*Using **PROMS** in **cardiovascular research** and to assess the **quality of care***

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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

Philip Moons [1,2,3]*, Tone M. Norekvål [4,5], Elena Arbelo [6,7,8], Britt Borregaard [9,10], Barbara Casadei [11,12], Bernard Cosyns [13], Martin R. Cowie [14], Donna Fitzsimons [15], Alan G. Fraser [16], Tiny Jaarsma [17,18], Paulus Kirchhof [19,20,21], Josepa Mauri [22], Richard Mindham [23], Julie Sanders [24,25], Francois Schiele [26], Aleksandra Torbica [27], and Ann Dorthe Zwisler [9,28,29]

Patient-Reported Outcomes (PROs) in cardiovascular clinical practice: Implications for quality of care and management

Components of PROs

Symptoms

Functional status (physical, psychological, social domains)

Health-related quality of life (incl. utility)

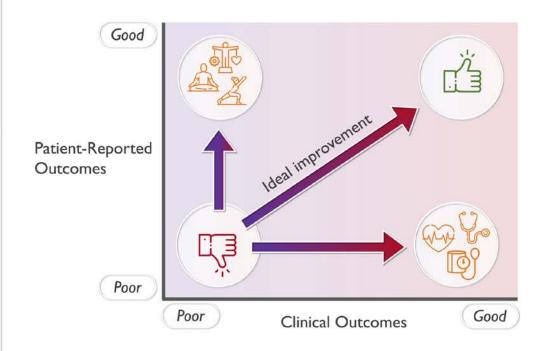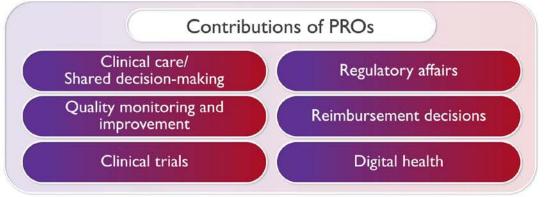Overall quality of life (incl. general well-being, satisfaction with life)

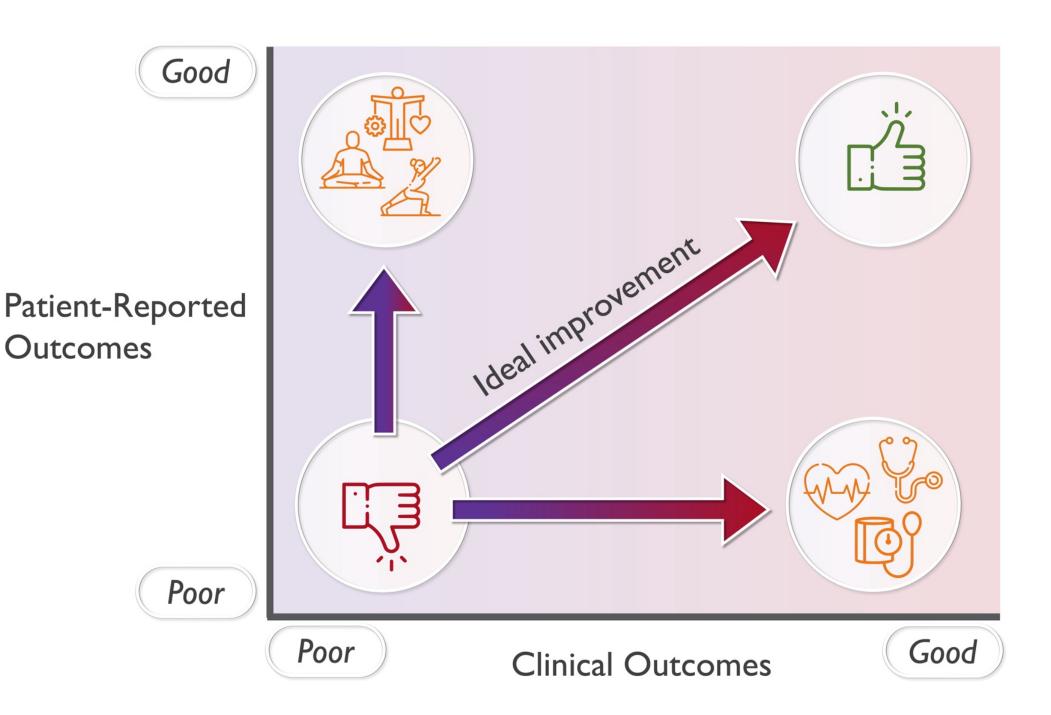Health behaviours (incl. adherence, self-care, self-management)

Experiences with care (PREMs) (incl. treatment satisfaction, quality of care)

Effective healthcare improves both clinical and patient-reported outcomes

Good

Patient-Reported Outcomes

Ideal improvement

Poor

Poor — Clinical Outcomes — Good

Contributions of PROs

Clinical care/ Shared decision-making

Regulatory affairs

Quality monitoring and improvement

Reimbursement decisions

Clinical trials

Digital health

Components of PROs

- Symptoms

- Functional status (physical, psychological, social domains)

- Health-related quality of life (incl. utility)

- Overall quality of life (incl. general well-being, satisfaction with life)

- Health behaviours (incl. adherence, self-care, self-management)

- Experiences with care (PREMs) (incl. treatment satisfaction, quality of care)

Contributions of PROs

Clinical care/
Shared decision-making

Regulatory affairs

Quality monitoring and
improvement

Reimbursement decisions

Clinical trials

Digital health

102 *instruments*

Table 1 Disease-specific PROMs (multidimensional or domain-specific) developed for cardiovascular patient populations

Name	Domain	Developed for	Level of support
Cardiac patients			
Cardiac Event Threat Questionnaire (CTQ)[31]	Multidimensional	Cardiac patients	/
Cardiac Health Profile (CHP)[32]	Multidimensional	Cardiac patients	−[33]
LifeWare Cardiac Assessment Index (LIFEWARE CAI)[34]	Multidimensional	Cardiac patients	−[33]
Multidimensional Index of Life Quality (MILQ)[35]	Multidimensional	Cardiac patients	+[33]
Quality of Life Index-Cardiac Version (QLI-CV)[36]	Multidimensional	Cardiac patients	−[33]
Duke Activity Status Index (DASI)[37]	Physical functioning	Cardiac patients	/
Specific Activity Scale[38]	Physical functioning	Cardiac patients	/
Cardiac anxiety questionnaire[39]	Anxiety	Cardiac patients	/
Cardiac Depression Scale (CDS)[40]	Depression	Cardiac patients	/
Cardiac distress inventory[41]	Psychological functioning	Cardiac patients	/
Arrhythmias and electrophysiology			

Name	Domain	Developed for	Level of support
University of Toronto Atrial Fibrillation Severity Scale (AFSS)[53]	Multidimensional	Atrial fibrillation	−[46,51]
Cardiff Cardiac Ablation PROM (C-CAP)[54,55]	Multidimensional	Pre- and post-ablation	/
Arrhythmia-Specific questionnaire in Tachycardia and Arrhythmia (ASTA)[56]	Symptoms	Arrhythmias	−[33,46,51]
Umeå 22 Arrhythmia Questions (U22)[57]	Symptoms	Arrhythmias	−[46]
Canadian Cardiovascular Society-Severity of Atrial Fibrillation (CCS-SAF)[58]	Symptoms	Atrial fibrillation	−[46]
Mayo Atrial Fibrillation-Specific Symptom Inventory (MAFSI)[59]	Symptoms	Atrial fibrillation	−[46]
Symptom Checklist—Frequency and Severity Scale (SCL) aka Toronto AF Symptoms Check List[60]	Symptoms	Atrial fibrillation	−[51]
Knowledge, Attitude, and Behaviour questionnaire to patients with Atrial Fibrillation undergoing Radiofrequency Catheter Ablation[61]	Self-management	Atrial fibrillation	/
Knowledge and self-management tool[62]	Self-management	Atrial fibrillation	/
VALIOSA (Satisfaction with remote cardiac monitoring)[63]	Experience with care	Implanted cardiac devices	/
Modified Postoperative Recovery Profile questionnaire re (PRP-CABG)[64]	Multidimensional	CABG	/
Coronary Revascularisation Outcome Questionnaire (CROQ)[65]	Multidimensional	CABG or PTCA	+[33]
Angina Pectoris Quality of Life Questionnaire (APQLQ)[66]	Multidimensional	Ischaemic heart disease	+[33]
Cardiovascular Limitations and Symptoms Profile (CLASP)[67]	Multidimensional	Ischaemic heart disease	+[33]
Health Complaints Scale (HCS)[68]	Multidimensional	Ischaemic heart disease	−[33]
HeartQol[69,70]	Multidimensional	Ischaemic heart disease	+[33]
Quality of Life Index (QLI)[71]	Multidimensional	Ischaemic heart disease	/

Table 1 Continued

| Name | Domain | Developed for | Level of support |

Left Ventricular Dysfunction Questionnaire (LVD-36)[108]	Multidimensional	Heart failure	+[33,100,103]
MD Anderson Symptom Inventory e Heart Failure (MDASI-HF)[109]	Multidimensional	Heart failure	−[33]
Minnesota Living with Heart Failure (MLHF)[26]	Multidimensional	Heart failure	+[33,97,100,103]
Patient-Reported Outcomes Measurement Information System-Plus-Heart Failure (PROMIS-Plus-HF)[110]	Multidimensional	Heart failure	+[33]
Quality of Life Questionnaire in Severe Heart Failure (QLQ-SHF)[111]	Multidimensional	Heart failure	−[33,97,103]
Short version of the Kansas City Cardiomyopathy Questionnaire (KCCQ-12)[112]	Multidimensional	Heart failure	/
Traditional Chinese Medicine inquiry (TCM inquiry)[113]	Multidimensional	Heart failure	/
Heart Transplant Stressor Scale[114]	Multidimensional	Heart transplantation	/
Rating Question Form[115]	Multidimensional	Heart transplantation	/
Rotterdam Quality of Life Questionnaire[116]	Multidimensional	Heart transplantation	/
LVAD Stressor Scale (modified)[117]	Multidimensional	LVAD	/
Quality of Life with a Ventricular Assistive Device Questionnaire (QOLVAD)[118]	Multidimensional	LVAD	−[33]
Heart Failure Somatic Awareness Scale (HFSAS)[119]	Symptoms	Heart failure	−[33,46]
Heart Failure Somatic Perception Scale (HFSPS)[120]	Symptoms	Heart failure	−[46]
Memorial Symptom Assessment Scale-Heart Failure (MSAS-HF)[121]	Symptoms	Heart failure	−[33,46]
San Diego Heart Failure Questionnaire (SDHFQ)[122]	Symptoms	Heart failure	−[33,100]
Symptom Checklist (SCL)[123]	Symptoms	Heart failure	−[46]
Symptom Status Questionnaire—Heart Failure (SSQ-HF)[124]	Symptoms	Heart failure	−[46]
Heart Failure Functional Status Inventory (HFFSI)[125]	Symptoms; Functional capabilities	Heart failure	−[33,100]
European Heart Failure Self-care Behaviour Scale (EHFScBS)[126,127]	Self-care	Heart failure	+[128,129]
Evaluation Scale for Self-monitoring by Patients with Chronic Heart Failure	Self-care	Heart failure	−[128]

Instrument	Construct	Disease/population	Level of support
Heart Failure Functional Status Inventory (HFFSI)[125]	Symptoms; Functional capabilities	Heart failure	−[33,100]
European Heart Failure Self-care Behaviour Scale (EHFScBS)[126,127]	Self-care	Heart failure	+[128,129]
Evaluation Scale for Self-monitoring by Patients with Chronic Heart Failure (ESSMHF)[130]	Self-care	Heart failure	−[128]
Self-care of Heart Failure Index (SCHFI)[131]	Self-care	Heart failure	+[128]
Spiritual Self-care Practice Scale (SSCPS)[132]	Self-care	Heart failure	−[128]
Valvular diseases			
Heart Valve Disease Impact on daily life (IDCV)[133]	Multidimensional	Heart valve disease	−[33]
Toronto Aortic Stenosis Quality of Life Questionnaire (TASQ)[134]	Multidimensional	SAVR/TAVI	−[33]
Blood pressure			
Impact of Syncope on Quality of Life (ISQL)[135]	Multidimensional	Syncope	−[33]
Orthostatic Hypotension Questionnaire (OHQ)[136]	Multidimensional	Hypotension	+[33]
Quality of Life Instruments for Chronic Diseases—Hypertension (QLICH-HY)[137]	Multidimensional	Hypertension	
Hill-Bone Compliance Scale[138]	Medication adherence	Hypertension	−[139]
Treatment Adherence Questionnaire for Patients with Hypertension (TAQPH)[140]	Medication adherence	Hypertension	−[139]
Therapeutic Adherence Scale for Hypertensive Patients (TASHP)[141]	Medication adherence	Hypertension	−[139]
Hypertension Self-Care Profile (HBP SCP)[142]	Self-care	Hypertension	/

AF, Atrial Fibrillation; CABG, Coronary Artery Bypass Grafting; DS, domain-specific; ICD, Implantable Cardioverter Defibrillator; LVAD, Left Ventricular Assist Device; PTCA, Percutaneous Transluminal Coronary Angioplasty; SC, Single construct; SAVR, Surgical Aortic Valve Replacement; TAVI, Transcatheter Aortic Valve Implantation Level of support; /, psychometric properties not evaluated any systematic review; −, the cited systematic review indicated that none or only some of the psychometric properties of this instrument have met COSMIN standards; +, systematic review indicated support for most psychometric properties; ++, systematic review indicated support for all psychometric properties.

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 devices[218] and the recommendations from the International Standardization Organization[219] 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 need 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 maximize the value of this added layer of information and insight.
- PROMs should be integrated with 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.

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