

# 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?




# 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](http://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 rationale 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



# Outcome reporting - Cardiac Arrest Clinical trials

## Box. Cerebral Performance Category (CPC) Scale

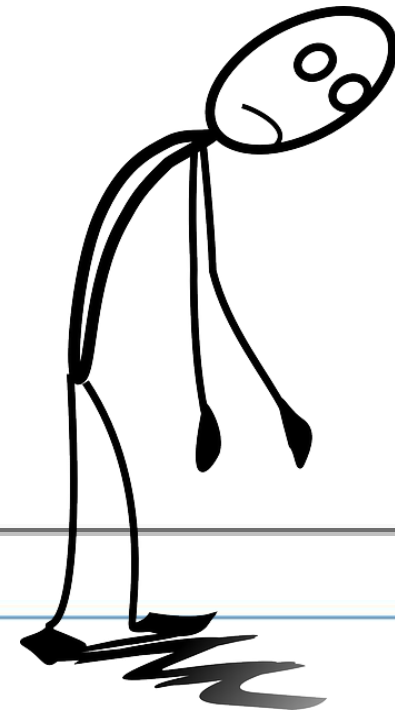
CPC 1: Full recovery or mild disability

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](http://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?

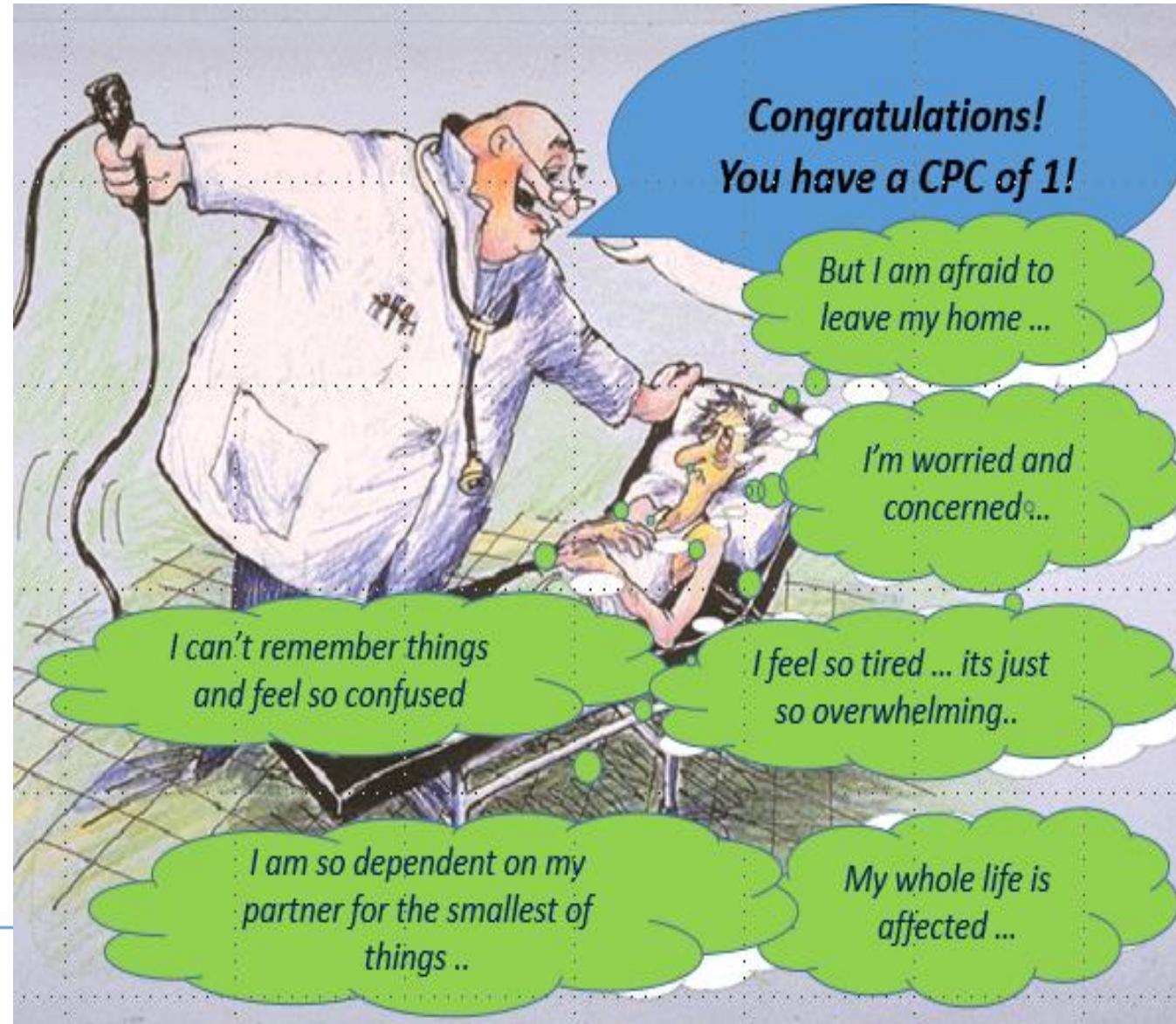
Semi-structured interviews with survivors and partners

- their lived experience
- health outcomes that really matter

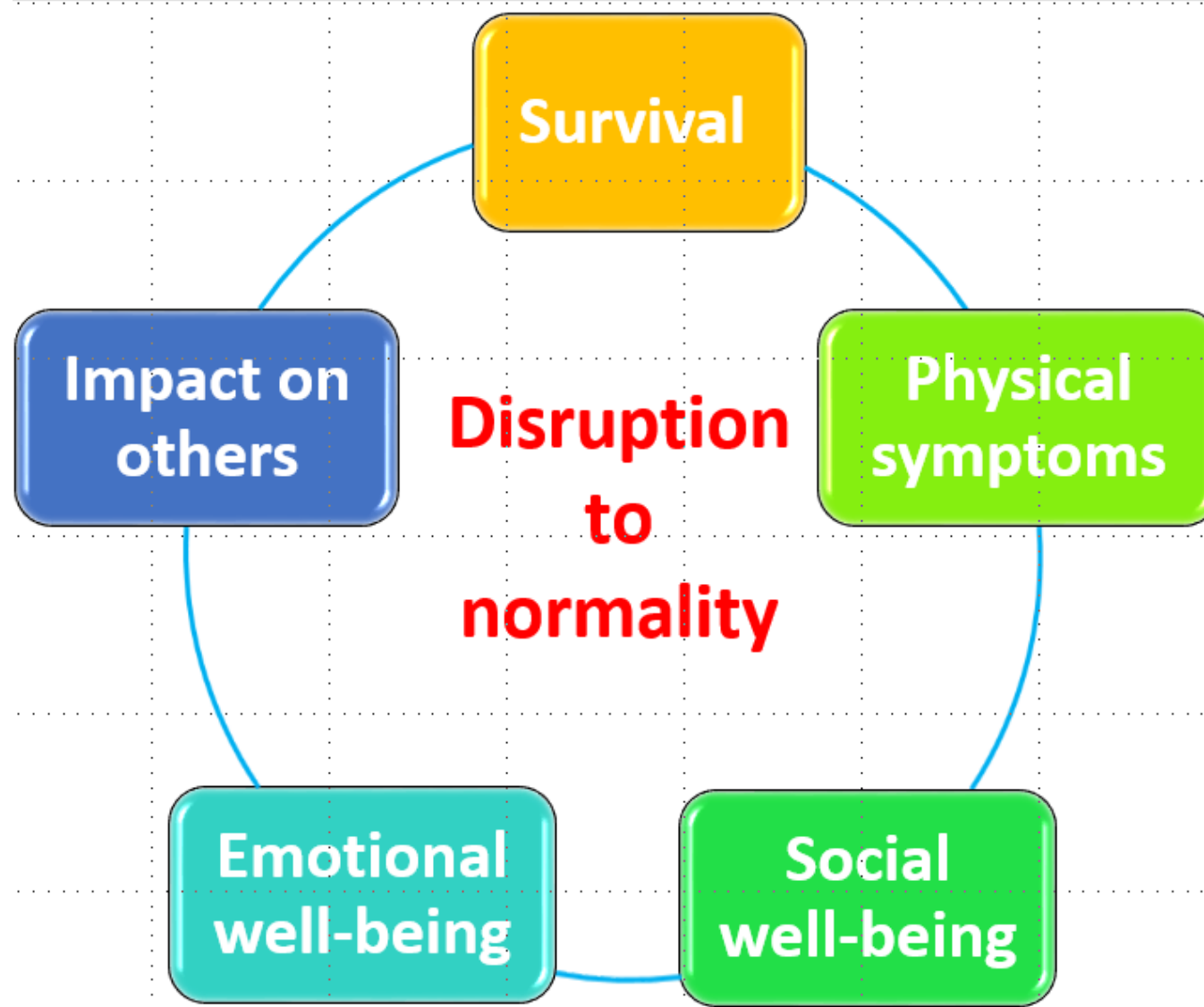
## ► In-depth qualitative analysis

## ► A convenience sample

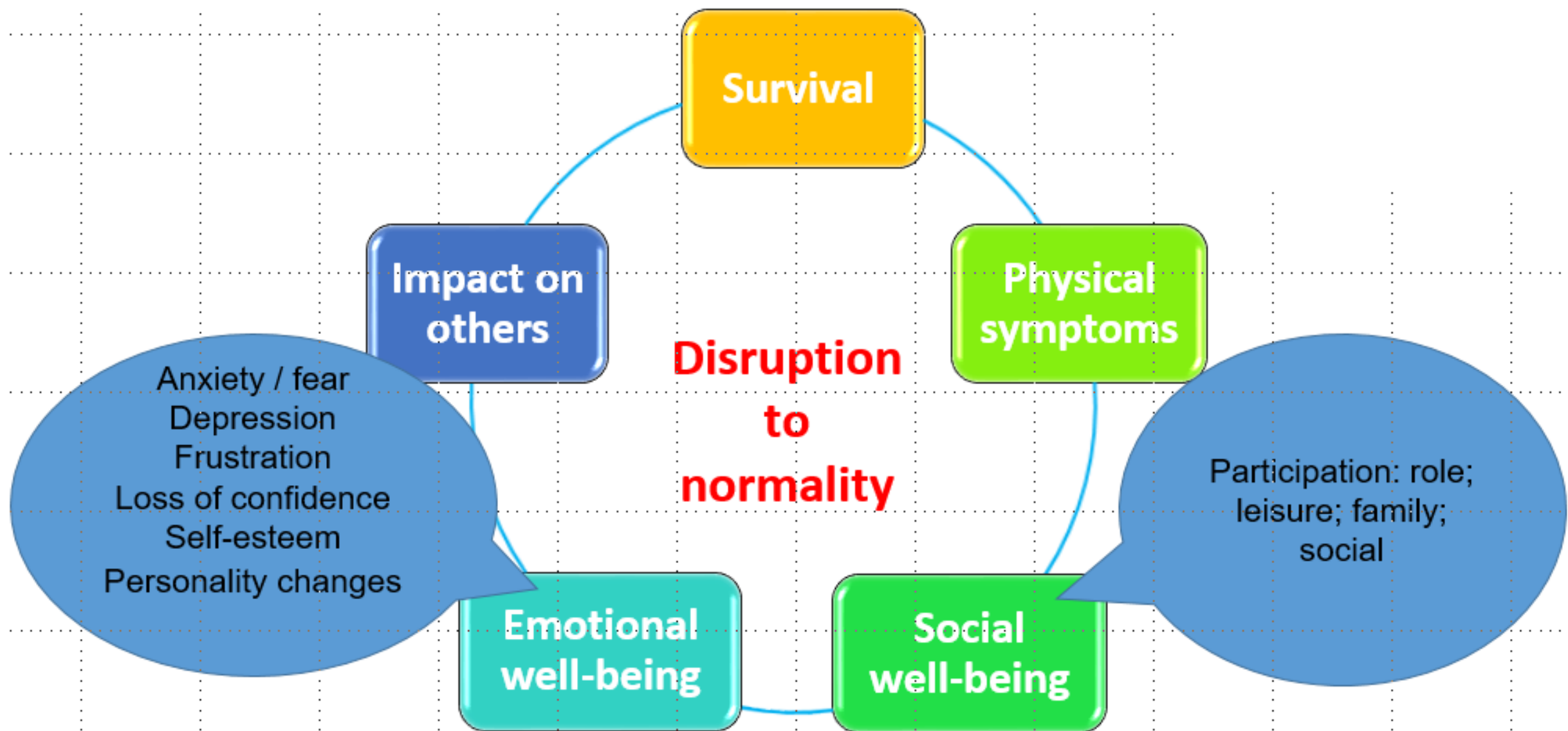
- 8 Patients (n5 Males) and 3 partners
- mean 62.8 years (SD 13.6); range 41-79
- mean of 6.25 months post arrest



# 1.1 Results



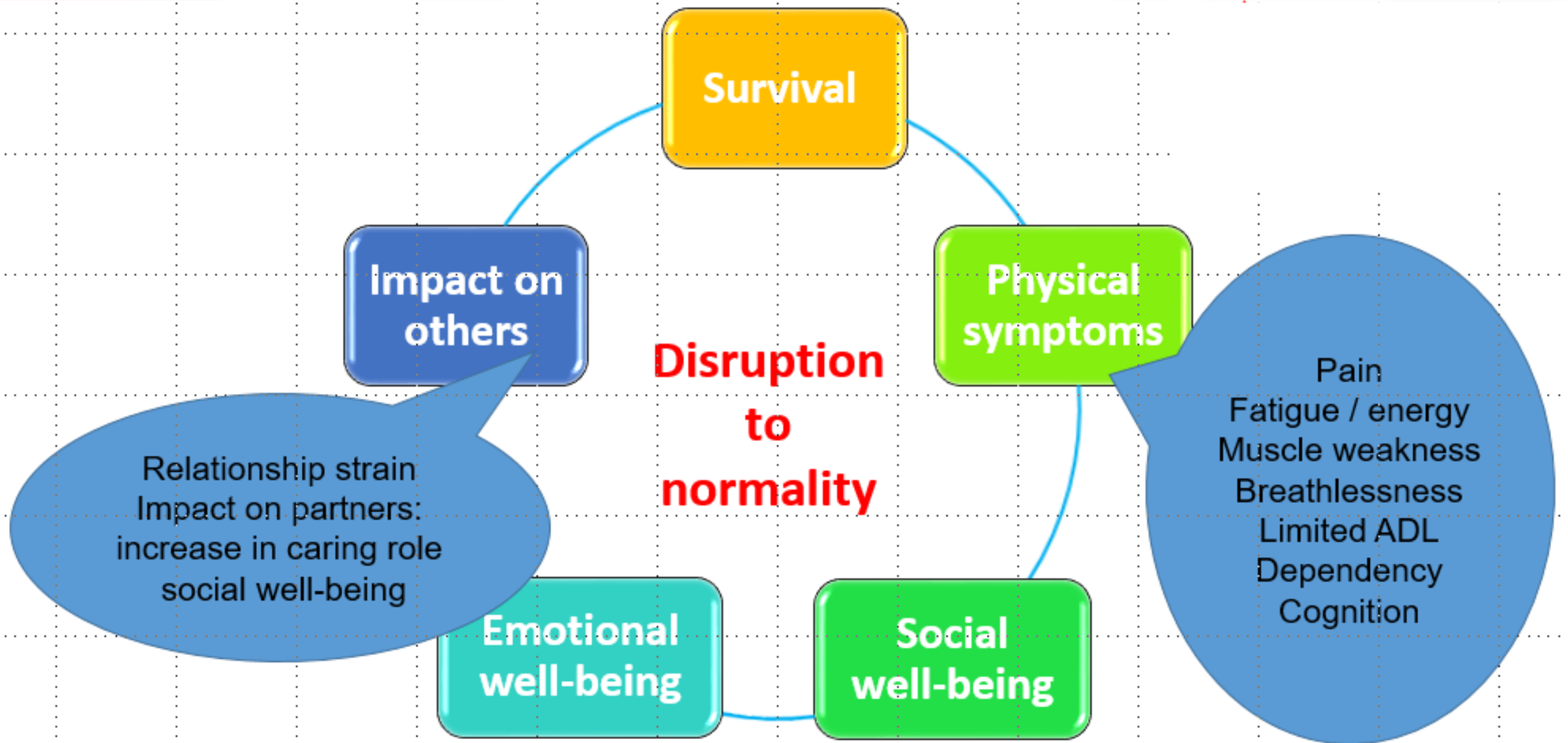
**Patients have real problems that we are not capturing**



**Patients strive to regain their former life**







**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%**

<u>Core Area</u>	<u>Outcome Domain</u>	<i>During CPR</i>	<i>Immediately after CPR</i>	<i>During hospital stay</i>	<i>At hospital discharge</i>	<i>Within 1 year</i>
<b>Pathophysiological manifestations</b>	Circulatory function	○	●	● ▲		
	Respiratory function			▲		
	Renal function					
	Brain function (neurological markers)		○	○ ▲		
	Adverse events					▲
	Process measure of CPR *					
<b>Survival</b>	Survival	●	●	● ▲	● ▲	● ▲
<b>Life impact</b>	Consciousness and cognition		○	○ ▲	● ▲	● ▲
	Physical symptoms				●	● ▲
	Activities of daily living				●	● ▲
	Health related quality of life				○	● ▲
	Emotional well-being					▲
	Family impact					▲
	Participation				△	● ▲
	Fatigue					▲
<b>Economic impact and resource use</b>	Cost effectiveness					
	Hospital free survival *					

# COSCA: Step 1 – WHAT to measure?

## ▶ 1.3 International Consensus Meeting

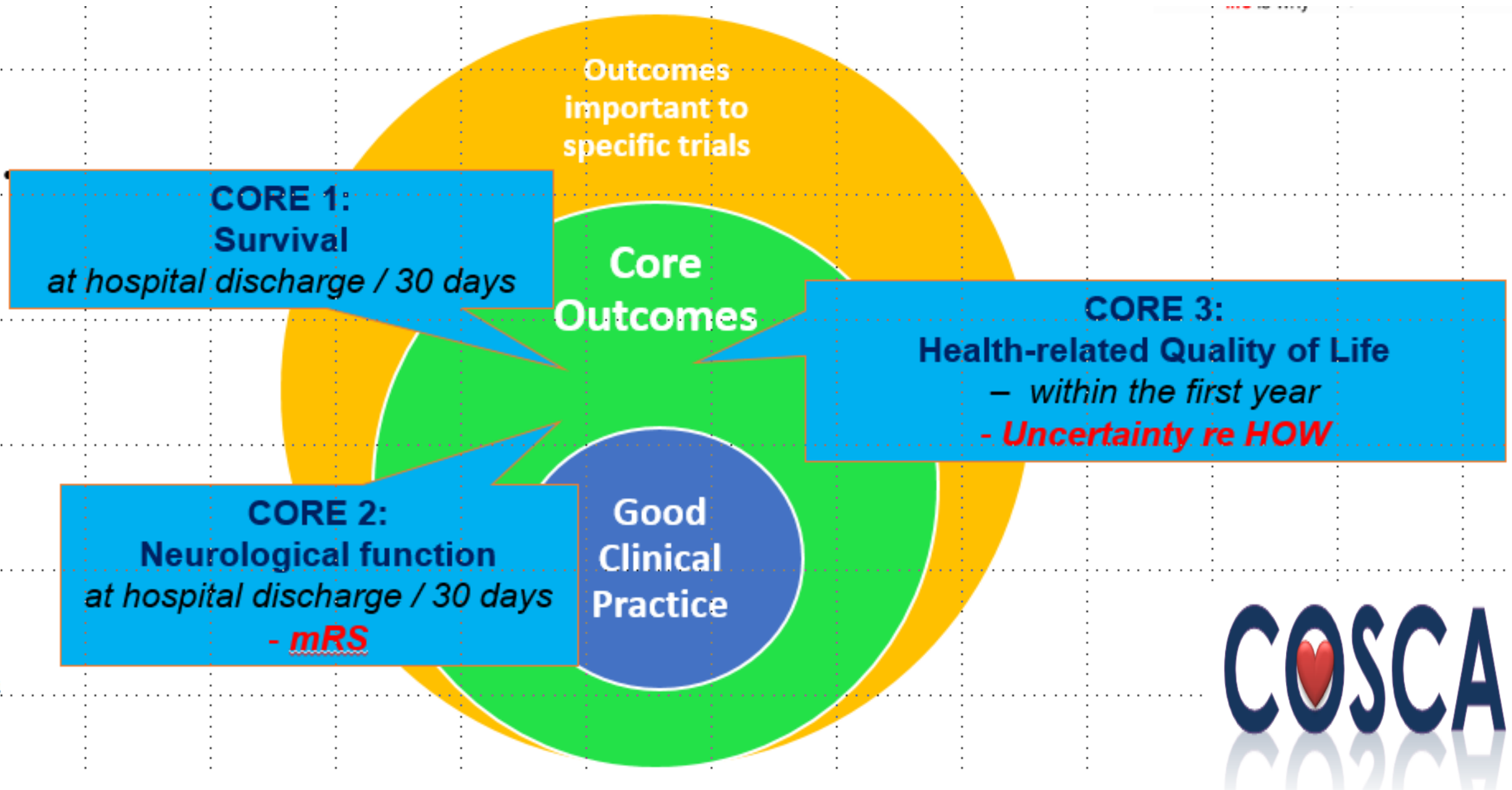
- ▶ 23 international voting participants including 4 patient representatives
  - UK, Netherlands, USA, Canada, Australia, Finland, Singapore, Sweden, Finland, New Zealand and Germany
- ▶ Structure:
  - Plenary presentations
  - Small and large group discussions plus voting
  - Seek consensus on (70% agreement):
    - What to measure
    - When to measure
    - (*How to measure – Step 2*)



Vinay, Barry, John, Laura, Cathy, Anne, Kirstie, Gavin



# COSCA – What to measure



# 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
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# 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