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Techniques in Vascular and Interventional Radiology

Not Just Guess Work: Tips for Observation, Brainstorming, and Prototyping

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Much has been written about brainstorming and prototyping in medical devices. These 2 topics are the crucial ingredients to innovation; which, if well seeded by organized and structured forays into each, will net much higher quality and more valuable results. Structure and process, although slightly counterintuitive as applied to brainstorming and prototyping, can greatly improve the value proposition of the innovation itself.

KEYWORDS brainstorming, prototyping, innovation

Background

This article is intended, more or less, as a condensed "how-to" on brainstorming and prototyping, with as many relevant examples from my own experience as possible. These 2 topics are the crucial ingredients to innovation; which, if well seeded by sound and (slightly) structured forays into each, will net much higher quality and (ideally) more valuable results.

It is also written with a specific focus on medical devices, as this is the lens through which I have personally experienced most of these activities; although many of the tips and keep-in-minds mentioned could easily apply to other areas of innovation. What follows is essentially what I have picked up from 8 years as a hardware engineer at a national laboratory building nuclear physics experiments (where brainstorming sessions were extremely frequent and exhilarating), the principal engineer in a medical device start-up focused on a solution for preventing diastolic heart failure (DHF), the principal engineer at another medical device start-up with a solution to laparoscopic port hole closure, as a fellow in Stanford's Biodesign program in medical device innovation (the source of a lot of this advice), a Sr Staff R&D engineer for a large medical device company working on mitral valve repair, and currently, as the cofounder and CTO of a medical device company in women's health.

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With that in mind, it should be mentioned that what follows is by no means comprehensive—in that each topic could easily span a full-length article—rather, here is a high-level survey of things to think about and hopefully, encourage further thinking on. Lastly, there is no shortage of literature on innovation (in general or specific to medical technologies) and for more in-depth discussion on these topics, the reader is referred to richer sources of information like Stanford's Biodesign text or website (http://biodesign.stanford.edu/) or any of the multitude of books on the topic (my favorites are listed at the end).

Why Process Helps

Is it important to have a process for brainstorming? Should not brainstorming almost by definition be an unbounded session of improvisational brain jazz? Well, yes and no. Yes, because brainstorming should stretch your creative problem-solving (and brainstorming is definitely problem-solving) to the furthest limits of your mental energies. However, unless there is a means, or a process to capture and focus your efforts, you risk wormholes of distraction or simply drifting into solving the wrong problem. Adding a little structure to brainstorming helps you maximize the creative bits that are more actionable and grounded and hence more relevant to your next steps (ie, prototyping).

By Process, I mean setting up a few constraints before you begin to brainstorm to help you collect the most relevant and important creative bits. Think of Process in this context as a framework for a discussion (ie, brainstorming): let us say everything we can about X, but let us not worry about Y for the moment. For example before

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brainstorming about, say, "a way to increase medication compliance in people with Congestive Heart Failure" (which you have previously validated, through multiple mechanisms and filters, as a clearly important unmet clinical need which if you solve, helps mankind immeasurably), you focus first on thinking of any solution that "increases med compliance" but leave out the "in people with CHF". This is mainly because the more qualifiers, or things on your To Solve list, the harder it is to get rolling on solutions without shooting them down prematurely because they do not check all the boxes. Complexity is the enemy of execution, so the simpler the objective (eg, to brainstorm solutions to X), the more ideas you will be able to generate quickly.

Having structure also helps ensure that you have covered all your bases. Brainstorming and prototyping are activities where creativity reigns supreme and therefore tend to be fairly disorganized. A fantastic way to guide your brainstorming (or prototyping) efforts into all the avenues of thought or physical construction is to have categories that you brainstorm (or prototype) within. For example, you might separate potential brainstorming solutions into ones in which you would classify as mechanical, electrical, chemical, and biological, then think of everything you can, separately, within those categories (we routinely used this as Biodesign fellows, to brainstorm solutions to various needs). Similarly, for prototyping, you might consider first only sketching out how the solution is used by the user; for example, by limiting your efforts to storyboarding. Then, move onto only paper construction prototypes and so on.

A final thought on introducing process to brainstorming (especially) is that it removes the activity from the space of isolated epiphanies and makes it more a skill that can be practiced and improved. Although the thought of spontaneous invention is often romantic (from stories of famous inventors having ah-hah! moments in sleepless and delirious hours of contemplation), for most, this just usually is not the most fruitful approach. A tiny bit of structure and a little forethought can really help in both augmenting your ingenuity and harvesting its fruit.

On "Failure"

Take a look in any book, article, or blog, or listen to any podcast or online lecture, about innovation and invariably, dependably, you will hear the all-solving-fortune-cookie advice: "fail early, fail often" (in a variety of contexts). Not to say this is not sound advice for innovation; it absolutely is (reasons to follow). But how, exactly, do you do this? And how do you do this while ensuring that you are "failing" in most productive way (ie, learning the most from each "failure")? Again, a little structure can help us to answer these questions.

First, though, let us clarify what we mean by "failure". Failure in the context of early brainstorming or prototyping (in my opinion) is when a solution or prototype does not meet a very specific objective. For example, say you were prototyping a medical device that was supposed to be delivered to a specific chamber of the heart with some sort of intravenous catheter. To traverse the torturous route of vasculature to the heart, this catheter would need to be capable of a host of complicated operations: translations and rotations in different planes and angles. However, an early prototype of this might simply test only one of these operations; say, a prototype that deflects 15°, in one plane, at the distal end. A "failure" of this prototype would mean that whatever you cobbled together, say, a garden hose with some wires taped to the outside, to make the "catheter" deflect 15°, simply did not work. This is good; this is insight. Maybe insight on material choice (garden hose too stiff?), construction (wires attached to the outside of the hose work better than the inside?), or approach (deflecting long, narrow things like hoses is pretty easy with wires attached in the right spot!); all of which informs your *next* prototype. What your garden hose with taped wires really represents is one specific embodiment of a solution. The ways in which that embodiment "fails" to accomplish the objective (ie, deflecting 15°) is where you learn the most. Hence, "failing early" is testing these low-fidelity prototypes with very simple objectives and "failing often," is simply doing this over and over to furnish as much insight as humanly possible; each time leading to another, slightly better prototype. The more failures, the more prototypes, the more valuable insight. The more insight, the more constraints on the final embodiment of your solution (ie, the final prototype); so in a way, failing early and often is systematically shaping your solution by removing what would not work. You can whittle your way to the answer!

Another reason to fail early is that there is far less expense when things are actualized early on. Prototyping in the early stages is best done with low-fidelity constructions (more on this later), so inherently, the costs of materials are less. Also, the costs of failure are low: really, only those of the materials themselves as the time to construct crude representations of an idea is typically short. Alternatively, failures of prototypes in later stages cost much more in terms of potentially necessary re-tooling, re-engineering, and associated timeline slippage of product development. Failing early can also limit the amount of emotional investment you have in one idea. Although it is generally discouraged to favor one idea over another from anything but objective measures that one is in fact better than the other, it is still easy to fall in love with an idea. Be it your personal skill set (eg, I tend to gravitate toward mechanical solutions to problems as that is what I know) or some other reason, it definitely happens. Iterating on ideas in brainstorming and on prototypes quickly and early can help limit biased emotional attachment.

The Dream Team

Who should be involved in the early stages (brainstorming and prototyping) of innovation in medical technologies?