



Core Outcome Measures in Effectiveness Trials

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Twitter statement

- Speakers will indicate if they do not wish for their talk/photo to be tweeted
- When quoting speakers use their Twitter username
- Please ask poster authors before taking photos of their work and putting on Twitter
- Use the official hashtag #COMETVII

Personal statement

- **Conflict of interest:** I chair the COMET Management Group
- **Funding sources for COMET:** MRC, European Commission, NIHR

COMET Initiative

- To raise awareness of current problems with outcomes in clinical trials
- To encourage COS development and uptake
- To promote patient and public involvement in COS development
- To provide resources to facilitate this
- To avoid unnecessary duplication of effort
- To encourage evidence-based COS development

REVIEW

Open Access

The COMET Handbook: version 1.0



Paula R. Williamson^{1*}, Douglas G. Altman², Heather Bagley¹, Karen L. Barnes¹, Jane M. Blazeby³, Sara T. Brookes³, Mike Clarke^{4,5}, Liz Gargon¹, Sarah Gorst¹, Nicola Harman¹, Jamie J. Kirkham¹, Angus McNair³, Cecilia A. C. Prinsen⁶, Jochen Schmitt⁷, Caroline B. Terwee⁶ and Bridget Young¹

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GUIDELINES AND GUIDANCE

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

Jamie J. Kirkham¹, Katherine Davis¹, Douglas G. Altman², Jane M. Blazeby³, Mike Clarke⁴, Sean Tunis⁵, Paula R. Williamson^{1*}

How would you decide whether a relevant COS was of sufficient quality COS?

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Harman et al. *Trials* 2015, **14**:70
<http://www.trialsjournal.com/content/14/1/70>



STUDY PROTOCOL

Open Access

MOMENT – Management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey

Nicola L. Harman¹, Iain A. Bruce², Peter Calley³, Stephanie Tierney³, Mohammad Owise Sharif¹, Kevin O'Brien¹ and Paula R. Williamson^{4*}

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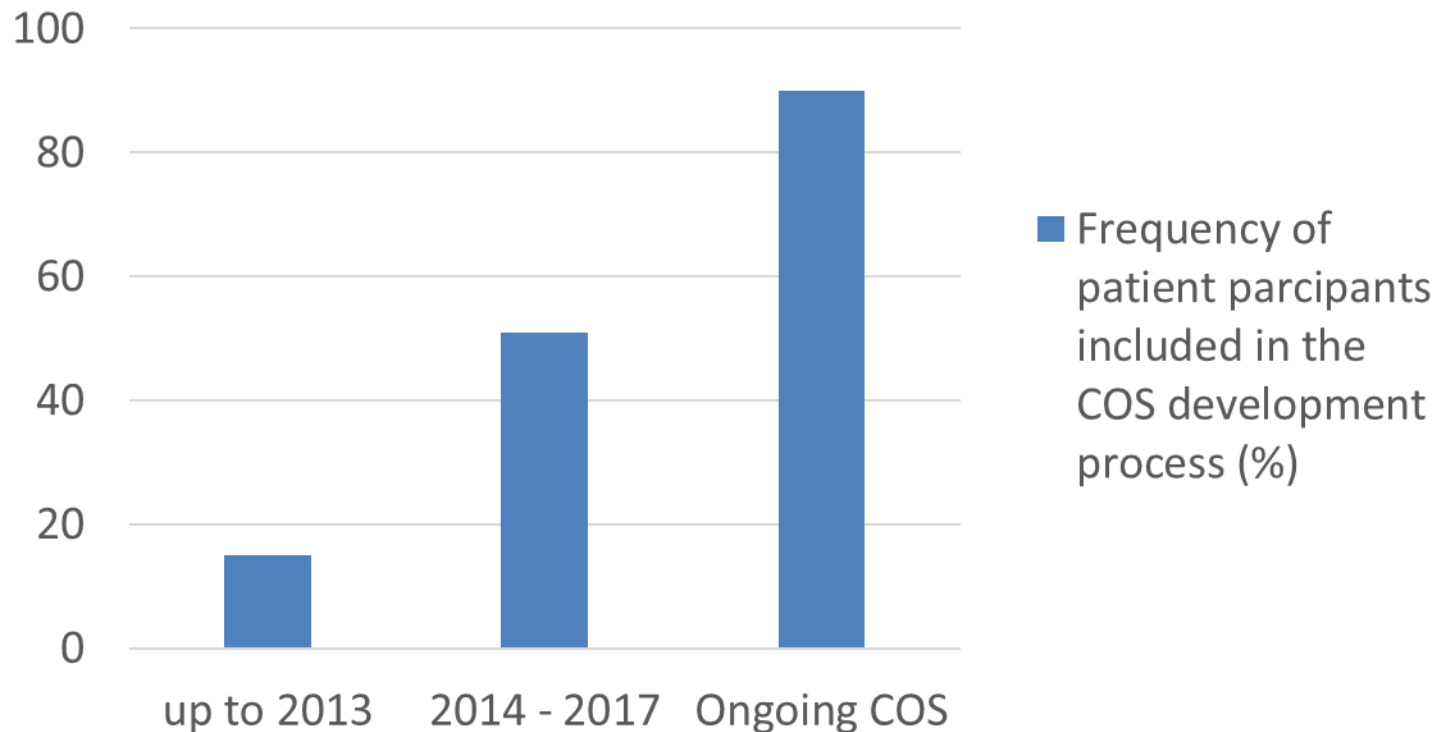


GUIDELINES AND GUIDANCE

Core Outcome Set–STAndards for Reporting: The COS-STAR Statement

Jamie J. Kirkham¹, Sarah Gorst¹, Douglas G. Altman², Jane M. Blazeby³, Mike Clarke⁴, Declan Devane⁵, Elizabeth Gargon¹, David Moher⁶, Jochen Schmitt⁷, Peter Tugwell⁸, Sean Tunis⁹, Paula R. Williamson^{1*}

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



COS outcomes (not involving patients)

Domain	n (% of 234)	Domain	n (% of 234)
Mortality/survival	82 (35)	Perceived health status	0 (0)
Physiological/clinical (≥1)	213 (91)	Delivery of care	43 (18)
Functioning (≥1)	84 (36)	Personal circumstances	0 (0)
Physical	70 (30)	Resource use (≥1)	67 (29)
Social	14 (6)	Economic	33 (14)
Role	10 (4)	Hospital	16 (7)
Emotional/wellbeing	19 (8)	Need for intervention	34 (15)
Cognitive	13 (6)	Societal/carer burden	3 (1)
Global quality of life	90 (38)	Adverse events/effects	82 (35)
Life impact	126 (54)		

COS outcomes (involving patients)

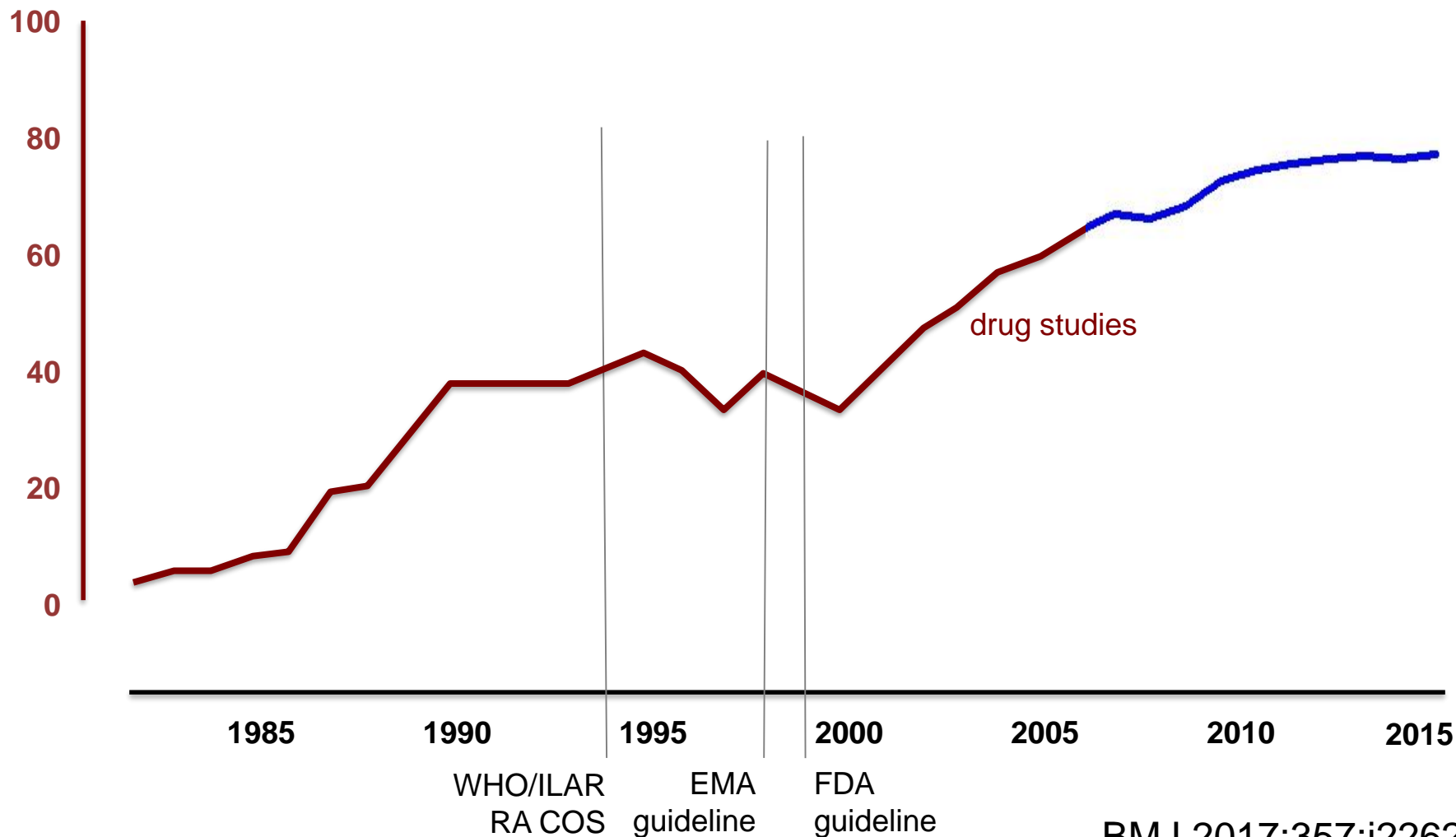
Domain	n (% of 65)	Domain	n (% of 65)
Mortality/survival	17 (26)	Perceived health status	0 (0)
Physiological/clinical (≥1)	61 (94)	Delivery of care	10 (15)
Functioning (≥1)	44 (68)	Personal circumstances	0 (0)
Physical	41 (63)	Resource use (≥1)	17 (26)
Social	11 (17)	Economic	4 (6)
Role	1 (2)	Hospital	8 (12)
Emotional/wellbeing	10 (15)	Need for intervention	11 (17)
Cognitive	8 (12)	Societal/carer burden	2 (3)
Global quality of life	31 (48)	Adverse events/effects	23 (35)
Life impact	51 (78)		

Developments

- 64% 'what', 36% 'what and how'
- Early phase: devices, pre-clinical
- COS for clinical practice:
 - for research: n=270 studies (88%)
 - for research and practice: n=37 studies (12%)
 - ongoing studies: **46%** for research and practice

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

Studies measuring
full RA COS (%)



COS Uptake and Endorsement

It is important to assess the uptake and use of COS in clinical trials, and other research, in order to avoid the development of these COS contributing to the research waste which their development aims to reduce. Assessing uptake can also highlight the benefits of measuring and reporting COS in trials while allowing review and feedback to ensure ongoing relevance, and removal of barriers and facilitators to uptake.

The following organisations actively endorse the use of COS and the COMET database.

Trialists

- ▣ [SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials](#)

Trial Funders

- ▣ [National Institute for Health Research \(NIHR\), UK:Guidance Notes For Completing Full Proposals](#)
- ▣ [Horizon2020:](#)
- ▣ <http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/sc1-pm-10-2017.html>
- ▣ [Deutsche Forschungsgemeinschaft \(DFG\) German Research Foundation](#)
- ▣ [Proposal Preparation Instructions: Clinical Trials Programme – Draft Proposals](#)
- ▣ [Proposal Preparation Instructions: Clinical Trials Programme – Full Proposals](#)
- ▣ [Arthritis Research UK \(ARUK\)](#)
- ▣ [Health Research Board \(HRB\)](#)

Trial Registries

- ▣ [ISRCTN](#)

Regulatory Authorities



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Podcasts

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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

Podcasts

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

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

Hans-Georg Eichler (Senior Medical 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.

Implementing core outcomes in kidney disease: report of the Standardized Outcomes in Nephrology (SONG) implementation workshop

Allison Tong^{1,2}, Braden Manns^{3,4}, Angela Yee Moon Wang⁵, Brenda Hemmelgarn^{3,4}, David C. Wheeler⁶, John Gill⁷, Peter Tugwell⁸, Robert Pecoits-Filho⁹, Sally Crowe¹⁰, Tess Harris¹¹, Wim Van Biesen¹², Wolfgang C. Winkelmayer¹³, Adeera Levin⁷, Aliza Thompson¹⁴, Vlado Perkovic¹⁵, Angela Ju^{1,2}, Talia Gutman^{1,2}, Amelie Bernier-Jean^{1,2}, Andrea K. Viecelli^{16,17}, Emma O'Lone^{1,2}, Jenny Shen¹⁸, Michelle A. Josephson¹⁹, Yeoungjee Cho^{16,17}, David W. Johnson^{16,17}, Bénédicte Sautenet²⁰, Marcello Tonelli^{3,4} and Jonathan C. Craig²¹; for the SONG Implementation Workshop Investigators²¹

COMET VII

- Patient participation and involvement
- How to influence COS uptake
- Global COS initiatives
- Methods - ‘what’, ‘how’, patient inclusion
 - workshops
 - contributed talks
 - posters



Drop in sessions

DelphiManager: Q&A drop in session

Registration desk

Day 1: 15.15-15.45 Break time

Day 2: 14.30-15.00 Break time

Including patients in COS development: Q&A drop in session

Zwanenzaal

Day 2: 12.30-13.00 Lunch