Core Outcome Measures in Effectiveness Trials
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Core outcome sets (COS)
and
the healthcare ecosystem

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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			

Source: Kirkham, J. J., M. Boers, et al. (2013). *Outcome measures in rheumatoid arthritis randomised trials over the last 50 years,* Trials 14(1): 324.

Core outcome sets for trials

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

Systematic review of COS for trials

- 337 published studies (410 COS)
- 280 ongoing studies

COMET INITIATIVE

Core Outcome Measures in Effectiveness Trials

Podcasts

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

COMET Webinar for Patient Organisations – "No Choice of Outcomes About us Without us!"

Heather Bagley (COMET Patient and Public Involvement Co-ordinator). July 2019.

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.

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

Improvements over time (Kirkham et al, *JCE 2019*)
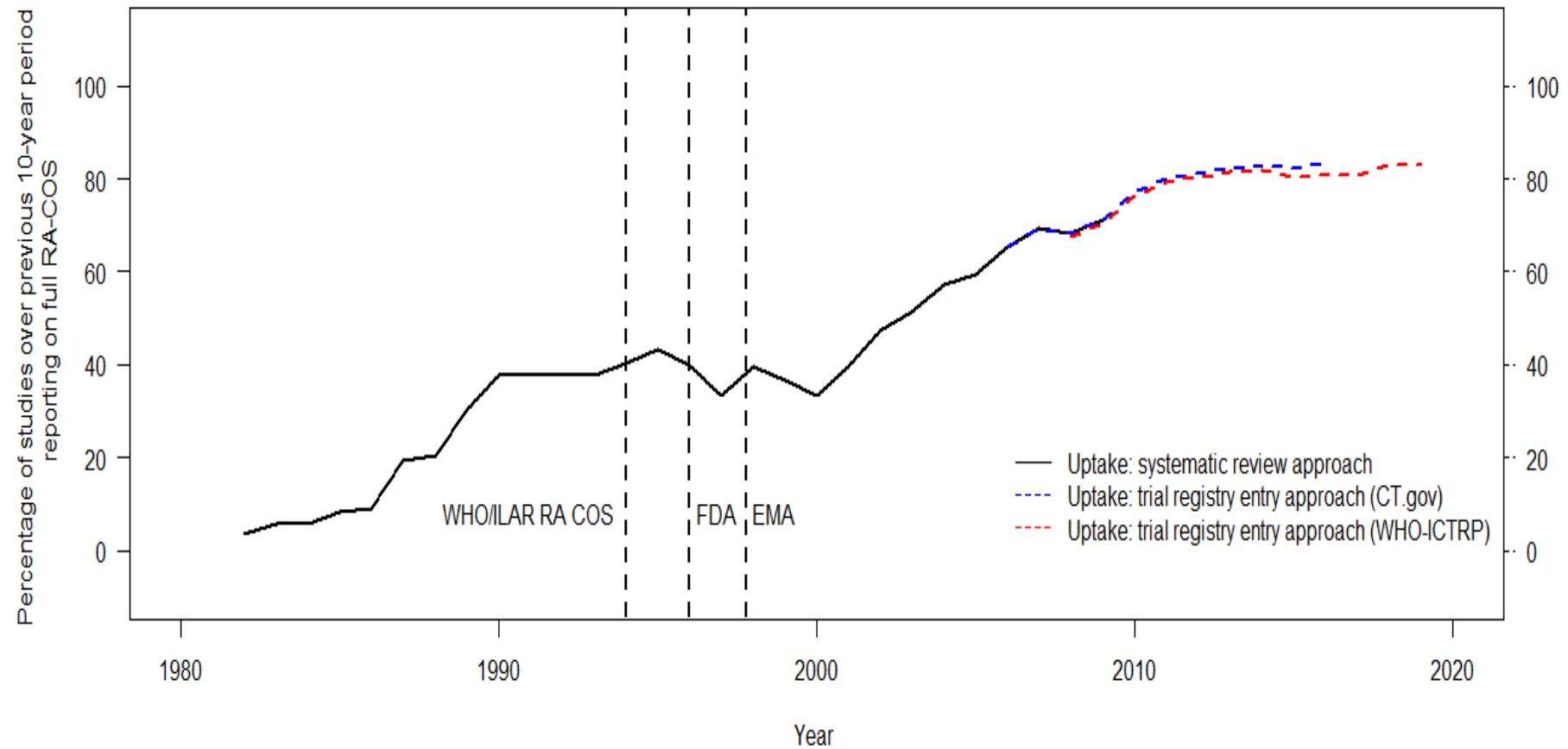
COS uptake

- **NIHR HTA applicants, 2012-2015** (Hughes, PLoS One)

- 36/95 (38%) searched for a COS

- 13/95 (14%) found and used a published/ongoing COS

- 17/82 (21%) could have used a potentially relevant COS

- **Cochrane systematic reviewers, Jan-Mar 2019**

- To be supplied once published

Clinical guideline development

- Developing NICE guidelines: the manual. [April 2017]

- Digital health interventions guidance [March 2019]

- Consultation on draft update to hip fracture guideline [early 2017]

Outcomes – from the very start

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COS for research AND practice

- Published: 36/337 (11%)

- Ongoing: 137/280 (49%)

NHS

The NHS Long Term Plan

"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

Measuring outcomes in routine care/EHR

- **Practical**

- **Instruments**

- **Multiple levels**

- Work by Violeta Razanskaite, University of Liverpool, to be supplied once published

GUIDELINES AND GUIDANCE

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

Jamie J. Kirkham[1], Katherine Davis[1], Douglas G. Altman[2], Jane M. Blazeby[3], Mike Clarke[4], Sean Tunis[5], Paula R. Williamson[1] *

"Doctors know about the illness, but patients know about the impact"

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

■ Frequency of patient participants included in the COS development process (%)
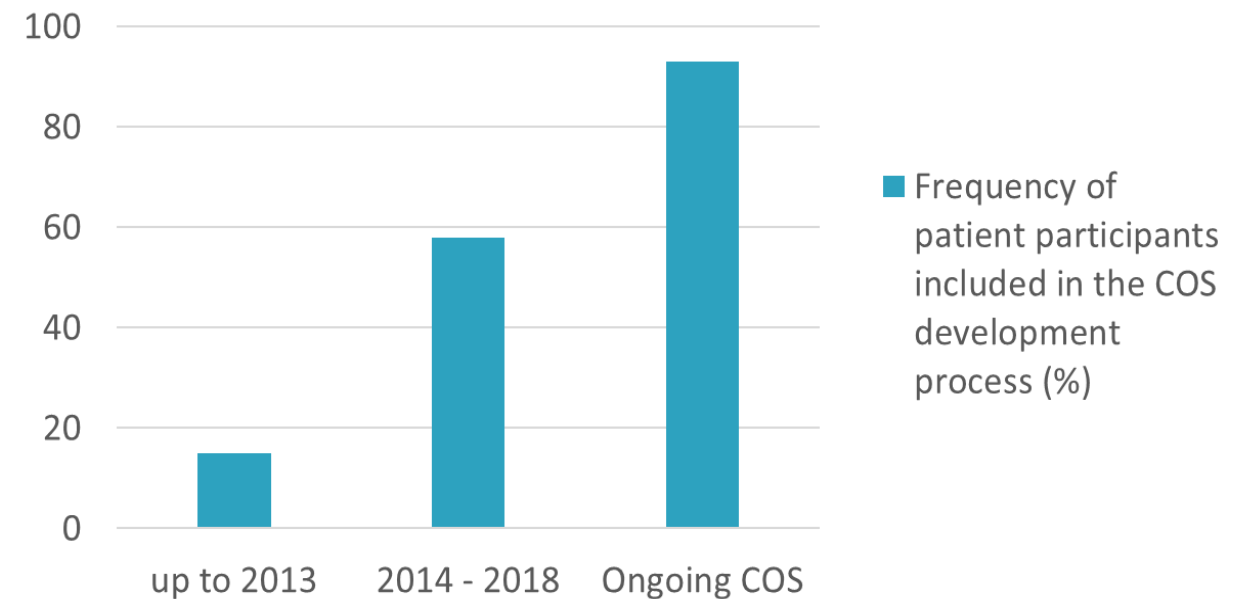
PoPPIE Group:
People and Patient Participation Involvement and Engagement

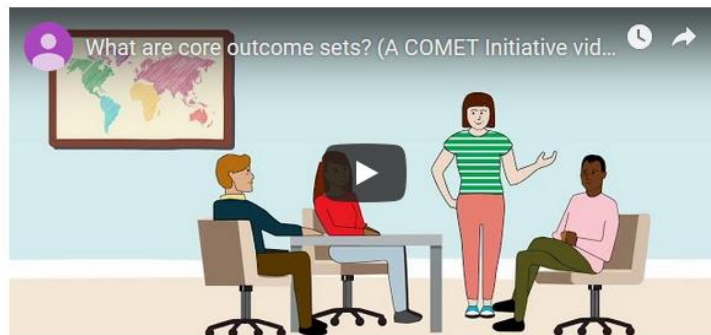To lead and oversee the public participation, involvement and engagement work of the COMET Initiative

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

What are core outcome sets? (A COMET Initiative vid...

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.

Harman et al. BMJ Open 2019
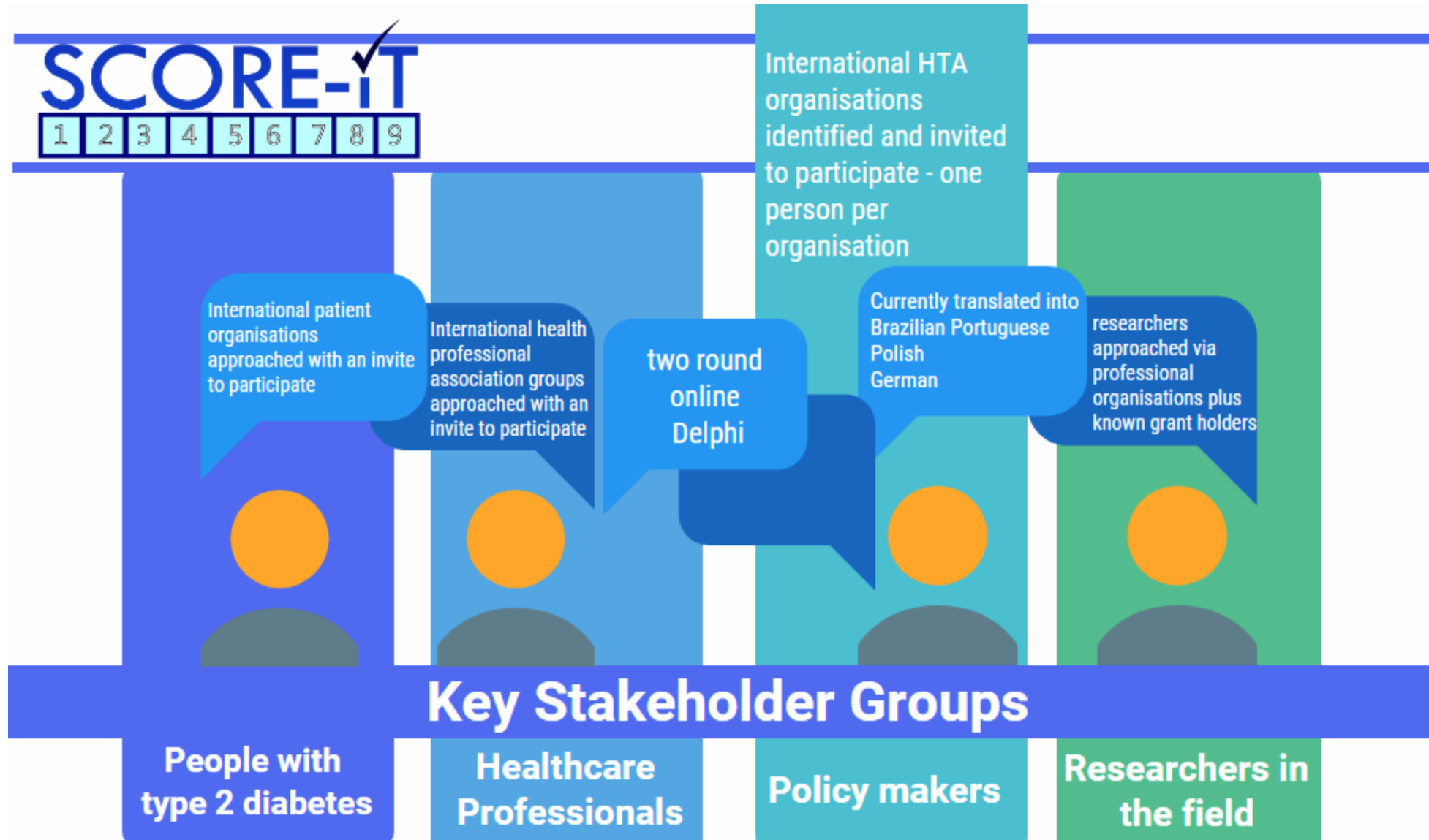
SCORE-IT COS for type II diabetes

- Matrix showing coverage through the healthcare ecosystem to be circulated once published

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