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PERFORMANCE-BASED RISK SHARING ARRANGEMENTS FOR DEVICES AND PROCEDURES IN CARDIAC ELECTROPHYSIOLOGY: AN INNOVATIVE PERSPECTIVE

**Giuseppe Boriani^{1,2}, Marco Vitolo^{1,3}, Emma Svennberg⁴, Ruben Casado-Arroyo⁵,
José L Merino⁶, Christophe Leclercq⁷**

¹ Cardiology Division, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Policlinico di Modena, Modena, Italy

² EHRA mHEALTH and Health Economics Section, European Heart Rhythm Association

³ Clinical and Experimental Medicine PhD Program, University of Modena and Reggio Emilia, Modena, Italy

⁴ Karolinska Institutet, Department of Medicine, Karolinska University Hospital Huddinge, Stockholm, Sweden

⁵ Department of Cardiology, Erasme Hospital, Université Libre de Bruxelles, Brussels, Belgium,

⁶ Arrhythmia & Robotic EP Unit, University Hospital La Paz, Autonoma University, IdiPaz, Clinica Viamed-Santa Elena, Madrid, Spain

⁷ Department of Cardiology, University Hospital of Rennes, Rennes, France.

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***Corresponding author:**

Prof. Giuseppe Boriani, MD, PhD

Cardiology Division, Department of Biomedical, Metabolic and Neural Sciences,

University of Modena and Reggio Emilia, Policlinico di Modena

Via del Pozzo, 71, 41124 Modena, Italy

E-mail: giuseppe.boriani@unimore.it

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Abstract

There is an increasing pressure on demonstrating the value of medical interventions and medical technologies resulting in the proposal of new approaches for implementation in daily practice of innovative treatments that might carry a substantial cost.

While originally mainly adopted by pharmaceutical companies, in recent years medical technology companies have initiated novel value-based arrangements for using medical devices, in the form of “outcomes-based contracts,” “performance-based contracts,” or “risk-sharing agreements”. These are all characterized by linking coverage, reimbursement, or payment for the innovative treatment to attainment of prespecified clinical outcomes.

Risk –sharing agreements have been promoted also in the field of electrophysiology and offer the possibility to demonstrate the value of specific innovative technologies proposed in this rapidly advancing field, while relieving hospitals from taking on the whole financial risk themselves.

Physicians deeply involved in the field of devices and technologies for arrhythmia management and invasive electrophysiology need to be prepared for involvement as stakeholders. This may imply engagement in the evaluation of risk-sharing agreements and specifically, in the process of assessment of technology performances or patient outcome. Scientific Associations may have an important role in promoting the basis for value-based assessments, in promoting educational initiatives to help assess the determinants of the learning curve for innovative treatments and in promoting large-scale registries for a precise assessment of patient outcomes and of specific technologies’ performance.

Key words: ablation; cardioverter-defibrillators; health technology assessment; innovation; pacemaker; risk.

Introduction

The process of testing and validation of drugs and devices, according to the requirements of evidence-based medicine, is lengthy and costly and innovative therapies are usually commercialized at a high price.¹

In Europe, the gross domestic product-and health spending per capita show important variations between different countries^{2,3} and this factor, combined with different characteristics and coverage of health care systems⁴ may create barriers for the implementation of innovative and costly treatments. The access to innovation, especially for medical devices, is even more challenging nowadays, since health care systems are characterized by increasing demand, rising costs, insufficient funding and difficulties in defining priorities^{5,6}. The dramatic situation created worldwide by the COVID-19 pandemic is currently challenging the ability of healthcare systems to adapt to this novel scenario and there is a growing need for a rapid implementation of novel technologies, first of all in the field of telehealth management, teleconsultation and remote monitoring of different categories of patients^{7,8}.

This could allow a radical change in the organization of health care systems, with a more efficient integration of advanced technologies with a re-organization of the processes of care, as well as of decision-making, also with implementation of Machine Learning and Artificial Intelligence⁹.

According to the approach of Health Technology Assessment (HTA), manufacturers are required to provide proof of the value for money of their technologies, when adopted in the real world and the economic assessment constitutes a crucial element for HTA agencies¹⁰⁻¹⁴. In case of innovative treatments which may positively impact on diseases, a complete economic assessment, with a long-term time horizon, may not be available at the time of proposal for clinical use, which is often combined with high upfront costs and results in a long process for widespread clinical adoption in daily life. This results in some uncertainty in adopting the same technologies/treatments in the “real-world” and a high financial pressure, with hesitancy in establishing reimbursement practices. Indeed, reimbursement is a key issue for the implementation of any technology, since on one hand the lack of reimbursement may constitute a barrier to widespread adoption, but on the other establishing a reimbursement tariff from the side of payers requires appropriate validation of efficacy of the specific treatment/technology in a well-defined set of patients. Nowadays there is the possibility to overcome the classical dichotomy on decisions with regard to reimbursement, that were based on coverage vs. no coverage¹⁵. Now, implementation of new and expensive technologies with alternative

approaches as compared to the traditional and conventional approach based on upfront payment for the full price of the technology can be considered.

The field of medical devices has several differences in relation to pharmaceuticals that should be acknowledged; the shorter life cycle of devices in relation to drugs, a market that is very dynamic and much more competitive as patents are easier to circumvent for medical devices (easier to claim equivalence).

Another barrier of adoption of devices is the complexity and number of national or regional HTA bodies and the fact that in most of the cases the developers are small companies. Assessment and reassessment are challenging given the frequency of product modifications and the level of competition. On the other hand, the updated Medical Devices Regulation will affect deeply the cardiovascular field in a near future,^e since cardiovascular devices comprise at least 50% of all high-risk medical devices (class III).

Our aim is to briefly report on the potential for considering the use of risk-sharing arrangements, and similar options characterized by being an alternative to the conventional approach based on upfront payment for the full price of the technology, in the field of technologies for cardiac electrophysiology to cure cardiac arrhythmias, with implantable or not implantable devices. In this review we will report that risk-sharing arrangements have already been proposed and adopted in the field of electrophysiology for some technologies (e.g. antibacterial envelope, wearable defibrillators).

Innovation and potential gaps in adoption of innovative treatments

As stressed by WHO¹⁶ there are important barriers to consider in order to improve access of appropriate medical devices supply, regulation and innovation. This may result in variability across different countries and settings with regard to availability, accessibility, appropriateness and affordability of medical devices. The difficulties in making an innovative technology rapidly available for patients in every specific health care system is maximised when the technology is a disruptive innovation. By definition a disruptive innovation is characterized by the capacity to create new networks and organizational changes, involving new players, leading to improvement in value as well as distribution of values between a series of stakeholders ^{14, 17}

Widespread adoption in clinical practice of innovative therapies, especially when associated with a high upfront cost may be challenging, in relationship to a variety of factors, in some case specific to the type of health care system and its financial capacity¹⁴.

For implantable cardiac electronic devices, which require both a high technological standard and a reliable proof of clinical value, validation of efficacy has regularly been obtained in the past through randomized clinical trials, with specific recommendations for appropriate use delivered by consensus guidelines^{18, 19}.

However, despite the high degree of available evidence, supporting an approach based on HTA¹⁴ important barriers still exist, including the characteristics of reimbursement practices^{20, 21}, and in some cases lack of consensus between administrators and physicians^{5, 22}.

The current practices of reimbursement for devices across Europe, substantially based on diagnosis-related group (DRG) system, with marked variability from country to country, is frequently characterized by delays in defining a formal code and associated tariff for new, innovative treatments and in many cases this results in reduced and delayed adoption and implementation of effective new treatments⁶. This may be the case for the antibacterial envelope, proposed for reducing the risk of CIEDs infection, of proven efficacy but with added costs^{23, 24} or the case of wearable defibrillators, to be used in patients at high risk of ventricular tachyarrhythmias with no indications for an implantable defibrillator.^{25, 26}

The major differences between drugs and devices have to be considered by policy makers, in view of the profound implications for decision making that they imply^{27, 28}. For instance there is need to estimate the learning curve of most innovative devices and related techniques, as well as the impact of this factor on the effectiveness, safety, and costs associated with implementation, which could require post-market data collection and analysis²⁹.

Coverage with evidence development

Coverage with evidence development is a method for facilitating the clinical use of innovative therapies, and specifically of medical devices, at a time when approval for market release has already been obtained, but the processes of collection of clinical evidence is limited and still ongoing, even if there are substantial reasons to expect that they may effectively respond to high unmet medical need.^{30, 31} The schemes proposed for “coverage with evidence development” are motivated by some uncertainty on the safety, efficacy, and

cost-effectiveness of a specific device treatment, but allow a temporary reimbursement of the treatment, combined with collection of data to produce the evidence that will allow a more motivated decision on coverage and reimbursement at a later stage, after analysis of collected clinical data^{30,31}. This type of schemes has been presented and developed with variable terminology in different countries, such as ‘coverage with evidence development’ in the USA, ‘conditionally funded field evaluations’ in Ontario (Canada), ‘interim funding schemes’ in Australia, ‘only with research’ in UK, and ‘conditional reimbursement schemes’ in Belgium and in The Netherlands³¹. A recent systematic review³¹ highlighted that there are a series of unsolved issues related to application of these schemes in the setting of medical devices and there is need to improve their use for improved decision making in adoption of new technologies.

Risk sharing arrangements as a new perspective

Increased investments in medical technology have been associated with improved patient outcomes, thus supporting the value of investments in the field, on the basis of specific assessments of the value of medical technologies^{32,33}

In recent years, new strategies and approaches have been proposed to improve implementation of highly effective but costly treatments through a shift toward alternative models for payment and reimbursement, such as value-based arrangements for both expensive drugs and medical devices, in the form of “outcomes-based contracts”, “payment by results”, “performance-based contracts” or “risk-sharing agreements”, all characterized by linking coverage, reimbursement, or payment for the innovative treatment to attainment of prespecified clinical outcomes^{1,34}.

It is noteworthy that this innovation was introduced in the last years in the pharmaceutical setting and particularly in Oncology, the sector with the highest price for innovative drugs^{33,35,36}.

These schemes involve a “pay-for-performance” or “risk-sharing” element between payers and pharmaceutical companies, and have been variably named, as “performance-based risk-sharing arrangements”, ‘risk sharing schemes’, performance-based contracts, or effectiveness guarantee schemes^{1,33,35,36}. All these agreements include a plan by which the performance of the product in clinical practice is tracked in a specific patient population over a specified period of time, and the level or continuation of reimbursement is based on the health and economic outcomes achieved³³. In the perspective of the payers

this solution aims to reduce the uncertainty on treatment effectiveness, thus maximising the value for the money spent. For the manufacturers this solution may reduce the risk of delayed or incomplete adoption of the new treatment fuelled by some uncertainty on the performance in the “real world”.

A dedicated Task Force of ISPOR (The Professional Society for Health Economics and Outcomes Research)³³ addressed the issue of implementation of innovative treatments and reported that two distinct types of arrangements can be considered according to the primary aim:

- To provide additional evidence for decision-making and this is the case of “Coverage with evidence development” schemes
- To appropriately manage the implementation and utilization in the “real world” and this is the case of “performance risk reimbursement “ schemes.

Coverage with evidence development was already discussed, so we will now focus of risk sharing agreements. For risk-sharing arrangements a series of opportunities and challenges can be predicted and they should be object of careful consideration, according to different perspectives (**Table 1**)³⁷.

In the field of value-based arrangements and risk-sharing agreements Scientific Associations such as EHRA (European Heart Rhythm Association) and ESC (European Society of Cardiology) can play a crucial role, in collaboration with EU bodies and national regulatory authorities for several very important tasks, in line with the “virtuous circle” of HTA¹⁴:

- Coordinate the assessment of the clinical evidence supporting clinical implementation of new devices after regulatory approval and appropriately define the specific clinical outcome that may be the reference for value-based assessments;
- Help in promoting educational initiatives to help assess the determinants of the learning curve for innovative treatment, an important factor conditioning the speed and extent of implementation of innovative technologies;
- Promote the institution, validation and verification of large-scale registries for a precise assessment of patient outcomes. These prospective registries could be the reference for objectively assessing patient outcome, but this would require the guarantee on data reliability, with possibility of verification and audits by stakeholders³⁸;

- Contribute to establish a constructive dialogue among the stakeholders (payers, physicians, regulators, manufacturers) targeted to achieve the common goal of making possible the use of innovative technologies that may effectively respond to high unmet medical needs (**Figure 1**).

These important roles for Scientific Associations obviously parallel the general commitment to sustain innovation through appropriate consultation with European Union bodies and the Associations of manufacturers⁶.

Current experiences of risk-sharing agreements in the field of electrophysiology and arrhythmia management

New payment methods have been proposed by manufacturers firstly in the United States, implying some risk sharing, i.e. health care organizations may be rewarded, in case of assumption of some degree of financial risk when managing the quality and costs of care of a patient population treated with some specific technologies.³⁹

In the field of electrophysiology a series of contracts (“Outcome guarantee models”) have been put in practice with some hospitals, with manufacturers giving back to providers large discounts or rebates if certain clinical/economic outcomes are not met after use the specific technology.⁴⁰

One example is that Medtronic offered a risk sharing agreement on the use of the Tyrx antibacterial envelope, including Medtronic will reimburse hospitals for selected costs if use of the Tyrx antibacterial envelope fails to prevent infection in patients implanted with a cardiac electronic implantable device (implant/replacement or upgrade of a pacemaker or defibrillator or device for cardiac resynchronization therapy). Since the Tyrx envelope is a technology with proven evidence of benefit²³, this proposal appears to facilitate its introduction in practice in patients at risk of CIED infection²⁴.

Additionally, in the United States Biosense Webster, a division of Johnson and Johnson, has proposed a risk sharing agreement for the Thermocool open-irrigated radiofrequency catheter designed for a more effective power delivery to the tissues for ablation procedures. The company guarantees a discount on the cost of the catheter if the same ablation procedure has to be repeated in a patient within a year of a prior procedure performed with this catheter.⁴¹

Again in the United States Abbott has proposed an agreement for the Quadra device for cardiac resynchronization therapy, with MultiPoint Pacing, including a 45% rebate on the net price for cardiac resynchronization therapy if a lead revision is needed as a result of specific reasons within the first year of implantation.⁴²

It is clear that for manufacturers the approach of risk-sharing is completely different from the conventional guarantee, since what is object of the former types of agreements includes the clinical result in terms of outcome of the patient, rather than device failures or technical features.

In consideration of the heterogeneity and complexity of procurement and regulations in Europe, it is not surprising that limited experiences of implementation of risk-sharing agreements were reported in literature with regard to Europe. Actually, risk sharing agreement appear to be an interesting option for many countries. However, taking into account the complexity of the European scenario and the open issues of such option (**Table 1**), it is advisable that if manufacturers consider risk-sharing as an interesting approach also for some European contexts, a gradual approach will be applied, with appropriate choice of the criteria for technology assessment and with appropriate monitoring of the implementation and of the results.

Definition of the clinical performance of a specific technology may be particularly complex when more than one technology and one manufacturer are involved in the same procedure. This could be the case of a procedure of atrial fibrillation ablation with a radio-frequency or cryoballoon catheter, including the use of a 3-D mapping system, as well as pre-procedure CT or MRI scans. It is clear that an appropriate assessment of the performances related to the different technologies should be accurately defined, in order to limit the risk of competitive measurements. In the abovementioned case, the evaluation of the performance related to atrial fibrillation ablation using a radio-frequency catheter or a cryoballoon could be targeted to lack of atrial fibrillation recurrences during the follow-up, while for the mapping system the appropriate performance could be related to a short time for complete mapping. Moreover, for pre-procedure imaging with CT or MRI, the appropriate performance could be related to a valid assessment of the complex anatomical relationships between the left atrium, the pulmonary veins, and the surrounding structures, resulting in appropriate choice and positioning of the catheters, avoiding longer procedures with higher radiation doses. Scientific Association will have an important role in the proposal of appropriate performance assessments, by instituting committees of experts, working in collaboration with manufacturers and policy-makers.

New perspectives and future developments in risk-sharing

In the future the revolution linked to availability of Big Data will facilitate to weigh and share risks, also in the field of medicine and health care ⁴³⁻⁴⁵. Machine learning and distributed computing will allow to better map and predict the risks of medical interventions for specific patient profiles and this will lead to a reduced risk of uncertainties for health care providers, payers and manufacturers of medical technologies, facilitating the adoption of risk sharing arrangements, as well as improving decision making, thanks to better identification of potential responders to treatments.

In this perspective the future basis for a wider use of outcome-based and value-based organizing payments will imply the appropriate functioning of systems for collection of large amount of data, in a reliable and safe environment, in the form of dedicated and validated datasets that could improve knowledge on the course of .diseases in response to early implementation of highly innovative treatments with a high upfront cost. ⁴⁶

Conclusions

There is an increasing pressure on demonstrating the value of medical interventions and medical technologies and this resulted in the proposal of new approaches for implementation in daily practice of innovative treatments that are characterized by a substantial cost.

While originally mainly adopted by pharmaceutical companies, in recent years medical technology companies have started to a novel ways of value-based arrangements for using medical devices, in the form of “outcomes-based contracts,” “performance-based contracts,” or “risk-sharing agreements” all characterized by linking coverage, reimbursement, or payment for the innovative treatment to prespecified clinical outcomes. Usually in risk sharing agreements manufacturers offer to return percentage of price if the treatment applied through the innovative technology does not meet certain performance goals, while the hospital will be charged of the full price if the treatment applied using the new technology will attain all the expected results.

Physicians deeply involved in the field of devices and technologies for arrhythmia management and invasive electrophysiology need to be prepared for involvement as stakeholders in the process of evaluation of risk-sharing agreements and specifically, in the process of assessment of technology performances and patient

outcome. Scientific Associations may have an important role in promoting the basis for value-based assessments, in promoting educational initiatives to help assess the determinants of the learning curve for innovative treatments and in promoting the institution, validation and verification of large-scale registries for a precise assessment of patient outcomes and of specific technologies' performance. Finally, there is the possibility that machine learning will allow to better map and predict the risks of medical interventions for specific patient profiles, thus reducing the uncertainties for health care providers, payers and manufacturers of medical technologies, facilitating the adoption of risk sharing arrangements, as well as improving decision making, thanks to better identification of potential responders to treatments.

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Table

Table 1. Opportunities and challenges related to implementation of risk-sharing agreements according to different perspectives. Modified from Gonçalves FR et al. ³⁷

Perspective	Opportunities	Challenges
Patients and the community	<ul style="list-style-type: none"> • Possibility of access to innovative treatments • Potential health improvement • Facilitation of investments for innovation 	<ul style="list-style-type: none"> • Risk that the treatment may not exert the expected benefits if the adoption occurs at an early stage • Protection of data • Adequate informed consent
Health care providers	<ul style="list-style-type: none"> • Rapid adoption of innovative treatments • Limitation of the short-term impact on available budgets • Reduction of the risk related to effectiveness and value of the applied treatment • Improved knowledge through collection of additional evidence • Improved management of uncertainty on effectiveness 	<ul style="list-style-type: none"> • Administrative procedures for implementing the agreements • Complexity of monitoring patient outcome through adequate datasets • Complexity of the evaluation of performance indicators • Complexity of implementation on a large scale • Complexity of managing multiple risk-sharing agreements
Payers	<ul style="list-style-type: none"> • Possibility to collect additional evidence, supporting subsequent decisions • Improved management of uncertainty on effectiveness • Possibility to improve patient targeting (identification of patients most likely to benefit from the treatment, avoiding to treat patients who would not benefit) 	<ul style="list-style-type: none"> • Need for proper identification of measurable performance indicators • Need for integrated information systems with precise and reliable data collection at local and national level • Need to allocate funding and resources for data collection and appropriate monitoring of indicators in line with risk-sharing agreement
Manufacturers	<ul style="list-style-type: none"> • Possibility of earlier introduction of innovative treatments into the market • Possibility to establish value rather than price as a reference for payers • Possibility to increase collection of data on evidence of benefit, also from the “real-world”, to support full implementation of effective treatments • Competitive differentiation 	<ul style="list-style-type: none"> • Administrative costs for submission and acceptance of the agreements • Demonstration of benefit depending on appropriate patient targeting (difficult in too severe patients) • Risk of not demonstrating effectiveness • Financial risks • Competitive market and shorter cycle for devices as compared with drugs. • Periodic assessments and reassessments of this process are needed, due to potential modifications of the context and the market, high level of competition and timing of competitors entry (faster than in development of new drug treatments).

Figure

Figure 1. Background and steps for promoting risk-sharing agreements, with a dialogue and a collaboration among health care providers, payers, HTA bodies, manufacturers and scientific associations, with the target to provide value to patients and the community.

Legend: HTA: health technology assessment.

