Academic Entrepreneurship for Medical and Health Scientists

Volume 1
Issue 4 *Ideation*

Article 1

9-23-2019

Identifying Unmet Needs: Problems that Need Solutions

Diane Dao
University of Pennsylvania Health System

Jacob Brenner
University of Pennsylvania

Identifying Unmet Needs: Problems that Need Solutions

Summary

- Invention is not an innate skill available to only a select few; it can be learned.
- Defining the need is the first step to determining the solution.
- A need statement helps define the problem concisely.
- Need specification is critical to defining the attributes required for device success.
- Invest in ideas that have the best chance of success by considering the market size, reimbursement pathways, and technology gaps.
- An algorithmic approach can be used in the stages of invention.

Identifying Unmet Needs:
Problems That Need Solutions

Diane Dao, MD, MPH,[1] and Jacob Brenner, MD, PhD[2]

Topic Relevance by Timeline

Summary

- Invention is not an innate skill available to only a select few; it can be learned.
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Introduction

When we, as scientists think of invention, we think of the "eureka moment" when inspiration merges with a growing need, discovery, or creation. In reality, the process of invention is like exercising any other muscle of the brain. Even though most doctors are not currently trained in innovation, the skills of invention can, in fact, be taught and learned. This chapter will explore the process of defining unmet needs and establishing the foundational steps to invention. We will also discuss the guiding principles to invention: defining potential needs, prioritizing a selected need, identifying a need statement, creating need specifications, and inventing through an algorithmic approach.

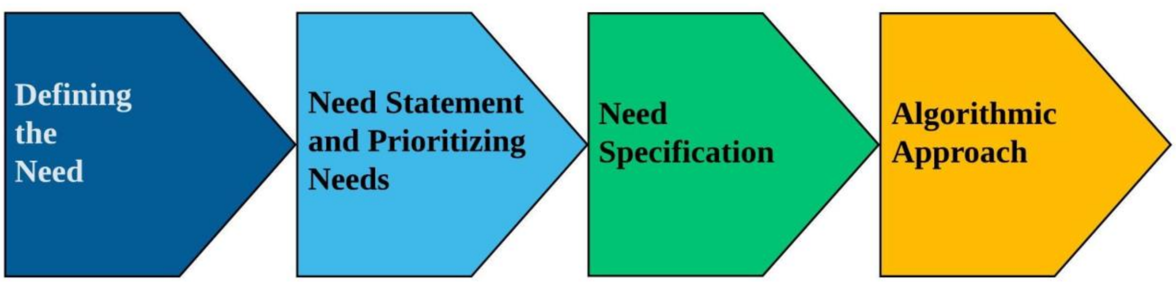
[1] University of Pennsylvania Health System
[2] Perelman School of Medicine, University of Pennsylvania

Invention Can be Learned

A common misconception about invention is that it is dependent on an individual who has an innate ability to generate a new idea. This misconception can be particularly pervasive in the medical community, as we are not trained to think of ourselves as inventors. However, scientists have invented for centuries. Consider cardiothoracic surgery, which has existed since the 1950s; It required many innovative thinkers to create the milestone inventions that allow a surgeon to open a patient's chest, arrest the heart, and perform cardiac surgery. At that time, it would have seemed unfathomable that cardiac surgery could be performed without a chest incision, yet now, it is a reality. Today, transcatheter aortic valve replacement (TAVR) meets all of these criteria and exhibits significantly lower morbidity and mortality. These inventions were not "lightbulb moments" that required a genius to understand, but rather a logical path with iteration and perseverance that led to the evolution of minimally invasive cardiac surgery.

There exists a unique opportunity in medicine to teach physicians, students, and faculty about the stages of invention, which can empower them to become leading innovators in the healthcare field (see the chapter "Careers in Academia and Industry: Transitions and Challenges"). One model of teaching invention has come from Stanford Biodesign. Founded in 2000 by physicians Paul Yock and Josh Makower, Stanford Biodesign is an ecosystem for academic entrepreneurs to investigate and discover new ideas to effectively and efficiently address healthcare needs. A trainee may start with the dream to invent and help patients. But, how can they achieve this? Stanford Biodesign has developed a systematic approach to uncovering needs; variations of these principles will be discussed in this chapter (Figure 1).

Figure 1. Systematic Approach for Uncovering Needs.



Defining the Need

Along the path to a new device invention, there are a few key steps. They include: need specification, prototyping and testing, regulatory considerations, and reimbursements. This chapter will focus on need specification, but it will also anticipate and consider the subsequent steps of invention (e.g., prototyping, regulatory, and reimbursement). This method consists of identifying the need, establishing the need statement, and defining the need specification. Once the need is identified, the need statement should concisely and clearly state the problem. The need specification should summarize the requirements for an invention to succeed in the market, and it will be discussed further in the "Need Specification" section later in this chapter.

At Stanford Biodesign, all teams are required to conduct two months of clinical immersion in order to observe various procedures in different settings, ranging from the operating room to a clinic. In this stage, talking to key stakeholders, such as physicians, nurses, and administrators, in the clinical field can provide valuable insights (Zenios et al.). First and foremost, an academic entrepreneur must observe. The goal of this observation period is to truly examine, decipher, and understand the overarching healthcare environment rather than ask for discrete problems and needs. It is important to ask questions, but it is equally important to evaluate their responses as what they request may not be the most effective solution. By the end of this two-month period, the teams at Stanford Biodesign generate 200 needs. This process of clinical immersion can be adopted in any context. Looking broadly and creatively at this list of needs will help inform the later stages of invention.

Need Statement and Prioritizing Needs

The first step in pioneering a new invention is to create a need statement, which is a concise statement of the goal of the invention. A successful need statement will have a clearly defined problem, population, and outcome. We will use two examples to demonstrate how challenging and crucial the need statement is for the next steps in developing the invention.

One need could focus on the use of sternotomy wires after coronary artery bypass grafting (CABG). Different need statements could be:

- Need #1: A way to prevent sternotomy complications.
- Need #2: A way to prevent infections related to sternotomy wire.
- Need #3: A way to revascularize the coronaries without sternotomy.

For the first need statement, the use of sternotomy staples as a possible solution may have been considered, but the need statement itself does not detail a particular problem or goal; this makes it a poor example of a need statement. In the second need statement, determining a way to prevent low-grade infections provides more insight and specifics regarding the causes of complications, such as wound dehiscence caused by infections. Contrastingly, the third need statement broadens our view to consider ways to revascularize the coronary arteries, post-sternotomy, in a minimally invasive way. This third example illustrates how a well-defined need statement may lead to the development of an innovative device, technology, or procedure. For example, this third need statement could have led to the development of percutaneous interventions, like stenting.

Another possible need to consider could be the treatment of cancer. The need statement could be defined in the following ways:

- Need #1: A way to cure cancer.
- Need #2: A way to minimize the side effects of chemotherapy while maintaining anti-tumor effects.
- Need #3: A way to ablate stage IA non-small cell lung cancer (NSCLC) tumors without thoracotomy.

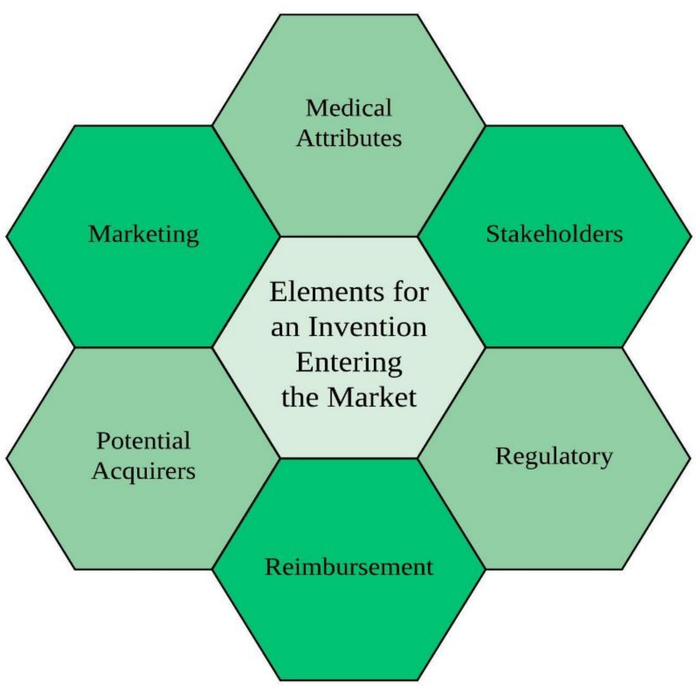
The first need simply states a broad goal and does not provide additional value or specifications for the invention process. Instead, define a need statement similar to need statement two, according to which the goal is to cure cancer through chemotherapy while minimizing toxicity. A need statement like this, with a specific, well defined goal, could have led to the development of a transarterial chemoembolization (TACE) procedure, which is now the standard of care for hepatocellular carcinoma. Lastly, need statement three is also well constructed and could lead to an invention that would ablate stage IA NSCLC tumors bronchoscopically. This would be much less invasive, and it would significantly reduce the morbidity and mortality associated with opening the chest for typical treatment.

Because invention requires time, resources, and funds, it is important to prioritize crafting well-constructed need statements to maximize the highest chances of success for the invention. Determining how to prioritize a need statement is largely dependent on three key criteria: market size, technology gap, and reimbursement (see the chapter “Conducting Insightful Market Research”). While some may argue that the market size should not be the most critical aspect, it is, in fact, the crux of invention. If there is no established market, or the target audience is very small, or the target audience is difficult to reach, an invention will have significant challenges to becoming viable in the long-term. Market size can be determined by multiplying the number of patients by the illness severity. For example, a large patient population with a greater illness severity will have a significant market size, which has the potential to significantly improve patients’ lives. If the patient population is small with a low illness severity, the potential to reach and significantly impact those patients is low and would pose difficulty in launching an invention. The next need statement for consideration is the technology gap. The gap in technological improvement can be very small if there are numerous developing technologies, or it can be very large if there is a deficit of new technology being developed. The size of the technological gap represents the opportunity costs for putting a new invention on the market. For example, it will be more challenging to succeed in markets that are inundated with new technologies that only provide equivalent or marginal impact. Thirdly, the success of an invention relies on reimbursement structures that fund the cost of developing and manufacturing the invention (see the chapter “Reimbursement Strategies and CPT Codes for Device Development”). Without these reimbursement structures, the invention will not be cost effective or cost sustainable. The next section will discuss how need specification can also inform future success in early invention.

Need Specification

Once a specific need statement has been identified, detailed information is required for the need specification. The need specifications encompass all of the elements required for an invention to enter the market, including: 1) medical attributes, 2) stakeholders, 3) regulatory, 4) reimbursement, 5) potential acquirers, and 6) marketing (Figure 2). In regards to medical attributes, an inventor must assess how invasive the procedure is and what clinical endpoints must be met. The feasibility and cost associated must be considered if a large clinical trial is required to prove the safety and efficacy. Important stakeholders, like physicians who will perform the procedures, can help determine applicability and usability. Regulatory bodies may also inform the necessary size of a trial to determine the safety and efficacy, as well as whether a device will require premarket approval. Perhaps the most important aspect of need specification is reimbursement. For instance, every procedure requires a Current Procedural Terminology (CPT) code, which indicates the fees paid to practitioners and facilities (e.g., health systems). The American Medical Association and Center for Medicare and Medicaid are critical governing organizations that determine CPT codes, which can take years and hundreds of millions of dollars to obtain. If a device requires a new CPT code, it may be unrealistic for an academic entrepreneur to procure it, or at least pose a severe delay in their timeline. Most devices can be placed under existing CPT codes, which is an important design constraint for innovators. (see the chapter "Reimbursement Strategies and CPT Codes for Device Development"). Lastly, leads to potential acquirers and marketing strategies will shape how successfully a device enters the market. Concrete reimbursement paths and market analysis will be vital to venture capital firms and investors. If all elements in the need specification are met, members of the target audience are more likely to embrace the implementation of the device as a potential, effective solution.

Figure 2. Elements for an Invention Entering the Market.



Algorithmic Approach

Once the need statement and need specification are addressed, an inventor can shift focus to the development of the innovative device. An algorithmic approach can be used for this step. First, look at current and past treatments to understand why each succeeds and why each fails. Looking as far back as the 1930s, open renal sympathectomy was used to fix hypertension. Although this is no longer indicated in the treatment of hypertension, it led to the development of innovative treatments, like the percutaneous renal nerve ablation catheter in 2007. Second, make a disease work for you. For example, a device to treat urinary incontinence can be made to emulate the mechanisms of urinary retention. Lastly, think about how similar processes occur in nature. Bears hibernate for months on end, yet they do not get pressure ulcers because of their intrinsic cooling mechanisms. How can a device simulate these natural processes? By utilizing these methods, inventors will likely brainstorm a few possible innovations that fit the specified need. Once these innovations are in progress, collate the varying attributes of needs specification for each invention and check the top inventions' intellectual property (IP) positions (see the chapters "Intellectual Property: Ownership and Protection in a University Setting" and "Intellectual Property: Commercializing in a University Setting").

Conclusion

Identifying unmet needs lays the critical foundation for invention in healthcare. As we have illustrated in this process-oriented approach, invention can be learned through need identification and specification. Paul Yock from Stanford Biodesign once said that a well characterized need statement is the DNA of a good invention (Zenios et al.). Need specification identifies the criteria necessary for a successful device. These initial steps will be invaluable to later stages of invention, including prototyping, team building, funding, networking and more.

Resources

1. *Biodesign: The Process of Innovating Medical Technologies*
    a. This book was written by Stefanos Zenios, Josh Makower, and Paul Yock to share and illustrate the Biodesign methodology executed at Stanford Biodesign.
    b. Book available on Amazon: https://www.amazon.com/Biodesign-Process-Innovating-Medical-Technologies/dp/0521517427?ie=UTF8&*Version*=1&*entries*=0
    c. Book's accompanying website: http://ebiodesign.org/
2. "The Biodesign Process: From Needs Finding to Commercialization"
    a. This presentation was given by Dr. Rajiv Doshi, Executive Director of Stanford-India Biodesign, in 2011, and provides an overview of the Stanford Biodesign program.

   b. Presentation available here: http://thor.inemi.org/webdownload/Pres/Med_Elec_May11/Biodesign.pdf
3. "Dr. Jake Brenner, Thinking Like a Medical Entrepreneur, and Penn Health Tech"
   a. This Penn HealthX podcast provides insights for young entrepreneurs into how to use their knowledge to design, build, and commercialize medical technologies.
   b. Podcast available here: https://soundcloud.com/pennhealthxpodcast/22-dr-jake-brenner-thinking-like-a-medical-entrepreneur-and-penn-heath-tech
4. *Biodesign: The Process of Innovating Medical Technologies*
   a. In this book, Professor Stefanos Zenios offers insights into innovation in medical technologies at Stanford.
   b. Review available here: https://www.gsb.stanford.edu/faculty-research/books/biodesign-process-innovating-medical-technologies
5. "A structured process for unmet clinical need analysis for medical device innovation in India: early experiences"
   a. This article in *BMJ Innovation* provides an example of using the biodesign process in the medtech ecosystem in India.
   b. Article available here: http://innovations.bmj.com/content/early/2015/05/28/bmjinnov-2014-000010.full
6. "Medical Device Innovation"
   a. Paul Yock, Professor of Medicine and Founding Co-Chair of Stanford's Program in Biodesign, led an interactive panel discussion on medical device innovation in the video. Panelists include Darin Buxbaum of Hourglass Technologies, Darren Hite of Aberdare Ventures, Mohit Kaushal of the West Wireless Health Institute, and Uday Kumar of iRhythm.
   b. Video available here: https://www.youtube.com/watch?v=EZNyRy_9qGs
7. "Stage 1 - Needs Finding"
   a. In this video, faculty and fellows from the Stanford Biodesign program describe the importance of needs finding and what innovators should expect as they undertake this stage of the biodesign innovation process.
   b. Video available here: https://www.youtube.com/watch?v=6Zan0ajET38

References

Zenios, Stefanos, et al. "Biodesign: The Process of Innovating Medical Technologies." *Stanford Graduate School of Business*, 2009, https://www.gsb.stanford.edu/faculty-research/books/biodesign-process-innovating-medical-technologies.

Chapter Last Updated 9/23/2019.