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Designing devices for global surgery: evaluation of participatory and frugal design methods

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Introduction: Most people living in low- and middle-income countries have no access to surgical care. Equipping under-resourced health care contexts with appropriate surgical equipment is thus critical. "Global" technologies must be designed specifically for these contexts. But while models, approaches and methods have been developed for the design of equipment for global surgery, few studies describe their implementation or evaluate their adequacy for this purpose.

Methods: A multidisciplinary team applied participatory and frugal design methods to design a surgical device for gasless laparoscopy. The team employed a formal roadmap, devised to guide the development of global surgical equipment, to structure the design process into phases. Phases 0–1 comprised primary research with surgeons working in low-resource settings and forming collaborative partnerships with key stakeholders. These participated in phases 2–3 through design workshops and video events. To conclude, surgical stakeholders (n = 13) evaluated a high-fidelity prototype in a cadaveric study.

Results: The resulting design, "RAIS" (*R*etractor for *A*bdominal *I*nsufflation-less *S*urgery), received positive feedback from rural surgeons keen to embrace and champion innovation as a result of the close collaboration and participatory design methods employed. The roadmap provided a valuable means to structure the design process but this evaluation highlighted the need for further development to detail specific methodology. The project outcomes were used to develop recommendations for innovators designing global surgical equipment. To inform early phases in the design roadmap, engaging a variety of stakeholders to provide regular input is crucial. Effective communication is vital to elucidate clear functional design requirements and hence reveal opportunities for frugal innovation. Finally, responsible innovation must be embedded within the process of designing devices for global surgery.

Conclusion: A community-wide effort is required to formally evaluate and optimize processes for designing global surgical devices and hence accelerate adoption of frugal surgical technologies in low-resource settings.

Keywords: Frugal design, Gasless laparoscopy, Global surgery, Low- and middle-income countries, Participatory design, Surgical technology

To improve global access to medical technologies, the World Health Organization suggest development of medical devices should focus on *Affordability*, *Availability*, *Accessibility*, and *Appropriateness (known as the "4 As")*[1]. As four fifths of all medical device sales revenue is generated in the Americas and Europe, most systems are designed for high-resource settings and do not align with the "4 As" in the context of a low-resource setting[1]. Consequently effective provision of surgical equipment for low- and middle-income countries (LMICs), where an estimated 40% of health care equipment is out of service[2], is not a simple case of redeploying existing technology. Instead, there is increasing recognition that new technologies must be designed specifically to provide robust "4A" solutions for low-resource contexts[1,3,4].

In contrast with conventional medical device design[5], approaches to innovate in "global surgery" are immature. Participatory and frugal design methods have been recognized as 2 key approaches, particularly to ensure local clinical needs and contextual challenges are embedded in the design process[6–9]. Participatory design mandates the involvement of end-users and other stakeholders in design activities (eg, defining requirements) and as an ideal extends to their having an equitable role as innovators throughout the design process[10]. Frugal design aims to maximize value to users by achieving similar or better performance to existing solutions using less resource (eg, mosquito netting as a mesh for hernia repair offers similar clinical outcomes at a fraction of the cost[11]). Frugal medical innovations have been disruptive in both high income country and LMIC markets and the approach has been celebrated as having significant potential to improve global health care[7,12].

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Written consent was obtained from the subject of all photographs used in diagrams.

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To implement approaches like participatory and frugal design effectively requires a structured approach, typically using a high-level "design process model." Unfortunately only one example specifically addresses the challenges of design for global surgical devices, the 4-phase "Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide" (Design for Safe Surgery Roadmap) reported by Oosting et al[13]. To date, the roadmap has only been implemented by its creators, but shows promise[14]. To build on these foundations and address the current paucity of information on global surgical design requires a community-wide effort. Implementing, evidencing and assessing these processes can provide tangible evidence to guide future practice. Accordingly, this paper evaluates the use of participatory design and frugal engineering approaches, structured using the Design for Safe Surgery Roadmap[13], to design a surgical device appropriate for use in low-resource settings[1].

Methods

The Design for Safe Surgery Roadmap[13] describes 4 interlinked phases. Phase 0 focuses on identifying and describing the unmet health care need, followed by phase 1 which defines the local surgical context, exploring factors such as health care system structure. These then inform phase 2, determining the design requirements and a long-term strategy for bringing the device to market (and/or clinical use). Finally, phase 3 is to "Act," engaging in cocreation with LMIC stakeholders to iteratively develop a design and prototypes.

This study, in which surgeons and engineers from the National Institute for Health Research Global Health Research Group in Surgical Technologies (NIHR GHRG-ST) worked together with Indian surgeons (based rurally and in research facilities) and a product design company in the United Kingdom, spanned the entire process described by the Design for Safe Surgery Roadmap[13], from need identification through design and evaluation. Here we describe our approach to implementing methods across the phases of the roadmap.

Phase 0: need identification

The need identification process was undertaken through primary research, focusing on interviews with rural surgeons in Northeast India (the end-users) underpinned by a literature review.

A primary clinical need was identified: to improve the provision of laparoscopic surgery in rural or low-resource areas through the redesign of a surgical lift system currently being used to perform gasless laparoscopy[7,15–19]. Gasless laparoscopy is a frugal technique but to become widely adopted it must provide a comparable alternative to conventional laparoscopy. Key to this objective is optimizing the abdominal wall lift-devices[20] (**Fig. 1**).

Phase 1: understanding the context

The majority of activities within this phase were conducted in India, to obtain maximum input from LMIC stakeholders, in accordance with the principles of participatory design. The design team attended a training program for rural surgeons in gasless laparoscopy[21] to discuss, understand and define the clinical context. The research process was predominately qualitative, involving semistructured interviews, observations of surgical practice using existing abdominal wall lift devices and group

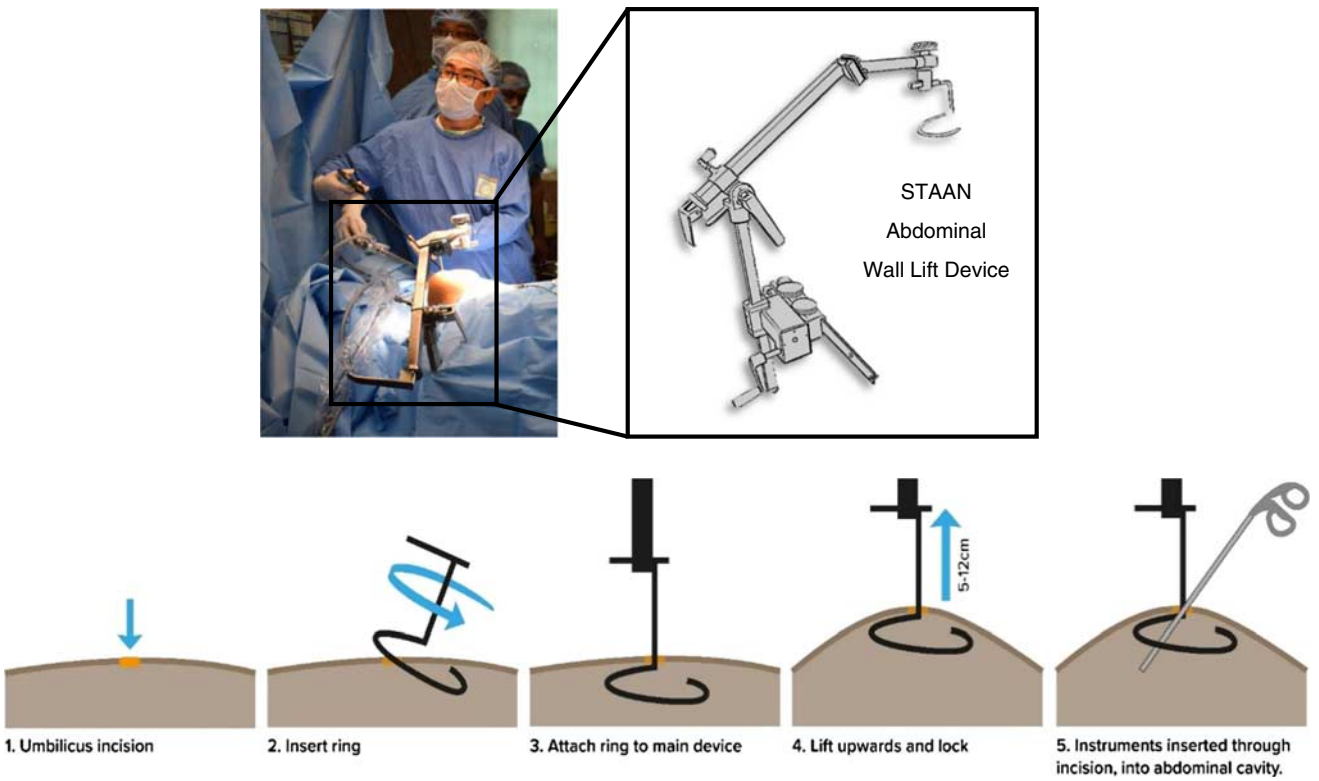


Figure 1. Gasless laparoscopic procedure and the STAAN Abdominal Wall Lift Device[20].

discussions with rural surgeons and associated support teams to understand the limitations of those devices and potential barriers to them using gasless techniques in the future. Through these interactions, 3 key stakeholders were invited to join the design team as representatives of the wider rural surgical community.

Phase 2: determining design requirements

The Design for Safe Surgery Roadmap[13] does not specify specific methods to determine design requirements but instead provides examples of strategies that are relevant to global surgery. Accordingly, methods for developing design requirements were

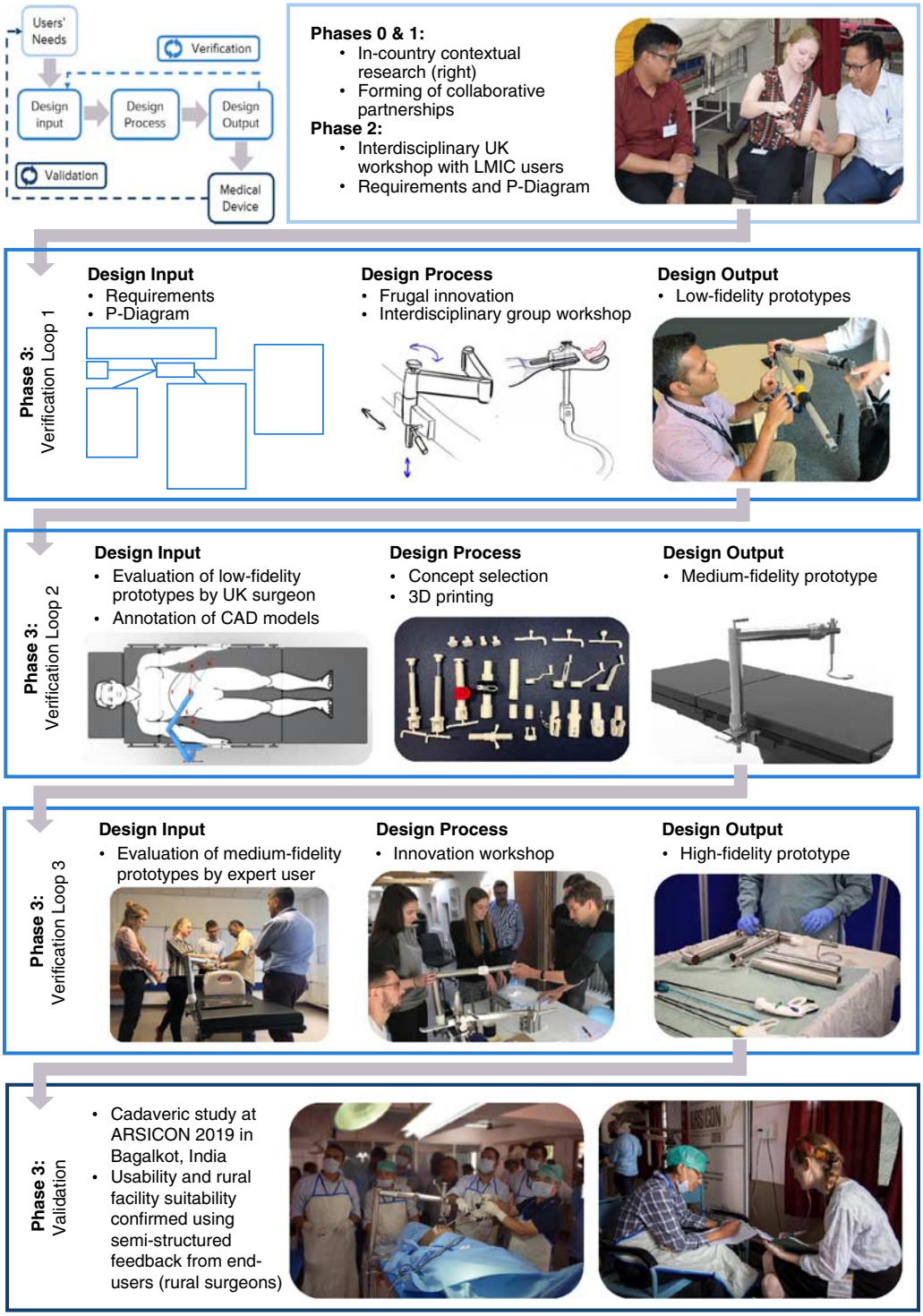


Figure 2. Implementation of the Design for Safe Surgery Roadmap[13] in the case study, with phase 3 structured using the waterfall model[23].

selected by the authors to align with the overarching principles of participatory and frugal design.

A workshop was convened with the key LMIC stakeholders and the NIHR GHRG-ST team as a means to collaboratively translate information gathered in phases 0 and 1 into a series of formalized requirements. The participants were asked to form a consensus and determine the minimum and ideal level of device functionality necessary for safe and effective surgery in a low-resource setting. Requirements were categorized as either "necessary" (key to device function) or desired (supplementary to the core function) to enable design prioritization which focuses on essential functionalities in accordance with the principles of frugal design.

The categorized requirements and the contextual information from phase 1 were then used to create a Parameter Diagram (P-diagram). P-diagrams are a tool used in "Six-Sigma" design to capture and define the key details of a system (eg, inputs, desired functions, "Error States" and variations in the environment/context)[22]. In this context it provides a means to concisely but robustly capture and communicate this key data with the wider team.

Phase 3: act

In the final phase of the roadmap[13], the focus shifts onto designing, prototyping and testing a solution to the surgical need, based on the now-established requirements and details of the local context. Aside from advising designers to engage in participatory design and cocreation, the roadmap provides little advice for conducting this phase. Therefore, the waterfall model was implemented as a process endorsed by the United States Food and Drug Administration for medical device development[23]. The model, shown in **Figure 2**, consists of an iterative technical development process that embeds regular design verification and validation[24].

To encourage a controlled design process that embeds participatory design, the waterfall model was initiated with ideas developed during the phase 2 workshop and a verification plan was developed in which LMIC stakeholders provided feedback in a regular, structured format. This encompassed the use of teleconferencing and in-person meetings to contribute ideas, review design decisions, and evaluate designs and prototypes.

A milestone was defined to evaluate a feature-complete design of the device. This was implemented as a surgical workshop with a cohort of rural surgeons using a high-fidelity device prototype on human cadavers. A wide cohort of participants was involved by aligning the workshop with a large rural surgery conference[25]. Participants were either currently practicing rural surgery in LMICs, or in related training. Participants were asked to perform 2 tasks: assembling the device from its component parts and performing a simulated diagnostic laparoscopy on a cadaver model, using the prototype. The design team moderated a discussion with the participants as they performed the surgical tasks to elicit critical feedback on the operative process. This was followed by a semistructured debrief interview after each participant had completed their session.

Results

In this section the case study outcomes are considered to evaluate the insights and challenges discovered during each stage of implementing the Design for Safe Surgery Roadmap[13]. **Figure 2** provides a visual description of the design phases as they were conducted during the case study.

Phase 0 and phase 1: need identification and contextual research

The roadmap[13] provided sufficient guidance to structure work in these initial phases, with instruction to focus on key topics including barriers to surgical care, aspects of safe surgery and the health care system structure[26]. The primary research informed the designers on the rural, low-resource surgical environment and the process of gasless laparoscopy. It revealed opportunities to improve on their current abdominal wall-lifting device; for example, highlighting challenges in setup, transport, sterilization, and maintenance.

Phase 2: determining design requirements

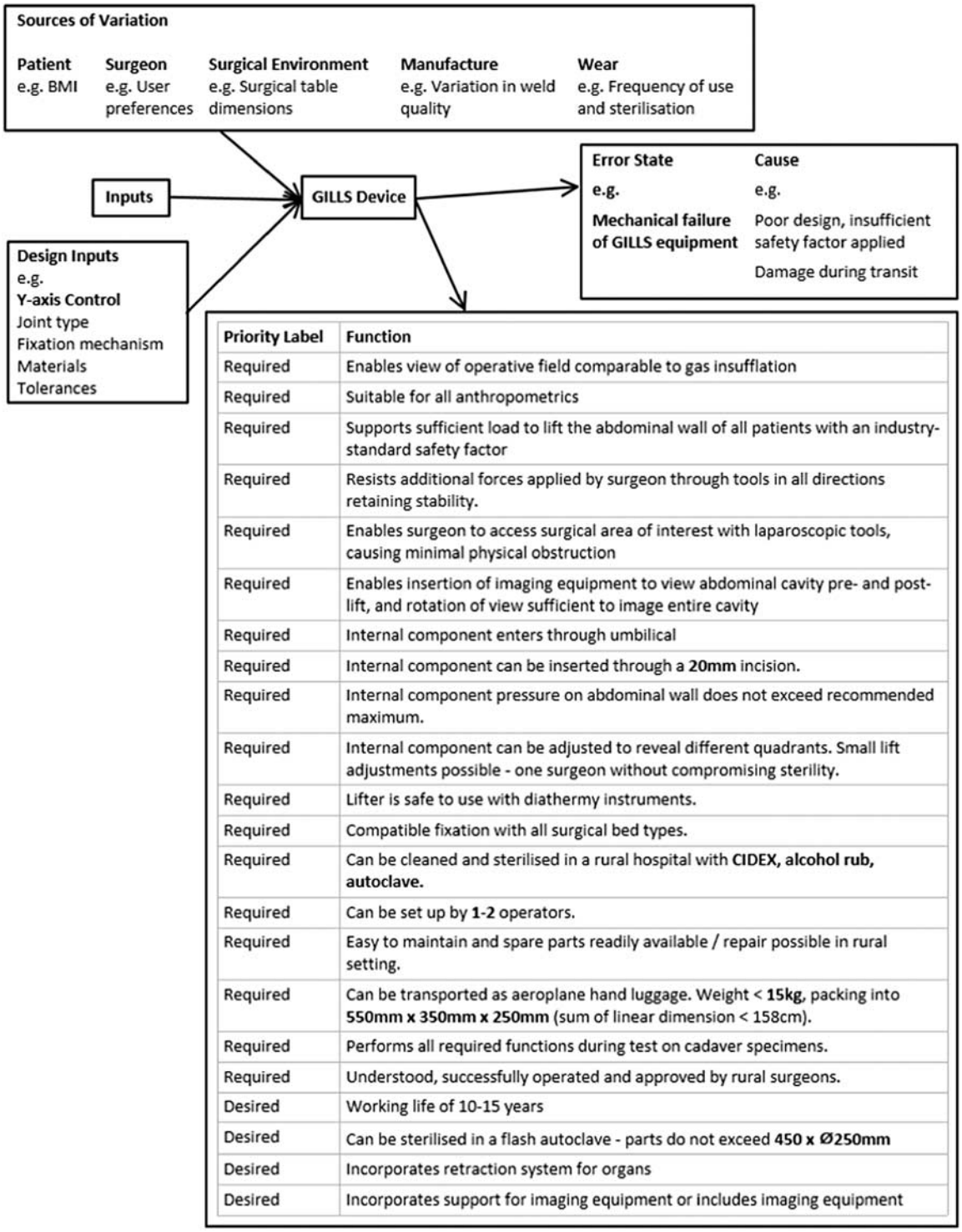
Phases 0 and 1 prepared the team well for this next phase of work, with information on clinical need and context clearly documented and experienced LMIC stakeholders augmenting the core team. The requirements generated during the interdisciplinary workshop and the relevant information about the surgical environment collected in phases 0 and 1 were formalized into a P-diagram (**Fig. 3**). This process was instructive in elucidating that to minimize the potential for variation in device performance it would be necessary to consider external (nondevice) factors including training and dissemination. These outcomes formed the basis for the implementation strategy: priority actions being to identify partners to support delivery of surgical training, marketing and distribution of the device in LMICs. Potential error states developed became a first step toward ensuring the quality and safety of the design in a low-resource environment[27].

Phase 3: act

Figure 2 shows the iterative waterfall process conducted by the team in this phase, consisting of 3 verification loops. This highlights the level of co-design involved in this approach, in which participatory input and feedback from LMIC stakeholders occurred during each verification stage to guide development of the design process.

In the first design verification loop, the requirements and P-Diagram from phase 2 formed the design input. Participants in the innovation workshop explored concepts for frugal approaches to a new device. The session was documented with extensive use of sketched concepts to rapidly convey and progress complex ideas amongst the group. Candidate concepts were then selected and developed further by the design team, culminating in a set of "low-fidelity" prototypes (Low-fidelity prototypes often focus on a core aspect or function of a product to help designers answer key questions in early design stages. They are characterized by a low level of detail and functionality. Examples include sketches or models created from plastic prototyping materials which bear little resemblance to the final product. High-fidelity prototypes aim to resemble the finished product as closely and in as much detail as possible to replicate the experience of the user interacting with the final product.) as the output of the loop.

The second loop involved an assessment of the initial low-fidelity prototypes by UK and LMIC stakeholders, combined with computer-aided design models and mock surgical scenarios, to select 2 concepts. These were further developed in discussion



Priority Label	Function
Required	Enables view of operative field comparable to gas insufflation
Required	Suitable for all anthropometrics
Required	Supports sufficient load to lift the abdominal wall of all patients with an industry-standard safety factor
Required	Resists additional forces applied by surgeon through tools in all directions retaining stability.
Required	Enables surgeon to access surgical area of interest with laparoscopic tools, causing minimal physical obstruction
Required	Enables insertion of imaging equipment to view abdominal cavity pre- and post-lift, and rotation of view sufficient to image entire cavity
Required	Internal component enters through umbilical
Required	Internal component can be inserted through a **20mm** incision.
Required	Internal component pressure on abdominal wall does not exceed recommended maximum.
Required	Internal component can be adjusted to reveal different quadrants. Small lift adjustments possible - one surgeon without compromising sterility.
Required	Lifter is safe to use with diathermy instruments.
Required	Compatible fixation with all surgical bed types.
Required	Can be cleaned and sterilised in a rural hospital with **CIDEX, alcohol rub, autoclave.**
Required	Can be set up by **1-2** operators.
Required	Easy to maintain and spare parts readily available / repair possible in rural setting.
Required	Can be transported as aeroplane hand luggage. Weight < **15kg**, packing into **550mm x 350mm x 250mm** (sum of linear dimension < 158cm).
Required	Performs all required functions during test on cadaver specimens.
Required	Understood, successfully operated and approved by rural surgeons.
Desired	Working life of 10-15 years
Desired	Can be sterilised in a flash autoclave - parts do not exceed **450 x Ø250mm**
Desired	Incorporates retraction system for organs
Desired	Incorporates support for imaging equipment or includes imaging equipment

Figure 3. P-diagram for the case study, showing examples of the inputs and error states and the requirements in detail.

with specialists in design and manufacturing, to evaluate their robustness to the variation in clinical setting and "error states" described in the P-Diagram. The output was a medium-fidelity prototype with a range of potential configurations.

In the third design verification loop, the team evaluated the medium-fidelity prototype in a simulated surgical scenario to explore different configurations (eg, mechanisms for limiting movement). This highlighted several key clinical areas which required further design input. An interdisciplinary workshop was convened to facilitate generation of solutions to address these issues. The design output was manufactured into a high-fidelity (fully functional) prototype as a key milestone in the

design process for evaluation in the cadaveric study with LMIC stakeholders. Outcomes from the study provided valuable feedback to inform the future development process. In particular, it enabled the identification of focal points which required more attention and areas which met the system requirements and could be finalized. This approach thus helped maximize ongoing resource and reduce the potential complexity of the design process.

Discussion

Our journey through the process of designing surgical systems for use in LMICs has revealed a number of themes for best practice which resonate with recommendations throughout the literature.

Participatory design and stakeholder engagement: early, often, sustained

Participatory design encourages embedding stakeholders within the team: "designing with," rather than "designing for." This is an important distinction and has profound implications on design methods, communication and project expectations. A key challenge is that of engaging the "right" stakeholders. Identifying an appropriate cross-section of stakeholders is critical to fully define the design context. Including multiple representatives from each discipline (eg, surgeons, nurses) increases the robustness of the design methodology and avoids over-reliance on individual opinion. For example, in this case-study, surgeons differed in their approach to positioning instrumentation which, although subtle, influenced our overall solution.

The initial phases of participatory design are arguably the most important, because inclusion of LMIC stakeholders in early decisions not only reduces design risk and focuses the project where it can best create impact, but also builds trust between collaborators and enables LMIC stakeholders to take ownership in the project. Convening the design team with LMIC stakeholders is an ideal means to start this process. We found that surgical demonstrations were instrumental in enhancing our understanding of the surgical procedure, equipment and the roles of the various stakeholders. Semistructured interviews and group discussion provided an ideal format for capturing this contextual information.

It is also crucial to sustain regular LMIC stakeholder engagement throughout the development process: as the design progresses, further input from LMIC stakeholders is necessary to inform design decisions, resolve uncertainties and refine concepts into prototypes of increasing fidelity. In our case study, an innovation workshop was used to begin the innovation process, enabling engineers, designers and surgeons to work collaboratively on concept generation and selection. Specific functionality was then optimized through a series of repeated and focused participatory design sessions.

A final important aspect of participatory design relates to translation toward clinical use. In surgery it is essential to establish advocates and champions for new techniques and tools, as part of the implementation strategy[13]. Building partnerships with LMIC surgeons can thus aid to build research and clinical trial capacities, both to inform design and to prepare for in-country device clinical evaluation[7].

Communication

Good communication is fundamental to effective participatory design. It can challenging in this context when team members and stakeholders typically have diverse professional backgrounds and reside in different geographical locations. Strategies to address potential confounds are therefore essential to successful design.

The value of meeting in-person cannot be overstated, particularly during initial phases of the design process. It provides a wealth of rich contextual information to catalyze innovation and helps develop strong collaborative relationships within the team. From this foundation, it is far easier to adopt remote working practices such as video conferencing. However, meeting in person is also time and resource demanding, so making the most of these opportunities through interactive activities that would be challenging to conduct at distance (eg, live surgical demonstrations) is essential. To complement this, remote communication methods provide a flexible set of tools with which to maintain collaboration throughout the design process while accommodating varied working patterns and time differences.

Design tools

The Design for Safe Surgery Roadmap[13] 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.

In phase 2, creating a P-diagram furthered understanding of potential sources of variation and failure modes and helped formally map the resources and inputs available to the project. This provided a comprehensive resource for reference and assessment throughout later phases of the design process.

In phase 3, our experience highlighted the value of the iterative waterfall model, in particular to embed regular stakeholder input. This revealed additional nuances of the surgical context and enabled efficient development and assessment of design concepts. Validation was a particularly important aspect of this iterative design process, particularly through physical workshops to form project milestones. A key consideration in this respect is how to capture and formalize the wealth of rich information which results. We found that use of semistructured interviews, coupled with post hoc thematic analysis, was invaluable. It allowed a variety of stakeholders to participate and has proved a robust means to evaluate developments that can be otherwise difficult to quantify in other studies[28].

Frugal engineering in a complex environment

A frugal innovation must achieve an optimized and appropriate performance level[29]. This is a delicate balance requiring comprehensive understanding of the design context; specifically the resources available, essential requirements and the relative value of different aspects of functionality.

Generating well-researched minimum functional requirements is therefore essential to reveal opportunities for frugal innovation. However, this also risks over-constraining the design space. For example, here an initial requirement was that the system should be "Easily repaired in a rural or remote setting," to avoid disruption caused by waiting for biomedical equipment technicians to visit the setting. Later, during validation, our stakeholders revealed that they would prefer to call in a specialist. Earlier identification of this factor would have helped optimize our design strategy, for example to ensure minimal device wear.

Responsible innovation

Frugal engineering mandates cost reduction, but in design for LMIC surgical contexts it is also essential to consider broader aspects (maintenance, procuring spare parts) and health-economic costs (equipment down-time, prolonged hospital stays for patients, training staff). Ultimately, the innovation process must not negatively impact the quality of the care provided.

This is illustrated when considering the need for sterilization. Global recommendations specify steam sterilization for this class of surgical device[30]. However, LMIC stakeholders revealed that rural hospitals are likely to employ alternative methods of sterilization such as alcohol-based cleaning fluids. In this instance the design team maintained a requirement for compatibility with flash auto-clave in accordance with principles of responsible innovation: it provided an opportunity to promote best-practice and ensures long-term acceptance as resources and infrastructure improve.

The value of using a roadmap

In this work we have considered the "Design for Safe Surgery Roadmap"[13], and reported our implementation in a case study spanning the complete roadmap. While the roadmap does not seek to provide guidance on the specific tools and methods which should be employed in every phase, it has provided invaluable structure to inform our specific approach in this work.

The high-level structure of the roadmap[13] is appropriate for the varied contexts that global surgical devices target. However, from this work, the authors propose a set of recommendations for enhancing its usefulness. Suggesting carefully evaluated design tools for each phase could help designers manage aspects such as risk or failure modes, or aid them in producing frugal, participatory designs. Another useful step would be to document and rank the risks involved in each stage of the design process to help teams optimize allocation of their resources.

Finally, while the roadmap[13] provides structure for the initial phases of design, alternative models used in conventional medical device design (eg, the Linear Life Cycle Model)[31] extend beyond this point of development to consider aspects including design for manufacture, regulatory approval, training, maintenance, packaging and disposal. These considerations are important in design for LMICs and may differ according to the context, so further guidance for global surgical device designers in these stages is required.

Ethical approval

Ethical approval for the cadaveric study at the Annual National Conference of Association of Rural Surgeons of India (ARSICON) 2019 was granted on November 5, 2019 by Martin Luther Christian University in Shillong, India (Ref: VI/I(8)/UREC/EA/272/2015-6116) and approved on November 15, 2019 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.

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Author contribution

M.M.W. conducted the background research and led development of the paper. She co-lead design and research activities within the case study. P.B. co-lead design activities within the case study. N.A., A.M., L.B., and J.G. provided surgical expertise throughout the design process, participating in design reviews, research activities and workshops. R.H. provided design and development guidance on matters including regulatory approval, manufacturing and good practice. P.C. supervised the research project, providing feedback and guidance while managing correspondence within the international team. He also participated in both design and research reviews and activities. All authors contributed to the drafting and revising of this work.

Conflict of interest disclosures

The authors declare that they have no financial conflict of interest with regard to the content of this report.

Research registration unique identifying number (UIN)

This study is registered with the Research Registry, at https://www.researchregistry.com/browse-the-registry#home/. The unique identifying number is: researchregistry6381.

Guarantor

Millie Marriott Webb.

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