DESIGNING TO MAXIMIZE VALUE FOR MULTIPLE STAKEHOLDERS: A CHALLENGE TO MED-TECH INNOVATION

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ABSTRACT
An inductive, multi-case analysis was conducted to examine how design practices involving physicians and medical device developers influence outcomes in early stage medical device companies. This research was motivated by an interest in understanding the role of users in the device development process, specifically in terms of how user interaction influences the acceptance or rejection of new products. To examine this area, an analytic framework for case-based research was first developed, based on exploratory interviews with leaders in the medical device field. Retrospective case studies were then conducted on eight entrepreneurial firms (four rival pairs) in the areas of pulse oximetry, robotic surgery, cardiac bypass surgery, and minimally invasive spine surgery. Based on a mixed-methods analysis of qualitative and quantitative data, the study showed that product adoption relied on maximizing benefits for product stakeholders, while minimizing required changes in physician behavior. The data further illustrated that total benefit to product stakeholders was influenced to the greatest degree by benefits afforded to hospitals and physicians, assuming patient benefit was greater than or equal to the standard of care. This study highlights the importance of identifying the often-conflicting needs of medical device stakeholders, and then optimizing devices to satisfy the needs of those with the greatest influence over product use and adoption.

Keywords: medical devices, user-centered design, case-based research, stakeholder analysis

1 INTRODUCTION
A two-year study was conducted at Stanford's Center for Design Research to examine collaboration practices between physicians and device developers in the medical device field [1]. Using medical device cases as an example, this research aimed to advance knowledge and understanding in the field of user-centered design.

There is a body of existing work that describes the benefits of user-centered design [2, 3] and user involvement in medical technology innovation and evaluation [4, 5]. However, there is limited research that describes how the process of physician-developer interaction influences product outcomes. Knowledge of such interaction is particularly relevant to the large and growing number of complex and high-risk medical devices, in which physicians are the primary end users and patients are the recipients of care.

To address gaps in existing literature, this research examined design and development practices involving physician interaction in eight medical device companies, and established causal relationships between practices and product outcomes. The focus of this paper highlights practices associated with maximizing value for multiple product stakeholders, in order to increase device use and adoption. An examination of product benefits and costs revealed differences in product value from the vantage point of users and stakeholders with conflicting needs. Although patients are typically considered the focus of medical device design, the findings highlighted the critical influence of physicians and hospitals in the use and adoption of new medical products.

In the broader context of complex systems design, this study brings to light challenges and opportunities associated with designing products in industries where end-users and end-customers frequently differ. Specifically, the findings highlight the importance of identifying product stakeholders and their influence on the use and adoption of new medical devices. This enables device developers to optimize product benefits to address the requirements of those with similar and conflicting needs.

2 METHOD – A CASE-BASED RESEARCH DESIGN

A two-phase multi-case inductive research study was conducted to examine the question: how do design and development practices involving physician-developer interaction[1] influence the clinical and financial outcomes of early stage medical device companies? An analytic framework for case-based research was first developed based on 13 exploratory interviews with leaders in the medical device field. Eight retrospective case studies (per Table 1) were then conducted on four rival product pairs in the areas of pulse oximetry, robotic surgery, cardiac bypass surgery, and minimally invasive spinal fusion surgery. In order to isolate differences in design and development practices per dyad, cases with similar attributes that resulted in divergent outcomes were selected, per Table 2. Development efforts ranged from 1975 to 2009 for the cases studied. The primary data sources for the retrospective cases included 40 semi-structured interviews with physicians and device developers from each company; design and development documents (IP and FDA approval data); clinical performance data (adverse event reports and journal articles); and financial performance data (private and public financing and SEC filings).

Table 1. Matrix of Retrospective Comparitive Case Studies

Case	Location	Temporal Boundary	Device Type	Clinical Area
Case 1: PulseX	California	1975 - 1986	Diagnostic Instrument	Pulse Oximetry
Case 2: PulseY	Colorado	1981 - 1987		
Case 3: RobotX	California	1989 - 2003	Therapeutic Instrument	Robotic Surgery
Case 4: RobotY	California	1984 - 2003		
Case 5: HeartX	California	1991 - 2001	Therapeutic Implant & Instrument	Cardiac Bypass Surgery
Case 6: HeartY	California	1993 - 1999		
Case 7: SpineX	Massachusetts	2000 - 2009	Therapeutic Implant & Instrument	MIS Spine Surgery
Case 8: SpineY	Massachusetts	1992 - 2009		

Table 2. Similarities and Differences among Cases Examined

Case Similarities	Case Differences
• Venture-backed entrepreneurial firms • Firms with a medical device focus • Products requiring physicians as end users, with patients as care recipients • Mechanical/electrical devices – no combination products or drugs • 510(k)-path products • Similar development years per dyad	• Geographic location (same for all dyads except Case 1 and 2) • Funding types (Private Only vs. Private & Public) • Outcomes per dyad (Financial amount at exit & Degree of Technology Adoption)

[1] Physician-developer interaction refers to the interaction between physicians and medical device developers (i.e. designers, engineers and marketing associates).

Following the period of data collection, within-case and across-case analyses were performed [6]. Audio recordings from each interview were manually transcribed and coded using *NVivo Qualitative Analysis Software (v. 8.0)*. The interview data was coded for design and development practices involving physician-developer interaction. Development practices that influenced company and product outcomes were then analyzed using logic models [7] and tables and graphs [9] to examine causal relationships between practices and outcomes. Design and development practices were further examined and validated using a combination of qualitative and quantitative evidence.

3 RESULTS

A key finding from the study revealed the importance of designing products to maximize benefits for multiple stakeholders, while minimizing required changes in physician behavior. This balance between benefit and user behavior change led to an increase in technology adoption for the cases studied. Design and development practices that had a positive or negative influence on maximizing value for product stakeholders are summarized in Table 3. The practices highlighted are those documented in a minimum of two interviews per case and 50% of the cases. These practices were further explored through an examination of costs and benefits for technology stakeholders, as summarized in section 3.1.

Table 3. Design & Development Practices with a Positive or Negative Influence on Maximizing Value for Product Stakeholders

Practices with [+] Influence on Outcomes	**Practices with [-] Influence on Outcomes**
• Design products to provide a cost reduction and an increase in profit margins for hospitals and payers. • Design products that require minimal changes in user behavior for physicians and clinical staff members. • Design devices that increase physician procedure volumes. • Design products that provide clinical benefits to patients, in comparison to the existing standard of care. • Integrate existing technology, when possible. • Focus on designing for user experience. • Course correct in response to changing user preferences – i.e. switch from MIS to open procedures to facilitate ease of use. • Design whole procedures over individual components; focus on “what’s the job to be done?”	• Develop products that require significant shifts in user practice. • Develop procedures that take significantly longer to perform than the gold standard, and decrease procedure volumes. • Provide a non-compelling benefit to stakeholders or a non-mandatory clinical procedure. • Regard user interface as secondary to technical benefit. • Develop procedurally and technically difficult surgical procedures, with steep learning curves.

3.1 Product Benefit v. Cost Analysis

To probe deeper into the design and development practices in Table 3, a range of technology-specific metrics pertaining to stakeholder benefits were examined for one product area per case. The behavioral changes required to use each device, relative to the existing standard of care, were examined as a metric of product cost.

Benefits to Product Stakeholders

Product benefits were assessed according to the advantages afforded to each primary stakeholder: patient, physician, healthcare facility, and payer (insurer). Using an analysis method similar to the Pugh Chart[2] concept selection process, at least one product area from each company was compared to the existing standard of care as a baseline. For instance, pulse oximeters from PulseX and PulseY were compared to arterial blood gas measurements. Computer-assisted surgical robots from RobotX and RobotY were compared to conventional laparoscopic surgery. Comparisons were based on clinical data from 55 peer-reviewed studies. Examples of metrics for patient benefits included average blood loss, hospital stay, and patient mortality rate. Physician benefit metrics included factors such as total operative time, degree of visual access, and financial gain. Hospital benefit metrics included patient volume, facility prestige level, cost and profit margins. Payer metrics included the reimbursement amount received for a procedure, and the number of procedures performed per year.
Mean product benefit (per equation 1) was calculated per product area by summing the benefit values for each stakeholder category and dividing this value by the total number of metrics. A summary of product benefit scores per case is shown in Table 4.

$$\text{Mean Product Benefit} = \frac{\sum(\textit{PatientBenefit}, \textit{PhysicianBenefit}, \textit{HospitalBenefit}, \textit{PayerBenefit})}{\text{Number of Metrics}} \quad (1)$$

Table 4. Product Benefit Data per Case, Relative to Standard of Care

	Product Benefit to Stakeholders Relative to Standard of Care								
	Patient		Physician		Hospital		Payer		Mean Product Benefit
Case [Product]	Sum	Mean	Sum	Mean	Sum	Mean	Sum	Mean	
PulseX [PX1]	1	0.14	2	0.33	2	0.50	2	1.00	0.37
PulseY [PY1]	1	0.14	6	1.00	2	0.50	2	1.00	0.58
RobotX [RX1]	0	0.00	-2	-0.17	-2	-0.50	0	0.00	-0.17
RobotY [RY1]	0	0.00	2	0.17	2	0.50	0	0.00	0.17
HeartX [HX1]	3	0.43	-5	-0.83	-2	-0.50	0	0.00	-0.22
HeartY [HY1]	4	0.57	-1	-0.17	4	1.00	0	0.00	0.39
HeartY [HY2]	3	0.43	2	0.33	4	1.00	0	0.00	0.50
SpineY [SY1]	4	0.67	-5	-0.83	-1	-0.20	0	0.00	-0.11

Product Costs (User Behavior Change)

Product cost was assessed in terms of required behavior change, or the degree to which physician behavior deviated from the existing standard of care. Required changes in physician behavior were evaluated as a metric of cost, since themes that emerged from the data focused on the switching costs associated with changes in user practice when adopting a new technology. A value for behavior change was qualitatively based on the following three metrics: procedural differences (type of actions/steps); roles and communication shifts; and medical tools used. A value of "0 - 33%" was assigned if the new technology required minimal change in user behavior compared to the existing standard of care; "34 – 66%" for a medium degree of change; and "67 – 100%" for a high or significant departure from the gold standard.

Linking Product Benefit & Behavior Change to Technology Adoption

Using product benefit and behavior change data described above, the ratio of total product benefit to behavior change was compared to technology adoption, across dyadic pairs, as shown in Figures 1 (a-

[2] A Pugh Chart is a design tool for comparing ideas against a design criteria early in the design process [9].

c). In these comparisons, compound annual growth rate (%CAGR) was used as a metric for short-term technology adoption. For each of the product pairs[3], the data illustrates that an increase in technology adoption corresponded to an increase in the ratio of product benefit to physician behavior change.

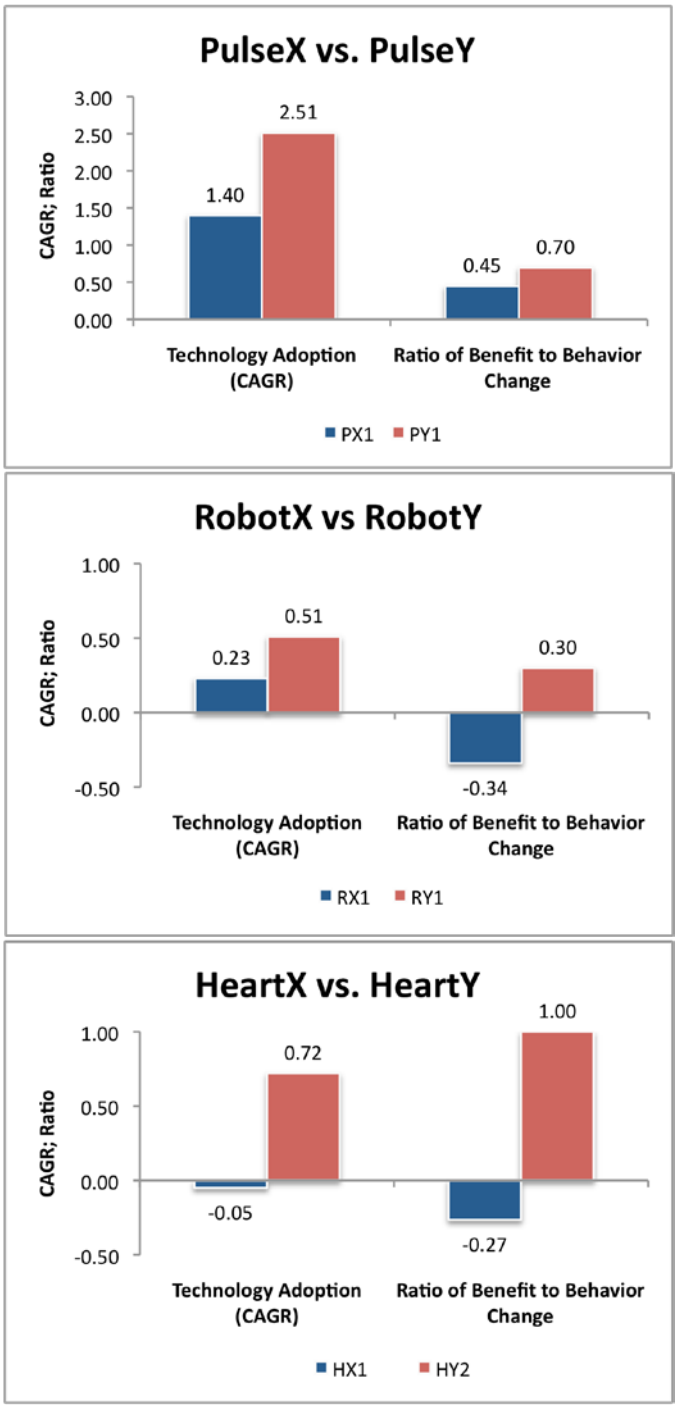

Figure 1 (a-c). Benefit to Behavior Change Ratio Compared to Technology Adoption

To explore which of the four stakeholders (patient, physician, hospital and payer) had a dominant influence on total product benefit, the difference in mean product benefit per stakeholder category was examined per dyad (from the data in Table 4). The results are shown in Figures 2 (a-d).

[3] SpineX and SpineY were excluded from the comparative analysis since the clinical fusion data for SpineX was too recent to evaluate.

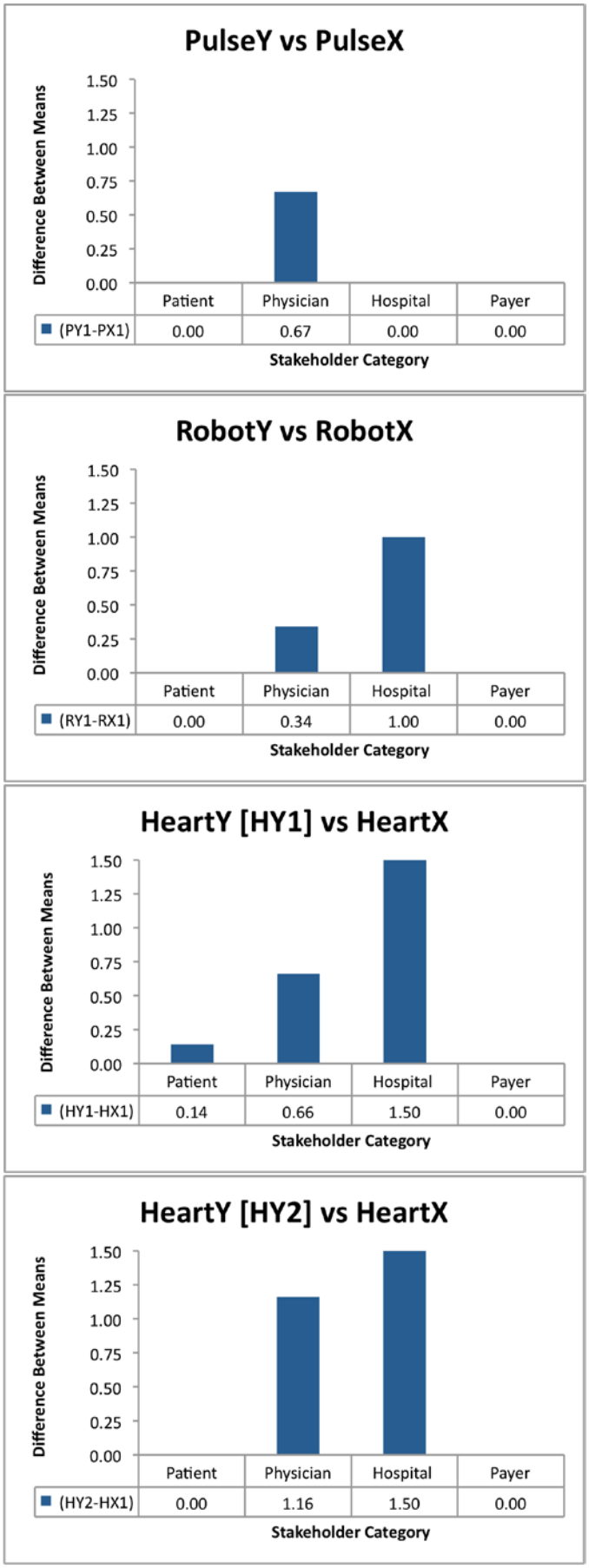

Figure 2 (a-d). Difference in Mean Product Benefits per Dyad

The data in Figures 2 (a-d) illustrate that the greatest difference in benefits between dyads is seen for benefits provided to hospitals and physicians. These findings emphasize the importance of designing products to enhance user experience and financial benefit for stakeholders, in addition to improving clinical benefits for patients. As an interesting example to highlight from the above graphs, HeartY's initial product (HY1) was technically better for patients, in comparison to the standard of care and to HeartX's products, but not as beneficial to doctors. In order to increase product use, the company quickly course-corrected and launched its second-generation product, HY2, which provided greater physician benefit, unfortunately at the expense of patient benefit (although HY2 still performed better than the gold standard).

4 DISCUSSION

The data presented in this paper showed that maximizing benefits for technology stakeholders while minimizing required user behavior changes contributed to an increase in technology adoption for the cases studied. An examination of product costs and benefits revealed differences in product value from the vantage point of stakeholders with conflicting needs. The data showed that the greatest differences between the high and low performing products (or product Y vs. X) were seen in terms of benefits afforded to hospitals and physicians, with patient benefit being greater than or equal to the standard of care in each case. In other words, medical devices providing clinical benefits to patients (end customers) were not widely adopted, unless they provided benefits to both physicians (end users) and hospitals (product buyers).

The findings highlight the importance of carefully assessing which stakeholder requirements have the greatest influence on product adoption, and then designing and optimizing technology to satisfy such needs. Although patients are typically considered the end users (and primary focus) of med-tech innovation, the data shows a somewhat contradictory result. It illustrates that product acceptance and use depend heavily on a product's ability to enhance physician user experiences, and to increase financial benefits for hospitals and physicians.

The impact that hospitals and physicians had on the cases examined may be attributed, in part, to the dependency of hospital benefit on physician benefit, and physician benefit on patient benefit. For instance, if patients experienced positive clinical outcomes, physicians often experienced higher patient volumes and benefited financially. Likewise, if a physician's volume increased for a particular procedure, hospital profit margins typically increased, assuming that the added procedures did not incur additional costs. Therefore, although the greatest differences in benefits between high and low performing products were seen in terms of benefits to hospitals and physicians, patient benefits had to exceed the standard of care in order for a product to experience sustained clinical use.

In the context of user-centered design for the development of complex systems, this research brings to light the challenges associated with designing products in industries where end-users and end-customers frequently differ (i.e. the aerospace and defense industries). This study highlights the importance of identifying the often-conflicting needs and requirements of stakeholders, and then optimizing devices to address the needs of constituents with the greatest influence over the acceptance or rejection of new products. Future research is required to understand the dynamics of stakeholder relationships and the interdependencies among end users, end customers, and product buyers across a range of innovation settings.

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