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Biodesign process and culture to enable pediatric medical technology innovation

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ABSTRACT

Innovation is the process through which new scientific discoveries are developed and promoted from bench to bedside. In an effort to encourage young entrepreneurs in this area, Stanford Biodesign developed a medical device innovation training program focused on need-based innovation. The program focuses on teaching systematic evaluation of healthcare needs, invention, and concept development. This process can be applied to any field of medicine, including Pediatric Surgery. Similar training programs have gained traction throughout the United States and beyond. Equally important to process in the success of these programs is an institutional culture that supports transformative thinking. Key components of this culture include risk tolerance, patience, encouragement of creativity, management of conflict, and networking effects.

Innovation is broadly defined as a new idea, product, or process. It requires both invention and implementation. In medicine, innovation is the process through which new scientific discoveries with clinical relevance are carefully cultivated and propelled from the bench to the bedside. Industry and academic institutions often overlook the early stages of innovation. Industry considers this time period "too risky" while the academic institutions consider the process "too commercial" for their research mission. The field of pediatrics compounds these problems by adding valid concerns regarding the market, funding, and the complex ethics of pediatric innovation and therapeutics.[1,2] Without willing and knowledgeable innovation participants, medical technology innovation will stagnate in both adult and pediatric fields. To avoid this we must encourage and train entrepreneurs, engineers, and physicians to become the translators between the worlds of science and clinical practice. Innovation is rarely the "ah-ha" moment of an eccentric genius and more often the result of a prepared mind in a culture that supports transformative ideas. The Biodesign program at Stanford University has evolved to become an academic hub of medical technology design and development. The program focuses on educating future medical technology leaders on the process of innovation through the flagship fellowship, but also extends opportunities to high school, undergraduate and graduate students as well as faculty members. This manuscript is intended to describe a process of medical technology innovation, through the example of the Biodesign fellowship, and a culture that encourages transformative projects based on the last 15 years experience of the Stanford Biodesign program.

Biodesign process

In response to the need to train young innovators, Drs. Paul Yock and Josh Makower began a systematic training program in medical device innovation called Stanford Biodesign. The Biodesign fellowship is a constantly evolving 10-month program that teaches need-based innovation (Figure 1) consisting of needs identification, needs filtration, concept generation, concept filtration, and early stage implementation of the inventions.[1,3]

Every year, international engineers, physicians, business graduates, and scientists with an interest in medical technology innovation are invited apply to the Stanford Biodesign Program. Clinical candidates typically have either partially or fully completed specialty or subspecialty training. Engineering and scientist candidates typically have formal education at the Master's or PhD degree level. Usually several candidates, from either clinical or science backgrounds, have earned MBA's or have industrial operations experience. Out of the typically 100–120 applicants, approximately 25 are selected to participate in an intensive 2-day interview experience at Stanford. In particular, the interviews are

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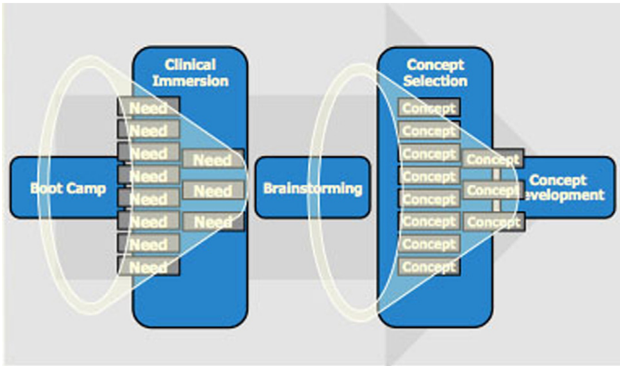

Fig. 1. Core Biodesign Process which consists of bootcamp, needs identification, needs filtration, concept generation, concept filtration, and implementation of leading concepts.

designed to evaluate candidates' responses to invention challenges, identifications of healthcare needs, and effective teamwork. After the interviews, two teams of four fellows each, and one specialty team of four fellows are created. These teams are created after much deliberation, taking into consideration the interplay of professional strengths, personalities, industry experience, and teamwork skills. Specifically, each team is designed to have at least one person in each of the following roles: the organizer, the thinker, the builder, and the clinician.[3]

Teamwork is central to the Biodesign process and cannot be emphasized enough. Throughout their time as Fellows, the teams will transform from four strangers with a common career interest into a group of inventors and potentially founders of a medical technology company. To encourage the type of collaboration needed to succeed in innovation, the teams consult with a Stanford Design School psychiatrist to discuss and work through any teamwork and leadership struggles that arise.

The fellowship schedule begins in August and finishes with graduation in June the following year. The year begins with a 4-week period called “bootcamp.” It is a largely didactic phase with four key components. The first component begins when the clinical focus for the year is announced. Each year a new clinical focus is selected, bringing in the associated Stanford department for collaboration. Prior focus areas include cardiology, neurology, urology, trauma, critical care, and radiology. The selection process works to ensure the associated department can willingly and effectively provide an immersive educational and clinical experience. Throughout bootcamp, the paired department invites clinical and research faculty lecturers to provide subject matter background as well as present their current research areas. This allows Fellows to develop the essential relationships with the clinicians they will be working with and observing over the following months. It also introduces them to expert researchers with whom they may partner to leverage new technologies. Distinct from the two department based teams, the specialty team obtains its focus area from the clinicians on the team. These clinicians are Stanford trained or associated and therefore are able to establish connections between their team and their clinical department to organize lectures and observations.[3]

Historically, pediatrics has been a low priority in terms of medical innovation. Industry concerns include small markets, high FDA barriers, and a poor payer mix. Frequently, improvements are first pursued in adult medicine and subsequently translated into pediatric treatments or procedures. However, pediatrics can prove to be an area of effective strategic focus. There are great demands for pediatric solutions and those solutions may in turn benefit adult medicine—historical examples include ECMO and nonoperative management of solid organ injury.[2] Aligning clinicians and scientists to investigate the field may validate alternative routes for pediatric medical technology innovation. Options include alternative funding options like angel investors or grants, pediatric specific indications for FDA approval, an alternative company structure such as a non-profit or through licensing of the newly developed technology. The Biodesign process can lead to many effective solutions, and promotes medical technology innovation that can benefit any field in healthcare, including pediatrics.[2]

After a deep dive into the area of clinical focus, the second component of bootcamp involves key lectures in engineering and business principles. Excellence in these fields will be needed for applied medical device innovation. Topics covered include: collaborative design thinking, prototyping, market analysis, intellectual property protection, regulatory and reimbursement issues, funding strategies, and quality-focused design. Given the location of Stanford within Silicon Valley, more than 100 experts in each of the above areas have partnered with Biodesign to give lectures in their areas of expertise. Along with these lectures, the Biodesign textbook gives a step-by-step guide on the medical technology innovation process. The third component is the “bootcamp mini-project,” an exercise to rapidly cycle through the full Biodesign process and preview the year's activities. The need to be addressed is preselected but still requires characterization, scoping, brainstorming, and solution selection. While it is possible to continue to work on the mini-project, the goal is to give the teams a practice round to better understand need characterization and brainstorming principles. The fourth and final component is teamwork. The Fellows are purposely intermixed into random teams, without knowledge of their final teams, to encourage all of the Fellows to interact with each other, explore team dynamics, and participate in formal and informal teambuilding exercises.[3]

After bootcamp, the Fellows enter a 6-week period of clinical immersion. All Fellows are encouraged to contact their clinical mentors and spend time in the hospital, clinics, and outpatient settings to observe and identify needs. They will follow physicians, nurses, staff, patients, and families to identify more than 200 needs based on direct observation of clinical practice. After the needs are identified, the second half of the 6 weeks is spent validating the observed need. Fellows work to determine if a need consistently exists, to better understand and characterize the need, and to begin to network with experts in that field. Frequently, validation requires repeat clinical experiences and continuous examination of the observed need with a wide variety of practitioners, from trainees to experts, whether community or academia based. After this field work, the observations are compiled into carefully crafted need statements—single sentences that capture the clinical problem, the target population, and the goal outcome.[3]

The next 2 months are spent in “need filtering.” This is often the most challenging time of the fellowship and requires the Fellows to process through the 200 identified needs to identify the most promising opportunities. This requires broad information acquisition and deep evaluation to identify promising needs and eliminate less promising needs. It includes evaluating dozens of aspects including: clinical context, market characteristics, stakeholders, and current technologies. The top needs are further characterized by designing a need specification, a list of components that are essential to the clinical and market success of a proposed solution.[3]

Finally, after months of research, observation, and validation, the Fellows are allowed to start brainstorming. By this point, they have proven to themselves that the need is valid, that clinicians and patients would adopt a new offering, and that the market demands a solution. Brainstorming is the most actively creative phase of the fellowship; the Fellows are encouraged to create a long list of concept solutions then narrow down to their top three