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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

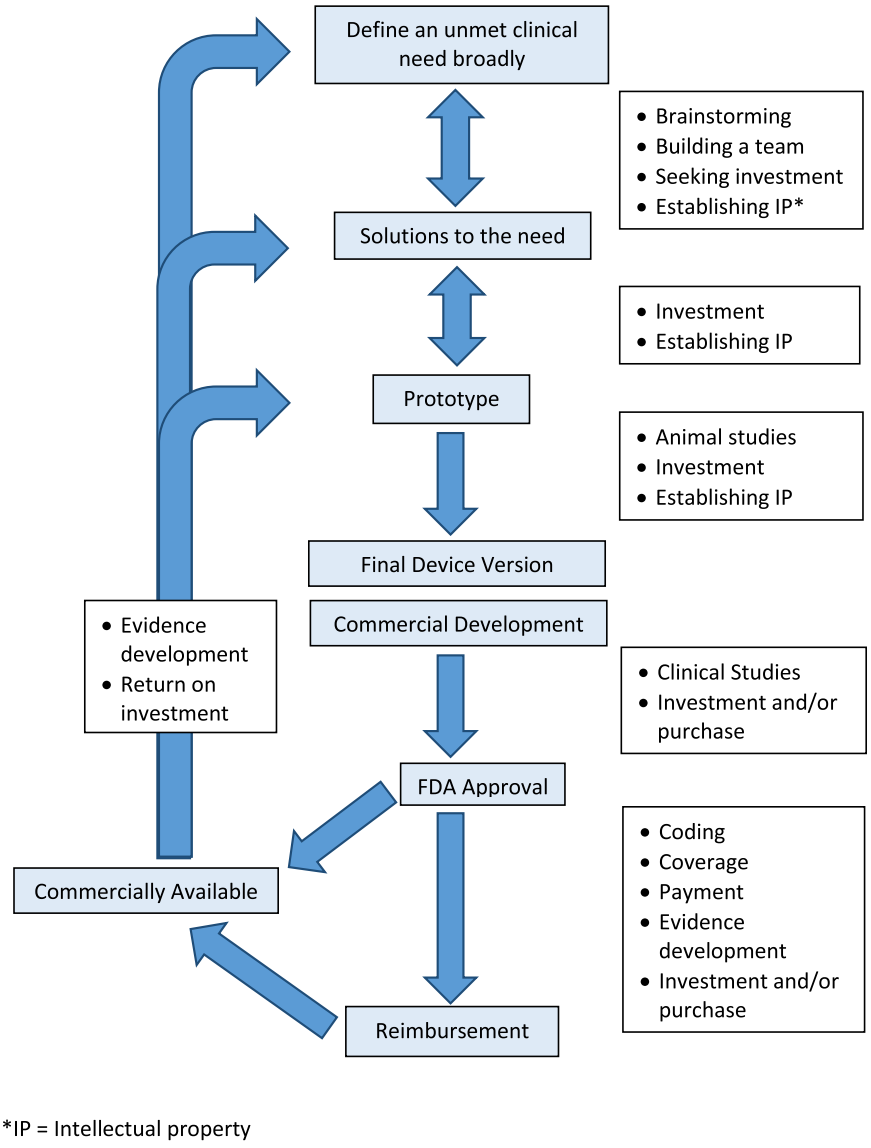

Figure 1 Medical device innovation from an idea to the bedside. FDA = Food and Drug Administration.

all subsequent time, effort, and money will be devoted to identifying and implementing a solution.

Urgency and Magnitude of the Need

It is important to characterize the urgency and magnitude of the unmet clinical need. These factors have implications for product design, the required level of evidence for regulatory clearance/approval and reimbursement, and ultimately commercialization. For example, device development for the pediatric population has been stalled in part because of a mismatch between urgency (generally high) and the magnitude of the need (generally small). In other words, the projected profitability from pediatric device development is outstripped by the resources required to bring a device to market. As such, most devices used in pediatrics have not been rigorously studied in pediatric patients[10] and many unmet needs exist in this population. Programs and initiatives designed to help innovators address urgent unmet clinical needs such as those for pediatric patients are discussed below.

Meeting the Unmet Need

Identifying Solutions

Innovating to solve an unmet clinical need requires input from various experts from within and outside the point of care (eg, biomedical engineers) and outside medicine altogether (eg, intellectual property lawyers). Indeed, the inspiration for solutions or the solutions themselves may be found completely outside medicine. Therefore, it is important to search broadly for solutions and defer judgment until a proposed solution or idea has been adequately vetted.

Even the best technology may not succeed purely on its own merits. Various considerations discussed below, such as human factors engineering, planning for regulatory approval, and understanding the intellectual property milieu, may be just as important as the level of innovation or creativity.

Table 1 Considerations for physician innovators

Major task	Associated tasks
Identify the unmet clinical need	• Frame the unmet need as broadly as possible • Understand the need through personal experience, experience of colleagues, the literature, and available tools
Meeting the unmet need	• Brainstorm possible solutions with an open mind • Consider the urgency and magnitude of the unmet need • Build a team with a wide variety of expertise
Plan a path to FDA approval	• Determine the appropriate path to approval (level of risk, 510(k) vs PMA vs HDE) • Determine clinical evidence requirements (if any)
Plan a path for coverage	• Determine whether the device will primarily serve a Medicare population (>65 y) as this has implications for data requirements • Determine clinical evidence requirements (if any) that may differ from those for FDA • Identify appropriate codes or existing coverage policies that may apply (LCDs, NCDs, and private payer determinations) • If existing coverage structure is insufficient, develop a strategy to address the gap (eg, new code, coverage with evidence development, and new technology add-on payment)
Establish an intellectual property strategy	• Conduct a survey of prior art and establish an intellectual property strategy that respects those boundaries (eg, collaboration and patent purchases)
Establish a funding strategy	• Identify the total amount of investment needed to meet key milestones • Identify potential investors and sources of capital (friends/family, angels, venture capital, and grants) on the basis of which type of investor aligns well with the needed amount of capital to reach a certain milestone • Consider existing device manufacturers in the field and whether a partnership makes sense • Survey the landscape for "macro-trends" (eg, federal funding levels, important national and international financial trends, and move toward value and mobile health) • Seek investment (lump sum vs tranche) with a plan for how to provide return on investment • Get feedback from investors
Evaluate the innovation in the global market	• Understand how the innovation could fit into large global markets • Evaluate the regulatory requirements outside the United States and how efficiencies can be built into evidence development for various regulatory agencies

HDE = humanitarian device exemption; FDA = Food and Drug Administration; LCD = local coverage determination; NCD = national coverage determination; PMA = premarket approval.

Practical considerations for device commercialization are increasingly important as well. A solution may involve different levels of technology to address specific needs. For example, iRhythm Technologies, Inc. (San Francisco, CA), uses a sophisticated cloud-based algorithm and "high technology approach" to analyze and manage the electrocardiographic data collected by their Zio® Patch cardiac rhythm patch monitor. In contrast, the company needed a simple, "low technology" approach to gather the devices and data from patients in order to improve access and reduce costs, so it employs the United States Postal Service mail for returning monitors. This "Netflix model" is simple, cost-effective, and widely accessible.[11]

It is noteworthy that the vast majority of novel medical devices represent incremental improvements over existing devices.[12] This underscores an important aspect of device development: it is generally an iterative process (Figure 1). The unmet need for a new device may quickly become obsolete via adaption of an existing device.[13] For example, in the early days of transseptal puncture for left-sided cardiac interventions, direct visualization may have been particularly helpful. Instead, the field advanced by using other existing technologies (eg, intracardiac echocardiography). Thus, the ideal window for an innovative device to provide direct visualization for transseptal puncture was small, and once the window closed, obsolescence followed.

Building the Team

A good team is essential for effectively vetting potential solutions to the unmet clinical need. The more diverse the experience and expertise of team members, the greater the potential to arrive at a truly innovative solution. In addition to providing a counterweight to the traditional physician innovator, team members with complementary, or "orthogonal," experience and expertise may bring issues to light that would have otherwise been overlooked. Collaboration can also result in "cross-pollination" such that collaborators are inspired to address tangential or unrelated problems in their respective fields in new ways.

As medicine moves away from a top-down model of treating disease in hospital and acute care settings to one in which patients are involved in health care decision making and longitudinal care outside the hospital setting, it is increasingly important to collaborate with engineers who have varied experience in fields such as user-centric design and human factors engineering. These fields draw from a variety of disciplines to understand how humans interact with systems and apply that knowledge to develop technologies that maximize the benefits of the interaction.[14] In the context of medical device innovation, a focus on human factors can reduce user error and improve the user experience (for both physicians and patients) in an ultimate effort to improve health.[15] The science behind human factors engineering is not new, but there are more resources available to

guide innovators as it becomes more central to medical device design and regulation.[16,17]

Geography is one practical concern that may influence collaboration with innovators and experts from varied fields. While technology can facilitate remote collaboration, there is no perfect substitute for face-to-face interaction. The need to be in close geographical proximity to collaborators cannot be overemphasized. To date, geographical centers of medical device innovation are few in number and are often characterized by a concentration of capital resources and experts and a culture of innovation. Innovators may need to consider relocation to a place that meets these criteria. However, it is difficult to predict where the next fortuitous collection of resources, experts, and circumstances may arise.

Consultants can often fill gaps in the variable areas of expertise required to bring a device from an idea to market. The advantages and disadvantages of hiring a consultant versus a staff member to complete a task or provide expert input depend on the medical product in question, the regulatory milieu, available resources, anticipated timeline, and other factors. Carefully consider whether external or internal collaboration is needed for any task along the device development path. In general, external collaborators (eg, consultants) may approach problems with less urgency than staff.

Intellectual Property

Intellectual property is a fundamental asset required to develop innovative medical devices. Protecting it allows the innovator to earn recognition and/or financial benefit from the innovation. There are various ways to protect intellectual property, but patents are the most widely used tools in the field of medical device innovation.

A patent gives the patent holder the right to temporarily "exclude others from making, using, or selling" an invention that is novel and nonobvious.[18] If violated, patent disputes are settled through litigation that is typically too costly for the physician innovator, so partnerships with institutions and/or device manufacturers may be helpful in protecting an innovative idea. However, if overlap with previously patented innovations is discovered along the innovation pathway, this need not be the end of the road. Many patents are inactive, abandoned, or for sale; any of these scenarios may not impede ongoing research and development even in the context of intellectual property overlap.

Funding and Return on Investment

For the typical physician innovator, securing adequate funds to bring an idea to market requires investment from external sources. Delivering a return on investment to investors is a great responsibility with varying consequences of failure, depending on the investment source. Therefore, establishing a thoughtful funding strategy is essential. The first step in a sound funding strategy is determining how much capital is required to achieve key milestones. This estimate drives the funding strategy; underestimating financial needs or revising a development plan based on available or easily obtained funds may lead to the slow death of an innovation. Even if the sum is daunting for innovators or potential investors, it is essential to honestly characterize financial needs on the basis of the necessary preclinical, clinical, and regulatory requirements.

Tranche financing, where a committed sum is divided into smaller pieces that are paid out as sequential milestones are met, may be more palatable and easier to secure than a lump sum in situations where a large amount of capital is required. Tranche financing may also be preferable to "piecemeal" funding that does not enable the project to achieve important milestones in a meaningful amount of time. Regardless of the financial structure of investment, understanding potential hurdles and proposing solutions to investors will go a long way in building trust and confidence.

Understanding the total amount of funding required is also important because this information can help determine what type of investor might be best suited for the project at its given stage. For instance, capital raised from friends/family or angel investors might be sufficient if a small amount is needed up front to achieve an early milestone, whereas venture capital might be needed for larger sums.

The world of heart rhythm medical device technology is relatively small. Consequently, an innovative device or device startup company may be an attractive acquisition for an established manufacturer. Collaborating early with these potential partners might prove mutually beneficial. If alignment with an established company is not possible or desirable, there are other new nontraditional entrants to the medical device field because of the consolidation of investment resources and the intersection of interests (eg, big data). A good example is the Google Baseline Study, which includes the use of a wearable medical device that measures heart rate and other physiological data.[19]

Macro-trends are a critical piece of the device funding landscape. Trend analysis can guide the timing of solicitations for investment funding. For example, the financial crisis of the late 2000s had a major impact on the availability of funding for medical device innovation.[20,21] Changes in federal funding for medical device innovation tend to occur more slowly, but are also important. Consider the 21st Century Cures legislation, which would increase federal funding for innovative research for a limited time. In addition, small business innovative research grants and small business technology transfer grants can provide the funds to demonstrate proof of concept for innovative device projects that involve more research or risk than the market will generally tolerate.[22]

The ability to demonstrate value is becoming increasingly important as the health care landscape shifts focus to the population level.[23–25] In addition, addressing population health means empowering patients to fully participate in health care decisions. Mobile devices and other consumer technologies have made it possible for patients to monitor, track, and record health data. At the same time, increasing availability of medical information on the Internet has enabled patients to formulate opinions about diagnostic

and therapeutic interventions. These changes have resulted in widely available mobile device apps, some of which may assist in recruiting and enrolling subjects for clinical trials. One example is Health eHeart, a large cardiovascular cohort study that enrolls and manages patients and data through a sophisticated online portal.[26] These initiatives can provide inspiration for medical devices and clinical trial infrastructure through innovative partnerships.[19] Acknowledging these trends may attract nontraditional funding sources.

Interactions with investors can be valuable experiences even if agreement is not reached. Feedback from an investor who chooses not to collaborate may lead to constructive changes that facilitate more productive interactions with future investors.

The Regulatory Pathway

Food and Drug Administration

In the United States, the FDA's Center for Devices and Radiological Health regulates medical devices on the basis of risk. Class I devices pose the least risk and Class III the most (Table 2). Risk-based classification determines the FDA evaluation mechanism: 510(k) versus PMA. The quality and quantity of evidence required to demonstrate safety and effectiveness differ considerably between those devices evaluated through the 510(k) premarket notification process (typically Class II) and those evaluated in the more rigorous PMA process (typically Class III). Specifically, devices evaluated within the 510(k) premarket notification process need to establish "substantial equivalence" to a prior "predicate" device. This typically means that the new device has the same intended use as the predicate device and that it either has similar technological characteristics or, if using different technology, does not raise new questions of safety and effectiveness. However, once the device is cleared, the intended use may not necessarily predict how it will be used in clinical practice.

For example, the LARIAT® device (SentreHEART, Redwood City, CA) was approved through the 510(k) pathway with no clinical testing based on a predicate device labeled to facilitate "suture placement and knot tying for use in surgical applications where soft tissue are being approximated and/or ligated with a pre-tied polyester suture."[27] On paper, this device is substantially equivalent to the predicate surgical device, but in practice, the LARIAT® device has been used off-label to exclude the left atrial appendage, with the goal of reducing stroke risk in patients with atrial fibrillation.[28] However, this outcome, as well as the safety of the device as a left atrial appendage excluder, was not examined premarket. In light of the evidentiary gap in premarket clinical testing and postmarket safety concerns related to off-label use,[28] critics are questioning the widespread use of LARIAT®[29] and calling for more clinical evidence to support the use of LARIAT® as a left atrial appendage excluder.[30] While the FDA does not regulate the practice of medicine (including the off-label use of FDA-regulated products), the FDA has issued a safety communication on the use of LARIAT® to exclude the left atrial appendage.[31] This may impact endorsement by professional societies, reimbursement by payers, and use by practicing physicians. It remains to be seen whether the manufacturer will be compelled to generate additional evidence for an indication to exclude the left atrial appendage. Thus, while the 510(k) pathway may be the shortest distance to market, incomplete or inadequate clinical evidence for expected off-label or labeled use may present serious problems in the postmarket space.

Most high-risk devices such as ablation catheters and defibrillators require a PMA. A PMA application is complex and requires a great deal of technical, regulatory, and preclinical information. In addition, a PMA requires data from clinical investigations that are typically conducted under an investigational device exemption (IDE) that must be granted by the FDA before any use or testing of a new product in human subjects. The FDA provides extensive guidance to help manufacturers, investigators, FDA staff, and others determine risk and plan IDE studies.[32,33] Notably, evidence generated outside the purview of the FDA (eg, outside the United States) is not necessarily excluded from consideration by the FDA if it is of sufficient quality to support an application for premarket notification (510(k)) or approval (PMA).[34]

Table 2 FDA's risk-based device classification

Risk class	Definition/characteristics	Typical approval pathway for heart rhythm devices	Example
I	Devices are subject to a comprehensive set of regulatory authorities called general controls that are applicable to all classes of devices	Exempt	Stethoscope
II	Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance (eg, bench testing, patient registries, and postmarket surveillance)	510(k)	CARTO navigation system (Biosense Webster, South Diamond Bar, CA)
III	Those devices that are implantable and/or provide "life-supporting or life-sustaining" therapy; general controls, by themselves, are insufficient, and there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require controlled clinical testing and premarket approval	PMA	WATCHMAN device (Boston Scientific Corporation, Marlborough, MA)

FDA = Food and Drug Administration; PMA = premarket approval.

As previously stated, the urgency and magnitude of the unmet clinical need have some bearing on the pathway to regulatory approval. Programs such as the humanitarian use device/humanitarian device exemption provide a pathway to study FDA-regulated devices relevant to small populations (<4000 patients) with a lower evidentiary threshold for approval.[35] There have been some high profile experiences with this pathway.[36,37]

Often, a device may be approvable via either the 510(k) or the PMA pathway. For example, had the LARIAT® device manufacturer pursued a PMA for the device in order to include an indication for left atrial appendage exclusion, an IDE trial would have been required with all the associated cost, longer time requirements, and outcome uncertainty. In contrast, the WATCHMAN device (Boston Scientific Corporation, Marlborough, MA) has a similar clinical application to the LARIAT® device, but WATCHMAN was evaluated in IDE studies and approved via the PMA pathway after much delay and financial investment.[38,39] This investment ensured that patients were protected while the device was evaluated in the intended population for the intended use. It also provided a clearer pathway to reimbursement, among other benefits.

There is general recognition by various stakeholders that existing device lag is due, at least in part, to regulatory inefficiencies.[40] As such, the FDA has embraced initiatives designed to open doors for medical device innovation and development in the United States.[41] Some of these initiatives include expedited review of medical devices for an unmet clinical need[42] and the early feasibility pathway.[43] Other initiatives involve enhancements of existing programs such as the presubmission process, which facilitates early interaction with the FDA to guide innovators and improve transparency surrounding application expectations.[44] While early feedback from the FDA is most relevant for meeting regulatory requirements, the input of experts at the FDA may help improve product and/or study design. Lastly, in recognition of the evolving pressures on the clinical trial enterprise, the FDA has recently provided guidance for alternative approaches to clinical trial conduct and interpretation. These include the ability to defer some evidence collection to the postmarket space[45] and the use of alternative statistical strategies that harness the power of existing knowledge with Bayesian statistics[46] or during the course of the trial with adaptive design.[47] Among other things, the 21st Century Cures legislation is aimed at streamlining the regulatory process for medical devices including those considered a "breakthrough" and allowing the use of less rigorously collected data for device evaluation.[48] It remains to be seen how this act, if signed into law, would directly impact the medical device innovation process.

Most evidence for medical devices is developed within the regulatory paradigm. This evidence informs decisions by payers regarding reimbursement, professional societies regarding clinical guidelines and recommendations, hospitals and health systems in terms of purchasing, practicing physicians in terms of point-of-care use, and ultimately patients. Given that so much depends on the quality of the evidence generated in the regulatory trials, deliberate consideration of trial design is imperative.

Reimbursement

Ensuring coverage for a new medical device involves creating a billing code (or identifying a relevant existing code), obtaining a coverage determination(s), and establishing a payment level. These necessary components are separate from FDA requirements. Indeed, some rigorously studied medical devices with proven benefit may not meet payer standards for coverage. For example, the subcutaneous implantable cardioverter-defibrillator (ICD; EMBLEM™ S-ICD, Boston Scientific Corporation, Marlborough, MA) is still considered "experimental" by some payers, which vastly reduces the reimbursement level despite FDA approval in 2012 and reimbursement by CMS. Conversely, some medical devices may be covered for off-label indications never studied or approved by the FDA.

Coding

Medical specialty groups such as HRS contribute to the process of developing and updating the Current Procedural Terminology (CPT®) codes that are used to identify medical procedures so that billions of claims can be processed every year. CPT® codes are used in conjunction with International Classification of Diseases, Tenth Revision, Clinical Modification (*ICD-10-CM*) diagnosis and procedure codes to identify professional services and medical necessity. The codes also link the services to the appropriate diagnosis-related group. Additional procedure codes maintained by CMS—the HCPCS Level II Codes—are used to identify technologies that are part of the Medicare fee schedule. Many new technologies do not disrupt existing coding or coverage and payment decisions. However, in the case of a novel device, the existing codes may be inadequate, necessitating the potentially long and complex processes for establishing proper coding.[49] The CPT Editorial Panel provides a process for attaining Category III codes that are used to capture utilization data for non–FDA-approved "experimental" technologies. Increasingly, the codes are being used for billing after FDA approval or clearance has been granted and until a Category I CPT code is developed. For breakthrough technologies, innovators can apply for a "new technology add-on payment" or "pass-through payment" designation by CMS for use in the inpatient and outpatient settings, respectively.[50] These programs are aimed at correcting disincentives for using new innovative technologies. They encourage providers to use devices before appropriate adjustments can be made to coding and payment, a process that usually takes 2–3 years.

Coverage and Payment

The pathway to coverage can be long and may be repetitive as coverage is sought by CMS and other payers. However, CMS decisions typically set a benchmark for other payers. In fact, the process for CMS to finalize a national coverage determination (NCD) is often lengthier than the time it takes

for FDA to make an approval decision and does not begin until market clearance or approval is obtained.[51,52] Private payers may be able to arrive at coverage decisions more quickly.[25] Long delays for coverage are potentially problematic for medical device innovators since the lifespan for some medical devices is rather short.[13,49] Therefore, establishing a plan to achieve coverage is an essential step to getting a new innovative device to market and should be considered as early as possible. In some cases, the CMS standard of "reasonable and necessary" can be considered alongside the FDA standard of "safe and effective" during evidence development in the premarket phase. Furthermore, as FDA is working toward a balance between pre- and postmarket data,[45] CMS has issued guidance to help industry consider whether postmarket data may be used to support a coverage decision under the coverage with evidence development program. For example, in 2005, ICDs were approved for primary prevention in patients with heart failure and low ejection fraction contingent on the ongoing data collection in these patients.[53,54] In that context, the National Cardiovascular Data Registry ICD Registry was born. More recently, transcatheter aortic valve replacement technology received coverage from Medicare through a coverage with evidence development.[55] However, the future of CEDs is uncertain because there are few examples of CEDs leading to relevant, timely evidence generation that can adequately inform policy decisions. In many cases, studies to answer outstanding questions at the time of the coverage determination were never conducted or were launched despite inadequate funding and/or serious flaws in design and/or implementation.[56]

Most coverage decisions for new technologies are made locally—there have been thousands of local coverage determinations (LCDs) and only a few hundred NCDs in the history of CMS. Moreover, only a small subset of NCDs is related to medical devices. Typically, this includes devices that are accompanied by clinical evidence of true innovation or breakthrough, substantial variation in LCDs, or concerns about inappropriate use. LCDs must comply with NCDs but can otherwise vary widely in how they are considered and applied (eg, claim-by-claim basis vs local policy) and the amount of payment per instance.[52,57]

To make an NCD, CMS typically requires supporting evidence of high-quality clinical investigation(s) from peer-reviewed literature regardless of the evidence base included in any FDA application for clearance or approval. However, the additional CMS requirement that there be broad experience by nonconflicted physicians may be at odds with the critical role that physicians play in the innovation process.[58] Physicians with early device experience are often the same physicians working directly with device manufacturers. It remains to be seen how policies related to physician-industry interaction will evolve in the context of the Physician Payment Sunshine Act.[59] Because of the aforementioned issues, innovators may anticipate a prolonged time gap between FDA approval of a new medical device and CMS establishment of an adequate coding, coverage, and payment structure. Only the best planned device ventures can survive this delay.

The Global Market

Some unmet needs are specific to the United States, but many problems have global implications. Therefore, it is increasingly important to consider how a solution to an unmet need could be applied internationally. In addition, many large strategic companies are focused on growing in markets outside the United States. A project with global implications may be an attractive candidate for acquisition by one of these firms. For example, China and India are enormous markets for health care consumption and evaluating a device in the context of these markets may reap tremendous rewards.[60,61] Interaction with regulatory bodies is an important consideration since each market has its own set of rules.[62,63] In addition to regulation, a medical device innovator must account for potential differences in pathophysiology, perceptions/preferences, and lifestyle in order to be successful in global markets. In some cases, introducing an innovative device outside the United States first (as a marketed product or in clinical trials) can be informative for subsequent introduction in the United States or vice versa. Importantly, as noted above, evidence from studies of medical devices outside the United States is not necessarily excluded from consideration by US regulatory bodies.[34]

The Role of Professional Societies

Professional societies have evolved to meet the changing needs of members and have embraced their role in improving cardiovascular health in the United States and globally.[64,65] Professional societies can impact and encourage the process of medical device innovation in a variety of ways.[64] First, local and national professional society meetings provide a forum for face-to-face interaction among physicians, industry representatives, researchers, and others in order to develop collaborative relationships that enable innovation.

Second, these meetings serve as a tool for the dissemination of innovative ideas and technologies.

Third, professional societies can serve as a clearinghouse for collecting, evaluating, and summarizing the available evidence in specific disease categories in the form of professional guidelines, expert consensus reports, society-run peer-reviewed journals, and reports such as this one. Traditionally, the purpose of these documents is to provide education to members, but they can also serve as a roadmap for innovators by identifying areas of unmet clinical need, including those based on weak clinical evidence.

Fourth, by partnering with the FDA and CMS, professional societies can assist innovators in meeting requirements for device surveillance in some disease- and device-specific areas. For example, the National Cardiovascular Data Registry has conducted multiple postmarket evaluations. As a result, it has been identified as a reasonable platform on which to perform clinical trials, including IDE studies of new devices or existing devices for new indications.[66–68]

Professional societies can also bring practicing physicians together with regulators, and other stakeholders to help steer device development in the direction of unmet clinical

needs.[69] Specifically, professional societies can represent the practicing physician's perspective on meaningful study end points in device clinical trials and the practical application of innovative devices in clinical trials as well as postmarket adoption.[70]

Last, professional societies can interact with legislative and regulatory authorities on behalf of members. For example, societies can distill the opinion of members and report these opinions to the local or federal legislature(s) when pending legislation may have an impact on members' ability to innovate. For example, the 21st Century Cures legislation may have a significant impact on medical device innovation, including devices for heart rhythm disorders. HRS advocates for legislation that would be most beneficial to its members and the patients they serve.[71] In addition to legislators, societies can mediate and build relationships between members concerned with medical device innovation and the groups that regulate devices (eg, FDA) and medical device coverage (eg, CMS). For example, HRS provides content expertise for committees charged with establishing codes for new medical devices.[72]

Conclusion

Physicians are in an important position to develop innovative medical devices. However, the complex processes of obtaining funding, establishing intellectual property, navigating regulatory approval from the FDA, establishing coverage mechanisms from CMS and other payers, and commercializing and marketing a device can be barriers to physician innovators. Professional societies, including HRS, are an excellent source of support for physician innovators through a variety of mechanisms including advocating for legislation and regulatory reforms that support innovation, surveying and disseminating relevant scientific information, and bringing stakeholders together to collaborate. Providing the opportunity for physicians to participate in medical device innovation may help reduce device lag in the United States and ultimately result in the increased availability of devices that are well-designed, safe, effective, and beneficial to patients appendix.

Appendix

See Table A1.

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Table A1 Author Disclosure Table

Writing group member	Institution	Consulting/ honoraria	Speakersâ€™ bureau	Equity interests/ stock options	Royalty income	Officer/trustee/ other fiduciary role	Intellectual property rights	Research grant	Fellowship support	Salary
Emily P. Zeitler, MD	Duke Clinical Research Institute and Duke University Hospital, Durham, North Carolina	None	None	None	None	None	None	None	None	None
Uday N. Kumar, MD	Stanford University, Stanford, California	5: iRhythm Technologies	None	5: iRhythm Technologies, Element Science 1: Qurious.io 3: Sympara Medical	None	5: Element Science 1: Qurious.io 3: Sympara Medical	5: iRhythm Technologies, Element Science	None	None	5: Element Science
Sana M. Al-Khatib, MD, MHS, FHRS	Duke Clinical Research Institute and Duke University Hospital, Durham, North Carolina	None	None	None	None	None	None	None	None	None
David Slotwiner, MD, FHRS	Weill Cornell Medical College, New York, New York	None	None	None	None	None	None	None	None	None
Paul Varosy, MD, FHRS	University of Colorado Anschutz Medical Campus, Aurora, Colorado	None	None	None	None	None	None	1: National Institutes of Health 2: Patient-centered outcomes	None	None
David R. Van Wagoner, PhD, FHRS	Cleveland Clinic Lerner College of Medicine, Case Western Research University, Cleveland, Ohio	1: Glaxo Smith Kline 1: Amgen	None	None	None	None	None	5: National Institutes of Health	None	None
Gregory M. Marcus, MD, FHRS	University of California, San Francisco, San Francisco, California	5: InCarda	None	1: InCarda (equity)	None	None	None	5: National Institutes of Health 5: PCORI 4: Medtronic 4: Pfizer 5: SentreHEART 4: RDS	None	None
Fred M. Kusumoto, MD, FHRS	Mayo Clinic, Jacksonville, Florida	None	None	None	None	None	None	None	None	None
Laura Blum, MA	Heart Rhythm Society, Washington, District of Columbia	None	None	None	None	None	None	None	None	None

0 = $0; 1 = <$10,000; 2 = >$10,000 to <$25,000; 3 = >$25,000 to <$50,000; 4 = >$50,000 to <$100,000; 5 = >$100,000.