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Co-creating sensible care plans using shared decision making: Patients' reflections and observations of encounters☆

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ABSTRACT

Objective: To evaluate how the use of a within-encounter SDM tool (compared to usual care in a randomized trial) contributes to care plans that make sense to patients with atrial fibrillation considering anticoagulation.
Methods: In a planned subgroup of the trial, 123 patients rated post-encounter how much sense their decided-upon care plan made to them and explained why. We explored how sense ratings related to observed patient involvement (OPTION12), patient's decisional conflict, and adherence to their plan based on pharmacy records. We analyzed patient motives using Burke's pentad.
Results: Plan sensibility was similarly high in both arms (Usual care n = 62: mean 9.4/10 (SD 1.0) vs SDM tool n = 61: 9.2/10 (SD 1.5); p = .8), significantly and weakly correlated to decisional conflict (rho = −0.28, p = .002), but not to OPTION12 or adherence. Plans made sense to most patients given their known efficacy, safety and what is involved in implementing them.
Conclusion: Adding an effective intervention to promote SDM did not affect how much, or why, care plans made sense to patients receiving usual care, nor patient adherence to them.
Practice Implications: Evaluating the extent to which care plans make sense can improve SDM assessments, particularly when SDM extends beyond selecting from a menu of options.

1. Introduction

Decisions that make sense to patients and for their lives are more likely to be useful, usable, and effective [1,2]. One method for ensuring decisions make sense is shared decision making (SDM), where patients and clinicians work together to uncover patients' problematic situations and how to respond well to them. When SDM is used successfully, patients and their clinicians should arrive at a plan of care that is desirable (e.g., meets their values and preferences), is feasible in practice, and makes sense intellectually, emotionally, and practically for patients' lives. As such, SDM can be seen as a conversation method to achieve high-quality and person-centered care that best fits individual patients and their lives [3,4].

SDM research has not yet given sufficient attention to how SDM conversations culminate in a plan that best fit patients and their situations. That is, SDM research has a stronger emphasis on *what* is done (what "dance steps" are taken) [5] rather than *how* the rhythm, coherence, and humanity (the "dancing") [6] of an encounter unfold to form plans that make sense. By a plan that makes sense, we mean that patients and clinicians *intellectually understand* that the decision made is the best way forward, that the plan *attends to the emotion* of the situation and decision making, and that the plan *can be implemented* in the patient's life [6,7]. Evaluating SDM encounters in

☆ On behalf of the Shared Decision Making for Atrial Fibrillation (SDM4AFib) Trial Investigators.

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terms of whether the plan makes sense requires understanding on what basis patients attribute "sense" to decisions—*why* does a plan make sense? It also opens the possibility of probing whether the technical steps, behaviors, and outcomes of SDM are correlated with senseful plans and action.

In previous research, we showed that patients' perceived sense of their care plans and their perceived involvement in decision making were linked, although both self-reported measures tended to have high ceiling and, possibly, halo effects [7]. In the current study, we hypothesized that (1) implementing an intervention to promote SDM would lead to care plans that make more sense to patients, and (2) that sensible care plans lead to care that fits well in patients' lives and are therefore more likely to be implemented with high fidelity, i.e., better treatment adherence. To test these hypotheses, we conducted a secondary subgroup analysis of a large multicenter randomized trial, the SDM4Afib trial [8]. In the SDM4Afib trial, we compared care of patients with atrial fibrillation considering anticoagulation medication to prevent strokes in usual care, with the use of a within-encounter SDM tool (conversation aid). The SDM4Afib showed that using the SDM tool led to improved patient involvement in SDM and clinician satisfaction, without affecting treatment decisions or encounter length [9].

The aims of this secondary subgroup analysis were to (1) assess whether compared to usual care, the use of a within-encounter SDM tool leads to patients perceiving higher sensibility of their care plan, (2) assess whether higher sense of care plans lead to improved decisional comfort and treatment adherence, and (3) explore patients' motives on *why* decided-upon care plans make sense to them, using written reflections.

2. Methods

2.1. Design

Between January and December of 2018, we asked all patients participating in an ongoing multicenter randomized trial, the SDM4Afib trial [8,9], to fill in reflective questions on their encounter and their care plan.

2.2. Setting

In January 2018, three of the five participating healthcare networks had started enrolling participants patients intro the trial and participated in this secondary analysis. These three healthcare networks in Minnesota (USA) include an academic medical center, a suburban group practice and an urban safety-net health system. We included patients at the departments of cardiology, cardiac electrophysiology, internal medicine and family medicine.

2.3. Participants

All clinicians who participated in the care of patients with atrial fibrillation at the participating departments were eligible. Participating clinicians provided written informed consent prior to enrolling patients. Adult patients (≥18 years of age) were eligible if they had a diagnosis of nonvalvular atrial fibrillation, were at high risk of a thromboembolic event (i.e., had a CHA_2DS_2-VASc score of ≥1 in men or ≥2 in women), and were able to read and understand the informed consent document. Patients could be new to anticoagulation medication (Start cohort) or currently receiving anticoagulation (Review cohort).

2.4. Intervention

As part of the SDM4Afib trial, encounters were randomized to usual care either with or without the use of ANTICOAGULATION CHOICE (http://anticoagulationdecisionaid.mayoclinic.org), an SDM conversation tool for use during the clinical encounter [10]. The tool calculates the patient's risk of stroke using the CHA_2DS_2-VASc score [11], and offers the patient's tailored risk of stroke at one or five years, with and without anticoagulation medication, using natural frequency expressions ("out of 100 people like you") and 100-person pictographs. The tool then supports the comparison of available anticoagulation options – Warfarin and DOACs (direct oral anticoagulants) – across patient-important issues, such as how to use the medications, the need for periodic monitoring, reversibility, impact of lifestyle or of medical factors on the risk of bleeding, and estimated out-of-pocket costs.

2.5. Measures

Patients completed a paper survey immediately post-encounter. With permission, we recorded the encounter (audiovisual or audio only). We reviewed medical and pharmacy records 12 months post-enrollment to assess primary adherence to their treatment [8].

2.5.1. Patient surveys

Immediately post-encounter, we asked patients to reflect on what about the conversation went well and what could be improved, whether and why they think their clinician understands them and their situation, and what they and their clinician are planning to do about the patient's situation. This reflection exercise [7] was followed by an open-ended narrative question on 'sense' ("Why does that [care] plan make sense to you") in order to get to the patient's motive, for accepting the plan, and a linear analogue self-assessment (LASA) on "How much sense does that plan make to you?" on 0–10 scale ranging from 'as little as can be' to 'as much as can be' [7]. Patients completed the Decisional Conflict Scale (DCS) to assess comfort with the decision made [12]. Scores are reported on a 0 (least decisional conflict)–100 scale.

2.5.2. Encounter observations

As part of the SDM4Afib trial, pairs of trained reviewers independently and in duplicate used the OPTION12 scale to code clinicians' behaviors to involve patients in decision making [13]. We verified inter-rater reliability (Lin's agreement) at baseline and after 33% and 66% of recordings of the total trial sample (range 0.84–0.96). OPTION12 scores are presented on a 0–100 scale, with 100 reflecting maximum SDM behaviors [13]. In addition, we captured the length of the encounter.

2.5.3. Pharmacy review

Twelve months post-enrollment, and blinded to randomization status, we reviewed medical and pharmacy records to assess primary adherence (first prescription filled among patients prescribed an anticoagulant). We noted the care plan as documented in the medical record (start, continue, or stop anticoagulation) of the index encounter. We contacted patients' pharmacies to receive patients' records on the first fill post encounter (primary adherence).

2.6. Analyses

2.6.1. Statistical analyses

We used descriptive statistics to describe cohort with counts and frequencies for categorical variables and means and standard deviations for continuous. We used *t*-tests to compare continuous scores between arms and the Pearson test statistic to access if a correlation existed between Sense (LASA score) and decisional conflict, OPTION12 and length of encounter. We conducted a hierarchical generalized linear model with the outcome of decisional conflict adjusting for the fixed effect of treatment arm and sense score (categorized as LASA score=10 vs Other response) with the healthcare system as the random effect. We report the adjusted

difference of the mean with 95% Confidence intervals. To explore the association between sense scores and primary adherence, we compared the odds that patients with LASA Scores of 10 vs. Other responses filled their first prescription post encounter.

2.6.2. Qualitative analyses of reflections

Four reviewers (a linguist/decision scientist, human-interaction designer, research assistant and a clinician), blinded to study arm, LASA scores and SDM scores, analyzed all written patient reflections. If reflections contained more than one statement, these were analyzed separately.

We used Kenneth Burke's Pentad of Motives to deductively categorize patient reflections by their reasons as to why their care plans made sense. The unit of analysis was any argument, reason, or explicit justification for why a plan made sense, provided by the patient within their reflection. Kenneth Burke's Pentad is a highly influential heuristic from rhetoric used to understand the motivations behind a person's actions or discourse [14]. An analysis using Burke's pentad considers how actions or words "offer *some kind* of answers to these five questions: what was done (act), when or where it was done (scene), who did it (agent), how he did it (agency), and why (purpose)." [14] Accordingly, the expressed justifications for why a plan made sense were categorized as being motivated by the qualities or attributes of one of these five elements, defined as: (1) Agent: a person/persons—whether a co-agent (friend) or counter-agent (enemy)—and their values, preferences, or relationships; (2) Agency: a tool, instrument, or means, such as a specific treatment option, an SDM tool, or an intervention; (3) Act: something that has been or is being done, such as a conversation, deliberation, or general treatment program; (4) Scene: a setting or context, either medical or personal, such as patient situation, history, experience, diagnosis, social determinants, or home circumstance; and (5) Purpose: an outcome, medical or personal goal, feeling, or state that is trying to be achieved.

The four reviewers independently categorized all reflections. In consensus meetings, the reviewers discussed all coded justifications and their categorizations until they reached agreement. In a second round of discussion, the reviewers checked all reflections and categorizations again to see whether additional changes needed to be made, based on discussions in the course of the first round.

3. Results

3.1. Participant characteristics

During the survey period, 150 patients were approached for participation. Of these, 123 (82%) patients participated in the study and offered written reflections on why their care plan made sense. The encounters between these patients (Table 1) and their 43 clinicians (Table 2) in this subgroup were randomized to usual care alone (N = 62) or with ANTICOAGULATION CHOICE (N = 61). We obtained pharmacy records for 116 of the 123 participants.

3.2. Numerical evaluations

Patients gave high ratings reflecting how much sense their care plans made to them in both the Start (N = 19, Mean=9.2, SD 0.98) and the Review (N = 104, Mean 9.3, SD 1.34) cohorts. We found no between-arm differences in these ratings (mean 9.4 (SD 1.0) in usual care vs 9.2 (SD 1.5) with the SDM tool; p = .8). Ratings were significantly, weakly, and inversely correlated to patients' decisional conflict (DCS, rho=−0.28, p = .002). Expressed in another way, patients who found their plans to make sense (top LASA score of 10) reported less decisional conflict that patients who did not (Other LASA scores) (15.5 vs 23.0, adjusted mean difference −7.5 95% CI −12.9, −2.0). Table 3 describes the decisions made and the primary adherence (first fill post encounter) related to these decisions by LASA score. The odds of not filling the first prescription were lower in patients who found their plans to make sense (top LASA score of 10) than in patients reporting lower sense scores (11 of 80 (14%) vs. 11 of 43 (27%), odds ratio 0.46, 95% CI 0.18–1.18) although this difference was not significant. We found no significant correlations with OPTION12 scores (rho=0.01, p = .9) or with encounter duration (rho=0.01, p = .9).

Table 1
Patient characteristics.

	SDM tool (N = 61)	Usual care (N = 62)
Age, Mean (SD)	68 (10)	70 (11)
Female, N (%)	17 (28)	19 (31)
Male, N (%)	44 (72)	43 (69)
Race[1], N (%)		
White	52 (84)	47 (77)
Black	9 (15)	12 (19)
AI/AN	1 (2)	0
Asian	0	1 (2)
Other	0	1 (2)
Hispanic[2], N (%)	1 (2)	0
Inadequate Health Literacy[3], N (%)	2 (3)	1(2)
Subjective Numeracy Preference Subscale, Mean (SD)[4]	4.4 (1.0)	4.6 (1.3)
Subjective Numeracy Scale, Inadequate Numeracy (Average score < 4)	16 (26)	16 (28)
CHA_2DS_2-VASc Score, Mean (SD)	3.4 (1.7)	3.3 (1.5)
Cohort		
Start (Treatment Naïve), N (%)	12 (19)	7 (11)
Review, N (%)	50 (81)	54 (89)
Sense of the care plan (LASA score), Mean (SD)	9.2 (1.5)	9.4 (1.0)
Motive for sense, N (%)[5]		
Agent	12 (19)	7 (11)
Agency	8 (13)	7 (11)
Act	24 (39)	23 (37)
Scene	5 (8)	11 (17)
Purpose	13 (21)	11 (17)
Unable to code	6 (9)	10 (16)

1 – Race is missing 1 response in the Usual Care arm.
2 – Ethnicity is missing 3 responses in the Usual Care arm.
3 – Health literacy [28] is missing 3 responses in the Usual Care arm.
4 – Subjective Numeracy [29] is missing 4 responses in the Usual Care arm.
5 – Numbers don't add up to 100% as patient's responses could contain more than one motive

Table 2
Clinician characteristics.

	N (N = 43)[1]
Age, Mean (SD)	47 (11)
Female, N (%)	21 (50)
Male, N(%)	21 (50)
Clinician type, N (%):	
Physician	29 (69)
Nurse practitioner	8 (19)
Physician Assistant	2 (5)
Pharmacist	3 (7)
Practice type, N (%)	
Cardiology	5 (12)
Cardiac Electrophysiology	13 (31)
Internal Medicine	17 (40)
Family Medicine	7 (17)
In Residency/Fellowship, N (%)	6 (14)
Enrolled Patients per Clinician: Median (Range)	2 (1, 12)

1 – One clinician did not respond to baseline survey.

3.3. Patients' reflections

A total of 121 expressions of why a care plan a makes sense were extracted from the reflections of 107 patients (range 1–2). In addition, reflections of 16 patients could not be coded as these did not offer any discernible reason for why the care plan made sense (e.g., "Yes", "Ok", "It

Table 3
Adherence to decision.

	Sense Top Score (N = 80)	Sense Other Response (N = 43)
Initial Medication Decision (EMR)		
Warfarin	42 (53)	24 (56)
DOAC	32 (40)	11 (26)
No Anticoagulant	6 (7)	8 (19)
First Medication Filled (pharmacy records)		
Warfarin	33 (43)	16 (39)
DOAC	32 (42)	14 (34)
No Anticoagulant Filled	11 (14)	11 (27)
Pharmacy Data Missing	4	2

makes sense", "Very much so", "It just does", "Continue on anticoagulation", "To check up in a year", "Second opinion", "No repeat of Afib symptoms"). Table 1 describes the distribution of motives trial arm.

3.3.1. Agent

When reflecting on why the designed care made sense to them, 19 patients highlighted the contribution of people involved and their values and preferences. Patients indicated for example: "It's what I want", "I don't [want] to rush any decisions", "I don't want blood thinners yet", "It's what I think is the best choice for me" and "I need to know what's causing the problems".

Patients also highlighted their relationship with their clinician, presenting them as a co-agent: "The doctor is following step by step. I am confident in [doctor]", "It is well thought out and well planned with my input and my doctor's input", "Because [hospital] with my cardiologist and other staff have made, in my estimation, a great effort to address and remedy the heart problems I had", and "[Doctor's] recommendations based on my particular condition".

3.3.2. Agency

Fifteen patients focused their reflection on tools, instruments or means, mostly focusing on characteristics of specific treatments that function as a tool or means to achieve a goal: "Less blood work", "Less labs", "Routine, cost", "The price for other medication is too high", "It opens up my diet options that are restricted by warfarin", and "Inexpensive, easily reversible, with less potential for side effects".

3.3.3. Act

Patients justified their care plan on the basis of what is currently being done, or has been done in the past (N = 47 cases). They discussed, in general, how they had experienced their course of treatment: "Because it's working", "Because if something is going well, there is no need to change it", "It will be easier if I switch because of not having to be tested which can be difficult for me to make at times", "I am willing to pursue it and take it as a trial, the final will be my decision on my body's reaction", "Current treatment is medically sound and appears to be effective", and "Used to it, confidence in the plan".

In other cases, they referred to the act of conversation (decisional) that they had with their clinician: "We've explored all feasible alternatives", "Because […] I haven't had the opportunity to talk about my options", and "More necessary information is needed for both parties".

3.3.4. Scene

In 16 cases, patients focused on their setting or context when reflecting on the sense of their care plan. Some made general statements on their context: "Suits my situation", "Because of my age, I may reconsider my plan as I get older", and "it just seems good for me now".

Others focused on their medical context: "I have kidney disease & need to stay away from medication that can harm me" and "Because with my heart condition […] works with the blood thinner and my lifestyle", or on their personal context: "Suits my budget" and "Because it meets my needs and lifestyle".

3.3.5. Purpose

Patients also referred to what they are trying to achieve, or what their goal is (N = 24 cases). These goals often related to patients' health: "Hopefully it keeps me stable and healthy", "Should help things go back to normal", "To prevent stroke", and "Addresses the greatest risk to life first, then quality of life second". In some cases, patients' goals related to working toward making a decision or feeling comfortable with the care plan, such as: "Monitor will allow us to make a decision" and "To be sure and confident".

4. Discussion and conclusion

4.1. Discussion

Our results showed that after decisional encounters, patients with atrial fibrillation offered consistently high ratings of how much sense their care plans made to them. We postulated that the use of an effective SDM tool could produce decisions that patients would find made intellectual, emotional, and practical sense to them. Yet, we found that there was no difference in sense ratings across arms of the trial comparing usual care with and without an effective SDM tool. Since the use of the SDM tool increased the likelihood of observing SDM inducing behaviors in clinicians, as judged by the OPTION12 score, we explored whether greater effort to involve patients produced more sensible plans. Our results are not consistent with this inference. Then we explored the extent to which sense ratings related to other measures of intellectual, emotional, and practical sense. We found a weak correlation between sense ratings and decisional conflict (DCS). We also found no significant association between sense ratings with primary adherence to the plan. Together, these results do not support our hypothesis that sense ratings reflected patient's sense that the plan made intellectual, emotional and practical sense to them. Most patients were able to reflect on why their decided-upon care plan made sense to them, and these reflections demonstrated a wide variety of motivations.

When successful, SDM should lead to a care plan that is more likely to *respond well* to the patient's problematic situation; be *feasible* given the existing demands on the patient's time, energy and attention; and be *desirable* given the patient's experience, expectations, preferences, goals and values. Therefore, we expected SDM to contribute to designing care plans that made more sense to patients, and which fitted well within the patients' lives [15]. Our study however could not confirm that high degrees of patient involvement in decision making led to care plans that were more sensible or more feasible to implement in daily life.

Our study had some limitations. First, although we have pilot-tested and used our reflection questions and single-item measure on sense in previous research, this measure has not been validated and may not be able pick up the variability in patients' perceptions. At the same time, the field of SDM is familiar with—has even validated—measures with high ceiling effects, and our measure showed a relationship to the Decisional Conflict Scale [12], the most often-used outcome measure for SDM intervention studies [16]. Second, our trial also showed high observer scores for patient involvement. These OPTION12 scores were higher in our usual care arm than is usually found in other SDM trials [17], and use of the SDM tool further increased these scores [9]. It may well be that the 2014 guidelines of the three major cardiovascular organizations, which gave their strongest, class 1, recommendation for using SDM with patients with nonvalvular atrial fibrillation at risk of strokes [18], has led to greater awareness and better implementation of SDM strategies in practice. These

consistently high scores may have contributed to our inability to find a relationship between patients' involvement in decision making and patients' perceived sense of their care plans. However, research has found no consistent relationship between observer-based and patient-reported evaluations of decision making [19,20]. Third, we have low confidence in our finding that patients' adherence to treatment was similar for those reporting top versus lower sense scores. Other than the absence of a relationship between sense and adherence, and the lack of correlation given the narrow distribution of results for these two variables, these findings could also be explained by the relatively high number of patients in our sample already on anticoagulation medication (review cohort). For them, a single encounter with their clinician during their ongoing treatment may not affect either the sensibility of their existing care plan, or their adherence to this care plan. In addition, in any trial focusing on adherence [16,21], the challenge remains to include patients with documented nonadherence at baseline, otherwise limiting the opportunities for improvement in adherence. Finally, for our analysis of patients' reflections we chose to use Burke's pentad of motives [14]. As can be seen in our description of the data, in some cases the motives may overlap. Working with a diverse group of four reviewers, we aimed to assign the motive that best described the essence of each reflection. Rather than a comprehensive inventory, we sought to map patients' most prominent reasonings to why their care plan made sense to them.

Evaluating the sensibility of the care plan and fidelity of its implementation may shed light on what contribution that technically "correct" SDM, i.e., taking the right steps, in the correct sequence, at the right time [6], makes to high quality decisions. It further opens questions regarding how decisions come to be senseful. The act of SDM should allow for this sense to develop. Indeed, it may be fruitful to conceive of SDM as the development of sense in care plans through the conversations of patients and clinicians. This would turn our attention to *development of sense* as a process measure of SDM. Just as child development is a longitudinal indicator of a child's health, so too, the temporal development of sense may be an indicator of the health of an SDM encounter.

This exploration may correct notions of what constitutes effective SDM and orient efforts to improve its usefulness, for example by focusing on the humanistic and conversational aspects beyond the mere completion of technical steps. By advancing research on its purpose, SDM may once again be a means to better care rather than an indicator or outcome of programs to promote patient-centered care [22].

The exploration of motives for plans of care is a novel contribution to the study of shared decision making. That most participants belonged to the review cohort allowed most of them to indicate that the plans of care on which they had already embarked made sense because they had proven effective, feasible, and safe to each of them. It is consistent with the literature on the therapeutic alliance that some made sense of the plan given its recommendation by a trusted clinician. That practical considerations of the plan (i.e., agency motive) contribute to sense-making confirms the importance of including this information in discussions about options [23]. Similarly, that patients find justification in the plan's purpose speaks to the importance of discussing what the options can accomplish in relation to the goals and priorities of each patient [24]. That the patient's situation contributes to making sense of the plan speaks to the importance of noticing the patient's problematic human situation beyond its pathophysiological derangements to include the patient's personal and social condition [25]. To us, our findings continue to make the case for the importance of situating SDM within the conversations between people who come together to receive and give care.

4.2. Conclusion

Our study showed that after decisional encounters in usual care with or without the use of a within-encounter SDM tool, patients consistently perceive their care plans to make sense. We were unable to show a compellingly strong association between observed SDM behaviours during patient-clinician encounters and sense ratings, or of sense ratings with decisional comfort or primary adherence.

4.3. Practice implications

While our group has intentionally focused on promoting SDM within the clinical encounter to facilitate the co-creation of plans of care that fit well and make sense, our study could not find evidence of this effect despite an effective and properly implemented SDM tool. The study's limitations—particularly the ceiling effects of our sense-making LASA, the high prevalence in this sub-study of patients already on anticoagulation, and the high LASA scores in the control arm—preclude us from concluding that an intervention to promote SDM did not contribute to patient sense-making. Instead, the main contribution of this sub-study is to propose a way of evaluating SDM that goes beyond technical process measures and draws attention to the quality of the decisions made. Existing efforts in this regard have sought to estimate the concordance between the features of the option chosen and the values espoused by the informed patient [26]. This approach seems less applicable or feasible to the kinds of decisions clinicians and patients living with chronic conditions routinely make as the issue here may be less, 'which options are most concordant with my values?', but rather, 'how can treatment work within, and contribute to, my life and what I find meaningful in it?' Indeed, only 19 of 123 (15%) patients in this study attributed the sense of the care plan to attributes of an agent (which include the agent's values and preferences), while 47 (38%) patients attributed the sense of the care plan to an act—predominantly how treatment is, or would, fit into their day-to-day life. Patients with chronic conditions and their clinicians often must work together to uncover the true nature of the patient's problematic situation and to co-create a way forward that advances this situation in a manner that patients can understand, value, and implement in their lives [27]. Considering the extent to which the resulting plan of care fits well, in terms of its sense, is a method, demonstrated here, that may be better suited to the evaluation of forms of SDM that are different from selecting from a set menu of known options.

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CRediT authorship contribution statement

Kunneman: Conceptualization, Methodology, Analysis, Investigation, Writing - original draft, Writing - review & editing, Approval of final manuscript, Funding acquisition. **Hargraves:** Methodology, Investigation, Writing - review & editing, Approval of final manuscript. **Sivly:** Investigation, Writing - review & editing, Approval of final manuscript. **Branda:** Formal analysis, Writing - review & editing, Approval of final manuscript. **LaVecchia:** Methodology, Writing - review & editing, Approval of final manuscript. **Labrie:** Methodology, Writing - review & editing, Approval of final manuscript. **Brand-McCarthy:** Methodology, Writing - review &

editing, Approval of final manuscript. **Montori:** Conceptualization, Methodology, Analysis, Investigation, Writing - review & editing, Approval of final manuscript, Supervision and funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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- *Park Nicollet- Health Partners*: Carol Abullarade, Bruce Burnett, Lisa Harvey, and Shelly Keune.
- *University of Alabama at Birmingham:* Elizabeth Jackson, Erik Hess, Timothy Smith, Shannon Stephens.
- *University of Mississippi Medical Center*: Bryan Barksdale, James Hamilton IV, Theresa Hickey, Roma Peters, Memrie Price, Takeki Suzuki, Connie Watson, and Douglas Wolfe.

Data safety and monitoring board

Gordon Guyatt (chair), Brian Haynes, and George Tomlinson.

Expert advisory panel

Paul Daniels, Bernard Gersh, Erik Hess, Thomas Jaeger, Robert McBane, and Peter Noseworthy (chair).

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