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Research and Applications

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Design and development of a digital shared decision-making tool for stroke prevention in atrial fibrillation

Julio C. Nunes [1,2], Tina Baykaner[3], Krishna Pundi[3], Katie DeSutter[1], Mellanie True Hills[4], Kenneth W. Mahaffey[1,3], Samuel F. Sears[5], Daniel P. Morin[6], Bryant Lin[3], Paul J. Wang[3], and Randall S. Stafford[7]

[1]Stanford Center for Clinical Research, Stanford University, Palo Alto, California, USA, [2]Department of Psychiatry, Yale University, New Haven, Connecticut, USA, [3]Division of Cardiovascular Medicine, Stanford University, Palo Alto, California, USA, [4]StopAfib.org, American Foundation for Women's Health, Decatur, Texas, USA, [5]Division of Cardiovascular Medicine, East Carolina University, Greenville, North Carolina, USA, [6]Cardiovascular Research, Ochsner Medical Center, New Orleans, Louisiana, USA and [7]Stanford Prevention Research Center, Stanford University, Palo Alto, California, USA

Corresponding Author: Julio C. Nunes, MD, Stanford Center for Clinical Research, Stanford University, 3180 Porter Dr, Palo Alto, CA 94304, USA; jcnunes@stanford.edu, julio.nunes@yale.edu

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ABSTRACT

Background: Shared decision-making (SDM) is an approach in which patients and clinicians act as partners in making medical decisions. Patients receive the information needed to decide and are encouraged to balance risks, benefits, and preferences. Informative materials are vital to SDM. Atrial fibrillation (AF) is the most common cardiac arrhythmia and responsible for 10% of ischemic strokes, however 1/3 of patients are not on appropriate anticoagulation. Decision sharing may facilitate treatment acceptance, improving outcomes.
Aims: To develop a framework of the components needed to create novel SDM tools and to provide practical examples through a case-study of stroke prevention in AF.
Methods: We analyze the design values of a web-based SDM tool created to better inform AF patients about anticoagulation. The tool was developed in partnership with patient advocates, multi-disciplinary investigators, and private design firms. It was refined through iterative, recursive testing in patients with AF. Its effectiveness is being evaluated in a multisite clinical trial led by Stanford University and sponsored by the American Heart Association.
Findings: The main components considered when creating the Stanford AFib tool included: design and software; content identification; information delivery; inclusive communication, user engagement; patient feedback; clinician experience; and anticipation of implementation and dissemination. We also highlight the ethical principles underlying SDM; matters of diversity and inclusion, linguistic variety, accessibility, and health literacy. The Stanford AFib Guide patient tool is available at: https://afibguide.com and the clinician tool at https://afibguide.com/clinician.
Conclusion: Attention to a range of vital development and design factors can facilitate tool adoption and information acquisition by diverse cultural, educational, and socioeconomic subpopulations. With thoughtful design, digital tools may decrease decision regret and improve treatment outcomes across many decision-making situations in healthcare.

Key words: shared decision-making, research tools, medical design, patient decision aid, atrial fibrillation

Lay Summary

Better healthcare results when patients and clinicians act as partners in making medical decisions. Atrial fibrillation is a common heart rhythm problem that increases the risk of stroke. This risk can be mitigated by taking blood thinning medications. Using a user-centered design strategy with the goal of improving treatment understanding and acceptance, we created a digital decision-making aid with modules for patients to use ahead of doctor's visits and for clinician use during visits. The tool was developed in partnership with patient advocates, multi-disciplinary investigators, and private digital design firms. The main components considered when creating this tool included: design and software; content identification; information delivery; user engagement; inclusive communication; patient feedback; clinician experience; and anticipation of implementation and dissemination. The Stanford Afib Guide is available in English and Spanish at an eighth grade reading level at https://afibguide.com/. A central feature is the use of a cartoon video that presents information and anticipates patient concerns without requiring the reading of text. These factors facilitate tool adoption and information acquisition by diverse cultural, educational, and socioeconomic subpopulations. The tool's effectiveness is now being evaluated in a multisite randomized clinical trial.

INTRODUCTION

Shared decision-making (SDM) is an approach to care in which patients and clinicians act as partners in making medical decisions.[1,2] It has been defined as a method where patients receive the best available needed information to make a clinical decision, and are supported to consider different options to achieve informed preferences.[3] The main elements that constitute SDM include: (1) a patient-provider relationship; (2) mutual sharing of information; and (3) willingness from both sides to reach a consensus that is both clinically sound and culturally informed.[4,5]

The SDM approach is not only a panorama of face-to-face care, but also an underlying framework that can guide the development of new clinical tools, symptom rating scores, systems of care, educational curriculums, and informational materials.[6] Since its first mention in 1982,[7] SDM has opened opportunities for the development of care that modifies the traditional paternalistic role of physicians into one aimed at collaboration.[2] SDM has been used in a broad range of clinical settings with the aim of facilitating improved communication and, thereby, outcomes.[1,3,6,8] Patients whose decisions are consistent with their goals have increased satisfaction and engagement as well as greater adherence to treatment. This approach results in increased clinician responsiveness to patient's individual preferences and values.[1,3,6] While clinicians often assume that all patients are equally "ready" for decision-making, frequent barriers often compromise patient decision-making, including lacking health literacy, health numeracy, information on the risks and benefits of alternative treatments, and motivation to engage in decision-making. Aided by advances in digital technology and software innovations, the development of decision aids for SDM seeks to overcome these barriers.[8]

SDM has been applied to atrial fibrillation (AF), including decision-making around the use of anticoagulants to prevent embolic strokes resulting from clot formation in the left atrium. Systematic review of 10[9] and 14[10] patient decision aids for stroke prevention in AF has recently been conducted. The overlapping studies included in these 2 meta-analyses used a variety of effectiveness measures to test many distinct SDM approaches, ranging from patient handouts to various computer-based decision aids used before or during a clinician encounter. Results suggested mixed findings with overall small effects in reducing decisional conflict, enhancing uptake of anticoagulation, and patient knowledge. Many past studies, however, relied on small sample sizes and short follow-up. Interventions prior to a clinical encounter appeared to be more effective than those limited to the clinical encounter.[9] A more recent, large clinical trial has shown similarly small, nonsignificant impacts.[11]

The "Engaging Patients to Help Achieve Increased Patient Choice and Engagement for Atrial Fibrillation Stroke Prevention" study (ENHANCE-AF) represents the development and testing of a novel SDM tool seeking to overcome the issues that may have compromised previous work.[12] The investigators used the principles of end-user design to develop a digital SDM tool for patients considering anticoagulation for stroke prevention in (AF). Effective SDM requires reliable patient understanding of disease as well as of the benefits and consequences of available treatment options. However, health literacy is generally low, limiting patients' capacity to thoroughly appreciate the complexity and details of such options; health literacy also tends to decline with age, raising additional challenges for providers working with older populations.[13]

The current paradigm of AF decision aids is largely text-based, with tools that are not rigorously tested for either clinician or patient usability and impact. AF is the most common clinically significant cardiac arrhythmia. Over 70% of patients with AF are older than 60 years and 1/3 of them are not on guideline-recommended anticoagulant therapy.[14] The development of an informative tool capable of patient empowerment for decision-making aims to confront barriers to patient acceptance of therapy and improve treatment outcomes, adherence, and satisfaction.

The ENHANCE-AF SDM digital tool is an example of how end-user design, technology, and clinical knowledge may be allied synergistically to develop patient-centered resources beneficial to care. We describe the creative process of the ENHANCE-AF SDM digital tool and explore its key conceptual elements. This case-study aims to explain and exemplify core aspects that should be considered by tool developers and researchers in their design of SDM tools for other conditions. With the goal of increasing autonomy and informed decision-making to patients across specialties, we propose that the ENHANCE-AF experience may serve as a paradigm for the creation of new, high-quality SDM tools.

METHODS, DESIGN, AND TOOL EVALUATION

Design and software

The design conception process of the digital SDM tool used in ENHANCE-AF was led by Stanford University and developed in partnership with Daylight Design (San Francisco, CA). Considering

a patient-centered approach with a goal of increasing health literacy regarding AF and anticoagulation, both design and visual-conceptualization were critical factors for engagement. Patients from various socioeconomic levels, education levels and degrees, racial-ethnic backgrounds, ages, and health literacy levels participated in both the conceptual phase and the clinical trial. The digital tool was developed in plain language English to accommodate limited literacy with a corresponding version in Spanish, the second most frequently spoken language in the United States.[15]

Blackbird Studios (San Francisco, CA) developed the tool's software. The web-based program was built to maintain high performance and stability on multiple hardware platforms (computer, tablet, and smartphone), web browsers, and with varying internet speeds and bandwidth, including the ability to function off-line.

Considering both design and software programing needs, the SDM tool was designed in 2 distinct 3-month-long phases. Phase 1 was guided by the Daylight Design team and consisted of research, synthesis, concept generation, and detailed design. Blackbird Studios led Phase 2, dedicated to software development and launch. Figure 1 summarizes both phases showing these multiple steps. In both phases, the Stanford University-based team conducted all administrative and regulatory efforts. Both phases involved a multidisciplinary, multisite team of investigators, as well as AF outpatients, clinicians, and other stakeholders.

Phase 1 focused on developing a deep understanding of patients' information needs, emotional motivations, and features of decision-making satisfaction, including common fears and misconceptions as well as threats to long-term drug adherence. We interviewed patients and clinicians in-person and by phone to determine typical and atypical decision-making experiences around anticoagulation for stroke prevention in AF. While committed to highlighting the evidence-based value of anticoagulation for stroke prevention, a fundamental decision was to support well-informed patients if they decided against taking an anticoagulant. Overall, we determined that the digital tool would be most effective if focused on informing patients prior to a clinical encounter where a decision regarding anticoagulation would be made. A complementary clinician tool was designed to allow clinicians to reinforce the patient-tool messaging and facilitate illustrated responses to patient questions. These user needs were translated into the design of the patient-tool and complementary clinician tool, including user experience, wireframes, and visual design. Key design decisions, informed by patient feedback, included:

1. The application would not require data collection and would be applicable to all AF patients for whom anticoagulation would be guideline recommended
2. Mapping out a patient experience pathway (conceptually and visually) with sequential components, including: (1) an animated informational video presenting key messages, (2) frequently asked questions, (3) a check-in quiz reinforcing key messages, and (4) a wrap-up with a worksheet for patients to record questions for the clinician visit
3. For the overall tool and for each of these 4 components, identifying key topics and evidence-based messages with a clear and concise sequence of presentation
4. An overall graphic cartoon scheme with animated, human appearing characters of different bright skin colors (greens, blues, and purples) along with a special heart-shaped character that functions as a guide and mascot
5. An abbreviated companion clinician-tool with identical messaging as well as additional resources, a risk-score calculator, and selected animations to be used by a clinician during clinical encounters.

At the conclusion of Phase 1, a conceptually complete, still motion prototype was developed with scripts in plain-language English and Spanish and the accompanying visual components. This prototype accommodated multiple patient-determined pathways depending on selected topics and level of desired detail. Patient testing focused on 3 key clinical populations, patients with AF in a specialty Arrhythmia Clinic, AF patients in a primary care internal medicine resident clinic, and AF patient advocates affiliated with StopAfib.org. These patient-oriented developmental activities were covered under several Institutional Review Board (IRB) protocols: (1) Two Stanford IRB protocols (Nos 49771 and 47039) focused on patient interviews in the creation of content, (2) A Stanford IRB protocol (No. 51678) focused on developing and testing patient outcomes, and (3) A WCG IRB protocol (No. 1274461) covered all clinical sites for patient testing and tool refinement as well as the clinical trial of tool effectiveness[12] (clinicaltrials.gov ID: NCT04096781). Verbal informed consent was obtained for patients participating in the development process.

In Phase 2, a series of build sprints were conducted to transform the conceptual prototype into a functioning digital tool. Working on most critical features first, continuously released test builds were available for review and feedback from both the investigators and the patient reviewers. Key components of this process included: (1) script refinement and recording using female voice actors in English and Spanish selected for a kind, yet authoritative and older sounding voice, (2) completion and subsequent refinement of animation both for the introductory video and several vignettes illustrating patient responses to frequently asked questions, (3) programming of tool navigation with multiple decision-points and alternative patient pathways, (4) initial and concluding pages that provided appropriate acknowledgments and disclaimers, and (5) integration of all components, including synchronizing the recorded narration with the animated segments and the optional closed captioning. Testing by both the investigators and the patient reviewers served to refine the tool and to find and fix programming bugs following each building stage. At the end of Phase 2, the tool was ready for rigorous testing in a randomized controlled trial by patients with AF.

Throughout Phases 1 and 2, we employed a streamlined approach for accumulating and implementing advice provided by clinicians and patients. Input received from patients was generally directed to our primary patient advocate consultant, Ms. Hills, who synthesized these comments into specific actionable feedback in refining the tool. In a similar fashion, clinician comments were directed to Drs Wang and Stafford, experts in AF management, who determined how best to address their input. Particular attention was paid to issues of potential misinterpretation and, for patients, language that was too complex. As a general trend, most early comments resulted in tool modification, whereas later comments resulted in changes when 2 or more reviewers noted similar concerns. A final phase of tool testing involved cognitive testing. In this process, patients used the tool and were asked to provide feedback both during their use and through a structured interview after tool use. The Stanford AFib Guide patient tool is available at: https://afibguide.com/ and the clinician tool at https://afibguide.com/clinician.

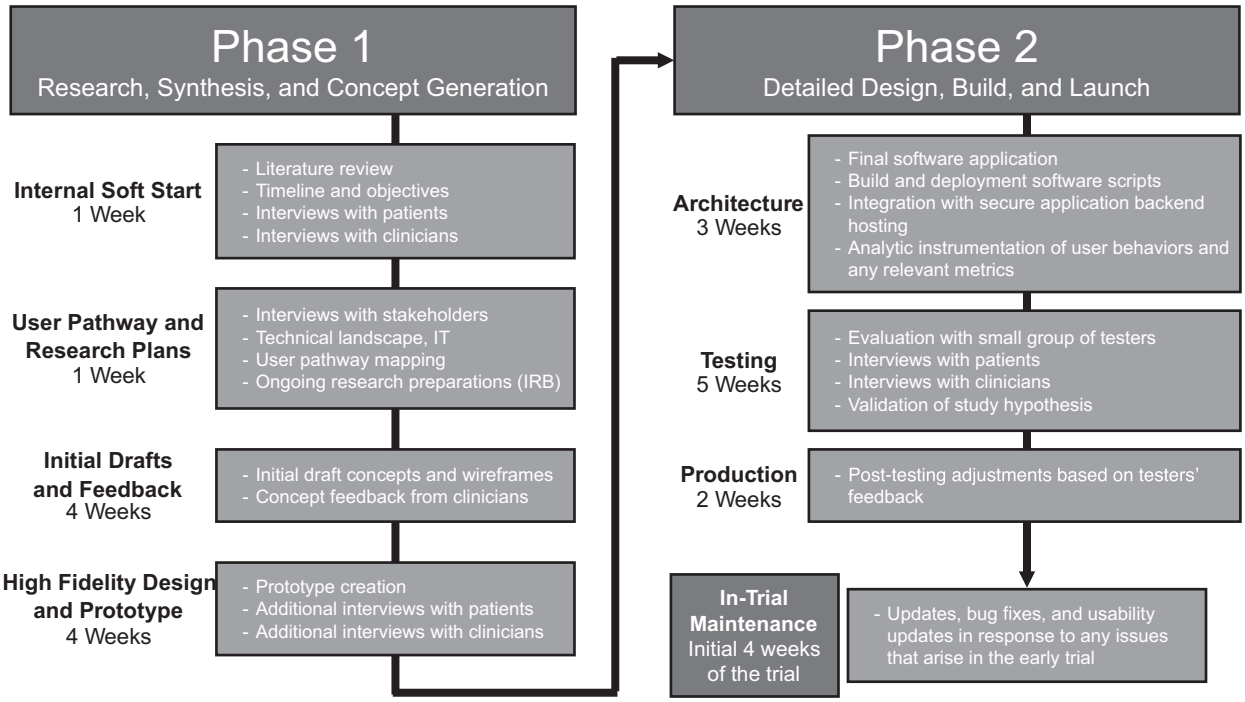

Figure 1. Flowchart of design, software, and timeline considerations. Phase 1 focused on understanding the needs of patients and stakeholders; research insights informed the design of a prototype. In Phase 2, test builds were continuously reviewed for final production of the research tool.

Content identification

AF patients are frequently confused about the risks and benefits of taking an anticoagulant.[11] To facilitate the selection of the most critical information, a multidisciplinary group composed of clinicians, patients, patient advocates, and AF researchers identified 5 primary learning points: (1) AF can lead to a stroke; (2) a stroke can be disabling or lead to death; (3) taking an anticoagulant will reduce one's stroke risk; (4) blood thinners carry the risk of excessive bleeding; and (5) taking a blood thinner is ultimately a patient's choice based on weighing the personal implications of potential risks and benefits.

Information delivery

The platform is structured as a learning pathway in which the patient follows "Hearty," the tool's mascot, through different learning opportunities (Figure 2). To address patient literacy and numeracy as barriers to knowledge transfer, the tool was built around an introductory video with detailed, but easily accessible, cartoon depictions of AF and stroke risk (Figure 3A). Our selection of various bright skin colors was motivated by a desire to convey an abstract appreciation for the diversity of the AFib population without depicting any specific racial or ethnic groups. The video incorporated simple spoken content, large text subtitles, and repetition of the primary learning points (Figure 3B). This was followed by the option to repeat the video, or explore other commonly asked questions, which were answered in text or audiovisual format. Some of these audiovisual aids were also made available in the accompanying clinician-tool for incorporation into the discussion during the clinic appointment. To accommodate patients living with visual disabilities, both the patient and the clinician tools have a voice-over function that digitally reads the written portions of the tool.

Many design features were aimed at surmounting communication barriers common in the delivery of information and motivational messaging about chronic disease treatment. We aimed for inclusive communication using ample illustrations that minimized the need for reading while still including text captioning as an option. Other features included English and Spanish versions, a script written at an eighth grade reading level, multiple reinforcement of key terms and messages, features for hearing and visually impaired patients, and recognition of distinct learning styles (particularly auditory vs visual learners). Several of these features are shown in Figures 2, 3, and 4. An important goal of this inclusive approach is to improve AF-specific health literacy.

User engagement

To ensure patient engagement with the content, patients are allowed to choose which additional questions they want to explore further, with a wide range of inquiries gathered from sequential real patient interviews (Figure 4A). A short check-in quiz is presented after the initial introductory video and commonly asked questions. Immediate feedback and explanations are given to reinforce the primary learning points (Figure 4B). After presentation of the educational content, patients are provided with a worksheet containing optional questions and summary sections to prepare them for their clinician encounter. The forms are available in both English (Supplementary Appendix SA) and Spanish (Supplementary Appendix SB).

Readability and patient feedback

We refined the content and tool functionality to be easily accessible for diverse racial-ethnic, language, and health literacy subpopulations. The tool is specifically designed to be easily comprehensible for an eighth grade literacy level or higher, which comprises 95% of the US population.[16] Several language choices, such as using the term "blood thinners" instead of the medical jargon "anticoagulants," are intentional and aim to facilitate comprehension. We also included audio and closed caption options for both English and Spanish to further

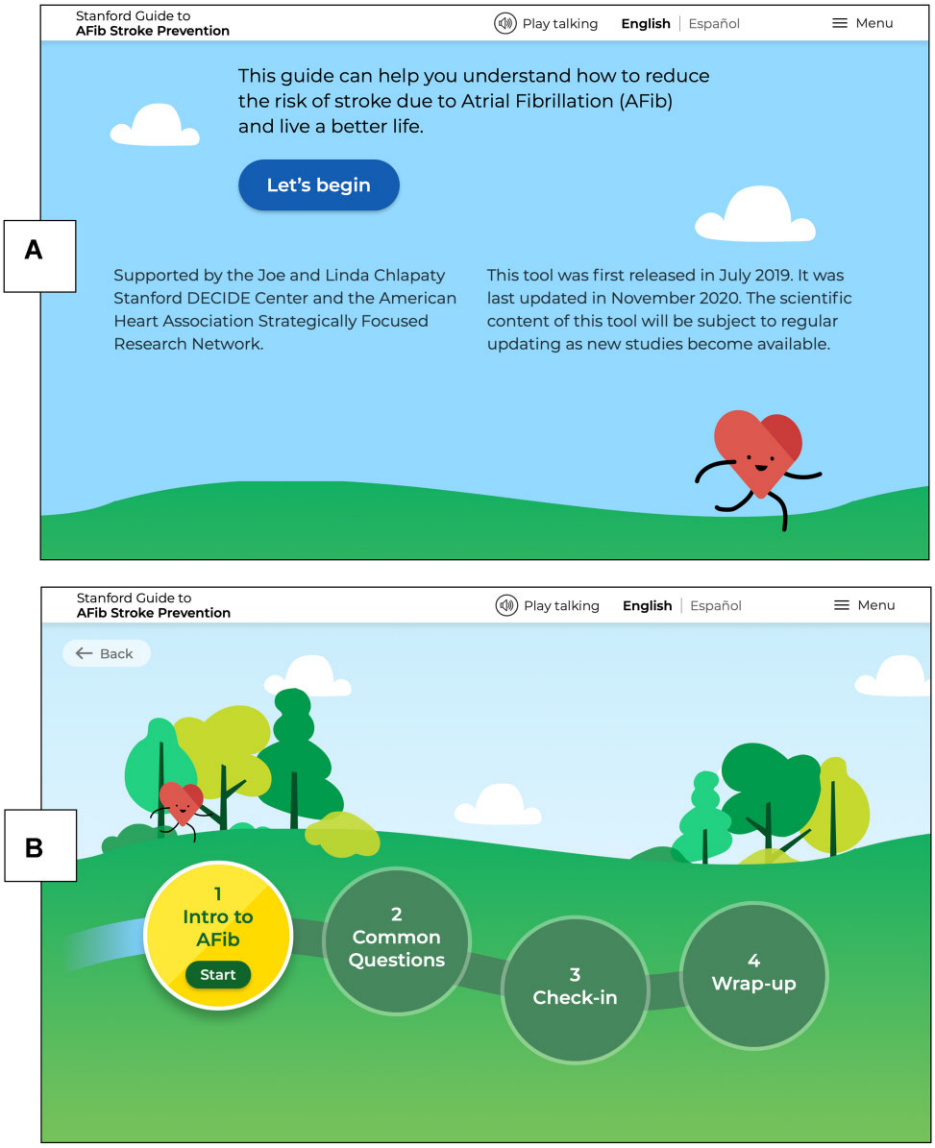

Figure 2. Opening page and learning pathway. (A) The opening page highlights the objective of the digital tool and offers information regarding authorship and financial disclosures. (B) Patients start interacting with the tool by engaging with "Hearty," the tool's main character. They follow a learning path that starts with a video and finishes with the fillable worksheet to be brought to the physician appointment.

broaden the reach of this tool. To ensure readability we also assessed the tool with the Flesch-Kincaid Readability Test, obtaining a score of 75.5 (easily understood by 11- to 12-year olds).[17]

A total of 25 patients were interviewed at different stages of tool design to gather feedback and ensure that vocabulary and concepts presented were truly accessible. The early design meetings focused on patients' decision-making needs, with subsequent meetings addressing the usability of the tool for different levels of general and health literacy. Additionally, patients enrolled on the tool-arm of the ENHANCE-AF clinical trial have the opportunity of offering feedback after their participation.

Clinician experience

The research group interviewed practicing clinicians and considered their needs to guide the creation of an abbreviated tool for clinicians' use during patient visits. This accompanying tool was designed to be used after the patient was exposed to the main tool, maximizing learning through spaced repetition. This version emphasizes key messages presented in the patient tool (Figure 5A), while also including additional displays of stroke probabilities with and without anticoagulation by risk scores (Figure 5B). Such scores were calculated based on assessment of CHA_2DS_2-VASc scores and their associated annual probabilities of stroke.[18] It also offers muted versions of the animations in the video to be used as teaching resources. For both the tool and the usual-care arms of the ENHANCE-AF clinical trial, clinicians are asked to reflect upon their clinical encounters with study participants and offer feedback via the Clinician Satisfaction with Decision Making scale.

Both tools, patient- and clinician-versions, fulfill 58 of the 69 (84%) applicable criteria suggested by the International Patient Decision Aid Standards (IPDAS) guidelines. These criteria aim to standardize patient decision aid tools, improve quality and effectiveness of such tools, and guide tool documentation and reporting.[19] The 2017 IPDAS guidelines and their rationale are described in

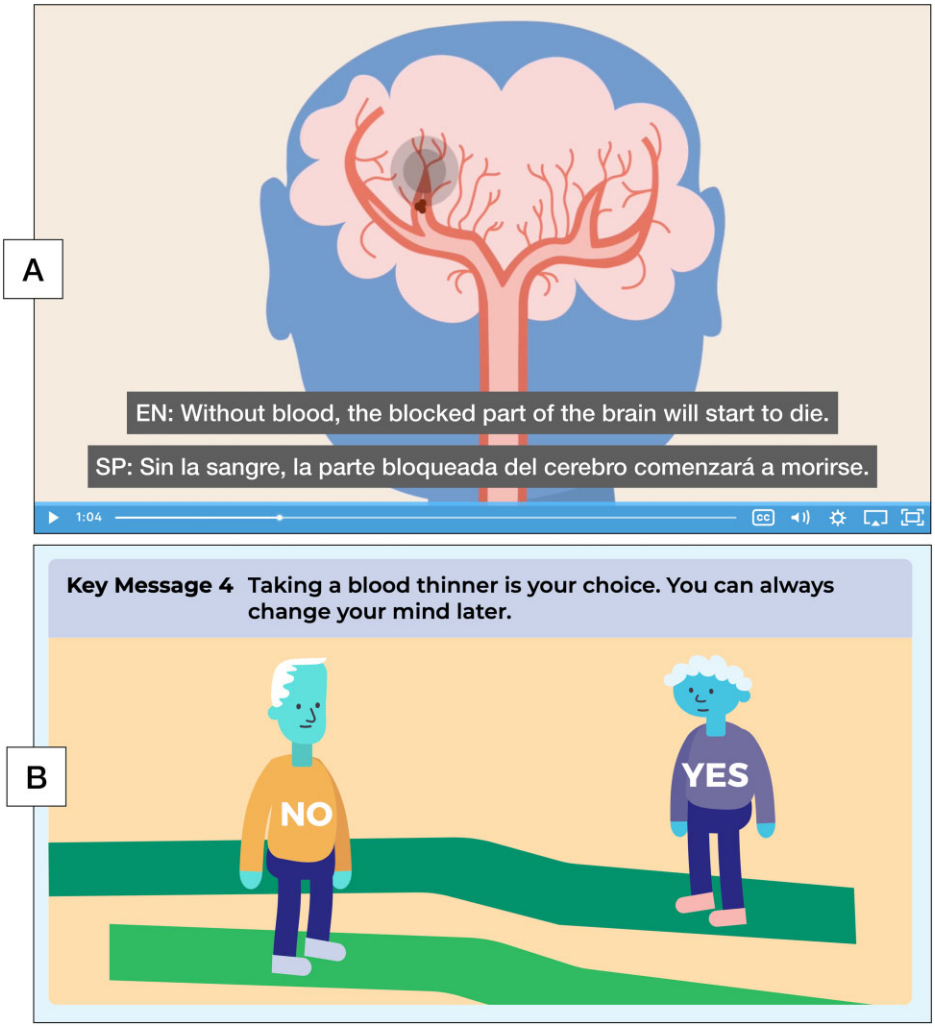

Figure 3. Excerpt from the introductory video and key messages. (A) The video displays cartoon depictions of the mechanism of atrial fibrillation, how to measure stroke risk, when to start an anticoagulant, and what are the anticoagulation options. The intent of the video is to introduce the conceptual knowledge required for decision-making. (B) After the initial presentation, patients assimilate the newly acquired knowledge through visual representations and repetition of the main learning topics.

Sepucha et al.[20] Supplementary Appendix SC catalogs the IPDAS criteria fulfilled by the ENHANCE-AF tools. For 4 criteria not fulfilled, we decided that fully compliant presentation of probabilities would negatively affect patient satisfaction and decision-making quality by introducing excessive numeric information. It was determined that some criteria, such as complete citations for supportive journal articles, allowing patient word searching, feedback on patient entered data, printing as a single document, were not critical or not feasible for the topic of AF stroke prevention as presented via video and other digital formats.

Clinical evaluation of the tool's impact

This tool is being evaluated in the ENHANCE-AF multicenter, randomized, controlled open-label trial. The rationale and detailed methods for this clinical trial were previously described.[12] In brief, the study compares the effectiveness of the digital tool versus usual care for AF stroke prevention in 1000 AF participants. The main endpoints focus on patients' experience with the decision-making process, including scales measuring decisional conflict,[21] decision regret,[22] preparation for decision,[23] and AF knowledge.[12] Additional endpoints are related to adherence to anticoagulant use; risk of major bleeding; and risk of experiencing a transient ischemic attack, stroke, deep vein thrombosis, pulmonary embolism, and death. The participants are evaluated immediately after, at 1 month after, and at 6 months after the completion of their clinician visit.

The study sites were purposefully chosen to recruit a highly diverse study population as each site serves patients from a variety of racial/ethnic, language, socioeconomic, and health literacy backgrounds. Sites include Stanford Healthcare, Ochsner Clinic (New Orleans LA), Cleveland Clinic, Eastern Carolina University (Greenville NC), and Cooper University Health Care (Camden NJ).[12] Researchers, clinicians, patients, and other stakeholders of each of these institutions were not only a part of the clinical trial, but also of the early development stages, as key providers of input and feedback.

Implementation and dissemination

The digital SDM tool will be updated to reflect the most recent professional society guidelines on the clinical management of AF. Following completion of rigorous randomized, controlled trial testing,

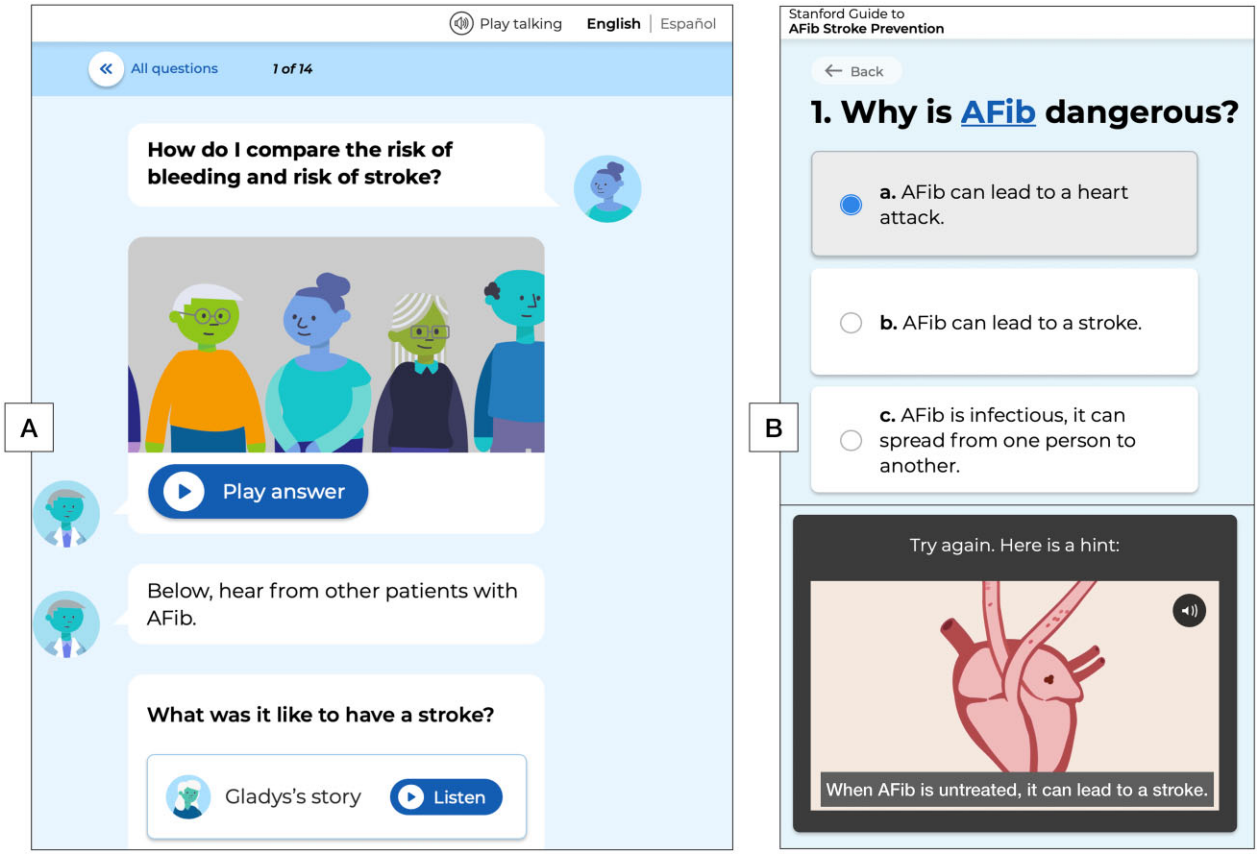

Figure 4. Most common questions with answers and the check-in quiz. (A) The tool offers a list of common questions answered in clear, accessible language. Additionally, short audio stories from real patients are included to add peer-to-peer perspectives. (B) After the initial video and Q&A, patients reinforce their knowledge with a short quiz. If a question is answered incorrectly, a video excerpt allows for review of the specific topic.

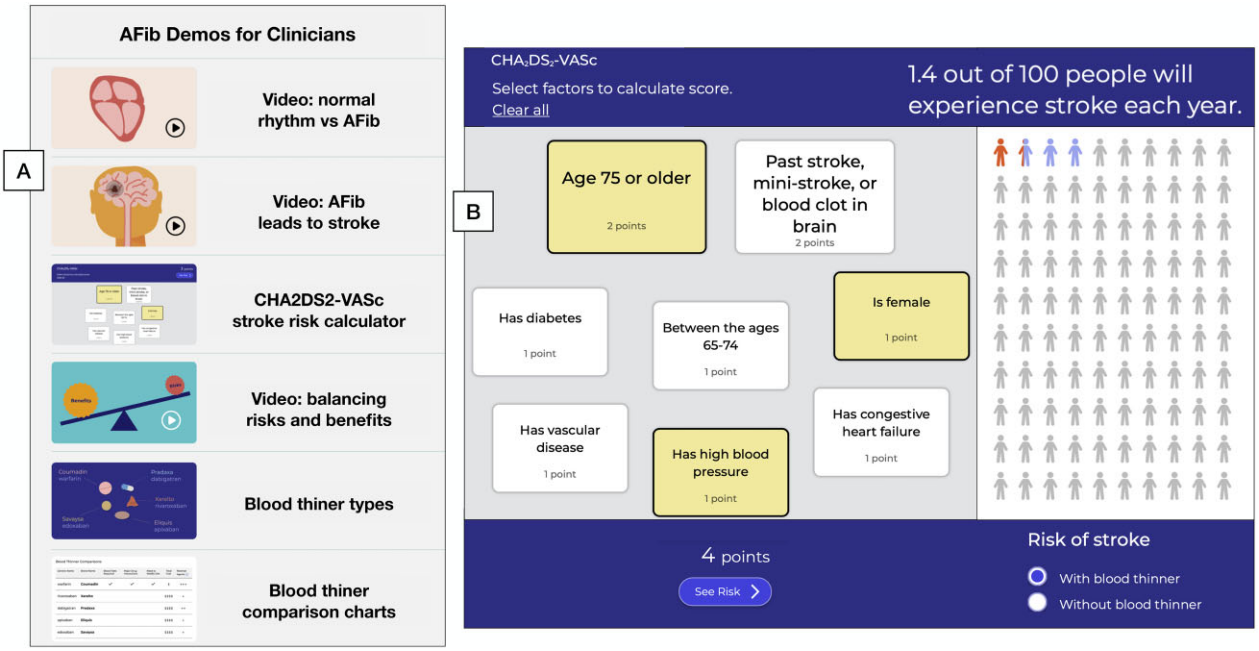

Figure 5. The clinician tool. (A) The animations in the clinician tool are also available without sounds, allowing clinicians to use the illustrations as a background to their explanations during a patient encounter. (B) Useful resources such as risk score calculators are included for easy access and real-time demonstration of risk.

it will be available in the public domain, free of costs, for use on handheld devices as a web-based application and for use on desktop and laptop computers. The website and the outcomes of the clinical trial will be disseminated at medical, nursing, and quality outcome conferences. If effective at improving SDM, the group will further engage stakeholder organizations, policy makers, professional organizations, academic centers, and electronic health record manufacturers to achieve maximal reach.

Table 1 summarizes key aspects to be considered when designing a novel SDM tool and offers practical examples of how they were implemented in the ENHANCE-AF trial.

DISCUSSION

We present the conceptualization of a SDM tool for stroke prevention in AF. We incorporated a high-fidelity design approach, informed by interviews with clinicians, patients, and other stakeholders, to create a digital tool that enables accessible, informed decision-making for patients with various levels of health literacy, numeracy, and cultural backgrounds. Particularly unique to this SDM tool are: (1) the diversity of points-of-view providing feedback on the tool and (2) the rigorous clinical trial evaluating patients' satisfaction with decision-making. We propose this model as a new paradigm for the development, refinement, and evaluation of future SDM tools in clinical practice.

Distinct features of the Stanford AFib Guide

In relationship to past decision tools for AF, the Stanford AFib Guide differs in several respects. The use of a digital platform that does not require the reading of text is a key feature of the tool. Similarly, the tool technology allows patients to tailor the amount of information presented to them, particularly though the Frequent Questions module. While personalized statistical information can be generated, the tool avoids over-emphasizing numeric information. While this leads to discordance with IPDAS standards, our patient testing indicated that detailed statistical information was viewed unfavorably and did not improve satisfaction with the stroke prevention decision-making process. Additionally, many of the already available AF SDM tools were not validated in a clinical trial.

Ethical principles of SDM

The importance and justification of SDM as a standard of clinical care lie on the very ethical principles that guide the practice of medicine. SDM skills are not usually taught and emphasized during medical education or spontaneously exhibited by clinicians.[24] The development of such skills requires both exposure to the practice and agreement with its core ethical principles.[25]

Both self-determination and relational autonomy are considered key factors. Self-determination is related to the natural tendency human beings have of protecting themselves and ensuring their own well-being.[26] Relational autonomy presumes that these self-protecting and self-guiding tendencies are not completely independent but based on mutual collaboration and interpersonal relations.[27] By assimilating these 2 fundamental concepts, SDM proposes that clinicians and patients act collaboratively with the aim of increasing patients' understanding of their clinical scenario, allowing for autonomous, beneficent, and clinically sound decisions.

Stacey et al[28] set an example that supports this practice. Their meta-analysis of 86 randomized clinical trials showed that patients who are actively involved in their own care are more likely to opt for more conservative treatment options. In these trials, investigators measured health literacy, decision-confidence, and knowledge gain between usual care and SDM-intervention groups. The better-informed patients had more accurate expectations regarding different treatments' benefits and risks.[28] In ENHANCE-AF, patients are exposed to the positive and negative aspects of using anticoagulants for AF but are also empowered to recognize that, ultimately, the decision to start the medication or not is theirs to make (Figure 3B).

Health literacy, accessibility, and language proficiency

The concept of health literacy has evolved and adapted at the same time its related research has developed.[29,30] On one side, there is a connection between low health literacy and worse prognosis of health conditions, which raises the consideration of it being a marker of good health.[31] This connection is related to the gap between patients' literacy levels and what is required to understand health information materials and fulfill goals of care.[32] Health literacy can also be understood as a set of personal knowledge and skills that allow for greater autonomy when making health-related decisions.[33] At advanced levels, it allows patients to critically analyze the usefulness, safety, applicability, and reliability of a medical intervention and thus, to take on greater participation in their own care.[34] In both cases, health literacy asserts its importance as a social determinant of health and must be considered when designing interventions based on SDM philosophy. By using a vocabulary accessible for people of eighth grade literacy level or higher, the ENHANCE-AF tool attempts to fulfill its goal of increasing AF-related health literacy in an inclusive manner.

Additionally, the design of interventions must account for people with differing physical and cognitive abilities. There are 61 million people with disabilities in the United States, representing 26% of the population.[35] Previous studies demonstrated that this population is less likely to be actively involved in health-care decision-making processes, not necessarily because of unwillingness, but due to barriers to participation.[36–38] Technology facilitates accessibility as digital tools may have resources to benefit people living with various impairments (eg, visual and hearing impairments, attention-deficit/hyperactivity disorder, color vision deficiency).[39] ENHANCE-AF sets an example for accessibility by employing: (1) large, scalable fonts; (2) voice-over resources; (3) written versions of all the audio material; and (4) clean, uncrowded design that facilitates focus on one element at a time. Regrettably, it does not currently offer a version for people living with color vision deficiencies, which could further increase accessibility.

Accessibility should also be considered from a linguistic perspective. Of the 292 million people aged 5 or older in the United States, around 61 million speak a language other than English at home and of those, 25 million have low proficiency in English.[40] The scarcity of translated and validated research and clinical tools has been cited as one of the barriers to increasing diversity and inclusion in both clinical practice and research.[41,42] When designing SDM tools, target-population profiling serves the dual purpose of increasing dissemination and inclusion. The ENHANCE-AF tool currently offers a Spanish version; other translations are expected in the future. Both the English and the Spanish versions are part of the validating clinical trial.[12]

Testing, implementation, and dissemination

The initial testing of the study tool occurred in the later stages of its development, during Phase 2. Generative and evaluative interview

Table 1. Essential methodological concepts for building, validating, and disseminating shared decision-making tools; the ENHANCE-AF experience illustrates each concept and its aspects

Concept	Key aspects	The enhance-AF trial experience
Design and software	• Selection of a design company. • Selection of a software specialist. • Type of tool and platform. (eg, app store, web-based, and installable file). • Online or offline use. • Audiovisual conceptualization, esthetical aspects, and storytelling.	• Tool developed with Daylight Design and Blackbird Studios. • It is a web-based platform, available online and offline. • Its esthetic is composed of accessible cartoon-styled videos and characters that explain the risks and benefits of using anticoagulants for AF.
Content identification	• Topics selection to ensure thorough but time-optimal learning. • Description of the condition, its diagnosis, and treatment options. • Main risk and benefits of each option.	• A multidisciplinary group composed of clinicians, patients, advocates, and AF researchers identified key learning points.
Information delivery	• Target population. • Level of literacy and numeracy. • Languages other than English. • Accessibility resources (eg, audio, captioning, and large font size).	• The tool displays an introductory video with easily accessible depictions of AF. It uses simple spoken content, large subtitles, a read-over audio function, and repetition of the learning points. • The language utilized can be understood by people in the eighth grade literacy level, in both English and Spanish.
User engagement	• Information delivery methods. • Reinforce learning points several times. • Preparing the patient to discuss topic with their clinician.	• A check-in quiz with immediate feedback, and explanations are given to reinforce the primary learning points. • In the Frequently Asked Questions section, audio stories gathered from real patients provide peer-to-peer experiences. • Interactive forms to specify questions to discuss with the clinician are available.
Patient feedback	• Usefulness of the selected learning topics. • Evaluating if the language and content are truly accessible. • Testing the accessibility resources.	• Patients were involved at all stages of design. Meetings addressed the patients' decision-making needs and the usability of the tool for different levels of literacy. • Participants randomized to the tool-arm of the clinical trial also offered feedback on content and user experience.
Clinician experience	• Additional resources for use in the clinical encounter. • Opportunity for feedback. • IPDAS criteria.	• A clinician tool containing muted animations from the patient's video is available, serving as teaching resources. • An interactive risk score calculator is included. • Both clinician and patient tools mostly fulfill applicable IPDAS requirements.
Clinical evaluation	• Randomized clinical trial. • Satisfaction with decision-making measurement tools.	• ENHANCE-AF is a multicenter, randomized, controlled open-label trial. It compares the effectiveness of the digital tool versus usual care for AF stroke prevention. • The endpoints include patients' satisfaction with the decision-making process, perception of shared decision-making, and readiness to decide. • Outcome measurement tools include the DCS, PDMS, and DRS.
Implementation and dissemination	• Availability and cost of the tool. • Dissemination of clinical trial results. • Methods of tool dissemination. • Future content updates.	• The tool will be available in the public domain, free of costs. • The website and the outcomes of the clinical trial will be disseminated at medical, nursing, and quality outcome meetings. • Dissemination partners include stakeholder organizations, policy makers, professional organizations (eg, AHA), academic centers, and electronic health record manufacturers. • Updates will occur biannually based on new clinical guidelines.

Abbreviations: AF: atrial fibrillation; AHA: American Heart Association; DCS: Decisional Conflict Scale[21]; DRS: Decision Regret Scale[22]; IPDAS: International Patient Decision Aid Standards[20]; PDMS: Preparation for Decision-Making Scale.[23]

sessions with both patients and clinicians, who interacted with a refined version of the tool, were central to the final approval of the tool for use in the clinical trial. Patients with a varied set of AF-specific perspectives were intentionally selected to evaluate the tool, including those with proactive management of the disease, newly diagnosed patients, people who were not proactive in care, and those who were hesitant to start treatment. These feedback sessions built upon preliminary wireframing and story-boarding sessions that occurred in Phase 1 (see Supplementary Appendix SD). Recursive testing of those interviewed aimed to ensure clarity, comprehension, and relevance of each of the tool's components. Feedback from patients and clinicians was incorporated into a modified version of the tool, which was then subjected to further feedback and refinement. All the feedback and testing were obtained from patients and clinicians at multiple study sites across the country, with the support of StopAfib.org, which shared the tool with their associated patients.

Once designed and refined through feasibility testing, a randomized controlled trial (ENHANCE-AF) was initiated as described above. This trial tests the effectiveness of the tool in improving scores on the Decision Conflict Scale, as well as key secondary outcomes.[12] The scale is applied before the clinician visit (after using the Patient Tool), as well as after the clinician visit (when exposed to the companion Clinician Tool). Once the trial is completed (expected analysis November 2022) additional analysis will indicate the tool's effect on various outcomes across multiple participant subpopulations.

Should the tool prove effective in comparison to usual care, dissemination of the tool is the next step. We hope that the tool will be widely adopted for SDM around anticoagulation for stroke prevention in AF.

Lessons learned and applications

We draw several lessons from the ENHANCE-AF SDM tool design and its clinical trial. First, the understanding of SDM as a seemingly intuitive, but hard to practice approach to clinical care. Several barriers[38] and possible solutions to address them[37] have been proposed. But ultimately, SDM is only possible if clinicians, patients, and health care administrators agree and are all willing to participate. The introduction of SDM paradigms may require cultural changes in clinical care, but common beliefs that SDM is "not necessary" or that "patients will make the wrong decisions if given the chance" should not preclude advance and collaboration.[24,43]

Second, specific considerations regarding target-populations are of utmost importance. The implementation and dissemination of digital SDM tools will be hindered if its language, accessibility resources, validating-population, software-accessibility, and hardware-compatibility are overlooked. In the ENHANCE-AF trial, several enrolled participants did not have personal access to a computer or web-browser; thus, the dissemination of the tool for personal-use will be limited in this population. We learned that for more patients to be able to access our application, clinicians and clinics will require systems to ensure that patients can access the tool despite their lack of resources (eg, having tablets or computers in waiting rooms). When designing patient-centered resources, equity, diversity, and inclusion should be prioritized.

SDM becomes especially important when navigating technically complex decisions, particularly when the benefits of the decision do not clearly outweigh its consequences. In some cases, patients may not understand the details behind the decision or clinicians could be accustomed to a paternalistic role and impose their preferences; both patients and clinicians may benefit from learning the SDM strategy and using decision aid resources. Other considerations favoring the applications of SDM include: (1) when there is a gap between treatment recommendations (for instance, when medical societies recommend different treatment options for the same disease; when community and academic recommendations differ); (2) when there is potential for clinician bias or conflict of interest; (3) when the patient's culture and personal preference may alter the balance between benefits and consequences; and (4) when health disparities suggest inconsistent messaging and availability of treatment options between different patient groups (such as racial-ethnic minorities vs White populations).

Limitations

We identify several limitations to the design process, the ENHANCE-AF tool, and its validating clinical trial. First, health literacy was not specifically measured in the trial, only the confidence in decision-making; tools that are proven to increase health literacy in addition to decision-making autonomy should be more impactful.[31] Also, the tool is not yet available in common languages other than English and Spanish. The investigators plan to expand the number of offered languages, however, new testing rounds with patients and clinicians would have to validate these translations. Additional accessibility resources, such as color-aids for people living with color vision deficiency, were not implemented. To keep the tool simple, we did not undertake further tailoring that might have enhanced user engagement. For example, patients could have potentially been offered choices regarding their preferred learning style or narrator voice. Finally, further studies need to determine the significance of each design concept suggested here, as the available evidence is still based on the empirical experience of different research groups and not in high-quality comparison trials.[19] While IPDAS standards place particular weight on detailed display and discussion probabilities, it is unknown whether this truly translates into more satisfying decisions because numerical information often increases patient anxiety.[44]

CONCLUSION

When designing a SDM tool, developers and researchers need to consider a variety of key concepts to ensure accessibility, content-quality, information-delivery, user experience, evaluation, implementation, and dissemination. Building this form of educational and patient empowering resource is challenging, but offers many benefits to clinicians, patients, health care systems, and overall quality of care. Due to these potential benefits, including increased patient autonomy, and confidence and satisfaction with decision-making, we support the design and use of similar tools for other medical conditions. The Stanford AFib Guide patient tool is available at: https://afibguide.com and the clinician tool at https://afibguide.com/clinican.

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AUTHOR CONTRIBUTIONS

JCN: conceptualization, literature review, manuscript initial drafting, revisions, preparation of figures and table. TB: conceptualization, description of the case-study, manuscript initial drafting, and revisions. KP: conceptualization, description of the case-study, and revisions. KD: description of the case-study and revisions. MTH: conceptualization, revisions. KWM: conceptualization, revisions. SFS: conceptualization, revisions. DPM: conceptualization, revisions. BL: conceptualization, revisions. PJW: conceptualization, supervision, revisions. RSS: conceptualization, supervision, manuscript initial drafting, revisions.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *JAMIA Open* online.

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STATEMENT OF RESPONSIBILITY

This paper has been submitted exclusively to the Journal of the American Medical Informatics Association, it has not been previously published, the work behind the paper meets applicable ethical standards, and all authors take public responsibility for the work and satisfy the requirements of authorship.

DATA AVAILABILITY

The data underlying this article will be shared on reasonable request to the corresponding author.

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