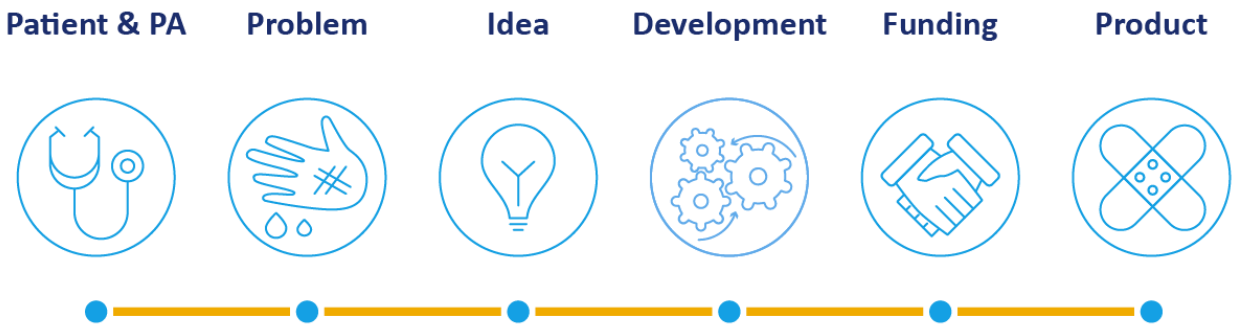
Problem to Product



North Carolina Biotechnology Center

Contents

Patient & PA 1
Problem Identification 2
Idea 3
Development 4
Funding 5
Product 5

Patient & PA

Healthcare is an industry in urgent need of innovation.

Patients, payers, and politicians are asking for improved results when it comes to healthcare service delivery.

The challenges we face today call for more novel approaches—in a word, innovation!

Healthcare innovation requires the informed guidance and support of healthcare providers, particularly PAs, who are exposed daily to problems needing creative solutions to improve both delivery of care and outcomes for patients.

The PA profession is projected to grow 30% from 2014 to 2024, much faster than the average for all occupations.[1] As caregivers on the front-line, we are well positioned to provide valuable input on the real-world application and feasibility of new healthcare technologies. AND, they are also well-positioned to identify problems. A problem that a

PA sees every day on the job can turn into a novel solution or product to address that problem.

1. *Physician Assistants Grow, Expand Value-Based Care Role* https://www.forbes.com/sites/brucejapsen/2015/04/22/physician-assistants-write-value-based-care-prescription/#56f12e55140c

Problem Identification

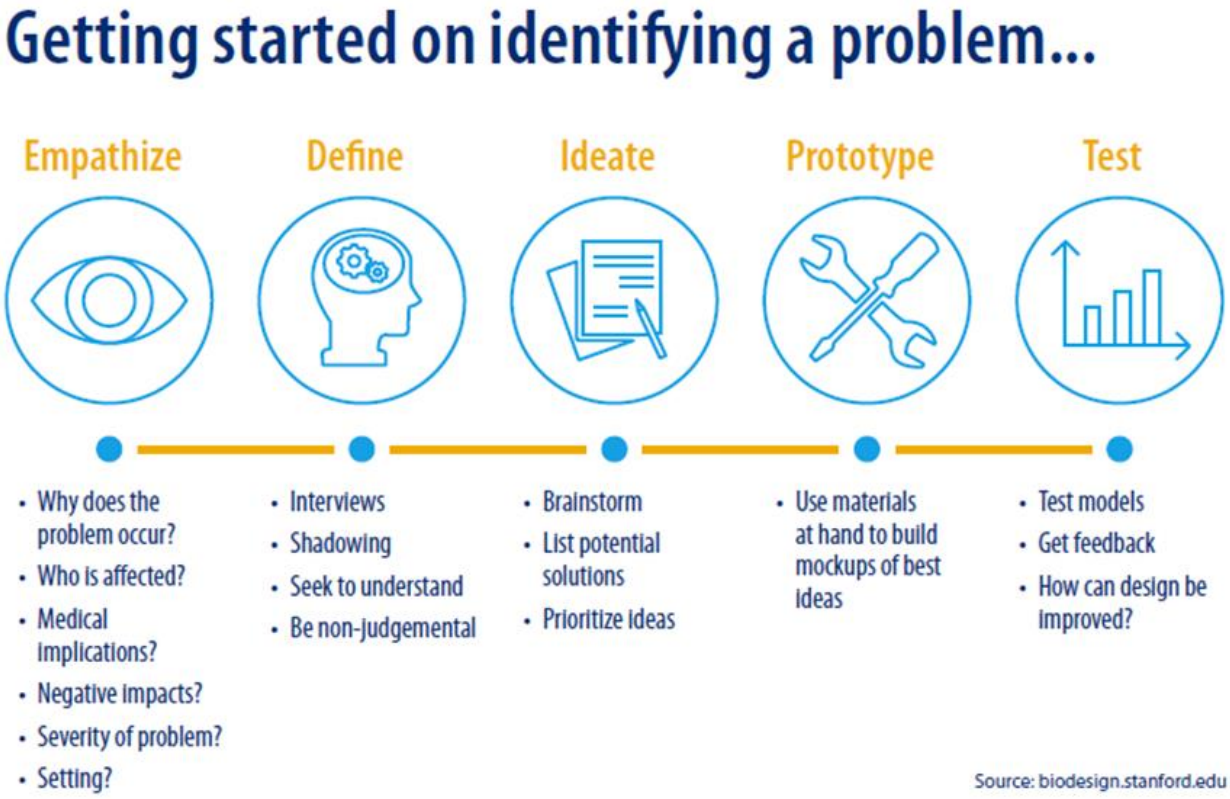
At its core, innovation is about the creation of products and services that solve a problem or unmet need. Too often innovators focus on creating new technologies or products before they sufficiently understand and characterize the problem they are trying to solve. Thus, the critical first step in the innovation process is identifying problems

that are "worth solving". In the healthcare setting, innovations are generally thought to focus on unmet medical needs such as diseases that lack adequate treatment options. But, many important products are developed to improve healthcare delivery, create efficiencies for caregivers, or increase patient satisfaction with their care. In addition, the scope of a problem "worth solving" can vary drastically. An innovation such as the pacemaker can have an immense impact on the world and change how care is given, but innovations do not have to change the world to be valuable. Working one on one with an individual patient to identify and solve their problems may not change the world at large, but it can change the world of that patient's life.

The goal of problem identification in medical technology innovation is to understand and define the causes and consequences of a specific problem at a very fundamental level. Problem identification is often the most important yet frequently overlooked step in any innovation process. Innovators who invest time in problem identification early on will invariably save themselves time and resources later.

The two most important pieces of information to collect during this phase are: costs associated with the problem and patient outcomes associated with the problem. Ultimately, costs and outcomes are two of the primary drivers of the success of medical technology innovation. An innovator who finds a way to reduce costs (to payers and hospitals) while improving patient outcomes (reducing readmission rates, complications, recovery time, prognosis, etc.), is more likely to succeed.

Once an innovator understands a problem sufficiently well, they can convert that problem into a need or need statement, which summarizes the problem, affected population and the outcome(s) associated with that problem. By the end of this phase of design, an innovator should be able to make a well-informed decision about whether an identified need (and problem) is worth pursuing. A thoroughly well-defined and selected need will make idea generation a pleasant and easily-directed exercise.



Idea

Ideation, sometimes referred to as brainstorming, is often viewed as one of the most exciting parts of innovation. Ideation is a divergent process that relies on a clearly defined problem and need. The goal of ideation is to generate as many ideas as possible that provide solutions to the identified unmet need. When conducted properly, brainstorming is an extremely high-energy and fun experience.

The trick to a great brainstorming session is learning to separate the two competing goals of ideation: generating ideas and selecting ideas. The best way to perform ideation is to start with a well-defined need and generate as many solutions as possible. Innovators should be careful to avoid eliminating ideas before brainstorming is complete as it often stifles discussion and worse: it limits the number of ideas generated. Wild and impractical ideas often lead to brilliant and focused solutions, so it's important to entertain and compile all ideas before filtering.

Only after the innovators have completely exhausted their solution space should they consider focusing on selecting and refining specific ideas. Selecting a solution to pursue requires innovators to compile and analyze information about intellectual property (ex: are there existing patents or publications that describe this solution?), market size (is

there a market that can sustain this idea?), regulatory pathway (How might this device be regulated? Will the cost and time required for regulation in the target country be feasible?), cost to manufacture, sterilizability, etc.

Inventors should spend time creating an exhaustive list of "filters" used to check their ideas against, being careful to consider factors specific to the problem or need being explored. At the end of the Idea phase, innovators should be able to make a "go/no go" decision about the best ideas. Solutions that make it through the rigors of selection and filtration will go on to be prototyped.

Development

The development phase is where solutions go from idea to reality. The goal of development is to create and test a prototype of solutions generated during ideation. A second goal of development is to select the most viable version of a prototype and refine it to the point of being able to raise funding. A well-defined need, thoroughly-vetted solution, and the correctly defined and designed experiments are often the key to successful development.

Prototyping can take many forms. The easiest way to begin, is to first establish the goal of a given prototype. Should it demonstrate functionality? A particular aspect of functionality? A new process? The way the device might look?

All of the aforementioned questions could result in a different prototype for the same solution. Innovators who spend time up front deciding what the goal of a prototype is will save time and resources—for example, if an innovator has a new material to be used as a surgical implement, one of the goals might be to test sterilization—which would likely only require testing a sample of that material, not necessarily an entire device.

Once the goals of a prototype are established, the individual prototypes should be developed. Often that requires engaging a design firm, maker network, or similar. In many cases, however, innovators can craft fundamental proofs of concept using common materials. After the necessary prototyping is complete, they can be tested and demonstrated to potential investors or funding agencies. Additionally, plans can be laid for a final prototype that can be tested in humans or animals. These final prototypes are often used as the basis for verification and validation testing (verification = Is the device built correctly? Validation = Does the device solve the problem?). When concepts from ideation are reduced to practice in the form of prototypes, securing intellectual property is the last step before seeking funding. Generally, securing intellectual property will take the form of a provisional or full patent—however, trade secrets may also be a good option depending on the type of innovation.

Funding

If you've proven that your product or technology is valid and has potential, you will need to seek funding to further develop it and complete several activities to get it into the hands of those who can benefit from it.

Often raising funds is one of the most daunting steps of the entire innovation process. Not only will this phase be where your designs and ideas may be challenged the most, it is also the phase where having the right team makes the biggest difference. Since medical device innovation is such a technically and logistically complicated process that relies on the inputs from a complicated network of stakeholders, it is incredibly important to seek out help in areas where your team is weak.

It is often stated that investors fund great teams rather than great ideas. Team members or advisors to consider include experts in: regulation, reimbursement, business/market analysis, grant writing, engineering, entrepreneurship, medicine, and clinical trials. Truthfully, the team should be built as early as possible (ideally far before this phase), but prior to seeking funding is a good time to step back and re-evaluate any missing components.

Once you have the right team, the right need, the right solution and some demonstration that your solution is viable, seeking funding is a matter of convincing someone else that your idea is worth funding. With persistence and open-mindedness, a great team with a good idea can find funding to carry their product through testing to market.

Product

The ultimate goal of design and innovation in healthcare is to provide products that improve and save lives. Products can vary from those that can be sold directly to consumers without any required FDA studies or approvals, to those that require additional testing, clinical studies and FDA clearance before they can be deployed to help people. Taking an idea from prototype to market can be a long, and often expensive task. Additional hurdles in the form of packaging design, sterilization, scale-up, and manufacturing can be greatly alleviated with the right team. Even after getting through regulation and clinical trials, often a reimbursement structure for managed care needs to be established.

While the entire process may seem daunting, the best way to learn and achieve is to do it!