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# Stakeholders, Prototypes, and Settings of Front-End Medical Device Design Activities

*Successful medical device design necessitates an understanding of stakeholder-driven requirements early in a design process to assure device safety and usability, and support successful and positive patient experiences. Prototypes can be used during stakeholder engagement in the design front end to gather the information that will inform design decisions. However, an understanding of medical device industry practices for front-end stakeholder engagement with prototypes is lacking. Through interviews with medical device design practitioners, this study explored the variety of stakeholder groups engaged by design practitioners, prototype types used during stakeholder engagements, and settings in which engagements occurred during front-end design activities. This study describes the 14 types of stakeholders, 14 types of prototypes, and six types of settings described by practitioners as well as patterns across engagement strategies, stakeholders, prototypes, and/or settings during front-end activities. These outcomes can contribute to broadening designers' stakeholder engagement planning and practices.*

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**1 Introduction and Background**

Medical devices are part of the large array of health technologies that help increase access to healthcare [1]. A medical device is an instrument “intended for use in the diagnosis [...], cure, mitigation, treatment, or prevention of disease [...] and which does not achieve its primary intended purposes through chemical action” [2]. Throughout a design process, medical device designers often engage and seek feedback from diverse stakeholders that are involved in the commercialization and use of devices. Stakeholders include healthcare practitioners, patients, professional and advocacy groups, government officials and legislators, payers [3], risk managers, clinical engineers, maintenance personnel, trainers, and supervisors [4,5]. The beneficiaries—users, payers, and purchasers of medical devices—are often different people [6], potentially leading to conflicting needs [7]. Furthermore, medical devices are subject to a strict regulatory environment that mandates the use of prototypes to test concepts with users [8] during usability testing and fully functional devices during clinical trials [9]. Therefore, diverse stakeholder engagement is an inherent part of medical device design.

**1.1 Stakeholder Engagement During Medical Device Design.** Engaging a broad range of stakeholders throughout a medical device design process leads to more successful designs; it

is particularly critical for designers to successfully engage stakeholders during the front end of design [10,11], which includes problem and needs finding, identification and definition of design opportunities, articulation of requirements and specifications, and idea generation and development [12]. Stakeholder engagement provides design practitioners with insights into the design context and the values and behaviors of stakeholders [10] and leads to the elicitation of latent priorities [13]. However, barriers exist to stakeholder engagement, such as the intense resources needed to engage medical device users, the limited availability of certain medical professionals and patient populations, and communication gaps between design practitioners and stakeholders [10,11].

**1.2 Benefits of Prototype-Based Stakeholder Engagement.**

Prototypes have been promoted as tools for engaging stakeholders during design processes [3,14]—to elicit knowledge, needs, and requirements [15,16]. Prototypes are physical or virtual objects that can have many forms, including sketches, digital models, and physical three-dimensional (3D) objects. Prototypes represent design ideas for the end-product as well as subcomponents of the potential end-product, processes for engaging with the product, and experiences with the product [17]. For example, storyboards can be used to represent a user’s process of interaction with a medical device interface [5], while virtual reality can be used to simulate a procedure involving a novel medical device [18].

Prototypes provide various ways for stakeholders to participate actively in design activities [19,20], including when stakeholders

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85 have trouble articulating knowledge relevant to the design [21].  
 86 Prototype-based engagements facilitate designers' abilities to elicit  
 87 stakeholders' input throughout the various stages of a design process  
 88 [22] by centering conversations on perceptions of and interactions  
 89 with the prototypes [14]. Prototypes can support various designer-  
 90 stakeholder activities, such as communicating a design concept [22],  
 91 gathering feedback on a design concept, having stakeholders interact  
 92 with a prototype [23], cocreating with stakeholders [24], helping to  
 93 establish a common language between designer and stakeholder,  
 94 exploring the problem space, and eliciting requirements from stake-  
 95 holders [11]. Lauff et al. [25] described prototypes as intentional tools  
 96 that facilitate communication. Among the limited studies that have  
 97 explored the effects of using specific prototype forms with specific  
 98 stakeholder groups, several studies have found that the prototype form  
 99 used during user feedback sessions and usability testing affects the  
 100 feedback received from stakeholders and the results of usability activ-  
 101 ities [26–28]. Thus, the choices of prototypes to engage various stake-  
 102 holder groups can influence the outcomes of the engagement.

### 103 1.3 Current Use of Prototypes in Medical Device Design.

104 Prototypes in medical device design have traditionally been lever-  
 105 aged to explore the technical feasibility of a project, to improve a  
 106 device's functionality and performance [29], and in later design  
 107 stages, to verify specifications are achieved and validate the ful-  
 108 fillment of clinical needs [8,30]. Some evidence suggests that  
 109 medical device design practitioners tend to use late-stage proto-  
 110 types when seeking stakeholder feedback, therefore obtaining user  
 111 information only during the later stages of a design process [31].  
 112 Stakeholder engagement practices are often defined in the context  
 113 of usability studies meant to identify, quantify, and mitigate use  
 114 errors [9,13]. Therefore, prototyping for medical device design is  
 115 often seen as a phase that comes later in a design process [5]  
 116 rather than as a tool that can also be leveraged at the onset. While  
 117 in other fields, prototypes are prominently described as being used  
 118 in front-end activities (e.g., human-computer interaction, where  
 119 sketches are widely used to mockup interfaces [32], and codesign,  
 120 where probes are used to explore the problem space [16]), there  
 121 are limited publications that describe front-end prototyping with  
 122 stakeholders in the medical device design field.

123 Human factors, the field within which usability testing  
 124 emerged, does emphasize the importance of early involvement of  
 125 users in medical device design, particularly through observations,  
 126 interviews, and focus groups [5]. Human factors and ergonomics  
 127 research have shown that the integration of user-specific require-  
 128 ments early in the design processes of medical devices leads to  
 129 improved safety and usability of devices, improves patient out-  
 130 comes and satisfaction, and reduces device recalls and the need  
 131 for modifications later in design processes [13]. Human factors  
 132 engineering has established methods for early user engagement,  
 133 consisting of user testing with both early nonfunctional prototypes  
 134 and downstream functional prototypes, to identify user-device  
 135 interaction issues as early as possible [5]. However, human factors  
 136 research focuses on the study of user-interface interaction. Aside  
 137 from user-interface interaction, the use of prototypes to engage a  
 138 wider variety of stakeholders during the earliest phases of  
 139 design—such as for need identification, problem definition,  
 140 requirements elicitation, and idea generation—is underexplored  
 141 within the medical device design field.

### 142 1.4 Medical Device Design for Low- and Middle-Income

143 **Countries.** In general, medical device designers work within  
 144 strict regulatory environments and navigate changing healthcare  
 145 reimbursement policies that create barriers to timely and success-  
 146 ful commercialization [30]. In addition to these challenges, medi-  
 147 cal device designers working on solutions for use in low- and  
 148 middle-income countries (LMICs) face a wide-ranging set of con-  
 149 straints [33–37], including the lack of pathways to commercializa-  
 150 tion of medical devices; lack of funding; low-profit margins;  
 151 varied regulatory and intellectual property protection pathways;

supply chains deficiencies; lack of supporting infrastructure; harsh  
 use conditions; unique local norms and preferences; maintainability  
 challenges; and other constraints. Many of these challenges are spe-  
 cific to LMIC settings and are seldom at the forefront of design  
 methods for high-income country (HIC) settings. Several authors  
 have reported that medical device designers from HIC contexts  
 engage a broader set of stakeholders more frequently during the early  
 stages of medical device design activities aimed at creating solutions  
 for use in LMIC contexts [38–40], where various constraints and  
 contextual factors may differ considerably from HIC contexts [41].  
 One early stakeholder engagement activity is to use prototypes, for  
 example, as collaboration tools in codesign approaches, as exem-  
 plified in Caldwell et al. [38]. Practitioners who design medical devices  
 for use in LMICs can offer unique insights into early prototyping  
 behaviors for stakeholder engagement.

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1.5 **Research Focus.** Through interviews with medical device  
 design practitioners working in industry, we investigated the variety  
 of stakeholder groups engaged by design practitioners, the prototypes  
 they used during stakeholder engagements, and the settings in which  
 the engagements occurred during front-end design activities, which  
 included problem identification and needs finding, problem defini-  
 tion, background research, concept generation, early prototyping,  
 and concept selection. We further investigated front-end design pat-  
 terns across stakeholders, prototypes, and settings. In this study, we  
 leveraged a broad definition of prototypes to include *representations*  
*of processes* (e.g., a clinical procedure), *systems, or subparts of a*  
*designed product or its use context*. Prototype examples included  
 mockups, computer-aided design (CAD) models, drawings, scenar-  
 ios, and existing products used as prototypes. What distinguished a  
 prototype from an artifact was the intentional way the artifact was  
 used by the designer as a prototype. This study contributes to  
 advancing understanding of stakeholder engagement practices, ulti-  
 mately supporting the improvement of front-end design activities  
 and design decision making for prototype-based stakeholder engage-  
 ment, including specific context-related decisions.

## 2 Methods

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2.1 **Research Aims.** The following research question guided  
 the study: During front-end medical device design activities, what  
 stakeholders are engaged with what prototypes, and in what settings?

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2.2 **Participants.** Potential participants were identified through  
 existing contacts, networking at medical device conferences, and  
 online searches. Potential participants were then emailed to deter-  
 mine their interest in participating in the study. Interested participants  
 completed a background questionnaire detailing their prior medical  
 device design experiences, their experiences using prototypes to  
 engage stakeholders during front-end design, as well as their years of  
 industry experience with mechanical or electromechanical medical  
 device design (one or more years of experience required). This  
 approach to recruitment led to the identification of key informants  
 with the expertise and knowledge we aimed to elicit in this study.  
 Participants joined the study voluntarily, provided informed consent,  
 and received US\$75 for their participation.

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Twenty-two participants were interviewed from sixteen medi-  
 cal device companies. In order to identify practices across differ-  
 ent companies working in diverse design contexts on a variety of  
 medical device types, we sought to obtain a balance among partic-  
 ipants from multinational companies and companies working in  
 global health settings (in LMICs), as well as among participants  
 from companies that ranged in size. All but one company was  
 headquartered in an HIC. Participant information is provided in  
 Table 1 (individual level) and Table 2 (aggregate level).

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2.3 **Data Collection.** Semi-structured interviews were con-  
 ducted in person with five participants and via videocall with 17 par-  
 ticipants. A semi-structured interview approach ensured that a

216 standard set of questions were asked while allowing flexibility to  
 217 pursue tailored follow-up questions [42]. The interviews lasted  
 218 87 minutes on average and ranged from 55 to 152 minutes in length.

219 The interview protocol was developed following recommended  
 220 practices for interview development, including beginning the  
 221 interview with descriptive questions, grounding open-ended ques-  
 222 tions in the relevant literature and aligning with the research ques-  
 223 tion, and including follow-up questions to gain additional detail  
 224 [43]. The protocol was revised iteratively as the result of 11 pilot  
 225 interviews (that were not part of this study) conducted with  
 226 designers who had industry experience.

227 The definitions of “front end,” “prototype,” and “stakeholder”  
 228 were read aloud to the participants at the beginning of the inter-  
 229 view to establish a shared language between the interviewer and  
 230 participants. The definitions of the front end, prototype, stake-  
 231 holder, and setting are provided in Appendix A. The interviewer  
 232 then asked participants to focus on a single prior project and  
 233 describe instances when they engaged stakeholders with proto-  
 234 types during front-end design activities. Participants were asked  
 235 about how they engaged stakeholders using prototypes, which  
 236 stakeholders were engaged, what prototypes were leveraged, and  
 237 the settings of the engagements. At the end of the interview, par-  
 238 ticipants were asked to compare their experiences of stakeholder  
 239 engagement with prototypes across projects. Sample interview  
 240 questions are included in Appendix B. The study was determined  
 241 to be exempt and was approved by the University of Michigan  
 242 Institutional Review Board (HUM00137476).

243 **2.4 Data Analysis.** Engagement events served as the unit of  
 244 analysis for associations among strategies, stakeholders, prototypes,  
 245 and settings leveraged by practitioners during front-end design activ-  
 246 ities. We defined an engagement event, based on guidance from  
 247 Montgomery and Duck’s work [44], as a front-end activity where  
 248 one or more prototyping strategy(ies) was/were used to engage one  
 249 or more stakeholder(s) with one or more prototype(s) in a particular  
 250 setting. All instances of engagement events were described using the  
 251 participants’ descriptions of prototyping strategies, stakeholders, pro-  
 252 totypes, and settings. Excerpts from a single engagement event could  
 253 be contiguous or scattered throughout the transcript. An example  
 254 engagement event is provided in Appendix C.

255 Two researchers first jointly identified engagement events in  
 256 one transcript. This process established coding reliability and

257 allowed the researchers to resolve discrepancies through discus-  
 258 sion. Then, each researcher read 11 transcripts and identified and  
 259 described engagement events. Finally, one of the researchers  
 260 reviewed all engagement events to verify consistency across the  
 261 dataset. An average of six engagement events per transcript were  
 262 identified, for a total of 127 engagement events (between one and  
 263 11 engagement events per transcript).

264 After the engagement events were identified, transcripts were  
 265 coded using two different coding schemes. The first coding  
 266 scheme identified types of stakeholders, prototypes, and settings  
 267 using an inductive analysis approach [45], where patterns were  
 268 recognized across the data through continuous comparison to  
 269 articulated patterns. Discrepancies in coding were resolved  
 270 through discussion across two coders. Next, the codes were  
 271 refined following Urquhart’s [45] recommendations for qualitative  
 272 coding, in this case by using existing classifications of prototype  
 273 forms [16,46–50] and stakeholder groups [3,4,13,51–57].

274 The second coding scheme used an existing prototyping strat-  
 275 egy codebook developed as part of prior work involving the same  
 276 dataset [58]; the codebook comprised 17 prototyping strategies  
 277 used to engage stakeholders during front-end medical device  
 278 design activities (shown in Table 3).

279 To analyze the engagement events, the authors counted the num-  
 280 ber of times a specific association of strategy, stakeholder, prototype,  
 281 and/or setting occurred. Therefore, the engagement events revealed  
 282 trends of associations among strategies, stakeholders, prototypes, and  
 283 settings and examples of such associations directly taken from  
 284 designers’ project experiences. Because of the discrepancy in the  
 285 number of engagement events per transcript, the choice was made to  
 286 keep the counts of associations at the transcript level rather than at  
 287 the engagement level, so as not to increase the impact of transcripts  
 288 with larger numbers of engagement events.

289 **3 Findings**

290 **3.1 Stakeholder Groups, Prototype Forms, and Engage-**  
 291 **ment Settings of Front-End Prototype-Based Stakeholder**  
 292 **Engagement.** Across all prototyping strategies, participants  
 293 engaged a wide range of stakeholders. These stakeholders were  
 294 categorized into three groups: (1) users, (2) expert advisors, and  
 295 (3) implementation stakeholders. Users included active users,

**Table 1 Participant information**

Participant code	Product type discussed in the interview	GH/MN	Company size
A	Treatment (infusion)	GH	Small
B	Treatment (infusion)	GH	Small
C	Diagnostics (hypothermia)	GH	Medium
D	Treatment (phototherapy); diagnostics	GH	Small
E	Equipment (vaccines)	GH	Medium
F	Treatment (blood transfusion)	GH	Small
G	Treatment (infusion)	GH	Large
H	Treatment (hypothermia)	GH	Small
I	Training (maternal health)	GH	Medium
K	Training (maternal health)	GH	Medium
N	Treatment (intubation)	MN	Small
O	Treatment (surgical equipment)	MN	Large
P	Unknown	MN	Large
Q	Diagnostics (imaging)	MN	Large
R	Treatment (surgical equipment)	MN	Large
S	Diagnostics (imaging)	MN	Large
T	Treatment (catheterization)	MN	Large
U	Treatment (catheterization)	MN	Large
V	Unknown	MN	Medium
W	Treatment (prosthetics)	MN	Medium
X	Treatment (catheterization)	MN	Small
Y	Unknown	MN	Medium

GH: global health focus; MN: multinational focus; small: 1–10 employees; medium: 10–200 employees; large: over 1000 employees. Participants with an unknown product type did not provide any specific details about a medical device for confidentiality reasons.

**Table 2 Company and participant background information**

Category	Company headquarters			Company type			
Number of companies	USA 14	India 1	Norway 1	Sole proprietorship 1	Public FP 13	Partnership 1	Nonprofit 1
Category	Age (years)						
Number of participants	Under 30 6	30–40 9	Over 40 6	Unknown 1			
Category	Job tenure (years)						
Number of participants	2 years or less 5	Between 2 and 5 years 6	More than 5 years 11				
Category	Highest degree						
Number of participants	Bachelor's 7	Master's 13	Ph.D. 2				
Category	Gender						
Number of participants	Women 9	Men 13					

296 passive users, proxy users, and secondary-usage stakeholders.  
 297 Broadly, participants described active users and proxy users as  
 298 stakeholders who provided information on the clinical need being  
 299 fulfilled and on the device design. The next main category of stake-  
 300 holders—expert advisors—included people with clinical, product,  
 301 and other knowledge who provided expertise based on their profes-  
 302 sional experience. Implementation stakeholders, including stake-  
 303 holders such as manufacturing, marketing, and supply chain  
 304 stakeholders, provided information on nonclinical aspects of the  
 305 device. Definitions and examples of each stakeholder group  
 306 extracted from the interviews are included in Table 4. Interview  
 307 excerpts are provided in the table, below the definition and exam-  
 308 ples for each group.

309 A variety of prototype forms were used by participants to  
 310 engage stakeholders during front-end design activities. Prototypes  
 311 predominantly represented device ideas or processes. These  
 312 prototypes were categorized into three groups: (1) physical three-  
 313 dimensional (3D) prototypes, (2) two-dimensional (2D) proto-  
 314 types, and (3) digital 3D prototypes. Physical 3D prototypes were

typically described as tangible objects made of craft materials, 315  
 integrated prototypes, existing products used as prototypes, or 316  
 pilot experiments involving a physical prototype used in a real- 317  
 world setting. Crafted prototypes, one type of physical 3D proto- 318  
 type, were made quickly by participants, with readily available 319  
 materials, parts, and rapid prototyping processes. In contrast, inte- 320  
 grated prototypes, another type of physical 3D prototype, were 321  
 made with processes that more closely resembled that of a com- 322  
 mercialized product. 323

2D prototypes were 2D representations of a 3D object, made by 324  
 hand, with digital tools, or a combination of both methods. For 325  
 example, participants described using hand drawings, photorealistic 326  
 renderings, and engineering drawings, and described processes 327  
 through storyboards. 328

Digital 3D prototypes, including computer-aided design draw- 329  
 ings, video recordings, and interactive renderings, were also lever- 330  
 aged with stakeholders during front-end design, notably with 331  
 more technical stakeholders or when showcasing the vision of the 332  
 finished product to stakeholders. Definitions and examples of 333

**Table 3 Prototype-based stakeholder engagement strategies of medical device design practitioners [58]**

Strategy	Label
Brief the stakeholder about the project and the prototype(s) shown	Brief
Encourage the stakeholder to envision use cases while interacting with the prototype(s)	Envision
Have the stakeholder interact with the prototype(s) in a simulated use case	Simulate
Introduce the prototype(s) to the stakeholder in the actual use environment	Introduce
Lessen a prototype's completeness when showing it to the stakeholder	Lessen completeness
Make prototype extremes to show the stakeholder	Extremes
Modify the prototype(s) in real-time while engaging the stakeholder	Modify
Observe the stakeholder interacting with the prototype(s)	Observe
Polish the prototype(s) shown to the stakeholder	Polish
Present a deliberate subset of prototypes to the stakeholder	Subset
Prompt the stakeholder to select prototypes and prototype features	Select
Reveal only relevant information to the stakeholder specific to the prototype or its use	Reveal
Show a single prototype to the stakeholder	Single
Show the stakeholder multiple prototypes concurrently	Multiple
Standardize the refinement of prototypes shown concurrently to the stakeholder	Standardize
Supplement a prototype shown to the stakeholder with different prototype types	Supplement
Task the stakeholder with creating or changing the prototype(s)	Create

**Table 4 Stakeholder group definitions, examples, and data excerpts: implementation stakeholder, user, and expert advisor**

Stakeholder group	Definition	Example(s) within medical device context
Implementation stakeholder	Is directly involved in the adoption of the device and influences the success of the device	
Supply chain stakeholder	Influences the device supply chain; can be an intended actor of the device supply chain <i>[We engage] the supply chain people who tell you what kind of [parts] are available. (P)</i>	Distributors, integration engineers, suppliers and vendors, quality verification stakeholders
Community partner	Collaborates with the design team through a community organization partnership <i>Before going to [a sub-Saharan African country] I emailed several partners who work in family planning and I said, "Listen I'm interested in visiting." (K)</i>	Nongovernmental organizations, abroad offices and organizations, partner universities
Manufacturing stakeholder	Provides manufacturing expertise and insights into implementation constraints; can be the intended device manufacturer <i>When we are in the early phases of design and we are still in the concept generation of the product itself, we do include manufacturing there, because we want to make sure that if we design something that the floor cannot currently produce, they tell us. (Q)</i>	Manufacturing stakeholders internal to the company, external manufacturers engaged as individuals or as company representatives
Financial decision maker	Contributes money, materials, or goods to the project; are engaged when raising funds or reporting progress <i>During the concept phase, to go through each phase [...] you need to go in front of a [board] and present what you have been doing during these different phases. (P)</i>	Internal board members, company leadership during a design review, external granters, project managers, donors
Government stakeholder	Works in government agencies affecting the device implementation in a country <i>There were a few doctors from the government that we reached out to in the early stages of collecting feedback on the idea. We were [...] showing them concepts on paper. (C)</i>	Ministry of health officials who purchase medical devices, members of regulatory bodies (e.g., FDA)
Regulatory stakeholder	Provides expertise on the laws and regulations that govern medical devices <i>If we were to discuss regulatory risks with our consultants, what we would do, we would show them [...] a very detailed description of what the product would do. (F)</i>	Research councils, regulatory experts employed by the company or a hospital to provide regulatory guidance on the device
Marketing stakeholder	Provides expertise on the market landscape, often working in a marketing or sales role <i>Then you have marketing people coming in to say okay here is the market landscape and this is the trend. What are the popular [products] and here's what people don't like about certain types of things. [...] They want to see the [prototype] as it is. (P)</i>	Stakeholders knowledgeable about the medical device market, stakeholders interfacing with users and customers to conduct market research
Customer	Purchases the device but is not the intended user or distributor <i>Once you have something functional, that was when we started sending stuff to investors and to our customers, [to get] evaluated. (H)</i>	Hospital purchasing departments, hospital department heads
User influencer	Influences the use of the device by the active user <i>[What] was very important was the response of the others in the family. We realized that [...] when you put something on a baby, it is not totally the mother's decision. (C)</i>	A mother's family whose beliefs impacted what devices could be used on an infant
User	Uses the device and/or benefits from its primary function once the device is commercialized	
Active user	Operates the device's primary function; also called "primary user" <i>I ran a couple of focus groups with local nurses, based on ideas that our engineers had for upcoming products to see [...] what needs the nurses had that weren't being fulfilled. (B)</i>	Patients who actively use medical devices, healthcare workers (e.g., doctors, nurses), caregivers, and medical trainers and students
Passive user	Is impacted by the outcome of the device but has little to no control over the use of it; also referred to as "incidental user" <i>When you are actually putting the prototype on the baby, the baby is not still. (C)</i>	Patients on whom a procedure was performed with a medical device, (e.g., infants, children, adult patients, and prosthetic users)

**Table 4 (continued)**

Stakeholder group	Definition	Example(s) within medical device context
Proxy user	Shares similarities with the active user but is not an intended user of the device; is leveraged when active users are not accessible <i>I got to the point where I said: “Who has the largest hands here? Who has the smallest hands here?” [...] I’d go around and try [3D printed models] in different people’s hands. (R)</i>	Healthcare practitioners who work in a setting that differs from that of the intended users, laypeople (e.g., friends, co-workers), or the designers themselves
Secondary-usage stakeholder	Interacts with the device outside of its primary function, throughout the product use-phase; also called “secondary user” <i>We would get [the prototype] out in the hands of some service engineers and we would say, “install this and align this tube [...] and tell us what is weird about it.” (S)</i>	Technician, immunization manager, maintenance stakeholder involved in service and upkeep of the device (e.g., installation, charging, sterilization)
Expert advisor	Provides expertise on the device design and usage, and the problem space based on their professional knowledge and experience <i>We can invite people with a special competence within materials or digital solutions that we don’t have in our team. (I)</i>	Clinical experts, product experts, other medical device company employees, academics, professors, members of partnering organizations

**Table 5 Prototype form definitions, examples, and data excerpts: physical 3D, digital 3D, 2D**

Prototype form	Definitions	Example(s) within the medical device context
Physical 3D	A physical, three-dimensional representation of an idea	
Crafted prototype	A physical prototype made of materials that were readily available and quick to assemble; these prototypes were often qualified as rough	
<i>Rapid prototype</i>	A crafted prototype made from a rapid manufacturing method, such as 3D printing, laser cutting, rapid machining, or molding  <i>3D printing is a more functional evaluation, I would say. Say, for example, [our device has] a space where we keep the [medication], we could organize the [medication], and we use trays to pull in, pull out, and stuff like that. That’s more functional. (E)</i>	A 3D printed prototype of a device’s outer shell made from stereolithography (ABS); a 3D printed functional prototype of a transportation device for medicine
<i>Constrained prototype</i>	A crafted prototype made from materials with fixed form, such as hardware parts and modified existing products  <i>They had ketchup bottles that you squeezed—it was whatever material that was available—and it had the power to communicate that ‘you would put something on your body, and you can control these [ketchup bottles]. But it wasn’t anywhere convincing as a final solution. (I)</i>	Plier handles used to mimic functional actuation; scrub brushes and other items with ergonomic gripping handles used to test grip when users wore bloody gloves
<i>Freeform prototype</i>	A crafted prototype made from easy-to-shape materials such as clay, foam, wood, and other craft materials  <i>We use more foam to do esthetic models when we want to do some styling of a product [we ask:] “Does this product relate to the ruggedness of the product that you want?” (E).</i>	A versatile clay handle that could be molded into various shapes; a foam model to test the fit of the device concept in the laboratory space
Integrated prototype	A physical prototype that had one or more refined aspects of the form or function, built using refined materials and processes  <i>You would rather get a looks-like, feels-like prototype model in their hands, and describe how it’s going to work. (G)</i>	An esthetically accurate but nonfunctional prototype of an injection device; a fully functional prototype of an infant treatment device with no esthetic finish
Existing product	A product on the market used as a prototype to benchmark, trigger memories and reactions, and/or serve as a reference in conversations  <i>We did use some bigger syringes to actually give an example of what [the device] would look like, sometimes. [...] So, usually, that was the replacement image that we would give so people would understand the general operation. (F)</i>	Existing body simulators shown to discuss the important anatomy to include in the product; current operating room tools used as stimuli for conversation
Pilot	A small-scale test where stakeholders used a physical prototype in its intended environment for multiple days  <i>We’ll leave a prototype behind in a facility for a month, then we’ll go pick it up and we’ll see what happened to it? [...] Just to try to like see more about the lifetime. (K).</i>	A functional training-device prototype used by teachers and students in a clinical setting for multiple days

Table 5 (continued)

Prototype form	Definitions	Example(s) within the medical device context
Digital 3D	A dynamic three-dimensional representation of an object or process, created in part with digital tools	
CAD model	A 3D CAD model, sometimes accompanied by computational tests  <i>[For this project], we don't do a lot of hard prototypes. A lot of it is virtual prototypes. [...] Very rarely do we build a full system and send it [to the hospital] just because that's like a million-dollar prototype. (Q)</i>	Center of gravity analysis of a handheld battery-powered device; finite element analysis of a 3D model
Video recording of a prototype	A video recording of a physical prototype  <i>We make a video of a prototype we're making and have one or two key questions or have Skype calls. (K)</i>	A video of a heat test of a device
Interactive rendering	A digital model that could be manipulated to move and mimic functionality through digital interfaces  <i>We had [stakeholders] program the [operation] on the tablet with the screen mocked up. (V)</i>	A digital interface flow mockup; a CAD model of a device manipulated on-screen to mimic the function
2D	A still representation of an object or a process, created by hand and/or with digital tools	
Drawing	A sketch (rough or refined) used to generate and communicate ideas and/or design concepts to/with stakeholders  <i>So, sometimes we just tried kind of pencil and paper to make it look like not even printed out from CAD. Like, just redraw what I had in CAD with pencil and paper because then people would give me more, like, "Oh, she's early on, I can go ahead and give my input." (N)</i>	Stakeholders' drawings of ideal device features; a sketch of the device functional architecture; industrial drawing of device features; drawing of the overall system
Storyboard	Consecutive images detailing a use case of a product to communicate the intended interaction of the product with a person or environment  <i>They' repanels, and it's one of the best explanations we have. [...] Being able to put that together to show context operation and the situational context around it has been much easier, [...] being able to show that visually, versus just trying to explain it. (F)</i>	A series of images depicting how to store, clean, and interact with a device in a clinical setting; a series of images depicting the current workflow of clinicians and how the device integrates into the workflow
Photograph	A photography of a physical object, sometimes digitally altered  <i>The entire first six months, we didn't really send any physical prototypes at all, instead, we would just take pictures, [...] have a ruler in the picture, and then send any sort of test data. (H)</i>	Photographs of a nonfunctional prototype used to compare with photographs of predicate devices
Rendering	A virtual image digitally processed using color and shading to make it appear three-dimensional  <i>When it comes to the user interface, [...] we've just done on the computer and graphics. We can actually send people a bunch of illustrations and [ask]: "What do you think of this? What does this mean to you?" (A)</i>	A rendering of the instruction manual of the device; fast and low-cost renderings of the device with different color variations; device interface mockup
Engineering drawing	An image of the internal mechanisms of a device appended with written information about the image  <i>We would send them pictures of cross-sections, pictures of various parts involved, a more verbal description of what this part does, and what this component does. (E)</i>	Drawing of the inner mechanisms of a device with a list of components, specifications, and dimensions; labeled pictures of device parts with a description of functions

334 prototype forms in the medical device design context are included  
335 in Table 5.

336 Participants engaged stakeholders with prototypes in various  
337 settings, which were categorized into four groups: (1) meeting  
338 spaces, (2) simulation environments, (3) real use environments,  
339 and (4) distant settings. Definitions and examples within the medi-  
340 cal device context for each setting are included in Table 6.

341 **3.2 Associations of Stakeholders, Prototypes, and Settings.**

342 The patterns observed for the stakeholder group engaged, the  
343 prototype(s) used for the engagement, and the setting in which the  
344 engagement occurred were defined as associations of stakeholders,

prototypes, and settings. The summarized frequencies of the associations at the transcript level are depicted in Fig. 1. Details about some of these associations are provided in this section. Italicized words within the text refer to categories of stakeholders, prototypes, settings, and strategies.

All stakeholders, notably *users*, were most often engaged in *meeting spaces* where they could interact casually with the prototype(s) presented. Participants described meeting *users* most often in the *user's own meeting space* because of availability and time constraints, with various forms of prototypes.

When engaging *users* in *simulation environments*, participants described only using *physical 3D* prototypes. Design practitioners

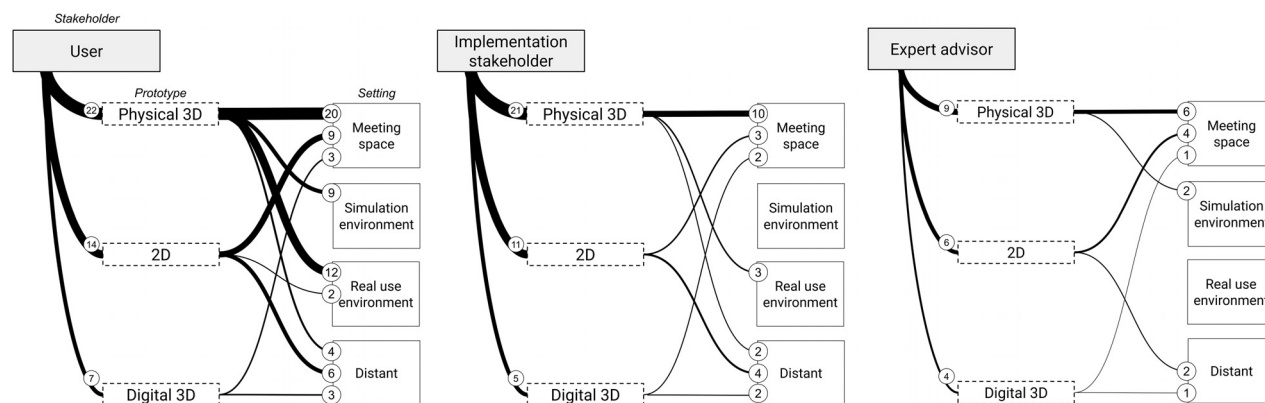
**Table 6 Setting type definitions, examples, and data excerpts**

Setting type	Definition	Example(s) within medical device context
Meeting space	A face-to-face meeting environment that did not include elements of the real use environment of the device	
<i>Designer's workspace</i>	A space familiar to the design team	designer's conference room or office
	<i>When you do the testing, you actually invite nurses, or you have a van you reserve to have nurses come to this venue. (P)</i>	
<i>Stakeholder's workspace or living space</i>	A space familiar to the stakeholder	Hospital procedure rooms and hallways when interacting with clinical professionals, user's home, doctor's office
	<i>We were interacting with [...] the head of the departments sitting in their offices. (C)</i>	
<i>Neutral location</i>	A space unfamiliar to both designer and stakeholder	A conference or convention, a networking event, a hack-a-thon
	<i>We were at a little symposium conference or something where we had a booth, and we had our demo setup and all. (X)</i>	
Simulation environment	An environment made to resemble the user's environment	Cadaver lab, usability lab with anatomical models for demonstration and/or testing purposes
	<i>We used simulation mannequins and the clinical simulation center at the hospital a lot when we would meet with users so that they could try it out. (N)</i>	
Real use environment	An environment where the device would be used once commercialized	In the community or private home of the user, a hospital operation room or patient room, a training environment, a manufacturing floor
	<i>So, when we interact with the nurses it was actually in the ward next to the baby. (C)</i>	
Distant	A virtual online environment through which communication takes place	Skype call during which prototypes were demonstrated to stakeholders, a physical or virtual prototype was sent to the stakeholder (via mail or email) and stakeholder provided feedback via email or phone call
	<i>With those visuals, we send it to them, and then we get on a teleconference call, and say, "This is our new design. What do you think? Do you have any feedback?" (E)</i>	

357 replicated the conditions of use with supporting objects and arti-  
 358 facts used in the actual use environment. Some *simulations* were  
 359 unrefined, using readily-available materials to simulate the envi-  
 360 ronment, and some *simulations* were conducted in cadaver labs,  
 361 wet labs, or other high-fidelity *simulation environments*.

Participants asked *users* to perform tasks with the prototype 362  
 within the simulated setting or demonstrated the prototype to 363  
*users*. 364

Participants also described engaging *users* mainly with *physical* 365  
 3D prototypes in the *real use environments* spanning one or 366



**Fig. 1 Stakeholder-prototype-setting associations. Transcript level counts of associations are included for each association and the connecting lines thickened as counts increase.**



367 multiple stages of the product’s lifecycle, so they could prompt  
 368 the user to perform tasks with the prototype in the use environ-  
 369 ment. In two cases, 2D prototypes were used to supplement the  
 370 physical 3D prototypes, such as a digital interface on a tablet that  
 371 demonstrated the programing interface of the device.

372 To engage distant users, although 2D and digital 3D prototypes  
 373 were easier to send to users, participants also sent physical 3D  
 374 prototypes home with users to test over multiple days or sent  
 375 physical 3D prototypes to distant users via mail, to then gather  
 376 feedback on their experience.

377 Participants described engaging implementation stakeholders with  
 378 prototypes most often in meeting spaces. Because many implementa-  
 379 tion stakeholders were internal to the participants’ companies, they  
 380 were engaged in the designer’s space. Participants reported that  
 381 implementation stakeholders were seldom engaged in a simulation or  
 382 real use environment. One participant gave a prototype to the cus-  
 383 tomer to perform their own tests in a real use environment and one  
 384 participant brought a physical 3D prototype to the manufacturing  
 385 floor to gather feedback from manufacturing stakeholders on the  
 386 manufacturing process. A subset of implementation stakeholders was  
 387 engaged remotely, in a distant setting. Community partners in other  
 388 countries were often engaged remotely, along with international sup-  
 389 ply chain, manufacturing, government, and regulatory stakeholders,  
 390 either through sending prototypes via email or mail or by showing  
 391 prototypes via videocall.

392 Expert advisors were also cited as being mostly engaged in the  
 393 designer’s space or engaged in a distant setting when meeting in per-  
 394 son was not possible, in which case using 2D and digital 3D proto-  
 395 types were easiest. If the advisors were clinical specialists, then they  
 396 might have been engaged in a simulation environment to try out the  
 397 prototype or witness a demonstration. No participant described engag-  
 398 ing expert advisors with prototypes in the real use environment.

399 **3.3 Associations of Stakeholders, Prototypes, and Strategy**  
 400 **for Prototype-Based Stakeholder Engagements.** In this section,  
 401 multiple patterns observed for the stakeholder groups engaged,  
 402 the prototypes used for the engagement, and the strategies leverag-  
 403 ed during the engagement are presented. These patterns were  
 404 defined as associations across stakeholders, prototypes, and strat-  
 405 egies, and the summarized frequencies of the associations at the  
 406 transcript level are presented in Figs. 2–4. First, the associations  
 407 related to users with prototypes and strategies (Sec. 3.3.1) are pre-  
 408 sented, then implementation stakeholders (Sec. 3.3.2), and finally  
 409 expert advisors (Sec. 3.3.3). This section contains excerpts of

engagement events during which participants explained their  
 choice of association.

3.3.1 *User–Prototype–Strategy Associations.* The patterns  
 observed for prototypes and strategies employed with users are  
 summarized in Fig. 2 (the strategies are ordered alphabetically in  
 all subsequent figures to support comparison across figures). Partic-  
 ipants most often described engaging users with physical 3D  
 prototypes during front-end design activities. In a subset of the  
 engagement events, a 2D prototype was chosen to achieve a given  
 engagement strategy, while digital 3D prototypes were used in  
 presentations, to prototype an interface, to supplement other proto-  
 types, or were sent to distant users.

Participants discussed using physical 3D objects to engage  
 users (Fig. 2(a)) with all 17 strategies. For example, Participant N  
 said she felt that users could not envision the idea through other  
 prototype forms:

Having something physical that they could hold and having  
 something that they could move, and use, made the quality of the  
 interaction so much better because some people just can’t imagine  
 that next step.

Participant F expressed that a physical 3D prototype generally  
 led to ‘better’ feedback than other forms:

A lot of those early, early 3D printed and machined prototypes,  
 definitely for end-users over in [a sub-Saharan African country] got  
 the best responses. [...] With the physicians, there was a lot of inter-  
 est around how some of the very specific features of the device and  
 how would apply to specific surgeries. A lot of the nurses were more  
 focused on usability.

Participants leveraged different forms of physical 3D proto-  
 types for different strategies (Fig. 2(b)). To task the stakeholder  
 with creating or modifying prototypes (create), participants used  
 crafted prototypes. For example, Participant N described making a  
 rough handle prototype out of foam and asking users to shape it as  
 they desired:

We did a rough cut of how the handle shape would be and then we  
 just let them shave it off how they think it would be good. [...] We  
 used playdough to have them think: ‘How would you want this built  
 out? How big would you want it? Where do you want the thumb to  
 sit?’.

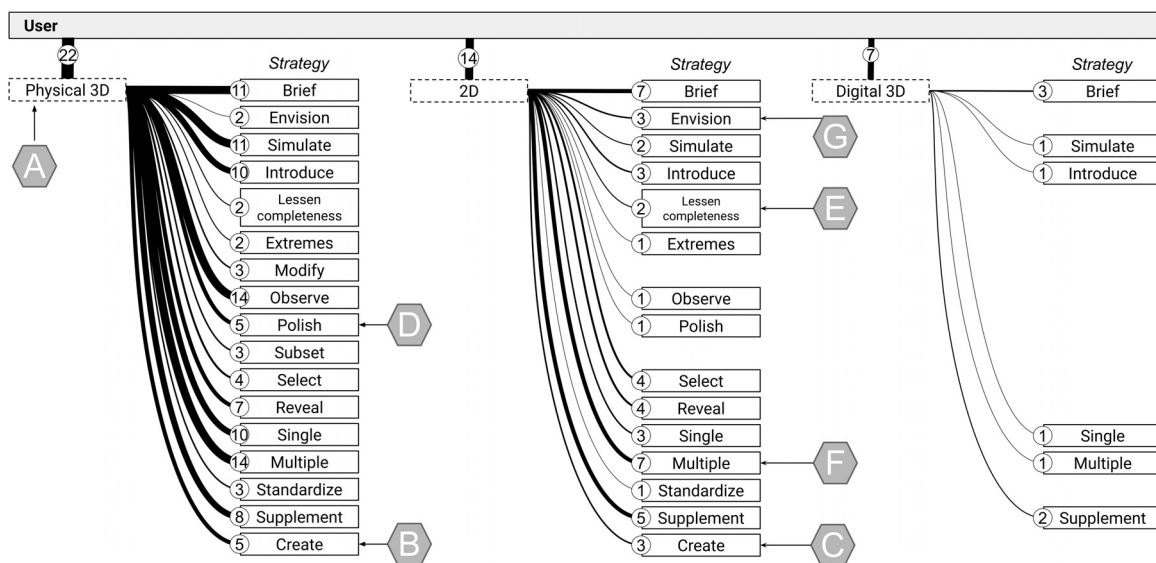


Fig. 2 User–prototype–strategy associations. Transcript level counts of associations are included for each association and the connecting lines thicken as counts increase.

449 Users tasked by Participant N with manipulating malleable  
 450 materials and combining the manipulated materials with a base  
 451 prototype enabled the users to make quick and easy modifications  
 452 to communicate their preferences.

453 Participants expressed using 2D prototypes to engage users  
 454 with the create strategy (Fig. 2(c)). However, using drawings for  
 455 active stakeholder engagement was perceived as ineffective for  
 456 Participant B, who described users' discomfort when asked to  
 457 draw:

458 We said, 'Here is a card, you can draw what you think the [device]  
 459 would be, or you can write down characteristics that you would have  
 460 in something that you would make. [...] Only two [users] drew.'

461 Participants described leveraging the strategy to polish the proto-  
 462 types shown to the stakeholder (polish) with physical 3D proto-  
 463 types and users (Fig. 2(d)). For example, Participant A described  
 464 removing less esthetically pleasing and unfinished elements of a  
 465 prototype to avoid distracting users:

466 [Users] can't help but focus on the unfinished aspects even though  
 467 you know it's not really a concern at this point. So when I'm trying  
 468 to put something out in the field, I'm trying to get it as finished as  
 469 possible, even just esthetically. I need to spray paint it or something  
 470 because people will look at a 3D print and be like, why is it this  
 471 color?

472 For a subset of strategies, physical 3D prototypes were seen as  
 473 detrimental during early engagements with users. For example,  
 474 Participant N discussed using 2D prototypes, such as drawings, to  
 475 not bias users with a more advanced prototype and to encourage  
 476 them to provide input, following the strategy to lessen a proto-  
 477 type's refinement when showing it to the stakeholder (lessen com-  
 478 pleteness) (Fig. 2(e)):

479 Sometimes we just tried kind of pencil and paper, [...] just redraw  
 480 what I had in CAD with pencil and paper because then people would  
 481 give me more, like, 'Oh, she's early on, I can go ahead and give my  
 482 input.'

483 Participants also described using renderings, another form of  
 484 2D prototypes, to show multiple prototypes to the stakeholder con-  
 485 currently (multiple) (Fig. 2(f)). Participant A described how ren-  
 486 derings allowed different design concepts to be compared without  
 487 creating multiple different physical 3D prototypes, hence saving  
 488 resources:

Because you can do shading and stuff and make it look pretty good 489  
 and it saves you from having to go through an actual production of a 490  
 3D print or something like that which is not cheap. 491

Another example was the use of 2D prototypes to encourage 492  
 the stakeholder to envision use cases while interacting with the 493  
 prototype(s) (envision) (Fig. 2(g)). 2D prototypes provided 494  
 Participant D with additional opportunities to evoke use cases: 495

Showing this abstract device that's floating on a white background, a 496  
 lot of times people can mistake even understanding what the device 497  
 does. [...] We also did a version where we a little bit clumsily 498  
 photoshopped it into a photo of a real person [...] and tried to show 499  
 where the device would go. 500

3.3.2 Implementation Stakeholder-Prototype-Strategy Asso- 501  
 ciations. A wide variety of implementation stakeholders, such as 502  
 manufacturing, marketing, and government stakeholders, were 503  
 engaged during the front end. The association frequencies of 504  
 implementation stakeholders with the prototypes and strategies 505  
 used are summarized in Fig. 3. 506

Physical 3D prototypes and 2D prototypes were both used with 507  
 implementation stakeholders. Digital 3D prototypes were sent to 508  
 distant implementation stakeholders or were used during design 509  
 reviews with financial decision-makers. 510

Some participants showed polished prototypes to financial deci- 511  
 sion-makers (Fig. 3(h)). Participant A described polishing 3D 512  
 printed prototypes when engaging financial decision-makers to 513  
 impress and lend legitimacy to the project: 514

For funding purposes, it would be the nicest looking, most functional 515  
 device you had at any given time because you want to impress. You 516  
 do not want to show them a bunch of junk. 517

Some participants described using digital 3D prototypes during 518  
 design reviews with the company's internal financial decision- 519  
 makers (Fig. 3(i)), as exemplified by participant Q: 520

Another stakeholder is like the leadership team, right? The people 521  
 who are our leaders guide the direction. With them, we would use a 522  
 combination of the 3D models and finite element analysis to show 523  
 them that the design is solid and fair. 524

However, when engaging external financial decision-makers or 525  
 customers, some participants cited using physical 3D prototypes 526  
 (Fig. 3(j)). Participant C, for example, chose physical 3D 527

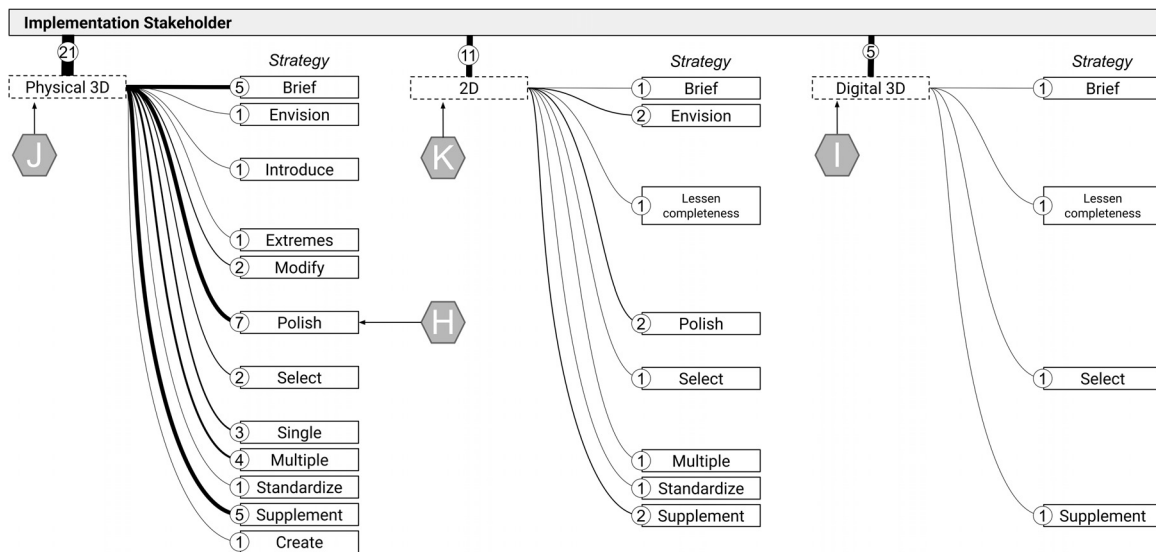


Fig. 3 Implementation stakeholder-prototype-strategy associations. Transcript level counts of associations are included for each association and the connecting lines thickened as counts increase.

528 prototypes because they perceived them as more convincing than  
529 other prototype forms:

530 We were pitching our concept [to external financial decision-  
531 makers]. If we were showing things to them which were not real, if  
532 for example, if I'm showing a presentation or showing a booklet  
533 [...], that was less convincing as opposed to if I had this thing that I  
534 would actually demonstrate in front of them.

535 Participant E described engaging *government* and *regulatory*  
536 stakeholders with 2D prototypes during front-end design to dis-  
537 cuss device features and regulatory and manufacturing risks (Fig.  
538 3(k)). Participant E described how these specific prototypes,  
539 including *drawings* and *storyboards*, were relevant to the concerns  
540 of this stakeholder group:

541 We would send them pictures of cross-sections, pictures of various  
542 parts involved, and a more verbal description of what [each compo-  
543 nent did], and a very detailed description of what the product would  
544 do. That is [...] enough for regulatory people to comment, and come  
545 back and tell, or, "You seem to have a reusable component. You  
546 seem to have a sterilizable product." [...] [For the ministry of health  
547 officials] it does not make sense to take a huge foam mockup to  
548 them. They are more interested in what does it cost and where are  
549 you manufacturing it, and what is the battery life [...]. You make  
550 really quick sketches or renders to just convey the idea. [...] They're  
551 not going to be fixated on the visuals [and] would just look at the  
552 bullet points [...] I think PowerPoint presentations with visuals of  
553 sketches, [...] storyboards would be good enough.

554 3.3.3 Expert Advisor–Prototype–Strategy Associations. Partic-  
555 ipants described engaging *expert advisors* with a variety of pro-  
556 totypes during front-end design, but described leveraging fewer of  
557 the 17 strategies with *experts* than with other stakeholder groups.  
558 Associations of *expert advisors* with prototypes and strategies are  
559 summarized in Fig. 4.

560 *Expert advisors* generally provided technical feedback, such as  
561 feasibility, based on their domain-specific knowledge. Hence, partic-  
562 ipants discussed showing *expert advisors* more technical proto-  
563 types, such as functional *physical 3D* prototypes, *2D* prototypes of  
564 various concepts and device architectures for down-selection, and  
565 *digital 3D* prototypes. Some clinical *advisors* also provided feed-  
566 back on the ergonomics of *physical 3D* prototypes.

567 One strategy most cited to gather feedback from *expert advisors*  
568 during front-end design was to *supplement the prototype shown to*  
569 *stakeholders with additional representations (supplement)*, with

2D and *physical 3D* prototypes (Fig. 4(l)). Participant W  
described bringing *drawings* and a physical mockup to an engage-  
ment with an *expert advisor*:

In between user tests, we'd go to an [expert advisor] with a new idea  
or concept in mind, usually accompanied by a drawing or a really  
crude physical mock-up that shows how it's supposed to work, and  
consult the [expert advisor] and get their feedback, opinions about  
whether or not they thought that idea would work from a patient  
standpoint, make sure it would work from an anatomy standpoint.

#### 4 Discussion

Our findings revealed that medical device design practitioners  
engaged a diverse set of stakeholders with prototypes during their  
front-end design processes. Although the stakeholder groups  
engaged by participants in this study have been reported in the lit-  
erature (broadly, not specifically with respect to front-end design  
engagement supported by prototypes), only a subset of the stake-  
holder groups are currently represented in design frameworks.  
The stakeholder group *users*, including *active* and *passive users*,  
appear in multiple stakeholder frameworks [3,57,59]. The promi-  
nent presence of *users* in stakeholder frameworks aligns with liter-  
ature tying user engagement to project success, notably during its  
earliest stages [5,60]. Other stakeholder groups reported in this  
study have been less frequently incorporated into published stake-  
holder frameworks. For example, *proxy users*, *secondary-usage*  
stakeholders, and *expert advisors*, which were identified in this  
study, have only been described in individual medical device  
design studies [4,13,61], but are absent from many frameworks  
(e.g., Refs. [3,57], and [59]).

Yock et al. [3] and USAID ready, set, launch [57] mentioned  
trade groups and healthcare facilities as two important stakeholder  
groups to engage during a design process. Although healthcare  
facility stakeholders were mentioned several times by participants  
as the gatekeepers to healthcare practitioners (*active users*),  
healthcare facility stakeholders were not engaged with prototypes  
by the participants in this study. The lack of healthcare facility  
stakeholders mentioned in this study might have resulted from the  
types of medical devices discussed and/or because of the contexts  
in which the participants worked.

A variety of prototypes were leveraged by the medical device  
design practitioners in this study to engage stakeholders during  
the design front end. Multiple classifications of prototype forms  
exist, but no single classification matched the breadth and depth  
of prototype forms described by the participants. The list in this

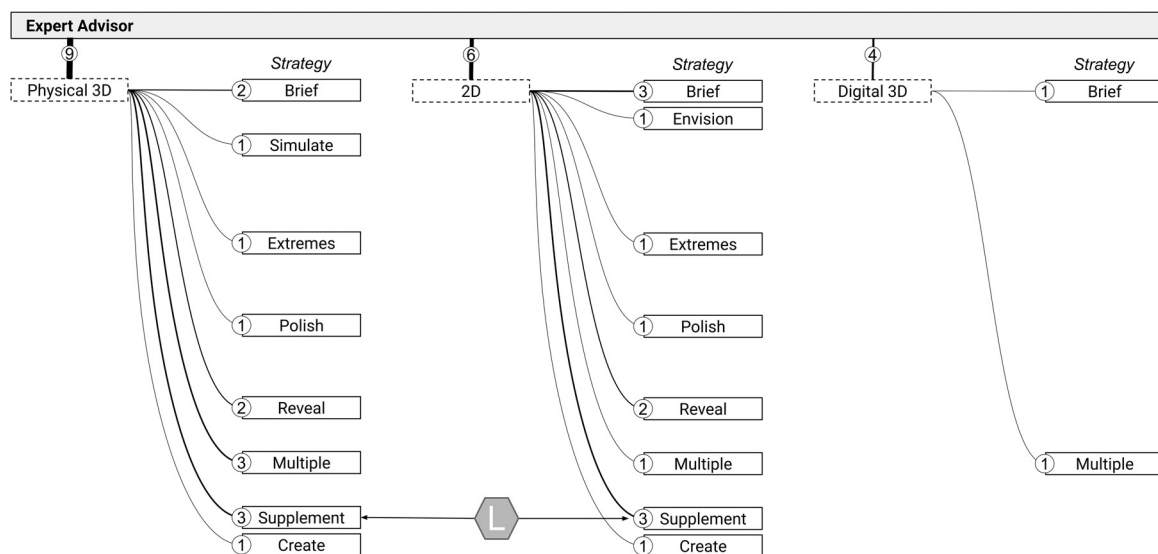


Fig. 4 Expert advisor–prototype–strategy associations. Transcript level counts of associations are included for each association and the connecting lines thickened as counts increase.

613 study most resembles taxonomies that describe the materials and  
614 fabrication approaches for creating prototypes [62–65]. These tax-  
615 onomies were used to help define the codes.

616 Simple *physical 3D* prototypes were typically described by partic-  
617 ipants by the manufacturing methods used to fabricate them and/  
618 or the materials used to develop the particular form factors (e.g., *3D*  
619 *printed*). However, when describing more complex *physical 3D*  
620 prototypes, created with multiple types of materials and/or fabrica-  
621 tion methods, participants tended to instead describe their function-  
622 ality and/or esthetic properties. Hence, the *integrated* prototype  
623 category emerged based on the work by Jensen et al. [47]. Houde  
624 and Hill [32] stated that describing prototypes by the tools used to  
625 create them and their level of refinement can be distracting, and  
626 they proposed that prototypes should be described by their goals  
627 rather than their form. While some participants did use “goal-  
628 oriented” language to describe early prototypes (e.g., “works like”),  
629 most did not. One can hypothesize that the materials of simple pro-  
630 totypes and the refinement of more complex prototypes may be  
631 salient characteristics that were easier to recall and thus used as  
632 descriptors, while the goals of the prototypes might not have been  
633 as easy to articulate or were not readily recalled by design practi-  
634 tioners’ during the interviews (i.e., might have required specific  
635 interview prompts to elicit this information).

636 Furthermore, when making *2D* prototypes, participants commonly  
637 described *drawings* of concepts or *photographs* of physical  
638 prototypes that were then enhanced through digital alterations.  
639 Hence, the distinction between paper and digital prototypes was  
640 blurred. Similarly, some *CAD models* (*digital 3D* prototypes)  
641 were used as a basis for *renderings*, and the actual *CAD model*  
642 was seldom shown to stakeholders. The advent of virtual and aug-  
643 mented reality prototyping technologies may increase the use of  
644 *digital 3D* prototypes in the future [66] and might further blend  
645 the lines between *2D*, *digital 3D*, and *physical 3D*. Hence, a  
646 material-focused description of prototypes might be increasingly  
647 difficult to articulate as prototypes are created through mixed  
648 media to a greater extent.

649 Several settings were identified in this study for engaging stake-  
650 holders with prototypes during participants’ front-end design  
651 activities. Most front-end stakeholder engagements with proto-  
652 types occurred in *meeting spaces*. In addition, early in their design  
653 processes, participants engaged *users* in *simulation* and *real use*  
654 *environments*, which aligns with regulatory guidelines for medical  
655 device development that mandate designers to seek to understand  
656 the actual use environment of a device, through user feedback and  
657 observations [67]. The use of *simulation environments* is well  
658 reported in medical device design literature [9]. The advent of vir-  
659 tual reality may enhance the opportunities for designers to engage  
660 stakeholders in *simulation environments*, a resource-intensive  
661 endeavor [68] and one not emphasized in this study sample.

662 In addition to *users*, a few participants also engaged *implemen-*  
663 *tation* stakeholders in *real use environments*, such as on the manu-  
664 facturing floor, to explore other parts of the lifecycle of the device.  
665 The high proportion in the sample of engagements conducted in  
666 *real use environments* may have stemmed from the fact that half of  
667 the study sample designed medical devices for use in LMICs, and  
668 hence traveled to their *users*, with potentially greater access to the  
669 *real use environment*. Testing a prototype in its use environment  
670 has been shown to be essential to uncovering previously unknown  
671 requirements [69]. Mattson and Wood, 2013, suggested integrating  
672 testing of the artifact in the *real use environment* throughout the  
673 whole design process rather than as a “final step” [39].

674 Participants also leveraged *distant* environments to avoid the  
675 financial expenditures and time associated with in-person visits.  
676 The use of *distant environments* was sometimes coupled with lon-  
677 ger periods of prototype testing performed in the *real use environ-*  
678 *ment* when participants sent *physical 3D* prototypes to *users* to  
679 evaluate in the *real use environment*.

680 The findings from this study illustrate the broad combinations  
681 of strategy, stakeholder, prototype, and/or setting choices made by  
682 medical device design practitioners for stakeholder engagements

with prototypes during front-end design activities. Some associa- 683  
tions appeared more frequently in the dataset, for example, partic- 684  
ipants demonstrated a preference for *polishing* prototypes as 685  
opposed to *lessening the completeness* of the prototype when 686  
engaging *implementation* stakeholders. This tendency might have 687  
been due to a high number of engagement events where *financial* 688  
*decision-makers* were shown *polished* prototypes to gain their 689  
support, where the commonly accepted practice of showing *users* 690  
low-fidelity prototypes *constructed quickly [providing] limited or* 691  
*no functionality* to encourage preliminary feedback [70, p.78] did 692  
not apply. Furthermore, the strategy to *supplement* was common 693  
across all stakeholder groups and prototype forms, which might 694  
indicate that for many stakeholder engagement activities, a single 695  
prototype form does not adequately support the full range of 696  
stakeholder engagement activities. 697

698 In our data set, *expert advisors* were not associated with a wide 699  
variety of strategies nor engaged at high frequencies. This finding 700  
may have resulted from the existence of common disciplinary 701  
“language” shared between designers and *advisors* and/or the 702  
nature of the relationship between *advisors* and medical device 703  
companies where *advisors* may have been perceived to be 704  
extended members of the design team and therefore the engage- 705  
ments might have been less formal and resulted in less strategic 706  
pre-engagement planning work.

707 Participants highlighted associations of *2D* and *digital 3D* pro- 708  
totypes with specific stakeholders, based on the technical back- 709  
ground of stakeholders. For example, nontechnical nonuser 710  
stakeholders were often shown *2D* prototypes (particularly *gov-* 711  
*ernment* and *regulatory* stakeholders), while technical stakehold- 712  
ers (e.g., *expert advisors*, internal *financial decision-makers*), 713  
were shown *CAD models*. *CAD models* can communicate func- 714  
tional and technical aspects of the prototype and might be harder 715  
to understand when one is not familiar with *CAD* software, which 716  
could explain their limited use with stakeholders other than those 717  
interested in the project’s technical feasibility. Prior research in 718  
the automotive industry has shown that to convince stakeholders 719  
of the potential of a project, such as *financial decision-makers*, 720  
strategies comparable to *supplement* are leveraged, and *physical* 721  
*3D* and *2D* prototypes such as PowerPoint slides, and diagrams 722  
have been used in conjunction with *video recordings* of mockup 723  
scenarios [71]. In contrast to internal *financial decision-makers*, 724  
external *financial decision-makers* were presented with *physical* 725  
*3D* prototypes that were *polished*. Changing the engagement 726  
parameters based on the stakeholders’ technical backgrounds has 727  
been recommended by authors in the software design space 728  
[72,73] and one can see such changes described in the study data. 729  
Future research could include the technical background of stake- 730  
holders in their categorization as well as their internal/external 731  
categorization.

732 The many associations found in this study can form the basis of 733  
a toolkit for stakeholder engagement with prototypes during front- 734  
end medical device design. While more research is needed to 735  
understand specific associations, a reassuring subset of the find- 736  
ings aligned with associations that have previously been reported 737  
in the literature across various design fields. For instance, strat- 738  
egies leveraged primarily with *users*, such as to *simulate*, *observe*, 739  
*subset*, and *reveal*, were strategies typically found in guidelines 740  
for usability testing and medical device design [3,9]. Participants 741  
described applying such best practices during very early informal 742  
testing scenarios to better understand the requirements around 743  
usability and user preferences. *Physical 3D* prototypes were 744  
emphasized by participants as the most effective prototypes to 745  
engage *users*, an existing recommendation in engineering design 746  
texts [74].

747 **4.1 Limitations.** Limitations of the study included partici- 748  
pants’ open interpretations of what constituted front-end design 749  
activities. Although a definition was provided at the start of each 750  
interview, participants had varying perceptions of what consti- 751  
tuted front-end design activities. Further, participants had

752 different job roles and worked on different types of medical devices, which may have affected their front-end design experiences. 753 To partially mitigate such effects, the pool of prospective participants was intentionally limited to those individuals that had prior 754 experience designing mechanical and electromechanical medical 755 devices. Although narrowing the participant pool controlled for 756 some factors, it limited the diversity of the sample with respect to 757 the broader medical device industry. Participants were mostly 758 from U.S.-based companies, which further limited the generaliz- 759 ability of practices across geography and contexts. 760

761 The stakeholder groups emerged based on participants' descrip- 762 tions of their roles and the type of feedback stakeholders provided. 763 However, some stakeholders could have belonged to multiple 764 groups. For example, a clinician expert advisor or a community 765 partner could have sometimes acted as a proxy user or active user. 766 Hence, frequencies of stakeholder groups, along with prototype 767 forms, setting types, and associations, require further study to 768 determine a more specific prevalence of behaviors. 769

770 **4.2 Implications.** Practitioners, both novice and professional, 771 can use the lists developed in this study to evaluate their stakeholder 772 engagement plans and strive to consider more diverse approaches 773 to front-end design stakeholder engagements with prototypes. By 774 developing general definitions of stakeholders, prototypes, and set- 775 tings, the results may be applicable across industries and contexts. 776 The domain-specific examples provided illustrated different stake- 777 holders, prototypes, and settings with nuanced explanations, appli- 778 cable to medical device design. The associations of strategy, 779 stakeholder, prototype, and setting exemplify the various intentional 780 choices of design practitioners when engaging stakeholders with 781 prototypes during the design front end. High-frequency associations 782 can be used as guidelines for promoting novice designers' aware- 783 ness of ways of engaging stakeholders with prototypes. Lower fre- 784 quency associations could inspire potentially novel stakeholder 785 engagement approaches for seasoned practitioners.

786 **5 Conclusion**

787 This study provided a comprehensive description of stakehold- 788 ers (*users, implementation stakeholders, and expert advisors*), 789 prototypes (*physical 3D, 2D, and digital 3D*), and settings (*meet- 790 ing space, simulation environment, real use environment, and dis- 791 tant*) leveraged by practitioners during front-end medical device 792 design activities. The breadth of stakeholders, prototypes, and set- 793 tings illustrates the many ways practitioners conduct front-end 794 activities (e.g., engaging *proxy users* and *government* stakeholders 795 with prototypes, using *constrained* and *free form physical 3D* pro- 796 totypes or *photographs* and *video recordings* of prototypes). The 797 descriptions and categorizations of stakeholders, prototypes, and 798 settings, as well as the rationales provided for using specific forms 799 of prototypes for engaging specific groups of stakeholders in cer- 800 tain settings, have the potential to enhance existing design frame- 801 works and inform design practitioners' front-end prototyping 802 practices with stakeholders. The results of this study were based 803 on practitioners' perceptions and recollections of prototyping 804 strategies used; additional research could explore which of these 805 strategies are most effective in various contexts. Future work 806 should also explore the transferability of these findings across 807 industries.

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**Appendix A: Definitions Framing the Research Questions** 819 820

Word	Definition
Front-end design activities	Front-end design activities include problem identification and needs findings, problem definition (e.g., requirements and specifications development), background research, concept generation, early prototyping, and concept selection. Front-end design activities do not include evaluative activities (e.g., clinical trials, requirement verification, summative usability testing).
Prototype	A representation of a process (the procedure), a system, or a subpart of the designed product, such as mockups, CAD models, drawings, scenarios, and other representations of the product or its use.
Stakeholder	Anyone who will affect or be affected by the product at some point, including end-users, colleagues, manufacturers, clients, policymakers/ministry officials, technicians, and procurement officers.
Setting	Locations where an interaction between a designer and a stakeholder occurred using a prototype during the front-end activities of medical device design.

**Appendix B: Sample Interview Questions** 821

Theme	Example question
Stakeholder groups	Who were the stakeholders you engaged with during your project?
Prototype forms	Could you go over the different types of prototypes you used during the front-end phases of the project to engage with stakeholders?
Associations	Did you use different types of prototypes when you were in a different setting with different stakeholders? Could you describe these choices? Can you tell me how you used these prototypes to engage with the different stakeholders? Could you describe the interactions with stakeholders in more detail?
Engagement event exploration	Could you focus on a requirement that was really informed by the use of a prototype(s) with stakeholders? One that you might not have uncovered, had you not had the prototype? Why was the prototype crucial in the discovery? Who was the stakeholder? Where did the interaction take place? Was the context important to this discovery?

**Appendix C: Example Engagement Event From Ref. [75]** 822

823 Interview data excerpt: 824 I had to work on ways how to attach [the device]. We got a collection 825 of nurses, both U.S. based nurses<sup>1</sup> but also nurses here in the U.S. who 826 had experience or were from other countries<sup>2</sup>. (...) What we were

827 putting in front of users was a little more polished<sup>3</sup>. It was stereolithography print in ABS<sup>4</sup> and it sort of had titer tolerance dimensioning  
828 and it contained a battery and everything like that. Then I had my own  
829 overlays made that would put on the front, so they were pretty good-  
830 looking prototypes<sup>5</sup> by the time we were getting the really detailed  
831 user feedback at that point.  
832

834 Engagement event: Participant conducts an engagement activity  
835 with <sup>1</sup>proxy user (stakeholder group) and <sup>2</sup>active users (stakeholder group), where the <sup>4</sup>3D-printed prototype (prototype form)  
836 used in the engagement is <sup>3,5</sup>polished (strategy type).  
837

838 Any additional interview excerpts pertaining to this stakeholder  
839 engagement event were associated with this engagement event.  
840 For example, the participant described the composition of the  
841 engagement room later in the interview, which was then associated  
842 with this engagement event.

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