

A Perspective on Needs Identification for Successful Cardiovascular Device Innovation

Elizabeth Goldenberg¹ and Wesley Pedersen MD²

¹Research Associate, Twin Cities Heart Foundation, Minneapolis, MN, USA.

²Director of Research and Device Innovation at Twin Cities Heart Foundation, MN, USA.

*Correspondence:

Wes R. Pedersen MD, Director of Research and Device Innovation at Twin Cities Heart Foundation, MN, USA, Tel: 1-612-669-9129; Fax: 1-612-924-4148.

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ABSTRACT

A compelling “need” identification is essential prior to initiating the lengthy, demanding and often frustrating pathway necessary for cardiovascular device innovation and development. Over the past few decades both iterative and transformational treatments have been especially profound in cardiovascular interventional and surgical approaches which have necessitated innovation in devices to bring these novel approaches to fruition. Stakeholders in the development of such devices have included amongst others, clinicians, patients and institutions. Given the numerous hurdles for medical device development including the need for multidisciplinary teams, establishing intellectual property portfolios, conducting market in tandem with academic research, funding, identifying regulatory and reimbursement strategies, a rigorous process for needs verification is mandatory. This vital first step needs to be methodical and is the topic of brief discussion in this perspective manuscript.

Keywords

Biomedical, Cardiovascular, Device, Innovation, Needs.

Discussion

Identification of compelling needs serves as an essential foundation upon which are built successful innovations for cardiovascular and other medical devices. Needs verification remains essential irrespective of the stakeholders, each having their unique requirements. It is noteworthy that cardiovascular physicians strategic focus such as interventionalists, cardiac and vascular surgeons are uniquely positioned for identifying relevant device needs. These physicians have a central role in interfacing with the multitude of stakeholders which have separate or overlapping needs, creating opportunities for device innovation (Figure 1) By way of example, an operator may experience frustration with methods for implanting an iterated or transformational device. The identified need can in short be transformed into an opportunity for a novel solution. Such a scenario brings light to needs opportunities which may be fortuitous or deliberate for various stake holders discussed below. It's been noted that identified needs for novel

surgical instruments and methods are commonly brought forth by a less experienced operator. Extensively experienced surgeons have learned to use “work arounds” with antiquated tools with relative safety and an only modest drag on surgical efficiency [1]. These operators may be less open to the utility of novel approaches.

Needs identification was critical to the explosive and transformational cardiovascular innovations for coronary and peripheral arterial disease revascularization in the 1980's and '90's. With the transcatheter technology developed during this period it was more expeditious pursuing opportunities for needs in the structural heart, especially valvular heart disease spaces in the first two decades of this century. A growing population of elderly or debilitated patients with this quality of life and survival limiting diseases there is an expansive need for minimally invasive or transcatheter interventions who are not candidates for standard surgical approaches. Physicians have long been aware of this populations needs for innovation.

Needs criteria has to be vetted prior to embarking on the complex, demanding and lengthy process of device innovation. Needs

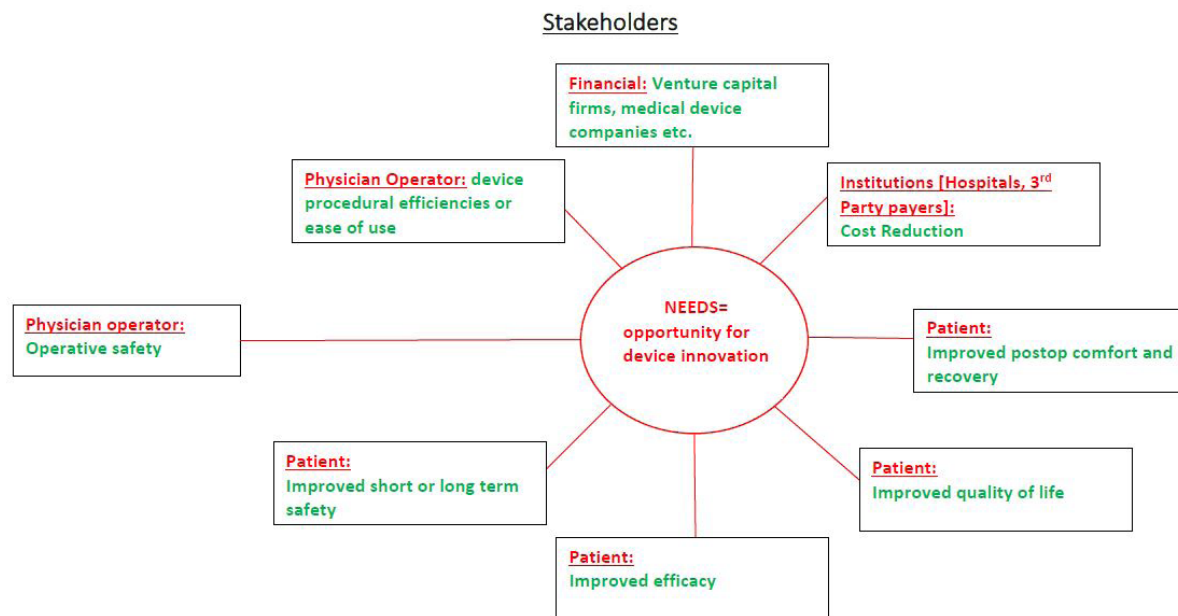


Figure 1

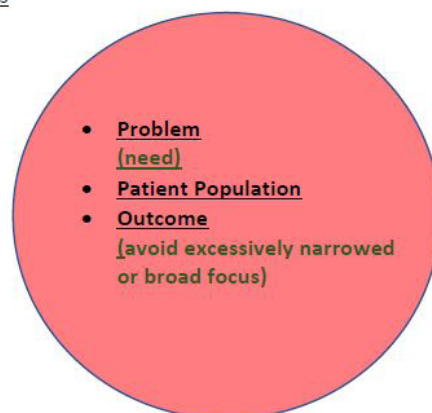
Figure 2. Cardiovascular Device Needs Verification

- Requires needs screening
 - Verify by multiple operative repetitions and other operator consensus with similar strategic focus
 - In depth understanding of pathology
 - Population size and growth trajectory
 - Roadblocks in prior art
 - Competitive technology
 - Market value
 - Regulatory approval process
 - Methods for reimbursement
 - Funding sources

Figure 3. Needs Statement: Purpose

- A foundation for the process of device innovation
- A concise statement, used for reflection and iteration during development
- Solution neutral
- Outcome focused

Includes



verification should be systematic (Figure 2). Validation should include demonstrating a consistent need by the operator over the course of multiple surgeries and confirmed by other operators with the same strategic focus. A deep dive into the microscopic and gross anatomic pathology needs to be undertaken to better understand the optimal therapy under consideration. Defining the target patient size, roadblocks in prior art, market competitors, and value should be researched simultaneously.

The likely regulatory process [2] and reimbursement options are then collated with the above into a business plan to request funding from a variety of potential sources.

Stakeholders nevertheless are varied and although generally not in conflict with each other often have different needs. The physician operator may identify the need for enhanced operative efficiency or improved ease of use for a surgical instrument. The patient along w/ their physician would certainly see the need for safe and better outcomes. In addition, a less painful and more rapid recovery have relevance to a patient stakeholder. Hospital institutions along with third party payers may focus on the need for cost reduction. Venture capital firms or other funding sources are looking for value and cardiovascular or other device companies look for innovation beneficial to patients that are profit generating.

If appropriate research confirms a needs-based opportunity for proceeding with a cardiovascular device innovation process, a "Needs Statement" should be drafted before moving to the next steps in development. The essential elements integrated into the statement has been well described [3]. The Needs Statement should be concise, represent a living reference document that can be iterated during the innovation process. The elements incorporated include: 1) the problem 2) the target population 3) the desired outcome (Figure 3). Although it should be concise, it should leave opportunity for iterative Needs Statement changes during the innovation process including pivots for unexpected impasses. The statement should be solution neutral to avoid not pursuing a superior treatment option if discovered during the process of innovation. The statement should remain outcome focused, having initially identified a uniquely important outcome.

Finally, a practicing physician having identified an opportunity to innovate a device which may offer gratifying patient based or personal financial rewards can be intoxicating. The decision to peruse two career paths carries challenges. For an interventionalist, cardiac or vascular surgeon the opportunity for bringing the device concept to commercialization themselves generally depend on the innovator maintaining their procedural skillset at least to begin with. The entrepreneurial career pathway which usually accompanies successful device innovation, is carried out in parallel. Startup ventures by nature are demanding, risky and emotionally draining even without the demands of maintaining a practice in interventional or surgical cardiovascular medicine. Academic and marketing research trials can create very real conflicts of interest with ethical and legal pitfalls. Remedies for this risk have been outlined previously, at the center of which is always full disclosure [4]. Identifying a trusted nonconflicted champion for the device innovation is highly preferred to maintain a safe distance and avoid a biased influence. One can still contribute to the innovation process as a founder with substantial input at arm's length from conflicts.

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