Inclusion of the patients’ perspective in the development of patient-reported outcome measures used in elective coronary revascularisation:
A narrative review

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Background

Patient reported outcome measurements (PROMs)
Instruments that assess the health or wellbeing from the perspective of the patient without interpretation by a clinician or other health provider

(FDA Guidance, 2009)
Background

**Patient reported outcome measures** (PROMs) are needed to improve patient-centred care.

Patients should have input in the development of a PROM

- Definition PROM: An individual’s assessment of their health or well-being that comes directly from the individual without interpretation by a clinician or anyone else (FDA Guidance, 2009).

- “PROMs differ little from traditional instruments unless they truly incorporate the patient’s perspective” (Trujols et al, 2013)

- Patients and health care professionals rank importance of outcomes differently
Background

Elective procedures for coronary revascularisation:

Percutaneous coronary intervention (PCI)

Percutaneous transluminal coronary angioplasty (PTCA)

- May be appropriate for patients with angina who remain symptomatic despite pharmaceutical treatment.

- Can reduce the symptoms of angina, but compared with optimal pharmaceutical treatment alone, it does not prevent myocardial infarction or death.
Background

2010 review of psychometric properties
• 24 cardiovascular-specific PROMs
• (10 generic PROMs)

Aim

To explore *if* and *how* patients were involved in the development of the 24 cardiovascular-specific PROMs.
Methods

Data collection
• Identifying publications describing the development of the PROM
• Data extracted by 2 reviewers
  ▪ Target condition (the condition the PROM was developed for)
  ▪ Methods applied for domain and item selection: literature, patient input, expert input and/or statistical analysis
  ▪ Methods used to obtain patient input: focus groups, semi-structured interviews, surveys, ranking of listed items and/or other
  ▪ Diagnosis and number of patients involved

Results

9 multidimensional PROMs
8 full text available
6 involved patient input

1 No full text
- Heart surgery symptom inventory (HSSI)

1 No pt input
- Seattle Angina Questionnaire (SAQ)
1 Not described
- Quality of life index-cardiac version (QLI-CV)

• 1 Focus groups
• 2 Semi-structured interviews
• 2 Structured interviews/surveys
• 1 Combination
### Instrument Patient input in domain/item selection

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Patient input in domain/item selection</th>
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<tbody>
<tr>
<td>Cardiac symptom survey</td>
<td>157 <a href="#">CABG patients</a> completed questionnaires with open-ended questions to list symptoms and feelings and describe what aspects were noticeable or bothersome.</td>
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<tr>
<td>Coronary revascularisation outcome questionnaire (CROQ)</td>
<td>10 PTCA and 10 <a href="#">CABG patients</a> completed semi-structured interviews asking patients about their experience of PTCA or CABG procedures.</td>
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<tr>
<td>Duke activity status index (DASI)</td>
<td><strong>50 patients undergoing maximal exercise testing</strong> completed structured interviews asking whether or not s/he could perform each of a list of activities.</td>
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<td>Kansas city cardiomyopathy questionnaire (KCCQ)</td>
<td>Focus groups - no details provided.</td>
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<tr>
<td>Quality of life after myocardial infarction questionnaire (QLMI)</td>
<td>Semi-structured interviews – no details provided. Questionnaires completed by 63 <a href="#">MI and cardiac rehab patients</a> who rated concern and importance of 97 items.</td>
</tr>
<tr>
<td>Symptoms of illness score (SOIS)</td>
<td>318 <a href="#">CABG patients</a> completed structured questionnaires evaluating symptoms, functioning and wellbeing post-surgery</td>
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</table>

### Results

- **15 unidimensional PROMs**
- **13 full text available**
- **3 involved patient input**
  - 3 Semi-structured interviews
- **2 No full text**
  - Rose dyspnoea questionnaire
  - Cardiac adjustment scale
- **5 No patient input**
  - Barnason efficacy expectation scale
  - Cardiac depression scale
  - Cardiac surgery symptom inventory
  - Cardiac symptoms scale
  - ENRICHD social support index
- **5 Not described**
  - Angina questionnaire
  - Cardiac self-efficacy scale
  - Control attitudes scale
  - Symptom inventory
  - Symptom scale
**Results**

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<td>Cardiac event threat questionnaire (CTQ)</td>
<td>64 MI patients were asked to describe the event or situation they had been most concerned about during the past month and rate the degree of threat.</td>
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<td>Rose angina questionnaire</td>
<td>36 angina, 15 MI and 23 non-cardiac patients completed a questionnaire. In semi-structured interviews, the 36 angina patients were asked “what is chest pain like?” and respond yes or no to the appropriateness of each of a series of terms describing quality of pain.</td>
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<td>Specific activity scale</td>
<td>During semi-structured interviews, participants (n=?, diagnosis=?) were asked whether specific activities were performed and what symptoms were provoked by it or why they were unable to perform the activity.</td>
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**Discussion**

Is patient input sought in the development of cardiovascular PROMs?
- Poorly described
- Representativeness of samples?

Need for standardised reporting of PROM development to facilitate consistency and transparency
Discussion

3 Multidimensional PROMs developed with patient-centred methods
- **CROQ**
- **Cardiac Symptom Survey** - incisional pain, *tiring easily/fatigue*, difficulty sleeping, poor appetite, and swelling of feet/legs, chest pain, depression, and shortness of breath
- **QLMI** - *low energy, worn out*, restricted in life, usual social activities, return to work, dependence, dizziness, need to rest, restlessness, knowing how much exercise to do

Of the 17 outcomes identified:
- PROMs developed with patient-centered methods included 8-11 outcomes
- PROMs not developed with patient-centered methods included 0-9 outcomes

Discussion

International Consortium for Health Outcome Measurements (ICHOM)
- **7-item SAQ** - physical limitation, chest pain and quality of life
- **Rose dyspnoea scale** - shortness of breath
- **2-item Patient Health Questionnaire (PHQ)** – depression

*4 of the 17 outcomes identified as important*
Conclusion

Only 3 of the 24 PROMs used in elective procedures for coronary revascularisation involved patients in their conceptual development.

For 12 PROMs the patient involvement was unclear.

This highlights that the patients’ perspective is often overlooked or not described when developing instruments that aim to measure outcomes that are important for patients.

Thank you

I feel lucky to be alive. The doctors were absolutely fabulous.

The stent hasn’t worked for me. I get so short of breath, I can’t do anything, really...

My bruises are just horrific!

I wrapped myself in cotton wool because I was afraid to damage my heart.

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