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## Review

# “What Is the Right Decision for Me?” Integrating Patient Perspectives Through Shared Decision-Making for Valvular Heart Disease Therapy

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### ABSTRACT

Innovations in the treatment of valvular heart disease have transformed treatment options for people with valvular heart disease. In this rapidly evolving environment, the integration of patients' perspectives is essential to close the potential gap between what can be done and what patients want. Shared decision-making (SDM) and the measurement of patient-reported outcomes (PROs) are two strategies that are in keeping with this aim and gaining significant momentum in clinical practice, research, and health policy. SDM is a process that involves an individualised, intentional, and bidirectional exchange among patients, family, and health care providers that integrates patients' preferences, values, and priorities to reach a high-quality consensus treatment decision. SDM is widely endorsed by international valvular heart disease guidelines and increasingly integrated in health policy. Patient decision aids are evidence-based tools that facilitate SDM. The measurement of PROs—an umbrella term that refers to the standardised reporting of symptoms, health status, and

### RÉSUMÉ

Les innovations dans le traitement de la cardiopathie valvulaire ont transformé les options thérapeutiques pour les personnes atteintes d'une telle maladie. Dans ce domaine en évolution rapide, il est essentiel d'intégrer les points de vue des patients afin de réduire l'écart potentiel entre ce qui peut être fait et ce que veulent les patients. La prise de décision partagée et la mesure des résultats déclarés par les patients sont deux stratégies qui s'inscrivent dans cet objectif et qui occupent une place grandissante dans la pratique clinique, la recherche et les politiques de santé. La prise de décision partagée est un processus d'échange individualisé, intentionnel et bidirectionnel entre les patients, les familles et les professionnels de la santé où l'on tient compte des préférences, des valeurs et des priorités des patients pour arriver, par consensus, à une décision de haute qualité sur le traitement. La prise de décision partagée est approuvée dans beaucoup de lignes directrices internationales sur la cardiopathie valvulaire et est de plus en plus intégrée aux politiques de santé. Les aides à la décision pour les patients

The mortality and morbidity benefits of the contemporary treatment of valvular heart disease are well studied, reported, and integrated in clinical practice and outcome-monitoring frameworks. The recent acceleration of research focused on clinical outcomes has facilitated the development of guidelines and health policy to provide access to multiple treatment modalities to improve survival, reduce hospitalisations, and mitigate complications. This explosion of research is primarily

driven by clinicians who seek to offer improved treatments to their patients. Contemporary evidence does not always prioritise questions that may be of most importance to patients. The potential gain in survival and reduced burden of disease fail to capture the entirety of, or the order of priority, that patients may place on making the right decision for them.

This review will focus on two of these person-centred questions of increasing interest in the clinical, health policy, and patient advocacy communities: “What is the right decision for me?” and “If you treat my valve, will I feel better?” Central to these considerations are the concepts of shared decision-making (SDM) and the measurement of patient-reported outcomes (PROs) to achieve a quality decision and the desired outcomes in the treatment of valvular heart disease from a patient's perspective. In these discussions, we will highlight the challenges of integrating SDM and the

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See page 1061 for disclosure information.

other domains of health-related quality of life—provides unique data that come directly from patients to inform clinical practice and augment the reporting of quality of care. Sensitive and validated instruments are available to capture generic, dimensional, and disease-specific PROs in patients with valvular heart disease. The integration of PROs in clinical care presents significant opportunities to help guide treatment decision and monitor health status. The integration of patients' perspectives promotes the shift to patient-centred care and optimal outcomes, and contributes to transforming the way we care for patients with valvular heart disease.

measurement of patients' perspectives in clinical practice to achieve a truly person-centred shift in the delivery of improved care for people living with valvular heart disease.

## **“What Is the Right Decision for Me?” SDM to Achieve Patient-Centred Outcomes**

### **Shared decision-making**

SDM is an essential component of patient-centred care. It involves a bidirectional process that occurs when patients, family, and health care providers exchange information and discuss care decisions in the context of patients' priorities, and the best available evidence.<sup>1,2</sup> Whereas patient education primarily aims at unilaterally “giving” information, SDM involves more individualised and intentional communication to ensure that patients are active participants in decisions about their care.<sup>3</sup> In contrast to the historical view that evidence-based guidelines hold the highest prominence in achieving fully informed consent, SDM ensures that patients are invited to participate in the decision-making process, that they are adequately informed about the treatment options they face, that their preferences are elicited, and that their priorities are integrated into treatment recommendations.<sup>4</sup> Where obtaining informed consent is seen as a legal process that ascertains patients' permission to pursue one particular treatment based on the risks provided, SDM invites patients to engage in a conversation about treatment options based on their desired level of involvement, incorporates their preferences, and enables a decision to be made jointly based on the best available evidence.<sup>5,6</sup>

In SDM interactions, clinicians engage in an iterative sequence of tasks with their patients: They gauge patients' preference of degree of desired involvement, identify that there is a choice to be made, outline information on reasonable options, elicit patient preferences, deliberate with their patients and family, and reach a consensus on a decision<sup>7</sup> (Fig. 1). The goal is to achieve a high-quality treatment decision that aligns with the patient's values. At a systems level, the adoption of SDM strengthens the shift from clinician-driven to patient-centred health service delivery and is in keeping with the demonstrated value of the heart-team approach to the management of valvular heart disease.<sup>8</sup>

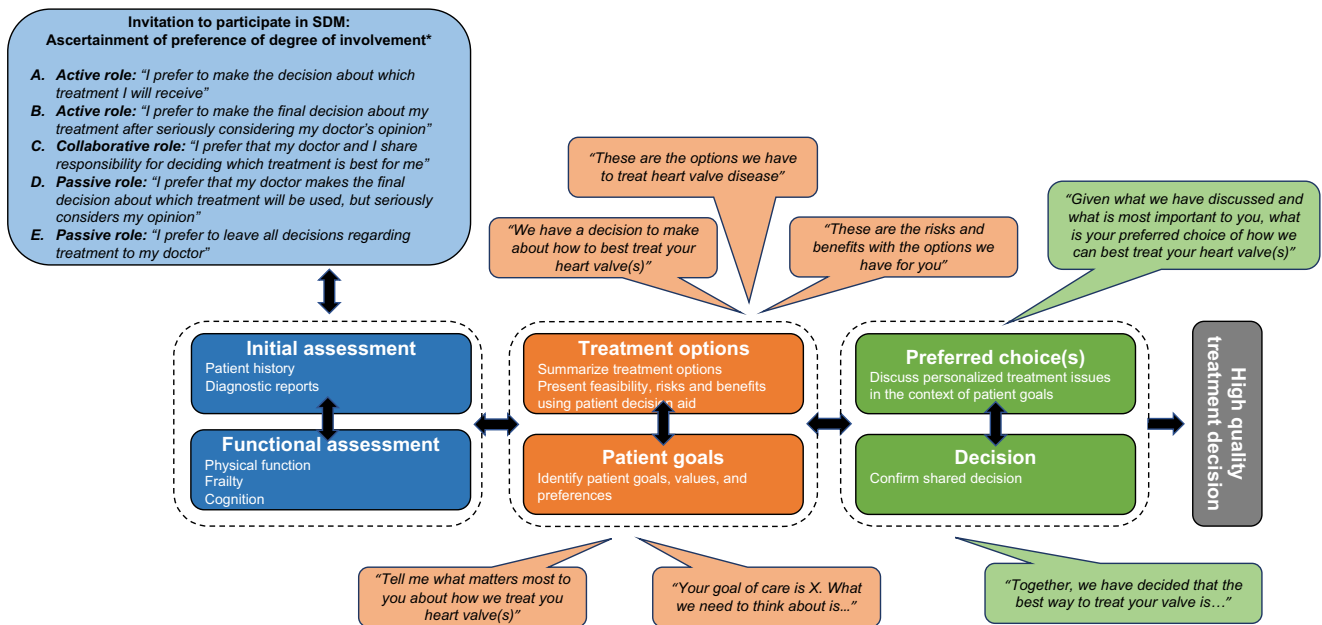
sont des outils fondés sur des données probantes qui facilitent la prise de décision partagée. La mesure des résultats déclarés par les patients — un terme générique qui désigne la déclaration uniformisée des symptômes, de l'état de santé et d'autres domaines de la qualité de vie liée à la santé — fournit des données uniques qui viennent directement des patients, ce qui oriente la pratique clinique et augmente la production de rapports sur la qualité des soins. Il existe des méthodes sensibles et validées pour obtenir des résultats génériques, dimensionnels et propres à la maladie signalés par les patients atteints de cardiopathie valvulaire. L'intégration des résultats signalés par les patients aux soins cliniques offre d'importantes possibilités de mieux guider la décision sur le traitement et de surveiller l'état de santé. L'intégration des points de vue des patients favorise le virage vers des soins centrés sur le patient et des issues optimales, et contribue à transformer notre façon de soigner les patients atteints d'une cardiopathie valvulaire.

The Canadian Cardiovascular Society,<sup>9</sup> the American Heart Association/American College of Cardiology,<sup>10</sup> and other international guidelines have strongly endorsed SDM to guide treatment selection across cardiac care, including valvular heart disease management.<sup>11</sup> These recommendations are driven by the growing evidence that SDM improves clinical practice and patients' care pathways, PROs, and experiences, and reduces health care costs. Benefits of participating in SDM include increased sense of control over illness, confidence in knowledge, and overall satisfaction with care.<sup>12,13</sup> In the words of a surgical patient who participated in the decision between mechanical and tissue devices, they described focusing on “the journey, not the destination” in these words:

*“I just hope everyone's decision is what makes the most sense to them and gives them the most comfort and peace of living with this disease ... The decision was ultimately mine ... If I could give one piece of advice to providers, it would be to really listen to their patients. Listening to the patients and their unique needs is paramount, and tailoring the treatment plan to their singular needs and abilities, and even preferences, ensures that the patient will easily cooperate on the road to healing. It also builds trust.”<sup>14</sup>*

### **Patients' priorities in the treatment of valvular heart disease**

In addition to decreasing their risk for mortality, improved quality of life (QOL) and decreased symptom burden are central to patients' motivation to undergo treatment for their valvular heart disease. When asked “What are you hoping to gain from having this procedure?,” responses elicit patients' hope of feeling better and experiencing improved physical, social, and mental health.<sup>15</sup> As such, treatment options may include surgical or transcatheter valve replacement (eg, surgical [SAVR] or transcatheter [TAVR] aortic valve replacement or implantation [TAVI]), on-going medical management to monitor for changes in symptoms, or transition to a palliative approach focused on symptom management.<sup>16</sup> Maintaining independence, reducing symptoms, and increasing their ability to do a specific activity or hobby illustrate patient-defined goals and priorities in the treatment of their valvular heart disease.<sup>17,18</sup> Thus, patients may define procedural success as being able to return home after a rapid



**Figure 1.** Components of a shared decision-making (SDM) process to achieve a high-quality decision. Iterative activities to promote knowledge exchange; invitation for patients to share goals, values, and preferences; individualised discussion of feasibility of options, risks, and benefits; preferred choice; and final treatment decision. Modified from Degner et al.,<sup>56</sup> Légaré et al.,<sup>44</sup> and van Beek–Peeters et al.<sup>1</sup>

return to their baseline mobilisation and overall functional status, without experiencing delirium or other iatrogenic complications and able to recover quickly to benefit from the physiologic impact of their new valve. For example, in a study of patient-centred benefit-risk analysis of TAVR, patients placed greater value on attributes that favoured TAVR over SAVR, including reduced procedural invasiveness and accelerated recovery to benefit from the QOL associated with valve replacement, despite considering the more established record of SAVR related to device durability and lower risk of pacemaker.<sup>19</sup>

Clinicians recognise that patients are widely diverse and differ significantly in their desire and capacity to be involved in making a treatment decision for themselves. Questions such as “Doctor, what would you do if you needed a new valve?” or “Just tell me what you think is best for me” may indicate patient preference, or anxiety or uncertainty about their role. Social position and intersectional factors such as language, literacy, culture, and social determinants may affect if and how much patients want or can be involved. Importantly, patients determining their treatment alone is not the goal of SDM. Although the onus is on the health care team to open the door for patients to be invited to participate, it is equally important to anticipate that patients’ preferred level of engagement in SDM, whether choosing a more active or passive role in decision-making, will differ widely.

### Challenges of SDM

The implementation of SDM in patient care is in its infancy and faces significant challenges.<sup>20</sup> There is a disconnection between clinicians’ perception that patients do not want to be actively involved in their treatment decision and are best served with the assurance of a strong and definite

medical recommendation or decision, and the growing evidence that patients want to participate meaningfully and appropriately in choosing what is right for them.<sup>21</sup>

Clinicians are concerned that SDM is time consuming, burdensome to their practice, and challenging to or unwelcomed by patients.<sup>22</sup> Paradoxically, they also report that SDM is already happening in the setting of consultations and provision of consent and does not merit current scrutiny or policy interference.<sup>23</sup> Although there is no evidence that SDM steers patients to one treatment option over another,<sup>7</sup> there remains a strong culture of clinicians knowing what is best for their patients based on their expertise, and perhaps wishing to protect patients from making what would be a “bad decision” from their perspective. Nevertheless, considering patients’ risk factors, concomitant diseases such as mitral valve involvement or coronary artery disease may raise physicians’ concerns of “endorsing” a recommendation that may lead to a suboptimal clinical outcomes and compromise patient care. Clinicians have also expressed worry that the use of SDM may falsely give patients the impression that they can “choose an option off a menu” without the full consideration of the complexity of their valvular heart disease and overall condition. These examples illustrate the risks of not reaching the desired goal of a good treatment decision from the clinician’s perspective. They also highlight the imperative need of supporting health care providers to integrate SDM in their practice through education and research focused on overcoming these challenges.

In contrast, there is significant evidence that most patients want to participate in discussions about their treatment and prefer to be asked their opinion regarding their options. However, patients often feel they do not have the knowledge nor do they feel empowered to initiate this discussion and question physicians’ authority<sup>22</sup>; although the intention may be to formulate a personalised treatment plan, this can be

**Table 1.** Example of question prompts for patients to consider when engaging in shared decision-making for the treatment of aortic stenosis

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**What are my options?**

1. What choices do I have to treat my aortic stenosis?
2. When do I need to make this decision?

**What are my major risks if I have SAVR, TAVI, or on-going medical management (ie, “do nothing”)?**

1. How long would you expect me to live after my valve replacement?
2. What is my risk of stroke associated with my valve replacement?
3. What will happen if I don't do anything?

**What are other risks I should think about if I have SAVR or TAVI?**

1. What is my risk of bleeding and needing a blood transfusion after SAVR/TAVI?
2. What is my risk of needing a permanent pacemaker after SAVR/TAVI?
3. What is my risk of new atrial fibrillation (irregular heart rhythm) after SAVR/TAVI?

**What will my recovery look like after SAVR or TAVI?**

1. How long will I be in hospital after SAVR/TAVI?
2. How likely is it that I will a complication that will cause me to be back in hospital in the first month after SAVR/TAVI?
3. How long will it take me to ...
  - a. Feel better?
  - b. Return to my daily activities?
  - c. Return to work?
  - d. Be able to drive?
  - e. Lift more than 10 pounds?
4. Will I need blood thinners after SAVR/TAVI?
  - a. If yes, what kind and for how long?
  - b. If yes, will I need to have my blood clotting tested after SAVR/TAVI?

**What long-term questions should I think about?**

1. How long will my SAVR/TAVI valve last?
2. If my SAVR/TAVI valve stops working in the future, what will my next option be?

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SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

difficult to achieve when patients do not express their goals.<sup>17</sup> The ensuing risk of decisional conflict—defined as experiencing “uncertainty about the course of action to take when choices involve risk, loss, regret, or a challenge to personal values”<sup>24</sup>—can negatively affect patient outcomes. Decisional conflict may result in delayed decision-making and consent to treatment, regret about treatment decision, and conflict with health care providers in the event of poor outcomes. Furthermore, they may feel unable to prioritise decisions about their health, which may have a negative effect over time.<sup>25</sup> There is a pressing need to mitigate this risk and close the gap that can separate the perspectives of patients and clinicians.

### How can SDM be integrated in the treatment of valvular heart disease?

The interest in SDM extends beyond patients, clinicians, and researchers. The shift to improving patient engagement in treatment decisions is benefitting from the endorsement, encouragement, and mandated adoption from policy makers across jurisdictions. The recently revised US Centers for Medicare and Medicaid Services National Coverage Determination for TAVR, which drives health policy and funding models, used the strongest endorsement to date, but stressing that they “support patient SDM in AVR, but there is not a fully developed tool at this time.”<sup>2</sup>

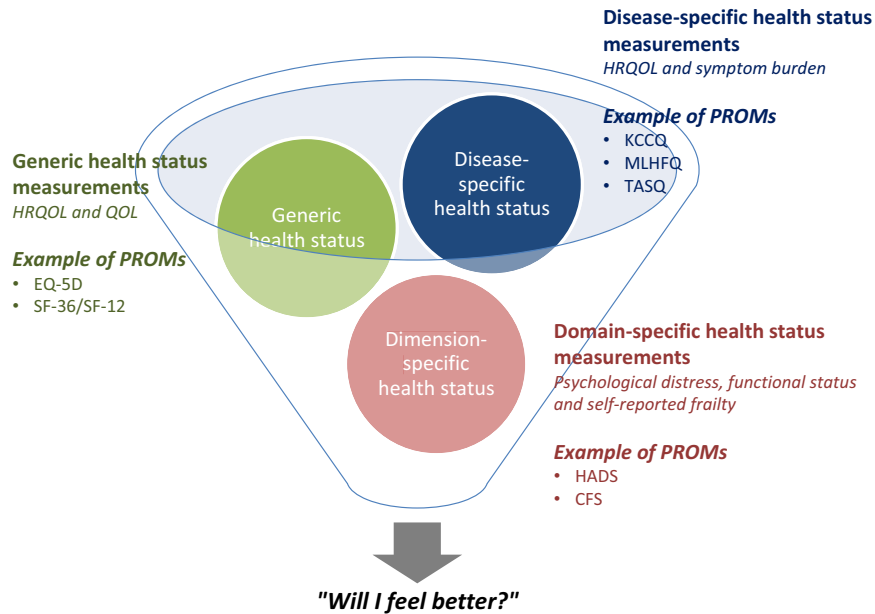
Increasing availability of evidence-based tools and other strategies to facilitate the integration of SDM in clinical care is

of the highest priority to capitalise on this momentum and to gain credibility and adoption among multiple stakeholders. Patient decision aids (PDAs) are designed to support the process of SDM and help guide the conversation between patients and clinicians. The International Patient Decision Aids Standards specify that, at a minimum, PDAs must explicitly (1) describe the condition related to the decision, (2) define the decision to be made, (3) outline options, (4) provide current evidence-based information on the positive features of the options (eg, benefits, advantages) and (5) the negative features (eg, risks, harms, disadvantages), and (6) help patients clarify their values regarding outcomes of options.<sup>26</sup>

In decision-making, values refer to the desirability or undesirability of specific attributes of a treatment option. To support this essential step, values clarification exercises (eg, descriptions of the characteristics of the options, patient stories, rating or ranking scales, prioritisation exercises) are included in PDAs and are designed to help patients consider their values, preferences, and priorities for key characteristics, benefits, and risks of the decision they face.<sup>26</sup>

To our knowledge, there are currently 4 publicly available PDAs to support patients with aortic stenosis to choose between SAVR, TAVR, and medical management (available at <https://sharedcardiology.org/tools/>): the American College of Cardiology (ACC) Cardiosmart Decision Aid, the Severe Aortic Stenosis Decision Aid created with ACC support, a Patient-Centred Outcomes Research Institute—sponsored risk calculator and patient education toolkit, and the British Medical Journal Rapidrecs tool for TAVI vs SAVR. Examples are shown in Supplemental Fig. S1. Currently, these PDAs are based on data from intermediate, high, and prohibitive surgical risk clinical trials. They present a narrow range of attributes of treatment options (eg, stroke risk, mortality risk, and discharge home).<sup>27</sup> PDAs are less common in cardiac surgery, although surgical treatment decisions may have significant implications for lifestyle and risk preferences. For example, with the relative equipoise of data comparing risk-adjusted outcomes of stroke and survival in SAVR with mechanical or tissue prosthesis, there is an on-going debate about the optimal option for subsets of patients, including consideration of the risk of reoperation and lifelong anticoagulation.<sup>28</sup> To help address this gap, there is emerging evidence supporting the use of PDAs in cardiac surgery (see, eg, <https://decisionaid.ohri.ca>). Patients who participated in a Dutch multicentre randomised trial of an online PDA to support SDM in the setting of prosthetic surgical heart valve selection reported increased knowledge and reduced psychosocial stress.<sup>25</sup> In a randomised study of the use of a PDA during the surgical consultation, patients were presented information related to risk estimates of reoperation and bleeding by age, sex, and valve type and education about the impact of anticoagulation in the form of vignettes describing 4 patients' decisions about their preferred type of surgical valve. The intervention was associated with significantly higher knowledge scores, more accurate risk estimates, and lower decision conflict.<sup>28</sup>

The integration of SDM in clinical practice must target both patients and clinicians as a dyad or team.<sup>29</sup> In addition to the development of high-calibre PDAs, other interventions that can facilitate SDM and improve decision quality include decision coaching and question prompts (Table 1). For



**Figure 2.** Domains of patient-reported outcome measurements (PROMs). The capture of generic, disease-specific, and dimension-specific patient-reported outcomes provides a comprehensive approach to reporting patients' perspectives on their health care; the purpose of measurement drives the selection of instruments. CFS, Clinical Frailty Scale; EQ, EuroQoL; HADS, Hospital Anxiety and Depression Scale; HRQOL, health-related quality of life; KCCQ, Kansas City Cardiomyopathy Questionnaire; MLHFQ, Minnesota Living with Heart Failure Questionnaire; SF, short-form health survey; TASQ, Toronto Aortic Stenosis QOL.

patients, the use of 3 questions—"What are my options?" "What are the benefits and harms of those options?" and "How likely are the benefits and harms to occur?"—has been proposed as a simple strategy to elicit the minimum information needed to facilitate SDM in conjunction with clarifying patient values.<sup>28</sup> Based on studies that have demonstrated the effectiveness of this approach,<sup>29</sup> the UK Health Foundation MAGIC (Making Good Decision in Collaboration) program has adopted "Ask 3 Questions" in their efforts to promote SDM across UK National Health Services care delivery.

For clinicians, the availability of educational resources, training sessions, audits and feedback, reminders, and patient-mediated interventions (such as PDAs) has been shown to enhance quality of care.<sup>30</sup> The development of clinical pathways and other processes of care that create seamless inclusion of the principles and tools of SDM can help address issues related to systems-based change management.<sup>20</sup> This presents opportunities to develop a truly programmatic approach

across the continuum of treatment of valvular heart disease, including leveraging the contributions of well established cardiac clinics, where conversations may begin, and the expertise of nursing to enhance communication and dedicate time to meeting individual patients' needs.

SDM will continue to gain prominence as TAVI becomes a treatment option for younger and lower-risk patients, and as additional transcatheter approaches continue to emerge for mitral and other heart valve diseases. Driven by patient demand and advocacy, health policy, clinician interest and emerging science, we can anticipate a significant learning curve to change the culture and processes of care, develop effective strategies, and measure the full effect of SDM on patient and health systems.<sup>2</sup>

## "If You Treat My Valve, Will I Feel Better?" PROs in the Treatment of Valvular Heart Disease

### Patient-reported outcomes

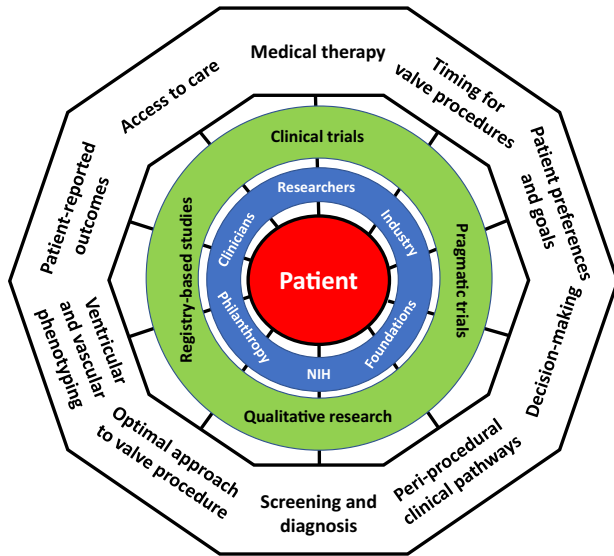
Most people living with heart failure report favouring improved QOL with a risk of worse survival over their current health status with a likelihood of longer survival.<sup>31</sup> It may be reasonable to extend this priority to patients with valvular heart disease given the significant burden of symptoms associated with the natural history of degenerative valve disease. To this end, the patient is the only source of data available to help answer the question "Will I feel better?" and provide unique and essential information about outcomes after valve interventions from their perspective. PROs assess various domains of patients' health and health care, including symptoms, physical, mental/psychological, and social functioning, well-being, and overall QOL. PRO data come directly from

**Table 2.** Summary of clinical benefits of patient-reported outcomes to clinical practice

1. Raise awareness of and facilitate the early detection of physical health status, psychological problems, daily functioning, and well-being that might be otherwise overlooked
2. Make patients' and family members' concerns more visible
3. Inform the selection and use of therapeutic interventions
4. Monitor disease progression and response to treatment
5. Establish shared patient-clinician objectives
6. Result in improved care plans
7. Improve communication, patient satisfaction, and adherence
8. Enhance collaboration among members of the health care team
9. Monitor outcomes as a strategy for quality improvement

**Table 3. Examples of instruments used in valvular heart disease research to measure patient-reported outcomes**

Name of instrument	Year developed	Number of items	Domains captured	Summary scales	Access
<b>Generic health and dimension-specific instruments</b>					
Medical Outcomes Study Short Form (SF-36 and SF-12) <sup>45,46</sup>	1992/1996	36 and 12	Vitality Physical functioning Bodily pain General health perceptions Physical role functioning Emotional role functioning Social role functioning	Physical component score Mental component score	License required—proprietary
EuroQoL 5 Domains (EQ-5D) <sup>47,48</sup>	1990/2011	5	Mental health Mobility Self-care Usual activities Pain/discomfort Anxiety/depression	Utility score Visual analog scale	License required—fees determined according to intended use
Veterans RAND 36 (VR-36) and 12 (VR-12) <sup>49</sup>	2015	36 and 12	General health Physical functioning Mental health Role limitations Bodily pain Energy/fatigue Social functioning	Physical component score Mental component score	Available for noncommercial use without charge
Patient-Reported Outcomes Measurement Information System (PROMIS) short forms	On-going	Multiple instruments	Multiple generic and dimension-specific domains		Open access
<b>Cardiac health-specific instruments</b>					
Kansas City Cardiomyopathy Questionnaire (KCCQ) <sup>50-52</sup>	2000/2015	23 and 12	Physical limitation Symptom stability Symptom frequency Symptom burden Self-efficacy Quality of life Social limitation	Total symptom score Clinical summary score Overall summary score	License required—proprietary ( <a href="http://cvoutcomes.org">cvoutcomes.org</a> )
Minnesota Living with Heart Failure Questionnaire (MLHFQ) <sup>53,54</sup>	1980	21	Physical Emotional	Overall score	License required—proprietary (University of Minnesota)
Toronto Aortic Stenosis Quality of Life Questionnaire (TASQ) <sup>55</sup>	2020	16	Physical symptoms Physical limitations Emotional impact Social limitations Health expectations	Total score	



**Figure 3.** Conceptual model of patient-centred research in valvular heart disease. A working group of the US National Heart, Lung, and Blood Institute composed of clinicians, researchers, and patient advocacy experts developed a conceptual model to identify and define the multifaceted components of patient-centred research in valvular heart disease to support the integration of patients' perspectives in the research agenda. NIH, National Institutes of Health. Modified from Lindman et al.<sup>43</sup> under Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International (CC BY-NC-ND 4.0).

the patient and preclude the interpretation of responses by a health care provider.<sup>32</sup>

### PRO measurement

Patient-reported outcomes measurement (PROM) is an umbrella term that captures standardised data collection strategies focusing directly on patients' appraisal of their health status at a single point in time.<sup>32</sup> PROMs are a means of obtaining the added dimension of patients' viewpoint to augment clinical opinions and outcomes.<sup>33</sup> As such, PROMs can help identify and prioritise problems, manage expectations and support SDM and commonly measure specific concepts, including generic, disease-specific, or dimension-specific constructs.<sup>34</sup> Their use in clinical practice can contribute to baseline assessment and screening for hidden problems and symptoms, monitoring disease trajectory or the impact of treatment, and support communication, focusing on improving not only the patients' functional status but also their overall sense of well-being. There is increasing recognition, adoption, and scrutiny of PROMs in the era of patient-centred care to inform patient management and SDM, advance clinical research, and develop health policy.<sup>35</sup>

The selection of PROMs should reflect the goals of measurement. Generic instruments measure the domains of QOL and health-related quality of life (HRQOL) and can be used to compare outcomes across different populations. Disease-specific PROMs include instruments measuring self-reported health status related to specific health conditions and associated symptom burden, and dimension-specific instruments ascertain health status that spans psychological distress, functional status, and self-reported frailty (Fig. 2). Together or

in single use, PROMs can contribute to a comprehensive assessment of patients' health status across the continuum of care. The scientific scrutiny of the timing, interval, and method of measurements continue to elucidate practice.<sup>36</sup> Clinical benefits of PROMs are summarised in Table 2.

### Measuring PROs in patients with valvular heart disease

The measurement of QOL is perceived as problematic because available instruments cannot successfully capture all important domains of a person's life. Nevertheless, the field of PROM research is driven by the pursuit of theoretically driven objective, sensitive, and validated questionnaires that provide precise and clinically meaningful instruments. PROMs must use comprehensive, reliable, and valid instruments that are easy to score and interpret and minimise respondent and clinician burden.<sup>35</sup> Importantly, PROMs must be subject to rigorous psychometric validation within the target patient population, including the assessment of reliability (ie, internal consistency and test-retest and interrater reliability), validity (ie, ability of a measure to quantify the dimension it is aimed to measure), and responsiveness (ie, sensitivity to capture true underlying change) to ensure their value.<sup>37</sup>

In this context, PROMs that have emerged as most frequently used in clinical trials and practice to capture patients' perspective of living with and/or being treated for valvular heart disease include the generic 36-item/12-item short-form health survey and the EuroQoL 5D, and the cardiac disease-specific Kansas City Cardiomyopathy Questionnaire and Minnesota Living with Heart Failure Questionnaire. More recently, the Toronto Aortic Stenosis QOL and HeartQoL questionnaires have been validated in patients with valvular heart disease. Selected details are highlighted in Table 3.

### PROs in valvular heart disease interventions, clinical trials, and registries

In 2009, the US Food and Drug Administration formalised the recommendations for inclusion of PROMs in clinical trials to evaluate the effectiveness of interventions, support labelling claims, and strengthen evidence-based practice. The past decade of clinical trials of interventions to treat valvular heart disease have adopted these recommendations and systematically included comparisons of PROMs across treatment modalities. All TAVR and transcatheter mitral valve repair pivotal trials have adopted a standardised reporting of QOL benefits. This new standard of reporting has accelerated the availability of essential data to improve the integration of patients' perspectives across the continuum of care. The growing body of evidence has enabled researchers to provide more nuanced modelling of predictors of change in QOL, including delineating what might constitute a "good outcome." The composite end point of death or poor QOL, or decline in QOL, provides a combined definition that integrates the 2 potential benefits of heart valve interventions—reduced mortality and improved QOL—while recognising that patients who have good QOL at baseline may not improve symptomatically after the intervention but could still derive a clinically meaningful benefit of the procedure.<sup>38</sup> Across clinical trials, observational studies, and national registries, there is important scientific activity underway to match QOL research to the rapid pace of innovation in valvular heart



disease, inform the appropriate selection, format, and timing of measurements, and enable the uptake of PROMs in valvular heart disease programs to leverage what has been gained in research to improve clinical care. The integration of PROs in clinical practice contributes to transforming these unique data from passive use of information to an active use that enables individual patients' perspectives to become central to their care. There is a pressing need to test interventions that can demonstrate the effect of PROs on improving patient-clinician dialogue, treatment, consultation experiences, and outcomes in clinical care.<sup>39</sup>

### Challenges ahead: PROMs in valvular heart valve programs

The routine adoption of PROMs in clinical care remains a significant challenge for clinicians and heart valve programs, and their use has not yet been brought to the forefront of crucial discussions on optimising patient care.<sup>31</sup> Barriers include a lack of familiarity with the instruments, their limited match to the unique experiences of people living with valvular heart disease (eg, people who do not report heart failure symptoms, young surgical patients), uneven support from health care providers, lack of technological solutions to enable easy and seamless data collection and reporting, and debate about the evidence.<sup>40</sup> The central problem of interpretability—for example, what changes in score constitute a signal of trivial, small, moderate, or large patient benefit or harm, and how ought the changes over time and across patients be gauged—remains highly debated. In addition, logistical concerns include workflow barriers and increased burden on staff to collect data, the absence of seamless technological solutions compliant with privacy requirements and linked to existing medical records, and a lack of focus on end-users, especially older people who require tailored approaches to complete the measurements. Strategies have been proposed to support the successful implementation of PROMs in clinical practice and optimise their contributions to clinicians' capacity to screen patients for previously unrecognised health problems, monitor changes in health status, and stimulate better communication.<sup>41</sup>

### Accelerating the Integration of Patients' Perspectives in the Management of Valvular Heart Disease

Collective efforts on the part of health care providers, administrators and policy makers are needed to help shift the culture of health care from clinician driven to a more patient-centred approach. Strategies to achieve this goal in a meaningful way must include changes across systems of care, quality indicators, and training to address the barriers identified in this review. This effort is under way across cardiac care, with the pursuit of disease-specific outcome measurements for patients with conditions ranging from heart failure, coronary artery disease, and congenital heart disease to atrial fibrillation with the use of international guidelines for the development of PROMs.<sup>42</sup>

The overarching theme of this review relates to promoting patient engagement in the management of valvular heart disease—a significant shift in the culture of health care. This process provides information in ways that invite meaningful

participation and emphasise active listening to achieve a high-quality decision through SDM. Furthermore, patient engagement is supported by the inclusion of PROMs as clinical data and quality indicators, and facilitated by health care provider buy-in, technological solutions, and policy leadership that create seamless processes between patients and their health care teams. Clearly, this work is not yet done. To meet this challenge, the US National Institutes of Health convened a meeting in 2019 of a National Heart, Lung, and Blood Institute working group composed of clinicians, research experts, and patient advocacy experts to identify gaps, barriers, and recommendations to set priorities for patient-centred research in valvular heart disease. Stressing the importance of matching research efforts to patients' complex and diverse journeys of care, the consensus recommendations strongly endorsed the pressing need to inform research focused on SDM and PROMs across the continuum of care (Fig. 3).<sup>43</sup> This leadership illustrates current opportunities to continue to narrow the gap between the rapid innovation in the management of valvular heart disease and patients' perspectives of the care we provide.

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### Supplementary Material

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