

**TITLE:**

**Finalising an item bank for a first draft cardiac rehabilitation PROM**

**AUTHOR NAMES AND AFFILIATIONS:**

Dr Aynsley Cowie<sup>a</sup>

Emma Kerr<sup>b</sup>

Dr Janet McKay<sup>c</sup>

Dr Lesley Allan<sup>d</sup>

Dr Patricia Thomson<sup>e</sup>

<sup>a</sup>Consultant Physiotherapist in Cardiology, Cardiac Rehabilitation, Lister Centre, University Hospital Crosshouse, NHS Ayrshire and Arran, Kilmarnock, Scotland KA2 0BE  
[aynsley.cowie@aaaht.scot.nhs.uk](mailto:aynsley.cowie@aaaht.scot.nhs.uk)

<sup>b</sup>Assistant Psychologist, Community Forensic Mental Health Team, Ailsa Hospital, NHS Ayrshire and Arran [emma.kerr@aapct.scot.nhs.uk](mailto:emma.kerr@aapct.scot.nhs.uk)

<sup>c</sup>Consultant Nurse in Cardiac Care, Cardiac Rehabilitation, Lister Centre, University Hospital Crosshouse, NHS Ayrshire and Arran [janet.mckay@aaaht.scot.nhs.uk](mailto:janet.mckay@aaaht.scot.nhs.uk)

<sup>d</sup>Psychologist, Acute Psychology Department, West Glasgow Ambulatory Care Hospital, NHS Greater Glasgow and Clyde [lesleya.allan@nhs.net](mailto:lesleya.allan@nhs.net)

<sup>e</sup>Senior Lecturer/Co-Director of Masters in Advanced Practice Programme, School of Health Sciences and Sport, University of Stirling [patricia.thomson@stir.ac.uk](mailto:patricia.thomson@stir.ac.uk)

**CORRESPONDING AUTHOR:**

Dr Aynsley Cowie, Cardiac Rehabilitation, Lister Centre, University Hospital Crosshouse, NHS Ayrshire and Arran, Kilmarnock, Scotland KA2 0BE [aynsley.cowie@aaaht.scot.nhs.uk](mailto:aynsley.cowie@aaaht.scot.nhs.uk), tel. 01563 825085

*This document is the Accepted Manuscript version of a Published Work that appeared in final form in British Journal of Cardiac Nursing, copyright © MA Healthcare, after peer review and technical editing by the publisher. To access the final edited and published work see <https://doi.org/10.12968/bjca.2018.13.11.555>*

## **ABSTRACT**

**Background:** A Scotland-wide scoping exercise identified the need for a new patient-reported outcome measure (PROM) to suit the range of diagnostic groups now accessing cardiac rehabilitation (CR). Previously, a literature review of existing tools guided a qualitative methodology involving CR staff and service users.

**Aim:** This paper describes the merging of literature review findings with qualitative data to finalise the item bank for a first draft tool (PROM-CR1).

**Methods:** Conceptual ideas identified from existing tools were aligned with key- and sub-themes within the qualitative data. Quotes most reflective of the qualitative language were used to evidence themes and develop 40 construct indicators which were used to build PROM-CR1.

**Results:** PROM-CR1 contains 40 items across 'physical', 'social', 'psychological' and 'therapeutic' domains, plus 'general health and well-being', 'physical', 'social', and 'psychological' summary scores.

**Future Directions:** PROM-CR1 will be piloted with both staff and service users, and refined to develop a finalised tool (PROM-CR) for clinical practice.

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

## 1. INTRODUCTION

In 2015, a Scotland-wide scoping exercise was undertaken to help facilitate modernisation of cardiac rehabilitation (CR) services in line with the Scottish Government's 2020 vision that *"all patients with heart disease should be supported by CR to live longer, healthier and independent lives"* (Divers, 2015; Scottish Government, 2014). The scoping exercise found a lack of robust outcomes measures, and identified the need to define a new patient-reported outcome measure (PROM) for use within the CR community to allow service users to provide validated evidence of health and quality of life (QoL). There was recognition that, within the field, there were many different generic and disease-specific health and QoL assessment tools demonstrating varying degrees of validity, reliability and sensitivity (Thompson et al, 2016). However, none had been tested across the increasing diverse range of diagnostic groups currently accessing CR.

Therefore, the overall aim of this study was to develop a new CR PROM (PROM-CR) able to provide robust health status information across a range of cardiac diagnoses. In developing this new PROM, a seven-step survey design process (Gehlbach et al, 2010) was adopted. Previously, we have described the first two steps of this process (Cowie et al, 2018). In step one, a literature review was undertaken to identify existing PROMs used within CR, to help establish the overall construct of a first draft tool (PROM-CR1) and identify initial conceptual ideas of interest. For step two, conceptual ideas identified from the literature review were used to guide a qualitative data collection methodology.

The current paper will describe steps three and four – outlining how qualitative data were combined with literature review findings to establish PROM-CR1's conceptual framework, and the construct indicators informing its initial bank of items, and the rationale for how the tool was built. Future publications will thus describe steps five (expert validation), six (service user interpretation) and seven (piloting for validity and reliability) as the tool is refined into a finalised version (PROM-CR) for use in clinical practice.

## **2. 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).

## **3. SUMMARY OF STEPS ONE AND TWO**

### **3.1 Step One – Literature Review**

Systematic searches of the PubMed database were undertaken by the assistant researcher, to identify generic and disease-specific PROMs used within CR, and to identify articles evaluating psychometric properties of the tool (Cowie et al, 2018). This methodology was replicated by the main researcher to ensure no key articles were omitted.

A total of 14 existing PROMs (five generic and nine disease-specific) were identified within the field. Fifty-four articles examining the tools' psychometric properties were found, and used to critique the tools against recognised criteria (Mackintosh et al, 2009). This critique confirmed variation in validity, reliability and sensitivity across the tools currently in use (Thompson et al, 2016), and that none have been tested across the diverse diagnostic groups now accessing CR. Additionally, the most prevalent conceptual ideas ('general health', 'physical', 'social' and 'psychological') identified within existing tools were selected as the main prompts to help guide the

qualitative data collection methodology, along with an open prompt around 'other factors' influencing health and QoL.

### **3.2 Step Two – Qualitative Data Collection**

In focus groups, 15 staff members (13 nurses, one physiotherapist, one medical secretary) and 14 CR service users with a range of cardiac diagnoses (mean age 67 years; 10 males / four females) discussed the impact of a cardiac diagnosis upon health and QoL (Cowie et al, 2018). To enable comparable and contrasting opinions to emerge, staff and service users attended separate focus groups (Webb, 2002). To reduce possibility of obtaining skewed data from one 'stand alone' group, two of each type of group (i.e. four in total) were held (Morgan, 1997).

To add depth to the data, and achieve completeness, 12 semi-structured interviews were also held – four with CR staff (one dietitian, one clinical psychologist, one physiotherapist, one nurse), and eight with service users (mean age 68 years; five males / three females). The interview questions largely followed the focus group prompts, however as the service user focus groups had highlighted the importance of understanding a cardiac diagnosis, this was incorporated within the schedule. The assistant researcher led, audio-recorded and transcribed all focus groups and semi-structured interviews with support from the main researcher.

Transcriptions were analysed using a three-stage constant comparison method (Strauss and Corbin, 1999) which enabled identification of data saturation after four focus groups and 12 interviews, and highlighted three key themes (each with defined sub-themes): 'expectations and entitlement' ('self', 'others'), 'adjustment and acceptance' ('diagnosis', 'lifestyle changes', 'confidence loss') and 'control and choice' ('daily life and health' and 'care'). Though the literature review did guide the qualitative methodology, notably the qualitative data were largely reflective of that measured across existing tools.

#### 4. STEP THREE – COMBINING THE DATA

In discussion with the steering group, the researchers completed a ‘mapping exercise’ - aligning conceptual ideas from the literature review with qualitative data to derive a list of 40 construct indicators. **Table 1** displays the outcomes from this exercise.

All key themes (and their defined sub-themes) identified within the qualitative data were aligned with the prompt (conceptual idea (derived from the literature review), from which data were most frequently generated. Themes were evidenced with the quotes from staff and/or service users that the researchers agreed were most reflective of the context of, and language used to describe, the data. To optimise respondent comprehension of the initial item bank, where possible, the list of construct indicators was developed using the language within the quotes (Bowling, 2005).

#### 5. STEP FOUR – DEVELOPING DOMAINS AND ITEMS

In developing the item bank, the researchers arranged the 40 construct indicators into potential domains. Initial domains agreed were ‘physical’, ‘social’ and ‘psychological’ conceptual ideas identified from the literature review – each containing its aligned indicators from **table 1**. Notably, only indicator [1] was aligned to the conceptual idea of ‘general health’, which the researchers agreed was due to little variation in verbalisation of ‘feeling well’ and being ‘in good health’. The researchers thus agreed that the tool should open with an ‘overall health and well-being score’. Accordingly, and to enable identification of whether items within each domain accurately reflect the overall perception of that aspect of health/QoL, an overall score was added to ‘physical’, ‘social’ and ‘psychological’ domains.

As indicators [15], [39] and [40] were developed from qualitative data emerging around ‘other’ factors influencing health/QoL, the researchers agreed that these should form a ‘therapeutic’ domain, encompassing knowledge and understanding, control, involvement in care and support. Indicators [37] and [38] were also thought to fit within ‘therapeutic’, and were subsequently moved from ‘psychological’.

From their combined clinical and research experience, the research team decided to structure the 40 items as statements (retaining the qualitative language as far as possible), with which service users will rate their agreement: *1-strongly disagree* to *5-strongly agree*. Although ‘not applicable’ options can skew Likert scales (Bowling, 2005), including *0-n/a* was considered essential because not all items within the construct will apply to all service users.

A two-week recall was considered appropriately long to eliminate the impact of small daily health changes upon responses, yet short enough to be recalled easily (Bowling, 2005), whilst being able to detect change before and after a typical 8-12 week out-patient CR programme. A time-bound recall was deemed inappropriate for the ‘therapeutic’ domain, thus its items relate to ‘current’ perceptions. For ‘physical’, ‘social’ and ‘therapeutic’ domains, a higher score denotes a more negative impact upon health/QoL, whilst scoring was reversed for the therapeutic domain, and for the overall summary scores, to reduce acquiescence bias (Bowling, 2005; Gehlbach et al, 2010). Scale performance will be fully examined through steps five to seven of the design process.

**Appendix A** contains PROM-CR’1 initial item bank, arranged in domains, and with scales.

## **6. DISCUSSION**

This paper describes steps three and four of 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. In steps three and four, qualitative data were combined with literature review findings to establish PROM-CR1’s conceptual framework, and the construct indicators informing its initial item bank.

From the ‘mapping’ exercise, **table 1** shows that some of the qualitative data were generated solely by service users. Despite not emerging from within staff data

collection, these were included to ensure that no important data were missed from the list of indicators. Certainly, it is service users (rather than staff) who are PROM-CR1's target audience, and steps five and six of the design process will ascertain both staff and service users' perceptions of content relevance (Gehlbach et al, 2010). Unintentionally, none of the construct indicators were derived solely from staff.

In building the tool, items were structured as statements – a questionnaire approach often criticised for failing to represent a 'natural' conversation (Gehlbach et al, 2010). However, after reflecting upon existing tools, the steering group agreed that the Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Rector et al, 1987) is the most user-friendly, acceptable tool currently used within CR practice in NHS Ayrshire and Arran – largely due to its use of statements measured by a six-point Likert scale. Certainly, from the critique of the psychometric properties of existing disease-specific tools undertaken in step one (Cowie et al, 2018), the MLHFQ was amongst those demonstrating the most favourable evidence.

It should be noted that the qualitative methodology did not incorporate the perceptions of those who opted out of CR input – thus the item bank does not reflect the views of this particular sub-group. Although PROM-CR1 will be predominantly used with those who are engaged with CR, items were worded to ensure that they may be relevant regardless of CR uptake (i.e. there is no reference to CR within any construct indicator). Finally, although lengthy in its current state, it is hoped that the finalised tool (PROM-CR) that emerges from the pilot will be more streamlined.

## **7. 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. In step three, conceptual ideas identified from existing tools were aligned with key-themes and sub-themes identified within the qualitative data, and evidenced with quotes from staff and/or service users considered most reflective of the data, and used to generate 40 construct indicators. **In step four, an initial item bank for PROM-**



CR1 was created - consisting of one item on 'general health and well-being', and a further 39 items arranged within 'physical', 'social', 'psychological' and 'therapeutic' domains. Each domain was assigned its own summary score. This item bank 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.

## **8. KEY MESSAGES**

- A Scotland-wide government scoping exercise identified the need for a new patient-reported outcome measure (PROM-CR) for use across the wide range of cardiac diagnostic groups now accessing cardiac rehabilitation (CR).
- A literature review of existing tools and a qualitative data collection methodology involving CR staff and service users were used to develop the framework for a first draft of the tool (PROM-CR1) and the construct indicators forming its initial item bank.
- PROM-CR1 contains 40 items arranged across four conceptual ideas (domains) of health: 'general health', 'physical', 'social', 'psychological' and 'therapeutic'.
- The item bank will be validated with CR staff and service users, and the tool refined for piloting within CR.

## REFERENCES

- Bowling A (2005) Mode of questionnaire administration can have serious effects on data quality. *Journal of Public Health*; **27(3)**:281–91
- Cowie A, Kerr E, McKay, Allan L, Thomson (2018) A New Patient-Reported Outcome Measure for Cardiac Rehabilitation (PROM-CR): Initial Steps in Developing the Item Bank. *British Journal of Cardiac Nursing* [XXXXXX]
- Divers F (2015) Scoping of Cardiac Rehabilitation Services in Scotland 2015. Scottish Government, Edinburgh
- Gehlbach H, Artino AR, Durning (2010) Survey development guidance for medical education researchers. *Academic Medicine*; **85**:925
- Mackintosh A, Gibbons E, Fitzpatrick R (2009) A Structured Review of Patient Reported Outcome Measures for People with Heart Failure: An Update. Department of Public Health Oxford.
- Morgan DL (1997) Focus Groups as Qualitative Research, 2nd Edition. SAGE Publications, California
- Rector T, Kubo SH, Cohn JN (1987) 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*; **3**:198-209
- Scottish Government (2014) Heart Disease Improvement Plan. Scottish Government, Edinburgh
- Strauss A, Corbin J (1999) Basics of Qualitative Research. Techniques and Procedures for Developing Grounded Theory, 2nd Edition. SAGE Publications, Newbury Park
- Thompson DR, Ski CF, Garside J, Astin F (2016) A review of health-related quality of life patient reported outcome measures in cardiovascular nursing. *European Journal of Cardiovascular Nursing*; **15(2)**:114-25
- Webb B (2002) Using focus groups as a research method: A personal experience. *Journal of Nursing Management*; **10**:27-35
- World Medical Association (1964) Human Experimentation Code of Ethics of the World Medical Association – Declaration of Helsinki. *British Medical Journal*; **2(5402)**:17

Literature Review Conceptual Idea	Qualitative Data Key Theme	Sub-Theme	Staff and / or Service User Quotes to Evidence:	[No.] Construct Indicator
General health and QoL	Expectations and Entitlement	Self	<b><i>It’s just about generally feeling well” [FG1, staff];</i></b> <i>“Overall, feeling like you’re in good health” [FG3, su]</i>	[1] Overall health and well-being
Physical			<b><i>“They need to be able to carry out everyday activities” [I0, staff];</i></b> <i>“You are limited doing just simple, everyday activities” [FG3, su]</i>	[2] Limited ability to undertake everyday activities
Physical			<b><i>“Engaging in the things they enjoy” [FG1, staff]</i></b> <i>“Doing your hobbies...being able to engage fully” [FG4, su]; “I would like to do the things I enjoy from before” [I6, su]</i>	[3] Unable to engage in hobbies enjoy / previously enjoyed
Psychological			<b><i>“There’s also frustration about limitations” [FG2, staff];</i></b> <i>“I get frustrated about what I can physically do” [FG3, su]</i>	[4] Frustrated due to physical limitations
Psychological			<b><i>“He felt like he’d failed and he was disappointed” [FG1, staff]; “I just had this sense of being a failure” [FG4, su]</i></b>	[5] Feeling like a failure
Psychological		Others	<b><i>“People are often anxious about pressures upon them to return to work...and financially” [FG2, staff]</i></b> <i>“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]</i>	[6] Worry or anxiety about job and / or financial security
Social			<b><i>“They [partner] can end up smothering you” [FG3, su]; “I think the family wrap them in cotton wool” [FG1, staff]</i></b> <i>“You almost get a bit of celebrity status with friends” [I5, su]; “Once you’re home, friends kind of ignore you” [FG3, su]</i>	[7] Treated differently by partner, family, friends
Social			<b><i>“You feel like you’re annoying each other, being at home” [FG3, su]; Tensions within the family” [FG2, staff]</i></b> <i>“Friends would really annoy me, and I felt I annoyed them” [I3, su]</i>	[8] Tensions within relationships with partner, family , friends
Psychological			<b><i>“Feeling of being a burden to other people” [FG2, staff]; “You can feel a bit like a burden” [FG3, su]</i></b>	[9] Feeling like a burden to others
Psychological			Adjustment and Acceptance	Diagnosis
Psychological	<b><i>“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]</i></b>	[11] Worry about diagnosis and / or recovery		
Social	<b><i>“The family will often experience stress” [FG2, staff]</i></b> <i>“It does cause stress, on your husband or wife, your family and your friends. Everyone feels it” [FG3, su]</i>	[12] Stress experienced by partner, family, friends		
Psychological	<i>“I just burst out crying...and that’s not me” [FG3, su];</i> <i>“I’m much more tearful, weepier. It happens all the time [I1, su]</i>	[13] More tearful than usual		
Psychological	<b><i>“They just feel down” [I10, staff]; “You feel down, you feel depressed” [FG4, su]</i></b> <i>“Understanding your own diagnosis is important [FG3, su]</i> <i>“Because I have enough knowledge, I feel better” [I2, su]</i>	[14] Depressed or ‘down’ [15] Enough knowledge and understanding about heart condition		
Physical	Lifestyle Changes	<b><i>“Chest pain...breathlessness...fatigue” [FG2, staff]; “That pain in my chest” [FG3, su]</i></b> <i>“You’re halfway through something and short of breath” [FG3, su]; “When I do anything, fatigue floors me” [FG4, su]</i>		[16] Symptoms (pain, shortness of breath, fatigue)
Physical		<b><i>“You find that...they’re not eating enough to keep well” [FG1, staff]</i></b> <i>“My appetite has altered hugely” [I1, su]</i>		[17] Altered appetite
Physical		<b><i>“Getting enough sleep is very important” [FG1, staff]; “My biggest problem was sleep. Or lack of” [FG3, su]</i></b>		[18] Sleeping well
Physical		<i>“They certainly talk about being ‘slowed down’” [I10, staff]; “It’s a slowing down. You feel it.” [FG3, su]</i>		[19] Feeling ‘slowed down’
Physical		<b><i>“Reduced sex drive can be an issue” [FG2, staff]; “Sexually.. just don’t feel like it” [I7, su]</i></b>		[20] Reduced libido (sex drive)
Psychological		<b><i>“They pick up on lots of symptoms that’s.....exaggerated by the presence of actual cardiac symptoms” [I11, staff];</i></b> <i>“You’re aware of your own heart beat” [FG3, su]; “Feeling tense, all over. Your muscles” [I6, su]</i>	[21] Symptoms of anxiety (e.g. heart racing, tense muscles..)	

Psychological		Confidence Loss	<b>"It can have a huge impact not only actual ability to do things but perceived ability as well" [I11, staff]</b>	[22] Less confidence in ability to undertake daily activity
Psychological			"I spent time thinking – 'can I really do this?'" [FG3, su]; "I had no confidence in what I could do daily" [I2, su]	[23] Apprehension about going out alone
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]	
		Lifestyle Changes	"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]	[24] Worry or anxiety about travelling away from home
Social			<b>"The lifestyle changes are hard....a healthier diet.." [FG1, staff]</b>	[25] Had to change diet
Social			"I think change in diet as well...cutting out the things that you really like...it's a struggle" [FG3, su]	
Social			<b>"They struggle with things like....stopping smoking" [FG1, staff]; "I've stopped smoking...which is so hard." [FG3, su]</b>	[26] Smoked less
Social			<b>"They have to restrict their drinking..alcohol...and that affects their social lives" [FG1, staff]*</b>	[27] Restricted alcohol intake
Social			"My friends are drinkers..so I don't see them as much now" [FG4, su]*	
Social			<b>"Socially they limit things because it's often difficult" [I10, staff]</b>	[28] Limited ability to socialise
Social			"After the heart problem, everything just stopped socially" [FG3, su]	
Social			<b>"Withdrawing from activities...is common" [I11, staff]; "You can feel quite isolated really" [FG3, su]</b>	[29] Feeling isolated or withdrawn
Social			<b>"They can lose that sense of community role" [FG2, staff]; "The concept of self...and role is compromised" [I11, staff]</b>	[30] Limited ability to maintain role within community
Physical			"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			<b>"They often talk about not being able to drive" [FG1, staff]; "I couldn't drive for months and that was a bind" [FG3, su]</b>	[31] Unable to drive
Physical			<b>"Not being able to work, that's hard for them" [FG2, staff]; "I just wanted to be able to earn again" [FG3, su]</b>	[32] Unable to work / earn a living
Social		Daily Life and Health	"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];	[33] Financial constraints
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]	[34] Restricted ability to travel because of insurance costs
Physical			<b>"I think they just want to be able to get back to their own day-to-day structure and routine" [FG3, staff]</b>	[35] Maintain preferred daily structure and routine
Physical			"I just really wanted to get back to my old routine" [I9, su]	
Psychological			<b>"Doing what you want, spontaneously" [FG1, staff]</b>	[36] Unable to do anything spontaneously without prior planning
Psychological			"You just can't go out and do anything spontaneously" [FG3, su]; "You have to plan everything out now" [FG4, su]	
Psychological			<b>"It's important to give them more control"[FG1, staff]</b>	[37] Control over heart condition
Psychological			"The feeling that I couldn't control my own condition" [FG4, su]; "It was difficult to lose control of my body" [I3, su]	
Other		Care	<b>"They really value the support from staff...just someone to speak to" [FG1, staff]</b>	[38] Enough support from healthcare professionals
Other			"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]	[39] Able to ask questions
			<b>" They want to take active role in their recovery as well, and not just do what they've been told to do" [FG1, staff]</b>	[40] Fully involved in care
			"You want to make decisions on your care and treatment" [FG4, su]	

**Table 1: Merging of Literature Review Finding and Qualitative Data to Develop Construct Indicators**

[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; Construct indicators are numbered for identification purposes]

## Appendix A – PROM-CR1's Initial Bank of Items with Domains, Summary Scores and Scales

[Items are cross referenced to their construct indicator number [no.] from table 1]

This question relates to **how you feel overall**. Please circle the most appropriate number.

[1] Over the past **two weeks**, how would you rate your overall health and well-being:

Poor										Excellent
1	2	3	4	5	6	7	8	9	10	

This section relates to the **physical impact** of your heart condition.

Please rate your level of agreement/disagreement with each statement by circling the most appropriate number.

<i>Over the past <b>two weeks</b>, my quality of life has been affected because...</i>	n/a	Strongly Disagree				Strongly Agree
[16] I have experienced symptoms (e.g. pain, shortness of breath, fatigue..)	0	1	2	3	4	5
[2] My ability to undertake everyday activities has been limited	0	1	2	3	4	5
[35] I have been unable to maintain my preferred daily structure and routine	0	1	2	3	4	5
[36] I have been unable to do anything spontaneously without prior planning	0	1	2	3	4	5
[19] I have felt 'slowed down'	0	1	2	3	4	5
[18] I have not slept well	0	1	2	3	4	5
[17] My appetite has been altered	0	1	2	3	4	5
[20] My libido (sex drive) has been reduced	0	1	2	3	4	5
[3] I have been unable to engage in hobbies that I enjoy /previously enjoyed	0	1	2	3	4	5
[32] I have been unable to work / earn a living	0	1	2	3	4	5
[31] I have been unable to drive	0	1	2	3	4	5

Over the past **two weeks**, how would you rate your overall physical well-being:

Poor										Excellent
1	2	3	4	5	6	7	8	9	10	

This section relates to the impact of your heart condition on your **social life and lifestyle**.

Please rate your level of agreement/disagreement with each statement by circling the most appropriate number.

<i>Over the past <b>two weeks</b>, my quality of life has been affected because.....</i>	n/a	Strongly Disagree				Strongly Agree
[8] Tensions arose within relationships with my partner, family and/or friends	0	1	2	3	4	5
[7] My partner, family and/or friends treated me differently	0	1	2	3	4	5
[12] My partner, family and/or friends experienced stress	0	1	2	3	4	5
[28] My ability to socialise was limited	0	1	2	3	4	5
[29] I have felt isolated or withdrawn	0	1	2	3	4	5
[30] My ability to maintain my role within my community was limited	0	1	2	3	4	5
[25] I had to make changes to my diet	0	1	2	3	4	5
[26] I smoked less	0	1	2	3	4	5
[27] I consumed less alcohol	0	1	2	3	4	5
[34] My ability to travel was restricted because of insurance costs	0	1	2	3	4	5
[33] I experienced financial constraints	0	1	2	3	4	5

Over the past two weeks, how would you rate your overall social well-being:

Poor

Excellent

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

This section relates to the emotional impact of your heart condition.

Please rate your level of agreement/disagreement with each statement by circling the most appropriate number.

<i>Over the past <u>two weeks</u>, my quality of life has been affected because I felt...</i>	n/a	Strongly Disagree				Strongly Agree
[13] More tearful than usual	0	1	2	3	4	5
[14] Depressed or 'down'	0	1	2	3	4	5
[4] Frustrated due to my physical limitations	0	1	2	3	4	5
[9] That I was a burden to others	0	1	2	3	4	5
[5] Like a failure	0	1	2	3	4	5
[21] Symptoms of anxiety (e.g. heart racing, shallow breathing, tense muscles)	0	1	2	3	4	5
[22] That I had less confidence in my ability to undertake everyday activities	0	1	2	3	4	5
[23] Apprehensive about going out alone	0	1	2	3	4	5
[24] Worried or anxious about the prospect of travelling away from home	0	1	2	3	4	5
[6] Worried or anxious about my job and/or financial security	0	1	2	3	4	5
[11] Worried about my diagnosis and/or recovery	0	1	2	3	4	5
[10] That I wanted to blame myself or others for my diagnosis	0	1	2	3	4	5

Over the past two weeks, how would you rate your overall emotional well-being:

Poor

Excellent

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

This section asks about the impact of the care that you have had.

Please rate your level of agreement/ disagreement with each statement by circling the most appropriate number.

<i>Currently, I feel that I...</i>	n/a	Strongly Disagree				Strongly Agree
[15] Have enough knowledge and understanding about my heart condition	0	1	2	3	4	5
[39] Am able to ask questions about my heart condition	0	1	2	3	4	5
[37] Have control over my heart condition	0	1	2	3	4	5
[40] Am fully involved in my care	0	1	2	3	4	5
[38] Have enough support from healthcare professionals	0	1	2	3	4	5