

Outcomes

The **O** in PICO refers to the outcome(s) measured in a review or study.

- [Which outcomes to annotate](#)
- [Domain & Measure](#)
- [Composite Outcomes](#)
- [Classification categories](#)
- [How to Annotate](#)
 - [Compliance with ...](#)
 - [Discontinuation of ...](#)
 - [Disease Specific Mortality](#)
 - [Frequency of Medication Use](#)
 - [Life expectancy](#)
 - [Resolution of symptoms](#)
 - [Response rate/Response to treatment](#)
 - [Safety and Tolerability](#)
 - [Survival](#)
 - [Symptom Burden](#)
 - [Time to ...](#)
 - [Withdrawals due to Adverse Events](#)

Which outcomes to annotate

Reviews (methods)
<ul style="list-style-type: none">• all primary outcomes• secondary outcomes are NOT being annotated unless they are found in the Summary of Findings table (SoFt)• all outcomes in the Summary of Findings table (SoFt)• only annotate an outcome once if it is reported in both the SoFT and in the primary outcomes• use separate (new) group for each outcome except for Composite Outcomes (see below)

Domain & Measure

- Outcome Domain refers to “what” is being measured for the outcome (e.g. anxiety, symptoms, exacerbations, quality of life, pain, etc.)
- Outcome Measure refers to the way the outcome was measured (e.g. Glasgow Outcome Scale, McGill Pain Questionnaire)

Domain & Measure with identical or synonymous concepts

- No need to annotate both Domain and Measure with identical or synonymous concepts
- Wherever possible annotate Domain using an appropriate Domain concept or Measure using an appropriate Measure concept - i.e. if the concept is available from the correct dropdown
- If a Measure concept isn't available in the Measure dropdown but is available in the Domain dropdown, then go ahead & annotate as if it was a domain

Composite Outcomes

- These outcomes should be annotated in the same Outcome group using OR or AND

Group	Outcome	Category	Vocabulary term	Boolean operator	Category	Vocabulary term
1	perinatal death or severe morbidity	Mortality	Perinatal Death	OR	Physiological or clinical	severe morbidity
2	maternal death or severe morbidity	Mortality	Maternal Death	OR	Physiological or clinical	severe morbidity
3	death and morbidity	Mortality	Death	AND	Physiological or clinical	morbidity

[Back to Top](#)

Classification categories

The classification categories come from the [COMET](#) (Core Outcome Measures in Effectiveness Trials) Initiative. Their Outcome Taxonomy Guide is available [HERE](#).

The expandable tables below list a number of examples but are by far definitive lists.

- List of Categories with examples of concepts that all within each category

Category	Types & examples	
Adverse events	Outcomes that have been explicitly labelled as some form of unintended consequence of the treatment	
	Types	Examples
	<ul style="list-style-type: none">• Adverse event• Adverse effect	Adverse effects
		Adverse events
		Complications
		Death
		Drug reactions
		Harm
		Hospitalisation
		Negative effects
		Safety
		Serious Adverse Events
		Toxicity
Compliance with treatment	Types	Examples
	Adherence to intervention	patient adherence
		health promotions behaviour questionnaire findings
Device /intervention failure	Type	Examples
	<ul style="list-style-type: none">• Device failure• Intervention failure	Any treatment failures

Function	Type	Impact of disease or condition on	
	Physical functioning	<ul style="list-style-type: none"> ability to work physical activities of daily living (e.g. ability to walk, independence, performance status, disability index, measures relating to exercise, sleep, motor skills, sexual dysfunction) 	
	Social functioning	<ul style="list-style-type: none"> social functioning (e.g. ability to socialise, behaviour within society, communication, psychosocial development, aggression, recidivism, life enjoyment, participation) 	
	Role functioning	<ul style="list-style-type: none"> role ability to care for children work status 	
	Emotional functioning /wellbeing	<ul style="list-style-type: none"> emotions overall wellbeing <p>(e.g. ability to cope, worry, frustration, confidence, self-esteem, psychological status)</p>	
	Cognitive functioning	<ul style="list-style-type: none"> cognitive function (e.g. memory lapse, lack of concentration, attention) 	
Infection	Types	Examples	
	<ul style="list-style-type: none"> Infection Infectious diseases 	Sepsis	
		Bacteraemia	
		Specific infectious diseases e.g. malaria	
		Markers of infection e.g. parasitaemia	
		Viral load	
		HIV status	
Mental health	Type	Examples	Notes
	Mental Health	depression	any mental health-related conditions
		addiction	assessments of signs or symptoms relating to these conditions
		psychosis	
		dementia	
		anxiety	
		schizophrenia	
		post-traumatic stress disorder	
Mortality	Type	Examples	
	<ul style="list-style-type: none"> Death Mortality 	All Cause Mortality	
		Overall Mortality	
		All Cause Survival	
		Overall Survival	
		Cause-specific survival	
		Cause-specific mortality	

Pain		
	Type	Examples
	<ul style="list-style-type: none"> Pain Pain relief 	Pain
		Pain Scores
		Pain Measures
		Pain Scales
Physiological or clinical		
	Type	Examples
	Signs & symptoms	<ul style="list-style-type: none"> presence of disease or symptoms absence of disease or symptoms remission duration of symptoms number of relapses improvement no improvement clinical success person's own view of general health
	Biological Markers	<ul style="list-style-type: none"> blood components tissue analysis urinalysis bacteriological measures microbial measures oxygen saturation arterial blood gas test cholesterol
	General physical health measures	<ul style="list-style-type: none"> blood pressure respiratory and heart rates BMI, lung function measures infant weight oxygen saturation fingerclip
	Major morbidity event	<ul style="list-style-type: none"> Stroke
Psychosocial		
	Type	Example
	<ul style="list-style-type: none"> Social 	social problems
		smoking cessation
		smoking abstinence
		Levels of maternal inconvenience
		number of parental visits
		mother's view of a child
		parent-child interaction
		Consumption of healthier food, drink etc.
Quality of Life		
	Type	Example
	<ul style="list-style-type: none"> Quality of Life 	health-related quality of life (HRQL)
		quality of life

Resource use	Type	Examples
	Economic	<ul style="list-style-type: none"> Cost analysis general costs
	Hospital	<ul style="list-style-type: none"> inpatient or day case hospital care (e.g. duration of hospital stay, admission to ICU) number of admissions readmission following treatment
	Operative	<ul style="list-style-type: none"> surgical procedures (e.g. caesarean delivery, time to transplantation) number of procedures
	Medication	<ul style="list-style-type: none"> medication (e.g. concomitant medications, pain relief, rescue medication, medication errors) need for additional drugs or "dose of drug"
	Societal/carer burden	<ul style="list-style-type: none"> financial or time implications on carer or society as a whole (e.g. need for home help, entry to institutional care, effect on family income, care burden)
Satisfaction with care	Type	Examples
	<ul style="list-style-type: none"> Satisfaction with care 	patient's views about the services they receive
		clinician's assessment of adequacy of care or appropriateness of treatment
		Carer's views on treatment received by those being care for
Withdrawals or dropouts from study	Type	Example
	<ul style="list-style-type: none"> Withdrawal from study 	Dropouts
		Withdrawals
		Cancellations

- List of Concepts and what category to use for each one

Concept	Category
All cause mortality	Mortality
All cause survival	Mortality
Cause specific mortality	Mortality
Cause specific survival	Mortality
Clinical Success	Physiological or clinical
Death	Mortality
Duration of symptoms	Physiological or clinical
Improvement/no improvement	Physiological or clinical
Life Expectancy	Mortality
Number of relapses	Physiological or clinical
Overall mortality	Mortality
Overall survival	Mortality
Person's own view of general health	Physiological or clinical
Presence/absence of disease or symptoms	Physiological or clinical

Remission	Physiological or clinical
-----------	---------------------------

How to Annotate

The table lists examples of which terms to select for commonly used outcomes

Outcome	Annotation (terms, categories, decisions)			
Compliance with ...	Compliance with Treatment			
Discontinuation of ...	Treatment Discontinued			
Disease Specific Mortality	Example	Annotation	Category	
	COPD-specific mortality	COPD AND Death	Mortality	
Frequency of Medication Use	Term	JIRA comment		
	Administration Of Medication	LDO-1171 - Getting issue details... <div>STATUS</div>		
Life expectancy	Term	JIRA ticket for more information		
	Survival	LDO-1292 - Getting issue details... <div>STATUS</div>		
Resolution of symptoms	Clinical Resolution			
Response rate /Response to treatment	Synonyms		Domain term to use for all synonyms	
	Response rate		Therapeutic Response	
	Response to treatment			
	Clinical response to treatment			
	Response to therapy			
	Finding related to therapeutic response			
	Complete response			
Safety and Tolerability	Outcome	Category	Domain	Notes
	Safety	Adverse Events	(term to be inserted)	<div><div><div><div><div><div></div></div></div><div><div><div></div></div></div></div><div>Please note!</div><div>Do NOT use the term "Safety Finding" or terms for "Drug Tolerance".</div></div></div>
	Safety finding		(term to be inserted)	
	Safety as assessed by proportion of neonates with adverse events ...		(term to be inserted)	
	Efficacy and safety outcomes		(term to be inserted)	
	Safety data		(term to be inserted)	
	Safety laboratory parameters		(term to be inserted)	

Survival	Terms to use		Category	Notes		
	Progression free survival	Mortality	<ul style="list-style-type: none">There are several narrower terms under the broader term SurvivalIf survival outcomes are mentioned on their own, then use the specific term			
	Event free survival					
	Disease free survival					
	Overall survival					
	Review	Outcome	Domain	Measure	Classification	Notes
	CD008981	Survival free of any disability	Disability	Event-Free Survival	Mortality	<ul style="list-style-type: none">The aim is to annotate the "free of X" part in Outcome Domain and use the appropriate "Y-free Survival" term in Outcome Measure
Symptom Burden	Duration of Symptom or Morbidity Index					
Time to ...	Time to Clinical Improvement					
	Time to Clinical Recovery					
	Time to defervescence					
	Time to cough				Cough	
	Time to Dyspnea				Dyspnea	
	Time till the virus nucleic acid test goes negative/				2019-nCoV RT-PCR	
	Transition time of novel coronavirus nucleic acid					
Withdrawals due to Adverse Events	Withdrawal Due to Adverse Events					

[Back to Top](#)