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From Unmet Clinical Need to Entrepreneurship: Taking Your Informatics Solution to Market

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Abstract

This paper will describe the process for taking a decision support solution to market as a start-up business. The nurse inventor and Co-Founder of RightCare Solutions, Inc. will share the steps from answering a clinical question, to registering an invention, creating a business plan and company, obtaining venture funding, and launching a commercial product. We will share positives about the experience such as how to get start-up funds, gaining national exposure and access to an excellent team, disseminating your work broadly, further enhancing the product, and obtaining equity, and financial rewards. We will discuss cons such as losing control, dilution of ownership, and conflict of interest. This paper will encourage nurse informaticians to think differently and learn about the steps in the process from an experienced team.

Keywords

nursing informatics; decision support; entrepreneur

Introduction

Seven years ago our team completed a National Institute of Nursing Research (NINR) funded study that produced a decision support system for discharge planning. The Discharge Decision Support System, D2S2, had a predictive accuracy of 83% for identifying patients who should be referred for post-acute care.[1] The goal of using the tool was to assure that we identify the right patients for post-acute care to get them the care they need to prevent post discharge complications such as readmission. Unfortunately, at the time, there was little interest in utilizing such a tool in clinical practice. However, as the regulatory and reimbursement landscape evolved for hospitals including the signing of the Patient Protection and Affordable Care Act[2] (PPACA) in 2010, the financial ramifications of readmissions became a top issue for United States' hospitals. As part of the PPACA, the Hospital Readmission Reduction Program[3] tied 30-day readmissions directly to financial

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penalties. This accelerated the commercial opportunity and paved the commercial need for technology, like the D2S2, and the creation of a new company.

There are many steps and factors to consider as one sets out on this entrepreneurial journey. With a unique idea, good timing, a strong leadership team, and a vision for success, the entrepreneurial journey is a rewarding one and worth considering.

1. Addressing an Unmet Clinical Need with Decision Support

A team of nurse researchers at Penn Nursing was analyzing data from a transitional care study conducted with high-risk older adults. We discovered that, although high-risk for readmission and other poor outcomes, less than 50% of the patients received referrals for post-acute services such as home care. Further study indicated that patient characteristics did not differ significantly among those referred and those not referred,[4] those considered high risk and not referred were readmitted at high rates,[5] and clinicians identified several reasons why patients might be missed given the clinical environment and discharge planning processes.[4] Based on these findings, the NINR funded the team to develop a decision support tool, D2S2, to assist discharge planners in making these important decisions.

The resulting D2S2 is a screening tool administered upon admission that stratifies patients as high or low risk for poor discharge outcomes. The tool then alerts discharge planners of high-risk patients and recommends a referral for post-acute care. The system was validated with a holdout sample in the original NINR study, was subsequently made more user friendly for clinical applications, and was tested twice and shown effective and scalable in hospital translational efforts.[6,7]

2. Protecting Your Intellectual Property

When the national concern about high 30-day readmission rates emerged, we knew that the time was right for the D2S2. Dr. Bowles contacted the Center for Technology Transfer at the University of Pennsylvania to register it as an invention. This registration began the process of protecting the intellectual property (IP). Generally, when employees invent something, the employer owns the resulting intellectual property. University policies such as the Patent and Tangible Research Property Policies and Procedures outline faculty rights and privileges. [8] Depending on your organization's policies, you may or may not share ownership of that intellectual property and the amount of ownership will vary. Be sure to check the policies. Also, if you think you might have a product for commercialization be careful not to publish or present details that divulge your property. The Center for Technology Transfer and the UPStart Program at the University of Pennsylvania helped us to register the IP and file for a patent. This was an iterative process with patent attorneys including discovery of all documents and details about the product. They also advised us on whom to name as co-inventors, if any. A helpful definition was a co-inventor should be anyone without whom you could not have achieved the work.

3. The Business Plan and Vision

Once the intellectual property is accurately defined and filed for protection, an inventor has two options for proceeding with commercialization of their product. One is to license it through the Center for Technology Transfer to any existing company who wants to pay for it. The other is to create your own company around the product. We chose to do the latter. A dedicated company focused solely on translating our research could move the development of the product faster than a larger existing company, which has other priorities. Also, it allowed the researcher to stay actively involved (as much as desired), whereas larger companies may not provide the same level of access and dedicated commitment. If licensed to an existing company, the researcher is likely to lose even more control, receives no equity, and has more limited access or rights to information.

The next step is to develop a business plan and assemble a committed management team. A typical business plan contains key sections including: defining the market unmet need or the problem statement, a description of the technology/product (or planned product), management profiles, commercial size opportunity, business model (how do you generate revenues?), and a financing plan. Besides guiding the business development, the business plan is a tool to communicate your vision, intentions, and potential to others. It is also essential when seeking funding and to attract the management team. As a business plan and company vision is being put together, it is important to solicit outside expertise from a trusted group of industry experts and professional advisors. It is also important to understand that the business plan and strategy will evolve over time; it will change as the company grows, marketplace evolves, and new information is learned.

4. Building a Management Team

The other essential ingredient is the management team. Who is going to make this happen on a daily basis? Who is going to recruit talented employees with specific skills? Who is going to be responsible for raising capital to grow the business? At the very least, the founder must identify a Chief Executive Officer or Business Manager to help develop the business plan and launch the business. The relationship between the academic founder and founding CEO is critically important and requires high trust, support, and open communication. Finding and selecting this CEO is not an easy undertaking. These are not job opportunities that are typically posted on popular job boards. To find the right types of individuals, it requires networking and relationships. Think about the types of individuals and character traits that are important for any company executive such as demonstrated leadership, strong team-builder, deep industry expertise, and personal integrity.

5. Accessing Funding Sources

One of the first key tasks was to raise start-up funds and to seek larger capital to support building the business. Start-up funds can be sourced in a variety of ways including government grants, friends or family investors, competitions with cash prizes, and now crowd-funding websites, just to name a few. Being in a university setting enabled the leadership team to enter the Wharton Business Plan competition with nearly 200 other business plans and they won! The team went on to win a national contest sponsored by

Janssen Pharmaceuticals called the Connected Care Challenge and finished as a finalist in a third competition. These early wins were important to establish excitement, build momentum, and credibility. Ultimately, with the early success, we sought larger amounts of funding from traditional venture capital firms to keep growing. This process required many detailed company presentations and multiple diligence meetings over a number of months with prospective investment professionals at many firms to find the one or two interested in providing financial support to move the company from start-up to commercialization. Additional sources of funding may come from the state or federal government and are worth pursuing in parallel. In addition to venture funding, we were awarded a Phase 1 Small Business Innovation Research grant (SBIR) from the NINR as well.

6. Commercial Launch

Launching a new product is a complex and challenging process, particularly in healthcare and hospitals specifically. After the initial version of the product was developed, the focus of the company has now shifted toward commercialization. This next phase of the company requires more capital, more people, and more resources including marketing materials, sales reps, account managers, outside agencies, conference participations, and a lot of travel to prospective client sites. As the company prepared for the commercial launch, a significant amount of work went into better understanding the purchasing decision process of the customers, refining the marketing messages appropriately, and developing a value-add pricing structure that attracts customers. With a dedicated team and additional capital resources from investors, the company has been able to translate our research into a commercial ready software product deployed across the country much faster with higher quality. Thus as a result, more patients and discharge planners can benefit from the D2S2 tool directly.

7. An Entrepreneurial Education-Lessons Learned

The process of seeking funding was a positive experience overall. It was exciting being able to share our work with a more diverse audience than the usual health care professionals we usually speak with. The experience brought national exposure to our team and Penn Nursing. The dissemination of information about the work happened faster than our traditional venues of publication and presentations. The team used the web, Facebook and Twitter to get the word out. Winning the contests brought press coverage and the thrill of victory. Obtaining venture funding validated our belief in the opportunity and provided the resources to make further enhancements to the product and to hire the leadership team. All of these events were exciting and positive experiences.

However, with that outside funding come the realities of relinquishing control. At the start, the nurse inventor and founder of the company shared ownership of the company with the university. But once investors, additional management members join, and other employees entered the scene, that percentage of ownership is shared once again. This is called dilution. However, with the additional capital resources from the outside investors, the expanded management team, and other employees, the company is growing and becoming more valuable. Therefore the economic value of the ownership is actually increased despite the

dilution. For example, 100% ownership of something worth \$1 equals \$1, but 10% ownership of something worth \$10 million equals \$1 million. Building a company is truly a team effort and requires multiple skill sets and capital to design, create, build, and sell products. These are skills and efforts beyond the scope and capabilities of just the founders.

Along with investment capital came a board of directors who make decisions about the company and its strategic direction. Although included in board meetings as an observer, the academic founder may experience a feeling of loss of control. In addition, conflict of interest concerns prevent any fiduciary involvement of the inventor in company governance or financial decisions. Also, if the inventor continues to present, publish and research on the same or related topics, a conflict of interest disclosure must be declared letting the audience know the inventor holds equity in a commercial company. A conflict of interest management plan is required if in an academic setting and continuing to do related research.

8. Conclusion

Few nurses have extended their roles into the world of entrepreneurship. The journey has been an exciting and educational process and certainly worthwhile. The learning curve is steep as you enter a new world of terms, discussions, and rules not familiar to health care professionals. Although there are pros and cons, the ability to translate research to practice and rapidly disseminate our research evidence to a wide audience of patients is the most rewarding aspect of the experience. Finally, watching the skilled leadership team build an entire software platform, create new jobs across the country, and thriving business around our work is incredible.

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