Easing the Pressure Points for Translation of Surgical Innovation

Edward J Harvey, MD, MSc and Stephanie Parent-Harvey, BS

Division of Orthopaedic Surgery, McGill University health Center Research Institute, McGill University

Innovation is easily the most overused, and perhaps misused, buzzword in medicine. The interchangeability between invention and innovation is what causes the confusion. Inventions are not innovations. Incremental improvement is not innovation and may not even be invention. The understanding of these concepts clears up many problems in translation of ideas to intellectual property (IP) and then to commercialization. Every day in operating rooms around the world surgeons have ideas on how to improve their condition. Barely any of these fit the concept of innovation let alone invention. The proof is that there are very few ideas brought into a commercial ecosystem from these thoughts. Inventions need to have a uniqueness that allows them protection – by copyright or patent in most cases. Trademarks and trade secrets are other ways to individualize your ideas but less common in medicine. Patents are a social contract between a society and an inventor. A governmental approved agency grants the inventor a sectoral monopoly, while the inventor must bring their idea to public domain.

Many ideas are not protectable, either due to prior usage or claims, or because of non-patentable properties. Certain concepts may seem like an invention but may be refused due to the argument that there is evident construction or clever engineering. This means most people would think of this and it is seen as an evident improvement. Just because you paint your fridge green does not mean you can patent it. If you do have an idea that seems destined to be granted patent protection, that is an invention. It is not an innovation. For example, the airplane was an invention but the use of the airplane to allow rapid transport of people and freight all over the world is the innovation. Innovation is the scaling of technology to address a societal need that results in wealth development- monetary or societal benefit of some type. That means invention is a small part of innovation. The renaming of university departments and the adding of innovation in job titles is probably not reflecting true innovation but certainly is a buzzword for the decade.

Innovation is a lot harder to accomplish than renaming some people as innovation gurus. Innovation in medicine is actually even harder. This is due to many issues. Regulatory hurdles protect both patients and incumbent companies. Economics is another hurdle in that new medical innovations need to be better, or at least as good, as what is offered; but they also need to be cheaper in order to be added to a hospital budget. That is a bad combination for most products. This is why we see innovation in expensive care scenarios- like cardiac and vascular surgery. But medical device sales is an extremely lucrative field. In 2016, US spending on medical devices and in-vitro diagnostics was $173.1 billion, 5.2% of total national health expenditures[1]. The US is the world's largest market for medical devices. Translating your idea down the commercialization pathway requires jumping these hurdles and others. Much innovation in medicine is new product performance ideas. The doctor envisions a new plate, robot, scalpel, or other product they encounter every day. The issue is that every other person doing that profession can see the same weaknesses and come up with the same idea. This results in a race to economic parity as you battle other products coming to the same space. Going down the innovation funnel means fighting off these other products from entering your space. The method of choice for venture capitalists interested in your idea is patent protection. The way to obtain that protection is through money invested in proof of concept- either studies or functioning prototypes. You need to get money before you can be given money - a real problem for development!

Getting to this point in commercialization development is already rarified air. Driving the idea to this point means you are derisking the investment for you, your customers, and investors. Most doctors will sell their concept to an interested party rather than endure the pain that follows. But if you do progress further in the derisking process there is definitely a bigger chance of reward. The path forward is a true monetization process. A lot of money is needed for production, capitalization, and popularization. This is a cash requirement – mean development cost for a novel therapeutic complex medical device was $54 million[1]. There is no real shortcut around this in the medical device world. In software products you can put out a minimally viable product that you can fine tune over time with help from consultants and customers. Devices however must go through a design freeze at some point to have FDA review and perhaps approval. Drug discovery and development is an even more expensive endeavor requiring over a billion dollars. Obviously, this is a huge barrier to entry making this pathway difficult except for institutions and companies with very deep pockets. The concept of monetization is not hard but is still a complex of difficult pathways where the only goal for your product moving forward is to make money or get further investment. The real way to accomplish this is to build a great product that drives value and attracts money because certainly you need a lot of money to bring any

device to market. The start-up financing cycle is further complicated after founding because as you grow your team there is an increased need for money. In the early stages of a new company your financial growth is made-up in friends and family contributions or through seed capital from government and other institutional investors. It is the best policy that you seek non-dilutive funding at this stage if possible. Grants and loans are the prime target. But after you see your idea through patent protection and proof of concept there's a need to show economic viability to all other investors. This is where many companies fail. Part of the monetization start-up phase requires passing regulatory control and certainly this is something that venture capitalists look at in a very in-depth manner. You need to take your proof-of-concept device to the point where you able to file for regulatory clearance which is generally a 510K in the United States or on the other hand performed human clinical trials. These are two points the investors are looking at. There are several ways to get FDA or equivalent approval. These include premarket notification better known as 510K premarket approval, de novo evaluation for new products or of a class 3 device, and other more esoteric classifications. Most people in surgery are looking at incremental improvement on a previous concept and this is more of a premarket notification. Most medical devices come in on this 510K premarket notification. There is a similar process in most countries, although there is a global trend to accept American FDA clearance in other countries. Regulatory clearance and IP protection represents a major derisking point for both you, your company, your idea, and investors. It is really at that time there's a decision point for your idea where you are either going to sell or license the product or embark on a real-world company. Starting a company means bearing with market valuations and the vagaries that go along with commercialization. This decision point usually involves the incorporation of the concept that you must make your idea work for commercialization. This dictates that you either have to make something no one else has, such as a niche product or process, or you have to make the product cheaper than everything else in the market. Sometimes you must do both things, and this is very difficult. Getting through this stage in the monetisation phase means that you are now headed towards a scale up concept. This is capitalization where you must bring in money to develop your product and sell it. It would be ideal if you could do this without loss of control of your company or product designation however this is not always possible. Derisking your product means bringing other people in to make it successfully scale, and this team building is really one of the major sticking points in hurdles for eventual success.

Scaling a device or idea means bringing it to market with a team of experts. Part of this is building capital in order to bring your concepts to reality. You also must define goals for your product and company. This requires you to create infrastructure and build your team while generating sales and delivering value. Although these all seem to be sequential, they actually all happen at once. This is the controlled mayhem that can sink many products. It is this at this time that most doctors realize that they cannot do this while maintaining a clinical practice or they may realize they actually don't have the economic toolkit to do this themselves. This is when team building becomes very important. How do you know if your idea is going to make it going forward? You should have an idea that your product is going to improve patient care physician satisfaction, while fulfilling payer requirements. Physician fulfillment is usually the easiest part of this because most medical products are brought forth from dissatisfaction with the physicians' day-to-day workflow. Patient care is the other concept that is fairly simple because most of the physician's day-to-day workflow is centred on patient care. The concept of making sure that the payer is happy is a foreign concept to most physicians. It becomes more of a costing exercise and risk management for the eventual purchasers of the product that will allow your device to get to a bigger population. Investors like genuine enthusiasm amongst physician users at this point of the innovation cycle. Communication is extremely important at this point in the journey. You need to be able to communicate to your investors how you are making money. This needs to be crystal clear in the way you communicate it. You need to analyze the market, and both understand and communicate intended primary market size and expanded secondary market size to investors. You need to have a market fit optimization or value to all the parties the physicians, patients, and providers is clear. It would seem at this point that it would be simple to bring your product to the masses however the last value of death in the innovation cycle is popularisation. Good products can fail even at this point. It is very difficult to sell your product early on in its life cycle to the late majority or even the early majority of consumers. Your product is often being purchased by the early adapters and innovators and it is difficult to understand who is actually buying your product without in depth market evaluation. Investors look to this type of evaluation as being one of the final milestones to see whether they will invest in your idea. Sales, and lots of sales, is what will significantly increase funding interest in your product. This means that you need a break-even point in your company evolution, and you will need to understand the runway or when you will run out of money. If you can get through all these hurdles and products and you have a clear innovative product with a clear need or market and your product is preferably technologically driven, then you can win the innovation race. It is a marathon and not a sprint.

References

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