

Classification of COS outcomes

Dr Susanna Dodd

North West Hub for Trials Methodology Research

University of Liverpool, UK

Classification of COS and SRs

- Cochrane and COMET databases currently annotate studies according to “PIC” of PICO
 - Population
 - Intervention
 - Comparison
 - Outcomes: **not currently classified/searchable**
- Motivation: interest in outcome profiles across COS/SRs
 - AEs, HRQL, survival

Outcome classification structures

- Existing classification structures: **none adequate**
 - ICF (The International Classification of Functioning, Disability and Health, 2001)
 - Wilson & Cleary (1995)
 - PROMIS, NIH Toolbox (Neuro-behavioural)
 - DOMS (Dementia)
 - ASCQ-Me (Sickle Cell Anaemia)
 - Outcomes Measures Framework (OMF, Porter 2010) (e.g. applied to cancer, Carpenter 2012)
 - OMERACT (Rheumatology, Boers 2014)

Classification of COS outcomes in SRs

- 100/300 COS included SR in COS development
- 23/100 used their own classification method
- 6/100 used existing classification method
 - ICF to define context/content of categories (4)
 - One of these studies compared their own classification domain to American College of Rheumatology/European League Against Rheumatism classification systems, as well as ICF
 - Wilson & Cleary (1)
 - Roberts & Counsell (1)

Core domain	Smith	Williamson/Clarke (original)	Williamson/Clarke (revised)
Adverse events	1: AEs	1: AEs	1: AEs
Death	2: Mortality/survival	2: Mortality/survival	2: Mortality/survival
Physiological or clinical	3: Physiological/ clinical	3: Physiological/ clinical	3-24: Physiological/clinical
	4: Infection	4: Infection	
	5: Pain	5: Pain	
Life impact	6: ADLs	6: ADLs	Functioning 25: Physical 26: Social 27: Role 28: Psychological/wellbeing 29: Cognitive
	7: Psychosocial	7: Psychosocial	
		8: Mental Health	
	8: QoL	9: HRQL	
	9: Compliance	10: Compliance	31: Delivery of care (includes satisfaction, patient preference, adherence, withdrawal, tolerability, etc.)
	10: Withdrawal		
	11: Satisfaction		
Resource Use	12: Medication	12: Resource Use	Resource Use 32: Economic 33: Medication 34: Hospital 35: Operative 36: Societal/carer burden
	13: Economic		
	14: Hospital		
	15: Operative		

Physiological/clinical domains

- Blood and immune system conditions
- Cancer
- Cardiovascular conditions
- Diabetes and other endocrinal, nutritional and metabolic conditions
- Digestive tract conditions
- Ear, nose and throat conditions
- Eye conditions
- Fertility, pregnancy and childbirth
- Genetic conditions
- Gynaecological conditions
- Infections
- Injuries, accidents and wounds
- Kidney conditions
- Liver conditions
- Mental health and behavioural conditions
- Musculoskeletal conditions
- Neurological conditions
- Oral and dental health
- Respiratory conditions
- Skin conditions
- Urological conditions
- **General symptoms**

COMET database: COS outcomes

Domain	n (% of 300)	Domain	n (% of 300)
AEs	103 (34)	Physiological/clinical (≥ 1)	277 (92)
Mortality/survival	100 (33)	HRQL/Functioning (≥ 1)	175 (58)
Delivery of care	47 (16)	HRQL	122 (41)
Resource use (≥ 1)	87 (29)	Functioning (≥ 1)	125 (42)
Economic	38 (13)	Physical	106 (35)
Medication	30 (10)	Social	25 (8)
Hospital	23 (8)	Role	10 (3)
Operative	22 (7)	Psychological/wellbeing	33 (11)
Societal/carer burden	5 (2)	Cognitive	20 (7)

Physiological/clinical (≥ 1)		277 (92% of 300 COS)	
Blood and immune system	20 (7)	Injuries, accidents, wounds	7 (2)
Cancer	34 (11)	Kidney	9 (3)
Cardiovascular	45 (15)	Liver	6 (2)
Diabetes (endocrinal, nutritional, metabolic)	4 (1)	Mental health and behavioural	23 (8)
Digestive tract	26 (9)	Musculoskeletal	57 (19)
Ear, nose and throat	4 (1)	Neurological	47 (16)
Eye	6 (2)	Oral and dental health	17 (6)
Fertility, pregnancy, childbirth	8 (3)	Respiratory	33 (11)
Genetic	1 (0.3)	Skin	12 (4)
Gynaecological	5 (2)	Urological	7 (2)
Infections	18 (6)	General Symptoms	57 (19)

Future work: overlapping domains

- Health Related Quality of Life (HRQL)
 - Commonly reported in trials/SRs, usually without further detail
 - HRQL tools may measure features/outcomes relevant to other domains
 - For example, function
 - HRQL will therefore remain an outcome category in its own right
 - Await guidance from relevant research bodies about what should/not be included within HRQL measures/tools(e.g. PROMIS, Cochrane PRO group)
- AEs
 - Only includes outcomes specified as safety, harm, negative effects, adverse effects/events/drug reactions, toxicity, complications, sequelae
 - Potential to consider beneficial as well as adverse effects
 - Relabel domain “Unintended effects”?

Future work: Resource Use domains

- Resource use domains
 - To be informed by DIRUM standardised resource-use measure project (www.methodologyhubs.mrc.ac.uk/research/network-projects/ N57)
 - Top 10 resource use items to be measured in trials
 - HOSPITAL CARE: Number of hospital admissions (inpatient stay or day case)
 - HOSPITAL CARE: Length of stay (e.g. dates or number of nights)
 - HOSPITAL CARE: Number of hospital outpatient appointments
 - EMERGENCY CARE: Number of visits to accident and emergency
 - EMERGENCY CARE: Number of admissions to hospital, after accident and emergency
 - CARE AT A GP SURGERY OR HEALTH CLINICAL OR OTHER COMMUNITY SETTING: Number of appointments
 - CARE AT A GP SURGERY OR HEALTH CLINICAL OR OTHER COMMUNITY SETTING: Type of professional seen
 - HEALTHCARE AT HOME: Number of healthcare professional visits at home
 - HEALTHCARE AT HOME: Type of healthcare professional seen at home
 - MEDICATION: Name/class of medication

References

- Boers M, Kirwan JR, Wells G, Beaton D, Gossec L, d'Agostino MA, et al. Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. *Journal of Clinical Epidemiology* 2014;67(7):745-53
- Carpenter WR, Meyer AM, Abernethy AP, Sturmer T, Kosorok MR. A framework for understanding cancer comparative effectiveness research data needs. *Journal of Clinical Epidemiology* 2012;65(11):1150-8
- Gliklich RE, Leavy MB, Karl J, Campion DM, Levy D, Berliner E. A framework for creating standardized outcome measures for patient registries. *Journal of Comparative Effectiveness Research* 2014;3(5):473-80
- ICF: international classification of functioning, disability and health. World Health Organisation, editor. Geneva: World Health Organization; 2001
- Porter ME. What Is Value in Health Care? *New England Journal of Medicine* 2010;363(26):2477-81
- Roberts L, Counsell C. Assessment of clinical outcomes in acute stroke trials. *Stroke; a journal of cerebral circulation* 1998;29(5):986-91
- Smith V, Clarke M, Williamson P, Gargon E. Survey of new 2007 and 2011 Cochrane reviews found 37% of prespecified outcomes not reported. *Journal of Clinical Epidemiology* 2015;68
- Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA* 1995;273(1):59-65