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Biomedical device innovation methodology: applications in biophotonics

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Abstract. The process of medical device innovation involves an iterative method that focuses on designing innovative, device-oriented solutions that address unmet clinical needs. This process has been applied to the field of biophotonics with many notable successes. Device innovation begins with identifying an unmet clinical need and evaluating this need through a variety of lenses, including currently existing solutions for the need, stakeholders who are interested in the need, and the market that will support an innovative solution. Only once the clinical need is understood in detail can the invention process begin. The ideation phase often involves multiple levels of brainstorming and prototyping with the aim of addressing technical and clinical questions early and in a cost-efficient manner. Once potential solutions are found, they are tested against a number of known translational factors, including intellectual property, regulatory, and reimbursement landscapes. Only when the solution matches the clinical need, the next phase of building a “to market” strategy should begin. Most aspects of the innovation process can be conducted relatively quickly and without significant capital expense. This white paper focuses on key points of the medical device innovation method and how the field of biophotonics has been applied within this framework to generate clinical and commercial success. © 2017 Society of Photo-Optical Instrumentation Engineers (SPIE) [DOI: [10.1117/1.JBO.23.2.021102](https://doi.org/10.1117/1.JBO.23.2.021102)]

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1 Introduction

Medical devices diagnose, cure, treat, or prevent disease through affecting the body and do not achieve this primarily through chemical action nor do they require being metabolized to achieve their effect.¹ The pathway for commercialization of medical devices, from idea to patient, involves a carefully planned process as there are many risks and challenges that must be managed.² Because the ultimate aim for any medical device is to improve outcomes for patients, this need should be considered at the start of the process and not the end.²⁻⁴ Invention in academia, without focusing on the unmet clinical need, can often create a technology looking for an application; in other words, a solution looking for a problem. Often, this is to some extent inevitable, as researchers must focus on technical aspects of invention to ensure device prototypes can be developed. However, a device that does not have sufficient patients, markets, or reimbursement, which can potentially benefit from it, is a common cause for failure of early stage medical devices and arguably should not be developed in the first place.^{3,5-7} Often, in academic settings, particularly in highly technical fields such as biophotonics inventors can be isolated from patients and industry, and these gaps need to be bridged

early with constant interaction and consultation from the beginning.^{5,8} Collaboration also needs to occur across fields, including engineering, science, business, and clinical expertise; a team will struggle when one of these core fields is lacking.⁹⁻¹³ Industry collaborations can also provide an alternative pathway for funding, such as PIXELTEQ’s innovation grant program that has accelerated their multispectral sensing and imaging applications in medicine.¹⁴ Unless diligence is placed at every step of development, an individual concept is destined for failure. These developmental steps have been carefully defined and refined into the process of medical device design, also known as “biodesign.”^{10-12,15,16} Biophotonics has been fortunate to see a wide range of very successful companies flourish and is thus an excellent area to illustrate the process of medical device innovation. Companies, such as Xenogen, Nellcor, Zeiss Medical, and Heidelberg Engineering, are having large impacts in the healthcare sector. In this review, to illustrate particular aspects of the device development journey, we mention companies ranging from early start-ups to well-established medical device players.

2 Identification Phase

2.1 Identifying and Screening Needs

Medical device development should begin with a thorough understanding of what problem needs solving. A formal

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needs-finding process is useful in identifying specific clinical gaps or problems that are not addressed by existing solutions or technology.⁵ In medical device invention, this is predominantly performed by identifying an unmet or undermet clinical need.^{3,17} The chief executive officer of ViOptix (Fremont, California), a company that uses near-infrared technology to measure oxygen saturation in soft tissues affected by reconstructive surgery, recently stressed the importance of focusing on the problem first prior to determining a specific solution at the 2016 Biomedical Conference and Exhibition.^{18,19}

Understanding the need involves understanding everything there is to know about the problem, including the disease process, current and future treatment options, health economics of the problem, and who are the stakeholders that combine to create or influence the problem.^{10,20} This is often the essential first step in the device innovation process.^{10,15,21} Either in an academic or industry setting, needs-finding may occur as a result of researching investigating specific topics, either directly or through trainees and postdoctoral researchers with whom they are working. Needs-finding is particularly applicable in the realm of biophotonics, a multidisciplinary field that involves the application of optical techniques to biological processes, from molecular to tissue levels.²² Moreover, innovation in biophotonics is likely to grow; for example, industry veterans have described a rising demand for optical sensors in medical equipment.²³

Interviews with potential end-users and stakeholders are an additional source of important information for needs-finding.¹⁵ An innovator might dedicate a significant block of time to needs-finding and then to sort through all of the medical problems identified, organize, and screen these needs according to their own interests and strategic focus.¹⁵

A need represents an opportunity for a yet undefined solution to improve the current system. A key distinction, here, is that needs-finding identifies areas in need of improvement and does not specify solutions at this stage. This can be challenging for individuals who are more familiar with the process of applying existing technology to new domains or problems. However, maintaining focus first on the unmet need can lead to increased likelihood of success in the long term.

2.2 Understanding the Disease State and Existing Solutions

A thorough understanding of the fundamentals of a clinical process is an essential and early step in the innovation process.¹⁵ This relates not only to the clinical physiology, pathophysiology, and mechanism of action of the process but also the epidemiology and economic impact as well as the workflows surrounding use and acquisition protocol of the device.¹⁵ Consideration of the processes that surround the core use of a device at this stage is frequently helpful for concept generation, a later step in the process.

For example, a medical device company, Dornier, recently developed a new holmium laser fiber designed with heat-resistant technology to withstand the high temperatures necessary for sterilization.²⁴ The holmium:YAG laser has been described as the gold standard for endoscopic lithotripsy.²⁵ In addition to realizing that urologists require an efficacious laser for lithotripsy, this new heat-resistant technology was designed to circumvent the problems of heat damage that other equipment is susceptible to during cleaning.²⁴ By realizing that damage or delay from high-temperature sterilization

could affect the clinicians' efficiency over the day and the long term use of the device, the team identified an additional area in which their device could gain an advantage over competitors.

Moving beyond the fundamentals of a disease process, it is essential to develop a rigorous understanding of the existing and emerging solutions for a given problem or need.¹⁵ This enables the innovator to identify the solutions that are already in place or coming into play and to ascertain what specific shortcomings in current solutions persist. A thorough analysis of existing solutions identifies essential patient and clinical factors that prior solutions utilized. This analysis can then delineate a line against which new potential solutions can be compared.¹⁵

In the case of Earlens (Menlo Park, California), the company began with an evaluation of hearing loss and saw that it most commonly affects more than half of U.S. adults over 70 years of age²⁶ and 15% of the population between 20 and 69 years of age.²⁷ There are already a variety of specific hearing amplification devices available to help these patients, including in-the-ear devices, receiver-in-ear devices, behind-the-ear devices, and ear canal devices, as well as digital and analog formats. Importantly, they found that along with the usual problems of hearing aids, such as the stigma associated with wearing them, there were significant audio feedback issues limiting use beyond certain levels of hearing loss.^{28,29} Identifying the gap in the hearing loss population allowed Earlens to invent a solution that amplifies sound through light and, therefore, avoid traditional hearing aid feedback issues.^{30,31}

2.3 Stakeholders and Market Analysis

In the field of medical technology, a stakeholder is any party or person that will be affected, positively or negatively, by a change in the workings of the medical system in its provision of medical care.¹⁶ In a traditional medical model of stakeholder analysis, these parties are the physicians, the patients, the health-care facilities, and the payors but can include other entities. Understanding the varied and diverse participants and stakeholders engaged in the use of a new medical device or solution is essential. Physician engagement during development was key in the adoption of optical coherence tomography (OCT) in ophthalmology. OCT is now the gold standard for the diagnosis of a number of ophthalmological diseases, such as macular disorders.^{32,33} This relates not only to the physician who is using the end product but also the hospital system that permits use of the device and the payors that may cover the cost of the device.¹⁵ These payors can be private insurance companies or government programs, such as Medicare or Medicaid in the USA. Stakeholder analysis also includes the patient, who will presumably benefit from the device, but may also incur out-of-pocket costs.¹⁶ Patient and user feedbacks are critical in the early and prototyping stages.^{34,35} OCT has been paired with surgical microscopes to provide intraoperative monitoring of microsurgical anastomoses, which may improve patient outcomes.³⁶ One challenge with OCT was that decreasing cost and/or imaging speed came at the expense of imaging resolution; as part of the iterative process of improving OCT, one group designed alternative processing methods and algorithms to solve this issue.³⁷

When performing a stakeholder analysis, it can be helpful to delineate the "cycle of care," which describes how patients move through their healthcare environment, and "flow of money," which details the payments and charges surrounding the clinical

process.¹⁵ An innovator should first identify all stakeholders with an interest in the clinical process and then explore obstacles and attractive attributes that may cause each level of stakeholder to either resist or support the adoption of a new technology.¹⁵ An early, sound stakeholder analysis will inform, direct, and smooth the process of device development.¹⁶

A brief stakeholder analysis, as encountered by Earlens (Menlo Park, California), is presented in Table 1. One can see that since the patient pays the majority of the cost for a hearing aid, they are the primary decision-maker in this process.

Market analysis completes the first stage of the device innovation process. Many researchers have identified an unmet need and produced an innovative and effective solution only to realize after the fact that their solution was not economically viable or directly competed with an existing solution from a powerful competitor in a crowded marketplace. For this reason, market analysis is an integral step in screening potential needs. An example is Coherent's (Santa Clara, California) success in the medical laser market. The medical laser market was estimated at \$5 billion in 2016 and predicted to increase to \$11.5 billion in 2022, with an annual growth rate of from 2017 to 2022.^{38,39} Coherent must keep an eye on such market projections as well as existing and potential future competitive technologies if they are to maintain their market position.

Bringing new solutions to market is an expensive endeavor, and the innovation team must ensure there is an accessible and sufficiently sized market that will support the development of their idea.¹⁵ When assessing a healthcare market, it is important to evaluate both the current size and potential for future growth as well as competition in the specific market. One efficient method to perform market analysis begins with a high-level, broad analysis to survey a market, which estimates the total market and gaps that could be addressed by a new solution. This analysis continues with market segmentation, which divides the total market into distinct sections that share specific needs, and closes with identification of a target market, which specifies what market segment will have the most to gain from a new solution.¹⁵

2.4 Needs Statement

Often, the research performed through the identification phase is organized into a statement that combines an exact problem,

population, and outcome.¹⁵ The problem describes the health care issue requiring improvement, the population identifies the patient group to whom a solution will be directed, and the outcome states the measurable, targeted change that will occur.¹⁵ Forcing specificity and precision with the needs statement enables the innovation team to identify key measures that will judge the success of their solution and focus their future search on a specific solution in subsequent steps of the innovation process. OCT in combination with elastography and/or microelastography has a large number of potential clinical applications, but it was the ability of the founders of OncoRes Medical (Perth, Western Australia, Australia) to focus and define the unmet need of tumor margin assessment in breast-conserving surgery that led to accelerated development and opportunities for investment.⁴⁰⁻⁴⁴

Hearing loss is a prevalent, chronic condition that affects tens of millions of Americans and has a significant social and professional impact.^{45,46} Individuals with hearing loss wait on average a decade for an intervention after initially experiencing hearing loss.⁴⁷ In addition, acceptance and uptake of hearing aids have been demonstrated to be poor.²⁸ Many patients note that there is a stigma to using hearing aids and that while hearing aids provide some hearing benefit, the technology has limitations in terms of feedback and frequency range. The scope of this problem is large, and while there are currently alternative solutions, e.g., traditional hearing aids, to help these patients, this problem represents the origins of a clinical need. An early needs statement for a company, such as Earlens (Menlo Park, California), that uses light to drive a photo actuator on the tympanic membrane, could be "a way to improve hearing among adult patients with sensorineural hearing loss to improve speech comprehension and device compliance."

3 Invention Phase

3.1 Brainstorming

Ideation and concept generation are the next step once the identification phase is complete, and inventors will begin to explore potential solutions. This can take the shape of brainstorming ideas with all members of the innovation team, with the goal of generating many potential solutions. It can be helpful to identify attributes of any theoretical solution that are "must have" and "nice to have" to aid in prioritizing specific solutions during

Table 1 An example of a stakeholder analysis for a hearing loss device.

Stakeholder	Role	Primary benefits	Primary costs	Net impact
Patient	Decision maker—purchaser	Improved hearing and associated improvements in social and professional interactions	Financial cost, not frequently covered by health insurance	Uncertain—depends how solution compares to existing hearing aid options
Audiologist	Influencer	Improved hearing for patients. May benefit directly from sale of device. Benefits indirectly from clinic appointments to program device	With multiple new hearing devices on the market, it may be challenging to learn all of them	Likely positive
Otolaryngologist	Influencer	Improved hearing for patients. May benefit directly from sale of device	None significant	Positive
Payors	Influencer	Minimal	In rare situations may cover the cost of a hearing aid	Neutral

the next phase.¹⁵ Design thinking has transformed the ability for cross collaboration, and the focus for teams looking to generate ideas is to aim for quantity over quality at first and encourage wild ideas. Short, focused, and team-based sessions that lead to a rapid generation of ideas are encouraged. By taking this approach, maximum results can be achieved in a short amount of time by building excitement, gaining alignment of participants, and transferring ideas around the group.^{48,49} One such brainstorming session, involving clinicians and engineers, led to an innovative noninvasive way to detect anemia using reflectance spectra of the palpebral conjunctiva.⁵⁰

3.2 Prototyping

After a robust list of potential solutions has been created, the team selects a subset of solutions to focus on based upon those that are most promising. Solutions can be grouped anatomically, mechanistically, by technical feasibility, or by their level of appeal to funders or influencers.¹⁵ Once a lead concept has been selected, they can be explored through touch and feel. Building a prototype should be done to answer technical questions as cheaply and as quickly as possible.⁵¹ Addressing the biggest risks first is worthwhile as long as these do not require a large amount of money and time. Each stage of prototyping can be built upon in a stepwise fashion, gradually reducing the technical risk of the idea at each stage.⁵² The temptation can be to build the best prototype possible, but this can be a waste of resources if it is determined that there is a “no go” point or technical risk that should have been identified earlier in the process before committing too much time and resources.⁵² Rather than build a complete wearable photoplethysmography device, competitor inventors can begin by working on the wearability first, before integrating the science. If the new device is not as wearable, then it is highly unlikely to gain adoption, even if the science is superior to a competitor device.⁵³

4 Implementation Phase

4.1 Intellectual Property

A sound intellectual property (IP) and regulatory strategy are crucial aspects of any specific solution. A strong IP position can protect one’s idea, serve as a barrier to entry for other competitors, and may generate revenue through license agreements.¹⁵ Patents form the groundwork of an IP strategy. Simply stated, a patent is a document that grants exclusive rights and ownership to make, sell, or import an invention. Perhaps more importantly, it excludes others from making, using, selling, or importing this IP. For an idea to be patentable, it must have “utility,” “novelty,” and “not be obvious” in light of prior art.

Understanding the patent process and employing legal counsel, who can help identify any freedom to operate issues, is a key component when forming one’s IP strategy. In the U.S. and other jurisdictions, it is commonly recommended to file an inexpensive provisional patent to acquire an early priority date prior to filing a full utility patent, which can be expensive and time consuming. After a national filing, one may consider filing internationally, which can be associated with significant costs.¹⁵ While the end goal of a patent application is an issued patent, the innovator must keep in mind that filing a patent application can be a long, expensive, and litigious process. Recently,

the overall patent success rate has been higher for medical device patent owners compared to all patent owners.⁵⁴

4.2 Regulatory Strategy

A thorough consideration of the regulatory pathway for any new medical device is essential.^{55,56} The regulatory process takes a significant amount of time and effort that not only permits a device to be marketed but also informs sales and marketing strategies as well as risk management policies.^{15,57} Often, research experiments are specifically designed for Food and Drug Administration (FDA) approval or preapproval, as was the case for an OCT system used by cardiologists for coronary artery imaging.⁵⁸ If a device meets criteria to be regulated by the FDA, the innovators must identify which pathway they intend to pursue, 510(k) or premarket approval (PMA); this is a complex decision that must include information, such as what class of medical device their innovation is as well as if a predicate device exists.

Typically, clearance under the 510(k) pathway relies upon the idea of equivalence to a predicate device, which has already been cleared by the FDA.^{15,59} The team must identify the predicate device they are aiming to demonstrate equivalence to. Additionally, a *de novo* 510(k) pathway is an option for devices that do not have major risks but for which no predicate device exists.^{15,59} The PMA pathway requires a far more detailed and lengthy application, including clinical trial data in which investigators must demonstrate a reasonable assurance of safety and effectiveness.^{15,57,59} Clinical trials and thus PMA submission are quite expensive, with the median costs for clinical trials in the millions if not tens of millions of USD.⁶⁰ Recently, iCAD (Nashua, New Hampshire) received PMA approval for a three-dimensional digital breast tomosynthesis cancer detection and workflow solution, based in part on the results of their clinical trial.⁶¹

Earlens, who designed a new light-driven hearing aid, needed to acquire FDA approval, which requires demonstration of safety and efficacy. Presumably, based on traditional and approved hearing devices and a lack of light-driven devices, they were required to develop down the *de novo* 510(k) pathway. A detailed safety and effectiveness study of the device demonstrated that there was no worsening of residual hearing in patients with hearing loss who were trialed with this device for 120 days and that no serious device or procedure-related adverse events occurred with use.⁶² This study also showed an improvement in word recognition scores with the device, a commonly used metric of understanding speech. These data were used to support a *de novo* 510(k) submission to the FDA.⁶²

4.3 Reimbursement

Ultimately, a medical device will need to attract reimbursement from payors, or patients will need to pay for the entire cost. Reimbursement codes can be confusing but can be the ultimate factor that makes or breaks a medical device company.^{63,64} When there is no direct reimbursement, hospital-based purchasing groups that make decisions on value become critical. This ties into evolving health care economics where decisions that look to save “health care dollars” are more important than improving “health care standards.”⁶⁵ It has been recognized that one factor for the sustained success of OCT in ophthalmology was the development of new reimbursement codes.⁶⁶

4.4 Quality

Medical devices are required to fulfill certain levels of quality systems along the journey to full regulatory approval. The FDA requires that good quality assurance practices, including design controls, are employed for medical device design.⁶⁷ Even investigational device exemptions, which may be applied such that a device can be used in a clinical study to acquire safety and efficacy data, require design controls.⁶⁸ Quality standards can add significant cost when introduced early, and so decisions must be made along the development pipeline as to when is best to implement different systems.⁵²

Regardless of the implementation of a particular quality system, the development must be pursued with the end goals of patient care and a successful business in mind and careful documentation must be made.⁵² An example of a failure in quality development was when manufacturers of pulse oximeters used different wire configurations resulting in several burns at the site of the red light-emitting diode.⁶⁹

4.5 Developing a Business Strategy

The device innovation process can largely be conducted by the innovators themselves up to this point, at least to a basic level. While devices of different complexities require varying amounts of financial support, the process to this stage can often be accomplished without significant capital expense or outside expertise. While prototyping may require minor funds, early prototypes need not and should not be expensive. Filing for patents is expensive, but a small number of provisional patents are inexpensive and delineating an early IP strategy need not be costly.

Only after all the the above considerations and challenges have been met can a medical device progress to the next phase of raising capital to bring the idea to market.¹⁰ A detailed description of the business strategy is beyond the scope of this review. Adding to the challenge, inventors also need to go through the process in an evolving health economics climate where the trend is away from introducing innovations that bring large costs but only have an incremental improvement in health.^{70,71} Performing the process correctly is important; regardless of the market size, it can take 5 to 10 years to bring a medical device to market in a biophotonics industry.^{10,72}

5 Conclusion

Biophotonics researchers are at the forefront of medical device development, but the difference between success and failure relies on diligence through a defined process of problem identification, invention, and implementation.

Disclosures

Peter Luke Santa Maria is a consultant for Earlens (Menlo Park, California). Brendan F. Kennedy is a founder and shareholder in OncoRes Medical (Perth, Western Australia, Australia). In addition, he performs funded research for this company. The other authors have no relevant conflict of interests to declare.

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