Biomedical Innovation, Surgical Innovation, and Beyond

ABSTRACT:

"*There's a better way; find it*"

-Thomas Alva Edison

Some of the most remarkable human advances in the last hundred years have been health care related. Many of these advances have involved luck…the right people, the right circumstances. The Biodesign Innovation Programs at Stanford attempt to increase the probability that the right people and the right circumstances come together.

There are several major and minor hypotheses presented throughout this paper. A major hypothesis is that in today's medical world, clinical practice continues to become more highly focused and at the same time, technology also is becoming more focused and complex. As a consequence, the innovation process (the chances that the right people are present at the right circumstance) is less efficient than it could or should be.

Traditionally, little attention has been given to the *process* of innovation in general and specifically to the process within medicine. It is time to look at the innovation process and how structured programs can be devised to bring together unmet market needs, novel technologies, and creative individuals from the various medical and surgical specialties to make innovation happen.

One of the first university initiatives to address this issue has been the *Innovation Program* at Stanford University, run as a component of the Program in Biodesign by Drs. Paul Yock and Joshua Makower. This paper delineates an expansion of this program to the surgical disciplines, *The Surgical Innovation Program.* A further extension is also in the works which extends the hypotheses of the innovation programs to the *research* environment in which research theses, or dissertation topics are chosen using the "needs assessment" approach.

INTRODUCTION:

"Only the answers change; the problems remain the same"

-Sir William Osler

The *Program in Biodesign* is part of a university-wide initiative in the biosciences at Stanford, Called Bio-X. Biodesign has helped fund and develop a number of courses and other initiatives in the area of biomedical technology invention and implementation.

The Innovation Program has been a central focus of this education effort. Modeled on the Pfresh Tech Program developed by Dr. Makower at Pfizer in the 1990s, The Innovation Program is structured around a dedicated fellowship in biomedical technology innovation and a two-term graduate course that exposes a large and multidisciplinary group of students to the process. The central mission has been to create a process based approach to creating innovators and innovation leaders in the same way medical, law, and engineering schools train for their respective disciplines. Not surprisingly, the process of innovation is its own animal, necessitating its own education process.

In the '04-'05 year, the *Innovation* program has expanded, partnering with the Department of Surgery to create the *Surgical Innovation Program.* Further expansion in the next 1-2 years will include extension to the basic and applied research arena where a similar philosophy will applied to stimulate more basic engineering and biomedical projects.

With the creation of the Surgical Innovation Program the structure of the Innovation Program structure has been changed in some key respects. For 2005-2006, there will be two innovation fellowship teams, one in surgery and one in cardiovascular medicine. In subsequent years, new teams from different disciplines may be added. Another major change has been the addition of an optional second year of fellowship. This second year, during which fellows will have the opportunity to pursue further development of a technology area, provides more depth to the experience in each clinical area and stronger linkage to the clinical departments.

The first year continues to be organized in a similar way to the original innovation fellowship. This year looks in depth at needs finding as well as delineating the process for entering the clinic to find new needs. The first year also includes an all important "boot camp" in which the fellow is exposed to many of the important concepts in the innovation process such as intellectual property consideration, project finance, company creation, etc.

The second year has a project focus and allows the fellow to tailor their curriculum to his or her career goals. The project is one chosen from the first year. Depending on the nature of the project, the experience of the fellow, and the future interests of the fellow, funding for the project may come from the NIH (in the form of SBIR or STTR), from private investors (in the form of sponsored research), or seed grants (such as from NCIIA, the Bio-X center, or entities such as the technology licensing office at Stanford).

BODY:

The fellowship is really about the people and the team. Furthermore, this has been narrowed down further to the fellow personality as being the key ingredient to the success of the program. It has also been found that a team of about 4 people is ideal for this type of program. Generally, the team further subdivides into groups of two who then immerse themselves in the clinical setting, working side by side in the clinic with physicians and observing real time therapies.

Interview Process and Team Selection

"Getting good players is easy…gettin' 'em to play together is the hard part"

-Casey Stengel

The program begins with a very intense and careful selection process in which individuals are identified who not only show leadership potential but demonstrate specific character traits which have been found to lead to success within the innovation program. Such "traits" can be different from the "academic skills" often sought by degree programs and include such characteristics as an ability to seek and accept new paradigms, an ability to work in a team environment, and an ability to quickly assimilate new technology in the context of clinical scenarios.

In addition to the individual, the team and the predicted interactions and synergies between the individuals is also very important. Predictably then, the characteristic which is of most concern is the ability of the candidate to work in a team. As will be further illustrated below, the structure of the program demands teamwork as a critical component of its success.

It is also essential that the team members synergize with one another both in background and personality; the personalities within the team need to be additive and preferably synergistic, rather than overlapping. For this reason, combining one or more engineers with one or more clinicians has, in theory, seemed to be an optimal synergy. Historically, within the program and within several of the medical technology incubators in the area, this combination has proven to be a very successful one. There are surely other combinations of fellows which can be successful and in reality, there isn't a set formula; every group is judged on its own merits.

Applicants should show some evidence that they can adapt to new paradigms and that they have the resourcefulness to find, synthesize, and apply new technologies and concepts quickly and broadly across different biomedical disciplines. One of the major hypotheses is that technology is developing at a quick pace while physicians are becoming increasingly focused in their clinical practice; therefore, a gap exists and the chances that an "aha moment" will occur is decreased. In order to increase the probably of the "aha moment" occurring, it will be necessary to further broaden one's horizons such that a greater knowledge base is attained. It is not expected that one can by any means master a new technology in one year but rather, can quickly grasp its salient features an apply it to the clinic.

The above skills are demonstrated in an intensive interview process. A great deal of time is spent crafting the interview questions to specifically allow for demonstration of these skills; questions are formulated based on a prior review of the application by the interviewer. This is perhaps another aspect in which the innovation program differs from many traditional academic programs, some of which do not even have an interview.

The interview questions begin by questioning prior innovative experiences the individual may have had; emphasis is placed on the degree of individual contribution to the process. Further queries involve team experiences. Other queries entail forward thinking clinical scenarios and which beg the open question of "what do you see as the clinical problem and what would the ideal technology look like which would solve this problem."

<u>Needs Finding</u>

"Creativity involves breaking out of established patterns in order to look at things in a different way"

--Edward de Bono

Innovation fellows begin the year with an intensive "boot camp" in which some of the key accessory ingredients for innovation are taught; included, are the all important issues such as patents, funding resources, regulatory pathways, and technology transfer. These issues are not typically taught in a formative way in the traditional academic setting (including business school!) but as anyone involved with biomedical technology innovation knows, these issues can be more important than the technology itself. The boot camp in itself is almost an independent curriculum and its details are evolving as well. Experts on the issues are brought in for lectures as are experienced start-up executives who understand the real-world impact of the issues as well.

Following the boot camp, a process called "needs finding" begins. The fellows, including at least one clinically trained person and at least one science or engineering trained person, together undergo a clinical immersion in which they experience patient care first hand. The major motivation for this exercise is to allow the fellows to witness clinical procedures, techniques, and philosophy as currently practiced. The fellows are trained (part of the boot camp) to ask the "why" and "how" of the procedure and then the "what if." They are also trained to look for difficulties the physicians may be encountering, particular obstacles, or technicalities which could be modified or streamlined in some way.

Clinical needs are phrased into a simple statement. An example of a "need statement" may read something like "a need to restore blood flow in a chronically occluded blood vessel…."

The process of accumulating needs has in the past lasted approximately 1-2 months. In the surgery arm of the fellowship, however, the immersion lasts quite a bit longer to accommodate a set of rotations through the subspecialties such as ENT, plastic surgery, orthopedics, vascular surgery, minimal access surgery, robotic surgery, etc. The hypothesis for the number of rotations is that exposure to the various surgical fields will broaden one's horizons and allow the fellows to bring intellectual and technologic aspects, herein termed "technology sharing," from other fields to the clinical need at hand.

An example which illustrates the power of "technology sharing" is that of radiofrequency (RF) energy; RF energy has been used for a long time (since 1926) in clinical surgery, utilizing alternating current flowing through tissues to vibrate molecules and generate heat. It was only recently that radiofrequency has been used for widely diverse diseases such as vertebral disk healing, uterine bleeding, and closure of defects in the heart. One could say that it took from 1926 to 1990 to really appreciate the utility of RF energy. Had Drs. Bovie and Cushing had an innovation fellow, it may not have taken 65 years.

The typical "needs yield" from the clinical immersion may be as high as 200-300 clinical needs. The subsequent 4-6 weeks are spent sorting through the needs, ranking and characterizing them further. This time period is perhaps the most important part of the fellowship. It is here that the magnitude of the clinical problem is established. The clinical problems (all 200-300!) are discussed outside the clinic, in a quiet environment, among the fellows without distractions. This is perhaps the only such forum in history that has discussed so many clinical problems in such a short period of time with an eye toward technological solutions. Questions are asked and technical issues debated. Further questions are formulated for physicians and library research.

Going back to the need statement above, an example of a follow-up question may be "does restoration of flow in fact provide any benefit or has collateral flow already developed." This question directly addresses the issue of "what is the clinical utility if the need were to be solved?" It may seem obvious that restoring blood flow is a good thing (a lot of innovations fail because the need is not further interrogated beyond this point); on the other hand, if the blood is in fact restored, there may not be any further clinical benefit. In the fellowship, such a question would be posed to clinicians and/or taken to the library for investigation as well. Answers are then plugged back into the needs database for re-calibration.

Ranking of Needs:

"We are continually faced with a series of great opportunities brilliantly disguised as insoluble ideas"

-John W. Gardner

Typically, after 1-2 months of needs characterization, there are 5-10 "best needs." The rank order of the needs is determined through a ranking system which combines parameters such as clinical impact, provider impact, technical feasibility (i.e. can the problem be solved in a reasonable time frame), character of the problem (blue sky, incremental improvement, mixed), and a subjective "gut feeling" score.

Brainstorming

"If at first the idea is not absurd, then there is no hope for it"

-Albert Einstein

At this point, the fun really begins. Daily brainstorming sessions are followed with prototypes in the "product realization" laboratory. Paradigms are shattered (for better or worse); ideas are brought in from left field, right field, and the bleachers to solve problems; new pathophysiological paradigms are even invented. Of course, there are ideas which should stay in the bleachers, but once in a while, out pops a Fogarty catheter. It's actually quite a remarkable process; watching it leads one to think that the process may be quite useful in scientific research as well…indeed, this is another hypothesis in this paper and is a harbinger of where the program is headed.

Teaching Component

"Creative thinking is not a talent, it is a skill that can be learnt. It empowers people by adding strength to their natural abilities…"

-Edward de Bono

Having just gone through the process themselves, fellows now teach an official Stanford course in which undergraduates and graduate students participate in a miniature form of the fellowship. The part that is missing is the clinical immersion and needs identification period. Because of time constraints, the needs and clinical knowledge are essentially given to the student teams and the teams either further characterize the needs, or take them as presented. Over a 3 month period, the student teams brainstorm, build prototypes, investigate patents and markets, and write business plans for entry into the campus-wide business plan competition.

The Innovation fellows supervise the process, answering questions, assisting with prototype design, and providing physician connections. In the course of teaching, they solidify the process in their own minds. At the end of the course, the students present to a group which includes venture capitalists, industry veterans, and academicians. The fellows assist in building the story for these presentations which gives them experience for their own inevitable fundraising efforts.

Prototype and Design Phase

This process is ongoing for the fellows from the brainstorming time to the end of the year, taking place concurrently with the teaching course in the middle of the year. The Bio-X facility at Stanford contains several prototyping facilities as well as experience technicians and faculty. Typically the top one or two needs are chosen to further prototype. Going back to the synergy in the team, typically at least one fellow is chosen who has extensive background in developing prototypes.

Externship

An externship period exists between the class and the final presentation period (2 months) where fellows are placed in a work environment of interest to their future careers. In some cases, this involves a start-up company. In other cases, the externship involves further clinical exposure. In part, this phase is flexible depending on the goals of the individual. A brief internship with the Food and Drug Administration has also been a path for the fellows.

Year 2

"What's missing isn't the ideas, it's the will to execute them"

-Seth Godin

The second year is in part optional. At the start of the biomedical innovation program in 2001, the fellowship was one year. As the program progressed, there was a certain attachment to the projects by the fellows which was evident in their review of the fellowship. Beginning with the Surgical Innovation Program, the fellowship will have an optional second year. In this year, a project from the first year will be advanced through the prototype and seed funding phases if the fellows so desires.

If the fellow desires to continue into a second year, the planning process will begin by the middle of the first year. As discussed above, part of the mission of the program is to educate the fellow with respect to the various funding mechanisms that exist and these mechanisms will be accessed as the project is further planned.

An additional highly compelling aspect of the second year is that the fellows will mentor the first year fellows in the process.

Other options available for the fellows in the second year include a master's degree in bioengineering, work at a start-up company, etc. The myriad of options available to fellows in the second year points to the breadth of experience obtained in the first year.

Beyond the Fellowship

Fellows from prior classes have gone on to a wide array career paths. For the most part, however, they are focusing on innovation in one way or another. Some of the fellows are working in the venture capital industry; other fellows are working in start-up companies they themselves founded; one fellow is doing an internship at the Food and

Drug Administration; two of the fellows are working in the advanced technologies section at Medtronic.

Conclusions

In summary, the innovation programs at Stanford University teach and develop unique ways of finding and approaching clinical problems in medicine and surgery. What began as a program for a few individuals to creatively explore their inventiveness in the cardiovascular sciences, has now evolved into a philosophy which transcends several fields of medicine. The next mission of the program leaders to transfer the process to the basic bioengineering and medical sciences to enable the projects to be firmly grounded in a clinical and/or market need so that the work of the people and the funds are truly used resourcefully.