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Physicians are in an excellent position to significantly contribute to medical device innovation, but the process of bringing an idea to the bedside is complex. To begin to address these perceived barriers, the Heart Rhythm Society convened a forum of stakeholders in medical device innovation in conjunction with the 2015 Heart Rhythm Society Annual Scientific Sessions. The forum facilitated open discussion on medical device innovation, including obstacles to physician involvement and possible solutions. This report is based on the themes that emerged. First, physician innovators must take an organized approach to identifying unmet clinical needs and potential solutions. Second, extensive funds, usually secured through solicitation for investment, are often required to achieve meaningful progress, developing an idea into a device. Third, planning for regulatory requirements of the US Food and Drug Administration and Centers for Medicare & Medicaid Services is essential. In addition to these issues, intellectual property and overall trends in health care, including international markets, are critically relevant considerations for the physician innovator. Importantly, there are a number of ways in which professional societies can assist physician innovators to navigate the complex medical device innovation landscape, bring clinically meaningful devices to market more quickly, and ultimately improve patient care. These efforts include facilitating interaction between potential collaborators through scientific meetings and other gatherings; collecting, evaluating, and disseminating state-of-the-art scientific information; and representing the interests of members in interactions with regulators and policymakers.

KEYWORDS Innovation; Medical device; Professional societies

ABBREVIATIONS **CMS** = Centers for Medicare & Medicaid Services; **CPT®** = Current Procedural Terminology; **FDA** = Food and Drug Administration; **HRS** = Heart Rhythm Society; **ICD** = implantable cardioverter-defibrillator; **IDE** = investigational device exemption; **LCD** = local coverage determination; **NCD** = national coverage determination; **PMA** = premarket approval

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Background

The United States is a world leader in medical device innovation. However, a "device lag" has developed over the past few decades and other countries often have access to new medical devices in advance of the United States—sometimes by years.[1] Some proposed reasons for this device lag include barriers to human subject investigations of early device iterations in the United States, the higher costs associated with device development in this country, the premarket approval (PMA) process by the Food and Drug Administration (FDA), the coverage determination process by the Centers for Medicare & Medicaid Services (CMS), and lack of information available to would-be innovators. While some fundamental differences may prevent complete elimination of this device lag, various initiatives have been designed and implemented to reduce it by addressing one barrier or another. However, general information for the would-be innovator remains sparse.[2–4] Therefore, the Heart Rhythm Society (HRS) convened a forum on medical device innovation on May 12, 2015, in conjunction with the 2015 Heart Rhythm Society Annual Scientific Sessions in Boston, MA. The goal of the forum was to address device lag and the absence of information for potential innovators via an open discussion on medical device innovation for the treatment of heart rhythm disorders. Those discussions are the basis for this document, which outlines a process for physicians and other stakeholders to bring new innovative medical device ideas to the bedside. Developing new medical devices is complex, iterative, and intimidating to those outside the medical device industry, and there is a dearth of information in the public domain.[5,6]

This document outlines the major elements of introducing an innovative idea to the bedside, including managing intellectual property; securing financial investment for research, development, and commercialization; a discussion of applicable regulations by the FDA; the pathway to coverage by the CMS and other payers; and other considerations (Figure 1 and Table 1).

Preliminary Considerations for Physician Innovators

Practicing physicians can innovate in a variety of ways, including enrolling patients in research of new devices or identifying innovative ways to use existing devices. However, developing a new medical device takes special consideration and thoughtful planning. The process is nonlinear (Figure 1) and often necessitates reconsideration of the initial unmet need and possible solutions. Sometimes this repeated evaluation and reevaluation prolongs the timeline unacceptably or consumes available funds before real progress can be made. As such, developing a new device or new device company can consume enormous resources of time and money. This can be especially burdensome to the practicing physician. Therefore, it is probably unrealistic to approach a medical device innovation project as a part-time job. A physician innovator may plan to exit a project when a device reaches a certain development milestone that is of less interest to him or her, or an innovator may commit to shepherding a project from an idea to the bedside. Regardless, it is important to set limits a priori regarding the circumstances that would compel an innovator or an innovating group to abandon a project and direct resources to a project with more promise and/or more progress.[6] These a priori limits will vary considerably on the basis of whether the innovation in question is a stand-alone product or a new device company. In the former case, many small partnerships are needed to bring an innovation to market. While the intent is to achieve a better overall result through partnerships, each of these relationships could stall overall progress and dissolution of the effort may not be equally damaging to each partner. In the latter case of building a new device company, more resources and personnel are generally at stake.

The reality is that most new ideas do not work and most new business ventures are unsuccessful. This is especially true when the technology at stake is innovative and will challenge the status quo in regard to regulatory evaluation, reimbursement, and adoption. Therefore, the motivation for the physician innovator should be related to the process of discovery and invention rather than profitability. The latter may prove unattainable regardless of the quality of the idea at stake, regulatory approval, or the innovator's resolve.

The Unmet Clinical Need

Identifying the Need

As users of technology, physicians are favorably positioned to influence medical device innovation through 2 mechanisms: (1) having specific knowledge of needs and methods in their field that may not be transferable to other experts and (2) benefiting directly or indirectly from an innovation.[7–9] Indeed, there is empirical evidence that physician-founded medical device companies or those based on physician-generated intellectual property are more likely to be successful than those started by nonphysicians.[8] However, user experience may not identify a genuine unmet clinical need. Additional insight from the literature, experts in the field, subspecialty leadership, patient organizations, and device manufacturers can be helpful in clarifying and validating the need.

When identifying the unmet need, it is important to balance the significance of the clinical problem against the investment in finding a solution. In many (but not all) cases, a worthwhile solution is defined by the potential to improve patient outcomes. Other possible benefits include improvements in efficiency of health care delivery or improved patient and/or provider satisfaction. The importance of fully investigating the unmet need cannot be overstated because