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Interconnections of basic science research and product development in medical device design

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Abstract—**The relationship between basic science research and product design/development are intertwined. This paper explores the definition of basic science and design as it relates to medical device development. It is intended to serve as a reference for both researchers and device developers to assist in trans-disciplinary collaborative efforts in improving patient care as each are of equal importance. The definition of a medical device is broad and varied. This paper is aimed towards those devices which interact with tissue and are rooted in the tenets of science. Both the scientific method and the design process are compared with similarities and opposites identified. The paper concludes identifying fundamental principles of medical device development and highlights the importance of both entities.**

I. Introduction

MEDICAL device development is rooted in the synergies combining the "what if" of design process within product development with sound "scientific method" problem solving skills. Whereas the goal of science is understand the world, the goal of design in product development is to improve lives through commercially viable products. In medical device design, both science and design are inherently connected. For a design to be clinically successful, technical efficacy and reliability must be the foundation while expressing functionality through incorporating applied human factors and sensitivity towards aesthetics and market perception [1]. This paper addresses the inherent connection of science in design

II. Basic Science

According to the AMA, basic science research is the investigation of a subject to increase knowledge and understanding. The information gathered from basic science research is essential for "translating" or applying new discoveries to patient care [2].

Basic science research has the objective to advance knowledge; its beauty is in the quest for understanding of the world as we know it. It is conducted via the development a hypothesis, the design an experimental protocol to test the hypothesis, the conduct of an experiment or survey, and the use of an appropriate statistical analysis of the data. The process explores the breaking apart of elements in experimentation within a particular environment. That said, often it is in the unexpected results during experimentation that leads to a practical application of the knowledge gained. Traditionally, basic science research is considered as an activity that is preceded by applied research or translational research, which in turn precedes the development into practical applications and most often completed in an academic setting. The reality for medical device design is that the basic fundamental scientific principles applied to a product design to treat a particular disease are constantly being verified and tested through both direct application in patient care and full clinical trials. In essence the science behind the device is under constant review and exploration. These reviews are conducted not only within institutions but also in the industrial entities that have vested interest. In essence, medical device design requires constant exploration of the basic science principles that a device is founded upon.

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III. Design

As a word, design is both a noun ("a design") and a verb ("to design"). The definition of design is varied and complex depending upon the author of the definition. For example, an engineer may define the design of the device as the elements within a product/device which affords functionality e.g. a motor. For an industrial designer, the definition of design may be viewed as a more rigorous form of art with a clearly defined purpose meeting the needs of a particular user group. The practice of industrial design implies a conscious effort to create something that is functional, easy to use and aesthetically pleasing. There is a consistency of opinion which exists in that all design efforts in product development result in a tangible viable product that is useful, usable and desirable [3]. Figure 1 highlights the core values and concerns of a cross-functional design team to balance fundamental disciplinary tenets of function (engineering), appearance (industrial design) and value (business). For a design and subsequent product development effort all of these attributes must be taken into consideration.

For medical device design, these values for design are evident but not necessarily equally weighted. Obviously clinical utility is of utmost importance; however user groups are increasingly aware of requirements relating to the perception of value and appearance.

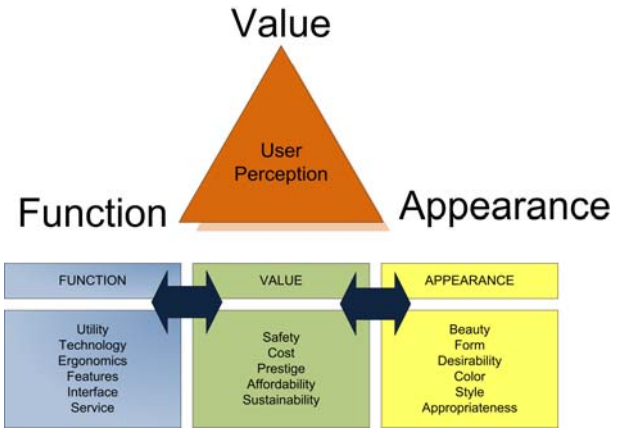

Figure 1.Cross Functional Properties [1].

IV. CONNECTIVITY OF BASIC SCIENCE AND PRODUCT DEVELOPMENT

Leonardo da Vinci, both an artist and a scientist, was free to explore and discover anatomy/physiology in manners unique to himself and his abilities in both disciplines. Although he was obviously unable to commercialize all of his innovations, his work is representative of the possibilities within the interplay between professional disciplines. Unfortunately most of us do not have the freedom of exploration or the skills of expression of a da Vinci. As a result we must learn necessary trans-disciplinary skills and capitalize on theory of group capacity thereby tapping into expertise in basic science as well as design development.

For medical device design, all design solutions are founded in basic science. Figure 2 depicts the connections of basic science with product development. As indicated in the diagram, design is typically utilized after a scientific theory

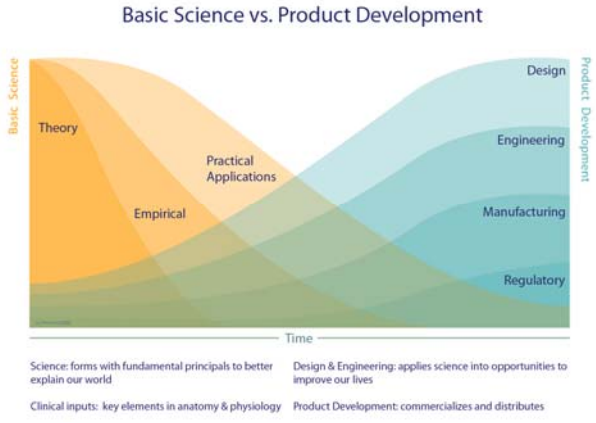

Figure 2.Relationship between basic science and product development

has been proven and initial feasibility has been vetted. A subtle difference can also be noted in that for product development, all of the core areas which need to be addressed are not likely to be the expertise of a single individual. Likewise, in basic science a novel theory may very well be the result of independent efforts, although this is decreasing in prevalence as basic science exploration is increasingly cross-disciplinary.

It is important to note the intentions of this diagram are to highlight undulations of activity relative in time for both communities. Neither is finished, just more or less active.

V. SCIENTIFIC METHOD VS. DESIGN PROCESS

Table 1 identifies the general steps in both the scientific method and the design process. While there are similarities between steps the major difference between the processes is in repeatability.

For medical devices it is important to have a balance of both approaches. The scientific method accounts for quantitative and qualitative data analysis which then must be translated into actionable requirements for design. These requirements become the drivers of design development with the prioritization of features and, ultimately, influence the final design.

For medical device development it is important to have the ability to trace all design decisions to a device requirement that is justifiable via scientific experimental exploration or explicit/implicit user communication. Avoiding this step can create pitfalls during regulatory review. All organizations within the medical device industry vary with regard to specific development process but each of the steps listed below remain common and are fundamental to medical device development. For most devices the process starts by defining the device's clinical objective in terms of end-effecter function or tissue interaction, then working toward a method of controlling it. In essence, good medical device design is as much as about identifying the key problems as it is about solving them.

1. Comparative Analysis: seeking appropriate materials and technology for the device

All design is re-design. In the process of problem definition, analogous technologies and methodologies can assist the design team to identify similar problems found in other disparate worlds e.g. the same company that manufactures a robotic arm for space exploration also manufactures a robotic arm for neurosurgical applications Another example would be that a gastroenterology endoscope is the medical version of a drain pipe camera.

2. Analysis of anatomy and physiology

Specifically, researching the anatomy or disease state in which the device will interact. By analyzing the biomechanics of the tissue type, appreciating thickness, viscosity, and response to stimulation, the design team can avoid many pitfalls and make better decisions.

Scientific Method	Design Process
1. Select topic	1. Define problem
2. Gather observable, empirical, and/or measureable evidence	2. Research: users & ethnography, technology, context, etc.
3. Formulate hypothesis	3. Develop Design Requirements
4. Design and conduct an experiment	4. Brainstorm: Ideate
5. Analyze the data and draw conclusions	5. Decide & Detail
6. If necessary, revise hypothesis and repeat	6. Verify Design
This process must be repeatable or will lack credibility.	**This process is fuzzy. It may or may not be done in this order and does not require repeatability.**

Table 1. Scientific Method vs Design Process

3. Benefits of reading and interpreting scientific journal articles

While the web is an excellent source for competitive benchmarking for business opportunity determination it is not subject to the rigors of scientific journal publication. Peer reviewed journals mitigate marketing exaggeration and serves as a source of reliability and clinical efficacy reporting for many medical devices.

4. Importance of hands-on medical device training

Typically designers learn through experimentation and observation. Allowing a design team to perform the intended task (in a controlled, simulated setting) aids in realizing the overall clinical goal, allows for the exploration of anatomy and tissue type and provides a great team building experience.

5. Using computational tissue modeling as a means of predicting clinical success,

In many ways, the success of a design is dependent on its relationship between look, feel, and function. Currently, the process employed to optimize this relationship is more art than science. While AAMI/ANSI and other organizations provide a multitude of standards, the design process itself is fluid, variable, and obtuse. The problem that exists is that the process is driven by the individual knowledge (which is also fluid, variable, and obtuse). Employing computational models of tissue-device and user-device interaction provides transparency of the process and brings consistency across device designs.

6. Using biological inspirations to address and solve clinical problems,

Biomimicry as inspiration for device development can be found in both the scientific and the design professions. This method of creative thinking can broaden the solution possibilities.

7. Going beyond published research and developing applicable testing procedures,

Going through the design verification process ensures that a design meets the intended design requirement as mandated by the FDA. This means that if you say your device is white, you must have a test to verify that it in fact is white. Determining the test methodology and mitigating factors is complex for most medical devices. It as much the "art" in the design of experiments as it is the "science" being explored. If the testing data is not accurate or logical, the design decision and possible subsequent clinical application of a technology may fail (or succeed unwittingly). For example, a poorly designed bench-test my yield positive results while in vivo application may fail with difficult identification of causation.

8. Observe and interview thought leaders and key partnerships: utilizing ethnography [4]

Medical devices are sold through the current thought leaders and their respective research. There is great pride within the medical community with regards to clinical prowess. Since the science of medicine is still somewhat subjective in patient specific care, personal beliefs and location play a role in decision making. By utilizing social science methodologies, a design team can determine beliefs, practices and opinions that form tenets for a particular user group. While these tenets may seem like barriers, they must be recognized as the current standard of care.

9. Multi-disciplinary approaches to problem solving.

Design education and the practice of design thinking employs the skills necessary to problem solve through the exploration of form, among other methods. This problem solving through form and geometry is necessary when designing tools that interact with tissue, especially in cases where the device use requires intricate interaction through complex anatomy. By capitalizing on disciplinary strengths a truly collaborative solution can be accomplished. Figure 3 illustrate the collective efforts of a multi-disciplinary team from students in the University of Cincinnati Medical Device innovation and Entrepreneurship Program (UC MDIEP) student team. These sketches of a stem cell harvest device both analyze the problem visually through sketching and begin to identify potential solutions.

10. Regulatory will affect the final product solution architecture as well as the design/development process

Regulatory pathways are often viewed as a significant hurdle if best practices are not a priority for a development

team. Additionally it is important to recognize that not all regulating entities have the exact same processes, expectations and standards e.g. in the USA the regulating body is the FDA, while Europe is regulating by Medical

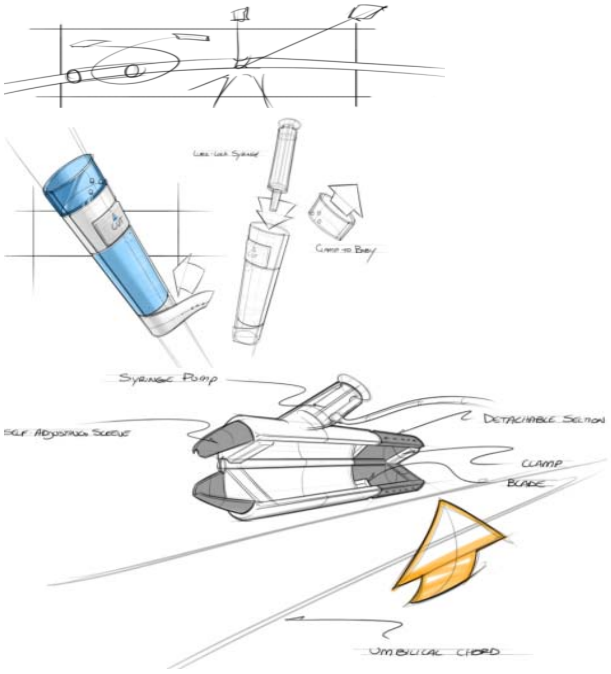

Figure 3. Stem Cell Harvest System

Device Directives (MDD). There is however a task force, the Global Harmonization Task Force (GHTF) to synergize mandates with the hopes of easing the burden for international device development.

VI. Conclusion

Design allows for the translation of complexity into easy-to-use, innovative products. By informing ourselves about the specifics of medical conditions e.g. disease, tissue characteristics through scientific explorations and utilizing a thorough design process as an innovation strategy, patient centered advances in the field of medical device design can be readily achieved. Following a thorough design process should incorporate principles found in basic science research.

In summary, the relationship between basic science research and product design/development are becoming increasingly intertwined and neither will ever be finished. For science, we don't know what questions we will ask and for design, we don't know what life will bring us.

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