Public Involvement in Patient Reported Outcome Measures (PROMs)

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Plan of action

- Developing a Core Outcome Set for Cardiac Arrest Clinical Trials: the COSCA initiative
  - Defining health outcomes
  - Current state of health outcome assessment in CA trials
  - What matters to patients?
  - What matters to health professionals?
  - Working towards consensus

- Contribution of PPI to COS development
What is a Health Outcome?

- The way I feel is hard to quantify!
- How hard on a scale of one to ten?
What is a Health Outcome?

The result(s) that people care about most when seeking (or providing) treatment, including functional improvement and the ability to live normal, productive lives

ICHOM: International Consortium for Health Outcome Measurement
(www.ichom.org)

If the measured end-points were the only things that changed, would the patients be willing to accept the treatment?

(Guyatt et al, 2007)
Which outcomes ‘matter’ following a cardiac arrest?

What is successful resuscitation?

– ‘Survival’ ….

– Individual is not cognitively impaired and reports an ‘acceptable quality of life’ (Beesems et al, 2014)

– No significant deterioration when compared to their pre-morbid state (Bossaert et al, 2014)

No assessment guidance
Outcome reporting in Cardiac Arrest Clinical Trials

- 61 trials reported >160 individual outcomes (2000-2012)

  What? Survival (85%), Process of care, Body structure/function
  Who? Clinician-reported outcome assessment
  When? Up to and including hospital discharge
  Why? Often poor rational for outcome selection

- Significant heterogeneity in outcome reporting

- Something MISSING???
  - Limited focus on ‘what matters to patients?’
    - No assessment of the patients perspective
    - Limited short-term assessment
    - No patient-reported long-term assessment

(Whitehead et al, 2015)
Outcome reporting - Cardiac Arrest Clinical trials

Box. Cerebral Performance Category (CPC) Scale

CPC 1: Full recovery or mild disability

CPC 2: Moderate disability but independent in activities of daily living

CPC 3: Severe disability; dependent in activities of daily living

CPC 4: Persistent vegetative state

CPC 5: Dead
How do we know if we are ‘restoring quality of life?’
A Core Outcome Set for Cardiac Arrest

- COSCA: A small group of outcomes which should be routinely reported as a minimum in Cardiac Arrest effectiveness trials (www.comet-initiative.com)

- COS Co-construction
  - Multiple stakeholders to reflect key perspectives
  - Patients as participants and research partners

- International steering group
- International participants

Clinical Research Ambassador Group (CRAG)
COSCA: Step 1 – WHAT to measure?

1.1 What matters to patients?
Semi-structured interviews with survivors and partners
- their lived experience
- health outcomes that really matter

In-depth qualitative analysis

A convenience sample
- 8 Patients (n=5 Males) and 3 partners
- mean 62.8 years (SD 13.6); range 41-79
- mean of 6.25 months post arrest
1.1 Results

Patients have real problems that we are not capturing.

Diagram:
- Survival
- Physical symptoms
- Social well-being
- Emotional well-being
- Impact on others

Disruption to normality
Disruption to normality

Survival

Impact on others
- Anxiety / fear
- Depression
- Frustration
- Loss of confidence
- Self-esteem
- Personality changes

Physical symptoms
- Participation: role; leisure; family; social

Emotional well-being

Social well-being

Patients strive to regain their former life
Disruption to normality

- Survival
- Physical symptoms
  - Pain
  - Fatigue/energy
  - Muscle weakness
  - Breathlessness
  - Limited ADL
  - Dependency
  - Cognition
- Emotional well-being
  - Relationship strain
  - Impact on partners:
    - Increase in caring role
    - Social well-being
- Social well-being

Responding to new symptoms and limitations
COSCA: Step 1 – WHAT to measure?

1.2 Delphi Survey: what matters to international stakeholders?

- Total of 44 outcomes across 5 time-points:
  - during CPR; immediately after CPR; during hospital stay; hospital discharge; within 1st year

How important is the outcome for a core outcome set?

- Round 1: GRADE Scale 0-9 (Not important – Critically important)
- Round 2: Rank the top 10 (5) most important outcomes

Result: 15 countries

- Round 1: n= 99 Health Professionals; n= 69 survivors / partners
- Round 2: n= 55 Health Professionals; n= 43 survivors / partners

Consensus: Pre-defined at 70%
<table>
<thead>
<tr>
<th>Core Area</th>
<th>Outcome Domain</th>
<th>During CPR</th>
<th>Immediately after</th>
<th>During hospital stay</th>
<th>At hospital discharge</th>
<th>Within 1 year</th>
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<td>Process measure of CPR</td>
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COSCA: Step 1 – WHAT to measure?

1.3 International Consensus Meeting

23 international voting participants including 4 patient representatives
- UK, Netherlands, USA, Canada, Australia, Finland, Singapore, Sweden, Finland, New Zealand and Germany

Structure:
- Plenary presentations
- Small and large group discussions plus voting

- Seek consensus on (70% agreement):
  - What to measure
  - When to measure
  - (How to measure – Step 2)
COSCA – What to measure

Core Outcomes

Outcomes important to specific trials

CORE 1: Survival at hospital discharge / 30 days

CORE 2: Neurological function at hospital discharge / 30 days - mRS

CORE 3: Health-related Quality of Life – within the first year - Uncertainty re HOW
Conclusion – PPI, Important Outcomes and COS

- Involvement of patients as participants and partners crucial to COS development
  - Current status in CA clinical trials:
    - Patient perspective not assessed
    - Current approaches ‘over-estimate well-being’

- As participants:
  - Survivors have real, wide-ranging problems that we currently do not assess
  - Enabled the patient voice to be heard throughout the COS development process

- As partners:
  - Clear guidance for what was acceptable and relevant

- As participants and partners:
  - A unique voice to the consensus meeting – keeping the values of patients high on the agenda
  - Part of the writing team
Thank-you

- **COSCA Core team:** Warwick University:
  - Laura Whitehead, Gavin Perkins, Kirstie Haywood
- **COSCA Collaborators:**
  - Jonathan Benger, Steven Brett, Maaert Castren, Judith Finn, Vinay Nadkarni, Ken Spearpoint
- **COSCA PPI:** Clinical Research Ambassador Group (CRAG) and participants in consensus meeting
- **COSCA Writing Group**
- **Endorsement from ILCOR and AHA**
- **Participants:** Interviews, Delphi and Consensus meeting