



Human-centered design for medical devices and diagnostics in global health

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Abstract

So much lifesaving medical technology exists in the world, yet so little of it benefits communities with low resources. Purchase price is only one barrier. The World Health Organization found nearly three quarters of devices provided by industrialized countries are not used when they reach low resource communities. Most medical devices and diagnostics fail to operate effectively in environments with power fluctuations, high temperatures, high humidity, dust, insect infiltration, poor availability of spare parts, high-cost consumables, and low staff-to-patient ratio. To provide robust, well-designed products for low-resource environments, devices need to be developed to address the needs of the local clinics, hospitals, and communities. Human-Centered Design (HCD) is a set of tools, processes, and mindsets that can help a team uncover the essential needs of diverse stakeholders involved in the success of medical technology for global health. This paper provides an overview of the HCD techniques we have found most useful in developing medical technology for global health applications. To illustrate the HCD techniques and their benefits, we present a case study of Design that Matters' Firefly phototherapy. The device is now treating newborn jaundice in low-resource hospitals in over 20 low and middle-income countries.

Keywords: medical device design; health technology; medical technology; phototherapy

Introduction

In this paper, we set out to provide an overview of human-centered design (HCD) processes, methods, and mindsets that are best suited to developing diagnostics and medical devices with positive impact for low-resource communities. HCD can enable new medical devices and diagnostics to be designed to be affordable over the life of the product, durable, and usable in low-resource environments. We intend with this paper to enable teams to incorporate HCD techniques into medical technology (medtech) and diagnostic development, leading to more impactful technology reaching those who need it the most. We present a case study on the development of a phototherapy device to treat newborn jaundice in low-resource hospitals.

The word *design* often evokes images of fashion and art. In human-centered design, the word *design* denotes the act of intentionally creating something meaningful. Common industry practices of human factors engineering, usability engineering, and user experience are encompassed within human-centered design (Harte et al., 2014). However, HCD expands the focus beyond the direct user to inquire into the motivations, preferences, and viewpoints of all stakeholders who will affect the distribution, uptake, and impact of a product. In medtech, the array of stakeholders can be wide-ranging.

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In its most impactful form, HCD asks practitioners to reach beyond the question of whether a device will be safe, effective, and sellable to ask whether a product will deliver intended impacts in communities. Some call the application of HCD to positive social impact “Design for Social Impact”. We propose that building upon the knowledge and perceptions of communities who will adopt devices is paramount to achieving significant positive impact. With medtech designed for particular contexts and users, there is potential to improve long-standing global health challenges ranging from reducing childhood mortality from pneumonia to managing chronic diabetes. In our experience, HCD contains a powerful set of methods and mindsets to achieve the goal of high-impact technology. Using HCD, teams can:

1. uncover the essential needs of diverse stakeholders involved in the success of medical technology for global health;
2. generate creative solutions;
3. evaluate product alternatives quickly and effectively without months of testing; and
4. arrive quickly at a solution that satisfies the critical needs of direct users and other stakeholders.

The HCD methods detailed in this paper have roots in multiple design traditions described well by Giacomini (2014). HCD relies in particular on the traditions of ethnography, participatory design, codesign, contextual design, and empathic design, which are well-illustrated and compared by Steen et al. (2011).

The practice of human-centered design became adapted to business by companies such as IDEO, Frog, Continuum and others in the 1980s and 1990s (Szeczapanka, 2017). Since then, the methods were widely adopted among organizations such as healthcare system Kaiser Permanente (Kachirskaia & Mate, 2018); medical device companies Johnson & Johnson and Roche Diabetes Care (Nilsson & Sheppard, 2018); and global health funders such as USAID and the Bill and Melinda Gates Foundation (Cheney, 2018). In addition, the HCD approach and some of its methods are recognized by the International Standards Organization in 13407 – “Human centred design processes for interactive systems” (ISO, 1999). Evidence of human factors and usability engineering are increasingly required for medical device regulatory approvals including U.S. FDA approval and international CE marking (ANSI/AAMI, 2019, US FDA, 2016, ISO, 2015).

The impact of human-centered design

Many global health practitioners seek proof that human-centered design will lead to greater positive impact for low-resource communities. Bazzano et al. 2017 analyzed 21 publications from peer-reviewed and grey literature sources selected because they discuss aspects of HCD as connected to health outcomes. One of their conclusions was that existing publications do not quantitatively study the connection between HCD and health outcomes. Bazzano et al. also noted other gaps in existing literature including a lack of publications describing a full project cycle, little description of HCD methodologies used, and absence of gathering stakeholder feedback in-context. The 21 selected publications focused on software applications, clinical decision tools, and websites used in global health, but none addressed medical devices or diagnostics.

In this publication, we do not present quantitative evidence connecting the use of HCD to health impact, but we do present sources illustrating the impact of HCD in other domains. Analyses have indicated that user experience design and human factors engineering have an impact on the financial success of products. The primary argument is that a small investment of time and money in early application of HCD creates outsized savings later in development. (Mantei & Teorey, 1988; Bias & Mayhew, 2005; Rajanen, 2003; Conklin & Yakemovic, 1991; Karat, 1993; Mauro, 1994). For example, Karat (1994) references a study of a software product for which \$20,700 spent on usability resulted in a \$47,700 return on the first day the improvements were implemented, while for another system, \$68,000 spent on usability resulted in a \$6,800,000 return in the first year. In addition, the US FDA medical device regulatory agency studied the impact of human factors engineering on medical device design, issuing this statement (US FDA, 2011):

With increased safety, the likelihood of your incurring expenses associated with product recalls or liability is reduced; when Human Factors Engineering/Usability Engineering approaches are used in the design of devices, particularly if the perspective of users is taken into account, the overall ease of use and appeal of a device can simultaneously be enhanced.

Notably, these analyses concern themselves with product financial success and not positive impact for communities. Product financial success is not always correlated (and can be inversely correlated) to positive impacts for communities (Jewett, 2019). However, in our experience, designing products with communities saves time and money in costly redesigns; a vital benefit to underfunded global health initiatives that often not translated from the prototype phase to a final product (Johansen, 2018). HCD may be used to generate multiple medical device and diagnostic concepts and arrive more quickly at a solution that is desirable to stakeholders. Both correct use and positive product perception are necessary for safe and effective medtech. We believe that HCD increases chances of positive impact through better honing the design concepts to meet the stakeholder needs early in the design process.

The human-centered design process

HCD, done properly, permeates all phases of product development from forming the right team to product launch, and involves a wide range of skills. We propose that HCD increases the likelihood of successful product uptake in healthcare. As shown in Figure 1, human-centered design starts by considering what is desirable to stakeholders. Then the team must find opportunities at the intersection of viable businesses and feasible technologies. While technical feasibility and business viability are not discussed in detail in this paper, engineers and scientists will typically understand how to address technical feasibility, but not business viability. Teams founded by engineers and scientists should also include business experts as advisors or members of their team early in the process. Finding a solution that is desirable, feasible, and viable is critical to the success of any product for medical or consumer use.

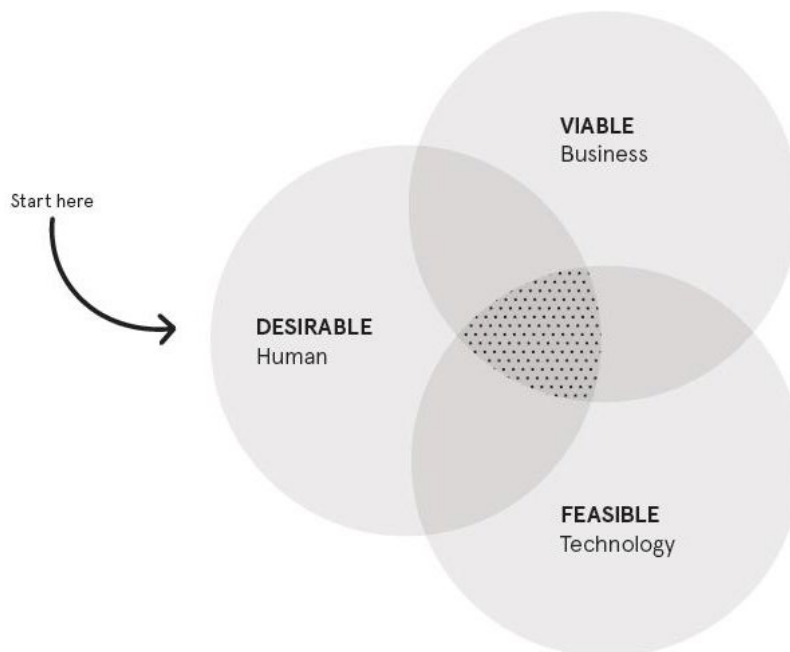


Figure 1: The human-centered design approach (IDEO.org, 2015).

The HCD process helps to ensure that all user needs are identified and addressed before the lengthy and expensive process of detailed development. Figure 2 shows a simplified overall product development process. The items in gray include HCD steps that are described in detail below.

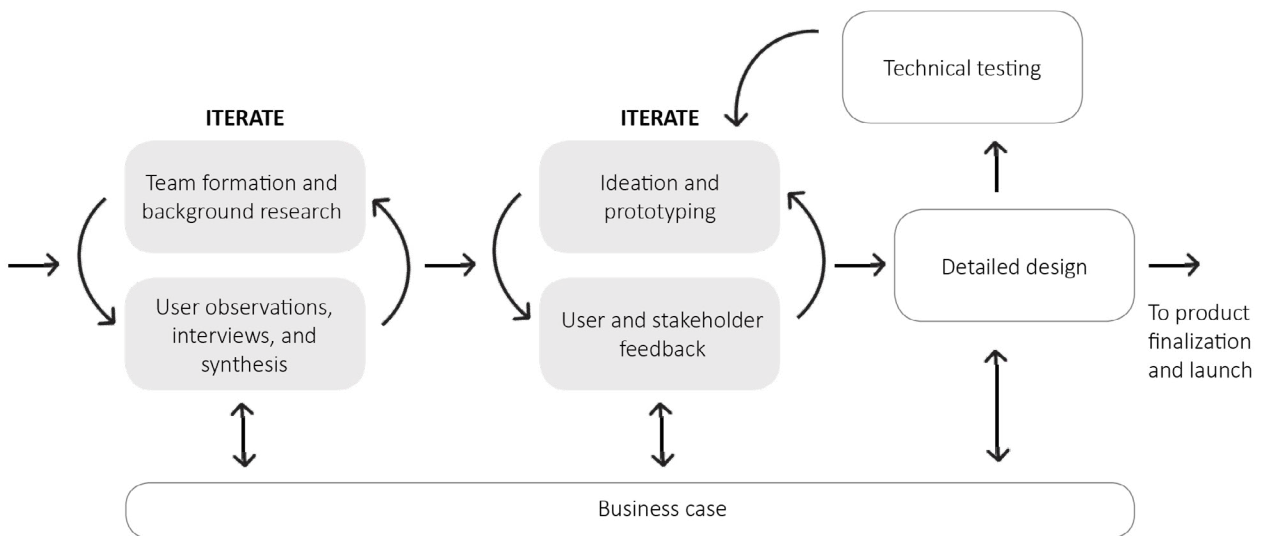


Figure 2: The human-centered design process and how it integrates with product development.

As practitioners with experience in applying HCD to over twenty global health medtech projects targeting low-resource communities,* we provide anecdotal evidence of the value of human-centered design. We illustrate the methods and benefits of HCD using the case study of Design that Matters' Firefly phototherapy to treat newborn jaundice as well as short examples from other projects.

Beyond medical devices, HCD can also be used to design diagnostics (Johansen, 2018, Linnes et al., 2017), and it can be used to design intangible innovations such as systems, services, and processes within global health (USAID & Bill & Melinda Gates Foundation, n.d.). The methods we recommend in this paper are particularly directed at the design of medical devices and diagnostics for global health.

Case study: Firefly phototherapy

Globally, over 100,000 newborns die and more than 50,000 are left permanently disabled due to jaundice each year. The burden of death and disability due to jaundice lies primarily in Sub-Saharan Africa and South Asia (Olusanya et al., 2018). An estimated 10% of all newborns worldwide need phototherapy treatment to avoid the ill effects of jaundice (Bhutani et al., 2013). Phototherapy is a minimally-invasive treatment that requires shining as much blue light as possible on the newborn's skin. This enables newborns to pass excess bilirubin out of their body safely through urine and stool so it will not cross the blood-brain barrier (Maisels & McDonagh, 2008).

Non-profit organization Design that Matters (DtM) developed Firefly phototherapy in collaboration with Medical Technology Transfer and Services (MTTS) and East Meets West Foundation to address the need for better tools to treat newborn jaundice in low-resource hospitals (Johansen, 2018). As of the publication date of this paper, Firefly is estimated to have treated over 200,000 newborns with jaundice in over 20 low and middle-income countries throughout Africa, Asia, and the Caribbean.

Team formation and background research

As we can see from Figure 2, identifying the right expertise is one of the most critical elements of designing a successful product and is where we started. Required expertise typically includes, but is not limited to, design, clinical, scientific, engineering, process development, logistics, manufacturing, regulatory, quality, and business expertise. All of the team members need to approach the problem with an open mind regarding the underlying

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user needs and challenges. The best product requires collaboration; no one individual has all the experience and expertise needed to design the best possible product.

In order to instill human-centered design into the development process, all team members must have an awareness of HCD and at least one team member must become an HCD champion who is proficient in HCD practices. Human factors engineers, usability engineers, industrial designers, user experience designers and product designers are professionals who are likely to have past experience in HCD techniques as they apply to medical devices. However, the HCD champion could be from any discipline: science, engineering, medicine, business, or others. The HCD champion must lead stakeholder engagement for iterative feedback and integration of this feedback into product development.

HCD closely resembles the scientific method including steps of developing a base understanding (secondary research, user research, observations); forming an hypothesis (product concept); testing the hypothesis (user testing); analyzing the results (synthesis, frameworks for design); revising the hypothesis (iteration of the design); and retesting as required (Newton, 1686). One key difference is that HCD uses more qualitative than quantitative techniques to test hypotheses. Applying HCD in medical device development therefore requires engineers and scientists to develop new skills in collecting and analyzing qualitative data.

While the team is forming, background research grounds project planning and assists the team in identifying the appropriate team members, users, stakeholders, available technologies, and existing approaches.

Team formation and background research: Project Firefly

To bring Firefly newborn phototherapy from an idea to impact, Design that Matters convened a diverse team. The company included engineers and designers. The lead engineer with deep HCD experience led the HCD process. Experts from manufacturing and commercialization partner MTTs Asia provided insights into existing newborn equipment successes and challenges, and prepared to finalize the product design and introduce the technology to the market once it was ready. Newborn health program implementation experts at non-governmental organization East Meets West Foundation provided access to doctors, nurses, and maintenance technicians at multiple hospitals for interviews and prepared to incorporate the device into their newborn health programs. Over 100 volunteers in academia and industry spanning engineering, design, business, and healthcare contributed to stakeholder interviews, brainstorming, design reviews, and concept exploration. Reduced rate engineering consultants with design for manufacture experience were engaged in detailed design. During initial background research, the team identified a range of existing approaches to jaundice treatment including traditional overhead phototherapy lights and flexible phototherapy blankets.

Stakeholder observations and interviews

When considering the range of user needs, the team first needs to identify the range of stakeholders. For example, let's consider a simple rapid diagnostic test like an HIV rapid test. Stakeholders certainly include patients and their families, lab technicians, and nurses. Stakeholders also include Ministries of Health, central laboratories, purchasing organizations, logistics (tests and related items like lancets, gloves), people reporting results, and others. A good design will account for the needs of all stakeholders. If there isn't an existing product or process, an existing alternative with similar use steps is considered. For instance, in the development of a new point-of-care molecular diagnostic for tuberculosis, the development team considered a modern and complex existing system like the GeneXpert used for centralized testing, as well as smear microscopy. The team considered all phases of the diagnosis from providing a sample through obtaining the result (Fisher et al., 2017; Doerfler et al., 2018).

User observation is a qualitative approach. HCD does not limit its investigations to usability issues, but is structured to engage a range of stakeholders and contexts that might influence the purchase, use and maintenance of medical technologies. The goal is not to have a statistically significant result, but rather to uncover the range of important, unstated needs in depth, with a limited number of observations. However, a helpful benchmark for the number of stakeholders to engage comes from Virzi (1992) and Nielsen & Landauer (1993). They found that evaluations with only five users would identify 80% of usability issues in a simple piece of software. We have found that five to ten sets of observations in different locations is normally sufficient if the locations are

selected to represent extremes, for example, including sites that range from rural to urban, busy to slow, and large to small. Similarly, speaking with five to ten stakeholders at each site who represent a variety of roles and experience levels usually gives a sufficient picture of the primary needs that the product should satisfy. The intention is to identify the majority of needs efficiently by covering a range of users and stakeholders with a manageable number of observations.

Often, the most important information comes from questions one does not think to ask. For this reason, visits typically combine observations with open-ended interviews. The visits should be done at the location of intended product use wherever possible. Observations include understanding workflows, hand-off points, and detailed processes. The most powerful method to document observations is through pictures and video with permission of patients and healthcare workers. If photo and video are not possible, observations can be documented in notes. This allows the information to be effectively shared with other team members and partners during the multi-year device development process.

For interviews, it is important to prepare potential questions to ask, but the interview should not follow a rigid script. The most informative interviews are conversational, starting with very open-ended questions (e.g. “Describe your workflow”, “Describe a typical day”, “What is the biggest problem in the process?”). When conducting user visits, the purpose is always to uncover the core underlying needs rather than simply recording an answer to a question. Asking follow up questions like “why do you do that?” can provide unexpected answers. The interviewer should also feel open to asking spontaneous questions based on the conversation. A 30-minute interview, beginning with only three or four open-ended questions, will often be sufficient.

Stakeholder observations and interviews: Project Firefly

To gather information relevant to the design of Firefly phototherapy, DtM identified stakeholders through background research and interviews with partners MTTs and East Meets West Foundation. Device end users included newborns with jaundice; their parents and grandparents who may stay near the device and turn it on and off during breaks for breastfeeding; nurses who will operate and clean the device; doctors who will recommend and develop treatment protocols using the device; and biomedical technicians who may inspect, repair, and clean the device. Additional stakeholders included purchasers such as ministries of health, non-governmental organizations and public and private hospitals; manufacturers; local regulatory bodies within target countries; and international regulatory bodies, for example for obtaining the CE mark.

We will focus on end-user observations in this case study. To learn more about the needs and use patterns of end-users, DtM conducted observations in a range of primary, secondary, and tertiary-level hospitals in Southeast Asia treating newborns. The following are several examples of observations DtM conducted that uncovered important insights that guided product design.

At some hospitals, DtM observed newborns covered with a blanket because nurses or parents did not realize it is important for phototherapy light to reach as much skin as possible (Figure 3). At one hospital, DtM found that newborns were being treated with a white observational light built into the phototherapy device because hospital staff did not realize the white light did not provide phototherapy. In many hospitals, phototherapy intensity was set to standard level instead of intensive brightness, even though most patients were severely jaundiced. The intention was to save electricity and lengthen the useful life of the fluorescent bulbs which tended to last only one month.

During a visit to a tertiary hospital in the Philippines, the DtM team observed newborns with jaundice sharing limited overhead phototherapy in crowded beds (Figure 4). These overhead phototherapy lamps are designed to be bright enough to provide treatment to only one newborn in the center of the lighting field. Newborns at the outskirts of the light may not receive effective phototherapy. Interviews with healthcare professionals did not reveal this issue because the staff did not realize the phototherapy light is too dim at the edges of the light field.



Figure 3: An overhead phototherapy device treats newborns at a hospital in Vietnam (photo CC BY-SA 4.0 Design that Matters).



Figure 4: Overhead phototherapy devices treat newborns at a tertiary hospital in the Philippines (photo CC BY-SA 4.0 Design that Matters).

Synthesis

Once a round of observations and interviews has been completed, the next step is to consolidate the observational data, the literature, and competitive offering information into a set of summary frameworks and product requirements that will best guide the development process to achieve positive impact. Design principles, patient and healthcare provider journey maps, stakeholder maps, and user or stakeholder personas are all examples of useful frameworks. We provide an example of design principles applied in the case study; the other common frameworks are covered in detail in the Design Kit from IDEO.org (2015).

The product requirements document may be a more formal document for a regulated medical device or simply a set of bullet points describing what needs the product should to satisfy. One simple and common approach involves generating a series of one-line or one-phrase needs sourced from the observations and interviews. These needs along with any requirements from international standards come together to form a product requirements document and a market requirements document (ISO, 2016).

In the early stages of development, the goal of the product requirements document is to describe only the essentials of what the end product should do, while not detailing a specific solution. For instance, if the team is designing a better way to communicate test results from a central laboratory to patients, a generative requirement would be to “communicate the result within seven days from sample draw”. An overly specific requirement would be “the patient receives a text message within seven days of whole blood draw”. If the team designs to the second requirement, it would only design for patients with a mobile phone who live where mobile service exists, and whole blood would be the only sample type considered. At the earliest stages, the product requirements should give the development team as much flexibility in their solution as possible, while reducing the scope only where options have been intentionally considered and ruled out. As development proceeds, the requirements may become more and more specific as a leading design solution is selected and pursued.

Synthesis: Project Firefly

After completing initial user and stakeholder research in seven countries across Southeast Asia, DtM created a set of high-level design principles as well as a set of detailed product requirements to guide design. The following are the four design principles that inspired Firefly Phototherapy development.

- **Effective:** Not only should the device provide intensive phototherapy, but it should also look like it can provide intensive phototherapy. Perceptions of efficacy are as important as actual efficacy in driving stakeholder adoption.
- **Comforting:** The head of neonatology at a district hospital in Vietnam inspired the team to make the device like a “high-tech bird’s nest”; comforting, and fitting snugly to, the newborn like a nest for baby birds, while demonstrating that it is high-tech and effective.
- **Maintainable:** The need for maintenance beyond cleaning should be eliminated, by designing for durability. In Firefly’s target settings, easy-to-clean means wipeable with isopropyl alcohol and other disinfectants to reduce infection. Durability was increased by eliminating moving parts that would easily wear out.
- **User-friendly (hard-to-use-wrong):** The design should ensure that overburdened healthcare professionals at district-level hospitals feel confident using Firefly. The device should not only be easy to use, but also hard to use incorrectly for busy staff.

The DtM team also created a product requirements document that included elements from the international standards for newborn phototherapy equipment expressed in a way that reflected the design principles (IEC, 2009). To make Firefly hard-to-use-wrong, one requirement was to provide only intensive-level phototherapy. With the advent of high-power, long-lasting LEDs that use little electricity and the knowledge that it is not possible to overdose on phototherapy, DtM saw an opportunity to simplify the controls and prevent busy healthcare professionals from choosing a setting that was too low. In addition, DtM included product requirements beyond international standards that reflected the hard-to-use-wrong design principle. One example was to size the device so only one newborn would fit directly centered under the brightest part of the lighting field.

Ideation and prototyping

Once the team has synthesized learnings from fieldwork and updated the requirements, the next step is to develop a range of concepts or approaches to accomplish the goal. At this stage, the goal is not to try to find the single best solution, but rather to consider the range of potential solutions. The final design may be one of these ideas, but more likely, will be a combination of ideas with other features added as the team learns more about the designs.

Brainstorming is one approach to developing a wide range of ideas to consider. Many approaches exist for an effective brainstorm, but this paper describes the approach used by IDEO.org (2015). The IDEO.org Design Kit provides the following list of brainstorm rules and descriptions:

- **Defer judgment** - anything works for the duration of the brainstorm.
- **Encourage wild ideas** - crazy ideas often have a nugget of a great idea.
- **Build on the ideas of others** - be positive and encouraging.
- **Stay focused on the topic** - it is very easy to stray from the topic in a wild brainstorm.
- **Conduct one conversation at a time** - it is important to hear everyone's ideas to inspire new ideas.
- **Be visual** - sketches tell a better story than words.
- **Go for quantity** - don't worry about perfection.

A good brainstorm lasts 15 minutes to one hour and will yield 35-100 ideas with perhaps half being feasible and five to ten being solid approaches. As many ideas as possible should be produced, regardless of quality. Any idea is welcome in a brainstorm; judgment will be applied later. Generally, five to eight people are a good number for an effective brainstorm. The group should include the extended team and perhaps an outside person or two who has expertise in an area relevant to the project. The ideas should be captured on sheets of paper and posted in the room. Sketches are highly recommended. After the brainstorm, the ideas should be sorted into themes. Themes are solutions that have something in common as defined by the team.

After the brainstorm, the goal is to quickly and affordably test critical assumptions about stakeholder desirability, technical feasibility, and business viability. The team should develop three to five rough concepts based on the brainstorms. These concepts are almost certainly combinations of brainstorm ideas and new ideas. These concepts should be embodied in a fast and rough way to test critical assumptions. In some cases, a two-dimensional sketch or a photo-realistic product image can help to explore aspects of the concept. For example, a mobile app might be embodied by a few sketched screens known as a wireframe. In other cases, a three-dimensional prototype may be warranted. Even simple representations of the idea made from cardboard and tape can be useful. The goal of these early prototypes is not to make the real product or meet every requirement in one prototype, but rather to test assumptions across the domains of stakeholder desirability, technical feasibility, and business viability.

Concept sketches, images, and prototypes are extremely helpful assets to solicit stakeholder feedback. The assets must be at a sufficient level of fidelity to convey the idea to stakeholders who may be unfamiliar with the product design process but need not be technically sound. These assets are used by the team to verify that the innovation addresses the needs identified in stakeholder interviews and observations. The team can use images and prototypes to preview the product architecture, gather feedback about the user interface options, and explore reactions to varied aesthetics even before solving the technical challenges of the product.

The value of the rapid, iterative prototyping process is to discover and address possible failure points early in the development process before it is too expensive to correct them. A good design results much more quickly from a series of less refined prototypes than a single prototype developed in more detail.

Ideation and prototyping: Project Firefly

In one of the earliest brainstorm sessions for Firefly, DtM considered the best product architecture for hard-to-use-wrong phototherapy. To seed the brainstorm, the team researched various types of lighting technology including LEDs, transparent materials including plastic and glass, and plastic light pipes that transmit LED light from one end to another. Brainstorm ideas included a lightpipe device that could enable mothers to hold their newborns during therapy, configurations with transparent materials enabling phototherapy from below, and various ways to incorporate a single-sized infant bed. After the brainstorm, the team combined the ideas

that best represented the design principles and product requirements into photo-quality rendering concepts shown in Figure 5. The renderings provided a sufficient level of detail to enable early stakeholder feedback, before the technical details for each concept would be addressed. DtM's partner, East Meets West Foundation, showed these concepts to 88 healthcare professionals at a jaundice training conference in Vietnam. The result: ideas like "cocoon" at top left which would require caregivers to hold the device in their arms were immediately discarded. Moms are not able to hold babies all day, and nurses do not have time given the low staff-to-patient ratios. The preferred architecture was the shade as it appeared to fit in small spaces in crowded hospitals and looked reliable and familiar.



Figure 5: Early phototherapy device concepts (image CC BY-SA 4.0 Design that Matters).

User and stakeholder feedback

In returning to the field for additional rounds of feedback, the team can visit a range of users similar to those who were visited in initial observations and interviews. Visiting the same stakeholders multiple times throughout product development can be beneficial when they are a proven source of articulate feedback. In addition, through revisiting the same stakeholders, partnerships may be developed that would benefit technology launch. It's also beneficial to include new stakeholders who have never been exposed to the idea before. To gather user input, at least two members of the team ideally visit the users where the product might be used. During the visit, the idea of a prototype is explained briefly, and the user is asked to step through the process they expect to use with the prototype, ideally in the location where they would use it. If the product or process would normally include instructions, those should also be prototyped and included. In a real use environment, the user is likely to have little more than the product and instructions. This approach allows the team to better understand what parts of the process are difficult to understand or easily misunderstood. In addition, the user should be told that the team is in the middle of the design process and their feedback is needed to incorporate into the final design. People are reluctant to criticize a design if they think it is complete.

Prototyping and user feedback can most efficiently occur in parallel with technical design and development. Many teams with which we have worked, want to wait until they have a fully functional design before gathering stakeholder feedback. There is often a reticence to spend budget to show stakeholders ideas that may not ultimately be technically feasible or viable for the business. Our experience is that the product design process is more efficient if multiple early ideas are shown to stakeholders in parallel with technical exploration. Teams

can engage technical and business experts to help choose early ideas that seem most likely to be technically feasible and viable for the business. We have found that conducting at least one round of feedback with multiple concepts representing a variety of possible product directions enables the most honest and comprehensive stakeholder feedback, because it prompts stakeholders to share information they may not have otherwise thought to share before seeing the range of what is possible. This enables the team to focus technical efforts on one or two leading product directions that are highly likely to satisfy stakeholders. Once a fully functional design has been created, it is much more expensive to change based on stakeholder feedback. In addition, the team is less willing to change the design once a single fully-functional prototype has been created because they are more psychologically invested in the design. Stakeholder desirability, technical feasibility and business viability must all be considered for a successful product. Time and money may be saved in the long-run by adding these cycles of stakeholder feedback to the development process.

User and stakeholder feedback: Project Firefly

After gathering feedback from neonatologists and neonatal nurses in Vietnam about multiple early concepts, the DtM team decided to build a “looks-like” and “interacts-like” prototype to convey the “shade” concept to hospitals in Vietnam. Based on feedback and prior field observations, DtM added lighting below the infant bed in hopes it would make the device more effective and hard-to-use-wrong. The prototype used low-power blue LEDs made for hobby electronics and a painted medium-density fibreboard housing to simulate the product. DtM had not yet solved the technical challenge of how to provide uniform, intensive, blue lighting from above and below, but engineering experts on the team felt it might be possible. By bringing this more detailed “interacts-like” model before substantial technical development had taken place, DtM learned invaluable lessons about how the device would be used, which became inputs to technical development.

The DtM team asked nurses to use the prototype and a baby doll to show how they would set up the device for use in the neonatal intensive care unit. One nurse suggested she would place a sheet over the device to shield bystanders from the bothersome blue light. Because the interview took place in the hospital, the nurse was able to show the team how she would drape the material she would use over the device, as shown in Figure 6. Allowing for draping a sheet over the top light became a product requirement. This requirement required the team to overcome technical challenges of ensuring the top light would not overheat in warm hospitals even when covered with a sheet.



Figure 6: Unexpected use discovery in Vietnam (photo CC BY-SA 4.0 Design that Matters).

DtM's "interacts-like" phototherapy prototype was also helpful in determining the appropriate size of the Firefly bassinet. The team's goal was to design a bassinet small enough to fit only one newborn. The purpose was to avoid cross-infection or reduction in therapy effectiveness due to multiple infants sharing one phototherapy device. The team based the size of the prototype bassinet on ergonomic data about the range of typical newborn sizes. Though the sizing may be suitable for a newborn, bringing a physical prototype early in development allowed exploration of aspects of device use that were not available in ergonomics tables. These activities include inserting the baby into the bed and drawing blood from the baby while in the bed. During the user input session, a particularly large infant was at the hospital (Figure 7). With the permission of the mother, the clinicians placed the infant in the bassinet and pantomimed different procedures such as a blood draw to determine the appropriate bassinet size. The prototype was too small to be convenient, leading to product requirements related to the height and angle of the bassinet side walls that also drove the overall size of the device.



Figure 7: Observations in Vietnam to determine appropriate device size (photo CC BY-SA 4.0 Design that Matters).

Detailed design

We do not provide a description of the detailed design process of a medical device or diagnostic, though this process is described in many books, periodicals, and international standards. Iterative stakeholder feedback will continue in the detailed design phase. This stakeholder feedback takes the form of formative and summative human factors testing that focuses on correct and effective use of a detailed design. Formative and summative human factors testing is described in ISO/IEC 62366 (ISO, 2015). Detailed design and pacing of iterative feedback will vary based on the type of innovation. Major changes to the design are not simple at this point. Continued stakeholder engagement provides an opportunity to prototype training and communication materials. It also provides insight into how the product may be rolled out in the field.

Final design: Project Firefly

The final Firefly design is shown in Figure 8. From the earliest stages of the project through licensing to MTTS Vietnam, DtM engaged over 100 healthcare professionals and parents in seven low and middle-income countries through iterative stakeholder feedback. By determining the ideal product requirements early, the

DtM team was able to complete detailed design and build devices for clinical evaluation in Vietnam in only five months. Having very early stakeholder feedback meant the device was designed to be the appropriate size the first time. The team avoided creating expensive, plastic injection molding tooling for the bassinet and base housing that would have had to be scrapped, redesigned and retooled. Identifying early that staff would drape the top light with a sheet, meant that MTTs has not received reports of the Firefly top light overheating over seven years of use.



Figure 8: The final Firefly phototherapy device, manufactured and sold by MTTs Asia (photo CC BY-SA 4.0 Design that Matters).

The final product is hard to use incorrectly, enabling it to be used safely and effectively by the busiest professionals at the most rural hospitals. The design includes a small bed size to reduce cross-infection and promote effective treatment by restricting use to a single infant. The bassinet locks into a base to hold the newborn centered on intensive lighting from above and below. The intensive lighting from top and bottom covers a larger skin surface area, increasing treatment speed by 45% compared to traditional overhead phototherapy lights (Arnolda et al., 2018). Reduced treatment time may shorten costly hospital stays and enable discharging the newborn earlier to the comfortable home environment to bond with mother and family. The iterative HCD process identified opportunities early in the design process that paved a direct path to a reimagined phototherapy experience that better fits a low resource environment. The team was able to bridge the divide between prototype and launched product by identifying necessary product requirements early, cutting cycles of technical development.

Conclusions

Usable and economically-sustainable medical devices and diagnostics are critical to advancing healthcare worldwide, but most existing technology is not designed for the majority of the world. HCD can provide scientists, clinicians, engineers and ministries of health with the tools to bridge the gap from promising prototypes to launched products by creating better alignment with stakeholder needs early in the process.

In our experience, gathering stakeholder insights when the cost of changes is still low can increase the likelihood that much-needed global health innovations reach the market. Though HCD activities may add a modest amount to cost and time early in the project, studies outside the domain of global health have shown

that up-front investment in HCD can lead to a tenfold return on investment in the long-run (Bias & Mayhew, 2005). The advantages include yielding medical devices that are better accepted by stakeholders and avoiding expensive redesigns and recalls. For these reasons, many healthcare, medical device and global health funders are integrating HCD into their organizations.

While more work can be done to study the connection between HCD and positive health impact in communities, we believe there is ample evidence to include an iterative approach to stakeholder engagement in any medtech program, especially where positive health impact for communities with low resources is the end goal.

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