User-Centered Innovation for the Design and Development of Complex Products and Systems

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Abstract In this chapter, we examine user interaction for the design and development of complex products and systems. Through a two-phase research effort, we explore and test the influence of user involvement (i.e. novice/average and expert/lead users) in early stage design and new product development.

In Phase I, we document the roles of users and stakeholders in early stage design, based on a review of existing literature and inputs from practitioners in the design and engineering fields. From this review, we develop a systematic framework for determining which user entities designers should target for the design and development of new products and systems. In order to increase adoption success, the *Design Stakeholder Identification, Assessment and Ranking Framework* is optimized to specifically address the needs of users and stakeholders with the greatest degree of influence over product use and adoption.

Phase II of this research captures the effects of including expert and novice product users at discrete phases of the product development process, with an emphasis on early stage concept design and ideation. Through a controlled experiment, novice and expert users from the healthcare setting provided inputs for the conceptualization of an intramuscular drug delivery system. Based on inputs from users of each group, four conceptual prototypes were developed. Using quantitative assessment methods, we are currently examining if there are significant differences between concepts that have been designed based on inputs from users of either group. Factors of particular interest include the perceived usability, functionality, efficiency, adaptability, and cost-benefit of product concepts.

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Through Phase I and II of this work, we aim to impact design-thinking research through providing an improved understanding of user and stakeholder roles in the development of complex systems, and new insights regarding user-centric product design teams.

1 Background

One of the core design thinking principles is user-centric design. It not only demands thorough needs finding methods and anthropological approaches, but also requires development teams to test iterative prototypes directly on users, whenever possible. For the design of complex products and systems, identifying the "real" user among multiple stakeholders is a difficult challenge. In the healthcare field, for instance, although patients are often considered the "users" of medical technology, so too are doctors, nurses, hospitals, and insurers. Thus, the question remains: who is the target user? Once "the" user group is identified (if there is only one), then which subjects does one design for within a specific user group – a highly advanced and technologically adept lead/expert user, or the average user?

There is an established field of research on the role of "lead users" that emerged from studies on sources of innovation (von Hippel 1976; von Hippel 1986). Lead users have been described as individuals or organizations who experience needs for a given innovation earlier than the majority of the target market (von Hippel 1986), and who are positioned to benefit from obtaining a solution to those needs. Existing research has shown that users, as opposed to manufacturers or suppliers, have been the first to develop new commercially successful products, with user innovation concentrated among the lead users of those products and processes (von Hippel 1986; Urban and von Hippel 1988; Shah 1999; Lüthje 2003).

However, conflicting views regarding the role of lead users in product design have been conveyed. Ulwick (2002) described that, "lead users can offer product ideas, but since they are not average users, the products that spring from their recommendations may have limited appeal." Similarly, a retrospective analysis of eight medical device firms (Shluzas 2011; Shluzas et al. 2011; Shluzas and Leifer 2012) illustrated that companies often prefer to work with industry thought leaders in the conceptual design and product testing phases of development. However, surgical procedures developed primarily based on input from lead-user surgeons often result in the development of technology that is difficult for a broad range of product users to embrace. To close the usability gap between first and second-generation products, the companies studied implemented post-market revisions based on feedback from "average users" in the clinical field.

In drawing analogies to the Technology Adoption Lifecycle (Moore 1991), lead users often demonstrate similar characteristics to those of innovators and early adopters. That is, they are often risk takers, have a high degree of opinion leadership, and are fast to adopt new innovations (Rogers 1962). In contrast, average users are frequently aligned with the early majority and late majority of consumers in an adoption lifecycle. They are typically more risk averse and tend to adopt new innovations after varying degrees of time (Rogers 1962).

A review of existing literature on user interaction for the development of complex products and systems reveals the need for a greater understanding of the dynamics and inter-relationships among user types across a range of industry settings. In particular, there is a need for research that examines how lead/expert users (e.g. early adopters and innovators) and average/novice product users (e.g. the early majority) uniquely contribute to the design, and subsequent adoption, of products and services.

In this chapter, we present a multi-phase research effort aimed at examining user interaction for the design and development of complex products and systems, across a range of high-technology industries. The first phase of research focuses on the question: Which users and stakeholder groups should developers target for the design of complex products and systems? The second phase of research then centers on the questions: Within each targeted user group, which subjects does one design with and for during the product development process – a technologically adept expert user or the "average" user; and does designing with and for particular users and user groups have an impact on the usability, functionality, novelty, and cost-benefit of new products and systems?

2 Phase I: The Identification of Target Users and Stakeholders

Which users and stakeholder groups should developers target for the design of complex products and systems?

To explore this question, we first present a literature-based comparison between the conceptual notion of "users" and the direct inclusion of "users," within several design methods. After having determined that the concept of "user" varies greatly among design methods and throughout stages of product innovation, we modify the notion of "user" in favor of a more balanced, role-based stakeholder perspective. In doing so, we provide a systematic framework for determining which user entities designers should focus on throughout the design process. Contrary to current processes for assessing and prioritizing users and stakeholders that are often fragmented and qualitative, the framework we propose combines new and existing tools into one systematic process. The *Design Stakeholder Identification, Assessment and Ranking Framework* (Agrawal et al. 2012) is geared toward the design and development of complex systems, involving an embedded network or ecosystem of users and stakeholders. It intends to provide designers with a comprehensive tool for ensuring that the needs of stakeholders with a high degree of influence over product/system adoption are met.

2.1 The Conflicting Notion of "Users" in Existing User-Centric Design Methods

The notion of "user" is central to design methods and approaches. According to (von Hippel 1976) 75 % of the commercially successful industrial goods innovation projects were user-driven, rather than technology driven. Depending on the extent of user involvement, there is a continuum of user concepts spanning from a concrete existing user (e.g. lead user); to an observable user or participatory designer with whom one may directly interact (Abras et al. 2004); to an abstract conceptualization of user that views users as customers in axiomatic design (Suh 2001). Since users play a critical role in determining the success of a product and its impact on a community, the selection of the 'right user group' during the design process is critical for the success of any design method. The 'right user group' may vary from one industry to another and from one product to another. In fact there might be more than one 'right user group' for the same product within the same industry.

Every design method has its own interpretation of user and its own criteria for defining the role of the user. As shown in Table 1, we broadly segment design methods into two categories: artistry inspired design methods that focus on iteratively learning from, interacting with, and reflecting on real users; and science inspired design methods that generally have an abstract, conceptual notion of users. The former category, inspired by Donald Schön, focuses on generative metaphors and learning systems (Schön 1983). Design methods derived from this artistry inspired design understanding are more applicable to fuzzy front-end exploration design tasks. The latter category was inspired by the work of Herbert Simon and focuses on quality and efficiency (Simon 1976). Methods from this science inspired design approach are generally more applicable to technical design optimization tasks. For design methods in each category, we present examples of the types of users involved and their corresponding degrees of user involvement.

2.2 Importance of Selecting the "Right" Users and Stakeholders in the Design Process

The range of user types shown in Table 1 illustrate that target users may vary for the development of an individual product, based on the design method chosen. For example, the current development of Boeing's 787 Dreamliner has involved multiple users, including the crew, passengers, airline operators, aircraft manufacturers, and regulatory authorities. Although passengers are one of the aircraft's final end users, so too are pilots and the crew. But the choice of buying an aircraft will depend on airline companies. Additionally, maintenance is a major factor in determining the actual airtime for a plane. Thus, involving the 'right user' in the design process is extremely important for the success and adoption of this product.

Table 1 Artistry and science inspired user-centered design methods

Type of design method	Example methods	User types	User involvement
Science inspired design methods:	Lean	Users as abstract concept of customers and stakeholders	Limited to no involvement
Focus on quality and efficiency; More applicable to technical/scientific design optimization tasks;	Six sigma process excellence		
Promoted e.g. by Simon (1976)	Quality function deployment		
	Cost-benefit analysis		
	Choice modeling		
	Minimum viable product		
Artistry inspired design methods:	Lead user innovation	Real users, may be separated into adopter categories (innovators to laggards)	Active involvement
Focus on generative metaphor and learning systems;	Participatory design		
More applicable to fuzzy front end exploration design tasks;	Inclusive/universal design		
Promoted e.g. by Schön (1983)	Usability/human factors design		
	Experience design		
	Crowd sourcing		

For simplicity sake, but also based on existing teaching dogma, users are quite often seen as individuals; when in reality, users are part of a complex stakeholder network with delicate and often non-obvious relationships. Per the 'Stakeholder Network Theory' (Rowley 1997), each firm encounters a different set of stakeholders that aggregate into unique patterns of influence. They respond to the interaction of multiple influences from the entire stakeholder set. In fact, the notion of conducting participatory observations and creating concrete user narratives and personas is gaining ground in design practices. But, there is a danger that designers may focus on the "wrong user," one who may not significantly contribute to the future adoption of the product/service/solution. We therefore aim to identify and analyze the stakeholder network, as a foundation for the user group selection process.

Also, the roles of the user groups may vary significantly from one industry to another. For instance, the government may be the end-user for defense products, but it would be a legislative authority for a healthcare product. Thus, understanding the user in terms of stakeholders and their roles in the context of different industries is critical to developing a framework for classifying user-centric design methods. Due to this context dependency, each product/system and industry requires an independent analysis to identify each user group's specific role in a particular design situation.

2.3 Design Stakeholder Identification, Assessment and Ranking Framework

We present a systematic framework to help design teams better understand the roles of different users and stakeholders, and to prioritize their involvement in the design process. The four stages of the *Design Stakeholder Identification, Assessment and Ranking Framework*, detailed in the paper by Agrawal et al. (2012), include the following steps:

1. Gap analysis (or needs finding)
2. Customer value chain analysis

3a. Cycle of use analysis
3b. Monetary flow analysis

4. Final stakeholder ranking

Step 1 (pre-step) – Gap analysis

The purpose of this initial step is to identify a potential new product, or new features of an existing product, that address unmet needs. This step is intended to ensure that the design team has articulated a clear strategic focus such as a specific industry, target market, or a specific need. There should be a strong match between the expertise in the product team, the industry or market focus, and the potential of the market for product adoption. The outcome of this initial step is a list of requirements for the new product or product features. These could be grouped by functionality or use cases if necessary.

Step 2 – Customer value chain analysis (CVCA)

The purpose of this analysis step is to enable the design team to comprehensively identify pertinent stakeholders, their relationships with each other, and their role in the product's life cycle. The outcome of this analysis is a product value net that includes a list of all product stakeholders, their intents and incentives, and their inter-relationships. Typical value propositions for stakeholders include: money or payments, complaints, regulatory influences, services or necessary information, and tangibles such as hardware and materials.

The CVCA analysis (Donaldson et al. 2006) enables design teams to determine stakeholders with decision-making influence, based on the number of arrows pointing into or away from each stakeholder in the value net. Stakeholders with peripheral influence will less likely be at a focal point in the value net. As such, the value net diagram highlights the most important decision-making stakeholders involved in the development and use of a new product or product feature.

The design team should note key decision makers in a tabular format, before proceeding to the next step.

Step 3a – Cycle of use analysis

The purpose of this step is to assess different stakeholders' value drivers and incentives with respect to behavioral, technical, and social attributes. This step of the analysis should be performed from the usability perspective, with functional requirements grouped into "use cases" or procedural steps that users will perform while using a product or feature. The output of this analysis is a list of stakeholders, ranked according to the degree to which each is affected by a particular attribute, from a behavioral/usability, technical/utility, and social perspective.

Behavioral/Usability attributes focus on the degree of behavior change a user would have to make in order to use or adopt a specific product or new feature, in comparison to existing practices or procedures. A score of 0 is assigned for no change, one for minimum change, and five for a completely new way of accomplishing a specific task.

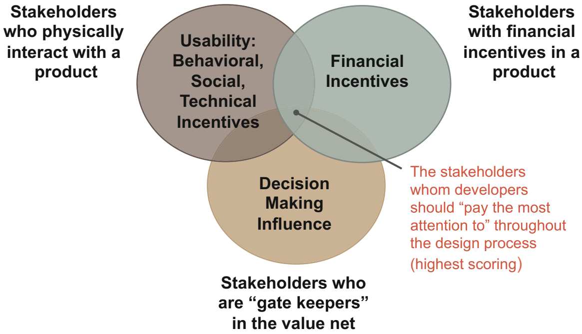
Technical/Utility attributes center on a product's technical functionality and performance. The ranking for each feature-stakeholder combination is based on how critical the stakeholder considers a particular feature to be. Another way to view this is with respect to the value a stakeholder places on the technical benefit (utility) of a new feature. A "must have" feature is scored 5, and a "nice to have" feature is scored 1, using a tabular assessment.

Social Interests are attributes that consider social factors, such as power and prestige, associated with using a particular product, technology, or product feature. This ranking is based on the stakeholder's perception of status associated with using a specific product or feature. In scoring social interests, a perceived large increase in social status is assigned a score of 5, and minimum or no change is assigned a score of 1. The process of combining scores in each area is captured in detail by Agrawal et al. (2012).

Step 3b – Monetary flow analysis

This stage of the analysis assesses stakeholders with financial interests in a product in order to identify key decision makers who would influence product adoption from a financial perspective. In this step, the team starts with a list of stakeholders from step 2 (CVCA), and documents constituents that pay for products or new product features. This involves quantifying the financial gain or loss that each stakeholder would potentially experience, given the introduction or adoption of a new product or feature. If a stakeholder could potentially experience a large financial loss (relative to other stakeholders), then he/she would be assigned a score of −5. On the other hand, if a stakeholder could potentially gain financially from the introduction of a new product or feature, then he/she would be assigned +5. If a stakeholder is not affected financially then the score is 0. At the end of this exercise, the team will have a financially focused stakeholder-product features table with scores ranging from −5 to +5 for each product.

Fig. 1 Schematic representation of stakeholder attributes



Step 4 – Final stakeholder ranking

The final analysis step facilitates designers in determining which stakeholders to involve in the product design and development process, and provides recommended user interaction strategies (per the design methods discussed in Sect. 2.1).

At this stage, the design team has three ranked tables – one from the decision-making perspective, the product use perspective, and the financial perspective. From this information, designers can differentiate between stakeholders with an interest in feature development (from a usability perspective), versus those who may be influential in driving product adoption. Stakeholders with over-lapping interests at the intersection of usability incentives, financial incentives, and decision-making influence, are those whose needs designers should dedicate the greatest amount of time and resources to (as schematically highlighted in Fig. 1).

With the stakeholder ranking information, a design team will be able to segment stakeholders into the following four categories:

2.3.1 High Ranking: In Decision-Making, Influence Usability, and Financial Incentives

As previously noted, it is essential to include stakeholders from this category in the design and development process, since they have financial and decision making power that drives product adoption, and are likewise involved in the physical use of a new product or product feature. It is recommended that stakeholders in this category work alongside design team members through participatory and iterative design methods (Schön-type), as well as through scientific methods such as focus groups, surveys, and the minimum viable product strategy (Simon-type interactions).

2.3.2 High Ranking: In Usability

Stakeholders in this category will be closely involved in actual product usage – either as end users, intermediate operators, or maintenance personnel, etc. These stakeholders will typically be individuals or groups who physically interact with a product and hence should be actively involved in the iterative, hands-on design and development process. To enhance product usability and functionality, stakeholders in this group should ideally engage in product design through methods such as participatory or inclusive design (as discussed in Sect. 3.1).

2.3.3 High Ranking: In Decision-Making Influence and/or Financial Incentives

Stakeholders in this category have a high degree of decision-making power and a vested financial interest in a new product or product feature. But these stakeholders are not involved in the direct physical use of a product (i.e. they have 0 ranking in the usability matrix). Since these stakeholders have no direct interaction with products but do have control over finances and/or product purchasing, it is recommended that their inputs be considered using the scientific/technical (Simon-type) design methods.

2.3.4 Low Ranking in Two or More Categories

Stakeholders who receive low scores in two or more categories are considered lower priority stakeholders. In terms of resource allocation, we recommend that the design team avoid allocating a large percentage of resources toward the development of products or product features to satisfy the needs of stakeholders in this group (unless their needs correspond with the needs of stakeholders addressed previously).

Following this four-step ranking and stakeholder categorization process, the team can utilize the framework to include high priority stakeholders in the product development cycle, in an effort to satisfy the needs of users/stakeholders with the greatest degree of influence over product use and adoption.

3 Phase II: The Influence of User Expertise on Product Innovation

The second phase of research is an ongoing study that focuses on the following research questions:

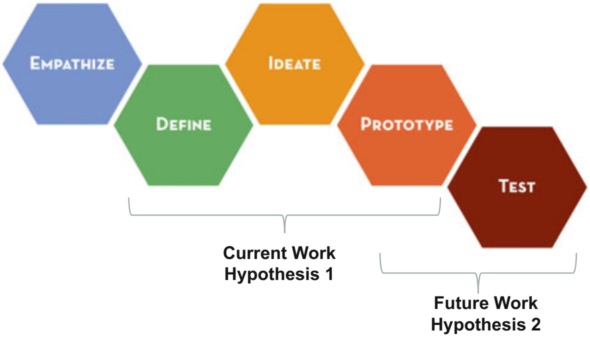


Fig. 2 Schematic representation of early stage design phases

Within each targeted user group, which subjects should one design with and for during the product development process – a technologically adept expert user or the "average" user?

Does designing with and for particular users and user groups have an impact on the usability, functionality, novelty, adaptability, and cost-benefit of new products and systems?

To examine these questions, we are studying the roles of expert and novice product users at discrete phases of the product development process, with an emphasis on early stage concept design and ideation (per Fig. 2). The goal of this research phase is to evaluate the degree to which designs differ, in terms of factors such as usability, functionality, and cost-benefit, when they are based on inputs from novice versus expert users. As previously noted, this research stems from an earlier study by Shluzas (2011), which illustrated that medical device developers often prefer to collaborate with industry thought leaders during the conceptual design and product testing phases of development. However, surgical procedures developed primarily based on input from lead-user surgeons (von Hippel 1986) frequently resulted in the development of technology that was difficult for a broad range of users to embrace.

In the current study, we hypothesize that at the conceptual phase of product design both expert and novice users will have a higher preference for design concepts based on input from expert users. This is due to the ability for experts to identify needs ahead of the target market (von Hippel 1986), and because experts have been shown to have a better understanding of functional relationships (Chi et al. 1981), and are better at identifying problem solving strategies (Klein 1999). However, at the usability and functional testing phases of design we hypothesize that both experts and novices will prefer designs that have been improved based on inputs from novice users. This is attributed to novice designs potentially being less reliant on user skill, more intuitive, and more adaptable to different usage scenarios.

To test these hypotheses, we chose to examine the design of intramuscular (IM) drug delivery devices, namely syringes, since these products involve daily interaction by users of varying skill levels. More specifically, these devices were selected because they are small on one hand, but also complex mechanical systems. Their usage involves multiple stakeholders with different design requirements (e.g. patients, caregivers, regulators, and manufacturers), and recruitment and access to expert and novice users (e.g. nurses with varying levels of training and experience) was feasible. Since syringes are designed for multiple use environments, studying their design provides an opportunity to examine the design of products intended for variable usage scenarios.

The experimental protocol, to examine the initial hypothesis involving user interaction for the design of early stage product concepts, involves six steps:

1. Research team recruits expert and novice users (n = 9–12 users per group).
2. User Input Sessions: Users provide needs and inputs, and rank their top 5 needs.
3. Research team separately aggregates and codes needs from the novice and expert user groups.
4. Designers (n=2) create computer aided design (CAD) models, based on design inputs from users of each group.
5. Users from each group select preferred design concepts.
6. Research team maps user preferences to designs based on inputs from either the expert or novice user groups.

3.1 User Input Sessions

For each user, we conducted a 60 minute user input session at either the Stanford Center for Design Research (CDR) or the user's place of employment. During these sessions, users were asked to complete an initial survey to document their injection experience and indicate the demographics of patients to whom they have administered injections. Users were then shown a brief video that illustrates the injection process, in order to frame the design exercise in the context of administering injections within a clinical setting. For about 30–45 minutes, users described their wants and needs through sketching, written, and oral descriptions. These sessions were videotaped to fully capture user inputs, and to provide inputs to designers at a later time. Finally, users completed the session with a post survey, in which they were asked to rank their top needs and document their technology adoption profiles.

3.2 Data Coding and Concept Generation

The user inputs were divided into novice and expert user groups. For each group, three overarching themes were synthesized and each user input (i.e. comment) was manually coded to gain a sense of the main design priorities by *quantity* of comments. To supplement each designer's empathy and understanding based on user inputs alone, designers researched IM injection details online (google) and watched online videos of IM injections (youtube). To generate designs, each designer selected quotes that "stuck out" as significant and representative of the users in each group.

For our cohort of novice users, three guiding priorities emerged from the coded data: (1) Safety, (2) Efficiency, and (3) Accuracy. Using these design priorities, designers first generated miniature concept hand-sketches. These mini-concepts represented small fragments of features (not fully functional designs). They next created two to four detailed composite sketches (fully functional syringes) on letter-sized paper that combined the most promising features. These detailed storyboard sketches served as the basis for generating 3D CAD renderings (in Rhino3d), corresponding technical drawings (in Solidworks), and an annotated design brochure (in Powerpoint). The process was repeated for expert users, but with the new priorities of: (1) Safety, (2) Accuracy, and (3) Efficiency.

Examples of two designs created based on inputs from the novice and expert user groups are shown in Figs. 3 and 4, respectively.

3.3 Mapping User Preference to Designs Based on Expert or Novice Inputs

Based on the top ranked design concepts from users of each group, we aim to map if novice users prefer designs based on inputs from novice users or expert users, and if expert users prefer designs based on inputs from either novices or experts, per the diagram in Fig. 5. Selection criteria include factors such as usability/perceived ease of use, functionality, speed and efficiency, adaptability, nurse safety, patient safety, and cost-benefit.

The intended theoretical and practical contributions of this research phase are: (1) to build on research in lead user innovation, by von Hippel (1976, 1986) and others, by illustrating the unique contributions that novice and expert users make at discrete phases of the design process, and how their contribution impacts product adoption; (2) to contribute to literature on design adaptability and intuitive design by illustrating which user groups facilitate the design of products for variable use scenarios; and (3) to extend literature in participatory design, from the human computer interaction and software development fields, to the design of tangible products. As a final goal, we aim for the designs created in this study to be used as future drug delivery devices in routine clinical care.

4 Discussion and Future Direction

Our research shows that there is substantial dissent in the nature and concept of ‘users’ among product development and design communities. Though often seen as individuals, users are frequently part of a complex stakeholder network that has been integrated into the development process through a series of interconnected relationships.

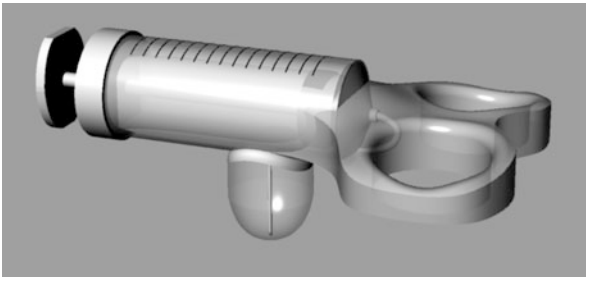


Fig. 3 Design concept (syringe) based on novice inputs

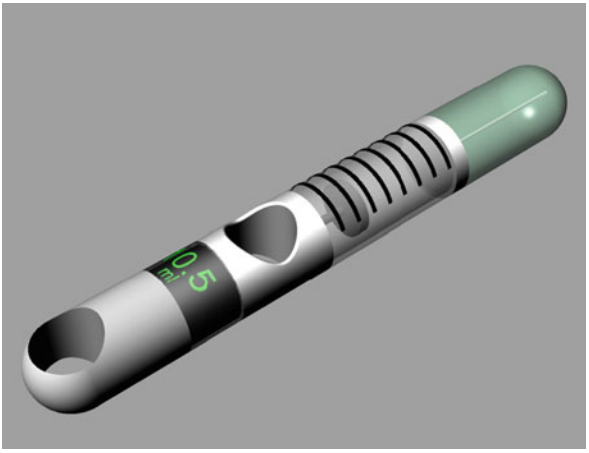


Fig. 4 Design concept (syringe) based on expert inputs

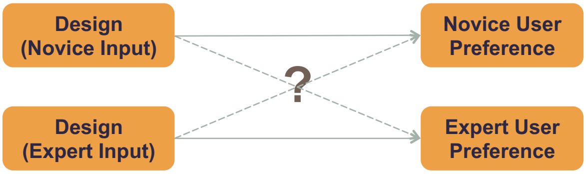


Fig. 5 Mapping user preference to designs based on inputs from novice or expert users

Phase I of our research demonstrates that in order to increase the success of products at a sub-system level (i.e. in terms of usability, functionality, social-status or financial gain), it is necessary for designers to identify all product stakeholders and target development efforts to satisfy the needs of constituents with the greatest degree of influence over product use and adoption. To accomplish this, we propose a four-step framework that provides a comprehensive system for evaluating stakeholder groups and allocating resources accordingly. Contrary to current processes for assessing and prioritizing users and stakeholders that are often fragmented and qualitative, the proposed *Design Stakeholder Identification, Assessment and Ranking Framework* combines several tools into one systematic process. It is geared toward the design and development of complex systems, involving an embedded network or ecosystem of users and stakeholders. This framework provides designers with a tool for ensuring that the needs of stakeholders with a high degree of influence over product/system adoption are met.

In Phase II we are currently examining the role of expert versus novice users in early stage product design. This work stems from earlier research (Shluzas 2011), which showed that medical device developers often prefer to collaborate with industry thought leaders in the conceptual design and product testing phases of development. However, surgical procedures developed primarily based on input from lead-user surgeons (von Hippel 1986) were shown to result in the development of technology that was often difficult for a broad range of users to embrace. By evaluating the impact of user expertise on technology development, this research aims to provide an improved understanding of user and stakeholder roles in the development of complex systems, and new insights regarding user-centric product design teams. The findings from this work should enable the research team to postulate an empirically founded hypothesis regarding which user groups to include in the conceptual design and ideation phase of product development.

In the future, we plan to examine the role of expert and novice users at the usability and functional testing phases of product development (i.e. for the development of three-dimensional prototypes). This future work intends to provide a clearer understanding of user roles at discrete phases of the product development process. In the context of user-centric design for the development of complex products and systems, we also aim to expand and test the insights gained from this research in different industry domains. We are particularly interested in evaluating the role of user groups for the design of products intended for adaptive and rapidly changing user environments (i.e. sustainability engineering and information technology).

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