

**SINGLE VERSUS MULTIPLE PROTOTYPES: MEDICAL DEVICE DESIGN PRACTITIONERS’
 RATIONALE FOR VARYING PROTOTYPE QUANTITIES TO ENGAGE STAKEHOLDERS
 DURING FRONT-END DESIGN**

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ABSTRACT

Engaging stakeholders during medical device design processes, especially during front-end design activities, is a critical consideration for successful product design, which includes the safety and effectiveness of devices. The use of prototypes with stakeholders is encouraged by proponents of human-centered design, but guidelines for front-end stakeholder engagement with detailed descriptions of prototyping practices are lacking. One important question design practitioners must ask for each stakeholder engagement is how many prototypes to use. This study investigated reasons design practitioners chose to use one or more prototypes to engage stakeholders during front-end design activities within their design projects. Participants described using multiple prototypes, for example, to allow stakeholders to compare across different design alternatives, and to convey to stakeholders that multiple alternatives are being explored. Participants described using a single prototype, for instance, to probe for deep responses about a narrow topic and to refine a single concept through feedback. These results have the potential to inform design decisions and pedagogical approaches to prototyping use.

Keywords: medical devices, prototyping, front-end design, stakeholder engagement

1. INTRODUCTION

Prototypes have been extensively used during feasibility studies, verification, and validation stages of medical device design [1]. Another valuable use of prototypes occurs earlier in a design process, to gather feedback from stakeholders about their values and behaviors [2]. During these front-end design activities, when designers define problems, develop requirements, and generate early design ideas [3], prototypes

present a pathway to elicit rich information about potential concept solutions and the context in which they would be used [4]. When using prototypes to engage stakeholders during the early stages of a design process, practitioners must carefully consider how the quantity and quality of prototypes may affect the information yielded.

Among the few studies that have explored the effects of prototype quantity on stakeholder feedback, Dow et al. (2010) demonstrated that the use of multiple prototypes enabled designers to more extensively explore diverse design solutions and improve their designs through the feedback received as compared to designers who used a single prototype [5]. Dow et al. (2012) found that designers who shared multiple prototypes with a peer generated more, more diverse, and better performing designs than designers who shared a single prototype with a partner. Further, they argue that “creating multiple designs may help both critiquers and creators separate egos from artifacts” (p. 51), encouraging candid feedback [6]. Camburn et al. (2015) found that designers can improve design performance both through creating multiple different prototypes or a single prototype that undergoes iteration [7]. The reasons designers choose one or multiple prototypes—especially when obtaining stakeholder input during front-end design—have not been a focus of study in the current design prototyping literature. Therefore, this study presents an initial step towards establishing a deeper understanding of design practitioners’ prototyping approaches regarding prototype quantities for stakeholder engagement during the front-end stages of design.

2. METHODS

This study addressed the following research questions: *Do design practitioners use a single prototype or multiple prototypes*

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to engage stakeholders during front-end design? Why do practitioners choose to engage stakeholders using a single or multiple prototype(s) during front-end design?

A qualitative research approach was used to identify practitioner motivations for using a certain quantity of prototypes to engage stakeholders during the design front-end. Qualitative methods are best suited for richly describing processes and relationships between broad concepts within design [8]. Recent studies on prototyping have leveraged qualitative and mixed methods approaches, e.g. [4].

For this study, potential participants were identified using professional networks, and 22 medical device design practitioners (mostly US-based) were recruited using purposeful sampling to ensure they had prior experience designing mechanical or electromechanical medical devices. Nine participants worked in large companies (1,000+ employees), one participant worked in a medium company (10-200 employees), and 12 participants worked in small companies (1-10 employees). Most had senior or lead engineering, design, or technology roles. Prior to recruitment, the University of Michigan Institutional Review Board reviewed and granted the study an exemption. All participants consented to be part of this study.

A semi-structured interview protocol was developed and piloted numerous times prior to data collection. The interview consisted of questions that elicited specific details of the participants' own professional experiences. The interview questions were embedded in a discussion of a specific design project during which prototypes were leveraged to engage stakeholders on one or more occasions throughout the front-end design phases.

The interviews were recorded, transcribed, de-identified, and verified against the audio-recordings for accuracy. Two study team members with formal training in qualitative research methods applied an inductive coding approach to identify prototyping strategies; using a single prototype and using multiple prototypes were two intentional front-end design prototyping strategies for engaging stakeholders that emerged. Inter-rater agreement (86%) between two raters was achieved and any disagreements were resolved through refinement of the prototyping strategy descriptions and discussion of the data.

The two strategies: "Show the stakeholder multiple prototypes concurrently" and "Show a single prototype to the stakeholder" were examined in depth for a subset of participants (n=18) for whom at least one of the two strategies was evident. Specifically, rationales for the use of each of these two strategies were subsequently identified and categorized.

3. RESULTS

Participants reported using multiple prototypes (n=6), a single prototype (n=1), or a single prototype and multiple prototypes (n=11) to address different design questions during their front-end stakeholder engagements. For participants who used both, they did so during separate occasions (i.e., during front-end engagements with different stakeholders) within the specific project they described throughout their interviews.

Participants engaged stakeholders using multiple prototypes representing different concepts, design features, requirements, or engineering specifications. Across participants, four reasons were identified for engaging stakeholders using multiple prototypes, which are listed in Table 1. Participant N described an experience involving the development of a requirement during which she prompted stakeholders to interact with multiple prototypes. Through the use of multiple prototypes the participant enabled the stakeholders to make comparisons across different design alternatives:

"We did all the combinations and put them all down on the table and had them try each one multiple times... without pre-biasing them saying "this one is [functional requirement] [...this one is not]". Just having them use it one to the next, then they could say, "I could really tell a difference between this one, not these two." Because that could then tell us what range of [the functional requirement], what range of [unit] was going to be okay."

TABLE 1 REASONS PARTICIPANTS PROVIDED FOR ENGAGING STAKEHOLDERS USING MULTIPLE PROTOTYPES DURING FRONT-END DESIGN.

Reasons for the use of multiple prototypes to engage stakeholders	# transcripts
<i>Communicate to stakeholders that multiple design alternatives are being explored</i>	4
<i>Elicit broad feedback from stakeholders across a variety of topics</i>	6
<i>Enable stakeholders to compare across different design alternatives</i>	15
<i>Make it easy for stakeholders to share their perspectives</i>	4

Participants engaged stakeholders using a single prototype representing one underlying concept. Three reasons were identified for engaging stakeholders with a single prototype, which are included in Table 2. For example, Participant R described presenting a single prototype to stakeholders to probe for depth about a specific topic – here, the unspoken need, that had not previously been verbalized by the stakeholders:

"[I was originally supposed to solve problem X, but in listening to all of the stakeholders and looking at all of their organized comments on image and requirement diagrams, it became clear they were complaining about something somewhat different than the stated problem X that they just could not verbalize well, the unspoken need. So I start trying to solve problem Z which sounds closer to what they are complaining about based on the diagrams. I prototype this solution and take it back to them and ask: 'Does this solve the problem?]'"

TABLE 2 REASONS PARTICIPANTS PROVIDED FOR ENGAGING STAKEHOLDERS USING A SINGLE PROTOTYPE DURING FRONT-END DESIGN.

Reasons for the use of a single prototype to engage stakeholders	# transcripts
<i>Refine specific attributes of a concept based on stakeholder feedback</i>	7
<i>Show stakeholders a concept using minimal resources</i>	2
<i>Probe stakeholders' responses about a specific topic in depth</i>	5

4. DISCUSSION

Participants used both a single prototype and multiple prototypes to engage stakeholders during the front end of design. The choice to use either approach was driven by the types of design questions posed and the information sought, as illustrated by the reasons participants provided. Some of the reasons found in our study align with the literature. For example, Dow et al. (2010) argued that comparison aided designers in understanding key ideas from the feedback they received on prototypes [5]; similarly, in our study Participant N noted that the use of multiple prototypes enabled stakeholders to make comparisons across design alternatives.

Our findings contribute to understanding the rationale behind engaging stakeholders with varying prototype quantities. Both the use of multiple prototypes and a single prototype elicited rich feedback, but this feedback varied in scope. Through the use of multiple prototypes, practitioners felt they could elicit broad feedback from stakeholders across a variety of topics. Conversely, when using a single prototype, practitioners could focus a stakeholder's attention on a narrow topic. Regardless of prior design knowledge, designers should consider the number of prototypes they use for stakeholder engagement based on their information needs and design goals.

Limitations of this study include a small number of participants, as well as the self-reporting of design practices. However, the sample size is consistent with similar research studies that aim to uncover rich details about participants' processes.

The focus of this study on the medical device domain provides valuable insight into practitioners' strategies that may help overcome some of the documented design challenges in the field, such as lack of user understanding of product development processes; need for managing user expectations; user creativity; among others [9].

5. CONCLUSION

Prototypes are powerful tools for engaging stakeholders in design processes, especially during problem definition and early concept development. This study described reasons design practitioners engaged stakeholders using a single prototype in some cases, and multiple prototypes in other cases. These findings have implications for design practitioners and designers in training.

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