

Outcome Measures in Cancer Survivorship

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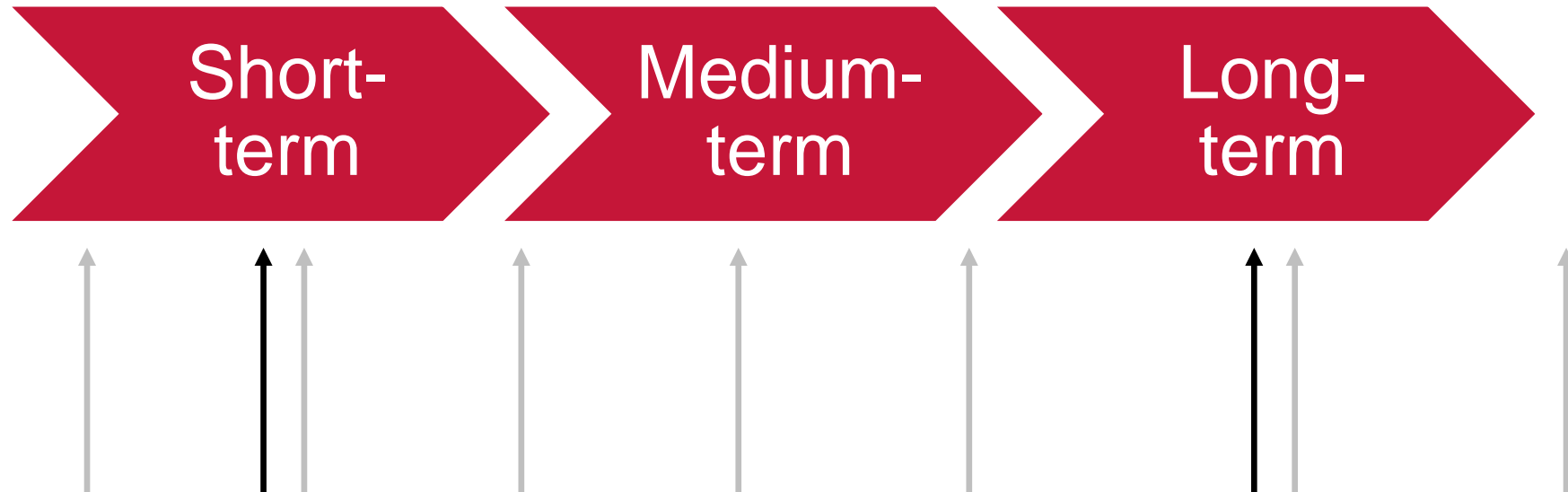
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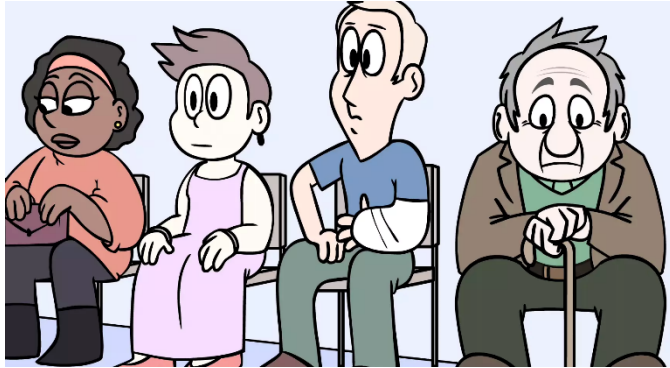
Outline

1. Outcome measures (who, what, when, or....)
 - a. When?
 - b. Who?
 - c. What?
 - d. How?
2. Considerations
3. Existing initiatives

WHEN?



WHO?



Patient-reported
vs. clinically assessed?



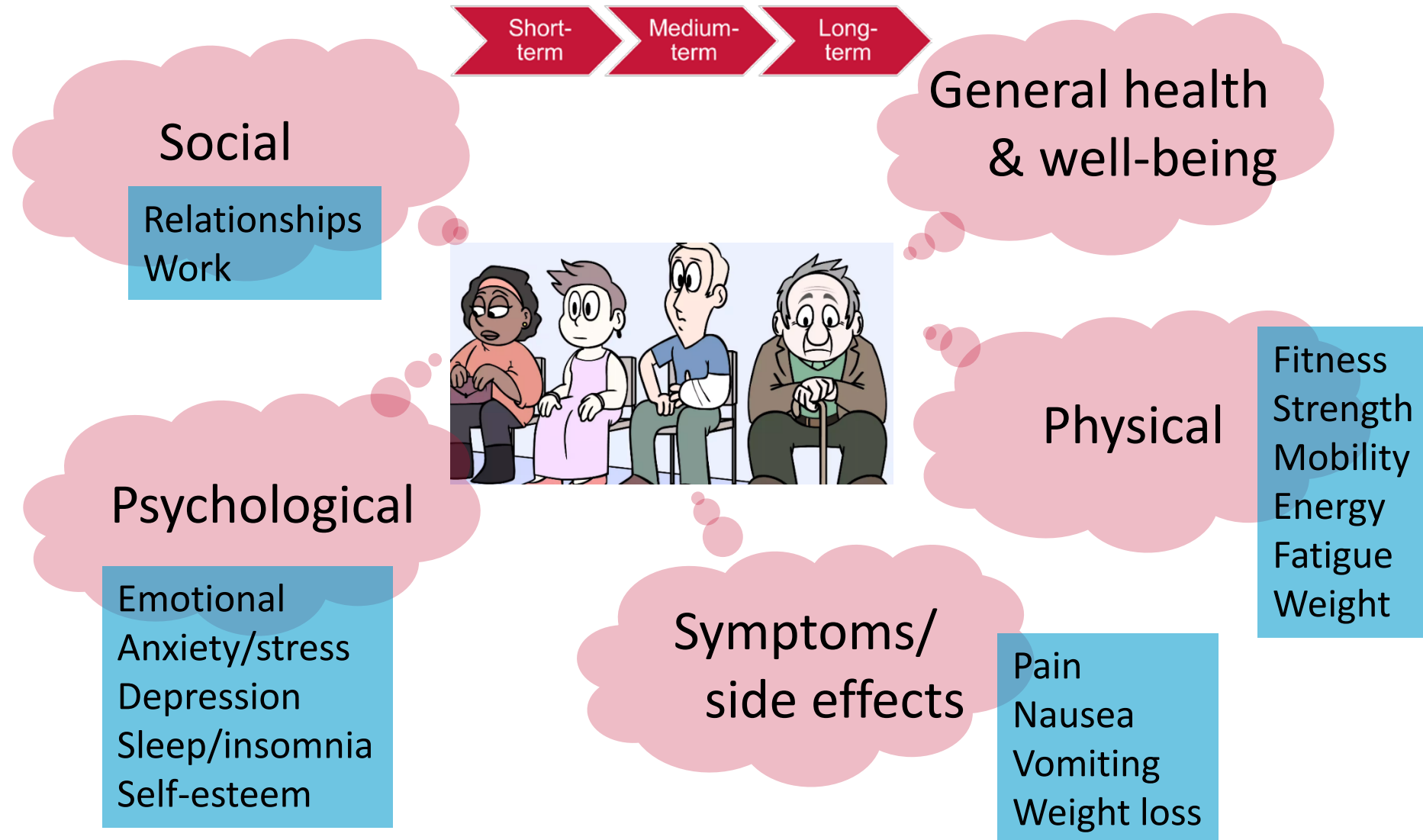
- In population of interest with regard to:
 - Geography
 - Age
 - Ethnicity
 - Disease

WHAT?

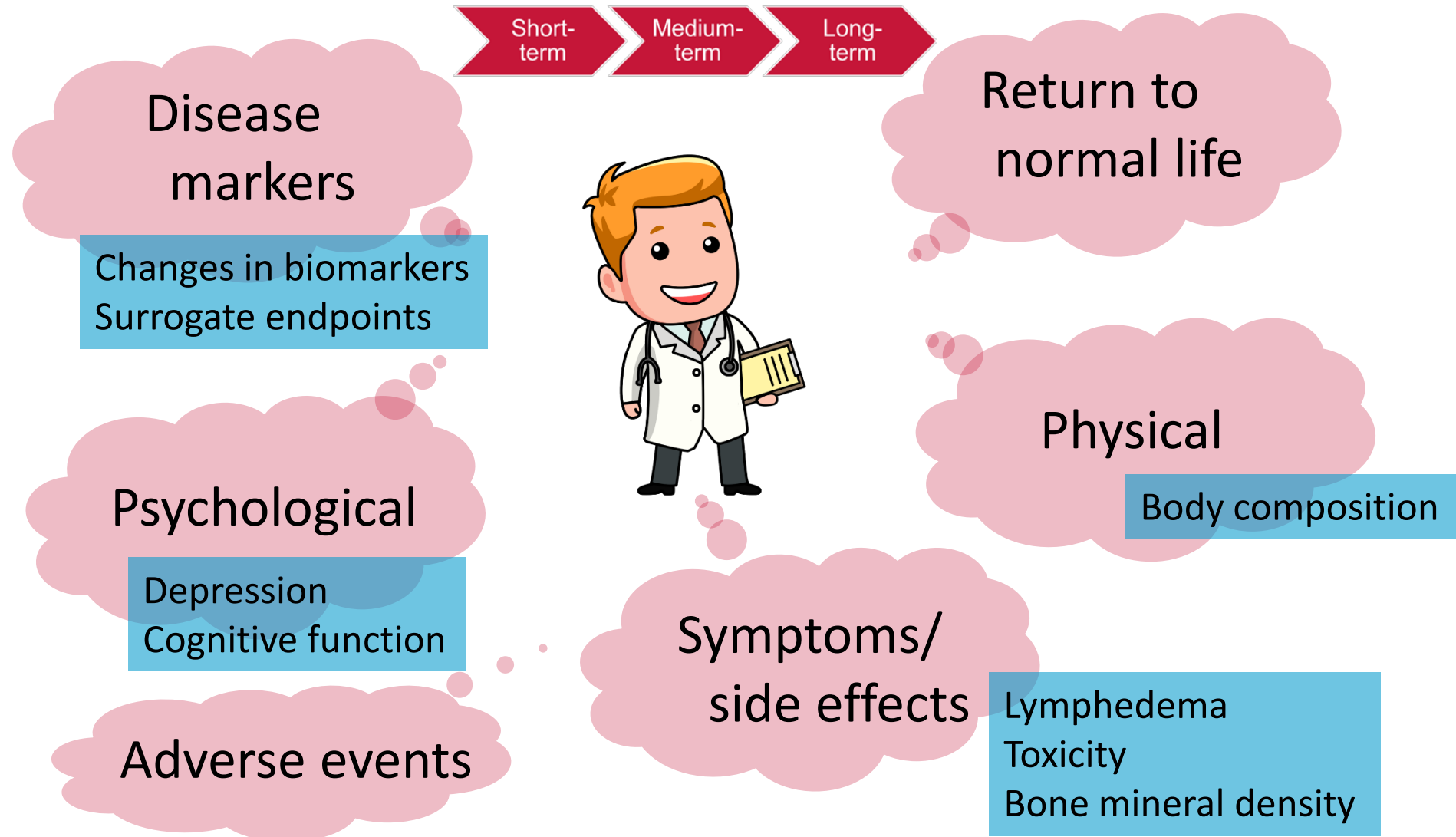
- Validated instruments
- Thorough assessment vs. patient burden



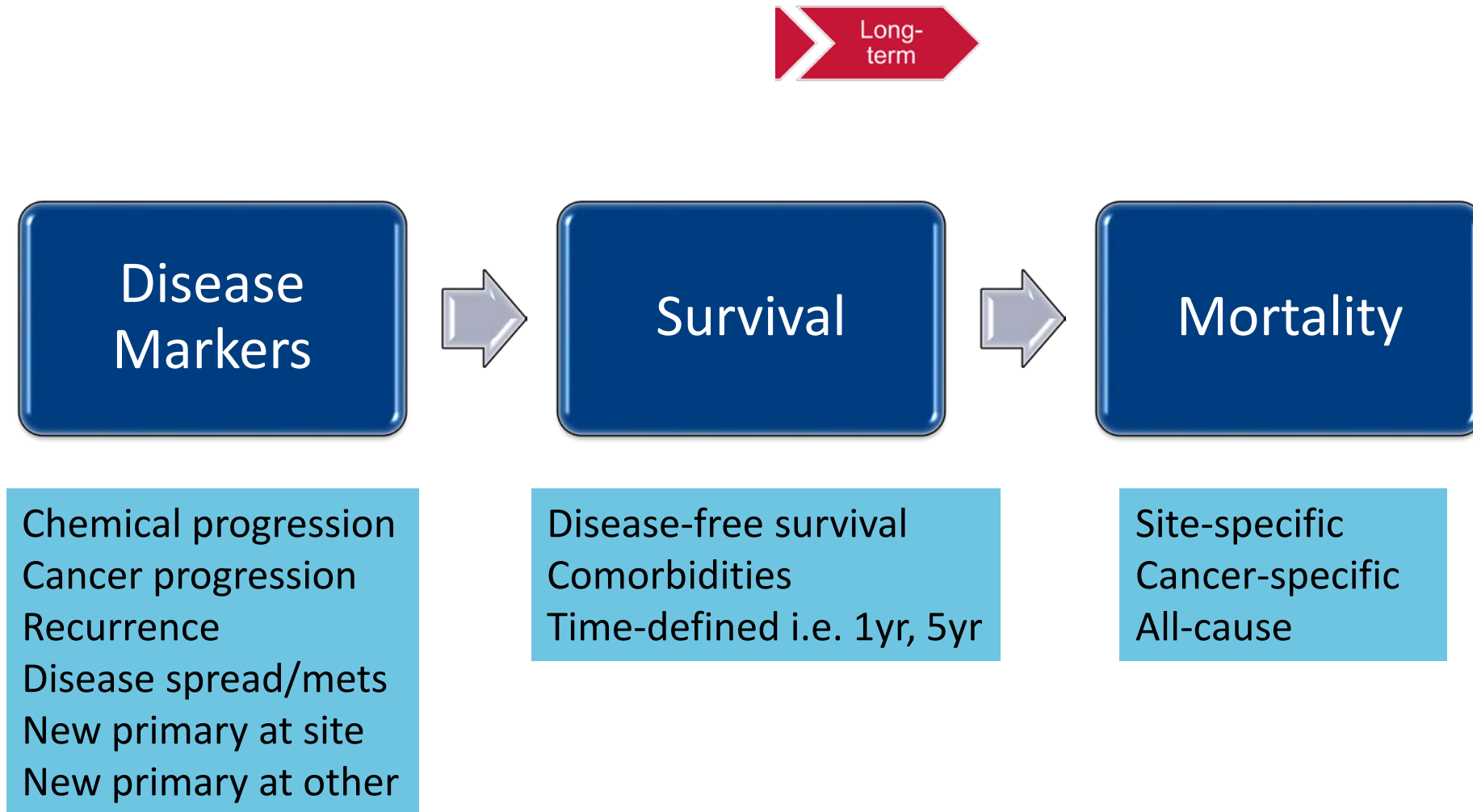
WHO, WHAT, WHEN? - Patient-Reported Quality of Life



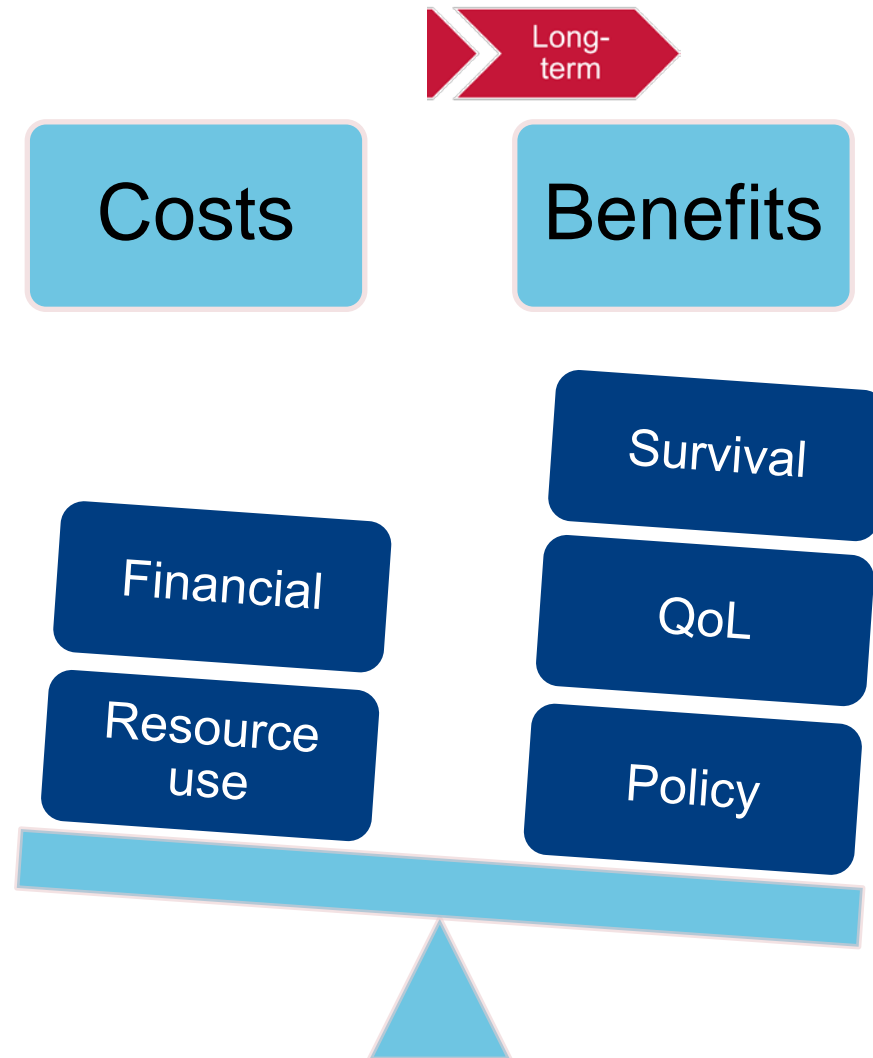
WHO, WHAT, WHEN? - Clinically-Reported Outcomes



WHEN & WHAT? - Long-Term Outcome Measures



WHEN & WHAT? - Long-Term Outcome Measures



HOW?

General QoL	CARES-SF	Cancer Rehabilitation Evaluation System-Short Form
	EORTC-QOL-30	European Organization for Research & Treatment of Cancer, QoL
	EQ5D	Euro QoL 5D
	FACT	Functional Assessment of Cancer Therapy
	QLACS	Quality of Life in Adult Cancer Survivors

Considerations

- Ensure all stakeholders involved in defining outcomes
- Completeness of outcome ascertainment
- Subjectivity in self-reported outcomes
- Heterogeneity by:
 - Disease stage & grade
 - Treatment received
 - Cancer subtypes
- Heterogeneity across studies in outcome definitions
 - Definitions of recurrence –death/ second cancers?



Core Outcome Measures in Effectiveness Trials

www.comet-initiative.org

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



- Raise awareness of problems with outcomes in trials
- Encourage COS development and uptake
- Promote patient/public involvement in COS development
- Provide resources to facilitate this
- Avoid unnecessary duplication of effort
- Encourage evidence-based COS development
- Major reduction in selective reporting
- Increases consistency across trials to maximise potential to contribute to systematic review

REVIEW

Open Access



The COMET Handbook: version 1.0

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Abstract

The selection of appropriate outcomes is crucial when designing clinical trials in order to compare the effects of different interventions directly. For the findings to influence policy and practice, the outcomes need to be relevant and important to key stakeholders including patients and the public, health care professionals and others making decisions about health care. It is now widely acknowledged that insufficient attention has been paid to the choice of outcomes measured in clinical trials. Researchers are increasingly addressing this issue through the development and use of a core outcome set, an agreed standardised collection of outcomes which should be measured and reported, as a minimum, in all trials for a specific clinical area.





Accumulating work in this area has identified the need for guidance on the development, implementation, evaluation and updating of core outcome sets. This Handbook, developed by the COMET Initiative, brings together current thinking and methodological research regarding those issues. We recommend a four-step process to develop a core outcome set. The aim is to update the contents of the Handbook as further research is identified.

Keywords: Core outcome set, Clinical trial, COMET Initiative, Patients and the public

Search:

- Obesity
- COS for clinical trials
- COS for patient-reported outcomes

5 matches

	Study Title	Year	Disease Category	Disease Name	Study Type	View
<input checked="" type="checkbox"/>	Core Outcome Set for Studies on Obesity in Pregnant Patients (COSSOPP) <i>Principal Investigator Dr. Rohan D'Souz...</i>	Unpublished	Pregnancy & childbirth	Obesity	COS for clinical trials or clinical research COS for practice Definition Patient perspectives	
<input checked="" type="checkbox"/>	Defining core outcomes for school-based intervention studies on preventing childhood overweight and obesity - Dr. A.J.G. Wirix, Junior postdoctoral ...	Unpublished	Child health Public health	Obesity Weight management	COS for clinical trials or clinical research COS for practice	
<input checked="" type="checkbox"/>	Development of an infant feeding core outcome set for childhood obesity prevention interventions <i>Karen Matvienko-Sikar (Principal investi...</i>	Unpublished	Child health	Obesity Feeding the infant	COS for clinical trials or clinical research COS for practice	
<input checked="" type="checkbox"/>	Clinical trial design for obesity agents: a workshop report <i>Anderson, J. W. Pi-Sunyer, F. X. Danfort...</i>	1998	Endocrine & metabolic	Obesity	COS for clinical trials or clinical research	
<input checked="" type="checkbox"/>	The patient perspective of living with surgery for morbid obesity: Creating a patient 'core' outcome set, and investigating ways to improve follow-up care. <i>Karen Coulman, School of Community and S...</i>	Published	Endocrine & metabolic	Obesity	COS for clinical trials or clinical research Patient perspectives	

Age Range

18 - 100

Sex

Either

Nature / type of Intervention

Rehabilitation

Surgery

Method(s)

Consensus meeting

Delphi process

Interview

Systematic review

Systematic reviews of published quantitative and qualitative research will be undertaken to create a long list of outcomes that may be important to obesity surgery patients. This will be supplemented with qualitative interviews with obesity surgery patients to see if published outcomes reflect the outcomes that patients themselves consider to be important. The interviews will also establish how post-operative support in the NHS can be improved. Delphi questionnaire rounds followed by consensus meetings with obesity surgery patients will be undertaken to reduce the long list of outcomes to the most important 'core' outcomes to create a patient core outcome set for obesity surgery.

Stakeholders Involved

Consumers (patients)

KEY MESSAGES for Outcome Measures

1. Need to decide Who, What, When and How
2. Input from all stakeholders
3. Consider sources of heterogeneity
4. Use existing initiatives such as COMET to ensure robust, standardised outcomes

