

More Difficult Than You Might Think: Bringing a Product to Market in the Eye Bank Setting

Christopher G. Stoeger, MBA, CEBT¹, Corrina Patzer, BA¹

Abstract: Bringing a new product to market in the changing landscape of an eye bank setting takes skill, perseverance, and intentionality throughout the entire organization. This article explores some of the key issues an eye bank should consider when taking a concept from idea to reality.

Key Words: Eye bank, new product development

“People think focus means saying yes to the thing you’ve got to focus on. But that’s not what it means at all. It means saying no to the hundred other good ideas that there are. You have to pick carefully. I’m actually as proud of the things we haven’t done as the things I have done. Innovation is saying no to 1,000 things.”

This is a quote from Steve Jobs at the Apple Worldwide Developers’ Conference in 1997. What does saying “no” have to do with an eye bank journal article about bringing a product or service to market? At our organization, we have spent a lot of time on really good ideas that just didn’t work out. For example, at one point in time, Lions VisionGift (LVG) had a contract with a hospital system to use their femtosecond laser in order to process corneas for Descemet Membrane Automated Endothelial Keratoplasty (DMAEK). We called this f-DMAEK.¹ This was one of the most exciting projects we have ever pursued; the enthusiasm was palpable throughout our processing and R&D departments. Who wouldn’t want to bring a product to market that combines the ease of DSAEK surgical manipulation with the rapid and perhaps better visual recovery of DMEK?² And the method included lasers, making it even more compelling. However, after a massive R&D effort on a scale that was unprecedented for our organization at the time, we elected to pull the plug on this exciting technology. Why? How did we get so far in the first place?

First, our results, while never stunning, were always encouraging. Perhaps, if our initial results had been worse,

we never would have made such a large investment of time and resources in the project. Secondly, the landscape in DMEK changed throughout the project. Surgeons who had not expressed interest in DMEK suddenly started adopting it.³ DMEK became a common practice in our service area and the need for what constituted a much more complex procedure was greatly diminished once a standard DMEK technique was adopted by the high volume surgeons we serve.⁴

Which brings us back to the original point, sometimes bringing a product to market is as much about *not* bringing a product to market as it is creating something new. A lot can go wrong or circumstances can simply change, resulting in no new product. Assumptions must be constantly tested against reality as new information is acquired. Appropriate action, although not always easy, must be taken. The process is not for the faint of heart. For LVG’s f-DMAEK program, could we have done anything differently that would have avoided the investment of more than 150 research tissues and countless work hours? It is impossible to know for sure, but it is likely, we could have determined a final course of action earlier in the process.

There are things that can be done on the front end to assess a project’s merit and help determine if development of a particular product is right for an organization. It is helpful to be as intentional as possible throughout the new product/service development pipeline. What follows are some general rules of thumb that we have found helpful after years of trial and error. New product and service development can sometimes be quite straightforward, and it can also be a circuitous path that is difficult to define. Most often it is the latter. No one set of rules will accommodate this process. There are books and courses and consultants to aid this process. This sharing of LVG’s experience is intended to bring some clarity to the process and to suggest to others to ask better questions the next time they are debating whether to bring on a new service or product.

Author Affiliations: ¹Lions VisionGift, Portland, OR USA, ¹Lions VisionGift, Portland, OR USA,

Before we dive deeper into this discussion, we must define what we consider as a new product or service in eye banking. Is marking the orientation of a DMEK graft with an “S” considered a new product or service? How about the addition of autologous serum eye drops as a service? At our organization, both of these items took a fair amount of resources to implement, and for the purpose of this article, can be considered new products. If bringing something new to customers or to a new customer demographic, then consider that as a new product or service offering for the eye bank. For this article we will consider a new service to be synonymous with a new product.

A robust program for analyzing new concepts is important. It is comprised of four main components: Defining the product (what), determining if the product meets the organization’s goals and strategies (why), understanding the customers, market, and potential revenue from the new product (who), and finally, taking the concrete steps associated with bringing the product to market (how). We will examine each of these areas in greater detail in the remainder of the article. It is important to understand that these components do not, and likely cannot, all take place in sequential order. Often there is complex interplay between each of these aspects of product development.

WHAT ARE WE DOING?

Bringing a product to market starts with an idea. It could start from a conversation with a Medical Director or a surgeon asking for something not currently provided. Perhaps, since many eye banks are considering the future of corneal transplantation, ideas are routinely being vetted for consistency with the eye bank’s mission. It is important to have a way for these ideas to be considered and developed. Some organizations have very robust systems in place for bringing ideas to the table. For example, at LVG, we have a department dedicated to organizational growth, which includes a Research and Development Scientist. Staff in this department are highly attuned to vetting new ideas. However, new ideas don’t come solely from these individuals, because it is known within our organization that we have expertise and time devoted to exploring new products and services. This creates a rich environment from which new ideas can be explored, evaluated, and given a chance to grow.

The “what” piece can and should include an analysis of the risk associated with bringing a product to market. When considering risk, an analysis should include the regulatory pathway, likelihood of success, costs associated with development and marketing the product, and even the intellectual

property landscape. This analysis may take place multiple times throughout the product development life cycle as new information is gathered by the organization.

WHY ARE WE DOING THIS?

Before the conversation starts regarding a specific new product, it is helpful to have a strategic discussion about what the eye bank wishes to bring to the table in the future. Considerations might include: Is the organization open to bringing new ideas to market? How focused is the eye bank’s mission? Would it be unreasonable to process a tissue for research? Would it fit the mission to create a device that makes surgery easier and safer? What are the internal skill sets and the weaknesses? It is impossible to plan for all possibilities, but having a discussion at a very high level can prepare an organization for setting aside the resources needed to take action, or pass, the next time an opportunity presents itself. A discussion of this nature can prime an organization to seek the kinds of opportunities it desires to make a reality.

The “why” portion of the new product development life cycle can answer some important questions about the product in relation to the market. Is this a revenue generator? A response to a competitor’s product? Will it create greater efficiency for the organization? Is a surgeon/ customer asking for this? Will this diversify your revenue stream? Does it fit the mission and strategic vision?

For example, let’s say that an organization has developed a novel software program to solve an internal problem. Perhaps inventory at the organization was initially difficult to manage and now it is handled with such ease and granularity that now a piece of your cost structure is controlled in a much more refined manner. Wouldn’t other eye banks benefit from this piece of software? Could this product be brought to market? A product such as this begs many questions about support levels and deployment and protection of intellectual property once the product is released. Does it fit the organization’s mission to bring the product to market? Is it compatible with the organization’s strengths? If the answer is, “yes”, then proceed to the next step.

WHO IS THIS PRODUCT FOR?

The target market of this product is very important to consider. Perhaps a product presents a surgical advantage to the surgeon, but the cost is substantially higher. That could be a difficult product to market depending on reimbursement issues. For example, initially there was a lot of interest in femtosecond laser shaped penetrating kerato-

plasty grafts. While this technology was very exciting as it promised wound architecture that fits like a lock and key, it was only utilized 154 times in the US last year (2016).⁵ Why? It may never be completely known, but this technology is expensive on a number of levels. The population of patients that could pay out of pocket for this procedure was quite small, and the surgeon base with the infrastructure and desire to implement the procedure was even smaller. Thus, a rather intriguing technology has been relegated to the fringes of the cornea transplant community, at least in the US. So this is an example of a product that promised some benefit but not enough to radically alter practice paradigms and justify attendant cost increases.

Figuring out who the market is may be one of the most important pieces of the product development life cycle. Knowing to whom you must market, enables a much deeper understanding of the ability to reimburse for costs, the volume of demand, and a built-in quality feedback loop that can be used during the development process.

HOW WILL THIS GET IMPLEMENTED?

The “how” of bringing a product to market can take many steps depending on the product. For example, if the product is a medical device, then regulatory requirements may be substantial and of a much different scale and skill set than typically found in an eye bank. Here, knowing the limitations and seeking appropriate help early on (e.g. starting a dialogue with the FDA early) can help avoid excess time and resource expenditures down the line. The how of bringing a product to market is often the biggest piece of the process. The “how” portion is also where cost structure is crystalized and requires a feedback loop back to the “what” and “why” phases. Perhaps an eye bank wishes to subsidize a new product that is in the interest of its mission. This should only be done intentionally in order to ensure continuity of services the eye bank already provides.

There are some very obvious costs associated with any new product, such as the cost of purchasing the supplies needed to create the product. But other costs may not be so obvious. For example, any new service or product requires staff training, process validation, marketing costs, accounting costs, and information systems support. If additional staff is required, then the cost of personnel tied to the procedure can be calculated, but how much is the administrative overhead for human resource management? It is common to underestimate the true costs associated with providing a new service. Therefore, consider everything related to the costs of a product and factor in the likelihood that something may be overlooked.

Focusing on costs will help formulate an implementation and sustainability plan that will act as an outline for the project. Once an outline is formed, a team representing the eye bank’s stakeholders who will be engaged to bring the product to market must review the work to be done and split it up accordingly. Project management becomes the dominant force in this stage of new product development. A checklist overview of the components to consider when developing the project plan can be found in Table 1. This is a high-level view of a product development plan which can get extremely complex depending on the nature of the product.

Table 1

Checklist of items to consider before bringing a new product to market

What are we doing?

- Define your product.
- What are the projected costs?
- What is the regulatory environment?
- Is there intellectual property tied to this product?
- Do you have the internal skills to bring this product to market?

Why are we doing this?

- Does it align with our mission?
- Does this achieve a strategic goal?

Who is this product for?

- Define your market.
- Is the market sufficient to justify the investment?
- Do you have access to this market?

How will this get implemented?

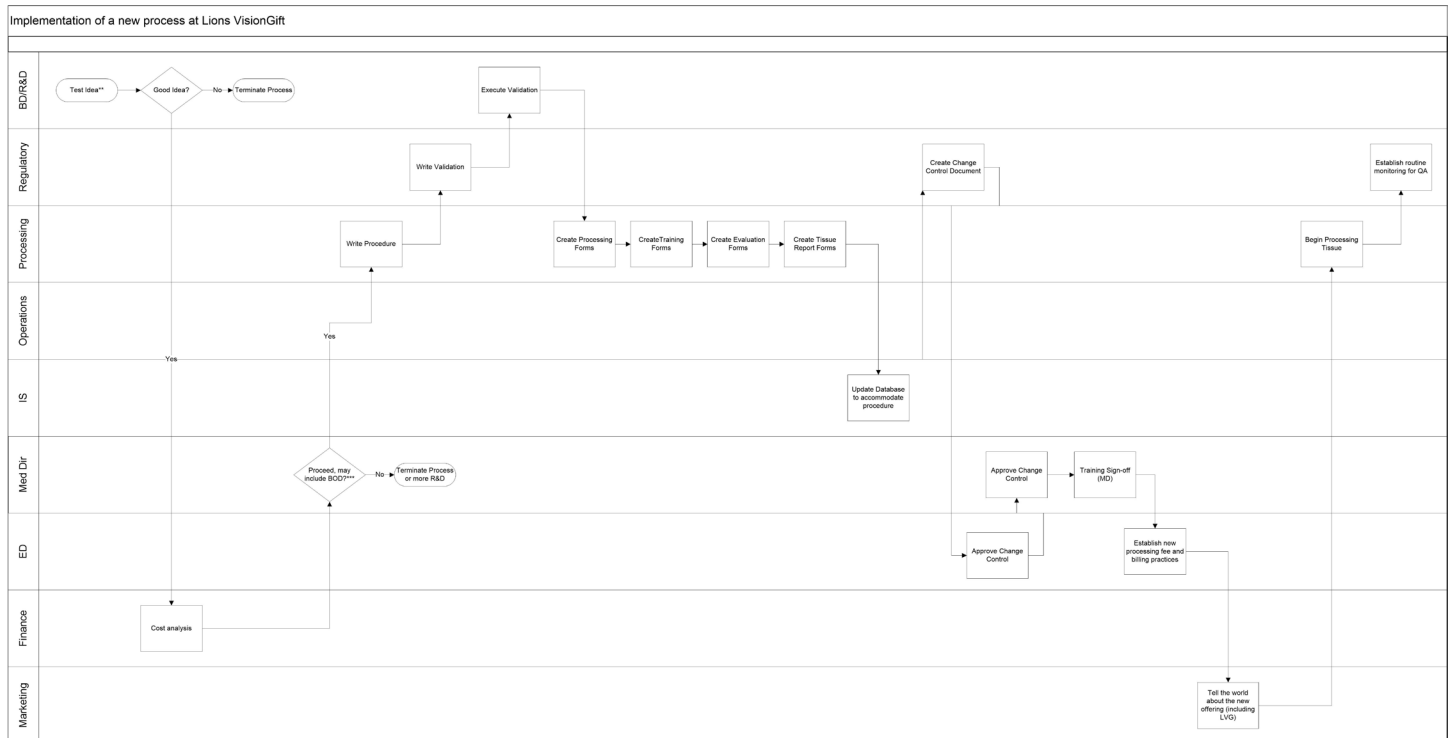
- Costing
- Product development/R&D
- SOP(s)
- Validation(s)
- Form(s)
- Project staffing
- Product staffing
- Training
- Information Systems Updates
- Pricing
- Billing
- Communication plan – internal
- Communication plan – external (marketing)
- Ongoing quality monitoring and further improvements
- Distribution

CONCLUSION

Bringing a product to market offers inherent change to an organization, which may be as simple or complex as the product itself. This process is never truly simple as shown in the work flow diagram in Figure 1. Organizations willing to develop new products must be willing to embrace

provided in Table 1 will mitigate the risks associated with each item. No plan is foolproof; but a fool fails to plan. Don't fall into the trap that a well-planned project doesn't need to be constantly tested, and do not be afraid of failure. Some failure is bound to happen when tackling large projects and is in fact the sign of a healthy environment of innovation. Now go forth and change the world.

Figure 1 Conceptual product development work flow diagram with swim lanes showing the different departments involved. Steps are described in a linear time frame despite the fact that some steps take place concurrently or out of sequence depending on the project.



change and intentionally manage implementation processes or these processes can wreak havoc. That said, it can be very rewarding to bring something new to the world. New products can make a tremendous difference in the lives of recipients and surgeons while at the same time they have the potential to diversify eye bank revenue streams. As non-profit entities dedicated to a charitable benefit, eye banks tend to focus on the benefit to the community when considering new endeavors. And this is good. A healthy awareness of the financial impact of new products will help protect the rest of the organization's established service lines.⁶

There are many items to consider when bringing a product to market. Due diligence on every aspect of the checklist

REFERENCES

1. Jardine GJ, Holiman JD, Galloway JD, et al. Eye Bank-Prepared Femtosecond Laser-Assisted Automated Descemet Membrane Endothelial Grafts. *Cornea* 2015.
2. McCauley MB, Price FW, Jr., Price MO. Descemet membrane automated endothelial keratoplasty: hybrid technique combining DSAEK stability with DMEK visual results. *J Cataract Refract Surg* 2009;35(10):1659-64.
3. Terry MA. Endothelial keratoplasty: why aren't we all doing Descemet membrane endothelial keratoplasty? *Cornea* 2012;31(5):469-71.
4. Terry MA, Straiko MD, Veldman PB, et al. Standardized DMEK Technique: Reducing Complications Using Prestripped Tissue, Novel Glass Injector, and Sulfur Hexafluoride (SF6) Gas. *Cornea* 2015;34(8):845-52.
5. Eye Bank Association of America. 2016 Eye Banking Statistical Report. Washington D. C.: Eye Bank Association of America, 2017.
6. Hanna C. Eye Bank Finances in the 21st Century: Tools to Educate Leaders for the Eye Bank of the Future. *International Journal of Eye Banking* 2016;4(1):1-5.