Design Approaches to Developing Technologies for Global Surgery

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Submitted in accordance with the requirements for the degree of

Master of Science (Eng) by Research

The University of Leeds

School of Mechanical Engineering

June 2021

Declaration

The candidate confirms that the work submitted is his/her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

The following paper which contributed to this thesis was published in the International Journal of Surgery Global Health. The author of this thesis planned and carried out all studies within this paper, and prepared the publication. Co-authors provided feedback on the manuscript which was used to refine the content and also proof read the manuscript.

Marriott Webb, M., Bridges, P., Aruparayil, N., Mishra, A., Bains, L., Hall, R., Gnanaraj, J., & Culmer, P. (2021). Designing devices for global surgery: Evaluation of participatory and frugal design methods. *IJS Global Health*, 4(1), e50

Acknowledgements

While the research in this thesis is my own, it would not have been possible without the incredible team who worked together to design the device described in this research.

To all the clinical stakeholders involved, thank you. You were patient, you were creative and you made this project a success. I feel privileged to have worked with and learnt from you. Special thanks go to Pd-m International, in particular Pippa. Pippa, your skill and commitment to high standards raised the game and motivated all of us to do better. You are an absolute inspiration. Also, thank you to the technicians and manufacturing team at the University of Leeds - Graham, Ross, Tony, Sarah - for making ideas possible.

And of course, thank you Pete! Your leadership in this project made it a pleasure to be a part of. As a supervisor, you have been truly fantastic.

My wonderful family - thanks for being a constant melting pot of opinions and for always feeling close even when we're far apart.

Finally, thank you Sean, for your endless understanding, kindness and pints of squash. Your ability to see the best in everything got me to the finish line. Also thanks Cathy and Alan, for giving me a room to hide from Sean in and work on this!

Everyone who works to improve healthcare globally, you are heroes, thank you!

Abstract

Surgical care is a fundamental component of an effective healthcare system, yet most people living in low and middle-income countries have no access to it. Critical to addressing this is the ability to equip low-resource healthcare contexts with appropriate surgical technologies. An estimated 40% of healthcare equipment is unused in these contexts, and there is increasing recognition that new technologies must be designed specifically for them, to provide Affordable, Available, Accessible, Appropriate and Quality solutions.

For this, researchers suggest conventional approaches to medical device design are not appropriate, but recommended alternative approaches are in early development stages, and since their use is rarely reported in the literature, little evidence exists with which to improve them. This thesis addresses this paucity of evidence, and describes the integration, implementation, and evaluation of recommended approaches to designing technologies for low-resource healthcare contexts.

A design roadmap, and the principles of frugal innovation and participatory design are applied to design a device for gasless laparoscopy in rural hospitals in Northeast India. The evaluation of these approaches considers their influence on the development of the design through a review of the design history of the device and uses an exploratory qualitative study to understand whether the participatory approach was beneficial to the clinical stakeholders, who were participants.

The design roadmap provided appropriate structure and advice for the design process but requires further development. A thorough understanding of the use context, local stakeholder participation and ability to maintain quality are important for innovating frugally, but specific methods to guide frugal innovation are required. Clinical stakeholders benefited from participating throughout the design process and supported the process by revealing potential barriers to collaboration as well as potential solutions to them. The results highlight the value and potential for using these approaches to increase global access to surgical care.

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Abbreviations

AWL	Abdominal Wall Lift
CAD	Computer-Aided Design
CO_2	Carbon Dioxide Gas
DALY	Disability-Adjusted Life Year
Design for Safe Surgery Roadmap	Roadmap for the Design of Surgical Equipment for Safe Surgery Worldwide (Oosting et al., 2018)
FDA	Food and Drug Administration
FI	Frugal Innovation
FMEA	Failure Mode and Effects Anlaysis
GHRG-ST	Global Health Research Group in Surgical Technologies
HIC	High-Income Country
HRHC	High-Resource Healthcare Context
HTA	Health Technology Assessment
LMIC	Low- and Middle- Income Country
LRHC	Low-Resource Healthcare Context
NASA TLX	National Aeronautics and Space Administration Task Load Index
NIHR	National Institute for Health Research
OT	Operating Theatre
OTT	Operating Theatre Table
PD	Participatory Design
P-diagram	Parameter Diagram
RAIS	Retractor for Abdominal Insufflation-less Surgery
SDG	Sustainable Development Goal
UHC	Universal Health Coverage
UK	United Kingdom
UN	United Nations
US	United States
WHO	World Health Organization

Chapter 1

Introduction

This chapter introduces the context within which the research project and objectives evolved. The state of global access to surgical care and the approach taken by a Global Health Research Group to improve this is summarised. Through involvement in this work, it became clear to the author that the majority of surgical technologies do not meet the needs of surgical providers in low-resource settings. Addressing these needs requires a different design approach, which is not well understood. This becomes the justification for the aims and objectives of this research and the methods selected to achieve them.

1.1 Context

The work described in this thesis was conducted as part of wider research into improving surgical care in low-resource healthcare contexts (LRHCs), coordinated by the Global Health Research Group in Surgical Technologies (GHRG-ST), which is funded by the United Kingdom's (UK) National Institute for Health Research (NIHR) as part of an initiative to address 'Global Health' concerns across a range of clinical domains. According to the UK government, 'Global Health' concerns affect people worldwide and require international collaboration to address [1].

1.1.1 Inequality and Privation in Global Access to Surgical Care

As a part of the Sustainable Development Goals (SDGs) [2], Member States of the United Nations (UN) pledged to achieve Universal Health Coverage (UHC) by 2030. Providing essential health services reduces morbidity and mortality for their populations and gives them better chances of avoiding poverty and enjoying long-term economic development [2–4]. Surgical care is one of these essential health services [3,5,6]. To be effective, it must be safe, quality, timely, accessible and affordable [7].

An estimated 5 billion people lack access to surgical care. While these people exist worldwide, they are disproportionately concentrated in Low- and Middle- Income Countries (LMICs), where nine in ten people cannot access surgery [3]. Health burdens can be measured in Disability-Adjusted Life Years (DALYs), which sum the number of years of life expected to be lost and the number of years of life expected to be affected by disability for a cause [8]. Access to surgery could avert 77.2 million DALYs in LMICs every year [9].

In sub-Saharan Africa, under the right conditions, this could cost just $33 per DALY prevented [10]. In fact, one study found that almost all surgical interventions they assessed were very cost-effective in LMICs [11]. Despite this, the costs incurred accessing surgery in LMICs can

cause entire households to fall below the poverty line [3,12]. To prevent this and achieve UHC [2], the international community must prioritize and invest in surgery [3]. Financial flows into surgery must be tracked and surgical data collected to better inform policy. And finally, we must utilise innovation and technology to reduce costs and optimise resource allocation in the delivery of surgical and anaesthesia care in LRHCs [3,13].

1.1.2 Using Innovation to Improve Access to Surgery

The GHRG-ST has supported increased use of one such innovation, gasless laparoscopy [14], as a means of superseding laparotomy and improving surgical care in LRHCs. Laparotomy is one of the Bellwether procedures, which all first-level hospitals should have capacity to perform [15]. Where possible, it is replaced by laparoscopy, because of benefits such as shortened hospital stays, reduced pain, smaller wounds, and overall cost savings [16]. For low-earning populations, especially those with no leave or sick pay, days spent accessing surgical care come at the cost of losing wages, so these benefits are more pronounced. However laparoscopy is not currently feasible in many LRHCs. Conventionally, it is performed by 'insufflating' (inflating) the abdominal cavity using pressure-controlled carbon dioxide gas (CO_2) (termed a pneumoperitoneum) which requires use of a general anaesthetic, monitored by an anaesthetist. This, alongside other specialist equipment and consumables required, places a high resource requirement on the technique which is challenging to provide in LRHCs. Hence, adoption of laparoscopy in LMICs has been slow [17].

Gasless laparoscopy is an alternative method, using a device that manually lifts the abdominal wall [18]. It can be performed under spinal (rather than general) anaesthesia and without pressurised CO_2 gas, thus removing the need for associated equipment: a significant reduction in resource required. It could also reduce the risk of airborne viral transmission during laparoscopy [19–21]. Scoping work conducted by GHRG-ST identified opportunities and barriers to uptake of this technique [22], which have formed cornerstones of the multidisciplinary research group's work:

- *Training and proctorship* [23,24]
- *Registry and long-term advocacy* [25]
- *Equipment* [26]

The last is the focus of this work. To increase the adoption of gasless laparoscopy, it must provide a comparable alternative to conventional laparoscopy. Studies currently report challenges such as longer operative times and a suboptimal view of the operative scene [27,28], central to which are the abdominal wall lift (AWL) devices, shown in Figure 1, which lack the

development and innovation seen in instrumentation used for main-stream surgery [29]. Accordingly, the GHRG-ST has been developing an improved AWL device, the Retractor for Abdominal Insufflation-Less Surgery (RAIS).

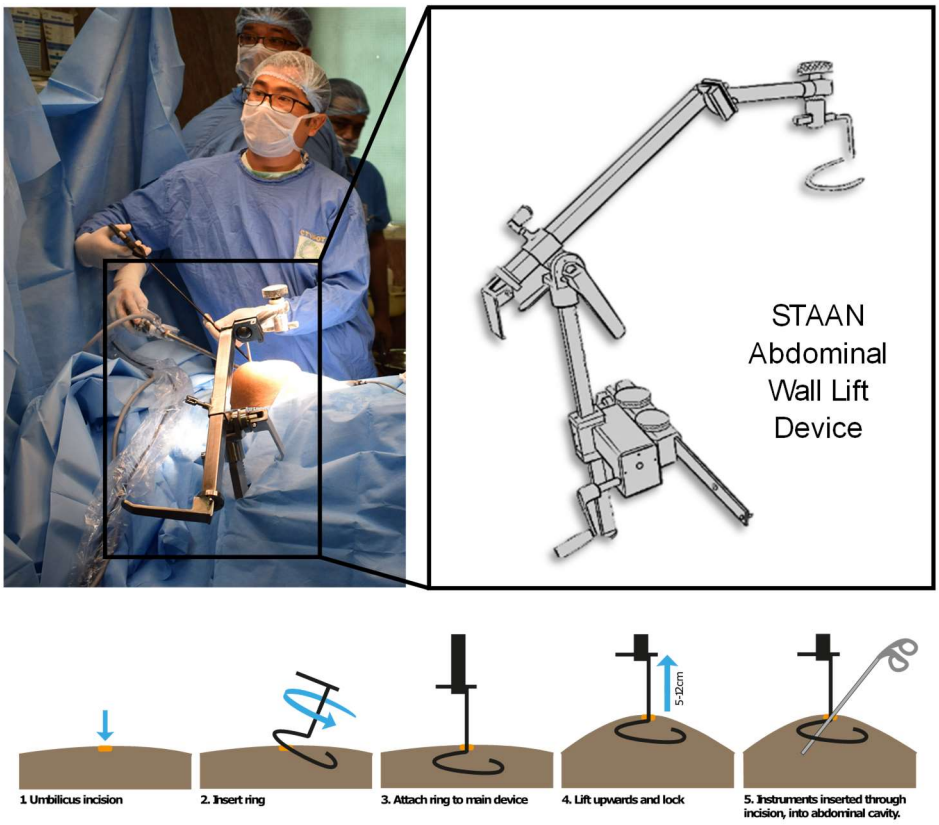


Figure 1: Principles of gasless laparoscopy and an existing abdominal wall lift device, currently in use in North-east India, from Marriott Webb et al. [26].

1.1.3 Designing a Technology for Global Surgery

Designing new health technologies is generally a difficult, but well-researched process. Established frameworks can be used to guide development, from identifying innovation opportunities through to product decommissioning [30]. However, designing surgical systems for LRHCs brings additional considerations and challenges. Limited existing literature on the topic, reviewed in Chapter 2, suggests that conventional processes are inappropriate. Alternative approaches have been proposed but appear inchoate, leading to varied interpretation and implementation by innovators and a lack of evidence with which to assess or improve them.

Therefore this research explores approaches to designing surgical technologies for LRHCs. Designing the RAIS system is used as a case-study to inform this research, providing evidence and tangible examples of implementing the approaches. One approach, which recommends

involving users in design, is assessed through two lenses: the impact of users on the RAIS design, and the impact of being involved on the users themselves, which is a novel study in this field.

1.2 Thesis Aims

The outcomes of this thesis are targeted at developing advice for innovators in designing disruptive surgical technologies to improve global access to quality surgery.

> ***Objective 1:*** *Identify existing approaches to designing health technologies for LRHCs and investigate how these have been implemented.*
>
> ***Objective 2:*** *Apply selected approaches to the design of a novel surgical device for gasless laparoscopic surgery.*
>
> ***Objective 3:*** *Document the design process, gathering evidence and tangible examples of how these approaches are implemented.*
>
> ***Objective 4:*** *Critically assess the impact of the approaches on the design development.*
>
> ***Objective 5:*** *Investigate whether the selected design approaches benefitted the clinical stakeholders involved in the process.*
>
> ***Objective 6:*** *Develop evidenced recommendations for further development of these design approaches.*

1.3 Thesis Overview

The thesis is presented in 6 chapters addressing the objectives in 1.2.

Chapter 2: Literature Review

To understand the need for a different approach to designing health technologies for LRHCs, the nuances of the design context are reviewed. Then Objective 1 is addressed by reviewing design approaches developed specifically for this context. The results of the review inform Chapter 3.

Chapter 3: Design Approach

A description of and rationale for the design approach selected to develop the RAIS device is provided, which includes aspects from the 'Design for Safe Surgery Roadmap' [31], frugal innovation and participatory design.

Chapter 4: Evaluation of the RAIS Design Development

The implementation of these design approaches is described, addressing Objective 3, and the challenges, benefits and opportunities experienced are considered. The impact of the approaches on the RAIS design is evaluated by examining the design development and the findings of clinical and mechanical evaluations of prototypes, addressing Objective 4.

Chapter 5: Evaluation of User Gains from the Design Approach

An exploratory qualitative study is used to investigate clinical stakeholders' perspectives what they gained from being involved in designing the RAIS device (Objective 5), and what facilitated and impeded these gains. The chapter concludes by reflecting on how the results might be used to enhance relevant outcomes of using a participatory design approach in this context, and hence relates the chapter content to Objective 6.

Chapter 6: Discussion, Recommendations and Conclusions

In the final chapter the learning outcomes of the project are summarised in six themes discussing important aspects of approaching designing a device for global surgery. The chapter concludes with recommendations for further development of the design approaches investigated in this thesis, to increase their usefulness for designers and create more impact on improving global access to surgery.

Chapter 2

Literature Review

The topic of surgical technology design for LRHCs is introduced with a review of current theories and knowledge. The first section investigates the nuances of LRHCs and why most technologies do not meet their needs. The second reviews benefits of using established design processes to develop health technologies and why they need adaptation for designing solutions which do meet LRHC's needs. Accordingly, recommended approaches to designing technologies for LRHCs are discussed, and their use by innovators in this context reviewed. It is concluded that to support surgical technology innovation for LRHCs these approaches need further development, using evidence generated from implementing and evaluating them.

2.1 The Need for Innovation in Surgical Technologies

2.1.1 What is a Surgical Technology?

For the purposes of this thesis, a surgical technology or device refers to any technology used during surgery which is intended for use on humans for a prescribed list of purposes, and does not achieve this purpose solely through pharmacological, immunological or metabolic means, separating them from, for example, vaccines or drugs [32].

For regulatory purposes, a surgical technology can fall into any class of medical device [33]. Due to a paucity of literature specifically addressing design of specifically surgical technologies, this review considers relevant research from the wider conversation around designing health technologies. Conversely, some findings of this research are likely to be relevant to other health technologies.

2.1.2 Issues with Repurposing Existing Technologies

More than prohibitively high upfront costs limits the uptake of surgical technologies in LRHCs. Even 'free' or donated surgical equipment is not always cost-effective [34–36]. About 40% of medical equipment donated to LMICs is not in use [36]. When donors fail to consider the context technologies will be used in or consult clinical engineering and maintenance personnel, donations arrive without spare parts, manuals or training and soon break down [34–37]. Repair can be prohibitively expensive because the necessary expertise resides on a different continent [12,36,38]. Equipment disposal can also be exorbitant [36,39].

So while cost is the most frequently considered factor in procurement planning, what most affects successful uptake of technologies is their alignment to the deployment setting [37]. Healthcare providers in LRHCs need technologies with technical specifications appropriate for their context of use that they can both afford and sustain with their resources. It must

designed for the context they work in [35,37,40]. However LMICs only account for a small proportion of global health research and development spending, and as almost four fifths of all medical device sales revenue is generated in the USA and Europe, it is no surprise that the majority of medical equipment is designed in and for western markets [38]. This equipment is neither appropriate nor always safe for LRHCs, whose needs are different to those of the current majority market [34,41]. For example, a mains-supplied surgical lighthead is sufficient in HICs, but some LRHCs experience frequent power outages, which could leave a surgeon operating blind [34,36]. A light with a battery backup is better, but generally such needs are not widely understood.

2.1.3 The Contexts Surgical Innovations Must Address

To understand nuances of LRHCs and their effects on technology uptake, we can look to Health Technology Assessment (HTA). HTA is a growing field aiming to understand all the effects, intentional or not, of implementing health technologies [42]. Considering the factors summarised in Figure 2, it provides a holistic perspective into why existing technologies can be unsuitable in LRHCs.

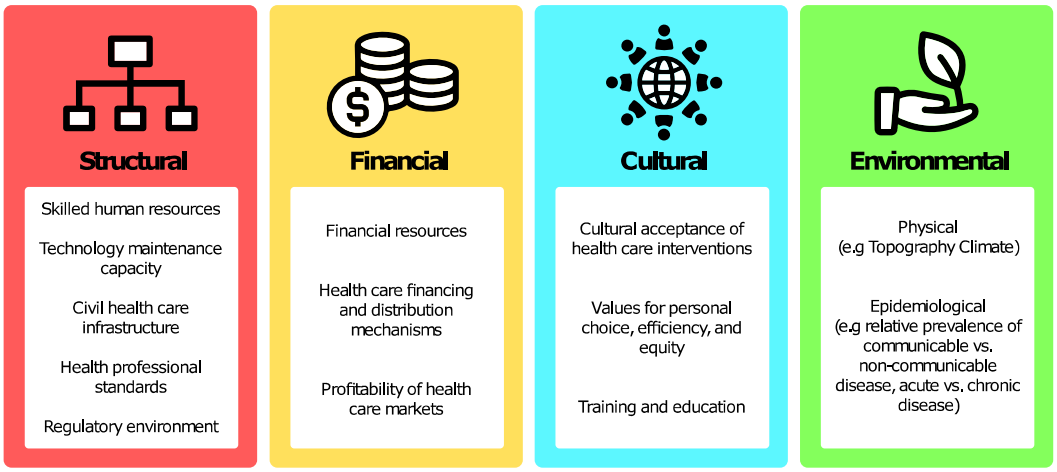


Figure 2: Contextual differences to be considered when implementing a health intervention. Content source [43]

A crucial consideration is whether the healthcare infrastructure can support a technology [37,43]. With relatively reliable supplies of highly trained healthcare workers, consumables, utilities and clinical engineers, High-Resource Healthcare Contexts (HRHCs) can utilise a wide range of technologies [44]. These technologies must conform to rigorous standards, providing assurance they can be safely used and interact with other devices in that context [45]. If they don't, procurement and legal teams can leverage the legal system to ensure the hospital or patient is compensated [45]. In contrast, infrastructure supporting LRHCs can vary radically [46,47]

and some operate with very little access it [12,22,41,45]. In these settings, technologies designed assuming the aforementioned infrastructure is in place can be difficult to implement [37,41]. For example contracts with suppliers, manufacturers and distributors may work differently [48]. Individual settings may generate their own solutions to infrastructural challenges, which should be taken into account: for example, in one hospital devices were cleaned and stored in Operating Theatre (OT) corridors by cleaning staff due to lack of a sterilisation department [39]. Finally, in some LRHCs resources are shared, such as specialist surgeons and equipment [12]. In such cases, portable equipment could be easier to implement: not usually a consideration in HRHCs [37].

The context also influences the cost-effectiveness of health technologies [3]. Both HRHCs and LRHCs overspend on technologies that barely improve health outcomes [38]. But for LRHCs with limited health budgets the opportunity cost is greater. Non-upfront costs of technologies can also constitute 80% of the total cost, which is often an unbudgeted expenditure for LRHCs [38]. Therefore, to be cost effective in LRHCs, technologies must address pressing healthcare burdens [49] and consider costs of use, training, repair, maintenance and disposal in that setting [3,36,39]. Finally, financers of the healthcare setting varies between governments, insurance schemes, private ownership, NGOs or even communities, and this affects technologies prioritisation. Some may mandate selecting the cheapest technologies, regardless of cost-effectiveness, which can complicate implementing appropriate technologies [3,39,50].

Implementing health technologies requires consideration of cultural values and mechanisms too. In some countries 80% of the population use traditional rather than modern medicine practitioners, such as herbal healers [12,51]. Acceptability of modern health technologies can vary [44,52] and in some settings household or community leaders make decisions about an individual's treatment, not the individual [12,53].

Finally, the physical environment of the context must be studied. Some technologies are sensitive to changes in altitude, humidity, temperature and air quality and can malfunction in extreme environments [37,41,44]. The health needs of populations also change with the physical environment [54].

2.1.4 The Need for Innovative, Global Surgical Technologies

Hence, there is demand for technologies designed to be affordable, available, appropriate, accessible, acceptable and quality in LRHCs [55]. Surgical technologies that achieve these criteria have become attractive products in HIC markets too due to their low cost, high

quality and robustness [56]. Contradicting historical flows of medical innovation from HICs to LMICs, this is sometimes known as reverse innovation [22,57,58]. Hence, technologies designed for LRHCs can improve surgical care globally. The World Health Organization (WHO) recognised this with annual calls for innovative health technologies designed for LRHCs between 2010 and 2016 [29]. Yet despite their potential, such innovations have had low success rates. The most recent call identified only 39 in prototype stages and 29 commercially available technologies, reflecting a 60.7% selection rate of technologies submitted with sufficient details and a 12% acceptance rate overall [29]. A review of health technologies designed for LRHCs in 2013 also found few were implemented at scale, and overall failed to address the largest health burdens in LMICs [49]. This suggests even the few innovators targeting LRHCs find designing appropriate technologies challenging.

One possible explanation is that despite progress in HTA, comprehensive data on aspects discussed in 2.1.3 is rarely available for LRHCs [41]. This lack of information is a barrier to industry investment in global health technologies [43] because designers must often make predictions using data from small samples of respondents [36,37,39]. This, among other aspects, introduces risk into health technology development that the industry does not have established strategies to mitigate. To improve the efficacy of research and development in this sector and support organisations to innovate and commercialise surgical technologies for LRHCs at scale, it has been suggested that specific design processes to develop LRHC-appropriate technologies may be required [49].

2.2 Conventional Surgical Technology Development

This section investigates conventional approaches to designing health technologies to understand whether they are appropriate for innovating for LRHCs.

2.2.1 Nuances of the Industry

Even for HRHCs, developing surgical technologies is a high-risk process [38]. It is rigorously controlled by standards and regulatory authorities [51]. Regulatory requirements are continuously evolving, requiring businesses to be flexible, innovative and to invest large sums in new technology development [30,48]. It often relies on public sector input: for research, infrastructure, funding and even to influence the market [51]. Furthermore, user perspectives and expectations vary significantly and often contradict those of purchasing stakeholders [30]. Ethics are fundamental to the entire sector and must be considered throughout product

development processes. These challenges make project failures common and expensive, leading to price inflation of successful products [51].

2.2.2 Conventional Medical Device Development Processes

Design processes are used to navigate this complexity [59]. They often consist of a chronological framework of and advice for completing design activities such as Quality Function Deployment, Functional Analysis, Pugh Matrices, Design for X or Failure Mode and Effects Analysis (FMEA). The Linear Stage-Gate process [60] and Medical Device Design for Six Sigma [61] are popular examples [59]. The way in which they collect, organise and explain knowledge of industry experts, generated through years of successes and failures, is invaluable [60]. Their use offers organisations benefits such as developing higher-impact products and reducing risk [62], but to be effective they must continuously evolve to keep up with healthcare contexts and be tailored to an organisation's resources and products [59,62,63].

2.2.3 Suitability for Use in Designing Global Surgical Technologies

Of course, there is useful content within these processes for developing technologies for LRHCs. However, they are based on the experience of experts that have primarily or only designed technologies for HRHCs and inherently target them. The stage-gate process is a good example [60]. Similarly to others [64], the overall structure of the process is tailored to comply with standards set by the United States Food and Drug Administration (US FDA) or the European CE mark, which may be inadequate to regulate health technologies in LMICs, because they do not consider the nuances of LRHCs [58,65]. The design activities created with HRHCs in mind do not consider issues performing the same in LRHCs: for example, it suggests assessing the financial impact of delaying product releases, which could come at great human cost in LRHCs [60]. Simply put, there are new priorities, risks, challenges and opportunities in innovating technologies for LRHCs, making existing processes less effective since they are no longer carefully tailored to the design context [62,63]. To develop technologies for LRHCs, new approaches are required [22,40,65].

2.3 Design Processes for Global Health Technologies

To address this, authors have undertaken developing new high-level design processes specifically for LRHCs. Reviewing the literature revealed four such processes, which, similarly to conventional medical device design processes, advise on overall structuring of the design development and what activities should be performed at each stage [31,58,66,67].

2.3.1 The Stanford Biodesign Process

The Stanford Biodesign process is the most established of these [67]. While the first edition focuses primarily on innovation in HRHCs [68], the second edition recognizes different global contexts necessitate different design considerations.

The overall structure (Figure 3) of the process remains very similar to the edition developed for the US market. Instead of adapting the process itself, the authors add supplementary advice for different global healthcare markets, including a background, a discussion of context-specific challenges and an array of tactics for innovators to utilise. For example, in India, one should 'search for needs in country', 'go deep on stakeholder analysis' and 'keep innovating beyond the technology' [67].

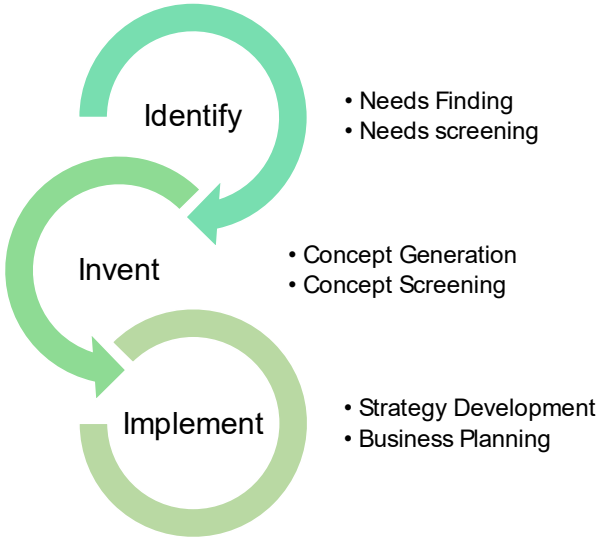


Figure 3: Stanford Biodesign Process. Adapted from [67]

Again, this raises questions as to whether conventional medical device design processes may be adequate for LRHCs. However what separates the Biodesign process from for example, the Stage-Gate Model [60] is its focus, from project initiation, on addressing clinical needs and creating value for stakeholders (see 2.4.1 for more on value innovation). The purchasing power of LRHCs is low and concentrating spending where it can create the greatest health benefit is important. Therefore, identifying a pressing clinical need to address is the first step towards designing global health technologies. On this, many processes agree [31,58,66,67,69,70].

2.3.2 The Globally Responsive Device Realization Process

While less detailed, and not fully expanded upon, the 'Globally Responsive Device Realization' process [58] shares a similar structure with the Biodesign process [67]. It also imparts

advice: one should recognize the importance of local clinical stakeholder experience in both need identification and implementation stages. The involvement of local stakeholders is a second matter agreed upon by all processes reviewed, and is discussed further in 2.4.2.

2.3.3 The Design Thinking Process

In fact, two innovators [66,69] went so far as to utilise a 'Design Thinking', or human-centered process for this design context. Not specifically intended for the design of health technologies, this process sets out broad steps (empathize, define, ideate, prototype, test, refine) intended to ensure continuous integration of stakeholder feedback and priorities into a design process. Each identified that this process alone was not sufficient to guide their development process and ensure the success of their product [66,69]. However, both successfully adapted the 'Design Thinking' structure, notably implementing their products at scale, and supplemented it with their own insights to guide future innovators.

2.3.4 The Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide

In contrast to the 'Design Thinking' approach, which is applicable to many design contexts, Oosting et al. (2018) developed a specific process for designing surgical devices for global contexts: the four-phase 'Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide' (Design for Safe Surgery Roadmap) (Oosting et al., 2018). The roadmap (Oosting et al., 2018) is more limited in scope than the Biodesign process, but more detailed and specific to a healthcare context than the 'Design Thinking' structure, while also placing emphasis on understanding and addressing nuances particular to LRHCs. Phase 0 of the roadmap (Oosting et al., 2018) focuses on identifying an unmet health need and Phase 1 on understanding the local context. Phase 2 concerns determining the design requirements and a strategy for implementing the device. Finally, Phase 3 is to 'Act', engaging in co-creation with LMIC stakeholders to produce a design and prototypes.

Collectively there is little evidence of these design processes being used in the literature, and similarly they are infrequently cited by studies which encourage innovation for addressing the need for appropriate technologies in LRHCs. In fact, in providing advice for innovators in this design context, more studies describe two core principles for design, which are discussed in the following section.

2.4 Core Principles for Designing Global Health Technologies

Several reviews identified two core tenets to designing and implementing global health technologies, which resonate with aspects of the design processes reviewed in 2.3:

participatory design (PD) and frugal innovation (FI) [3,22,37,38,40,44,49,55,71]. Instead of providing step-by-step design frameworks, these concepts describe design process aims, and principles which the designer should use to achieve them.

2.4.1 Frugal Innovation

2.4.1.1 Definition and general use

FI can refer to the process of designing frugal products or to the product itself. The FI process, also known as 'Jugaad', 'good-enough' or 'value' [57,72,73], is often simply described as providing more value to users using less resources [22]. FIs have been disruptive across different industries, from Tata's 'Tata Nano' [74], the world's cheapest car, to the 'Foldscope' [75], an origami microscope costing less than a dollar. According to Weyrauch and Herstatt [76], who have, in the author's opinion, considered definition of FI most thoroughly [77–79], FIs have three attributes (Figure 4) in common: "substantial cost reduction, concentration on core functionalities, and optimised performance level" [76].

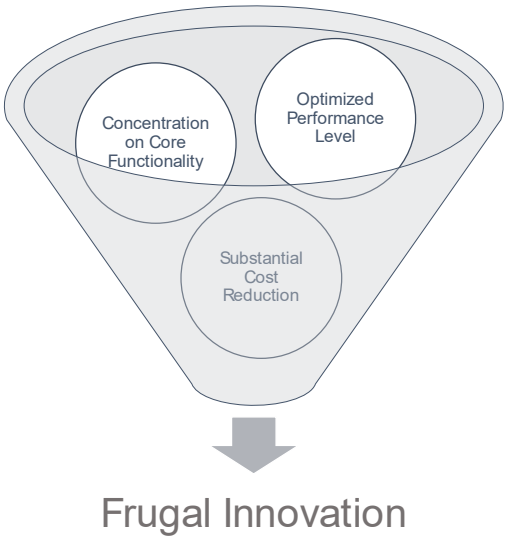


Figure 4: Principles of Frugal Innovation. Content source [76]

Hence FI encompasses more than cost-cutting or the problematic term 'simplification': a product can achieve the criteria with a complex or creative solution, but it must be low-cost and meticulously optimised for its purpose [80,81]. Avoiding over-design and inclusion of unnecessary functions facilitates increased value for stakeholders over conventional solutions [82].

2.4.1.2 Use in designing technologies for LRHCs

Several aspects of FI make it favourable for designing technologies for LRHCs. With large gaps in access to healthcare to address, its relationship with sustainable social development

and focus on affordability for the Base of the Pyramid is key [83,84], crucially without compromise on quality and robustness, which in healthcare is paramount. Examples of frugal surgical innovations include adapting cheap mosquito netting to replace surgical meshes in hernia repairs [82] and use of a flutter valve to drain fluids and air out of the thorax [57]. By providing comparable performance to existing technologies at a fraction of the cost, these innovations are disrupting the norms of innovation in the health technology sector and have the potential to improve surgical care in both LMICs and HICs [22]. Through calculated value optimisation FIs also frequently result in lower training and maintenance needs along with high robustness: desirable characteristics of products designed for LRHCs [22,40(p),44,57,73].

While the principles and theoretical frameworks describing FI are well-defined, methods for implementing it are not [76,77,79]. It is described as a complex process which has implications across all innovation functions, but there are few specific methods or design tools innovators can use to help their surgical innovations meet the 'frugal criteria' and they are not typically explored in-depth [77,79,85]. Instead, studies present varying and sometimes conflicting common features of FIs for designers to consider: for example 'lightweight' or 'adaptable' or 'use of local materials / manufacturing' [79,86,87]. These have limited practical use for designers: while they can set the objectives for innovation, they lack the detail to help designers prioritise these objectives according to the setting and achieve the delicate balance of optimising performance [76,85].

However, studies agree on one FI method: engaging and co-creating with 'prosumers', or stakeholders, in design [22,77–79]. Bringing together expertise from diverse settings and professions can enhance a team's ability to innovate frugally, and be fundamental to the success of those innovations [88]. Stakeholders can influence consumer behaviour whilst adding to the design team's competencies, facilitating new thinking [79]. In fact, many frugal surgical innovations originate in LMICs, where innovators have first-hand knowledge of LRHCs or access to stakeholders who do [57,73]. Often, while a major barrier to health technology designers in developing optimised frugal, global devices is a paucity of information on the context of use [89], a barrier to frugal innovators in LRHCs developing technologies is lack of experience in for example, navigating regulatory requirements and certifying products [73], or a lack of resources to support a full research and development process [44]. It is unsurprising then, that PD is mentioned frequently alongside FI [44,58] and it is predicted that multinational corporations with operations in LMICs will accelerate frugal technology development [44].

2.4.2 Participatory Design

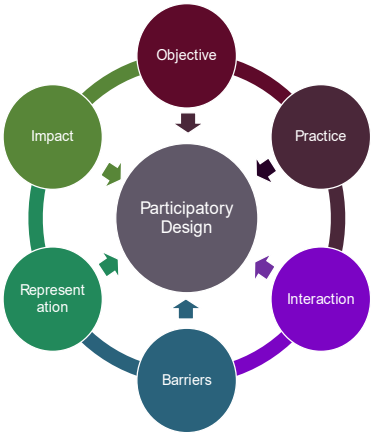
2.4.2.1 Definition and general use

Central to PD is the argument that individuals should be involved in the design of systems that they interact or produce work with [90]. It has different forms, including, but not limited to, 'co-design', 'co-creation', 'cooperative design' and 'design thinking' [91], but all are linked by a common idea. The idea is that some additional benefit, whether an improved system performance, learning and development of participating stakeholders, or something different, can be achieved through engaging stakeholders affected by a system's design in the process of designing it [92]. Although frequently interpreted to mean the same, PD is distinct from user-centred design, which is considered necessary in all health technology development for safety reasons and can be a regulatory requirement for a medical device design process [93,94]. Rather than collecting knowledge from stakeholders to feed into design activities, PD projects ensure stakeholders participate in design activities themselves [69,95]. PD has been frequently recommended as a principle for designing appropriate technologies for developing countries [83,96–99], and specifically for LRHCs [69,71,100–102].

2.4.2.2 Evaluating PD

PD is a diverse field and the concept is interpreted, implemented and reported on differently between and within industries. To evaluate use of it, practitioners recommend using frameworks, which elucidate what the essential aspects of PD projects are. A number of these have been developed [92,98,103,104]. Of these, the PartE framework was selected to review use of PD in global health technology design [104] because it offers a number advantages over others. Created by technology designers, but using rigorous qualitative methods, it is systematic and balances the focus of the evaluation between inputs, the process itself and outcomes, while others focus purely on outcomes [98,105]. The developers also engaged in an evaluation process to refine and increase the validity of the framework.

The framework splits PD into dimensions, shown in Figure 5. A PD project may display one or many attributes within each dimension. For example, the *Objective* dimension of a PD project could have three attributes: designing 'Material Things' (such as a rice-seeder for visually impaired community members in rural Cambodia [98]); changing 'Organisation, Rules and Information Flows' (such as ensuring those community members continue to present at community meetings and influence decision-making [98]) or changing 'Mind-sets and Paradigms (such as changing how people with disabilities are viewed by themselves and the community [98]).



	Dimension	Attribute				
		a	b	c	d	e
1	Objective	Material Things	Organisation, Rules, Information	Mind-sets, Paradigms		
2	Practice	Well-known Formats	Emergent Practices	Novel, Unpredictable Approaches		
3	Interaction	Contribution of resources & information	Exchange & Awareness of Contributions	Collaborative Contributions		
4	Barriers	Economic	Environmental	Political	Social	Individual
5	Representation	Direct, Autonomous	Indirect, Delegated	Appropriated, Self-appointed		
6	Impact	Short-term, Small scale	Long-term, Large scale	Indirect, Unintended		

Figure 5: PartE framework [104] for evaluating PD initiatives. Adapted from source.

Others recognised formally searching literature concerning development of technologies for LRHCs yields limited results, and that PD is a central focus of few studies [69,71]. Therefore the next sections use the PartE framework to structure a broad reflection on the involvement of users and other stakeholders from LMICs specifically in the process of developing technologies for LRHCs to learn about PD in this industry. Three types of studies contributed to this. The first are case-studies, typically reflecting on a single experience of designing a technology [101,102,106,107]. A second type details an approach to developing technologies for LRHCs, typically developed by a research collaborative or established health technology developer, reflecting on learning across multiple projects [58,69,108–110]. The third type reviews projects from multiple research groups and other innovation hubs targeting LRHCs, in the form of a systematic or informal review [69,71] or via qualitative study with experts [31,100].

2.4.2.3 Objective of PD in designing technologies for LRHCs

The *Objective* of involving stakeholders is most frequently optimisation of the health technology, falling into the *Material Things* attribute. Through working with stakeholders in LRHCs, innovators aim to reduce costs or improve alignment of devices to LRHCs [58,71,100–102,106–108]. Studies with additional objectives in the *Organisation, Rules and Information* and *Mind-sets and Paradigms* attributes argue that involving stakeholders purely for this is inefficient in this context. Hussain et al. [102] proposed that PD processes should prioritise the product and psychological empowerment of participants equally. They, and others, argue that for technologies to sustainably reduce global inequities in healthcare and be acceptable to poor and marginalised communities, other objectives are important: developing and linking up local human capacities to support technologies (such as training providers, manufacturers, biomedical technicians and innovation hubs) [58,69,108–110], changing existing perspectives on appropriate technologies for LRHCs [69,109] and empowering local champions

to innovate, drive and campaign for their scale-up and implementation [58,69,102,108–110]. This is a common perspective of studies built upon the experience of designing and implementing multiple technologies.

2.4.2.4 PD Practice in designing technologies for LRHCs

The *Practice* dimension focuses on practical methods for involving participants in design, which could be *Well-known, Emergent* or *Novel*. Again, most studies sit within the first attribute, using *Well-known* formats of participation like interviews [58,69,71,100,102,108], focus groups [69], questionnaires [58,100,107,108], and clinical observation [69,71,100,101,110], especially in early design process stages. Cultural probes, outcome-driven innovation [101] and design ethnography [110,111] were also used to elicit contextual information from stakeholders. Prototype making is used infrequently in early stages [100,102], but prototype evaluation is common in later stages [58,69,71,100–102,107–109].

Authors rarely mention *Emergent*, or context-adapted methods, but some elicited more useful findings by briefing or training multidisciplinary stakeholders on design methods prior to using them [69,100,101]. To overcome language barriers, authors found visual and physical aids (such as sketches and prototypes) and situating the device within the context (using sketches, storyboards and role-playing) useful [69,100]. Notably, one author designed 'Participatory Cards', enabling participants unfamiliar with drawing to build sketches [69]. Overall, the lack of *Novel* and *Emergent* methods used seems strange. Evidence shows that poor and marginalised communities disproportionately lack adequate healthcare [3,69], and deep understanding of these contexts is crucial for successful technology implementation. *Novel* methods help ensure all participants, regardless of education, language and social status can participate fully in the design process, and hence ensure their healthcare needs are met, but have not been explored.

2.4.2.5 PD Interaction in designing technologies for LRHCs

Interaction refers to how PD practitioners and participants exchange and generate knowledge. Attribute 'a' implies a one-way information transferral from participants to designers, but attribute 'b' describes stakeholders working as a team, recognising their own place among others in achieving project aims. In attribute 'c' participants are truly equal stakeholders in the design process, contributing and collaborating proactively and independently [104]. Overall, this dimension is difficult to assess since stakeholders are not the focus of many studies and it is unclear what individual contributions they make. However,

Interaction between stakeholders within the studies can be inferred from the *Practice* dimension.

The most popular methods – questionnaires [58,100,107,108], interviews [58,69,71,100,102,108] and observation [69,71,100,101,110] – all inherently generate one-way information flows, from participants to designers. Stakeholders are often involved to identify healthcare needs, collate information on contexts unfamiliar to designers and develop design requirements that represent stakeholder needs [80,100,101,107]. These initial activities are considered the most PD important stage, since participants can exert the most influence over the resulting device [100,112]. In later design stages, stakeholders evaluate concepts, however methods such as surveys and questionnaires again indicate this is a one-way information flow [71,107].

Some studies argue that involving participants throughout the design process as equal partners significantly increases the value of their contributions [58,69,102,108–110]. In fact, many consider bi-directional information flows, where participants contribute openly and co-create solutions, necessary to ensure sustainable technology implementation in LRHCs [58,102,108]. In the design of the frugal Pre-Pex device, now used at scale in district hospitals in Rwanda, Mody et al. [58] noted that strong the partnerships with local clinicians and institutions formed by involving them in every design process stage engaged the interest and creativity of local participants in implementing the device, which could affect their motivation to remain and solve further challenges in LRHCs.

2.4.2.6 Barriers to PD in designing technologies for LRHCs

The *Barriers* dimension intuitively refers to impediments to implementing PD initiatives [104]. In global health technology design, authors frequently cite a lack of sustainable funding to access stakeholders in LRHCs. This barrier has both *Economic* and *Environmental* attributes – design teams commonly live on different continents to the settings they are designing for, which can be remote [100,102], and justifying large travel expenses to interact with participants is challenging [69,100,102]. One designer expressed that if not for *Economic Barriers*, they would like user input into every design decision [100], and others relied on students volunteers due to finance constraints, causing issues when they prioritised or finished their studies and dropped out [100,108]. Mody et al. [58] highlighted that local infrastructure could be another *Environmental* PD barrier, especially in collaborating with local manufacturers, who were limited by unreliable supply chains and distribution channels.

Possible *Political Barriers* include lack of institutional boards in LMICs to review clinical studies which adds risk to conducting them with participants in LRHCs [58], and obtaining the

buy-in of multidisciplinary participants, from users to policy-makers, with different ideas and objectives [69,100]. However Holeman and Kane [69] see this as intrinsic to the need for PD, because through collaborating as equal stakeholders both the product and these different perspectives can be adapted simultaneously until they converge into a universally acceptable solution. *Social Barriers* to participation often only became evident when, like this, participants worked together over extended periods. Hussain et al. [102] noticed that social structures could hide voices, for example, when children defer to parents opinions. These participants can make valuable contributions, as discovered by Gheorghe [101] when evaluating individual diaries that clinical staff filled in (a cultural probes method). These participants did not contribute in front seniors but provided invaluable insights when asked privately. Language *Barriers* also caused misunderstandings and important factors to be overlooked, even when translators were used [102].

Finally, *Individual Barriers* to PD mostly centred around clinical participants having busy, unpredictable schedules, and even 'burning out' [69,100,101]. According to some designers, their frustrations using low-fidelity prototypes or with the progress of designs stemmed from their lack of design process experience of *Individuals* [100]. Overall, no studies directly asked participants what *Barriers* to PD they experienced, so, as with the other dimensions in the framework, these *Barriers* represent the designer's perspective only.

2.4.2.7 Representation of PD participants in designing technologies for LRHCs

Representation encourages reflection on which stakeholders are recruited and their ability to influence PD decisions. In attribute 'a' one stakeholder attempts to represent the interests of many without their explicit permission, in 'b' individuals represent themselves and in 'c' a representative has explicit permission to represent others, whether voluntary or enforced (paid) [104]. The *Representation* of stakeholders in decision-making was difficult to ascertain in almost all studies.

Again, the popular methods of interviews, questionnaires and observation to involve stakeholders suggests they were able to inform decisions, but were infrequently involved in the decision-making process itself [71]. For example, stakeholders are often asked to evaluate prototypes, but rarely to create or change them themselves, or to select final concepts [100]. Sometimes this falls into attribute 'c' *Entrusted* or *Delegated Representation*: by participating in an interview or workshop, the interviewee gives permission for the interviewer to represent their voice in decisions [101,107].

Observation, however, comes under attribute 'a' because the participants lack a voice in what information is recorded or how it is construed [110] so the observer *Appropriates* that stakeholder's voice in decisions. Another study interviewed 'proxy users' from HRHCs instead of stakeholders working in LRHCs to inform design decisions: another example of attribute 'a', and something they found problematic since proxy users held different views to users in LRHCs [100]. When *Representation* falls into this attribute, PD is not necessarily democratic and becomes subject to the designer's biases. Appropriating participant's experiences from texts or experts can smooth-over important factors [69]. One study argued that in the complex design context of global health technologies, it cannot compensate for embedding the everyday experience of stakeholders into the design process, which truly grounds the product in local contexts [69].

There are also examples of the final attribute, *Direct, Autonomous Representation*. In two studies, 'core teams' of collaborators involved clinicians and biomedical engineers from the target LRHC, suggesting they directly influenced decisions [108,109]. In another, participants created their own designs, which were transformed into higher-fidelity prototypes by the designer to achieve participant priorities [102]. Again, Holeman and Kane [69] consider this important for developing disruptive health technologies, as it ensures as many concepts as possible are explored without bias before a solution is agreed upon. As discussed, excellent FIs in global surgery often originate from innovators in low-resource contexts [81]. Therefore this attribute of *Representation* in design stages such idea-generation and iterative design and development [66] is thought to result in more disruptive and appropriate, acceptable, affordable, available, accessible and quality technologies [38,69,100].

2.4.2.3 Impact of using PD in designing technologies for LRHCs

The final PD dimension is *Impact*, which could be *Short-term* or *Small-scale Changes, Long-term or Large-scale Changes,* or *Unintended* or *Indirect Changes* [104]. Many studies progressed technologies through user testing [71,101,106,107,109] or formal clinical trials [58,71,100,108]. Despite promising results, these *Impacts* are attribute 'a', *Short-term and Small Scale Changes*, until they are implemented sustainably in LRHCs. While predicting the future of these technologies is difficult, reviews suggest most are never implemented at scale [49,71].

However, studies also attempted achieving *Long-term and Large Scale* impacts [58,69,108,110]. Mody et al. [58] described a low-cost technology's incorporation into the National HIV Prevention Strategy in Rwanda, training over 50 healthcare professionals in its use and engaging local teams to ensure its sustainable implementation. This work even increased

demand for male circumcision amongst young people. Ayah et al. [108] saw through drafting of novel national medical device standards and built innovation capacity and networks in Kenya. Evidently, *Impacts* must be weighed against the level of funding, and to say which project had the most *Impact* and why is not possible with the level of evidence presented in manuscripts. It is however, of interest to note that many *Long-term Impacts* identified are related to capacity, partnerships and skills developed innovating technologies [58,69,102,108–110]. Holeman and Kane [69] considered these outcomes necessary to enable longer-term and larger-scale impact of health technologies, since they must be continually evaluated and updated to adapt to ever-changing needs.

Finally, the *Impact* of PD on participants was only considered by one study [102], which argued that empowering outcomes of a design process were of equal value to the product outcomes, but still did not formally evaluate them. While many studies highlighted the importance of involving participants from LRHCs in PD [58,69,107,108], only two reflected on the extent they were able to participate in the design process [102,109]. The 'Global Health Technology 2.0' research and development model described assessing projects on the level of cocreation achieved but further detail was missing [109]. Hussain et al. reflected that they did not achieve true co-creation and participants needed training to become equal stakeholders. When compared to greater PD literature, the lack of evaluation any *Indirect Impacts* on participants is striking [92,98,103]. It has also been argued that stakeholders should set aims and outcomes for measuring the *Impact* of innovations on target contexts [105], but this has not been practiced in global health technology design.

2.4.2.7 Overall themes in PD practice

There are certainly benefits to involving participants from LMICs in the design process such as improved alignment of a health technology to a LRHC [31,89] and innovative, frugal designs [88,109], which are well-understood and sought after by PD practitioners in the field. However within each dimension, participation most frequently sits within the first attribute of the Part-E framework [104], indicating tendency towards a 'light touch' involvement of participants from LMICs. They rarely become fully integrated into the team and instead take the role of informants and reviewers. Whether an explicit choice, or a result of the frequently mentioned *Barriers* of funding and travel, some argue this is insufficient [101,109] and studies leaning towards increased participation, especially through manufacturing and implementation stages, see great benefit in doing so [58,69]. This co-creative approach can remove *Political* and *Social Barriers* to collaboration, increasing democracy and rendering multidisciplinary participants and designers equal stakeholders in the process and product

[58,69,102]. Such projects can emerge with well-placed advocates to drive successful implementation of the project outcomes [98]. Similar benefits have also been identified in wider medical device design literature [3,112,113] and the beneficial impact of sustained interaction and collaboration between HIC and LMIC students is recognised by biomedical engineering courses at universities despite high costs of transferring students [109,110,114,115].

However, the paucity of studies rigorously evaluating participation in global health technology design means few conclusions can be drawn about PD in this context. While in wider PD literature there is evidence of such benefits and studies which rigorously evaluate the effect of the dimensions similar to those described in the PartE framework [92], global health technology design projects rarely do. Beyond anecdotal evidence, exactly which, when and how stakeholders are involved, and what effect this creates has not been directly studied. Sustainable improvement to the design and uptake of appropriate technologies and access to safe surgery in LMICs could make vast improvements to quality of life for the majority of the world's population. To know what level of participation is right for each project, for the context of designing devices for global surgery and for achieving this aim, more rigorous evaluation of PD in global health technology design projects is needed.

2.5 Summary

Developing surgical technologies for LRHCs may be more difficult than conventional surgical technology design, since the 'design space' or number of viable design options is much reduced, due to resource constraints and fewer acceptable combinations of three variables (cost, robustness and maintenance) [48,116]. This review established that to cope with this challenge, improve adoption of surgical technologies in LRHCs and increase access to surgery globally, they must be designed using different approaches.

To address Objective 1 of the thesis, existing approaches to designing surgical technologies for LRHCs were reviewed. Significantly less experience in, research into, and guidance for global health technology design was identified in the literature than for conventional health technology design. Four design processes and two core principles addressing design for LRHCs were identified. Investigation revealed little evidence of design processes being implemented and that they are in relatively early development stages. Furthermore, the principles of FI and PD are interpreted and implemented differently by innovators and do not provide adequate structure or methods to aid in achieving the objectives they set out. In general, relevant projects have been criticised in systematic reviews for their diverse and

often poorly articulated or incomplete methodologies, lack of rigorously evaluated outcomes and an abundance of grey literature [49,71].

Without the same guidance that conventional medical device designers rely on, innovators must currently investigate how they should design their products as well as determining what their design will be. To address the paucity of evidence with which to develop and refine recommended approaches, this work sets out to describe implementing them in the design of a device for gasless laparoscopic surgery and to evaluate the benefits, challenges, opportunities and risks incurred. In particular, to address the lack of rigour in PD evaluation in this context, an attempt will be made to systematically describe and evaluate participation, and investigate benefits for the product and participants.

It may not be prudent or possible to set out a complete, structured design process for global surgical technology design. Each project must design for a different context and regulatory environment and may come with individual challenges and opportunities. Therefore the ultimate aim of this work is to begin building knowledge and evidence that innovators can use to predict some of these aspects, and develop proactive strategies to address them. Using this knowledge to mitigate project risk and increase impact of their surgical technologies, innovators can further improve global access to surgical care and contribute towards achieving UHC [2,113].

Chapter 3

Design Approach

This chapter describes the design approach pursued, providing a rationale for the main and supplementary activities planned for developing the design of a device for gasless laparoscopic surgery.

Work contributing to this chapter was published in the International Journal of Surgery Global Health:

Marriott Webb, M., Bridges, P., Aruparayil, N., Mishra, A., Bains, L., Hall, R., Gnanaraj, J., & Culmer, P. (2021). Designing devices for global surgery: Evaluation of participatory and frugal design methods. IJS Global Health, 4(1), e50

3.1 Introduction

The previous chapter revealed three key design approaches to the development of technologies for LHRCs: design processes suitable or even specifically developed for this design context, frugal innovation and participatory design.

These approaches complement rather than compete with one another. In fact, in some ways they are indivisible. The principles of FI help innovators set design objectives and priorities to develop disruptive global surgical technologies, but design processes and PD provide means to achieve those objectives. Design processes for LRHCs encourage use of PD, but reviewing use of PD in this context revealed that not only is it resource-hungry and interpreted and implemented in different ways, but the impacts of using it are rarely evaluated. Advice for designers on how to specifically structure and implement PD to achieve desired outcomes it is needed, which design processes may be able to provide. Hence, it is possible and even desirable to implement the three approaches simultaneously. Therefore this research project explores integrating them to design a device for gasless laparoscopic surgery – the Retractor for Abdominal Insufflation-less Surgery (RAIS).

Literature surrounding these approaches has been criticised for lacking clear methodology. Integrating them could make drawing distinct boundaries between them, and articulating how each has been implemented and what impact that has had, challenging. Therefore, this chapter aims to describe the plans made prior to designing the RAIS device for implementing these approaches to facilitate a structured, critical evaluation of each.

3.2 Planning the RAIS Design Process

3.2.1 Design Process Selection

Design processes can help organisations achieve greater impact with their products, and navigate risky and complex innovation sectors such as medical device design [30,117]. To be effective, they must be tailored to the organisation, product and resources available [63].

Four relevant processes to this design context were identified and compared in 2.3. With the aim of the wider research project being to meet the pressing clinical need within an ambitious timescale, investigating more than one process and comparing the designs developed was not possible. Therefore, based on the rationale in the following paragraphs, the Design for Safe Surgery Roadmap [31] was selected to structure the approach to designing the RAIS device.

The roadmap (Oosting et al., 2018) is more limited in scope than design processes employed for HRHCs. Comparing the level of detail to, for example, the Linear Life Cycle Model [118] as in Figure 6, makes this evident. The roadmap describes four phases in developing a surgical technology, but rather than fully defining completion criteria for the phases, or mandating design activities to complete within them, the roadmap presents general advice and some relevant examples. The user must consider how these examples translate to their own innovation development, and plan their own activities in each phase. This is particularly true for the latter two phases of the roadmap, while the first two phases provide more detailed guidance.

This detail scarcity forms part of the rationale for its selection over other relevant processes for designing the RAIS device. The process has less overhead than more complex schemes like Biodesign Process [67], and is thus feasible to implement as part of a small team, with limited timescales and resources available. These are crucial considerations for ensuring a design process enhances, rather than exhausts, the capabilities of an organization [117,119]. It is also tailored specifically for designing a surgical technology in a LRHC: the precise design context of the RAIS device. Finally, being in the early stages of development and yet to be implemented widely, the roadmap needs the community of innovators in global surgery to use, reflect upon, and improve it. In this way its strengths and weaknesses can be established and its continuous evolution initiated. Evidence of its use may encourage others to implement and disseminate it further. Therefore, providing a detailed account and evaluation of implementing the Design for Safe Surgery Roadmap [31] supplemented with

tangible examples to demonstrate its use and impact on the RAIS design development forms a useful contribution towards the literature and the objectives of this thesis.

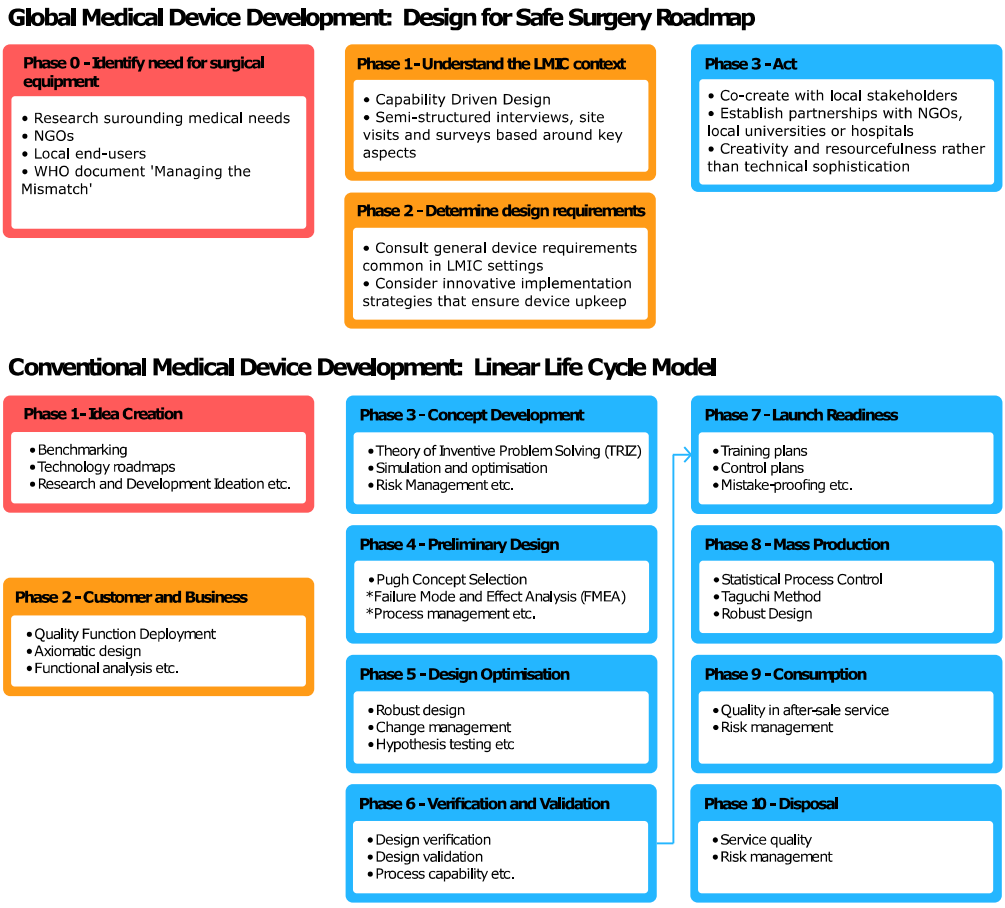


Figure 6: Comparison of the Design for Safe Surgery Roadmap [31] and the Linear Life Cycle Model [118]. Adapted from sources.

3.2.2 Design Process Structure

As discussed in the previous section, the roadmap does not present a complete guide to developing a surgical technology. This section details how the RAIS team planned and selected design activities within each roadmap phase.

Firstly, the design project ambitions spanned beyond the scope of the roadmap: past prototyping and testing; into manufacture, application for regulatory approval and clinical trials in India. Therefore an additional 'Design to Manufacture' phase was included, as shown in Phase 4 of Figure 7. Some organisations may involve manufacturers earlier, perhaps to create prototypes in Phase 3, and therefore design to manufacture may not constitute a distinct phase in every design process. However the RAIS team could utilise in-house prototyping capabilities, so manufacturer involvement was purposefully delayed until clinicians had tested and approved the design. This would facilitate rapid changes to

prototypes and iteration throughout Phase 3 of the roadmap. With advancements in and reduced costs of rapid prototyping [120], this is feasible for many organisations.

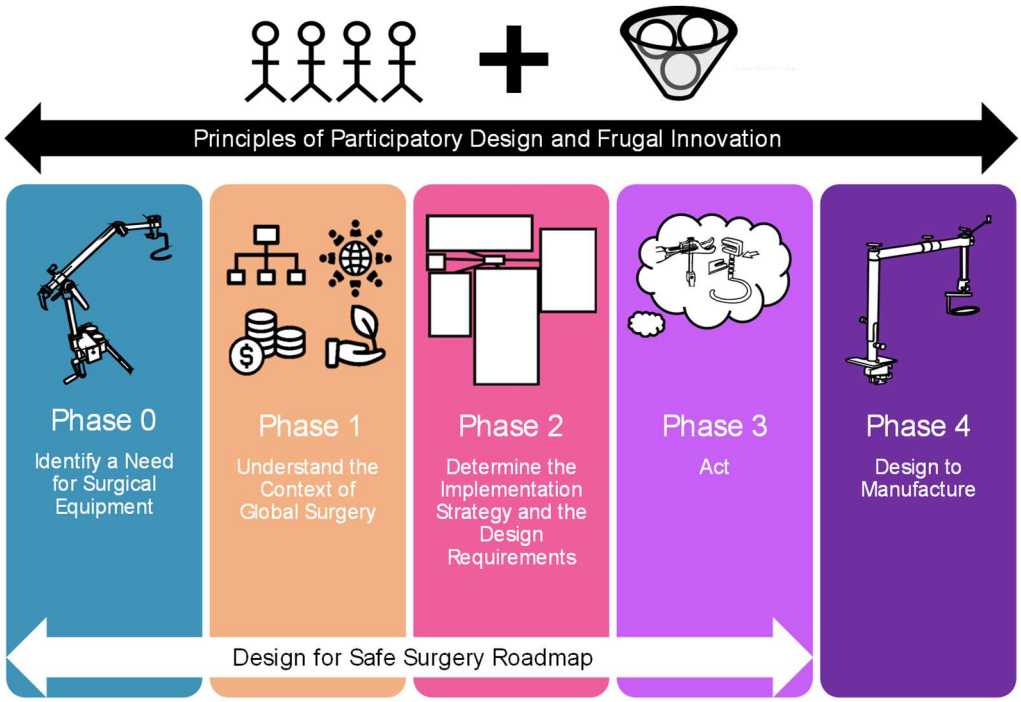


Figure 7: The RAIS Design process, developed using the Design for Safe Surgery Roadmap [31] and principles of Frugal Innovation and Participatory Design

3.2.3 Integrating Participatory Design and Frugal Innovation

The team used the principles of PD and FI to guide activities within the roadmap, as described in the following sections.

3.2.3.1 Frugal Innovation

While there are few specific methods for designing FIs, they must meet three criteria: substantial cost reduction, focus on core functionality and optimised performance level [76]. Co-creating with users is recommended [79], as well as prioritising numerous frugal characteristics [86].

Aspects of FI must be considered in every design phase. In Phase 0 of the roadmap, a pressing surgical need should be identified. FIs can improve surgical care globally [81], and this potential to create large-scale impact should be considered when selecting a need to address in order to create maximum impact on global surgical care. In Phase 1, the innovator develops an understanding of LRHCs. Understanding users is a key component of this, and FIs must optimise value for them [79]. Therefore the data collected in this phase is crucial to innovate frugally. FI also sets key design priorities, such as low cost and robustness [76,86], and therefore must be considered when setting requirements in Phase 2. To achieve an

optimised functionality and performance level [76], one should work closely and iteratively with local stakeholders [79], which is the basis of Phase 3. Finally, to keep costs low, consideration of manufacturer capabilities and supply is essential, and therefore focus on FI must be maintained throughout Phase 4 [76,121]. Hence consideration of FI was planned in every phase of the RAIS design approach, shown in Figure 7.

3.2.3.2 Participatory Design

Reviewing use of PD in technology design for LHRCs revealed most organisations took a 'light touch' approach to each Part-E framework dimension [104], and that participation occurred mostly in initial and evaluation design phases. However, some studies highlighted benefits to involving participants throughout the design process (see 2.4.2).

Experience of the GHRG-ST in LRHCs in Northeast India indicated that the design team would be unfamiliar with the context. Peer-reviewed literature concerning gasless laparoscopy is also relatively scare also provided limited useful information for designers [122]. However, the GHRG-ST had developed links with surgeons based in India who were passionate about and working to disseminate the technique more widely. Considering these challenges and opportunities, the team decided participation should be maximised. In terms of the Part-E framework, this meant focusing on overcoming *Barriers* to PD, and targeting attributes such as *Direct and Autonomous* in the *Representation* dimension, and *'Collaborative Contributions'* in the *Interaction* dimension. The *Objective* of using PD would be to design the RAIS device, falling into the *Material Things* attribute, and the prior experience of the team working with participants suggested *Well-known* formats of *Practice* would be appropriate, since all participants were qualified clinicians and all team members spoke English as a common language, reducing the difficulty of overcoming commonly-cited *Social* and *Political* PD *Barriers* such as differences in language or education [104].

Therefore plans were made to integrate PD into every roadmap phase (see Figure 7). This approach would also facilitate investigation of what value involving participants in a 'thorough, sustained' approach might add for an organisation, participants, and the resulting technology, by evaluating the PD outcomes for intended *Short-term* and *Long-term Changes* (see Chapter 4), as well as *Indirect and Unintended Impacts* (see Chapter 5) [104].

3.3 Method Selection

In this section, the methods selected by the design team to guide work within each phase of the roadmap are discussed.

3.3.1 Phase 0: Identify a Need for Surgical Equipment

The roadmap advises considering local knowledge of end-users when selecting a need to address; a sentiment echoed by PD and FI practitioners [69,79]. The need to develop a new device for gasless surgery was identified using the findings of primary research and literature reviews conducted by the GHRG-ST [123]. The primary research comprised of dialogue with stakeholders in LRHCs in Northeast India and involvement in their work to train rural surgeons in gasless laparoscopy [124]. On a thorough review of the need to improve the technology supporting this surgical technique, underpinned by consultation with local stakeholders, the team resolved to address it.

3.3.2 Phase 1: Understand the Context of Global Surgery

In this phase, the roadmap suggests using qualitative methods to gather information on key aspects of the LRHC of interest presented by the roadmap, or to populate existing frameworks created to aid innovators in defining the context [125].

With little peer-reviewed information on the context available, the team planned qualitative research to obtain the required design information. This paucity of existing data introduced some risk into the design process since there was little to verify the team's findings against. Several measures were planned to mitigate this risk. Firstly, the team reviewed the important contextual aspects described by the roadmap to develop appropriate interview questions [31]. While online interviews were one option, others have found engaging users with devices in a simulated or real environment of use can elicit more active contributions and useful information from them [100]. Therefore interviews, surgical observations and group discussions in the design context were planned. The team were still concerned about overlooking key contextual factors or assigning non-representative value on them based on input from limited user, but to mitigate this possibility PD was planned in later design phases.

After reviewing suitable methods for summarising the contextual findings from [89,125], a regularly-updated parameter diagram (p-diagram) was selected. P-diagrams are used in 'Robust' or 'Six-Sigma' Design [126]. In other design contexts, the tool is often used in early design phases to capture system details: the inputs, design controls, ideal functions, 'error states' and variations which could affect system performance [126]. The system within which the RAIS system must perform (in a low-resource operating theatre) is complex and can vary significantly, so the p-diagram was considered appropriate to capture data collected from qualitative methods concerning required device functions, design inputs, uncertainties and known failure modes (such as experiences of the device obstructing surgery, causing patient

harm, or being unavailable to rural surgeons). Hence, the P-diagram could be used to construct a holistic view of the design challenge for the designers to refer to, and also to initiate consideration of risk, safety and device quality, providing a basis for future documents used in regulatory submission, such as FMEA [30].

Hence, planned activities in this phase, which aims to answer a number of questions on the surgical context, comprised primary qualitative research, sustained participation of clinical stakeholders and use of a P-diagram.

3.3.3 Phase 2: Determine the Implementation Strategy and Design Requirements

After understanding the clinical need and context, an implementation strategy and series of design requirements should be developed. To guide innovators in this phase, The Design for Safe Surgery Roadmap [31] provides example requirements and implementation strategies for a global surgical context. It does not advise on how to approach selecting the right requirements or strategy for the technology. Therefore, methods of developing these were selected by the design team based on prior experience, with the aim of integrating the principles of PD and FI into the phase.

Developing accurate requirements is essential to design safety and greatly influences the product development [127]. Developing a feasible implementation strategy requires consideration of team resources, including those available to the clinical participants. Therefore, it was considered necessary to convene a workshop to collaboratively agree on requirements and an implementation strategy with clinical participants local to the design context. Others have shown that involving users in the early stages of design for LHRCs increases their influence on the design [71] and that well-planned workshops can be effective in elucidating relevant contextual information and engaging the creative capacity of participants [69,100,128]. Ensuring they could represent themselves in decision making was also intended to help achieve the desired attributes within the *Representation* and *Interaction* dimensions of PD. The p-diagram would be used to summarise the requirements and additional information on the design context generated in this session.

Hence, activities in this phase were centred around one, day-long workshop and use of a P-diagram to summarise outputs. Since the *Barrier* of geographical distance separated the clinical participants and design team, plans were made to maximise this opportunity to collaborate in person. Since stakeholders in LMICs often have the most innovative frugal ideas [121], the workshop would also be used to initiate Phase 3 of the design process by

brainstorming, selecting and refining concepts for the device with the participants. Further Phase 3 activities are discussed in the next section.

3.3.4 Phase 3: Act

For this iterative phase of design, prototyping and testing, the roadmap provides little advice. While co-creation with local stakeholders in recommended, how and to what extent this should be enacted is not discussed. Therefore the team selected an established model used in conventional medical device design to augment this phase: the waterfall model [129].

Reflecting on the importance of ensuring the safety of surgical innovations for LHRCs, the design team selected this approach to structure Phase 3 to support ensuring all design flaws and risks to patient safety were recognised and addressed prior to application for regulatory approval and clinical trials. The model, shown in Figure 8, addresses this by structuring the technical development process with iterative design verification and validation [129]. Alexander and Clarkson [130] defined verification and validation:

> *"Verification… is concerned with ensuring that, as the design and implementation develop, the output from each phase fulfils the requirements specified in the output of the previous phase…"*
>
> *"Validation… is concerned with demonstrating the consistency and completeness of a design with respect to the initial ideas of what the system should do" (p. 197)*

With the aim of achieving a safe and controlled design process which embeds PD, the waterfall model was used to develop a verification plan, where LMIC-based clinical participants could discuss, evaluate and ideate concepts in regular, structured stages. These opportunities would largely take the form of online meetings due to geographical distance, but one in-person visit to assess a physical prototype was also planned.

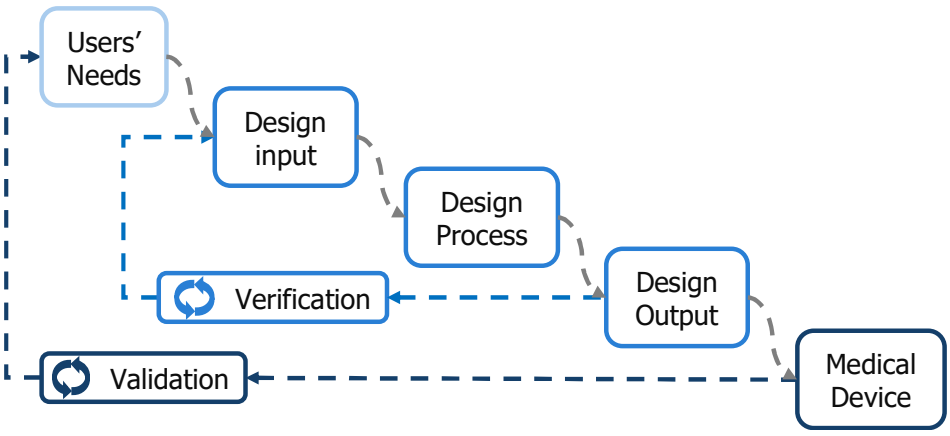


Figure 8: Waterfall Model [129]. Adapted from source.

The waterfall model also contains a validation step. Validation of medical devices designed for LRHCs must be carried out in those settings. As discussed in 2.1.3, the nuances of LRHCs affect technology performance. Therefore, testing in that context may reveal insights critical to the safety, performance and feasibility of implementing a technology there [22,58] and medical technologies must be tested with end-users in a context which represents the true context of use. However, this incurs additional considerations [22]. Low-resource centres can be far apart and operate on minimal staffing, making it resource-intensive to involve large numbers of users in validation. Therefore plans to take advantage of an opportunity for the design to be tested by a numerous end-users at a rural surgery conference in India were made [131]. If the final design was positively received by end-users this would be an end-point to the 'Act' phase. It also provided an opportunity to assess the design process was in producing a concept that met the requirements of end-users and target context.

Activities in this phase therefore comprised of a brainstorming workshop and structured prototype verification and validation opportunities, all of which involved clinical participants from LMICs.

3.3.5 Phase 4: Design to Manufacture

This phase was defined by the design team, since it surpassed the reach of the roadmap. In 2.1.2, barriers to the uptake of technologies in LRHCs were identified, such as access to spare parts, maintenance and repair services. Access to these is largely influenced by the manufacturer, and to overcome these barriers innovators should work with local manufacturers [51,58,108]. Following these recommendations, plans for this phase included selecting an in-country manufacturing partner with an understanding of LRHCs and the need for access to spare parts and repair in remote areas, as well as experience in local regulatory processes for medical devices.

Therefore activities planned in this phase included involving local clinical participants in identifying an in-country manufacturing partner, and working closely with them to produce a series of prototypes for iterative evaluation and refinement by clinical participants. Through discussion, collaboration and compromise between designers, manufacturers and clinicians, the aim of the phase would be to arrive at a design feasible to manufacture at a frugal cost and quality, whilst satisfying the requirements agreed in Phase 2 and meeting approval criteria set out by regulatory authorities for use in clinical trials.

3.4 Summary

This chapter addressed Objective 2 of the thesis by planning the implementation of selected design approaches to design the RAIS device for gasless laparoscopy. The methods utilised to implement the approaches were articulated in detail.

Overall the roadmap provided invaluable structure to plan the design approach and establish what resources might be needed at each stage. It also provided sufficient detail to help select methods and plan activities within Phases 0 and 1. However, the team found the roadmap provided little advice for approaching Phases 2 onwards. Of course, to make best use of the different resources, experience and opportunities available to specific organisations, the flexibility of the roadmap may be appropriate [59,63]. However the designer is left to compare a large number of design tools and methods available with little guidance on which might be helpful in this context, which can be a significant task. In this instance, the P-diagram [118] and waterfall model [132] were selected by the design team based on prior experience, but it is likely that many other, and potentially more appropriate, design tools could be substituted in their place. In these phases, considering the principles of PD and FI and provided more guidance on selecting rational design methods and strategies for this context.

This chapter laid foundations for a detailed evaluation of the usefulness of the approaches selected and how their use affected the RAIS design, which follows in the next chapter. An evaluation of the implementation and outcomes of these approaches will provide evidence useful for developing and refining them.

Chapter 4

Evaluation of the RAIS Design Development

Using the integrated design approach described in Chapter 3, with the extended 'Design for Safe Surgery Roadmap providing an overarching structure to the process, the team designed a lift device for gasless laparoscopic surgery. In each design process phase, this chapter discusses the challenges, benefits and opportunities identified implementing the selected approaches. Through evaluating their impact on the RAIS device design, the chapter aims to provide evidence which can be used to further develop and refine these approaches for innovating global surgical technologies.

Work contributing to this chapter was published in the International Journal of Surgery Global Health:

Marriott Webb, M., Bridges, P., Aruparayil, N., Mishra, A., Bains, L., Hall, R., Gnanaraj, J., & Culmer, P. (2021). Designing devices for global surgery: Evaluation of participatory and frugal design methods. IJS Global Health, 4(1), e50

4.1 Introduction

In this chapter the design activities and outcomes within each of the Phases 0-4 of RAIS design process (see Figure 7) are discussed. The insights and challenges gained through implementing each phase and through integrating PD and FI into the approach are described. The text in sections 4.2 - 4.6 contains this narrative and critical evaluation. To provide an overview of the process, an annotated timeline (see Figure 9 for overview, and Figure 10 for detail) of the design Phases 1-4 is provided, highlighting the iterative evolution of the RAIS device.

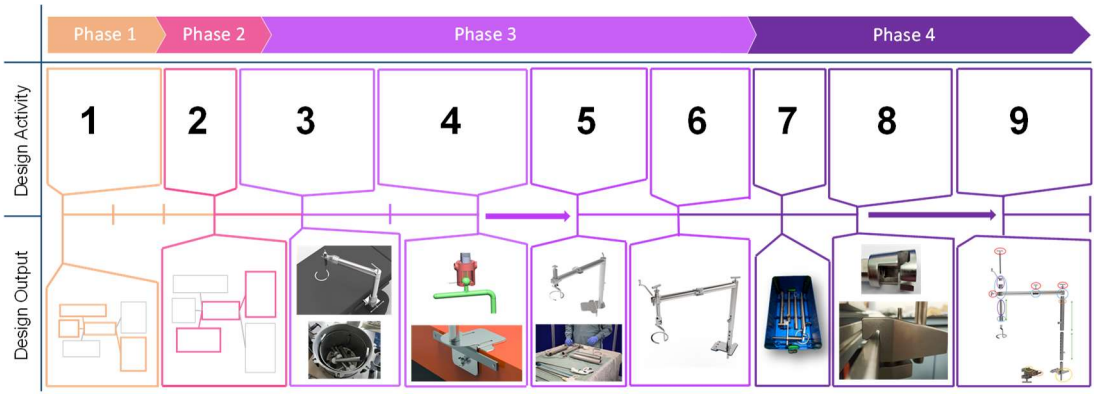
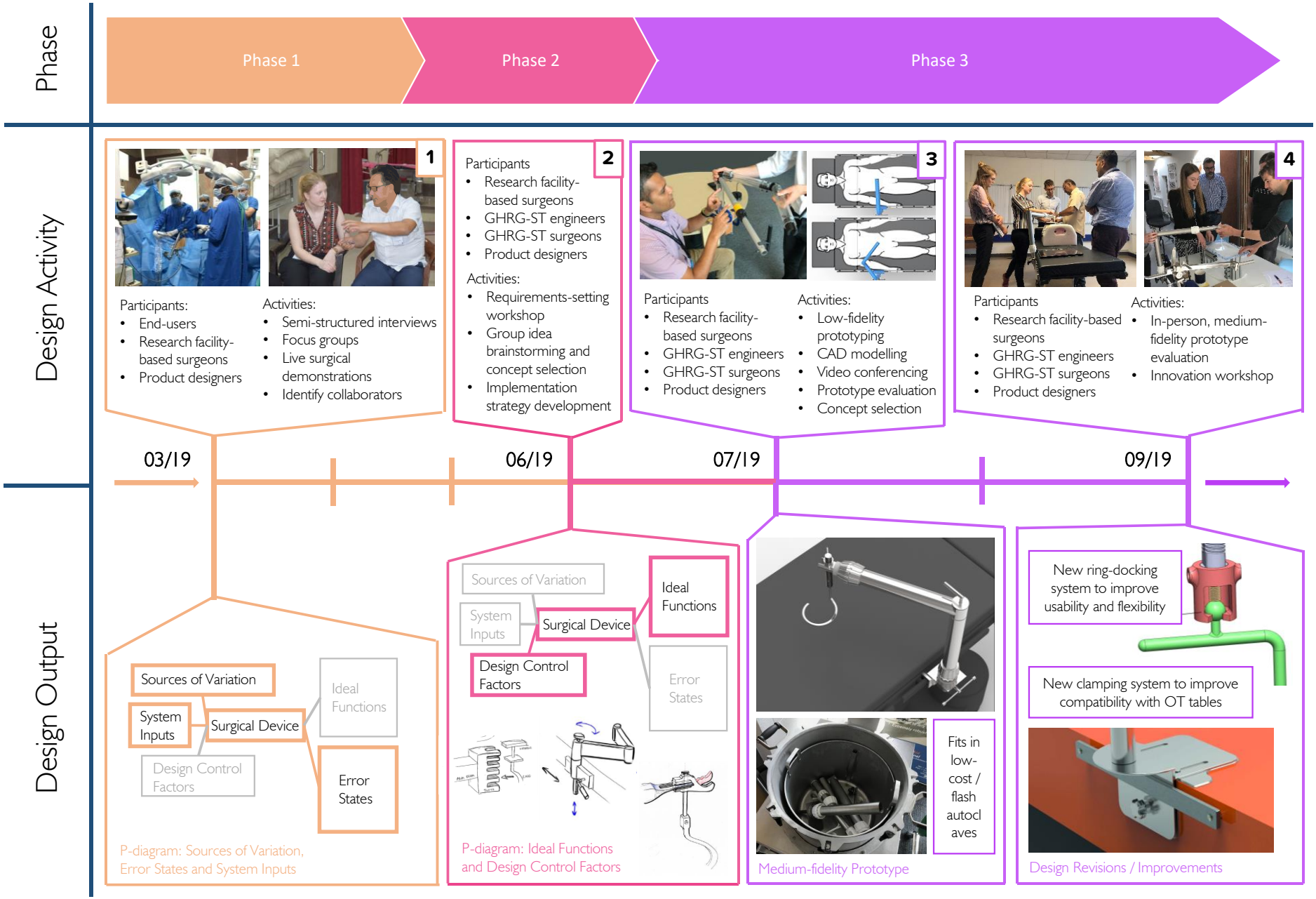
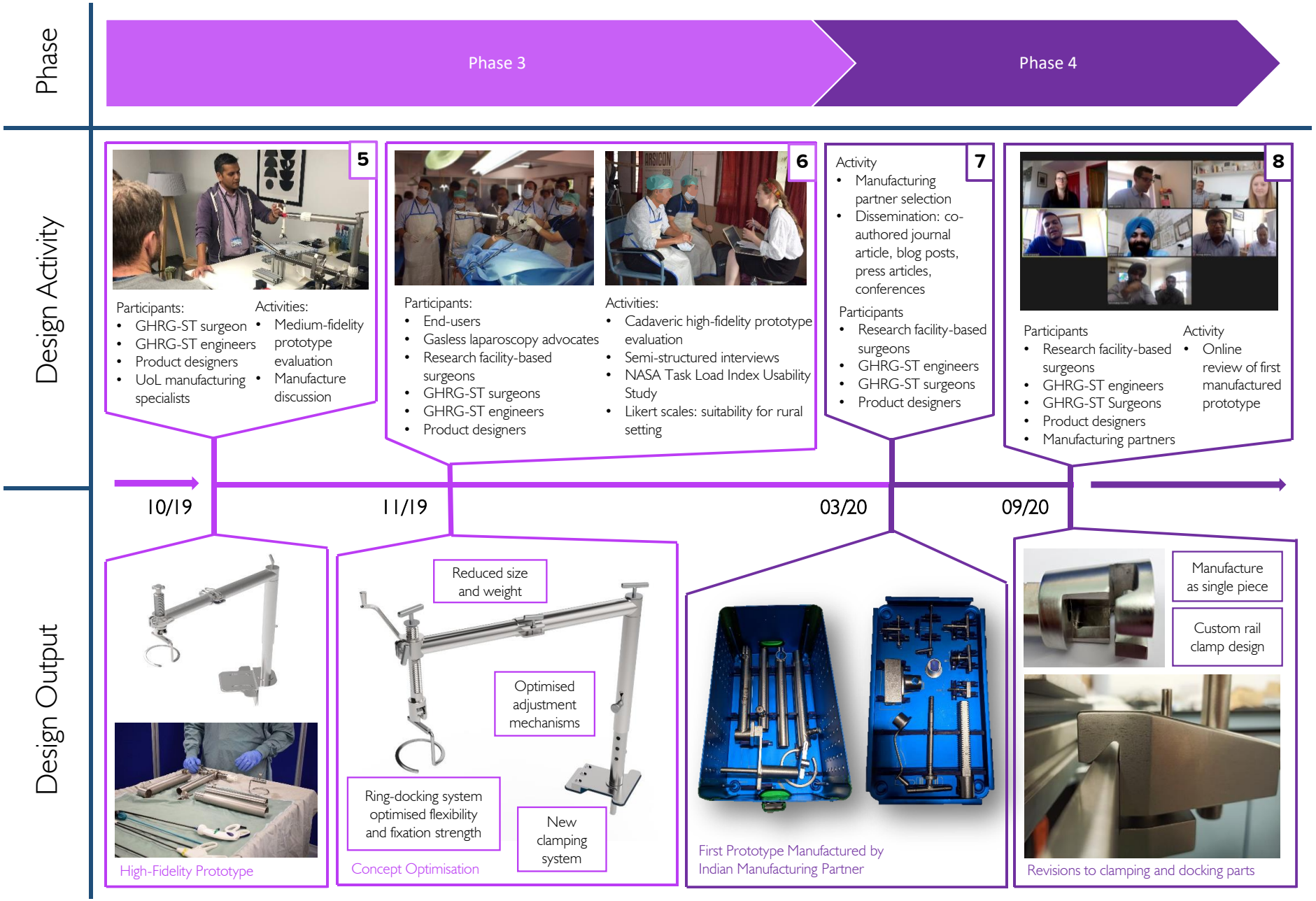


Figure 9: Overview of design process activities and RAIS design development (low detail level)


Phase
Phase 1
Phase 2
Phase 3
Design Activity
1
Participants:
End-users
Research facility-based surgeons
Product designers
Activities:
Semi-structured interviews
Focus groups
Live surgical demonstrations
Identify collaborators
2
Participants
Research facility-based surgeons
GHRG-ST engineers
GHRG-ST surgeons
Product designers
Activities:
Requirements-setting workshop
Group idea brainstorming and concept selection
Implementation strategy development
3
Participants
Research facility-based surgeons
GHRG-ST engineers
GHRG-ST surgeons
Product designers
Activities:
Low-fidelity prototyping
CAD modelling
Video conferencing
Prototype evaluation
Concept selection
4
Participants
Research facility-based surgeons
GHRG-ST engineers
GHRG-ST surgeons
Product designers
Activities:
In-person, medium-fidelity prototype evaluation
Innovation workshop
03/19
06/19
07/19
09/19
Design Output
Sources of Variation
System Inputs
Surgical Device
Design Control Factors
Ideal Functions
Error States
P-diagram: Sources of Variation, Error States and System Inputs
Sources of Variation
System Inputs
Surgical Device
Design Control Factors
Ideal Functions
Error States
P-diagram: Ideal Functions and Design Control Factors
Fits in low-cost / flash autoclaves
Medium-fidelity Prototype
New ring-docking system to improve usability and flexibility
New clamping system to improve compatibility with OT tables
Design Revisions / Improvements


Phase
Phase 3
Phase 4
Design Activity
5
Participants:
• GHRG-ST surgeon
• GHRG-ST engineers
• Product designers
• UoL manufacturing specialists
Activities:
• Medium-fidelity prototype evaluation
• Manufacture discussion
6
Participants:
• End-users
• Gasless laparoscopy advocates
• Research facility-based surgeons
• GHRG-ST surgeons
• GHRG-ST engineers
• Product designers
Activities:
• Cadaveric high-fidelity prototype evaluation
• Semi-structured interviews
• NASA Task Load Index Usability Study
• Likert scales: suitability for rural setting
7
Activity
• Manufacturing partner selection
• Dissemination: co-authored journal article, blog posts, press articles, conferences
Participants
• Research facility-based surgeons
• GHRG-ST engineers
• GHRG-ST surgeons
• Product designers
8
Participants
• Research facility-based surgeons
• GHRG-ST engineers
• GHRG-ST Surgeons
• Product designers
• Manufacturing partners
Activity
• Online review of first manufactured prototype
10/19
11/19
03/20
09/20
Design Output
High-Fidelity Prototype
Reduced size and weight
Optimised adjustment mechanisms
Ring-docking system optimised flexibility and fixation strength
New clamping system
Concept Optimisation
First Prototype Manufactured by Indian Manufacturing Partner
Manufacture as single piece
Custom rail clamp design
Revisions to clamping and docking parts

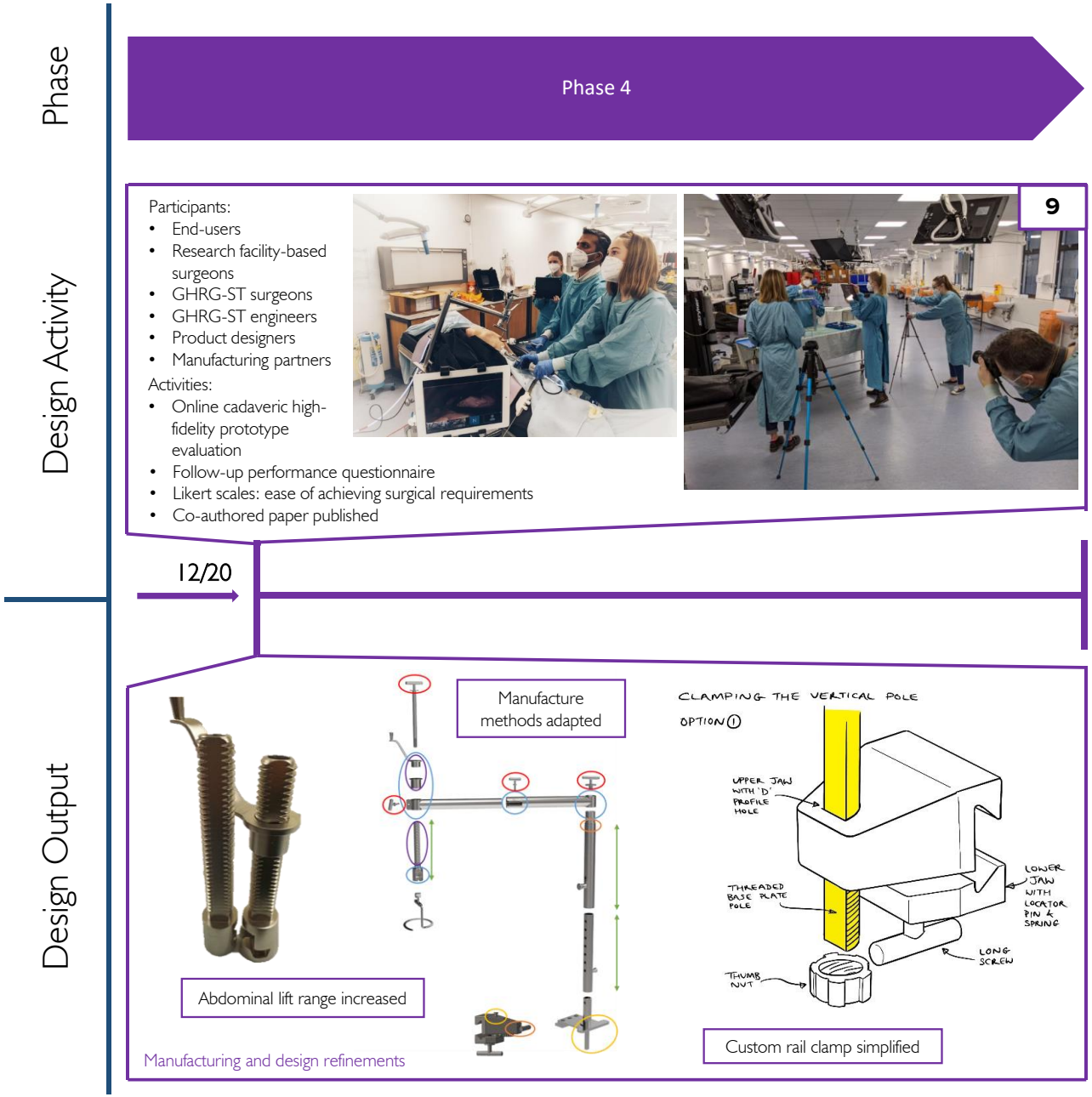


Figure 10: Timeline of design process activities and RAIS design development (high detail level)

4.2 Phase 0: Identify a Need for Surgical Equipment

4.2.1 Phase Activities

As described in 3.3.1, primary research, literature reviews and consultation with local stakeholders and end-users in Northeast India, conducted by members of the GHRG-ST, comprised this phase [14,22,23,123].

4.2.2 Phase Outcomes

From the phase activities, both the compelling clinical need and a potential solution was identified: to improve the provision of laparoscopic surgery for patients in remote areas of Northeast India using gasless laparoscopy, facilitated by AWL devices. Research to identify the clinical need informed the team on the 'Surgical Barriers for patients in LMICs' [31] and how they might be overcome using gasless laparoscopy. In Northeast India, use of surgical services is positively correlated with proximity to the service and financial status of patients [123]. Conventional laparoscopy via pneumoperitoneum is expensive, largely due to equipment costs [133,134], and facilities offering it are typically far from patients in remote areas. Gasless laparoscopy has potential to both significantly reduce costs and enable laparoscopy in remote facilities, while retaining the key benefits of conventional laparoscopy for patients [14,122].

Hence, gasless laparoscopy satisfies two FI criteria. Compared to conventional laparoscopy, it offers a substantial cost reduction, whilst affording patients the same, or even increased benefits [122]. However, its disruptive potential has not yet materialised. Stakeholders discussed several aspects which limited its wider adoption, including the third criteria for FI: the performance level of current AWL devices. Despite iterative improvements made [135] these require further development. Therefore, with the support of local stakeholders involved in disseminating the gasless technique, the design team resolved to redesign the AWL device.

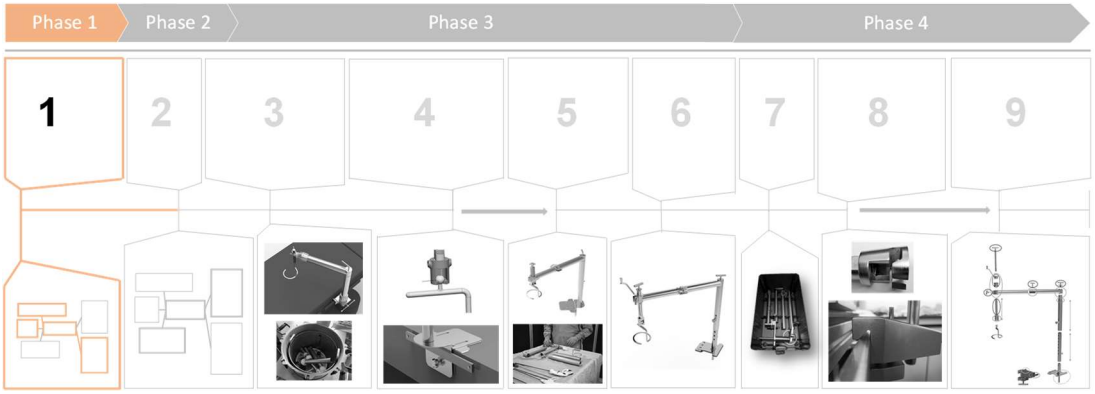
4.2.3 Phase Evaluation

In this phase, the roadmap proved useful to the design team, who on its advice, identified the need through consultation with local stakeholders. The team also found an understanding of 'Surgical barriers for patients in LMICs', which in the roadmap is not explored until the next phase of development, was instrumental in selecting this need over others, because of the solution's potential to overcome these barriers and increase surgical

access in LRHCs, which is central to the GHRG-ST's aims (see Chapter 1). The FI principles also influenced need selection. There are many surgical needs in LRHCs, so the team chose to target one with a potential solution meeting the frugal criteria, with aim of achieving disruptive surgical care improvement [76]. Establishing the focus on PD at this early stage was useful too, as the design team could identify and begin discussions with potential collaborators.

While the advice presented by the roadmap in this phase is useful, considering aspects of PD, FI and the next phase of the roadmap helped the design team to select this need. While the roadmap highlights some FIs in the introduction, it does not reference what criteria can be used to identify them, which the team found useful in this phase.

4.3 Phase 1: Understand the Context of Global Surgery



4.3.1 Phase Activities

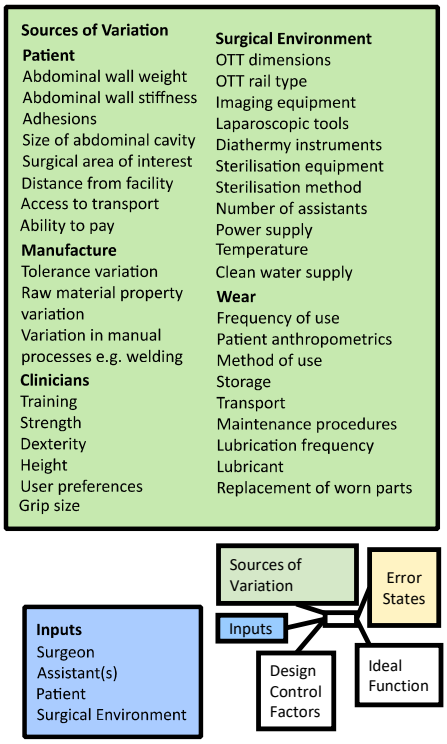
As described in 3.3.2, the design team planned qualitative methods such as interviews, focus groups and observation to research key aspects of the surgical context [31]. Surgeons performing gasless laparoscopy in Northeast India are few in number and typically work in remote locations [23] so performing these posed a challenge. The design team identified an opportunity to interact with a relatively large number of end-users during their attendance at a gasless laparoscopy training course [124].

Product designers performed ten individual, semi-structured interviews with attendees, examiners and facilitators at the event. They observed four live surgical demonstrations of the technique and culminated the research with a group discussion (see Activity 1, Figure 10). Throughout these interactions, they identified stakeholders interested in being involved further in the design project as participants. Then the compiled contextual information, informally collected as notes, videos, pictures, sketches and transcripts was presented to the

newly formed team including clinical participants. This team distilled the information into the p-diagram, discussed in the following sections.

4.3.2 Phase Outcomes

The contextual information collected is summarised as the 'Inputs', 'Sources of Variation' and 'Error States' components of the P-Diagram (see Figure 11).



Error State	Cause
Surgeon unable to view / treat surgical area of interest	Insufficient lift Tenting Obstruction to camera view Insufficient space to insert camera Device obstructs instruments (internal) Device obstructs surgeon (external)
Mechanical failure of GILLS equipment	Poor design, insufficient safety factor applied Manufacture anomaly Fatigue under repeated loading Damage during transit Mechanical or chemical damage from repeated sterilisation
OT failure	Bed rails deform under load applied by GILLS device
Harm to patient	Pressure exceeds recommended maximum on abdominal wall created by lifter during normal operation Pressure exceeds recommended maximum on abdominal wall created by lifter due to 'wobble' of device Internal damage from surgical instruments due to 'wobble' Electric shock or burn caused by build-up of charge in internal component
Harm to Surgeon / Assistant	Electric shock or burn caused by build-up of charge in surgical table / other conductive areas in operating environment.
Operators cannot set up equipment	Assembly too complex Small parts are easily lost and spares not provided Assembly requires more than two operators Operators are not adequately trained Assembly not compatible with surgical table Sterilisation not possible in rural setting
Surgeon cannot adjust equipment	Contact with adjustment device compromises sterility Adjustment requires force or handling not suited to one operator
Surgeon cannot access equipment	Equipment is too expensive Equipment is not portable Hospital decides not to invest -poorly presented product
Product cannot be repaired in-country	Parts are bespoke or require specialist manufacturing equipment / foreign supplier Spare parts not provided or available for surgeons to buy

Figure 11: Contextual Insights gained during Phase 1 of designing the RAIS device, summarised as the 'Inputs', 'Sources of Variation' and 'Error States' of the RAIS device p-diagram

4.3.2.1 P-Diagram: Inputs

Interviews with end-users revealed that to operate using an AWL device, the minimum required inputs are a patient, a surgeon with laparoscopic training, at least one operating theatre (OT) assistant and sterile OT with certain equipment available. These formed the 'Inputs' section of the P-diagram in Figure 11.

4.3.2.2 P-Diagram: Sources of variation

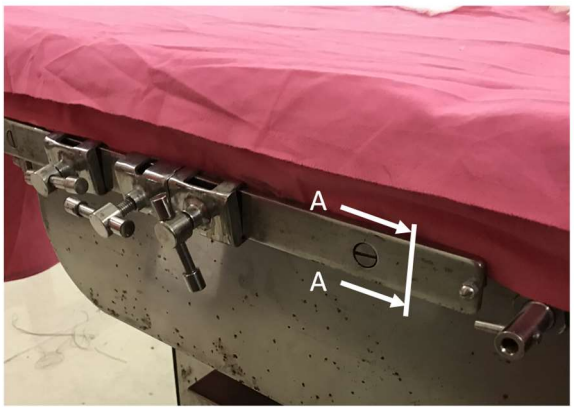
The 'Sources of Variation' section was populated with factors considered likely to vary and affect the AWL device performance. During interviews, asking multiple end-users to describe

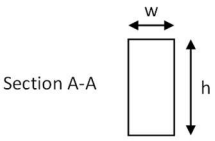
aspects within the 'Structures of the Healthcare System' component of the context [31] revealed insights about different surgical environments and the technologies and resources available to them. For example, end-users highlighted that their Operating Theatre Tables (OTTs) could be donated or bought second hand, and conformed to various national specifications. While they couldn't provide details of these, their input catalysed further useful data collection. Figure 12 details the results of the team's research on the dimensions of OTT accessory rails by country of manufacture.

"Personally, I use autoclave… know of others who use chemical solution"

"Locking system needs to be universal as tables differ"

"Bed widths differ"





Standard	Cross-Section	w (mm)	h (mm)
Denyers	Rectangular	6.40	38.10
Europe	Rectangular	10.00	25.00
Japan	Rectangular	9.00	32.00
United Kingdom	Rectangular	6.40	31.80
Swiss	Rectangular	10.00	30.00
United States	Rectangular	9.50	28.50

Figure 12: Variation in OTT Accessory Rails [136]

Another 'Source of Variation' interviews revealed was how much end-users might use and maintain the device, affecting its wear over time. In some instances end-users had no biomedical staff or formally trained OT assistants to assist with device maintenance.

"Lots of operations in a day"

"It needs to be portable so you can take it to pop-up surgeries"

"Maintenance is carried out as and when needed"

4.3.2.3 P-Diagram: Error States

The 'Error States' section was populated with ways in which the device could fall short of the requirements of the end-users and LRHCs [42]. Error states relating to 'Structures of the Healthcare System' [31] were also identified during interviews. Discussing factors that might prevent users from purchasing technologies revealed new insights. While some explained

they could only purchase the cheapest technologies available, others thought hospitals would invest in 'attractive', well-made and robust technologies.

Further error states relating to 'Aspects of Safe Surgery' [31], were elicited by asking new end-users to review an existing AWL device as experts trained them to use it on a simulated abdominal wall. New users highlighted the size and weight as a barrier to them transporting it easily and sterilising it using small 'flash' autoclaves. Instead a nurse would need to scrub the device by hand using harsh chemicals. Experienced users explained that its size also made it difficult to store sterile, and without a dedicated case, it was usually stored wrapped in drapes - something new users hadn't yet considered. While new users were pleased the existing device seemed difficult to damage, experienced users highlighted issues with joint wear, which sometimes slipped or became stuck.

More error states materialised through observation, supplemented with sketching and discussion. For example, while end-users were achieving an operable view during live surgery, the designers observed device adjustment required multiple assistants. When prompted, end-users revealed that the lifting handle was non-sterile and the sterile position-locking lever was out of the surgeon's reach, so getting an operable view required co-ordination of sterile and non-sterile assistants. Since many had few trained assistants who were usually needed elsewhere, this was frustrating. End-users also drew annotated sketches of the surgical instrument positioning for different operations to show how the device could obstruct surgical tasks. These 'error states' highlighted potential safety issues and opportunities for RAIS to increase value for the user.

4.3.3 Phase Evaluation

4.3.3.1 Design for Safe Surgery Roadmap

The Design for Safe Surgery Roadmap provided useful guidance to structure phase activities, giving detailed information on key research topics such as aspects of safe surgery and the healthcare system structure [31]. Our experience confirmed the proposed research methods, such as semi-structured interviews and site visits, were appropriate for a high-level mapping of the context and gaining novel insights into the research topics discussed. However subtle, but crucial insights were identified by augmenting interviews with sketching, handling existing equipment and observing live surgeries. These techniques were especially useful for identifying error states: an important first step towards ensuring the quality, safety and enhanced value for users of RAIS in a LRHC.

End-users also offered diverse information and opinions about the LRHCs they operate in, highlighting the importance of obtaining multiple perspectives at this early stage. Hearing diverse perspectives from new and experienced end-users, as well as technical staff, was critical. This was facilitated by attending a training camp, which ultimately provided excellent interactive information-gathering opportunities for designers. The team reflected on the importance of being resourceful and innovative in data collection methods in this context and felt the roadmap could provide advice on or examples of this. Others have identified similar opportunities to obtain input from multiple remote end-users, such as conferences or surveys (R. Oosting et al., 2020).

A final suggestion for roadmap enhancement would be to investigate ways of summarising and presenting the data collected in this phase, which can be extensive. The P-diagram was useful for preparing the knowledge for translation into an appropriate design, but other methods could be even more suitable.

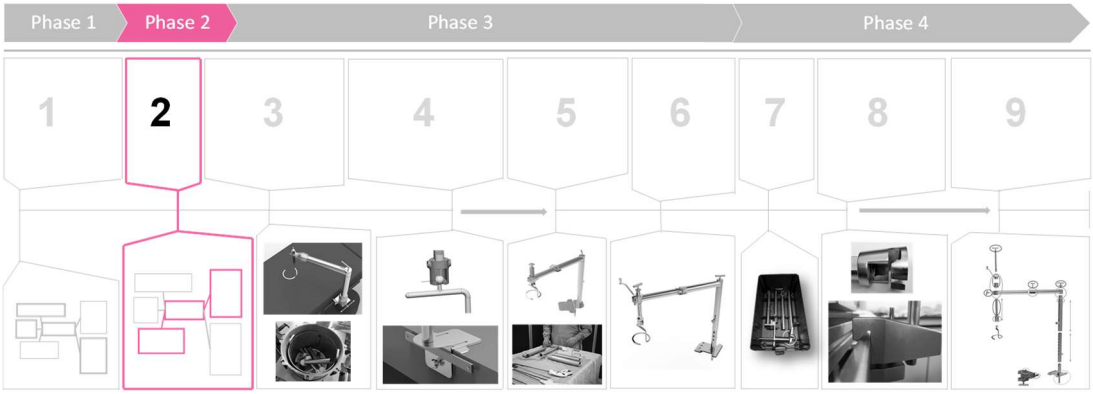
4.3.3.1 Participatory Design

In this phase *Interaction* with stakeholders mostly constituted *'Contribution of Resources and Information'.* However the data volume collected meant that some aspects of the context were overlooked or misinterpreted. At this stage both end-users and designers were unaware of what knowledge was relevant for designers. Therefore this phase also highlighted inadequacy of such *Interaction* and the importance of local stakeholder participation throughout all roadmap phases to continue progressing contextual understanding. Collecting data through qualitative methods in this phase provided an ideal opportunity to identify stakeholders interested in participating further.

4.3.3.2 Frugal Innovation

Activities in this phase revealed opportunities to increase the value of RAIS for end-users and enhance its frugality. However, while a broad overview of the context was obtained, the methods employed did not help quantify variation within it, which is necessary to optimise innovation performance, functions and cost (the frugal criteria) [76]. While qualitative methods are excellent for uncovering unknowns they can become unwieldy when used to collect quantitative data. Therefore these activities were more appropriate identifying areas where quantitative data may be needed for frugal optimisation than for collecting the data.

4.4 Phase 2: Determining Design Requirements and Implementation strategy



4.4.1 Phase Activities

The team planned building the requirements and implementation strategy as a collaborative process. Participants identified during Phase 1 convened with the design team for a day-long workshop to translate information gathered in Phases 0 and 1 into the Phase 2 outputs (see Figure 10, Activity 2).

Team resources, feasible timescales and contextual information were discussed to elucidate potential opportunities and challenges in implementing the device, and a high-level implementation strategy developed. Then product designers presented the contextual information gathered in Phase 1. Reflecting on the frugal principle of core functionality-focus [76], the workshop attendees listed the minimum and 'ideal world' device functions separately to understand which were essential, and which should only be included if they increased value for users significantly. All were summarised in the 'Ideal Function' P-diagram section (see Figure 13). The workshop concluded with product designers leading a brainstorming session, where all participants were encouraged to generate original, 'blue sky' design ideas, which were sketched, broken down and then dismissed or developed further collaboratively. Using these quick-fire concept reviews the team formalised the design space into 'Control Factors' for the P-diagram (see Figure 13).

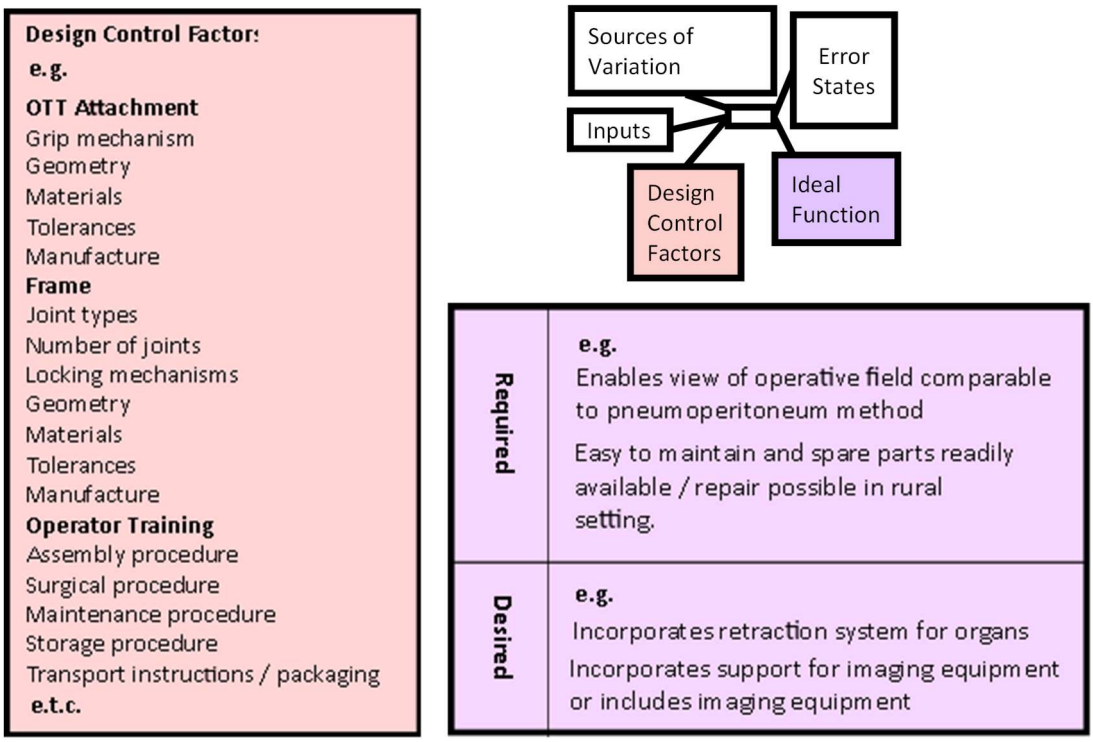


Figure 13: Requirements developed and results of group solution brainstorming, summarised as the 'Design Control Factors' and 'Ideal Function' of the RAIS device P-diagram.

4.4.2 Phase Outcomes

4.4.2.1 Implementation strategy

The agreed implementation strategy targeted remote areas because of their current inability to offer laparoscopic surgery and the enhanced benefits it offers for daily wage labourers. Research revealed laparoscopic training is limited in this setting, which the strategy reflected: the device would need to be implemented alongside training, likely to be funded by grants. Local stakeholders agreed that device cost reduction could facilitate them training more surgeons to further disseminate the technology. Visibility and awareness of the technology was also identified as a limiting factor in its adoption. Local stakeholders also advised providing more evidence of its effectiveness and feasibility in remote settings was needed, which they were well-positioned to investigate. Therefore identifying partners to collaborate with concerning training and dissemination of gasless laparoscopy also became central to the implementation strategy.

4.4.2.2 P-Diagram: Ideal Function

Following a review of the contextual information and implementation strategy, the team agreed on 18 minimum functional requirements for RAIS and 4 additional 'desirable' requirements. For example, a functional requirement for RAIS to 'provide a view equivalent

to laparoscopy via pneumoperitoneum' was introduced as a result of the implementation strategy. To tackle the challenge of increasing global visibility of gasless laparoscopy, the device needed to address concerns currently limiting uptake of the technology such as limited operating field of vision [137–139] and high training requirements [140]. The four 'desirable' requirements were non-functional, such as 'Incorporates retraction system for organs'. With no evidence of existing retraction systems being used with AWL devices, the value this might add for the user was unknown, but stakeholders speculated that it could reduce the issue of organs being 'sucked' towards the abdominal wall and reducing the operating vision and space for the surgeon (see Figure 14). Once investigated further, this requirement could be included or dismissed based on whether it met frugal criteria.

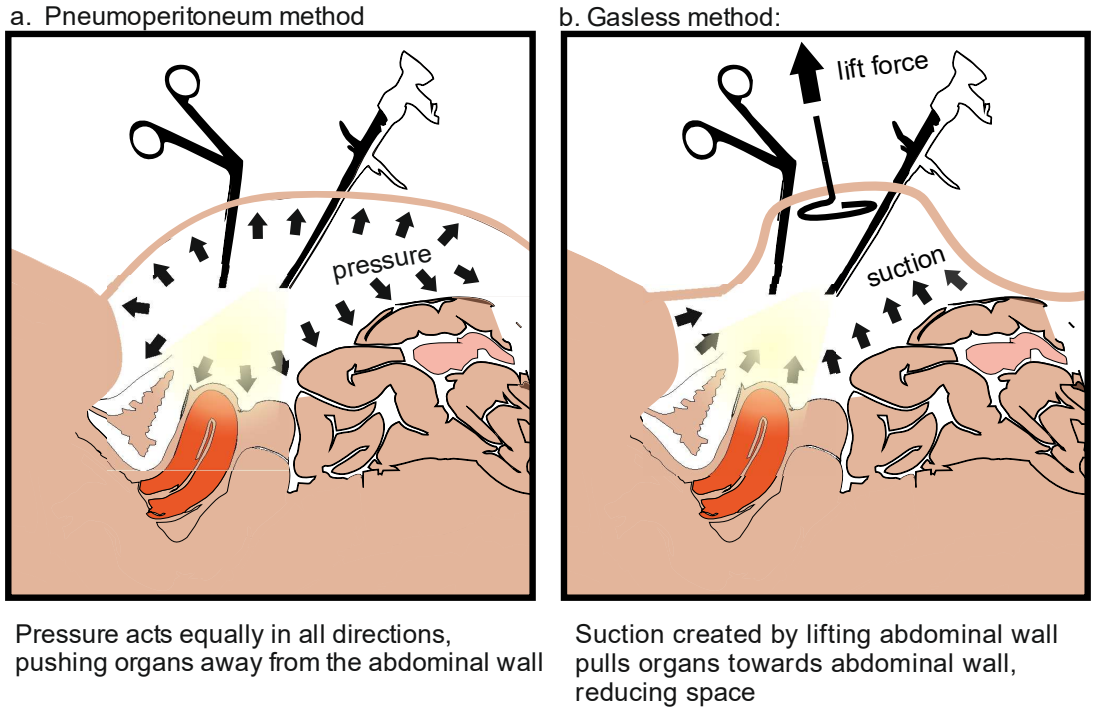


Figure 14: Operating view and space comparison: Pneumoperitoneum vs Gasless

The brainstorming session continued to reveal additional requirements. For example, a designer suggested supporting the abdominal wall weight using the ceiling or floor. Clinical stakeholders quickly dismissed this, explaining the surgeon had to tilt the OT to move the patients' internal organs, whilst maintaining the lift and view inside the abdominal cavity. This became a functional requirement. The session also helped designers assign value to requirements and prioritise them. For example, ideas for internal components were discussed which could improve the view, but were mostly rejected by stakeholders based on their difficulty to clean, which took priority for minimising infection risks. Requirements could also be refined during this session: by discussing with participants exactly how they

would transport RAIS, the 'portability' requirement for the device was refined to specify a maximum weight and dimensions to ensure it could be transported as plane hand-luggage.

The team also developed requirements which were discovered to be inaccurate later in the design process. For example, to minimise equipment down-time in remote facilities the team set a requirement that RAIS could be repaired with basic manufacturing equipment, which had a significant impact on the design, but later the team learned that many remote areas did not have these capabilities and this aspect did not add value for them.

4.4.2.3 P-Diagram: Design Control Factors

With iterative, participatory dissection of the requirements and solutions brainstormed, the device was progressively broken down into modular components: an attachment system, an internal component, a frame and a lift mechanism. These became the high-level design control factors, and several potential solutions were developed for each. Clinical stakeholders generated innovative ideas in this session such as an oval-shaped and a rotating, double-helix version of the internal component for enhancing the view, both of which were developed to become a part of the final RAIS system.

4.4.3 Phase Evaluation

4.4.3.1 Design for Safe Surgery Roadmap

Advice provided by the roadmap, such as to consider the implementation strategy in this phase because it influenced the requirements, was useful because it ensured the team prioritised requirements such as the surgical view. The example design requirements it provided were also confirmed as appropriate for the RAIS device by the contextual findings [31].

However, the team found the advice insufficient to decide what factors to consider when developing an implementation strategy, what data to collect or even how detailed the strategy should be. What requirements are suitable (e.g. functional, performance) was also unclear, or how they should be prioritised, ranked or refined. It is well known that designers commonly make a multitude of different errors during requirements-setting [141], and that requirements have a great deal of impact on what designs are produced [127,142], but there is little in the roadmap to help designers develop a good set of them. Overall, the roadmap seems to under-assign importance to this phase, which has huge influence over the resulting design, and provides examples rather than suggesting methods for approaching the activities, despite the availability of existing methods [143].

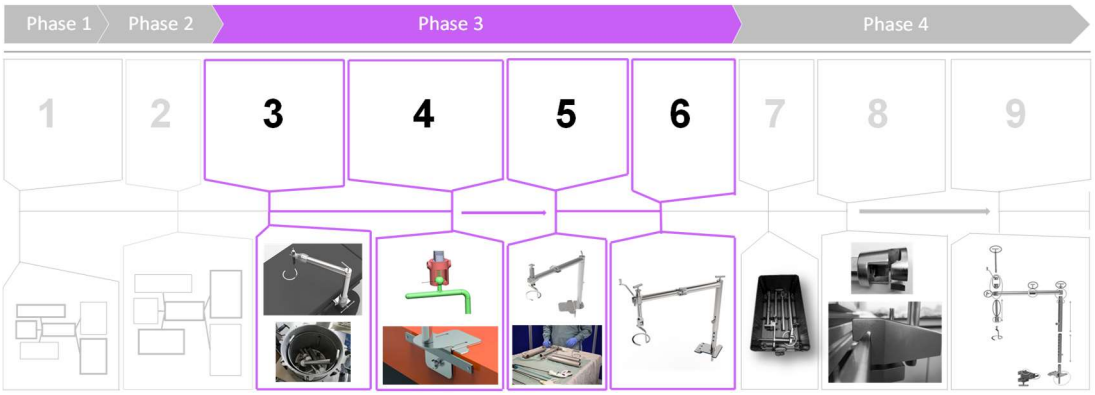
4.4.3.2 PD

The PD approach helped fill gaps in the roadmap's advice. Involving local stakeholders in plans and decision making for the implementation strategy invoked invaluable contributions from them, such as performing studies to enhance the visibility of gasless laparoscopy [14]. Open brainstorming, sketching and discussing concepts with local stakeholders also revealed new contextual insights and helped assign value to requirements in a similar way to methods like the 'Bollywood Technique' [144]. The emphasis placed on facilitating 'Direct, Autonomous' *Representation* of stakeholders, and *Interaction*s in the 'collaborative contributions' attribute in this phase was really useful for understanding the design space further. Participants also had innovative ideas which enhanced the RAIS design.

4.4.3.3 Frugal Innovation

In this phase the 'concentration on core functionalities' [76] aspect of FI encouraged the team to identify minimum functional requirements and include or dismiss other requirements based on the value they added for users. To achieve the second criteria, 'optimised performance level' [76], targeted data collection is necessary and this encouraged the team to challenge requirements at this stage, and establish exact performance needs, such as specific portability requirements. During the brainstorming session, all three criteria helped the team select which concepts to develop further in Phase 3 [76].

4.5 Phase 3: Act



Phase 3 spanned 5 months before the validation step (Activity 6, Figure 10). Activities 3, 4 and 5 in Figure 10 show the three verification loops implemented within this phase, highlighting the impact input from participating stakeholders had on the RAIS design.

4.5.1 Clinical Verification: Loop 1

This section refers to the first iteration of the waterfall verification loop (see Figure 8).

4.5.1.1 Activities

In the first verification loop (See Figure 10, Activity 3), the design input was the P-Diagram developed during the previous phase and ideas generated through brainstorming. The design process comprised of designers and engineers presenting bi-weekly updates to local stakeholders via video-conferencing to obtain feedback as the ideas were developed into Computer-Aided Design (CAD) models and low-fidelity prototypes. The feedback was used to iteratively improve the design. Hence, the concepts were developed into the loop design output: a medium-fidelity prototype containing all functional aspects of the design.

4.5.1.2 Outcomes

The ideas, feedback and knowledge of participants influenced the design significantly in this phase. For example, several joint configurations could enable the device to reach the correct position despite sources of variation such as bed size and patient anthropometrics. Presented with several options (Activity 3, Figure 10), participants selected the tubular telescopic design, which offered minimal obstruction and useful flexibility in device positioning for them. Without this input, the designers would have selected an option which was cheaper to manufacture or inherently stronger, but had less user value. Participants' knowledge also helped identify FI opportunities. For example, the rail variation shown in Figure 13 made designing a lightweight, low-cost universal attachment challenging, but by asking participants about other accessories clamped to the rails, the designers identified that all OTs had lithotomy poles, attached to the table using rail clamps. Therefore the approach pursued was to enable users to use their existing rail clamps to attach the RAIS device, a solution to variation and reduced cost for users.

4.5.2 Clinical Verification: Loop 2

This section refers to the second iteration of the waterfall verification loop (see Figure 8).

4.5.2.1 Activities

In the second design verification loop (see Figure 10, Activity 4), design input was provided by a participating local stakeholder visiting the UK, who assessed the medium-fidelity prototype using a simulated abdominal wall and OTT. The design process involved a design team workshop to ideate solutions for addressing concerns in the user feedback. Iterative prototyping using 3D printing was used to rapidly test and refine new concepts (see Figure 15). The design output was a high-fidelity prototype with additional 3D-printed options for several parts.

Figure 15: Examples of rapid prototyping used to develop RAIS concepts

4.5.2.2 Outcomes

In particular, the feedback from the in-person assessment highlighted two crucial flaws in the RAIS system which were overlooked by participants interacting via video-conferencing. The first flaw related to usability. The user highlighted that the device did not afford sufficient flexibility for positioning and lifting the internal component. The second related to the OTT attachment system, because the user disagreed with participants who had advised that remote facilities would have an appropriate rail clamp with which to attach the RAIS device to their OTT. Through the interdisciplinary workshop and iterative 3D printing, the team developed solutions which afforded more flexibility on device positioning and OTT attachment. The improved designs are shown as the output of Activity 4 in Figure 10.

4.5.3 Clinical Verification: Loop 3

This section refers to the third iteration of the waterfall verification loop (see Figure 8).

4.5.3.1 Activities

In the third design verification loop (see Figure 10, Activity 5), design input came from a surgeon based in the UK with experience in gasless surgery, or a 'proxy user' [100]. While others have cautioned against verifying designs with users not based in LRHCs, in this case the modified aspects required in-person assessment because they had been previously overlooked by stakeholders interacting via video conferencing. The proxy user assessed the device by performing a simulated laparoscopic procedure using the device on a cadaveric model. The design process comprised of engineers and designers refining 3D printed parts

to enable manufacture in stainless steel and the design output was a complete high-fidelity prototype suitable for travel to remote locations in India and testing with end-users.

4.5.3.2 Outcomes

This verification loop did not catalyse design changes. While the proxy user feedback suggested the proposed design changes solved issues highlighted in the previous loop, the team resolved to get feedback from end-users in LRHCs before further design modification.

4.5.4 Clinical Validation

Ethical approval for the cadaveric study at ARSICON 2019 was granted by Martin Luther Christian University in Shillong, India (Ref: VI/I(8)/UREC/EA/272/2015-6116) and approved by the Faculty of Medicine and Health Research Committee at the University of Leeds in the UK (Ref: MREC 19-029). Informed, written consent was obtained from all participants in the study.

A cohort of end-users in LRHCs participated in the RAIS clinical validation (See Figure 10, Activity 6). They used the high-fidelity prototype on cadaver models at a surgical workshop arranged by the team to take place at a rural surgery conference. Informed, written consent was obtained from all validation study participants.

4.5.4.1 Activities

First, each participant was briefed on the project and workshop purpose and given an instruction sheet (see Appendix A) and an opportunity to ask questions. Participants were then shown snapshots of the design progression and watched a video demonstration of how to assemble and use RAIS. They then performed two surgical tasks: 1) assembling the RAIS prototype and 2) using it to perform a simulated diagnostic laparoscopy on a cadaver model. Next, they were interviewed. During this recorded, semi-structured session, participants filled out National Aeronautics and Space Administration Task Load Index (NASA TLX) for both surgical tasks and answered a questionnaire on the feasibility of using RAIS in the LRHC they worked in.

The NASA TLX was selected to evaluate the usability and suitability of the device developed for its end-users. It has been used extensively in medical device development [145] and accounts for the additional dimensions of frustration and performance when compared to other workload analysis techniques [146]. The questionnaire comprised nine statements, each followed by a seven-point Likert Scale, which ranged from “Strongly Disagree” to “Strongly Agree”. Each statement enquired whether a commonly-cited challenge of using medical equipment in LRHCs (see 2.1.3) had been successfully mitigated by the RAIS design. The

questionnaire concluded with open questions for participants to share further barriers to using RAIS in LRHCs and any ideas, comments or relevant information. For the full questionnaire and TLX, see Appendix A. The investigation purpose was gain feedback on an initial prototype from users to move forward with and improve the design, not establish definitively whether the device met requirements, and therefore no formal statistical analysis was performed on the results.

4.5.4.2 Outcomes

Most validation study participants (total n=13) were general surgeons with previous experience of performing gasless laparoscopy in rural or low-resource settings (n=9). Other participants (n=4) included a General Practitioner, a Registered Nurse and two surgeons without prior experience in gasless laparoscopy.

The NASA TLX results indicated the device was easy to learn and use. For both workshop tasks using the RAIS device, participants reported low averages on all of the six NASA TLX subscales, indicating a low overall user workload in performing each surgical task on the cadavers, and a high user performance. For device assembly, the unweighted average was 5.5 (0.9, 10.1) on a scale of 1 to 21 and for device use to perform an AWL, 6.0 (1.2, 10.8). The 95% confidence intervals for the mean are large, which is expected due to the small sample size. However, the confidence interval upper extremes still lie below the workload scale midpoint, demonstrating RAIS' usability. The outliers shown in Figure 6, which indicate high workload, were correlated to participants with no experience performing gasless laparoscopy, which requires formal training [140].

The questionnaire results, summarized in Figure 16, strongly suggest the team produced a surgical device appropriate for a LRHC using the selected methods. Participants who disagreed with the first statement 'I have experience working in a rural or low-resource hospital' (n=1) were discounted from the results analysis. On average, participants gave the device normalized scores of 90.5/100 (86.1, 94.9) over eight statements. In question 5, participants rated their disagreement/agreement with the statement: 'A rural or low-resource hospital could repair this device'. This was the most controversial questionnaire statement, with the lowest average and most variable participant scores. When probed on answers, three of the four participants who were unsure or disagreed with the statement explained they could seek advice from local mechanics who could perhaps perform basic repairs, but ultimately there were no mechanics, engineers or manufacturers in their proximity that had experience with medical devices. User would feel uncomfortable trusting

local mechanics with a surgical device they could not easily replace. Hence, the questionnaire also revealed that one requirement set in Phase 2 was inappropriate.

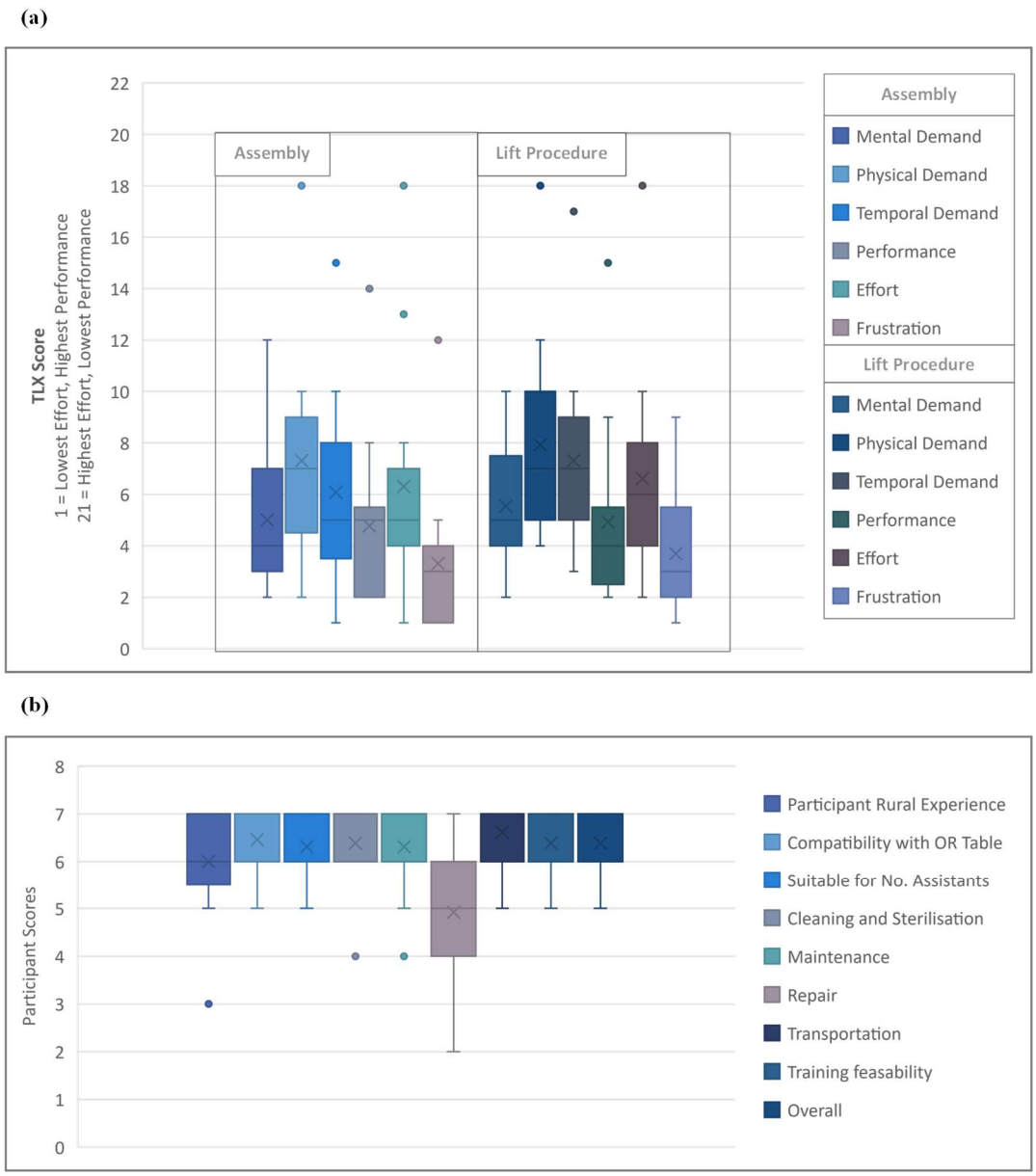


Figure 16: User Testing Results: a) Usability Study b) Rural Facility Suitability Questionnaire

It was recognised that several forms of response bias could have affected the usability and questionnaire results. It is widely acknowledged during product testing that informants often tell designers what they think they want to hear, a form of social desirability response bias [147]. This effect can be augmented by the presence of a foreign interviewer or an interviewer with a perceived as having a higher social status than the interviewee [148]. To mitigate the bias the team selected a member of the design team considered less-qualified (Postgraduate, 1yr experience) than most study participants (mostly practicing surgeons, 8+yrs experience) to perform the interviews. To further mitigate this effect, during the

briefing, cadaveric workshop and interviews investigators communicated that the purpose of the study was to identify flaws in RAIS and ways to improve the design and encouraged participants to answer honestly and discuss their criticisms of their design. Despite these efforts, there is likely to be remaining bias causing participants to over-score RAIS.

Nonetheless, throughout the interviews and in response to the questionnaire's open questions, participants also communicated ideas for improving RAIS and highlighted potential flaws. All statements of this nature were recorded, and distilled into a list by the author. Similar statements were grouped and the frequency aspects were mentioned was recorded. Design actions were developed from this feedback (Figure 17). New contextual insights were discovered too, such as difficulties communicating effectively during surgery with nurses and assistants, who sometimes had no formal training and spoke different languages. New flaws identified included aspects such as the potential to compromise sterility by tearing gloves on the device moving parts. Therefore the activities helped identify potential improvements to increase value for users without incurring additional expense.

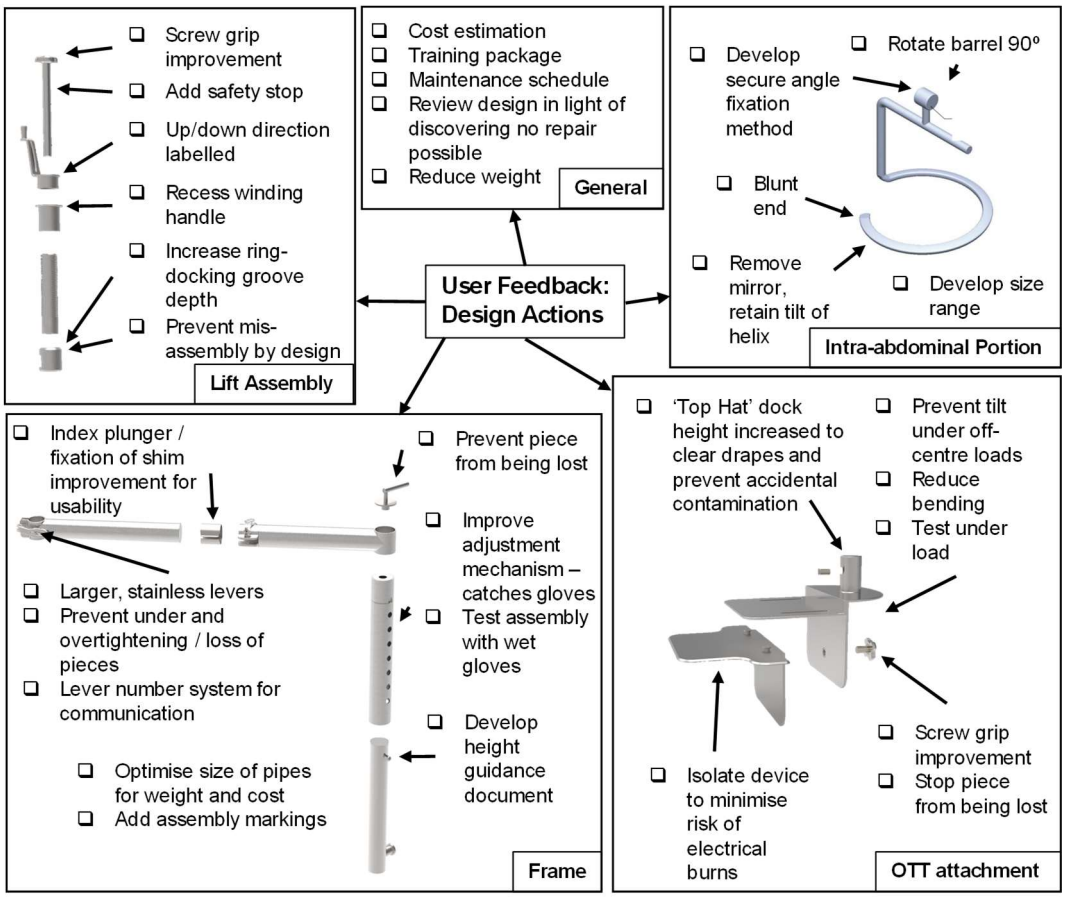


Figure 17: A summary of design changes and actions generated as a result of end-user feedback on RAIS Prototype 1

4.5.5 Phase Outcomes

In the 'Act' phase of the design process, the team developed a new concept to meet the clinical, contextual and user requirements for an AWL device for gasless laparoscopy in LRHCs. The outcomes were a high-fidelity prototype which was well-received by users, as well as a set of ideas for small improvements to the design.

4.5.6 Phase Evaluation

4.5.6.1 Design for Safe Surgery Roadmap

The iterative local end-user involvement and focus on resourcefulness and creativity rather than technical sophistication advocated by the roadmap [31] helped designers avoid potential pitfalls and develop a FI. Every verification or validation stage, even with the same end-users, resulted in ideas for design improvement, exemplifying the need for iteration. However, the roadmap provided little advice on methods for verification and validation. The team found interaction via video conferencing led to design over-simplification, since stakeholders could not pick up on usability aspects. An improved roadmap could highlight the benefits and drawbacks of using both virtual and in-person methods, and emphasize the need for both. The roadmap also suggested forming collaborations with local universities in this phase [31]. Indeed, stakeholders based at universities provided most of the iterative feedback. With experience in gasless laparoscopy and reliable access to video conferencing, they provided frequent valuable feedback. However, not being based in remote facilities, they overlooked some aspects related to those settings. Therefore ensuring end-users in remote facilities also had the opportunity to assess the RAIS design was important to supplement their contributions.

Finally, the roadmap did not provide sufficient advice on validating devices for LRHCs. On reflection, the validation event yielded a rich translation of quantitative and qualitative design information from end-users to designers. The workshop and study design were considered integral to this success. The initial briefing of participants to give them an overview of the process so far helped participants to understand the objectives of the project and stimulated critical thinking early on, with surgeons asking questions and offering opinions before even using the prototype. The open hands on evaluation in pairs gave surgeons an opportunity to thoroughly inspect the prototype and test it to their own specification, whilst also helping them to obtain an understanding of any potential difficulties for an operating theatre assistant through role play. Finally, the individual semi-structured interviews gave surgeons the opportunity to give both qualitative and

quantitative feedback, whilst the author was able to obtain a comprehensive understanding of their answers by prompting participants to discuss their scores. The timing of this milestone, which was planned within the first 5 months of the project commencing, enabled the design team to make changes to the device design based on the information gathered relatively easily, whilst in a stage prior to manufacturer involvement or regulatory submission. Consideration of bias in such studies is also vital [147,148], and not highlighted by the roadmap [31].

4.5.6.2 PD

Reviewing studies involving users in designing devices for LRHCs revealed most thought it best to prioritise involving them in early design phases. In the first verification loop, the design team focused purely on achieving the priorities and requirements set out by the participating local stakeholder, rather than considering technical feasibility, so they had almost complete control over the design direction. Technical aspects such as manufacturing feasibility and strength were prioritised afterwards, once the desired functionality had been achieved. Therefore later verification loops did require less user input. However, the validation stage revealed that user input could still add significantly to the design process, and that to get useful feedback, ensuring stakeholders feel comfortable criticising the design is an important consideration. Therefore the design team again found their sustained approach to PD yielded significant rewards. As with previous phases, the importance of consulting a variety of stakeholders was evident.

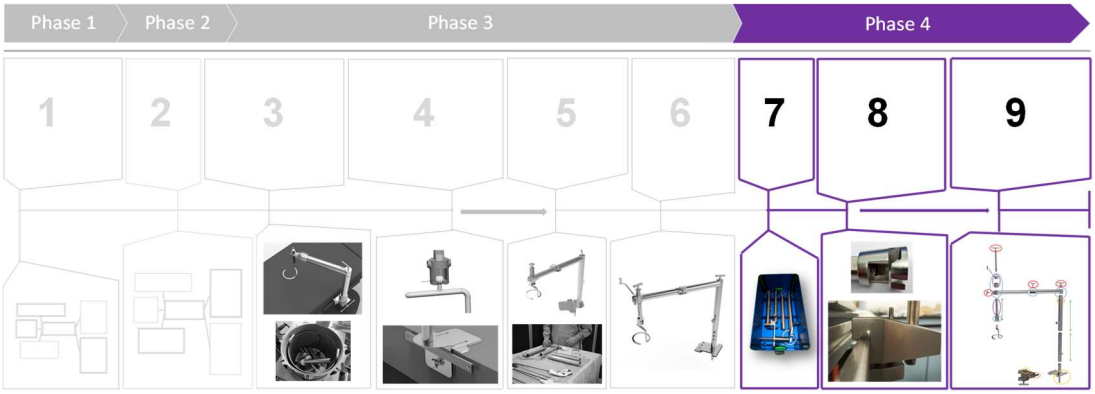
4.5.6.3 Frugal Innovation

Within each design verification loop, focus on the FI criteria helped guide the design process and select concepts, since there were many solutions for achieving requirements. Instead of aiming to impress users from the beginning, typically the team would first present the simplest, low-cost solutions, and then refine them based on iterative feedback from participants. Having users invested in the project enabled this, as they did not lose confidence when low-tech designs were presented to them [100], providing the design team with the opportunity optimise performance. This iterative participant feedback was crucial in developing the frugality of the device. Even in the final validation stage, end-users came up with further frugal ideas and ways to increase value for them without affecting the design cost or complexity.

Optimising the device performance also required use of sophisticated optimisation methods. For example, the design team relied heavily on use of FEA to optimise the device

for requirements such as lightweight and low cost, while maintaining robustness and appropriate safety factors.

4.6 Phase 4: Design to Manufacture



4.6.1 Phase Activities

In this phase, the team planned to identify an appropriate in-country manufacturing partner and produce a final RAIS device suitable for testing in human clinical trials. Together with participating local stakeholders, the team established criteria to select a manufacturing partner. In addition to capabilities in manufacturing and undergoing regulatory approval of new medical devices, willingness to participate in bi-directional discussions to refine the design for low-cost manufacture and produce iterative prototypes, similarly to clinical stakeholders, was desired. Understanding of the needs of LRHCs and an ability to supply product aftercare or spare parts to them was also necessary. Several manufacturers meeting these criteria were contacted, and site visits were arranged by members of the team in the product design industry to select a partner. During these visits, the team presented an overview of the device, highlighting key areas of manufacturing complexity, and provided several physical parts for the manufacturer to assess.

Due to the COVID-19 pandemic, all further activities involving stakeholders in India were conducted via video conferencing. Therefore the design to manufacture process comprised of bi-weekly online meetings between the design team and manufacturers, each focused on one aspect of the design. Local stakeholders participated to explain concepts and assess initial prototypes. The phase culminated with a live, online cadaveric demonstration of the first prototype to local clinical stakeholders, who provided feedback via a survey.

4.6.2 Phase Outcomes

The team met with three potential manufacturers to discuss developing the RAIS device. After these discussions, which involved and in-depth discussion of the project aims and expectations, all three manufacturers expressed an interest. However, one manufacturer stood out due to their obvious enthusiasm and understanding of the aims of the project, as well as personal experience of remote healthcare centres.

Following the bi-weekly meeting process, the manufacturer made several improvements to the device for users. For example, being aware of difficulties transporting and storing equipment, they developed a transport case that contained laser-marked positions for each component, to help users with assembly and disassembly and prevent them from losing parts (Activity 7, Figure 10). Understanding the focus on low cost but high quality, they worked closely with the design team and clinical stakeholders to make improvements in part strength, reduce manufacturing complexity and achieve clinical requirements. For example, through several design iterations, they designed manufacture of the lift assembly as one component (Activity 8, Figure 10), while retaining all the features required by clinical stakeholders. These innovations enabled the team to achieve the cost goals set out at the beginning of the project.

Through the online, interactive cadaveric evaluation session, involving the design team, manufacturers and clinical participants, stakeholders were able to identify enduring flaws in the prototype and suggest improvements. Participant survey feedback was positive, however they emphasized that without using the device in person, they could not be sure it was adequate, so the results had limited use.

4.6.2 Phase Evaluation

4.6.2.1 Participatory design

In identifying and selecting a manufacturing partner, participants and product design industry partners were indispensable, providing experience in industry and the local context. The sustained approach to involving local stakeholders meant in this phase participants could help optimise prototypes by testing them and highlighting when small modifications made for manufacture affected device performance or function significantly. They explained and demonstrated to manufacturers why complex manufacturing features were necessary and facilitated achieving the best compromises between manufacturing complexity and functionality. The online cadaveric evaluation showed that participants can provide useful contributions via video conferencing, but also reiterated the findings of phase 3, showing it

cannot substitute interacting with the device in a real clinical environment. Clinical stakeholders expressed this using the feedback survey.

4.6.2.2 Frugal Innovation

Working with a manufacturer with understanding of LRHCs helped further optimise the RAIS' value for users, who expressed great satisfaction with the manufacturer's custom case for storing and transporting the device (Activity 7, Figure 10).

4.7 Summary

This chapter investigated Objectives 3 and 4 of the thesis. By providing a detailed account and tangible examples of implementing the integrated approach developed in Chapter 3, the work here addresses the paucity of evidence relating to use of these approaches in designing technologies for global surgery. The systematic evaluation of work completed and the progression of the RAIS device design in each phase shows how each was influenced by the Design for Safe Surgery Roadmap and the principles of FI and PD.

The major limitation of the work in this chapter is that it only reflects on the effect of the approaches on the technology designed. While, as discussed, this was the primary aim of the project, it has also been argued that when using a PD approach, especially one which aimed to involve participants as more than just informants on the design context, the effect of this approach on the participants must also be evaluated [92,102].

Therefore, prior to discussing the overall suitability of and suggestions for improving the design approaches investigated, which relates to Objective 6 and is addressed in Chapter 6, the next chapter presents the results of a study investigating how clinical stakeholders benefitted from being involved in designing the RAIS device.

Chapter 5

Evaluation of User Gains from the Design Approach

Chapter 5 considers the effect of the design approach on the clinical stakeholders involved, to complement Chapter 4 which evaluated how it affected the RAIS design. An exploratory qualitative study, comprising of five semi-structured interviews with clinical stakeholders who participated in the design of RAIS, is described. The study investigates what clinical stakeholders gained from being involved and what affected these gains in terms of facilitating or impeding them. Evaluating these 'Indirect, Unintended' impacts in addition to the intentional impact (on the RAIS design) provides a more holistic insight into the potential benefits of involving users in designing technologies for global surgery.

5.1 Introduction

As discussed in 2.4.2.3, the *Objective* of using PD to design technologies for LRHCs is most commonly to improve or reduce the cost of the technology [104]. Indeed, this was the *Objective* of using a PD approach to design RAIS, and Chapter 4 highlighted its significant influence on the design development. However in wider PD literature, while prototypes, products or design concepts are still the most frequently evaluated *Impact* of PD projects [92,104], some projects prioritise gains for the participants, such as their psychological empowerment or up-skilling [105,149].

Several studies have argued that PD practitioners developing global medical technologies should prioritise participant gains [58,69,102], adapting their *Objectives* and overall approach to focus on mutual learning and developing local innovation capacities in LRHCs [88]. Yet PD participants are also likely to be surgical technology users in LRHCs, who are often in short supply, so it could be argued that use of their time should be minimised. PD can also be resource-intensive for organisations [92]. To justify using PD, it is important to be able to consider all the benefits of using it and be able to maximise outcomes. Critically lacking in literature is evidence of how participants benefit from PD approaches in this context and how these gains can be impelled. To lay the foundations for addressing the paucity of evidence in this area, an exploratory qualitative study was performed. The study aimed to answer two research questions:

1. What did clinical stakeholders gain from being involved in designing RAIS?
2. What affected these gains, in terms of facilitating or impeding them?

To investigate these research questions, 5 clinical stakeholders who participated in designing RAIS were interviewed. The results are intended to initiate and inform future studies by increasing understanding of concepts related to the *Impacts* of PD in this context [104]. Evidence from this and further studies could be used by organisations to achieve more

impact in increasing global access to surgery when using a PD approach to designing global surgical technologies.

5.2 Method

Exploratory studies often warrant using a qualitative approach, and in particular, semi-structured interviews. This method allows the researcher to explore thoughts, beliefs and feelings of participants, and delve more deeply into personal topics and reflection by asking follow-up questions to seek detail or clarification. They are especially useful for identifying new phenomena [150] and are commonly used to evaluate the outcomes of PD projects for participants [92,98,103] which can be hard to measure [103]. Hence they are particularly appropriate for exploratory research into the *'Unintended or Indirect Changes'* attribute of the *Impact* of a PD approach [104,151].

5.2.1 Recruitment and Consent

Ethical approval for this study was granted by the Faculty of Engineering and Physical Sciences Research Ethics Committee at the University of Leeds in the UK (Ref: MEEC 20-023). Informed, written consent was obtained from all participants in the study.

A sample of six clinical participants involved in the RAIS design process were purposively recruited for the study [152]. The participants selected were those involved in the project most frequently, and hence likely to have experienced impacts from being involved. The selection process also included an aspect of maximum variation sampling: to the best of the author's knowledge, the sample contained participants who had different experiences of the process and were likely to provide different insights. They had different clinical roles and varying levels of previous experience designing technologies.

Participants were recruited via email and provided with an information sheet (Appendix B). No participants declined to be interviewed, but the final interview did not take place as the author concluded that data saturation had been reached. An overview of the participants interviewed is provided in Table 1. All participants have been given pseudonyms to protect their identities.

Table 1: Overview of Participants and Interviews

Pseudonym	Activity Participation (see timeline)	Design experience	Interview Duration
Arpit	1-4, 6-10	Low	30:44
Bahar	1-4, 6-10	Low	37:35
Chaman	1, 5, 7, 8, 10	High	42:28
Danvir	1, 7	High	39:59
Ebrahim	1-10	Low	38:46

5.2.1 Data Collection

Participants were interviewed by the author. Since she had worked closely with participants, it was recognised that they might more likely to withhold criticisms or exaggerate gains during interviews. However, the professional relationship between the author and participants had been built around participants evaluating designs and concepts the author had developed, and it was felt that a trust had been developed where participants knew they could be critical and were actively encouraged to be so. Since her participation in the project was imminently ending and participants were aware that the author was junior to them in both age and profession, they had less reason to withhold frustrations. Furthermore, the author's in-depth knowledge and experience of the design process was considered an advantage in that it could allow her to pick up on subtle aspects. To reduce the potentially biasing effect of the author's previous experience and knowledge of the interviewees and design process on the collection of results, the author performed extensive research into interviewing techniques and reviewed the interview topic guide (Appendix C) and example questions with an experienced qualitative researcher in PD projects, with no prior involvement in the RAIS project.

Others have reflected that the timing of interviews affects the data collected, the advantage of 'sooner' being that participants remember events more clearly, and 'later' being that longer-term gains can be assessed [153]. However, longer-term gains are often difficult to unequivocally attribute to the PD approach since unrelated factors are likely to influence the participant's perspective over a number of years [153]. Therefore, the interviews were conducted at the end of Phase 4, 1 year and 9 months after the project commenced, whilst participants memories were likely to be clear.

Interviews were arranged at the convenience of participants and conducted using video-conferencing, which is considered equivalent or even superior to other interviewing methods [154]. Participants were interviewed individually, since it was felt this would make them more comfortable discussing personal feelings, and each was recorded with verbal and written permission. The topic guide (Appendix C) was based on an existing study with similar aims [105,153] and adapted to be more appropriate for this study's aims and participants through an iterative process including two pilot interviews with a non-clinical RAIS team member and another colleague. Each interview began with a discussion of the interview purpose, emphasizing that the focus was to examine how being involved had affected them personally. Once the interviewer felt the participants understood this aspect, she asked several 'warm-up' questions focused on the aspects below considered likely to affect their personal gains, to put participants at ease and add context to their responses.

1. Current role
2. Previous experience designing technology

Then, the following topic areas were discussed.

1. Motivations for participating
2. Feelings about personal contribution to and influence on the project
3. New knowledge and skills acquired
4. New possibilities emerged
5. New outlook on healthcare technology or own practice
6. Personal gains from participating in the project
7. Overall assessment of participation in the project

During the interviews, participants were encouraged to speak about anything else they felt was relevant. Specific questions were adapted throughout the interviews based on the responses of participants.

5.2.3 Data Analysis

Extensive reading informed the process employed to thematically analyse the data [155–157]. Interviews were transcribed by the author, helping to familiarise her with the data and form initial ideas of what might be relevant to the research question. Then the transcripts were reviewed to replace content which could be used to identify participants with pseudonyms. The transcripts were then analysed separately by the author and an additional coder, who, in contrast to the author's engineering background, had a clinical background and no prior experience of the RAIS project or participants. The complete analysis process is shown in Figure 18.

Figure 18: Thematic analysis process employed on the interview transcripts

The coding process was primarily inductive [158]. The transcripts were searched in terms of gains, frustrations, impediments and facilitators, to answer the pre-determined research questions in 5.1. Each coder reviewed transcripts independently and selected quotes relevant to the aims of the study. Each quote was assigned one or more evaluation codes, which were iteratively refined during the coding process. Code frequency was recorded. The coders individually reviewed their codes and organised them into categories. At this stage, the coders met to compare their categories, discussing their content and what each contributed in knowledge towards the research question. Through this discussion, the coders refined the 25 categories into 3 overarching themes with coherence, clear boundaries and enough meaningful data to support each conclusion, evidenced using code frequencies.

5.3 Results

Through the analysis process, 3 themes were developed:

- Motivations and Expectations
- Ways of Working, Collaborating and Communicating
- Acquiring Skills, Diversifying Careers and Expanding Networks

'Motivations and Expectations', explores the relationship between why clinical stakeholders became involved in designing RAIS, what they expected to gain from it for themselves and how that may have affected what they did gain. The second, 'Ways of Working, Collaborating

and Communicating' discusses how working within the RAIS team influenced the way participants approach their work, particularly with others, and how the approach taken to involving and communicating with participants may have influenced that. The final theme 'Acquiring Skills, Diversifying Careers and Expanding Networks' focuses on changes and new opportunities described by participants affecting their skills and careers, and what aspects of designing RAIS catalysed these.

5.3.1 Motivations and Expectations

Unanimously, participants considered helping others a significant personal goal, and altruism as their primary motivation for being involved in designing RAIS. The prospect of creating benefit for others drew them to the project, rather than an opportunity to further their own fortunes, particularly since it focused on addressing the needs of those they considered less fortunate than themselves.

> *"this whole idea of being part of a collaborative project, where the ideas and vision is driven by those who are going to use it was very appealing" -* ***Ebrahim***

> *"daily wage workers… why not give them the advantage of minimal access surgery through the gasless device" -* ***Bahar***

> *"the purpose to join this technology development of a device was to increase its accessibility… so more people can use it... we are looking for the developing countries... many areas in Africa.... Southeast Asia..." -* ***Chaman***

Of course, actions are rarely entirely selfless, and most participants expressed a sense of purpose, satisfaction and enjoyment gained through working on the project to help others. Arpit, Bahar and Ebrahim, who were involved in all design stages (Table 1), reflected that since this aim was shared by everyone, it also helped to unite team members from different professions and cultures. Chaman and Danvir, who had previous design experience, noted that this did not always happen, and that conflicts in objectives between themselves, whose priority was to provide the best solution for patients and surgeons, and engineers or manufacturers, whom they perceived as primarily wanting to make money, could make collaboration difficult.

> *"you know, you have a keen interest in doing surgery and finding solutions so you're seeing every day that okay, we are taking one step or multiple steps in a day, sometimes, towards that. That's a very fulfilling kind of feeling." -* ***Arpit***

> *"everybody was just on the same level… focused… making sure we get this project done and come up with this new device" -* ***Ebrahim***

"their motive is primarily making money... they said 30% of the money comes from disposables... but we insisted that, see we are doing it for a resource-poor setting... there is no point in adding something unnecessarily disposable... it may not have a huge market, but still, it will serve the purpose..." - ***Chaman***

Hence, a focus on user needs facilitated the forging of strong partnerships and associated benefits which are discussed further in the following two themes. On the other hand, perhaps this focus was so unmitigated that participants did not consider how they could benefit from being involved. Certainly, participants found it difficult to talk about personal gains. At the start of the interviews, when answering a question about the impact of some aspect on themselves, they would frequently drift back to discussing how that aspect affected RAIS instead, despite repeated emphasis that the interview was about how the process affected them personally. Ebrahim felt that considering personal gains might have even negatively impacted the project.

"I didn't get involved in this project, first of all, for personal gains, you know… one of the biggest barriers is when your personal gains come in the way… your personal biases come in…." - ***Ebrahim***

Interestingly, since participant motivations and expectations revolved primarily around helping others, so did most frustrations discussed by participants. Participants expressed dissatisfaction when their expectations of helping others were not met, for instance when they felt progress was too slow or the project hadn't yet had the impact they hoped. Some frustration with timescales was expressed by three of the five participants. Danvir highlighted that perhaps this frustration occurred when it was felt that team members based in HICs did not understand how pressing the need for the technology was, or feel enough urgency to implement it.

"I was expecting by this time there will be at least 10-12 centres in India… we're not there yet" - ***Arpit***

5.3.2 Ways of Working, Collaborating and Communicating

Despite limited motivation to further their personal interests, participants became more introspective further into the interviews, and began to articulate more personal gains.

"my purpose of getting involved was to, for... patients who are in the global south to benefit, for the collaborators to benefit, but eventually some of the other benefits has come to me as well and I wouldn't deny that" - ***Ebrahim***

In particular, the three participants involved in the most design activities and decision-making, Arpit, Bahar and Ebrahim (Table 1), described how working on the project

heightened their awareness and appreciation of the benefits of multidisciplinary collaboration. They developed interpersonal skills for teamwork, such as recognising the benefit of listening to and considering the ideas and perspectives of others and the value of their own contributions and role in the team.

> *"I think whenever you are starting working in a team with different skill sets and different, you know, viewpoints, one thing it teaches you is that you have to listen to others viewpoint and sometimes they are so much you know more learned… now I listen to others, and you know, try to have their version, their viewpoint on everything, so I think, I think that makes me a better team person" -* ***Arpit***

> *"Teamwork... brilliant, I think I have been repeating this again and again, but that is the most important thing which I have learnt" -* ***Bahar***

Arpit, Bahar and Ebrahim also described how they planned to or had already begun to use this interpersonal learning and newfound enthusiasm for collaboration to pass on their knowledge to others, and create changes to their workplaces and the way they approached solving problems.

> *"engineer people let's say they're working in health domain, they will do finding solutions on their own, without having any understanding about health, and the health people also will be finding the solution to the same problem with no contact with design and interviewing people. And now it shows me that, how stupid is that" -* ***Arpit***

> *"the way we have approached this designing process…I'm going to use it for future works… using that same experience of working with a group of collaborators who come with different backgrounds" -* ***Ebrahim***

Chaman and Danvir highlighted the value of these skills by describing the inherent conflicts they had previously experienced between the priorities of engineering and clinical stakeholders in a team, and the importance of understanding one another's perspective to resolve these and make the right compromises.

> *"We need to sort of come with a compromise, okay, so, we accept the sort of thing. So there is a lot of disconnect between the clinicians and the designers… learning has to be both ways, so the engineers need to learn what the actual need of the clinicians are, the clinicians also need to learn what is possible or not possible" -* ***Chaman***

However, whilst there were learning opportunities from working in this multidisciplinary team, these differences in professional and cultural backgrounds were a potential source of conflict. Clinical stakeholders described frustrations which centred on idiosyncrasies in paperwork and regulation between countries, with different ways of planning work and with the pace of work.

"in India, the pushy kind of system works better. It will be, okay, from tomorrow we have to do it, very tomorrow we have to do it. Whereas, right, there [in the UK] it's like okay, the timeline is next week or next next week or this month" - ***Arpit***

"when you're doing it [designing medical devices] with the team like a big University then you need to go by the standard protocols and all those things… nothing much is happening for quite a long time" - ***Chaman***

In particular, most participants based in India felt that their need to test prototypes in person in a clinical setting to provide accurate feedback was not fully understood or provided for by other stakeholders in the team, causing some frustration. Arpit and Chaman went on to highlight that they felt this lack of opportunity to test prototypes in person, which they attributed in part to the team being based across two continents, had limited the contributions they could make, and as a result Chaman was anxious about the quality of the final device. They felt their contributions were less valuable online and that limited their ability to be a part of the team.

"Had it been in, let's say the same country, we could have, I think, done much better" - ***Arpit***

"that's one problem we have with any of the company, they don't like us, keeping on changing the design or altering it because it makes it difficult for them, especially if they're considering producing in bulk and so on. But then before that actually when saying the final word, it's without using in different types of patients. It's again difficult to say that well okay this is the final and we don't want to make any more changes" - ***Chaman***

Influences on the way they worked and collaborated were only discussed by Arpit, Bahar and Ebrahim, who were involved in all design stages and decisions making and also had little previous experience in design (Table 1). These participants reflected on how regular communication from the design team to keep them up to date, having iterative opportunities to provide feedback and being involved in decision making and planning were factors that enhanced their experience of multidisciplinary collaboration.

"I have seen some teams failing because of this thing, either timelines are too short, so timeline is decided by one person or one portion of people, whereas others might, are not able to follow that" - ***Arpit***

"you are also giving us the feedback at every level. Now I will label it as... as a formative assessment... involving us… at every point, whenever you're raising some points or taking our feedback" - ***Bahar***

Being involved in this way helped not only reduce frustrations centred around their influence on the device, but made them feel valued and recognise that their contributions were

important, even if their ideas did not materialise in the final product. In particular, participants reflected on the role of good leadership and an ethos of equal stakeholder-ship recognised and practised by all team members, in improving their confidence and perceived performance throughout the project.

> *"if, let's say, they [my contributions] were rejected, they were rejected with a valid reason… til the point where I also said yes, it makes sense."*
> - ***Arpit***

> *"I had that, that unique advantage… I was able to raise pertinent questions… that helped the engineering team and the design team" -*
> ***Bahar***

> *"being valued was very important for every team member so, so I think because of that everybody felt that I, I can contribute more, over and above what I would have contributed because I'm being valued for who I am, not, irrespective of my background or my professional achievements of whatever you know, big or small."*

> *"the dynamics between the group was very useful because everybody ensured that everyone felt that they were part of the team"*
>
> - ***Ebrahim***

5.3.3 Acquiring Skills, Diversifying Careers and Expanding Networks

As well as interpersonal skills, four of the five participants learnt new technical skills. They described increased knowledge of engineering and design considerations, some of which they felt were useful in their current roles, such as knowing different types of materials which could withstand autoclaving. Through observing the team evaluating different designs with users, they gained an appreciation of the importance of fine detail and investigating norms in design. Arpit, Bahar and Ebrahim described developing a more critical mind-set surrounding healthcare technologies, and becoming more aware of opportunities for innovation and ways to improve their practice. They also gained awareness of the wider context of healthcare technology design, becoming more interested in aspects such as manufacturing, implementing and diffusing technology in LRHCs.

> *"I think it has helped me to push my innovative ideas that I would have otherwise not used... I felt that I could do this... come up with ideas... I've never engaged in the sort of activity before... because everything is just sort of given to you, that this is what are you going to do" -*
> ***Ebrahim***

Danvir and Arpit also revealed they had existing career aspirations or personal interests in biomedical technology, which they were able to explore further through being involved in the project. For both, utilising links with team members and the wider global health

community led to career developments. For example, as a part of the project, one participant was able to complete a course in biomedical engineering designed specifically for LRHCs. Other participants made new links through the project with members of the international community interested in gasless surgery and RAIS, facilitating new collaborations and research opportunities, although it should be noted that some of these opportunities were also likely to be linked to their involvement in other projects with the GHRG-ST, rather than specifically designing RAIS.

> *"it's... kind of a dream that one day we will work with such a team and we've designed something, and have something of our own, and when we saw this happening with RAIS and this team, I think there was no, no way I could have said no to this" -* ***Arpit***

Using the skills and knowledge obtained through designing RAIS, some participants even began to initiate their own innovation projects. Through these, and through disseminating their experience designing RAIS at events and conferences, participants shared their knowledge of designing for LRHCs to a much wider community.

> *"I got a glimpse into the world of designing and thanks to your team that we have started evolving, looking for more... low cost innovations and solutions...things which can we can start at our Institute and pass on across... colleagues… peers… other medical colleges…" -* ***Bahar***

Again, these gains had links to the way participants were involved, with opportunity to skill-share with, observe and be immersed in the practice of designers and engineers being crucial. Participants also reflected that maintaining an open mind-set and building meaningful, supportive relationships with other team members enhanced these learning and skill-sharing opportunities.

> *"one thing I have learned with this thing that whenever you sit with the new people with new or different kind of skill sets the learning curve certainly takes a upward, you know, rise" -* ***Arpit***

> *"The development of you know, very easy rapport… every person was very much approachable" -* ***Bahar***

5.4 Discussion

The purpose of this study was to explore whether clinical stakeholders made personal gains from being involved in designing RAIS, and what facilitated or impeded those gains.

Despite approaching the thematic analysis of the transcripts from very different backgrounds, with one coder having no prior experience of the project or stakeholders

involved, the two coders identified extremely similar codes and categories. The iterative process of refining these into three themes was straightforward and both felt satisfied that their categories and codes could be described fully within these.

The first theme, 'Motivations and Expectations' explored the significance of motivations and expectations in influencing participant gains. The responses of participants indicated that a shared goal and focus on user needs was important for experiencing gains from achieving personal goals, forging strong links between the team and for the motivation and enjoyment of clinical stakeholders. However, these motivations were central to frustrations experienced by clinical stakeholders too. Interestingly, as well as not having considered gains for themselves, when asked about disadvantages to themselves from participating, participants also had very little to say. Perhaps as well as personal gains, they consider personal drawbacks to themselves as less important than this goal of helping others. It was recognised throughout the project that participants gave their time generously, and it seems natural that if they felt they were making personal sacrifices for the project, then delays or barriers to them achieving their goal of helping others might cause frustration. In addition to this, participants frequently expressed not expecting or desiring to gain for themselves. This raises the questions as to whether there is indeed any benefit, for clinical stakeholders, resulting from being involved through different stages of the project, or whether it is more likely to result in them making personal sacrifices.

However, the second theme, 'Ways of Working, Collaborating and Communicating' highlighted opportunities for clinical stakeholders to learn new ways of working and collaborating arising from working closely with others in an interdisciplinary, multinational team. This environment catalysed interpersonal skill development for some participants, who had already begun to implement and use what they learnt to make changes to their day-to-day roles. Participants who did feel that they had gained in this area reflected that these gains were linked to the way they were involved. The project emphasis on frequent and sustained communication, a non-hierarchical team structure and ensuring everyone was recognised for their contributions in outputs were praised. Indeed, participants that were not involved in this way and purely provided feedback on prototypes expressed more dissatisfaction with outcomes and didn't describe any interpersonal skill development. Rather than gains, they described frustrations regarding difficulties collaborating across two continents and several disciplines. In fact, all participants that were geographically separated from the design team agreed they needed further opportunities to evaluate prototypes in

person to feel that their contributions were worthwhile and accurate, highlighting a key barrier to PD frequently mentioned by practitioners in this context [100].

The final theme, 'Acquiring Skills, Diversifying Careers and Expanding Networks' highlighted how using innovation skills and knowledge developed through working closely and skill-sharing with engineers and designers on RAIS, participants were able to make useful gains towards achieving their career ambitions, creating and even leading new innovation projects in global health. Networking facilitated by the project led to new collaborations and opportunities too. The gains described in this section were primarily driven by the stakeholders themselves rather than being intentional outcomes of the project, but again, involvement in the project provided a useful environment with opportunities that stakeholders were able to use to their personal advantage. Notably, all participants were passionate about directing gains they made to further their impact on improving global surgical care and all were enthused at the prospect of, or already developing, more low-cost, robust surgical technologies. Gains described in this theme were particularly useful for participants based at Universities, who gained skills, knowledge and networks to diversify their careers and initiate their own global innovation projects. Others have advocated for the forming of collaborations between universities, manufacturers and other stakeholders, similarly to the RAIS project, since they can provide an excellent environment for in-country for innovation [31,108,110].

Overall, participants described several *'Unintended or Indirect' Impacts* from being involved in designing RAIS from which they benefitted, mostly arising from the opportunity to work and skill-share within an international, multidisciplinary team. However working across large physical distances, slow timescales and perceived lack of influence on the design could lead to frustration rather than gains for participants. Furthermore, all the gains described by participants can only be indirectly attributed to being involved in the project, since they were primarily driven and achieved by the participants themselves and were not intentional outcomes of their involvement. However, in general there was a marked difference between the gains and frustrations described by participants involved in all design stages, and those involved purely in evaluation stages (Table 1). The design team's efforts to communicate, co-create and commend contributions were considered important by participants involved in all stages to the gains they experienced, as well as having opportunities to iteratively test prototypes in person.

The study does not provide a representative view of all participants involved in the RAIS project, and since the findings are based on a single data collection method, they cannot be

used to confirm any hypothesis. Of course, there is also likely to be a level of subjectivity to the results, but it is a unique study in the fact that it does investigate the perspectives of clinical stakeholders on this subject. The outcomes indicate that gains for clinical stakeholders may be worth investigating further, especially since some of the gains clinical stakeholders made while designing RAIS could help them to create long-term impacts by developing their own local surgical technology innovation capabilities. Focusing on developing innovation capabilities within LMICs themselves may help to overcome some of the most difficult aspects of designing in this context, such as working across large physical distances and gaining an understanding of unfamiliar contexts. Ensuring clinical stakeholders make relevant gains may also help to reduce their frustration with outcomes, as typically, medical device design is risky and projects often span many years [51]. Their continued support can be vital in disseminating new technologies [22,58] and may help scale-up and implement them. Therefore, while the magnanimous attitude of clinical stakeholders facilitated improvement of RAIS and strengthened the team, perhaps considering what they can gain from being involved is important too, especially since the gains made by stakeholders in this instance may help improve surgical care in LMICs even further in the future.

5.5 Summary

This addressed Objective 5 of the thesis, using three themes to discuss how the approach used to design RAIS benefitted the participants involved. These themes, developed through thematic analysis of semi-structured interviews with clinical stakeholder involved in the project, were:

- Motivations and Expectations
- Ways of Working, Collaborating and Communicating
- Acquiring Skills, Diversifying Careers and Expanding Networks

The themes also revealed some key factors, such as implementing an ethos of equal stakeholder-ship within the team, might have been important in facilitating or impeding stakeholder gains. Combined with evidence of how the design approach influenced the development of the RAIS technology, detailed in the previous chapter, the results of this chapter are useful for discussing the merit of the approaches used to design RAIS, and make suggestions for their development in the next chapter, which concludes the thesis.

Chapter 6

Discussion, Recommendations and Conclusions

In this chapter, the insights gained from selecting, implementing and evaluating the design approaches used to develop the RAIS device are discussed. The outcomes of this work form a set of recommendations, intended to guide designers and organisations through the process of innovating surgical technologies for LRHCs. The thesis concludes with suggestions for future work in this area.

Work contributing to this chapter was published in the International Journal of Surgery Global Health:

Marriott Webb, M., Bridges, P., Aruparayil, N., Mishra, A., Bains, L., Hall, R., Gnanaraj, J., & Culmer, P. (2021). Designing devices for global surgery: Evaluation of participatory and frugal design methods. IJS Global Health, 4(1), e50

6.1 Introduction

This thesis aimed to investigate approaches to innovating global surgical technologies, which is a fundamental strategical aspect of addressing inequalities in access to surgical care [22]. In this concluding chapter the insights gained developing RAIS and evaluating the design approaches pursued are discussed. Six themes for best practice were identified by scrutinising all learning outcomes from the design process and performing an iterative categorisation process, with feedback from design, engineering and clinical stakeholders involved in the project. They findings complement that of wider literature appraising design of technologies for LRHCs. The findings can be used by researchers and innovators to consider ways of developing design approaches further, to better support innovation of frugal surgical technologies and create more disruptive impact on increasing global access to quality surgical care.

6.2 Participatory Design and Stakeholder Engagement: Early, Often, Sustained

As discussed in Chapter 3, the PD approach planned focused on an ethos of embedding stakeholders local to the design context within the team, to enhance their *Representation* and *Interaction* within the project. The aim was to 'design *with*', rather than 'design *for*' this group. Chapters 3, 4 and 5 highlighted how this subtle distinction influenced the design

methods selected, the technology designed and the experience of and gains for clinical stakeholders involved.

Key challenges and opportunities in implementing this approach were identified. Engaging the 'right' stakeholders, or an appropriate cross-section of them, is critical to both fully define the design context and maximise positive outcomes from PD. Chapter 5 indicated that clinical stakeholders based at universities in LMICs, rather than working in LRHCs, could benefit more from being involved. In our experience these 'proxy users' were able to provide more regular input and are well placed to translate their gains from PD into further positive impacts [100]. However, Chapter 4 showed their input should supplement, not substitute, input from end-users living and working in LRHCs, since proxy users cannot always provide the same in-depth knowledge of these contexts. It also highlighted that it is desirable to have multiple representatives from each discipline (e.g. surgeons, nurses, researchers) to increase creativity, ideas and contextual knowledge, and decrease the risk of over-reliance on individual opinion which may not be representative.

Stakeholder input must also be strategically planned. The initial design phases may require more in terms of numbers of local stakeholders and frequency of their input, to build a base of contextual knowledge and inform early project decisions. Involving local stakeholders in these decisions helps focus the project where it can create impact and builds trust between collaborators, which Chapter 5 showed may be necessary to overcome barriers such as professional and cultural differences. Convening the design team with many local stakeholders within the target context is therefore an ideal means to both start the design process and begin building team dynamics which promote multi-directional flows of information and equal representation and stakeholder-ship. This should be sustained throughout the design process. All stakeholders can, and should, contribute to innovation and idea generation [109]. Their iterative input in multidisciplinary design sessions can also help inform decisions, resolve uncertainties and optimise design functionality. In our experience, they provided invaluable insights throughout the design to manufacture phase and their contributions as advocates and champions for the gasless surgical technique are central to the implementation strategy for RAIS. Their input also facilitated in-country device clinical evaluation. Hence, clinical stakeholders can become champions for new technologies and be fundamental to propelling the device throughout its dissemination into clinical use and adoption [22].

Finally, building strong partnerships with stakeholders local to LMICs throughout the project can support development of local and international networks with the capacity to innovate and evaluate further innovative, frugal surgical technologies within LMICs. Therefore considering and prioritising stakeholder gains from being involved could increase the impact of the PD approach on increasing access to and quality of surgical care globally.

6.3 Communication

This project also underlined the importance of good communication in PD. In this case-study the need was amplified by working across different disciplines and continents. This is a potential source of conflict, especially when expectations of the project and motivations for being involved differ.

The design team discovered effective strategies for communicating with end-users, such as use of semi-structured interviews, making use of follow up questions to clarify concepts and to learn about nuances and obscurities of performing surgery in remote contexts. Interacting with physical prototypes and live sketching greatly enhanced data collection and understanding between all team members during such interviews and group discussions. These hands-on methods necessitated in-person meetings, often in a real or simulated clinical setting, which clinical stakeholders all agreed was essential for them to thoroughly assess designs. However in this design context meeting in person can be time- and resource-hungry, so the unique opportunities it provides should be taken advantage of by conducting interactive activities that are challenging to perform virtually (such as live surgical demonstrations). Such interactions may also be crucial in initiating strong collaborative relationships, which can then be maintained using remote communication methods such as video conferencing on a regular basis.

When used to supplement in-person activities, remote communication tools such as email, video conferencing and informal instant messaging tools were essential in facilitating sustained collaboration and an active team dynamic over large physical distances. In particular, video conferencing enables stakeholders to view and control CAD models as well as sketch their own ideas. While in our experience this is not a substitute for testing devices in a clinical environment, it did help convey complex concepts and gave stakeholders more agency in the design process, since they were able to participate effectively in design sessions more regularly.

The team's overall approach to interdisciplinary collaboration, which prioritised aspects of communication such as listening to and recognising each other's contributions, and involving everyone in planning, updates and decision-making, was important in mitigating potential frustrations of clinical stakeholders. They valued this approach and several participants began to implement aspects of it within their own roles and encouraged others to use it.

6.4 Design Tools

The Design for Safe Surgery Roadmap [31] provides a general framework for design, within which it is useful to select specific methods and tools to address each phase of the process, as appropriate to the project.

While some progress has been made on developing novel methods for LMIC-centred design, their focus has been on earlier phases of the design process. For example, methods to aid definition of healthcare needs in 'Phase 0' are well-developed, and need selection can be based on existing research or evidence gathered using techniques such as Outcome Driven Innovation or Activity Theory [38,101,159]. Similarly, detailed methods are available to coordinate contextual mapping in 'Phase 1' of the design process [31,89,101]. However, to advise on later design challenges, such as developing design requirements, studies commonly present generalised design requirements for medical devices in LMICs, rather than developing device-specific guidance [3,31,37,38,44]. Most critically, there is a paucity of information on how to 'act' within the iterative design process described in Phase 3. PD and FI are particularly relevant in these stages, however few studies report the challenges of adopting the approaches in low-resource settings, for instance the practicalities of obtaining feedback from LMIC stakeholders or methods for implementing the principles of frugal engineering [83,101,102]. Finally, whilst it is agreed that surgical technologies developed for LMICs should be of comparable quality to those developed for HICs, the roadmap does not suggest use of methods to implement quality control or manage design risks [31].

Our experience found that employing techniques more commonly associated with design in HICs can provide valuable structure to guide work in these later phases. For example, the P-diagram used to summarise the surgical system within which the RAIS device must perform was useful throughout later phases of the design process, for developing and assessing concepts. The waterfall model used to structure stakeholder input enabled timely feedback on design iterations and this formative approach was appreciated by designers and clinical stakeholders alike. In each verification loop, the input from the HIC and LMIC users and

stakeholders revealed additional nuances of the surgical procedure and context, highlighted flaws in the design concepts developed and helped form ideas to eliminate them before the validation phase. As reflected earlier, conducting in-person workshops at key points was invaluable for optimising the design, and was considered elementary by stakeholders for design validation.

Risk evaluation methods such as FMEA help designers to manage and mitigate adverse events in many established design process models [30]. In the case study, these evaluation and feedback sessions structured using the waterfall model highlighted many risks previously unknown to the design team, which were recorded as error states in the P-diagram. In future stages of design, such as optimisation, well-recorded discussions during verification and validation sessions could be used to form the basis for FMEA and promote early design focus on safety and quality.

6.5 Frugal Innovation in a Complex Environment

By definition, FI involves a substantial cost reduction, typically through streamlining of functionality to achieve an optimised and appropriate performance level [76]. In this context it should be noted that when reducing costs, consideration of contextual influences such as the cost incurred by performing maintenance, procuring spare parts, equipment down-time, prolonged hospital stays for patients and training staff is essential.

The lack of dedicated methods to help the team innovate frugally led to the team developing their own strategy, of first setting out absolute minimal functional requirements to achieve, designing a solution, and then iteratively improving its value for stakeholders by carefully considering their feedback on prototypes. The team found the ‘three defining criteria’ of FI [76] helped them select concepts, and felt there is certainly scope to formalise this into a concept-selection tool for FI, similar to Quality Function Deployment or a Pugh Matrix [160].

The team learnt that FI requires in-depth knowledge of the context, and in particular how it affects the value of different device functions for end-users. Information to make design decisions can be sparse and the surgical context designed for can vary considerably in LMICs. Without specific information about these varying factors it is impossible to optimise design performance and value for users. Therefore, the knowledge of local stakeholders is also essential to reveal opportunities for FI. Our experience also revealed that they had valuable

frugal ideas, which their involvement in the project helped them to recognise the quality of. They began to utilise these to innovate their own frugal surgical devices.

6.6 Responsible Innovation

While cost reduction is a component of FI, the team found that in this context it cannot be the primary focus of the project. Chapter 5 revealed the importance of a shared objective in designing a device which improves global access to surgery, especially in terms of overcoming barriers to collaboration between professionals from different fields. Addressing the needs of patients and end-users must be paramount and the innovation process must not negatively impact the quality of the care provided. While some may consider this a luxury of research, FIs do not need to compromise on quality to be profitable [79]. Both corporations and universities with funded research initiatives have a part to play in global surgical innovation [51]. Of course, funded projects are well-positioned to make frugal surgical technologies more attractive for future commercial translation by assuming a portion of the risks in early stage technology development [117]. With this in mind, perhaps they may also give consideration to ensuring that stakeholders local to LMICs gain from being involved in design. Developing local innovation capacities in LMICs and linking up manufacturers, universities, innovators, end-users and policy-makers may ultimately be the most efficient way to address inequities in access to surgery across the world [88].

6.7 The Value of Using a Roadmap

Chapters 3 and 4 reported how the "Design for Safe Surgery Roadmap" [31] was adapted and implemented to design the RAIS device. A key strength of the roadmap was its specific recommendations for designing in this context. A prime example is the encouragement to co-create with local stakeholders in Phase 3. Chapter 4 revealed that the structured input of local stakeholders throughout our iterative design process had been instrumental in identifying and resolving major design flaws, ultimately producing an appropriate design for a low-resource context. This enabled the team to undertake a full design process and achieve a system ready for clinical evaluation and future surgical use. While the potential pitfalls were many, the participation and engagement of the multidisciplinary team were at the heart of this success.

While the roadmap did not address the challenges of selecting appropriate methods with which to complete each stage of the design process, perhaps the high-level nature of the

roadmap was appropriate, considering how varied contexts which global surgical devices target are, and how flexible the approach must be to succeed in each [31]. However, a fundamental impetus for using detailed medical device development models that do recommend specific methods (e.g. DFSS [118]) is to manage risk and ensure the safety of the devices produced [64,161], which is not directly addressed by the roadmap. For example, there is no mention of aspects such as quality management systems, which are feasible to implement, even for small and mid-sized enterprises and universities, especially if stakeholder resources are pooled [119,161]. A selection of carefully developed and evaluated design tools could help designers manage aspects such as risk or failure modes and aid them in producing frugal, participatory designs.

Finally, while the roadmap [31] provides structure for the initial phases of design, models such as the DFSS [118] extend beyond this point of development to consider aspects including design for manufacture, regulatory approval, training, maintenance, packaging and disposal. Furthermore, there is growing recognition that designers (specifically in the medical device industry) should move toward circular life-cycle models, which require detailed consideration of resource consumption, re-use and disposal within the design process [162]. These considerations are important in design for LMICs and for HICs, and may ultimately help generate even more appropriate solutions for LRHCs in LMICs. Equally, this may differ according to the context, so further guidance for global surgical device designers in later design phases should be investigated. Some of this work is underway [39].

6.8 Recommendations

Therefore, from this work, the authors propose 11 recommendations for innovators to enhance the roadmap [31] and integrate FI and PD in the context of innovating surgical devices for LRHCs:

Participatory Design and Stakeholder Engagement: Early, Often, Sustained

1. *Prioritize input from a variety of stakeholders based in LMICs in the initial design phases.*
2. *Collaborate with local stakeholders throughout the design process, including later phases such as design to manufacture, as equal stakeholders to innovate disruptive frugal designs and create more impact on global access to surgery by supporting development of innovation networks and capacities within LMICs.*
3. *Work with local manufacturers where possible, especially those with experience of LRHCs.*

Communication

4. *Use interactive, in-person methods in early design stages to learn about the context and form collaborative relationships with end-users.*
5. *Validation should include practical activities with stakeholders based in LRHCs, in contexts which emulate the surgical LRHC.*

Design Tools

6. *Semi-structured feedback methods are invaluable for capturing and analysing the contextual knowledge of stakeholders and their feedback in later verification and validation activities.*
7. *Adopt system-based techniques (e.g. P-diagrams) to capture unfamiliar and complex contexts and requirements.*
8. *Adopt conventional design process models to structure and control risk within the technical development process, ensuring stakeholders based in LMICs verify designs.*

Frugal Innovation in a Complex Environment

9. *Generate well-researched requirements to inform frugal idea generation, and re-evaluate these regularly as the project progresses and understanding of the context improves. Avoid over-constraining the design space with excessive or redundant requirements.*

Responsible Innovation

10. *In this context improving access to quality surgical care must be a priority over cost reduction.*

The Value of Using a Roadmap

11. *The Design for Safe Surgery Roadmap provides a valuable high-level tool for structuring initial design phases.*

6.9 Conclusions

This work produced desirable outcomes. The approach undertaken resulted in development of new surgical technology which is ready to undergo clinical trials and regulatory approval, and has drawn attention from further stakeholders in LMICs and HICs alike who are motivated and well-positioned to disseminate it and the gasless surgical technique further. The device and multidisciplinary approach to designing it has captured attention [163] and such outputs have drawn further attention to the need for development of technologies for global surgery, which is becoming ever more pressing due to the increasing health burden created by non-communicable diseases [3].

Of course, there are limitations to this research. While the future of the RAIS device seems promising, there are hurdles to overcome before it and the gasless laparoscopic technique are implemented at scale. Reflections on its progression in the long term may provide even

further food for thought in relation to the recommendations presented in this thesis. There is certainly more to learn about how these approaches affect the device and stakeholders involved in the long-term.

A strength of this research was the exploratory study into *Impacts* on participating stakeholders, discussed in Chapter 6. The semi-structured interviews elicited new findings, previously wholly undetected by the research team, which can be used to reflect upon and improve our approach to future projects. Evidence of such impacts is scarce in the literature and could also be valuable in providing additional impetus for others to use PD for designing surgical technologies for LRHCs. However, it was felt this study could have been improved. Pilot interviews with other, non-clinical stakeholders in the design team indicated that they also gained as much, if not more than the clinical stakeholders from being involved. Their inclusion in the study may have helped perform a more complete assessment of the value of opportunities for bi-directional learning created by working within global, multidisciplinary networks of innovators.

This frames another limitation of this work. Designing surgical devices is typically a time-consuming and complex process involving many stakeholders. Evaluating the entire development of a device requires a detailed analysis of a great deal of work complete by a large team. This is likely to be a major barrier for others attempting to carry out research similar to that described in this thesis, and especially for anyone attempting to compare multiple projects, which is needed to provide enough evidence to confirm or deny many hypotheses. While the objectives of this work were achieved and it provides a detailed case-study for others to consider, it is of limited used if it cannot be compared and contrasted with others. While an overview of an entire design process provides useful detail, this work could have benefitted from a more detailed look into some individual aspects of the design process. Further development of these approaches will require input from many stakeholders across the global health and design communities.

6.10 Further Work

To build on and help others implement the recommendations in section 6.8, further research is required. Firstly, there is scope to improve design processes for global surgical devices, such as the roadmap employed in this work. Future studies could use risk analysis methods such as the 'Process Failure Mode and Effect Analysis' tool [164] to understand and reduce risks in the process of designing technologies within this particular design context. With further

evaluation of the risks and opportunities specific to this design context, design processes such as the 'Design for Safe Surgery Roadmap' could be optimised for generating high-quality, disruptive technologies [63].

Secondly, the team found that FI in this context requires great skill in navigating complex and generally poorly-understood healthcare environments, and dedication to iteratively optimising the value of an innovation in that context. A perfect balance of quality, performance, functionality and cost must be struck. To aid innovators in achieving this, further work should investigate and adapt design methods to help generate FIs, helping designers to make the right design decisions to create disruptive technologies. For example, Quality Function Deployment and Pugh matrices could be used to prioritise functionalities and select the right concepts [30,160].

Finally, there is little existing advice on how to implement a PD approach in this context. Future work should aim to provide more evidence of the benefits of using a co-creative approach [109] and what methods are effective in generating outcomes which can foster the development of local innovation capacity in LMICs [165]. To generate this evidence, innovators should use PD evaluation frameworks such as the Part-E framework [104], or other established PD evaluation tools [98,103], to plan to target objectives in more than just the 'Material Things' attribute, implement appropriate attributes within each dimension to help achieve those objectives, and perform systematic evaluations of the PD outcomes. Using these innovative frameworks to holistically evaluate PD throughout the design process, innovators can demonstrate the benefits of this approach over others [92,98]. This will help to increase knowledge of the opportunities and challenges and how to maximise outcomes for the benefit of increasing global access to surgery. Ultimately, well-thought out and implemented PD projects could be used to pull together all the components of the machinery needed to create a production line of frugal surgical innovations, such as the RAIS device, in LMICs, and hence improve the quality of and access to surgical care globally.

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Appendix A

Instruction Sheet, NASA TLX and Questionnaire for Validation Study

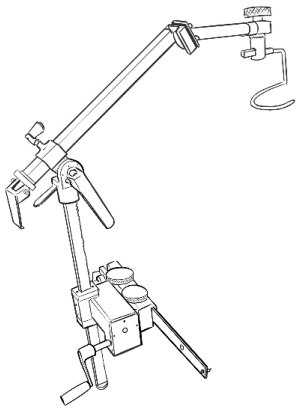
Project RAIS

Background

The Gas Insufflation-Less Laparoscopic Surgery (GILLS) technique enables surgeons in rural areas of India to perform minimally invasive surgery. It can be performed without general anesthetic as well as the carbon dioxide gas and expensive surgical instruments required for minimally invasive surgery using gas insufflation, which often rural hospitals cannot access. The current abdominal wall-lifting device (right) has shown the GILLS procedure to be safe and effective and is used by rural surgeons in Northeast India.

The NIHR Global Health Research Group - Surgical Technologies (GHRG-ST), based at the University of Leeds, has collaborated with partners in India and the UK to develop a new device. Our aim is to improve the device so that is better-suited to a rural facility (e.g transportable, sterilisable in a flash autoclave, easy to repair) and is easier for the surgeon to use. The GHRG-ST is also investigating the best ways in which High-Income Countries and Low and Middle-Income Countries can work together to design medical devices that work for low-resource environments.

Our new device and its method of use will be presented to you in a video. We would like to gather information on how easy it is to set up and use for a surgical procedure. We will do this by filming you setting up and using the device on a cadaveric abdominal wall, and asking you some questions. This is not a test and you may ask for help at any time.



Current STAAN abdominal wall-lifting device

New RAIS abdominal wall-lifting device

Instructions

If you wish to take part in the study, you must sign a consent form with an Investigator first. The Investigator will ask for a few details from you, and give you a randomized number to protect your data. Please write your number on the next sheet of paper in the box provided.

Video Demonstration

1. Head over to the 'RAIS' station.
2. Please watch the video introduction showing how to assemble and use the device carefully

Device Assembly

1. First watch the demonstrator assemble the device. Then assemble it yourself, remembering that:

    a) You are the operating surgeon.
    b) The piece that clamps to the surgical table is non-sterile, but imagine the rest of the device has been sterilized in a flash autoclave.
    c) You do not need to assemble the ring piece and the clamp piece yet (which attach the device to the cadaver and the surgical table)

2. Carry the assembled device over to the cadaver and attach it to the table.
3. Complete the appropriate NASA Task Load Index overleaf

Cadaveric abdominal wall lift

1. Check that an investigator is with you to help and guide you. You may ask the investigator to help you perform tasks as you would a surgical assistant or nurse.
2. Position the device a suitable height above the incision at the Umbilicus of the cadaver.
3. Insert the ring piece into the incision.
4. Attach the ring piece to the rest of the device and tighten in position.
5. Perform the lift of the abdominal wall.
6. Insert the scope to show you the operative field of view that you are achieving inside the patient on the screen.
7. Remove the scope, reduce the lift slightly and then move the ring inside the patient to adjust the view of the operative field. Increase the lift slightly again and insert the scope to look around.
8. Lower the lift and remove the ring from the patient.
9. Complete the appropriate NASA Task Load Index overleaf

Rural Facility Questionnaire

Finally, answer the questions on the last page of the booklet about your experience in rural facilities in India and abroad. A member of the research team will assist with answering your questions and may ask supplementary questions to gain further detail during the process.

Any questions, just ask!

Trial Participant Number:

DEVICE ASSEMBLY

Figure 8.6

NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

Name	Task	Date

Mental Demand — How mentally demanding was the task?

Very Low — Very High

Physical Demand — How physically demanding was the task?

Very Low — Very High

Temporal Demand — How hurried or rushed was the pace of the task?

Very Low — Very High

Performance — How successful were you in accomplishing what you were asked to do?

Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed wereyou?

Very Low — Very High

CADAVERIC LIFT PROCEDURE

Figure 8.6

NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

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Performance — How successful were you in accomplishing what you were asked to do?

Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed wereyou?

Very Low — Very High

Please mark your level of agreement using a 'circle' with the following statements using your experience and knowledge of a rural/low-resource hospital setting.

1. I have experience working in a rural or low-resource hospital						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
2. A rural or low-resource hospital could attach this device to the operating room table						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
3. A rural or low-resource hospital could set up and use this device with the normal number of surgical assistants/nurses available						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
4. This device could be cleaned and sterilised at a rural or low-resource hospital						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
5. A rural or low-resource hospital could maintain this device						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
6. A rural or low-resource hospital could repair this device						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
7. This device could be transported between rural hospitals						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
8. A surgeon in a rural or low-resource hospital could learn how to use this device						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree
9. Overall, this device is suited to use in a rural or low-resource hospital						
Strongly Disagree	Disagree	More or Less Disagree	Undecided	More or Less Agree	Agree	Strongly Agree

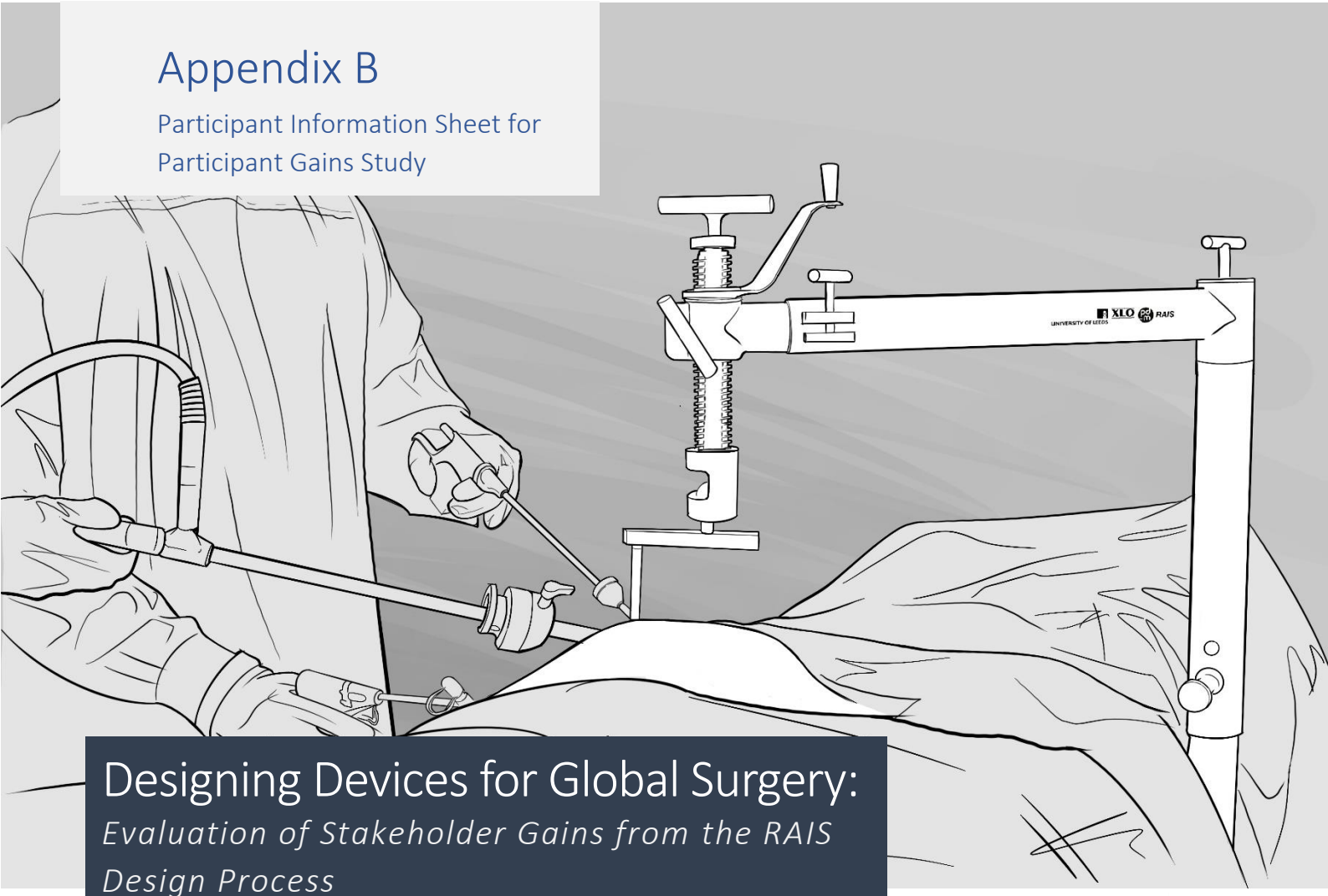
Please use the scale from 1-7 to mark which of the two different abdominal wall-lift devices for GILLS performs better in each of the following areas using your experience and knowledge.

10. Which system is easier to assemble?						
STAAN Device			Undecided			RAIS Device
1	2	3	4	5	6	7
11. Which device is easier to perform the abdominal wall lift with?						
STAAN Device			Undecided			RAIS Device
1	2	3	4	5	6	7
12. Which device is easier to clean and sterilise?						
STAAN Device			Undecided			RAIS Device
1	2	3	4	5	6	7
13. Which system would you find easier to transport and move around?						
STAAN Device			Undecided			RAIS Device
1	2	3	4	5	6	7
14. Which device would you prefer to use in rural surgery?						
STAAN Device			Undecided			RAIS Device
1	2	3	4	5	6	7

Please tell us about any other barriers you think may prevent this device being used in a rural hospital.
Please use the space below to provide any additional comments, ideas or relevant information you would like to tell us.

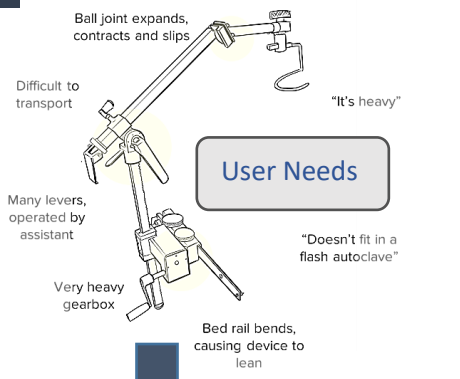
Appendix B

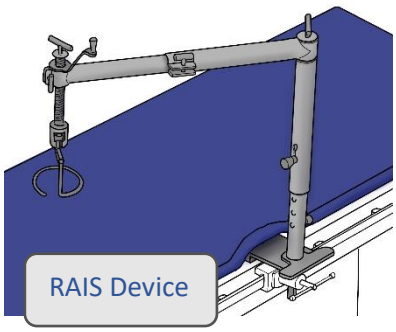
Participant Information Sheet for Participant Gains Study



Designing Devices for Global Surgery:

Evaluation of Stakeholder Gains from the RAIS Design Process





You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Study Introduction

Project RAIS is summarized on Page 4. Through the design of the RAIS device, different stakeholders, such as yourself, have been involved in designing the device. A timeline of stakeholder involvement in the design process can be found in the supplementary document: recruitment poster.

- The ***top half*** of each page of the Design Timeline shows who was involved, when they were involved, and what activities they were involved in.
- The ***bottom half*** of each page of the Design Timeline shows how the design changed after the stakeholders were involved.

This study focuses on the design process and stakeholders involved in the development of RAIS, not the RAIS device itself.

Study Information

Study Purpose

We are beginning to evaluate the outcomes of the design project. As well as assessing the RAIS device itself, we would like hear about the experience of stakeholders involved in the design process, and in particular anything stakeholders may have gained from being involved in designing the RAIS device. This will help us understand how involving multidisciplinary stakeholders in designing devices for global surgery affects the stakeholders themselves, and their thoughts and feelings about being involved.

Why have I been chosen?

You are being asked to participate in this study because you were involved in the design of the RAIS device, in one or more of the stages in the Design Timeline (p. 5-7).

We are interested in anything you might have to say about *your feelings about being involved in the design process, whether you personally gained anything from participating and why / why not.*

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form). You can still withdraw from the study at any time before the interview without it affecting any benefits that you are entitled to in any way. You do not have to give a reason.

What will happen if I take part?

If you would like to participate in this study, you will be asked to complete one short interview. This will be conducted via Zoom or Microsoft Teams. To complete the interview, you must have:

- ✓ A device with a microphone (e.g. laptop, tablet, smartphone)
- ✓ Internet connection

The interviews will take place in March 2021, but the time and date can be arranged according to your schedule.

Interview Process

1. If you decide to participate, first you will be asked to sign a consent form (see **page 5**). Please read this before the interview, and if you have any questions please contact the investigator (see **contact details below**).
2. The investigator will contact you to arrange a suitable day and time for the interview.
3. Before the interview, you will be sent a secure Zoom or Microsoft Teams meeting link.
4. When the meeting starts, the interviewer will check audio quality and ask your consent to record the session.
5. The interviewer will ask you a number of questions about *your experience of the RAIS design process, and any effect it has had on you*. You can expect the interview to last about 20-30 minutes, but there is no time limit.
6. When you are ready, the interviewer will conclude the interview.
7. An anonymous transcript of the interview will be reviewed by the principle investigator and one other investigator to discover themes about stakeholder experiences participating in this project.
8. Some of your words may be directly quoted in published works, namely the principal investigators thesis. You can still withdraw your responses from the data collected at any time up until the thesis is submitted (30th June).

If you have any questions about participating or would like any further information, please contact one of the investigators using the following details:

Primary contact email: M.MarriottWebb@leeds.ac.uk
Secondary contact email: P.R.Culmer@leeds.ac.uk

Study Information

What are the possible benefits of taking part?

There are no immediate benefits to people participating in the project. It is hoped that this study will be used to refine and improve future design processes for designing and implementing surgical devices suitable for low-resource settings, and hence accelerate the development and uptake of innovative surgical devices in low-resource settings.

What are the possible disadvantages and risks of taking part?

There are no reasonably foreseeable disadvantages to taking part. You will be asked a number of questions about your personal experience relating to participating in the design of the RAIS device. Your responses will not affect your current involvement in the RAIS project or any other project associated with the GHRG-ST. You may withdraw from the study at any time up until you have participated in an interview, and following that you may withdraw your data from the study up until the 30th June if you wish to.

Use and dissemination of research data

The research data will be analyzed at the University of Leeds following the study. The results may be published in peer-reviewed journals and international conferences, and will form a chapter of the principal investigator's thesis focused on the design of surgical devices for low-resource settings using participatory methods. We will take steps wherever possible to anonymize the research data so that you will not be identified in any reports or publications. Any personal data, such as contact information, that we collect about you during the course of the research will be kept strictly confidential and will be stored separately from the research data.

What will happen to my personal information?

All personal data will be regarded as confidential and will be handled accordingly. Participants will receive a 2 digit identification number in order of their enrolment, and this number will be linked to any personal details collected on a password-protected computer at the University of Leeds. This data will only be accessed by approved research staff working on the study. All hard copies of study documents and written consent forms will be kept in a locked cabinet in a locked office.

Will I be recorded, and how will the recorded media be used?

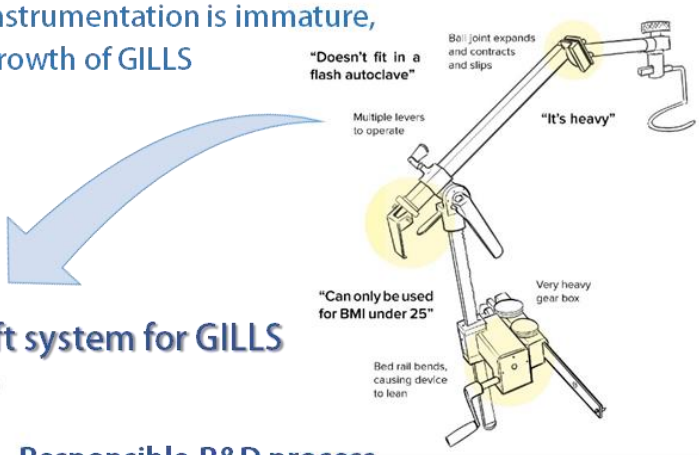
Research data collected as audio or video files for future evaluation will also be stored on a secure, encrypted computer at the University of Leeds, and will only be correlated to the participant identification number. The recorded audio files from the interviews will be transcribed by the investigator for use in thematic analysis. Your anonymized responses may be quoted for research purposes in future publications. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

Thank you for reading!

Project Lead: Dr Peter Culmer (p.r.culmer@leeds.ac.uk)

A clinical need to improve global access to surgery:

- Gas Insufflation-Less Laparoscopic Surgery (GILLS) enables laparoscopic surgery in low-resource settings
- Existing instrumentation is immature, limiting growth of GILLS



RAIS is a next-generation surgical-lift system for GILLS

Responsible R&D process

- Designed to address stakeholder needs in LMICs
- Developed with a multi-disciplinary team: UK & India; Academia, Clinical & Industry
- Evaluated in cadaveric studies with rural surgeons
- Engineered for standards compliance

The RAIS system delivers:

- Designed for LMICs and low-resource settings
- Faster and more intuitive set up
- Easily disassembled for (flash) autoclave
- Low weight and rugged for transportation
- Improved surgical usability
- Surgeon-controlled lift (no need for scrub nurse)
- Cost effective manufacture and repair

Current status:

- Pre-clinical prototype complete
- Currently undergoing cadaveric trials
- Design-to-manufacture complete
- Technical and design files maintained

School of Mechanical Engineering

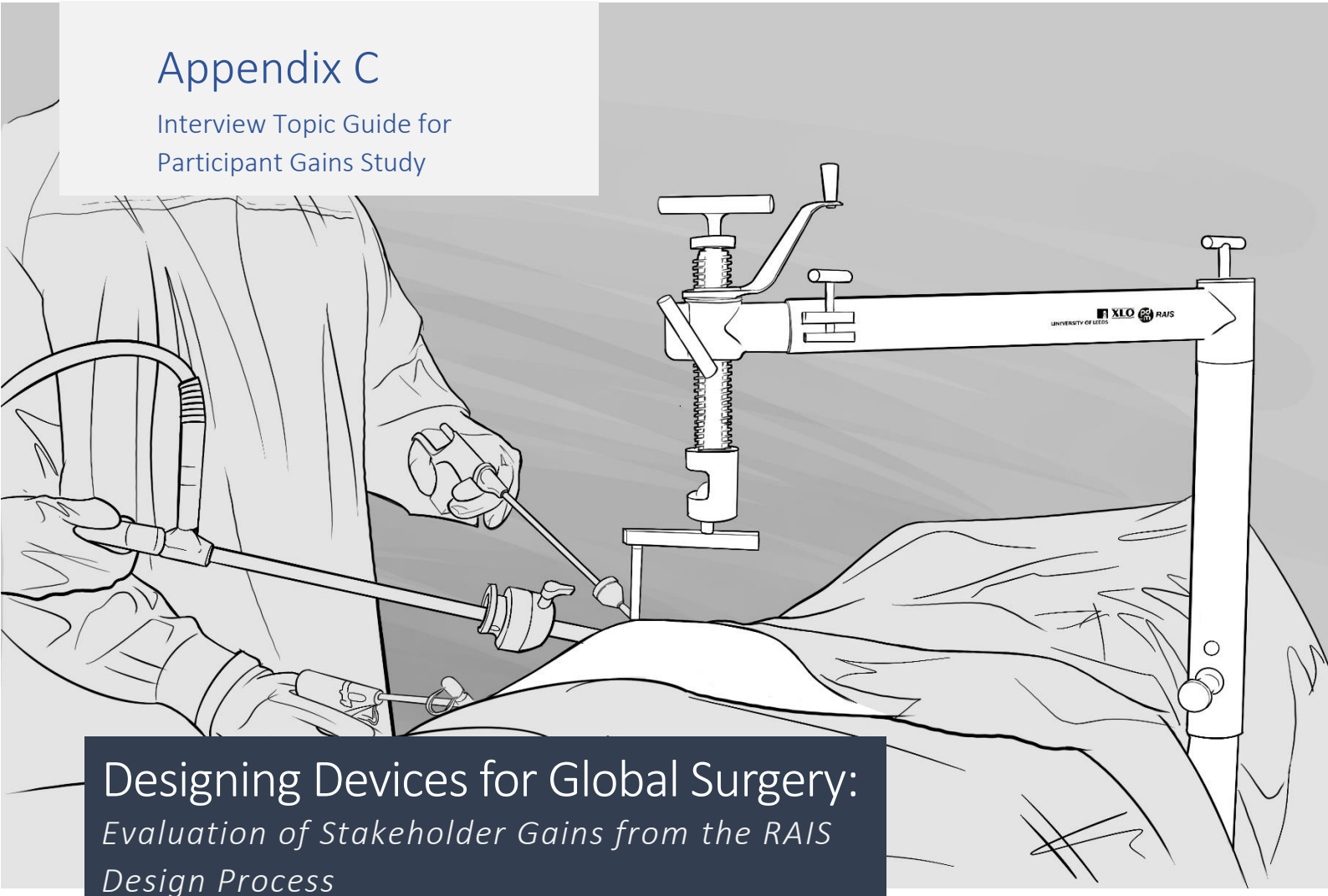
UNIVERSITY OF LEEDS

Consent to take part in: Designing Devices for Global Surgery: *Evaluation of Stakeholder Gains from the RAIS Design Process*	Add your initials next to the statement if you agree
I confirm that I have read and understand the information sheet dated 22.02.21 explaining the above research project and I have had the opportunity to ask questions about the project.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. Please contact Millie Marriott Webb if you would like to withdraw your data from the study at any time before the 30th June. Email: M.MarriottWebb@leeds.ac.uk Phone: +44 (113) 34 32141 If you choose to withdraw from the study, your responses and personal information will be permanently deleted and omitted from any current publications. It will not be included in any future publications or research.	
I understand that members of the research team may have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.	
I understand that the data collected from me may be stored and used in relevant future research in an anonymised form.	
I agree to take part in the above research project and will inform the lead researcher should my contact details change.	

Name of participant	
Participant's signature	
Date	
Name of lead researcher	
Signature	
Date	

Appendix C

Interview Topic Guide for Participant Gains Study



Designing Devices for Global Surgery:

Evaluation of Stakeholder Gains from the RAIS Design Process

Questions will be adapted based on interview progression and emerging themes.

Stage	Topic
Study Explanation	Participant should have already returned signed consent form, but ask if they have any further questions. Do you give your consent for me to record this interview? Explain reasons for conducting the study to set the discussion focus. Explain interview format. For example: 1) This is a very early-stage, exploratory study, in which I want to have an open discussion about whether you think there have been any advantages or disadvantages for yourself from being involved in designing the RAIS device and talk about the reasons for that. 2) I'd like to stress that your responses will be anonymised and I will not discuss them with anyone, so please say your true thoughts. 3) I've prepared seven topics and some questions to help stimulate our discussion. 4) You also don't need to answer any questions that you don't want to – just tell me to move on. You can take your time to understand the questions and form your answers. 5) Some of what we will talk about happened some time ago, so I have made a timeline to help stimulate your memories about your involvement in the project, which I can share on the screen if helpful for you. 6) Feel free to ask me any questions as we go along too, especially if anything is unclear. 7) Do you have any initial questions for me?

Stage	Topic	Example Questions
Warm up	Current role and previous participatory experience	Could you briefly describe to me what your job typically involves you doing? Have you ever been involved in designing something as a part of a group before this project? In particular, designing something that affects you – like a new healthcare technology, or a new space for your community, or even a new system of working e.g. an operating theatre process. What was your role in it?
Detailed Exploration	Motivations for participating	Why did you first become involved in designing the RAIS device? Do you remember how you felt about being involved in designing the RAIS device then? Was there anything in particular that made you want to be involved in designing the RAIS device? Is there anything that you think made you a good person to be involved in designing the RAIS device, perhaps over someone else? Was there anything that made you not want to be a part of designing the RAIS device, or anything stopping you from being involved?
	Feelings about personal contribution to and influence on the project	What do you feel you contributed to the project? How important do you think your contributions were? Do you think you could have contributed more? How? Why didn't you? Do you feel like any of your contributions weren't recognised?
	New knowledge and skills acquired	Have you acquired new skills or knowledge as a result of your involvement in designing the RAIS device? What are they? What was the most important thing you've learnt or discovered? What else did you learn? Have you applied any of the skills or knowledge you have gained so far? Have you passed on that skill or knowledge to any others?
	New possibilities emerged	Has being involved in designing the RAIS device opened up any new possibilities for you?
	New outlook on healthcare technology or own practice	Has participating in the project changed the way you view healthcare technologies at all? Has that had any impact how you work at all, or how you view your role? Has that made any change for your organisation / practice? What about for others around you?

	Personal gains from participating in the project	At this stage, is there anything else you thing you have gained from beings involved in designing the RAIS device? Could you have gained more? Is there anything that prevented you gaining personally from the project?
Summarise and reflect	Overall assessment of participation in the project	What is your overall assessment of your experience participating in this project? What is the most important outcome of the project for you? How will that affect you? What was the least important outcome of the project to you? If the device doesn't reach a stage where it can be distributed and sold to low-resource hospitals, will the project have had any impact? Could this have been different? How? Is there anything I haven't asked you that you'd like to say?