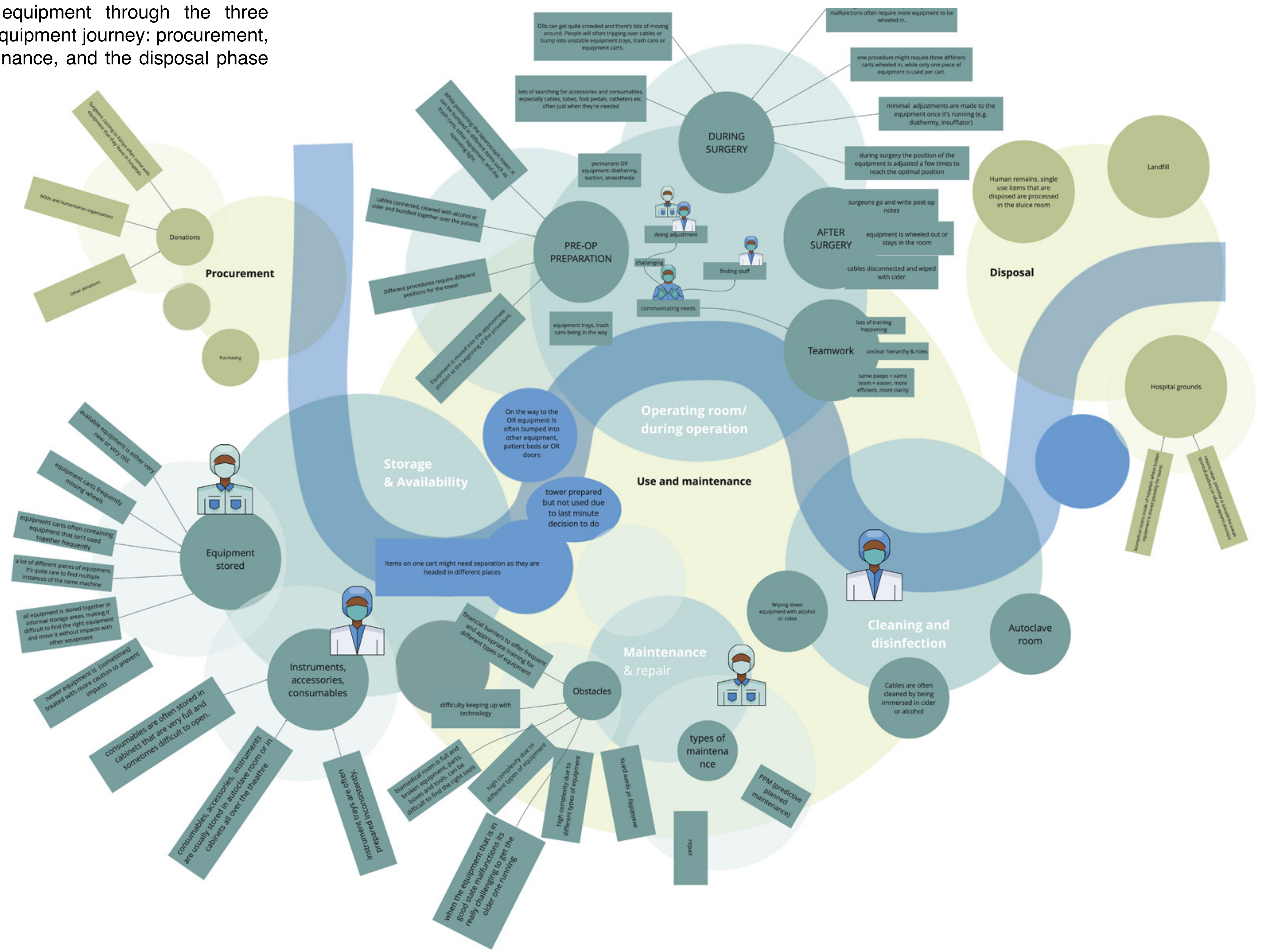
Setting up and preparing for laparoscopy, is seen as a moderate barrier to implement laparoscopy, however sustainable implementation in the surgical workflow seems to be quite challenging. Setting up for laparoscopic surgery usually takes more time as compared to open surgery, and the current process has many inefficiencies, such as difficulties preparing consistent instrument trays and positioning the patient and laparoscopic tower.

Limited opportunities to learn and practice laparoscopy is also seen as a moderate barrier, however observations show that laparoscopy is not practiced a lot. This is a significant obstacle for senior surgeons, that might have been trained in laparoscopy, to further practice and develop their skills, but also a barrier for novice surgeons to learn about laparoscopic techniques during their training.

Looking into the implications for the design of a new laparoscopic tower, it becomes apparent that it's important to keep the costs low, as high costs is the biggest barrier towards implementation. Choosing for a design that is locally manufacturable is detrimental, as sourcing spare parts remains a big barrier. Additionally, ensuring all relevant equipment is on the same cart can improve the efficiency of the surgical workflow.

How does the current surgical workflow look like from pre-operative set-up to post-operative sterilization and how can the laparoscopic tower be improved to integrate into the existing workflow?
Following the equipment through the three phases of the equipment journey: procurement, use and maintenance, and the disposal phase (Oosting R. M., 2019), several factors influence the surgical workflow from pre-operative set-up to post-operative sterilization.

Besides procurement through the official hospital channels, a lot of medical equipment and accessories are brought in by visiting surgeons, contributing to a high mix of equipment and accessories.
With a focus on the use and maintenance phase, the contextual factors influencing the use of the laparoscopic tower are presented in the following section.



What are the current bottlenecks and inefficiencies in the surgical workflow?

Once equipment is brought into the hospital, equipment circulates through various areas of the hospital and use stages. The equipment is stored, maintained, and moved to the operating room where it is used. Once the surgery is finished, equipment is sometimes cleaned or disinfected and then moved back to the storage areas. Each area/use phase has its own challenges.

Storage and availability

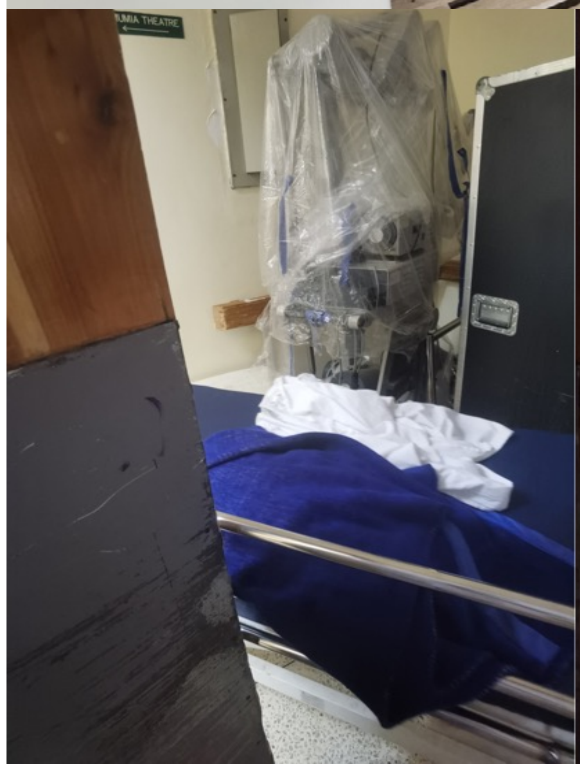
When observing the available equipment, it becomes apparent that the available equipment is either very old or very new. It's quite rare to find multiple instances of the same machine. Sometimes equipment that is not functional is stored together with functional equipment on one cart, often requiring a whole cart of equipment to be moved when one machine is needed. Equipment is stored in informal storage areas in the hospital hallway. As a lot of equipment is stored together, it is difficult to find the right carts and move it to the operating room without moving several pieces of equipment out of the way. Many equipment carts are missing wheels, and cables often get entangled. This often results in frequent collisions between equipment carts, which can damage the equipment.

Consumables and accessories are often stored in old cabinets located in the operating theaters, hallways or in an area close to the autoclave rooms. Cabinets are often over-filled and difficult to open, making it challenging to find the right consumables and accessories when needed.

Moving from storage to OR

Once equipment is taken out of the informal storage area, it is wheeled into the operating room. On the way, equipment is frequently bumped into other equipment, patient beds or the doors of the operating room quite frequently.

Patient beds often remain in front of the operating room, blocking access and making it difficult to bring the equipment in.



Operating room
Once the laparoscopic tower reaches the operating room, it is first prepared for the procedure in which it's going to be used. Once the operation is finished, the tower either remains in the operating room, or is wheeled back into storage or another room.

During pre-op the laparoscopic tower is positioned where the surgical team indicates. As it used for many different procedures, including ENT surgeries and uroscopy it is sometimes difficult to position the tower perfectly. This is also influenced by the different artifacts in the operating room – such as trash cans, other equipment, and the operating light – in which the tower is frequently bumped into. Once the tower is in the right position and the patient is ready, the cables are first wiped with alcohol or cidex and then connected to the insufflator, light source, and camera unit. The cables are usually bundled together with gauze and draped over the patient.

Once the tower is plugged in, and the cables are connected the surgery is often ready to start, however searching for accessories, consumables, and accessories (such as tubes, catheters, cables, foot pedals) often slows down the process. Many times, the search for accessories also interrupts and slows down the operation flow, as equipment, consumables and accessories are only brought in once the surgeon indicates they are needed for the next step.

Operation rooms can get quite crowded and there are a lot of people moving around. It is common for bystanders to trip over cables or bump into unstable equipment trays, trash cans or equipment carts while moving around. During procedures, additional equipment carts might be wheeled in, while often only one piece of equipment from the cart is necessary. This happens either due to compatibility issues, or because equipment that is frequently used together is not stored together all the time.

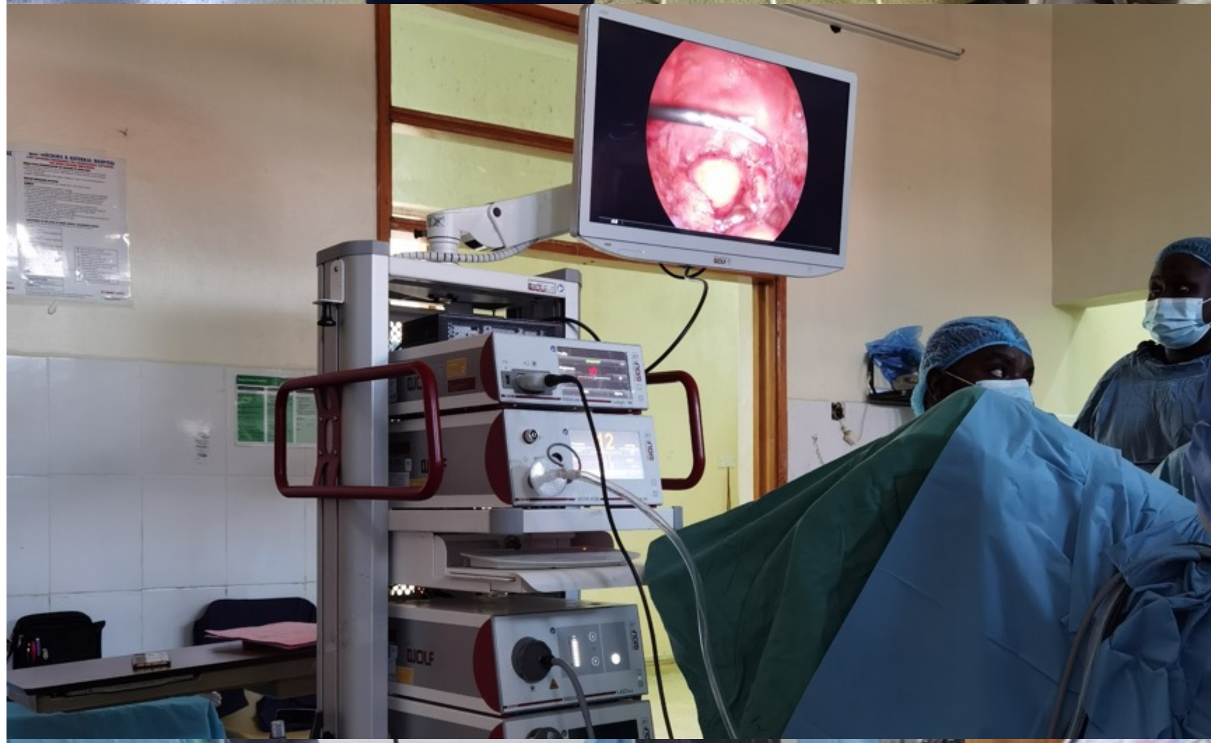
During surgery, settings on the equipment in the laparoscopic tower are adjusted rarely, however the position of the tower or the screen might be altered a few times to reach the optimal position and achieve the best visualization.

Once the surgery is complete, the cables are disconnected and wiped with alcohol or cidex. The tower is either wheeled out or remains in the room, even if it isn't used during the next procedure.

Cleaning and disinfection
When it comes to cleaning and disinfection, equipment is infrequently wiped with cleaning agents. Consumables that are re-used are immersed in alcohol or cidex and instruments are taken to the autoclave room.

Maintenance
Maintaining equipment is complex as there are many types of equipment that need maintenance and there are long waiting times to receive spare parts. The biomedical engineering room is often full of equipment awaiting repair, spare parts, and broken equipment that could be used for spare parts.

Disposal
When equipment stops functioning it is either stored inside the hospitals, either in hallways or biomedical engineering rooms or in storage areas outside of the hospital where defective equipment is stored.



What are the strong points of the new design when it comes to working within the current surgical workflow? How can it be improved to better integrate within the surgical workflow?

Looking at the current surgical workflow, the new design has both advantages and disadvantages. As the new design folds into a storage container, it ensures it can be moved easily between operating rooms and protect the equipment inside from frequent impacts with surrounding artifacts, as compared to the previous designs that are more open and leave the equipment vulnerable to impact. End-users often mentioned the easy mobility aspect as one of the main advantages of the laparoscopic tower.

The new design ensures the equipment can be fully closed in the case, thus preventing the build-up of dust and pests from interacting with the equipment. Fully closing the cart also ensures cables don't get entangled with wheels or other pieces of equipment.

The current design also has some disadvantages: first, while transporting the tower to the hospital it became apparent that the wheels are vulnerable, as they required frequent repair. Additionally, many equipment carts are missing wheels in the hospital, and there are many different types of wheels – which could make replacement difficult. Therefore, it's important that the wheels are very durable.

Another point of improvement is the laptop stand. Currently the laptop stand is very stationary, which can be challenges as the laparoscopic tower is used in many different positions and for ENT surgery and uroscopy. As there are many obstacles and people in the room and operating rooms can be very small, moving the whole tower can become challenging, therefore improving the mobility of the laptop stand is necessary.

How can the laparoscopic tower be improved to better meet the needs of use in a clinical set-up, including robustness, storage and use ergonomics?

To improve the new design to better meet the needs of use in a clinical set-up, some features need to be improved. As the tower is also used for uroscopy and ENT surgeries more equipment needs to be included to prevent many different equipment carts being wheeled in for one procedure. Based on observations, including the ENT drill would ensure the laparoscopic stack is suitable for ENT surgeries too. Additionally, the diathermy should also be included as it's frequently used for all three procedures and mentioned in the survey.

While the laparoscopic stack is perceived as suitable for regular use during clinical settings (4.07/5) and for long term storge (3.69/5), the survey shows that the tower might need improvements when it comes to mobility (3.15/5) and its ability to withstand impacts (3.07/5). The lower score for mobility is contradicting with the reactions received. While many participants indicated the new design is a good solution as it is mobile, it didn't score as high as other aspects. This can be because while the tower itself it's quite mobile, the laptop stand isn't as mobile as the previous designs, or because of its weight. The tower's ability to withstand impacts, also seems to be underestimated, as the tower is protecting equipment more than the previous designs. This can be attributed to the prototype missing a wheel, or potentially the fragility of the laptop holder.

To further improve the tower's robustness, mobility, storage capability and use ergonomics, the following aspects need to be further developed:

Wheels and stability

The tower's wheels are detrimental to its mobility, which is an important requirement. Therefore, ensuring the wheels are robust and resistant to wear and tear is very important. Hospital floors might not be clean, and gauze frequently gets stuck in the wheels. Additionally, hospital floors are cleaned with abrasive cleaners, meaning the wheels must be resistant to abrasive cleaners. It's also important to ensure the tower is stable when it's open, especially as by-standard might lean against it or bump into it when moving through the operation theatre.

Laptop stand and connection to scope

As the tower will be used for a high variety of procedures and in operating rooms of different sized, the laptop stands needs to be adapted. Additionally, the laptop stand should better protect the laptop from falling.

CO2 cylinder storage

Currently the area for the CO2 cylinders is limited to the smaller CO2 cylinders. Accommodating different sizes of CO2 cylinders will ensure the tower is more flexible. Additionally, the current position might cause some challenges when connecting the CO2 supply to the insufflator, as this is typically done in the back and the tubes connecting them are not very flexible. Therefore, this aspect also needs further exploration.

Materials

To further improve the tower's mobility and resistance to wear and tear, different materials should be explored to ensure the tower is resistant to corrosive materials and ensure a good balance between weight and robustness.

Additional equipment

To ensure the tower is suitable for laparoscopy, but also ENT and uroscopy, additional equipment should be included. While currently the tower only holds the insufflator and the CO2 supply, adding the diathermy and the ENT drill can ensure the tower is suitable for a wider variety of procedure and only one cart is wheeled in when a procedure is started.

Additionally, options to integrate an uninterruptible power supply to protect equipment against power surges and ensure it remains operational through short power cuts should be further researched. Finally, an accessory drawer to store relevant accessories and consumables should also be explored.

Figure 44 - CO2 cylinder mounted on the prototype

Figure 45 - tubes used to connect CO2 to insufflator

4.4 Conclusion

The biggest challenges of implementing laparoscopic surgery in Kenya are sourcing spare parts, the cost associated with procuring the equipment and the costs associated with maintenance and consumables. Therefore, it's important to ensure the new design has a low lifetime cost and makes use of standard parts that can be sourced and replaced locally.

The current surgical workflow has many inefficiencies, from equipment being stored on many different medical carts, to the frequent impacts the equipment needs to withstand while being stored, transported to the operating room, and used. It's therefore detrimental to ensure the new tower is resilient to external impact. As the new design uses the same parts as a flight case, its ability to protect the equipment from frequent impacts, while providing a safe storage area is one of its strong points.

To better integrate into the current surgical workflow, the new tower should integrate additional equipment such as the ENT drill and the diathermy, to ensure it can be used for laparoscopy, uroscopy and ENT surgery. Additionally, ensuring the wheels are robust and that there's a good balance between weight and mobility, can help further improve the tower when it comes to mobility. To further improve ergonomics in use, different solutions should be explored to make the laptop holder more mobile and ensure the tower can accommodate a wider variety of CO_2 cylinders.

After receiving feedback from end-users and observing the surgical workflow, the following requirements become apparent:

	Specification	Test
Requirements	Must have a low lifetime cost	Calculate the total cost of ownership, including initial purchase, maintenance, and expected lifespan, and ensure it is 50% below the industry average.
	Must have improved stability when open (to withstand impacts from people bumping into it or leaning against it)	
	The tower must support different sized diathermies weighing around 12 kilograms.	
	The tower must support different sized ENT drill consoles weighing around 10kg.	
	The tower must accommodate for different sizes of CO_2 cylinders up to a diameter of 180mm and a height of 510mm	
	The tower protect equipment form power dips and surges	
	The tower must function through short power outages up to 5 minutes	
	Wheels must be resilient to dirt and corrosive cleaning agents	Confirm with material data in CES Edupack that the wheel material can withstand corrosive cleaning agents.
Wishes	Must have a place for storing accessories	
	Must be able to function without being connected to a wall socket	
	Must have equipment centrally connected as to be switched on in one go	

5. Final design

This chapter provides a comprehensive overview of the final design, encompassing various aspects such as material selections, included equipment, design cues, and the incorporation of a laptop holder. Additionally, a concise cost estimation is presented, offering insights into the overall cost-effectiveness of the design.

5.1 Introduction

The validation phase showed the strong points and the weak points of the laparoscopic tower within the context of the surgical workflow in Kenya and resulted in a list of requirements to further improve the design. This chapter describes the improvements that were made to fulfill those requirements.

The new design needs to integrate the ENT drill and diathermy, which is more equipment than in the previous iteration. Therefore, it was decided to move the CO2 mounting outside to make space for the additional equipment, improve stability, improve the connection to the insufflator and ensure different sizes of CO2 cylinders can be accommodated. Additionally, the tower also integrates a uninterruptible power supply and contains a drawer for accessories. The laptop holder was also improved by making it a sturdier, integrated solution. The design details that have led to those decisions are described in this section.

5.2 Equipment

To integrate the equipment, two additional shelves are mounted on the tower. The depth was also increased to 500mm, to ensure most standard sized equipment will fit. It was decided to place the ENT drill on the lowest position, followed by the diathermy and the insufflator. This is because the ENT console only needs to be connected to the drill and then the settings are changed on the handheld device. Similarly, the diathermy requires minimal adjustment, and is therefore placed under the insufflator. The insufflator is placed on top as it requires more frequent adjustment, especially in the case in which a patient needs to be deflated quickly. This order also ensures that the equipment needed for the different types of surgery is close to each other: for ENT surgery the drill and the diathermy could be used together. For laparoscopy, it's the insufflator together with the diathermy, and for uroscopy the diathermy is the only piece of equipment used.

Uninterruptable power supply
To ensure the equipment is resilient to power surges and can function through short power cuts, an uninterruptable power supply was integrated into the design. Each piece of equipment connects to the uninterruptable power supply through the back inside of the case, and the uninterruptible power supply is externally connected to a socket.

Based on the equipment available in the hospital, the following equipment was chosen to estimate the total power needs the uninterruptable power supply must deliver, to ensure it is resilient to short power surges:

Insufflator: Stryker 40 Liter CORE High Flow Insufflator (Stryker insufflator , retrieved 2023)

Ent Drill: Styker CORE console (Soma technology , retrieved 2023)

Diathermy: Karl Storz AUTOCON III 300 CE, 220-240V (Karl Stortz Diathermy , retrieved 2023)

While the devices require 1230W in total, all three devices are not going to be used together at the same time. Therefore, the total power must be calculated for each of the combinations used for laparoscopy, ENT surgery and uroscopy. Figure 45 and 46 give an overview of the different equipment combinations and the total power needs per type of surgery.

ENT surgery requires a total of 1000W when running at maximum capacity, therefore it's important that the uninterruptible power supply can supply this power. Cost effective solutions should be further explored.

Equipment	Insufflator	Stryker console	Diathermy
Power needs	230W (Stryker insufflator ,2023)	600W (Soma technology ,2023)	400W (Karl Storz, 2023)

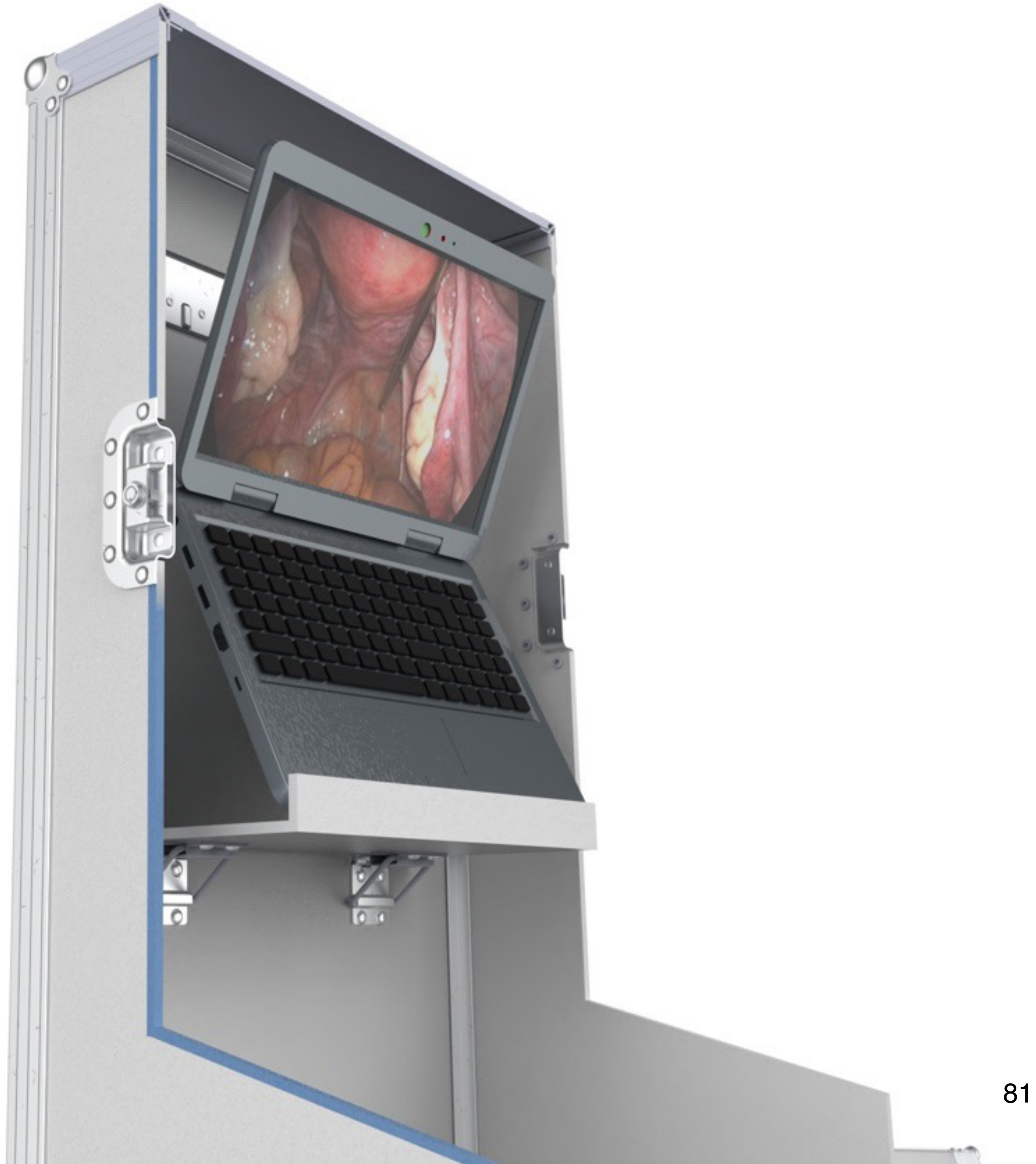
Figure 45 - equipment and power needs

Type of surgery	Laparoscopy		ENT		Uroscopy	
Equipment and power needs	Diathermy	400W	Diathermy	400W	Diathermy	400W
	Insufflator	230W	Console	600W		
Total	630W		1000W		400W	

Figure 46 - power needs per surgery type

5.3 Laptop holder

To keep the costs and number of parts low, it was decided to go for a simple, static solution for the laptop holder instead of a swivel solution. The solution consists of a simple shelf that keeps the laptop in place during surgery, by lodging it between the shelf front and the back and sides of the case. The shelf is supported by lid stay hinges, allowing the shelf to collapse when the case is closed.



5.4 CO2 supply

To make room for the additional equipment and ensure a good connection to the insufflator, the CO2 supply was moved from inside to outside. It was decided to mount one can of CO2 on the back, as mounting the CO2 supply on the back, as mounting the CO2 supply on the sides would make the tower too wide and thus difficult to transport – especially when moving through tighter areas. A standard mount is used, thus ensuring different sized cans are accommodated for.

5.5 Use cues

A brief user test was conducted to asses whether users could intuitively understand the process of opening the tower, and if the securing mechanism at the back would be noticed by users that are completely unfamiliar with the product. Simple arrows were added next to the locks on the side and the lock on the back.

A short scenario was presented to explain the context, in which users had to assume the role of a biomedical engineer attempting to set up the tower for the first time. Once the participants listened to the scenario, they had the opportunity to ask clarifying questions and then their interaction with the prototype was observed. Finally, participants were instructed to rate the perceived difficulty of the interaction on a scale from 1 to 5, as well as indicate whether they required guidance, or if the arrows were sufficient. Users also had the opportunity to give additional feedback.

The results of the user test revealed a notable level of confusion regarding the mechanism used for opening the tower. None of the three users observed the crucial element at the back. Furthermore, all participants expressed a need for more explicit guidance in order to successfully complete the task. This short test shows the importance of enhancing the clarity and intuitiveness of the tower's opening mechanism.

Based on these three types of use cues were designed. As users were mostly searching for cues on top to how the tower is opened, an illustration showing the tower in open and closed state was placed on top. To further highlight the opening mechanism, the parting lines were highlighted on the sides. Finally, the arrows next to the locks included numbers, thus minimizing the chances that users would skip the lock at the back.

Applying the use cues to the product
There are numerous ways to apply graphics to the plates. As the tower will be constantly exposed to cleaning agent, it's important to ensure durability. Therefore, permanent transfer processes are chosen to ensure durability. Screen printing is a cost-effective option in the long term, if a high number of products is manufactured (Europlas, retrieved 2023). For lower batches ultraviolet stereolithography is more suitable (Europlas, retrieved 2023).

5.6 Wheels and mount

The wheels are mounted on a simple steel plate featuring rounded edges that protrude in the corners of the flight case. This eliminates sharp edges and enhances stability. This design also ensures the wheel brakes remain accessible, preventing them from becoming obscured under the tower. As the plate is made from steel, local repair is possible through welding.

To ensure the wheels are robust, they must be resistant to corrosive materials used to clean hospital floors and be able to support the weight of the equipment together with the total weight of the body which is around 23 kg. Figure 48 shows an overview of the weight of each component, amounting to a total of 53.1 kg. Adding the body, the total weight is 76.1kg. Including the laptop, laptop holder and accessories, the wheels need to be able to withstand around 100kg.

Criteria used in database

Wheel diameter	Larger than 100mm
Load capacity	Larger than 100kg
Mounting type	Single bolt, stem, threaded stem
Break	Include break
Hub material	PP, Steel
Tyre material	Rubber

Figure 47 - criteria used in RS databese

The wheels must be antistatic, resistant to corrosive cleaning agents and alcohol-based cleaners and include breaks so that the equipment is fixed in position during use. Using the RS wheel castor data base (RS, retrieved 2023) common wheel materials are aluminum, polyamide, polypropylene, polyurethane, steel, and thermoplastics. The properties of those materials are compared using Granta Edupack to select the materials that have excellent resistance to both strong alkalis and alcohol-based cleaners. This shows that polypropylene and steel are the most suitable materials.

Equipment	Weight
Uninterruptible power supply	9 KG
Insufflator	9.1 KG (Stryker insufflator , retrieved 2023)
Diathermy	12 KG (Karl Storz, retrieved 2023)
ENT drill	9 KG (Stryker insufflator , retrieved 2023)
CO2 container	14 KG (Matheson gas, retrieved 2023)
Total	53.1 KG

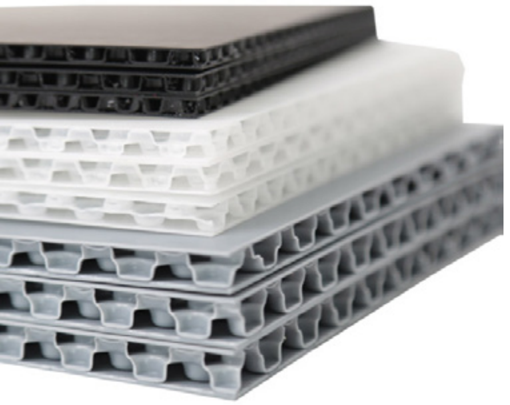
Figure 48 - weight per component

This results in 15 different results. Finding the balance between price and performance the LAG Swivel Castor Wheel, 120kg Capacity, 125mm Wheel was chosen (RS, retrieved 2023) This is because it can withstand 125 kg which can be useful and is also slightly bigger while at the average price range.

5.7 Materials

To ensure both durability and reduce the weight, polypropylene honeycomb panels are the ideal material choice. Those panels are also better suited for regular cleaning as compared to the typical PVC coated wood panels.

After contacting a flight case manufacturer in Nairobi, it was confirmed that at present only wooden panels are available. However, a more thorough assessment of the availability of plastic panels should be conducted. Plastic panels are still a viable option for local repair, as in the vent of breakage they can still be replaced with wooden panels.



5.8 Cost effectiveness

To assess the cost-effectiveness of the new laparoscopic tower in comparison to previous solutions, it's crucial to consider the lifetime expenses associated with implementing it within the Kenyan healthcare context. This includes initial procurement costs and expenses incurred during its operational lifespan. While estimating the life in service costs posed to be challenging, a rough approximation is made for the initial purchasing expenses.

To determine the approximate cost of a typical laparoscopic stack, prices from second-hand resellers were used as a proxy for the price of the product. Obtaining exact measures is challenging as there are considerable variations in medical device prices. The costs of both entire laparoscopic stack, individual components (e.g. light source, insufflator, camera), and additional equipment (e.g., diathermy and ENT drill) are determined. As there are many differences between equipment and limited information, an average price is calculated per component.

Typical laparoscopic stack	
Equipment	**Average cost**
Laparoscopic stack (including: screen, image processing unit, insufflator, light source, cart)	8.647,29 €
Light source	1.555,00 €
Camera unit	2.558,00 €
Insufflator	1.258,00 €
Screen and cart	3,676,29 €
Diathermy	1.278,00 €
Neuro drill console	1.265,00 €
Total cost with additional equipment	11.190,00 €

The projected total cost for a typical second-hand laparoscopic stack is approximately 11,190.29 euros. In contrast, the cost for the new solution (calculated from the production of one prototype in the Netherlands) stands at around 4,524 euros, reflecting a significant 60% reduction in expenses.

EasyTower	
Equipment	**Average cost**
EasyTower (including materials and labour)	723,00 €
Hardware (handles, locks, etc.)	189,00 €
Panels	234,00 €
Wheels	80,00 €
Wheel base	20,00 €
Labour	200,00 €
Total cost with equipment	4.524,00€

The cost estimation is quite limited, as it only takes purchasing costs into account. Taking the lifetime perspective, the solution is expected to be more cost effective as it contributes to prolonging the lifespan of expensive equipment, and as it is locally manufacturable and repairable, therefore reducing transportation costs significantly.

5. Discussion & conclusion

The last chapter of this theis summarizes what has been achieved and provides a list of recommendations for implementations and for further improving the context driven approach.

5.1 Conclusion and limitations

The project delivered a new design for a laparoscopic tower by using the “Roadmap for designing surgical equipment for safe surgery worldwide” (Oosting R., 2018). While the equipment need has been established at the start, this project has provided an extensive understanding of the global surgery context, developed a list of design requirements, and a new laparoscopic tower for the Kenyan healthcare system.

The Kenyan healthcare system consists of six layers, with district hospital representing the fourth layer and being the first point at which patients can access surgical care. Barriers towards accessing care include high costs and limited awareness of treatment options. As district hospitals are the first point at which surgical care is offered, those facilities are targeted in this project due to their pivotal role.

Offering surgical care requires functioning equipment, anesthesia and trained surgical staff. District hospitals have fewer resources compared to higher level hospitals. One of the limitations of this project is that there is limited information available on the surgical capabilities of district hospitals, due to the large disparities between hospitals.

The design process involved many iterations, including three prototypes to assess the feasibility and inform further design choices. This resulted in a final design that prioritizes mobility, durability, and ease of use. The design makes use of standard parts to facilitate easy procurement and replacement in Kenya and allows for local manufacturing. Limitations include the high use of manual labor, and limited insight in local manufacturing capabilities and supply chains.

A final prototype was made and validated within the Kenyan context to understand the strong points and limitations of the design. This was done through surveys and observations. There are many challenges toward implementing laparoscopy in the Kenyan healthcare system, including high procurement costs, and procuring spare parts. The new design tackles those challenges by reducing procurement costs by 60% and making use of readily available spare parts. End-users indicated the need to include additional equipment such as the ENT drill and diathermy, thus making the tower suitable for ENT and uroscopy procedures too. Limitations include low sample size in the survey and limited responses from surgeons.

The final design was adjusted to include the additional equipment and the CO2 supply was therefore mounted on the outside to make space for the additional equipment inside and facilitate a better connection to the insufflator. The laptop holder was re-enforced for better durability and integration. While the final design shows significant improvements, details regarding manufacturing and the option to include a more mobile yet frugal stand solution should be further explored.

5.2 Further reommendations and implementation

1. Design recommendations and validation
Following the completion of this report, a new prototype incorporating the design choices described in the previous chapters is made. The new prototype should undergo further validation within the context, including validation within provincial and district hospitals.

While the final design includes a lot of improvements, it is recommended to further explore the possibility of creating a more mobile laptop stand that allows for optimal visualization during surgery. This tower was designed with a laptop connected scope in mind. Currently such solutions are being developed within the MISIT lab. Once the scopes are developed, integration with the scopes should also be thoroughly studied.

The design of the new tower has only focused on the outside casing and bringing together loose equipment that is needed to perform laparoscopic surgery. To create a fully integrated solution, it is recommended to assess the need for re-designing frugal alternatives to the standard insufflator or further explore implementation of gasless surgery in sub-Saharan Africa.

2. Further testing and Pre-Manufacturing Trials:
To ensure the solution is suitable, the wider scope of implementation should be assessed. This includes taking a more strategic approach and evaluating the number of district hospitals that are equipped for implementing laparoscopy in the near future. To further confirm the solution is suitable, a few district hospitals that are already equipped to provide simple uroscopy and ENT procedures should be identified.

Long-term testing should be done in collaboration with these hospitals, by producing a low batch of prototypes that incorporate the changes from the previous validation. Those evaluations should include pricing evaluation, long-term performance evaluation and local manufacturing capabilities.

3. Go to market strategy
The data gathered from the previous two phases of the implementation plan will provide sufficient implementation to formulate a go-to-market strategy – including the pricing point, quantity and products and long-term cost effectiveness – allowing for sustainable implementation in Kenya and beyond.

5.3 Context driven approach

For this project, the “Roadmap for designing surgical equipment for safe surgery worldwide” (Oosting R. , 2018) was used as an approach. This approach ensures a thorough understanding of the barriers patients encounter to reach surgical care, the structure of the healthcare system, and the surgical structure – including the operating theatre process, the team offering surgery, the available devices and the types of surgery performed.

Based on my experience using this method for this project, I recommend including more questions in the first phase to ensure a more user centered approach, that also focuses on the use related context specific factors that influence the use of the surgical equipment.

1. What equipment combinations are frequently used together?

There are many tools and pieces of equipment necessary to provide surgical care. Understanding the common equipment combinations, ensures that the new equipment will seamlessly integrate within the operating ecosystem.

2. How is the equipment used and who are the main users?

Many different stakeholders are present in the operating room and different users have different interactions with the equipment. While the method already covers the surgical team, the interactions between the surgical team and the equipment are overlooked.

In the case of laparoscopic surgery for instance, the biomedical engineer and the circulating nurse have most interactions with the tower overall, but the surgeon has most interactions with the scope, screen and pedals that are connected to the different equipment. Understanding who is using the equipment and in what capacity is an important step towards developing a user-friendly solution

3. What are cultural norms and local practices that influence the use of the equipment?

Cultural norms and local practices have a significant impact on the dynamics within an operating room. In Kenya, community involvement holds a prominent place in all aspects of life. For instance, while one biomedical engineer can set-up equipment on their own, it is common for more people to set-up the equipment together as this provides them with the opportunity to spend quality time together and share information about the equipment. Understanding those cultural norms and local practices can help designers develop equipment that better fits within the daily life of end-users.

5.4 Personal reflection

This project was as much as a personal challenge as much as it was a passion project. With a lot of ups and downs, highs, and lows, it thought me how to become comfortable with the uncertainty that is inherent to the process of creation; of designing something new. Before starting this master’s degree, I have learned how to approach design through a very logical, engineering-based approach. Being a highly analytical person, it was difficult for me to “trust the process” and find my own unique and personal way to approach a design assignment.

Through this project I further developed my embodiment and research skills by creating a new laparoscopic tower for the Kenyan healthcare system. Not only have I improved my design skills, but I have also learned how to navigate self-limiting beliefs and develop a growth mindset.

When I started this project, I truly believe that I was born with “two left hands” and that it might be a bit too late for me to learn how to work with tools, or that it would be too difficult for me to make a tangible prototype from my design. This project allowed me to challenge this belief. Working on my final prototype for Kenya was a whirlwind of emotions: it was challenging, frustrating, difficult, but also highly rewarding. Seeing that I could overcome numerous challenging and having a physical manifestation of that has really brought me a lot of joy.

Through the process of making several prototypes, I realized that it’s okay to start prototyping, not with a final design in mind, but as a process that informs the design process and allows you to learn more about the product you are designing. Building rough prototypes, has thought me a lot and helped me learn things about the product that I otherwise wouldn’t have realized.

Taking the prototype to Kenya with me and having the opportunity to experience the context first-hand was a very special part of this project, which I will remember forever. Immersing myself in such a different context, meeting amazing people, observing surgeries, and receiving positive feedback on my prototype has brought me a lot of joy. This experience has thought me a lot about how powerful conversational items are.

While there are many things that I would have done differently – such as starting on my first prototype earlier, spending time on visualizations earlier, being more organized, or even writing this text earlier – I am happy I didn’t. This is because you learn a lot more from making mistakes, than from doing everything right – which is also something I have learned from the rough prototypes I created.

At the beginning of this project, I wanted to learn how to design for low resource settings, improve my CAD and rendering skills and build upon the skills and knowledge I acquired through my medesign electives and advanced embodiment design. This project has allowed me to develop all those skills – sometimes in unexpected ways. In previous medical projects, I only had the opportunity to talk to 1 or 2 stakeholders or maybe visit the facility once. This project allowed me to fully immerse myself in the hospital context, which thought me a lot about designing for healthcare.

While the product I have designed is not perfect, I am proud of the outcomes of this project and sincerely hope that I have positively contributed towards a more inclusive and sustainable implementation of surgical care.

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