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COLLABORATIVE CREATIVE DESIGN PROCESS IN MEDICAL DEVICE DEVELOPMENT

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Abstract: Designing and developing a medical device is a complex exchange of ideas and theoretical concepts requiring multiple disciplines working towards viable solutions. It requires collaboration and cross-disciplinary effort between designers, clinical specialists, scientists, and engineers. This paper focuses on collaborative creativity between designers and physicians as well as the influence of design practice in order to advance conceptual theory. A total of 23 teams were given either a problem or a theoretical solution to design for six months to develop. Tangible results include 23 intellectual property disclosures, 12 provisional patents filed with 4 converted to non-provisional patent applications. The teams creative processes varied dependent upon the starting point of the design process and all included an increased reliance upon an interchange of disciplinary knowledge, trust, and concept experimentation. Smaller teams which were better able to identify key parameters of the design concept and subsequently generous robust solutions.

Keywords: *medical device design, industrial design practice, collaborative creative design and process, creativity in a regulated environment, design of experiment, translational science,*

1. Introduction

This paper is based on observed interactions between designers, physicians, and engineers during the process of design of medical devices in the Medical Device Innovation Program at the University of Cincinnati. Gero (2010) poses several questions regarding the areas of team design process and outcome of team membership. This paper addresses the team process and behaviour in relation to outcomes within a specialized area of industrial design practice. A total of 15 multidisciplinary teams were observed in the design process from initiating solution generation through to demonstratable feasibility over the course of two academic years. This active program integrates the practice of industrial design with biomedical engineering and targets clinical problems which occur in the hospital setting. All problems have minimal or non-optimized device solutions and are important clinical barriers as communicated by collaborating clinical practitioners (mostly physicians). Example areas of device development include design teams working in the following areas: Neurosurgery, Neuro-intensive Care, Neurology, Emergency Medicine, Orthopedics, Thoracic

Surgery, Otolaryngology, Cardiology (interventional), Opthamology, Transplant Surgery, CardioThoracic Surgery and Pharmacy.

1.1. Medical device development process

The medical device development process is very similar to the the development of consumer product development with exception of design research rigor as mandated by regulated bodies which are country specific. In the United States, this is our Federal Drug Administration (USFDA). All medical device must pass through an approval process by the Center for Devices and Radiological Health (CDRH) within FDA in order to market a device with clinical indications of safety and efficacy. As such, the design process and its elements are impacted. The design process within the regulatory framework as seen in Figure 1 below illustrates a typical design process (rounded boxes) with the mandated regulatory development process represented (hard cornered boxes). The design process presented here, in itself is not necessarily novel to medical devices however the requirement that all steps within the process be addressed and documented is a specific trait of medical device development (USFDA).

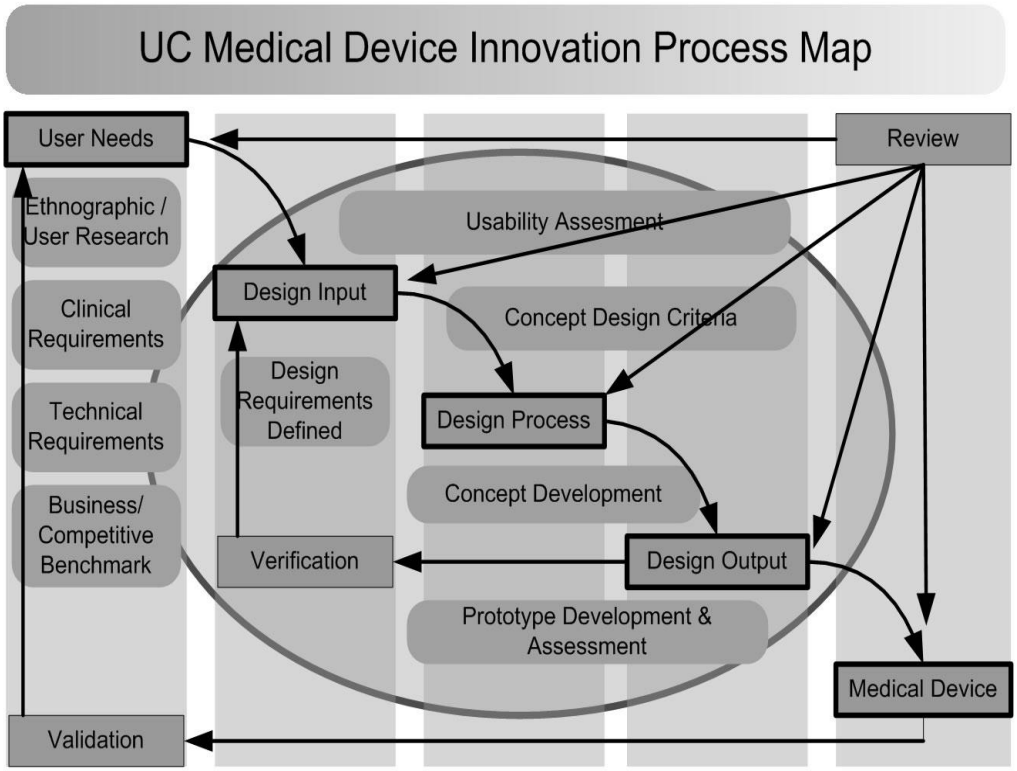

Figure 1. Medical Device Innovation Process Map. Blended design process of the regulated medical device development design control diagram as mandated by the US Federal Drug Administration and typical industrial design process

In many instances following this process in a rigid prescribed series of steps is a challenge and is not reflective of the variability of exploration by a design team. Due to this exploration it is intended by regulating bodies that the process by cyclical and reviewed at major milestones. During this process both science and design become interwined with blurred boundaries (Privitera, 2009).

1.2. Medical device development process

In order to diagnose or treat disease, a medical device must have its fundamental functional roots based in science. This may be a biological or physical scientific application. Firgure 2 below describes the interaction of scientific exploration throughout the design process. In order to be successful smaller feasibility of the underlying science behind a medical device is continuously challenged with each challenge growing in complexity and understanding (Privitera, 2009).

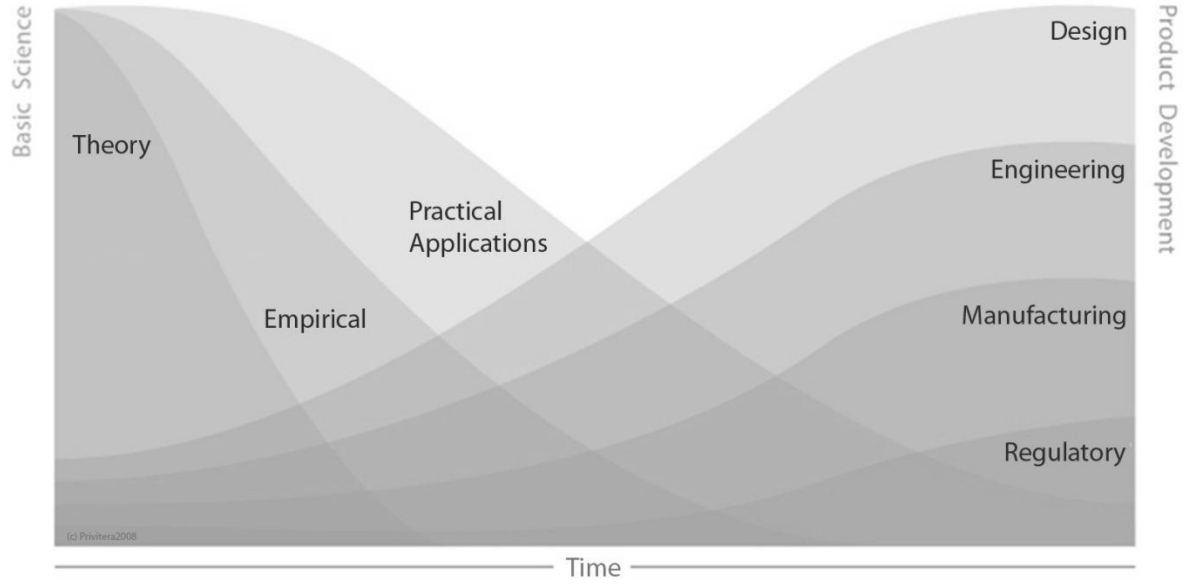

Figure 2. Basic Science vs. Product Development. Scientific research forms the fundamental principles to better explain our world whereas design and engineering apply science into opportunity to improve our lives.

Figure 2 also represents that the practice of science and the development of a medical device are intertwined yet still independent activities (Privitera, 2009). Medical device design relies on key clinical input beyond anatomy and physiology whereas product development is firmly routed in (most often) applied physical science towards commercialization and distribution.

2. Creative team

Teamwork when designing complex systems, especially ones which have a direct impact on patient health, is not optional. Each discipline or team member must find meanss of communicaoin and personal stype which allows for their disciplinary tenets to survive in the overall proposed design/s. Individual personality and bias do play a role throughout the design process. If bias is negative and/or judgemental regardless of discipline creativity of design is hindered.

Goldschmidt (2010) reports an expert from any domain has extended memory of cases and concepts within that domain. Further, that the ability to draw on similarities between the current task and cases that they are currently addressing result in making longer chains of associations. In medical device design experts (clinical) are imperative in order to communicate the context in which the device is to be used, challenges of clinical practice and keeping the goal of the target use at the center of device development. Clinical experts demonstrate evaluation of a proposed design immediately and communicate potential value, benefit or lack thereof. Designers and engineers on the design team are required to become well versed in the nomenclature, anatomy and physiology at the location of the

clinical problem being addressed. Freudenthal (2011) describes two distinct phases for the design of complex medical technology as initially learning about the clinical requirements i.e. environment of care, anatomy and physiology, etc and then secondarily shifting traditional pradigms to be open to new approaches. This requirement of learning is an additional commitment by design and engineering to gain knowledge in new areas (clinical practice) in order to inform design solutions and communicate effectively with clinical counterparts.

Motivation of individual team members is considered judiciously in proper team assignment in order to assure this additional commitment of learning can be achieved. This is accomplished by allowing participating designers to self select which topic of medical problem they desire to work. This self selection assures commitment to the undertaking of gaining non-traditional knowledge in order to apply design skills in this collaborative environment.

2.1. Clinical personnel

For this research the clinical advisors for all teams are experts within their domains and have mulitple years of mentorship with assisting young physician residents and fellows. These practitioners participate within the Medical Device Innovation Program as a volunteer to assist design teams develop empathy for their goals, processes and methodology in their clinical practice.

2.1. Design and engineering

Design students from the fields of industrial, fashion, digital and graphic design participate on design teams. The majority of which were industrial designers of upper level undergraduate or graduate level students. Engineering students were recruited from biomedical, electrical and mechanical engineering with the majority of students stemming from the biomedical field and all undergraduate students.

The team constituents were optimized based on project need and the likelihood of success i.e. engineers were invited to the team only when the discipline was required and vice versa for all participating design disciplines. This presents a variable in team size and disciplinary make-up which cannot be avoided to optimize the likelihood of a viable solution. In some instances recruiting of additional disciplines to complement a working team skill was completed.

3. Initiating the design process

All teams were presented an innovation brief to start their design process. The innovation brief, much like a design brief, identified either a potential solution or a problem. These innovation briefs are vetted by the clinical advisor and faculty mentors prior to the start to assure approporiate complexity and curricular fit. No design problem is repeated and each team was provided an open studio space available 24/7 days a week for 6 months. 9 of the 15 teams were presented with a problem innovation brief whereas 6 were presented briefs which contained a potential solution or pathway to follow for a given clinical problem. The table below represents the topics, team disciplines, size and discipline participation with patent filing results.

Table 1. Team and Project Descriptions

Projects	Brief Type	Team Size	Disciplines Participating	Filed Intellectual Property
Sleep Apnea Diagnosis	Problem	5	Industrial Design, Biomedical & Electrial Engineering	2 provisional
Assistive Surgical Skin Flap Device	Problem	3	Industrial Design, Biomedical & Electrial Engineering	None
Cranial Fixation	Problem	4	Industrial Design & Biomedical Engineering	1 provisional
Stomach Clamp Implant	Solution	3	Biomedical Engineering	None
Natural Orafice Volume Expander	Problem	5	Industrial Design & Biomedical Engineering	1 provisional
EEG Cap	Problem	4	Industrial Design & Biomedical Engineering	None
Sinus Dilator	Solution	4	Industrial Design & Biomedical Engineering	2 non-provisional patent filing
Catheter Interface	Problem	2	Industrial Design & Biomedical Engineering	1 provisional
Thoracic Tissure Retreival Bag	Problem	3	Biomedical Engineering	none
Shoulder Impant	Solution	4	Industrial Design & Biomedical Engineering	none
Liver Resection Device	Problem	3	Industrial Design & Biomedical Engineering	1 provisional
Multi-lumen Catheter	Problem	4	Industrial Design & Biomedical Engineering	none
Drug-eluding Balloon Catheter	Solution	2	Biomedical Engineering	none
Stroke Diagnosis using electro-spectroscopy	Solution	4	Industrial, fashion Design & Biomedical Engineering	2 non-provisional
Electrostimulation for Blink Reflex	Solution	5	Industrial, Fashion Design & Biomedical Engineering	1 provisional

3.1. Starting from a problem

An example problem statement from this type of innovation brief is ‘design a means to deliver a liquid embolyic agent while allowing for distal perfusion in the treatment of intracranial aneurysms.’ In laymans terms, a brain aneurysm (intracranial aneurysm) is a portion of the aterial system in the brain where the elasticity has degraded allowing for a ‘pocket’ to develop. An available therapy is to deliver a clot creating agent (embolic agent) within the pocket to block off any turbulent blood flow and restore normal flow parameters. Much like this explanation, the first step for the design team is to further define the problem in terms and examples they can understand. The process by which this is completed includes literature search on anatomy, clinical practices, and available tools. The use of contextual inquiry with visual procedure maps indicating stress points for the user as well as specific tools used, why and when (Visser, 2005).

3.1. Starting from a solution

An example problem statement from this type of innovation brief is to ‘design a device which stimulates a blink reflex using electrostrimulation and is intended for use in a pediatric critical care unit.’ In this instance the technology, while not specifically defined is targeted as is the location and

context of use. In this regard, the team is able to efficiently determine what questions need to be asked, who needs to be observed with the ability to put together a defined design process and subsequent schedule.

3.1. Challenges and success across teams

All teams were required to achieve a functional prototype and appearance model within 6 months. The differences in approach dependent upon starting point resulted in a communicated perception of 'easy or hard' and/or 'defined/less defined' exploration. The majority of teams started with problems to be solved with little constraint on creative problem solving other than 'it has to work at least in theory.' The approach taken by these teams included the design of anatomical models to represent their design problem. For example, for the surgical creation of a skin flap which is primarily used in breast cancer repair, the student team used grocery store chicken to complete initial experimentation. Creative approaches to explore and replicate the problem allowed the team to coalesce and develop empathy for clinical approach.

Team size was a variable and inconsistent across all teams. This did have an affect on creative problem solving and subsequent design. Smaller teams acted in a more aggressive manner towards solution identification and were more effective when multiple disciplines were included.

4. Novelty of design: ability to push beyond the obvious

Inherent to the interaction between design and engineering interchange is a fundamental difference in training wherein engineers (US based) tend to look for 'the' answer to a given problem whereas designers tend to look multiple answers and possibilities. Bringing these together in did balance each other out and pushed each discipline to seek the other view point. For the engineers, pushing beyond the obvious when functionality is required seemed futile, however for the designers having to assure that the possibilities they defined as a solution would potentially work resulted in a methodical approach and a reliance on this relationship.

Beyond disciplinary bias in the design process the personalities of each individual played a role. Natural tendencies, especially of the clinical partners in acceptance of novelty was evident. Simply stated each team personalities included 3 main characters: mavericks, midliners, and naysayers. Mavericks are those participants who leap to the new and novel and are extremely open to the possibility of 'what if.' Midliners were those who sat on the side, waited and watched, contributed when necessary however lacked in leadership. Naysayers were those that no matter what the design promised they always sought issue and communicated as such. In highly active teams each of these personality types were present and improved the solution. Dependent upon the fidelity in the design process the interaction and reliance of certain personalities did require management in order to facilitate moving forward.

5. Conclusions

Collaborative creative design process is as complex as the development of a medical device with all its variables. This paper focused on medical device design concludes the following learnings as a result of reflection and performance analysis:

- Designers and engineers on the design team are required to become well versed in the nomenclature, anatomy and physiology at the location of the clinical problem being addressed. This requires addidtional commitment by design and engineering to explore new areas in order to inform design solutions

- Small teams with defined roles and trust enable creative design. The 3 defined personality roles, mavericks, midliners, and naysayers provided consistent negotiation throughout the design process and at times required management.
- For medical device design, the reliance of disciplinary knowledge with respect to clinical care cannot be avoided.
- Defining the design parameters can be both a hinderance as well as topic of brainstorm activity.
- Within the medical device development context experimentation is critical to success. This includes the design development of the actual design and the design of the means by which the design is assessed as a replication of the clinical patient condition.

Medical device development is a specialized practice within design and most typically executed by industrial designers and increasingly practiced by interaction as well as fashion designers. The findings of this paper apply to medical device development in general regardless of discipline/s participating. The team constituents were optimized based on project need and the likelihood of success. As a result, this study has multiple variables which are unavoidable for design optimization however may be problematic when evaluating any individual element within the collaborative design process. Additionally due to eventual regulatory requirements for market release the design process is robust in documentation with formalized requirements embedded within the design process. Further research of individual elements within the medical device design process is warranted in order to optimize efficiency and maximize creative solutions for enhanced medical device development.

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