



**Core Outcome Measures in Effectiveness Trials**

[www.comet-initiative.org](http://www.comet-initiative.org)

@COMETinitiative

# Outcomes – from the very start



*Clinical trials are only as credible as their outcomes*

Tugwell, 1993



Equally true for systematic reviews as well



...and clinical guidelines



...and healthcare organisations

# Core outcome set for trials - 2010

- An agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care

# DMARD trials for rheumatoid arthritis

TRIAL	YEAR	PAIN	PT GLOB	SWOLLEN JOINT	TENDER JOINT	ACUTE PHASE	PHYSICIAN GLOB	FS	QOL	RADIOGRAPH
ERC	1960		Y			Y	Y	Y		Y
LEVY	1972				Y					
UROWITZ	1973			Y	Y	Y				Y
ANDREWS	1973	Y	Y		Y	Y	Y	Y		Y
CCC	1973					Y		Y		
SIGLER	1974					Y		Y		Y
DIXON	1975	Y				Y				
HUSKISSON	1976	Y			Y	Y				
MERY	1976		Y		Y	Y	Y			
SHIOKAWA	1977						Y			Y
WOODLAND	1981		Y		Y	Y		Y		
WILLIAMS	1983	Y	Y	Y	Y	Y	Y			
WARD	1983		Y	Y	Y		Y	Y		
ANDERSON	1985	Y	Y	Y	Y	Y	Y	Y		
WEINBLATT	1985		Y	Y	Y	Y	Y	Y		
WILLIAMS	1985	Y	Y	Y	Y	Y	Y	Y		
DOUGADOS	1988	Y	Y	Y	Y	Y		Y		
TUGWELL	1990	Y	Y			Y	Y	Y		
FURST	1990	Y	Y	Y	Y	Y	Y	Y		
DAVIS	1991			Y	Y	Y				
CLARK	1993	Y	Y	Y	Y		Y			
PINHEIRO	1993	Y			Y	Y		Y		
FORRE	1994	Y	Y	Y	Y	Y		Y		Y
ROZMAN A	1994		Y	Y	Y	Y	Y			

## COMET Initiative

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets' (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, and are also suitable for use in clinical audit or research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research in this area. [The COMET Handbook Version 1.0](#) is available [here](#).

**When searching the COMET database, please note that a systematic review is currently underway to identify eligible material, and we are continually updating the database as we identify eligible studies. Therefore, the records retrieved by any search might increase on a daily basis.**



### Search COMET database

The COMET database currently contains **1193** references of planned, ongoing and completed work.

The keyword used for the search will be compared with study title, abstract and author's surname.

[View full search options](#)

To view a demonstration of how to search the COMET database click [here](#)



### Core resource pack

Useful references for core outcome set developers.

This includes an overview of the problems with outcomes in trials, key issues to consider in the development of a core outcome set, examples of core outcome set development, and things to think about once a COS is agreed. To read more, click [here](#).



[Follow us on Twitter](#)



[Help, I want to...](#)

- [Search COMET](#)
- [Send general feedback / enquiry](#)
- [Tell us about a new project/study](#)
- [Report a missing study](#)
- [Find out about how to measure](#)
- [COMET blogs](#)
- [Subscribe to our mailing list](#)



NEWS [Latest News](#)



[www.comet-initiative.org](http://www.comet-initiative.org)



EUROPEAN  
COMMISSION



SEVENTH FRAMEWORK  
PROGRAMME



FUNDED BY

NIHR

National Institute  
for Health Research

# Systematic review of COS for trials

OPEN ACCESS Freely available online

PLOS ONE

## Choosing Important Health Outcomes for Comparative Effectiveness Research: A Systematic Review

Elizabeth Gargon<sup>1\*</sup>, Binu Gurung<sup>1</sup>, Nancy Medley<sup>1</sup>, Doug G. Altman<sup>2</sup>, Jane M. Blazeby<sup>3</sup>, Mike Clarke<sup>4</sup>, Paula R. Williamson<sup>1</sup>

PLOS ONE

Department of Health Services Research, University of Oxford, Botnar Research Centre, Oxford, University Belfast, Institute of Clinical Sciences,

RESEARCH ARTICLE

### Choosing Important Health Outcomes for Comparative Effectiveness Research: An Updated Review and User Survey

Sarah L. Gorst<sup>1\*</sup>, Elizabeth Gargon<sup>1</sup>, Mike Clarke<sup>2</sup>, Jane M. Blazeby<sup>3</sup>, Douglas G. Altman<sup>4</sup>, Paula R. Williamson<sup>1</sup>



PLOS ONE

RESEARCH ARTICLE

### Choosing Important Health Outcomes for Comparative Effectiveness Research: An Updated Review and Identification of Gaps

Sarah L. Gorst<sup>1\*</sup>, Elizabeth Gargon<sup>1</sup>, Mike Clarke<sup>2</sup>, Valerie Smith<sup>3</sup>, Paula R. Williamson<sup>1</sup>

**1** MRC North West of Liverpool, Liverpool, United Kingdom, **2** School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland

PLOS ONE

RESEARCH ARTICLE

### Choosing important health outcomes for comparative effectiveness research: An updated systematic review and involvement of low and middle income countries

Katherine Davis<sup>1</sup>, Sarah L. Gorst<sup>1\*</sup>, Douglas G. Altman<sup>2</sup>, Jane M. Blazeby<sup>3</sup>

**1** MRC North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool, United Kingdom, **2** Centre for Statistics in Medicine, Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom, **3** Centre for Public Health, University of Liverpool, Liverpool, United Kingdom



PLOS ONE

RESEARCH ARTICLE

### Choosing important health outcomes for comparative effectiveness research: 4th annual update to a systematic review of core outcome sets for research

Elizabeth Gargon<sup>1\*</sup>, Sarah L. Gorst<sup>1</sup>, Nicola L. Harman<sup>1</sup>, Valerie Smith<sup>2</sup>, Karen Matvienko-Sikar<sup>3</sup>, Paula R. Williamson<sup>1</sup>

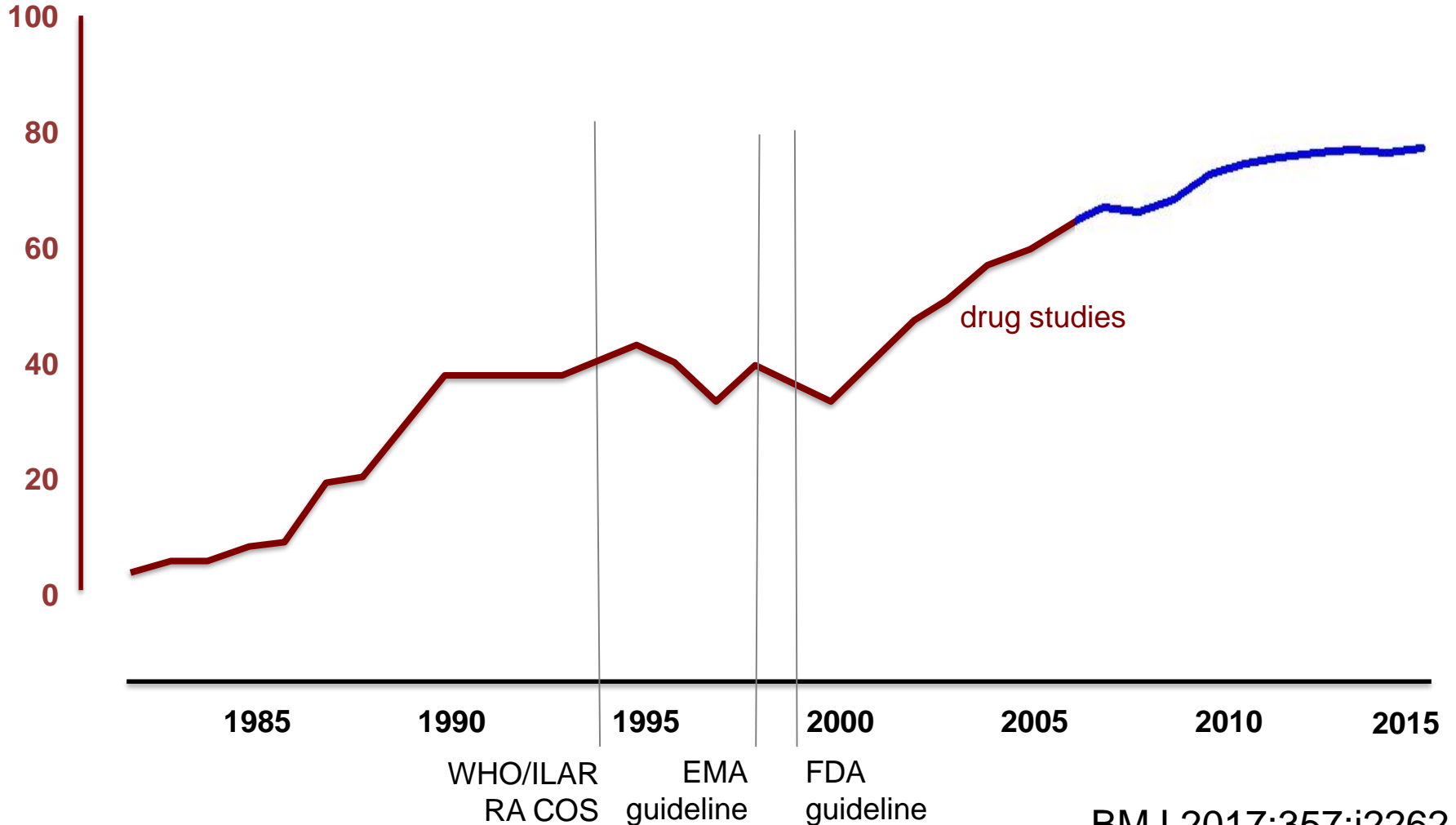
**1** MRC North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool, United Kingdom, **2** School of Nursing and Midwifery, Trinity College Dublin, Dublin, Ireland, **3** School of Public Health, University College Cork, Cork, Ireland



- 307 published studies (366 COS)
- 250 ongoing studies

# Improvements over time (Kirkham et al, *BMJ* 2017)

Studies measuring  
full RA COS (%)



# Podcasts

[Home](#)[About COMET](#)[Search](#)[Events](#)[Resources](#)[COS Uptake](#)[Contact](#)[Public](#)

Core Outcome Measures in Effectiveness Trials

- Database
- Blogs
- Publications
- Grant-funded projects
- Study protocols
- Downloadable slide set
- Core resource pack
- Plain Language Summary
- Adding trial meta-analysis
- Newsletter
- Public involvement
- Links
- Podcasts**
- Outcome classification
  - Adverse event outcomes
  - Physiological or clinical outcomes
  - Physiological or impact?
  - Delivery of care outcomes
  - Health related QoL measurement tools
  - Composite outcomes
  - Deposit your outcome classifications
  - Taxonomy with examples

## Podcasts

This collection of Podcasts highlights the importance of the development and use of COS to people from a range of different backgrounds.

**SBU endorses the usage of robustly developed COS in clinical trials and in systematic reviews**

**Sophie Werkö** (Project Manager, SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services), and **Marie Österberg** (Project Manager, SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services). May 2019.

**"This whole idea of COS is taking on a new role, a new importance..."**

**Hans-Georg Eichler** (Senior Medial Officer, European Medicines Agency). October 2018.

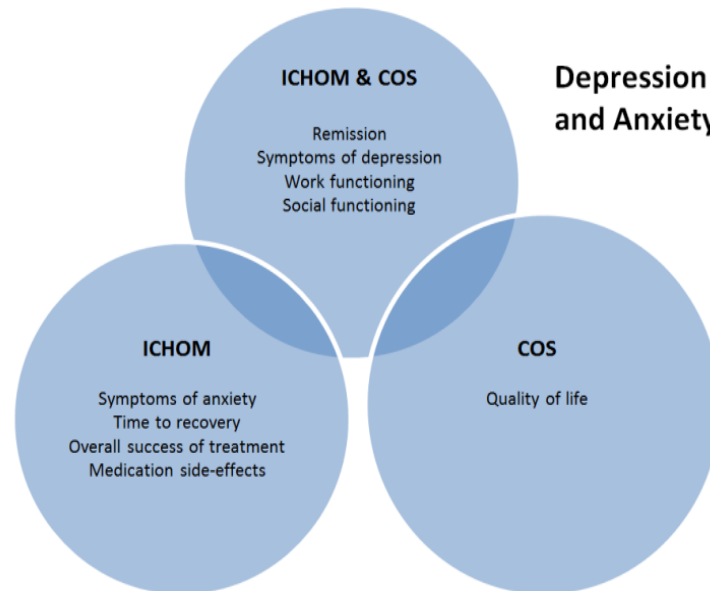
**"I believe that the development and use of core outcome sets is one of the most important advances to date in evidence-based medicine and surgery."**

**Hywel Williams** (Director of the NIHR Health Technology Assessment Programme, Professor of Dermato-Epidemiology and Co-Director of the Centre of Evidence-Based Dermatology). April 2018.



# COS for routine care

- COMET identifies and databases
- ICHOM sets - COS for research exists for 22/27



<http://www.ichom.org/medical-conditions/depression-anxiety/>

Rush et al. (2006). "Report by the ACNP Task Force on response and remission in major depressive disorder." Neuropsychopharmacology **31(9)**: 1841-1853.

# **COS for research AND practice**

- Published: 32/307 (10%)
- Ongoing: 119/250 (48%)



The NHS Long Term Plan

*“Practical priorities will drive NHS digital transformation ..... making data captured for care available for clinical research”*



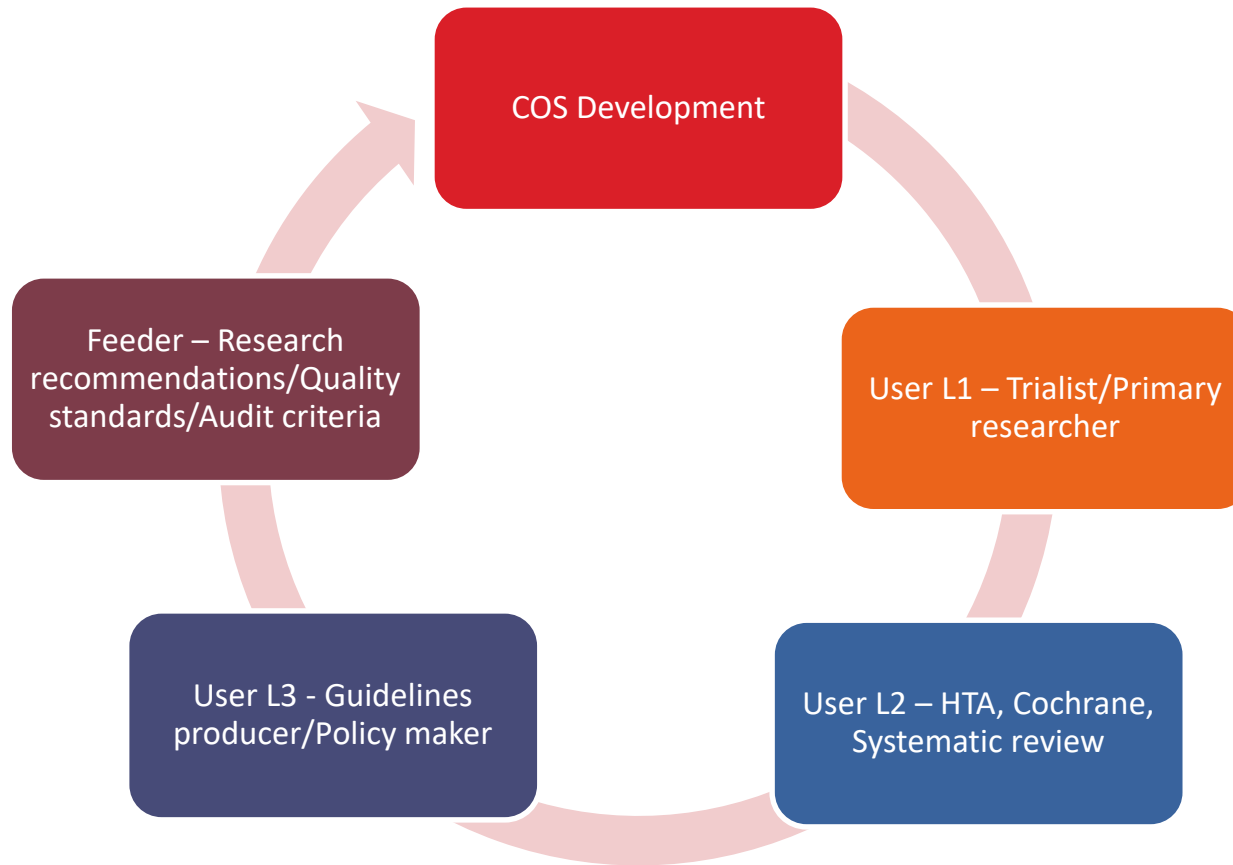
*“How can randomised trials become part of routine care and best utilise current clinical care pathways?”*



**PRioRiTy**

Prioritising Recruitment  
in Randomised Trials

# COS and the healthcare ecosystem



# Measuring outcomes in routine care/EHR

## - BARRIERS

- Practical – insufficient time, disruption to normal work routines, lack of appropriate infrastructure to enable data entry
- Instruments - too cumbersome, difficult to interpret, not relevant to decision-making at the time, lack of agreement on appropriate measures

# Measuring outcomes in routine care/EHR - FACILITATORS

- Multiple levels – policy changes within organisation, financial incentives, engaging clinicians in the planning stage of the process, transparency around rationale
- Instruments - fit for purpose, feasible in setting, supporting decision-making as integral part of health care process

# Minimum standards for COS development

---



---

GUIDELINES AND GUIDANCE

## Core Outcome Set-STAndards for Development: The COS-STAD recommendations

Jamie J. Kirkham<sup>1</sup>, Katherine Davis<sup>1</sup>, Douglas G. Altman<sup>2</sup>, Jane M. Blazeby<sup>3</sup>, Mike Clarke<sup>4</sup>,  
Sean Tunis<sup>5</sup>, Paula R. Williamson<sup>1\*</sup>

*PLoS Medicine* 2017; **14**(11):e1002447

# COS for research: Stakeholder input

- **Healthcare professionals** that would be able to suggest important outcomes (e.g. clinical experts, practitioners, investigators with particular experience in the condition)
- **Patient representatives** (e.g. patients, public, participants who have experienced the condition, family members, carers)
- **Those who will do the research that will use the COS** (e.g. clinical trialists, industry)
- Those who will use the research that should have used the COS (e.g. systematic reviewers, guideline developers, policy makers, regulators)

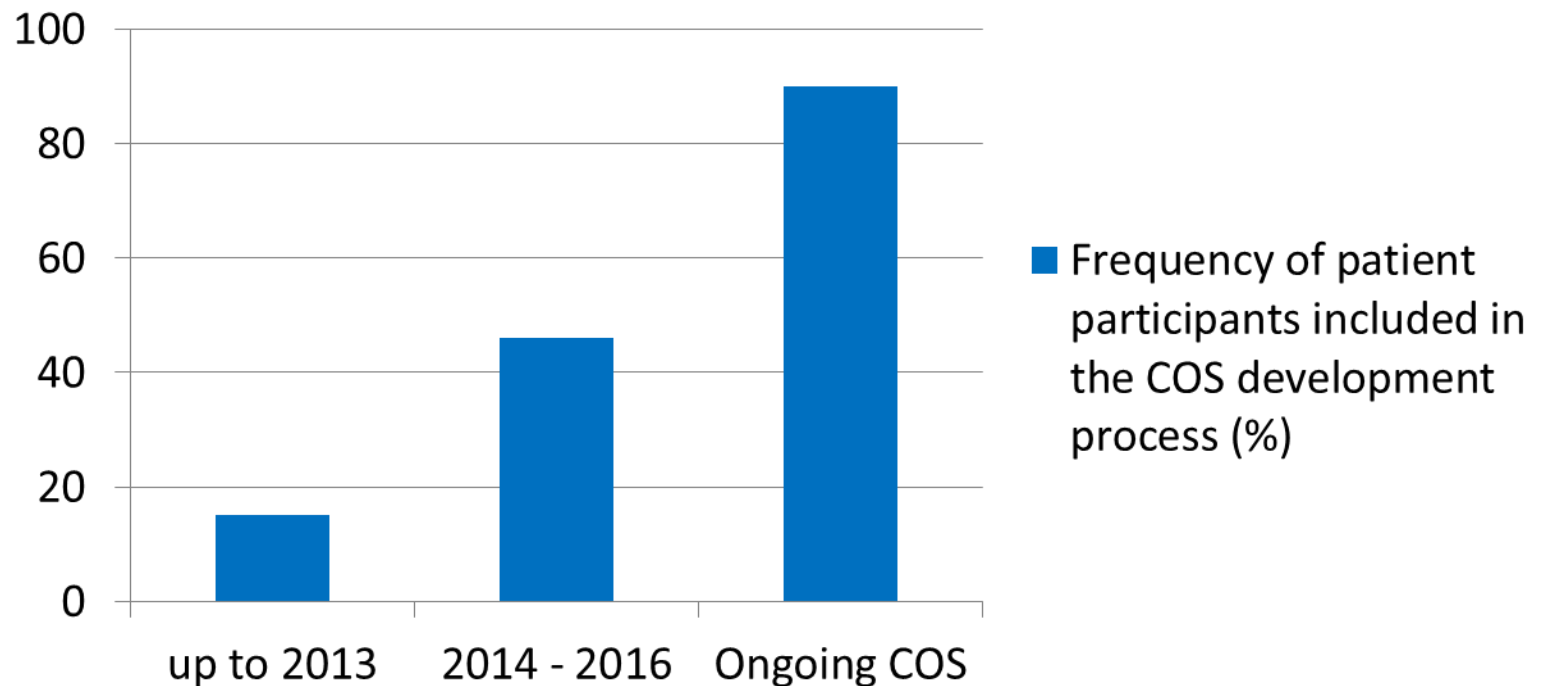


# **“Doctors know about the illness, but patients know about the impact”**

- Berglas 2016
- 30 CADTH guidelines
- Views from patients on guideline panels
- Only 50% of the outcomes that patients said matter to them are captured in primary studies

# Patient participation

- Patients, carers, patient support group representatives, service users

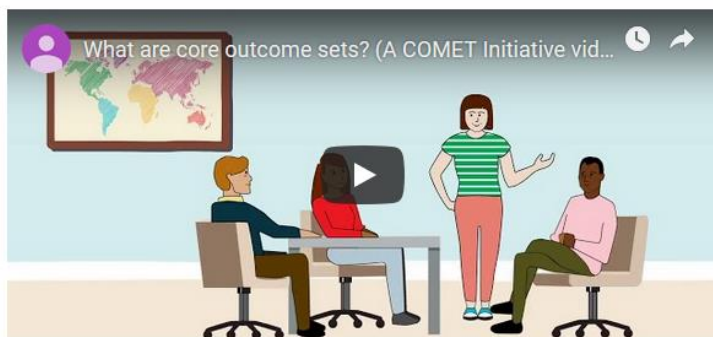


# PoPPIE Group: People and Patient Participation Involvement and Engagement

To lead and oversee the public participation, involvement and engagement work of the COMET Initiative



"What are Core Outcome Sets?" (A COMET Initiative video developed with patients & the public)



This video explains what core outcome sets (COS) are, why they are important and how patients and the public are involved in developing COS.

## Plain Language Summary

The COMET Initiative recognises the expertise and crucial contribution of patients and carers in developing relevant core outcome sets.

We have developed two plain language summaries:

- **The Core Outcome Set / COMET plain language summary** explains what outcomes are and the problems with using different outcomes in research. It also explains what core outcomes sets are, including how they are developed, and it sets out what the COMET Initiative is trying to achieve. You can download the Summary [here](#).

- **The Delphi Process plain language summary** explains what outcomes and consensus processes are and what happens in a Delphi process. You can download the Summary [here](#).

## Questions - Round 2

Please do not use the browser's back button. If you wish to go back to a page please use the dropdown list at the bottom of the page.

You have answered: 0 out of 48 outcomes

Page 1 of 51

Text for the questions page of round 2 should go here..

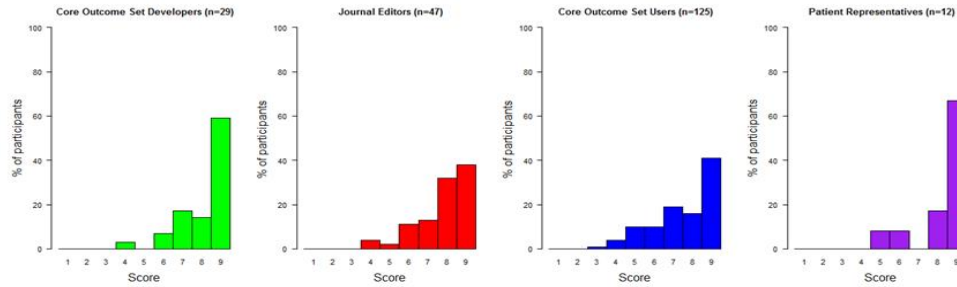
If you would like clarification on a variable, please hold your cursor over the variable and a text box will be displayed with additional information or definitions where available.

### Identification that paper reports development of a core outcome set

Your score from Round 1 is highlighted in yellow.

#### Summary of Round 1

TITLE: Identification that paper reports development of a core outcome set



Outcome	Not important			Important but not critical			Critical			Unable to score
	1	2	3	4	5	6	7	8	9	
Title	Identification that paper reports development of a core outcome set									
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please note: You will only be able to save/move to the next page if you have answered ALL the questions on this page.

Save and Exit

Next Page

SCORE-IT COS	ICHOM set	NICE QS	NICE QI	CPRD	DECIDE
Overall survival	✓			✓	✓
Death, with cause recorded				✓	✓
Heart failure	✓	✓	✓	✓	
Gangrene or amputation of the leg, foot or toe	✓	✓	✓	✓	
Diabetic ketoacidosis	✓	✓	✓	✓	
Hyperglycaemia	✓	✓	✓	✓	
Hypoglycaemia	✓	✓	✓	✓	✓
Cerebrovascular disease	✓	✓	✓	✓	
Hospital admissions due to diabetes	✓	✓	✓	✓	✓
Side effects of treatment	✓			✓	✓
Global quality of life	✓	✓	✓	✓	✓
Nonfatal myocardial infarction	✓	✓	✓	✓	
Visual deterioration or blindness	✓	✓	✓	✓	
Glycaemic control	✓	✓	✓	✓	✓
Neuropathy	✓	✓	✓	✓	
Kidney function	✓	✓	✓	✓	
Activities of daily living				✓	✓
Body weight	✓		✓	✓	✓



[www.comet-initiative.org](http://www.comet-initiative.org)

[prw@liv.ac.uk](mailto:prw@liv.ac.uk)

Twitter: @COMETinitiative