THE CLINICIAN INVENTION PROCESS:

GETTING A MEDICAL DEVICE FROM IDEA TO MARKET

THESIS

Presented to the Graduate Council of
Texas State University-San Marcos
in Partial Fulfillment
of the Requirements

for the Degree

Master of HEALTHCARE ADMINISTRATION

by

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San Marcos, Texas
May 2010

ACKNOWLEDGEMENTS

I would first like to thank my wife, Kim, and my boys, Joseph and Joshua, who have supported me throughout my program and the preparation of this thesis. Without their constant support and love I could not have completed this thesis or my degree program. Throughout my program I received support and encouragement from many other family members. I would like to single out Aunt Judy Pfeifer who made it her personal mission to help me find people that I could interview as part of my primary research survey. This most important research supporting my thesis was my survey of medical device professionals and clinicians. I am extremely grateful to the 125 persons who took time out of their very busy schedules to complete my questionnaire, send additional papers of interest, and otherwise offer encouragement and support. I would like to thank my supervisor, Judy Ingalls, for her support and allowing flexibility in my schedule as I worked on my thesis.

I am grateful to my committee members Eileen Morrison, Ed.D. and Ram Shamugan, Ph.D., for taking the time to review my thesis. My deepest appreciation and thanks goes to my advisor and committee chair, Jim Summers, Ph.D., for his support, expert advice, and inspiration throughout the process.

This manuscript was submitted on April 1, 2010

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ABSTRACT

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Clinicians who deliver patient care, including physicians, nurses, radiologists, and physical therapists, among others, are often the innovators who develop improved methods of care and medical devices. The process of conceptualizing, designing, developing, and launching a new medical device is a daunting task even for the most experienced medical device firm. It is an extraordinary accomplishment for the entrepreneurial clinician inventor who takes on the challenge.

The purpose of this thesis was to increase the success rate of getting these innovations from conceptualization to commercialization by focusing on critical steps and decision processes. An included process model provided the clinician inventor with a road map and guide to design, develop, and commercialize ideas for new medical devices. Factors critical to success, as well as major barriers and challenges which could impede the process, were addressed. The methodology employed included primary research conducted with medical device and process experts from the industry, inventor and non-inventor clinicians, and an extensive literature review. The results of this research and analysis produced a model for clinician inventors that can serve as a road map and a means of making the extraordinary process of commercializing a medical device less daunting.

CHAPTER I

INTRODUCTION

Clinicians are often the first to recognize the need for new or improved medical devices to address problems and/or inefficiencies encountered in the course of their everyday medical practice. It is these clinicians, who are not part of an established medical device company, who have a particular need for an organized approach to advance a product from idea to utilization. To help such clinicians this thesis develops a model to go more easily from a need to a commercial development. The approach required three phases to achieve these objectives. These objectives included: 1) a model detailing the key steps from idea to commercialization for innovative new medical devices, 2) a detailed list of critical success factors that drive the successful launch of new medical devices, 3) a detailed list of challenges and barriers that inhibit the successful launch of new medical devices, 4) identification of key decision points along the path to commercialization, and 5) identification and/or development of key tools that can aid clinician inventors as they navigate the process.

Phase one was an extensive review of literature including numerous case studies detailing clinician inventor success stories, or in rare cases, their documented failures.

These case studies included not only modern inventions, but also historical efforts such as the invention of the stethoscope in 1816 (Leyden, 2001), which are relevant for the present day inventor. Phase one also included the creation of a draft process based on the literature review findings that was later modified in phase two. This phase was used to interview process experts such as intellectual property lawyers who provided input on key aspects of the invention process such as patenting and negotiation of license agreements.

Phase two utilized in-depth interviews with both successful and unsuccessful clinician inventors, as well as those who are still in the invention process on the way to the development and launch of a new medical device. At the completion of phase two, the process model drafted in phase one was updated based on the input received. Phase three was an integration of the sources of data and provided final conclusions.

Statement of the Problem

The process of conceptualizing, designing, developing and launching a new medical device is a daunting task even for the most experienced medical device firm. It is an extraordinary accomplishment for the entrepreneurial clinician inventor (Gianneschi, 2000; Sturgeon, 1999) who takes on the challenge. The clinician inventor not only faces the traditional hurdles of the entrepreneur, but also the added challenges that come with the heavily controlled medical device market which is regulated by the Food and Drug Administration (FDA). These regulations, summarized by Pina and Pines (1998), require proof of safety and efficacy for any new medical device, often requiring pre-clinical and clinical studies. In addition, the design and development process must follow strict design control guidelines. While juggling these many issues, clinician inventors must also

manage their practices and patient care responsibilities and avoid potential conflicts of interest (Foote, 2001) between their invention development work and the institution where they practice.

With this myriad of barriers and challenges, it is very likely that potential clinician inventors are missing what they need to succeed and valuable medical inventions are being lost. This loss of inventive capacity, whether it be from discouragement of clinician inventors to such a degree they do not even begin the process of pursuing a new idea, or failure along the path to commercialization after they begin, good and valuable medical breakthroughs are lost. The problem addressed by this study was to examine challenges impacting the ability of a clinician to successfully commercialize a new medical device and discover ways to reduce this potential loss of valuable new medical breakthroughs.

Background and Significance

The key significance of this thesis was to increase the success rate for meaningful new medical devices by providing clinician inventors with a clearer path to market and new tools to aid in development and commercialization. The potential importance includes not only attempting to improve success rates for clinician inventors, but also to increase the number of potential medical device inventions entering the development pipeline. As stated in the introduction, the key study deliverables were:

1. A model detailing the key steps from idea to commercialization for innovative new medical devices.
2. A detailed list of critical success factors that drive the successful launch of new medical devices.

3. A detailed list of challenges and barriers that inhibit the successful launch of new medical devices.
4. Identification of key decision points along the path to commercialization.
5. Identification and/or development of key tools that can aid clinician inventors as they navigate the process.

Each of these deliverables could potentially contribute to a knowledge base for clinician inventors to have a better understanding of the process from idea to commercialization and, hopefully, encourage pursuit of their respective medical device inventions and innovations. There is no guarantee that improved knowledge of a process road map, hurdles, success factors, key decisions and development tools will help drive successful new medical device inventions. However, if one asks oneself the question of what would happen if these questions were not addressed, this researcher proposes that continued lack of knowledge would most likely contribute to fewer successful medical device inventions.

This study is aimed at better understanding the clinician invention process and key challenges faced by clinician inventors in attempting to turn an idea into a commercialized medical device that can effectively benefit patients. The intention of this researcher is to apply the knowledge gained from this research to provide clinician inventors with a better understanding of both the critical success factors and pitfalls they will face undertaking the development and commercialization of an innovative medical device. In addition, this work will provide a roadmap that helps clinician inventors with their respective efforts to commercialize a new medical device.

Research Questions

This thesis research includes a preliminary set of key research questions (listed below) that form the starting point for the research effort. The initial questions included:

1. What are the critical success factors of medical device commercialization?
2. What are the key process steps along the way from idea to commercialization?
3. What are the major barriers and roadblocks to successful commercialization?
4. What are the critical decision points along the way from idea to commercialization?
5. What else can be learned of value concerning the commercialization process from surveying the target population?
6. What can be learned from the literature to provide a clearer understanding of the clinician invention process model and other factors impacting successful commercialization?

Purpose of Study

The purpose of this study was to contribute to solving some of the problems faced by clinician inventors who are contemplating developing a new medical device. As stated in the background and significance sections, the concept that potential clinician inventors are missing what they need to succeed and valuable medical inventions are being lost, is the key problem this research was intended to answer. The study was also specifically designed to answer each of the six stated research questions and provide important insight to help address the challenges faced by clinician inventors.

Assumptions

The critical assumption for this study is the belief that the respondents to the survey were truthful in their answers. Other assumptions made were that respondents would be willing, in many cases, to provide referrals to complete a survey. This assumption about referrals was particularly important due to the difficulty in reaching and/or getting time from practicing clinicians and medical device industry experts.

Limitations

Since this study utilized a convenience sample and not a random sample, the results may not be necessarily extrapolated to the larger population of clinical inventors and/or industry experts. In addition, the use of the snowballing technique as a means of increasing the size of the sample by generating additional respondents, creates the possibility of bias. The bias introduced is the possibility of persons supplying referrals to recruit others of like mind.

Definition of Terms

The definition of key terms includes definitions for four items: judgment sample, clinician inventor, snowballing, and medical device.

Judgment sample.

The judgment sample is chosen based on judgment of the researcher and is meant to match the characteristics of the population under study. This method is subject to bias interjected by the researcher (Davis, 2000). The sample was also a sample of convenience, which is chosen because the group is easy to find and usually inexpensive to obtain (Veney and Kaluzny, 1998).

Clinical inventor.

Any practicing clinician, whether he or she is a physician, nurse, x-ray technician or any other practicing clinician who deals directly with patient care and/or any other person who is involved with providing patient care, who then becomes a medical device inventor. This definition was used in the survey instrument.

Snowballing.

The American Marketing Association online dictionary ("Dictionary of Marketing," 2007) offers this definition of a snowball sample: "A judgment sample that relies on the researcher's ability to locate an initial set of respondents with the desired characteristics; these individuals are then used as informants to identify still others with the desired characteristics."

Medical device.

"A machine, instrument, apparatus, or item used for diagnosis, treatment, or prevention of disease, which does not achieve its purpose through chemical action on or within the body (to distinguish it from a drug)" (Slee, Slee and Schmidt, 2001, p. 373).

Angel investor.

"Angel or angel investor is an individual who provides capital to one or more startup companies. Unlike a partner, the angel investor is rarely involved in management. Angel investors can usually add value through their contacts and expertise." ("Venture Capital," 2010).

CHAPTER II

LITERATURE REVIEW AND SUMMARY

Introduction

The literature review summary breaks down the articles collected over the last 3 plus years into 20 topics and the 7 major groups below. An overall summary is discussed at the end of the six major topic group summaries, which will synthesize the main points and draw parallels and conclusions relative to clinician inventors. Throughout each of the six major group summaries, the discussion is also related to the clinician invention process. The literature search process is described in Chapter III. The focus of the literature search was on what leads to successful launch of new medical devices that are conceived and pursued by clinician inventors. Each of the literature review sections that follow: people, general background, legal and regulatory, process, business, miscellaneous, and models all addressed this same focus.

People

This section discusses the importance of people as a key element in successful development and launch of a new medical device. The four topics included in the people group are: the team, ethics, the personal side of entrepreneurship, and clinician entrepreneur stories. The importance of the team in new ventures is fairly well

documented as a very important, if not vital, factor in the success of new companies regardless of industry. Jerome Schaufeld, director of the Slater Fund, a venture development firm focused on early stage companies, proclaims the team in Rosenberg (2005) as the primary issue and factors such as the technology, market and cash flow as secondary issues. The team evolves and changes over time as new management mixes with the original founders.

Frequently, when new team members enter, there are clashes with the founders (Maruca, 2000) as the new management team members fail to gel and integrate their efforts. Another issue that arose while examining people-related factors impacting medical device inventors was the broad topic of ethics. An ethical issue that bedevils clinical entrepreneurs is conflict of interest. Conflict of interest issues can occur in almost any business setting. However the clinician-patient relationship can create potential for conflict of interest almost anytime a clinical inventor gets involved in creating or helping create a new medical device. At some point, the clinician inventor is in a position to have to test, develop, and potentially market/promote the medical innovation.

A recent Stanford University summit report (Foote, 2001) summarized the issue succinctly saying:

> A governing principle is that research must be performed in a manner not biased by potential financial gain, often referred to as a financial conflict of interest, to the investigator or the institutions. The increasing collaboration between physician inventors and innovative companies presents new and challenging public policy issues. (p.1)

One institution facing the conflict of interest issue head-on was John Hopkins University Medical School. They created a culture that fosters innovation and entrepreneurial activity while maintaining the most valuable asset of the institution, its

reputation (Birch & Cohn, 2001). Bart Chernow, Dean of Research at the medical school says, "We as a university have become very entrepreneurial. We as an institution have taken our heads out of the sand" (p.1A).

John Hopkins University Medical School created an atmosphere that encouraged innovation and technology development leading to the creation of a patent portfolio second to only two other major research institutions, and over the period of a decade, launched 18 startup companies. John Hopkins University Medical School accomplished this cultural change by making it clear that business development and licensing were part of the mission of the university.

John Hopkins University Medical School had proactive efforts to seek corporate research investment and work with venture capital firms interested in technology being developed by John Hopkins University Medical School researchers. At the same time, the institution strives to maintain high integrity and has policies that govern conflicts of interest such as requiring scientists involved in research to disclose to patients and publications their financial ties in drug trials. Potential conflict of interest is raised whenever the researcher stands to gain from their financial interest in the outcome of their research. Ethics and ethical practices were also a key topic in the literature. Despite their efforts in 2001, John Hopkins University Medical School went through a government mandated four-day suspension (Greenberg, 2001) of some 2400 projects after a healthy volunteer in a study died. Government officials said their action was justified by neglect of safety requirements.

The federal Office for Human Research Protections (OHRP) found that the institutional review boards (IRBs) at John Hopkins University Medical School were "overworked, undersupported and employed unauthorized shortcuts to speed the flow of paperwork" (Greenberg, 2001, p.393). In a speech (Brandt, 2005) at Stanford University Medical School, John Hopkins University Medical School President William Brody discussed the issue of conflict of interest. He made the point that bias is inherent in research when a scientist has an idea and sets out to make that idea work. He goes on to say, "problems arise when such researchers act in a way that violates trust and put their interest before that of the public" (p.1). Brody also stressed that this type of bias (led by personal interest rather than public interest), or even allegations of such bias, threaten the trusted agent status that academic medical centers must maintain with the public. He concluded by making it clear that academic researchers must disclose possible conflicts and those institutions must oversee and properly manage these potential conflicts.

Related to the ethical issue of conflict of interest, another frequently mentioned issue was the seeking of patents in controversial areas such as gene therapy and surgical procedures (Havins, 2004; Stix 2006; Tolloczko, 2005). Tolloczko stated the issue very well:

> Does a contradiction exist between medical ethics and the Medical and Surgical Procedure Patents system? After all, the patent holder, in defiance of ancient medical tradition, may use his discovery not for good of the patient, but for personal gain (p.63).

Another important issue for clinical inventors (Agich, 2001) involved innovation in medicine where there is a deviation from the standard of care. The term "regulatory ethics paradigm (REP)" (p.295) was used to describe the issue.

Agich stated, "The REP holds that deviations from standard care involve a degree or kind of experimentation that requires the application of a set of procedures designed to assure the protection of the rights and welfare of the subjects of research" (p.296). The author brings the following criticism of the regulatory ethics paradigm:

> "The regulatory ethics paradigm tends to regard innovative treatment simply as a departure from standard and accepted treatment alternatives. It thus overlooks critical situations or fields of medicine in which accepted treatments are ineffective and burdensome," (p. 296).

Agich (2001), by his criticism, related the ethical and/or legal dilemmas facing a clinician inventor when using an unproven or new prophylactic, diagnostic, or therapeutic treatment for a patient. He gave an example of how the REP can stand in the way of innovation by requiring adherence to a formal scientific research process that assumed a degree of standardization of device, technique or procedure existed. Sometimes an innovation requires a developmental process that may be significant and complex and does not fit any standard research protocol. Agich used the example of complex surgery like a coronary artery bypass graft where the procedures had to evolve and were dependent on similar advances in the areas of imaging, anesthesia and post-operative care. He concluded that the REP acts as a barrier to innovation in medicine.

An additional skill necessary for successful innovation, which is not typically included as part of the medical school curriculum, is entrepreneurship. According to Bygrave (1997), "an entrepreneur is someone who perceives an opportunity and creates an organization to pursue it" (p.2). Clinician inventors who choose the path of forming a company to pursue development of a new medical device in essence must become entrepreneurs.

The stories in this section were chosen to highlight the importance of entrepreneurial skills in clinicians who aspire to launch new medical devices via their own company. Some believed that entrepreneurship principles can be taught and that aspiring entrepreneurs should be grounded in technical knowledge and business knowledge (Tan, 2005). Table 1 summarizes three independent views on entrepreneurial characteristics. These three views all offer a different perspective of entrepreneurs and in combination provided a more complete this of desired characteristics.

Table 1.

Entrepreneurial Characteristics

Bhide	McGrath	Bottles
Need for achievement	Passionately seek new opportunities	An expert in an area that Wall Street perceives as "hot"
Risk taking propensity	Pursue opportunities with enormous discipline	A public speaker who can enthusiastically communicate scientific and business plans to a variety of audiences
Internal locus of control	Pursue only the very best opportunities	A team leader who is willing to share equity in the company with other employees
Tolerance for ambiguity	Focus on execution	A recruiter and a motivator
Type A behavior	Engage the energies of everyone in their domain	An implementer who can achieve milestones quickly that allow the company to go public as soon as possible
		A realist who does not resent the terms of a typical deal

Note: Adapted from "The Origin and evolution of new business," by A. Bhide, 2000, p.92, New York, NY: Oxford University Press and "The entrepreneurial mindset," by R.A. McGrath and I. MacMillan, 2000, pp.2-3, Boston, MA: Harvard Business School Press and "The ideal physician entrepreneur," by K. Bottles, 2000, *Physician Executive*, 26, pp.55-58

Frank DeBernardis (Anonymous, 1998), executive director of the American College of Physician Inventors offers this view: "There are rare and few doctors who build companies. If they are happy being inventors and surgeons, running a company is so consuming that it takes them away from that"(p.13). The point being emphasized by

DeBernardis is true of virtually every inventor who has a full-time profession. It is next to impossible to continue any career, let alone that of a physician, while attempting to grow and manage a company. Eventually, the inventor must choose between career and running a company. This is a very important early stage decision that clinician inventors must face. Several articles (Gould, 2005; "Is This," 1997) discuss this important early stage decision. One scathing article ("Marketplace Trends," 2002) about physician entrepreneurs said that they suffer from cultural impairment characterized by arrogance, greed, entitlement and cheapness. This article is one example of how some critiques viewed physician entrepreneurs.

One success story of a successful physician entrepreneur was that of Rodney Perkins. Perkins was a physician who started a company called Collagen (Cassak & Levin, 2003). His first concept was a biosynthetic eardrum which was later abandoned due to an insufficient market size. His next two products were a burn dressing and injectable plastic surgery which eventually became the company's primary products. His story illustrates the value of tenacity and flexibility in the process of creating a successful start-up venture. Perkins failed in his first venture, a common problem among entrepreneurs. He continued to go to the market with viable products, making sure he chose a market large enough to support his new developments: a burn dressing and injectable plastic surgery. These commercial successes indicated the importance of market knowledge, not just technical expertise. Perkins demonstrated tenacity in continuing to try. Given the different markets for his products, he demonstrated considerable flexibility as well. These important traits were noted in Table 1 as tolerance for ambiguity and passionately seeking new opportunities.

Another success story (Leyden, 2001) dates back to 1816 when French physician Laennec invented the stethoscope. He, more or less accidentally, made the discovery as he was trying to listen to the heartbeat of an obese woman and needed a way to hear her heartbeat through layers of insulation. As he was straining to listen through fat, which, he described as a "great layer of fatness" (p.1), he recalled a principle of acoustics which states that sound is augmented when conveyed through certain solid bodies like wood. He cobbled together a crude prototype on the spot and the arduous process of developing a new medical device was begun.

Many stories in the literature told the origin of the original idea, usually solving a patient care problem for a specific patient at hand. One such story (Suzukamo, 2006) was told about nurse inventor Jane Angstrom who noticed patients in pain when the gauze bandages that held their catheters in place were removed. Her Cathcover, that addresses this problem, is now on the market. One of the innovative methods she used to help develop the idea was working with a sophomore engineering student from MIT to help develop the product. In this approach, Angstrom demonstrated her ability to engage the energies of everyone in her domain, one of the factors in Table 1.

Another story (Ko & King, 2003) of discovery comes from the now deceased Scribner who developed the Scribner Shunt used for kidney dialysis patients. He was haunted by the death of a patient who had a brief recovery on dialysis and then died. He states, "I literally woke up in the middle of the night with the idea of how we could save these people" (p.A1). His invention revolutionized kidney dialysis treatment, and through his tenacity, helped pave the way to establishing reimbursement for the treatment. Scribner believed that medical research should be conducted for the public good and

scientists should not reap huge profits from the inventions. He was a strong advocate for not-for-profit dialysis centers.

This effort demonstrated one of the traits from Table 1, which was his ability as a public speaker who was able to enthusiastically communicate both scientific and business plans to a variety of audiences. Yet another discovery (Fleming-Michael, 2002), based on a specific need of patients, comes from Smeed. He was asked by his team leader to find a way to avoid strapping uncomfortable equipment to burn victims or other patients. Smeed developed a special platform that mounts on a standard North Atlantic Treaty Organization (NATO) liter and holds portable medical equipment. This in turn solves the problem of strapping equipment to the patient, while allowing for more rapid transfer as a soldier moves from the battlefield to the battalion aid station and on to other care settings. In this example, Smeed demonstrated one of the key entrepreneurial traits, which is focusing on execution. Physician/inventor Wholey, in an interview with *Endovascular Today* ("An Interview," 2004), had this to say about determining customer need: "First there has to be a need for the product. Attempting to create a need for a product is frequently difficult and invariably unsuccessful" (p.74).This may seem like common sense advice, but many inventors invent first and try to establish a need later. Physician Makower, a sinusitis sufferer trying to solve his own malady, discovered balloon sinuplasty (Egan, 2006). Makower also developed a set of catheters that bypass blocked arteries that he sold to Medtronic for 90 million dollars. He had an unusual background which includes his MD, an MBA, and a mechanical engineering degree, which no doubt contributes to his ability to produce multiple successful inventions. Makower demonstrated the entrepreneurial characteristics of being a realist who does not resent the

terms of a typical deal and the passionate pursuit of new opportunities. Relating his experience to the commercialization process, he faced one of the most common and critical decisions-- whether to produce and sell the product or license to a major player and collect royalties. Another inventor (Cassak, 2003), Simpson had started over half a dozen successful device companies. He commented that he knows his limitations and does not do any engineering.

He said the secret is to hire people smarter than oneself, because inventing and commercializing a technology is a team effort. Simpson embodied several of the qualities of entrepreneurs discussed in Table 1 including engaging the energies of everyone in ones domain, being an expert perceived as credible by Wall Street, and being a public speaker who can enthusiastically communicate scientific and business plans to a variety of audiences. In the commercialization process, Simpson excelled at many tasks, but especially the task of building a management team.

One of the ugly sides of the invention process uncovered in the review was that of intellectual property disputes. Terry told the story (Norman, 1989) of his dispute with Mentor Corporation over his invention, a vision analyzer. In the early stage of his invention, Terry shared his idea with Mentor while seeking assistance with manufacturing and distribution. Terry ended up in a lawsuit over the intellectual property and spent $960 thousand dollars in legal fees. Terry later said about the dispute, "I've been disillusioned by the legal action. I really had the feeling that if you had a good idea, worked hard and helped people, then life would take care of itself and you'd be successful," (Norman, 1989, P.C01).

The experience of Terry reinforces the need to protect and defend ones intellectual property. The experience of Terry helps illustrate the need of entrepreneurs to understand the ethos, ethics and culture of business they are about to enter. Orthopedic nurse clinician and inventor Skewes (Ventura, 1999), who had also lost an idea and learned from the experience, recommended intellectual property protection as the first and foremost action item when one first had an idea.

Clinician inventors seeking to commercialize their inventions could learn valuable lessons from Fogarty. He had, over a 40-year period, acquired more than 100 surgical patents including the highly successful Fogarty balloon catheter and helped launch numerous medical device startup companies. He offered the sage advice that medical inventors need to have persistence to the point of obnoxiousness (White, 2006). Fogarty as cited in White (2006) also offered three rules for medical related technology: "1) How can I make this better? 2) How can I reduce pain, and 3) How can I get the patient out of the hospital more quickly?" (p.1).

He also pointed out that the long development cycle of five to seven years to get through the regulatory approval and reimbursement process is a major hurdle in the process of commercializing a medical technology. Another key issue raised by Fogarty was that lack of training for doctors to accommodate emerging technologies negatively impacted adoption rates for new technology. One lesson offered by Fogarty to address these hurdles was to consider licensing. Edwards Life Sciences licensed his first invention, the balloon catheter, and helped take it to market. There are several key lessons to be learned from these clinical inventors. Summary conclusions drawn from this section of literature review as the key lessons for clinician inventors include:

1. Be fully aware of the resource and time commitment challenges inherent in moving a new invention forward while managing an active patient practice.
2. Be flexible and open as the idea and invention formulates as the final product may be very different than the original concept.
3. Be aware of problems and challenges observed while delivering patient care, as these may be the genesis of the next great invention.
4. Establish a good team to supplement and/or provide needed skills to move the idea forward. One person cannot do it all.
5. Vigorously protect intellectual property and pick partners carefully.
6. Have a good understanding not only of the patient benefits of the product, but also the economic benefit within the healthcare system.
7. Clinician inventors need to be aware of ethical issues and conflict of interest concerns as they balance profiting from research, development and commercialization of medical innovations.

The human and personal side of the new product development process serves as a vital catalyst in the inception and subsequent commercialization of new medical devices. Many times the front-line clinician provides the spark of creativity that spawns the next important medical innovation. The ability to successfully address the seven issues and challenges stated above is an important task for the aspiring clinician inventor. The next section covers general background articles uncovered in the literature search.

General Background

The two topics contained in the general background section are: 1) industry and market overview and economics, and 2) R&D data, trends, strategy and product design. These topics are important to the aspiring clinician inventor as a means to help understand the industry characteristics in which the idea and/or venture will compete and attempt to thrive. An understanding of industry economics and trends also serves as a foundation for building a business plan to support the launch of the venture.

The medical device industry in the United States is made up of an estimated 5,394 companies producing 85 billion dollars in annual revenue. This 2004 estimate comes from the U.S. Department of Commerce (DOC) ("ERG Final Report", 2006). The DOC reported that the vast majority of these firms have fewer than 20 employees. Likewise, the U.S. is the largest producer of medical devices and technology in the world. The Advanced Medical Technology Association (AdvaMed) report (2004) stated that the following factors are vital to the development of new medical technology:

1. FDA regulatory requirements
2. Cost of clinical research
3. Medicare coverage and reimbursement requirements
4. R&D costs related to expansion and contraction into new markets
5. U.S. private payer coverage and reimbursement requirements
6. International regulatory requirements
7. Litigation risks and costs
8. R&D costs related to acceptance in existing markets
9. Availability/cost of capital funding
10. Sales, general and administrative expenses (SG&A) related to expansion and contraction into new markets, (p.17).

It should be noted that the expenses of marketing and sales, which are almost always a major expense item in medical device commercialization, are included in the SG&A costs. Although these factors were collected from established medical device firms, many of them dovetail with the challenges start-up medical companies also have to face. The clinical device inventor faces a multiplicity of challenges in getting a medical device successfully to market.

Nonetheless, several trends suggested that the rewards for perseverance and doing it right can be large. Consider the following well-known trends that will drive the demand for medical devices only higher. The most significant is the expected doubling of the

population over age 65 by 2030 (Goldman, et al. (2005), rising rates of obesity, (Thorpe, Florence, Howard & Joski, 2004), the changing healthcare habits of baby boomers (Benesh, 2004), ever worsening labor shortages, and a rising population of the uninsured (Gordian & Mango 2004; Lazarus, 2004; Max 2003; Shepherd, 2006; Simpson, 2004; "Top Seven Health," 2006).

Clearly, such trends will continue to drive the healthcare marketplace and the medical device industry. One trend noted by Stommen (2005) was increased concern and focus on reimbursement for medical technology. On the negative side, relative to trends that inhibit innovation, Leahey (2003) noted the impact of Group Purchasing Organizations (GPO's) on the purchase of medical technology. GPOs can have a great impact on the ability of start-up firms to compete. The exclusionary clauses (Leahey, 2005) in the GPO agreements favor larger firms and make it very difficult for small and medium-sized medical device firms to compete. A handful of GPO's are estimated (Sethi, 2006) to control 80% of the purchasing market.

Legal and Regulatory

The next section covers legal and regulatory issues that are of special importance to clinical inventors with a focus on patents and intellectual property. Not surprisingly, most of the articles addressing intellectual property protection were focused on patent protection. Nonetheless, they also covered other intellectual property methods and issues. The other primary means of intellectual property protection included trademarks, copyright and trade secrets. Goldman (1999) suggested that the medical inventor pay close attention to ownership rights especially as they related to employer agreements. Often employment agreements spell out that those ideas developed on company time

and/or involving the use of company resources will become the property of the company in whole or in part.

It is important for all inventors, including clinician inventors, to know the policies and procedures that govern invention and intellectual property at their respective workplaces. Another issue found in the literature was the existence of questionable invention submission companies (Sullivan, 2004) targeting inventors. Maenner and Bentley (2003) advised inventors to be aware of invention scam companies. Many of those firms simply want to collect fees and will do little to help anyone with a specialized medical device.

Likewise, medical device inventors need to be extra careful about public disclosure, and be ready to work with non-disclosure agreements, especially in dealing with manufacturers. The issue here for the inventor is related to U.S. patent law governing public disclosure which requires one to keep their idea confidential prior to their patent being filed. Non-disclosure agreements are an accepted method for one to share information regarding their invention with manufacturers and others needed to work with as one advanced their idea toward commercialization.

Another warning comes from Weisz (2006) to be sure not to lose ones' patent rights due to abandonment, when one had gaps in between ones work on the idea. Weisz mentioned that abandonment can also be the result of not meeting deadlines set by the United States Patent and Trademark Office (USPTO). Although Weisz does not offer any advice on how to avoid abandonment, published guidelines available from the USPTO Patent Act (1952) can help one better understand the issue and avoid unintentional abandonment.

Process

The review of innovation related processes is the next major literature review topic. The areas included in this section are licensing and strategic alliances. These alternative market entry strategies are important options for clinician inventors to understand and consider.

One of the main topics in the process area uncovered in the literature search was the process of licensing and/or alliances, where the start-up company works with the larger established firm to co-develop, manufacture and/or market the product. Figure 1 illustrates the various forms of market entry strategy on a relative time scale from long to short time for market entry. Often large corporations will pursue a licensing strategy or alliance to reduce their time to market. The more progress an inventor has made toward ultimate market commercialization of a concept, the more potential value they can offer a corporate partner.

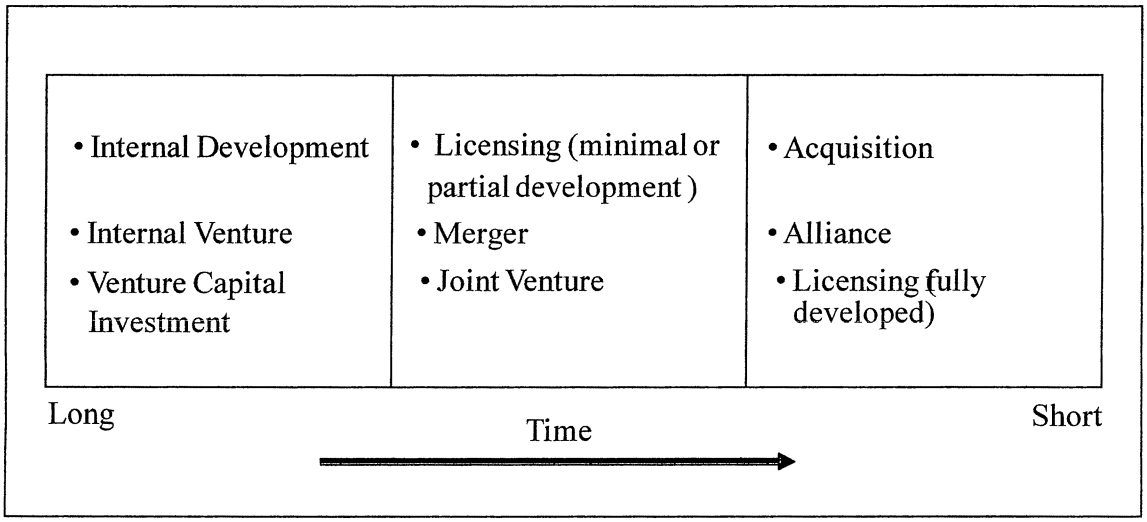

Figure 1. Time to market entry for multiple market entry strategies. Adapted from "Strategic Management of Healthcare (4th ed.)," by P. Ginter, L. Swayne and W. Duncan, 2002, p. 243, Malden, MA: Blackwell Publishers Inc.

Slowinski as cited in (Caggiano, 1999) found that 80% of strategic alliance deals were structured so that Company A was provided a unique product or technology, and Company B was provided access to markets or distribution. This model fits well with a medical device inventor seeking an avenue to market by eliminating the need to create a sales and distribution network. Slowinski warned of the four main ways that alliances fail. These included: 1) a change in strategy, 2) loss of a key person involved in the deal, 3) a priority mismatch between the parties, and 4) some sort of failure with the intellectual property. An example of intellectual property problems (Austin, 2003) was illustrated by the case of Arizona vascular surgeon Kelly, who ended up in a contenous patent related dispute with W.L. Gore over the use of Gore-Tex in artificial arteries.

Even when a license agreement is in place, things can go wrong for many reasons. Patent lawsuits can easily cost millions of dollars to litigate (Dockrey & Blanchard, 2002). Intellectual property and litigation attorney Hosteny (2002) offered an excellent series of tips for licensing agreements around three general principles: doing it right the first time, having agreements in writing, and taking a broad view of the agreement from the start. To expand on Hosteny's advice, the concept of doing it right the first time refers to the problems that are created later due to a poorly written agreement. Narrow agreements can require constant updates and revisions. Chatterji (1996) cited rapid access to proven technology and reduced financial exposure as major advantages to external sourcing of technology, most often associated with licensing agreements, but also applicable to merger and acquisition strategies.

The negatives of external sourcing/licensing from the inventor's perspective are: limited or no continuing role of the source organization (inventor or start-up team) in

future technology improvement, and the need for the company to have the internal capability to handle development and commercialization. Some major firms have been known to buy the license for a technology and shelve it to avoid having another competitor in the marketplace. The smaller company licensing the technology can have performance clauses and minimum royalty payments built into a license agreement to prevent or at least mitigate the impact of abuse or lack of performance in marketing the technology by the larger firm. The large company may be concerned with negatives (Ginter, Swayne & Duncan, 2002) from their perspective such as having to rely on an outside party for product development and not having their own proprietary technology. Depending on the type of licensing agreement, losing control of the technology may be too much of a sacrifice for the clinician inventor and would most likely depend on the reward being offered in the licensing deal. It is within the power of the inventor to insist on an ongoing and proactive role when a deal is made to license the technology. If a company really wants the technology, that company will usually work in a role for the inventor and/or team. The next section of the overall literature review is the business section which addresses the overall business related topics related to clinician invention and the general commercialization process factors.

Business

The four topics included in the business group are: 1) grants, funding, venture capital, and angel investors, 2) business success, failure factors, and start-up tips, 3) barriers, issues, key success factors, challenges and risks, and 4) marketing, business plans, and adoption. Baum (2000) offered the following steps for bringing a medical device to market: obtaining a patent, building a prototype, finding a manufacturing

partner, obtaining FDA approval, conducting preclinical and clinical testing as required, and marketing the product. A study published by Windover Information (Ferrari, 2005) discussed key characteristics for the success of a new medical device. These included having a novel and best in class technology, having a product with significant clinical impact and having competitive advantage. These elements needed to be combined with a solid execution of the business plan. The report goes on to point out that the most important element of success for a medical device company is clinical impact.

Another author (Gillette, 2004) approached the concept of successful inventions by posing a series of questions the entrepreneur should ask before moving forward. His questions were similar to those asked by managed care entities when they consider reimbursement of new technology. These questions included: How good is the idea? Is it better? Can you prove it is better? Is it actually easier to use and/or less costly than competitive options?

Ginter et al. (2002) summarized work done by (Barney as cited by Ginter et al. 2002) who offered four key questions to address competitive advantage of a firm. These are:

1. Value – Does the competency have value in the market?
2. Rareness – Is the competency rare in the market? Does only one organization have the competence?
3. Imitability – Can competitors imitate it easily?
4. Sustainability – Can the competency be maintained over time? Is it sustainable?

Gillette's point of view places emphasis on the competitive advantages of the product, while Ginter et al. (2002) emphasized the firm-level advantages and took a long-term view by addressing the question of sustainability. Ferrari brought in the importance of clinical impact and plan execution as key elements. Another author (Meyer, 1999) offered a similar list of 19 questions as an invention feasibility checklist. Table 2 summarizes Meyer's questions into four main categories.

Table 2.

Summary of Key Questions from Meyer

Market	Competition	Strategic and Personal	Other
Is there a market and will anyone buy it?	Does it offer real benefits?	If you intend to make it yourself, can it be a "stand alone" product?	Has a patent and prior art search been conducted and is it patentable? Or do you have the marketing muscle to sell an unprotected product?
Will customers pay a premium for the product?	Is it really novel and non-obvious?	If you want to license it, can it be integrated into an existing product line?	Has it been prototyped and can it be demonstrated?
What market share percentage can it hope to capture, and in what time period?	Does it solve a real problem? Or does it have attributes which will cause people to buy it?	Are you willing to stick with it for years?	Can others make claims against the title (eg , former employers?)
Is the market growing?	Is it revolutionary or a significant enough improvement that will have a market advantage over existing technology?	Are you willing to invest your own money or is there advance backing?	Is it manufacturable at a reasonable cost?
Is the current overall market category significant in terms of absolute money?	Are functional alternatives to the device readily available?		Does it need regulatory approval, and how long is this expected to take?

Note. Adapted from "Invention Feasibility Checklist," by H. Meyer, 1999, Retrieved August 9, 1999 from http://www.thehooktek.com/checklist.html.

His list is an excellent starting point to begin to think about ones market, product and other key issues as well as consider ones key strategic and personal decisions at the early

stage of ones concept and/or product development. Yet another set of success steps for innovation is offered by Hines (1999). He advised to first set a vision for the effort, then build a team to drive the process, invite outsiders to the party to help one avoid personal and team blind spots, and test the new idea with consumers as part of the design process. This gathering of outside input needs to be conducted with appropriate protection of your intellectual property.

A qualified patent attorney or patent agent should be consulted prior to external exposure of an idea. A different angle to looking at an idea is rather than asking "what must I do right," is to ask "what mistakes should I avoid" in the development process. Kelleher (2001) lists "the seven deadly sins of medical device development" (p.1) in his article. These sins include:

1) Launching ones' project too soon (this is kind of like saying "sell no wine before it's time")

2) Poor and inadequate project leadership (experience is a must)

3) Underestimating lead times (mistake of being overly optimistic)

4) Trying to do everything in parallel

5) Saving the hardest tasks for last (leads to failed projects or delayed projects)

6) Changing requirements (hard to deliver when the goal posts or targets change)

7) Giving engineers free reign (that may lack the discipline required in project management as they focus on creating the product)

Two other articles (Bounds, 2004; Labish, 1994) offered insight as to why businesses fail. Two important reasons cited for failure were inept management and outside forces that became overwhelming. Most investors in early stage companies place

great stock in a company's management team. They are aware of the importance of avoiding investment in an inept management team regardless of the attractiveness of the market and/or product. As far as addressing outside forces, the startup firm should have contingency plans that mitigate risks and elements of one's business plan that address expected performance under different scenarios that account for the impact of external factors.

A key point for clinician inventors is that they are subject to all of the traditional sources of business failure, as well as from the challenges faced dealing with the complexities of medical device development. One of the prominently mentioned factors in start-up success, regardless of industry, was adequate funding. Several articles (Jensen, 2002; Knapp, 2003) discussed the importance of having a business plan and management team in place as prerequisites for obtaining capital. Silverstein and Osborne (2002) offered a detailed list of ingredients for a business plan aimed at healthcare-related venture capital groups. Venture capitalists seek large markets, innovative technology that

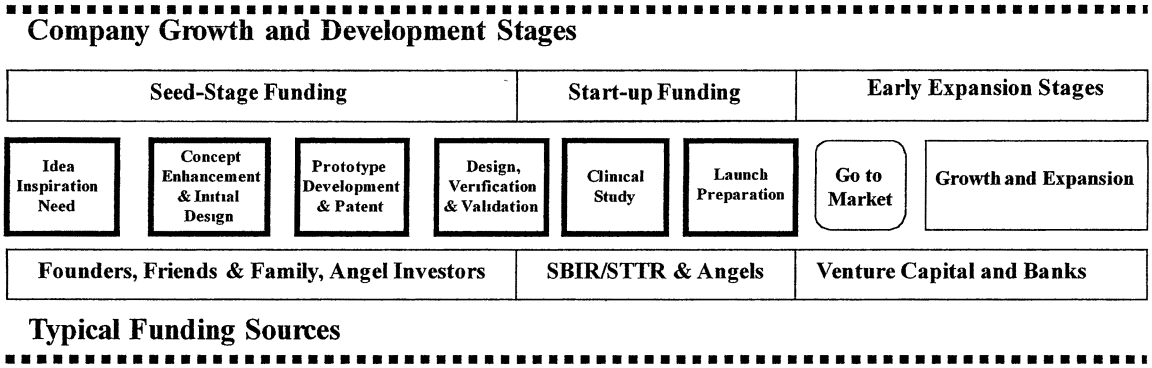

Figure 2. Funding sources by stage of company maturity.

Early stage companies need to know what is expected by each stage and attempt to attract different types of investors. Venture capitalists are viewed as being much more risk adverse (Grimes, 2003) since the dot com bubble years of 1999 and 2000.

However, recent trends indicate a warming to the medical device industry as a good investment area, which accounted for approximately 28% of all venture capital in 2005 (Hopkins, 2006). The final section of the literature review covers miscellaneous topics with relevance to the clinician invention process.

Resources for Medical Device Inventors

The miscellaneous section addressed companies dealing with clinical investors. These companies varied in purpose and scope of services. The companies offering services to clinical inventors included (Leslie 2003; "A Unique Surgeon," 2003; "Eureka Medical," 2005):

1) Doctor's Research Group – formed in July 1997 to evaluate, develop and market innovative surgical and diagnostic medical devices
2) Eureka Medical – a resource for medical professionals and independent inventors with ideas for medical products and healthcare products
3) Stanford Medical Device Network – a network that brings together entrepreneurial students, faculty and staff of the medical and engineering schools at Stanford University

These few examples show that there are entities of varying purposes and scopes aimed at helping clinical inventors. These companies represented only a fraction of the companies serving clinical inventors, but point out a potentially valuable resource for an aspiring clinical inventor.

Clinician inventors seeking help from any outside firm should select carefully and assess the firm's capability and reputation before deciding to work together.

Models

When thinking about the clinician invention process, an important comparison is the invention process itself, which is common to any would-be innovator. Most inventors must utilize the multiple processes of creativity, new product development, licensing, and alliances and/or technology transfer, to succeed in ones endeavors. All of these processes are impacted directly or indirectly by diffusion of innovation theory and subject to heavy influence from the world of entrepreneurship. All new products, if successful, must make their way through the diffusion curve shown in Figure 3 (Rogers, 1995) and gain acceptance in the marketplace.

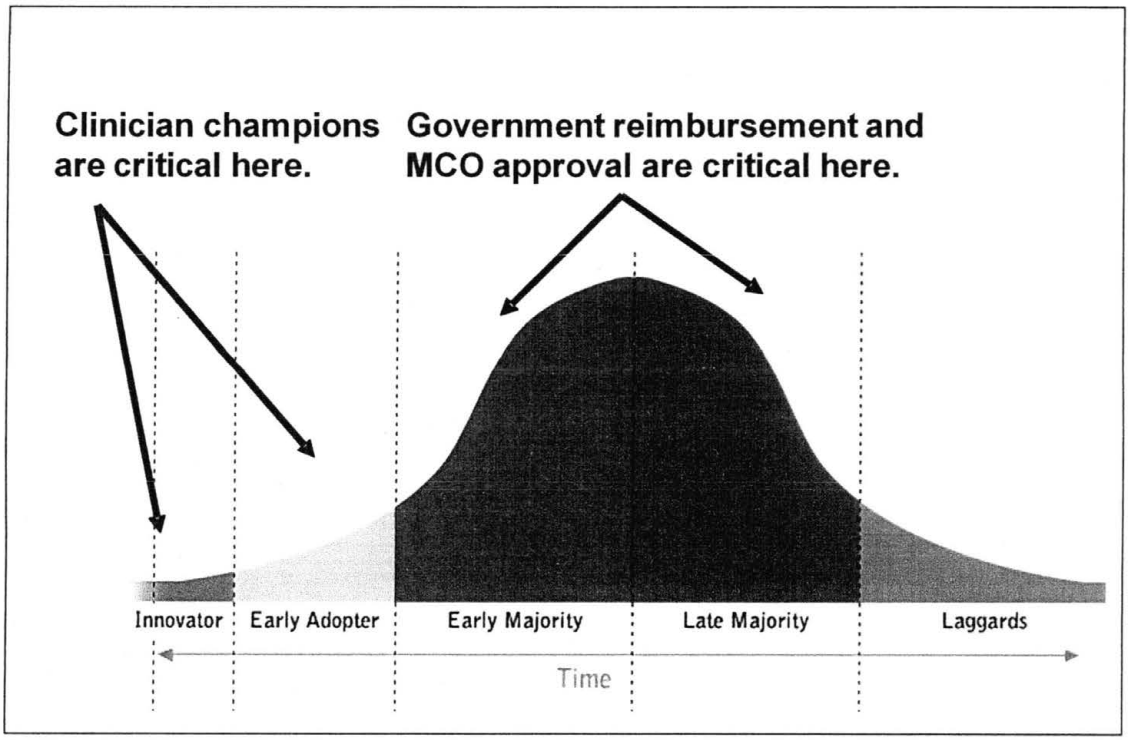

Figure 3. Rogers diffusion curve with medical device example. Adapted from "Diffusion of Innovation, (4th ed.)," by E. Rogers, 1995, New York, NY: John Wiley & Sons Inc.

Visualizing Rogers' diffusion curve overlaid on a product life cycle curve helps explain the need to integrate early stage business strategies and link product management, promotional strategy (to the various groups in the diffusion curve), and reimbursement strategy for a new medical device. The clinician inventor must understand the elements that will drive adoption of their innovation among the target audience. Within corporate organizations, one of the most popular methods for moving new products from idea to marketplace is the concept of a stage-gate model (Figure 4), popularized by Cooper, Edgett and Kleinschmidt (1998).

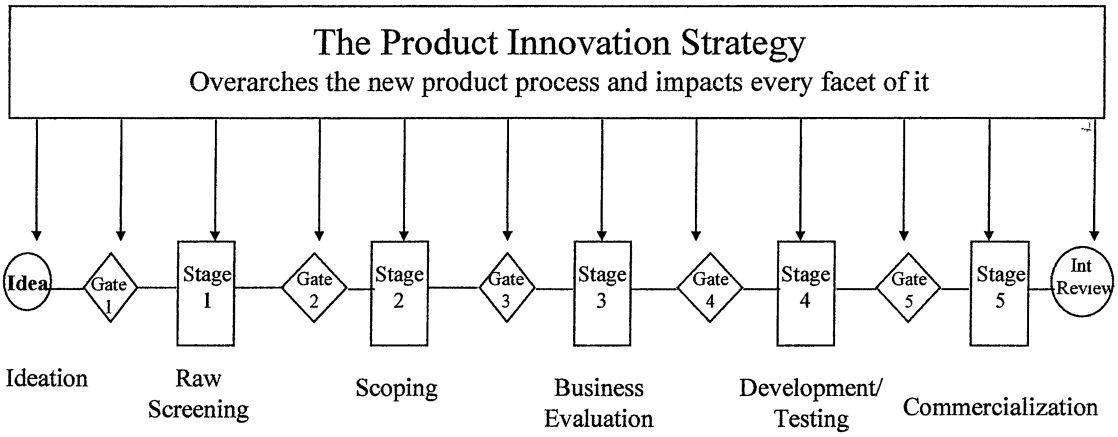

Figure 4. Coopers' stage-gate model. Adapted from "Portfolio Management of New Products," by R. Cooper, S. Edgett and E. Kleinschmidt, 1998, p. 288, Reading, MA: Addison-Wesley.

This model suggested a systematic approach where ideas progress through a series of stages (where work is performed) and through gates, where key decisions are made to either go forward with or stop a project. There are other models which examine the journey from idea to market that are similar, such as the high-tech product model offered by Boer (1999), which also divides the process into key stages. While Cooper's model is focused on how new products move through a pipeline inside a corporation,

Boer's approach was developed from the point of view of a researcher in an R&D setting, yet their steps are almost a mirror image. The main difference of note between the two models is Boer's emphasis on the conceptual project stage. This stage begins with a researcher (rather than ideation or customer research) who needs to justify spending time and resource on a project idea. He proposes three questions that have a research perspective that the proposer of a project should answer:

1. What is its technical advantage?
2. Is patent coverage likely and will it be broad?
3. Could the technology become a platform for other initiatives? (Boer, 1999, p. 28)

Just as Cooper and Boer saw the path to commercialization as a series of strategic decisions, likewise, clinician inventors, like corporations, should think of their journey as a series of key decision points. Decisions such as moving forward or killing a project, partnering or not partnering with an existing medical device firm, forming a start-up team and forming a company are some key decisions that must be made.

The odds of making this journey from idea to market are long indeed. Stevens and Burley (1997) claimed that it takes 3,000 ideas to produce one commercial success. Many specific challenges, hurdles and problems occur in bringing a medical device to market. These include, but are not limited to money to fund the development process (Smith & Smith, 2000), federal regulations, difficulty in obtaining product adoption (Denis, Hebert, Langley, Lozeau, & Trottier, 2002), rapid product obsolescence (Myers & Burchill, 2002) and reliance on reimbursement systems (Gelijns & Dawkins, 1994).

Other challenges identified included the need to establish proof of clinical safety and efficacy via pre-clinical and clinical studies, the start-up firms' geographic location relative to required resources (Deeds, DeCarolis & Coombs, 1999), pressure to lower health costs (Garber, Ridgely, Taylor, & Meili, 2000), resistance to change in clinical practice (West, Barron, Dowsett & Newton, 1999), pressure on personal and/or family time (Nesheim, 2000), the processes of patenting and protecting your idea (Armon, 2002; Hosteny, 1997; Pressman, 2001; Stix, 2002), and prototype development, to name a few. When relating this list back to the earlier list of challenges from the AdvaMed report ("Advanced Medical Technology Association," 2004), there was overlap on several factors but more emphasis on regulatory and financial challenges. The broader search, which used multiple sources, uncovered more factors relating to product adoption and other marketing factors. Combining these two lists creates a fairly comprehensive list of challenges and barriers to consider in attempting to develop and commercialize a new medical device.

In addition to the myriad of issues touched on above, another key aspect of the commercialization of new medical technologies discussed in the literature is the pathway to market. The huge choice that the clinician inventor must make involves examining questions such as: "Do I go it alone and start my own business or do I form an alliance with an existing medical device firm capable of manufacturing and marketing my device?" Successful clinician inventors such as Levine and Wardlaw (as cited in Chesanow, 2001), contended it is impossible to retain a medical practice while developing a medical device, let alone, simultaneously attempting to start a company to launch the new device.

They strongly recommended working with a corporate partner if one expected to stay sane and have a real chance for success. The decision to form a new company is a very serious challenge for the clinician inventor which may necessitate a change in their professional identity. The demands of starting a business and commercializing a new medical device limit the time for clinical practice. One way to address the dilemma is to commit less time to ones practice until one builds a team to take over the key roles needed with the new venture.

The other method is to choose a corporate partner to help with your efforts. Several works (Botkin & Matthews 1992; Harbison & Pekar 1998; Slowinski, Seelig and Hull 1996; Slowinski & Hull 1990) discussed the numerous advantages and disadvantages of forming alliances with corporate partners. It is important for the clinician inventor to understand the pros and cons of alliances for no other reason than to rationally evaluate the huge difference in resources required in starting one's own firm versus leveraging an alliance. The issue of leveraging resources is an excellent lead-in to discussing one of the major resource constraints faced by most start-ups (including clinician inventors) which is the funding of the venture (Bhide et al. 1999; Meyers, 1999). Throughout the journey to market, the funding requirements for the venture will vary in intensity and the source of funding will often change (Jolly, 1997). The need for external funding brought up the additional issue of valuation (Boer, 1999; Razgaitis, 1999), which is critical if equity-based financing is sought.

In overall summary, the literature search revealed a myriad of important considerations and issues for the aspiring clinical inventor. Clinician inventors face difficult decisions if and when they choose to form a company around their invention.

In addition to the usual entrepreneurial challenges of forming a team, developing a product and raising capital, clinician inventors must also make very difficult personal choices. Not least among these is whether to continue their clinical practice or devote full time to their invention and/or venture. Front-line clinicians are often the ones who see a problem and/or clinical need and envision a solution. Their ability to invent and develop new medical devices as illustrated in many of the examples discussed in this chapter is an important source of healthcare related innovation. The overall research methods, research design, and procedures are described next in detail in Chapter III.

CHAPTER III

RESEARCH METHOD, DESIGN AND PROCEDURES

Introduction

The major method used for this study was quantitative using a small sample. This included multiple methods including email surveys, a separate technique of personal interviews with a small non-random sample, and a detailed literature review. The sample used was a convenience sample supplemented with the snowballing method to identify additional participants and increase the overall sample size. A larger sample and use of random sampling methods would have been preferable. This option was not practical due to the difficulty in identifying clinical inventors and lack of a database and/or list from which to select a random sample to survey.

Research Design

This section summarizes the research methods used to complete this thesis. The main methods used included a literature review and a primary research survey. The primary research survey was designed to address several of the research questions described in the research objectives in Chapter One. Since this study was exploratory in nature, a primary research survey was utilized along with open-ended questions to elicit responses. Although a few personal and phone interviews were conducted, the vast

majority of responses were gathered from the use of email for both dissemination and return of survey questionnaires. This was an important design consideration since the sample group was hard to reach and geographically dispersed. The literature search was an important starting point which identified problems, challenges, success factors and key steps in the medical device development process. The literature search also served as the basis to develop a draft model of the clinician invention process. This model and the process for its development is described more fully later in this chapter and detailed in chapter 4.

Literature Review

The literature review consisted of an online search and examination of articles and books collected over the last three years. Appendix A shows 20 topic areas that are divided into six major groups. The key words in Appendix B were used to search online search engines including Google, Alta Vista and Hotbot. Numerous databases contained in the online libraries of Texas State University and the University of Texas at San Antonio were also searched using the same keyword list.

Model Development

The clinician invention model which is fully described in Chapter 4, was assembled in draft form based on the completed literature review. The draft model was based on Coopers' (1993) stage-gate model and the three-dimensional service blueprinting model developed by Kingman-Brundage (1990) who was the early pioneer of this methodology. The stage-gate model used by Cooper to describe the new product development process served as a useful starting point for a medical device development process.

Other dimensions utilized in the draft model included key decisions and key steps. These added dimensions were inspired by Brundage who used multiple dimensions to map service processes. The primary research survey results were used to add to the draft model built from the literature review.

Primary Research Survey and Sampling Method

The primary research survey was conducted using a combination of email surveys and personal interviews. These separate techniques were utilized to accomplish separate objectives. The personal interviews allowed for a pretest of the survey questions and feedback from respondents on whether the questions were clearly worded. The remainder of respondents participated by email which facilitated documentation of answers in the respondents own words. In addition, email responses allowed for participants to be geographically dispersed. Out of 125 surveys, only 5 were completed by personal interviews. The return sample breakout included medical device industry experts (49), process experts (26), clinician inventors (43), and clinicians who were not inventors (7). These total survey respondents comprised 50 respondents in the clinician group and 75 in the industry group. The sampling method used for the survey included a combination of judgment sampling and convenience sampling with snowballing.

The judgment sample was chosen based on judgment of the researcher and was meant to match the characteristics of the population under study. This method is subject to bias interjected by the researcher (Davis, 2000). The sample was also a sample of convenience which is chosen because the group is easy to find and usually inexpensive to obtain (Veney & Kaluzny, 1998). This advantage of being easy to find and inexpensive was the primary research reason for choosing a convenience sample along with the lack

of an available random sample. The last question on the survey form asked for referrals from the respondent, which is known as the snowballing technique. The sampling process began with the judgment and convenience sampling combination. The implementation of these methods is explained in the procedures section in the data collection discussion.

Procedures

The procedures section discussed the study participants, confidentiality, reduction of bias, instruments, data collection procedures, data analysis, and potential outcomes and application. These procedures were written in sufficient detail to allow another researcher to replicate this study. Chapter five includes discussion of ways these procedures can improved if similar methods are used by future researchers.

Participants

The four participant groups included medical device industry experts, process expert's clinician inventors, and clinicians who were not inventors. The study results in Chapter four detail the participant breakdown by each of the four target groups. The target was to complete at least 100 surveys although the final completed sample included 125 surveys. All subjects who completed surveys remained confidential and were only viewed by the author of this thesis. One respondent gave permission for a related list he created to be published and include attribution to him as an author. Whenever survey participants offered other names as potential survey participants, they decided whether or not to participate and their participation was also kept confidential.

Confidentiality

In all cases, the anonymity of respondents was maintained as was their privacy. Where it made sense to quote someone from the personal interviews, permission was

obtained from the individual being quoted and/or referenced. The protection of survey respondents is the ethical responsibility of the researcher and this trust was and will continue to be strictly upheld in this research. All references to the sample and results were done in a summary fashion that did not reveal the identity of any respondent.

Reduction of Bias

In order to reduce any bias introduced by the researcher in the survey process most of the surveys were completed by email. For those few personal interviews that were conducted, the researcher purposely read only the first ten surveys to test the survey instrument and only read the others once the surveys were nearly complete. In this way, the researcher avoided having knowledge of survey patterns while data was still being collected. Toward the end of the data collection, this could not be avoided since the researcher needed to start tabulating the results. However, no personal interviews were done at the end of the study; only email surveys were collected. This eliminated potential researcher bias from performing survey tabulation after survey patterns were known to the researcher. Survey questions were open-ended which allowed respondents to answer freely while reducing bias created by categorical response questions and/or interviewer bias associated with leading questions.

Instruments

The survey instrument is shown in Appendix C. The survey consisted of three main parts: an introduction, questions, and a sample classification. The instrument was designed as an exploratory research survey and contains all open-ended questions. Although this type of survey is very difficult and time consuming to summarize, it was the best way to obtain open, unrestricted input on the study topic. The first ten or so

surveys were considered as a pre-test and, if needed, were to be used to modify the survey questionnaire. Based on a quick review of the initial responses, it was determined that the survey was clear and was achieving the desired results. A personal thank you note was sent to all survey respondents and they were informed that they would receive an electronic copy of this thesis after completion.

Other questions from the survey included questions five, six and seven which are discussed in this section. Question five was a "catch-all" question aimed at identifying any additional insight the respondents have to help clinician inventors. Many of the comments to this question reinforced previous responses to questions one through four on the questionnaire. Many of the respondents wrote lengthy paragraphs in this section, so results were tabulated and combined when the same response was being provided by more than one respondent. Question seven asked respondents for referrals who could possibly complete the survey. Forty percent of the sample respondents provided referrals. Many respondents actually provided multiple referrals. As soon as a referral was received, an email was sent to the person to let them know in the introductory email how their name was retrieved.

The reliability of the survey instrument to produce consistent measurement was done in the pretest initially and then verified in the review of surveys as they were received and processed by the researcher. Since open-ended questions were used, it was apparent to the researcher that respondents were consistently answering questions in a way that indicated the questions were clear and unambiguous. Further testing of and quantification of the survey would be needed to establish validity. Without use of a random sample and a larger sample, validity remains an open issue.

Data Collection

The first step consisted of developing a personal contact list of physicians, nurses, physical therapists, process experts with medical device experience, and medical device professionals. This group was then contacted by email and asked to complete a survey. All respondents who completed a survey and responded to question seven provided a referral that could potentially complete a survey. This group who then responded following a referral by another respondent was considered part of the snowball sample. The second procedure after the initial judgment sample used internet search engines including Google, Alta Vista and Hotbot using key words from Appendix B to find additional prospects. In addition, physicians listed on Switchboard.com, which is a national compilation of yellow page listings, were also used to generate sample lists. All of the sampling methods used (judgment, convenience, and snowball) were considered nonprobability samples and do not use any chance or random selection process. These techniques are accepted in exploratory research and descriptive research (Berkowitz, Pol, and Thomas 1997; Davis 2000) as was done in this study.

The third step included sending reminder notices at 3 weeks and again at 6 weeks to nonrespondents. Toward the final cut-off in February, a final notice was sent to all nonrespondents. The first survey was completed on October 9, 2006 and the final survey on March 3, 2007. During the data collection period, the researcher received several requests to verify identity and status as a student. All survey communication used for reminders and any interaction with respondents is shown in Appendix D.

The thesis committee chairman was kind enough to respond to these inquiries and let the respondents know that I was a legitimate student conducting a real survey.

Many surveys were kicked back due to bad email addresses. Some sample participants responded that they did not have time to complete the survey and most simply never responded at all. Another common response was "I do not fit your sample" to which the researcher prepared a standard response explaining each of the three sample groups and where they fit into the sample. This reply often resulted in a positive response and a completed survey.

Data Analysis

The survey instrument utilized open-ended questions which were categorized using expost facto coding of responses and trends. Responses that were judged to be similar were combined in the response counts in the tables reported in Chapter IV. Where no similar response was found, the response was tabulated and included in the master list contained in the study Appendices E, F and G.

Potential Outcome and Application

The expected outcomes of this study included creation of a process map for moving from an idea for a medical device to market, identification of key success factors and challenges in this process, and building an understanding of the key decision points encountered in the process. The chief application was to provide a roadmap and guidelines for clinician inventors who have an intention of launching a new medical device but lack experience in the process. The hope was that this roadmap would both increase the number of inventions developed by clinicians and reduce the number of failed commercialization efforts.

CHAPTER IV

RESULTS

Evaluation and Interpretation of the Data

Evaluation and interpretation of data were restricted to be consistent with evaluation of qualitative data, which must be considered with strong caveats about extrapolation to a wider population. With strong caveats as to the application of the data, evaluation and interpretation included four main areas: 1) a comparison of results within two main sample groups of medical device professionals and clinicians, 2) a means to critique and modify the original process model, 3) a comparison of the survey results with findings in the current literature; and 4) a means to recommend areas of further research on this subject. The survey results are discussed with these four areas of evaluation and interpretation in mind. Each of the research questions discussed in Chapter One is also addressed with its own section heading.

Discussion of Survey Results

The survey conducted among medical device industry experts and clinicians resulted in 125 completed interviews. Figure 5 shows the breakdown of completed surveys into the four groups included in the sample.

These were medical device industry experts (49), process experts (26), clinician inventors (43), and clinicians who were not inventors (7).

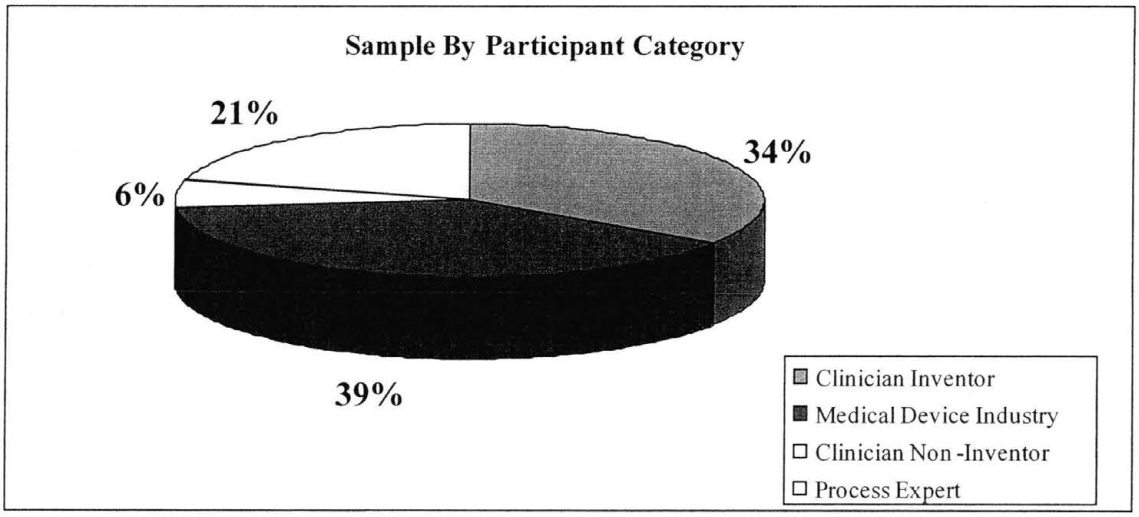

Figure 5: Primary research survey – sample by participant category.

This yielded a total of 50 respondents in the clinician group and 75 in the industry group. Since the clinician non-inventors are a very small sample of only 7 respondents, the results are discussed separately. The main comparisons are drawn between the clinician inventors (43) and the aggregate industry group which includes both the medical device personnel and process experts (75). Figure 6 shows the breakout of survey returns for the industry group and the clinician inventor group. The goal was to have samples of the two groups of fairly equal size, but slightly more responded in the industry group.

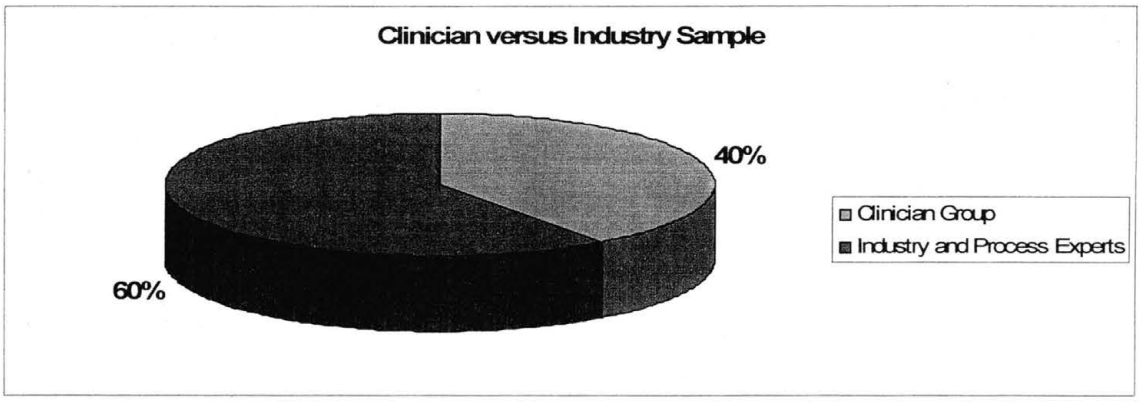

Figure 6. Primary research survey – sample returns by group.

Before discussing the survey results, several other characteristics of the sample are noteworthy and deserve consideration shown in Figure 7. The three main judgment and convenience sampling methods included personal contacts (26), databases (14), and the internet (63) combining to form 82% of the total completed sample. Personal contacts were persons known to the researcher including both clinicians and industry experts. Respondents from database sources were found using articles published in the Texas State University library databases. Persons who published articles that indicated they were medical device inventors and/or were knowledgeable about the medical device development process were targeted. The internet group was identified in a similar fashion as was the database group. They were targeted if they published articles that indicated they were medical device inventors and/or were knowledgeable about the medical device development process.

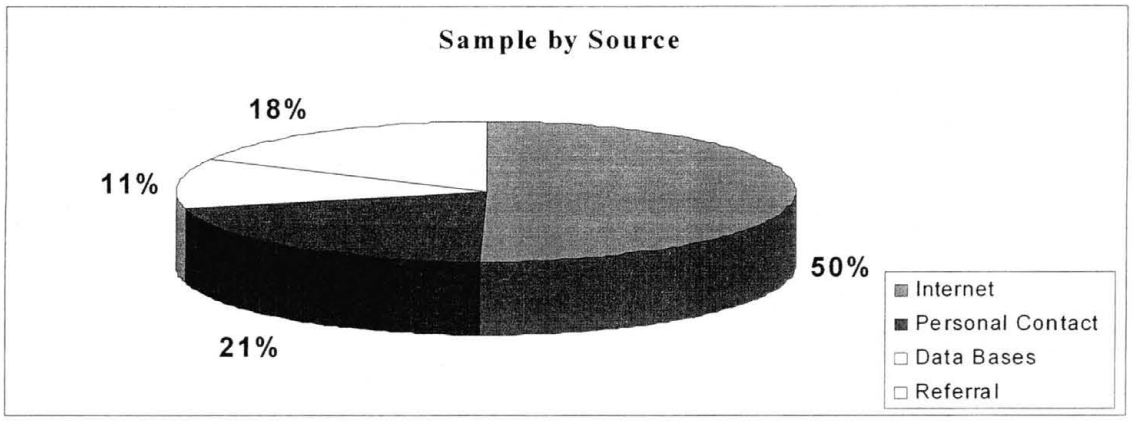

Figure 7. Primary research survey – sample by source of respondent.

Referrals (using the snowballing technique) yielded 22 surveys or 18% of the total completed sample. Figure 8 shows the breakdown of referrals. When respondents provided a referral name they responded 40% of the time. Considering that about 10% of the overall sample responded, the referral group responded at 4 times the rate of the regular sample. This vastly higher response rate from respondents who were referred by other respondents illustrates the value of the snowballing sampling technique.

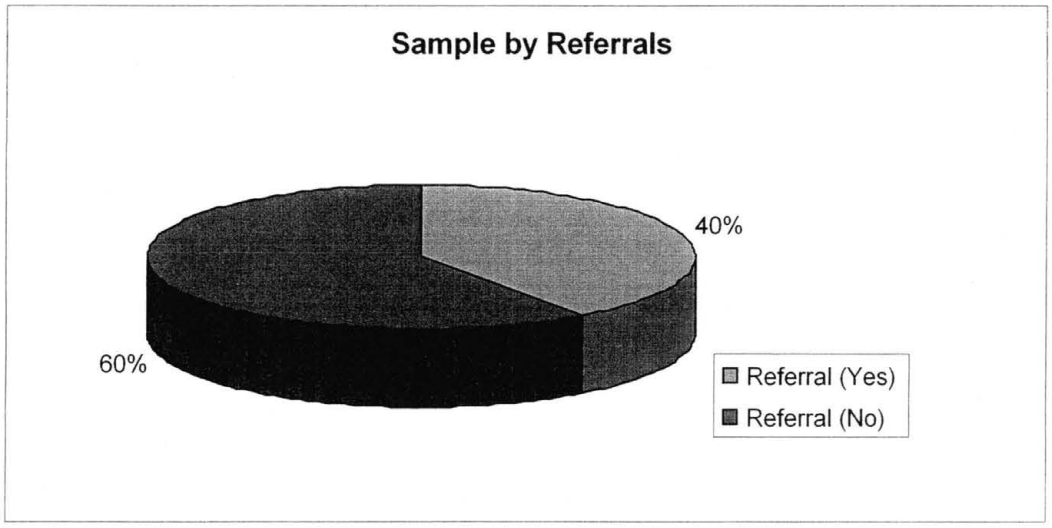

Figure 8. Primary research survey – respondent referral breakdown.

The backgrounds and specialties of the medical device industry professionals included, but was not limited to, company CEOs, vice presidents of R&D, business development and medical services, engineers, clinical and regulatory experts, and marketing and information technologists. The process experts included consultants, academicians, intellectual property experts, creativity experts (who facilitate ideation sessions and help design new products), market researchers, venture capitalists, physicians, medical journalists, a science ethics researcher, and others. The clinician group (inventors and non-inventors) included physicians with specialties and backgrounds in internal medicine, orthopedics, otolaryngology, ophthalmology, vitreoretinal surgery, emergency medicine, cardiovascular surgery, and neurosurgery and urology, among others. In addition, the clinician group included physical therapists, radiologists, and nurses with an assortment of backgrounds. Many of the medical device experts and clinicians had multiple levels of training such as lawyers with medical degrees, nurses with PhD's, and physicians with degrees in business and/or PhD's. Responses for the medical device and process experts were compared and contrasted with the clinician inventors for each question. The non-inventor clinician group will be discussed separately.

Research Question One – Critical Success Factors

Question 1 was: "What are the critical success factors of medical device commercialization?" The first question on the survey examines the critical success factors of the clinician invention process. The medical device and process experts identified a total of 43 critical success factors. Even though there was a smaller sample of clinician inventors (43) compared to 75 for the medical device and process expert sample,

they identified nearly as many critical success factors (37). Table 4 shows a summary of the critical success factors by group.

Table 3.

Critical Success Factors

Medical Device Industry Group	Clinician Group
Top Five Factors – High Importance	
1. Idea that meets unmet need (32)	1. Idea that meets unmet need (17)
2. Intellectual property protection (21)	2. Funding (14)
3. Clinical proof of safety and efficacy (18)	3. Management and support team (8)
4. Funding (13)	4. Drive and determination (8)
5. Sufficient market size (13)	5. External industry partner (7)
Next Three Factors - Medium Importance	
1. Superior product (11)	1. Sufficient market size (6)
2. Management and support team (11)	2. Superior product (6)
3. External industry partner (10)	3. Knowledge of development process (6)

Note. Numbers in parenthesis represent the number of survey respondents who gave that answer.

It is noteworthy that both the industry group and clinician group recognized a similar set of factors as being keys to successful medical device invention. The key differences included a lack of inclusion of intellectual property as a factor among the clinician group and a lack of drive and determination as a factor among the industry group. Another factor included by clinicians and not the industry group was knowledge of the development process, which may have been taken for granted among the industry group. One other factor that was mentioned by the industry group was clinical proof of safety and efficacy, but was omitted from the clinician group list. The top factor of having an idea that addresses an unmet clinical need was common to both groups.

The rest of the top five factors for the medical device and process expert group included, in order of highest ranking: intellectual property position, clinical proof of safety and efficacy, funding and adequate market size. The rest of the top five for the

clinician list also includes funding, but the other three factors are different. The top five factors included the management and support team, having drive and determination, and finding an industry partner.

In the next tier down, the three most frequently mentioned factors for the medical device and process experts included having a solid management and support team, finding an industry partner and having a superior product. The clinician groups' next tier factors also included having a superior product, adequate market size, and an understanding of the development process.

When the overall top eight critical success factors were considered, there were only a few differences. The clinician group did not include clinical proof of safety and efficacy in its top five factors, while it is one of the top five factors for the medical device and process expert sample. It is surprising that both groups rated market size fairly low. Most literature and popular thinking on new product success recognized the importance of having a large enough market size to make the opportunity an attractive one for investment and pursuit by a major firm.

Two of the factors in the clinician group do not appear in the top eight medical device and process expert group ratings. They are drive/determination and an understanding of the development process. It is interesting that the clinician group chose a personal factor (drive and determination) in its top five. The corporate environment tends to provide a safety net and more secure environment than is afforded entrepreneurs who are usually required to take on personal risk. That said, it seems the clinician inventors recognized that drive and determination is just one of many critical factors for success. It is somewhat amazing that an open-ended question would produce so similar a

list between the clinician inventors and medical device industry/process experts groups. One explanation is that these basic factors are truly critical and well-documented such that both industry experts and clinician inventors, although coming from diverse viewpoints, understand and perceive a similar set of critical success factors.

Research Question Two – Major Process Steps

Question 2 was: "What are the key process steps along the way from idea to commercialization?" Question two asked respondents to identify what they envisioned as the major steps in the invention process. The summary responses identifying the major process steps from the point of view of both the clinician and industry groups are depicted in Table 4.

Table 4.
Major Process Steps

Industry	**Clinician**
Top Seven Steps - High Importance	
1. Patent protection (38)	1. Patent protection (23)
2. Clinical testing (36)	2. Identify unmet need (20)
3. Specifications and prototype (28)	3. Specifications andprototype (15)
4. Funding (26)	4. Funding (13)
5. Alternative solutions and design (21)	5. Alternative solutions and design (13)
6. Identify unmet need (19)	6. Industry partner (12)
7. Proof of principle (19)	7. Build team, commercialization and product testing (11) Tie
Next Three Steps- Medium Importance	
1. Market assessment (18)	1. Clinical trials (10) Tie
2. Product manufacturing (18)	2. Basic science research (10) Tie
3. Industry partner and business plan (14) Tie	3. Proof of principle (5)

Note. Numbers in parenthesis represent the number of survey respondents who gave that answer.

The major process steps between these two groups were all but identical with minor differences in the frequency of being mentioned. Research results indicated that the key process steps identified by both groups were very close to the initial model created by the researcher prior to conducting the surveys. In all, the medical device and process experts identified 34 distinct steps and the clinicians identified 36 distinct steps. Research results indicated that these extremely detailed lists dovetail nicely with 31 sub-steps identified by the researcher in the original model. After reviewing the similarities with this list, just as in the case of the previous list in Table 3, the congruence between the industry and clinician groups is in itself noteworthy. Even though these groups experience the process from different points of view, they recognize the same major steps and much of the same sub-steps.

Medical device and process experts identified patent protection (38), clinical testing (36), specifications and prototype development (28), funding (26), alternative solution and product design (21), unmet market need identification (19), and scientific proof of principle (19) in the top seven process steps. The medical device and process experts were almost a direct overlay to the seven steps outlined in the original process model. The notable exception was the inclusion of funding by the medical device and process expert group and the exclusion of the go-to-market step, which may have been taken for granted. The next four most popular choices were market assessment (18), product manufacturing (18), and a tie for third between finding an industry partner and preparing a business plan (14). The clinician group also had patent protection as number one (23), followed by identifying an unmet market need (20), specifications and prototype development (15), funding (13), alternative solution and product design (13),

finding an industry partner (12), and a three-way tie between building a team, commercialization, and product testing (11).

The next three factors included a tie between clinical trials (10), basic science research (10), and lastly, establishing scientific proof of principle (5). Scientific proof of principle can be a very difficult part of the process and bears further definition. This step most often involves building a functional prototype to show the device works as intended. One of the better definitions found was offered by the Design Council (Powell, 2008): Proof of principle prototype – (POP) - "Prototype to prove out functional innovations, often in isolation. POP models or prototypes rarely replicate the final product appearance," (p.2).

Research Question Three – Major Barriers and Challenges

Question 3 was: "What are the major barriers and roadblocks to successful commercialization?" Question three asked respondents to identify the major barriers and challenges to successfully completing the process. The summary responses identifying the major barriers and challenges to successful commercialization from the point of view of both the clinician and industry groups are depicted in Table 5.

Table 5.

Major Barriers and Challenges

Industry	Clinicians
1. Lack of funding (25)	1. Lack of funding (24)
2. Lack of knowledge (22)	2. Lack of knowledge (17)
3. Lack of time (16)	3. Regulatory/FDA (8)
4. Regulatory/FDA (14)	4. Lack of time (7)
5. Ego and unrealistic expectations (13)	5. Attracting the team (5)
6. Attracting the team (10)	6. Competition (5)
7. Blind spots not being objective (10)	7. Convincing clinicians to change practice patterns (4)
8. Not recognizing when you need help (9)	8. Establishing clear intellectual property ownership (4)
9. Confirming clinical need and market potential (7)	9. Lack of belief in invention and lack of patience (3)
10. Finding an industry partner (7)	10. Unwillingness to share (3)

Note. Numbers in parenthesis represent the number of survey respondents who gave that answer.

These two lists were remarkably similar in their focus and frequency of mention. Both lists included several personal factors such as ego and unrealistic expectations and unwillingness to share. Overall, the medical device and process experts identified 39 different barriers and challenges and the clinician group identified 32. The medical device and process experts identified lack of funding as the most frequently identified barrier and challenge. The next group of barriers and challenges included: lack of knowledge (22), lack of time (16), regulatory and FDA issues (14), ego problems, and unrealistic expectations rounding out the top five most frequently mentioned items. The most frequently mentioned items included: attracting a team (10), having blind spots and being objective (10), not recognizing when you need help (9), confirming clinical need and market potential (7), and finding an industry partner (7) rounding out the top ten items. The clinician group also had lack of funding (24) as their top item, followed by

lack of knowledge (17), regulatory and FDA issues (8), lack of time (5), attracting a team (5), and competition (5) as their top items. Rounding out the clinicians group top ten were convincing clinician to change practice patterns (4), establishing clear intellectual property ownership (4), lack of belief in the invention and a lack of patience (3), and unwillingness to share a piece of the pie (3).

Research Question Four – Major Decisions

Question 4 was: "What are the critical decision points along the way from idea to commercialization?" Question four asked respondents to identify the most important decisions made as one progressed through the process. The summary responses identifying the key decisions inventors must make on the way to commercialization from the point of view of both the clinician and industry groups are depicted in Table 6.

Table 6.

Major Decisions

Industry	Clinician
Top Five Decisions – High Importance	
1. Product go/kill decision (22)	1. Team Selection (9)
2. Team selection (17)	2. Product go/kill decision (8)
3. Selecting funding sources and partners (17)	3. Selectior of best product alternative (7)
4. License deal or start a company (13)	4. Selecting funding sources and partners (7)
5. Determine FDA pathway (9)	5. Patent yes or no (6)
Next Three Decisions -	Medium Importance
1. Selection of best product altrnative (8)	1. When and where to seek help (5)
2. Patent yes or no (6)	2. Determine risk level (4)
3. Clinical practice or entrepreneur (6)	3. License deal or start a company (4)

Note. Numbers in parenthesis represent the number of survey respondents who gave that answer.

These two lists were also strikingly similar. It is interesting to note that the clinician group did not see the FDA path to clearance as a major decision. With that

minimal distinction, the lists are almost a mirror image with minor differences in the frequency of selection rankings. Among the medical device and process experts, the most frequently identified decision was the go/kill product decision. Rounding out the top five factors were team selection (17), selecting funding sources and partners (17), deciding whether to start your own company or license your product to a major firm (13), and selecting the right path to secure FDA clearance (9). The next most frequently mentioned decisions were: selecting of the best product alternative (8), deciding whether or not to seek a patent (6), and choosing between being a full-time physician or becoming an entrepreneur. The clinician groups' most frequently chosen decision was the selection of the team (9), followed in the top five by the product go/kill decision (8), selection of the best product alternative (7), selecting funding sources and partners (7), and deciding whether or not to seek a patent. The three next most frequently mentioned decisions were deciding when and where to seek help (5), deciding how much risk to take (4), and deciding whether to start your own company or license your product to a major firm (4).

Research Question Five – Other Survey Value

Question 5 was: "What else can be learned of value concerning the commercialization process from surveying the target population?" Research questions 5 and 6 on the primary research survey were summarized and used to answer research question 5. The medical device and process experts produced a total of 44 different responses. The most frequently mentioned advice was to foster contacts among major device companies and try to get a large company on board to help. Another frequently mentioned piece of advice was to get input on the idea from others and make sure one understands ones employment agreement which could impact the intellectual property

ownership. Other suggestions point out the need for stamina and determination, the need to be passionate about the idea and firmly committed, and finally, the need to recruit a very good team to help with the development of the idea.

The clinician group produced a total of 37 fairly unique thoughts. The most frequently mentioned advice to this question was to persevere and have patience when moving ideas forward. Other thoughts included:

1. Build a great team of experienced people to help with the idea
2. Expect a bumpy and hard road
3. Have confidence in your idea
4. Be willing to accept risks
5. Have adequate capital

The responses to question five seemed to be very closely related between the medical device and process experts and the clinicians. There were many other good suggestions compiled from the question which are contained in the appendices. Question six asked respondents to list other reference sources that could be useful in the research. The complete list of recommended reference sources is in Appendices A, B and C in response to survey Question 6. The medical device and process experts came up with 41 references. The non-inventor group contained only seven respondents. This group was included to provide some insights into how non-inventors view the invention process. This small sample, which was more like a focus group, seemed to mirror responses from the rest of the sample. Research results indicated that not having gone through the invention process did not prevent this group from having well thought out opinions on the subject. This could have been a built in bias to the survey since participants were

voluntary and most likely interested in the subject matter and consequently were, in general, more informed than the average clinician on the invention process.

Research Question Six – Process Model and Other Learning's

Question 6 was: "What can be learned from the literature to provide a clearer understanding of the clinician invention process model and other factors impacting successful commercialization?" This section applies information gathered in the literature search with emphasis on the clinician invention process and other factors that impact the successful commercialization by early stage clinician inventors. The process map derived from the overall literature review is discussed next. The process depicted in Figure 9 is a high level view of the clinician invention process map. The process map has three key components. First are the major steps of the process, which are captured in the six boxes in Figure 9. These major steps are the key activities that must occur as the inventor moves from an idea to the marketplace. Below each of these boxes is a list of key sub-steps that need to occur to complete the major milestone steps. Between each of these major steps are decision points depicted by the diamond shapes that identify the major decisions and outcomes that the inventor must make or achieve before moving to the next major step in the process.

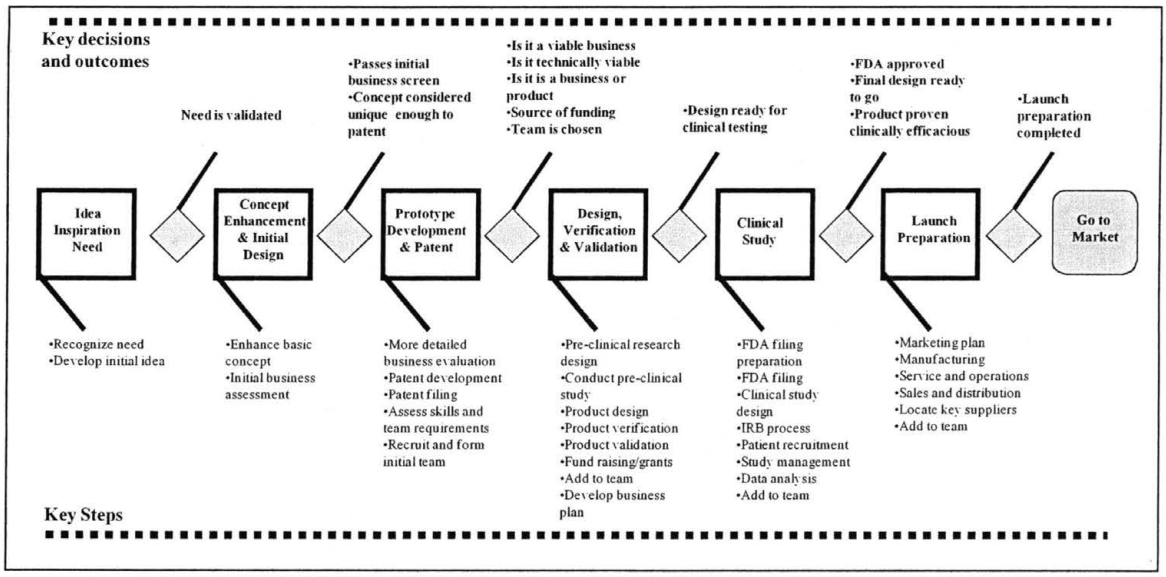

Figure 9. Clinician invention model – original model.

It is important to note that reliability and validity have not been established for this model. Future research and testing will be required to establish reliability and validity. The following is a brief description of the major steps and major decisions in this process. Later in Chapter V a revised model will be discussed that explains how this original model was modified based on the results of the survey of industry experts and clinician inventors.

Step 1: Idea, inspiration, and need recognition.

In the initial stage of the process the inventor has recognized a need in the marketplace for a brand new solution or significantly improved method to meet the identified need. Improvements can come in many forms: better outcomes, lower costs, ease of use, improved patient compliance or comfort, and any other type of improvement. At this stage, it is important to understand the factors that influence acceptance of the product by physicians and other healthcare providers that eventually drive adoption of the

technology when it is introduced in the marketplace (Gelijns & Dawkins, 1994; Ekelman, 1988).

Step 2: Concept enhancement and initial design.

At this stage, the inventor refines the initial idea and begins to think about how the product would take physical shape. This is an iterative process where continued brainstorming and experimentation lead to concept refinements. Input from other team members can be very important at this stage as a means of improving the overall concept.

Step 3: Prototype development and patent.

Step three has two vital components: the creation of a working product prototype and the initiation of the patenting process. This process usually involves advice and/or direct recruitment of team members who can do the engineering work to create a prototype, prepare patent filings, and begin the business planning process. This stage also represents the first major investments (in prototype development and legal fees for patent preparation) that the inventor must make. These investments reinforce the need to begin evaluation of the feasibility of the business side of the product and address the question of whether it can potentially be a profitable product and/or business. Many good checklists are available to help address business feasibility (Meyer, 1999; McGrath, & MacMillan, 2000) and can help the inventor sort through this vital question.

Step 4: Design, verification, and validation.

This stage involves the full product development process, including meeting the stringent FDA requirements for medical device development (Teixeira & Bradley, 2003). The design process at this stage usually involves pre-clinical research and must address safety issues prior to use in humans. With rare exception (such as a kit that contains all

pre-approved items), medical devices require one of three levels of approval. The FDA ("U.S. Department of Health," 1999) has 1,700 classified devices that fit into one of three classes of approval. Of the 1,700 devices classified by the FDA, there are 45% in class I, 47% in class II, and 8% in class III. There are so few exceptions to regulatory scrutiny that a separate model without the FDA process considered is not worth serious consideration. It is more important for the medical device inventors to be aware of which class of review their product may fall into and understand the specific requirements of that review process.

In addition to these important steps, the inventor continues to face decisions on who to add to the team and where to get funding. Each step toward market commercialization usually leads towards increasing needs for raising capital to fund the venture (Nesheim, 2000). If capital were exchanged for ownership, then the key issue of valuation would have to be addressed (Boer, 1999; Razgaitis, 1999). The financing of new ventures is a specialized field that requires an appreciation for how such ventures are analyzed, especially from a financial perspective (Smith & Smith, 2000).

Step 5: Clinical study.

Although a full-fledged clinical study may not be required for all medical devices, most medical devices need clinical research to support claims of efficacy and/or of positive outcomes. A clinical study involves a study of human patients (Day, 2002) beyond the preclinical studies using animals. For the most part (Denis, Hebert, Langley, Lozeau & Trottier, 2002) the diffusion of new medical innovations demands hard evidence to convince even the innovators and early adopters to try a new device and/or change their practice of medicine.

Step 6: Launch preparation.

This is the final stage before entering the market and includes a massive amount of preparation especially for a start-up firm. Key tasks include setting up manufacturing, sales and service, distribution, marketing, and overall operations.

Adjustments to the Original Model

After reviewing the survey results, multiple revisions were made to the original model. These revisions were prompted and driven by the survey responses based on the 125 completed surveys. Figure 9 illustrates the changes and revisions made to the original model.

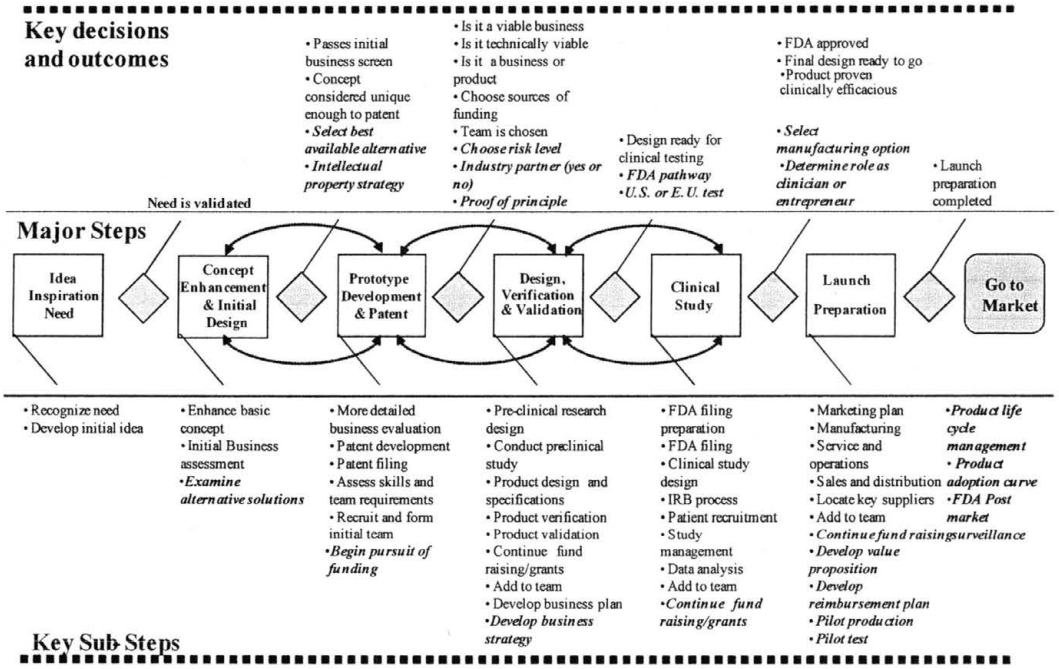

Figure 10. Revised – Clinician Invention Process Model. Changes from the original model are shown in bold italics.

The revisions (shown in bold/italics) included:

1. Adding scientific proof of principle to step four of the model which currently includes design verification and validation. This was a frequently mentioned major step for both the medical and process experts group and the clinician group.

2. Adding an illustration to the model diagram that steps two through five should be more iterative in nature. The survey respondents stressed the importance of flexibility and iterative innovation when moving the idea from concept to market.

3. Adding more detail to the sub steps already shown in the model. The 34 process steps identified by the medical device and process experts and the 36 steps identified by the clinician group provided a rich source of information to enhance the process sub-step list.

4. Adding "mini-milestones" in between each major process step to show additional decisions in between major steps. The researcher first encountered the term "mini-milestone" at a new product development benchmarking session in the 1990's. It was used in the context of having a series of smaller manageable milestones in the product development process. An article by an IBM employee (Perks, 2003) describes these milestones as "smaller versions of milestones. Major milestones are the end of a phase or increment. To achieve that point, a project needs mini-milestones along the way," (p.2). Rather than show a series of sub steps as milestones the researcher chose to show the additional decisions that are made between each major step in the process. These decisions are based on the twenty-three decisions identified by the medical device and process expert groups and the twenty-five decisions identified by the clinician group.

5. Adding new labeling to more clearly separate the sub-steps from major steps in the model.

Other changes the researcher considered, but decided not to make, included:

1. Adding funding as a separate step in the process. Funding was listed as a major step by both the medical device and process experts and the clinician group. It is not clear from the survey responses as to whether funding was being recommended as a single distinct step or whether the respondents viewed it as a continuous process. The researcher viewed funding as a continuous process that occurs throughout the overall invention to market process.

2. Create a separate branch in the process for licensing. This was one of the most frequently mentioned decisions and has a great impact on the middle to later stages of the process. This was addressed by adding a major footnote to the model but did not include adding dual tracks with separate layers of detail, which would have overcomplicated the model.

Even though the results discussed in Chapter IV were based on a focused and detailed literature search and a survey of 125 persons, this research was exploratory and preliminary. Much work is yet to be done to establish reliability and validity and application to a broad population of clinician inventors. Chapter 5 addresses ideas for future research on this topic, methodology lessons, synthesis and conclusions related to each of the six key research questions and some final thoughts on the challenges of launching a new medical device.

CHAPTER V

DISCUSSION

In the course of this research, including an extensive literature search and a survey of medical device industry experts and clinicians, several important challenges to successful medical device development were raised. One such challenge was the personal side of becoming an entrepreneur from a clinician's point of view. Clinicians themselves pointed out, in their survey responses, the personal decisions they would have to make when considering the path of entrepreneur inventor. Some of the major concerns were having to decide between their practice and the pursuit of their invention, personal financial risk, impact on the family, and entering a field where they had little knowledge and experience. These personal challenges when added to the already extraordinarily tough road to market for a medical device can create a seemingly insurmountable challenge for the aspiring clinician inventor. One author/consultant, Shukla (2005) provided an excellent set of personal questions for clinician inventors as they consider starting their firm to pursue their idea. Some of these key questions dealt with risk tolerance and others the presence of entrepreneurial characteristics. A sampling of Shukla's questions included:

1. Do you have the drive and stamina?
2. Can you make tough decisions?

3. Do you know your personal financial needs?
4. Can you afford to take the risk?
5. Is your family on board?
6. Can you afford to quit your day job?
7. How long are you willing to work at this?

These questions highlight the very personal journey taken by clinician inventors as they attempt to develop and commercialize a new medical device. With the very personal and challenging nature of the process in mind, this would be one of the potential topic areas for future research on this subject. Based on the results of this research and trends in the healthcare market, four main areas of follow-up and/or expanded research on this topic are recommended. The four areas are:

1. Quantify the major categories uncovered in this study using a formal survey and, where possible, random selection of participants. These categories would include the critical success factors, major barriers/challenges and major decisions. Reliability and validity would need to be established as a key part of this research effort just as the model in this study has not yet established reliability and validity.

2. Another potential study would be to take just one area, such as major barriers and challenges to medical device development, and study the issue in much greater detail. By taking a single issue in more detail, it is more likely potential solutions or useful constructs could be developed and later applied.

3. One of the subjects that clinician inventors raised was the personal side of the invention process. A study focused on the personal side of invention from a clinician's perspective could potentially provide tools to help inventors think through the personal issues.

Methodology Lessons

This research uncovered some relevant lessons for surveying a hard to reach target population using email as a primary method. In addition, lessons were learned about the sampling methods used in the study which included judgment, convenience, and snowballing. The internet search engines, especially Google, provided a ready source of leads and accounted for half of the completed surveys. Some respondents wanted to know how they were identified and readily accepted the internet as an accepted source of contact.

Many of the internet leads ended up being incorrect addresses, some were non-responsive, and some responded by saying "I refuse to participate." Some respondents were harsh saying, "Don't email me again." Even though it is very time consuming to find potential respondents via the internet and the response rate is low (research results showed about a 10% response rate) it is a great source when the target sample is hard to find and even more difficult to get to respond. The researcher found looking for the sample group was most effective when the key words "email address" and "contact information" were combined followed by use of the "search within results" tool on Google.

The ideal hit was a name, indication of a fit with the sample (based on the web site), and an email address. The researcher did not attempt to find internet contacts using phone numbers. In general, the most common internet-based response was no response at all. Another approach used to find potential respondents was online databases like PubMed and Science Direct, which are databases available through the university library.

When potential respondents from these databases were contacted, the title of the

article they had written was cited so they knew the context in which they were being contacted. In addition, all potential respondents were provided with general background information that explained the study. This group responded at a slightly higher rate of about 12% and accounted for 11% of the total sample. This group, based on their responses, seemed to see the connection as to why they were selected in the sample.

The exception was a few respondents that replied that the researcher should make sure to have read their article because they did feel they had the right expertise and did not fit the sample. In many cases with PubMed, it was only possible to obtain an abstract which led to some poor selections. All in all, the internet and database approaches were a great contribution to the research and all the rejection along the way is well worth the effort.

The researcher found that having an initial list of personal contacts as a starting point for building a sample group was very important in finding respondents. Due to experience in the medical field and a particularly tenacious relative who supplied numerous referrals, the researcher was able to start with a solid base of contact that yielded 21% of the overall completed sample. The final respondent group was referrals which came from using the snowballing sampling technique, which was question seven on the survey form. The question read: "Is there anyone else you can recommend that I can possibly interview on this topic?" This group yielded 18% of the overall completed sample. It is important to note that the snowball sampling technique can introduce bias into the survey results.

One such bias could be referrals that could tend to have similar opinions to the respondents that referred them for participation in the survey. Forty percent of all

respondents provided one or more referrals. A key lesson learned here was the need to ask for the email address of the referrals, which is a key to being able to reach them effectively. The researcher was able to contact most of the respondents and request email addresses after the fact, which some provided and some did not. A better design of the survey would be to include a request for the email addresses with the original questionnaire. The researcher only asked for referrals in the questionnaire itself. An increased emphasis on referrals in the introduction would be another recommended change in methodology. Another pattern in the responses was for some respondents to respond with minimal answers, while others provided very in-depth responses. The researcher was very grateful for all responses regardless of length. Given the very busy schedules of the target sample it may not have been possible to encourage more detailed responses.

Another recommended improvement to the process of sending and recording survey responses is to create a tracking database from the very first survey that was sent out. Since multiple reminders were sent, it became very difficult to keep track of the status of each person in the sample. After several hundred surveys were sent, it became very difficult to keep up and know when to send additional reminders and to track bad addresses, refusals, and those who promised to complete a survey at a later date. Use of some sort of sales management software or other database software could potentially solve the follow-up problem by effectively tracking contacts made during the survey process.

Some respondents decided they would rather complete the survey by phone (a total of five) which resulted in being very manageable. The use of phone interviews does

increase the likelihood of creating bias and whenever possible the idea of how easy the questionnaire was to complete by email was reinforced.

Offering potential respondents multiple ways to respond can result in improved response rates. The use of phone surveys can also be made more difficult when the person doing the research is working fulltime. Since several respondents requested additional information on whether the researcher was a legitimate student, any changes that can help reinforce proper student status (such as introduction from your thesis committee chairman) would be helpful and possibly increase response rates. It is also very important to have approval from your respective University's Institutional Review Board and share that approval with respondents who question the credentials of the researcher or purpose of the study. Although minimal problems were experienced with the survey instrument, it is also recommended that an expanded pretest of the survey as a way to work the bugs out of the questionnaire and overall process.

Synthesis and Conclusions of Study's Results and Findings

The study synthesis and conclusions were organized by research question to provide continuity with the overall study. The questions are restated below for ease of reference. Although conclusions were made about the researchers self-designed models and other aspects of what leads to successful development of medical devices, it is important to stress that validity and reliability have yet to be established. Future research in this area should be focused on establishing validity and reliability and these conclusions should be considered as a starting point. The six key research questions included:

1. What are the critical success factors of medical device commercialization?

2. What are the key process steps along the way from idea to commercialization?
3. What are the major barriers and roadblocks to successful commercialization?
4. What the critical decision points along the way from idea to commercialization?
5. What else can be learned of value concerning the commercialization process from surveying the target population?
6. What can be learned from the literature to provide a clearer understanding of the clinician invention process model and other factors impacting successful commercialization?

Each question is addressed in sequential order, followed by a brief set of overall conclusions and some final thoughts. The researcher found that in addressing Question 1, not all critical success factors are created equally and the success factors as shown in Figure 11 can be thought of in two categories: foundational and execution based.

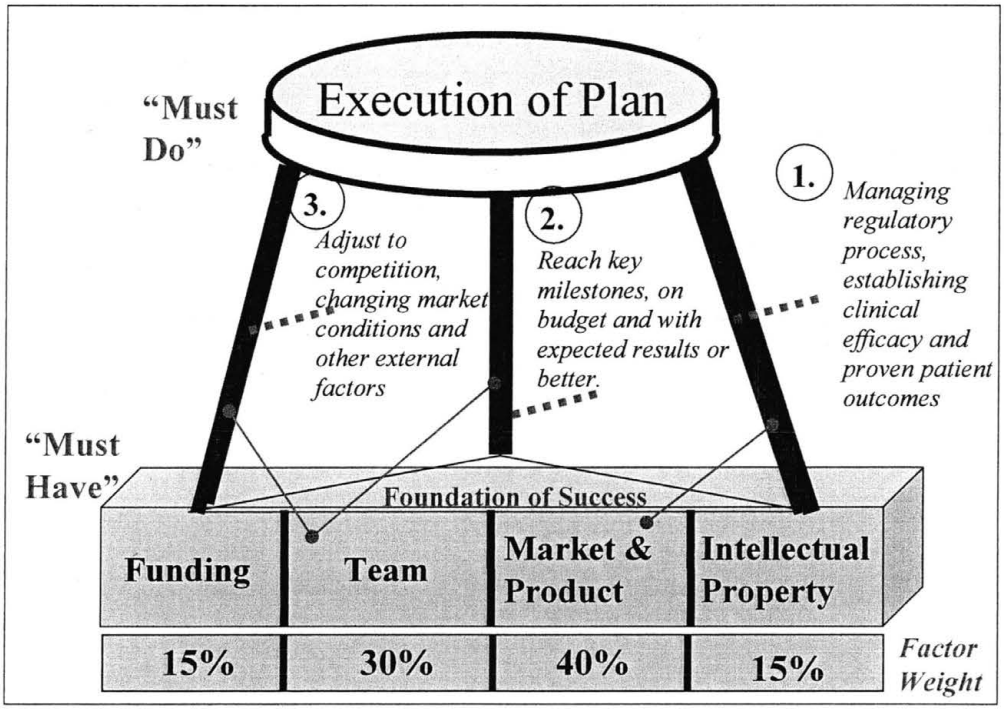

Figure 11. Critical success and execution model.

The foundational or "must have" items including funding, team, market/product and intellectual property are essential to be "in the game." Without these items, the potential to develop and launch a medical device and bring it to market are virtually nonexistent. Two of the items, funding and team, could be addressed by working with an established medical device company that could provide both expertise and investment. If these four foundational items are in place, the focus shifts to execution of the strategic and development game plan.

If the business plan has accounted for external factors and includes well thought-out contingency plans, the odds of successful plan execution can be improved. No plan can be foolproof, but a good plan can reduce the number of surprises and help the entrepreneur better face whatever unfolds. One of the survey respondents, Messenbrink, offers some excellent advice regarding planning a new venture, which is included as an Appendix H in this thesis.

Reaching key milestones on time and on budget requires the management team to be diligent, focused and tenacious. The third item under plan execution involves managing the clinical research and regulatory approval process. This third execution item is a link between the foundational item where the original product and corresponding market were envisioned. Without clinical efficacy and proven patient outcomes, the envisioned market and product will likely not materialize, although there are products with questionable benefits that do well in the marketplace, they are the exception and not the rule. Now considering Question 2, this addressed the major process steps in clinician device development from idea to commercialization and was the major emphasis of the synthesis and conclusions. Discussion is centered on the new modified process model, and comparison with other product development and invention process models shown in Table 7.

Table 7.

Comparison of Product Development and Invention Process Models

Robert Cooper (Stage Gate Model)	Dubois (Nova Biomedical)	Frank Samuel (10 Stages of Innovation)	Product Development Resources (Inventor Steps)	James Bright
1. Ideation	1. Opportunity Assessment	1. Discovery of New Knowledge	1. Build a Prototype	1. Scientific Suggestion and Recognition of Need
2. Preliminary Investigation	2. Concept	2. Awareness of New Knowledge by Researchers	2. Patent Search	2. Proposal of Theory or Design Concept
3. Detailed Investigation	3. Preliminary Engineering	3. Invention of a Product	3. Provisional Patent Filing	3. Laboratory Verification
4. Development	4. Breadboard	4. Patenting of a Product	4. Verify Prototype	4. Laboratory Demonstration
5. Testing and Validation	5. Development Engineering	5. Development of Replicable product	5. Determine Production Costs	5. Full scale or Field Trial
6. Full Production and Market Launch	6. Prototype	6. Clinical Trial for FDA Purposes	6. Determine Profitability	6. Commercial Introduction
	7. Final Engineering	7. Obtain FDA Approval	7. Full Patent Filing	7. Widespread Adoption
	8. Pilot Release/Beta	8. Health Insurance Coverage and Payment	8. Build Final Version of the Product	8. Proliferation
	9. Production and Support	9. FDA Post-marketing Surveillance	9. Prepare Package for Potential Licensees	

Note. Adapted from "Portfolio Management for New Products," by R.G. Cooper, S.J. Edgett, and E.J. Kleinschmidt, 1998, New York, NY: Oxford University Press and "Accelerating speed to market," by J. Dubois, 2003, Medical Product Outsourcing, pp. 38-42 and "Commercializing new technologies," J.R. Bright as cited by V.K. Jolly, 1997, Boston, MA:, Harvard Business School Press, p.16 and "Invention road map," by Unknown author, 2006, Product Development Resource Group and "Ten stages in the innovation of new medical devices" by F.E. Samuel as cited in New Medical Devices: Invention, Development, and Use, E.B. Ekelman (ed.),1988, National Academy Press, Washington, DC: pp. 145-154.

Among these models there are some interesting variances worthy of discussion. Coopers' Stage Gate Model (Cooper, 1998) was designed to address corporate product portfolio management and has more of an emphasis on screening and filtering out opportunities than the other models.

The model presented by Samuel (Ekelman, 1988) offers several key steps that occur after launch. The Product Development Resources model ("Product Development", 2006) includes a final step (prepare package for potential licensees) which assumes that licensing is the entry point to the market. James Bright (Jolly, 1997) added a key task of using full scale testing or field trial testing prior to commercial release of a product that was lacking in the other models.

Taking the collective wisdom of these approaches into account, the researcher added several key sub-steps to the model especially in the area of after-launch items. The seven major steps were maintained which were in congruence with the pattern from the five models in Table 7. The researcher disagreed with the Product Development Resources Group ("Product Development," 2006) concept that the process should end with licensing since the clinician inventor could decide to pursue starting a company. They ignored the possibility that the inventor can certainly form their own company and/or participate in a strategic alliance with a larger firm to perform certain functions without having to license their technology to anyone.

This researcher's main objective was to build a model for the clinician invention process that could serve as a roadmap for clinician entrepreneurs developing innovative medical devices. As Figure 9 depicts, the major steps in the original model seem to be validated based on the expanded literature review and the primary survey conducted with medical industry experts and clinician inventors. As the model also shows, revisions were made to add more detail to the model and illustrate the interactive and dynamic nature of the model.

The most significant change occurred in the dimension of decisions/outcomes where nine new decisions were identified and added to the model. Many of these changes involved personal decisions rather than technical or pure business decisions such as choosing personal risk level or deciding between being a practicing clinician or an entrepreneur. The eight new sub-steps added to the last two major steps shown in the model (illustrated in bold and italics in Figure 10) of launch preparation and going to market, were important changes. These changes helped add more depth to the tail-end portion of the process that was lacking in the original model.

The comparison of product development models shown in Table 7 depicts the major steps in five other product development and invention models. After close examination of these other models, the research results indicated that they further validate the original major steps, although some of these models have a few more steps and some different major steps. One of the major differences is that the corporate stage gate model is used to manage product portfolios and not just individual projects or products.

The clinician invention which is designed from the entrepreneurial view brings a personal dimension (such as "Do I give up my practice to develop my idea") and deals with a different resource model. Rather than competing for corporate resources among a variety of products, the clinician inventor is likely competing for funding from friends and family, angel investors, or even federal grants through Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. The complexity of early stage funding, personal issues and major hurdles such as the FDA approval process, really makes the entrepreneurial process significantly different than the corporate process. The other four models, (Samuel's study as cited in Ekelman 1988;

Bright's study as cited in Jolly 1997; Dubois, 2003; The Product Development Resource Group, 2006), all seem to fit well with the clinician invention model.

Question 3 addressed the major barriers and roadblocks to successful commercialization. Both the industry group and clinician group identified very similar barriers and challenges in the survey. The top two factors mentioned by both groups were lack of funding and lack of knowledge. It could be concluded that a process and road-map to guide clinician inventors could be important since lack of knowledge is a key barrier and challenge. This would have to be validated with further research, but a process road map is one potential method to help fill a knowledge gap. Two other factors mentioned by the industry group are also somewhat related to a knowledge gap. These were blind spots/not being objective and not recognizing when you need help. Ego and overconfidence could also contribute to both of these aforementioned challenges, but lack of knowledge could also play a role. Some of the other top barriers and challenges mentioned, including lack of funding, were also frequently mentioned in the literature review. These other factors such as attracting a team and regulatory challenges are also well known from the literature and are often mentioned as common challenges across other industries as well.

Now let us consider Question 4 which examined the key decision points encountered as one moved from idea to commercialization. The mini-milestone concept depicted in Figure 12 is one way to show the complexity of decisions faced by clinician inventors.

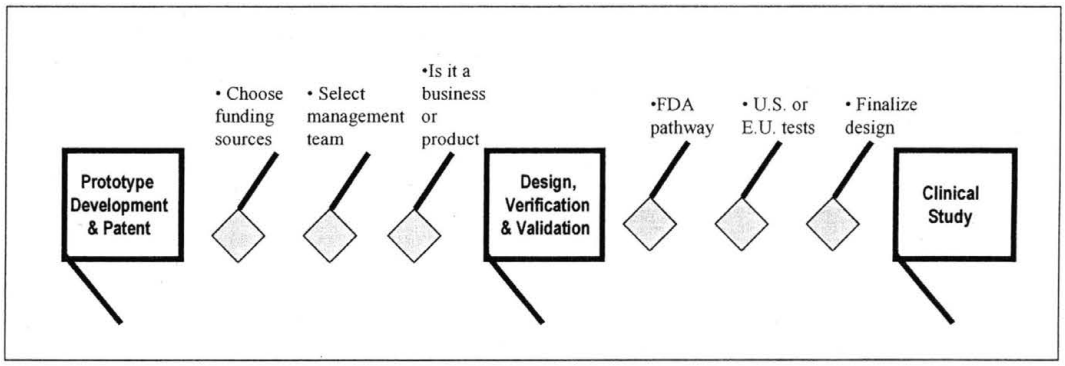

Figure 12. Mini-milestone model. Adapted from "Guide to running software development projects" by M. Perks, (2003). Retrieved March 29, 2007 from www.128.ibm.com/developerworks/websphere/library/techarticles/0306/perks/perks.html.

This addition to the process model helps to illustrate the plethora of decisions that occur as the clinician inventor moves from the initial concept stage to ultimate market commercialization. The typical Stage Gate Model (Cooper, 1994) shows a decision process between each major stage of work that occurs in the process. The researcher's model is depicted the same way for purposes of simplicity in an already overcrowded diagram. However, it is important to be cognizant of not only these multiple decisions that are occurring in between each major stage, but also the myriad of sub-steps and functional tasks that need to be performed.

Research Question 5 examined the additional value and insight from the survey of the target population. Many of the responses to this open-ended question simply reinforced the responses provided in response to Questions 1 through 4 on the survey instrument. The most common advice given by the clinician group was to have perseverance and patience as one tried to move an idea toward commercialization. The clinician group also pointed out the need for stamina and determination as well as having personal commitment to an idea.

These characteristics of perseverance, patience, stamina, determination, and commitment all highlighted the personal side of development and commercialization of a new medical device. The final research question, Question 6, examined the additional learning related to the clinician invention model and successful commercialization of new medical devices garnered from the literature search. The revised process model includes major improvements in recognizing key decisions and sub-steps that I believe make the model more useful and complete. The original model was based on the researchers experience working with Cooper's (1994) stage-gate model and having been exposed to the three-dimensional service blueprinting model developed by Kingman-Brundage (1990) who was the early pioneer of this methodology. These experiential foundations were the genesis of the original model contemplating the clinician invention model in the three dimensions of major steps, sub-steps and decisions. As mentioned in the conclusions related to Question 5, a process model and road map are a potential tool to address the challenge of lack of knowledge mentioned by both industry and clinician respondents to the survey. The researcher considers this connection of process/road map and potential to fill a knowledge gap as the most important area for potential follow-up research to establish validity and reliability.

One final thought the related to the initial problem statement: The process of conceptualizing, designing, developing and launching a new medical device is a daunting task even for the most experienced medical device firm. It is an extraordinary accomplishment for the entrepreneurial clinician inventor who takes on the challenge. These challenges are exacerbated when the inventor lacks:

1. A clear road map from idea to market

2. Knowledge of major barriers and challenges
3. Knowledge of critical success factors
4. Knowledge of key decisions required to navigate the commercialization process
5. Knowledge of key tasks and corresponding functions needed to complete each step in the process

It is the researchers hope that this thesis paper and developed clinician invention process model can serve as a means of making the extraordinary process of commercializing a medical device a little less daunting for the clinician inventor.

The intention is similar to that of physician Goldberg who founded the Medical Futures Organization and Innovation Award (MacDonald, 2002). The Medical Futures Organization helps medical inventors in the United Kingdom commercialize their medical new product ideas. Goldberg, when discussing the inspiration for his efforts, states "But, at the end of the day, if you can turn just one doctor's idea into something that will help people, then all the effort will be worth it" (Robinson, 2006, p.22). If one replaces the word "doctor" with the word "clinician" this researcher's wish would be exactly the same. The task and challenge of assuring validity and reliability of the self-designed clinician invention model with future research remains, but this researcher hopes a key first step was realized with this thesis.

APPENDIX A.

REFERENCE SUMMARY TABLE FOR LITERATURE REVIEW

This table was included as a guide for future researchers who may examine this topic area and as further documentation of the search method. The topics and groupings may be helpful in organizing a literature search strategy.

Topics	Groupings
• Physician/entrepreneurs stories • The team • Ethics • Personality, entrepreneurs and personal side decisions	**People**
• Industry and market overview, economics • Thesis examples, my papers and methods • R&D data, trends, strategy and product design	**Background**
• Patents and intellectual property • Reimbursement, regulations and managed care • Clinical testing	**Legal and Regulatory**
• Product development process and invention process • Incubators and technology transfer • Licensing, alliances and partnerships	**Process**
• Companies dealing with clinical investors	**Resources for Medical Device Inventors**
• Grants, funding, investment, capital. Venture capital and angel investors • Business Success, failure factors, and start-up tips • Barriers, issues, key success factors, challenges and risks • Marketing, business plans and adoption	**Business**

APPENDIX B.

SEARCH TERM LIST FOR LITERATURE REVIEW

Keyword Search List

- Doctor with inventor
- Doctor with entrepreneur
- Physician with inventor
- Physician with entrepreneur
- Clinician with inventor
- Clinician with entrepreneur
- Medical professional with inventor
- Medical professional with entrepreneur
- Physician with start-up
- Clinician with start-up
- Doctor with start-up
- Medical professional with start-up
- Medical with invention
- Medical with start-up
- Healthcare with start-up
- Healthcare with entrepreneur
- Nurse with inventor
- Nurse with entrepreneur
- Nurse with start-up
- Medical with product development
- MD with inventor
- MD with entrepreneur
- MD with start-up
- Technology transfer with medical devices

- Medical device development
- Medical device development with mistakes
- Medical device development with blunders
- Medical device design
- Device developer
- Medical device development and risks
- Medical technology development
- Medical devices and diffusion curve
- Medical product and diffusion curve
- Medical product and new idea
- Medical device and new idea
- Medical device manufacturers
- Medical device companies
- Medical device firms
- Medical device and patents
- Medical product and patents
- Medical device licensing
- Medical product licensing
- FDA approval
- Medical device and new venture
- Medical product and new venture
- Medical device development and success factors
- Medical product development and success factors
- Medical device invention and success factors
- Medical device invention and success ingredients
- Medical product invention and success ingredients
- Medical device invention and barriers
- Medical product invention and barriers
- Medical device invention and challenges
- Medical product invention and challenges
- Medical device invention and problems
- Medical product invention and problems
- Medical device invention and hurdles
- Medical product invention and hurdles
- Medical device innovation
- Medical product innovation

- Medical device introduction
- Medical product launch
- Medical device adoption curve
- Medical product adoption curve
- Medical device development and key decisions
- Medical product development and key decisions
- Medical device development and small business
- Medical product development and small business

APPENDIX C.

SURVEY INSTRUMENT

Introduction

This information is used to set the stage in the personal interview process. It can also serve as background information if the person being contacted prefers an e-mail survey.

Overview

This survey is part of a thesis research effort (in the Texas State University Master of Health Administration Program) to understand the overall clinician invention process, which is being defined for purposes of this research as:

The process a clinician inventor must go through to successfully shepherd a new medical device idea or concept from inspiration to successful commercialization in the marketplace.

The clinician inventor is defined as:

Any practicing clinician whether they are a physician, nurse, x-ray technician or any other practicing clinician who deals directly with patient care and/or any other person who is involved with providing patient care.

Objectives

The main objectives of the survey are to: 1) Build an understanding of the critical success factors in new medical device commercialization, especially from the point of

view of an aspiring clinician inventor; 2) Identify and/or Validate the major steps in the process; 3) Build an understanding of the major barriers and roadblocks to successful commercialization of a new medical device?; 4) Identify and/or validate the critical decision points faced by the clinician inventor as they move from idea to marketplace; 5) Identify additional sources of information related to the topic.

INTERVIEW QUESTIONS

Question 1. What do you see as the critical success factors in the clinician invention process? *(Use description above to define the process)*

Question 2. What do you see as the major steps in the process?

Question 3. What do you see as the major barriers and challenges faced by the clinician inventor in successfully completing the process?

Question 4. What do you see as the most important decisions along the way?

Question 5. What advice would you give to an aspiring clinician inventor to help them succeed?

Question 6. Can you recommend any books, articles or other reference sources on this subject that you think would add to this research effort?

Question 7. Is there anyone else you can recommend that I can possibly interview on this topic?

Sample Classification:

[ ] Clinician: Type: _____ (fill in major category and/or specialty)
[ ] Non-inventor [ ] Idea stage [ ] Patent [ ] To market

[ ] Medical Device Industry: Position and/or area: _____

[ ] Process or other expert: Category _____

APPENDIX D.

SURVEY COMMUNICATION

Regular Introduction:

I am a student in the Texas State University MHA program. I am conducting a survey as part of my master's thesis on the invention process for medical devices. Persons with your experience and background are very hard to find and your insights will be extremely valuable to my research. My three sample groups (described below) include clinician inventors, regular clinicians who **are not** inventors and medical device industry professionals.

Your help in filling out the attached survey would be a great help in my research. It can be filled out and returned by e-mail.

Sincerely,

John Fritz
Email: jfritz_1@msn.com
210-458-2457 office
210-355-6577 cell

P.S. **If you have previously responded please ignore this message.**

I have been receiving some responses from respondents that are not certain where they fit in the research sample. I actually have three sample groups, they are:

1. Clinical inventors who have an idea and have acted on it

2. Clinicians who have an idea for an improvement or new medical device but have not acted on their idea 3. Others who **are not** clinicians who have developed a medical device or are experts in the medical device industry in one or more functional areas such as intellectual property, engineering, product development, clinical research, marketing or any other part of the overall development process

Physician Office Version:

I am a student in the Texas State University MHA program. I am conducting a survey as part of my master's thesis on the invention process for medical devices. Physicians and nurses are a very important group in my research. All clinicians fit into my sample, whether you have worked on a medical related invention or not.

Persons with your experience and background are very hard to find and your insights will be extremely valuable to my research.

Your help in filling out the attached survey would be a great help in my research. It can be filled out and returned by e-mail.

Sincerely,

John Fritz
Email: jfritz_1@msn.com
210-458-2457 office
210-355-6577 cell

Physical Therapy Version:

I am a student in the Texas State University MHA program. I am conducting a survey as part of my master's thesis on the invention process for medical devices. Physicians, physical therapists, nurses and other who deliver patient care are a very important group in my research. All clinicians fit into my sample, whether you have worked on a medical related invention or not.

Persons with your experience and background are very hard to find and your insights will be extremely valuable to my research.

Your help in filling out the attached survey would be a great help in my research. It can be filled out and returned by e-mail.

Sincerely,

John Fritz
Email: jfritz_1@msn.com
210-458-2457 office
210-355-6577 cell

Follow-up with explanation of the sampling method

Let me know if you have any questions on my survey. Since this is a very difficult sample group to find, your response is very important and very much appreciated.

Sincerely,

John A. Fritz

P.S. I have reattached the survey form for your convenience. If you have already returned the survey, please ignore this message.

I have been receiving some responses from respondents that are not certain where they fit in the research sample. I actually have three sample groups:

1. Clinical inventors who have an idea and have acted on it,
2. Clinicians who have an idea for an improvement or new medical device but have not acted on their idea
3. Others who **are not** clinicians who have developed a medical device or are experts in the medical device industry in one or more functional areas such as intellectual property, engineering, product development, clinical research, marketing or any other part of the overall development process

Do not fit in sample

I actually have three sample groups, they are:

1. Clinical inventors who have an idea and have acted on it
2. Clinicians who have an idea for an improvement or new medical device but have not acted on their idea
3. Others who **are not** clinicians who have developed a medical device or are experts in the medical device industry in one or more functional areas such as intellectual property, engineering or marketing. You are in sample group three. Your input would be greatly appreciated. I will be comparing results from the three groups.

Final Reminder:

Due to an inadequate sample size I am sending one last reminder concerning my thesis survey. I plan to continue taking in surveys **through February 12, 2007**, since I have not yet reached my needed sample size. I will not bother you with any more follow-ups. If you can complete a survey it would be a great help. I have attached the survey form again for your convenience.

Thank you,

John Fritz
Email: jfritz_1@msn.com
210-458-2457 office
210-355-6577 cell

P.S. I have reattached the survey form for your convenience. **If you have already returned the survey or told me you were not interested, I apologize and please ignore this message.**

APPENDIX E.

COMPILATION OF MEDICAL DEVICE AND
PROCESS EXPERT SURVEY RESPONSES

Responses summarized in Appendices A through C were complied by sorting them into the three categories. These were medical device industry experts, process experts, clinician inventors, and clinicians who were not inventors. The researcher used best judgment to classify similar responses, when in different words the respondent was really saying the same thing as another respondent. The number shown in the parenthesis after each response indicates the number of times that response was given.

Question 1. What do you see as the critical success factors in the clinician invention process? *(Use description above to define the process)*

1. A good idea that meets unmet or significant need, solves problem (32)
2. A secure and unburdened intellectual property position and educating the doctor on what is patentable, keeping good and accurate records and lab notebook (21)
3. A clear vision of how it can be developed into a product and be articulated to the market, drivers of behavior (9)
4. A simple explanation to investors as to why it is useful and potentially profitable (3)
5. Be objective and realistic (5)
6. Must provide clinically significant benefits with evidence (5)

7. Be superior to other devices used for the same purpose, be more efficient (11)
8. Provide valid scientific data that shows the invention is safe and effective (usually via a well-designed clinical trial), proof of concept and feasible design (18)
9. Design of the device must be documented and it must be tested (to meet design specifications) include Design Failure Modes Effects Analysis (DFMEA), technical feasibility, have a truly robust design (5)
10. Results must be submitted to FDA in the proper format to obtain marketing clearance and maintaining good FDA relationship, have a clear regulatory pathway (9)
11. Complete a comprehensive business and marketing plan to obtain the necessary financial support (5)
12. Aggressively pursue marketing plan to achieve timely return on investment and overall plan execution, superior and comprehensive marketing and sales effort (6)
13. Identifying an external industry-experienced executive who can partner with the MD to guide an idea toward a product realization and know when to let go (10)
14. Diversity of experience is key to innovation
15. Adequate funding and obtaining financing (13)
16. A working model/prototype, product design based on a solution to a problem (2)
17. Sufficient market size and profit potential (13)
18. The inventor must have a complete understanding of all of the medical technical parameters involved in applying the device or process
19. Reimbursement strategy, CPT code (cost effective product) (6)
20. Competitive strategy and competitive advantage (6)
21. Time and freedom to pursue the opportunity (5)
22. Support network and team to assist, good advisors (who are carefully selected) (11)
23. Experienced advisory board
24. Know the customer and target market, including early analysis of potential (6)
25. A willingness to share rewards with those who can help
26. Analyzing and understanding self and personal objectives with respect to how the invention is commercialized (and how much the inventor can and desires to be involved)

27. Ability to make adjustments when things go wrong
28. Fit into physician practice patterns, physician buy-in (2)
29. Perseverance and determination, desire to help others (5)
30. Be committed to the long haul
31. Required resources, not just funds
32. Getting an investigational device exemption (IDE) in the U.S.
33. Awareness that idea is only a small part of it (2)
34. Ease of manufacturing
35. Have a great attorney
36. The right tools
37. Imagination and experimentation, question how things are done (2)
38. Be able to negotiate a license agreement or find somebody who does
39. Do not take the invention to a major firm that would view it only as cannibalization of its current product lines
40. Integration of product and business development efforts
41. Knowing the entire decision influencer chain (physician, payer, patient and others)
42. Understanding of product costs
43. Successful partnership with an experienced medical device company

Question 2. What do you see as the major steps in the process?

1. Convincing scientific proof of principle (19)
2. Early determination of patentability, strong patent protection and good prior art searching, lab notebook, non-disclosure, help from a patent attorney, lab notebook with witnesses (38)
3. Securing financial investors and required funding, can include grants (26)
4. Identifying committed management, regulator, and manufacturing personnel, assemble management team and strong marketing and sales team (11)
5. Developing a pre-IND package that is simple, compelling, and easy for the FDA to understand, establishing clinical viability and safety, preclinical and clinical trials, clinical protocols, FDA and/or EU path and approval (36)
6. Come up with an idea that solves a huge problem, have a sizeable market (8)
7. Product specifications, build a prototype and develop good drawings, reduction to practice (28)
8. Conduct product testing and initial idea assessment (9)

9. Take product to market or license the product, overall implementation (4)
10. Marketing and sales effort and creating awareness, provide full clinical, technical and scientific information (9)
11. Identify unmet clinical need and clinical analysis of the problem, come up with original concept (19)
12. Experimentation, develop possible solutions and select best alternative, design for manufacturing, final design freeze (21)
13. Market assessment, market identification and a good competitive assessment, pay for a small study to confirm need (18)
14. Find a trusted industry partner and work with them to polish off the design and take it to market (or any other development entity) (14)
15. Create simple elegant design that solves the problem (5)
16. Create compelling value proposition (3)
17. Reimbursement, health insurance coverage and payment (7)
18. Preliminary production, trial or test and demonstrations (2)
19. Initiate FDA testing, UL, ISO or other required testing, design dossier and quality systems (5)
20. Product manufacturing, scalability and understanding of costs (18)
21. Product launch and commercialization (15)
22. Disclosure and generation of the original idea, discovery of new knowledge (6)
23. Business plan development, resource identification and execution (14)
24. Decide on start-up alternatives (license, partner, research role, etc.) (2)
25. Legal start-up and company formation (2)
26. License rights from employer
27. Making plan corrections
28. FDA post-marketing surveillance
29. Post coverage review by health insurers
30. Initial concept generation and brainstorming, awareness of need (4)
31. Find community partners such as regional economic development groups
32. Validation, peer review of concept, physician buy-in (5)
33. Business case development
34. Marketing strategy development

Question 3. What do you see as the major barriers and challenges faced by the clinician inventor in successfully completing the process?

1. Failure to complete key milestones and stay within budget, lack of urgency (4)
2. Dealing with huge egos, thinking your idea is the be-all/end-all, unrealistic expectations, unrealistic valuations (13)
3. Not being objective, blind spots to limitations or possible improvements, fully understand the problem being solved (10)
4. Lack of time and balancing the venture and your practice, ability to focus (16)
5. Achieving FDA approval and lack of understanding of regulatory process (14)
6. Obtaining sufficient financial backing and resources to complete the process, lack of funds (25)
7. Knowing when to quit if the product will not be financially viable (2)
8. Being able to perform a scientifically-valid clinical evaluation that is free from investigator bias (3)
9. Know when you need help and realize you may be ill-equipped to handle the challenges (9)
10. Buy-in from physicians and the rest of the market (4)
11. Having a me-too product , unable to build value beyond the original idea, inertia of the status quo (4)
12. Believing your technology is worth more than it is at an early stage, lack of knowledge about the licensing process (3)
13. Lack of knowledge and experience in all of the non-clinical business related areas (including patent process, manufacturing, engineering and distribution) areas required to commercialize a medical device, not knowing the steps to take, (22)
14. Most clinicians do not work well with others and need to remain on the periphery of the business, not knowing when to step aside (4)
15. Building a logical business plan and business model (3)
16. Obtaining needed funding (includes having a large enough market to attract funding) (7)
17. Achieving reimbursement (3)
18. Ability to attract the talent (team) to start a company and/or lack of a network of needed talent (10)
19. Confirming clinical need and market potential (7)
20. Premature disclosure
21. Lack of support from clinical partners or employer (2)
22. Striving for perfection without concern for cost/benefit and resource limits
23. Clinical trial costs (2)
24. Ability to find a manufacturing/industry partner, lack of effectiveness when found

(7)

25. Administrative obstacles
26. Inability to get a patent or otherwise protect the idea, or get the company started (5)
27. Not willing to share (2)
28. Overwhelming amount of research required
29. Family pressures to slow down
30. Finding the right lawyers
31. Overcoming technical hurdles
32. Risk tolerance and investors who are risk tolerant
33. Competitive forces, competition from major established firms (2)
34. Ability to successfully engineer the product
35. Being able to commercialize the device (2)
36. Timely introduction of the initial product before competitive options are launched
37. Do not let emotional investment cloud your judgment
38. Peer jealousy
39. Getting a foot in the door

Question 4. What do you see as the most important decisions along the way?

1. Choice of funding partners and/or development partners and when to partner (17)
2. Choice of management, regulatory teams, attorneys and advisors (17)
3. Willingness to take risks (such as investing in manufacturing without proven market) and how much do I invest myself (5)
4. The business model and overall strategy to get to market (5)
5. Deciding if the invention will be a financially viable product, based on an unbiased evaluation, good go/kill decision on the technology or product, large enough market, invest or do not invest (22)
6. Pursue a patent, can it be protected (yes or no) (6)
7. Take to market yourself or seek a licensing partner (is this a product or a company) (13)
8. Selection of best solution among alternative solutions to the clinical need you are addressing, effectively translating the need to a product and engineering decisions (8)
9. Understanding investment requirements per each milestone (2)

10. Choose your role as a physician or an entrepreneur (keep your practice or run a business) (6)
11. Determining if the idea will pass the "so what" test (is it needed) will customers buy it (5)
12. Deciding who will develop the product and what is needed to develop the product (2)
13. Deciding to give up 100% control and how much to share (5)
14. Determining the path to FDA clearance and clearing reimbursement hurdles, how to ensure safety and efficacy (9)
15. What is the exit strategy (2)
16. Choosing target patient populations, indications for use (2)
17. Buy-in and support from the family
18. Knowing that you need help and seeking help
19. Deciding your level of involvement and if you even want to do it (3)
20. How to work with your employment agreement and/or your tech transfer office (2)
21. Being well aware of what others have done, commit resources to understand competition (2)
22. Determining manufacturing platform
23. Licensing agreement

Question 5. What advice would you give to an aspiring clinician inventor to help them succeed?

1. Good luck, stay committed, and do not always play it safe, be passionate about your idea, do not lose heart (8)
2. A good idea is not enough. Success will require a great deal of effort, stamina and some luck, believe in yourself (5)
3. Discuss idea with a lot of different people, make sure clinician understands contracts they have with employers regarding ownership of IP, troubleshoot implementation of invention, do your homework (7)
4. Find a way to solve a problem without a good solution (3)
5. Protect but share your thoughts, find and network with other clinician inventors (3)
6. Hire good IP counsel, most IP counsel is bad. Partner with good business professionals and turn the technology over to them (4)

7. Foster many contacts in the device companies and try to get a large company on board (not just one company for prospects) (10)
8. Observe and discuss how clinicians cope with specific problems, within and outside the specialty. Observe how similar, but non-medical issues are resolved (2)
9. The team should have prior experience with the type of company, product or market the clinician is contemplating, even including the general business attorney (2)
10. If possible, work with an academic tech transfer group, they must be knowledgeable and well funded (2)
11. Find a local incubator organization
12. Document everything along the way with dates, names, witnesses, etc. (2)
13. Be realistic about the value of each invention and use benchmarks to justify your opinion (3)
14. Protect your IP early and often and keep very quiet in the early days (4)
15. Form an advisory board of been-there/done-that types (2)
16. Recruit experienced people to help with various aspects of planning, organizing, funding commercializing—especially true if the chosen approach is a start-up (6)
17. Attempt to collaborate with someone at, an institution with a demonstrated strong track record in "bench to clinic" commercialization, both in the form of industrial partnerships and establishment of startup firms (2)
18. Get advice early regarding process/entrepreneurial education and FDA process (3)
19. Stage your development so you can enter the market at a relative cost and develop attractive/competitive product pricing for quick sales in order to pay off debt and further R&D
20. Reconsider entering the competitive market if you are hitting the Harvard product life cycle on the downward slope of the market niche
21. My advice would be to pursue their ideas because there is always a need for a 'better mousetrap' and a clinician involved in an area is in a unique position to recognize where innovation may play a role
22. Same sort of advice as to the person who wants to open a restaurant. Work in one first and learn what there is that is not in a book, learn as much as you can about the business end, not just the technical side (4)
23. Talk to an insurer—and understand the evidence needed to secure reimbursement before proceeding (2)
24. I always encourage entrepreneurial activities, but with caution. For an

academician, entrepreneurial activity can impact a young faculty person's ability to publish which could negatively impact promotion and tenure. The clinician inventor will require a supportive infrastructure if he/she is to be successful

25. Be willing to hear honest feedback about the marketability of your product. Not every brilliant scientific discovery or invention is a good commercial opportunity, and it is important to be able to recognize the difference (2)
26. Be sure your family is on board
27. Work with a reputable firm to validate market potential
28. Make sure that clinical staff are involved and the time to complete clinical trials is included in plans from the outset
29. Partner with an engineer, trusted partner or consultant (2)
30. Build a strong network
31. Accept your strengths and weaknesses
32. Focus on the public benefit and not just the financial rewards
33. Invert the current thinking
34. To look at the invention as not your baby, but a commercial enterprise. It would help to take the personal part out of it and to roll with the punches
35. Understand who will use it, what value it brings them and who else is in the buying decision process
36. Do not, under any circumstances, approach an existing player in the market to develop your disruptive invention
37. Take advantage of all resources at your disposal
38. Be willing to pay for good help
39. Be willing to give up some control
40. Determine start-up costs and decide how much you are willing commit of your own funds
41. Do not be afraid to fail, lessons learned can be a great asset
42. It is about who is on your team
43. Surround yourself with quality and expertise
44. Take your estimates of time and money required and double everything (2)

Question 6. Can you recommend any books, articles or other reference sources on this subject that you think would add to this research effort?

1. Physician Invent Thyself by Michael Neuvirth www.doctorofinvention.com
2. A basic primer on patents

3. Pressman's book Patent It Yourself (4)
4. Conroe's Retrospectroscope
5. National Association of Venture Capital – Courses on investing and business plans
6. http://www.simplexitymd.com/ (New venture group for medical entrepreneurs)
7. EMB Society Web Site: http://embs.gsbme.unsw.edu.au/
8. IEEE Transactions on BIOMEDICAL ENGINEERING, published by the Engineering in Medicine and Biology Society (IEEE-EMB)
9. JAMA and other specialty clinical journals
10. Website www.devicelink.com
11. Website IC^2
12. FDA website, MATCH website (match.ac.uk down load deliverable D5 & D9)
13. 10 Stages in the Innovation of New Medical Devices, source: Frank E. Samuel, "The Perspective of the Medical Device Industry," in Karen B. Ekelman (ed.), Institute of Medicine, *New Medical Devices: Invention, Development, and Use* (National Academy Press, Washington, DC, 1988), pp. 145-154.
14. *Health Affairs* volumes on Medical Innovation Summer 1994, Sept/Oct 2001, read the multi-volume series the Institute of Medicine published in *Medical Innovation at the Crossroads*, in the early 90s.
15. Web site of the Advanced Medical Technology Association, or AdvaMed, (formerly the Health Industry Manufacturers Association, or HIMA) http://www.advamed.org/aboutourindustry.shtml.
16. Science Business by Gary Pisano
17. http://www.or-live.com/
18. BIO website
19. National Business Incubation Association
20. Reports put out by the big banks' analysts
21. H. Eskowitz, Capitalizing Knowledge. C. Freedom, L. Soete. Industry & Innovation
22. S. Vedantam. FDA Told U.S. Drug System Is Broken-Expert Panel Calls For Major Changes. Washington Post, September 23, 2006; A01
23. Addicted to Greed-Commercialization and the Pharmaceuticals Business, Dr. Vincent di Norcia, Emeritus Professor of Philosophy, the University of Sudbury
24. Intellectual Property and the Commercialization of Research and Development, Vincent di Norcia, Emeritus Professor of Philosophy, the University of Sudbury
25. Incubator in Madison, University has seed capital

26. See www.synecor.com news – June IN VIVO article on Synecor, LLC
27. http://www.fda.gov/cdrh/devadvice/
28. Most any books by Nolo Press on inventing and patenting
29. www.asktheinventors.com website
30. Books by Barbara Pitts and Mary Sarao
31. Medical Device Associations
32. Licensing Executive Society (LES)
33. Association of University Technology (AUTM)
34. FDA regulations and regulations on reimbursement
35. USPTO website
36. Philip Kotler books on Marketing Management
37. Speak to venture capitalists and investment bankers ; attend sessions on conducting an IPO
38. Books by Clayton Christensen
39. Books: The Tipping Point and Execution
40. Harvard Business Review
41. Books: Rembrandts in the Attic, Patent it Yourself, Edison in the Boardroom

APPENDIX F.

COMPILATION OF CLINICIAN INVENTORS SURVEY RESPONSES

Question 1. What do you see as the critical success factors in the clinician invention process? *(Use description above to define the process)*

1. Identified clinical need, have a new and innovative idea that has a scientific basis, and clinical efficacy, that is years ahead of competition, know the science (17)
2. Have drive, determination, passion, persistence, tenacity, enthusiasm and some luck (8)
3. High risk tolerance (2)
4. Be able to handle setbacks
5. Strong market knowledge, identification of market size and validation of true need (6)
6. Acceptance of key stakeholders including current practitioners (2)
7. Strong value proposition
8. Recognition of costs and required investment, required funding, multiple financing rounds (14)
9. Surround yourself with good people and building the team, have both clinical and technical knowledge, ethical advisors that understand the process (8)
10. Have a good product that can make a profit and has a sizeable market, obtain significant market penetration (6)
11. Good contacts and support services (including translational research) you can't do it alone, industry partners (7)
12. Patience to experiment during the development phase
13. Good marketing plan
14. Asking the right questions, investigation, recognition of a valuable idea, openness (2)
15. Ability to communicate without feeling like everyone will steal your idea

16. Patentability investigation, knowing how to protect the idea (4)
17. Keep costs low in the beginning phase, reasonable implementation (2)
18. Move forward constantly and rapidly, take it far as you can (2)
19. Time to work on the idea
20. Create a business model around the idea
21. Have a clear understanding of the development process (6)
22. Keep the idea close to your vest and document everything
23. Convincing someone else of the novelty and improved patient outcomes, communication skills (2)
24. Establish proof of concept
25. Build prototype
26. Convincing other clinicians to use it (assuming a positive trial) (2)
27. A product that produces real benefit for patients and cost effective for health system (2)
28. Short FDA approval process and road to reimbursement, documenting efficacy and safety, IRB red tape (4)
29. Support from employer/institution, improved reward system (2)
30. A distribution partner
31. Determination of manufacturing procedures including testing and compliance
32. High level engineering talent
33. Knowledge of regulatory and manufacturing process
34. Know yourself, be success minded and self-empowered
35. Easily understood by non-technical people
36. Have a desire to drive and push through the unknown
37. Solve an important problem

Question 2. What do you see as the major steps in the process?

1. Development of the original concept and comprehensive product definition (20)
2. Define drivers and barriers to adoption
3. Prototype development (15)
4. Design refinement, engineering specs and diagrams, commercial ready product, pilot production and test (13)
5. Seek outside collaborators (including industry partners) for manufacturing and/or marketing, licensing agreements (12)
6. Research need for product and evidence of product improvement over existing

alternatives, listen to end users, basic science research, have an understanding of ways to improve (10)

7. Competitive analysis
8. Patent protection, including good prior art searching (23)
9. Develop strategy for deployment and business plan with milestones (4)
10. Evaluation of safety and demonstrated safety and efficacy (3)
11. Development of accurate instructions for use, be able to explain concept well to others (2)
12. Premarketing device (2)
13. Demonstrated advantages, communication, create awareness, marketing, learning to sell, convince others of the novelty, commercialization process (11)
14. Due diligence process
15. Building the team with experience and motivation, that you can trust, includes high level engineering talent (11)
16. Validate your idea with the target market (including practitioners) , needs assessment, testing (11)
17. Acquire needed funding (13)
18. Conduct clinical trials, regulatory oversight, regulatory approval (10)
19. Proof of concept, alpha testing, beta testing (5)
20. Go to market as manufacturer or license the technology to a company
21. Translational research
22. Technology transfer (2)
23. Develop business model
24. Develop basic business structure
25. Learn to refine and adjust along the way, ongoing improvement (2)
26. Create a product development plan and business plan (4)
27. Production and manufacturing (4)
28. Publish in peer reviewed journals (3)
29. Establish reimbursement
30. Form a corporation
31. Obtain product liability insurance
32. Finding distributors (2)
33. Learn about the entire development process
34. Breadboard
35. Building name recognition
36. Assess the financial impact of the invention

Question 3. What do you see as the major barriers and challenges faced by the clinician inventor in successfully completing the process?

1. Regulatory hurdles and FDA approval (8)
2. Competition both present and future, heavy noise in the market (5)
3. Lack of time (7)
4. Money, inability to raise adequate funding, economic support, grants (24)
5. Lack of manufacturing, marketing knowledge, financial knowledge, engineering talent, licensing process knowledge and knowledge of the process of how to get to market (17)
6. Unwillingness to share part of the venture or let go (3)
7. Lack of clear IP ownership, ability to protect the idea, employer may have rights (4)
8. Lack of trust from physician colleagues (based on many poor examples of doctor inventors)
9. Belief in validity of invention, lack of confidence (3)
10. Lack of a great business model
11. Required research and development, technical hurdles (2)
12. Limited resources for marketing
13. Required patience and tenacity, life gets in the way (3)
14. Ability to communicate without feeling like everyone will steal your idea, disclosure (2)
15. Moving too slowly, not recognizing what is in the critical path (2)
16. Learning to think like a businessman
17. Finding the help you need and recognizing when you need others to navigate uncharted waters, lack of good management and implementation team (5)
18. Conflict of interest issues (2)
19. Getting physicians to change practice patterns, displacing old concepts (4)
20. Strong culture unwilling to change
21. Access to engineering skills
22. Constraints of regulatory process to allow experimentation (2)
23. Sifting through scams (watch out for invention firms that are dishonest)
24. Working with manufacturing companies that are supposed to help with development, but drop the ball
25. Lack of support from employer
26. Lack of experience with reimbursement

27. Not recognizing what personnel is needed or when they are needed
28. Hard to get good advice
29. Having a poorly conceived product, not truly unique (2)
30. Inadequate market size
31. Large competitors with experience and economies of scale
32. Isolation

Question 4. What do you see as the most important decisions along the way?

1. Where to seek help when problems arise, admit you don't know something (5)
2. Identification of the market, clinical, impact of idea (3)
3. Determination of final design, product testing and knowing when to change direction, the right product, "freedom to operate" (7)
4. Degree of inventor involvement and investment in time/effort/money (3)
5. Deciding how to fund the venture, especially in earliest stages (7)
6. Whether to license or sell or start your own company (4)
7. Decide on being a doctor, nurse, scientist or entrepreneur, or letting someone else run the company (4)
8. Decide how much risk you are willing to take, commitment to your own idea (5)
9. Decide who you can trust and work with (3)
10. Who to take money from and under what conditions (2)
11. Finding experienced people and deciding who will be on the team (9)
12. Is it patentable and what to patent, determining what is really novel (6)
13. Quick prototype
14. Keep moving forward until completion or quit in face of rejection (2)
15. Preclinical and clinical trials, product safety testing (3)
16. Deciding on if the idea is viable, will it help patients, cost of goods versus selling price (8)
17. Deciding how much ownership to give up
18. How much are you willing to change your original vision and course as needed (2)
19. Manufacturing method (most profitable)
20. How you penetrate the market and market analysis (2)
21. The right time to go to market and share the idea (3)
22. Picking the right development partner (that won't rip you off)
23. How to expand your product lines

24. When and how to acquire competitors or competitive products to drive expansion
25. How you will manage risk

Question 5. What advice would you give to an aspiring clinician inventor to help them succeed?

1. Confidence and commitment are key, believe in your idea, accept risks (4)
2. Persevere – keep moving forward with little steps. Be patient – great things take time, be prepared for the unknown, hang in there if you believe, be passionate about the idea (11)
3. Search the extant body of knowledge to make sure no one else has already developed something similar, don't reinvent the wheel (2)
4. Identify potential manufacturing problems
5. Build a great team (with experienced people), choose them wisely and do not confuse ownership with control (7)
6. Do not pursue me-too ideas, have a concept that improves patient outcomes (2)
7. Learn to live cheaply, ignore your critics and prepare your family for 5-10 years of material deprivation (relative to your old life as a "regular" doctor), control development expenses and keep costs low (2)
8. Purchase a book on product development, understand the phases involved, find consultants that have lots of experience and listen to them (2)
9. Be realistic about its potential. It is never as big as you might think (2)
10. Companies fail because of people, so business colleagues are crucial, build a network of people for guidance (2)
11. Expect a long and bumpy road, hardest thing you will ever do, this is not for the faint of heart (4)
12. To move forward ASAP and keep moving
13. Obtain suitable clinical research training and education
14. Think through your idea, document it and have it witnessed by two people, then look to industry for financial support (2)
15. It will be the most rewarding thing you have ever done
16. Have lots of cash, raise adequate capital (4)
17. Be sure the product will work and has a market of at least ten million
18. Keep meticulous notes on every idea that you have, including sketches, and end each entry with time, date, and your signature
19. Be willing to make modifications when the basic ideas are not compromised

20. Become computer savvy (to deal with the multitude of required forms)
21. Get help from Small Business Development Centers, other government help (2)
22. Take courses to learn the process (2)
23. Do as much preliminary work as you can before disclosure especially if FDA approval and patenting can be done
24. Respect others opinions to improve your invention so it will truly be utilized and persevere with your idea by finding support from other professionals
25. Be humble. Physicians are not trained to be inventors, innovators or CEOs
26. Aspiring to invent is meaningless, it is all about developing in-depth engineering and clinical knowledge, inventions will come
27. Understand the potential market (2)
28. To think, think, think, in every time in every moment
29. Find someone willing to partner /invest that you can trust
30. Obtain protection for your invention/product
31. Know your obligations to your current employer and your employers' rights to your work
32. Lay out a clear and convincing argument for the value of the invention and be prepared to make that argument both from the clinical viewpoint and the financial one
33. You must be able to sleep at night with the risk. This means probably that you have enough money to support your family and lifestyle while doing this new venture. If you don't, be careful. You may wind up broke and divorced.
34. If you are married, make sure your wife is on board. If you can't sell her on it, wait. It will be a losing battle otherwise.
35. Continue to develop all new ideas that are potentially profitable. There should be a pipeline of development such that if one business dies, a new begins.
36. If and when a big fish wants to move into your space and offers to buy you, sell to them and go into another open arena where there are few if any big fish. You cannot compete against the big fish for long and they will drive you out of business
37. If An inventor's desirable abilities are: organizational skills, setting and achieving goals, systematic thinking, creation of possibilities, pinpointing problems, and embracing failure

Question 6. Can you recommend any books, articles or other reference sources on this subject that you think would add to this research effort?

1. Magazine – Inventors digest (2)
2. Any high school textbook on basic accounting
3. How to Win friends and Influence People – Dale Carnegie
4. The E-Myth for Physicians
5. Book, Good to Great
6. Creating Breakthrough Products / Cagan & Vogel; Product Leadership / Cooper; Product
7. Design & Development / Ulrich & Eppinger
8. The Inventor's Guide for Dummies
9. USPTO website (2)
10. Networking
11. University of Virginia Patent Foundation
12. Innovators Dilemma (Clayton Christensen) and the Innovators Solution (Clayton Christensen and Michael Raynor) (2)
13. Von Bargen Mueller, L. (1995) An Inventor's Guide to Patents and Patenting published by the Association of University Technology Managers, Inc. The website to obtain copies is: http://autm.rice.edu/autm/
14. Books, Good to Great and The Box
15. Ten Faces of Innovation by Kelly
16. Diffusion of Innovations by Rogers
17. Harvard Business Review articles written on innovation
18. Donald Berwick, Disseminating Innovations in Healthcare
19. Physical Therapy and other therapy journals
20. Innovative Doctoring by Jeff Grossman, MD
21. Patent libraries
22. New Medical Devices: Invention, Development and Use http://www.nap.edu/catalog/1099.html
23. Richard Levy, Inventors Desktop Companion, Visible Ink Press
24. Book, Blue Ocean Strategy

APPENDIX G.

COMPILATION OF NON-INVENTOR CLINICIAN SURVEY RESPONSES

Question 1. What do you see as the critical success factors in the clinician invention process? *(Use description above to define the process)*

1. Industry partnership
2. Access to patients for testing new device (after proper preclinical testing and other requirements are met)
3. Stay focused and dedicated to accomplishing your goal
4. Have a trusted and reliable staff or team to work with (including mentors) (3)
5. Determine if invention is patented or patentable (2)
6. Identify unmet need
7. Adequate market size
8. Realistic evaluation of the idea
9. An invention that makes a difference to patients
10. Acceptance of the invention in clinical practice
11. Opportunity for profit, cost effective product (2)
12. Have an idea or concept that has been invented
13. Business plan

Question 2. What do you see as the major steps in the process?

1. Original concept generation and documentation (3)
2. Prototype (2)
3. Animal testing
4. Funding
5. Engineering and design, functionality (2)
6. Pilot testing, feedback on the idea (2)

7. Formulate a sound hypothesis and take appropriate steps to support it
8. Patent protection (4)
9. Market identification and competitive assessment (3)
10. Decision to license or manufacture
11. Identify the need and understand the problem being solved (2)
12. Manufacturing and production (2)
13. Initial sales, marketing and advertising input (2)
14. Evaluation and update (2)
15. Continued sales and expansion (long term) (2)
16. FDA approval (if needed)

Question 3. What do you see as the major barriers and challenges faced by the clinician inventor in successfully completing the process?

1. Time to devote to the development effort (2)
2. Regulatory and legal hurdles (3)
3. Finding an industry partner (2)
4. Frustration
5. Red tape
6. Finding funding (3)
7. Decision to license or manufacture
8. Difficulty in obtaining patents with the new rules
9. Inadequate marketing and sales experience
10. Lack of access in the business community
11. Perception of others as to the clinicians role in the process
12. People who are skeptics when it comes to new devices
13. Having people participate in research to test product

Question 4. What do you see as the most important decisions along the way?

1. Decision to invest in a prototype
2. Decision to invest major resources in human testing
3. Staying on course with the plan (2)
4. Type of patent to pursue (provisional or non-provisional)
5. Whether to license or manufacture
6. Financial structure

7. Planning for business development
8. Lack of skills to find and access a team
9. Overwhelming corporate and business constructs necessary for success
10. Maintaining safety
11. Is product cost effective
12. Risk versus benefit analysis

Question 5. What advice would you give to an aspiring clinician inventor to help them succeed?

1. Find industry partners with deep pockets (2)
2. Read as much as you can on the subject
3. Talk with colleagues
4. Find a mentor to help with the process
5. Be persistent, don't expect to succeed with the first invention (2)
6. Try to help change the new patent process
7. Learn the complete process
8. Be patient
9. Think about things from a patient perspective

Question 6. Can you recommend any books, articles or other reference sources on this subject that you think would add to this research effort?

1. Lawton R. Burns, The Business of Healthcare Innovation
2. Alan B. Cohen, Ruth S. Hanft, Technology in American Healthcare
3. Use Google
4. December 2006 USPTO report and Fortune article covering same
5. Everett Rogers, Diffusion of Innovations (2003)

APPENDIX H.

MIKE MESENBRINK'S TOP TEN LESSONS

This reference material was kindly provided by Mr. Mike Messenbrink who was one my primary research survey respondents. With his permission I have included his information which provides some excellent planning tips for aspiring entrepreneurs.

Top Ten Lessons Learned
by
Mike Mesenbrink
Harvard Business School Entrepreneur's Conference

1. Timing is everything, I would rather be lucky than smart!

2. Understand working without resources....there are no secretaries, and there is never enough of anything.

3. Develop a business plan even if the business seems to be "simple".

4. Make sure there is capital in the market place to fund your activities. Discuss leaving your current high paying job carefully with your spouse so both understand the risks and rewards.

5. It always takes more time and money than initially anticipated, when forecasting increase expenses and decrease revenues.

6. Always have a veteran person in the company to help guide and keep you in safe harbors and better yet, have a board of directors if possible. People are your single biggest asset.

7. Document everything in writing such as employment agreements, compensation plans when hiring management people and staff and be organized in your ability to retrieve documents.

8. Plan on having audited financials if you plan to take the company public or sell it…more expensive but a must do.

9. Make sure that all corporate governance issues are complete and timely. Examples: all contracts, NDA's, employment agreements, stock option agreements, corporate minutes, stock certificates, loans, equity instruments, financials, etc.

10. Be prepared for giant unplanned hurdles, e.g., wars that break out, economic recessions, personnel problems, sales that never seem to get booked, industries that collapse.

And the most important covenant of all:

Have a high regard for cash and make cash flow happen as quickly as possible…business is all about cash flow.

Outline of Starting the Business:
By
Mike Mesenbrink

I. Timing….. is everything, and it is important to discuss your ideas with people that are well grounded in business and experienced in the space.
   1. think twice about starting a business in bad economic downturns
   2. understand your big picture capital requirements
   3. conceptualize when you will most likely have revenues

II. Business Plan Development .....if you still think it is a good idea to leave your job and start something new then start to develop a business plan.
   1. a business plan will help you pull everything together
   2. business plans are like an equation and both sides have to balance; revenues higher then expenses
   3. even a simple business can be misleading when you add up all of the expenses of being in business and find yourself upside down
   4. a good business plan will take longer than you think
   5. develop a "value proposition" that is compelling
   6. understand the "exit strategy" for yourself and investors

III. Personnel
   1. people are what make a business; surround yourself with the best
   2. be realistic about salaries and plan on giving up equity to have good people; don't be greedy
   3. do not start with a large team...build as you go to keep costs down
   4. be diligent with people that you bring into the organization and temper their expectations
   5. work with your team and be kind to them to build a company culture, e.g., Southwest Airlines

IV. Capital
   1. all business start-ups require capital and it is usually difficult to raise
   2. make sure that you have access to start-up capital from "friends and neighbors"
   3. be realistic about valuations when raising capital and less concerned about dilution
   4. Management, the product/service and the market are the three most desired elements that "sophisticated money" will focus on

V. Operations
   1. be prepared to work long hours and feel like you are always behind the power curve chasing your tail
   2. tenacity usually pays off in ways not always understood in the beginning
   3. networking is important...recruit new people into the business idea...they can help by providing contacts

VI. Business Plan Tweaking
   1. the business plan will probably require modifications and that's okay
   2. be realistic about operating margins

VII. Cash Flow…the most important of all things
   1. remember the dot.bombs….they failed to manage cash
   2. try to build organically if possible and not rely on outside capital
   3. have a very high regard and reverence for cash and cash flow

VIII. Keep Reinventing The Company ……Do Not Become a Dinosaur
   1. in order to compete effectively we must constantly upgrade our products and services to gain market share
   2. markets are moving fast
   3. labor intensive companies must have products developed in other countries to compete on price

IX. Exit……IPO, Merge, Sell, Run the Company
   1. if successful retire or start another company

X. Have Fun…..try to make it fun for everyone involved

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VITA

Mr. Fritz has over 28 years of professional experience focused in the areas of technology commercialization, research and development (R&D), marketing, business development, market research and product development. He is currently a Technology Licensing Associate at the University of Texas Health Science Center at San Antonio. In this position he is responsible for evaluating and licensing technology developed at four University of Texas institutions. He began his professional career in 1981 with Entergy Corporation, a multi-billion dollar utility conglomerate headquartered in New Orleans. At Entergy, Mr. Fritz worked in market research, product development and market management. He established the first ever new product development process at Entergy in the late 1980's. While at Entergy, Mr. Fritz received the Peak Performer Award given to top annual performers and the Chairman's Award for Innovation. He also won the Electric Power Research Institute (EPRI) innovators award.

Mr. Fritz left Entergy in 1999 to pursue a new career opportunity at Kinetic Concepts Inc., a major medical device company headquartered in San Antonio. At KCI, Mr. Fritz worked in the areas of manufacturing, R&D, and business development. After departing KCI Mr. Fritz became Project Manager for Technology Commercialization at the Small Business Development Center (SBDC) Technology Center located at the downtown UTSA campus. At the Technology Center, Mr. Fritz works with start-up and early stage technology companies to help them develop and launch new technology

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Mr. Fritz has been a frequent lecturer nationally and internationally on the topic of new product development. Mr. Fritz received his B.S. in Management and M.B.A. in Marketing from the University of West Florida. He graduated with an M.S. in Management of Technology from UTSA and is completing his Masters in Health Administration at Texas State University-San Marcos with an anticipated graduation in May 2010.

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