
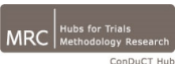



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Patient-reported outcomes of colorectal cancer surgery: a systematic review of outcome measures

Robert Whistance
NIHR Doctoral Research Fellow

Forsythe RO, Jones JE, Smith G, Pullyblank AM & Blazeby JM
On behalf of the Core Outcome and iNformation SEts iN SUrgical Studies – ColoRectal Cancer (CONSENSUS-CRC) study group

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Overview

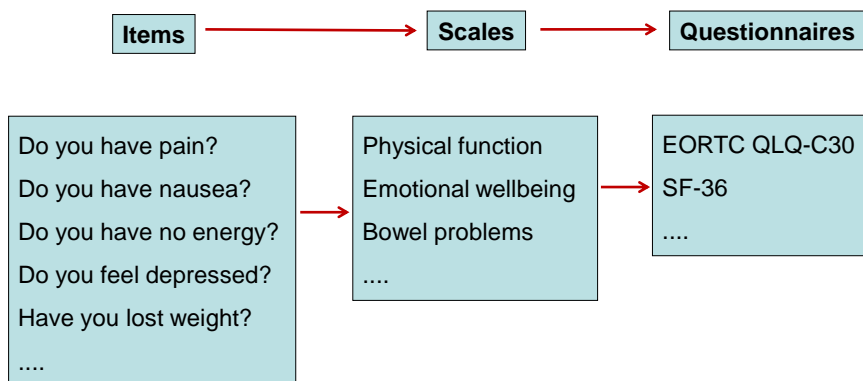
- Background
- Methods for standardising PRO measurement
- Progress so far

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🌟 Patient-reported outcomes (PROs)

- Unbiased effect estimates
- Function, symptoms & satisfaction
- Generic, disease-specific, symptom-specific

🌟 PRO measures



 **Choosing PROs in trials**

Comparison of adjuvant **cetuximab vs. 5-FU** after curative surgery for colorectal cancer

 **Choosing PROs in trials**


Comparison of adjuvant **cetuximab vs. 5-FU** after curative surgery for colorectal cancer

- Physical function
- Pain
- Vomiting
- Diarrhoea

EORTC QLQ-C30		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3.	Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

<u>PHYSICAL WELL-BEING</u>	Not at all	A little bit	Some-what	Quite a bit	Very much
I have a lack of energy	0	1	2	3	4
I have nausea	0	1	2	3	4
Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
I have pain	0	1	2	3	4
I am bothered by side effects of treatment	0	1	2	3	4
I feel ill	0	1	2	3	4
I am forced to spend time in bed	0	1	2	3	4

FACT-G



Problems with PRO inconsistency

1. Unable to compare practice/results of trials
2. Unable to synthesise data
3. Complicates trial design

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Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)

Pachler J, Wille-Jorgensen P



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COLLABORATION®**



Standardisation!

- Start afresh at the item level
- Re-group items into domains
- Choose which domains are most important

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 **Aims**

1. To identify PRO questionnaires used in CRC
2. To extract individual items
3. To group similar items into domains

 **Systematic review - search**

- Databases
- Validated terms
- Scoping searches



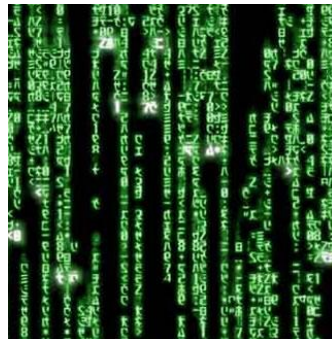
Systematic review - eligibility

- Limits
- Inclusions
- Exclusions



Systematic review – data extraction

- Study demographics
- Questionnaire names
- Reporting



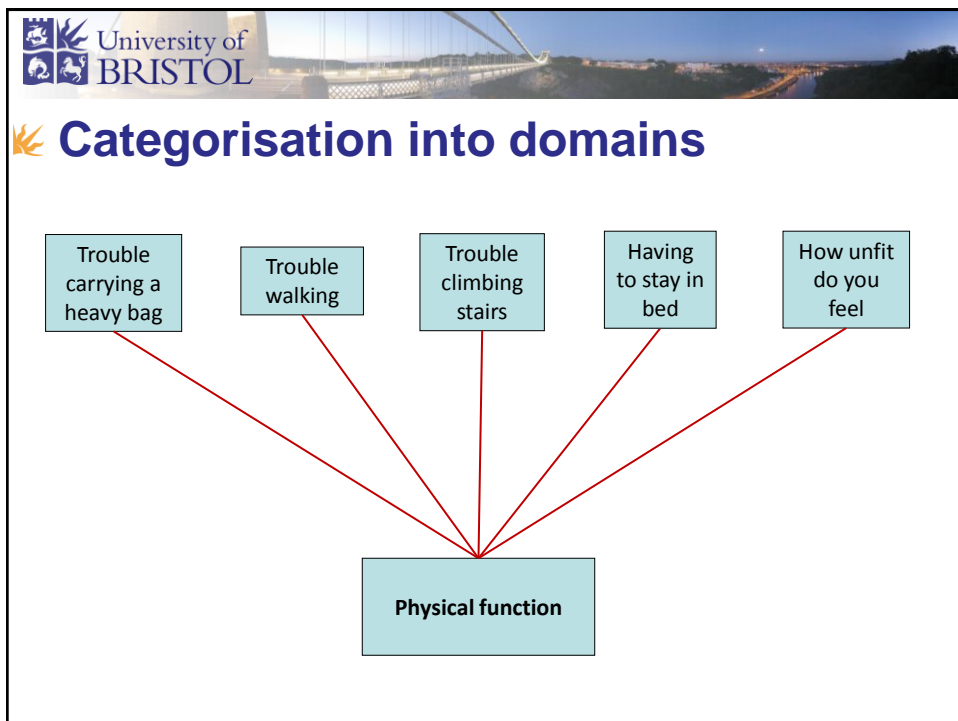
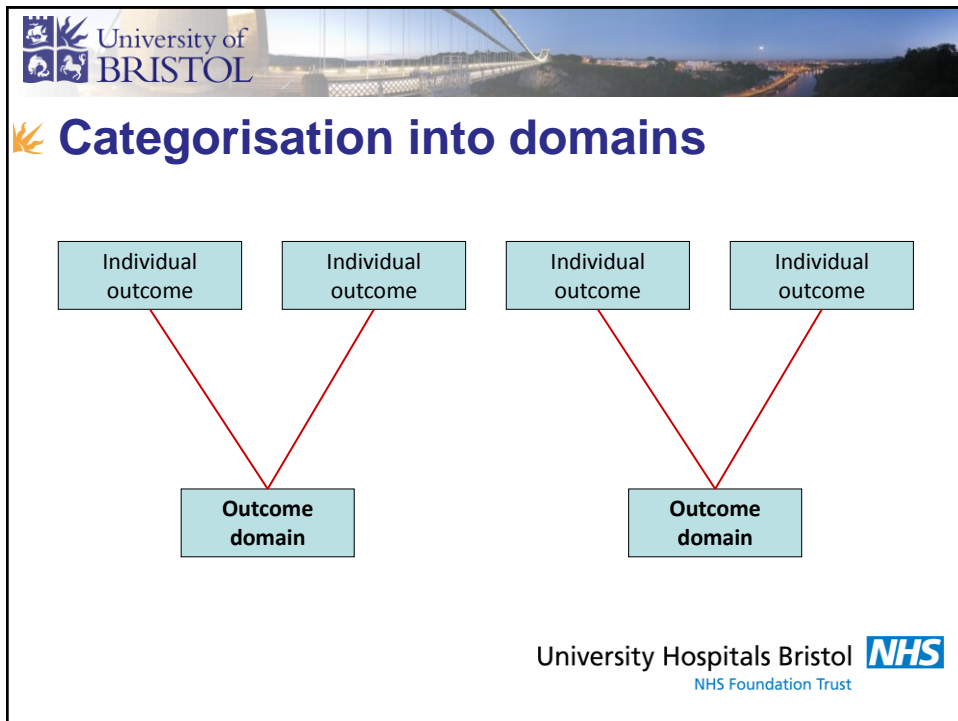
🔥 Systematic review - questionnaires

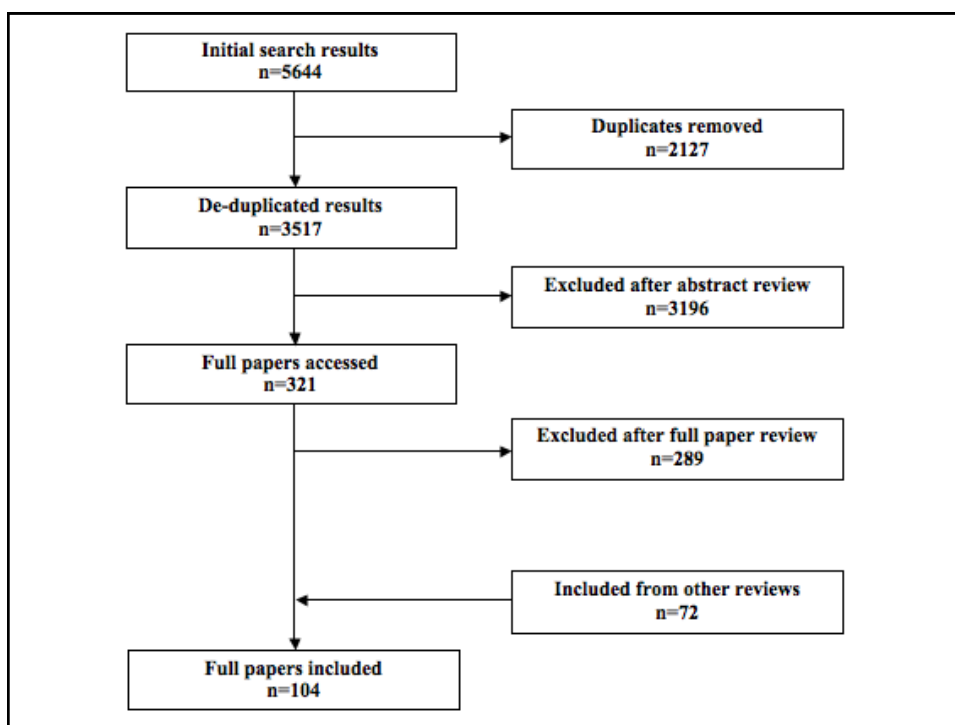
- Web searches
- Author contact
- Items extracted



🔥 Categorisation into domains


Domains = uni-dimensional themes pertaining to
the consequences of colorectal cancer surgery






Results

- 58 questionnaires –
 - 23 generic, 15 disease-specific, 17 symptom-specific, 3 unknown
- 40 (69%) reported once
- 54 (93%) validated




Results

Questionnaire	Frequency reported	Type
EORTC QLQ-C30	50	Generic
EORTC QLQ-CR38	33	Disease-specific
Short Form 36	20	Generic
FACT-C	5	Disease-specific
International Index of Erectile Function	4	Symptom-specific
Faecal Incontinence Quality of Life	3	Symptom-specific



Categorisation into domains

- 50 questionnaires available
- 920 questions (items)
- Grouped into 51 domains

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☀ Top domains

Domain n=51	Number of items n=920 (%)
Anxiety	85 (9.2)
Fatigue	67 (7.3)
Physical function	63 (6.9)
Faecal incontinence	53 (5.8)
Stoma problems	52 (5.7)
Role function	51 (5.5)
Social function	50 (5.4)
Pain	50 (5.4)
Depression	47 (5.1)




☀ Bottom domains



Domain n=51	Number of items n=920 (%)
Locus of control	3 (0.3)
Taste problems	3 (0.3)
Duration of bowel movements	2 (0.2)
Dyspepsia	2 (0.2)
Dysphagia	2 (0.2)
Trust in healthcare professionals	2 (0.2)
Urinary incontinence	1 (0.1)
Dysuria	1 (0.1)
Information needs	1 (0.1)



☀️ Next steps – core domains


Core PRO domain = agreed set of PRO domains reported as a *minimum* in all clinical trials of a given disease



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☀️ Next steps – core domains

- Survey stakeholders
- Reach consensus
- Determine core PRO domains

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Summary

- Inconsistency in questionnaire use in CRC
- Need for standardisation
- Core domains required

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Correspondence

Rob Whistance (robert.whistance@hotmail.co.uk)
Jane Blazeby (j.m.blazeby@bris.ac.uk)

Academic Unit of Surgical Research
School of Social and Community Medicine
University of Bristol
Bristol



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Specification levels for PROs

