SCIEPublish

Article

Shared Decision Making for an Implantable Pulmonary Artery Monitoring Device in Heart Failure: A Pilot Study

Kelly A. Bosak * and Sara Young

University of Kansas Medical Center, Kansas City, KS 66160, USA; diesel3398@yahoo.com (S.Y.)

* Corresponding author. E-mail: kbosak@kumc.edu (K.A.B.)

Received: 13 January 2025; Accepted: 6 March 2025; Available online: 20 March 2025

ABSTRACT: Pulmonary artery (PA) pressure can be monitored remotely by a microelectromechanical sensor (MEMS) permanently implanted in the pulmonary artery. This device allows early management of fluid overload in heart failure so that diuresis can be initiated promptly, and hospitalization and other adverse events can be prevented. To test the methods and measures proposed to explore patient and provider perceptions of Shared Decision Making for the CardioMEMS pulmonary artery pressure monitoring device. A convenience sample of eight patient-provider dyads was enrolled at an ambulatory academic cardiology clinic and completed the shared decision making questionnaire in the clinic prior to the procedure. The majority of providers reported complete agreement that shared decision making occurred. Patients' survey responses varied but remained positive. The survey used was feasible and effective. Dyad perceptions were positive and concordant in this small convenience sample. Future studies with larger samples are needed to develop interventions to promote behaviors necessary for shared decision making.

Keywords: CardioMEMS; Pulmonary artery pressure monitoring; Surgically implanted sensor; Heart failure; Shared decision making; Volume overload

© 2025 The authors. This is an open access article under the Creative Commons Attribution 4.0 International License (https://creativecommons.org/licenses/by/4.0/).

1. Introduction

Heart Failure (HF) is a major societal concern. HF is projected to impact over 8.5 million adults in the United States by 2030 [1]. The diagnosis of HF indicates impaired health and well-being and has a poor prognosis. This is exemplified in the 5-year mortality rate for patients with chronic HF and many cancers, which is similar [2]. This creates a significant burden for patients, and also for our health care system. The cost is approximately $160 billion dollars total for cardiovascular care alone [3]. Quality, patient-centered care and accountability are crucial for complex chronic conditions, such as HF. Advances in technology and state-of-the-science treatment options for HF necessitate patient-centered care management with evidence-based strategies and treatments. Shared Decision Making (SDM) is essential to navigate the complexities of care for patients with complex chronic conditions, such as HF. SDM occurs when a patient and provider exchange information, deliberate, and make decisions in accordance with patient preferences. Notably, the SDM process incorporates patients' beliefs, health-related fears, and what matters most to patients in selecting treatment options [4].

Novel advances in technology capable of minimizing the likelihood of hospital readmission can also minimize patient and caregiver burden and cost [5]. The primary cause of HF-related hospitalizations is fluid volume overload [2], which occurs in patients in the advanced stages HF. The characteristics of advanced stage of HF include multiple symptoms and marked limitation of functional ability. Ordinary activity often causes symptoms of fatigue, palpitations, shortness of breath, and/or chest pain in individuals with HF. The current standard of care is guideline-directed recommendations, including pharmacologic quadruple therapy consisting of four classes of medication supported by robust clinical trial evidence to reduce hospitalizations and mortality. Also included are devices, such as the implantable pulmonary artery pressure sensor that allows earlier intervention for fluid overload.

The standard of care for patients with advanced stage HF includes monitoring patient daily weights, early consultation with a cardiologist HF specialist, and prompt follow-up after hospital discharge for HF exacerbation [6].

https://doi.org/10.70322/cvs.2025.10001

Despite these conventional methods to monitor fluid overload, symptoms often become apparent only after the patient's condition has decompensated and hospitalization and/or diuresis are required [2].

One of the first miniature mechanical and electronic devices to monitor pulmonary artery pressures and fluid status was the Cardio-microelectromechanical system (CardioMEMS). This device received approval from the Food and Drug Administration (FDA) in May 2014 [7]. Currently, there are 12 pulmonary artery monitoring devices available on the market that have received FDA approval. A wireless sensor approximately the size of a grain of rice is permanently implanted in the pulmonary artery (PA) to measure pressures [2]. An external antenna is situated under the patient briefly to power the device, monitor the sensor, and measure PA pressures [8]. The information can then be transmitted to a secure online site for analysis. These devices are amenable to individualization to give alerts for pressure readings outside specified intervals and reported by text message to care providers. CardioMEMS is the PA pressure monitoring device used at the health system where this investigation was conducted.

Research showed a correlation between pulmonary artery pressure and worsening HF [2]. The CHAMPION clinical trial [9] enrolled symptomatic NYHA functional class III patients across the US. All participants received the CardioMEMS system. Treatment decisions were made by providers based on the PA waveforms to optimize fluid status on an outpatient basis. The safety and clinical efficacy of the CardioMEMS monitoring system were demonstrated and established a new paradigm for medical management using implanted sensors [10,11]. While patients provided informed consent for implantation, there is a lack of reporting of the patient's perspective regarding this device.

Patients with HF experience many symptoms that threaten their functionality, impair decisional capacity, and reduce survival [12]. Patients, caregivers, and providers must be aware of patient-centered communication and SDM as an essential component of quality care for patients with complex chronic conditions. The decision that a PA pressure monitoring device is the optimal choice is presented by the provider to the patient with the flow of communication in that direction. This is generally a one-way process. Engaging the patient in SDM for CardioMEMS is an important aspect of patient-informed care. SDM is recommended by the Institute of Medicine and the U.S. Preventative Services Task Force for clinicians when treatment options are presented [13].

The purpose of this pilot study was to investigate patient and provider perceptions of shared decision making for the CardioMEMS implantation procedure. SDM is considered an optimal approach to making complex health care decisions since the early 1980's, although the use as a specific technique has not often been reported [13]. SDM is a necessity for any patient faced with difficult decisions regarding their health. Complex chronic conditions, such as HF, often require patients to make many decisions guided by their healthcare provider along the trajectory of their illness. HF can lead to frequent hospital admissions for management of symptoms related to fluid volume overload. CardioMEMS is a recent advancement in treatment that serves to keep patients out of the hospital and manage HF symptoms before they escalate. The objectives of this investigation were to (1) test the methods and measures used to explore perceptions of patients and providers of SDM for the CardioMEMS procedure using the Shared Decision Making Questionnaires (SDM-Q-9, SDM-Q-Doc), and to (2) identify concordance between patient and provider survey responses and perceptions of the process.

The theoretical framework guiding this project was the Collaborative Deliberation Model by Elwyn and Fisher [14]. This model served as the guiding framework for investigating SDM for the PA pressure monitoring procedure. The factors that are essential to deliberation among the patient and provider for the CardioMEMS device, included, interpersonal engagement, recognition of alternatives, information comparing options, preference determination, and preference integration [15].

This framework also considers the context that mediates patient and provider interactions. Various contexts are of interest with the procedure to implant a PA pressure monitor, including the emotional state of those involved, resources available, and the advantages and disadvantages of this advanced technology for monitoring fluid volume. The alternatives, along with norms, such as social and healthcare cultural norms shape patient and provider preferences for this state-of-the-science intervention. In this theoretical model, the key to patient engagement is a respectful and empathetic communication approach [16]. An interdependence occurs when recognizing and deliberating about alternatives to a PA pressure monitoring device. Deliberation includes learning about patient preferences and integrating these factors to reach an agreement.

Implementation of collaborative deliberation in the HF setting as shown below in Figure 1, includes a series of strategies and the proximal, distal, and distant effects, and feedback that serve to strengthen ongoing use and mastery of collaborative deliberation strategies in the HF clinic setting [16].

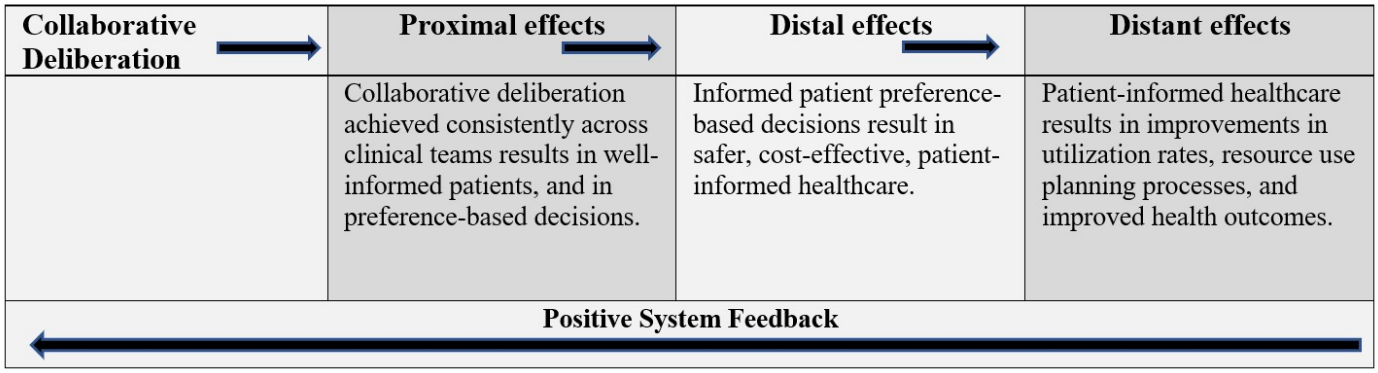

Figure 1. The Collaborative Deliberation Model (adapted from Elwyn et al., 2016 [16]).

2. Methods

This project used descriptive statistics (number, %) to gain a broader understanding of the perspectives of HF patients and their providers and discern the concordance of perspectives of shared decision making for the CardioMEMS procedure. This project was conducted during the months of December 2019 and January 2020. Following the pre-procedure clinic visit, the standardized Shared Decision Making Questionnaire (SDM-Q-9 and SDM-Q-Doc) was completed by the dyad.

A convenience sample was enrolled for this project of adult male and female patients over the age of 65 years plus their provider in dyads. The project was conducted in the cardiology HF clinics of a large academic quaternary healthcare system. The HF clinics of this health system treat an average of 500 patients per month in the health system associated clinics and outreach clinics. There are 11 physicians and 6 advanced practice providers that manage the care of HF patients in the main cardiology HF clinic. This HF clinic specializes in treating patients who have been diagnosed with advanced HF. Guideline-directed medical therapy, including innovative treatments such as CardioMEMS, is used in the care management of these HF patients. Over 100 patients in this health system have had the CardioMEMS device implanted to date.

Patients were included who had a diagnosis of advanced stage HF and were determined by their healthcare providers to be candidates to receive the PA pressure monitoring device. Criteria also included adult patients 18 years of age or above. The language interpreter line currently used in the clinic was available for enrollment and participation of any eligible patients who did not speak English.

Exclusion criteria included patients with memory impairments such as dementia. No patients were identified to have dementia, and no one was excluded for this reason. The surveys were completed in writing, an approach that would exclude patients with illiteracy from the study.

Informed consent was received from providers and patients who attended the pre-CardioMEMS clinic visit and verbally agreed to volunteer to complete the questionnaire. There were no perceived risks to the patient or provider. The data collected was directly from patient and provider input from the questionnaires. Other than patient age, no patient or provider identifiers were included on the forms. IRB quality improvement designation and exemption from further IRB oversight were received prior to beginning the project.

The instruments used were the standardized 9-item Shared Decision Making Questionnaire (SDM-Q-9) [17] completed by patients and the Shared Decision Making Questionnaire for Physicians (SDM-Q-Doc) [18] was completed by the providers (physicians, nurse practitioners). Each questionnaire was rated on a 6-point Likert scale with 1 = completely disagree to 6 = completely agree. The SDM-Q-9 questionnaire was found to have good acceptance, feasibility, and reliability [18]. This questionnaire has been tested in patients with a variety of chronic conditions and was found to be psychometrically sound, including in a primary care sample [17], and oncology practice [19]. The questionnaire has also been translated and validated in other languages [20,21]. To our knowledge, use of the SDM questionnaires has not been reported in the HF patient population.

Patients were identified by the clinic managers on the clinic schedules to complete the questionnaire at the pre-procedure consultation visit. Patients completed the SDM-Q-9 questionnaire and providers completed the questions from the SDM-Q-Doc in the HF clinic after the pre-procedure visit. Both surveys included an open-ended question at the end to provide candid comments regarding SDM during the CardioMEMS consultation. The data was analyzed using descriptive statistics. Responses from each patient-provider dyad were compared for concordance.

3. Results

A total of eight patient-provider dyads completed the questionnaires during the data collection period for a total of 16 surveys. The patients with HF were all 65 years of age or older. All participants spoke English, and no participants were identified as illiterate in this sample. All providers and patients approached agreed to participate. No one declined participation. The majority of the results of the provider SDM-Q-Doc were highly positive, rated "completely agree" on the 6-point Likert scale. One survey was the exception with somewhat disagreeing to the questions, "I made it clear to my patient that a decision needs to be made", and "I told my patient that there are different options for treating his/her medical condition".

The patient surveys were completed without requiring assistance and were slightly more varied. Again, the majority of responses remained overall positive. All patients replied, "completely agree" or "strongly agree" on the following questions: "My doctor made it clear a decision needs to be made", "My doctor and I weighed the different treatment options", and "My doctor and I reached an agreement on how to proceed". All but one patient answered, "completely agree" to the questions, "My doctor wanted to know how I wanted to be involved in the decision making", "My doctor made it clear there were different options to treating my condition", "My doctor helped me understand all the information", "My doctor asked me which treatment I preferred", and "My doctor and I selected a treatment together". A question stating, "The doctor provided advantages and disadvantages of treatment options" was the only question that all patients selected "strongly agree". Two questions were left blank on one patient survey. One patient provided a response to the open-ended comments included at the end of the survey. The patient commented, "Everyone is patient and explains everything. I never leave not knowing what is going on. They [providers] even explain to my family". The surveys completed by each patient and provider dyad were generally rated "completely agree" or "strongly agree" and were concordant.

4. Discussion

Patients indicated that they shared the decision making process for the CardioMEMS procedure with their physician. A limitation found in this project, as with most questionnaires using a Likert-type scale, was the tendency for respondents to select an option on the extreme end of the scale. In this project, the provider survey responses leaned toward the extreme positive end of the scale. We acknowledge that the small sample size makes it difficult to determine if the survey results demonstrate relationships among variables or are representative of the majority of provider and patient perspectives of SDM. Thus, this small sample was recognized as a limitation and was considered in reporting the results.

Patient responses were more varied, although their answers also centered around the positive end of the scale. These were concordant with the provider's responses and indicated that patients felt they were part of the decision making process in relation to the CardioMEMS procedure. The patient responses may also be related to the high level of confidence they have in their providers and the patient-provider relationship that has been built over time. Notably, the patient participants were all 65 years of age or above. HF increases with older age, and these individuals disproportionately face excess risk for hospitalization, morbidity and mortality [1]. Patient-informed decision making is imperative in this population.

Shared decision is gaining recognition among health care providers as is the current national cardiovascular guidelines to promote equity [22]. Reports of SDM have increased markedly over the last 10 years. SDM has undergone testing in patients with complex chronic conditions, including breast cancer [23], in patients requiring thoracic surgery [24], and in palliative care for various conditions, including serious neurologic conditions [25]. The evidence to date indicates that SDM is not commonly used in the clinical setting [26]. No reports were found of SDM use in patients undergoing PA pressure monitoring devices or other implantable or state-of-the-science Cardiovascular devices.

Additional investigation is needed to make conclusions about patients' feelings of autonomy and being an active part of the SDM process for decision making or if they defer to their provider to decide in their best interest. The patient's trust in their provider to present the best option was evident in this project. It is unclear if the patient's beliefs, health-related fears, and what matters most to patients in selecting treatment options were fully discussed and reflected in the survey questionnaires. Additional investigation is needed to ensure the integrity of the SDM process.

Notably, the providers completing the SDM-Q-Doc at this health system where this investigation was conducted were all physicians. However, providers in this cardiology HF clinic include nurse practitioners (NPs), and it is within their scope of practice to inform patients of the procedure and obtain informed consent. This can be accomplished but requires systems changes that allow NPs to assume an active role in the consent process. The SDM-Q-Doc was

originally developed and underwent psychometric testing in 2012 by a group of researchers in Germany [27], with a physician focus. NPs in the US are uniquely prepared and positioned in specialty clinics to educate other providers about the SDM process, which involves more than the completion of a survey. These providers can serve as role models for other providers to achieve SDM with patients. Further, minor revisions to the title and wording of the SDM-Q-Doc are recommended to accommodate NPs who are not doctorally prepared as well as other advanced practice providers such as physician assistants. Minor adaptations will optimize the survey instrument. A generic title for this instrument with the option to specify the role of the provider obtaining consent using SDM would more accurately reflect advances in the practice environment.

Limitations. This was a pilot project, and a small sample was recruited to test the survey methods and measures. This investigation was not intended for identifying relationships or assessing outcomes over time or generalizing to other clinic settings. The small convenience sample was recruited in the interest of time. We acknowledge that a small sample can introduce selection bias, however, we had no prior knowledge of patients' or providers' level of agreement in the SDM process before including them in the study. We achieved our aim to test the methods and measures used for a future, longitudinal clinical trial with recommendations for adapting and optimizing the SDM-Q measures.

5. Conclusions

SDM is associated with patient autonomy and influence and is becoming increasingly important with the complexities of HF management, the aging population of patients with HF, and the treatment advances available. This project explored the perspectives surrounding SDM for one PA pressure monitoring device, the CardioMEMS with patient and physician provider dyads. Concordance was observed in the responses of the dyads. The decision making process was open and detailed. Future research will be beneficial that focuses on the role of all providers in the clinic and the process to inform both patients and providers of the specific behaviors necessary for SDM. Investigation of SDM processes with a variety of provider roles is important to ensure information is shared, deliberation occurs jointly, and decisions are made that accurately reflect the patients' preferences. When conducted consistently, with integrity, and by all providers, the SDM process can result in healthcare that maximizes the use of resources, and ultimately, improves health outcomes for patients with HF.

Author Contributions

Conceptualization, S.Y. and K.A.B.; Methodology, K.A.B.; Software, S.Y., K.A.B. ; Validation, K.A.B.; Formal Analysis, S.Y., K.A.B.; Investigation, S.Y.; Resources, S.Y.; Data Curation, K.A.B.; Writing—Original Draft Preparation, S.Y.; Writing—Review & Editing, K.A.B., S.Y.; Supervision, K.A.B.; Project Administration, K.A.B.; Funding Acquisition (NA).

Ethics Statement

This project was reviewed by the Institutional Review Board at the University of Kansas Medical Center and was determined to not require approval, as this was a quality improvement project and not intended to be widely generalizable.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data is accessible to researchers. A request stating the reason(s) for obtaining and use of the data can be directed to the primary author.

Funding

This research received no external funding.

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.

References

1. Bozkurt B, Ahmad T, Alexander K, Baker WL, Bosak K, Breathett K, et al. Heart Failure Epidemiology and Outcomes Statistics: A Report of the Heart Failure Society of America. *J. Card. Fail.* **2023**, *29*, 1412–1451.
2. Ollendorf DA, Sandhu AT, Pearson SD. CardioMEMS HF for the Management of Heart Failure-Effectiveness and Value. *JAMA Intern. Med.* **2016**, *176*, 1551–1552.
3. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation* **2022**, *145*, e895–e1032.
4. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: A model for clinical practice. *J. Gen. Intern. Med.* **2012**, *27*, 1361–1367.
5. Schmier JK, Ong KL, Fonarow GC. Cost-Effectiveness of Remote Cardiac Monitoring with the CardioMEMS Heart Failure System. *Clin. Cardiol.* **2017**, *40*, 430–436.
6. Singh R, Varjabedian L, Kaspar G, Zughaib M. CardioMEMS in a Busy Cardiology Practice: Less than Optimal Implementation of a Valuable Tool to Reduce Heart Failure Readmissions. *Cardiol. Res. Pract.* **2018**, *2018*, 4918757.
7. Desai AS, Bhimaraj A, Bharmi R, Jermyn R, Bhatt K, Shavelle D, et al. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. *J. Am. Coll. Cardiol.* **2017**, *69*, 2357–2365.
8. Dickinson MG, Allen LA, Albert NA, DiSalvo T, Ewald GA, Vest AR, et al. Remote Monitoring of Patients With Heart Failure: A White Paper From the Heart Failure Society of America Scientific Statements Committee. *J. Card. Fail.* **2018**, *24*, 682–694.
9. Adamson PB, Abraham WT, Aaron M, Aranda JM, Jr., Bourge RC, Smith A, et al. CHAMPION trial rationale and design: The long-term safety and clinical efficacy of a wireless pulmonary artery pressure monitoring system. *J. Card. Fail.* **2011**, *17*, 3–10.
10. Leung CC. Current Role of the CardioMEMS Device for Management of Patients with Heart Failure. *Curr. Cardiol. Rep.* **2019**, *21*, 98.
11. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *Lancet* **2011**, *377*, 658–666.
12. Austin CA, Mohottige D, Sudore RL, Smith AK, Hanson LC. Tools to Promote Shared Decision Making in Serious Illness: A Systematic Review. *JAMA Intern. Med.* **2015**, *175*, 1213–1221.
13. Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision making and patient outcomes. *Med. Decis. Mak.* **2015**, *35*, 114–131.
14. Elwyn G, Lloyd A, May C, van der Weijden T, Stiggelbout A, Edwards A, et al. Collaborative deliberation: A model for patient care. *Patient Educ. Couns.* **2014**, *97*, 158–164.
15. Elwyn G, Fisher E. Higher integrity health care: evidence-based shared decision making. *Circ. Cardiovasc. Qual. Outcomes* **2014**, *7*, 975–980.
16. Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implement Sci.* **2016**, *11*, 114.
17. Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ. Couns.* **2010**, *80*, 94–99.
18. Doherr H, Christalle E, Kriston L, Härter M, Scholl I. Use of the 9-item Shared Decision Making Questionnaire (SDM-Q-9 and SDM-Q-Doc) in intervention studies-A systematic review. *PloS ONE* **2017**, *12*, e0173904.
19. Calderon C, Jiménez-Fonseca P, Ferrando PJ, Jara C, Lorenzo-Seva U, Beato C, et al. Psychometric properties of the Shared Decision-Making Questionnaire (SDM-Q-9) in oncology practice. *Int. J. Clin. Health Psychol.* **2018**, *18*, 143–151.
20. de Filippis R, Aloi M, Pilieci AM, Boniello F, Quirino D, Steardo L, Jr., et al. Psychometric Properties of the 9-Item Shared Decision-Making Questionnaire (SDM-Q-9): Validation of the Italian Version in a Large Psychiatric Clinical Sample. *Clin. Neuropsychiatry* **2022**, *19*, 264–271.
21. Alvarado-Villa GE, Moncayo-Rizzo JD, Gallardo-Rumbea JA. Spanish validation endorsement of SDM-Q-9, a new approach. *BMC Public Health* **2019**, *19*, 106.
22. Dennison Himmelfarb CR, Beckie TM, Allen LA, Commodore-Mensah Y, Davidson PM, Lin G, et al. Shared Decision-Making and Cardiovascular Health: A Scientific Statement From the American Heart Association. *Circulation* **2023**, *148*, 912–931.

23. Oprea N, Ardito V, Ciani O. Implementing shared decision-making interventions in breast cancer clinical practice: a scoping review. *BMC Med. Inform. Decis. Mak.* **2023**, *23*, 164.
24. Elwyn G, Brunelli A. Shared decision making and its relevance to thoracic surgery. *J. Thorac. Cardiovasc. Surg.* **2023**, *165*, 1967–1970.
25. Creutzfeldt CJ. Palliative Care and Shared Decision Making in the Neurocritical Care Unit. *Continuum* **2021**, *27*, 1430–1443.
26. Schoon Y. Shared decision-making is not common in clinical practice. *Heart* **2022**, *108*, 498–499.
27. Scholl I, Kriston L, Dirmaier J, Buchholz A, Härter M. Development and psychometric properties of the Shared Decision Making Questionnaire--physician version (SDM-Q-Doc). *Patient Educ. Couns.* **2012**, *88*, 284–290.