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BRIDGING THE 'VALLEY OF DEATH' IN PRODUCT DEVELOPMENT: A CASE STUDY OF THE DRILL COVER PROJECT

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Abstract

Innovation in the medical device industry is frequently driven by collaborations between engineers and clinicians in an academic setting. However, many such projects, especially within student design courses, end up abandoned and orphaned when approaching the proverbial "Valley of Death" in product development. In this paper, this challenge is described as three separate Valleys: a financial valley, an expertise-driven valley, and an academic-specific valley.

This paper then presents a case study of the Drill Cover Project, a student design project in the Engineers in Scrubs Program at the University of British Columbia. Observations of the Project's success to date are presented in a resulting model for how engineering design and technology commercialization courses can increase the likelihood and ability of student groups to bridge the three Valleys.

This model includes close collaboration with users, strong early leadership and team culture, supporting networks of mentors and product champions, and an impact-focused mission, which are all contributing factors to the success of the Drill Cover Project thus far.

Keywords: Design education, Collaborative design, Medical devices, Developing world, Entrepreneurship

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1 INTRODUCTION

This paper presents a case study of the Drill Cover Project, a student design project in the Engineers in Scrubs Program at the University of British Columbia, and a resulting model for bridging the "Valley of Death" in product development.

1.1 Academia at the Forefront of Healthcare Technology Innovation

The medical device sector is expected to experience tremendous growth in the coming years as Western societies face increasing healthcare costs and the pressures of an aging population (Baker, 2008). In the emerging markets of the developing world, economies are expected to grow rapidly within the coming decades, and with this growth will come a significant increase in spending on healthcare. It is estimated that 93% of the world's middle class will be living in the developing world by 2030 (Kharas, 2010). These factors combined will create a tremendous opportunity for technology innovation in healthcare that must be both affordable and appropriate for use across varying cultures.

While industry efforts in research and development contribute to a significant proportion of new product development, universities are often on the forefront of medical device innovation. The U.S. National Academy of Engineering (Ekelman, 1988) reports that "the process of medical device innovation is dominated primarily by individuals, usually in academic and clinical settings." The need for close collaboration between designers and end users is clearly established in the innovation literature, and this is no different for the work of designers in academic settings.

In academia, recent years have seen a surge in technology entrepreneurship programs focused on medical devices. Notable examples include the Stanford Biodesign Program, the Northwestern University Center for Device Development, and the Massachusetts Institute of Technology (MIT) Center for Biomedical Innovation. A key feature of these programs is close partnership and iterative technology evolution with clinical partners.

A challenge common to many student design teams is the Valley of Death in product development. Many groups that function well during the academic portion of the course-based design project tend to lose momentum once the course ends. Even well developed ideas and functioning prototypes are left orphaned due to lack of support, resources, and knowledge on the next steps of commercialization.

1.2 The Engineers in Scrubs Program

In 2011, the University of British Columbia launched the Engineers in Scrubs (EiS) training program (Hodgson et. al., 2014) with funding from the Canadian Natural Sciences and Engineering Research Council's (NSERC) Collaborative Research and Training Experience program (CREATE). This year-long course led graduate students in the Biomedical Engineering program through two phases: 1) an orientation to the clinical environment, and 2) an interdisciplinary team project in medical innovation. During the first phase, students are taken on tours of various facilities at Vancouver General Hospital including the emergency room, operating theatres, and intensive care units. Following this, a number of collaborative sessions, referred to as MedTech CAFÉs (Clinical Advances From Engineering), are held with clinicians in various medical departments. Physicians are initially invited to present a series of up to 20 problems, which are discussed and selected for further research. Students then take 2-3 weeks each to research one of the identified problems, focusing on market opportunity, clinical value, intellectual property considerations, and the overall competitive environment for the technology. The result is presented at another MedTech CAFÉ meeting where clinicians, students, and program mentors decide on the problems that student groups will focus on for the remainder of the program.

This paper presents a case study of the Drill Cover Project, a low-cost medical device for use in resource-constrained setting and developed as part of the EiS program. The project has thus far seen success in pushing forward, now over one and a half years after completion of the Engineers in Scrubs program, with ongoing clinical collaboration and momentum towards commercialization. Factors contributing to this successful traction through the Valley of Death are explored in this paper, providing a model for educators in technology design and commercialization courses to apply.

2 THE DRILL COVER PROJECT

As part of the MedTech CAFE process, surgeons from Vancouver General Hospital (VGH) and UBC's Department of Orthopaedics brought forth a problem that they commonly faced on surgical aid missions in Uganda through the Uganda Sustainable Trauma Orthopaedic Program (USTOP). Treating bone injury requires access to power surgical drills, however these drills can cost as much as $30,000. For surgeons at Mulago National Referral Hospital in Kampala, Uganda, and thousands of surgeons across the developing world, this device is financially out of reach. The VGH surgeons posed a design challenge for the student team: make surgical drilling safe, affordable, and easy.

Through the rigorous opportunity assessment phase, including conversations with surgeons in Canada, Uganda, and other developing countries, students learned that this problem was reflected globally.

Many developing world hospitals rely on Western donations of used equipment, however Malkin (2007) shows that donated equipment has a failure rate as high as 70% within its first year of use. This is in part due to the lack of spare parts and the local skills to repair the technology, which often ends up broken and out of service.

2.1 The Orthopaedic Environment in Uganda

Mulago Hospital was no different. The orthopaedics ward was equipped with a drill that was 15 years old, whose batteries were failing, and was a model no longer in production. Surgeons reported operating room stoppage as often as three times a week when the drill malfunctioned.

The emergency room theatres at the time had no power drills, and instead used a manual hand-crank drill. Surgeons reported that this drill took as much as 40 times longer to make a hole, and due to the force required to use it, there was often accidental plunge beyond the bone tissue, causing damage to soft neuro-vascular tissue. The authors' in-situ observation at Mulago Hospital saw surgeons dripping with sweat and exhaustion after using a manual drill. It impacted not only performance, but also motivation among surgical staff, who were then reluctant to take on more cases during the day.

For complex cases, the surgeons had purchased a power drill from the local hardware store. While this solution made drilling easier, there was no way to safely sterilize the hardware drill, which was not designed to withstand the environmental conditions of an autoclave. Using this drill posed a significant risk for infection. In addition, the performance parameters and especially the speed of some hardware drills can pose a high risk for thermal necrosis of bone tissue.

The Engineers in Scrubs team identified that this approach to using a hardware drill was common across the developing world, with some surgeons simply wrapping a towel around the drill to protect the patient. Dr Scott Nelson of CURE International, in collaboration with Joel Gillard and Randall Huebner of SIGN Fracture Care, had worked to develop a similar cover device, but it was left as an orphaned technology within the organization (Shearer and Zirkle, 2009). Other drill cover projects, such as the Ottawa Sterile Drill System, had similarly never scaled. The EiS student team set out to revive the design, and make improvements for enhanced safety in clinical use.

2.2 The Drill Cover Solution

The technology developed by the student group, in collaboration with clinicians in Canada and Uganda, is called the Drill Cover (Figure 1). It is a reusable, sterilizable, waterproof bag made of medical-grade fabric. The device features a surgical-grade stainless steel interface, which allows a 'dirty' hardware drill on the inside to connect to an external 'clean' chuck, without compromising the sterile seal of the Cover.

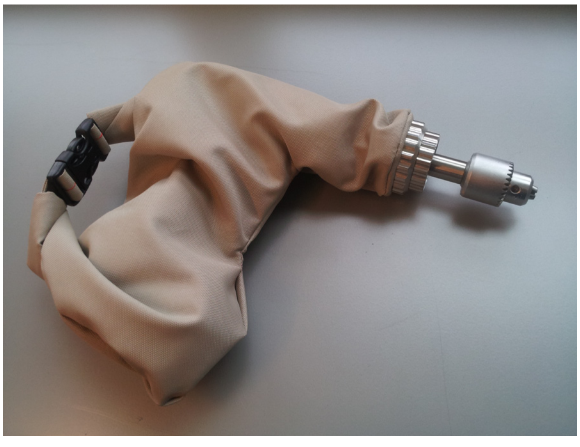

Figure 1. The Drill Cover

Building on previous evaluations by Dr. Scott Nelson of CURE International, the team settled on a particular power screwdriver that matched the speed, torque, and overall performance of a surgical drill. Surgeon feedback was generally positive on how closely the device felt and performed to the surgical drills they were used to using.

2.3 After the project course

Following the end of the EiS course, two students from the group continued on with the project. At this time, funding is often one of the major barriers to continuation, however the group received a small prototyping budget from the university. In addition, a grant from Grand Challenges Canada's (2014) Rising Stars in Global Health program was awarded to the team the following year.

At this time, the students also recruited fellow lab mates to support the activities moving forward, and with time the team formally expanded, attracting key members with very relevant domain expertise.

In the ongoing months, the new team took part in business training through the University of British Columbia's entrepreneurship@UBC program. This four-month intensive business accelerator challenged the engineering students to switch from analytical, scientific thinking to more adaptive, entrepreneurial ways of thinking. Throughout the program, the group had dozens of conversation with end users and customers, allowing them to validate assumptions and iterate on their business model on a weekly basis. This program also connected the team with a series of mentors who are still with them today.

At the time of writing, the Drill Cover project is en route to spin out as a socially-driven for-profit, Arbutus Medical (2014), which is pursuing high-volume manufacturing, regulatory approval, investment, and distribution through a number of channels across the developing world.

3 THE THREE VALLEYS OF DEATH

Thus far, the Drill Cover project has managed to overcome the proverbial "Valley of Death" (Figure 2) faced by many technologies and projects, especially in academia but also in industry, that end up orphaned and abandoned by their inventors.

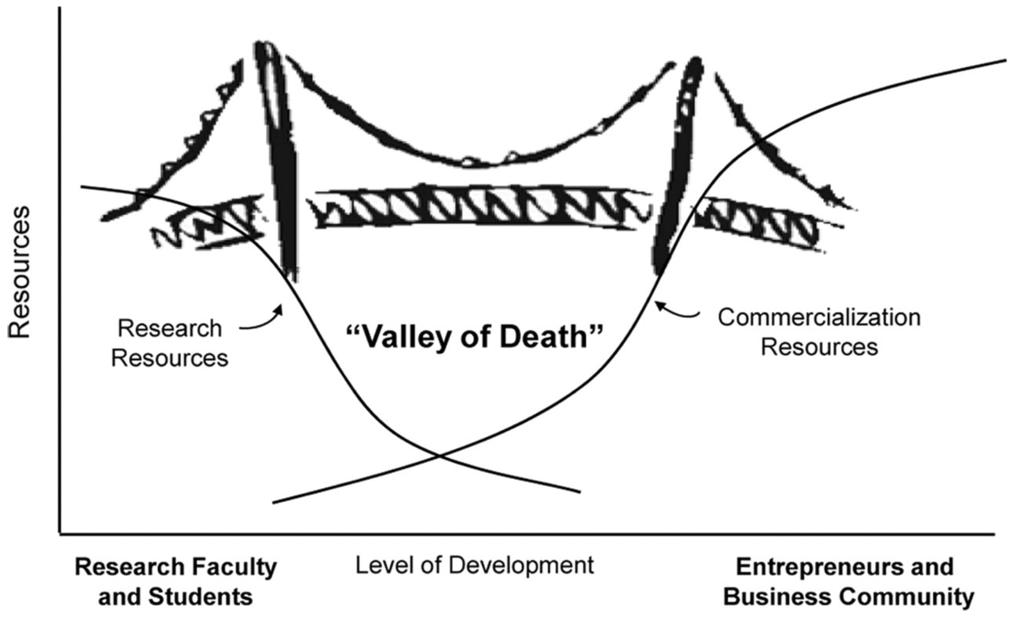

Figure 2. The Valley of Death (Barr et. al., 2009)

The "Valley of Death" is a term that refers to a phase in the product development process where research and development efforts must evolve and merge with business planning and execution as part of the progression towards commercialization. The Valley can be understood on several levels, and is described in this paper as three separate Valleys.

3.1 The Financial Valley of Death

The most common interpretation in the literature, referred to in this paper as the Financial Valley, is a point at which research funding is nearing an end due to the increasingly applied nature of the research, and yet the technology is too under-developed to receive interest from angel and venture capital funding. This Valley then, is a point where financial resources are becoming scarce, thereby leading inventors to abandon the idea due to lack of funds.

3.2 The Expertise Valley of Death

A second, Expertise Valley, can also refer to a difficult point where the knowledge and expertise in the organization, specifically technical and engineering expertise, no longer meet the need of the progressing commercialization process, which requires business acumen to bring the technology to market. This can bring a technology development project to a halt for two reasons: first, the inability of science-oriented researchers to understand, plan, and execute on go-to-market strategies, and second, if there are business-oriented members of the team, then this is a point where difficulties may arise in communicating and understanding the priorities between business and engineering team members.

3.3 The Academic Valley of Death

A third, Academic Valley, can be considered in the case of academic design projects, which refers to the orphaning of technologies at the conclusion of a credit-based academic course. This is a common problem, wherein students may indeed be driven by their interest in the technology design project, however the actual motivator of progress is the academic framework, reports and deadlines, and ultimately, the grades that students are striving to achieve upon completion in parallel with other courses and demands on their time.

4 A MODEL FOR BRIDGING THE VALLEYS OF DEATH

The three Valleys can often intersect at one point in time, but can also present differently and uniquely in each technology design project. In the case of the Drill Cover project, the authors purport that the team and technology have thus far managed to overcome the Academic Valley, and have made great

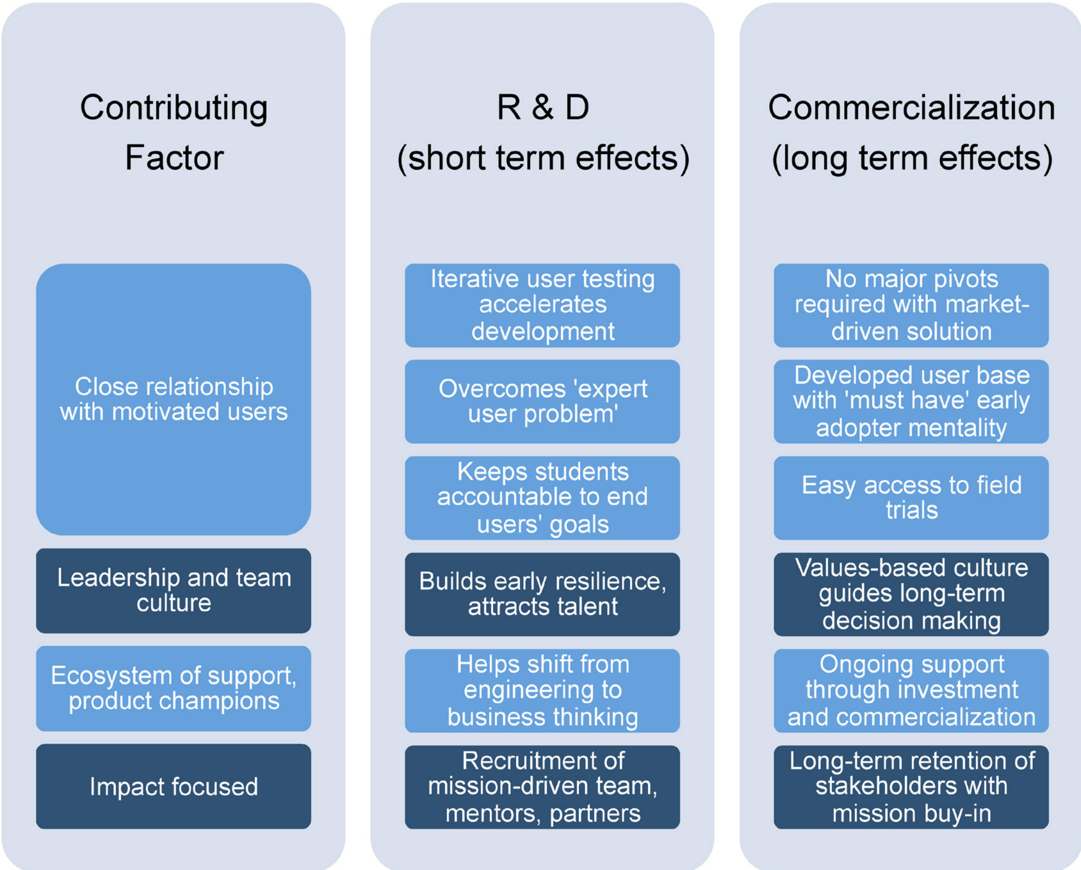

Figure 3. A model for bridging the Valleys of Death

progress across the Expertise Valley, but are still however facing the Financial Valley head on. This paper will go on to describe the numerous factors that contributed to the ongoing momentum of the project into and across the Expertise and Academic Valleys. The factors described below can give insight into how technology design courses can be enhanced to increase the likelihood and ability of students to bridge these Valleys of Death.

Based on observations of the Drill Cover project's progression over time, a model has been developed that features four contributing factors, each of which has a significant impact during the research and development phase of the course and post-course, but also brings great benefits as the project moves through the commercialization process (Figure 3).

4.1 Close Relationships with Motivated Users

The project began with close collaboration with clinical experts and mentors, which remained an important driving force throughout the school project and beyond. The surgeons who initially brought the idea were driven by a critical and pressing need that they had experienced in their own practice in Uganda. It was brought forth as a clearly identified, real need, with existing demand from customers. Because of this early validation, moving to commercialization required no great pivots for the team or product to find a market, as may have been the case if this was a technology-push based solely on an idea from a technologist.

These clinical mentors were able to provide ongoing, iterative support to the project, and were very deeply bought in to the project. Admittedly, they were more concerned with a resulting product that could be used clinically, than with the academic context of the course. This ensured that they would push the students to align their objectives for clinical impact as well.

Another benefit of having this talented and highly-motivated group of users is that it made the project feel real, rather than just an academic exercise. Barr et al. (2009) identifies that a key attribute linked to success of a technology commercialization education project is the perception of it being real, rather than an academic exercise with a less authentic feel. The authentic nature of projects has been seen to increase students' self efficacy, resilience, and sense of mastery, having encountered and overcome real-world setbacks throughout the design project that may otherwise not be present to challenge students in a purely academic exercise (Bandura, 2000). The resulting resilience allowed students to overcome more difficult challenges in the later commercialization phase, including seeking investment and shifting into entrepreneurial thinking, and was a factor to the continuation of the project.

A second important feature of a successful technology commercialization education program that Barr et al. (2009) identified is the need for iterative workflow. This iterative nature was present throughout the project with weekly meetings and ongoing communication that allowed students to quickly test, refine, or abandon certain concepts. More importantly, the clinical collaboration with the Canadian and Ugandan surgeons meant that the device could be field tested with a new iteration ready in time for each trip, typically twice per year, to Uganda. Real clinical results and feedback allowed students to make important advances in the technology development, and made the whole project more exciting and, again, real. This field test iteration was possible throughout the design course and continued on each of the following trips to Uganda after the course had finished.

The close support of clinicians throughout the process also helped to overcome the "expert user problem" faced in many design projects where the end product is intended for non-layperson users (Gheorghe and Van der Loos, 2013). This is especially the case in design for healthcare, where there is a significant gap in knowledge and language between clinical users who have a tacit understanding of anatomy, physiology, and the nuances of their own practices. In such situations, the users tend to understand the problem space very intimately, while the designers and engineers understand the technology space and process of development of a potential solution, while neither group understands both. Weekly interaction with the USTOP clinicians in the case of the Drill Cover Project meant that transfer of information and deeply nuanced clinical challenges could be accelerated.

Another important aspect of having close clinical collaborators who were deeply bought in to the project is that they were in essence keeping the team accountable. Students in the team identified that "we were more driven by the pressure and timelines put on us by the surgeons, to get a valuable solution into the field, than we were by the course deadlines and reports we had to submit for grades." At the same time, instructors were intentional in their decision to allow course deadlines to flex with the development of the product.

The influence of the surgeons was also identified as a major reason why the project continued, since the students felt as though "the technology was already helping patients, and couldn't just be dropped into the surgeons' lap because nobody would be there to continue it," and were motivated very much by the urgency of the need. One student remarked that, "when the course ended, the lead surgeon simply asked, 'so you're continuing this, right?' to which it was hard to say no." In addition to the surgeons themselves, by the end of the course the students had developed a very extensive network of supporters and potential customers who they also felt were keeping them accountable. This included groups like SIGN Fracture and CURE International, which had dedicated considerable time in mentoring the students with the hopes of this resulting in a medical device that could complement their current humanitarian offerings.

One student remarked that, "in a regular design course, [the technology] doesn't really have to work. You don't care, the Teaching Assistant doesn't really care, and you just need to pass the course. But the surgeons don't care about your course grades, they just want to use it! Seeing this as students, the reports and grades suddenly don't matter as much. You are more bought in to the outcome than the paper deadlines, and when the course ends, your obligation to these surgeons does not." It is clear that the academic framework becomes just a means, a scaffold, for getting buy-in to a real-world problem from both students and their clinical partners.

The list of stakeholders also included surgeons in Uganda at Mulago National Referral Hospital who by now had been well accustomed to using the Drill Cover and were constantly asking when it would be available for sale. Several of these surgeons reached out to the team through Facebook messages and e-mail asking about it. At one point, a surgeon in a remote part of Uganda had heard about the Drill Cover through word-of-mouth and had gone so far as to record a video of himself describing why he would find it of value, uploaded this to the video-sharing website YouTube, and sent an e-mail to the team requesting to buy one. The power of social media and global connectedness afforded through the Internet was adding a completely new dimension to what the Engineers in Scrubs program initially envisioned as "close clinical collaboration".

4.2 Leadership and Team Culture

The early leadership of initial inventors and the subsequent team culture that formed were key contributing factors to the project continuation across the third Academic Valley.

In many ways the project and technology were pioneering, and while this can be exciting, it can also draw negative response based on more traditional ways of thinking, which can be demoralizing and disheartening for a student team. While the group received a great deal of support, it was also difficult to convince some people of the team's vision, especially those more traditional in their views on how both industry and charity should work. On one hand the profitability of a business serving the poor was questioned, as was the profit motivation of an organization that purported to be socially-focused.

This difficulty was present across a number of areas as the team, soon orphaned with the conclusion of the EiS program, continued on as a hybrid in many ways. The dedication, persistence, and resilience of the team was key to allow them to push forward.

Through personal relationships, additional members were recruited with significant experience in clinical research, medical device development, and social enterprise across Africa. It was in part the passion and clear dedication of the original two inventors that attracted and inspired additional interested members who would find themselves aligned with the vision. One mentor commented that on this project "no one was greedy, the key people involved wanted to share the experience and to be inclusive in the decision making and work allocation. Having a team of people to help get through the difficult parts is vital, and the strength of the team far outweighed the sum of their individual contributions."

While many projects can evaporate upon graduation as new job opportunities tempt bright students, the Drill Cover Project team repeatedly turned down lucrative job offers in order to continue working on the technology. Team members also contributed a significant amount of their free time to the project. One team mentor remarked that "the students were in reasonably stable financial and social positions that allowed them to continue with the project." Although the team faced common challenges including student debt, funding from Grand Challenges Canada allowed newly graduated students to continue to receive a stipend, rather than pursue other full-time work. This ongoing commitment, enabled by early funding and in-kind support from various groups, was identified as a key factor keeping the group working successfully. "Commitment maintains momentum and boosts enthusiasm, and it would have significantly impacted the team if someone had dropped out once we were moving forward with the new team".

The composition of the team was equally important, and while not all members had a great deal of exposure to entrepreneurship, they were driven by the freedom and self-agency allowed by a project that they could direct themselves. The Engineers in Scrubs program generally attracted such students through self-selection, as well as through the application process that emphasized real-world clinical impact and collaboration to solve needs-driven problems.

4.3 Ecosystem of Support and Product Champions

From early on within the EiS project, the team began to attract significant global partners in the aid community who would become long-term supporters. Early on, aid organizations including CURE International and SIGN Fracture Care were instrumental to the team's thinking. These supporters helped shape the team's perspective on the problem and how to best address it with the technology solution. Through ongoing networking, the group developed a number of product champions across clinical settings, and within global aid organizations. Markham (2001) explains the value of product champions who can help push a project along, and even adopt the project as their own and commit to it despite no formal affiliation. A great example of this was one senior logistician within the aid sector who recognized the potential of the project and vigorously advocated for it across his network. This in turn generated further excitement within the team, and such champions became increasingly important sources of not only guidance and information, but also inspiration and motivation.

The team of all engineers were also supported by the University of British Columbia's entrepreneurship@UBC program. This intensive entrepreneurship training program, based on Lean Startup methodology (Ries, 2011), came at the time when the project team would otherwise be entering the second Expertise Valley. This program helped the engineers shift into a business mentality, testing market hypotheses, and connected them to business mentors who would then continue to serve as mentors after the formal program was finished.

In addition to the entrepreneurship program, the university's technology transfer office was able to provide a small prototyping fund, and mentorship on patent and legal concerns. The team subsequently applied for and was awarded funding from the Grand Challenges Canada Rising Stars in Global Health program. The ongoing trickle of money and champions translated into continuing hope and excitement from the team.

Overall, the team benefited greatly from the support of the university, whether in funding, in-kind access to workspace and equipment, ongoing media and press releases that elevated the profile of the project, and mentors. One team member reflected that, "having a workspace and community that I could call home made all the difference between seeking out more conventional employment or sticking it out with the project, especially if my only option was to work out of a coffee shop."

Working within an ecosystem of new venture and innovation support also had a strong impact on the team's perspective and expectations of the project. Specifically, the team was exposed to recent alumni who had succeeded at starting and running similar companies, albeit focused on the North American market. One student remarked that "seeing other companies take off out of a student design course similar to ours made it clear that this was possible, and it set both a new standard and an expectation for us to do the same."

4.4 Impact Focused

A key contributor to the success of the project is the mission-driven passion and excitement that is rallied within the team and among the wide network of supporters.

From the beginning, when surgeons were pitching ideas during the MedTech CAFÉs, it was the passion of one of the students that led to the selection of surgical drilling in Uganda as the problem of choice. After completing the initial research phase to identify the scale of the problem and the market opportunity, this student rallied others to follow his vision. Coller (2009) identifies several checkpoints for assessing the viability of technology prospects, the first of which being, "is it worth the effort?" This typically would refer to the commercial potential of the technology, in financial terms, however in the case of the Drill Cover project it was the clear and urgent humanitarian need that students deemed as evidence that it was, indeed, worth the effort. This motivation has been credited again and again throughout the project for its continuing success and for having attracted passionate and talented members to join the team following the course. One student commented that from her experience with other design courses, “many projects fizzle out because we don’t really have a connection to the technology, and here the humanitarian element kept the team super engaged and motivated to push on.” This impact focus should not be understated in importance, as the literature defining the motivations of Generation Y clearly points to the desire of students to make a difference in the world through their work.

The impact-focused goals of the project are also cited by business mentors for their continued engagement with the team, during and after the Engineers in Scrubs program. In addition to advisors, the team received support from various government offices that provide start-up support, including the National Research Council and the Department of Foreign Affairs, Trade, and Development. In these cases too, it was acknowledged that program representatives were not only convinced of the market potential of the technology, but they felt proud and excited to support an R&D project with a humanitarian mission, as this was not common in the partners they worked with.

5 CONCLUSION AND RECOMMENDATIONS

Thus far, the Drill Cover project has managed to overcome the proverbial “Valley of Death” faced by many technologies and projects, especially in academia but also in industry, that end up orphaned and abandoned by their inventors. Through identification of the factors that led to success, thus far, of the Drill Cover project, a model is presented in this paper for how curriculum enhancements can promote the success of projects across the three unique Valleys. The four factors presented in the model can facilitate progress both in the short term, during and after the course while still in the research and development phase, and also in the long term when efforts are focused towards commercialization.

The authors suggest that a close working relationship between student teams and highly engaged users can lead to a number of benefits including increased motivation through a project that feels “real” and is held accountable by users expecting a working solution, an accelerated learning and development process, as well as access to an eager user base during initial prototype refinement and also when going to market.

A technology commercialization education program must foster the development of leadership and a strong, values-driven team culture. This is important as a way to guide students through the setbacks they will undoubtedly encounter in the product development, and following that in the even more challenging commercialization process. The positive team culture can also benefit the team by attracting further direct and indirect support.

It was clear in the Drill Cover project how beneficial it was to have a wide network of supporting partners, and to be embedded within an ecosystem of entrepreneurship at the University. This provided access to not only business training, but also to mentors and peers, to a new way of problem solving, and importantly, access to inspiring examples of successful alumni who had shown that it was possible for them too to turn a student project into a commercial enterprise. In addition, having access to workspace, and the community that came with that, was an important factor in retaining team members who were making the choice to turn down other job offers.

Lastly, a focus on social and environmental impact is an increasingly important factor for students and recent graduates in both academic and industry pursuits. This is evidenced by the fact that some of the most successful Engineers in Scrubs projects to have travelled across the Valleys have been those with a humanitarian perspective. This often is the critical factor that drives passionate students, as well as their network of mentors and supporters, to take on a project with full ownership and tenacity.

5.1 The Drill Cover Future

At the time of writing, the Drill Cover Project is going strong. The group is in negotiations with the University for an exclusive license to spin-off the technology as Arbutus Medical, a socially-drive for-profit medical device company. The group aims to innovate not only technology, but a completely new way of serving surgeons and hospitals in the developing world profitably. Within the span of the next year, the team is pushing for formal regulatory approval that will open up markets across the developing world, as well as setting up linkages with high-volume manufacturers, and establishing relationships with distributors across East Africa as the first market of interest. With a pipeline of affordable, appropriately designed medical devices, Arbutus Medical aims to become a trusted supplier for surgeons and hospitals across the developing world, and is currently seeking funding and strategic partners to achieve this vision.

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