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STAKEHOLDER ENGAGEMENT WITH PROTOTYPES DURING FRONT-END MEDICAL DEVICE DESIGN: WHO IS ENGAGED WITH WHAT PROTOTYPE?

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ABSTRACT

Stakeholder engagement with prototypes during the front-end phases of medical device design can support problem identification, problem definition, and early concept generation. This study examined what prototypes were leveraged to engage specific types of stakeholders during front-end medical device design. Analysis of semi-structured interviews with 22 design practitioners in the medical device industry revealed some common associations of prototype choice for particular stakeholders. A few associations are highlighted: designers engaged users with physical three-dimensional (3D) prototypes, financial decision-makers with physical 3D and two-dimensional (2D) prototypes, government and regulatory stakeholders with 2D prototypes, and expert advisors with digital 3D prototypes. The rationale provided by practitioners revealed the intentional selection of prototype form for specific stakeholder engagements.

Keywords: medical device design, early design, front-end design, physical prototypes, digital prototypes, two-dimensional prototypes, stakeholder engagement

1. INTRODUCTION

Medical device design follows a traditional product design process, including needs assessment, concept development, preliminary design and evaluation, detailed design, design validation, and production [1]. However, medical devices are constrained by additional regulatory requirements [2], which require the careful testing of device prototypes throughout the development process [3]. Therefore, prototyping is a central tool of medical device design [4]. For example, prototypes are used extensively for validation purposes, such as in summative usability testing with fully functional devices [3].

In addition to supporting design activities during the later phases of device development, the use of prototypes during front-end product development activities (i.e., activities associated with problem finding, identification of design opportunities, idea generation, development, and screening [5]) can provide unique value to a design process [6]. Engaging stakeholders, defined as those who would be impacted by or who could impact a design [7] (e.g., physicians, patients, nurse practitioners, facility trade groups, patient advocacy groups, professional associations, government officials and legislators, public payers, private payers, and facility trade groups [1]), during front-end design can also lead to the early discovery of product requirements, which inform the safety and usability of device design, improve patient outcomes and satisfaction, and reduce device recalls and the need for modifications later in the process [8]. Furthermore, during early formative usability testing, prototypes can help reveal unintended interactions between the users and the device [9], which is a vital part of risk mitigation in medical device design.

Both the prototype form used and the stakeholder group engaged affect the quantity and quality of feedback elicited during front-end design engagements. For example, design practitioners note limitations in the quality of feedback provided when stakeholders are presented with preliminary drawings in comparison to more advanced physical prototypes [10]. Although literature describing prototype forms is expansive [11,12], and methods for stakeholder engagement have been established [8], there are limited data that investigate relationships between the prototype forms used to engaged

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different groups of stakeholders. Therefore, this study sought to investigate potential relationships between prototype forms and stakeholder groups and describe medical device design practitioners' rationale for these choices when engaging stakeholders during front-end medical device design.

2. METHODS

The following research question guided the study:

During front-end medical device design activities, what stakeholder groups are engaged with which prototype forms?

Potential participants were contacted through existing relationships, networking, and cold emailing, and completed a background questionnaire about their prior medical device design experiences. Twenty-two participants were interviewed, including engineers, designers, design researchers, and technology officers, from 16 medical device companies: five companies had over 1,000 employees, five companies had 10-200 employees, and six companies had 1-10 employees. Two companies were located outside of the U.S. Participants had between 1.5 and 38 years of design experience (median of 9 years) and had job tasks typical of design researchers (5) and design engineers (17), 14 of whom were in leadership positions within their organizations.

Semi-structured interviews, which balance the use of standard questions across participants with the flexibility to ask targeted follow-up questions, were conducted with each participant. Participants were asked to focus on a prior project and describe, in detail, experiences when they engaged stakeholders with prototypes during front-end design activities. Participants were asked about how they engaged stakeholders using prototypes, which stakeholders were engaged, and what prototypes were leveraged.

The interviews were audio-recorded, transcribed, and de-identified. Analysis included a focus on identifying prototype forms leveraged to engage specific stakeholder groups. The study researchers established initial categories of stakeholders and prototypes inductively—a process whereby patterns are established from the interpretation of textual data. Once categories of stakeholder groups and prototype forms were established, the data from across the transcripts were organized by one researcher into the categories. A second researcher reviewed the categorization, and any disagreements were resolved through refinement of the category descriptions and discussion of the data. The two researchers conducted multiple rounds of categorization of data and comparison to establish a final categorization representing patterns across stakeholder groups and prototype forms [13]. Stakeholder-prototype associations, consisting of a specific stakeholder group engaged with a specific prototype form, were identified across multiple transcripts. Excerpts were extracted to illustrate participants' rationale for specific stakeholder-prototype associations.

3. RESULTS

Participants used three different overarching forms of prototypes to engage stakeholders during front-end design activities: physical three-dimensional (3D), digital 3D, and two-dimensional (2D) prototypes, which are defined in Table 1. All participants described using physical 3D prototypes including various 3D objects such as prototypes built with test materials or near-final materials and existing products. Although physical 3D prototypes were the most commonly used prototypes by participants in our sample, 2D prototypes were also used for stakeholder engagement during front-end design. Participants conveyed very early ideas to stakeholders with hand drawn prototypes. Participants also used 2D prototypes to convey the value of an initial idea with photorealistic renderings or engineering drawings. Further, participants discussed using storyboards to describe processes to limit biasing stakeholders with potential solutions. Digital 3D prototypes were also leveraged with stakeholders during front-end design, notably with more technical audiences or when showcasing interactive prototypes and user interfaces.

TABLE 1: PROTOTYPE FORMS FOR STAKEHOLDER ENGAGEMENT (PROTOTYPE FORM; DEFINITION; TRANSCRIPT LEVEL COUNTS OF OCCURANCE, OUT OF 22)

Prototype form	Definition	#
Physical 3D	A physical representation of an idea that has a three-dimensional shape.	22
2D	A static two-dimensional representation of a three-dimensional prototype or a process, created by hand and/or with digital tools.	18
Digital 3D	A prototype created using Computer-Aided Design (CAD) software, viewed statically on screens or paper, or animated in a digital environment to simulate functionality.	12

Participants engaged three broad groups of stakeholders (Table 2) with prototypes during front-end design activities: users, implementation stakeholders, and expert advisors. All participants engaged users with prototypes including healthcare practitioners, patients, caregivers, and secondary users such as technicians. Most participants engaged implementation stakeholders with prototypes including manufacturing, regulatory, and marketing stakeholders. Implementation stakeholders provided specific domain knowledge related to implementation, such as manufacturing. Furthermore, implementation stakeholders included key partners in the participants' design processes such as stakeholders who provided financial support or community partners who collaborated with the participants. To gather feedback on the device design and problem space, participants also engaged expert advisors that provided clinical and design expertise.

TABLE 2: STAKEHOLDERS ENGAGED WITH PROTOTYPES (PROTOTYPE FORM; DEFINITION; TRANSCRIPT LEVEL COUNTS OF OCCURANCE, OUT OF 22)

Stakeholder type	Definition	#
User	A stakeholder who uses the device and/or benefits from its primary function once the device is commercialized.	22
Implementation stakeholder	A stakeholder directly involved in the adoption of the device and who strongly influences its success.	21
Expert advisor	An advisor who provides expertise on the device and the problem space based on their professional knowledge and experience.	16

The transcript-level counts of stakeholder-prototype associations revealed in this research are summarized in Table 3.

TABLE 3: STAKEHOLDER-PROTOTYPE ASSOCIATIONS (TRANSCRIPT LEVEL COUNTS)

	Users	Implementation stakeholders	Expert advisors
Physical 3D	21	21	9
2D	15	11	6
Digital 3D	5	3	4

A subset of the stakeholder-prototype associations is illustrated in Table 4. Physical 3D prototypes were tangible representations that were chosen when engaging users to lend a realness to the participants' ideas and increase the quality of feedback received. Financial decision-makers were engaged with both CAD models and physical 3D prototypes. Physical prototypes (e.g., 3D printed prototypes) were said to have a greater power to convince financial decision makers of the project potential. Government and regulatory stakeholders were engaged using 2D prototypes because their feedback mainly concerned product features that could be represented through drawings or storyboards depicting the use cases of the product. Lastly, expert advisors tended to have technical backgrounds and could provide feedback on early CAD models.

4. DISCUSSION

The findings provide insight into the typical stakeholder-prototype associations used by design practitioners to support front-end medical device design engagements. Participants described using different prototype forms to engage different stakeholder groups. Participants chose which specific prototype to use based on the 1) stakeholder group to be engaged, including the stakeholder group's interests and expertise (e.g., technical background of a stakeholder), and 2) ability of the prototype form to convey a specific type of information. Some associations highlighted in this paper have also been reported in the literature. For example, the use of physical 3D prototypes was emphasized by participants as the most effective prototype form to engage users, which aligns with an existing recommendation in engineering design texts [14]. Likewise, a case study in the automotive industry illustrates the importance of coupling physical 3D prototypes with supporting aids (e.g., slide decks and diagrams) [12], which is comparable to the prototype forms used to engage financial decision makers described in this study.

The findings also suggest that the design practitioners were intentional when choosing a particular prototype to use based on the stakeholder group to be engaged during the front end of

TABLE 4: EXAMPLES OF STAKEHOLDER-PROTOTYPE ASSOCIATIONS

Stakeholder		Associated prototype	Excerpt illustrating the stakeholder engaged with the associated prototype
User		Physical 3D	*"So 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." (N)*
Implementation stakeholders	Financial decision maker	Physical 3D and 2D	*"Through all these interactions usually prototypes really speak the loudest because nobody would like to see something stay on paper. You can present some nice 3D designs during a presentation but in the end to convince someone to invest more you need to have something in hand. (...) For example, some project leaders or the bosses who control the money (...), they would want to see what kind of product you want to develop. Then usually it's communicated through some industry drawings, 3D CAD or 3D printed." (P)*
	Government and regulatory	2D	*"We would send our stakeholders various kinds of renderings and pictures of the proposed product concept idea such as cross-sections, pictures of various parts used to construct the device, a more verbal description of every component's function, and a very detailed description of the entire product itself. These pictures with annotations and call outs are sufficient for different kinds of stakeholders to comment and provide valuable feedback in the early stages of the project." (E)*
Expert advisor		Digital 3D	*"The CAD models and the drawings were usually chosen with some of the more engineering-oriented academic side." (F)*

design. A more in-depth understanding of stakeholder-prototype associations is needed to encourage and guide novice designers during front-end medical device design stakeholder-engagement activities.

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