

Placing patient-reported outcomes at the centre of cardiovascular clinical practice: implications for quality of care and management A statement of the ESC Association of Cardiovascular Nursing and Allied Professions (ACNAP), the Association for Acute CardioVascular Care (ACVC), European Association of Percutaneous Cardiovascular Interventions (EAPCI), European Association of Preventive Cardiology (EAPC), Heart Failure Association (HFA), European Heart Rhythm Association (EHRA), European Association of Cardiovascular Imaging (EACVI), ESC Regulatory Affairs Committee, ESC Advocacy Committee, ESC Digital Health Committee, ESC Education Committee, and the ESC Patient Forum

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Running head: Patient-Reported Outcomes and cardiovascular health

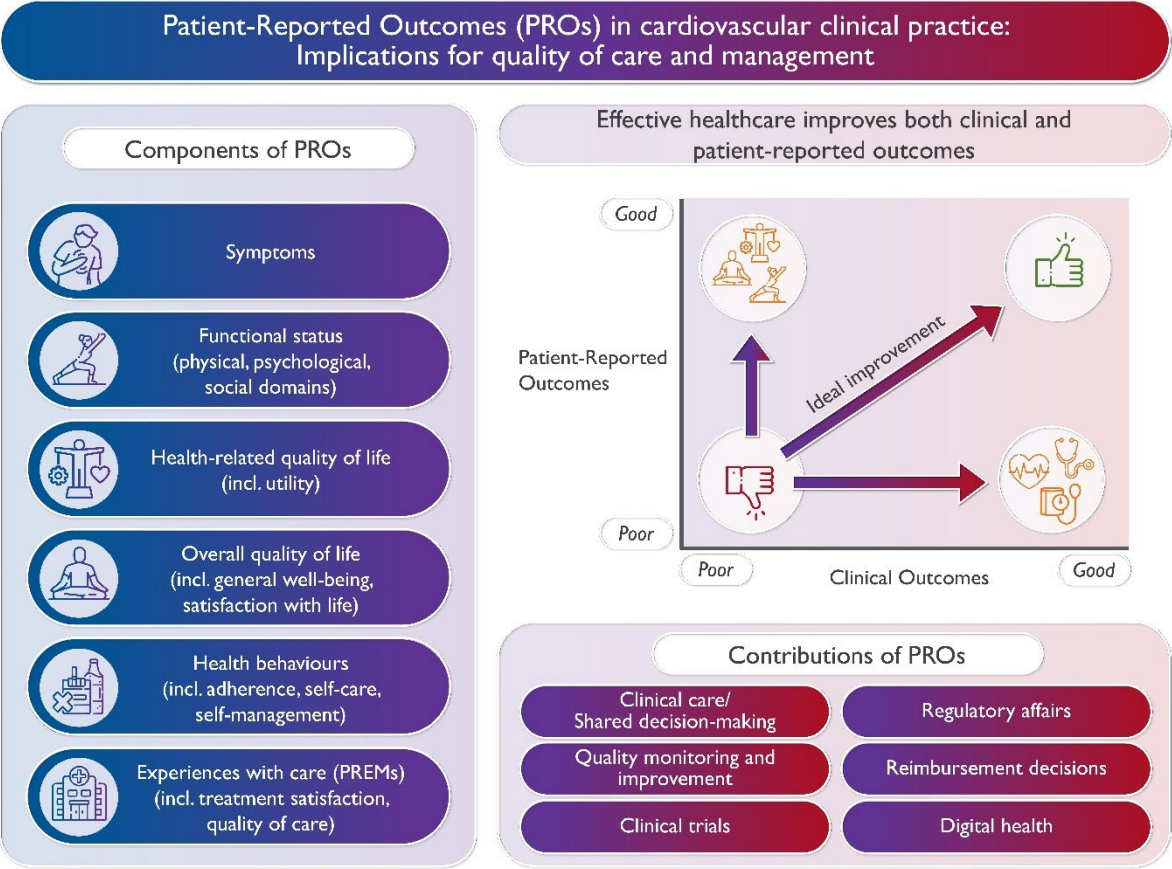
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Abstract

Patient-reported outcomes (PROs) provide important insights into patients' own perspectives about their health and medical condition, and there is evidence that their use can lead to improvements in the quality of care and to better informed clinical decisions. Their application in cardiovascular populations has grown over the past decades. This statement describes what PROs are, and it provides an inventory of disease-specific and domain-specific PROs that have been developed for cardiovascular populations. International standards and quality indices have been published which can guide the selection of PROs for clinical practice and in clinical trials and research; patients as well as experts in psychometrics should be involved in choosing which are most appropriate. Collaborations are needed to define criteria for using PROs to guide regulatory decisions, and the utility of PROs for comparing and monitoring quality of care and for allocating resources should be evaluated. New sources for recording PROs include wearable digital health devices, medical registries, and the electronic health record. Advice is given for the optimal use of PROs in shared clinical decision-making in cardiovascular medicine, and concerning future directions for their wider application.

Graphical abstract



The importance of patient-reported outcomes (PROs), their components, and their potential contributions in cardiology

1. Introduction

Patient-reported outcomes (PROs) are increasingly used as a standardised means of integrating and reporting patients' own perspectives in the assessment of their health and medical condition. PROs are typically defined as “*any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else*”.¹ Combined with clinical outcomes, PROs reflect the totality of outcomes of care in patients. Ideally, healthcare aims at improving both clinical outcomes and PROs (Figure 1).²

Whereas PROs were initially used for descriptive clinical research and population-based surveys, they gradually found their way into clinical practice.^{3,4} PROs are of particular importance for the monitoring and management of chronic conditions affecting quality of life. They can be used for individual assessment to support decisions and to evaluate aspects of quality of care.⁵⁻⁸ To support the use of PROs in the routine clinical setting, electronic- or ePROs have been developed recently, and real-time data collection is gaining more traction.⁹ Moreover, PROs are increasingly used to assess treatments and interventions in clinical trials, informing regulatory and reimbursement decisions for drugs and medical devices.¹⁰⁻¹⁴ However, the use of PROs is not without methodological challenges; there are gaps between the underpinning evidence and the current practical implementation, which challenges their use and interpretation.^{15,16}

Papers advocating for the use of PROs in the field of cardiology have been published by the American Heart Association (AHA) in 2013¹⁷ and the European Society of Cardiology (ESC) in 2014.¹⁸ The AHA statement advocated for the assessment of patient-reported health status as a measure of cardiovascular health,¹⁷ whereas the ESC document was a call for a more comprehensive integration of PROs in cardiovascular trials.¹⁸ Given recent developments and the continuous expansion of PROs in the clinical arena, this present

statement aims to define what PROs are, to describe how they can be measured in cardiovascular populations, and to discuss how PROs can be further integrated in cardiovascular research, clinical practice, and regulatory and reimbursement decisions.

Although this statement specifically addresses the use of PROs in cardiovascular populations, the topics discussed are relevant for other conditions and specialties as well.

2. Development of this statement

This statement was developed in an iterative way. First, the consensus panel/writing group was formed by identifying all relevant and important ESC constituent bodies, and ensuring the representation of these bodies in the writing group. Second, the writing group has met and the different sections to be included in the statement were determined. Third, mini-teams were formed to write each of the sections. The content of the different sections was based on the expertise of the panel members and the relevant literature in the domain. Fourth, the different sections were compiled and integrated. Parts were rewritten to avoid overlap between the sections, and to obtain a common writing style. Fifth, gaps or inconsistencies in the message were dealt with by the chairs of the writing group. Sixth, the entire statement was reviewed and revised by the writing group in two consecutive iterations. Seventh, the document was finalized and approval from the entire writing group was obtained. Eighth, the statement was submitted to the participating associations/councils/committee for review and approval.

3. What are PROs?

Although the definition of PROs by the U.S. Food and Drug Administration (FDA), as cited above, is widely accepted, there is less consensus on the components of PROs. According to this definition, PROs pertain to the status of a patient's health condition as directly reported by the patient.¹ Such patient-reported health status may include symptoms, functional status, and

health-related quality of life (HRQoL) (Figure 2).¹⁷ One of the earliest frameworks on PROs suggested that other outcomes, in addition to patient-reported health, are relevant such as global impression and well-being (which reflect overall quality of life), adherence to therapies and healthy lifestyles (which reflect health behaviours), and satisfaction with the treatment (which reflect experiences with care) (Figure 2).¹⁹ These extensions led to the following definition of PROs: *“any report of the status of a patient’s health condition, health behaviour, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else”*.^{20, 21} This extended definition was the first one that explicitly included patient experiences as PROs. Importantly, patient experiences here refer to experiences with the care processes, and do not pertain to the hospitality function of healthcare facilities. Patient experiences can be measured using patient-reported experience measures (PREMs: see below).

It is important to clarify that not all the information that is provided by patients can be viewed as PROs. For instance, data from wearables, such as activity trackers, could be construed as patient-generated outcomes, rather than PROs. Further, feedback from patients provided as free text, although being important, is also not a PRO.

4. How are PROs measured?

PROs are typically measured using patient-reported outcome measures (PROMs). However, given that experiences with healthcare are also considered as a PRO (see above), PREMs should be seen as an additional measure to assess PROs, next to PROMS.

There are three types of PROMs: generic, disease-specific, and domain-specific instruments.⁵ It is advised that these types of PROMs are used in combination as they provide complementary information.²² Generic PROMs comprise questions that are general in nature and therefore can be used in any population of respondents. Such generic PROMs are mostly

chosen when comparing different patient populations, patients with different levels of comorbidities, or when comparing a patient group with healthy controls. Generic PROMs are typically multidimensional and cover a broad range of functional domains, such as mobility, emotions or self-care. Examples of widely used generic PROMs are the EuroQol-5 dimension,²³ the SF-36²⁴ or PROMIS.²⁵

Disease-specific PROMs are used when outcomes relating to a specific condition are of interest. Such instruments are often more sensitive than generic PROMs when used in a particular patient population, because they can be more focused and detailed. Most disease-specific PROMs are multidimensional, such as the Minnesota Living with Heart Failure (MLHF) Questionnaire²⁶ or the Myocardial Infarction Dimensional Assessment Scale (MIDAS).²⁷

Domain-specific PROMs cover a specific symptom or issue. Since they measure a single phenomenon or construct, they are often, but not always, unidimensional and narrow in scope, but they can have varying levels of depth. An example of a domain-specific PROM with little depth is the unidimensional visual analogue scale for pain intensity.²⁸ By contrast, the McGill Pain Questionnaire is a multidimensional domain-specific PROM of greater depth, that is designed to measure the sensory, affective and evaluative aspects of pain and its intensity.²⁸ Some domain-specific PROMs are also disease-specific (e.g. health behaviours in congenital heart disease²⁹).

5. PROMs for particular cardiovascular diseases

An early standardised questionnaire that was used to assess cardiovascular symptoms was the one on angina pectoris that was developed and validated by Geoffrey Rose and published by the World Health Organization in 1962.³⁰ Nowadays it is considered to be the first instrument to document PRO. Since then, a plethora of disease-specific PROMs have been developed to

assess symptomatic burden, functional status or quality of life in diverse cardiovascular conditions, such as ischemic heart disease, heart failure, arrhythmias, cardiac surgery, heart transplantation and congenital heart disease. Table 1 provides an inventory of cardiac-specific PROMs. Most of these PROMs are multidimensional, whereas others measure a single construct such as behaviour. These disease-specific measures allow researchers and clinicians to measure PROs in a more sensitive fashion than when using generic measures. For some instruments, extensive and short versions are available. Several reviews and in-depth evaluations on cardiac-specific PROMs have been published over the past years, including reviews that scrutinized and compared the psychometric properties of different instruments.³¹⁻⁴² Based on the findings of these reviews, we provide summary information on the level of support for each individual instrument (Table 1). First, we checked whether the systematic reviews evaluated the instruments under study according to the COSMIN standards (see below). Second, for those reviews that did evaluate the standards, we determined whether all, most, or only some of the standards were met. Meeting all of the standards provides the strongest support for using these particular instruments. If the psychometric properties of the instruments have not yet been evaluated in systematic reviews, this indicates a need for further research rather than a reason to avoid using them.

In 2012, the International Consortium for Health Outcomes Measurement (ICHOM) was launched. ICHOM aims to develop condition-specific standard outcome sets to support the assessment of 'value-based care'. The ICHOM outcome sets comprise clinical and patient-reported outcomes, and are developed by working parties consisting of clinicians and patient representatives. To date, standard outcome sets for hypertension management in low- and middle-income countries,⁴³ atrial fibrillation,⁴⁴ congenital heart disease,⁴⁵ coronary heart disease,⁴⁶ and heart failure⁴⁷ and have been developed.

Another organisation that develops and inventorizes core outcome sets is the COMET initiative (<https://www.comet-initiative.org/>). COMET is a European Union/Medical Research Council funded organisation that supports and publishes resources, such as a handbook on ‘core outcome set’ development and standards for reporting, i.e. the COS-STAR statement.⁴⁸ Existing ‘core outcome sets’ for different conditions, including heart and circulatory problems, can be found on the COMET website: <https://www.comet-initiative.org/studies>. It is important to know that COMET comprises outcome sets that are developed for clinical trials, not necessarily for clinical purposes.

6. How to choose the most appropriate PROM?

Whether for clinical or research purposes, it is important to select PROMs that provide valid and reliable information in an efficient way. Hence, a sound evaluation of the attributes of the PROMs is essential to find high-quality PROMs that match the intended purposes. The initial evaluative systems were developed for HRQoL instruments.²¹ Later on, systems were developed for evaluating a broader range of PROMs.

One such system is the ‘Evaluating the Measurement of Patient-Reported Outcomes’ (EMPRO) tool.⁴⁹ The EMPRO tool comprises 39 items that are organized in eight attributes: Conceptual and measurement model (7 items); Reliability (8 items); Validity (6 items); Responsiveness (3 items); Interpretability (3 items); Administration burden (7 items); Alternative modes of administration (2 items); and Cross-cultural and linguistic adaptations (3 items). Each item can be scored using a 4-point Likert scale.⁴⁹ An online platform system for the EMPRO has been developed.⁵⁰

Another evaluation system, which is the most extensive and most widely used, is the ‘Consensus-based Standards for the selection of health Measurement Instruments’ (COSMIN). COSMIN developed a taxonomy⁵¹ and created checklists to assess the

methodological quality of individual studies⁵² and systematic reviews⁵³ of PROMs. The latest COSMIN checklist comprises 116 items over 10 domains: development (35 items); content validity (31 items); structural validity (4 items); internal consistency (5 items); cross-cultural validity/measurement invariance (4 items); reliability (8 items); measurement error (6 items); criterion validity (3 items); hypothesis testing for construct validity (7 items); and responsiveness (13 items).⁵³ Items are scores on a 4-point rating system. Whereas COSMIN provides in-depth information on the measurement properties (validity, reliability, and responsiveness), EMPRO gives a broader perspective on the PROM by also assessing modes and burden of administration of the questionnaire.

In general, it is advised to use a combination of generic and disease-specific instruments to include the advantages of both. When choosing PROMs, patient representatives should be involved (see section on Patient Perspective). It is also important to be aware that some PROMs or specific questions might pose ethical issues when used in research. For instance, it should not remain unnoticed until the end of data collection if a patient reports major depression associated with suicidal ideas. Extreme scores on questionnaires, additional information provided by a patient, or discussions between a patient and research personnel can provide critical information, which is called PRO Alerts.⁵⁴ A clear strategy is needed on what to do when PRO Alerts occur.⁵⁴ Recently, PRO ethical guidelines have been developed.⁵⁵ These guidelines include 14 ethical recommendations to be considered when PROs are assessed in clinical research.⁵⁵ A final aspect to bear in mind is the terms and conditions of the use of the selected PROMs. Most PROMs can be used free of charge. However, there are some PROMs with very strict regulations for their use and high licensing fees, which may even change over time.⁵⁶ In such case, it is appropriate to check if there are good alternatives that are free of charge.

7. What if there is no suitable PROM available?

If a relevant PROM for a specific condition or problem does not exist, there are three possible ways to proceed:⁵⁷ (i) a PROM for a condition that is closely related could be used; (ii) a generic instrument could be used; or (iii) a new PROM could be developed.⁵⁷ The first two options are suboptimal, but the latter option is time-consuming and requires expertise in instrument development and psychometrics. The development of a PROM comprises different steps, such as choosing a conceptual/theoretical framework, generating items, scale formation, testing face validity, and extensive psychometric testing.⁵⁸ The process of development and the psychometric evaluation needs to be thoroughly described.⁵⁹ When a PROM for a related condition is to be used, it is important that the use of the instrument is evaluated by cognitive interviews with patients having the specific disease to assess its relevance and comprehensiveness.

8. The Patient Perspective on PROs

The ESC Patient Forum has been included in the development of this position paper from its inception and its members were widely consulted and more specifically represented (RM, DF). In a focus group session on October 6, 2020 Forum members expressed broad support for the development and use of PROs in research and clinical practice. They expressed how PROs can facilitate a more holistic evaluation of how various cardiac treatments and procedures impact them as an individual, including mental and physical aspects. Where treatment side effects include fatigue or mood disturbance, these should be explained and patient preferences ought to be taken into consideration. Patient Forum members were keen to emphasise that life-prolonging treatment is often not what an individual patient or their families will wish for – rather, most people want to optimise their quality of life. Patients also

recognise heart disease as a chronic condition and want PROs to be regularly updated as time progresses, rather than being regarded as a static endpoint.

Patients believe PROs can serve as an aid to shared decision-making, and their application may tilt the balance in favour of an enhanced focus on patient-centred decision making. Indeed, patients consider PROs to be the appropriate complement to more clinically focused assessments. The introduction of ePROs and real-time data collection are viewed with interest, though a greater consideration of how they might be integrated into clinical practice is needed. Even greater deliberation is needed when PROs are being considered for remuneration of healthcare providers.

It is paramount that PROs should capture what matters to patients, and therefore meaningful involvement of patients at all stages of their development is required. The results from PROs obtained in a clinic or for research purposes should be used as a prompt to initiate communication with the patients, especially when the scores deviate from the normal range or from patients' previous responses. They can also support adherence by integrating feedback from the PRO to facilitate shared decision-making, particularly as patients' circumstances and choices change over time. Issues such as fatigue can have a much more dramatic impact for patients than a score conveys, with the statement 'Quality of life is My judgement, not yours' echoing strongly from this feedback.

9. PROs in routine clinical care

When used in clinical practice, PROs have the potential to capture patients' symptoms, functioning and individual health goals in a quantifiable way, that can be used as part of the dialogue between patients and clinicians concerning diagnostic and treatment decisions.⁶⁰ This shared decision-making is a critical element of person-centred care.⁶¹ Experience with routine assessment of PROs is built up in different clinical areas, such as cancer,^{62, 63}

rheumatic diseases,^{64, 65} and orthopaedics.^{66, 67} Within cardiology, there is growing interest from clinicians and patients, but the use of PROs in real-life clinical practice remains sparsely tested or implemented⁶⁸ and clinicians see several barriers.⁶⁹

The use of PROs in clinical practice can improve communication with patients and families, collaboration among healthcare professionals, monitoring of disease progression, and evaluation of treatment outcomes (Figure 3). Indeed, PROs can inform healthcare professionals to have a better understanding of the perspective of each particular patient, and they improve clinicians' assessment of the health status of patients.⁷⁰ PROs assess what matters to patients in a systematic way. In cardiac rehabilitation, PROs are particularly important and seem to be decisive for success as they predict positive outcomes.⁷¹ When PROs are assessed cross-sectionally, they can be compared with population benchmarks. It is also interesting and valid to assess PROs in a longitudinal fashion, because it allows the evaluation of within-person evolutions.

The use of PROMs in clinical care has been shown to be effective in improving patient management.⁷² Hence, giving feedback on PROM findings to healthcare professionals can be considered as an intervention. Clinicians who want to implement PRO assessment in their clinical practice can rely on the user's guide developed by the International Society for Quality of Life Research (ISOQOL).⁷³ Healthcare providers need to be educated how to interpret a new measure and how the results can be integrated into the processes of care. Indeed, information from PROMs, being routinely collected through smart phones, patient portals, in-clinic kiosks or tablets, should be integrated into the medical record in a location that is easily accessed by the clinicians (e.g. the page where the vital signs are located). Further, it is important that clinicians discuss the findings with patients.⁶⁹ Obviously, this all requires time, financial resources, personnel and digital infrastructures to implement the assessment of PROs successfully.

While the implementation of PROs in clinical care is aimed mainly at supporting healthcare professionals and healthcare systems by providing data for their clinical decision-making, PROs can also increase patients' understanding of their health status. In this respect, the use of graphical displays or dashboards is indispensable.^{74, 75} However, one needs to take the graphical literacy of patients and families into consideration.⁷⁶ Research has shown that visual analogies or infographics are more effective in increasing patients' understanding of their condition.⁷⁶

An important feature is that patients should be able to indicate the relative importance of each PRO. As such, they give a weighting to individual items according to what matters to them. Integrating relative importance of items in PROMs is in its infancy, but should be further developed to make PRO assessment more in line with the preferences of individual patients.

10. PROs in quality monitoring and improvement

There is growing awareness that PROs have a place in the evaluation of quality of care. This is rooted in the concept of value-based healthcare, which is defined as improving patient-relevant outcomes, relative to the cost per patient for achieving these improvements.⁷⁷ In this respect, PRO-based performance measures, also known as PRO-based quality indicators, are of key importance.²⁰ PRO-based performance measures entail an aggregation of information collected through PROMs or PREMs.^{20, 21} Data are aggregated for an accountable healthcare entity, such as a ward, a hospital, or a home care agency.²¹ Performance measures are preferably expressed as ratios. An example is the percentage of patients with depressive feelings, as shown by a score of >9 on the Patient Health Questionnaire-9 items (PHQ9), who have a follow-up score of <5 at 6 months. The higher the percentage, the better the care that has been provided, because the goals of treatment and care have been reached. Quality

indicators that are linked to ESC guidelines that encompass PROMs and PREMs^{8, 78, 79} are particularly useful for monitoring the quality of care from patients' perspectives. It is important that performance measures are risk-adjusted.⁸⁰

The monitoring of quality of care can also be conducted at regional, national or international level. For this purpose, quality registries are developed. Quality registries serve as a benchmark to compare healthcare institutions/organizations or to evaluate the effects of quality improvement initiatives. In many national or international registries, the variables related to PROMs and PREMs are not recorded.^{8, 78} Therefore, we call for including patients' perspective into these existing registries⁸¹ with appropriate public funding for relevant PROMs or PREMs that have been validated. Consensus about which PROs to use for each condition has yet to be reached across the national cardiac clinical registries in different countries. The development of data standards for the European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart) are exemplary in this respect. PROs, and more specific HRQoL, are named as key domains that have to be included in the registry.^{82, 83}

11. PROs in clinical trials

The importance of PROs in clinical trials has been recognized since the early 1990s. Indeed, it was found that the adverse event forms that were completed by physicians in two randomized controlled trials on antihypertensive agents captured only 7% of the symptoms that were reported by patients using a structured symptom distress scale.⁸⁴ Since then, increasingly more clinical trials have used PROs either as primary endpoints of interest, secondary endpoints, or exploratory/tertiary endpoints. In ClinicalTrials.gov, the proportion of trials that included PROs rose from 14% in 2004-2007⁸⁵ to 27% in 2007-2013.⁸⁶ Similarly, the Australian and New Zealand Clinical Trial Registry showed that 45% of the trials had PROs as trial endpoints in 2005-2017.⁸⁷ This illustrates that the value of PROs in clinical trials has

been widely recognized, because the typical endpoints in clinical trials do not always give an accurate reflection of all the risks, benefits, quality of life and costs for patients.⁸⁸

In clinical trials, PRO endpoints should be decided a priori, submitted for ethical review, and approved in the trial protocol. For this, existing ‘core outcome sets’ can be relied on. It is advisable to have an expert in psychometrics and clinical interpretations of PROs on the trial committee, and to involve patients in selecting suitable PRO instruments and designing how these instruments will be captured. Regulatory and professional bodies show an emerging consensus when it comes to selecting PROMs for clinical trials.⁸⁹ Nonetheless, the interpretation of PRO data in clinical trials can be challenging because of lack of familiarity with their clinical importance.¹⁶ Therefore, developers of questionnaires or experts in psychometrics should guide trialists on how to use, analyse and interpret the data obtained by that questionnaire. Recent examples are the specific guidance given on the use of the Seattle Angina Questionnaire and the Kansas City Cardiomyopathy Questionnaire in clinical trials.^{15, 16} When reporting PRO findings, recommendations for designing, analysing, and reporting, such as SPIRIT-PRO⁹⁰ and CONSORT-PRO,⁹¹ should be followed.

12. PROs in regulatory affairs

PROs are used for regulatory approval of drugs or medical devices, for example to support a product label claim. International regulatory agencies have acknowledged that valid, well-defined, and rigorously collected measurements of PROs can complement existing measurements of safety and efficacy, as evidence for making regulatory decisions.⁹²

Regarding medicines, fundamental steps that have been proposed toward making drug development a more patient-centred process include engaging patient representatives during the lifecycle of a drug’s development, identifying feasible patient-centred outcomes, and including PROMs in drug labels to support patients and providers when they make therapeutic

decisions. The FDA released guidance on the utility of PRO data in 2009, in order to streamline the review of PROMs and associated clinical trial data and to improve methods for considering patients' perspectives when reviewing medical products.¹ In 2019, the FDA specified that a beneficial effect on symptoms or physical function could be the basis for approving a drug to treat heart failure, even if it has no favourable effect on survival or hospitalizations.⁹³ Sponsors are encouraged to consult with the FDA early, to obtain agreement on proposed end-points.⁹³ In 2015, the European Medicines Agency (EMA) stated in a guideline on the investigation of medicines for acute heart failure, that "Improvement in quality of life and/or patients' self-assessed global clinical status, based on validated ordinal measures of response relative to baseline, could be used as secondary endpoint".⁹⁴ Further guidance in 2017 stated that PROs should be included as secondary endpoints in chronic heart failure studies, when they should be considered as supportive, but it also acknowledged that, under special circumstances, measures of symptom burden may be acceptable as a primary endpoint.⁹⁵

The EU Regulation on medical devices (MDR, EU 2017/745, implemented at 26 May 2021 after a transition period) has increased the requirements for clinical evidence concerning new high-risk medical devices.⁹⁶ Before approval, 'clinical investigations' (a term which includes clinical trials) should demonstrate a positive impact on "patient-relevant clinical outcomes" [MDR Article 2 (53) and Article 61].⁹⁶ After market access, manufacturers have responsibility for continued surveillance and they are required to submit an annual safety update report.⁹⁷ In a 2020 document, the FDA gives guidance on the collection, analysis, and integration of patient perspectives in the development, evaluation, and surveillance of medical devices.⁹⁸ It is argued that information from well-defined and reliable PRO instruments can provide valuable evidence for benefit-risk assessments and can be used in medical device labeling.⁹⁸ There are no specific European guidance documents on the application of PROs to

evaluate medical devices, but the ESC is leading a project (CORE-MD) that will summarise the evidence and recommend to regulators how that could be done.¹⁴ As part of the CORE-MD project, it will be scrutinized to what extent minimal clinically important differences (MCID) have been developed and used for regulatory purposes.

13. PROs for reimbursement and health economics purposes

Following the idea that “value lies in the eyes of the patient”⁹⁹, it is not surprising to witness increasing use of PROs to inform a broad range of decisions, including those related to coverage and reimbursement, as well as payments to providers.^{99, 100} For instance, there has been a strong endorsement to integrate PROs in a value-based payment reform that dramatically changes the provider reimbursement landscape in the US.¹⁰ PROMs and PREMs can be used in reimbursement decisions in pay-for-performance systems, because the quality of care is then also assessed through the lens of patients.¹⁰¹ An example is the Quality and Outcomes Framework in the UK where primary care practices are financially rewarded for achieving quality standards that include patients’ experiences.¹⁰² Indeed, pay-for-performance programs have to take patient experience into account, to avoid disheartening patients and discouraging them from providing feedback on which effective quality improvement must rely.¹⁰³ However, reimbursements based on PROs should account for adequate risk adjustments. If not, healthcare providers and practices may be penalized for taking care of sicker, more complex, or socially disadvantaged patients, who will have worse PRO scores.

PROs are increasingly recognized as an important focus in health technology assessments (HTAs). HTAs have become a dominant framework for making decisions related to coverage and reimbursement of new medical technologies, and dossiers submitted to HTA agencies often include PRO data, while HRQoL data and utilities (see Fig. 2) are often incorporated into cost-effectiveness analyses.

To date, there is still limited evidence of the use of PROs by HTA bodies in Europe and beyond.^{104, 105} The evidence available is focused mainly on understanding the use of quality-adjusted life years (QALYs), which are mostly based on generic HRQoL measures (i.e. EQ-5D).¹⁰⁶ The use of other types of PROs in informing reimbursement decisions (i.e. functional status, symptoms, activities of daily living) has not been sufficiently explored. The inclusion of PROs in reimbursement decisions varies greatly by country and also within a country by payer type, whether national, regional or local decision-maker.¹⁰⁷ This is not a surprise because the extent to which a country relies on the use of HTA in healthcare decision-making is influenced by the underlying culture and values embedded in the institutional context of the country's particular healthcare system.¹⁰⁸

14. PROs in a digital world

Recent advances in information and communication technology have led to a rapid increase in the means by which patients can provide insights into their health status. It is now possible to collect electronic versions of previously paper-based questionnaires, and to supplement this with data collected from real life, such as patient activity, pain levels, sleep quality, and social interaction. Such ePROs (PRO data using electronic data capture) are now firmly embedded in clinical trials and regulatory approval frameworks,¹⁰⁹ and increasingly used in routine clinical practice.¹¹⁰ Also electronic health records are increasingly integrating PROMs.¹¹¹ Guidance on the development of digital patient-reported outcome performance measures is available.¹¹²

ePROs can, at least in theory, be used more frequently and triggered by patients as well as by healthcare professionals or clinical trialists. This may influence the patient-healthcare professional interaction, facilitating a more flexible mode and frequency of follow-up or surveillance, a better patient-centred conversation supporting a shared care decision-

making approach, and a more nuanced understanding of how a condition or its treatment affects the individual.^{61, 113} ePROs also allow for Computer Adaptive Testing (CAT), the basic principle of which is to avoid asking questions that are redundant, given the responses to prior questions. For instance, if a respondent indicated that they are able to walk 1 kilometre without symptoms, whether they can walk a few hundred meters is no longer a relevant question and can therefore be omitted. With appropriate data display, ePROs can stimulate patients to manage their own monitoring and treatment, supporting them in the journey to self-care if so desired. In this respect, it is important to use visualization methods that are most effective in communicating with patients.⁷⁶ Arguably, ePROs can be used successfully only in patients with sufficient eHealth literacy.¹¹⁴

15. Future directions

In cardiology, the use of PROs is increasing. This statement has highlighted their applications in cardiovascular clinical practice, for monitoring of quality of care, and as input for regulatory and reimbursement decisions. Nonetheless, there is much room for further developments, for building capacity and expertise, and for wider adoption of evidence-based PROs in the cardiovascular arena. Research should explore which instruments are best for discerning patients' concerns and for impacting on decisions to improve outcomes, while respecting the preferences of individual patients on whether or not they wish to contribute their experience in this way. Suggestions for future developments are summarised in Box 1.

16. Conclusion

The use of PROs provides insights into the perspective of patients. This statement aims to stimulate the use of PROs in cardiovascular medicine by providing guidance to clinicians, researchers, and policy-makers. We propose a new definition of PROs and advise on future

developments and optimal use of PROs in shared clinical decision-making, quality monitoring and improvement, clinical trials, regulatory and reimbursement decisions, and the digital health arena (Graphical Abstract). We hope that this statement will provide a practical guide on the potential of PROs and stimulate the growth of a cadre of experts supporting further development and adoption of PROs in cardiology.

References

1. US Department of Health and Human Service Food and Drug Administration. Guidance for industry. Patient-reported outcome measures: Use in medical product development to support labeling claims. In. Silver Spring, MD: Food and Drug Administration; 2009.
2. Liu JB, Pusic AL, Temple LK, Ko CYK. Patient-reported outcomes in surgery: Listening to patients improves quality of life. *Bull Am Coll Surg* 2017;**102**:19-23.
3. Noonan VK, Lyddiatt A, Ware P, Jaglal SB, Riopelle RJ, Bingham CO, *et al*. Montreal Accord on Patient-Reported Outcomes (PROs) use series - Paper 3: patient-reported outcomes can facilitate shared decision-making and guide self-management. *J Clin Epidemiol* 2017;**89**:125-135.
4. Bingham CO, Noonan VK, Auger C, Feldman DE, Ahmed S, Bartlett SJ. Montreal Accord on Patient-Reported Outcomes (PROs) use series - Paper 4: patient-reported outcomes can inform clinical decision making in chronic care. *J Clin Epidemiol* 2017;**89**:136-141.
5. Lauck SB, Lewis KB, Borregaard B, de Sousa I. "What Is the Right Decision for Me?" Integrating Patient Perspectives Through Shared Decision-Making for Valvular Heart Disease Therapy. *Can J Cardiol* 2021;**37**(7):1054-1063.
6. Basch E, Barbera L, Kerrigan CL, Velikova G. Implementation of Patient-Reported Outcomes in Routine Medical Care. *Am Soc Clin Oncol Educ Book* 2018;**38**:122-134.
7. Spertus JA. Understanding How Patients Fare: Insights Into the Health Status Patterns of Patients With Coronary Disease and the Future of Evidence-Based Shared Medical Decision-Making. *Circ Cardiovasc Qual Outcomes* 2018;**11**(3):e004555.
8. Arbelo E, Aktaa S, Bollmann A, D'Avila A, Drossart I, Dwight J, *et al*. Quality indicators for the care and outcomes of adults with atrial fibrillation. *Europace* 2021;**23**(4):494-495.
9. Schwartzberg L. Electronic Patient-Reported Outcomes: The Time Is Ripe for Integration Into Patient Care and Clinical Research. *Am Soc Clin Oncol Educ Book* 2016;**35**:e89-96.
10. Squitieri L, Bozic KJ, Pusic AL. The Role of Patient-Reported Outcome Measures in Value-Based Payment Reform. *Value Health* 2017;**20**(6):834-836.
11. Psotka MA, von Maltzahn R, Anatchkova M, Agodoa I, Chau D, Malik FI, *et al*. Patient-Reported Outcomes in Chronic Heart Failure: Applicability for Regulatory Approval. *JACC Heart Fail* 2016;**4**(10):791-804.
12. Steinberg BA, Dorian P, Anstrom KJ, Hess R, Mark DB, Noseworthy PA, *et al*. Patient-Reported Outcomes in Atrial Fibrillation Research: Results of a Clinicaltrials.gov Analysis. *JACC Clin Electrophysiol* 2019;**5**(5):599-605.
13. Patrick DL, Burke LB, Powers JH, Scott JA, Rock EP, Dawisha S, *et al*. Patient-reported outcomes to support medical product labeling claims: FDA perspective. *Value Health* 2007;**10 Suppl 2**:S125-37.
14. Fraser AG, Nelissen R, Kjærsgaard-Andersen P, Szymański P, Melvin T, Piscoi P. Improved clinical investigation and evaluation of high-risk medical devices: the rationale and objectives of CORE-MD (Coordinating Research and Evidence for Medical Devices). *Eur Heart J Qual Care Clin Outcomes* 2022;**8**:249-258.
15. Spertus JA, Jones PG, Sandhu AT, Arnold SV. Interpreting the Kansas City Cardiomyopathy Questionnaire in Clinical Trials and Clinical Care: JACC State-of-the-Art Review. *J Am Coll Cardiol* 2020;**76**(20):2379-2390.
16. Thomas M, Jones PG, Arnold SV, Spertus JA. Interpretation of the Seattle Angina Questionnaire as an Outcome Measure in Clinical Trials and Clinical Care: A Review. *JAMA Cardiol* 2021;**6**(5):593-599.
17. Rumsfeld JS, Alexander KP, Goff DC, Jr., Graham MM, Ho PM, Masoudi FA, *et al*. Cardiovascular health: the importance of measuring patient-reported health status: a scientific statement from the American Heart Association. *Circulation* 2013;**127**(22):2233-49.

18. Anker SD, Agewall S, Borggreffe M, Calvert M, Jaime Caro J, Cowie MR, *et al.* The importance of patient-reported outcomes: a call for their comprehensive integration in cardiovascular clinical trials. *Eur Heart J* 2014;**35**(30):2001-9.
19. Acquadro C, Berzon R, Dubois D, Leidy NK, Marquis P, Revicki D, *et al.* Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of the Patient-Reported Outcomes (PRO) Harmonization Group meeting at the Food and Drug Administration, February 16, 2001. *Value Health* 2003;**6**(5):522-531.
20. National Quality Forum. Patient reported outcomes (PRO) in performance measurement. In: Washington DC: National Quality Forum; 2013.
21. Cella D, Hahn EA, Jensen SE, Butt Z, Nowinski CJ, Rothrock N, *et al.* Patient-Reported Outcomes in Performance Measurement. Durham (NC): Research Triangle Institute; 2015. p. 91.
22. Devlin NJ, Appleby J. Getting the most out of PROMS: Putting health outcomes at the heart of NHS decision-making. London, UK: The King's Fund; 2010. p. 83.
23. EuroQol Group. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy* 1990;**16**(3):199-208.
24. Ware JE, Snow KK, Kosinski M, Gandek B. *SF-36 Health survey: Manual & interpretation guide*. Boston: The Health Institute, New England Medical Center; 1993.
25. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, *et al.* The Patient-Reported Outcomes Measurement Information System (PROMIS): Progress of an NIH Roadmap Cooperative Group During its First Two Years. *Med Care* 2007;**45**(5 Suppl):S3-S11.
26. Rector TS, Kubo SH, Cohn JN. Patients' self-assessment of their congestive heart failure. Part 2: Content, reliability and validity of a new measure, the Minnesota Living with Heart Failure questionnaire. *Heart Failure* 1987;**3**:198-209.
27. Thompson DR, Jenkinson C, Roebuck A, Lewin RJ, Boyle RM, Chandola T. Development and validation of a short measure of health status for individuals with acute myocardial infarction: the myocardial infarction dimensional assessment scale (MIDAS). *Qual Life Res* 2002;**11**(6):535-43.
28. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res (Hoboken)* 2011;**63**(Suppl 11):S240-S252.
29. Goossens E, Luyckx K, Mommen N, Gewillig M, Budts W, Zupancic N, *et al.* Health risk behaviors in adolescents and emerging adults with congenital heart disease: psychometric properties of the Health Behavior Scale-Congenital Heart Disease. *Eur J Cardiovasc Nurs* 2013;**12**(6):544-57.
30. Rose GA. The diagnosis of ischaemic heart pain and intermittent claudication in field surveys. *Bull World Health Organ* 1962;**27**(6):645-58.
31. Alguren B, Coenen M, Malm D, Fridlund B, Martensson J, Arestedt K, *et al.* A scoping review and mapping exercise comparing the content of patient-reported outcome measures (PROMs) across heart disease-specific scales. *J Patient Rep Outcomes* 2020;**4**(1):7.
32. Subramanian M, Kozower BD, Brown LM, Khullar OV, Fernandez FG. Patient-Reported Outcomes in Cardiothoracic Surgery. *Ann Thorac Surg* 2019;**107**(1):294-301.
33. Kotecha D, Ahmed A, Calvert M, Lencioni M, Terwee CB, Lane DA. Patient-Reported Outcomes for Quality of Life Assessment in Atrial Fibrillation: A Systematic Review of Measurement Properties. *PLoS One* 2016;**11**(11):e0165790.
34. Kelkar AA, Spertus J, Pang P, Pierson RF, Cody RJ, Pina IL, *et al.* Utility of Patient-Reported Outcome Instruments in Heart Failure. *JACC Heart Fail* 2016;**4**(3):165-75.
35. Thompson LE, Bekelman DB, Allen LA, Peterson PN. Patient-reported outcomes in heart failure: existing measures and future uses. *Curr Heart Fail Rep* 2015;**12**(3):236-46.
36. Chew DS, Whitelaw S, Vaduganathan M, Mark DB, Van Spall HGC. Patient-Reported Outcome Measures in Cardiovascular Disease: An Evidence Map of the Psychometric Properties of Health Status Instruments. *Ann Intern Med* 2022;**175**(10):1431-1439.

37. Chen Y, Lu M, Jia L. Psychometric properties of self-reported measures of self-management for chronic heart failure patients: a systematic review. *Eur J Cardiovasc Nurs* 2023;zvad028.
38. Garin O, Ferrer M, Pont A, Rué M, Kotzeva A, Wiklund I, *et al.* Disease-specific health-related quality of life questionnaires for heart failure: a systematic review with meta-analyses. *Qual Life Res* 2009;**18**(1):71-85.
39. Zimmerman L, Pozehl B, Vuckovic K, Barnason S, Schulz P, Seo Y, *et al.* Selecting symptom instruments for cardiovascular populations. *Heart Lung* 2016;**45**(6):475-496.
40. Tegegn HG, Wark S, Tursan d'Espaignet E, Spark MJ. Measurement Properties of Patient-Reported Outcome Measures for Medication Adherence in Cardiovascular Disease: A COSMIN Systematic Review. *Clin Drug Investig* 2022;**42**(11):879-908.
41. Sale A, Yu J. Quality of life instruments in atrial fibrillation: a systematic review of measurement properties. *Health Qual Life Outcomes* 2022;**20**(1):143.
42. Garin O, Herdman M, Vilagut G, Ferrer M, Ribera A, Rajmil L, *et al.* Assessing health-related quality of life in patients with heart failure: a systematic, standardized comparison of available measures. *Heart Fail Rev* 2014;**19**(3):359-67.
43. Zack R, Okunade O, Olson E, Salt M, Amodeo C, Anchala R, *et al.* Improving Hypertension Outcome Measurement in Low- and Middle-Income Countries. *Hypertension* 2019;**73**(5):990-997.
44. Seligman WH, Das-Gupta Z, Jobi-Odeneye AO, Arbelo E, Banerjee A, Bollmann A, *et al.* Development of an international standard set of outcome measures for patients with atrial fibrillation: a report of the International Consortium for Health Outcomes Measurement (ICHOM) atrial fibrillation working group. *Eur Heart J* 2020;**41**(10):1132-1140.
45. Hummel K, Whittaker S, Sillett N, Basken A, Berghammer M, Chalela T, *et al.* Development of an international standard set of clinical and patient-reported outcomes for children and adults with congenital heart disease: a report from the International Consortium for Health Outcomes Measurement Congenital Heart Disease Working Group. *Eur Heart J Qual Care Clin Outcomes* 2021;**7**(4):354-365.
46. McNamara RL, Spatz ES, Kelley TA, Stowell CJ, Beltrame J, Heidenreich P, *et al.* Standardized Outcome Measurement for Patients With Coronary Artery Disease: Consensus From the International Consortium for Health Outcomes Measurement (ICHOM). *J Am Heart Assoc* 2015;**4**(5):e001767.
47. Burns DJP, Arora J, Okunade O, Beltrame JF, Bernardez-Pereira S, Crespo-Leiro MG, *et al.* International Consortium for Health Outcomes Measurement (ICHOM): Standardized Patient-Centered Outcomes Measurement Set for Heart Failure Patients. *JACC Heart Fail* 2020;**8**(3):212-222.
48. Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, *et al.* Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. *PLoS Med* 2016;**13**(10):e1002148.
49. Valderas JM, Ferrer M, Mendivil J, Garin O, Rajmil L, Herdman M, *et al.* Development of EMPRO: a tool for the standardized assessment of patient-reported outcome measures. *Value Health* 2008;**11**(4):700-8.
50. Garin O, García-Forero C, Vilagut G, Pardo Y, Alayo I, Oriol Zerbe C, *et al.* PRM217 - The Online Version of EMPRO: a new platform system for the standardized appraisal of PRO Instruments. *Value Health* 2018;**21**:S393.
51. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, *et al.* The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol* 2010;**63**(7):737-745.
52. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL, *et al.* The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol* 2010;**10**:22.
53. Mokkink LB, de Vet HCW, Prinsen CAC, Patrick DL, Alonso J, Bouter LM, *et al.* COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. *Qual Life Res* 2018;**27**(5):1171-1179.
54. Kyte D, Draper H, Calvert M. Patient-Reported Outcome Alerts: Ethical and Logistical Considerations in Clinical Trials. *JAMA* 2013;**310**(12):1229-1230.

55. Cruz Rivera S, Aiyegbusi OL, Ives J, Draper H, Mercieca-Bebber R, Ells C, *et al.* Ethical Considerations for the Inclusion of Patient-Reported Outcomes in Clinical Research: The PRO Ethics Guidelines. *JAMA* 2022;**327**(19):1910-1919.
56. Marcus A. Pay up or retract? Survey creator's demands for money rile some health researchers. *Science* 2017;**15**(3):169-182.
57. Comins JD, Brodersen J, Siersma V, Jensen J, Hansen CF, Krogsgaard MR. Choosing the most appropriate PROM for clinical studies in sports medicine. *Scand J Med Sci Sports* 2021;**31**(6):1209-1215.
58. Comins JD, Brodersen J, Siersma V, Jensen J, Hansen CF, Krogsgaard MR. How to develop a condition-specific PROM. *Scand J Med Sci Sports* 2021;**31**(6):1216-1224.
59. Gagnier JJ, Lai J, Mokkink LB, Terwee CB. COSMIN reporting guideline for studies on measurement properties of patient-reported outcome measures. *Qual Life Res* 2021;**30**(8):2197-2218.
60. Wohlfahrt P, Stehlik J, Pan IZ, Ryan JJ. Empowering People Living with Heart Failure. *Heart Fail Clin* 2020;**16**(4):409-420.
61. Snyder CF, Aaronson NK, Choucair AK, Elliott TE, Greenhalgh J, Halyard MY, *et al.* Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. *Qual Life Res* 2012;**21**(8):1305-14.
62. Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, *et al.* Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. *Ann Oncol* 2015;**26**(9):1846-1858.
63. Stover A, Irwin DE, Chen RC, Chera BS, Mayer DK, Muss HB, *et al.* Integrating Patient-Reported Outcome Measures into Routine Cancer Care: Cancer Patients' and Clinicians' Perceptions of Acceptability and Value. *EGEMS (Wash DC)* 2015;**3**(1):1169.
64. Bartlett SJ, De Leon E, Orbai AM, Haque UJ, Manno RL, Ruffing V, *et al.* Patient-reported outcomes in RA care improve patient communication, decision-making, satisfaction and confidence: qualitative results. *Rheumatology (Oxford)* 2020;**59**(7):1662-1670.
65. Subash M, Liu LH, DeQuattro K, Choden S, Jacobsohn L, Katz P, *et al.* The Development of the Rheumatology Informatics System for Effectiveness Learning Collaborative for Improving Patient-Reported Outcome Collection and Patient-Centered Communication in Adult Rheumatology. *ACR Open Rheumatol* 2021;**3**(10):690-698.
66. Hamilton DF, Giesinger JM, Giesinger K. Technological developments enable measuring and using patient-reported outcomes data in orthopaedic clinical practice. *World J Orthop* 2020;**11**(12):584-594.
67. Tew M, Dalziel K, Clarke P, Smith A, Choong PF, Dowsey M. Patient-reported outcome measures (PROMs): can they be used to guide patient-centered care and optimize outcomes in total knee replacement? *Qual Life Res* 2020;**29**(12):3273-3283.
68. Gallagher AM, Lucas R, Cowie MR. Assessing health-related quality of life in heart failure patients attending an outpatient clinic: a pragmatic approach. *ESC Heart Fail* 2019;**6**(1):3-9.
69. Wohlfahrt P, Zickmund SL, Slager S, Allen LA, Nicolau JN, Kfoury AG, *et al.* Provider Perspectives on the Feasibility and Utility of Routine Patient-Reported Outcomes Assessment in Heart Failure: A Qualitative Analysis. *J Am Heart Assoc* 2020;**9**(2):e013047.
70. Sandhu AT, Zheng J, Kalwani NM, Gupta A, Calma J, Skye M, *et al.* Impact of Patient-Reported Outcome Measurement in Heart Failure Clinic on Clinician Health Status Assessment and Patient Experience: A Substudy of the PRO-HF Trial. *Circ Heart Fail* 2023;**16**(2):e010280.
71. Salzwedel A, Koran I, Langheim E, Schlitt A, Nothroff J, Bongarth C, *et al.* Patient-reported outcomes predict return to work and health-related quality of life six months after cardiac rehabilitation: Results from a German multi-centre registry (OutCaRe). *PLoS One* 2020;**15**(5):e0232752.
72. Boyce MB, Browne JP. Does providing feedback on patient-reported outcomes to healthcare professionals result in better outcomes for patients? A systematic review. *Qual Life Res* 2013;**22**(9):2265-78.

73. International Society for Quality of Life Research (prepared by Aaronson N ET, Greenhalgh J, Halyard M, Hess R, Miller D, Reeve B, Santana M, Snyder C). *User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice*, version 2 (January 2015). 2015.
74. Liu LH, Garrett SB, Li J, Ragouzeos D, Berrean B, Dohan D, *et al.* Patient and clinician perspectives on a patient-facing dashboard that visualizes patient reported outcomes in rheumatoid arthritis. *Health Expect* 2020;**23**(4):846-859.
75. Tolbert E, Brundage M, Bantug E, Blackford AL, Smith K, Snyder C. Picture This: Presenting Longitudinal Patient-Reported Outcome Research Study Results to Patients. *Med Decis Making* 2018;**38**(8):994-1005.
76. Reading Turchioe M, Grossman LV, Myers AC, Baik D, Goyal P, Masterson Creber RM. Visual analogies, not graphs, increase patients' comprehension of changes in their health status. *J Am Med Inform Assoc* 2020;**27**(5):677-689.
77. Porter ME. A strategy for health care reform--toward a value-based system. *N Engl J Med* 2009;**361**(2):109-12.
78. Schiele F, Aktaa S, Rossello X, Ahrens I, Claeys MJ, Collet JP, *et al.* 2020 Update of the quality indicators for acute myocardial infarction: a position paper of the Association for Acute Cardiovascular Care: the study group for quality indicators from the ACVC and the NSTEMI-ACS guideline group. *Eur Heart J Acute Cardiovasc Care* 2021;**10**(2):224-233.
79. Aktaa S, Gencer B, Arbelo E, Davos CH, Désormais I, Hollander M, *et al.* European Society of Cardiology Quality Indicators for Cardiovascular Disease Prevention: developed by the Working Group for Cardiovascular Disease Prevention Quality Indicators in collaboration with the European Association for Preventive Cardiology of the European Society of Cardiology. *Eur J Prev Cardiol* 2022;**29**:1060-1071.
80. Tran AT, Fonarow GC, Arnold SV, Jones PG, Thomas LE, Hill CL, *et al.* Risk Adjustment Model for Preserved Health Status in Patients With Heart Failure and Reduced Ejection Fraction: The CHAMP-HF Registry. *Circ Cardiovasc Qual Outcomes* 2021;**14**(10):e008072.
81. Nelson EC, Dixon-Woods M, Batalden PB, Homa K, Van Citters AD, Morgan TS, *et al.* Patient focused registries can improve health, care, and science. *BMJ* 2016;**354**:i3319.
82. Aktaa S, Batra G, Cleland JGF, Coats A, Lund LH, McDonagh T, *et al.* Data standards for heart failure: the European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart). *Eur Heart J* 2022;**43**(23):2185-2195.
83. Aktaa S, Batra G, James SK, Blackman DJ, Ludman PF, Mamas MA, *et al.* Data standards for transcatheter aortic valve implantation: the European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart). *Eur Heart J Qual Care Clin Outcomes* 2022.
84. Anderson RB, Testa MA. Symptom distress checklists as a component of quality of life measurement: Comparing prompted reports by patient and physician with concurrent adverse event reports via the physician. *Drug Information Journal* 1994;**28**:89-114.
85. Scoggins JF, Patrick DL. The use of patient-reported outcomes instruments in registered clinical trials: evidence from ClinicalTrials.gov. *Contemp Clin Trials* 2009;**30**(4):289-92.
86. Vodicka E, Kim K, Devine EB, Gnanasakthy A, Scoggins JF, Patrick DL. Inclusion of patient-reported outcome measures in registered clinical trials: Evidence from ClinicalTrials.gov (2007-2013). *Contemp Clin Trials* 2015;**43**:1-9.
87. Mercieca-Bebber R, King MT, Calvert MJ, Stockler MR, Friedlander M. The importance of patient-reported outcomes in clinical trials and strategies for future optimization. *Patient Relat Outcome Meas* 2018;**9**:353-367.
88. Warsame R, D'Souza A. Patient Reported Outcomes Have Arrived: A Practical Overview for Clinicians in Using Patient Reported Outcomes in Oncology. *Mayo Clin Proc* 2019;**94**(11):2291-2301.
89. Crossnohere NL, Brundage M, Calvert MJ, King M, Reeve BB, Thorner E, *et al.* International guidance on the selection of patient-reported outcome measures in clinical trials: a review. *Qual Life Res* 2021;**30**(1):21-40.

90. Calvert M, Kyte D, Mercieca-Bebber R, Slade A, Chan AW, King MT, *et al.* Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols The SPIRIT-PRO Extension. *JAMA* 2018;**319**(5):483-494.
91. Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD. Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. *Jama* 2013;**309**(8):814-22.
92. Kuehn CM. A Proposed Framework for Patient-Focused Policy at the U.S. Food and Drug Administration. *Biomedicines* 2019;**7**(3):64.
93. US Department of Health and Human Service Food and Drug Administration. Treatment for Heart Failure: Endpoints for Drug Development: Guidance for Industry. Silver Spring, MD: Food and Drug Administration; 2019.
94. European Medicines Agency. Guideline on clinical investigation of medicinal products for the treatment of acute heart failure (CPMP/EWP/2986/03 Rev. 1). London, UK: European Medicines Agency; 2015, 15.
95. European Medicines Agency. Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure (CPMP/EWP/235/95, Rev.2). London, UK: European Medicines Agency; 2017, 15.
96. Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. In: *Official Journal of the European Union*, (ed). Brussel: European Parliament and of the Council of the European Union; 2017, 1-175.
97. Fraser AG, Byrne RA, Kautzner J, Butchart EG, Szymański P, Leggeri I, *et al.* Implementing the new European Regulations on medical devices-clinical responsibilities for evidence-based practice: a report from the Regulatory Affairs Committee of the European Society of Cardiology. *Eur Heart J* 2020;**41**(27):2589-2596.
98. US Department of Health and Human Service Food and Drug Administration. Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation. Draft Guidance for Industry and Food and Drug Administration Staff, and Other Stakeholders. Silver Spring, MD: Food and Drug Administration; 2020.
99. Ciani O, Federici CB. Value Lies in the Eye of the Patients: The Why, What, and How of Patient-reported Outcomes Measures. *Clin Ther* 2020;**42**(1):25-33.
100. Weszl M, Rencz F, Brodszky V. Is the trend of increasing use of patient-reported outcome measures in medical device studies the sign of shift towards value-based purchasing in Europe? *Eur J Health Econ* 2019;**20**(Suppl 1):133-140.
101. Wasson JH, Sox HC, Miller HD. Aligning Payments, Services, and Quality in Primary Care. *JAMA* 2021;**326**:805-806.
102. Roland M. Linking physicians' pay to the quality of care--a major experiment in the United Kingdom. *N Engl J Med* 2004;**351**(14):1448-54.
103. Schlesinger M, Grob R, Shaller D. Using Patient-Reported Information to Improve Clinical Practice. *Health Serv Res* 2015;**50** Suppl 2(Suppl 2):2116-54.
104. Drummond M, Torbica A, Tarricone R. Should health technology assessment be more patient centric? If so, how? *Eur J Health Econ* 2020;**21**(8):1117-1120.
105. (EUnetHTA) ENFHTA. Endpoints used for relative effectiveness assessment: Clinical endpoints. Diemen, the Netherlands: EUnetHTA; 2015.
106. Brazier JE, Rowen D, Lloyd A, Karimi M. Future Directions in Valuing Benefits for Estimating QALYs: Is Time Up for the EQ-5D? *Value Health* 2019;**22**(1):62-68.
107. Barnieh L, Manns B, Harris A, Blom M, Donaldson C, Klarenbach S, *et al.* A synthesis of drug reimbursement decision-making processes in organisation for economic co-operation and development countries. *Value Health* 2014;**17**(1):98-108.
108. Torbica A, Fornaro G, Tarricone R, Drummond MF. Do Social Values and Institutional Context Shape the Use of Economic Evaluation in Reimbursement Decisions? An Empirical Analysis. *Value Health* 2020;**23**(1):17-24.

109. Marquis-Gravel G, Roe MT, Turakhia MP, Boden W, Temple R, Sharma A, *et al.* Technology-Enabled Clinical Trials: Transforming Medical Evidence Generation. *Circulation* 2019;**140**(17):1426-1436.
110. Ahmed S, Ware P, Gardner W, Witter J, Bingham CO, Kairy D, *et al.* Montreal Accord on Patient-Reported Outcomes (PROs) use series - Paper 8: patient-reported outcomes in electronic health records can inform clinical and policy decisions. *J Clin Epidemiol* 2017;**89**:160-167.
111. Snyder C, Wu AW. *Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records*. Baltimore, MD: Johns Hopkins University; 2017.
112. National Quality Forum. Building a roadmap from patient-reported outcome measures to patient-reported outcome performance measures - Technical guidance, Updated final draft. Washington DC: National Quality Forum; 2022.
113. Greenhalgh J, Gooding K, Gibbons E, Dalkin S, Wright J, Valderas J, *et al.* How do patient reported outcome measures (PROMs) support clinician-patient communication and patient care? A realist synthesis. *J Patient Rep Outcomes* 2018;**2**:42.
114. Norman C. eHealth literacy 2.0: problems and opportunities with an evolving concept. *J Med Internet Res* 2011;**13**(4):e125.
115. European Commission. Health technology and cosmetics. Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC (MEDDEV 2.7/1 revision 4). Brussels: European Commission; 2016.
116. International Standardization Organization. Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155). Geneva, Switzerland; 2020.
117. Bennett SJ, Puntenney PJ, Walker NL, Ashley ND. Development of an instrument to measure threat related to cardiac events. *Nurs Res* 1996;**45**(5):266-70.
118. Währborg P, Emanuelsson H. The cardiac health profile: content, reliability and validity of a new disease-specific quality of life questionnaire. *Coron Artery Dis* 1996;**7**(11):823-9.
119. Mithal M, Granger CV, Naughton JP, Haberl ED, Jones JD. Measuring Functional Status and Health-Related Quality of Life in Patients Participating in an Outpatient Phase II Cardiac Rehabilitation Program. *Crit Rev Phys Rehabil Med* 2007;**19**(2):153-167.
120. Avis NE, Smith KW, Hambleton RK, Feldman HA, Selwyn A, Jacobs A. Development of the multidimensional index of life quality. A quality of life measure for cardiovascular disease. *Med Care* 1996;**34**(11):1102-1120.
121. Ferrans CE, Powers MJ. Quality of life index: development and psychometric properties. *ANS Adv.Nurs Sci.* 1985;**8**(1):15-24.
122. Hlatky MA, Boineau RE, Higginbotham MB, Lee KL, Mark DB, Califf RM, *et al.* A brief self-administered questionnaire to determine functional capacity (the Duke Activity Status Index). *Am J Cardiol* 1989;**64**(10):651-4.
123. Goldman L, Hashimoto B, Cook EF, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. *Circulation* 1981;**64**(6):1227-34.
124. Eifert GH, Thompson RN, Zvolensky MJ, Edwards K, Frazer NL, Haddad JW, *et al.* The cardiac anxiety questionnaire: development and preliminary validity. *Behav Res Ther* 2000;**38**(10):1039-53.
125. Hare DL, Davis CR. Cardiac Depression Scale: validation of a new depression scale for cardiac patients. *J Psychosom Res* 1996;**40**(4):379-86.
126. Jackson A, Rogerson M, Le Grande M, Thompson D, Ski C, Alvarenga M, *et al.* Protocol for the development and validation of a measure of persistent psychological and emotional distress in cardiac patients: the Cardiac Distress Inventory. *BMJ Open* 2020;**10**(6):e034946.
127. Wood KA, Stewart AL, Drew BJ, Scheinman MM, Froelicher ES. Development and initial psychometric evaluation of the Patient Perspective of Arrhythmia Questionnaire. *Res Nurs Health* 2009;**32**(5):504-16.
128. Härdén M, Nyström B, Kulich K, Carlsson J, Bengtson A, Edvardsson N. Validity and reliability of a new, short symptom rating scale in patients with persistent atrial fibrillation. *Health Qual Life Outcomes* 2009;**7**:65.

129. Härdén M, Nyström B, Bengtson A, Medin J, Frison L, Edvardsson N. Responsiveness of AF6, a new, short, validated, atrial fibrillation-specific questionnaire--symptomatic benefit of direct current cardioversion. *J Interv Card Electrophysiol* 2010;**28**(3):185-91.
130. Coyne KS, Edvardsson N, Rydén A. Development and Validation of the AFImpact: An Atrial Fibrillation-Specific Measure of Patient-Reported Health-Related Quality of Life. *Value Health* 2017;**20**(10):1355-1361.
131. Badia X, Arribas F, Ormaetxe JM, Peinado R, de Los Terreros MS. Development of a questionnaire to measure health-related quality of life (HRQoL) in patients with atrial fibrillation (AF-QoL). *Health Qual Life Outcomes* 2007;**5**:37.
132. Spertus J, Dorian P, Bubien R, Lewis S, Godejohn D, Reynolds MR, *et al.* Development and validation of the Atrial Fibrillation Effect on Quality-of-Life (AFEQT) Questionnaire in patients with atrial fibrillation. *Circ Arrhythm Electrophysiol* 2011;**4**(1):15-25.
133. Yamashita T, Kumagai K, Koretsune Y, Mitamura H, Okumura K, Ogawa S, *et al.* [A new method for evaluating quality of life specific to patients with atrial fibrillation : Atrial fibrillation quality of life questionnaire (AFQLQ)]. *Japanese Journal of Electrocardiology* 2003;**23**(4):332-343.
134. Braganca EO, Filho BL, Maria VH, Levy D, de Paola AA. Validating a new quality of life questionnaire for atrial fibrillation patients. *Int J Cardiol* 2010;**143**(3):391-8.
135. Maglio C, Sra J, Paquette M, Dorian P, Bygrave A, Wood KA, *et al.* Measuring quality of life and symptom severity in patients with atrial fibrillation. *Pacing Clin Electrophysiol* 1998;**21**(4):839.
136. White J, Withers KL, Lencioni M, Carolan-Rees G, Wilkes AR, Wood KA, *et al.* Cardiff cardiac ablation patient-reported outcome measure (C-CAP): validation of a new questionnaire set for patients undergoing catheter ablation for cardiac arrhythmias in the UK. *Qual Life Res* 2016;**25**(6):1571-83.
137. Withers KL, White J, Carolan-Rees G, Patrick H, O'Callaghan P, Murray S, *et al.* Patient reported outcome measures for cardiac ablation procedures: a multicentre pilot to develop a new questionnaire. *Europace* 2014;**16**(11):1626-33.
138. Walfridsson U, Arestedt K, Stromberg A. Development and validation of a new Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA) with focus on symptom burden. *Health Qual Life Outcomes* 2012;**10**:44.
139. Kesek M, Tollefsen T, Höglund N, Rönn F, Näslund U, Jensen SM. U22, a protocol to quantify symptoms associated with supraventricular tachycardia. *Pacing Clin Electrophysiol* 2009;**32 Suppl 1**:S105-8.
140. Dorian P, Guerra PG, Kerr CR, O'Donnell SS, Crystal E, Gillis AM, *et al.* Validation of a new simple scale to measure symptoms in atrial fibrillation: the Canadian Cardiovascular Society Severity in Atrial Fibrillation scale. *Circ Arrhythm Electrophysiol* 2009;**2**(3):218-24.
141. Wokhlu A, Hodge DO, Monahan K, Haroldson J, Wock KJ, Asirvatham SJ, *et al.* Unique AF-Specific Symptom Score Assesses Long-Term Symptom Relief After Ablation. *Circulation* 2008;**118**(Suppl 18):S589.
142. Bubien RS, Knotts-Dolson SM, Plumb VJ, Kay GN. Effect of radiofrequency catheter ablation on health-related quality of life and activities of daily living in patients with recurrent arrhythmias. *Circulation* 1996;**94**(7):1585-91.
143. Xu W, Sun G, Lin Z, Chen M, Yang B, Chen H, *et al.* Knowledge, attitude, and behavior in patients with atrial fibrillation undergoing radiofrequency catheter ablation. *J Interv Card Electrophysiol* 2010;**28**(3):199-207.
144. McCabe PJ, Schad S, Hampton A, Holland DE. Knowledge and self-management behaviors of patients with recently detected atrial fibrillation. *Heart Lung* 2008;**37**(2):79-90.
145. Ruiz Díaz MA, Egea García M, Muñoz Aguilera R, Viñolas Prat X, Silvestre García J, Álvarez Orozco M, *et al.* Patient satisfaction with remote monitoring of cardiac implantable electronic devices: the VALIOSA questionnaire. *BMC Health Serv Res* 2020;**20**(1):354.
146. Bratt A, Allvin R, Wann-Hansson C. Modifying a generic postoperative recovery profile instrument to an instrument specifically targeting coronary artery bypass grafting. *Scand J Caring Sci* 2017;**31**(3):475-486.

147. Schroter S, Lamping DL. Coronary revascularisation outcome questionnaire (CROQ): development and validation of a new, patient based measure of outcome in coronary bypass surgery and angioplasty. *Heart* 2004;**90**(12):1460-6.
148. Marquis P, Fayol C, Joire JE. Clinical validation of a quality of life questionnaire in angina pectoris patients. *Eur Heart J* 1995;**16**(11):1554-60.
149. Lewin RJ, Thompson DR, Martin CR, Stuckey N, Devlen J, Michaelson S, *et al.* Validation of the Cardiovascular Limitations and Symptoms Profile (CLASP) in chronic stable angina. *J Cardiopulm Rehabil* 2002;**22**(3):184-91.
150. Denollet J. Health complaints and outcome assessment in coronary heart disease. *Psychosom Med* 1994;**56**(5):463-74.
151. Oldridge N, Höfer S, McGee H, Conroy R, Doyle F, Saner H. The HeartQoL: Part I. Development of a new core health-related quality of life questionnaire for patients with ischemic heart disease. *Eur J Prev Cardiol* 2014;**21**(1):90-7.
152. Oldridge N, Höfer S, McGee H, Conroy R, Doyle F, Saner H. The HeartQoL: part II. Validation of a new core health-related quality of life questionnaire for patients with ischemic heart disease. *Eur J Prev Cardiol* 2014;**21**(1):98-106.
153. Rukholm E, McGirr M. A quality-of-life index for clients with ischemic heart disease: establishing reliability and validity. *Rehabil Nurs* 1994;**19**(1):12-6.
154. Wan C, Li H, Fan X, Yang R, Pan J, Chen W, *et al.* Development and validation of the coronary heart disease scale under the system of quality of life instruments for chronic diseases QLICD-CHD: combinations of classical test theory and Generalizability Theory. *Health Qual Life Outcomes* 2014;**12**:82.
155. Spertus JA, Winder JA, Dewhurst TA, Deyo RA, Prodzinski J, McDonell M, *et al.* Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease. *J Am Coll Cardiol* 1995;**25**(2):333-41.
156. Chan PS, Jones PG, Arnold SA, Spertus JA. Development and validation of a short version of the Seattle angina questionnaire. *Circ Cardiovasc Qual Outcomes* 2014;**7**(5):640-7.
157. Wilson A, Wiklund I, Lahti T, Wahl M. A summary index for the assessment of quality of life in angina pectoris. *J Clin Epidemiol* 1991;**44**(9):981-8.
158. Valenti L, Lim L, Heller RF, Knapp J. An improved questionnaire for assessing quality of life after acute myocardial infarction. *Qual Life Res* 1996;**5**(1):151-61.
159. Hillers TK, Guyatt GH, Oldridge N, Crowe J, Willan A, Griffith L, *et al.* Quality of life after myocardial infarction. *J Clin Epidemiol* 1994;**47**(11):1287-96.
160. Miller KH, Grindel CG. Comparison of symptoms of younger and older patients undergoing coronary artery bypass surgery. *Clin Nurs Res* 2004;**13**(3):179-93; discussion 194-8.
161. Nieveen JL, Zimmerman LM, Barnason SA, Yates BC. Development and content validity testing of the Cardiac Symptom Survey in patients after coronary artery bypass grafting. *Heart Lung* 2008;**37**(1):17-27.
162. LaPier TK, Chunkwon J. Development and content validity of the heart surgery symptom inventory. *Acute Care Perspect* 2002;**11**:5-12.
163. Jenkins CD, Jono RT, Stanton BA, Stroup-Benham CA. The measurement of health-related quality of life: major dimensions identified by factor analysis. *Soc Sci Med* 1990;**31**(8):925-31.
164. Artinian NT, Duggan C, Miller P. Age differences in patient recovery patterns following coronary artery bypass surgery. *Am J Crit Care* 1993;**2**(6):453-61.
165. Plach SK, Heidrich SM. Women's perceptions of their social roles after heart surgery and coronary angioplasty. *Heart Lung* 2001;**30**(2):117-27.
166. Devon HA, Rosenfeld A, Steffen AD, Daya M. Sensitivity, specificity, and sex differences in symptoms reported on the 13-item acute coronary syndrome checklist. *J Am Heart Assoc* 2014;**3**(2):e000586.
167. McSweeney JC, O'Sullivan P, Cody M, Crane PB. Development of the McSweeney Acute and Prodromal Myocardial Infarction Symptom Survey. *J Cardiovasc Nurs* 2004;**19**(1):58-67.

168. DeVon HA, Ryan CJ, Ochs AL, Shapiro M. Symptoms across the continuum of acute coronary syndromes: differences between women and men. *Am J Crit Care* 2008;**17**(1):14-24; quiz 25.
169. Keresztes P, Holm K, Penckofer S, Merritt S. Measurement of functional ability in patients with coronary artery disease. *J Nurs Meas* 1993;**1**(1):19-28.
170. Lawlor DA, Adamson J, Ebrahim S. Performance of the WHO Rose angina questionnaire in post-menopausal women: are all of the questions necessary? *J Epidemiol Community Health* 2003;**57**(7):538-41.
171. Lerner DJ, Amick BC, 3rd, Malspeis S, Rogers WH, Gomes DR, Salem DN. The Angina-related Limitations at Work Questionnaire. *Qual Life Res* 1998;**7**(1):23-32.
172. Cedars AM, Ko JM, John AS, Vittengl J, Stefanescu-Schmidt AC, Jarrett RB, *et al.* Development of a Novel Adult Congenital Heart Disease-Specific Patient-Reported Outcome Metric. *J Am Heart Assoc* 2020;**9**(11):e015730.
173. Kamphuis M, Zwinderman KH, Vogels T, Vliegen HW, Kamphuis RP, Ottenkamp J, *et al.* A cardiac-specific health-related quality of life module for young adults with congenital heart disease: Development and validation. *Quality of Life Research* 2004;**13**:735-745.
174. Uzark K, Jones K, Burwinkle TM, Varni JW. The Pediatric Quality of Life Inventory in children with heart disease. *Prog Ped Cardiol* 2003;**18** 141-148.
175. Marino BS, Shera D, Wernovsky G, Tomlinson RS, Aguirre A, Gallagher M, *et al.* The development of the pediatric cardiac quality of life inventory: a quality of life measure for children and adolescents with heart disease. *Qual Life Res* 2008;**17**(4):613-26.
176. McCrindle BW, Williams RV, Mital S, Clark BJ, Russell JL, Klein G, *et al.* Physical activity levels in children and adolescents are reduced after the Fontan procedure, independent of exercise capacity, and are associated with lower perceived general health. *Arch Dis Child* 2007;**92**(6):509-14.
177. Macran S, Birks Y, Parsons J, Sloper P, Hardman G, Kind P, *et al.* The development of a new measure of quality of life for children with congenital cardiac disease. *Cardiol Young* 2006;**16**(2):165-72.
178. Mannheimer B, Andersson B, Carlsson L, Währborg P. The validation of a new quality of life questionnaire for patients with congestive heart failure-an extension of the Cardiac Health Profile. *Scand Cardiovasc J* 2007;**41**(4):235-41.
179. van Kessel P, de Boer D, Hendriks M, Plass AM. Measuring patient outcomes in chronic heart failure: psychometric properties of the Care-Related Quality of Life survey for Chronic Heart Failure (CaReQoL CHF). *BMC Health Serv Res* 2017;**17**(1):536.
180. Dunderdale K, Thompson DR, Beer SF, Furze G, Miles JN. Development and validation of a patient-centered health-related quality-of-life measure: the chronic heart failure assessment tool. *J Cardiovasc Nurs* 2008;**23**(4):364-70.
181. Tian J, Zhao J, Zhang Q, Ren J, Han L, Li J, *et al.* Assessment of chronic disease self-management in patients with chronic heart failure based on the MCID of patient-reported outcomes by the multilevel model. *BMC Cardiovasc Disord* 2021;**21**(1):58.
182. Guyatt GH, Nogradi S, Halcrow S, Singer J, Sullivan MJ, Fallen EL. Development and testing of a new measure of health status for clinical trials in heart failure. *J Gen Intern Med* 1989;**4**(2):101-7.
183. Moshkovich O, Benjamin K, Hall K, Murphy R, von Maltzahn R, Gorsh B, *et al.* Development of a conceptual model and patient-reported outcome measures for assessing symptoms and functioning in patients with heart failure. *Qual Life Res* 2020;**29**(10):2835-2848.
184. Grady KL, Jalowiec A, Grusk BB, White-Williams C, Robinson JA. Symptom distress in cardiac transplant candidates. *Heart Lung* 1992;**21**(5):434-9.
185. Green CP, Porter CB, Bresnahan DR, Spertus JA. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. *J Am Coll Cardiol* 2000;**35**(5):1245-55.
186. Ahmad Hisham S, Hashim R, Putri W, Jamil N, Latiff A. Development & Validation of a Bilingual Psychometric Instrument for Assessment of Knowledge, Attitude, Self-care Practice and Health-related Quality of Life (KAPQHF) among Heart Failure Patients. *Journal of Cardiovascular Disease Research* 2020;**11**:04-11.

187. O'Leary CJ, Jones PW. The left ventricular dysfunction questionnaire (LVD-36): reliability, validity, and responsiveness. *Heart* 2000;**83**(6):634-40.
188. Fadol A, Mendoza T, Gning I, Kernicki J, Symes L, Cleeland CS, *et al.* Psychometric testing of the MDASI-HF: a symptom assessment instrument for patients with cancer and concurrent heart failure. *J Card Fail* 2008;**14**(6):497-507.
189. Ahmad FS, Kallen MA, Schifferdecker KE, Carluzzo KL, Yount SE, Gelow JM, *et al.* Development and Initial Validation of the PROMIS®-Plus-HF Profile Measure. *Circ Heart Fail* 2019;**12**(6):e005751.
190. Wiklund I, Lindvall K, Swedberg K, Zupkis RV. Self-assessment of quality of life in severe heart failure. An instrument for clinical use. *Scand J Psychol* 1987;**28**(3):220-5.
191. Spertus JA, Jones PG. Development and Validation of a Short Version of the Kansas City Cardiomyopathy Questionnaire. *Circ Cardiovasc Qual Outcomes* 2015;**8**(5):469-76.
192. Fu TC, Lin YC, Chang CM, Chou WL, Yuan PH, Liu MH, *et al.* Validation of a new simple scale to measure symptoms in heart failure from traditional Chinese medicine view: a cross-sectional questionnaire study. *BMC Complement Altern Med* 2016;**16**(1):342.
193. Jalowiec A, Grady KL, White-Williams C. Stressors in patients awaiting a heart transplant. *Behav Med* 1994;**19**(4):145-54.
194. Grady KL, Jalowiec A, White-Williams C. Patient compliance at one year and two years after heart transplantation. *J Heart Lung Transplant* 1998;**17**(4):383-94.
195. de Jeu JH, Pedersen SS, Balk AH, van Domburg RT, Vantrimpont PJ, Erdman RA. Development of the Rotterdam Quality of Life Questionnaire for Heart Transplant Recipients. *Neth Heart J* 2003;**11**(7-8):289-293.
196. Grady KL, Meyer P, Mattea A, White-Williams C, Ormaza S, Kaan A, *et al.* Improvement in quality of life outcomes 2 weeks after left ventricular assist device implantation. *J Heart Lung Transplant* 2001;**20**(6):657-69.
197. Sandau KE, Lee CS, Faulkner KM, Pozehl B, Eckman P, Garberich R, *et al.* Health-Related Quality of Life in Patients With a Left Ventricular Assist Device (QOLVAD) Questionnaire: Initial Psychometrics of a New Instrument. *J Cardiovasc Nurs* 2021;**36**(2):172-184.
198. Jurgens CY, Fain JA, Riegel B. Psychometric testing of the heart failure somatic awareness scale. *J Cardiovasc Nurs* 2006;**21**(2):95-102.
199. Jurgens CY, Lee CS, Riegel B. Psychometric Analysis of the Heart Failure Somatic Perception Scale as a Measure of Patient Symptom Perception. *J Cardiovasc Nurs* 2017;**32**(2):140-147.
200. Zambroski CH, Moser DK, Bhat G, Ziegler C. Impact of symptom prevalence and symptom burden on quality of life in patients with heart failure. *Eur J Cardiovasc Nurs* 2005;**4**(3):198-206.
201. Shabetai R. Cardiomyopathy: How far have we come in 25 years, how far yet to go? *Journal of the American College of Cardiology* 1983;**1**(1):252-263.
202. Friedman MM. Gender differences in the health related quality of life of older adults with heart failure. *Heart Lung* 2003;**32**(5):320-7.
203. Heo S, Moser DK, Pressler SJ, Dunbar SB, Mudd-Martin G, Lennie TA. Psychometric properties of the Symptom Status Questionnaire-Heart Failure. *J Cardiovasc Nurs* 2015;**30**(2):136-44.
204. Dracup K, Walden JA, Stevenson LW, Brecht ML. Quality of life in patients with advanced heart failure. *J Heart Lung Transplant* 1992;**11**(2 Pt 1):273-9.
205. Jaarsma T, Strömberg A, Mårtensson J, Dracup K. Development and testing of the European Heart Failure Self-Care Behaviour Scale. *Eur J Heart Fail* 2003;**5**(3):363-70.
206. Jaarsma T, Arestedt KF, Mårtensson J, Dracup K, Strömberg A. The European Heart Failure Self-care Behaviour scale revised into a nine-item scale (EHFScB-9): a reliable and valid international instrument. *Eur J Heart Fail* 2009;**11**(1):99-105.
207. Köberich S, Kato NP, Kugler C, Strömberg A, Jaarsma T. Methodological quality of studies assessing validity and reliability of the European Heart Failure Self-care Behaviour Scale: a systematic review using the COSMIN methodology. *Eur J Cardiovasc Nurs* 2021;**20**(5):501-512.
208. Hattori Y, Taru C, Miyawaki I. Development of an evaluation scale for self-monitoring by patients with heart failure. *Kobe J Med Sci* 2011;**57**(2):E63-74.

209. Riegel B, Carlson B, Moser DK, Sebern M, Hicks FD, Roland V. Psychometric testing of the self-care of heart failure index. *J Card Fail* 2004;**10**(4):350-60.
210. White ML, Schim SM. Development of a spiritual self-care practice scale. *J Nurs Meas* 2013;**21**(3):450-62.
211. Padilha KM, Gallani MC, Colombo RC. Validity of an instrument to measure the impact of valve heart disease on the patient's daily life. *J Clin Nurs* 2007;**16**(7):1285-91.
212. Frank D, Kennon S, Bonaros N, Romano M, Lefèvre T, Di Mario C, *et al.* Trial protocol for the validation of the 'Toronto Aortic Stenosis Quality of Life (TASQ) Questionnaire' in patients undergoing surgical aortic valve replacement (SAVR) or transfemoral (TF) transcatheter aortic valve implantation (TAVI): the TASQ registry. *Open Heart* 2019;**6**(1):e001008.
213. Rose MS, Koshman ML, Ritchie D, Sheldon R. The development and preliminary validation of a scale measuring the impact of syncope on quality of life. *Europace* 2009;**11**(10):1369-74.
214. Kaufmann H, Malamut R, Norcliffe-Kaufmann L, Rosa K, Freeman R. The Orthostatic Hypotension Questionnaire (OHQ): validation of a novel symptom assessment scale. *Clin Auton Res* 2012;**22**(2):79-90.
215. Wan C, Jiang R, Tu XM, Tang W, Pan J, Yang R, *et al.* The hypertension scale of the system of Quality of Life Instruments for Chronic Diseases, QLICD-HY: a development and validation study. *Int J Nurs Stud* 2012;**49**(4):465-80.
216. Kim MT, Hill MN, Bone LR, Levine DM. Development and testing of the Hill-Bone Compliance to High Blood Pressure Therapy Scale. *Prog Cardiovasc Nurs* 2000;**15**(3):90-6.
217. Ma C, Chen S, You L, Luo Z, Xing C. Development and psychometric evaluation of the Treatment Adherence Questionnaire for Patients with Hypertension. *J Adv Nurs* 2012;**68**(6):1402-1413.
218. He W, Bonner A, Anderson D. Patient reported adherence to hypertension treatment: A revalidation study. *Eur J Cardiovasc Nurs* 2016;**15**(2):150-156.
219. Han HR, Lee H, Commodore-Mensah Y, Kim M. Development and validation of the Hypertension Self-care Profile: a practical tool to measure hypertension self-care. *J Cardiovasc Nurs* 2014;**29**(3):E11-20.

Box 1: Optimal practice and future directions for the use of patient-reported outcomes (PROs)

PROs in clinical/shared decision-making

- Clinicians should familiarize themselves or be educated about what PROs are, how they can be used and how to interpret the data.
- The measurement of PROs is to be integrated into standard clinical practice (i) to benchmark individual patients with the population and (ii) to assess within-person evolutions to evaluate the effectiveness of treatment and patient management
- PROMs should be adapted such that patients can indicate the relative importance of each PRO to make PROs preference-sensitive.
- Healthcare professionals should give feedback to patients on their PRO scores. The use of PROMs can enhance patients' understanding and improve their health behaviours.
- When communicating PRO scores with patients, the use of visual analogies is advocated, because most people have limited experience of interpreting graphs.
- Managers and administrators need to provide the time, personnel, financial resources and digital infrastructure to clinicians to allow them to implement evidence-based (validated) PRO assessments.
- PROs should be included among methods used to inform the development and evaluate the effectiveness of population health programmes.

PROs in quality monitoring and improvement

- Quality of care assessment should include PRO-based performance measures, which ought to be risk-adjusted.
- Professional guidelines, such as those of the ESC, should encompass a description of which PROMs and PREMs could be used to assess the performance of, and/or the adherence to, their recommendations.
- For cardiac clinical registries, international consensus should be reached about which generic and disease-specific PROMs and PREMs to include for each cardiac condition.

PROs in clinical trials

- PRO endpoints should be decided *a priori* and included in the ethical review and the trial registration.
- Trial committees should have PRO expertise.
- Patients should be involved in selecting suitable PRO instruments.
- Guidance for the use, analysis, and interpretation of PROs in clinical trials should be developed.
- Recommendations for designing, analysing and reporting PRO findings should be used (e.g. SPIRIT-PRO; CONSORT-PRO).
- PRO Alerts are advised to capture issues that require prompt intervention.

PROs for regulatory purposes

- Minimal requirements for PROMs suitable for regulatory purposes should be developed.
- Minimal clinically important differences (MCID) should be determined for all PROMs that are (to be) used for regulatory purposes.

- Existing EU guidance on the clinical evaluation of medical devices¹¹⁵ and the recommendations from the International Standardization Organization¹¹⁶ should be revised to include specific advice concerning PROs.

PROs for reimbursement and health economics purposes

- The use of a broad range of PROs (i.e. functional status, symptoms, activities of daily living, empowerment) in informing reimbursement decisions should be further evaluated.
- Consensus has to be reached among patients, clinicians and decision-makers on choosing the appropriate PROMs.
- Reimbursements based on PROs should account for risk adjustments and case mixes.
- Health Technology Assessment (HTA) should consider both generic and disease-specific measures, in order to allow comparisons across conditions as well as to capture specificities of a particular disease.
- International consensus on adequate data gathering methods ought to be reached to promote integrated PRO assessment in health decision-making across countries.

PROs in digital healthcare

- A good information governance and digital infrastructure needs to be in place to allow the use of ePROs.
- Computer Adaptive Testing (CAT) should be implemented to reduce the response burden and produce optimal tests.
- The digital literacy of patients has to be evaluated, to avoid that the digital transformation is increasing health inequalities and inequity in society.
- Clinicians need to be trained on how to interpret and apply ePRO data, allowing time in the workflow (and if necessary, reimbursement) to maximise the value of this added layer of information and insight.
- PROMs should be integrated in electronic health records.

CAT: Computer Adaptive Testing; HTA: Health Technology Assessment; PRO: Patient-Reported Outcomes; PROMs: Patient-Reported Outcome Measures; PREMs: Patient-Reported Experience Measures; PRIMs: Patient-Reported Importance Measures.

Figure legends

Graphical abstract:

The importance of patient-reported outcomes (PROs), their components, and their potential contributions in cardiology

Figure 1: Effective healthcare improves both clinical and patient-reported outcomes

Figure 2: Components of patient-reported outcomes and their measures

Figure 3: Benefits of the use of patient-reported outcomes in clinical practice

Figure 1: Effective healthcare improves both clinical and patient-reported outcomes

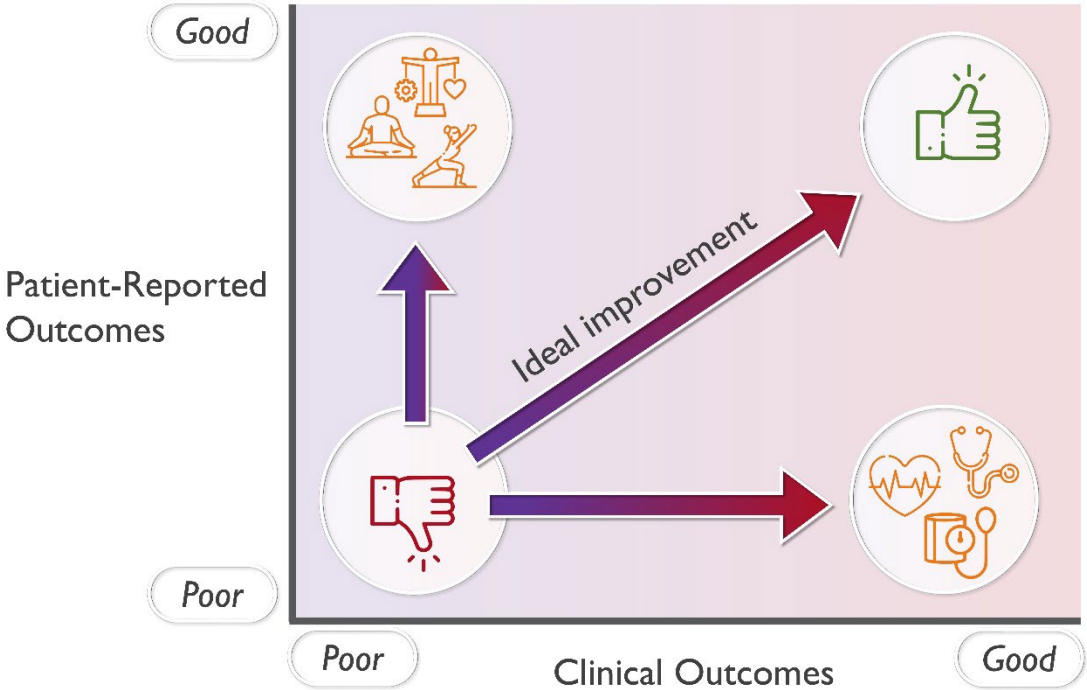


Figure 2: Components of Patient-Reported Outcomes and their measures

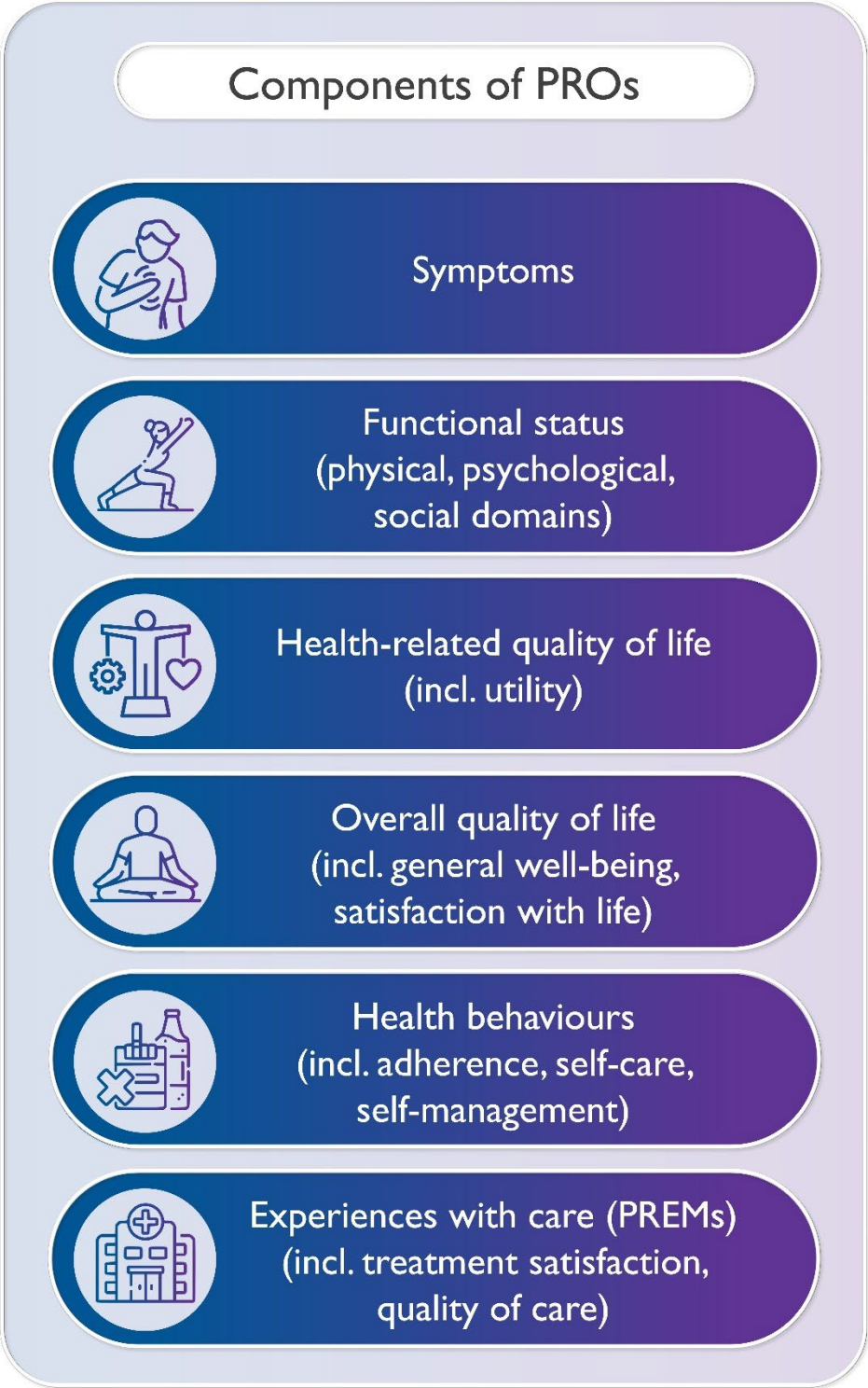


Figure 3: Benefits of the use of patient-reported outcomes in clinical practice

