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1 **Title:** Embracing the promise of Patient Reported Outcome Measures in cardiology

2

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20

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24 Over recent decades, progress in cardiology has tended to be technology driven and
25 evaluated by outcomes determined by clinicians. The advent of evidence-based medicine
26 has mandated the development of large-scale clinical trials in which treatment success is
27 evaluated according to endpoints which are clearly defined, easily measured and capable of
28 being assessed and applied in a defined population. However, the results of such trials have
29 historically concentrated on outcomes such as longevity of life and survival. These are easier
30 to quantify and have traditionally been prioritised over Patient Reported Outcome Measures
31 (PROMs). Whilst 'hard endpoints' remain important to patients, they need to be
32 supplemented by measures of quality of life, symptoms, and function - which, by their
33 nature, are more subjective and dependant on the individual patients perspective on the
34 impact of their illness.(1)

35

36 PROMs are self-reported, psychometrically validated tools that are used to quantify aspects
37 including well-being, health-related quality of life, comfort, activities of daily living and
38 symptoms from patients' perspective alone.(2) Some PROMs can be applied to a broad
39 range of cardiovascular disease populations for ease of use within clinical practice. Others
40 are disease specific to cater to the nuances attached to specific treatments(3). They offer a
41 mechanism for formally evaluating (and often enumerating) important aspects of lived
42 experiences with a health condition without interpretation by clinicians or others,(4) and
43 have wide applicability in routine care, quality monitoring and improvement, clinical trials,
44 regulatory affairs, reimbursement, and health economic evaluation.(3). Clinical trials have
45 shown that a poor health-related quality of life is significantly associated with future
46 cardiovascular events,(5) and incorporating the routine use of PROMs could help identify
47 patients that are at particular risk of an adverse clinical outcome. The routine use of PROMs

48 in clinical practice may promote shared decision making, and ultimately enhance patient
49 experience and satisfaction with the care that they receive.(6) In addition, analysis of the
50 data derived from correctly constructed PROMs in clinical trials may improve knowledge of
51 how decision making may be influenced factors such as age, culture, ethnicity,
52 socioeconomic status and employment.

53

54 Informed by a Global Cardiovascular Outcomes Consortium, we have recently set out a
55 comprehensive suite of clinician-determined clinical outcome measures that may be
56 evaluated in patients with a range of cardiovascular diseases.(7) This work was undertaken
57 to address an unmet need for consistent reporting of clinical outcome measures to improve
58 the quality and generalisability of research and the usefulness of registries in cardiology, in
59 order to improve outcomes for our patients.(1) Whilst these clinical outcomes are clearly
60 important, they are only part of the story: for some people, improvements in survival may
61 mean life-years gained with a limited quality of life.(8) Clinicians should listen to and
62 measure patient reported outcomes to understand how they live, to help us measure what
63 matters, align our clinical care with what is important to the patient and identify targets for
64 therapeutic interventions.

65

66 Despite this, in practice a clinical-based judgement concerning a patient's health-related
67 quality of life is often part of a clinician's decision on whether or not to offer potentially
68 lifesaving treatments. PRO tools are often not used in preference for clinician based clinical
69 assessments. For example, the clinician determined New York Heart Association score is
70 often used alongside ejection fraction to determine eligibility for implantable cardioverter
71 defibrillator and cardiac resynchronisation therapies instead of a validated heart failure

72 PROM.(9) Knowledge of the factors that may influence patient expectations, their
73 interpretation of the risks and benefits of treatment options and their ultimate long term
74 assessment of the success of health care interventions will help to individualise patient care.
75 This has been shown in other specialities, for example in oncology, where routine collection
76 and use of PROMs has been shown to enhance both clinician-patient interactions, increasing
77 clinician awareness of patients' symptoms, alongside improved symptom management with
78 concomitant improvements in patient well-being and satisfaction.(10, 11) However,
79 corresponding examples of the use of PROMS are lacking in cardiology. Despite this, an
80 increasing interest in patient-centred care has precipitated a proliferation in the
81 development of PROMs in cardiology, and there are now over one hundred instruments to
82 choose from.(3) To that end, the abundance of PROMs options presents a challenge for both
83 clinicians and researchers in selecting the most appropriate instrument. In addition to their
84 varying methodological robustness in terms of the psychometric properties, many have
85 logistical barriers such as licencing restrictions, cost to use, and many have only been
86 validated in one language.(12)

87

88 Although widely used in other specialties, the current PROMs landscape in cardiology is
89 complicated and esoteric. Selecting an instrument that is psychometrically valid, practical to
90 administer, and accessible to the patient population of interest is critical – and is not
91 straightforward. We propose, as a first step, the formulation of a checklist to evaluate the
92 logistical barriers to using PROMs in clinical practice. Supported by patient participants,
93 methodology experts, and the Global Cardiovascular Outcomes Consortium we must now
94 evaluate, synthesise, and prioritise PROMs to identify those that are most useful for
95 researchers and cardiologists across Europe. As we have done for 'hard outcomes', we will

96 present a menu of considerations for selecting appropriate PROMs to ensure that quality of

97 care outcomes includes patient-centred outcomes.

98

99

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