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Shared Decision Making in Cardiac Electrophysiology Procedures and Arrhythmia Management

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Abstract

Shared decision making (SDM) has been advocated to improve patient care, patient decision acceptance, patient-provider communication, patient motivation, adherence, and patient reported outcomes. Documentation of SDM is endorsed in several society guidelines and is a condition of reimbursement for selected cardiovascular and cardiac arrhythmia procedures. However, many clinicians argue that SDM already occurs with clinical encounter discussions or the process of obtaining informed consent and note the additional imposed workload of using and documenting decision aids without validated tools or evidence that they improve clinical outcomes. In reality, SDM is a process and can be done without decision tools, though the process may be variable. Also, SDM advocates counter that the low-risk process of SDM need not be held to the high bar of demonstrating clinical benefit and that increasing the quality of decision making should be sufficient. Our review leverages a multidisciplinary group of experts in cardiology, cardiac electrophysiology, epidemiology, and SDM, as well as a patient advocate. Our goal is to examine and assess SDM methodology, tools, and available evidence on outcomes in patients with heart rhythm disorders to help determine the value of SDM, assess its possible impact on electrophysiologic procedures and cardiac arrhythmia management, better inform regulatory requirements, and identify gaps in knowledge and future needs.

Keywords

Arrhythmias; Electrophysiology; Shared Decision Making

Journal Subject Terms

Catheter Ablation and Implantable Cardioverter-Defibrillator; Atrial Fibrillation; Health Equity

Introduction

Why Shared Decision Making?

Shared decision making (SDM) is a process in which patients and clinicians together take into account evidence, risk-benefit assessments, expected outcomes, and patient preferences and values to make decisions. SDM advances the ethical principle of patient autonomy. As a response to perceived poor communications between providers and patients, requirements to document SDM have been added or proposed for several aspects of arrhythmia management and even mandated prior to certain procedures as a condition of reimbursement in the USA. Advocates of SDM cite studies of decision aids (tools that can assist in SDM), reporting that decision aids improve patient-reported outcomes with little additional clinical time.[3, 4] However, many clinicians assert that SDM already occurs with the process of obtaining informed consent and during problem-based discussions within clinical encounters,[5] and note the additional imposed workload from mandated documentation requirements without evidence that use of formal documentation or SDM tools enhances clinical outcomes. Although the process of informed consent ideally should incorporate principles and practices of SDM, patient advocates note that for some, informed consent is often a one-way, paternalistic delivery of information with the patient signing consent for a procedure or not, whereas SDM is intended to be a two-way exchange of information. As a method of care, SDM provides an opportunity to help educate our patients about their disease process and address important life-impacting medical issues and patient priorities. SDM often adds levels of complexity, but can be satisfying to the provider. In a recent randomized SDM trial on anticoagulation in atrial fibrillation (AF) in 922 patients, using an SDM conversation tool (compared to no tool) increased patient involvement in decision making and clinicians' satisfaction, without affecting treatment decisions or encounter length.[6] Subjects in both arms reported benefits in communication quality, knowledge and low decisional conflict, though accuracy in their assessment of their risk was low in both groups.

The goal of our article is to: (1) review SDM methodology, and available tools and evidence on outcomes, (2) assess the impact of SDM on cardiac arrhythmia management, and (3) identify future clinical and research needs. The authors include experts in SDM, practicing cardiologists and electrophysiologists, and a patient advocate. Common terms used in the field of SDM are defined in the Definitions Box.

Outcomes Measured and Reported with SDM

A goal of SDM is to coproduce and decide with each patient a plan of care that makes sense to each patient as a response to the situation they are facing. That plan should make sense intellectually (consistent with evidence, responsive to their situation), emotionally (balancing the tolerability of the plan for the patient), and practically (it is feasible in the life of the patient, so that it can be implemented in a way that preserves the expected safety and effectiveness of the plan). On aggregate, SDM may increase uptake of sensible interventions that are underused, and may reduce the uptake of interventions that do not make sense and are overused.

Typical SDM Outcomes.

SDM outcomes are measured using patient-reported, provider-reported, and/or observer-based measures. Patient-reported outcome measures of SDM are surveys typically administered to patients before and after clinical encounters (e.g., clinic visit) to allow patients to self-report on the extent, quality, and outcomes of the SDM that occurred during the encounter. Examples include knowledge, risk perception, satisfaction, anxiety, decisional conflict, and decision regret, among many others. A common patient-reported outcome measure survey is the SDM-Q-9,[7] a set of nine questions wherein patients can self-report on their perspective of their involvement in SDM. A provider version of the SDM-Q-9 can be applied in research or quality programs to compare provider self-report to paired patient measures or observer-based measures. Observer-based outcome measures of SDM are completed by an independent observer who either sits in on the visit, listens to, or views a recording of the encounter. These observers then use a standardized framework to assess the extent and quality of the SDM that occurred in the encounter. The Option scale[2] is a commonly used observer-based outcome measure of SDM, although other methods exist. A systematic review of measures used to assess SDM can be found in two recent Cochrane reviews, one that evaluates patient decision aids[3] and one that evaluates interventions for increasing SDM.[8]

Patient/Clinical Outcomes.

SDM outcomes[9] can be conceptualized in three domains: affective-cognitive, behavioral, and health outcomes. Examples of common affective-cognitive outcomes include satisfaction and decisional conflict. Behavioral outcomes include making a decision about adherence to the chosen option (including no treatment). Health outcomes assessed in SDM vary and may include patient-reported outcome measures (e.g., health related[10, 11] or disease-specific[12, 13] quality of life, patient-perceived treatment burden[14]), disease-specific laboratory values (e.g., hemoglobinA1c), or subsequent healthcare or procedure utilization.

SDM is a process that can be done with or without a decision aid, but SDM outcome trials often test the benefits of decisions aids. In such trials, no difference between groups in health outcomes is common. Outcomes related to patients' values (i.e., how patients value outcomes arising from various options)[1] include: likeability of the values clarification methods, knowledge, decision-making processes, decisional conflict, uncertainty, satisfaction, decision preference, treatment intent, actual health behaviors, regret and, in some cases, health outcomes or cost.[15] A recent systematic review reported SDM had a significant association with affective-cognitive outcomes in 54% of studies and behavioral outcomes in 37% of studies.[16] The strength of the evidence was weakest for health outcomes, where the impact of SDM was significant in 25% of studies, all of which used patient-reported outcome measures (e.g., symptom reduction) rather than clinically-assessed outcomes.

A Cochrane review of 105 studies demonstrated that decision aids improve patient knowledge, satisfaction, patient/provider communication, increase patient involvement in decision making, the likelihood that treatment choice reflects patient values and goals, and reduce patient decisional conflict and regret with little additional clinical time (~2.6 minutes).[3, 4] There was moderate to high quality evidence on attributes of the decision (such as improved patient knowledge and risk perception) and attributes of the decision-making process (such as reduced decisional conflict related to feeling uninformed, feeling unclear values), and a reduced proportion of patients who were passive in decision-making. However, the majority of these outcomes were in tightly controlled efficacy trials.

Little is known about SDM outcomes in electrophysiology. SDM outcomes for patients who received a decision aid compared to control groups for anticoagulation in AF and implantable cardioverter-defibrillator (ICD) implantation are shown in Table 1.

A systematic review of six patient decision aids for stroke prevention in AF showed consistent findings.[22] *There was no evidence of adverse effects on health or satisfaction reported with interventions to facilitate SDM, nor was there evidence of health outcome improvement*.[3, 13, 23] Evaluations to date have primarily focused on shorter-term patient-level outcomes. Broader-level measures such as organizational and healthcare system level outcomes (e.g. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPHS) or other patient experience metrics) may warrant further investigation.

Decision Aids

Characteristics of Decision Aids.

Decision aids and similar tools have historically been designed to improve provider-patient communication through shared understanding, and by incorporating patient preferences seek to promote SDM. Importantly, decision aids are not equivalent to, but help to facilitate SDM. While standard informational materials and decision aids both provide educational information on the diagnosis and risks and benefits of treatment options, decision aids include components designed to improve the quality of patient-provider communication and to help patients clarify their values and goals.

Whereas the format of delivery of decision aids has varied – including paper booklets, websites, and apps – most decision aids (1) describe the medical condition, (2) describe the risks and benefits of treatment options (including no treatment) often using quantitative or qualitative displays, (3) use values clarification methods, and (4) promote patient-clinician discussion.[22] Decision aids can be broadly characterized as *patient decision aids*, designed for use outside clinical encounters, or *encounter decision aids*, which are incorporated into clinician visits. Decision aids are distinct from "clinical decision supports" designed to help clinicians determine the most ideal therapy based on a patient's characteristics.

International Patient Decision Aid Standards.

With rapid proliferation of decision aid tools being developed, it is important to assess if a decision aid provides reliable health information in a patient-centered manner. The International Patient Decision Aid Standards, developed from a collaboration of researchers, practitioners, patients, and policy makers established in 2003, are an evidence-informed framework for improving the content, development, implementation, and evaluation of patient decision aids and a set of criteria that can assess the quality and effectiveness of patient decision aids.[24] The framework includes: 1) a checklist to provide precise, quantitative judgments of the decision aid's quality at criterion (item), dimension, or global levels; 2) a 6-item qualifying and 10-item certifying criteria that reflect the minimal set of standards that could be used to certify the quality of a decision aid; and 3) a broader 28-item quality criteria.[25, 26]

Creating Decision Aids.

While creating patient decision aids through a deliberate patient- or user (clinician)-centered design is the gold standard, current design and development processes are not standardized and vary significantly. However, a review of existing decision aids summarizes features common to development processes as follows: (1) scoping and design in collaboration with patients and clinicians, (2) development of a prototype, (3) 'alpha' testing with patients and clinicians in an iterative process, (4) 'beta' testing in 'real life' conditions, and (5) production of a final version for use and further evaluation.[27]

Unfortunately, not all decision aids are developed and tested using patient- or user-centered design. Further, most depend on a significant amount of text-reading despite 14% illiteracy, 50% low health literacy, and low numeracy scores in the American population.[28] Decision aid creation should optimize the user experience by focusing on end-users, using an iterative and collaborative problem-solving approach. An effective, user-centered tool design usually begins with patient interviews and observations, resulting in concept generation. Then wireframe mockups are iteratively presented to targeted patient users who have experienced the decision (alpha testing) and then currently face the decision (beta testing), receiving patient input to usability and understandability throughout this process.

Certified Tools.

National Quality Forum is a US nonpartisan organization that in 2016 began serving as a certifier of SDM tools. However, very few SDM tools have been submitted to the National Quality Forum, and *there have been no cardiology SDM tools either submitted or approved*. National Quality Forum now supports the concept of setting up a process for certification of all patient decision aids at the national level. However, questions remain about how to ensure that a certification process becomes sustainable at such a broad scale.[29]

SDM Clinical Trial Study Design

Designing Trials in SDM.

Well-controlled comparative effectiveness clinical trials provide the strongest evidence of causal relationships between SDM tool use and desired outcomes. Most standard clinical trial designs can be utilized, but may differ from traditional randomized arrhythmia clinical trials, for example using patient-reported outcomes as primary outcomes, or cluster or healthcare unit randomization units. In considering primary and key endpoints, SDM tools can have multiple goals that may or may not be concordant with clinical effectiveness. For example, improvements in patient satisfaction and health-related quality of life may not necessarily result in improved traditional clinical benefits. A pilot study may help obtain patient and clinician input for primary endpoint selection. Nevertheless, inclusion of clinical health outcome endpoints is encouraged to enhance future adoption, implementation, and dissemination. Composite endpoints may be useful to integrate different perspectives and capture outcome tradeoffs. Subgroup information should be pre-specified and collected for assessment of heterogeneity of effects. Adaptive designs can identify patient subgroups that benefit from SDM.[30] Following Patient Centered Outcomes Research Institute (PCORI) methodology standards is also useful for SDM trials.[31] Training of clinicians in study procedures may be more critical for SDM trials that randomize patients to minimize risk of treatment contamination, as clinicians may be participating with patients in both arms of the study.

SDM in Cardiac Electrophysiology and Arrhythmia Management

As noted above, evidence on the effect of SDM or decision aids on outcomes remains sparse in cardiac electrophysiology and arrhythmia management with only limited SDM health outcomes data available for anticoagulation for atrial fibrillation (AF) and implantable cardioverter-defibrillator (ICD) implantation (see Table 1). Table 2 lists links to SDM tools for electrophysiology-related care.

Implantable cardioverter-defibrillators (ICDs).

In appropriately selected patients at higher risk from sudden cardiac death (SCD), ICDs reduce mortality by aborting lethal ventricular arrhythmias. However, psychological adjustment and health-related quality of life may be lowered in the setting of repeated shocks.[32] Further, ICDs can be limited by lead failures, device malfunction, and inappropriate shocks,[33] and may potentially cause unnecessary suffering at the end of life.[34, 35]

Patients with devices recommended for primary prevention of SCD face the ICD decision in several contexts: 1) initial implantation, including type of device (e.g., transvenous or subcutaneous); 2) generator replacement; 3) considering whether to include defibrillation function in devices placed for cardiac resynchronization therapy (CRT); and 4) end-of-life care.[36] Each decision hinges on whether the patient’s goals align with accepting a device with its anticipated benefits, risks, and burdens. However, decision making is often difficult due to competing goals. For example, patients may wish to extend life through ventricular arrhythmia treatment, while simultaneously holding the conflicting preference to die peacefully in their sleep.[37]

The current state of SDM in ICD care has been reported to be suboptimal. Reports frequently highlight suboptimal practice with respect to patient education and inclusion in decision making.[38, 39] Patients with ICDs frequently report never having had a conversation about peri-procedural risks, expected benefits, or potential health-related quality of life impact; express mixed preferences for desiring to be involved in decisions; tend to overestimate the benefits and underestimate the risk of ICDs; and are often uninformed about device deactivation options.[40] Studies of clinicians' perspectives identify guideline-based, rather than patient-preference-based, decision making.[40]

Recent policy and new research are intended to address these needs. SDM for ICDs is a Class 1 recommendation (level of evidence B-NR [non-randomized]) in the 2017 ACC/AHA/HRS Ventricular Arrhythmia/SCD guidelines.[41] In its most recent national coverage determination, the Centers for Medicare and Medicaid Services (CMS) mandated the use of a decision aid for ICDs for patients considering primary prevention ICDs. Trials of decision aids for ICDs are ongoing.[42]

After CMS mandated use of SDM for ICDs, an on-line survey of physicians (350 surveyed, 124 responded, 102 [84%] met inclusion criteria) reported that 88% of physicians reported discussing the pros and cons of receiving an ICD and taking into account the patient's preferences and health goals; 62% reported discussing end of life issues, including deactivation of an ICD; 43% reported using an existing SDM tool, with the Colorado SDM tool being the most common (89%); 37% answered that women perceive ICD implantation differently from men; and 39% thought that Black patients perceived ICD implantation differently from Whites.[43] Achieving a true SDM approach would ideally synthesize such potential individual differences into both the risk assessment and the tailoring of information in the process.

Cardiac Resynchronization Therapy (CRT).

In clinical trials, CRT reduced mortality and hospitalizations in heart failure patients with moderately to severely reduced left ventricular ejection fraction (LVEF) and intraventricular conduction delay, and also benefited patients with mildly reduced LVEF and high ventricular pacing burden. However, CRT implant carries higher risk than other cardiovascular implantable electronic devices for both initial implant and generator changes.[44, 45] Current U.S. guidelines for CRT state that "patients should be involved in SDM whenever feasible, particularly for class of recommendation IIa and IIb, for which the benefit-to-risk ratio may be lower."[46]

Further complicating decision making, CRT can be offered with or without a defibrillator. While CRT and ICD functions can be contained within the same device, they are quite different: CRT ideally improves cardiac function and LVEF, leading to potential improvements in quality and quantity of life; ICD aborts sudden cardiac death, but does not improve cardiac function or quality of life, and may lead to inappropriate shocks or shocks at end of life.

Therefore, decisions about CRT are complex and demand an assessment of the patient's preferences and values regarding quality and quantity of life.[47, 48] Current guidelines and the trials upon which the guidelines were based offer a starting point. However, these resources are not individualized and fail to account for patient-specific features that impact response and outcomes following CRT. Scoring systems that provide tailored estimates of benefits and risks exist, but none has been tested prospectively or assessed in the SDM process prior to CRT implant.[49-51] At this time, any impact SDM has on patient or clinical outcomes remains unknown, and significant work remains to determine the optimal way to engage and inform patients in these decisions.

Pacemakers.

The 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay[52] recommends SDM components should be followed when counselling patients regarding the indications and risks of permanent pacing for symptomatic bradycardia. Although pacemaker implants and replacements are typically low to moderate risk procedures, but SDM may be particularly relevant in patients who have limited life expectancy or who are at high risk for procedure-related complications due to frailty or older age. Additionally, SDM is advantageous if there is less compelling or incomplete evidence for pacing (e.g., new left bundle branch block after transcatheter aortic valve procedures; conduction system vs. cardiac resynchronization therapy pacing), consideration of newer technologies (e.g., leadless pacing), or when discussing generator replacement if the initial indication appears resolved (e.g., transient heart block).

Atrial fibrillation and Anticoagulation.

There is considerable interest in the application of SDM to AF care, particularly for the decision to initiate long-term anticoagulation for stroke prevention. In 2014, the ACC/AHA/HRS issued a class 1 recommendation (level of evidence C) for SDM to individualize anticoagulation use in patients with AF at risk of stroke.[53] In response to these guidelines, numerous tools have been developed[3, 22, 54-56] and clinicians have begun to incorporate these into daily practice. Although the content,[54, 57-59] comprehensiveness,[22] and patient-centeredness of these tools may vary, they all seek to help patients understand key information, provide estimates of individualized risk, and help clarify patient-specific priorities for care. In doing so, these tools are designed to facilitate a conversation that addresses both the available clinical evidence and individual patient preferences and values.

One driver of interest in SDM in the AF anticoagulation context is suboptimal anticoagulant prescription rates and challenges with ongoing adherence and persistence, which represent opportunities to potentially improve clinical outcomes using well-proven therapies in appropriate patients. Consistently, only 55-70% of indicated patients are prescribed anticoagulation,[60] which arguably reflects not only patient decisions but also physician knowledge and judgment. Nevertheless, of patients prescribed anticoagulation, less than half remain on therapy at one year; and patients not on anticoagulation have been shown to have increased stroke risk[61, 6263] Low anticoagulation rates are likely multifactorial, including the hidden benefit of anticoagulation (as avoided stroke is clinically silent), whereas the potential harms, costs, and inconveniences weigh more heavily on patients' daily lives. In a study of self-reported treatment burden in 331 patients with AF and 183 no AF controls, treatment burden was: (1) higher in patients taking vitamin K antagonists than those taking direct oral anticoagulants (DOACs); (2) higher in females, younger patients, and permanent AF; and (3) an independent predictor of decreased QOL.[14] Thus, an important goal of clinical practice for stroke prevention in AF is improving anticoagulation prescription and adherence, for patients whose risk factors and values align with that strategy.

Therefore, implicit in the call for SDM in AF is the hope that engaging patients in an active SDM process will result in better communications that lead to more informed patient decisions and improved adherence to treatment.[64] Whether such efforts will change treatment rates, decisions between anticoagulation choices, or impact long-term medication adherence or clinical outcomes remains to be proven. Nevertheless, adherence is a key outcome in at least one large, prospective, randomized clinical trial examining SDM in AF patients.[55] The Shared Decision Making for Atrial Fibrillation (SDM4AFib) encounter-randomized trial of patients with nonvalvular AF considering or reviewing anticoagulant therapy randomized 922 patients (244 clinicians) to standard care or use of the Anticoagulation Choice SDM tool.[6] No significant differences were found on treatment decisions or encounter duration, but patient involvement and clinician satisfaction were significantly higher in the SDM arm. Additional studies will also examine similar effects and adherence to therapy. To date, there has been little attention to SDM for other aspects of AF management, such as rate vs. rhythm control or AF ablation.

Left Atrial Appendage Closure.

In the AHA/ACC/HRS 2019 AF management guidelines, percutaneous or surgical left atrial appendage closure (LAAC) has a class IIb recommendation (level of evidence B-NR). Historically LAAC was performed surgically at the time of concomitant open-heart surgery; more contemporary approaches are via minimally-invasive surgery or use catheter-based tools and devices, broadening the candidate population. However, there is ongoing debate over the net benefit of this procedure,[65, 66] LAAC is not appropriate for all AF patients, and there are important missing data regarding direct, randomized, head-to-head, long-term comparisons between percutaneous LAAC and chronic, systemic anticoagulation with DOACs for stroke prevention in AF.[67] Therefore, SDM is a vital part of patients understanding the benefits and risks of LAAC, and was mandated as part of CMS' coverage decision for the latest catheter-based approaches to LAAC.[68]

Implementation of SDM for LAAC might include integration with a decision aid that addresses the alternatives (i.e., oral anticoagulation), as well as the benefits and risks of LAAC itself. Yet this remains unresolved, and clinicians seem to be primarily relying on broad SDM tools for stroke prevention in AF.[69] Some of the challenges to implementing a comprehensive SDM tool for LAAC are (1) the many outstanding questions around LAAC, including comparative effectiveness versus DOACs, long-term management strategies (e.g., long-term antithrombotic regimens, periprocedural considerations, cardioversion, etc.);[70] (2) the SDM process being potentially conducted by clinicians unfamiliar with the LAAC procedure; and (3) that different methods of LAAC can cross disciplines (e.g., cardiac surgery vs cardiac electrophysiology) with attendant inherent preferences and familiarity.

Demonstration of patient or clinical benefit to SDM for LAAC has yet to be demonstrated and optimally should be included in clinical trials of LAAC SDM tools.

Ablation for Cardiac Arrhythmias.

Catheter ablation for AF, as well as ventricular and supraventricular arrhythmias, is an attractive option for many patients with symptomatic or life-threatening arrhythmias. These procedures can carry considerable risks and costs, and outcomes can vary significantly. Navigating the complexity of these decisions necessitates a careful and individualized SDM process.

Much of the interest in SDM as it relates to ventricular arrhythmias and sudden death has been focused on decisions regarding ICD implantation, and in AF on anticoagulation and LAAC decisions. However, current society guidelines recommend SDM play a broad role in all decisions regarding ventricular arrhythmia treatment, stating that "in patients with ventricular arrhythmia or at increased risk for SCD, clinicians should adopt a SDM approach in which treatment decisions are based not only on the best available evidence but also on the patients' health goals, preferences, and values."[71] Patients with ventricular tachycardia often face high mortality rates usually from underlying severe cardiac disease.[72, 73] SDM itself can be challenging when outcomes are uncertain (both with and without intervention), and patient preferences for various treatments and their acceptance of SCD or AF risk may evolve throughout the course of their illness. The process requires that clinicians help patients synthesize the available evidence and fully explore patients' values, goals, and preferences, and come to a decision together. This requires a great deal of subject matter expertise as well as a sensitivity to patient perspectives and context. The 2019 consensus statement on ventricular arrhythmia ablation mentions that SDM skills should be developed to effectively communicate and counsel patients.[74] The 2017 AF ablation consensus statement made no mention of SDM, though such a process may be useful in this arena.[75]

Genetic Testing.

Clinical integration of genetic testing for patients with suspected inherited arrhythmias or cardiomyopathy is becoming more feasible. However, genetic testing has limited diagnostic yield, results may have implications on insurability, and result interpretation is complex. These issues highlight the need for pre-test genetic counseling by a trained professional to ensure SDM regarding testing, and again after testing.[76] Genetic analysis can be helpful for clinical diagnosis and management of inherited arrhythmias and cardiomyopathies, but is limited by the fact that genetic testing is an imperfect science; our ability to detect gene variants exceeds our ability to interpret the implications of each variant on a patient's disease. Given an overall low genetic literacy in the general population, pre-test counseling is key to setting appropriate expectations about possible test results, assessing the patient's perception of risk, discussing possible medical management based on the test outcome, and reviewing the current standing of regulations around insurance, including the Genetic Information Nondiscrimination Act and its limitations (e.g., GINA does not cover some forms of insurance including life, long term care, and disability). It is important for the provider and patient to arrive at the decision to pursue genetic testing together, considering the patient's values, autonomy, and preferences.[77] Genetic counselors are trained to provide patient care in a non-directive manner, which lends themselves well to an SDM approach, especially if a patient's medical management can benefit from a specific genetic diagnosis.[78]

Post-testing, the provider and patient work together to develop a management plan if the genetic diagnosis is made or remains uncertain, or if the diagnosis is secure despite negative testing, and to navigate informing blood relatives of their options for clinical screening and/or familial gene variant testing, if applicable. Since inherited arrhythmia and cardiomyopathy syndromes may confer risk for SCD in family members, it is important to have considered a family communication strategy and potential for psychological impact if faced with a familial diagnosis.[79] Overall, communication about genetic testing should be focused on helping the patient make informed choices that consider knowledge of genetic risk, future implications, and personal preferences, particularly around risks and benefits of available therapies, as randomized trials and data regarding genetic implications for therapies remain sparse.

Return to Play for Athletes Diagnosed with Cardiovascular Disease.

Recognition of cardiovascular disease in athletes is rising due to a combination of pre-participation screening, expansion of familial cascade screening for inherited arrhythmia conditions, early recognition and evaluation of symptoms, and improved survival after cardiac arrest. For athletes wishing to return to sports participation after cardiac diagnosis, historically, the 2005 Bethesda guidelines provided binary yes/no approaches to medical restriction versus allowing return to play. However, while sports participation may carry risk, sports also provide multiple physical and psychological benefits, and restriction from sports can severely impact quality of life.[80] Since 2005, several trends have contributed to a movement toward SDM for return to play decisions amongst athletes, families, physicians, schools, and sporting organizations.[81]

First, data are emerging for several scenarios, such as presence of an ICD[82] and Long QT Syndrome,[83] that sports participation may carry lower risk than previously thought. Second, the 2015 joint AHA/ACC statement, "Eligibility and Disqualification Recommendations for Competitive Athletes With Cardiovascular Abnormalities", now includes a number of class II recommendations regarding sports participation.[84] Similarly, the recent AHA/ACC Guideline for Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy now explicitly endorses SDM for participation in vigorous or competitive sports.[85] Finally, eligibility recommendations now include discussion about individualized decision making for all cardiac conditions including those in which the main recommendation remains "restrict." Understanding the role of sports in the patient's life can help guide the athlete and family through the difficulties of thinking about risk, as can describing the wide spectrum of tolerance for risk amongst patients and families. If the final decision is to return to play, physicians and other caregivers should support all stakeholders, including athletes, parents, team physicians and athletic departments, to ensure all recommended safety measures are in place to mitigate risk.

Impact on Care Team Practices

Impact on Physicians, Nurse Practitioners, Physician Assistants, and Nurses.

Multidisciplinary care teams in cardiology deliver high quality, cost-effective care and have an opportunity to integrate SDM into clinical practice.[86-90] While SDM can be facilitated by various members of the care team, most research has focused on physicians as primary facilitators of SDM. Yet overall adoption of SDM by physicians is low across specialties.[91] Many physicians are supportive of SDM in theory; however in practice they report a number of perceived barriers to routine adoption, including time constraints, lack of applicability of SDM due to patient or clinical characteristics, lack of physician training/self-efficacy, and the perception or reality that some patients are not interested in participating in decision making.[91] Physicians' perceptions of the impact of SDM on time may be overestimated. In one study SDM added <3 minutes to the clinician encounter;[6] in SFM4AFib, no significant difference in time was found (mean 32 min SDM, 31 min standard care);[6] and in a meta-analysis of 13 SDM studies, 9 showed no difference in time, 3 took longer, and 1 was shorter with SDM.[92] Education and training in SDM has the potential to increase clinician perception of efficacy, which may facilitate adoption of SDM across the multidisciplinary team.[8] Emerging models that emphasize SDM as a clinical problem resolution method may enhance clinician recognition of the pertinence of SDM.[5]

Many cardiology practices utilize nurse practitioners and physician assistants.[86, 93] Along with their physician colleagues, these providers are well-positioned to engage patients in healthcare decision making and treatment plans;[94] unfortunately, their roles in doing so are often overlooked. In terms of SDM, patients have suggested that the process be distributed among multidisciplinary care team members, particularly nurses, who are considered mediators of information and trusted advocates.[95] Integrated within an evidence-based practice context,[88] nurses can identify decisions faced by patients, screen for decisional conflict, and if present, identify decisional needs and provide support to address them. Nurses can also monitor progress in decision making, from deliberation to implementation, steps which can be enhanced by SDM interventions such as decision aids and/or decision coaching. In electrophysiology, several interventions to support SDM have relied on nursing involvement.[17, 20, 96] Nurse and nurse practitioner-led AF clinics also offer the fundamental elements and structure to support greater patient involvement in treatment decision making.[87, 97] Nurses' role in SDM fits well within nursing scope of practice and professional competencies (e.g., patient education, values-based decision making). Recognition of the knowledge, skills and contributions of advanced practice providers, behavioral / mental health providers and pharmacists as key team members to facilitate quality health decision making with patients is an opportunity for enhancing multidisciplinary team SDM practices.

Cost and Cost effectiveness.

The premise of SDM is that decisions will better reflect patients' values and patients will be better informed. Whether higher quality decisions result in more cost-effective care is an area of great interest to healthcare policy makers. Some data have shown that patients who have received decision aids were more likely to choose more conservative treatment options, which can result in lower healthcare costs.[3, 8] However, a 2014 systematic review of 7 studies reporting the impact on healthcare costs as a result of decision support interventions concluded there was insufficient evidence that these tools drive down healthcare costs.[98] Of the seven studies presented in this review, three predicted system-wide savings, ranging from $8 to $3068 per patient. Costs were decreased among studies that showed lower utilization as a result of decision support. For example, a study at Group Health (now Kaiser Permanente) found lower hip and knee surgery rates and costs following widespread implementation of decision aids, therefore being cost-effective at the institution level.[99] In addition, a randomized trial of SDM for six preference-sensitive conditions found patients who received the SDM intervention had 5.3% lower healthcare costs, resulting from 10% fewer elective surgeries including 21% fewer elective heart surgeries.[100] For patients, SDM therefore may result in cost savings, via fewer procedures and hospitalizations. However, overall, there is limited evidence to support the impact of SDM of healthcare costs, with heterogeneity in the approaches to measure such costs and limited follow up time, which may underestimate benefits.

Dissemination, Adoption, Implementation, and Maintenance

Engaging both patients and clinicians in SDM can be challenging. Outcomes in real-world implementation have been minimal. Integration of formal tools into routine care is rare, and the quality of SDM for most medical decisions remains suboptimal. The reasons for limited adoption of patient decision support interventions are likely multifactorial. A systematic review of decision aid implementation identified a host of logistical barriers, including clinicians' perception of time necessary to use decision aids, lack of reimbursement, and perceived bias inherent in the decision aids themselves.[101]

Strategies and examples of successful adoption.

One common strategy for implementation is a model in which clinicians and staff refer patients to patient decision support tools.[101] This approach places the onus on health care professionals, who are often indifferent due to a reported lack of confidence in the content of decision support interventions, concerns about disruption to established workflows, and a belief that the clinician is already doing SDM. For some of these tools, additional burden may also be placed on patients as they are asked to spend time consuming information in the absence of a clinician who might speed the process.

Examples of relatively successful adoption of singular decision support tools tend to leverage existing processes and create wins for the patient, clinician, and system. An example is a decision aid for patients considering left ventricular assist devices (LVADs) that has been integrated into the highly structured LVAD evaluation process.[102] Tools must be obviously helpful to patients, easy-to-use, integrated into the flow of care, and seen as valuable (i.e., decreasing overall work or adequately incentivized). Examples of sites with EP decision aids are shown in Table 2.

Systematic approaches to broad implementation of SDM exist. Examples of large entities that develop, test, and identify the best ways to embed SDM, who have all reported organization-wide adoption of decision support tools for selected conditions include: The

Agency for Research and Healthcare Quality, Mayo Clinic Shared Decision Making National Resource Center, The Ottawa Hospital Research Institute, The Informed Medical Decisions Foundation, The Center for Shared Decision Making at Dartmouth-Hitchcock Medical Center, Massachusetts General Hospital, [103] the Colorado Program for Patient Centered Decisions, and Kaiser Permanente (formerly Group Health) in Seattle[104]. These institutions currently house materials for patient decision support in the areas of LVADs, ICDs, stroke prevention in the setting of AF, and CRT devices. In 2010, the Health Foundation in the UK commissioned the MAGIC (Making Good Decisions in Collaboration) program to design, test, and identify the best ways to embed SDM into routine primary and secondary care using quality improvement methods.[105] Yet, all of these examples have encountered barriers to wider adoption. Third parties who systematically collect (e.g., Ottawa Hospital Research Institute) or develop tools (e.g., Healthwise, Emmi) and make them easily available can be helpful; integration of these tools has now occurred for >20% of Americans through their electronic health record (EHR). But mere availability has been insufficient to promote routine use in clinical practice.

As a first step for implementation, clinical teams must understand the reason behind an intervention and appreciate the benefits of SDM to their clinical practice. Without sufficient buy-in, clinician and systems are unlikely to invest the resources necessary to effectively implement an intervention.[106] A site/practice champion is also helpful for implementation.

Role of training.

In addition to workflow integration and professional society endorsement, incorporation of SDM into clinical practice relies on effective training. In training clinicians on SDM, prior research has demonstrated the benefit of structured practice and simulation sessions in developing a logical framework and technical skills to naturally integrate SDM into clinical workflow.[107] When incorporated as part of medical education (e.g. medical school, pre-licensure healthcare professionals), there remains limited rigorous evaluation of the impact of SDM training, including on its long-term use.[108, 109] When subsequently training healthcare professionals to use decision aid tools, the end goal remains to promote meaningful provider-patient discussions. As a result, the focus of training should be to help clinicians navigate the various aspects of a tool to more effectively enhance knowledge transfer and encourage/facilitate patient input.[105] In combination, this allows for easy integration of future interventions while continuing to build on a set of skills that continually reinforces SDM.

Family members and decision surrogates.

Approximately 39 million people in the U.S. act as informal caregivers for adults (most of whom are spouses or partners), and these caregivers may also act as surrogate decision-makers. Only a few studies have evaluated the impact of decision aids on surrogate SDM, mostly involving patients with cognitive impairment.[110] In some of these studies, surrogates who had a decision aid available reported lower decisional conflict, more consistent treatment,[111] and improved knowledge.[112, 113] However, surrogate decision making is commonly driven by advanced directives without decision aids, and as several studies question the efficacy of advanced directives and surrogate decision making on outcomes,[114] more research on adding decision aids for surrogate decision makers is needed.

Changing the culture of care delivery; spectrum of autocratic health care delivery to SDM.

Traditionally, decision making in medicine has been dominated by a fairly paternalistic approach in which information flows from the physician to the patient and the patient then makes a decision on therapy for a medical problem. Paternalism of physicians varies widely as does the desire by patients to receive a paternalistic approach. There has been a strong drive in cardiology to adopt a true SDM approach in which the physician and multidisciplinary team are fully informed about patient values, goals, and preferences, and the patient and caregiver/family are fully and objectively educated about choices.[115]

Equity in adoption and dissemination.

Several factors can affect equity in the adoption and dissemination of SDM interventions for arrhythmia management, including (1) patient health literacy, (2) readability of patient decision support tools, (3) buy-in from clinicians regarding the utility and informational content of decision support tools, (4) reimbursement for time spent facilitating SDM, and (5) systemic and clinician implicit biases.[116, 117] Evaluating SDM processes by patient age, gender, race/ethnicity, socioeconomic status, and geography will help identify and document equity in the dissemination of arrhythmia management SDM interventions.[118] A systematic review and meta-analysis reported that SDM interventions may be more beneficial to disadvantaged groups than higher literacy/socioeconomic status patients, suggesting that SDM might help narrow health disparities.[118] A pilot randomized study of a targeted patient-centered educational video on sudden cardiac arrest and ICDs reduced racial differences in patient preferences for an ICD.[119]

Cross-cultural issues.

Cultural differences between patient and providers may involve language, race/ethnicity, religion, socioeconomic status, and communication preferences.[120] Cross-cultural differences may also exist regarding patients' preferred role in decision making, beliefs about the origins of disease and ways of healing, and how emotion is expressed. One study of middle-aged residents from 7 Eastern and Western countries found that people who desired higher self-involvement in medical decision making wanted less family involvement; whereas those who valued social hierarchy and relational-interdependence wanted more family involvement.[121] Implementing a SDM process may mitigate pre-existing assumptions and enhance cultural humility by encouraging clinicians to elicit patients' values, preferences, and goals for treatment.

Addressing health literacy and psychological barriers.

Low health literacy is linked to poorer health outcomes, including higher mortality.[122] Decision making for cardiac conditions is often complex because individuals may have low understanding of their condition, and management decisions are often multifaceted. One approach to improving arrhythmia knowledge is mobile health applications. However, a study published in 2019 that evaluated AF apps for patients reported that most lacked scientific validation and on average were written at the 12th grade level.[123] A better understanding of how to support patients with low literacy and numeracy is needed to advance patient engagement and health outcomes. Documents such as the AHRQ Health Literacy Universal Precautions Toolkit Components and Modification for Atrial Fibrillation (AF) Clinical Care and Practice[124] provide guidance in developing educational tools that address health literacy.[124, 125] As SDM strategies for arrhythmia management are tested, it will be critical to ensure the inclusion of diverse patient populations, including individuals with low health literacy and numeracy, and diverse medical practices (e.g., academic medical centers, community-based hospitals, solo practices, and clinicians serving in medically underserved and rural areas) that may impact the willingness and/or capacity to implement SDM.

Successful participation in SDM also may be hampered by psychological distress or altered mood states. The nature of spontaneous and unpredictable symptoms with arrhythmias may trigger anxiety and depressive symptoms. Acknowledgement of associated distress and altered mood and an offer of counseling by mental health experts may improve the SDM process.

Leveraging Health Information Technology.

Technology has the potential to help bring patient-centered care and SDM to scale by making relevant information and tools easily and widely available. Facile EHRs that incorporate patient decision aids into routine care offer a promising approach for overcoming barriers to implementing SDM in practice. SDM tools can be linked or embedded in the EHR, and the patient can be automatically notified or sent paper tools. Digital health systems may be used for patient management, and SDM tools may be effective in guiding the decision making process. Similarly, diagnostic tools embedded in digital health may present options for the preferred path for diagnostic pathways, particularly for disease screening. However, seamless integration and maintenance has been challenging due to a variety of issues, including poor interoperability of software and lack of prioritization of SDM among various possible automated alerts.

Role of Societies and Guidelines.

Specialty societies can play a unique role in the adoption and implementation of SDM. Importantly, societies have already started endorsing SDM in several guidelines (Table 3). A recurrent barrier to adoption of decision aids is that clinicians lack trust in the content of the decision aids.[101] There is evidence that urologists may be more likely to trust the content of a decision aid if it were endorsed by their specialty society.[128] However, simply inserting use of SDM decision aids in recommendations can lead to difficulties in implementation, if there is no consideration of barriers, costs of implementation, relevancy to clinical practice, and availability of and evidence for easily usable tools.[129, 130]

SDM as a requirement for reimbursement

Examples of required SDM and impact, outcomes (LAAC, ICDs).

Policymakers have increasingly acknowledged the importance of patient-centered care. SDM was explicitly supported by the Affordable Care Act in 2009. In 2013, the Food and Drug Administration launched the Patient Preference Initiative which incorporates patient perspective into regulatory decision making, and SDM is considered part of the approval process for new drugs and devices. Recently, CMS began including requirements for SDM with the use of patient decision aids as a condition of reimbursement for LAAC device placement and ICDs (Table 4).

These mandates have been met with mixed reviews. A common criticism is that the requirements predate clear evidence of their benefit. Some have suggested that until the content and design of decision aids are evident, such mandates may not have the desired impact and outcomes.[131] At the same time, it is possible that implementation of SDM would not occur in absence of an associated mandate.[101] Regardless, the mandates have fostered an environment of innovation in the SDM process by developing and evaluating tools to meet these requirements.

Recommendations or considerations for when regulatory bodies might require SDM.

SDM tools that are recommended or mandatory should focus on interventions that have demonstrated clinical benefit but have equally important risks that patients must consider. Criteria for SDM should indicate specific domains or characteristics that should be included. Domains such as those proposed by the National Quality Forum and International Patient Decision Aid Standards committee may serve as guides. Health literacy should be a required consideration. As regulatory bodies contemplate requiring SDM,[132] considerations should be given to factors contributing to effective implementation: 1) availability of validated SDM tools; 2) scientific evidence that SDM yields improvement in patient-reported or clinical outcomes; 3) transparency in the process of developing the mandate including the opportunity for public comment; and 4) description of an implementation pathway. Professional societies such as the American Heart Association, American College of Cardiology, the Heart Rhythm Society, and the Heart Failure Society of America, and patients/patient organizations should be engaged to develop or promote development of SDM tools and implementation pathways.

Summary, Gaps and Future Directions

Despite a proliferation of tools to promote SDM for patients with cardiac electrophysiology needs and insertion of regulatory requirements for SDM in various areas, certification of tools remains elusive, and decision support interventions and widespread adoption has not occurred outside of interventions for which regulatory agencies require SDM as a condition of reimbursement. Ideally, components of SDM do enter into clinical encounter discussions. In reality, the process may be variable, and systematic use of decision aids in SDM may help to facilitate decision making taking into account patient preferences and values. Links to sites with electrophysiology and arrhythmia-related tools are included in Table 2.

For cardiac electrophysiology conditions and procedures, as well as for SDM in other conditions, the impact of SDM and decision aids on clinical effectiveness outcomes remains difficult to establish. Typical patient-reported outcome measures, such as satisfaction, anxiety, decisional conflict or regret are outcomes that have not been the typical focus of electrophysiologists whose primary sights have been to prolong life, avoid sudden death, and improve arrhythmia-related quality of life. However, the risk of performing SDM is minimal, and so we cannot expect to require the typical clinical outcomes of reduction in major cardiac adverse events expected of new devices or drugs. A systematic review of decision aids for stroke prevention in AF showed there was no evidence of health outcome improvement, nor evidence of adverse effects on health or satisfaction reported with interventions to facilitate SDM.[22] Also, a recent randomized study of SDM in stroke prevention for AF demonstrated no effect on treatment decisions or encounter duration, but improvement in several measures of patient and clinician satisfaction.[6] In some arenas, demonstration of increased adherence to medical therapies, such as anticoagulation for AF where there has been evidence of poor adherence, may yield an additional convincing rationale for SDM.

That SDM is recommended increasingly in professional society heart rhythm management guidelines and consensus documents has raised controversy in view of the limited evidence base supporting the impact of decision aids and SDM on outcomes in device and ablation candidates and other complex decision making (see summary, Table 1). As we have noted, however, primary goals in SDM have not necessarily been to improve healthcare outcomes, but to promote patient autonomy, a true shared understanding of medical issues, alignment with patient values and goals, and the production of plan of care that makes practical, intellectual, and emotional sense for the patient and their life. SDM may be particularly relevant in patients at high risk for device implants or procedures, or in areas of incomplete evidence, as in some decisions on pacing, CRT, ablation, genetic testing, and sports participation.

For ICDs and LAAC, CMS reimbursement requires documentation of SDM. In such contexts, when documentation of SDM is mandated for reimbursement, ideally there should be consideration as to the availability of: 1) relevant and validated SDM tools; 2) scientific evidence that SDM yields improvement in patient-reported or clinical outcomes relevant to the procedure, test or treatment; 3) transparency in the process of developing the mandate including the opportunity for public comment; and 4) description of an implementation pathway.

Keys to implementation of SDM in practice will also involve creating tools that (1) are updated with evolving clinical evidence and practice norms and (2) can be implemented without undue additional clinical burden, potentially facilitated by a multidisciplinary care team. A static tool may quickly become out of date and one that requires manual data entry may be cumbersome and disruptive to the patient encounter. Alternatively, one might imagine SDM tools that are powered by automated data analytics that pull from the EHRs or other sources to provide real-time personalized risk estimates, actual out of pocket costs that may vary with changes in insurance coverage or formularies, and prompt discussions that center around areas of particular importance to an individual patient (e.g., a history of intracranial bleed or potential drug-drug interactions). Such tools may facilitate clinician work flow and may be of particular value in promoting meaningful SDM in an efficient manner.

Gaps and future directions are shown in Table 5. We cannot overemphasize the need for additional randomized studies in electrophysiology to evaluate SDM processes. Trials of decision aids for ICDs and anticoagulation for AF are ongoing. Studies should include diverse patient populations, such as individuals with low health literacy and numeracy, African American and Hispanic patients amongst other ethnic/racial groups, to help identify and document equity and needs for the dissemination of arrhythmia management SDM interventions. Moreover, inclusion of health outcome endpoints are encouraged to enhance future adoption, implementation, and dissemination.

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Abbreviations:

AF	Atrial fibrillation
ACC	American College of Cardiology
AHA	American Heart Association
CMS	Centers for Medicare and Medicaid Services
CRT	Cardiac resynchronization therapy
EHR	Electronic health record
HRS	Heart Rhythm Society
ICD	Implantable cardioverter-defibrillator
LAAC	Left atrial appendage closure
LVAD	Left ventricular assist device
LVEF	Left ventricular ejection fraction
SCD	Sudden cardiac death
SDM	Shared decision making

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Box - DEFINITIONS

Shared decision making (SDM):

a process in which patients and clinicians together take into account evidence, risk-benefit assessments, expected outcomes, and patient preferences and values to make decisions.

Decision aids:

tools that can assist in SDM.

Values:

how patients value outcomes arising from various options[1]

Preferences:

Patients' most favored health care options[1]

Values-based outcomes:

Patient-reported outcome measures:

survey measures, typically administered to patients before and after clinical encounters, in which patients self-report the extent, quality, and outcomes of the SDM that occurred during the encounter. Examples include knowledge, risk perception, satisfaction, anxiety, decisional conflict, and decision regret. A common patient-reported outcome measure survey is the SDM-Q-9

Observer-based outcome measure:

completed by an independent observer who either sits in on the visit, listens to, or views a recording of the encounter. These observers then use a standardized framework to assess the extent and quality of the SDM that occurred in the encounter. The Option scale[2] is a commonly used observer-based outcome measure of SDM, although other methods exist.

Table 1.

Shared Decision-Making Outcomes for Patients who Received a Decision Aid Compared to Control Group

Author (Yr)	n	Knowledge	Risk Perception	Satisfaction	Anxiety	Decisional Conflict	Decision Regret	SDM-PROM	SDM-OBOM	Treatment selection	Adherence to Chosen Option	Health-Related Quality of Life	Biophysical (e.g., blood pressure)
Atrial Fibrillation/Anticoagulation													
Kunneman (2020)[6]	922	◊	◊	●/◊	○	◊	○		●	○	○	○	○
Fraenkel (2012)[17]	135	●	○	○	○	○	○	○	○	◊	○	○	○
Thomson (2007)[18]	109	◊	○	○	◊	●	○	○	○	◊	○	○	◊
Man-Son-Hing (1999)[19]	287	●	●	◊	○	◊	○	○	○	●	◊	○	○
Implantable Cardioverter Defibrillator													
Carroll (2017)[20]	82	●	○	○	○	●	○	○	○	◊	○	○	○
Lewis (2021)[21]	30	●	○	○	○	◊	○	◊	○	◊	○	○	○

PROM = Patient-Reported Outcome Measure; OBOM= Observer-Reported Outcome Measure. For Kunneman (2020), clinicians reported greater satisfaction in the intervention arm than the control arm, whereas patients did not significantly differ in satisfaction by study arm.

Key:

● positive result

◊ mixed or null result

ø negative result

○ outcome not assessed

Table 2.

Sources of patient decision aids for electrophysiology-related care and website links.

Name	URL	EP-related Decision Aids	Free for Use
The Ottawa Hospital Research Institute (Inventory of decision aids)	https://decisionaid.ohri.ca/AZlist.html	• Pacemaker • Implantable cardioverter-defibrillator • Supraventricular tachycardia ablation • AF: ablation, cardioversion, stroke prevention • CRT	Yes
American College of Cardiology, CardioSmart	https://www.cardiosmart.org/SDM/Decision-Aids/Find-Decision-Aids	• ICD • AF stroke prevention (anticoagulation and LAAC)	Yes
Colorado Program for Patient Centered Decisions	https://patientdecisionaid.org/	• ICD • ICD replacement • CRT • AF: stroke prevention* (4 categories of risk, with LAAC) • LVAD	Yes
Health Decisions	https://www.healthdecision.com/products	• AF stroke prevention	No
Healthwise (Tool development)	https://www.healthwise.org/	• Pacemaker • ICD • Supraventricular tachycardia ablation • AF: ablation, cardioversion, stroke prevention • CRT	No

*developed in partnership with the American College of Cardiology.

AF = atrial fibrillation; CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator; LAAC = left atrial appendage closure; LVAD = left ventricular assist device

Decision aids sites without an electrophysiology-related decision aid:

Mayo Clinic (atherosclerosis)

https://shareddecisions.mayoclinic.org/

University of Utah (links to Mayo)

https://uhealthplan.utah.edu/quality-improvement/shared-decision-making.php

Dartmouth-Hitchcock

https://med.dartmouth-hitchcock.org/csdm_toolkits/specialty_care_toolkit.html

Stanford (statin)

https://med.stanford.edu/hrp/research/tools.html

Emmi (decision aid development)

https://www.emmisolutions.com

Table 3:

Examples of US Guidelines or Society Statements Endorsing Shared Decision Making in Cardiac Electrophysiology

	Guideline	COR	LOE
Pacemaker implantation	2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay[52]	I	C-LD
ICD implantation	2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death[41]	I	B-NR
CRT	N/A		
Anticoagulation for AF	2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation[53]	I	C
LAAC	2015 ACC/HRS/SCAI Left Atrial Appendage Occlusion Device Societal Overview[126]	Advocated, not graded	
Ablation for VT and AF	N/A		
Genetic Testing	N/A		
Sports Participation	2019 HRS expert consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy[127]	Advocated, not graded	

ACC = American College of Cardiology; AF = atrial fibrillation; AHA = American Heart Association; COR = class of recommendation; CRT = cardiac resynchronization therapy; HRS = Heart Rhythm Society; ICD = implantable cardioverter-defibrillator; LOE = level of evidence; N/A not available or not addressed; SCAI = Society for Cardiovascular Angiography and Interventions; US = United States; VT = ventricular tachycardia

Table 4:

Centers for Medicare and Medicaid Services (CMS) mandates for SDM

Lung Cancer Screening Date: 02/05/2015	*Counseling and SDM visit furnished by a physician or qualified non-physician practitioner that is documented in the medical record and includes:* • *Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting* • *SDM including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure* • *Counseling on the importance of adherence to annual LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment.* • *Counseling on the importance of smoking cessation (or abstinence) and, if appropriate, furnishing information about tobacco cessation intervention*
AF stroke reduction using LAAC Date: 02/08/2016	*A formal SDM interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the SDM interaction must be documented in the medical record.*
ICD Date: 02/15/2018	*For these patients… a formal SDM encounter must occur between the patient and a physician… or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist)… using an evidence-based decision tool on ICDs prior to initial ICD implantation. The SDM encounter may occur at a separate visit.*

AF = atrial fibrillation; LAAC = left atrial appendage closure; ICD = implantable cardioverter defibrillator; LDCT = low-dose computed tomography; NVAF = non-valvular atrial fibrillation; SDM = shared decision making

Table 5:

Summary, Gaps and Future Directions

Measurement of SDM and Outcomes	Shared decision making (SDM) has been shown to improve patient-reported outcomes and quality of decision making, but only rarely demonstrates improvement in clinical endpoints.
	Demonstration of improvement in measurable clinical outcomes is a major gap in the field of SDM and is in need of further research, ideally in the form of randomized clinical trials.
	SDM interventions implemented across integrated healthcare systems through the electronic health record (EHR) may yield data for correlation with clinical outcomes.
SDM Tools and Interventions	Development of SDM tools has proliferated, including for arrhythmia management, but certification remains lacking. Decision aids should ideally be appraised for quality and effectiveness using measures such as the International Patient Decision Aid Standards.
	Future development of decision aids should ideally be patient-centered, tested in diverse populations (age, sex, race/ethnicity, socioeconomic status), actively incorporate patient input, and account for variable health literacy/numeracy and psychological and cultural barriers to care.
	Atrial fibrillation and reduction of stroke risk using oral anticoagulants or LAAC is a major focus of SDM interventions. An ongoing need and challenge is demonstration of improvement in clinical outcomes, treatment rates and medication adherence.
	The complexity of clinical discussions surrounding implantable devices and invasive procedures will ideally utilize support tools that evolve with clinical evidence and recommendations, streamline efficiently with clinical practice, and naturally personalize recommendations through integration from the EHR.
Implementation and Dissemination of SDM	SDM interventions are more likely to be successfully disseminated when integrated into existing clinical processes of multidisciplinary teams, appraised in the context of system-wide adoption, and endorsed by specialty societies
	Implementation of SDM will require intentional training of clinicians.
	Wider dissemination of SDM interventions may occur when they are designed to address cultural barriers, health literacy, and psychological barriers.
	Requiring documentation of SDM for healthcare reimbursement should be based on scientific evidence that SDM yields improvement in patient-reported or clinical outcomes.
	Generation of data on the impact of SDM on outcomes is limited by suboptimal adoption of SDM in the absence of linkage to reimbursement, but gaps in need of further research may be facilitated where SDM is implemented across healthcare systems andEHRs. Additional data on the impact of SDM may further motivate clinicians to employ and increase skills in SDM.