TITLE:

Developing an initial item bank for a new cardiac rehabilitation PROM

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ABSTRACT

Background: A Scotland-wide government scoping exercise identified the need for a new patient-reported outcome measure (PROM) suitable for the wide range of diagnostic groups now accessing cardiac rehabilitation (CR).

Aim: This paper describes the initial steps underpinning development of the item bank for a first draft tool (PROM-CR1).

Methods: A literature review of existing tools was undertaken to guide a qualitative data collection methodology involving 19 CR staff and 22 service users.

Results: Four conceptual ideas for health/quality of life were identified from the literature review: 'general health', 'physical', 'social' and 'psychological'. Three key qualitative themes, largely reflective of literature review findings, were identified: 'expectations and entitlement', 'adjustment and acceptance' and 'control and choice'.

Future Directions: These data will be combined to form PROM-CR1's initial item bank, which will be piloted with staff and service users and refined to generate a finalised tool (PROM-CR) for use in clinical practice.

Key Words: Patient-reported outcome measures, cardiac rehabilitation, quality of life

1.   INTRODUCTION

The Scottish Government's (2014) Heart Disease Improvement Plan advocated modernisation of cardiac rehabilitation (CR) services to meet its 2020 Vision: *"All patients with heart disease should be supported by CR to live longer, healthier and independent lives".* To facilitate the process, a Scotland-wide scoping exercise was undertaken (Divers, 2015), which found that CR services lack robust outcomes measures.

Patient-reported outcome measures (PROMs) provide validated evidence of health and quality of life (QoL), allowing service users to act as their own 'gold standard', and report upon outcomes that they consider important (Appleby and Devlin, 2010). As PROMs data predict mortality, cardiovascular events, hospitalisation, and cost of care, the scoping exercise recommended that the CR community should define a new PROM to help measure the health impact of rehabilitation (Divers, 2015).

Within the field, there are many different generic and disease-specific health and QoL assessment tools demonstrating varying degrees of validity, reliability and sensitivity (Thompson et al, 2016). None have been tested across the increasing diverse range of diagnostic groups now accessing CR.

Whilst generic PROMs allow comparisons between different medical conditions, they can be too broad to fully assess the impact of one particular illness, however disease-specific PROMs, although more sensitive, can miss broader aspects of a disease (Dempster and Donnelly, 2000). For comprehensive assessment, the current recommendation in CR is to use both a generic and a disease-specific tool, which is both time-consuming and burdensome for service users and clinicians (Thompson et al, 2016).

2.   AIM

The overall aim of this study was to develop a new CR PROM able to provide robust health status information across a range of cardiac diagnoses. This paper describes

the initial steps which underpin development of the item bank for the first draft tool (PROM-CR1).

3.   STUDY DESIGN

This paper describes the first two steps of a seven-step survey design process (Gehlbach et al, 2010). In step one, a literature review was undertaken to identify existing PROMs used within CR, to help establish the overall construct of PROM-CR1 and identify initial conceptual ideas of interest. To ensure a critical overview, psychometric properties of these tools were examined (Appleby and Devlin, 2010).

For step two, conceptual ideas identified from the literature review were used to guide a qualitative data collection methodology. Focus groups and individual semi-structured interviews were used to ascertain how CR staff and service users verbalise their perceptions of the impact of a cardiac diagnosis upon health and QoL. Focus groups were held first to allow group interactions to stimulate a breadth of comparable and contrasting perceptions (Morgan, 1997; Webb, 2002). These data were explored in more depth within semi-structured interviews, to obtain completeness of data (Morgan, 1997).

Future publications will describe steps three to seven. In steps three and four, qualitative data will be combined with literature review findings to establish PROM-CR1's conceptual framework and domains, and the construct indicators informing its initial bank of items. Steps five (expert validation), six (service user interpretation) and seven (piloting for validity and reliability) will describe refinement of a finalised version of the tool (PROM-CR) for use in clinical practice.

4.   STUDY LOCATION AND ETHICAL APPROVAL

The study was reviewed and approved by the West of Scotland Research Ethics Committee (WoS REC1) [REC ref.:15/WS/0151; IRAS project ID:184318], and Research and Development department within NHS Ayrshire and Arran.   All participants provided written, informed consent, and all procedures were undertaken within NHS Ayrshire and Arran between February and September 2016 by two

researchers: a main researcher (consultant physiotherapist with vast clinical and research experience within CR), and an assistant researcher (assistant psychologist working within the CR team). They formed a project steering group with a further four clinicians not directly involved in data collection: a cardiac nurse consultant, a cardiologist, a clinical psychologist and a senior nursing lecturer. The study conforms to principles outlined in the Declaration of Helsinki (World Medical Association, 1964).

5. STEP ONE – LITERATURE REVIEW

5.1 Methodology

A systematic search of the PubMed database was undertaken by the assistant researcher to identify generic and disease-specific PROMs used within CR using the following key words: "*health-related quality of life questionnaire*" AND "*heart*" OR "*heart disease*" OR "*cardiac" OR "cardiac rehabilitation"*. A second search of PubMed was undertaken to identify articles evaluating psychometric properties of the selected tools, using full and abbreviated names of the tools in combination with: "*psychometric properties*" OR "*validity*" OR "*reliability*" OR "*sensitivity*" OR *"development"* AND "*heart disease*" OR "*cardiac*" or "*heart*". The entire search methodology was replicated by the main researcher to ensure no key articles were omitted. All duplicates were removed.

To be included in the review, articles were required to meet the following criteria:
- Published in English
- Examining tools:
  - measuring more than one domain of health or QoL
  - tested in adults (aged ≥18years) with a cardiac diagnosis initiating CR referral (myocardial infarction [MI], cardiac surgery, percutaneous coronary intervention [PCI], stable angina pectoris [AP], arrhythmias, heart failure [HF], or implanted devices)

5.2   Results

As shown in **fig. 1a**, 14 tools (five generic and nine disease-specific) were identified. Characteristics, measurement domains and the diagnostic groups in which the tools have been tested are shown in **table 1**. As shown in **fig. 1b**, 54 articles examining the tools' psychometric properties were identified, and used by the assistant researcher to critique the tools against recognised criteria (Mackintosh et al, 2009). The process was verified by the main researcher. As shown in **table 2**, across the generic tools, the Medical Outcomes Short Form-36 [SF-36] (Ware and Sherbourne, 1992) met the criteria most closely; certainly, although complicated to score and analyse, the SF-36 is the recommended generic tool for use in CR (Thompson et al, 2016).

Within the disease-specific tools, there was variation across the criteria, and none demonstrated favourable evidence in relation to floor/ceiling effects. The MacNew Heart Disease Quality of Life Tool [MacNew] (Höfer et al, 2004), Kansas City Cardiomyopathy Questionnaire [KCCQ] (Green et al, 2000) and Minnesota Living with Heart Failure Questionnaire [MLHFQ] (Rector et al, 1987) demonstrated most favourable evidence. As the KCCQ and MLHFQ are designed for use in HF, and the MacNew has only been tested in those with a diagnosis of MI or AP, the appraisal confirmed the need for a new PROM which can be applied across a wider range of cardiac diagnoses.

The main and assistant researchers examined the conceptual ideas within the existing tools, for potential use in guiding the qualitative data collection methodology (**table 1**). They agreed that the most prevalent conceptual ideas ('general health', 'physical', 'social' and 'psychological') should be used as qualitative prompts, but to enable others to emerge, agreed to include an open prompt around 'other factors' influencing health and QoL.

6. STEP TWO – QUALITATIVE DATA COLLECTION

6.1 Methodology

6.1.1 Sample and Recruitment

6.1.1.1 Staff

By email, the main researcher invited all 61 clinicians and support staff within the cardiology managed clinical network (MCN) in Ayrshire to participate in the focus groups. Of the 17 who expressed interest, 15 were able to attend. Following the groups, a further four staff members from the MCN, purposefully identified to include a range of professions, were invited by the main researcher to participate in individual semi-structured interviews. All four agreed to take part.

6.1.1.2 Service Users

Within NHS Ayrshire and Arran, all CR service users are asked to verbally consent to being added to a CR database which may be accessed by clinicians for correspondence. In batches of 50, the main researcher identified CR service users most recently added to the database, fulfilling the following criteria:

Inclusion Criteria
- Cardiac event (MI, cardiac surgery, PCI, AP, arrhythmia, HF, implanted device) within past six months
- Aged ≥18 yrs

Exclusion Criteria
- Physical/mental impairment realistically preventing data collection
- Documented evidence that service user not informed of diagnosis (e.g. due to physical/mental impairment)

The assistant researcher sent all a letter of invitation with tear-off slip (to confirm/refute interest within two weeks), study information sheet, and SAE. From

the first two batches of 50 service users (i.e. 100 in total), 28 were willing to participate.

Of the 28, the first 20 to reply were invited by the assistant researcher by telephone to participate in two initial focus groups and 14 were available to attend. The remaining six agreed to be held in reserve, along with the other eight willing service users – and of those, eight were contacted (purposefully, to include a range of cardiac diagnoses) to participate in semi-structured interviews. All eight agreed. Immediately before every focus group and interview, there was time for further discussion about the study, and for provision of informed, written consent.

6.1.2 Focus Group Procedures

All focus groups were held in meeting rooms at clinical sites within NHS Ayrshire and Arran. Staff and service users attended separate focus groups, to enable comparable and contrasting opinions from the two groups to emerge (Webb, 2002). Of the 15 staff recruited, six participated in the first focus group, and nine in the second. Of the 14 service users recruited, seven participated in the first focus group, and seven in the second. The researchers agreed that at least two of each type of group would be held to reduce the possibility of obtaining skewed data from one 'stand alone' group, and that groups would continue to be arranged until there was data saturation (Morgan, 1997).

All focus groups were facilitated by the assistant researcher, whilst the main researcher took notes throughout. Both were familiar to clinicians participating in the groups (beneficial in encouraging the 'flow' of discussion between colleagues), yet had not been involved in the care of any of the service users (ensuring unbiased opinions).

All groups were audio-recorded and all participants were assured that the all discussions would remain anonymous. The assistant researcher began each focus group reiterating the study purpose, and explaining the discussion format and main question to be answered: *"How does diagnosis of a cardiac condition impact upon someone's health and QoL?"* [staff], or *"How has your diagnosis of a cardiac*

condition impacted upon your health and QoL?" [service users]. Initial conceptual ideas identified from the literature review prompted discussions around: perceptions/definitions of general health and QoL, and physical, social, psychological and 'other' factors influencing health and QoL after a cardiac diagnosis. Average focus group duration was 57 minutes (range 49-72 minutes).

6.1.3 Semi-Structured Interview Procedures

All individual, semi-structured interviews with four staff and eight CR service users were conducted in meeting rooms at clinical sites within NHS Ayrshire and Arran. All interviews were audio-recorded, and were facilitated by the assistant researcher, who assured participants that all discussions would remain anonymous.

The assistant researcher began every interview reiterating the purpose of the study, and explaining the discussion format and main question to be answered: *"How does diagnosis of a cardiac condition impact upon someone's health and QoL?"* [staff], or *"How has your diagnosis of a cardiac condition impacted upon your health and QoL?"* [service users]. As with the focus groups, conceptual ideas identified from the literature review formed the basis of an interview schedule used with both staff and service users, incorporating: perceptions/definitions of general health and QoL, and physical, social, psychological and 'other' factors influencing health and QoL after a cardiac diagnosis.

For staff, the schedule was tailored to each profession, to help different professional perceptions to emerge (as an example, the dietetic schedule is shown in **table 3**). Within both service user focus groups, participants often discussed the importance of understanding their cardiac diagnoses. To further explore this, an additional question was added to both types of schedule (**table 3**): *"To what extent would you say that it's important for someone to have a good understanding of his/her diagnosis?"* [staff], or *"To what extent would you say that it is important to have a good understanding of your diagnosis?"* [service users]. Average interview duration was 33 minutes (range 25-48 minutes).

6.1.4 Qualitative Data Analysis

After every focus group and interview, the recording was transcribed and the written transcription analysed using a three-stage constant comparison method (Strauss and Corbin, 1999): stage 1 - data chunked into small units and coded, stage 2 – codes grouped into categories ('sub-themes'), and stage 3 – 'key themes' identified expressing the content of the codes within sub-themes. This process was undertaken by the assistant researcher and discussed and negotiated with the main researcher. Although the researchers ensured that data analysis of one group/interview did not force the direction of subsequent discussions, data generated contributed to subsequent prompting, where appropriate. This process enabled researchers to identify the need to incorporate the question on understanding a cardiac diagnosis within the interview schedules, and to identify that data saturation had occurred after two of each type (staff and service user) of focus group, and after four staff and eight service user semi-structured interviews.

6.2 Results

6.2.1 Participant Characteristics

Details of all participants are shown in **table 4**.

6.2.1 Summary of Key Themes

Three key themes (and their sub-themes) identified from the data - 'expectations and entitlement' ('self', 'others'), 'adjustment and acceptance' ('diagnosis', 'lifestyle changes', 'confidence loss') and 'control and choice' ('daily life and health' and 'care') - are shown in **table 5**, evidenced by relevant quotes from staff and service user participants, and aligned with the prompts (conceptual ideas from the literature review) from which they were most frequently generated.

6.2.1.1   Expectations and Entitlement

Across focus groups and interviews, many staff and service users acknowledged that everyone is entitled to have, and expects, a 'good' QoL, often described as 'feeling well' or being 'in good health'. Many participants discussed expectations that service users place upon themselves after a cardiac diagnosis – how they compare their abilities to undertake everyday tasks and return to work and hobbies, to their pre-diagnosis abilities.

Although only mentioned by a few staff, many service users described frustration and a sense of failure resulting from this constant comparison, and described how perceived expectations of others compound these feelings. Often there was worry around employers' expectations about return to work and job security, and around family and friends treating them differently, causing relationship tensions and feeling burdensome to others.

6.2.1.2   Adjustment and Acceptance

Many service users and staff discussed difficulties in adjusting to, and accepting, a cardiac diagnosis, with several stating that the service user often blames himself/herself, or others. Several staff and service users described how worrying about the impact of the diagnosis, their recovery potential, and the stress that the diagnosis places upon their families and friends, can make them anxious, tearful or depressed. Only the service users verbalised the importance of having 'enough' knowledge and understanding about their condition to help them accept their diagnosis.

Numerous participants discussed the impact of lifestyle changes imposed by a cardiac diagnosis. Many recognised the wide-ranging physically limiting impact - cardiac symptoms (pain, shortness of breath, fatigue), altered appetite, poor sleep quality, feeling 'slowed down', and loss of libido – and several staff explained how physical anxiety symptoms are often mistaken for cardiac symptoms – intensifying anxiety symptoms, and causing confidence loss. Several service users described their subsequent apprehension about going out alone, or travelling away from home.

In addition to imposed lifestyle changes, both staff and service users acknowledged challenges associated with adhering to recommended changes – a healthier diet, smoking less and consuming less alcohol – with many explaining how these can cause social withdrawal, and isolation. Both staff and service users recognised the limiting effect of being unable to maintain a previous role community role, or to drive or work post-diagnosis, with financial constraints caused by loss of earnings further limiting socialisation. Although not mentioned by staff, in addition to anxiety around holiday travel, a few service users verbalised frustration about travel insurance restrictions.

6.2.1.3   Control and Choice

Several staff and many service users recognised the importance of having control and choice; it was considered an entitlement for every person to have control over his/her daily life. Many staff and service users recognised the value of being able to control their preferred daily structure and routine. A few emphasised a desire to be able to change this structure spontaneously, without having to consider the impact upon their condition.

Several service users described their difficulties in adjusting to losing control over their heart and health, and many staff explained how a key goal of CR is to help service users regain this control. Both staff and service users discussed the importance of having 'enough' healthcare support, and several service users highlighted the importance of being able to ask questions to feel involved in their care and more in control of their condition.

9.   DISCUSSION

This paper describes the first two steps in a seven-step survey process used to create a new PROM for CR. In the first two stages of developing an initial item bank for the first draft (PROM-CR1), a literature review of existing tools was undertaken and its findings used to guide a qualitative data collection methodology.

The qualitative data were largely reflective of those measured across existing tools. Although several of the reviewed tools (Seattle Angina Questionnaires [SAQ] (Chan et al, 2014; Spertus et al, 1995), Cardiovascular Limitations and Symptoms Profile [CLASP] (Lewin et al, 2002); Chronic Heart Failure Questionnaire [CHQ] (Guyatt et al, 1989) enquire about specific symptoms, in the present study discussions around symptoms were more broad, and experiences varied. This perhaps reflects the wide range of diagnoses of the service user participants, and the fact that staff participants typically care for a diverse range of cardiac conditions.

Of the conceptual ideas identified from existing tools, 'self efficacy and knowledge' (from the KCCQ) and 'disease perception' (from the SAQ) were less prevalent than those selected for use as qualitative prompts, however consistently emerged within service user focus group discussions, and were therefore incorporated within the interviews. It is widely acknowledged that PROMs should not enquire about treatment satisfaction (Appleby and Devlin, 2010), thus this conceptual idea (used within the SAQ) was disregarded after the literature review, and did not emerge within qualitative data, even during discussions around care.

Finally, from the 'Quality of Life Index-Cardiac [QLI-C] (Ferrans and Powers, 1985), neither 'economic' nor 'spiritual' conceptual ideas were considered sufficiently prevalent conceptual ideas for use as qualitative prompts. Whilst economic concerns around finances and returning to work emerged within qualitative data obtained from both staff and service users, spiritual issues were not verbalised at any point.

The mean age and gender split of service users recruited to the qualitative methodology is fairly typical of those attending CR, however within the diagnoses, there was high proportion who had suffered an MI, and no one who had undergone elective PCI (without prior MI). The main and assistant researchers discussed the need to continue to purposefully recruit, however agreed that the range of cardiac diagnoses across those recruited were sufficiently varied to have achieved appropriate data saturation. Certainly, when piloting PROM-CR1, its performance within and across the diagnostic groups will be examined.

10. CONCLUSIONS

In the first two stages of developing a first draft PROM for CR (PROM-CR1), a literature review of existing tools was undertaken and its findings used to guide a qualitative data collection methodology undertaken with CR staff and service users. From the literature, four conceptual ideas for health/QoL were identified: 'general health', 'physical', 'social' and 'psychological'. Qualitative data were organised in three key themes - 'expectations and entitlement', 'adjustment and acceptance', and 'control and choice' – and were largely reflective of literature review findings. These data will be combined to develop an initial item bank for PROM-CR1, which will be tested for validity and reliability, with both staff and service users, and refined to develop a finalised tool (PROM-CR) for use in clinical practice.

11. KEY MESSAGES

- A Scotland-wide government scoping exercise identified the need for a new patient-reported outcome measure for use across the wide range of cardiac diagnostic groups now accessing cardiac rehabilitation (CR).

- In the initial stages of developing an bank for a first draft tool (PROM-CR1), a literature review of existing tools was undertaken to identify conceptual ideas to guide a qualitative data collection methodology involving CR staff and service users.

- Four conceptual ideas for health/QoL were identified from the literature review: 'general health', 'physical', 'social' and 'psychological'.

- Qualitative data were organised in three key themes - 'expectations and entitlement', 'adjustment and acceptance', and 'control and choice' – and were largely reflective of the literature review findings.

- These data will be combined and PROM-CR1 piloted with staff and service users to create a finalised version of the tool (PROM-CR) for use in clinical practice.
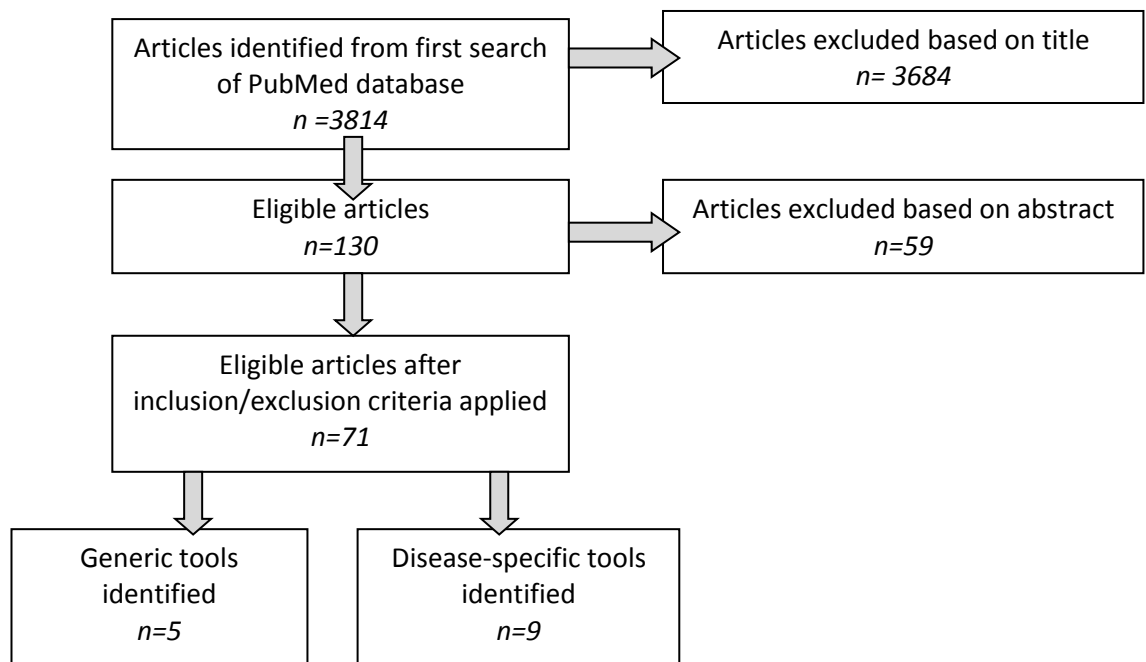
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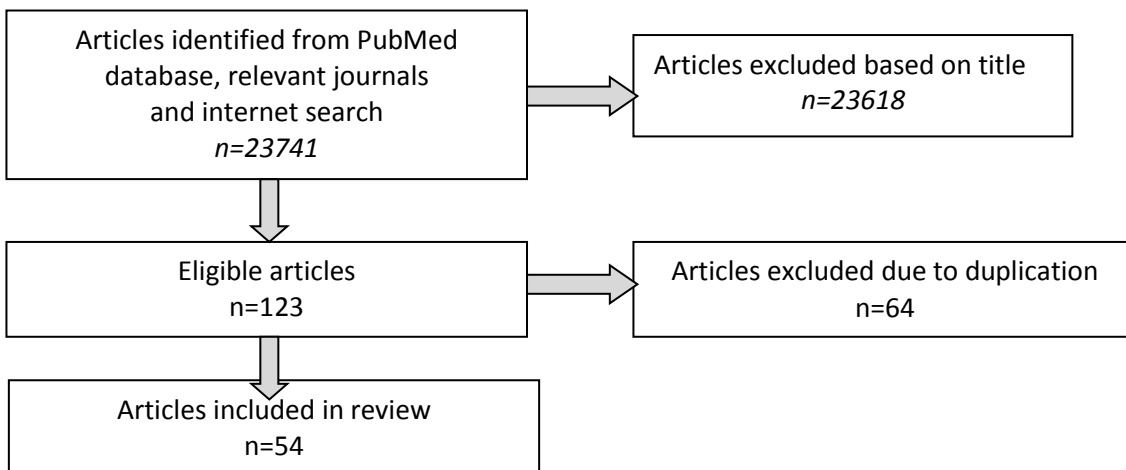
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Fig. 1a: Identification of Generic and Disease-specific Tools

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┌─────────────────────────────┐         ┌─────────────────────────────┐
│ Articles identified from    │────────▶│ Articles excluded based on  │
│ first search of PubMed      │         │ title                       │
│ database                    │         │ n= 3684                     │
│ n =3814                     │         └─────────────────────────────┘
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│ Eligible articles           │────────▶│ Articles excluded based on  │
│ n=130                       │         │ abstract                    │
│                             │         │ n=59                        │
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│ Eligible articles after     │
│ inclusion/exclusion         │
│ criteria applied            │
│ n=71                        │
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┌──────────────┐  ┌──────────────────┐
│ Generic tools│  │ Disease-specific │
│ identified   │  │ tools identified │
│ n=5          │  │ n=9              │
└──────────────┘  └──────────────────┘
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Fig. 1b: Examination of Psychometric Properties of Selected Tools

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┌─────────────────────────────┐         ┌─────────────────────────────┐
│ Articles identified from    │────────▶│ Articles excluded based on  │
│ PubMed database, relevant   │         │ title                       │
│ journals and internet search│         │ n=23618                     │
│ n=23741                     │         └─────────────────────────────┘
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┌─────────────────────────────┐         ┌─────────────────────────────┐
│ Eligible articles           │────────▶│ Articles excluded due to    │
│ n=123                       │         │ duplication                 │
│                             │         │ n=64                        │
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│ Articles included in review │
│ n=54                        │
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PROM NAME	Number of Items	Recall Period	Method of Administration	Measurement Domains [→ Conceptual Ideas Identified from Measurement Domains*]	Target Populations
SF-36	36	4 wks	Self or interviewer	8 - Vitality, Physical Function, Bodily Pain, General Health, Role-Physical, Role-Emotional, Role-Social, Mental Health [→ **General Health**; **Physical**; **Psychological/Emotional**; **Social**]	Generic
SF-12	12	4wks	Self or interviewer	8 - Vitality, Physical Function, Bodily Pain, General Health, Role-Physical, Role-Emotional, Role-Social, Mental Health [→ **General Health**; **Physical**; **Psychological/Emotional**; **Social**]	Generic
EQ-5D	5	Today	Self	5 - Mobility, Self Care, Usual Activity, Pain & Discomfort, Anxiety & Depression (+ Global Health Rating) [→ **Global Health**; **Physical**; **Psychological**]	Generic
NHP	45	At this moment	Self or interviewer	5 - Physical Mobility, Social Isolation, Emotional Reactions, Pain, Sleep & Energy [→ **Physical**; **Psychological/Emotional**; **Social**]	Generic
SIP	136	Today	Self or interviewer	2 - Physical, Psychosocial [→ **Physical**; **Psychological**]	Generic
MacNew	27	2wks	Self	3 - Physical, Emotional, Social [→ **Physical**; **Emotional**; **Social**]	MI or AP (attending CR)
SAQ	19	4wks	Self	5 - Physical Limitation, AP Stability, AP Frequency, Treatment Satisfaction, Disease Perception [→ **Physical**; **Treatment Satisfaction**; **Disease Perception**]	AP, MI, PCI, cardiac surgery
SAQ-7	7	4wks	Self	3 - Physical Limitation, AP Frequency, Quality of Life [→ **Physical**]	AP, MI, PCI, cardiac surgery
CLASP	37	2wks	Self	2 - Symptoms, Functional Limitations [→ **Physical**]	CHD, AP
CHQ	20	4wks	Interviewer	3 - Dyspnoea, Fatigue, Emotional Function [→ **Physical**; **Emotional**]	HF
KCCQ	23	2wks	Self	5 - Physical Function, Symptoms, Social Function, Self-efficacy & Knowledge, Quality of Life [→ **Physical**; **Social**; **Self-efficacy & Knowledge**; **Quality of Life**]	HF
MLHFQ	21	1mth	Self	2 - Physical, Emotional [→ **Physical**; **Emotional**]	HF
CHAT	46	2wks	Self	4 - Symptoms, Activity Levels, Psychosocial, Emotions [→ **Physical**; **Emotional**]	HF
QLI-C	36	Now	Self	4 - Health & Functioning, Psychological/Spiritual, Social & Economic, Family (+Quality of Life Overall) [→ **Health**; **Physical**; **Psychological & Spiritual**; **Social & Economic**; **Quality of Life**]	All with cardiac diagnosis

Table 1: Generic and Disease-Specific PROMs Currently Used Within Cardiac Rehabilitation – Items, Recall, Method of Administration, Measurement Domains [Conceptual Ideas Identified from Measurement Domains] and Target Populations *[*, most prevalent conceptual ideas selected as qualitative prompts underlined; SF-36, Medical Outcomes Short Form-36 (Ware et al, 1992; SF-12, Shortened 12-item version of Medical Outcomes Short Form-36 (Ware et al, 1996); EQ-5D, EuroQoL-5D (The EuroQoL Group, 1990); NHP, Nottingham Health Profile (Hunt et al, 1985); SIP, Sickness Impact Profile (Bergner et al, 1981); MacNew, MacNew Heart Disease Quality of Life Tool (Höfer et al, 2004); SAQ, Seattle Angina Questionnaire (Spertus et al, 1995); SAQ-7, Shortened 7-item Version of SAQ (Chan et al, 2014); CLASP, Cardiovascular Limitations and Symptom Profile (Lewin et al, 2002); CHQ, Chronic Heart Failure Questionnaire (Guyatt et al, 1989); KCCQ, Kansas City Cardiomyopathy Questionaire (Green et al, 2000); MLHFQ, Minnesota Living with Heart Failure Questionnaire (Rector et al, 1987); CHAT, Chronic Heart Failure Assessment Tool (Dunderdale et al, 2008); QLI-C, Quality of Life Index – Cardiac (Ferrans and Powers, 1985); MI, myocardial infarction; AP, angina pectoris; CR, cardiac rehabilitation; PCI, percutaneous coronary intervention; CHD, coronary heart disease; HF, heart failure; VAS, visual analogue scale; wks, weeks; mth, month]*

Appraisal Criteria	SF-36	SF-12	EQ-5D	NHP	SIP	MacNew	SAQ	SAQ-7	CLASP	CHQ	KCCQ	MLHFQ	CHAT	QLI-C
Test-retest Reliability	+	0	+	0	+	+	+	++	+	0	++	+	0	+
Internal Consistency	++	0	0	+	+	+++	+	0	0	+	++	+++	+	+
Content Validity	+	+	++	+	+	++	+	+	0	+++	+++	+	+++	-
Construct Validity	+	+	++	+	+	++	+	++	+	+	++	++	+	0
Sensitivity/Responsiveness	+	+	-	-	+	+	+	+	+	+	+	++	0	-
Floor/Ceiling Effects	-	0	-	-	0	-	-	0	0	0	-	-	0	0
Acceptability	++	0	++	++	0	+	+	+	+	0	+	+++	0	0
Burden	+	++	++	++	-	++	+	++	+	0	+	+	0	0

Table 2: Appraisal of Existing Tools' Psychometric Properties Adapted from Mackintosh et al (2009)

[-, evidence does not support criteria; 0, not reported or no evidence in favour; +, some limited evidence in favour; ++, some good evidence in favour, but some aspects do not meet criteria or are unreported; +++, good evidence in favour; SF-36, Medical Outcomes Short Form-36 (Ware et al, 1992; SF-12, Shortened 12-item version of Medical Outcomes Short Form-36 (Ware et al, 1996); EQ-5D, EuroQoL-5D (The EuroQoL Group, 1990); NHP, Nottingham Health Profile (Hunt et al, 1985); SIP, Sickness Impact Profile (Bergner et al, 1981); MacNew, MacNew Heart Disease Quality of Life Tool (Höfer et al, 2004); SAQ, Seattle Angina Questionnaire (Spertus et al, 1995); SAQ-7, Shortened 7-item Version of SAQ (Chan et al, 2014); CLASP, Cardiovascular Limitations and Symptom Profile (Lewin et al, 2002); CHQ, Chronic Heart Failure Questionnaire (Guyatt et al, 1989); KCCQ, Kansas City Cardiomyopathy Questionaire (Green et al, 2000); MLHFQ, Minnesota Living with Heart Failure Questionnaire (Rector et al, 1987); CHAT, Chronic Heart Failure Assessment Tool (Dunderdale et al, 2008); QLI-C, Quality of Life Index – Cardiac (Ferrans and Powers, 1985); MI, myocardial infarction; AP, angina pectoris; CR, cardiac rehabilitation; PCI, percutaneous coronary intervention; CHD, coronary heart disease; HF, heart failure; VAS, visual analogue scale; wks, weeks; mth, month]

Interview Schedule Examples	
Clinician (Dietitian)	**Service User**

Quality of Life
   1. What does the term "quality of life" mean to you? / What kinds of things do you think provide a good quality of life for someone?
   2. In what way can a heart condition affect someone's diet and/or appetite?
 	
Physical
   3. In what way can changes in diet and/or appetite affect someone's physical quality of life?
 	
Psychological
   4. In what way can changes in diet and/or appetite affect someone's psychological quality of life?
 	
Social
   5. In what way can changes in diet and/or appetite affect someone's social quality of life?
 	
Other Factors
   6. What other factors do you consider to be important in relation to patients and diet and or appetite?
 	
Understanding
   7. To what extent would you say that it's important for someone to have a good understanding of their diagnosis?
	Quality of life
	   1. What kinds of things do you associate with having a good quality of life?
	
	Physical
	   2. Can you tell me about any physical changes that you have experienced as a result of your heart condition/event/surgery?
	   3. In what ways have these physical changes/difficulties affected your quality of life?
	
	Psychological
	   4. Can you tell me about any psychological changes that you have experienced as a result of your heart condition/event/surgery?
	   5. In what ways have these psychological changes/difficulties affected your quality of life?
	
	Social
	   6. Can you tell me about any changes that you have experienced in your social life and/or relationships as a result of your heart condition/event/surgery?
	
	Other Factors
	   7. Can you think of any other factors that can impact on quality of life following a heart condition/event/surgery?
	
	Understanding
	   8. To what extent would you say it is important to have a good understanding of your diagnosis?

Table 3: Example Interview Schedules – Clinician (Dietitian) and Service User

Participant Characteristics
Focus Group 1 – Staff (n=6)
CR Nurses – 4; HF Nurses – 1; Physiotherapist – 1
Focus Group 2 – Staff (n=9)
CR Nurses – 4; HF Nurses – 4; Medical Secretary – 1
Interviews 1-4 – Staff (n=4)
Dietitian – 1; Clinical Psychologist – 1; Physiotherapist – 1; CR Nurse – 1
Focus Group 3 – Service Users (n=6)
Mean age: 66yrs (range 62-84yrs); 4 males / 3 females
Referring Diagnoses
MI – 6, with: Previous history of AP – 2, PCI post-MI – 3, Defibrillator implanted post-MI – 1, Pacemaker in situ – 1, HF (ischaemic) – 1
Focus Group 4 – Service Users (n=6)
Mean age 68yrs (range 64-86yrs); 6 males / 1 female
Referring Diagnoses
MI – 7, with: Previous history of AP – 2, PCI post-MI – 3, Defibrillator implanted post-MI – 1
Interviews 5-12 – Service Users (n=8)
Mean age 68yrs (range 54-79yrs); 5 males / 3 females
Referring Diagnoses
MI – 5, with: Previous valve surgery – 1, PCI post-MI – 2, CABG post-MI – 2, Arrhythmia (atrial fibrillation) – 1, HF (dilated cardiomyopathy) – 1

Table 4: Participant Characteristics

[CR, cardiac rehabilitation; HF, heart failure; AP, angina pectoris;
PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft surgery]

Literature Review Conceptual Idea	Qualitative Data Key Theme	Sub-Theme	Staff and / or Service User Quotes to Evidence:
General health and QoL	*Expectations and Entitlement*	*Self*	**It's just about generally feeling well"** [FG1, staff]; "Overall, feeling like you're in good health" [FG3, su]
Physical			**"They need to be able to carry out everyday activities" [I0, staff];** "You are limited doing just simple, everyday activities" [FG3, su]
Physical			**"Engaging in the things they enjoy" [FG1, staff]** "Doing your hobbies...being able to engage fully" [FG4, su]; "I would like to do the things I enjoy from before" [I6, su]
Psychological			**"There's also frustration about limitations" [FG2, staff];** "I get frustrated about what I can physically do" [FG3, su]
Psychological			**"He felt like he'd failed and he was disappointed" [FG1, staff];** "I just had this sense of being a failure" [FG4, su]
Psychological		*Others*	**"People are often anxious about pressures upon them to return to work...and financially" [FG2, staff]** "I was off work and didn't know if I was going to get back or not. It was a worrying time, without that security" [I3, su]
Social			"They [partner] can end up smothering you" [FG3, su]; **"I think the family wrap them in cotton wool" [FG1, staff]** "You almost get a bit of celebrity status with friends" [I5, su]; "Once you're home, friends kind of ignore you" [FG3, su]
Social			"You feel like you're annoying each other, being at home" [FG3, su]; **Tensions within the family" [FG2, staff]** "Friends would really annoy me, and I felt I annoyed them" [I3, su]
Psychological			**"Feeling of being a burden to other people" [FG2, staff];** "You can feel a bit like a burden" [FG3, su]
Psychological	*Adjustment and Acceptance*	*Diagnosis*	**"They might blame themselves as well, you know" [FG1, staff]** "What did I do wrong? There must have been something" [I3, su]
Psychological			**"I think sometimes for them to move past that diagnoses, it's hard...they end up too scared to kind of...move on" [FG2, staff];** "I just worry – what's ahead, will it get worse, what to expect" [I1, su]
Social			**"The family will often experience stress" [FG2, staff]** "It does cause stress, on your husband or wife, your family and your friends. Everyone feels it" [FG3, su]
Psychological			"I just burst out crying...and that's not me" [FG3, su]; "I'm much more tearful, weepier. It happens all the time [I1, su]
Psychological			**"They just feel down" [I10, staff];** "You feel down, you feel depressed" [FG4, su]
Other			"Understanding your own diagnosis is important [FG3, su]; "Because I have enough knowledge, I feel better" [I2, su]
Physical		*Lifestyle Changes*	**"Chest pain...breathlessness...fatigue" [FG2, staff];** "That pain in my chest" [FG3, su] "You're halfway through something and short of breath" [FG3, su]; "When I do anything, fatigue floors me" [FG4, su]
Physical			**"You find that...they're not eating enough to keep well" [FG1, staff];** "My appetite has altered hugely" [I1, su]
Physical			**"Getting enough sleep is very important" [FG1, staff];** "My biggest problem was sleep. Or lack of" [FG3, su]
Physical			"They certainly talk about being 'slowed down'" [I10, staff]; "It's a slowing down. You feel it." [FG3, su]
Physical			**"Reduced sex drive can be an issue" [FG2, staff];** "Sexually.. just don't feel like it" [I7, su]
Psychological			**"They pick up on lots of symptoms that's......exaggerated by the presence of actual cardiac symptoms" [I11, staff];** "You're aware of your own heart beat" [FG3, su]; "Feeling tense, all over. Your muscles" [I6, su]
Psychological		*Confidence Loss*	**"It can have a huge impact not only actual ability to do things but perceived ability as well" [I11, staff]** "I spent time thinking – 'can I really do this?'" [FG3, su]; "I had no confidence in what I could do daily" [I2, su]
Psychological			"It affects your willingness to travel anywhere...especially on your own....even out of the house" [FG4, su] "Back then, I would never been able to say that I'm going out on my own". [I2, su]
Psychological			"I'm afraid to go on holiday abroad, that's one that bothers me, flying to the sun. I worry about the hassle at the airport." [FG4, su]; "Travel is certainly an issue – it makes you anxious" [FG4, su]

Social		Lifestyle Changes	**"The lifestyle changes are hard....a healthier diet.." [FG1, staff]** "I think change in diet as well…cutting out the things that you really like…it's a struggle" [FG3, su]
Social			**"They struggle with things like....stopping smoking" [FG1, staff]**; "I've stopped smoking…which is so hard." [FG3, su]
Social			**"They have to restrict their drinking..alcohol...and that affects their social lives" [FG1, staff]*** "My friends are drinkers..so I don't see them as much now" [FG4, su]*
Social			**"Socially they limit things because it's often difficult" [I10, staff]** "After the heart problem, everything just stopped socially" [FG3, su]
Social			**"Withdrawing from activities...is common" [I11, staff];** "You can feel quite isolated really" [FG3, su]
Social			**"They can lose that sense of community role" [FG2, staff]; "The concept of self...and role is compromised" [I11, staff]** "I used to cut my neighbour's grass and now I can hardly cut my own! That's hard to come to terms with… [FG3, su]
Physical			**"They often talk about not being able to drive" [FG1, staff];** "I couldn't drive for months and that was a bind" [FG3, su]
Physical			**"Not being able to work, that's hard for them" [FG2, staff];** "I just wanted to be able to earn again" [FG3, su]
Social			"The drop in money... then links in with the social thing, you get invited but can't afford to go" [FG3, su] ; "Being financially constrained is such an issue" [I5, su];
Social			"Being restricted to travel... the hardest. Travel insurance" [I1, su] "I have returned to travelling again, but insurance costs are so restricting" [I4, su]
Physical	Control and Choice	Daily Life and Health	**"I think they just want to be able to get back to their own day-to-day structure and routine" [FG3, staff]** "I just really wanted to get back to my old routine" [I9, su]
Physical			**"Doing what you want, spontaneously" [FG1, staff]** "You just can't go out and do anything spontaneously" [FG3, su]; "You have to plan everything out now" [FG4, su]
Psychological			**"It's important to give them more control"[FG1, staff]** "The feeling that I couldn't control my own condition" [FG4, su]; "It was difficult to lose control of my body" [I3, su]
Psychological		Care	**"They really value the support from staff...just someone to speak to" [FG1, staff]** "Everyone needs a different amount of support." [FG4, su]
Other			"The biggest thing for me has been accessing information – being able to ask questions" [I1, su] "You want to ask for answers about wrong with you" [FG4, su]
Other			**" They want to take active role in their recovery as well, and not just do what they've been told to do" [FG1, staff}** "You want to make decisions on your care and treatment" [FG4, su]

Table 5: Qualitative Data Aligned with Conceptual Ideas Obtained from Literature Review

[Quotes are displayed in "...." followed by [Focus Group (FG) or Interview (I) Number, and 'staff' (for staff quotes) or 'su' (for service user quotes); Bold type, staff quote; Focus group and interview numbers are only provided to show the spread of data obtained across all participants - i.e. they are not intended to enable attribution of a quote to a particular individual; For clarity, qualitative data are presented in the order in which they are described within the main text, therefore the 'lifestyle changes' sub-theme is split]