Adoption of Modular Laparascopic Surgical Instruments for Low- and Middle-Income Settings

Master thesis submitted to Delft University of Technology in partial fulfilment of the requirements for the degree of

MASTER OF SCIENCE

in **Management of Technology**

Faculty of Technology, Policy and Management

by

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To be defended publicly on Tuesday April 12, 2022 at 10:00 AM

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Executive summary

The quality of health care around the world is considered more important and topical, given the COVID-19 crisis, which had a significant impact on health care worldwide. Affluent countries were able to obtain resources fairly quickly to combat the spread of the virus. In developing countries, however, obtaining these resources proved more challenging. Equality at the global level is needed to counteract inequality at this level. But even within countries, the accessibility of health care facilities to local populations and the disparity between rich and poor can be extensive. The lack of primary resources means that local hospitals cannot purchase and use sophisticated medical equipment. This brings to the topic of this study, which is about the analysis to enable the adoption of a surgical thrift innovation in LMICs, focused on India.

The focus of this study is the adoption of laparoscopic instruments in low- and middle-income countries (LMICs). Laparoscopic instruments are minimally invasive surgical techniques with many advantages over open surgery for various diseases. In addition, India is used as a country of analysis and has challenging characteristics mainly related to inequality within the health-care system.

Using a literature review and interviews, data is collected on stakeholders, barriers, incentives, and strategies for enabling the adoption of laparoscopic instruments in LMICs focused on India. The following stakeholders, including barriers and incentives, are identified. First of all, the state must be mainly responsible for implementing healthcare policies and accountable to maintain these policies. These aspects are essential considering inadequate infrastructures, lacking accountability, and lack of health insurance availability for patients.
Moreover, academic institutions and training institutes can provide training and exchange knowledge. Providing innovative solutions and research can increase the quality of local health care. Lack of knowledge and training are widely recognised barriers, as is a lack of confidence and competence to perform laparoscopy.

In addition, laparoscopic instruments are currently not widely used in rural areas. This is mainly due to cost constraints, the inappropriateness of medical instrument design, maintenance problems, and the lack of local networks to sell laparoscopic devices locally. Sales-related parties are primarily responsible for these barriers. Complementary strategies such as using local salespersons, conducting validation processes, providing training, adapting the design, and smoothly running certification processes can be used to overcome these challenges.

Next to this, hospitals also face barriers. Mainly lack of staff, the culture of the hospital, and lack of supporting equipment for laparoscopy hinder the adoption of laparoscopic instruments. The use of checklists, quality control and standardisation, and hospital collaboration can enable local hospitals to adopt and purchase laparoscopic equipment. However, this study has shown that it is essential to distinguish between the backgrounds of hospitals. These are rural versus urban and private versus public hospitals. barriers such as disposable equipment increases costs for hospitals are more generic and occur in all types of hospitals, while lack of essential services

such as water and electricity were mainly identified from a rural private background.

Hospital specialists were also identified as a stakeholder group. This group consists mainly of individuals and faces challenges related to lack of support and extrinsic motivation to work in an urban environment. Consultants can be used to teach specialists how to perform laparoscopic procedures and can create local awareness about this type of procedure.
Finally, Indian citizens are also involved in the adoption of laparoscopic devices. They primarily experience barriers, such as not being able to afford health care. The affiliation of hospitals with insurance companies may solve this problem. These problems are especially prevalent in rural areas. Furthermore, the incentives found in this study are also mainly related to patient benefits. It reduces the time to return to work and reduces the changes in infections, morbidity and mortality compared to open surgery.

This study can be considered a first step in explaining what is required for the distribution of surgical instruments in LMICs and describes the context-specific essential characteristics of surgical instruments.

Acknowledgements

After completing the courses for Management of Technology, which were taken almost entirely online due to the COVID pandemic, I looked for a graduation topic related to the healthcare domain. The motivation for this was to bring a change in the healthcare system by doing research. With this, I would like to contribute to bridging the inequality within the health care system of low and middle-income countries. This ambition is made possible by the following persons, whom I would like to thank for contributing to this research.

First, I would like to thank Saba Hinrich-Krapels for the pleasant cooperation during the thesis period. The meetings we had were often very useful and helped me to gain new insights during the process of conducting this research. I would also like to thank Roland Ortt for the nice constructive meetings that taught me to put things in perspective. I would also like to thank Tim Horeman-Franse for the interesting case study on the SATA-LRS products, which among other things triggered me to study LMICs and India in particular. Finally, I would like to thank Bert Enserink for the advisory role. The meetings with the enthusiastic committee were always helpful for this research.

Furthermore, I would also like to thank the interviewees for their time, input and energy that made it possible to do my research on India. It was nice to find that everyone was equally enthusiastic about participating in this research. I experienced the interviews as a piece of enrichment for my vision and knowledge.

Last but not least, I would like to thank my girlfriend, who had to go through sometimes stressful periods during the thesis. She and my family always supported and encouraged me to keep going and make the best of it.

Spijk, April 2022

Aart-Jan Bareman

"The fear of the Lord is the beginning of wisdom."(Proverbs 9:10)

Contents

List of Abbreviations

LMIC	Low- and middle-income country
RQ	Research Question
SQ	Sub-Questions
SATA	Shaft Actuated Tip Articulated
LRS	Low-Resource Setting
WHO	World Health Organisation
SSI	Surgical Site Infection
HIC	High-income country
SP	Sterility Practice
MAS	Minimal Access Surgery
GNI	Gross National Income
HAI	Healthcare Associated Infection

List of Figures

List of Tables

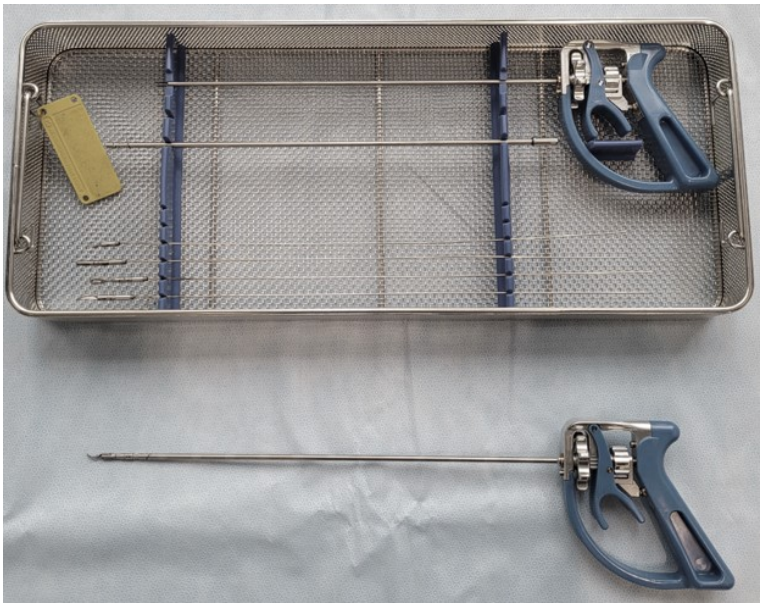
Chapter 1

Introduction

"At least half of the world's population cannot obtain essential health services" (WHO, 2017). Inadequate healthcare quality is a burden in low- and middle-income countries (LMICs) that must be improved by enabling the adoption of new medical devices designed for the LMIC context. Especially given the high disease burden of the three most common diseases in LMICs, namely malaria, tuberculosis, and HIV/AIDS (Roser & Ritchie, 2016). In addition to these diseases, the COVID-19 pandemic has led to a disruption of local healthcare systems. Consequently, all of this leads to high mortality and morbidity rates (Walker et al., 2020). Moreover, in LMICs, more advanced care is located in relatively affluent large cities, unlike rural areas, where people often cannot reach hospitals and do not always have the resources to pay for basic and surgical care. (Gnanaraj & Rhodes, 2015). To reduce the morbidity and mortality rates in LMICs, low-cost surgical care is needed to improve healthcare quality. A strategy to approach this is to enable the adoption of the so-called "frugal innovations". According to Knorringa et al. (2016), frugal innovation could be defined as follows: "Frugal innovation aims to bring products, services and systems within reach of billions of poor and emerging middle-class consumers. By significantly reducing costs while ensuring value for the user, frugal innovation opens up opportunities for new business models and can disrupt innovation processes across entire economies." In addition, frugal innovations can be used to solve costs constraint problems. There is a huge demand for low-cost devices specifically designed for resource-constraint environments (Knorringa, Peša, Leliveld, & Beers, 2016). This is also emphasised by Otuya et al. (2018); such innovations improve the efficiency of diagnosis and assessments and will provide better medical services in low resource settings. However, in the context of these healthcare systems and surgical instruments, it is not easy to make innovations successful (Otuya et al., 2018). In addition, much support is needed following the study of White et al. (2018), which shows that according to the World Health Organisation (WHO), this support consists of strong leadership, flexibility and teamwork. Due to a lack of knowledge, resources, and hierarchical cultures, these barriers often block new frugal innovations. (White et al., 2018).
Furthermore, new insights into adopting new medical devices in LMICs can be analysed from several angles. First, current barriers to medical device adoption and diffusion need to be identified, including strategies to overcome these barriers. Furthermore, it is necessary to know which parties are involved with their powers (influence) and interests. Approaching the right stakeholders with complementary strategies and responsibilities can lead to the adoption of frugal medical innovation by early adopters (Rogers Everett, 1995). In addition, knowledge is required about the context of the application that can be translated into the proper context-driven design requirements and identifies the needed facilities. Finally, it is critical to know the incentives for local markets to purchase (new) equipment, followed by the necessary strategies to target medical devices to LMIC markets.

1.1 Unit of analysis

The word "laparoscopy" contains two words, "laparo", meaning "in the abdomen (tummy)," and "scopy", meaning "to see." This word stands for a minimally invasive surgical technique, which means that a small incision (about 1 to 2 cm) is needed for the operation, combined with a camera (LUMC, 2021).
Laparoscopic instruments are innovative surgical tools that enable minimally invasive surgery. This study primarily focuses on a new line of laparoscopic instruments called SATA-LRS (Shaft Actuated Tip Articulated for Low-resource settings). These instruments are distinguished from other laparoscopic instruments by several unique product features, which are shown in Figure 1.1). Unlike conventional laparoscopic instruments, the SATA-LRS instrument has a combination of modularity and additional degrees of freedom, allowing the instrument to be reused for different procedures and increasing instrument interoperability by enabling the rotation of 340 degrees. Additionally, the handle interface is designed to provide the precision needed for operations. Furthermore, the SATA-LRS instruments allow interchangeability between different end-effectors. This means that one device is needed during the operation instead of five. The end effectors include scissors, atraumatic graspers, needle drivers, clip applicators, and more (Lenssen, Dankelman, & Horeman, 2022).
These instruments are incredibly relevant in these rural areas mainly due to their minimally invasive nature of these instruments. In general, the less invasive, the faster the recovery, and the less chance of additional complications. However, until 2014, only 20 per cent of the world's population could afford and use laparoscopic instruments. When these instruments can be cleaned to established sterilisation standards and used without robots, they will become attractive to LMICs, even in rural areas. (Gnanaraj & Rhodes, 2015), (Lenssen et al., 2022).



(a) SATA-LRS

(b) Example of conventional laparoscopic instruments (Indiamart, 2022)

Figure 1.1: SATA-LRS versus conventional laparoscopic instruments

As introduced, laparoscopic surgical instruments are potentially very suitable for application in LMICs because of their modular design. Modular design means that the instrument can be easily cleaned, but also that it is possible to connect different end-effectors to one handle. This is more financially advantageous than purchasing a series of devices for each application.

Moreover, the technology could also be considered potentially disruptive due to its modularity and interchangeable steerable tip features. Christensen (1997) defines disruptive innovation as "Disruptive technologies bring to a market a very different value proposition than had been available previously. Generally, disruptive technologies underperform established products in mainstream markets. But they have other features that a few fringe (and generally new) customers value. Products based on disruptive technologies are typically cheaper, simpler, smaller, and, frequently, more convenient to use" (Christensen, 1997). The SATA-LRS laparoscopic instruments have the characteristics specified above.

1.2 Problem statement

About 96.2 million surgical procedures are performed in LMICs every year (O'Hara, Patel, Caldwell, Shone, & Bryce, 2015). However, it can be concluded from the introduction that there is no primary care for half of the world's population. This is mainly due to the lack of medical equipment and supplies. According to WHO following the systematic review of Diaconu et al. (2014), there are two leading causes of this problem. First, most high-end medical devices and equipment are developed for high-income countries (HIC). This is motivated by the profits made in these countries. Since the devices are developed for these countries, the design requirements are automatically adapted to this purpose. As a result, the application of these medical devices in low-income countries is not in line with needs (Diaconu, Chen, Manaseki-Holland, Cummins, & Lilford, 2014).
Second, Diaconu et al. (2014) also argue that the medical device selection process is unregulated. There are no standard parties involved. Purchasing decisions are often made at the national level rather than the regional or organisational level. The inability to make informed decisions and related guidelines lead to poor procurement of medical products and equipment. Furthermore, there are no standard stakeholders who can make purchasing recommendations or access suppliers in LMICs. In addition, prioritisation, which identifies which medical equipment is most urgently needed, is not integrated into purchasing practices. In short, there is a lack of knowledge and available research on how to enable the purchase, and related adoption of new medical equipment (Diaconu et al., 2014).
Nowadays, also laparoscopic interfaces are often used and developed in and for HICs. This research aims to research what is needed to make these surgical instruments attractive to LMICs with the result that they could be widely adopted. Many actors and factors play a role in making frugal innovations attractive to developing countries. Arshad (2021), for example, identifies the following relevant factors to be considered for the diffusion of frugal innovations to emerging markets. These are: network, economic and political aspects, similarities between markets, social systems, informal structures, entrepreneurial spirit, communication channels, or organisational structures (Arshad, 2021). However, it can be concluded from the literature that LMICs differ among themselves and, consequently, there is no specific general model that can be applied to enable the adoption of laparoscopic devices (Mills, 2014). More context-dependent research is needed to understand all factors with their corresponding socio-technical system. Then, the extent to which these factors can be generalised for LMICs can be investigated. Thus, no one clear strategy can be used to enable the adoption of such frugal innovation. To delineate the scope of the study with respect to LMICs, India is used as the country for the analysis.
This leads to the main problem, which is the lack of understanding of how frugal innovations, such as laparoscopic instruments, can be introduced in LMICs, particularly in India.

1.3 Research Questions & Deliverables

1.3.1 Research Question

In order to analyse the defined problem statement, a research question and corresponding sub-questions are formulated to guide this research. The main research question (RQ) is as follows:

> ***"How could the adoption of surgical frugal innovations such as laparoscopic instruments be enabled in LMICs?"***

The research question relates to what it takes to enable the adoption of frugal innovations, such as laparoscopic instruments, in LMICs. A systems approach will be used to identify all actors and factors at the macro and micro levels for this question. This includes exploring ways to enable the adoption of surgical instruments at the international, national, organisational and end-user levels. This includes related barriers and the incentives and strategies to enable the adoption of frugal innovations such as the laparoscopic instruments intended for LMICs.
The environment or context in which the technology will be used must have the appropriate facilities to enable the optimal use of technology. Context-specific analysis regarding the current state of the art is required to know whether the local infrastructure of hospitals needs to be adapted or whether the product needs to be adapted to a specific context, resulting in design requirements. In addition, the acquisition processes, which influence the purchase of new surgical equipment, are also taken into account. All these aspects are divided into sub-questions (SQ).

Laparoscopic instruments, as introduced, form the unit of analysis used as a case study for this research. Further, as indicated, the scope of this study is primarily focused on India as LMIC for the analysis. This country was chosen because of existing connections with local medical specialists who collaborate with TU Delft on research projects. Moreover, healthcare in India is also a challenging environment where inequality plays a significant role in various ways (International, 2022). Details of this are provided in this report.

1.3.2 Sub-Questions

To accurately analyse the study's main question, several SQs are composed. The first SQ relates to the stakeholders involved. To make a new technology a success, it is essential to know what the socio-technical system looks like, which can be done by identifying the stakeholders involved in the technology and affected by it. This is also the case for minimally invasive surgical instruments such as laparoscopic devices. Consequently, all stakeholders should be analysed with their corresponding power and interests:

> **SQ1.** *"Which stakeholders are involved in the successful adoption of medical products such as laparoscopic instruments in developing countries?"*

After the analyses of the system, related barriers must be identified. Barriers related to development and diffusion block technology adoption in particular geographical proximity. However, this study focuses on all the barriers related explicitly to adopting surgical devices like laparoscopic instruments. Therefore, the questions read as follows:

SQ2. *"What barriers exist which are blocking the adoption of frugal surgical devices such as laparoscopic instruments aimed at LMICs?"*

Furthermore, the research analyses the incentives of potential end-users to use new surgical technologies. It is required to know the motivations of potential end-users to purchase and use certain products or services. Therefore, the third SQ analyses the incentives for the procurement of laparoscopic instruments in resource constraint hospitals:

SQ3. *"What are the incentives for LMIC healthcare markets to purchase/use surgical instruments such as laparoscopic instruments"*

The last question relates to the strategies required to adopt frugal innovations, like laparoscopic instruments, in LMICs. For this question, a system approach will be used to map out all the actors and factors aligned on a large scale. It is related to the identified barriers and includes all the steps needed to enable the adoption of frugal innovations like the laparoscopic instruments intended for LMICs:

SQ4. *"What strategies are needed to enable the adoption of frugal surgical devices such as laparoscopic instruments aimed at LMICs?"*

1.4 Structure Report

This report begins with the problem identification, whereafter the main and sub-questions are composed to analyse the problem identification. The first section of the report provides background information about LMICs and the Indian healthcare system. Starting with an analysis of the technology pathway ending in the current state of the art of the instruments in general and for LMICs.
Further, a literature review examines the current state of the art of surgical instruments like laparoscopic instruments in LMICs and partly India. The current state of the art includes stakeholders, barriers, incentives and strategies. After the literature review, a conclusion is provided with implications for research.
After this, the methods and approach sections describe the data that will be used to complement the findings and literature gaps from the literature study. Data will be collected through semi-structured interviews with nine Indian surgeons, five academic experts, and innovators. Ultimately, all the data collected will be combined to map the socio-technical system using a stakeholder map regarding adopting modular steerable laparoscopic instruments with interchangeable end-effectors in India. Part of this result is described in the discussion, comparing the results from the literature and the findings from the interviews, which also identifies the competencies and interests of all stakeholders involved. It then concludes with limitations, implications for future research, and scientific contributions. Finally, the main and sub-questions of the study are answered.

Chapter 2

Background & Context

This chapter specifies the background and context of the analysis. It also includes an analysis of the technological trajectory of laparoscopic instruments, using the model of development and diffusion of Ortt et al. (2008), examining the current situation in LMICs compared to HICs.

2.1 Characteristics LMICs

2.1.1 LMICs in general

Healthcare systems in LMICs could be distinguished from several angels like GNI, funding sources, common diseases, healthcare infrastructure, and staff and training. Following these angles, the most pressing characteristics are described.

Funding sources
LMICs stand for low and middle-income countries and are defined by GNI (gross national income) per capita (Bank, 2021). This affects the availability of money to fund healthcare spending. According to Mills (2014), the funding sources in LMICs differ from those in HICs. There are several ways to pay for healthcare. In HICs, this is entirely different compared to LMIC healthcare markets. In LMICs, about 50% of the healthcare need to be from personal expenditures ('out-of-pocket'). This percentage is 20% lower in middle-income countries. In HICs, only 14% pays the care without intermediaries, shown in figure 2.1. This means that there is no shared economic burden in LMICs. In HICs, healthcare expenditures are spread among a large population, resulting in a large pool of money and affordable healthcare systems. Healthcare access in LMICs will only be available to the society's poorest people when an optimisation process regarding taxes for more prosperous people, insurance coverage, and subsidisation of the poorest group is well established. However, it is questionable whether more affluent people are willing to pay taxes to make healthcare accessible for the poorest group (Mills, 2014).

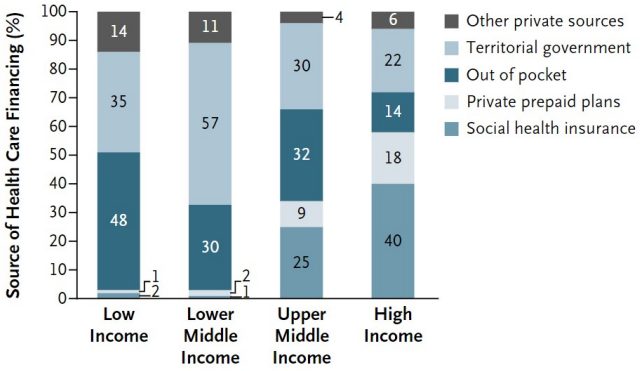


Figure 2.1: Sources of payment among different healthcare systems (Mills, 2014)

Burden of Diseases

Furthermore, there is also a huge burden concerning common diseases. These diseases could be distinguished in injuries, communicable diseases (CDs) like lack of nutrition, neonatal, and non-communicable diseases (NCDs) (Roser & Ritchie, 2016). Most of these diseases can be successfully treated in high-income countries. However, in LMICs, it is difficult to address these types of diseases. Primary prevention tools are less effective and being used (Haileamlak, 2018), (WHO, 2021d). A subset of these NCDs, such as gynaecologic (female reproductive system), gastroenterology (digestive system), and urologic (urinary system) procedures, are usually treated with laparoscopy (NHS, 2021).

Healthcare Infrastructure

Healthcare infrastructure refers to the quality of healthcare facilities. Some of the most important infrastructure aspects are described. According to Ogunsola et al. (2020), in LMICs, the structural design of these facilities is often not designed for a low-resource environment. Chemical reactions from cleaning and sterilisation activities damage surfaces over time. The result is a less sterile and clean working environment for healthcare workers. In addition, hospitals are often not designed for adequate airflow, whether mechanical through fans or natural ventilation. Further, small walkways and windows mean that airborne microbes are not filtered through the airflow. This results in higher infection rates of CDs (Ogunsola & Mehtar, 2020). Furthermore, the narrative review by Ogunsola et al. (2020) indicates that the massive demand for care and limited supply often leads to overcrowded hospitals. This affects the inability to keep a hospital clean before other patients come in. Bacteria and viruses spread between these beds/toilets/corridors. Restrooms are also a concern; a survey of toilet facilities in healthcare facilities globally found that more than 20% of the hospitals have adequate toilets, but they are not adequately cleaned. This is often caused by the lack of basic facilities such as clean running water, which increases the rate of HAIs. The aforementioned primary facility is one of the biggest challenges in LMICs, according to Ogunsola et al. (2020). Lack of clean (running) water affects the entire healthcare infrastructure. Not only sanitation but also hand washing and cleaning of medical equipment are affected. The narrative review highlights that studies have shown that about 25% of all health facilities in the world do not have quality measures in place regarding clean water (Ogunsola & Mehtar, 2020). This is happening despite the WHO WASH (Water, Sanitation and Hygiene) guidelines intended to improve water quality in resource-poor areas. In addition, clinical waste is not adequately disposed of, resulting in local contamination of the environment (Ogunsola & Mehtar, 2020). Last but not least important, the healthcare facility concerns the power supply in LMIC hospitals according to the WHO (2015). A stable electricity supply can be defined if power outages are less than two per week. No or poor access to electricity leads to failed operations and damage to equipment and medicines. However, there are sometimes emergency generators. But these cannot provide the

required supply needed to power all applications (WHO, 2015).

Staff and Training
This section addresses the responsibility and knowledge of health workers. Ogunsola et al. (2020), also argues that the lack of training facilities and education hinders the local health infrastructure from being qualified to carry out proper cleaning and maintenance activities(Ogunsola & Mehtar, 2020). Considering cleaning, low-skilled health workers are often responsible. A lack of clear job descriptions prevents these workers from being held accountable. Guidelines must be followed, and regular checkups conducted to keep health workers up to standard (Ogunsola & Mehtar, 2020). Lack of training, the vast workload on staff, and no access to education also increase the rate of HAIs and lack of infection prevention and control (IPC). Not only knowledge about cleaning activities is lacking, but also about the use of medicines. Antimicrobial resistance, for example, is one of the consequences of not using antibiotics appropriately, after which patients become resistant to antibiotics (Alp & Damani, 2015). In addition, training is required to use new equipment. Much equipment (about 40-70%) is not used in the way it is intended, and this leads to unsafe operations and loss of other resources (Diaconu et al., 2017).

2.1.2 Indian Healthcare Market

GNI
According to World Bank data, India is classified as an LMIC (Bank, 2021). Although there is a positive trend in the growing economy, this growth has been disrupted by the COVID19 pandemic in the last two years (Times, 2022). India can be characterised as a country with extreme differences between rich and poor. Rich people are getting even more prosperous and poor people even poorer, while these rich people hardly have to pay taxes (International, 2022). According to Oxfam International (2022), in 2017, 10 out of 77% of the national wealth was owned by the rich, whereas 73% of the national income went to the rich. As opposed to 67 million people, where income increased by 1.5% overall. Moreover, it takes someone in rural areas about 942 years to earn the same money as the rich earn in one year. These figures affect the healthcare system concerning the expenditures that can be spent on personal healthcare (International, 2022).
In addition, as indicated, Balarajan et al. (2011) emphasise that inequality is central to the LMIC country of India. This is primarily due to differences in socioeconomic status, geography and gender. This effect is compounded by people's responsibility for their health and expenses. The local population often pays the financial burden on healthcare. There are no other agencies, such as insurance companies and the government, that cover (part of) the costs of private care. Only 10% of India's population has health insurance, which is a government-selected group of people (Balarajan, Selvaraj, & Subramanian, 2011).

Healthcare inequality
Many Indians do not have access to healthcare. Millions of people do not have access to basic healthcare facilities. Of which 63 million have to live in poverty to afford their care. Despite all these facts, government spending on healthcare is one of the lowest globally. It focuses more on commercial healthcare. This causes mortality rates of 17% of maternal deaths worldwide and 21% of children under five (International, 2022). Figure 2.2 shows an example of the differences between a hospital in a rural area, Gardanibag Hospital in Patna (Bihar), and an operating room in an urban hospital in Dehli.

(a) Hospital in a poverty-stricken area (International, 2022)

(b) Hospital in urban settings (Rosewalk, 2020)

Figure 2.2: Hospital in a poverty-stricken area versus an urban hospital in Delhi

Access to health services is an essential factor in the quality of healthcare. According to Balarajan et al. (2011), lack of access to health facilities is one of the significant factors in the high mortality rate associated with maternal mortality. Gender differences, geographical context and religion (caste system) also influence this variable. Poor people tend to use health facilities in public hospitals more, while rich people also use public facilities and often receive better care and stay longer. To some extent, the government has health expenditures. But these are spread across the states regardless of the demand for care in a given state (Balarajan et al., 2011).
Balarajan et al. (2011) add that financial and physical access is lacking. Poor people tend to settle and orient themselves in low-resource areas, where they have more chances to pay for products and services. In addition, in rural areas, more health workers are often unskilled and lack knowledge, leading to low-quality care. As a result, poor people are more likely to be treated by a less qualified health worker than in urban areas. This is compounded by the lack of infrastructure in rural areas and the distance from urban areas (Balarajan et al., 2011). Balarajan et al. (2011) created a conceptual model of these factors associated with health inequality in India.

From the above, it can be concluded that healthcare infrastructure is highly dependent on contextual factors of hospitals. In general, urban hospitals have a good quality of care that is clinically safe, effective, patient-centred and up-to-date. Staff are often well qualified and work with more sophisticated equipment than in rural hospitals. In contrast, rural hospitals often have more in common with the challenges described in the previous section (Balarajan et al., 2011).

2.2 Technology trajectory of Laparascopic instruments

In this study, laparoscopic instruments are used as the unit of analysis. Therefore, it is essential to analyse the development and diffusion of this technology to understand the technology trajectory and current state of the art in both HICs and LMICs and how and why they differ. To understand this, it is necessary to understand the phases preceding diffusion with their associated milestones, innovators, barriers and enablers.

Laparoscopy is a well-known and widely used surgical procedure today that has its origins in 1805. In that year, the technology basics were invented, using light candles and mirrors to diagnose a dog's bladder. However, almost a century later, in 1901, the first laparoscopic surgery on a dog was performed by pioneer Hans Christian Jacobaeus in Stockholm. The first human procedure took place in 1910 and was used for diagnostic purposes. After this procedure, he recognised that it was a technique worthy of further development, but he also faced much criticism (Hatzinger et al., 2006).
After the technology lost its interest, in 1929, Heinz Kalsk developed an improved laparoscopic technique that has better quality lenses and a forward viewing scope. With this technological improvement, he was rewarded with the title "Father of Modern Laparoscopy"(Kelley, 2008).
One year later, laparoscopy gained more attention in the United States (US). John Ruddock, an internist, emphasised that this operation technique was safer than laparotomy.
In 1936, an essential milestone in the technology pathway was set. A Swiss gynaecologist called Boesch performed sterilisation of the Fallopian tubes. Despite this vital technology application, 35 years later, only one per cent of the US was using the laparoscopic technique for sterilisations. However, in 1976, almost 60% of the sterilisation was performed using the laparoscopic instrument (Kelley, 2008).
The technology's gradual and not revolution pathway was caused by technology boundaries like increased complication rates and the unwillingness to use this new technique (resistance to change). Nevertheless, opportunistic medics refined and further developed the laparoscopic technique. With an automated insufflator, intra- and extracorporeal knot tying, and safer electrocoagulation tools, the instruments' safety and range of applications were improved. This resulted in the criticised first laparoscopic operation of the appendectomy (Kelley, 2008).
In 1986 a cholecystectomy (removal of the gallbladder) was performed. However, this was criticised by the public and censored by the courts. The technology did not arouse popularity even long after its invention. Yet one of the most crucial components of the technology was missing, namely video laparoscopy. Although this technology was invented in the 1960s, 20 years later, a pilot program was used to test video in conjunction with surgery. About five years later, this was also used in conjunction with laparoscopy (Kelley, 2008).
Another important milestone of the technology acceptance was met with the first video laparoscopic cholecystectomy surgery was performed by the French surgeon Philip Mouret in 1987. After an American College of Surgeons meeting in October 1989, the technology faced a breakthrough also for non-gynaecologic applications (Kelley, 2008), (Alfa-Wali & Osaghae, 2017). Surgeons from all over the world were convinced by the technique and followed the training to implement it in their practice. Moreover, a Society of Laparoendoscopic Surgeons (SLS) was established, containing a team of dedicated surgeons with new medical standards and training provisions.
From 2000 onward, laparoscopic surgery for vascular treatments became more applied with robotics. In the beginning, this combination was not regarded as being optimal and was refused by many surgeons (Kelley, 2008). However, the price factor hampered growth initially (Alfa-Wali & Osaghae, 2017). Despite this, Laparoscopic instruments experienced unprecedented growth after commercialising them and became a revolutionised technology (Mansour,

Guru, & Shokeir, 2011),(Mishra et al., 2020). The added value of using robotics in combination with laparoscopic instruments was the ability to perform more advanced surgeries. Especially in urology, gynaecology and cardiac surgery, robotics, in combination with the Da Vinci robot, has become increasingly popular in the application of laparoscopy (Kelley, 2008).
Furthermore, in the last two decades, Laparoscopic surgery has become a new standard procedure and replaced a lot of open procedures in HICs (Mishra et al., 2020), (Zhu et al., 2017), (Oosting, Wauben, Madete, Groen, & Dankelman, 2020).

The following figure shows the most common procedures performed in HICs.

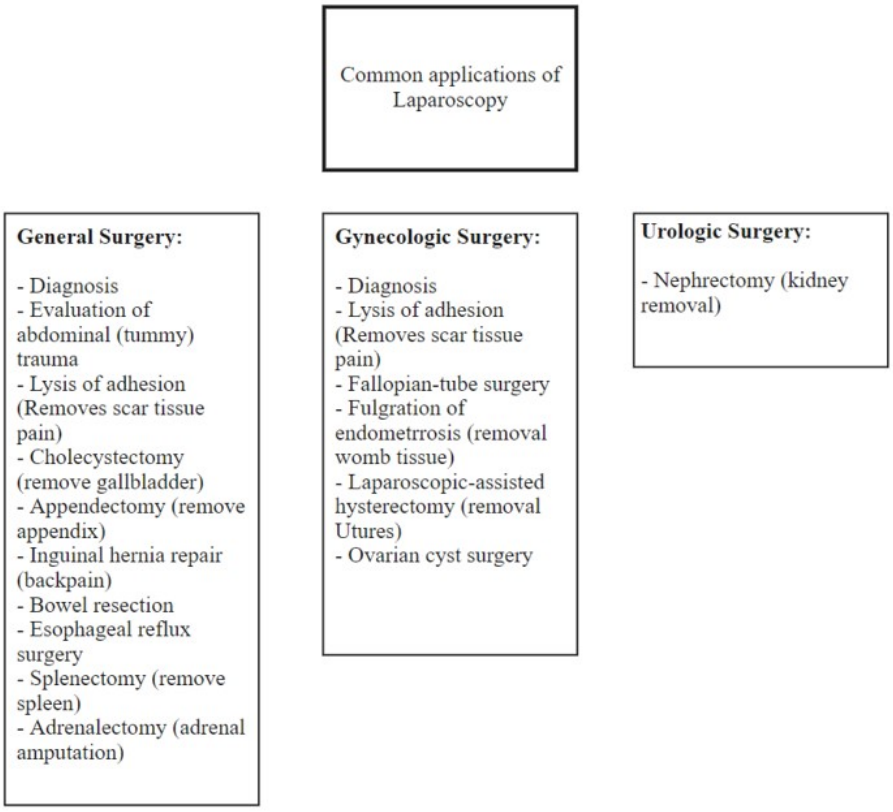


Figure 2.3: Most common laparoscopic procedures (Peterson, 2012)

This technology trajectory of the breakthrough technology shows characteristics that can be approached with the model of development and diffusion. This model describes three distinct phases called innovation phases, the adaptation phase and the market stabilisation phase (Ortt, Zegveld, & Shah, 2008).

In the case of laparoscopic instruments, the innovation phase started at the beginning of the 19th century, followed by the adaptation phase. However, the technology did not show any breakthroughs despite several important milestones. The last phase started about 1989 after the created awareness at the conference and the first successful cholecystectomy video laparoscopic procedure. From this point onwards, the technology diffusion started to grow in combination with video laparoscopy and the additional use of robotic systems. The length of the trajectory can be declared by the resistance to change, distrust in the technology, and the missing combinations of different technologies.

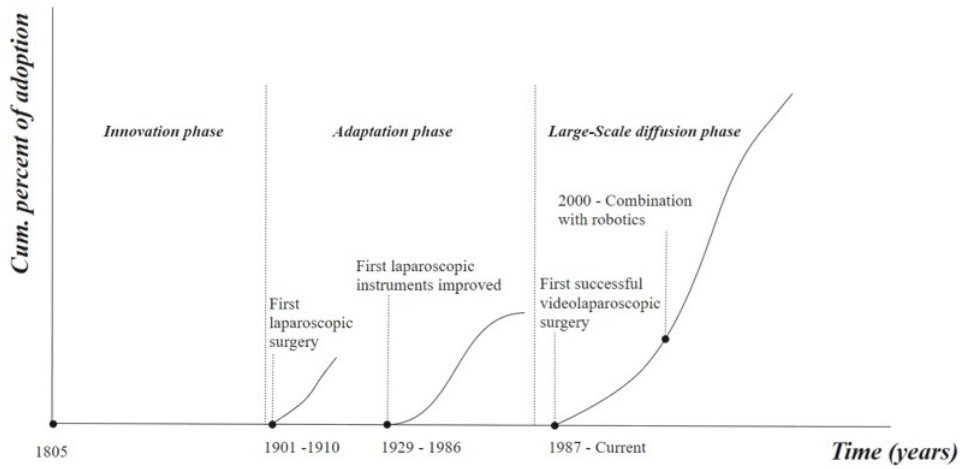


Figure 2.4: Model of development and diffusion of laparoscopic instruments HICs (Peterson, 2012)

The described technology represents the development and diffusion in the HICs. However, in the LMICs, this technology is not as advanced as in these countries. Due to many barriers, the technology is hindered in its adoption in LMICs for instance, in India, only two per cent of the citizens has access to Minimal Invasive Surgery (MAS) (Mishra et al., 2020). In addition, LMICs are often limited to donated or low-cost instruments from HICs. Some cases involve leases, or a combination of different forms of procurement (Alfa-Wali & Osaghae, 2017). LMICs are financially dependent not only on HICs but also on maintenance. In several LMICs, this is done by the medical device companies. Often located somewhere in HICs (Oosting, Wauben, et al., 2020).
Notwithstanding the fact that laparoscopic instruments did not show a breakthrough like in the HICs, LMICs still have access to (basic) (gasless) laparoscopy (Alfa-Wali & Osaghae, 2017). In general, the following procedures are performed, hysterectomies, tubal-ovarian surgery, cholecystectomies, appendicectomies, herniorrhaphies, and diagnostic laparoscopy. This partially overlaps with the procedures performed in HICs. Furthermore, depending on the contextual factors of hospitals, such as private or public, and rural or urban, laparoscopy may or may not be used for procedures (Alfa-Wali & Osaghae, 2017).
Given these facts, Figure 2.4 could also be translated to LMIC contexts, resulting in the following figure:

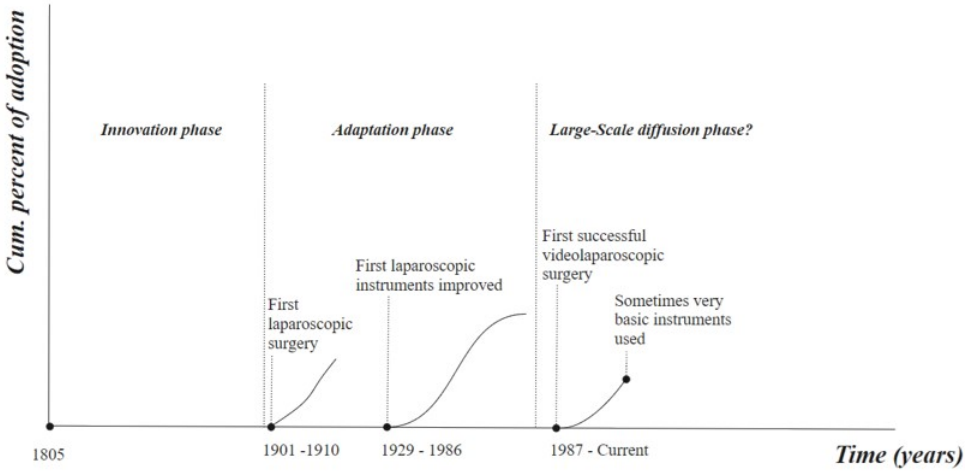


Figure 2.5: Model of development and diffusion of laparoscopic instruments LMICs (Peterson, 2012)

From the analysis of Figure 2.5, it can be concluded that the innovation phase and the adaptation phase remain the same. This part of the graph shows the general development of laparoscopic instruments. However, when zooming in on the large-scale diffusion phase, this section is expressly distinguished from the HICs. Whether laparoscopic instruments in LMICs have already entered the large-scale diffusion phase is questionable. Therefore, part of this study is about identifying the barriers related to the diffusion of laparoscopic instruments in LMICs, with a focus on India.

Chapter 3

Methodology & Approach

3.1 Approach

Guiding literature concerning the research methods is used from (Sekaran & Bougie, 2019). The research strategy will mainly consist of interviews and desk research. Whereby the local Indian hospitals are the unit of analysis. This research aims to find a strategy to enable the adoption of surgical devices like laparoscopic instruments in India. Identified strategies from both literature and interviews are gathered. Additionally, the practical relevance contains attempting to discover new connections and patterns with the result that new insights are gathered regarding the involved stakeholders and their position in the more extensive network.

In the following figure is the approach shown.

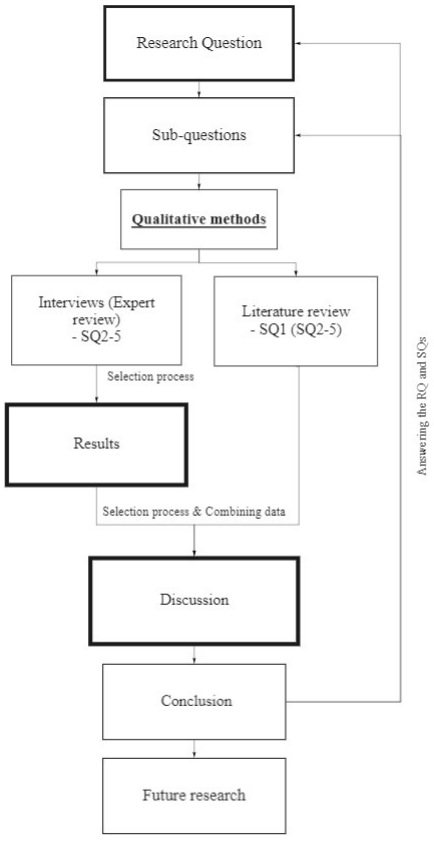


Figure 3.1: Research Methods & Approach

3.2 Scientific literature

Google Scholar, Scopus, Pubmed, and Web of Science are used to find relevant primary and secondary data. A combination of these search engines and the "snowball" method is used to find as many articles related to this research.
The ultimate goal of this chapter is to identify what literature is available on the adoption of surgical instruments in LMICs. In addition, literature gaps are used as a starting point for the interviews. The questions are based on these gaps to find additional information.

3.3 Search strategy

This section describes how the literature was analysed. "PRISMA" by Moher et al. (2009) was used to guide the selection method. Two major academic search engines, Scopus and Pubmed, were used. These search engines were chosen for this study because the topic is related to healthcare-related articles. These search engines were used to find more articles related to this literature review. In addition to these search engines, more general information was searched using google (Scholar) and from grey literature classified as "other sources". The premise and goal of this research are to find an answer to the research question. Therefore, alternative keywords and synonyms related to the main and sub-questions were identified, which were mainly found using the MeSH database of (National Center for Biotechnology Information) NCBI (NCBI, 2022). Combinations of the synonyms are used to expand the number of potential articles related to the research. These are listed along with the total number of articles found in the following table.

Table 3.1: Alternative keywords search for search string

Research question	**Alternative Keywords**
"How could the adoption of surgical frugal innovations such as laparoscopic instruments be enabled in LMICs?"	Emerging markets, Surgical instruments, Developing countries, Low resource, healthcare system, Developing Economies, Companies , Emerging Economies Barriers, Misalignment, Procurement , Adoption, Acquisition, Purchasing, good-enough innovation Challenges, LMICs, Third World Countries, Diffusion Laparoscopic, Emerging markets

The '**AND**' command is used to narrow the search, and the '**OR**' command to get more related articles. Furthermore, the criterion "All fields" is used to find the maximum number of articles related to the topic. In addition, three different search terms are used because three different topics are distinguished. The first topic deals with laparoscopic instruments, while the second and third focus more on general surgical instruments and minimally invasive surgery. Therefore, the first search term specifically analyses laparoscopic instruments in light of adoption, including corresponding alternative keywords. However, for the last two broader topics, the rest of the search terms remain the same since they are examined in the same context. This results in the following search terms:

- "laparoscopic*" AND ("lmic*" OR "low and middle income countr*" OR "low and middle income" OR "low and middle income" OR "Global south" OR "low resource" OR "low-resource setting" OR "third world countr*"OR "developing economic*"OR "emerging market*") AND (adopt* OR purchas* OR implement* OR procure* OR acquire* OR acquisition).

- "surgical instrument*" AND ("lmic*" OR "low and middle income countr*" OR "low and middle income" OR "low and middle income" OR "Global south" OR "low resource" OR "low-resource setting" OR "third world countr*"OR "developing economic*"OR "emerging market*")

- ("minimal* invasive surger*" OR "minimal* invasive surgical*") AND ("lmic*" OR "low and middle income countr*" OR "low-and-middle-income" OR "Low and middle-income"OR "Global south" OR "low resource" OR "low-resource setting" OR " Third world countr*" OR "Developing economic*" OR "emerging market*")

The above search terms were combined, resulting in a total number of records to be screened of n=60. In addition to these search terms, the snowball method was used with publications that fit the topic. This strategy increases the number of potential papers available for this literature review. Following this, a selection process was applied to exclude irrelevant data. This selection process is shown in Figure 3.2.

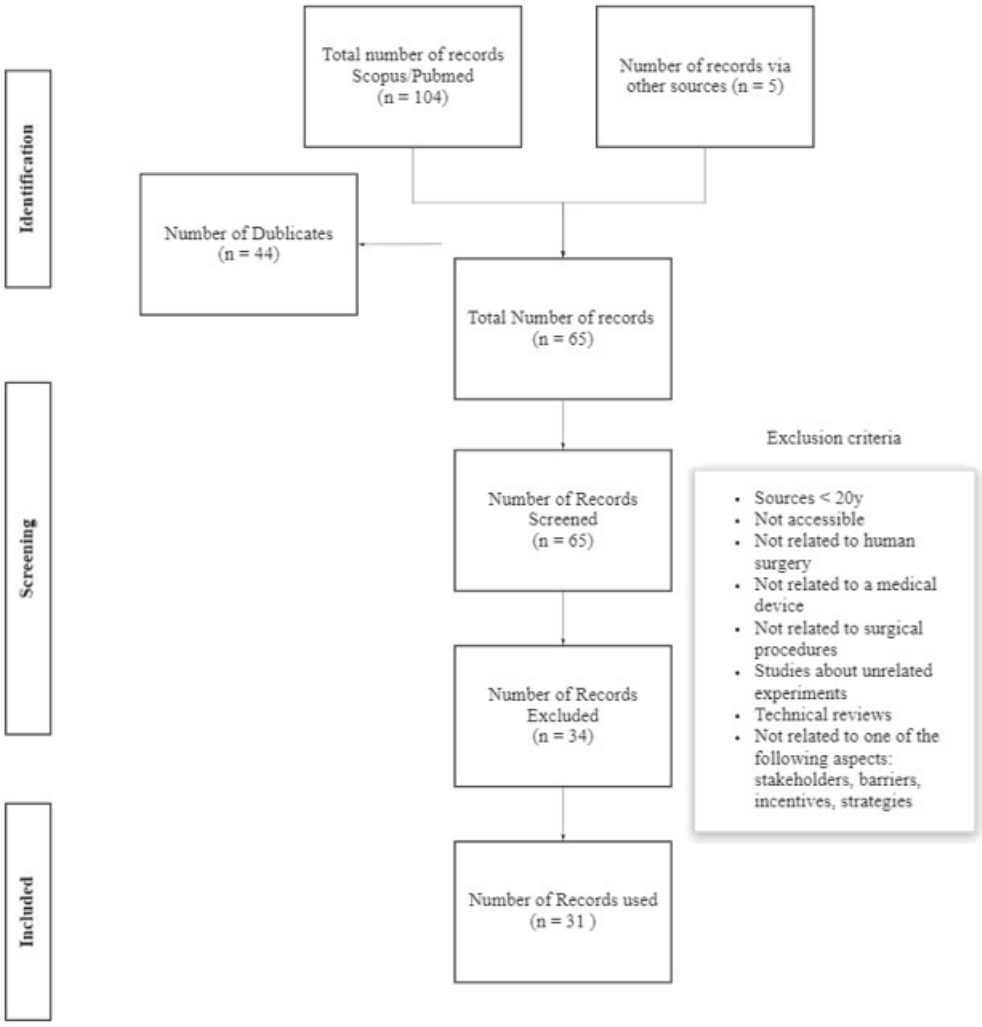


Figure 3.2: PRISMA flow-chart of the literature search (Moher et al., 2009)

The exclusion process began with a screening based on the date of origin and accessibility. If the articles were published more than 20 years ago and are not accessible, these articles were excluded because they are outdated or cannot be included in this study. This is due to the analysis of recent market developments and trends related to surgical devices in LMICs. In addition, only data related to human surgery are relevant, as the scope of this study is human surgery. Another exclusion criterion implies that the sources must relate to surgical instruments and procedures. Much of the literature relates to other devices and is not explicitly focused on healthcare-related products or services. In addition, some studies relate to experiments related to surgical instruments. However, this study is more about fact-finding and descriptive analysis and does not cover experiments on humans. Another exclusion criterion is the technical evaluation of a specific product, which is not relevant to this study. Finally, literature is also excluded if it does not address the following topics: stakeholders, barriers, incentives, and strategies.

3.4 Interviews

This chapter describes the results of the interviews (expert review) conducted with a total of n=14 participants, as shown in Table 3.2 The interviews are pseudo-anonymised, which ensures that no direct information is given that could lead to the interviewee being identified. More background information is provided in the following table. A total of nine Indian sur-

geons were interviewed. A distinction is made between rural and urban hospitals, private/non-governmental hospitals, and government hospitals. With an average duration of 30-45 minutes, all interviews took place online, partly because of the Covid19 pandemic.

Anonymised name	**Background**	**Specialisation**	**Trained in Laparoscopy**
Indian Surgeon 1	Professor & surgeon, public urban hospital	N.A	Yes
Indian Surgeon 2	Rural non-governmental hospital	N.A	No
Indian Surgeon 3	Urban & rural tribal hospitals	Paediatric	No
Indian Surgeon 4	Professor, surgeon & advisor rural hospitals	Upper Gastrointestinal (GI) surgery	Yes
Indian Surgeon 5	Surgeon & consultant rural hospitals	Laparoscopy	Yes
Indian Surgeon 6	Trust/private tribal hospital	N.A.	No
Indian Surgeon 7	Rural hospitals, National board India & Consultant	Training rural surgery India	Yes
Indian Surgeon 8	Private urban mission hospital, serving large rural population	Chief Medical Officer	Yes
Indian Surgeon 9	Rural surgeon in a community health centre & Governmental hospital	N.A.	Yes
Professor	TU Delft BME	LMICs	N.A.
Professor	Leeds University BME	LMICs	N.A.
Expert LMICs	Technician	Sterilisation	N.A.
Phd Student	TU Delft BME	Sterilisation India	N.A.
Company	Developer Laparoscopic instruments	Laparoscopy	N.A.

Table 3.2: Overview of participants interviews

The purpose of the interviews was to obtain additional background information on the SQs, primarily in response to the identified gaps in the literature. Given the semi-structured nature of the interviews, no strict interview protocol was followed. However, the interview protocol contains guiding questions related to the SQs. A different protocol was used for the academic experts and innovators interviewed since they provided different perspectives and experiences to the 'end-users'. Both protocols can be found in the Appendix.

To extract relevant empirical data from the interviews, ATLAS.ti was used for the analyses. ATLAS.ti is a program that can be used for research purposes to analyse data. All interviews were coded, using the following process. First, the coding process included 'open coding', meaning that raw codes were applied to the interviews. Second, 'axial coding' was used to identify themes and group the codes. Due to the consistency of the interview protocol, most codes could be classified according to the themes from the RQ and the corresponding SQs. Finally, for the Results chapter, 'selective coding' was used to note essential information from the interviews. This critically analysed the interviews and noted connections, contradictions, and commonly cited quotes.

Chapter 4

Literature Review

In this chapter, a literature review is conducted. This includes identifying gaps in knowledge, gathering new insights about LMIC markets, and applying surgical instruments. Current barriers and factors related to the application of laparoscopic surgical instruments in LMICs are also analysed. After analysing the literature, a critical conclusion is drawn based on the literature review findings, and implications for this study are provided.

4.1 Levels of analysis

The analyses of literature related to the adoption of surgical devices in LMICs can be categorised into different levels. Stewart et al. (2004) identified several levels of adoption barriers in the construction industry. As shown in 4.1, these exist on an individual, firm, and network level (Stewart, Mohamed, & Marosszeky, 2004).

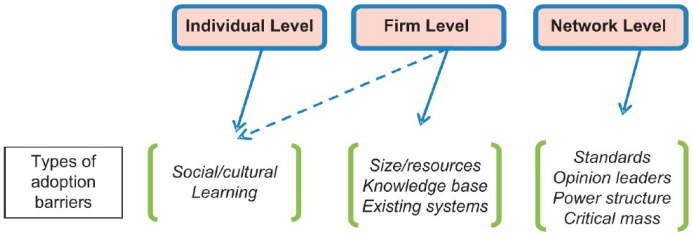


Figure 4.1: Adoption barriers on different levels (Stewart et al., 2004)

For the purpose and convenience of this study, these levels of impairment are restated to the context of healthcare systems, not limited to barriers to adoption. The "Individual Level" represents the end-users (surgeons) of laparoscopic instruments and includes patients. Furthermore, the "Firm-level" represents the hospitals in LMICs, and the "Network-level" involves government structures, national and international aspects, and contains standards, policies and regulations. The translation of the model of Stewart et al. (2004) results in the following figure.

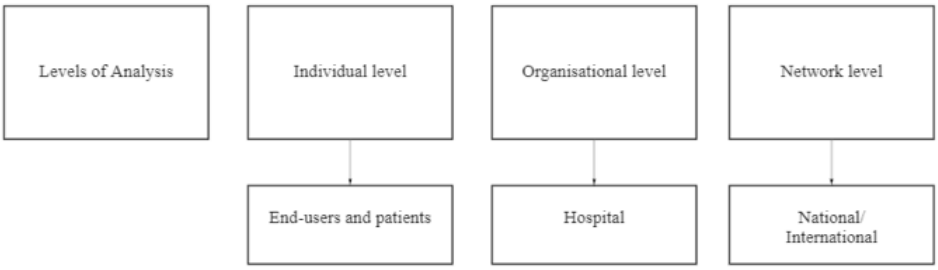


Figure 4.2: Analyses on different levels related to the healthcare industry

The first SQ covers the current state of the art of minimally invasive surgical instruments used in LMICs. This includes the existing barriers at these levels and the strategies and stakeholders that exist at the three levels. However, the incentives focus more on both the end-user and hospital levels.

4.2 Individual Level

Barriers
The lack of expertise and training is often cited in the literature as a barrier. Surgeons, nurses, anaesthesiologists and other medical personnel, who are next to patients on an individual level, are often unable to use sophisticated equipment (Schwartz, Jeng, & Chuang, 2017), (Harvey et al., 2020). This includes the lack of maintenance due to a lack of knowledge on how to maintain and repair equipment, which is a massive challenge for hospitals in LMICs (Oosting, Wauben, et al., 2020), (Harvey et al., 2020), (Alfa-Wali & Osaghae, 2017), (Farrow et al., 2021).
There is a lack of training at several levels. Starting with the lack of training (programs) related to medical equipment maintenance (Harvey et al., 2020), (Adisa, Lawal, Arowolo, & Alatise, 2012), (Aruparayil et al., 2021). But more importantly, not all medical experts, like surgeons, are not familiar with laparoscopic surgical techniques (Harvey et al., 2020), (Mansour et al., 2011), (Adisa et al., 2012). As a result, medical personnel, including anaesthesiologists, do not know how to recognise complications associated with these types of procedures (Mishra et al., 2020). These complications are often related to anaesthesia, haemorrhage, and infection control, resulting in unsafe situations for the patients (Alfa-Wali & Osaghae, 2017), (Chao, Mandigo, Opoku-Anane, & Maine, 2015). The opportunity for training is also lacking due to the lack of technical support. High-quality training facilities such as laboratories are often unavailable in LMICs due to a lack of resources (Farrow et al., 2021), (Alfa-Wali & Osaghae, 2017), (Aruparayil et al., 2021), (Chao et al., 2015), (Gheza, Oginni, Crivellaro, Masrur, & Adisa, 2018).

Furthermore, barriers related to patients are identified, which mainly deals with costs-related barriers. If patients cannot pay for advanced healthcare, it is not enough for hospitals to use advanced equipment. When the outcome of surgery is the same, but surgeons could use different instruments, either expensive medical equipment or cheaper open procedures, the patient would prefer the most affordable option in a system where payment is out of pocket functions (Choy, Kitto, Adu-Aryee, & Okrainec, 2013), (Mishra et al., 2020). Laparoscopic procedures are still more expensive than open surgery. This lack of money can have several causes, including conflicts between or within societies due to war, corruption, and other socioeconomic crises (Alfa-Wali & Osaghae, 2017). Therefore, it is necessary to know the social situation to promote the adoption of these devices. The cost-related barrier is considered one of the most critical barriers in the literature, as it is the most frequently cited barrier in the literature on barriers related to the adoption of medical devices (Schwartz et al., 2017).

Incentives

The incentives take into account the benefits to the end-user and patients of using laparoscopic instruments to replace open surgery. Following Chao et al. (2015), using these instruments for hospitals is optimal bed utilisation; a patient can be discharged sooner. Standardised discharge is a way to make this profitable for hospitals. In addition, it is more cost-effective when laparoscopy is compared to other equipment costs such as ultrasound, CT and MRI; the ratios are as follows, 1:500:2500:4500. Also, from this point of view, it is attractive for hospitals to introduce laparoscopy in their practice. In addition, the supply of medical equipment and the use of antibiotics, analgesics and other drugs and medical supplies will be significantly reduced (Chao et al., 2015). Also, laparoscopic surgery, especially in resource-poor areas, is useful because of the lack of blood transfusion and running water (Pizzol et al., 2021). The operation technique would be beneficial for hospitals in LMICs concerning cases of gynaecological diseases, cholelithiasis, appendectomy, cholecystectomy, splenectomy and oesophagectomy according to Velanovich (2000), and Pizzol et al. (2021). In hospitals where diagnostic imaging is not applicable, surgeons can use laparoscopic instruments in cases of tuberculosis, intra-abdominal complications, pelvis inflammatory illnesses and traumatic injuries. When imaging is available, surgeons can use laparoscopic devices for diagnostic and therapeutic application in case of gynaecological procedures and biliary tree-related complications (Chao et al., 2015). However, laparoscopic surgery does not always show better outcomes. In the case of Hernia repair, it is better to use open surgery. This is proven to be more effective, resulting in less post-operation complications (Velanovich, 2000), (Chao et al., 2015).

Laparoscopic instruments and procedures also affect the patients positively. First of all, according to the literature, it has been shown that laparoscopic surgery results in better postoperative outcomes due to its minimally invasive character. The better outcomes can be measured in terms of postoperative pain, decreasing convalescence, additional complications, and blood loss, which makes that laparoscopic procedures have better surgical outcomes compared to open surgery (Schwartz et al., 2017), (Adisa et al., 2012), (Mansour et al., 2011). Other authors are arguing that it also decreases the morbidity, mortality, and the risks on infections (SSIs) (Oosting, Wauben, et al., 2020), (Chao et al., 2015), (Alfa-Wali & Osaghae, 2017), (Harvey et al., 2020), (Chao et al., 2015), (Mansour et al., 2011).

In LMICs, local patients often do not have access to safe and affordable surgery (Schwartz et al., 2017). If laparoscopic procedures become cheaper and more widely used in these countries, it will improve health care quality. In general, it can be stated that laparoscopic procedures cost more time; however, it reduces the stay in hospital time and ensures improved back to work time (Pizzol et al., 2021), (Chao et al., 2015). With this, also the elective surgery wait times are decreased. The faster recovery time is primarily in poor status situations relevant when a breadwinner needs to be back to work to support the family financially, and the hospital bill will be lower (Chao et al., 2015). However, not all the literature on this area is raise the same advantages and disadvantages. Several authors raise the question of whether a faster return to home serves patients in case of a laparoscopic procedure. In HICs, extra stay in hospitals is far more expensive than in low resource countries and can not be compared (Schwartz et al., 2017). In terms of money, an extra stay in hospital costs about three dollars per day on average (Choy et al., 2013).

Also, salaries and costs are variables that need to be considered. Due to low wages, the pressure to increase back to work time is lower. Furthermore, earlier discharge is no incentive for hospitals to use laparoscopy due to the significantly low-cost savings. Thereby the procedure self is often equally or more expensive than open procedures and in the absence of health insurance

companies more challenging to afford the care. Hospitals are often not the only party involved at this point. Also, insurance companies are sometimes not willing to pay for laparoscopic procedures and only reimburse traditional open procedures. In addition, the change of procedures and starting with a new type of instruments and workflows require startup costs or donated equipment. The last cost-related burden is the cost of anaesthesia. Procedures time increases with the application of laparoscopy; therefore, more extended anaesthesia is needed (Chao et al., 2015). Due to increased procedure times, fewer patients per day can be treated (Alfa-Wali & Osaghae, 2017). All of this results in the conclusion that only relative welfare patients can afford laparoscopic procedures (Chao et al., 2015).

Other critical remarks related to the practice of laparoscopic procedures in LMICs are the limited availability of scans, and radiotherapy (Chao et al., 2015), (Schwartz et al., 2017). With the result that gynaecological cancer must be treated using open surgery (Schwartz et al., 2017). This is also the case with appendectomy, where clinical advantages are achieved by using open surgery. Even in cases where laparoscopy could be beneficial for patients in case of positive postoperative results, there is often a shortage of trained personnel and the procedure time is longer (Chao et al., 2015). This is reinforced by the idea that local healthcare professionals (stakeholders) consider traditional open surgery to be safer than laparoscopy. Even more given the fact that there are no validated models which consider that laparoscopic surgery is safer than open surgery in LMICs (Chao et al., 2015).

4.3 Organisational Level

Barriers hospital

Forrester et al. (2018) analysed n=40 studies related to Health-care-Associated Infection (HAI) in LMICs. Infections after or during surgery are a significant problem in LMICs. These are also known as Surgical Site Infections (SSIs). The number of SSIs in LMICs is twice as high as in HICs resulting in higher mortality, morbidity, and economic costs for surgical care (N. N. O'Hara, Patel, Caldwell, Shone, & Bryce, 2015). Due to a lack of central sterile supply units (CSSD), which guarantees sterility for surgical instruments. Further barriers to sterilisation are the lack of basic resources such as electricity, clean water and knowledge, and equipment (Chao et al., 2015), (Aruparayil et al., 2021). This is often caused by the lack of access to consumable supplies (Farrow et al., 2021). But also the working space and the staff for sterilisation are missing in LMICs, unlike in HICs (Qazi et al., n.d.), (Forrester, Powell, Forrester, Fast, & Weiser, 2018). If medical instruments are not cleaned adequately according to WHO guidelines, they will corrode, which is a result of a lack of training/knowledge and lack of water and electricity (Fast, Teka, et al., 2019),(Fast, Uzoka, et al., 2019). This is emphasised by Fast, Teka, et al. (2019), and Fast, Uzoka, et al. (2019); using observation studies, it is concluded that chlorine is often used to clean devices. However, this affects the quality of the devices and destroys mechanisms (Fast, Teka, et al., 2019),(Fast, Uzoka, et al., 2019). Electronically driven, steam-powered autoclaves are suitable to use in this process, but these two basic facilities are often lacking. When instruments corrode, surgeons must no longer use them for surgical procedures. Despite this fact, they are still used (Forrester et al., 2018).

An additional problem with HAI in LMICs is that the infections will result in higher mortality rates and more extended hospital stays. This makes the stay more expensive than needed. The HAI are in LMICs in general 15-25 per 100 patients in contrast to the United States (US) where it is 4 per 100 patients (Weinshel et al., 2015). Furthermore, maintenance on autoclave sterilisation is often lacking, with the result that the devices are not used in the way they are intended to use (N. N. O'Hara et al., 2015).

Given the barriers, it is questionable whether it is possible to carry out a safe operation when basic resources are lacking. N. O'Hara (2015) identified the following barriers: a shortage of personnel, no suitable facilities, overcrowded hospitals, and distance to the local health institution. Moreover, the supply chain and infrastructure hinder the delivery of medical products. Basic equipment is missing, and therefore even primary care cannot be provided (N. O'Hara, 2015). Autoclave sterilisation is required to sterilise medical instruments. However, the quality of such devices is often inadequate. The reason for this problem is that devices are generally not designed for LMIC countries and certainly not for rural areas. As a result, there is a lack of technical knowledge to use and repair the systems (N. O'Hara, 2015).
The lack of clinical guidelines is also a barrier hindering the adoption and diffusion of laparoscopic devices. Clinical guidelines are helpful as guidance for healthcare workers in hospitals to create a uniform approach concerning safe procedures (Chao et al., 2015). Clinical guidelines are often lacking, and if they are available, they are not always followed according to N. N. O'Hara et al. (2015), and Chao et al. (2015).

As mentioned, the cost of procedures also places a burden on patients in LMICs to access (basic) care. Depending on the procedure and the materials required, the costs increase (N. O'Hara, 2015), (Adisa et al., 2012), (Harvey et al., 2020), (Mansour et al., 2011). These costs combined lead to high initial setup costs associated with the application of laparoscopic procedures (Gheza et al., 2018). Next to this, there are also standard costs. These costs can be divided into preoperative, operative and postoperative costs. In general, costs include the salary of stakeholders like surgeons, assistants, anaesthetists, technicians, and nurses (Schwartz et al., 2017), (Kramer et al., 2016). In addition, indirect costs play a role, such as the transportation of medical equipment, electricity use, and the shipment of medical materials needed during the procedures. In addition, depending on the procedure, for example, screws, materials to close wounds and other equipment costs are incurred. Even more, when additional training is provided to healthcare workers, there are education and training costs involved (Schwartz et al., 2017).

Besides, Choy et al. (2013) identified three different of barriers. The first one is related to organisational structures, the second one considers the hierarchical nature of the surgical environments, and the latter is related to expertise and skills. These barriers must be considered important barriers that block the adoption of laparoscopic procedures. In detail, about hierarchical structures of hospitals, senior surgeons often determine what equipment is used for procedures and also choose how to approach a procedure (Choy et al., 2013). This also influences the barrier to training. For example, knowledge obtained from training is frequently not shared among junior surgeons. Furthermore, according to Mansour et al. (2011), it appeared that senior surgeons are not comfortable to use this new operation technique, resulting in resistance to change and distrust in the new technology (Fast, Teka, et al., 2019), (Fast, Uzoka, et al., 2019), (Alfa-Wali & Osaghae, 2017), (Chao et al., 2015).
Given these cultural barriers, it is challenging to manage hospitals and, with this, to promote the use of laparoscopic instruments (Mansour et al., 2011), (Chao et al., 2015). Schwartz et al. (2017) add that misalignment exists between suppliers from HIC and LMIC hospitals since there is often insufficient knowledge of hospital structures, with the consequence that product adoption is hindered (Schwartz et al., 2017).

The last organisational related and barrier well-cited is lacking infrastructure in LMICs (Oosting, Wauben, et al., 2020), (Chao et al., 2015). Infrastructure influences the local access to care and the supply of basic resources such as electricity and running water. This barrier has an enormous impact on other barriers and the type of instruments used for surgery. For instance, the lack of constant electricity and the supply of distilled water hampers the use of autoclave

sterilisation. With the result that improvements on SP practices are hampered (Fast, Teka, et al., 2019), (Fast, Uzoka, et al., 2019). This results in a complex dynamic resource constraint barrier (Choy et al., 2013). From the patient's side, lacking infrastructure hampers access to reach hospitals both physically and via communication channels, and with this, lacks access to timely surgery (Aruparayil et al., 2021), (Chao et al., 2015).

Organisational strategies
On the organisational level, knowing hospital cultures and structures is required following Choy et al. (2013). This understanding gives insights into social interactions and is essential for the efficient use of resources for patient care. Mapping out all relationships and transferring them into diagnostic frameworks increases understanding of bottlenecks in the social structures of hospitals. With this, stakeholders can provide targeted solutions. Such a framework can then also be applied when technology moves across cultural, socioeconomic and geographical borders (Choy et al., 2013).

The lack of training is considered a barrier to developing and disseminating laparoscopic instruments. Several strategies from the literature could be used to address this barrier, starting with enabling simulations and didactic training programs for collaboration between hospitals and intraoperative exercises combined with videos of surgical procedures to increase the knowledge of how to use the instruments for which they are intended. This can be accomplished with locally manufactured low-cost materials and local laboratories. The above proven methods will only work if the training lasts at least three days (Chao et al., 2015), (Harvey et al., 2020), (Morrow et al., 2016).
Promoting these training programmes can result in team spirit to qualify and use new types of procedures. It would create more trust in the healthcare system and give surgeons accomplishments and motivation to use laparoscopic instruments. Training can be imposed for only emergency and basic procedures, after which more advanced practices could be incorporated (Chao et al., 2015). Other authors add that it is required to promote sub-specialisation. This results in subdividing tasks with every healthcare professional its expertise (Choy et al., 2013). For the above, it is essential to target young healthcare professionals eager to learn and implement new practices, according to Schwartz et al. (2017). Senior surgeons often determine the approach in local hospitals; it is unfortunately not effective to target them because they are the most conservative (Schwartz et al., 2017). Furthermore, some surgeons are travelling to HICs to gather knowledge and gain experience from procedures on how to use instruments. Based on this experience, the practices are copied and used/taught in LMICs, resulting in unsafe surgical care. Learning by doing is essential for laparoscopic procedures. A solution for this is training programmes like "The fundamentals of Laparoscopic Skills" for laparoscopic procedures used in the United States (US). However, cheaper versions of such programmes could be implemented in LMICs (Alfa-Wali & Osaghae, 2017). Nevertheless, not all authors agree on the idea that sub-specialisation is necessary to increase the quality of care. There is often a vast demand for surgical care in LMICs and a shortage of qualified staff. Therefore, surgeons should be all-round and not sub-specialised to treat as many patients as possible within a given time frame (Alfa-Wali & Osaghae, 2017).

Furthermore, there are also strategies to overcome the barriers to sterile processing (SP). According to Cuncannon et al. (2020), education, training, mentoring and team approaches are needed to guide local medical professionals through SP. It was found that after the training was applied in 25 hospitals, medical experts used 0.5% fewer corrosive instruments. But there were also clinical improvements that emerged from post-training assessments (Cuncannon, Dosani, & Fast, 2020). Furthermore, Cuncannon et al (2020) adds that,quality assurance and monitoring

can be achieved by using biological and chemical indicators. Even though biological indicators are bulkier and require more resources, chemical indicators are more convenient (Fast, Teka, et al., 2019). Furthermore, Fast, Teka, et al. (2019), states that in combination with the Clean Cut programme, which includes six internal and outpatient monitoring indicators, the SP can be improved (Fast, Uzoka, et al., 2019). Following Harvey et al. (2020), implementing standard rules, guidelines and systematise SP with this, helps to guarantee quality SP practices (Harvey et al., 2020).

Another strategy contains the application of innovative ideas in resource-poor countries. These ideas consist of making the resources needed for sterilisation affordable for LMICs. In addition, different packaging can reduce the need for re-sterilisation. In India, it was found that when instruments were packaged non-woven, the need for re-sterilisation was less urgent (Cuncannon et al., 2020).

Furthermore, following the scoping review on methods, policies and barriers related to surgical instruments, by Forrester et al. (2018), safe procedures could be ensured by meeting the "surgical safety checklist" composed by the WHO. This list includes chemical, physical and biological standards related to sterilisation. These standards are generally not met in LMICs, which increases the risk of infection. Various guidelines have been issued on how to meet the requirements. However, this can only be achieved through proper training of hospital staff, cleaning equipment, supervision and policies in this area (Forrester et al., 2018).

Additionally, Harvey et al., (2020) argues that improving infrastructure and education improves the quality of care and the ability to apply laparoscopic instruments. However, this article is limited because it only states what needs to be improved and not how it can be achieved (Harvey et al., 2020).

Context-specific design is also part of a strategy to adapt a product to a market. To achieve this, the design requirements must allow for it. Minimal requirements to use these instruments in local hospitals are the availability of camera systems, insufflation systems, needlescopic instruments and access instruments like trocars (Mansour et al., 2011). It is critical to know the usage context to make the mentioned systems. According to Oosting, Ouweltjes, et al. (2020), the following aspects need to be considered to make a context-driven design of surgical instruments like laparoscopic devices. First of all, a distinction is needed between the type of hospitals and the type of surgeries. Secondly, there is a demand for available equipment. Based on the procedure, the equipment should be available. Third, there should be a clear picture of the type of procurement and the possibilities of acquiring affordable instruments. This also depends on the purchasing departments of local hospitals, which are also a stakeholder in this regard. Fourthly, the supply of primary resources must be established. If this is non-exist, it is essential to have instruments that are not so much dependent on these resources. There must be an opportunity for training in the fifths place, and team composition must be aligned concerning the vision of procedures. Furthermore, maintenance related issues must be addressed. This entails that there must be a (local) opportunity to repair and upkeep instruments. Also, the lack of sterility must be addressed and improved. After all, there must be opportunities to store instruments safely (Oosting, Ouweltjes, et al., 2020).

Based on these research findings, the following context-driven design requirements were identified. Surgical instruments should be durable, easily transportable, safe and efficient, powered by batteries or generators, easy to maintain, inexpensive and non-disposable. Developers of medical instruments targeting LMICs should be aware of and consider these context-driven

design requirements (Chao et al., 2015). Especially considering the challenging development of laparoscopic devices targeted to LMICs, it is vital not to make the devices similar to how they are applied in HICs. For example, robotic systems like the 'Da Vinci' system are too expensive (1.2 million dollars) and require maintenance (Mansour et al., 2011). It is essential to have requirements for medical equipment in the sense that it fits the context of the application (Alfa-Wali & Osaghae, 2017), (Chao et al., 2015).
The context-driven design requirements can be translated to enable the application of laparoscopic instruments in LMICs. In the first instance, the devices must be reusable (Chao et al., 2015). Not all articles agree on this aspect, and when considering reusability compared to single used instruments, maintenance is required, which is identified as a barrier due to lack of knowledge and awareness (Mansour et al., 2011). On the other hand, reusable instruments can be used for to up 18 years and can save up to 300 dollars per patient (Chao et al., 2015). However, to make it profitable and increase the healthcare quality, robust, durable and affordable laparoscopic instruments need to become the new norm in LMICs (Mansour et al., 2011), (Alfa-Wali & Osaghae, 2017). Next to this, it is required to be low-cost (Alfa-Wali & Osaghae, 2017). This can be achieved to reduce electricity costs by using natural light sources. But also by enabling the opportunity to sterilise and reuse clips, use laparoscopic ligatures developed in India, or exclude clips and apply other sutures techniques.
In addition, the use of local spinal anaesthesia in combination with laparoscopic procedures also reduces the costs. All of this, in combination with eliminating expensive parts of the instruments replaced by alternative methods or designs, are needed (Chao et al., 2015), (Mansour et al., 2011). Furthermore, monitoring systems are one of the basic requirements to enable laparoscopic surgery. When there are sufficient monitoring systems, safe and affordable laparoscopic surgery can be revolutionised (Mishra et al., 2020). Concerning the monitoring/camera systems, it is needed to consider disposable camera covers (Harvey et al., 2020). To develop this, it is required to cooperate with parties from the supply side (Gheza et al., 2018).

Furthermore, laparoscopic procedures have challenging usability related requirements. Training is needed to get control over the devices and use them properly. To enhance cheap and effective training, simple solutions like card boxes and old shoeboxes are proven to improve laparoscopic practice. Hand-eye coordination in combination with haptic feedback and past-pointing exercises is required. Cheap skills laboratories can be used for this (Alfa-Wali & Osaghae, 2017), (Chao et al., 2015). Lastly, Alfa-Wali & Osaghae (2017) suggests recording frequently performed procedures such as appendectomy and cholecystectomy and sharing these video recordings via the Internet and using this as a learning/training platform (Alfa-Wali & Osaghae, 2017).

4.4 Network Level

National and International Barriers
As identified on the organisational level, cultural and social barriers are also existing on the network level (Adisa et al., 2012). Part of these barriers is the inequalities between healthcare systems, both international and within countries. Some hospitals do have access to laparoscopic surgery for several years, in contrast to government hospitals where laparoscopic surgery is often lacking (Aruparayil et al., 2021). The graphical location of hospitals causes these inequalities. A distinction must be emphasised between rural and urban areas and between rural and urban areas. In urban areas, hospitals are often private, and the quality of care and access to resources is significantly better than in rural areas. In contrast to hospitals in rural areas, insurance companies are often connected to more welfare urban hospitals. This also influences the decision on what type of instruments are used for a specific procedure (Alfa-Wali & Osaghae, 2017). In addition, generalising LMICs is a point of criticism. A distinction must be

made between countries and common diseases within that country. After which, a closer look is needed to assess which diseases could be treated with laparoscopic instruments (Alfa-Wali & Osaghae, 2017).
Several barriers are added by Mills (2014), such as the lack of policies related to medicines and drug supply. Lack of cooperation between government agencies and local hospitals. Dependence on donors, limiting the ability to operate independently. Inadequate response to the demand side. Centralised systems, instability within government structures and policies. This may be due to the government agencies' weak accountability or other political instability. In addition, a lack of free press can lead to a biased view of the healthcare sector. Lastly, surgeons also move to HIC/urban areas because of the financial rewards(Mills, 2014).

National and International Stakeholders & Strategies
NAI Stakeholders exist at different levels. In healthcare, there are generic and specific product-related parties who are affected or influence a particular product or service. The WHO is an important international player within the healthcare industry. They provide for instance guidelines and recommendations in how to do right SP practices (Fast, Teka, et al., 2019), (Fast, Uzoka, et al., 2019). In addition, they can also provide quality control of the medical equipment used/purchased, for example, an online monitoring system connected to health workers in different countries. This can also create less dependence on donors. More equipment should be developed in-house and should be developed locally without compromising the quality of the equipment (N. N. O'Hara et al., 2015). Some authors suggest that working with universities, and in particular biomedical engineering (BME) departments, establishing new medical standards for medical products and practices is required (Oosting, Ouweltjes, et al., 2020). Another party are the Ministry of Health. Chao et al. (2015) argues that collaborating between donors and the ministry can improve healthcare quality by developing national programs. However, other articles recommend broader cooperation. Cooperation is needed between governmental and non-governmental organisations, local hospitals, and non-profit organisations. This cooperation should be aimed at improving SP practices and healthcare systems. For example, Mills (2014) suggests the Paris Declaration and Accra Agenda for Action as parties that can improve the global cooperation of healthcare systems. This can be achieved through new policies, regulations, financial assistance, government support and accountability, press freedom for informed media, improved provisioning mechanisms, decentralised authorities, autonomous parties, and the provision of other needed resources (Mills, 2014), (Cuncannon et al., 2020). Despite such collaboration, the lack of financial support and resources, hierarchical sociological structures within organisations, and limited training and knowledge remain aspects that pose challenges (Cuncannon et al., 2020). Chao et al. (2015) adds that stakeholders at the organisational and individual level should also be involved in working with the aforementioned parties and adds academic institutions, which should evaluate the socioeconomic environment, including its risks and benefits when improving the healthcare system. In India's healthcare system, it has already become apparent that there is inequality within this sector. Some patients have access to laparoscopic instruments while others do not have the resources or other pronounced barriers prevent using these instruments. There are also inequities in the context of stakeholders. Insurance companies or government agencies financially support only a tiny percentage of the Indian population. Both parties have the power to block the use of laparoscopic instruments. They often prefer open surgery to laparoscopic surgery and therefore do not cover the cost of these procedures (Chao et al., 2015). Collaboration between medical (equipment) suppliers, government and insurance companies can promote access to medical supplies and stimulate cost reduction of medical devices (Alfa-Wali & Osaghae, 2017). Partnership building, improving practices, guidelines and policies is required. There are several stakeholders involved in SP improvements in LMICs. Six papers reported the following parties, WHO Surgical Safety

Checklist (SSC), Safe surgery 2020, Global surgery 2030, Clean Cut programme. Together with organisations, such as Assist International, Lifebox Foundation and GE Foundation, financial and operational support was provided to implement these opportunities. Local professionals agreed with this partnership approach and recognised it as relevant and achievable (Cuncannon et al., 2020). This approach needs also be established internationally via partnerships to increase the acceptability of laparoscopic instruments (Schwartz et al., 2017). Specifically, concerning the commercial availability of laparoscopic instruments, it is required to cooperate between companies, biomedical engineers, and non-governmental organisations (Oosting, Wauben, et al., 2020). Furthermore, cooperation between Ministries of health and donors can improve the quality of related surgical care. There are already parties to improve healthcare practices in LMICs, like The College of Surgeons of East, Central and Southern Africa (COSECSA), West African College of Surgeons (WACS), Pan-African Academy of Christian Surgeons (PAACS), and Rural surgeons in India association. These healthcare associations play a key role in sharing knowledge, providing guidance, and advising on the use of laparoscopic instruments with associated equipment (Chao et al., 2015),(Wilkinson, Aruparayil, Gnanaraj, Brown, & Jayne, 2021).

4.5 Overview of literature findings

Several implications for further research emerged after analysing the literature regarding the surgical instruments used in LMICs. These could be broken down using the SQ as a common thread.

Returning to the SQ analysing the barriers of surgical devices used in LMICs, it could be argued that barriers exist at each level of analysis, as shown in Figure 4.3. A wide range of literature also identifies current healthcare system barriers in LMICs concerning medical devices. Some of the literature is very specific about the barriers, but most are more general.

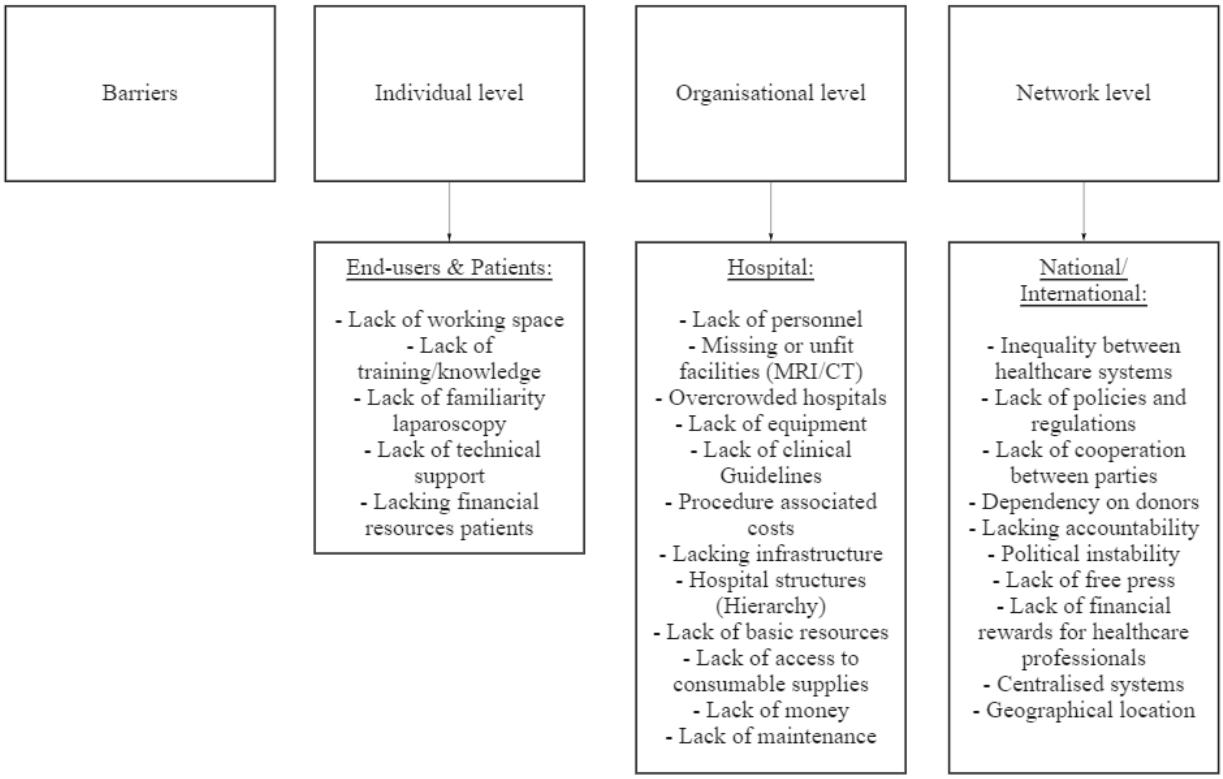


Figure 4.3: Overview of identified barriers

Another research question focused on the incentives of individuals and organisations to apply laparoscopic tools in their practice, as shown in Figure 4.4. Two levels of analysis were combined in the analysis of this question. The literature is clear and unanimous on the incentives related to the applicability of laparoscopic instruments.

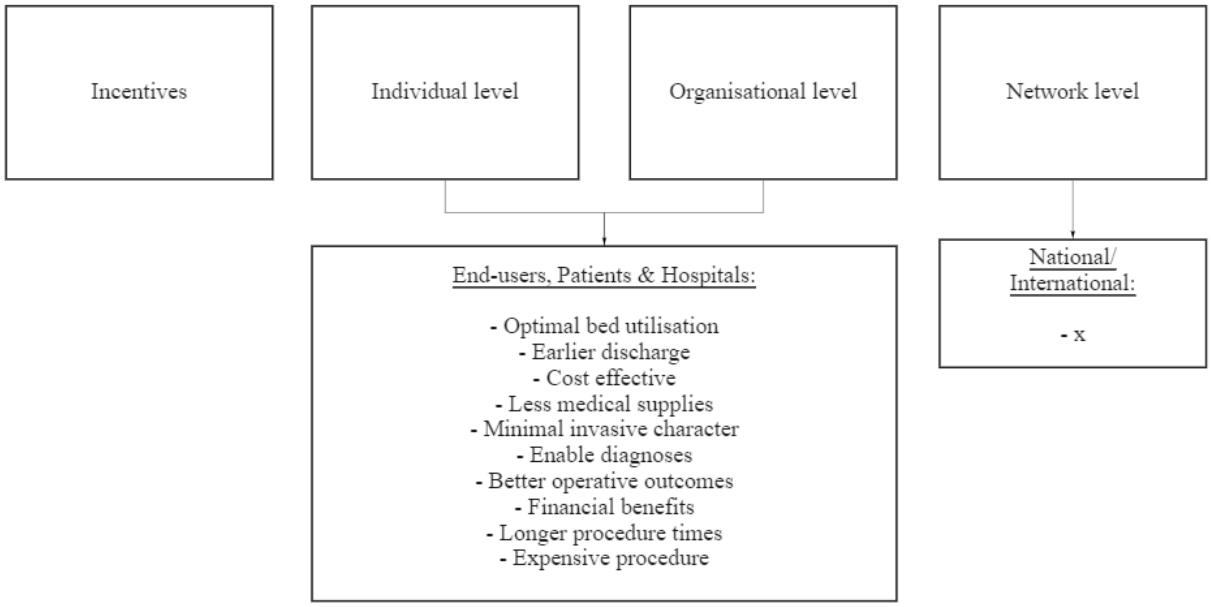


Figure 4.4: Overview of identified incentives

Next, the literature identified the stakeholders involved in the use of surgical instruments such as laparoscopic instruments, as shown in Figure 4.5. It was found that there are a few stakeholders at the individual level and the organisational level. At the former level, the end-users, namely surgeons and patients, constitute the stakeholder group. Patients are classified at this individual level. However, they are not the end-users but rather the individuals affected by the application of laparoscopic instruments and, therefore, part of the individual level. While at the broader level, the stakeholders include technicians, anaesthesiologists, nurses, finance departments, hospital directors and other staff.

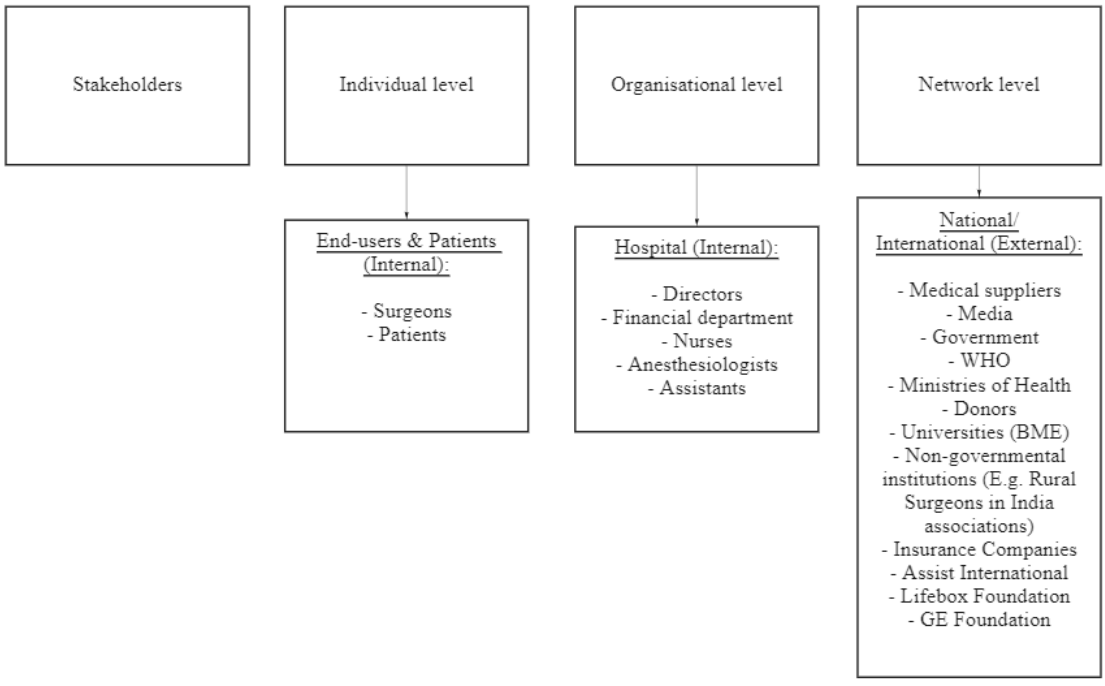


Figure 4.5: Overview of identified stakeholders

The literature also addressed some implications for strategies and recommendations to overcome the identified barriers. Again, both product-specific and more general barriers were mentioned in this literature section. It was found that individual-level strategies are inextricably linked to organisational ones. Therefore, all the strategies are listed under the organisational header in figure 4.6. At the network level, more high-level strategies emerged. These appeared to be closely related to the stakeholders and their potential current/future responsibility for action. Many parties raised from these analyses, and several authors have a vision of how these parties should work together to increase the quality of local healthcare. A summary of all strategies is displayed in figure 4.6.

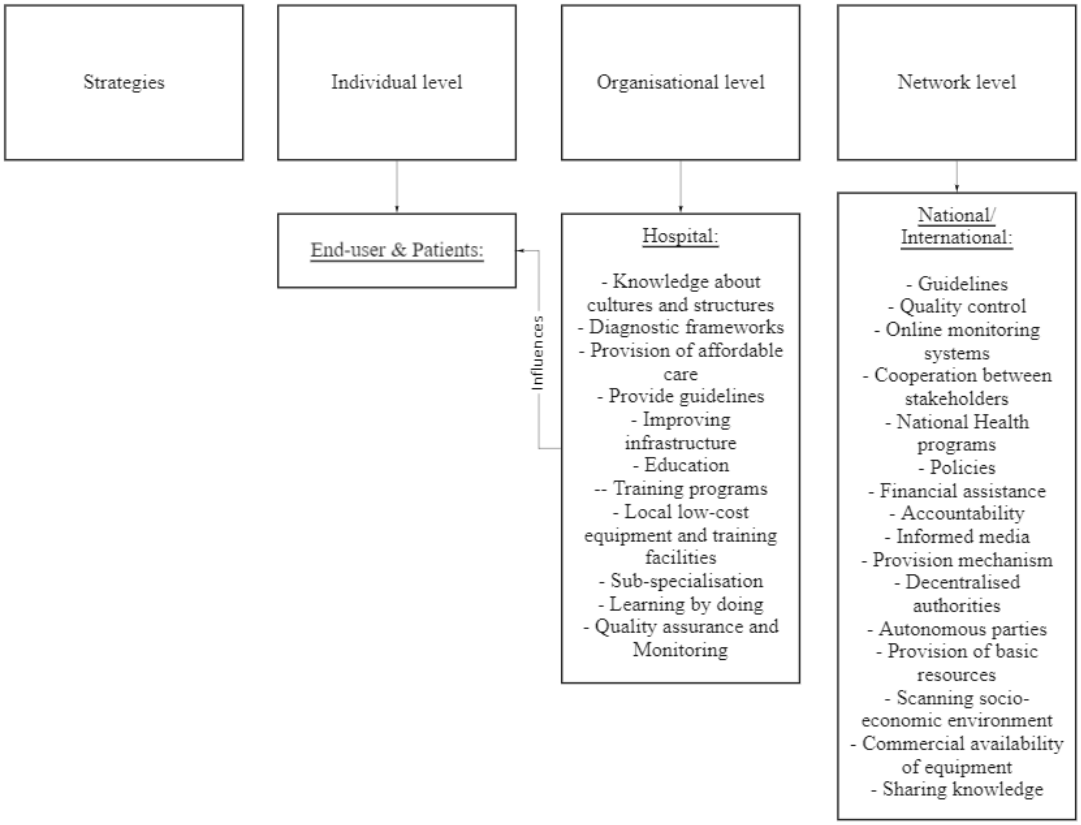


Figure 4.6: Overview of identified strategies

4.6 Implications for research

This chapter highlights the implications for research. Based on the gaps in the literature and the implications for research, the interview questions are designed to bridge these gaps.

Barriers
For this study, it is necessary to determine what barriers exist to using laparoscopic instruments in India. This should be determined with additional data from interviews. Then the barriers from the literature can be compared, and it can be concluded to what extent the more generic barriers can be generalised for the use of a specific surgical instrument. Interestingly, the literature on network-level barriers distinguishes between low-resource contexts. However, further analysis of these contextual factors using laparoscopic devices will be conducted. Especially considering that the authors caution against generalising LMICs in this context. In addition, additional literature is required on the adoption of laparoscopic devices in India. Some literature was found concerning sterility practices and laparoscopy in India but did not focus on adopting laparoscopic devices in India.

Incentives
There is inconsistency regarding the benefits to patients when using laparoscopic instruments. Some authors agree on the benefit of faster recovery times and fewer postoperative complications. But it is questionable whether patients would benefit from a faster return home. In this regard, context-dependency plays a role. In low-resource settings, an additional hospital stay is often not expensive, unlike in more affluent hospitals. Also, according to several authors, the cost of the procedures is more expensive than traditional open surgical procedures. This makes it less attractive to use laparoscopy in their practice. Added to this is that operation times are longer and fewer patients can be treated per day. This is a pressing fact given overcrowded hospitals and the demand for care in resource-poor areas. This combined information leads to the conclusion of an author that only welfare people can afford this type of surgery.
It is worth exploring why the benefits and incentives of laparoscopy do not match. Data from surgeons in India is needed to research this misalignment.

Stakeholders
The stakeholders were found to be highly context-specific. Therefore, through interviews, this network of stakeholders with their influences and interests will be further explored, and missing stakeholders will be added. At the network level, there are more generic stakeholders. Therefore, more literature was collected on this level. For this level, implications for research have already been described in an earlier section of this paper, at page 28. However, on all levels, stakeholders must be identified in relation to the adoption of laparoscopic equipment to find an answer to the main RQ.

Strategies
Upon close analysis of individual and organisational strategies, it can be argued that some "strategies" are more like recommendations to be followed to overcome challenges. Many of these strategies deal with how training programs should be implemented, and most relate to SP practices. Some authors argue that sub-specialisation is needed to increase the quality of procedures, but not all authors agree. Furthermore, apart from the data collected, very little was revealed about procurement processes. This is a critical gate that must be passed before a product can be used in hospitals. Therefore, more information on this aspect is needed. Context-driven design requirements are also noted. This refers to the facilities required for a specific product. Indeed, a hospital's facilities may indirectly exclude medical devices as a

product for adoption in a particular context. The literature in this section is a guide for further data collection. A distinction is made between six aspects that must be clear to know what facilities are needed. More data will be collected on these considerations. Furthermore, some training materials are suggested in the context of the application of laparoscopy. More insights are needed to know what is explicitly needed in what context. Moreover, the extent to which local hospitals (India) need training also about SP practices should be assessed. And what they see as added value strategies to adopt laparoscopic instruments. One of the organisational level strategies is worth mentioning because it is closely related to this research. It argues that a diagnostic framework is needed that encompasses all relationships and social structures of hospitals, after which a deeper understanding of hospital structures and bottlenecks is obtained. Further analysis on this is needed to identify all stakeholders at different levels, with associated roles, power and interests, again in the context of India. This can then be followed by identifying the central stakeholders for LMICs in general and more country-specific stakeholders.

Chapter 5

Results

5.1 Interpretation on empirical data

This section describes the main findings of the interviews. As indicated in Chapter 3, the identified themes correspond to the structure of SQs. Therefore, this section begins with more factual findings from the interviews, namely the mapping of the stakeholders involved. It provides an overview of their positions, contribution, category group, power, and importance in implementing laparoscopic instruments in India. The importance of the stakeholders is not based on the frequency of codes from the interviews. All the stakeholders listed are factual information, while in the other chapters, the emphasis is more on personal findings. However, the classification of stakeholders is not based on the interviews but on the literature review, which is structured as follows: individual level, organisational level and network level. Furthermore, the stakeholders were classified. The groups are clustered stakeholders that have common characteristics. After the table, these groups are used to describe the stakeholders further.
Following the description of the factual data, the interviewees' findings, with respect to the remaining SQs, are described, beginning with the barriers, the incentives, and strategies. Each theme is divided into categories. Related codes are placed in a table and further described in a specific section. These tables also show how often a code recurred in the interview, called the frequency of a code. In this way, the empirical data from Indian surgeons are incorporated. Relevant findings from the academic and innovator experts' perspectives are also added.

The following table lists all identified themes and sub-themes, including the data structure from personal findings.

Table 5.1: Overview of themes and sub-themes interviews

Themes and Sub-themes	***Frequency***
Barriers	***n=89***
Costs	n=20
Facilities	n=17
Supplier	n=5
Human Resources	n=33
Patients	n=5
Infrastructure	n=8
Training & Support	n=39
Acquisition	n=16
Incentives	***n=23***
Strategies	***n=120***
State	n=12
Academic & training institutes	n=21
Sales-related parties	n=56
Hospitals	n=20
Specialists	n=6
Cooperation among stakeholder groups	n=5

For the data on barriers, incentives, and strategies, a distinction is made between background variables from the interviewees. From the literature review and background section, it became clear that a significant inequality exists in India's healthcare system. Therefore, Table 3.2 distinguishes between rural and urban areas and between private (non-governmental) and public (governmental) hospitals. The main difference between these categories is that the private context is mainly independent of the government, while public hospitals have a relationship. Moreover, the difference between urban and rural is mainly related to the wealth status of both patients and hospitals. Since these background factors affect the generalisability of hospitals in the health infrastructure of India, the following types of hospitals are distinguished:

- Rural Private n=6
- Rural Public n=1
- Urban Private n=1
- Urban Public n=1

According to this list, most respondents have a rural private background. Therefore, quotes from surgeons generally belong to a rural private background unless otherwise specified. As a result, most of the findings contribute to this context.

5.2 Stakeholders

This section provides an overview of all stakeholders mentioned in connection with the introduction of laparoscopic instrumentation. Table 5.2 are the stakeholders as a result of the interviews listed. The stakeholder groups are shown in the first column, followed by examples of stakeholders in the next column. Furthermore, it is added to which category the parties belong, aligning with the literature review. Finally, the corresponding power and interests are given.

Table 5.2: Overview of categorised identified stakeholders with power and interests related to the application of laparoscopic instruments

Group	***Stakeholder***	***Category***	***Power***	***Interest***
State	Government	Network level	Policies Regulation Funding	Healthcare quality
Insurance companies	Insurance providers		Provide health-insurance	Enable access to healthcare
Non-profit organisations	International health organisations: - WHO - NIHR - GHRC		Setting norms & Standards Composing guidelines Policy formulation	Increase healthcare quality Financial protections
	Non-governmental organisations (NGO)		Financial support, and health projects	Social welfare of patients
Academic & Training Institutes	Harvard Institute		Identify, test, scale-up scientific solutions	Provide innovation
	Leeds University			
	TU Delft			
	Royal College of Surgeons (India)		Provide training and education	Increase knowledge & skills
	India Institute of Medical Science			
	Medical colleges (India)			
	International Training Teams Institute			
	Training institutes (India)			
Sales related parties	Companies (suppliers)		Provide equipment & service	Profit & Supply medical equipment
	Sales persons			Distribution equipment
	Service providors			Repair equipment

Table 5.2 continued from previous page

Group	*Stakeholder*	*Category*	*Power*	*Interest*
	Donors			Provision equipment
	Funding partners			Financial support
Types of hospitals	Hospitals	Organisational level	Provide care for patients Local regulating body	Care provision
Hospital departments	User department		Test purchasing requests	Control technical requirements
	Maintenance department (technicians)		Provide maintenance and control	Enhancement equipment
	Sterility departments		Provide and control sterility practices hospitals	Reduce infections, morbidity, and mortality rates
	Purchasing departments		Purchasing decisions	Control finances
Specialists	Biomedical engineers		Knowledge about mechanical aspects equipment	Enable use of expensive equipment
	Nurses		Assist surgeons	Enable the use of laparoscopic equipment
	Hospital director		Manage hospital	Enhance local healthcare quality
	Anaesthesiologists		Provide anaesthesia	Enable different type of procedures
	Surgeons	Individual level	Treating patients Choose procedure type	Striving for best post-operative results
	Consultants		Provide support, training, and care local hospital	Create confidence and autonomy to use laparoscopy
Indian citizens	Patients		Give preference on procedure type	Quality of life

State
The first named party in the table is the government. This stakeholder has regulatory and funding power primarily with an interest to increase and ensure healthcare quality. The National Council for Accreditation of Hospitals and Health Centres is a government agency where guidelines are developed. These guidelines are a comprehensive set of principles that ensures patients' safety in terms of fire safety and the comprehensive infrastructure of the operation facility, according to Surgeon 8. This also has accreditation levels at entry-level and full level. Usually, hospitals affiliated with insurance companies are part of the accreditation. It is not yet mandatory to meet the accreditation levels, but in the future, it will be. In addition, standard guidelines must be met to receive approval to operate as a hospital. This is monitored locally by supervisory parties. This applies to both private and public hospitals. However, public hospitals differ from private hospitals in terms of government funding. Especially when it comes to the purchase of new equipment, public hospitals get their relatively inexpensive equipment funded by the government without approval. This can be purchased on the Government E-market (GEM). Expensive equipment requires approval from a committee called the user department and the head of the institute. The higher the amount, the more clearances are needed. Depending on the Minister of Health (decision maker), this application is approved earlier or later.

Non-profit Organisations
According to Surgeon 1, 80% of healthcare are privately owned, while 20% of hospitals are government-owned. NGOs are part of the private hospital groups. This group mainly focuses on providing social welfare for the people of India without making a profit. They have the authority to fund health projects, such as enabling the use of laparoscopic instruments in hospitals.

Academic & Training institutes
In Table 5.2 are several academic and training institutes listed. The academic parties are primarily engaged in conducting research and providing science-based solutions to bridge the healthcare gap in India. They first try to identify the clinical needs of rural contexts, after which a cost-friendly solution is offered and sold, according to a professor from the University of Leeds (Table 3.2). One example of such a project is that they were involved in making inexpensive and effective laparoscopic training materials. The result was that 85 surgeons were successfully trained. Several surgeons were involved, including local medical training institutes. The training institutes have the authority to provide training and exchange knowledge on laparoscopic instruments. Most of them are private institutes. Almost all laparoscopic training courses are conducted in India and can be taken partly via the internet. However, most of these institutes are still located in urban areas.

Sales related parties
The next group of stakeholders is mainly involved in the procurement and post-purchase process. Currently, most medical equipment suppliers are from Germany, China and India. According to some surgeons, hospitals would prefer to have more suppliers from India in the future. These companies may not be allowed to make too much profit to keep prices affordable for the entire healthcare system in India. In addition, to sell their equipment, conferences are sometimes used. But local vendors proved to be more effective, especially for hospitals in rural areas. Word of mouth is essential to keep abreast of (new) equipment, such as laparoscopic equipment. This also applies to service providers. They need to be available locally to repair equipment as quickly as possible. Furthermore, donors and (international) funding partners are crucial for rural (private) hospitals. They can supply missing equipment and provide financial support to purchase new equipment.

Hospitals
The following group considers all hospitals types in India. The different types are described at the beginning of this chapter. Their primary interest is to provide care to patients with the help of management and staff that implements government guidelines and policies to enhance the quality of healthcare within hospitals.

Hospital departments
The hospital departments consist of user departments that consider purchase requests and control how new equipment meets technical requirements. On the other hand, purchasing departments are responsible for liaising with suppliers and controlling finances. These departments ensure that purchase-related decisions are made collectively. Therefore, this department is the body that initiates and controls the entire purchasing process. Furthermore, the maintenance department consists of technicians responsible for maintaining the equipment. This personnel must also be trained to handle equipment such as laparoscopic devices.
Lastly, the hospital department is responsible for sterility practices in the hospital. The importance of using laparoscopic instruments is to reduce SSIs, morbidity and mortality. However, not all departments exist in every hospital in India. Mainly urban hospitals are more structured and consist of several departments. In rural areas, a surgeon may have multiple roles representing the departments listed above.

Specialists
Specialists are surgeons (consultants), nurses, hospital directors, biomedical engineers, and anaesthesiologists. Surgeons mainly perform open surgery and partially laparoscopy. However, in India, a group of surgeons is also active as surgeon consultants. This group is called the Association of rural surgeons in India. This team is a group of specialised surgeons affiliated with all rural surgeons. They mainly provide training and assist with surgical procedures on-site by invitation. Through this connection, word of mouth and the practice of laparoscopic surgery have led to its introduction in several rural hospitals.
Other hospital specialists are nurses who have a support role during surgical procedures. This party allows laparoscopy to be performed if they are trained because, in some hospitals, they are also supposed to be responsible for maintaining this equipment. However, biomedical engineers should be responsible for this part. They know the technical and mechanical aspects of these devices. These specialists are especially needed for advanced equipment. Their support role enables hospitals to purchase advanced equipment. Furthermore, anaesthesiologists are also essential specialists in the context of the application of laparoscopic devices. Anaesthesia is required for patients who are treated using laparoscopy. If they are not available, surgeons are mainly limited to open surgery. The last specialist involved in the hospital is the hospital director, sometimes a senior surgeon. This stakeholder includes the board of directors, the CEO, an administrator, and the chief medical director responsible for staffing and whether guidelines are followed. But even for this group of specialists, not all hospitals have the same structure, and one surgeon can have multiple functions in one.

Indian citizens
The last group of stakeholders are the Indian citizens who have the right to access healthcare facilities. The use of laparoscopic instruments benefits the patients above all. They have the power to choose the type of procedure with the best postoperative outcome. However, patients must be informed about the treatment options to make the right decision.

5.3 Barriers

The interviews show that the nine Indian respondents identified n=89 different barriers. Some barriers are grouped and fall under the same category to reduce the total number of barriers.

Costs
Cost is one of the most frequently mentioned barriers due to the interviews and is therefore identified as the first theme.
Lack of money is the most frequently mentioned barrier among cost-related barriers, showing that it is the most critical barrier to equipment purchase. They are followed by the barrier of patients' inability to pay for care, mentioned three times. Disposable equipment is also cost-prohibitive and is considered a barrier. Training costs are also considered a barrier, and finally, due to cost-related challenges, much planning is required to deliver the hospital equipment. The codes related to the listed cost barriers are grouped, are listed in the following table, and discussed further after the table.

Table 5.3: Codes costs barrier

	Frequency
Barriers - Costs	***n=20***
Barrier | Rural | Private & Public | Lack of money	*n=11*
Barrier | Rural | Private | Patients unable to cover procedure cost	*n=3*
Barrier | Urban & Rural | Private | Disposable increases costs	*n=3*
Barrier | Rural | Private | Training associated costs	*n=2*
Barrier | Rural | Private | Planning required due to cost constraints	*n=1*

The cost barrier influenced the purchase process and discouraged surgeons from purchasing new (laparoscopic) equipment. In addition, laparoscopy requires training. Training facilities could enable the practice of advanced equipment. Currently, however, training costs are high. This means that surgeons should think twice before undertaking training. Not only do these costs come into play, but the hospital's operating costs must also be covered by the patients, five surgeons confirmed. However, the patient population in rural areas cannot always afford surgical procedures. As a result, some hospitals can barely make ends meet with operating costs and patient income. This also affects the salaries of surgeons. Therefore, these medical specialists often receive low salaries:

> ***Surgeon 8 (Urban / Rural / Private):*** *"...if the people are still impoverished and can't handle it, then the hospital will also try to reduce the bill and give as much as they can to make it clear to them, but we would encourage them to try to pay the bill as soon as possible for those who can. Those who can't. So we will not withhold their treatment."*

> ***Surgeon 7:*** *"...if they are not a charity based hospital, they will refuse to operate on you if you cannot pay. Because there's no proper insurance system in India that gets covered. So, for example, in a charitable hospital, if a patient can't pay and we know his socioeconomic status is inferior. Then we just have to say OK, fine, you just pay what you can. What can we do? So we have to absorb that loss that we make and recover from people who can pay."*

It has been shown that surgeons are willing to improve the quality of local healthcare. This could be done by purchasing laparoscopic equipment and ancillary equipment such as robots, CT and MRI scans, and getting rid of disposable equipment that causes recurring and unnecessary costs. However, even a basic set of laparoscopic equipment requires a reasonably significant investment and incurs additional costs for supporting equipment, which is a barrier to purchasing such equipment. Moreover, patients cannot bear the cost of improving the quality of care by purchasing advanced equipment because they are often unable to afford treatment. This is seen as a concern by Surgeons 7 and 4.

> ***Surgeon 7:*** *"That is a concern because ours is a trust hospital. We are not running for profit, so our main ideas are to use money paid by the patients for the running cost of the services basically like salaries and stuff like that."*

> ***Surgeon 4:*** *Yeah, it's so mainly the ongoing running cost of the hospital had to be managed with the income from patient care. And very little came as support from outside.*

Because of cost constraints, alternative methods are used to perform minor procedures. For example, it is sometimes impossible to perform a basic urological procedure. Diagnostic cystoscopes are too expensive; they cost about 600,000 rupees (7147.37 euros). However, the demand for this type of basic procedure is increasing. As a result, alternative equipment such as laptops is used for improvisation.

The cost barrier also affects the sterility and workflow of operations. To perform proper laparoscopic procedures, anaesthesia is required. To this end, the personnel and supporting equipment must be available. A distinction is made between spinal anaesthesia and general anaesthesia. In spinal anaesthesia, the lower body is anaesthetised through the spinal cord. This contrasts with general anaesthesia, where gases are used to anaesthetise the patient. General anaesthesia is therefore considered more expensive and blocks the transition from open to laparoscopic surgery supported by several surgeons:

> ***Surgeon 3:*** *"It's not easy to switch from open to laparoscopic because there is a significant learning curve. So and there for a longer time and the need to change from spinal anaesthesia in many cases to general anaesthesia. Which would be more expensive and not so easily available in rural areas?"*

> ***Surgeon 5:*** *"We are trying to do most of the surgeries and spinal anaesthesia here because the equipment for general anaesthesia is not available, and anaesthesiology is also not there, so that is where we started this gasless. Laparoscopically surgeries where we don't need general anaesthesia for laparoscopic surgeries."*

As mentioned, sterility practices are also affected by cost. Therefore, low-cost alternatives are preferred. The most inexpensive solution in this regard is the use of glutaraldehyde. This is a liquid disinfectant. However autoclave is recommended for proper sterilisation of equipment before and after surgery, but the simplest autoclave is often too expensive.

Facilities
The lack of facilities is also considered a barrier to surgical instruments such as laparoscopic instruments. The first and most frequently mentioned barrier concerns the lack of supporting equipment for laparoscopy. This barrier is mentioned much more in proportion to the other barriers. This indicates that the main missing facility is support equipment for laparoscopy. The other barriers and their corresponding codes are as follows:

Table 5.4: Codes lacking facilities

	Frequency
Barriers - Facilities	***n=17***
Barrier | Rural | Private & Public | Lack of support equipment for laparoscopy	n=12
Barrier | Rural | Private & Public | (Partial) lack of availability of laparoscopy	n=2
Barrier | Rural | Private | Lack of proper sterilisation equipment	n=1
Barrier | Rural | Private | Lacking functioning guidelines	n=1
Barrier | Rural | Private | Government guidelines hard to comply with in rural areas	n=1

Facilities within hospitals are relevant to the performance of procedures. Government guidelines are intended facilities to control the quality of care in hospitals. However, not all of these guidelines can be followed in some rural areas because they are mainly tailored to urban settings. This means that some basic guidelines, such as distance between beds, and air conditioning in pharmacy rooms, are not feasible in these areas because (basic) facilities are lacking. Furthermore, inadequate facilities exist at various levels. For example, missing ventilators and lack of resources to perform anaesthesia are mentioned. It also includes a lack of money, which affects the purchasing process. A surgeon says that much planning is needed for these processes. Because if there is not enough money, hospitals become more dependent on other funding sources. This has to be organised by the local hospital purchasing facilities.
In addition, there is often a lack of equipment. This forces surgeons to think laterally. They sometimes have to perform the procedure with the bare minimum of equipment, notes one surgeon. Moreover, the most cited problem in laparoscopic procedures is the lack of support equipment for laparoscopy, like anaesthesia facilities:

> ***Surgeon 5:*** *"...however they do not even have equipment for general anaesthesia so most of them we try and do tender spinal anaesthesia and all the minimal invasive equipment initially we carry it."*

Rural areas often lack the supporting equipment for laparoscopic instruments, including associated camera systems, gases and medications, and the equipment itself. Most surgeons reported having some essential laparoscopic equipment, but this equipment is lacking for more advanced procedures, such as appendectomy. There is a lack not only in private hospitals but also in government hospitals. The following quote emphasises this:

> ***Surgeon 7:*** *"...I would say a large bulk of hospitals in rural India don't have laparoscopic equipment. It's pretty expensive to set it up."*

Supplier
Barriers were also raised on the supply side of surgical instruments. Companies are considered the suppliers of medical equipment. Therefore, the relevant codes relate to profit and

service. No specific barrier stands out in this category of barriers due to the frequency mentioned. Therefore, the barriers can be considered equally important. Supplier-related barriers are shown in Table 5.5.

Table 5.5: Codes supplier barriers

	Frequency
Barriers - Supplier	***n=5***
Barrier | Rural | Private | Companies want to make profit	n=2
Barrier | Urban | Private | Supplier responsible for long repair times	n=2
Barrier | Rural | Private | Lacking fast service from companies	n=1

Some disagreements exist about companies that sell medical equipment and provide additional services. When something gets stuck in remote places, the companies are unable to provide service in time:

> ***Surgeon 8 (Urban / Rural / Private):*** *"...when it comes to maintenance and servicing they are slow, so sometimes we have lot of downtime."*

In addition, the companies sell their instruments at too high a margin. This makes (laparoscopic) instruments more expensive than necessary. Moreover, it seems that companies are better at producing expensive equipment than producing inexpensive devices. A surgeon states that they are hindering the distribution of these types of medical instruments:

> ***Surgeon 4:*** *"...However, equipment manufacturers also hinder the distribution of these devices because of the profits they want to make. The costs go into research and development. So if one could convince equipment manufacturers to make things and not depend so much on how much profit they will make, it will make a big difference to available distribution and cost-effectiveness."*

Human resources

A lack of personnel is also mentioned as a barrier. Issues related to this are mentioned 33 times. Table 5.6 shows that staff shortage is mentioned n=15 times. This indicates that this is a widely recognised problem in private rural hospitals. The culture of a hospital is also considered a barrier. This is mentioned six times, independent of a surgeon's background. Furthermore, lack of confidence is also a barrier to using laparoscopy. After the table, further details on these most pressing barriers and the others are given.

Table 5.6: Codes human resources barriers

	Frequency
Barriers - Human resources	***n=33***
Barrier | Rural | Private & Public | Lack of personnel	n=15
Barrier | Urban & Rural | Private & Public | Culture hospital	n=6
Barrier | Rural | Private | Lack of confidence to use laparoscopy	n=4
Barrier | Rural | Private & Public | Extrinsic motivation to work in urban hospitals	n=3
Barrier | Urban | Public | Lack of accountability government	n=2
Barrier | Urban | Public | Lack of internal communication regarding mistakes	n=1
Barrier | Urban | Public | Convince non medical people about benefits laparoscopy	n=1
Barrier | Rural | Private & Public | Lack of familiarity with laparoscopy	n=1

Lack of personnel is an urgent topic. This includes qualified radiologists, anesthesiologists, paediatricians, and orthopaedics. In the case of laparoscopy, qualified anaesthesiologists are unmissable. Three surgeons confirm this:

> ***Surgeon 9 (Rural / Public)****: "...because of a lack of an anesthesiologist. Only when there is an anaesthesiologist do I go ahead with laparoscopy. Otherwise, we do it all with spinal anaesthesia and without an anaesthesiologist."*

Further, there is a lack of supportive or assistive staff. As a result, there is no shared responsibility. This also leads to a lack of time for surgeons when they need to meet patient demands, which affects the ability to improve the quality of local healthcare. There is no more time to think about improvements and try out new types of equipment. Surgeons, therefore, have to perform more traditional surgeries as a result. :

> ***Surgeon 6:*** *"...it's hard to do something new, to learn something new is very, very hard because our time is short. It eats up our family time. So that's the problem. So we need to have more people helping, more technical people who know what to do, etc."*

> ***Surgeon 3:*** *"The number of surgical procedures that are needed to be done is significantly large, and the workforce for that, including the anaesthesia and the surgeon, is very limited and therefore, with this a resource limitation."*

Another human resource problem is that surgeons are extrinsically motivated by urban facilities and significantly higher wages. Surgeons who are willing to receive training tend to go to urban training facilities to get training. After which, they want to stay for the reasons described. Therefore, consultants/ surgeons try to do their training locally in rural areas. Also, medical students like to work in urban contexts to cover the cost of their studies and because they are trained in urban contexts where all equipment and resources are available during training.
Another human resource issue is surgeons' lack of confidence and ability to perform laparoscopic procedures. There is often no backup or assisting staff. This affects the decision about the procedure type (open versus laparoscopy).
Furthermore, the culture in hospitals determines the sphere in a hospital. Surgeons used the example that when there is much adherence to senior surgeons who have the command and

control, and these surgeons are not familiar with laparoscopic instruments in their workflows, the application of these instruments is hindered.

> ***Surgeon 7:*** *"...most of these hospitals that I work with are under an organisation. So there's a set of the chain of command and control. There's a level of seniority. So you just have to adhere to that.", "The thing is, of course, many of these hospitals maybe are run by, say, the older generation of surgeons. They've never been trained. So they prefer to continue doing their way."*

Added to this are the responses that hospital staff prefer to stick to routines, which creates resistance to changing workflows. This also influences the decision to purchase new equipment from which supplier. Some hospitals want to be as independent as possible concerning supplying parties.

Patients

Barriers also affect patients' access to health care. Not many barriers related to patients were found. Indian surgeons participated in the interviews and not patients, explaining the low number of patient-related barriers. Moreover, two barriers, mainly related to private rural hospitals, were mentioned equally, while one barrier was mentioned in the context of urban public hospitals. None of the barriers seems to be more important than the others, judging by the frequency mentioned and is thus equally important. The mentioned barriers are listed in the following table:

Table 5.7: Codes patient barriers

	Frequency
Barriers - Patients	***n=5***
Barrier | Rural | Private | Lack of insurance for rural hospitals	n=2
Barrier | Rural | Private & Public | Access to healthcare	n=2
Barrier | Urban | Public | Awareness of benefits procedure type	n=1

In private rural settings, insurance systems do not cover the cost of healthcare for patients. This means that patients must be able to pay for their care. However, in rural areas, patients cannot always bear these costs, as illustrated in the section on barriers to cost. This affects the incoming costs of hospitals. Therefore, it also ultimately affects access to healthcare. In addition, patients often have the option to choose the type of surgery. However, it turned out that patients are not always aware of the advantages of laparoscopy. As a result, open surgery, which is still the most commonly performed surgical technique, is chosen.

Infrastructure

Infrastructure is a means of accessing healthcare facilities, but the infrastructure within hospitals must also support the use of facilities. Barriers to infrastructure relate to the stable provision of essential services and the lack of infrastructure around hospitals. Barriers are mentioned four times, indicating that both are considered important. The following codes were found concerning the infrastructure barriers:

Table 5.8: Codes lacking infrastructure

	Frequency
Barriers - Infrastructure	***n=8***
Barrier | Rural | Lack of stable supply basic resources	n=4
Barrier | Rural | Lacking infrastructure around hospitals	n=4

Providing basic services such as electricity and gas is a relevant element for performing procedures. Aesthetic gas and carbon dioxide are especially needed for laparoscopic procedures. This is often sourced from neighbouring or urban areas. However, the stability of supply is not always the case. This is also the case with electricity supply. An unstable supply causes spikes, which is insufficient for equipment that runs on electricity. Therefore, generators are often used as a backup system.
Also, roads are not always available. This hampers the supply of medical equipment and the accessibility for patients to reach hospitals. Also, consulting surgeons experience trouble reaching local hospitals.

> ***Surgeon 3:*** *"...those are villages in the forest or on the edge of the forest, where the roads are often not all-season roads, so it's hard to access care."*

Training and Support
The next theme identified in relation to barriers to private hospitals in rural areas concerns barriers related to training and support. Lack of training is a crucial barrier in private rural contexts, mentioned n=24 times during the interviews. Besides training and support, this barrier is the most frequently mentioned barrier when all barriers are considered. In addition, lack of support and lack of knowledge are important barriers that need to be addressed. All barriers related to training and support are shown in the following table:

Table 5.9: Codes lacking training and support

	Frequency
Barriers - Training & Support	***n=39***
Barrier | Rural | Private | Lack of training	n=24
Barrier | Rural & Urban | Private & Public | Lack of support	n=6
Barrier | Rural | Private | Lack of knowledge	n=5
Barrier | Urban | Public | Guidelines not followed properly	n=2
Barrier | Rural & Urban | Private | Lack of emphasised care in rural areas	n=2

Furthermore, lack of training is one of the most frequently mentioned barriers. The interviews revealed that training is required to perform laparoscopic procedures. Several surgeons admitted that they are not adequately trained to perform laparoscopic procedures:

> ***Surgeon 6:*** *" ...so that's why we have still not invested in laparoscopy in a big way because. We are not trained enough."*

Local healthcare professionals must be trained to become confident and competent in performing laparoscopies. If this is not the case, the benefits of laparoscopic procedures do not outweigh the benefits of open procedures in terms of efficiency and safety. Moreover, there is no incentive

to purchase laparoscopic equipment. Because then the costs will outweigh the benefits.
Especially in rural areas, there is a lack of training, often underemphasised. Several surgeons agree that training in urban areas is out of proportion compared to training in rural areas. Because the demand is higher in rural areas than in urban areas. Moreover, medical students are already trained during their studies primarily with advanced equipment, while this equipment is often not available in rural settings. A skewed relationship exists in this regard as well.

> ***Surgeon 2:*** *"Most training happens in tertiary care hospitals or teaching hospitals. Medical colleges, which I don't believe is the way because there is like an ocean of learning to be done in rural areas. Patients have a spectrum of complaints, so there is a great learning potential."*

Senior surgeons were often not trained during their studies. This is since laparoscopy was not practised several years ago. Therefore, there was no incentive to learn this technique. To be competent, additional training in their spare time is often required. For this, training facilities are needed. However, there is a lack of national training programs with periodic mentoring. This makes surgeons dependent on consultants who must provide the training locally.

Furthermore, lack of knowledge results in hospital staff lacking the knowledge to use specific equipment. Biomedical engineers are lacking in knowledge of the mechanical aspects of the equipment. In addition, poor hospitals are often unable to purchase advanced equipment, as already indicated. Therefore, other sources of funding are sometimes used. However, this causes other problems. There is a misalignment in terms of available knowledge on using the donated equipment. As a result, equipment is lying around unused in the hospital. Also, equipment is not used in the way it is intended. Single-use equipment is often reused until it is not reusable anymore.

On-site support is also needed to use the equipment and manage human resources. Experts in health technology or medical equipment are usually not available. This is also related to the lack of maintenance of the equipment. Especially when the equipment becomes more sophisticated, support in maintenance and repair is required. Most surgeons are not qualified to do this, as they are responsible for the procedures, not the technical aspects. Even technicians are not able to maintain and repair devices:

> ***Surgeon 2:*** *"So the technician who is currently with us is not trained in all these aspects of things, so if you're buying from a new company, we would definitely want the company to be involved in the maintenance and repairs etc."*

The final barrier, which was less frequently mentioned, is that following guidelines and checklists are essential to optimise local healthcare quality and the safety of procedures. Even though guidelines work well, this is lacking, according to a surgeon from an urban setting. Margins of error need to be reduced.

Acquisition
The final sub-theme concerns barriers related to the acquisition. This mainly involves barriers related to the purchase of new equipment. The relevant codes are listed in Table **??**. The lack of government support is considered important by all backgrounds and followed by the challenge of convincing parties regarding health expenditures, the long process of getting new equipment

Table 5.10: Codes acquisition barriers

	Frequency
Barriers - Acquisition	***n=16***
Barrier | Rural & Urban | Private & Public | Lacking government support	n=9
Barrier | Urban | Public | Hard to convince parties related to health expenditure	n=3
Barrier | Urban | Public | Long process to get new equipment	n=2
Barrier | Urban | Public | Paper work	n=2

and much paperwork. In addition, it appeared that barriers related to the government are mostly mentioned in urban public contexts.
Agreements on purchasing decisions in public hospitals require multiple levels of approval. This can take up to seven to eight years in some cases. Depending on who needs to approve, the process will take longer or not. This is seen as a barrier to getting and trying out new equipment. Especially when the type of equipment is different from what surgeons are used to working with. Approvals and the length of the process are also determined by the amount the equipment costs. The higher the cost, the more approvals are required, and the more people are involved.

The purchasing process often involves the government, especially for public hospitals. For private hospitals, the government provides no or little financing. These hospitals struggle with initial financing. Added to this, due to government restrictions in India, fewer foreign contributions are coming into mission hospitals, for example. As a result, local hospitals or surgeons are forced to purchase their equipment. Even when these hospitals participate in government health programs:

> ***Surgeon 6:*** *"We work with the government, we provide them, we work with them and stuff, but we don't get any funds from the government right now."*

This is in contrast to an urban government hospital where the government bears (part of) the cost of new equipment if there is an excellent reason to purchase equipment. However, other barriers arise with this type of hospital. For example, there are difficulties in convincing politicians and non-medical stakeholders of the utility of a particular device or equipment:

> ***Surgeon 1 (Urban / Public):*** *"I think there are bottlenecks, and I think the biggest for us is to convince the non-medical people about the utility of a specific product, especially when it's an expensive item. For example, just making them understand that it is also important to have robotic surgery for a public hospital, so it is difficult."*

The last barrier raised by Indian surgeons related to urban government hospitals has to do with documentation. Documentation is an essential part of the processes in the hospital. However, much time goes into this. Online systems are preferable to be more efficient and make processes run more smoothly. This also has to do with the climate footprint, part of the government guidelines.

Academic and Innovators experts

From an academic and innovator's point of view, several barriers have also been raised. First, CE certification in the medical field is a considerable challenge. Getting a product certified takes a long time, and in addition, it creates a mismatch between the context factors and the developed equipment, and the costs for validation are high, according to all academic and innovators participants. For example, the LMIC expert uses a case where surgeons can no longer use hand-controlled autoclaves. They must be digitised because of sterility standard requirements. However, they do not always fit in the infrastructure:

> ***Expert LMICs (translated):*** *"Technology, hand-held autoclaves that have a greater degree of survival than the advanced devices. That just shows every time. As long as the infrastructure, electricity, water supply, and knowledge and logistics needed to support that equipment are not available. It's just not going to work. It's not possible."*

This increasing quality of medical devices is also a reason for concern, according to the TU Delft professor:

> ***TU Delft professor (translated):*** *"That's what you see more and more, that's the problem that's going to arise now, though, which is that here in a high-income setting, our equipment is becoming more and more complex, it's becoming more and more automatic, and they can do more and more, they're becoming more and more expensive, so not at all suitable for developing countries by donations will become less and less. And here, the repair and people themselves someone is just brought in, they have companies just on standby. Yes, that's just not possible in remote areas, so this problem is getting bigger and bigger."*

Furthermore, the TU Delft professor and the PhD student endorse the lack of knowledge, especially in rural areas. The medical (support) staff often has a basic education. Therefore, laparoscopy would not be the preferred option at first glance, given the advances in surgical techniques. In addition, hierarchical structures are seen as a barrier:

> ***PhD Student BME (translated):*** *"So the surgeon is actually at the top of the pyramid, and he is responsible for everything that happens in the surgical department. So eh, that means that it's even about subjects that he doesn't know much about, so the supporting logistics of cleaning, sterilising, purchasing, maintenance, things like that. He still wants to advise on that, without really knowing much about it. So what you want is for the support staff to have a more autonomous role in relation to the surgeon."*

Also, Western companies are often reluctant to target LMICs while also targeting HICs. Because new business models are needed. And if an instrument can be cheaper, more robust and of the same quality as the products designed for HICs, disagreement arises in HIC hospitals that they have to pay more for the products while the same products are in the company's portfolio can also be made cheaper. According to the PhD candidate, new parties or companies specifically focused on LMICs are needed. The last barrier mentioned is related to awareness of the barriers. Local hospitals will not change if they do not recognise how surgical procedures can be improved. In addition, the TU Delft professor observes that cheap Chinese equipment is often used as a solution due to profit margin and lack of money. However, this equipment often does not have the desired quality. Local awareness about having to focus much more on quality than price is a learning process.

5.4 Incentives

This section reports on the reasons for using or not using laparoscopy compared to open surgery for a specific type of treatment. This comparison is based and functions on types of procedures performed with open surgery but can also be performed minimally invasively.
First, the advantages of laparoscopy are outlined, and then the disadvantages are described. In table 5.11 are all the incentives listed. This table showed that surgeons' most widely recognised shared incentive is that laparoscopy provides a faster return to work for patients. Furthermore, laparoscopy is considered safer, and because of its minimally invasive nature, it brings advantages over open surgery. The disadvantages, which have to do with cost, are not often mentioned.

Table 5.11: Overview of incentives to use laparoscopy

	Frequency
Incentives laparoscopy	***n=23***
Incentives | Rural & Urban | Private & Public | Advantages laparoscopy faster back to work time	n=9
Incentives | Rural | Private | Advantages laparoscopy minimal invasive	n=5
Incentives | Rural | Private | Advantages laparoscopy safer	n=4
Incentives | Rural & Urban | Private |Advantages laparoscopy efficiency	n=2
Incentives | Urban | Private | Advantages laparoscopy no large cost difference	n=2
Incentives | Rural | Private | Disadvantages laparoscopy cost and investment	n=1

The first incentive to use laparoscopy has to do with the efficiency of the procedures. If a surgeon is well trained, the procedure time can be reduced. One surgeon used gallbladder surgery as an example:

> ***Surgeon 8 (Urban / Rural / Private):*** *"...45 minutes laparoscopy, sometimes even half an hour. Open would give us an hour and a half to almost 2 hours. There is a definite time benefit."*

The next advantage of laparoscopy is primarily a benefit to the patient. The recovery time is much shorter compared to open surgery. On this, six of the nine surgeons agree. The faster recovery allows patients to return to work sooner and increases long-term health. It also reduces the surgeons' responsibility for the patient's health, which is sometimes a burden for surgeons. The recovery time depends on the morbidity and complications after surgery, which is also significantly less. This is a particularly crucial aspect for poor patients who are breadwinners.

> ***Surgeon 4:*** *"More and more people are resorting to laparoscopic surgery also because surgeons have understood the advantage of fewer complications. And faster return time to normal activities lessens the hospital stay. It lessens the cost, and it also lessens the morbidity to some extent."*

> ***Surgeon 1 (Urban / Public):*** *"The main benefit of laparoscopy is that you get back to work early."*

Patients are also becoming increasingly aware of the benefits of these types of procedures, as some surgeons explain the benefits of the procedures, intending to do what is best for the patient in terms of the procedure's outcome. Therefore, laparoscopy is being used more depending

on the type of disease. These benefits have increased the acceptance of this new technology through experience and word of mouth.

Furthermore, the minimally invasive nature of laparoscopy offers cosmetic benefits and less postoperative pain and trauma. In the process, it also reduces the risk of wound infections. Therefore, laparoscopy is considered safer for patients.

> ***Surgeon 2:*** *"it's got definite benefits compared to open surgery in terms of early recovery and less pain, no scar."*

> ***Surgeon 3:*** *The operative time makes this surgical procedure safe because of its bipolar nature. There is less chance of unintentional tissue injury.*

Another incentive is that laparoscopy is cheaper or equally beneficial to the patient than open surgery, considering the consumables used for the surgery. Two surgeons mentioned this. Although disposables are the highest cost, there are not many differences. One surgeon indicated that it is even cheaper than open surgery. However, ongoing costs could be cheaper, but the initial investment in laparoscopic equipment is relatively high, as already mentioned, which is a disadvantage of laparoscopy.

> ***Surgeon 8 (Urban / Rural / Private):*** *"We are not finding much difference in the cost. Open and laparoscopy are almost the same."*

Academic and innovators experts
The CEO of the company that develops laparoscopic instruments has the incentive to enable the application of surgical instruments in LMICs as well. HICs focus mainly on optimising equipment, whereas in LMICs, these instruments can mean the difference between life and death. This also motivates the other academic and innovators interviewees to be involved in projects related to the improvement of the local healthcare system.
Furthermore, a professor from the University of Leeds, who has much experience in India, explains that Indian surgeons are well motivated to make the most of things even when there is much scarcity. This motivates them to improve health facilities as well.

5.5 Strategies

The findings of the interviews regarding strategies and recommendations can be categorised using combined codes following the different stakeholder groups shown in Table 5.2. This subsection identifies stakeholders associated with a specific action or strategy enabling laparoscopic device adoption. However, not every individual stakeholder was associated with a strategy in the interviews. Therefore, not all groups of individuals are mentioned in this section.

State
For the government agencies, responsibility and accountability are essential aspects that can ensure that the quality of local health care can be guaranteed and inequality disappears. In addition, according to the surgeons, there is a need for the implementation of related health policies. However, this is not mentioned much, nor are the other government-related strategies.

Table 5.12: Overview of government-related strategies

	Frequency
Strategies Stakeholders State	***n=12***
Strategy | Rural & Urban | Private & Public | Responsibility & accountability	n=8
Strategy | Rural | Private | Healthcare policies	n=2
Strategy | Rural | Private | Bridge divide rich and poor	n=1
Strategy | Rural | Private | Make laparoscopy available	n=1

The following codes were found:

The first strategy relates to government accountability and responsibility. Currently, there is a considerable gap within the healthcare system in India. According to several surgeons, it is up to the government to take responsibility for this gap, and efforts must be made to bridge it using health policies—both at the national and regional levels. For example, infrastructure is something specific for the government to improve, enabling the availability of laparoscopic instruments. The availability of laparoscopic instruments should be equal across the country. Larger cities generally have better access to medical facilities than small and rural areas. Furthermore, public-private partnership programs can bring together governmental and non-governmental parties/hospitals. In addition, financial support for NGOs and private organisations is also a strategy for improving local healthcare. But for this effort to succeed, the government must be more accountable, as most policies already exist and support poor people with primary care.

> ***Surgeon 6:*** *"The government has some of these programs. It's called the public-private partnership where the government tries to work with the non-government organisations to set up some programs."*

> ***Surgeon 7:*** *"if there were proper accountability of the government policies in terms of implementation of the programs, many of these rural places would be benefited even without a private hospital or a charity centre doing."*

Academic and Training Institutes

Codes related to training as a strategy to enable the use of laparoscopic devices were mentioned by all surgeons surveyed. This relatively high frequency is consistent with the high frequency of barriers related to training. Furthermore, competence, trust, and independence were mentioned n=5 times, and this is an essential strategy that needs to be addressed and researched to optimise local health care. The following table shows the codes.

Table 5.13: Overview of academic and training institutes-related strategies

	Frequency
Strategies Stakeholders Academic and training institutes	***n=21***
Strategy | Rural & Urban | Private & Public | Provide local training (and tools)	n=12
Strategy | Rural | Private | Create competence, confidence, and independence to perform laparoscopic procedures	n=5
Strategy | Rural | Private & Public | Research to optimise local healthcare	n=4

Training is a crucial element in the implementation of laparoscopy practice. The barriers section shows that lack of training is seen as a barrier to the use of laparoscopy. Therefore, both

training institutes and academic institutions have training facilities. A strategic move is that if students and junior surgeons are well trained, they will apply it in practice. They are often eager to learn and not bound by conservative practices. Furthermore, if hospitals provide training internally and get a hybrid character to make training easier to access, this reduces the training costs, and hospitals are gradually becoming a training centres. Next to this, on-site training in small local hospitals is preferred. Often such hospitals are run by one surgeon, who cannot be missed as they often work seven days a week. Training institutes are also part of the strategy to improve knowledge and skills concerning laparoscopy.

> ***Surgeon 4:****"we use the help of an open network of bigger centres which are not university-affiliated but large training institutions who are happy paying these people."*

> *"...by end-large the local people were identified to be adequate by training."*

For laparoscopic training, inexpensive training tools can be used to gain experience and learn the basic skills without incurring many training costs. This was also one of the projects of the University of Leeds to offer cheap and effective training boxes. These boxes are equipped with a lamp and a camera. Combined with experience with a patient with the help of a mentor, these tools proved to be effective. International academic institutions often conduct research that is crucial to enabling innovation. Research collaboration is a strategy to provide scientific solutions. Often (international) academic institutions fund this research. The Association of Rural Surgeons of India is also involved in this research. All these parties together are focused on implementing solutions to healthcare problems.

The last code relates to building confidence and competence to perform laparoscopic procedures independently. This is an indirect result of the training provided. The result is that more laparoscopy is performed, and the procedures become safer and more efficient, both for the patients and for the surgeons.

> ***Surgeon 4:*** *"...building the confidence of the surgeons and although they know the technique, building it, the confidence that they can do it on their own is one that you make them confident and competent."*

> ***Surgeon 2:*** *"The training should be catered in such a way that you should be independently and confidently."*

Sales related parties

Also, strategies to enable the adoption of laparoscopic instruments were raised in the interviews with the sales-related parties. When analysing Table 5.14 shows that there are many codes for adapting the medical device to the context. These primary design requirements need to be considered when targeting this device to hospitals in India. An additional table was created to clarify what these requirements are. All nine Indian surgeons came up with these context-specific requirements for laparoscopic devices. In addition, laparoscopy must be made financially available by sales-related parties. Furthermore, local salespersons are required additional (free) training. These aspects are important because they were mentioned relatively often during the interviews.

Table 5.14: Overview of sales-related parties strategies

	Frequency
Strategies Stakeholders sales related parties	***n=56***
Strategy | Rural | Private & Public | Adapt the laparoscopy devices to its contexts	n=32
Strategy | Rural & Urban | Private & Public | Make laparoscopy financial available	n=10
Strategy | Rural | Private | Provide local salespersons and service	n=8
Strategy | Rural | Private & Public | Provide (free) training	n=6

One of the frequently mentioned barriers is cost. The basic setup of laparoscopic instruments requires a significant investment, which not all hospitals can afford. Therefore, the instruments must become financial available. Companies are responsible for this and need to make this cost-effective equipment:

> ***Surgeon 4:*** *"Make available equipment that is cheaper and more cost-effective. So that it would not become exorbitantly expensive for someone to begin laparoscopy."*

> ***Surgeon 5:*** *"The thing is what we really need is some people to work on or do research on low-cost equipment which is specific for rural area."*

Costs are associated with the research and development process of laparoscopic devices. Therefore, design requirements must be taken into account. The following table shows these requirements.

Table 5.15: Design requirement of laparoscopic instruments

	Frequency
Strategy- Design Requirements	***n=32***
Urban | Public | Climate footprint	n=2
Rural | Private | Consistent model	n=1
Rural & Urban | Private | Durability	n=2
Rural | Private | Easy to repair/maintain	n=6
Rural & Urban | Private | Ergonomic	n=1
Rural & Urban | Private | Generic	n=1
Rural | Private | Intuitive / ease of use	n=3
Rural | Private | Operate with electricity fluctuations	n=2
Rural & Urban | Private | Quality	n=2
Rural & Urban | Private | Reusable	n=6
Rural | Private | Robust	n=1
Rural | Private | Sterilising	n=1
Rural | Private | The lesser parts the better	n=2
Rural & Urban | Private | Upgrade possible	n=1
Rural & Urban | Private | Multi-functional	n=1

Two context-specific requirements are mentioned six times and are considered necessary, following the academic and innovator experts' perspectives. These are reusability and easy to maintain. Reusable equipment is essential for hospitals, primarily to reduce equipment costs. Some hospitals do not even buy disposable equipment. Especially in rural areas, reusable equipment is cost-saving indirectly for patients but also for hospitals:

> ***Surgeon 6:*** *There is no doubt it has to be reusable if it's going to be in a rural area, it has to be reusable."*

Furthermore, maintenance is also essential. Laparoscopic devices should be easily repairable by local technicians or surgeons. This also applies to parts of the devices to avoid delays. Due to other barriers, service is not always available within a short time.

> ***Surgeon 4:****"...if something goes wrong it will never be repaired, and then it's a white elephant."*

This leads to the following code about the required service from companies. Service entails repair service but also a warranty from the suppliers. Seven surgeons agree that this additional service is required, preferably by a local salesperson, and that it needs to be part of the company contract when buying new equipment.

> ***Surgeon 2:*** *"...so if you're buying from a new company, we would definitely want the company to be involved in the maintenance and repairs etc."*

The last supplier-related code is about the training. The following code shows that local hospitals expect training from the supplier.

> ***Surgeon 7:*** *"They have to give you on site training on how to use it."*

Especially when the equipment becomes more complicated; otherwise, it will not be used properly and will not serve its purpose. Therefore, a company's strategy to enable the adoption of laparoscopy is to provide additional service in the form of training after the purchase.

Hospitals

Strategies related to hospitals were primarily the application of checklists. Given the frequency of n=10, this is an important aspect. Furthermore, the connection between hospitals and insurers is vital for accessible health care for all types of patients. In addition, quality control and standardisation can ensure the local quality of health care. Several other hospital-related strategies are mentioned. However, compared to the three first mentioned strategies, they are mentioned less frequently. The list of strategies is as follows:

Table 5.16: Overview of hospital-related strategies

	Frequency
Strategies Stakeholders Hospitals	***n=20***
Strategy | Rural & Urban | Private & Public | Use checklists	n=10
Strategy | Rural | Private | Connect to insurance instances	n=4
Strategy | Rural & Urban | Private | Provide quality control and standardisation	n=3
Strategy | Urban | Private | Build community health programs	n=1
Strategy | Rural | Private & Public | Higher wages	n=1
Strategy | Urban | Public | Contacts with politicians	n=1

First, hospitals are recommended to implement checklists. Most interviewed surgeons already use (adapted) checklists from the government and WHO. However, one surgeon also indicated that checklists are required for sterility practices. If these checklists are not followed, there would be a breakdown in communication between hospital teams and departments, resulting in errors in the treatment of patients.
Secondly, improving the local quality of healthcare requires quality control and standard procedures among hospitals. The results of the same type of procedures should not vary from hospital to hospital. Moreover, establishing a community health program in different regions is the first step to achieving standardisation and higher healthcare quality between different hospitals. This type of project requires resources, including personnel. However, it does not appear to be attractive for many surgeons to work in rural areas. Therefore, additional funds are needed to give surgeons added value to operate (also) in rural areas.
Another strategy relates to the purchase of new equipment. Mainly when it comes to a government hospital, it is crucial to have an excellent network to get approval to purchase new equipment. Therefore, says a surgeon, it is necessary to approach the right politician as there is much diversity in this.
The last code refers to the connection and policy change regarding health insurance. They can play an essential role in the healthcare system, especially in the private sector, where hospitals are usually not connected to health insurance. When this connection exists, more money will be available to buy equipment, pay higher salaries, and poor patients will have better access to health facilities:

> ***Surgeon 1 (Urban | Public):*** *"...they will give financial support to the private hospitals, or even people directly, so that they can get their health covered by the health insurance model, in India also, especially in the rural areas."*

Specialists
The final group of stakeholders are the specialist. Corresponding strategies are identified, like shown in Table 5.17. All strategies related to specialists are mentioned in the same context with the same frequency. Therefore, engaging consultants, spreading word of mouth and creating awareness about laparoscopy are equally important.

Table 5.17: Overview of specialists-related strategies

	Frequency
Strategies Stakeholders Specialists	***n=6***
Strategy | Rural | Private | Use consultants	n=2
Strategy | Rural | Private | Spread word of mouth	n=2
Strategy | Rural | Private | Create awareness about laparoscopy	n=2

Consultants, who are surgeons, play a vital role in disseminating knowledge and skills between different hospitals. These types of hospitals are mainly private rural hospitals. Even when hospitals are short-staffed, these consultants can help by performing local surgeries. They often bring their own equipment, including laparoscopic equipment. In this way, they create awareness of this equipment and its use through word of mouth. Moreover, this also stimulates innovation locally. This approach is proving to be very effective, and local surgeons are eager to learn how to work with laparoscopic equipment.

Surgeon 5: *"...local surgeons are interested in learning about minimally invasive surgery, either laparoscopy or urology. It's great once they learn it themselves. Then we move on to the next place."*

Cooperation between stakeholder groups

Not all strategies are focused on one stakeholder group; strategies among stakeholder groups have also been identified. However, Indian surgeons have not implied many strategies that consider collaboration among stakeholders. The mentioned strategy is shown in the following table:

Table 5.18: Overview of cooperation between stakeholders strategies

	Frequency
Strategies cooperation between stakeholder groups	***n=5***
Strategy | Rural | Private | Popularise laparoscopy with collaboration between stakeholders	n=5

Collaboration among stakeholder groups is important to enabling the adoption of laparoscopic instruments. For example, the Association of Rural Surgeons in India works with international academic institutions and companies to enable innovative solutions by conducting research, providing funding and developing instruments. For example, TU Delft runs a project with surgeons in India to optimise sterilisation processes. In addition, a surgeon is proposing how specifically laparoscopic instruments can be popularised in India using cooperative efforts:

Surgeon 4: *"I think there should be surgical groups that have a special interest. In the field of laparoscopic surgery, there are associations. There are national organisations. Some groups are interest groups. And they need to come together to try to develop a program that will allow you to popularise this technique. Once you popularise it, you get the other stakeholders involved, like the manufacturers. And the government can make sure that this becomes more viable so that instruments become cheaper and more available. Insurance companies are paying more for laparoscopic surgery. The government makes the regulations easier for people to get certified as laparoscopic surgeons. So I think the first thing is to create this interest group and then slowly push it forward unless there is a core group or an organisation whose mission is to popularise laparoscopic surgery. That's not going to happen. One hospital might be able to popularise in their area, but they can't. What happens is they have enough work to do in their own hospital. They can't then be involved in training people who go to other places, running seminars and so on, so it has to be a group of people, maybe 5 or 10 mission hospitals together, and different surgeons who take turns do this, and each hospital will have a turn in the year to do their part of it."*

Academic and innovators experts

From the academic and innovator experts' perspective, the LMIC expert argues that the socioeconomic context must be identified for a new technology to be successful in LMICs. In addition, an understanding of the flow of money concerning the availability of money and where it comes from is needed. Furthermore, sterility would be essential. Especially considering laparoscopic instruments, which are often hollow tubes that are difficult to clean. Therefore, this aspect should be considered when developing the equipment, as it is not preferable to have single-use equipment. If dissection and sterilisation are not included in the design, this will introduce a

new problem, namely infections.
The TU Delft-, University of Leeds professor and PhD student adds that design requirements like robustness and cheap, modular equipment are needed to adopt laparoscopic instruments. Remarkably, considering the context barriers:

> ***PhD student (translated):*** *"A lot can be done quickly on a local scale if you introduce inexpensive instrumentation and provide good training with it, but if you look at it from a national system, the whole system within such a hospital has to be in better shape."*

The professor from the University of Leeds further points out that environmental aspects must also be considered, given global warming. Therefore, disposable equipment should be excluded:

> ***Professor Leeds university:*** *"I think now everything should be put under a big umbrella, which is environmental needs and then redesign everything, also considering commercialisation, scalability, and material cost."*

Good rural training can be delivered using low-cost and effective training tools. The Leeds professor was involved in a project of design control, prototyping and testing along with the Global Health Research Group in surgical technologies (GHRG), funded by the National Institute for Health Research (NIHR) and local Indian surgeons. This training tool is an inexpensive simulator that can provide training for laparoscopy. This tool has already proven effective for 85 surgeons.

Furthermore, a national policy with protocols on applying laparoscopic procedures is needed. According to the PhD student, if this is not implemented, not all hospitals will start using this type of procedure due to resistance to change and lack of knowledge.
Moreover, the TU Delft professor points out that obtaining CE certificates requires close contact with end-users. To make this process run smoothly, it is necessary to have contacts with people with a good network who have some experience with medical devices, hospital evaluation and certification processes. Also, validation processes need to occur in the country of development instead of at the end-users hospital. Lastly, the professor from Leeds university argues that scalability and commercialisation should be standardised so that medical approvals are more efficient.

Five strategies for the diffusion of laparoscopic instruments in LMICs are also indicated by the company's CEO developing laparoscopic instruments. First, it is suggested that in these countries, the starting point should be the top edge hospitals using conferences, after which the technology can be spread throughout the country. As rural surgeons travel to urban hospitals for training, they see the new innovative medical equipment being used, raising awareness. Especially since the rural context is not equipped for the new instruments, the results of the procedures and the perceived user experience are less reliable than in urban hospitals. In relation to this, qualitative representative product feedback is required from local physicians and surgeons to improve the product more specifically for specific situations.
Second, it is further argued that local distribution centres and salespeople are essential, who can also engage in the repair service. These individuals are needed to overcome cultural and language barriers. Thus, a local support network is required.
Third, the price barrier is difficult to overcome for a commercial company. Since a small amount

of money can make all the difference whether they buy or not for these hospitals.

> ***CEO (translated):*** *"I think to really become successful with these types of tools in the poorer countries, you first have to have enough customers in the rich countries, because then you get a larger scale, so then we can place larger orders with our producers and then that price goes down and then if those prices are low enough, then they can start working in those types of countries."*

Fourth, users, from surgeons to nurses to cleaning staff, must be trained to use these instruments.

Finally, certification must be completed. India has a different system than other countries in the world. So before one can and is allowed to market the product at all, it must be certified. This requires several steps that cost money.

5.6 Overview of interview findings

After the findings from the interviews, a conclusion can be drawn using an overview of the most critical aspect related to stakeholders, barriers, incentives and strategies. Not all codes are included. Only per aspect, the most frequently mentioned items are listed and incorporated in Table 5.19. This includes aspects that are mentioned twice or more often. If things are mentioned only once, it may indicate that it is less critical and not an aspect shared by several interviewees. Furthermore, the perspective of academic experts and innovators has also been incorporated into the table.

For each stakeholder group, barriers are listed that relate to the stakeholder group. Furthermore, incentives are mainly mentioned for patients. However, several incentives following surgeons have also been identified next to this. Finally, the strategies are listed at the stakeholder groups responsible for implementing the strategies.

Table 5.19: Overview of results of interviews

Stakeholder	***Barriers***	***Incentives***	***Strategies***
State			
	• Lack of accountability government • Lack of emphasised care rural areas • Lacking government support		• Responsibility & Accountability to implement policies and regulations • Healthcare policies (e.g. a national policy with protocols on the application of laparoscopic procedures is needed)

Table 5.19 continued from previous page

Stakeholder	*Barriers*	*Incentives*	*Strategies*
	• Hard to convince parties related to health expenditures		
Insurance providers			
	• Lack of insurance rural hospitals		• Provide insurance for all types of hospitals
Academical & Training institutes			
	• Lack of training • Training associated costs • CE certification	• Increase local healthcare quality	• Provide local training and tools • Create competence, confidence, and independence • Research to optimise local healthcare • Identify socioeconomic context
Sales-related parties			
	• Companies wants to make profit (profit margins) • Long repair times • CE certification • Products not adapted to context		• Adapt the laparoscopy devices to its contexts • Make laparoscopy financial available • Provide local salespersons and service • Provide (free) training • Validation processes in the country of origin • Start business in urban settings
Hospitals			
	• Lack of personnel • Culture hospital • Disposable increases the costs • Lack of support equipment for laparoscopy • Lack of availability laparoscopy	• Efficiency	• Connect to insurance providers • Use checklists • Provide quality control and standardisation • Perceived user experience of equipment required

Table 5.19 continued from previous page

Stakeholder	*Barriers*	*Incentives*	*Strategies*
	• Lack of stable supply basic resources • Lacking infrastructure around hospitals • Guidelines not followed properly • Long process to get new equipment		
Specialists			
	• Lack of confidence to use laparoscopy • Extrinsic motivation to work in urban settings • Lack of support • Lack of knowledge • Paper work		• Use consultants • Spread word of mouth • Create awareness about laparoscopy • Contacts to smooth out CE, hospital evaluation and certification processes
Indian citizens			
	• Lack of money • Patients unable to cover procedure costs • Lack of access to healthcare	• Faster back to work time • Minimal invasive • Safer • No large costs differences	

5.7 Interpretation on results from literature and interviews

This chapter compares the data from the literature review with the empirical data from the interviews. Each SQ is discussed separately. Further, unexpected results are described, and their significance is evaluated, after which limitations and implications for future research are described.

5.7.1 Comparison literature review and interviews

This section begins by looking for similarities and differences between the data from the literature review and the data from the interviews. The main differences are highlighted for each sub-question. It then discusses the extent to which the data are generalisable to the application of surgical instruments in LMICs. This section concludes with an analysis of contextual factors and attempts to identify patterns regarding barriers, incentives, and strategies related to hospital backgrounds.

Stakeholders
Following the data collected on the stakeholders involved, it can be concluded that all the stakeholders from the literature overlap with the data from the interviews. Figure 5.1 provides an overview of all identified stakeholders in this study. The overlapping parties from literature and interviews are marked with an asterisk. Interestingly, the literature review revealed that the media as a stakeholder could spread word of mouth. However, the literature does not elaborate on this stakeholder. Moreover, this party did not emerge in the interviews.

Furthermore, a distinction was made between internal and external stakeholders for the stakeholder overview. Internal stakeholders have a direct relationship related to the technology, while external stakeholders have an indirect influence on the technology (Investopedia, 2019). Sales-related parties are considered internal stakeholders because this party directly influences the design and sales-related aspects of laparoscopic instruments. Direct influence also exists on organisational and individual level parties. While the state, non-profit organisations, academic and training institutions and the media have an indirect relationship.

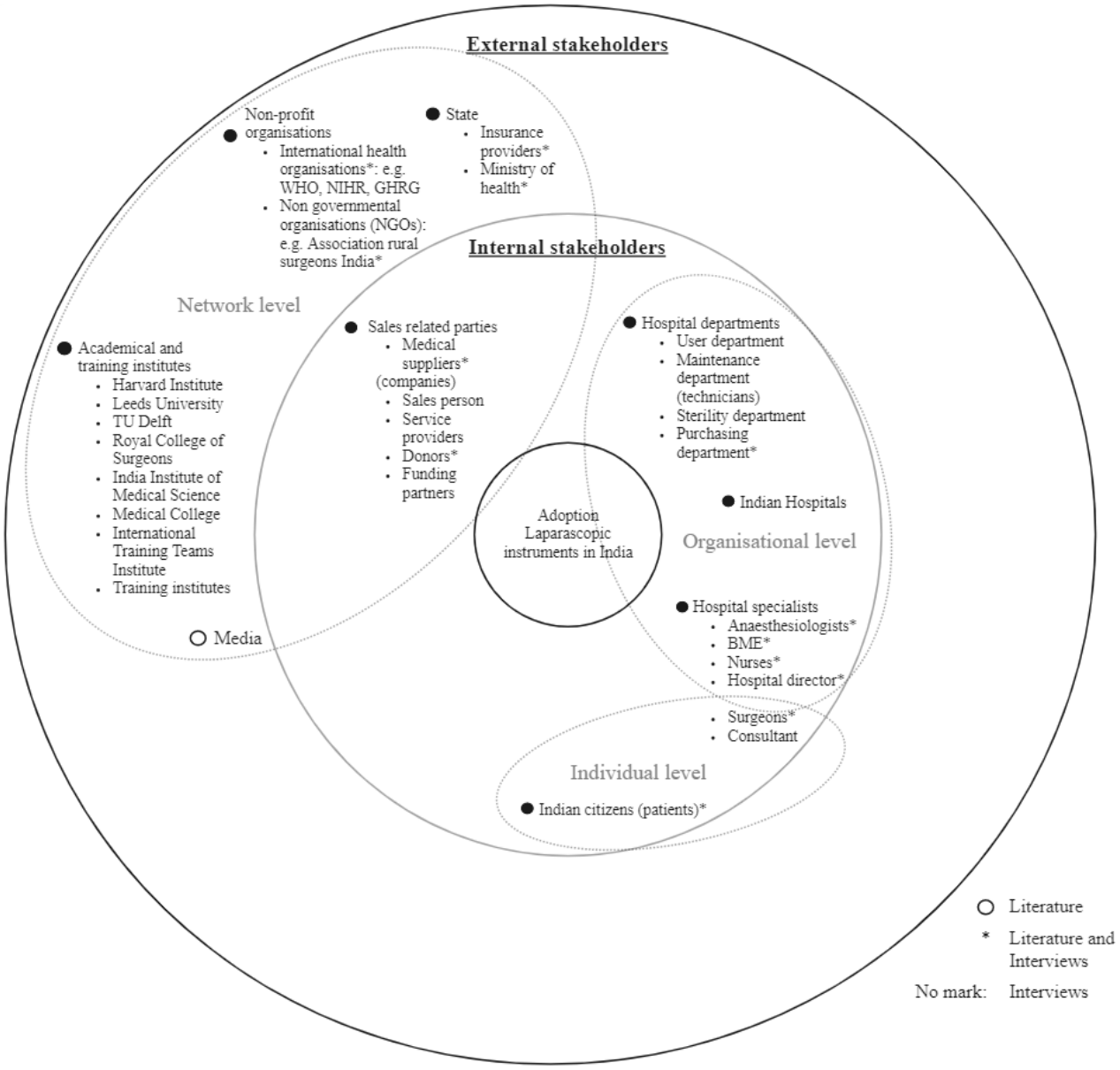


Figure 5.1: Comparison stakeholders literature and interviews

Barriers

To compare the data from the literature and those from the interviews, a table was used that shows the total number of, for example, barriers identified. The next column shows the total number of barriers identified in the literature and for the interviews in the fourth column. This comparison also functions for incentives and strategies.

Table 5.20: Overview of barriers identified from literature and interviews

Barriers	Number of barriers identified	Literature review	Interviews
Costs	5	4	5
Facilities	5	3	5
Supplier	4	1	3
Human resources	7	3	7
Patients	3	1	3
Training & Support	5	4	5
Acquisition	4	-	4

Costs
Almost all of the barriers related to costs emerged in the literature review and interviews. The barrier of required planning due to cost constraints is the only cost barrier that differs. However, in the interview, a surgeon with a private rural background mentioned this barrier only once. Therefore, this may be considered a more hospital-specific barrier than a shared barrier associated with different hospitals. Furthermore, the main similarity regarding the cost-related barrier is that it is one of the most frequently mentioned barriers in the literature and the interviews, as cost-related barriers were mentioned n=20 times.

Hospital facilities
According to Table 5.4, there are also barriers related to hospital facilities. Of the five barriers that emerged from the interviews, two do not overlap with the literature. These are the lack of availability of laparoscopic instruments and government guidelines that are difficult to comply with within rural areas. The first barrier was mentioned twice, and the similarity between them is that it occurs in a rural setting. However, one surgeon had a private background and one a public one. The second barrier was mentioned once by a surgeon from a private hospital in rural areas. It can be argued that the lack of availability of laparoscopic equipment is mainly due to a lack of money. The surgeon states that this barrier occurs mainly in rural areas due to lack of money and exists in many rural hospitals in India. This also partially explains that the barrier was mentioned from a rural background, regardless of the public or private setting. The next barrier had to do with imposed government guidelines to maintain quality in local hospitals. This barrier was also mentioned concerning a rural background. This may be particularly indicative of the skewed relationship with regard to inequality within the health care system in India. Also, this barrier is mainly a result of the lack of facilities, which is also mentioned in the literature. Thus, both barriers are consequences of other barriers that have emerged from the literature and interviews. However, these are located at a different layer and can be considered more generic.
Of the total n=17 facility barriers, lack of supporting equipment for laparoscopy was the most common barrier identified by the literature. Therefore, this is considered a barrier that needs to be addressed to adopt laparoscopic instruments in India.

Suppliers
The barriers related to the suppliers, which are the companies, do not overlap with the literature. Three barriers came from the interviews and none from the literature. In addition, several barriers were added due to the academic and innovators' interviews. The view of the barriers related to profit is consistent with the academic and innovators' perspectives. The relationship is a cause and effect of each other. Because Western companies often want/need

to make a profit, they adopt a particular business model that does not fit the development settings. Furthermore, it can be argued that the literature on barriers related to suppliers is under-researched.

Human resources

The following barriers are related to human resources. Lack of personnel is the most critical barrier, followed by the culture of hospitals. The main difference between these barriers is the context factors. Staff shortage is most common in rural hospitals, regardless of public or private background. In contrast, the hospital's culture is mentioned by urban and rural and public and private hospital backgrounds. Lack of staff is also mentioned in the literature, and this is also the case for the culture of hospitals. Lack of personnel is generic, while this is specified in more detail in the interviews. This can be explained by the fact that specifically related personnel are needed depending on the type of procedure. Furthermore, in the literature and interviews, the cultural barrier within hospitals is mainly associated with the hierarchical structures within hospitals. However, interviewees also added that this effect could be explained mainly by familiarity with laparoscopy and adherence to routines, resulting in resistance to change.

Interestingly, the level of correspondence among the barriers related to human resources is not high. Table 5.20 shows that of the seven barriers found, only three overlap. The most frequently mentioned barriers from the interviews that do not match are the extrinsic motivation to work in urban areas and the lack of confidence to use laparoscopy. These barriers come from surgeons with a rural background. The remaining barriers are the lack of government accountability and lack of internal communication within hospitals. Interestingly, these three barriers exist in an urban and public context.

The lack of confidence in laparoscopy is not surprising given the possible relationship between lack of training in these areas. Unlike urban areas, most rural areas do not have training centres. Moreover, extrinsic motivation is probably related to the lack of money, primarily a problem in rural areas. When analysing the barriers to following an urban government context, it appears that they are mainly context-dependent, as the lack of accountability is country-dependent. This could be why this barrier is not mentioned in the literature review. Internal communication occurs at the hospital level and depends on local communication among staff. Therefore, this is not considered a general barrier that could prevent the use of laparoscopic instruments.

Patient

Regarding patient-related barriers, there is a partial similarity between the findings of the literature and the interview results. The lack of access to healthcare due to inadequate financial resources is pointed out in both. In addition, there is not enough awareness of the benefits of laparoscopy in urban public institutions. This could be because the government is not fully aware of this procedure, resulting in minor inclusion of this practice in government-related hospitals.

Finally, the lack of insurance also affects patients and, in many cases, hinders their ability to receive primary care. However, this is not often mentioned. This may mean that hospitals do not see this as a general barrier. This may be explained by surgeons being interviewed and not patients, who are most likely to face this barrier.

Infrastructure

The data on infrastructure-related barriers are consistent and well-matched in the literature and interviews, both from academic and innovators and Indian perspectives. Only in the literature review was it suggested that poor infrastructure leads to overcrowded hospitals. However, this did not emerge from the interviews and is therefore not considered a barrier to Indian hospitals

in the context of this study.

Training and Support
Training and support are also mentioned as a barrier in the literature and the interviews. Lack of training is a significant barrier to the diffusion of laparoscopic instruments in India, as mentioned 24 times in the interviews with Indian experts. Training can be considered a general and inter-device related barrier. Because in the literature, lack of training was also seen as a more generic barrier independent of the surgical instrument or procedure. When laparoscopy is taken into account, training is even more critical because of the advanced surgical technique. In addition, four of the five barriers overlap with the literature. However, the lack of emphasised care in rural areas is not mentioned as a barrier in the literature. This barrier was brought up by surgeons with private hospitals in rural and urban areas, suggesting that urban hospitals are also aware of healthcare disparities.

Acquisition
The final barrier relates to acquisition. After the literature review, it is concluded that the literature on the adoption of medical devices in LMICs does not explicitly address the purchasing process. The result is that none of the barriers from the interviews matches the literature. If the barriers are further explained, it can be stated that the barriers related to procurement are context-dependent. The most crucial barrier has to do with government support. It is noted by all types of surgeons with different backgrounds, and therefore a significant barrier that needs to be included in the strategies to enable the adoption of laparoscopic devices.

Background factors barriers distinguished
To conclude the comparison of barriers, it can be noted that the main difference between the data is the contextual factors taken into account in the interviews. However, one should not lose sight of the fact that most of the participants have a rural private background, and thus the results contribute mainly to this background.
The different contexts were rural versus urban and private versus public. The study shows a relationship between the context of a type of hospital and the barriers identified. The barriers in urban settings are different from those in rural areas. Barriers in urban contexts are more related to optimising healthcare facilities, while rural hospitals face barriers related to primary resources. In addition, private and public contexts are also variables that must be considered. Private hospitals operate independently of the government, making them more dependent on other stakeholders than public organisations that are affiliated with and often funded by government agencies. These variables create the differences in terms of well-being and accessibility of health within India's healthcare system.

Incentives

Given the number of different incentives that emerged both in the literature and from the interviews, the codes were not subdivided into subthemes. The gap in the literature describes the inconsistency regarding the incentives. Therefore, the comparison of the advantages and disadvantages of laparoscopy that are the motives for whether or not to use this form of surgery was tested differently using interviews with the end-users. The following table combines the incentives from the literature and the interviews.

Table 5.21: Overview of incentives identified from literature and interviews

Number of incentives identified	**Literature review**	**Interviews**
10	10	6

The main difference between the data from the interviews and the literature is that the literature review used optimal bed occupancy as an advantage for laparoscopy. This is in line with the barrier also given by the literature about overcrowded hospitals. However, these or related aspects are not mentioned by the surgeons. This implies that this benefit does not primarily motivate local surgeons to use laparoscopy. Furthermore, the literature shows that the medical supplies required for laparoscopy are more minor, which may encourage the end-user to use these devices. The note that fewer medical supplies are needed is a fact, but this did not emerge from the interviews. This may indicate a lack of awareness about this aspect or that not much more benefit is created than open surgery, including the ability to diagnose. Furthermore, long procedure times are also mentioned. However, the duration of the procedure is even shorter, as appeared from the interviews with surgeons who mainly perform laparoscopy in rural areas as consultants. From this, it can be explained that the level of experience moderates this.

Background factors barriers distinguished

A distinction had to be made between rural and urban backgrounds to account for the inconsistency of the data from the literature review. The interviews revealed that urban surgeons do not experience financial disadvantages compared to rural surgeons. This may be supported by the encouragement of an experienced surgeon in laparoscopy operating in rural areas. This surgeon argues that the disadvantage of laparoscopy is the initial investment and associated costs. Moreover, most of the other drivers were recognised by surgeons from all types of hospitals. Which faster return to work is the most significant motive for using laparoscopy.

Strategies

This section discusses the results of the interviews and the literature concerning the strategies. This is done for the identified stakeholder groups. Starting with the state, followed by academic and training institutions, sales-related parties, and hospital specialists. Following the gaps in the literature review (Page 32), it was mainly found that the strategies do not specifically contribute to enabling the adoption of surgical instruments, such as laparoscopic instruments. After comparing the findings, it is discussed whether this is covered with the input from the interviews. For this comparison, the following table shows the correspondence level of each stakeholder associated strategy.

Table 5.22: Overview of strategies identified from literature and interviews

Stakeholder group	**Number of strategies identified**	**Literature review**	**Interviews**
State	4	4	4
Academic & Training institutes	3	2	3
Sales related parties	4	3	4
Hospitals	6	3	6
Specialists	3	-	3

State
Strategies related to government parties are mainly about the responsibility and accountability to be done with respect to India's healthcare system, including policies and regulations. This is mentioned by all types of surgeons and several academic and innovators experts. The literature review also revealed that this is important. Furthermore, all the strategies mentioned in the literature correspond with the interviews' findings. This implies that government-related strategies in LMICs are, to some extent, uniform in improving the local healthcare system. However, the findings of the interviews are generally more specific, as there is a huge gap between rural and urban hospitals, and all efforts should be aimed at bridging this gap through funding, policies, guidelines, infrastructure improvement, responsibility, accountability and collaboration with NGOs.

Academic & Training institutes
The most frequently mentioned strategy for this group of stakeholders is providing local education and training tools, including learning by doing and offering training programs, which came from the literature. This is followed by creating confidence, competence, and independence for laparoscopic procedures, only found in the interviews. And offering research is also considered significant, according to the literature review and the interviewees. All types of surgeons agree on the first strategy, in contrast to the latter. Surgeons with a rural private background only mention it. Thus, it is vital to create a certain degree of autonomy, especially in rural areas. Furthermore, the academic and innovators' perspective shows that offering research, prototyping, and implementation is successful. These strategies also emerged in the literature review. The literature review adds to the offering of research, the need to scan the socio-economic environment using diagnostic frameworks. This was also supported by several academic and innovators interviewees. Connections to academic institutions are essential for rural environments, especially considering that academic institutions are located in urban cities.

Sales related parties
This group of stakeholders, consisting mainly of companies and local suppliers, was not associated with specific strategies in the literature other than adapting the device to the context. However, strategies were mentioned to improve training and equipment facilities at low cost and make equipment commercially available. Interviewees also mentioned these and others. On the other hand, they see these strategies as the responsibility of the sales-related parties. Nevertheless, the strategies from the literature overlap well with the interview findings, which is shown in Table 5.22. One strategy that was not mentioned in the provision of local salespeople, which the CEO believes is critical to enable the use of laparoscopy locally.
Furthermore, given the background factors only for rural surgeons, companies must adopt laparoscopic devices to their context regardless of private or public background. This is also the

case for the provision of (free) training. Moreover, private rural hospitals need to have local vendors and services. Therefore, these strategies are crucial for application in rural contexts. Finally, table 5.15 lists the design requirements. Of the 15 requirements, eight overlap with the literature, and one requirement was added by the literature. This is easy to transport, which is mainly important for consulting surgeons operating in different rural hospitals. However, the design requirements from the literature are not specifically mentioned concerning laparoscopic equipment, which could explain the added requirement. The overlapping requirements also mentioned by most academic and innovators participants can be considered more generic and not device-dependent, while the remaining requirements are mentioned specifically in light of laparoscopic devices. Furthermore, it is notable that six requirements are mentioned for rural and urban contexts. The remaining requirements are mainly related to using in low-resource environments. The climate footprint is interesting to note, and it is only mentioned by urban public hospitals and one academic and innovators participant. This emphasises that urban settings require a different approach than low-resource settings.

Hospitals
Literature on hospital-related strategies partially matches the data obtained through interviews. First, implementation and adherence to the WHO and government checklist are essential for all types of hospitals. This is also highlighted in the literature. Furthermore, higher wages, contacts with politicians and connections with insurance agencies are mentioned in the literature. Contacts with politicians are necessary for urban public hospitals, as they depend on government approval in procurement processes. For the rural private context, affiliation with insurance companies is mentioned. This is understandable given that most of these types of hospitals are not connected to such agencies. The last non-matching strategy relates more to rural hospitals, as extrinsic motivation through paying higher wages is needed to continue to attract staff to work in rural settings.

Specialists
Also, concerning specialists, three different strategies emerged from the interviews. However, no related strategies were found in the literature. Since private surgeons mention the strategies in rural areas, these strategies are context-dependent and especially essential for the rural background where a network is needed to stay in touch with the healthcare community.

Other
According to the literature, there are several remaining strategies, decentralised authorities, autonomous parties, and online surveillance systems. Most of these strategies do not apply to the context of this study as there are decentralised authorities. India's healthcare system is well designed. However, the described challenges and associated strategies are still applicable. Online monitoring systems and autonomous parties are not further explained and linked to a specific stakeholder. Therefore, these strategies are not considered for this study.

5.7.2 Data combined

With the inputs from the literature and interviews, a power-interest matrix can be used to combine all the data and link strategies to stakeholders. The power and interests from table 5.2 are used to position the stakeholders in the matrix. A power-interest matrix shows how to deal with the different stakeholder groups, and it directly shows the position of their interest in the adoption of laparoscopic devices. In Figure 5.2 are the parties and positions shown.

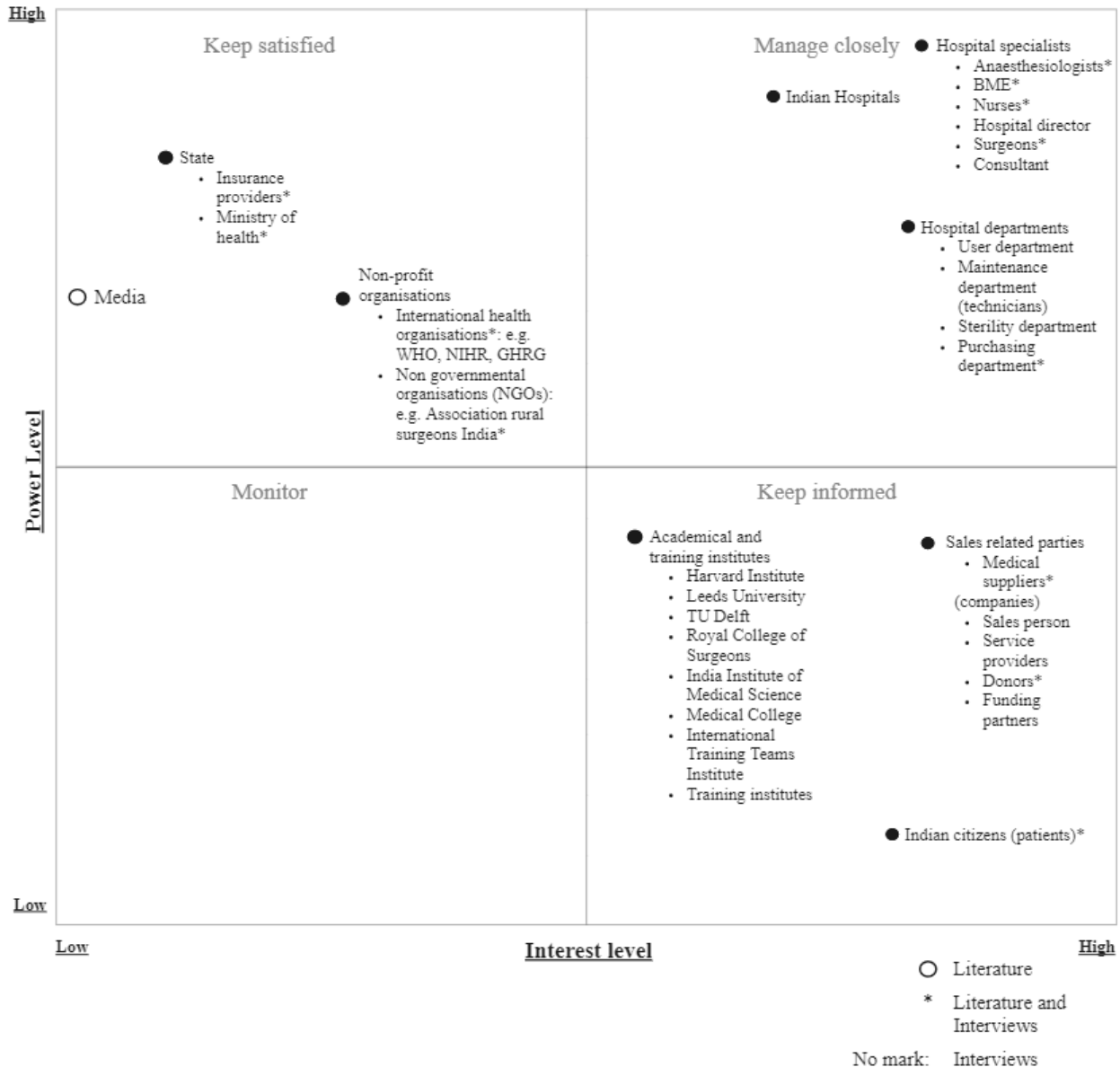


Figure 5.2: Position stakeholders in relation to the adoption of laparoscopic instruments

First, the media is a stakeholder with little interest but significant influence. Even though the literature review and interviews did not focus on this stakeholder, the media can share news about laparoscopy. Moreover, through media word of mouth, information can quickly be disseminated through social media or news sites. This makes them a powerful party that could be involved in creating awareness about the existence and benefits of using laparoscopy.
The following two parties need to be kept satisfied. The state has much power. However, it appeared from the literature that they have low interest, especially in (rural) private settings. Therefore, it is required to have this party on board and try to cooperate since they can create policies and guidelines, and insurance bodies are connected.
Non-profit organisations are also essential to keep satisfied. Many of these organisations are funding private hospitals and providing training and knowledge. On average, their interest level is higher than the government since, for example, the association for rural surgeons is active in training local people. On the other side, the WHO is also part of this stakeholder group; however, they function more in the background by providing guidelines and checklists but not only for this context.

The third group is classified as keeping informed. These stakeholders have a significant interest level. As for the patients, they have a great interest and benefit the most from laparoscopic procedures. However, they do not have much power and resources to change the system. Academic institutions and training institutes mainly provide research and education. These parties have partial power to influence the application of laparoscopy by providing research and innovative solutions. However, all these institutions are only partly involved in this and therefore have this position of interest. Sales-related parties do have much interest, specifically when they can make a profit from it. However, this has proven to be a barrier to adopting laparoscopic devices. Therefore, companies should change this and try to meet the design requirements given in the strategies section. But, it is not possible for an incumbent company to immediately change its business models resulting in limited power. In addition to suppliers, donors and other funding partners can partially influence the adoption of laparoscopic instruments by providing donated equipment. However, additional education and training are still needed.

The final group is the group that needs to be managed closely. These are hospitals, hospital departments and hospital specialists. Hospital departments need to support the workflows associated with laparoscopic devices. In each department of the hospital are medical experts. Cooperation and internal communication are required for collective decision-making. The interest level is high, as well as the power level. Furthermore, hospitals and networks between hospitals can also stimulate that laparoscopic devices will be adopted. The last and most essential decision-makers are the specialists. If they are willing to use or not use laparoscopy, then it directly influences the adoption of these devices concerning their practices. Therefore, it is vital to get aware of the benefits, mainly for the patients, and overcome the challenges related to adopting these devices.

5.7.3 Generalisability

Concerning the generalisability of the data, it can be concluded from the literature, which mainly dealt with the current state of the art in applying surgical instruments in LMICs, that barriers related to cost, training and infrastructure, and hospital structures are generic. However, when these barriers are further specified, they become more context-dependent. While barriers related to patients and providers are more hospital and country-specific.
After all, the results of the interviews and the literature overlap to a large extent implying that the overlapping incentives can be considered generic specifically for adopting laparoscopic instruments.

Chapter 6

Conclusion

6.1 Answering Sub-Questions

Four different SQs were used for this study. The first question analysed the stakeholders related to the adoption of laparoscopic instruments:

> **SQ1.** *"Which stakeholders are involved in the successful adoption of medical products such as laparoscopic instruments in developing countries?"*

The literature and interviews revealed that there are many stakeholders. Therefore, they were grouped according to their common characteristics. The first group is the Indian government, which includes insurance agencies. The next group is referred to as non-profit organisations; this group of stakeholders includes international bodies, such as WHO and NGOs in India. The third group is academic and training institutions that primarily provide training and education. The fourth group consists mainly of sales-related parties involved in procurement processes and the development of laparoscopic instruments. In addition, hospitals are also part of the stakeholder groups. In particular, different types of hospitals are distinguished for this study. Hospital departments are also part of the stakeholders involved that have a supporting role in enabling the adoption of surgical instruments. In addition, hospital specialists are also part of the stakeholder group. The study found that these individuals have much influence on the adoption of laparoscopic instruments. Finally, Indian citizens were also found as stakeholders subjected to the procedure. All these stakeholders, combined with their corresponding influences and position in the network, resulting in the following figure:

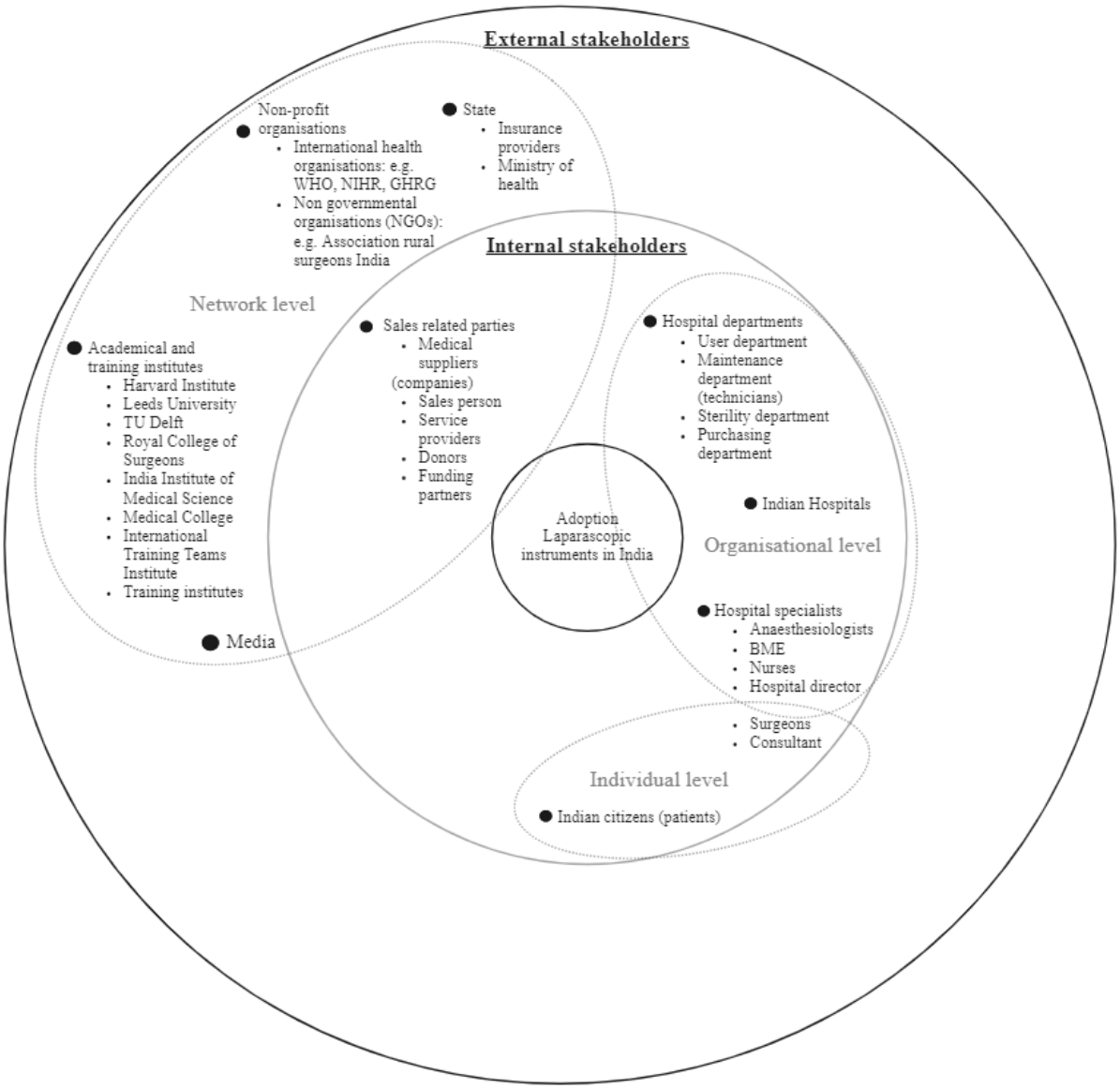


Figure 6.1: Comparison stakeholders literature and interviews

SQ2. *"What barriers exist which are blocking the adoption of frugal surgical devices such as laparoscopic instruments aimed at LMICs?"*

During this study, barriers were first identified from the literature. Then, barriers related to the adoption of surgical devices, such as laparoscopic instruments, were further collected through interviews. However, several influencing factors were found in the literature. These are the different contexts of surgeons, distinguishing between rural and urban and between private and public hospitals. Patterns are identified concerning the specific barrier and the surgeon's context. In addition, some more generic barriers are found that mainly correspond to those from the literature and interviews. Furthermore, a breakdown was made based on the number of barriers by theme. This starts with cost, followed by facilities, suppliers, human resources, patients, infrastructure training support, and acquisition. All of this together results in the following overview of barriers:

Table 6.1: All barriers with context factors

Barrier	Generic	Rural	Private	Urban	Public
Costs					
Training costs	x	x	x		x
Lack of money	x	x	x		
Patient unable to pay for care	x	x	x		
Planning required due to cost constraints		x	x		
Disposables increases costs	x	x	x	x	
Facilities					
Lack of support equipment laparoscopy	x	x	x		x
lack of proper sterilisation equipment	x	x	x		x
(Partial) Lack of availability of laparoscopy		x	x		
Lacking function guidelines	x	x	x		
Government guidelines hard to comply with		x	x		
Supplier					
Profit-making	x	x	x		
Lacking fast service		x	x		
Repair times			x	x	
Human resources					
Lack of personnel	x	x	x		x
Extrinsic motivation to work in urban settings		x	x		x
Lack of confidence to use laparoscopy		x	x		
Convincing non medical people about benefits laparoscopy				x	x
Lack of accountability government				x	x
Lack of internal communication				x	x
Lack of familiarity laparoscopy	x	x	x		x
Culture hospital	x	x	x	x	x
Patients					
Lack of insurance		x	x		
Access to healthcare	x	x	x		x
Awareness benefits laparoscopy			x		x
Infrastructure					
Lack of stable supply basic resources	x	x	x		
Lacking infrastructure	x	x	x		
Training and Support					

Table 6.1: All barriers with context factors

Barrier	Generic	Rural	Private	Urban	Public
Lack of knowledge		x	x		
lack of training		x	x		
Lack of support	x	x	x	x	x
Guidelines not followed properly				x	x
Lack of emphasised care rural areas		x	x	x	
Acquisition					
Long process to get equipment				x	x
Lacking government support	x	x	x	x	x
Hard to convince external parties				x	x
Paper work				x	x

In summary, it can be concluded from the table that all these barriers affect the application of laparoscopic instruments in LMICs. In addition to this, several general barriers were identified that are less context-dependent and more applicable to LMICs, as these barriers emerged from all types of contexts. In addition, the more salient barriers that emerged from the literature and interviews appeared to be more generic.

SQ3. *"What are the incentives for LMIC healthcare markets to purchase/use surgical instruments such as laparoscopic instruments"*

Incentives were examined to determine why laparoscopy would be incorporated into existing workflows, and shown in Table 6.2. Many incentives emerged from the literature. However, the interviews were required for further input due to a lack of internal consistency in the literature. After the analyses, it could be concluded that the benefits of using laparoscopy are mainly related to patients. Because the recovery time is reduced, patients can return to work more quickly. This aspect is mentioned a lot. These incentives also fit into a rural context where patients often rely on daily expenses earned through work. In addition, the other incentives can be summarised; safer compared to open surgery, minimally invasive, faster (in case of a high level of experience), cosmetic benefits, less morbidity and infections, less pain. The only drawback remains the relatively high initial investment required. However, not all data is aligned on this aspect.

Table 6.2: All incentives with context factors

Incentive	Generic	Rural	Private	Urban	Public
Advantages laparoscopy faster back to work time	x	x	x	x	x
Advantages laparoscopy minimal invasive	x	x	x		
Advantages laparoscopy safer	x	x	x		
Advantages laparoscopy efficiency	x	x	x	x	
Advantages laparoscopy no large cost difference			x	x	
Disadvantages laparoscopy cost and investment		x	x		

SQ4. *"What strategies are needed to enable the adoption of frugal surgical devices such as laparoscopic instruments aimed at LMICs?"*

Consistent with the analysed barriers, the strategies are also analysed in context. The strategies that emerged from the literature and the interviews are considered more generic. While others are more context-dependent, it is shown that strategies for urban settings differ from those for rural settings. This distinction is also needed concerning private versus urban contexts.

Table 6.3: All strategies with context factors

Strategy	Generic	Rural	Private	Urban	Public
State					
Responsibility & accountability to implement policies and regulations	x	x	x	x	x
Bridge divide rich and poor	x	x	x		
Make laparoscopy available	x	x	x		
Healthcare policies	x	x	x		
Academic & Training institutes					
Provide local training (and tools)	x	x	x	x	**x**
Provide research to optimise healthcare	x	x	x		**x**
Create competence, confidence independence to perform laparoscopic procedures		x	x		
Sales related parties					
Make laparoscopy financially available	x	x	x	x	x
Adapt devices to its contexts	x	x	x		x
Local sales persons required		x	x		
Provide (free) training		x	x		x
Hospitals					
Use checklists	x	x	x	x	x
Quality control and Standardisation		x	x	x	
build community health programs			x	x	
Pay higher wages to personnel	x	x	x		x
Contacts with politicians	x			x	x
Connect to insurance	x	x	x		
Specialists					
Use consultants		x	x		
Spread word of mouth		x	x		
Create awareness about laparoscopy		x	x		

In addition to Table 6.3, the study shows that the academic and innovators' perspective on strategies fits well with the Indian perspective. However, from the company's side, to enable the adoption of laparoscopic devices, it is necessary to first target the people with large networks resulting in word of mouth spreading in a country. An Indian surgeon adds that to make laparoscopy popular, it is necessary to work with all stakeholders involved. When stakeholder groups work together, including academic & innovators agencies globally, the adoption of laparoscopic devices can be made possible by applying the suggested strategies.

6.2 Answering Research Question

"What is needed for the successful adoption of surgical frugal innovations such as laparoscopic instruments targeting LMICs?"

This study began with the problem statement, which was the lack of understanding of introducing frugal innovations, such as laparoscopic instruments, into LMICs, particularly in India. From the background section, it became clear that the biggest problem in Indian health care is inequity affecting patients' access to health care and inequities in financing options. Especially given the lack of insurance coverage for healthcare expenses. It was further revealed that laparoscopic devices are not widely used in India, an LMIC.
Several **stakeholders** with corresponding power and interests emerged from the literature and interview data in this context. These parties include the *state, insurance companies, non-profit organisations, academic and training institutions, sales-related parties, hospitals, hospital departments, hospital specialists, and patients.* Collaboration among these parties is needed to enable the widespread adoption of laparoscopic instruments. In addition, the main **barriers** which are blocking the adoption are mainly related to *lack of financial resources, training, infrastructure and hierarchical hospital structures (hospital culture).* Moreover, regarding **incentives**, it became clear that laparoscopy in local hospitals mainly *benefits the patients with better surgical results and shorter hospital stays.* These are essential aspects for LMICs since rural patients often depend on out-of-pocket payments, and given that the sooner a patient can return to work, the better it is for poor patients to manage their daily expenses. Finally, **strategies** that can be applied according to the context of application were found. For the rural private context, *the use of consultants, dissemination of word of mouth and awareness about laparoscopy must be created.* Furthermore, the *introduction of checklists* in hospitals is helpful to guide the process of introducing new equipment. Also, companies should be *responsible for adapting medical equipment to low-resource settings* by using the identified design requirements and making the equipment *financially available.* The study also showed that the learning curve to using laparoscopy is steep. *Training and tools* must be made available to learn to use, *building confidence and competence.* Finally, there is a need to *implement health care policies with accountability and responsibility in implementing the policies.*

6.3 Contributions

This research contributed to both managerial and scientific perspectives. This is described in the following paragraphs.

6.3.1 Managerial

(1) Considering the managerial perspective, this study added a lot of new insights related to the adoption of surgical instruments and company barriers and strategies. The barriers can be used to adapt new business models to make laparoscopy financially available. (2) Furthermore, visions are shared from several perspectives on successfully approaching LMICs and what factors need to be considered. When combining these different views on the adoption of surgical instruments like laparoscopic instruments, a clear strategy is raised for companies to target LMICs. (3) All the stakeholders related to the adoption of surgical instruments in LMICs are mapped out, including corresponding power and interest. This is incorporated in the power-interest matrix and discusses how to deal with each stakeholder group. (4) For companies developing tools for LMICs, this research shows the required product features. Some of these were more generic and thus can be applied independently of the specific LMIC and product. But also, concerning laparoscopic instruments, design requirements were explicitly related to

the different contextual factors.

6.3.2 Scientific

The study also contributes to science. (1) The literature review showed that only a small amount of data was available on purchasing processes in LMICs. However, the interviews were used to understand how these purchasing processes function concerning the adoption of medical surgical innovation, including the associated barriers and strategies. (2) This study can be considered a starting point for adopting frugal medical innovations. The available literature in this domain appeared to be scarce. (3) The study shows that the technology trajectory of laparoscopic instruments fits the development and diffusion model and demonstrates the differences between two contexts, namely the HICs and the LMICs. The HICs have already entered the phase of large-scale diffusion, unlike the LMICs. Many barriers have been identified that are currently hindering the large-scale diffusion phase. (4) Furthermore, important context factors, similarities, and relationships between data are identified. This shows the factors to be considered concerning data on barriers, strategies, and incentives in LMICs. (5) Finally, it is noted that there are different levels of analysis regarding socio-economic systems. These levels exist at the individual level, the end-users, at the organisational level, which represents the hospitals, and at the macro level, which is the network level and analyses the national and international context. During the study, it became clear that these levels can also apply to barriers, incentives, stakeholders and strategies.

6.3.3 Practical

When reflecting on the findings of this study applied to the SATA-LRS instruments. Recalling the main product features of these instruments are modularity, which enables easy cleaning, additional degrees of freedom, which allows the interoperability of the instruments, and interchangeability between end-effectors, which makes it financially attractive compared to purchasing series of (disposable devices). It is relevant to analyse the extent to which the design requirements found in the literature on page 33 and interviews in Table 5.15 show similarities with the mentioned current design features. It can be concluded from this that all the current design requirements of the SATA-LRS instruments fit low-resource settings. For future development, it can be tested to what extent this device is easy to repair or maintain, which is essential following the interview findings. Furthermore, this instrument also has a minimal invasive character and therefore, the identified incentives with most of the advantages for patients apply for this instrument. When considering all this and incorporating the right strategies, this technology can become a disruptive frugal medical innovation for LMICs.

Chapter 7

Limitations & Future Research

7.1 Limitations

Several limitations should be kept in mind when reading this study.

- First, the group of interviewees was uneven concerning the background for the interviews. Six of the nine surgeons came from one or had experience in a rural private background. While the remaining Indian surgeons had different backgrounds. This affects the results of the interviews.

- Second, surgeons were interviewed for the incentives to use laparoscopy. However, the result could be different if the patients had also given their incentive regarding laparoscopy being preferable to open surgery so that this aspect would also be better validated from the patients' side. In addition, several stakeholders were identified. However, more in-depth analyses could be conducted to identify individual parties. Currently, groups are being formed, but the number of individual stakeholders could be expanded. Also, little is known about the media as a stakeholder. This party could be more specified, including its power and interests.

- Third, the experience level was not included in this study. Some surgeons appeared to have a lot of experience and consultations at other hospitals and therefore have more constructive data on hospitals in general, as opposed to someone who is tied to one hospital.

- Fourth, frequencies of codes sometimes occurred more than once in one interview. This may give the idea that a code from the interviews is seen as more important than it is. However, in some cases, when aspects are mentioned multiple times, it is considered important and therefore counted in the total number of frequencies for a specific code.

- Fifth, observations were not included in this study due to time constraints. These additional data sources are necessary to obtain a triangulation approach in the data. This increases the validity of the study (Sekaran & Bougie, 2019).

7.2 Future Research

This study can be considered the basis for more studies on the adoption of medical devices in the healthcare domain, especially in LMICs. After this study, several implications for future research could be indicated.

- First, observational studies were not conducted due to time constraints. To test and supplement the findings of this study, this method of data collection can be included. When data from observational studies are also added, construct validity is achieved by using this triangulation approach (Sekaran & Bougie, 2019).

- Second, scientific models can be used to test the findings of this study and determine the extent to which adoption in healthcare can be compared to adoption of high-tech products. After which related models could be adapted or applied to these contexts. Based on this, business models could be created for medical (frugal) innovations when companies target LMICs. This could increase both the adoption rate and the quality of local healthcare.

- Third, barriers must be linked to specific strategies, including responsible stakeholders. In this study, groups of stakeholders were first analysed. Further analysis and actions can be added to specific individuals to expand on this. In addition, further analysis is needed of which barriers can be addressed by which stakeholders and which barriers are out of reach and more structural barriers. For this purpose, barriers and associated niche strategies identified by (Ortt et al., 2008) can be used to complement this model specifically for medical device adoption in the healthcare context. The barriers and strategies need to be grouped into more generic categories to do this. In addition, incentives can explain the motives for using a particular strategy. An example is given in Figure 7.1, where the educate niche strategy is applied. However, the original purpose of this strategy is to transfer knowledge to suppliers and customers (Ortt et al., 2008). In this context, this strategy can be extended by adding knowledge transfer to the end-users, the surgeons. This strategy can be adopted by training institutes responsible for transferring knowledge.

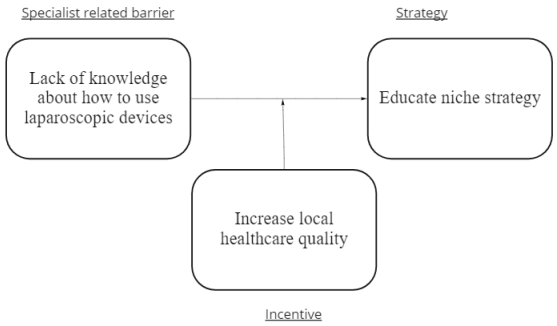


Figure 7.1: Example of a barrier, incentive and corresponding strategy

- Fourth, additional interviews with Indian surgeons from other backgrounds can be used to validate the findings of this study. Moreover, other LMICs can also be analysed using the same approach to see if the results are generalisable between LMICs. Based on these findings, a new framework can be built to optimise local healthcare in LMICs.

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Appendix

Interview Questions Indian Surgeons

Background

Technologies for Low- and Middle-Income Countries (LMICs) need to take into account local cost, usability and maintenance challenges, and 'modular' device designs can be one way of overcoming these challenges. However, despite research into the design advantages of these devices, the adoption challenges have not yet been investigated. This research aims to make the adoption of modular laparoscopic instruments possible in LMICs, starting in India with several hospitals. It aims to find the various actors and factors, including stakeholders that play a role in making this technology successfully adopted in India. The research analyses the application of the following laparoscopic instruments:

Questions:

Generic

- What is your profession?
- In what type of hospital are you working?
- Public/Private, Rural/Urban?

Organisational structures

- How many patients are treated on average per day for surgical procedures? Is this open surgery or laparoscopy, or both?
- What does the current structure in (terms of culture) of your hospital look like, e.g. how is your relationship with the director etc.?
- Can you describe the local infrastructure of the hospital where you work and how it relates to your surgical procedures?

Purchasing

- Can you describe the purchasing process for new equipment?
  (Eventually, additional questions:
  - How or when is it determined to buy new equipment?
  - Who decides on that?
  - Who pays for the equipment? Or is it donated?
  - Are there also external parties outside the hospital involved in the purchasing process?)

- How much budget is available for new equipment?
- What requirements must new equipment meet to function optimally in your hospital?

Usage

- How has new equipment been successfully introduced in your hospital in the past? Can you give an example?
- Do you know what laparoscopic instruments are? If yes, what could be an incentive to use laparoscopy instead of open surgery?
- In what way are patients benefiting or not when they are treated with laparoscopic instruments?
- How many procedures daily could be replaced by using the laparoscopic operation technique?
- What (additional) materials and equipment do you need in your hospital to use laparoscopic instruments?
- What would be your hospital's cleaning/sterilisation requirements to use laparoscopic instruments? How can these be met with current staff and resources?
- What would be the maintenance requirements in your hospital to use laparoscopic instruments? How can these be met with current staff and resources?
- What would be the training requirements in your hospital to use laparoscopic instruments? How can these be met with current staff and resources?
- Is there anything you would like to improve regarding sterility processes, procedures and associated workflows?

Interview Questions Academic Experts & Innovators

Questions:

- What is your profession?
- What is the relationship between your work and the LMICs?
- How would you describe the LMIC medical markets? (India)
- What are the current barriers that need to be overcome to reach LMICs successfully?
- How do you see laparoscopic instruments being implemented in LMICs in the future?
- What strategies would be appropriate to enable the adoption of surgical instruments (laparoscopic instruments) in this market?
- What are the biggest challenges to making a new technology a success in LMIC markets?
- What collaboration between what parties is needed to make new (medical frugal) technologies a success in LMICs?
- In what ways do laparoscopic instruments benefit the LMIC markets?