University of BRISTOL

MRC Hubs for Trials Methodology Research

ConDuCT-II Hub

Identifying & classifying a long list of outcomes

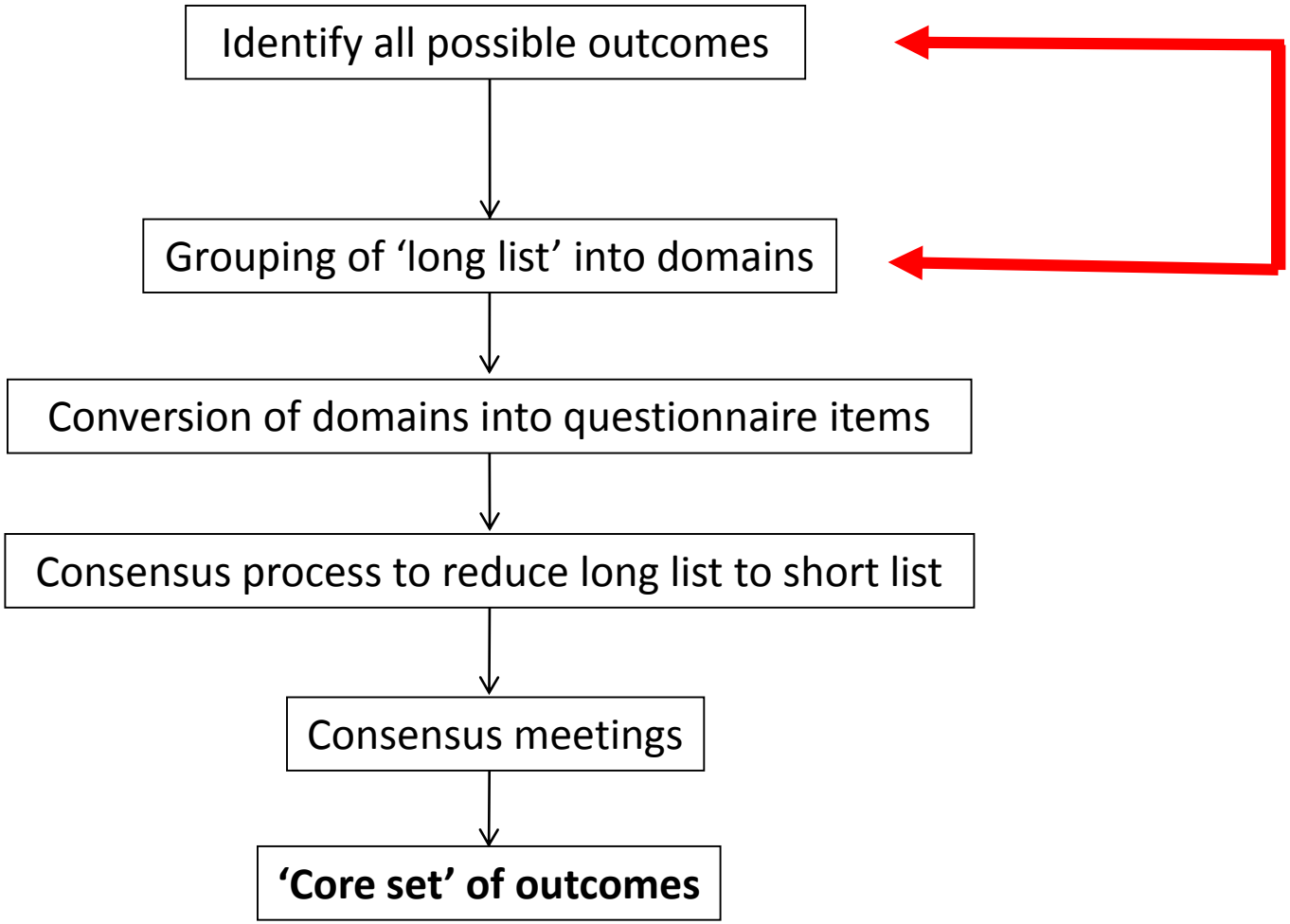
Jane M Blazeby

Professor of Surgery & Honorary Consultant Surgeon

Overview

- How to create a long list of outcome domains
- How to manage it to inform a consensus process

Methods for COS development



Long list of outcomes

- Define COS scope
  - Disease, population, intervention
  - Pragmatic or explanatory trials (other)

Scope: Disease, population, intervention

Disease: All stages, or focussed on particular category

- e.g. in colorectal cancer (all or M1 disease)

Population: All types of cancer or specific cancer type

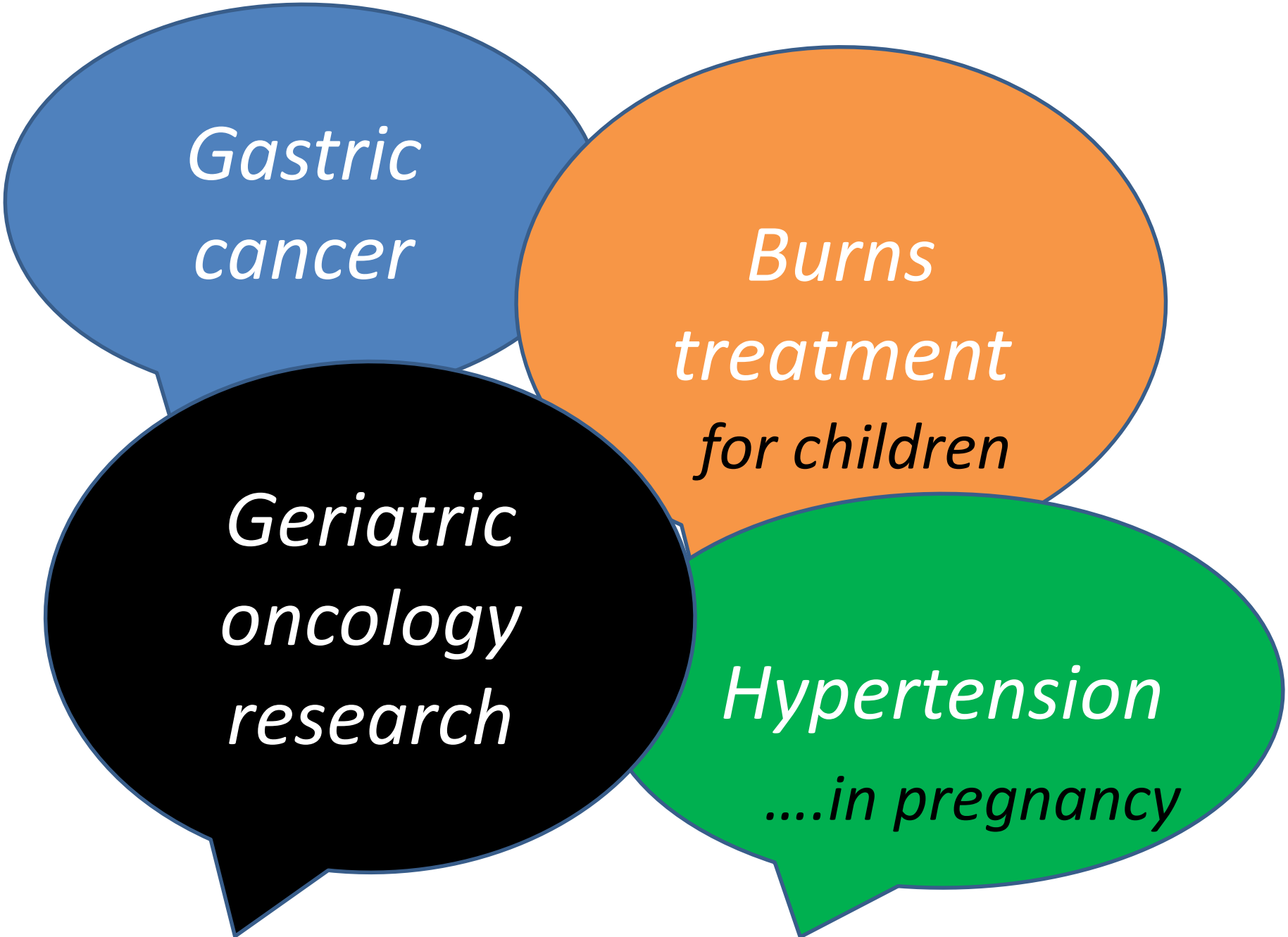
Intervention: All treatment types e.g. in morbid obesity, (all interventions or just surgery)

Scope: Pragmatic, explanatory trials etc.

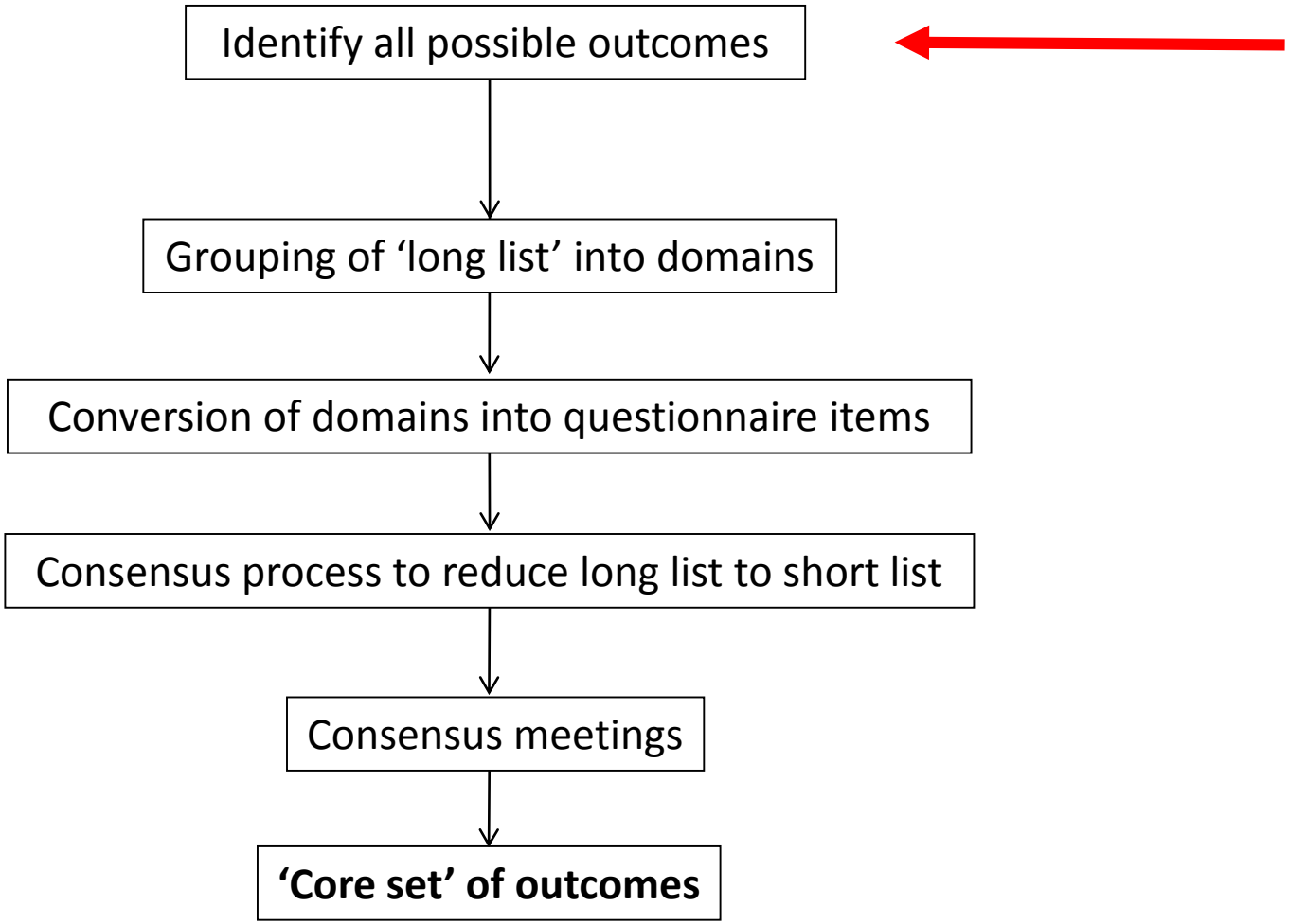
Pragmatic: clinical effectiveness endpoints - e.g. PROs, long term

Explanatory: Adverse events, short term

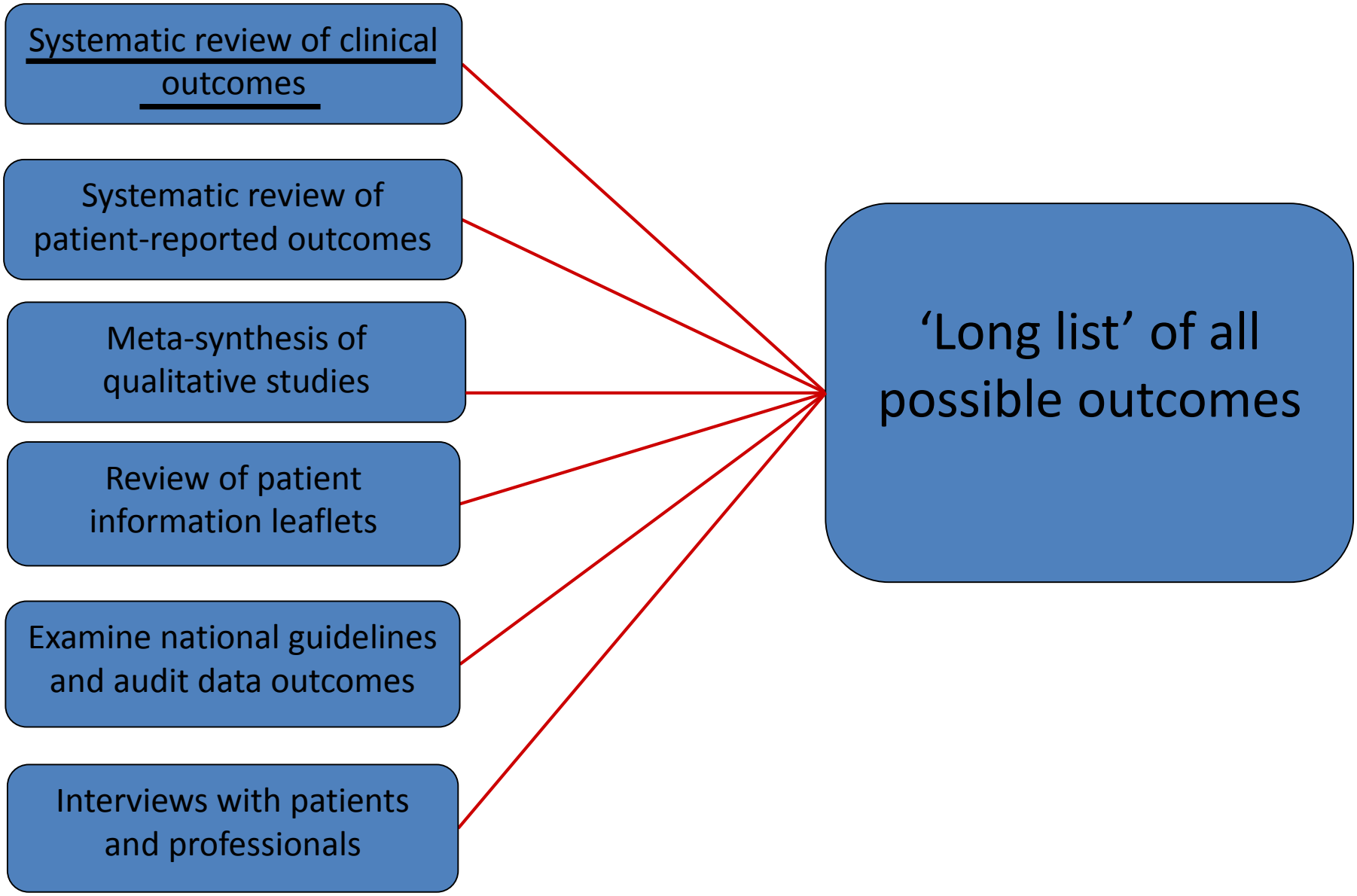
Audit/registry: In hospital mortality, treatment failure


Gastric cancer
Burns treatment
for children
Geriatric oncology research
Hypertension
….in pregnancy

Oesophageal cancer surgery



Identify all possible outcomes



ANNALS OF SURGERY
A Monthly Review of Surgical Science Since 1885

Minimally Invasive Esophagectomy

Lessons Learned From 104 Operations

Ninh T. Nguyen, MD, FACS, Marcelo W. Hinojosa, MD,* Brian R. Smith, MD,* Kenneth J. Chang, MD,† James Gray, BS,* and David Hoyt, MD, FACS**

Objectives: To review the outcomes of 104 consecutive minimally invasive esophagectomy (MIE) procedures for the treatment of benign and malignant esophageal disease.

Summary Background Data: Although minimally invasive surgical approaches to esophagectomy have been reported since 1992, MIE is still considered investigational at most institutions.

Methods: This prospective study evaluates 104 MIE procedures performed between August 1998 and September 2007. Main outcome measures include operative techniques, operative times, blood loss, length of stay, conversion rates, morbidities, and mortalities.

Results: Indications for surgery were esophageal cancer (n = 80), Barrett esophagus with high-grade dysplasia (n = 6), recalcitrant stricture (n = 8), gastrointestinal stromal tumor (n = 3), and gastric cardia cancer (n = 7). Surgical approaches included thoracoscopic/laparoscopic esophagectomy with a cervical anastomosis (n = 47), minimally invasive Ivor Lewis esophagectomy (n = 51), laparoscopic hand-assisted blunt transhiatal esophagectomy (n = 5), and laparoscopic proximal gastrectomy (n = 1). There were 77 males. The mean age was 65 years. Three patients (2.9%) required conversion to a laparotomy. The median ICU and hospital stays were 2 and 8 days, respectively. Major complications occurred in 12.5% of patients and minor complications in 15.4% of patients. The incidence of leak was 9.6% and of anastomotic stricture was 26%. The 30-day mortality was 1.9% with an in-hospital mortality of 2.9%. The mean number of lymph nodes retrieved was 13.8.

Conclusions: Minimally invasive esophagectomy is feasible with a low conversion rate, acceptable morbidity, and low mortality. Our preferred operative approach is the laparoscopic\thoracoscopic Ivor Lewis resection, which provides a tension-free intrathoracic anastomosis.

(*Ann Surg* 2008;248: 1081–1091)

The enthusiasm for minimally invasive surgery, which began with the first laparoscopic cholecystectomy, has since expanded to many other areas of abdominal and thoracic surgery. The speed by which adoption of a new minimally invasive operation evolves is often a reflection of the degree of technical difficulty of the procedure and the frequency of the operation. For example, within only a few years of the first clinical report of laparoscopic cholecystectomy, the number of laparoscopic cholecystectomies performed in the United State exceeded that of open cholecystectomies. In contrast, it took more than 5 years from the first report of laparoscopic Roux-en-Y gastric bypass for the treatment of morbid obesity before widespread dissemination of this complex operation occurred. It was not until 2004 that the number of laparoscopic gastric bypass operations exceeded that of open gastric bypass.[1,2] Open esophageal resection for benign or malignant disease is another complex gastrointestinal operation, and minimally invasive surgical approaches have been reported since 1992.[3] However, to date, there has been only 1 large study reporting outcomes of minimally invasive esophagectomy (MIE).[4] Although every imaginable technique for MIE has been described in the literature, it is difficult to determine the best minimally invasive approach for esophageal resection due to the limited experience with this complex operation at most centers. We have been performing MIEs since 1998 and previously reported on an initial experience of thoracoscopic and laparoscopic esophagectomy performed on 46 consecutive patients with a mean follow-up of 26 months.[5] Since that report, our surgical techniques have evolved, and we have made several important technical and philosophical improvements. The current report describes lessons learned in performing MIE on 104 consecutive patients over a 9-year period.

Operative Data

The mean overall operative time was 291 ± 88 minutes (range, 150–520). The mean operative time for thoracoscopic and laparoscopic esophagectomy with a cervical anastomosis was 333 ± 75 minutes, and the mean operative time for laparoscopic and thoracoscopic Ivor Lewis resection was 249 ± 72 minutes (Table 3). The mean estimated blood loss was 220 ± 224 mL (range, 50–1000 mL). Thoracoscopy was unsuccessful as a result of dense pulmonary adhesions in 1 patient and that patient underwent a laparoscopic hand-assisted blunt transhiatal esophagectomy. Three (2.9%) of 104 patients underwent conversion from laparoscopy to laparotomy; 1 patient had bleeding during division of the left gastric vessels, 1 patient required a colonic interposition, and the last patient had bleeding at the splenic hilum requiring iatrogenic splenectomy. There were no conversions from thoracoscopy to thoracotomy. Thirteen (12.5%) of 104 patients required

Morbidity

Major complications are shown in Table 4. Major complications occurred in 13 (12.5%) of 104 patients (including the 3 surgical deaths). Six patients had a gastrointestinal leak requiring reoperation; 4 patients had an anastomotic intrathoracic leak requiring thoracoscopic or thoracotomy drainage; 1 patient had a leak at the body of the gastric conduit from a nasogastric tube perforation; and the last patient developed a leak at the gastric conduit staple-line. Prolonged respiratory failure occurred in 1 patient. Pulmonary embolism occurred in 2 patients. One patient developed intraabdominal hemorrhage on postoperative day 6, when heparin was started for rate-controlled atrial fibrillation. There was no significant difference in the leak rate between patients who underwent gastric ischemic conditioning compared with patients who did not undergo gastric ischemic conditioning (5% vs. 9.4%, respectively, $P = .7$). There was also no significant difference in the leak rate between patients who had a pyloroplasty compared with patients who did not undergo pyloroplasty (9.7% vs. 6.8%, respectively; $P = 0.7$).

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TABLE 3. Outcomes According to Type of Minimally Invasive Esophagectomy (MIE)

Demographics and Outcomes	MIE With Cervical Anastomosis*	MIE With Thoracic Anastomosis
No. operations	47	51
Gender: males (%)	83	65
Age (yrs)	65 ± 10	64 ± 12
Operative time (min)	333 ± 75†	249 ± 72
Estimated blood loss (mL)	263 ± 179†	146 ± 117
Length of hospital stay (d)	12.1 ± 12.2	9.7 ± 8.1
Length of ICU stay (d)	4.8 ± 9.1	2.9 ± 4.4
Major complications (%)	12.8	11.8
Patients requiring transfusion (%)	12.8	9.8
Anastomotic stricture (%)	23.4	27.5
Leaks (%)	6.4	9.8

*Hand-assisted procedures were excluded from this group.
†$P < 0.05$ compared to MIE Ivor Lewis, 2-sample t tests.

ANNALS OF SURGERY
A Monthly Review of Surgical Science Since 1885

Reporting of Short-Term Clinical Outcomes After Esophagectomy

A Systematic Review

Natalie S. Blencowe, MRCS,† Sean Strong, MRCS,* Angus G.K. McNair, PhD,*† Sara T. Brookes, PhD,† Tom Crosby, FRCR,‡ S. Michael Griffin, MD,§ and Jane M. Blazeby, MD*†*

Objective: This review summarizes reporting of complications of esophageal cancer surgery.

Background: Accurate assessment of morbidity [illegible] for cancer is essential to compare centers, allow [illegible] clinical decision-making. A lack of defined stand[illegible] relevant treatment effects.

Methods: Systematic literature searches identified [illegible] 2005 and 2009 reporting morbidity and mortalit[illegible] cancer. Data were analyzed for frequency of compli[illegible] check whether outcomes were defined and classified for severity a[illegible] a validated system for grading complications was used. Info[illegible] reporting outcomes adjusting for baseline risk factors wa[illegible] a descriptive summary of the results of included outcomes[illegible] taken.

Results: Of 3458 abstracts, 224 full papers were r[illegible]ed and 122 were included (17 randomized trials and 105 observation[illegible] studies), reporting outcomes of 57,299 esophagectomies. No single complication was reported in all papers, and 60 (60.6%) did not define any of the measured complications. Anastomotic leak was the most commonly reported morbidity, assessed in 80 (80.1%) articles, defined in 28 (28.3%), but 22 different descriptions were used. Five papers (5.1%) categorized morbidity with a validated grading system. One hundred fifteen papers reported postoperative mortality rates, 25 defining the term using 10 different definitions. In-hospital mortality was the most commonly used term for postoperative death, with 6 different interpre-

> *"No single complication was reported in all papers, and 60 did not define any of the measured complications"*

recent evidence that short- and long-term outcomes are improving, [illegible]

[illegible]ng. If outcomes are not accurately defined, measured, and [illegible]orted, estimates may be misleading resulting in outcome reporting bias. Outcome reporting bias occurs when a subset of originally recorded outcomes are selected for publication on the basis of the results. This may influence the overall recommendations from trials.[5] Outcome reporting bias may be avoided by preselecting trial outcomes and ensuring that all are reported, irrespective of the magnitude of effect sizes observed in the final data set as is recommended by the updated CONSORT guidance for reporting standards in randomized controlled trials (RCTs).[6]

Validated methods of measuring surgical outcomes include the Clavien-Dindo[7] and Accordion systems,[8] which classify complications according to severity. The Clavien-Dindo classification was first published in 1992 but despite the provision of this valuable resource, which has been updated, it is not widely used leading to poor quality

Analyses of literature

- Verbatim terminology listed

Outcomes reported only once
% Change in HbA1c levels
% Estimated weight loss < 50%
% Estimated weight loss > 10%
% Excess body weight
% Excess weight loss at 2 years
% Follow-up of eligible patients
% kcal from carbohydrate
% kcal from fat
% kcal from protein
% of T2DM medication discontinued
% Patients achieved >25% EWL
% Patients achieved >33% EWL
% Patients achieved >50% EWL
% Patients achieved >75% EWL
>10% baseline weight loss
>5% baseline weight loss
10-year estimated CVR reduction
12-month percent change in BCRFs
2cm anchor migration
2h glucose – oral glucose tolerance test
30-d all-cause mortality rate
90-d all-cause mortality rate
Abdominal distension
Abdominal operation
Abdominal pain – not yet diagnosed
Abdominal pain – requiring laparoscopy
Abdominal scar
Abnormal liver function
Abscess – cutaneous
Abscess – intra-abdominal
Absolute decrease in the BMI
Acceptable weight loss
ACS NSQIP defined 30-d morbidities
Activities of daily living
Acute abdominal pain
Acute small bowel obstruction
Additional procedures
Adiponectin/kg fat mass
Adjustment port revisions
Adverse events
Alcohol/drug abuse
AliWolfe scoring scheme
Alkaline phosphatase
Alkaline phosphatase
All reported mortality
Amelioration of comorbidities
Amount of the meal consumed
An inability to walk 200 ft
An open surgical technique
Anastomotic bleed
Anastomotic leak/gastrogastric fistula
Anastomotic leak requiring surgery
Anastomotic leak/perforations
Anatomic band position
Anesthesiology time
Angina pectoris
Annual nephropathy transition rates
Anthropometric indices
Anthropometric parameters
Antidepressant use
Antidiabetic medication
Antihypertensive medication
Antiperistalitic roux limb
Arrythmia
Aspartate aminotransferase
Associated morbidity
Average absolute weight reduction
Average fluoroscopy time
Average implantation time
Average number of band fills/year
Average operative time
Average weight
Balloon intra-gastric migration
Band adjustment
Band adjustments within 3 years
Band distance from GE junction
Band erosion
Band erosion into the stomach
Band erosion/slippage/obstruction
Band intolerance
Band intolerance/inability to lose weight
Band port malfunction
Band port site infection
Band port skin erosion
Band punctures
Band replacement
Band replacements for immediate postoperative period
Band repositioning rate
Band volumes
Band-specific complications
BCRF
Bedside incision and drainage and wound
Being respected and accepted
Beta-blocker
Bile leakage
Bleeding disorder
Bleeding/haemorrhage- intra-abdominal
Blocked gastric pouch
Blood loss during stomach sectioning
Blood urea nitrogen
Blood vessel repair or ligation to contain bleeding
BMI change
BMI decrease
BMI greater than 35 kg m^{-2} at 3 years
BMI group
BMI loss
BMI reduction
Bodily pain
Body composition analysis
Body fat mass
Body height
Body image and appearance
Body weight loss
Bolus obstruction
Breakfast – d per week
Buttresses of the staple line
Cancer
Cancer diagnosed at follow-up
Cardiac arrhythmia
Cardiac comorbidity
Cardiac complications
Cardiac – history of CHF
Cardiac complications
Cardiovascular disease
Cardiovascular risk factors
Causes of late re-operations

Outcomes reported only once

Change in blood pressure
Change in CHD risk
Change in comorbidities – cured
Change in comorbidities – improved
Change in levels of fasting lipids
Change in weight
Change of HbA1c
Change of plasma glucose concentration
Changes in body weight
Changes in disease severity
Changes in indirect measures of insulin
Changes in insulin sensitivity
Changes in medication use
Changes in QoL
Changes in the proportion of

Death related to alcohol/drug abuse
Deep incision at surgical site
Deep venous thrombosis prophylaxis measure
Deep wound infection
Dehydration
Dehydration requiring readmission
Delayed transit
Dependence on medication and treatments
Dependence on supplementary oxygen
Depression
Details of endoscopic procedures
Device failure/leak
Device-related complications
Diabetes improvement

Eating factors – disinhibition
Eating factors – hunger
Eating what one likes
EBMIL (%)
EBW reduction (lb)
Economic data
Edmonton obesity staging score
Effectiveness and safety of the process
Employment status
Endoscopic dilatation
Endoscopic gastrojejunal bleeding treatment
Endoscopic gastrojejunal dilatation
Endoscopy
Energy intakes
Enterocutaneous fistula

And 10 more pages like this – Outcome only reported once

medication
Complete resolution of comorbidities
Complete slippage
Compliance
Compliance with postoperative visit
Complication – 90-d
Complication rate
Complications related to the omentectomy
Complications reported after surgery
Complications that led to re-operation
Composite end point of any event occurring
Composite estimates of effect size
Concurrent procedures

Diagnositic cost group (DCG) risk adjusted
Diagnostic upper GI endoscopy
Diagnostics
Diarrhoea
Diastolic blood pressure
Differences in lean body mass
Different stoma sizes
Digestive intolerance that was treated
Discharge location
Distribution of BMI
Distribution of comorbidities
Duration of IB therapy
Duration of weight loss
DVT or thrombophlebitis

Estimated blood loss
Estimated blood loss
Estimates of daily caloric intake
Evisceration on a trocar orifice
Evolution of comorbidities
EWL >40%
Excellent weight loss
Exceptional weight loss
Excess body mass index loss (EBMIL)
Excess body weight (EBW)
Excess weight loss (%EWL)
Excessive BMI loss (EBMIL)
Expending >2,000 kcal per week of physical activity
Factors associated with repeat IB

Analyses of literature

- Verbatim terminology listed
- Calculated frequency of each outcome

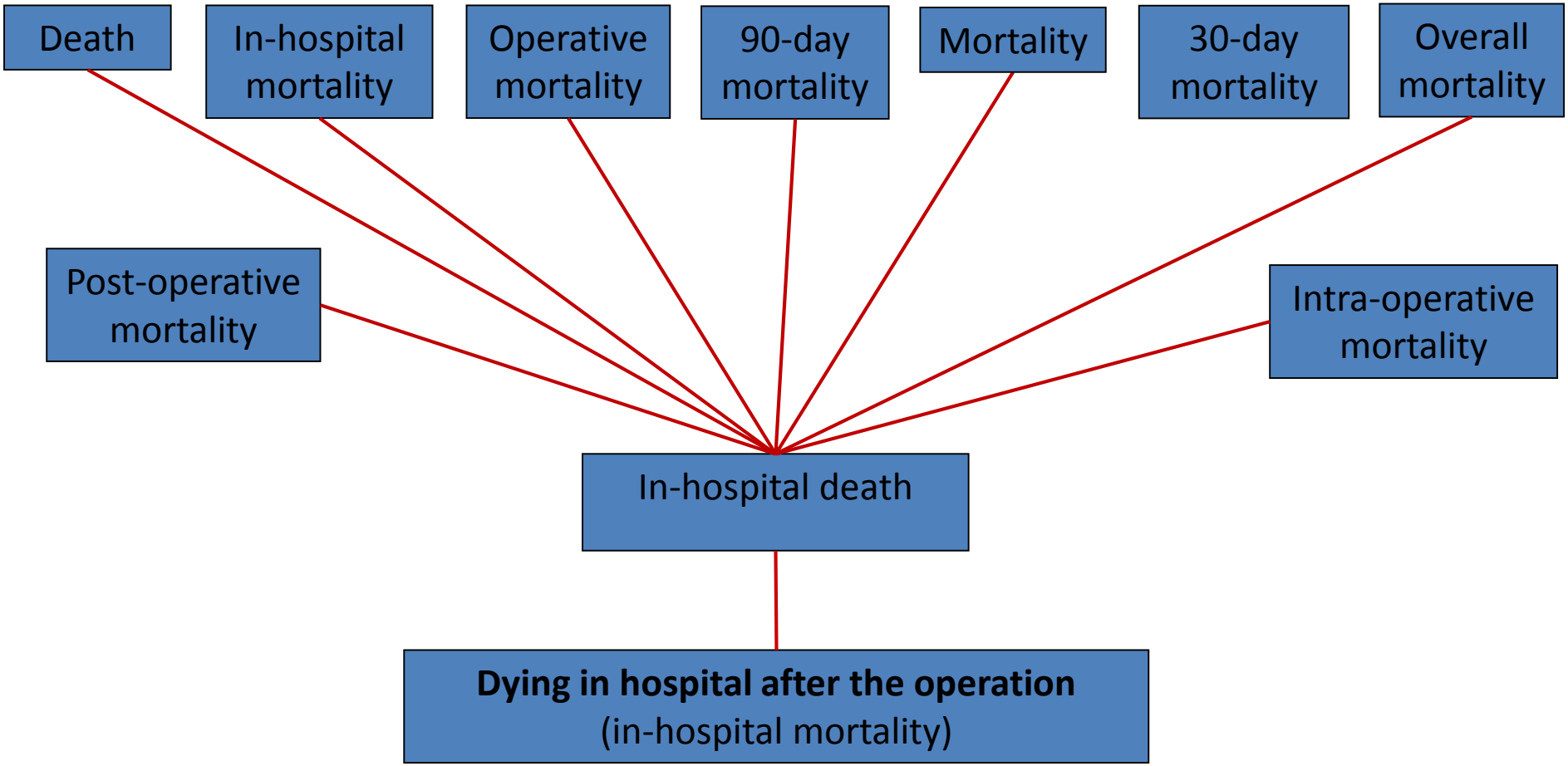
Table 1 Outcome themes, domains and definitions identified in the review

Theme	Outcome domain	Definition	Number of individual outcomes in each domain
Adverse events	Surgical complications	Any short- or long-term deviation from the normal postoperative course including symptomatic and asymptomatic complications. Excluded were known sequelae of surgery inherent to the procedure.	357
	Perioperative technical outcomes	Outcomes recorded directly in the operating theatre, anaesthesia, pre-surgery and immediate recovery period before return to ward or high-care environment.	45
	Mortality	Outcomes related to short- and long-term survival/death rates or cause of death	30
Clinical effectiveness	Obesity-related disease	Any condition or comorbidity whose prevalence has a correlation with obesity, or in which obesity is a risk factor or whose management is affected by a patient's weight, including diabetes and dyslipidaemia and the biochemical measurements of these conditions	267
	Anthropometry	Comparative study of human body measurements and properties, including all aspects of weight and weight change, failure of weight loss and related measures	117
	Treatment pathway outcomes	Outcomes related to the flow of patients through the healthcare system e.g. hospital stay, readmission rates	75
Physical symptoms, signs and measurements	Haematological or biochemical markers	Outcomes related to the reporting of blood, tissue or biochemical measures, within standard clinical practice or research, not including the standard measurements for the diagnosis and monitoring of obesity-related diseases, such as diabetes (included in the above domain)	80
	Observer assessment of symptoms and function	Signs and symptoms of obesity, its comorbidities or consequences of surgery reported by or to healthcare providers directly, and those assessed in clinical practice, including those related to nutritional deficiencies and their measurements.	65
Issues relating to quality of life and wellbeing after surgery	Patient-reported outcomes	Aspects of a patient's physical, social or emotional health assessed by patients themselves e.g. activities, quality of life, eating behaviours	52
	Total		1,088

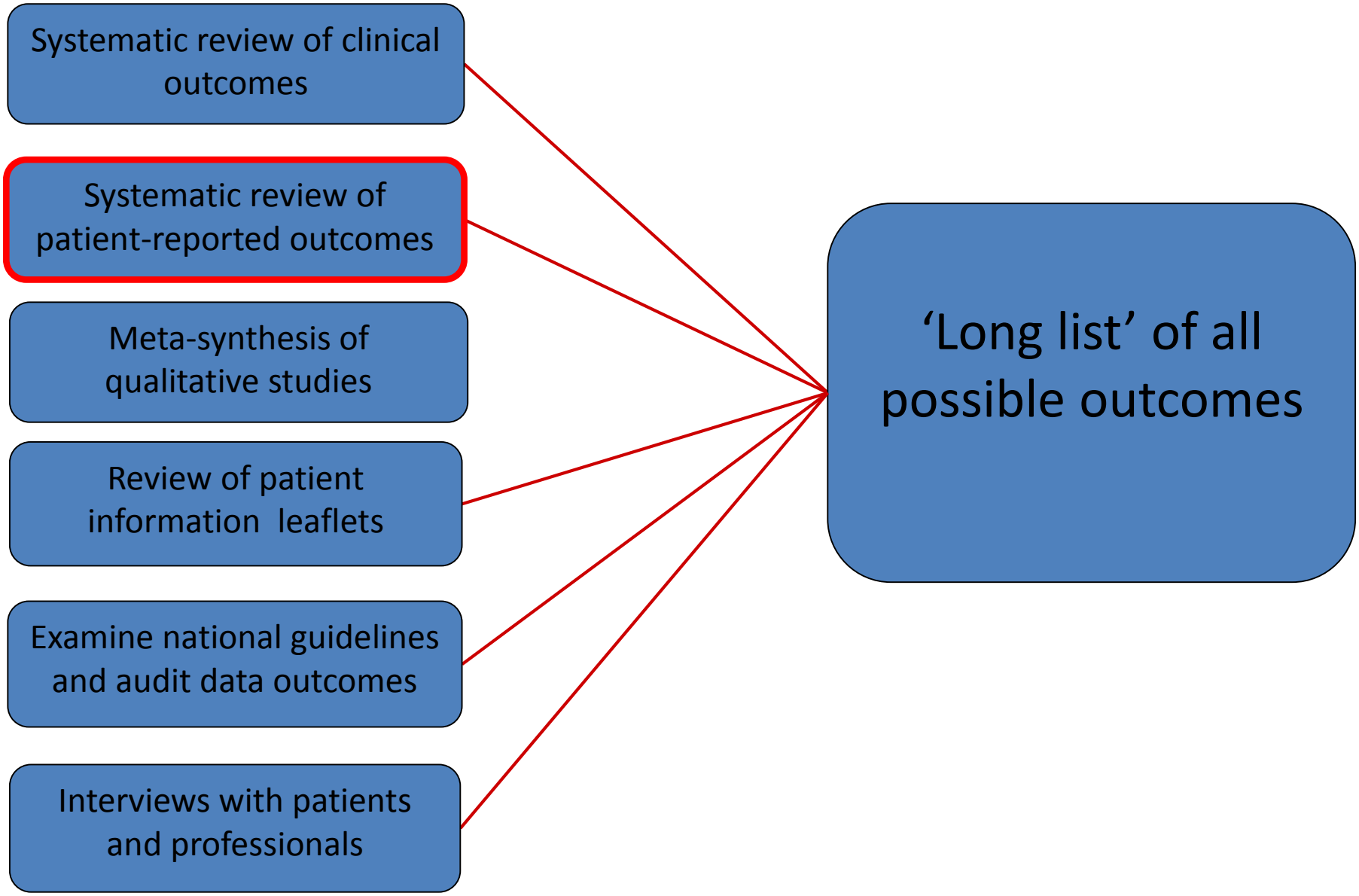
Analyses of literature

- Verbatim terminology listed
- Calculated frequency of each outcome
- Independent classification into domain

Verbatim outcomes from the literature classified to domains



Identify of possible outcomes



Analysis of individual items needed

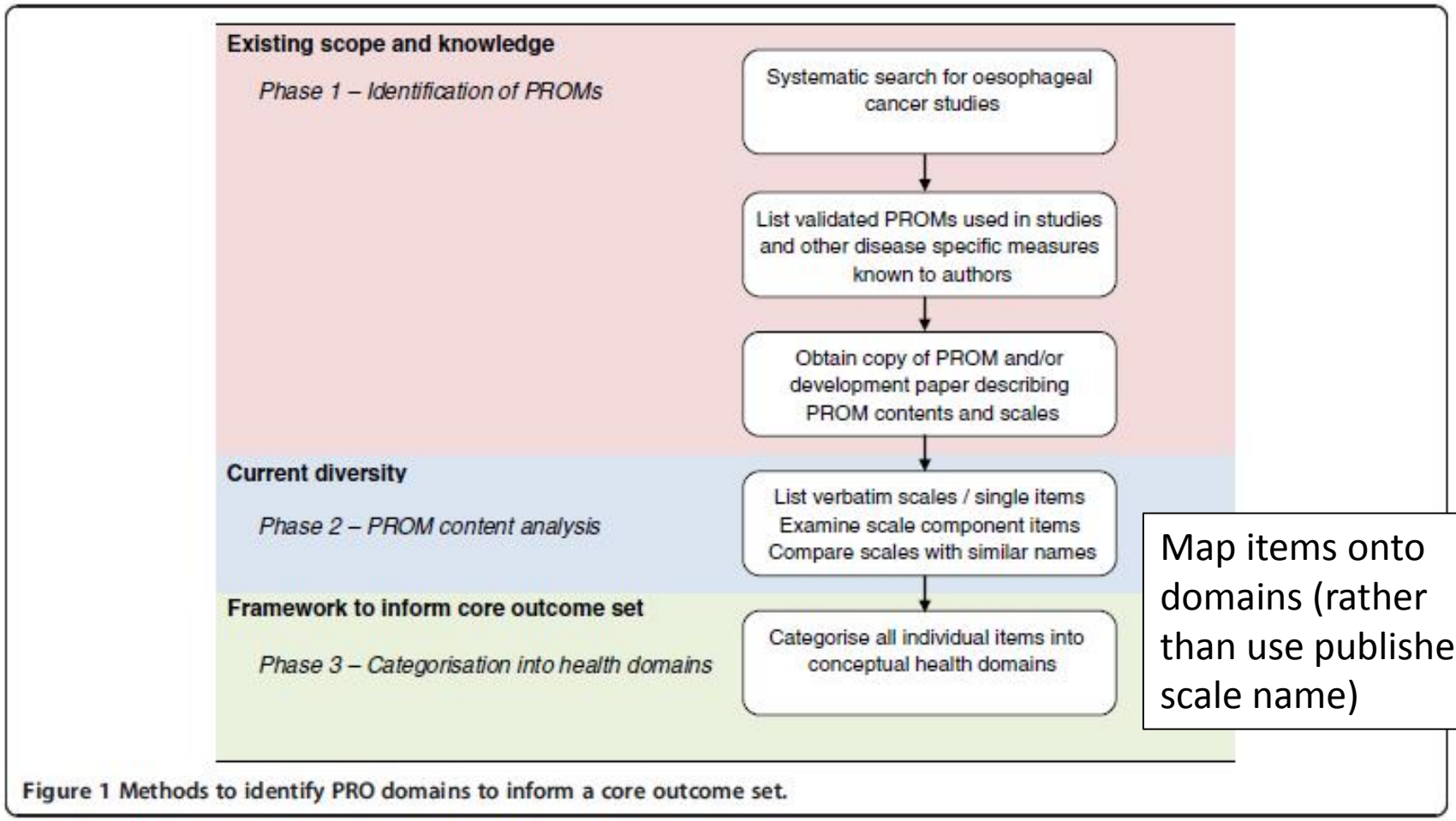


Figure 1 Methods to identify PRO domains to inform a core outcome set.

Map items onto domains (rather than use published scale name)

SF36 PROM

Scales

Physical functioning

Role-physical

Bodily pain

General health

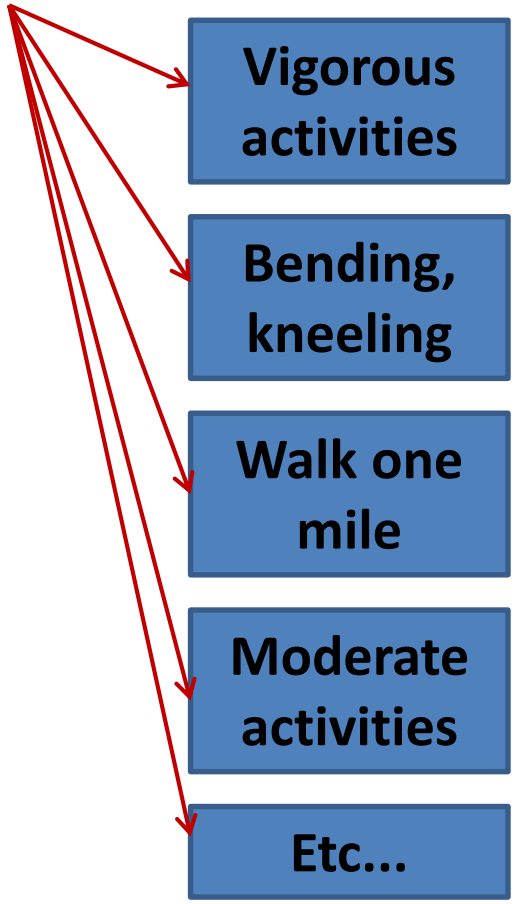
Vitality

Social functioning

Role-emotional

Mental health

Items



QualityMetric

QLQ-C30 PROM EORTC Quality of Life

Scales

Physical function

Role function

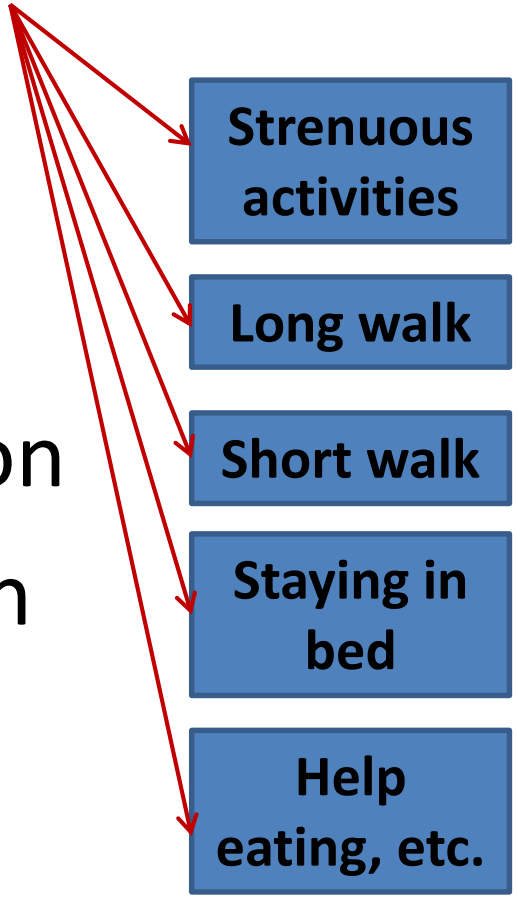
Social function

Emotional function

Cognitive function

Global QOL

Items



Items in physical function domains

GIQLI Physical function[1]	C30 Physical function[2]	SF36 Physical function[3]
Tiredness	Strenuous activity	Vigorous activities
Feeling unwell	Ability to walk	Bending, kneeling
Waking at night	Time spent in bed	Walk one mile
Changes in appearance	Time spent in a chair	Moderate activities
Strength	Need for help with self-care	
Endurance		
Feeling unfit		

1. Eypasch E et al. GIQLI Gastrointestinal quality of life index - development, validation and application of a new instrument. Br J Surg 1995, 82:216–222.
2. Aaronson NK et al The EORTC QLQ-C30 – an instrument for use in international clinical trials in oncology. J Natl Cancer Inst 1993, 85:365–376.
3. SF36 JE Ware et al.

Analysis of individual items needed

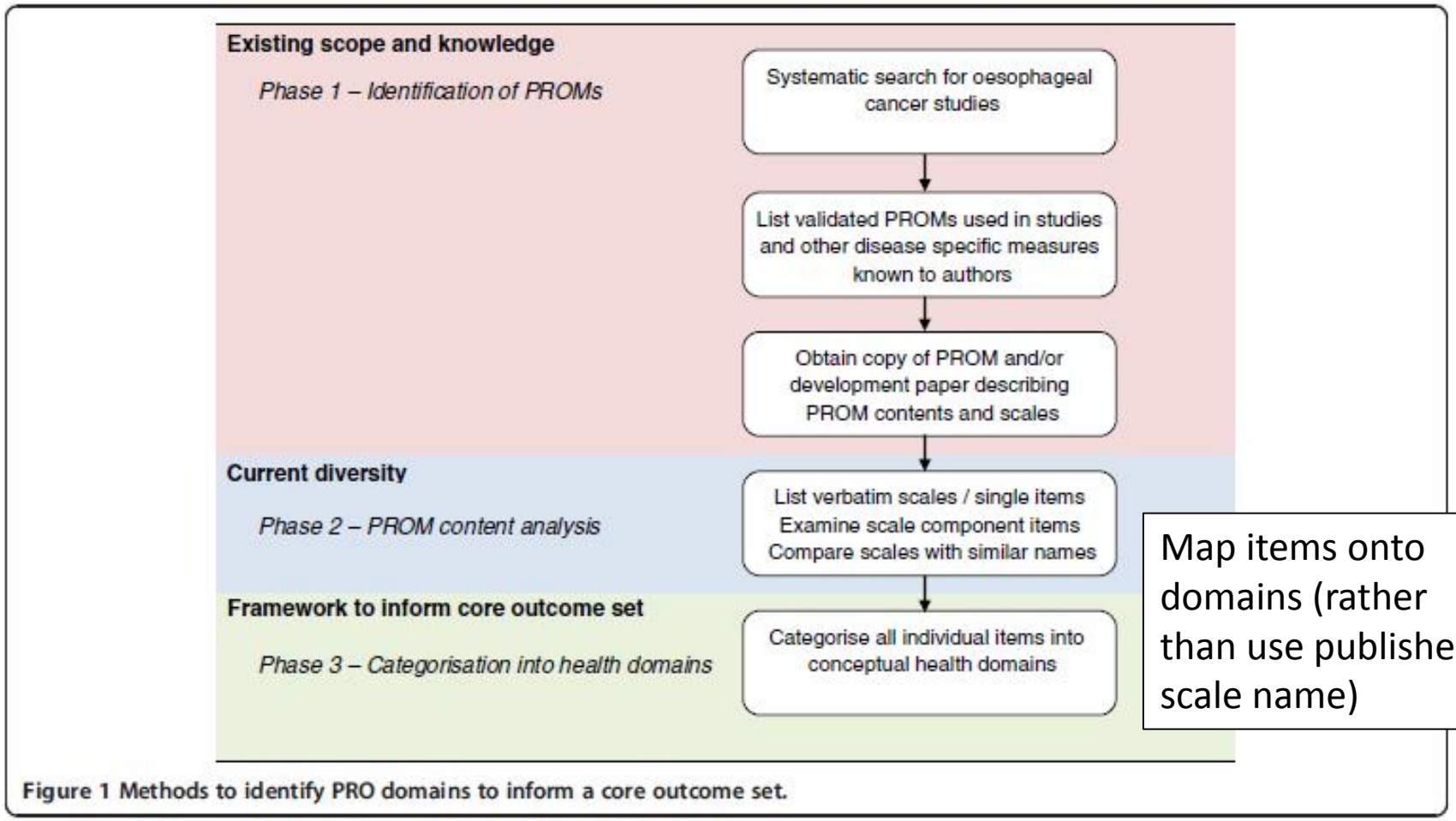


Figure 1 Methods to identify PRO domains to inform a core outcome set.

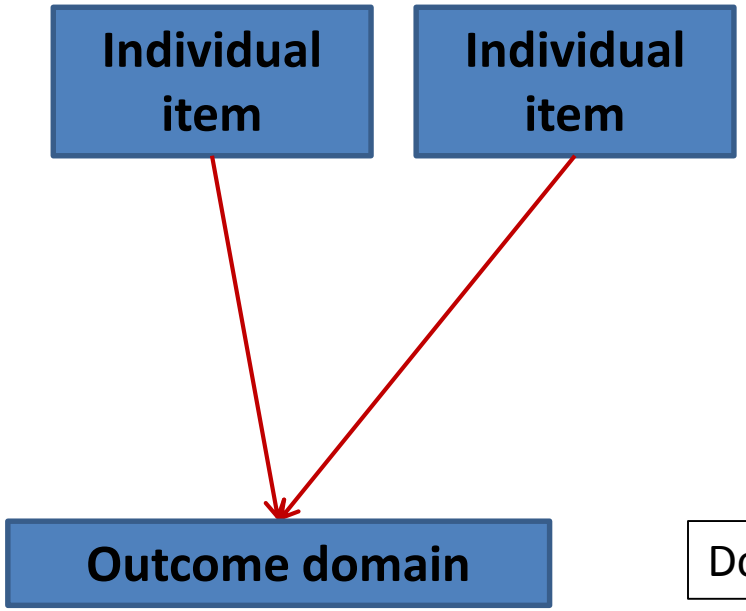
Map items onto domains (rather than use published scale name)

Mapping items onto domains

- Some limited methodology - Cochrane Handbook
- Meta-analysis of RCTs of psychosocial interventions in the treatment of pre-menstrual syndrome

- “Two investigators independently examined each instrument – including all domains – and group them into discrete conceptual categories”

Items, scales & domains

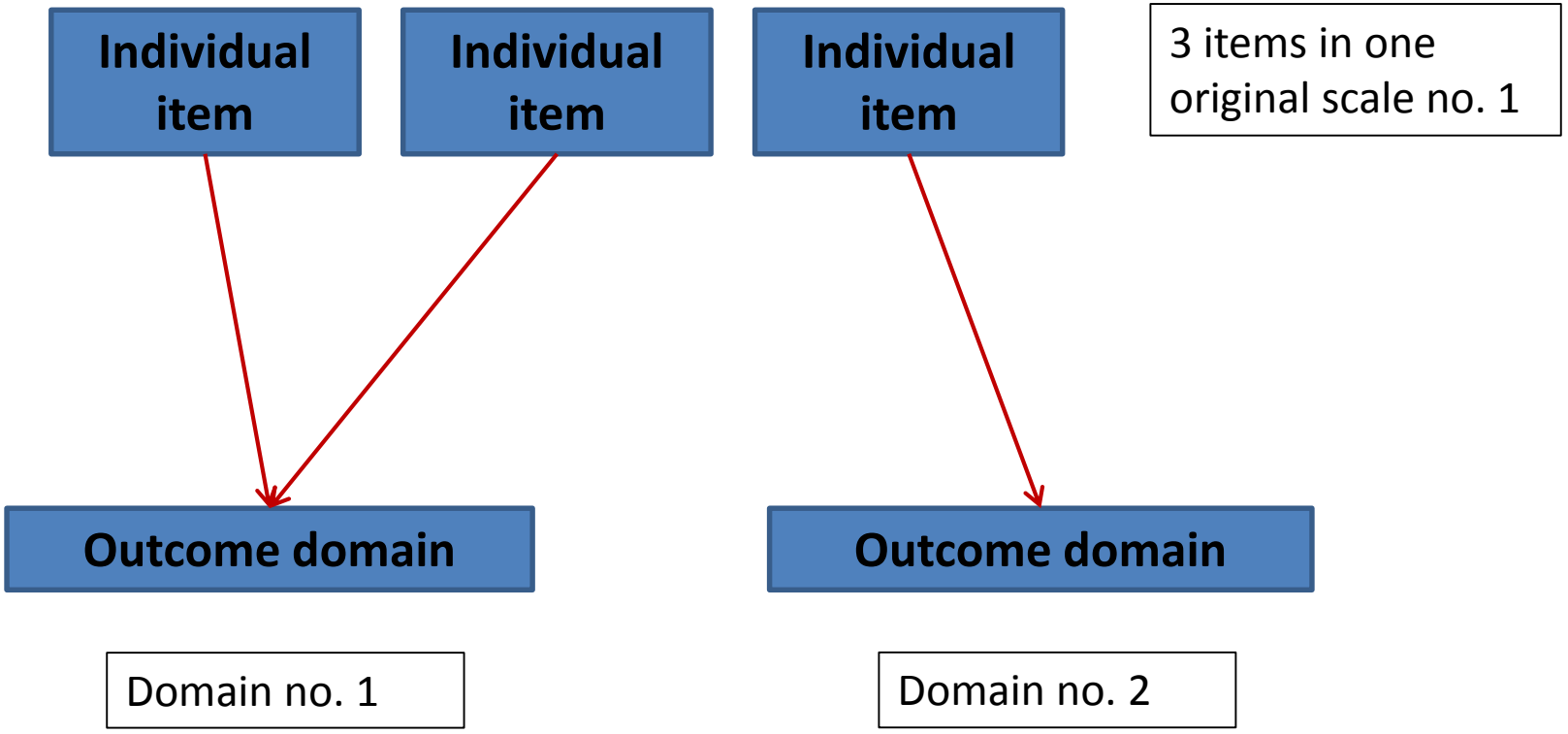


Scale no. 1

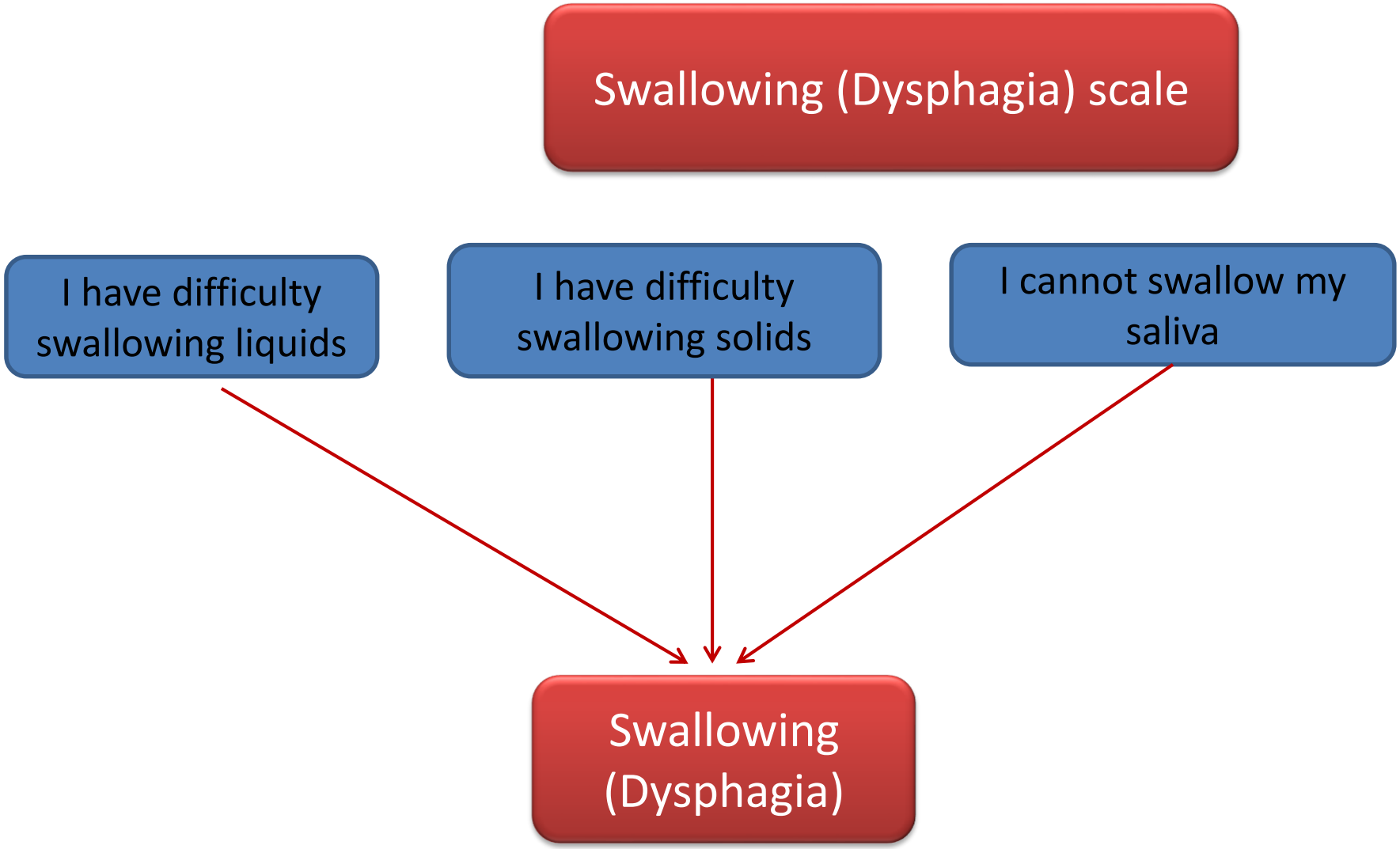
2 items in original scale

Domain no. 1

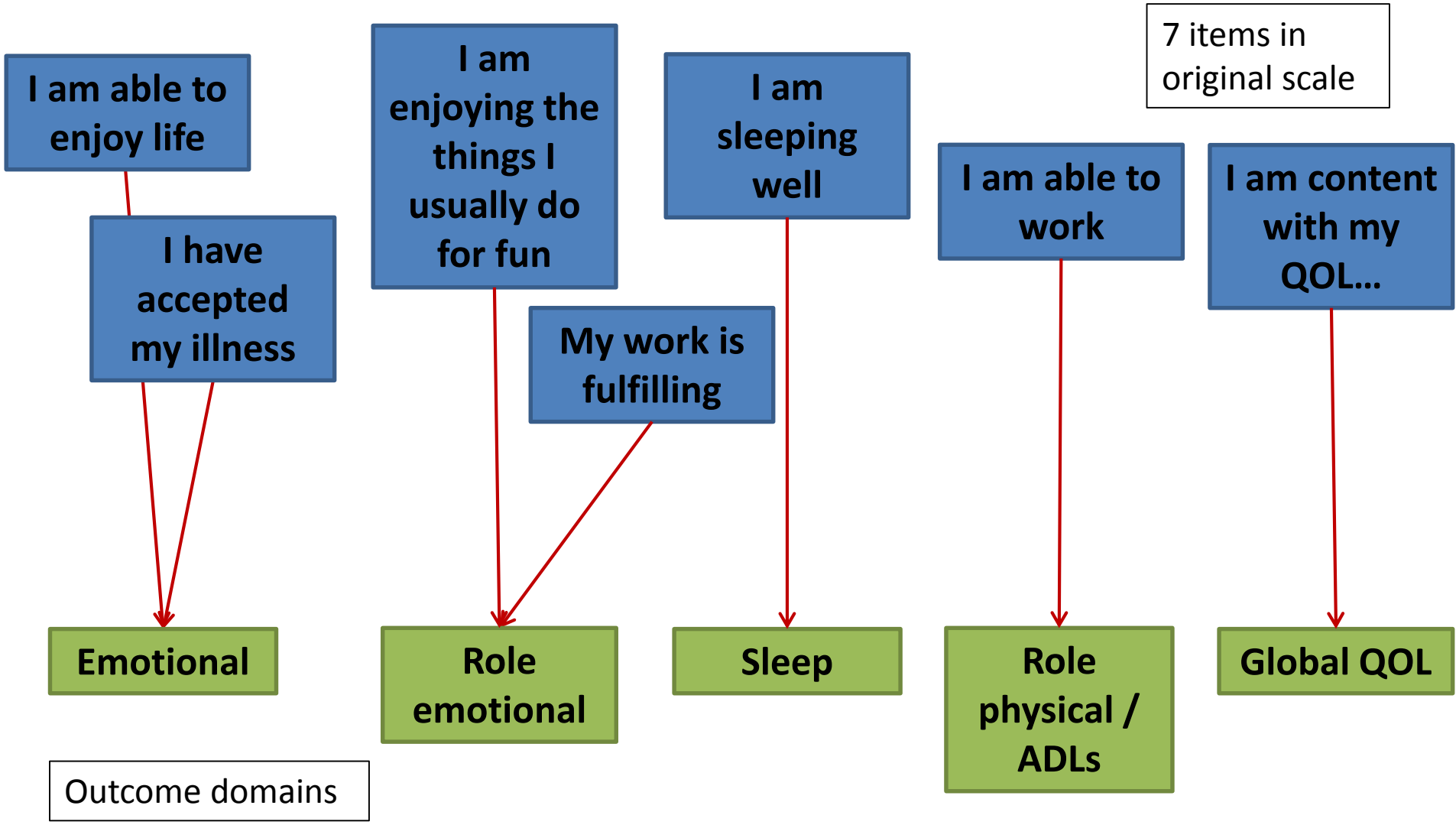
Items, scales & domains



Mapping items onto domains



FACT-G "Functional well-being"

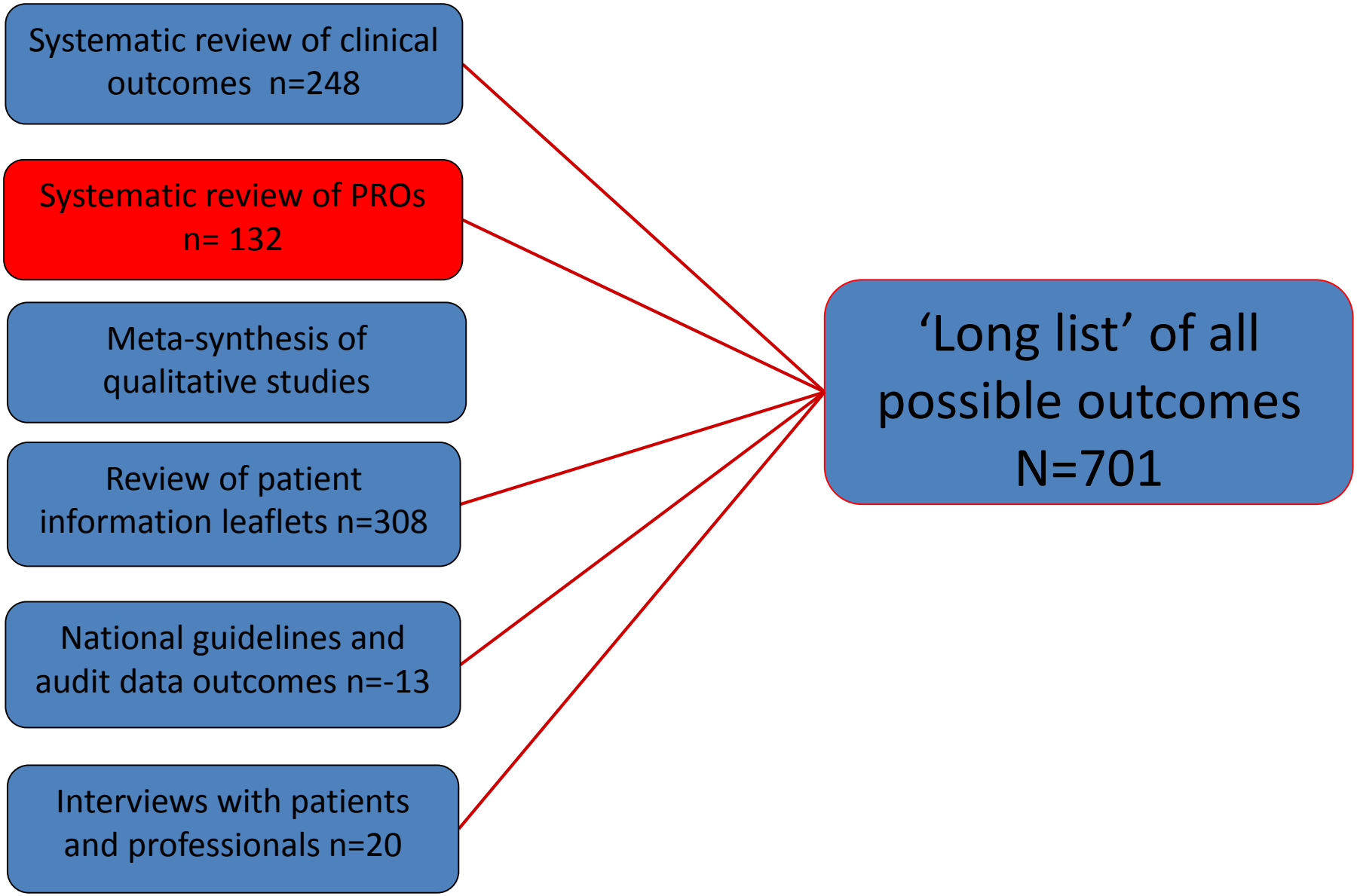


Mapping items onto domains

- Determined by expert opinion & patients
- Examined all items in the PRO measures

Gastro/Oesophageal Support and Help group

Identify of possible outcomes



Mapping items onto domains

- 132 was mapped onto **32 outcome domains**

32 domains used to create items in the survey

Macefield *et al. Trials* 2014, **15**:49
http://www.trialsjournal.com/content/15/1/49

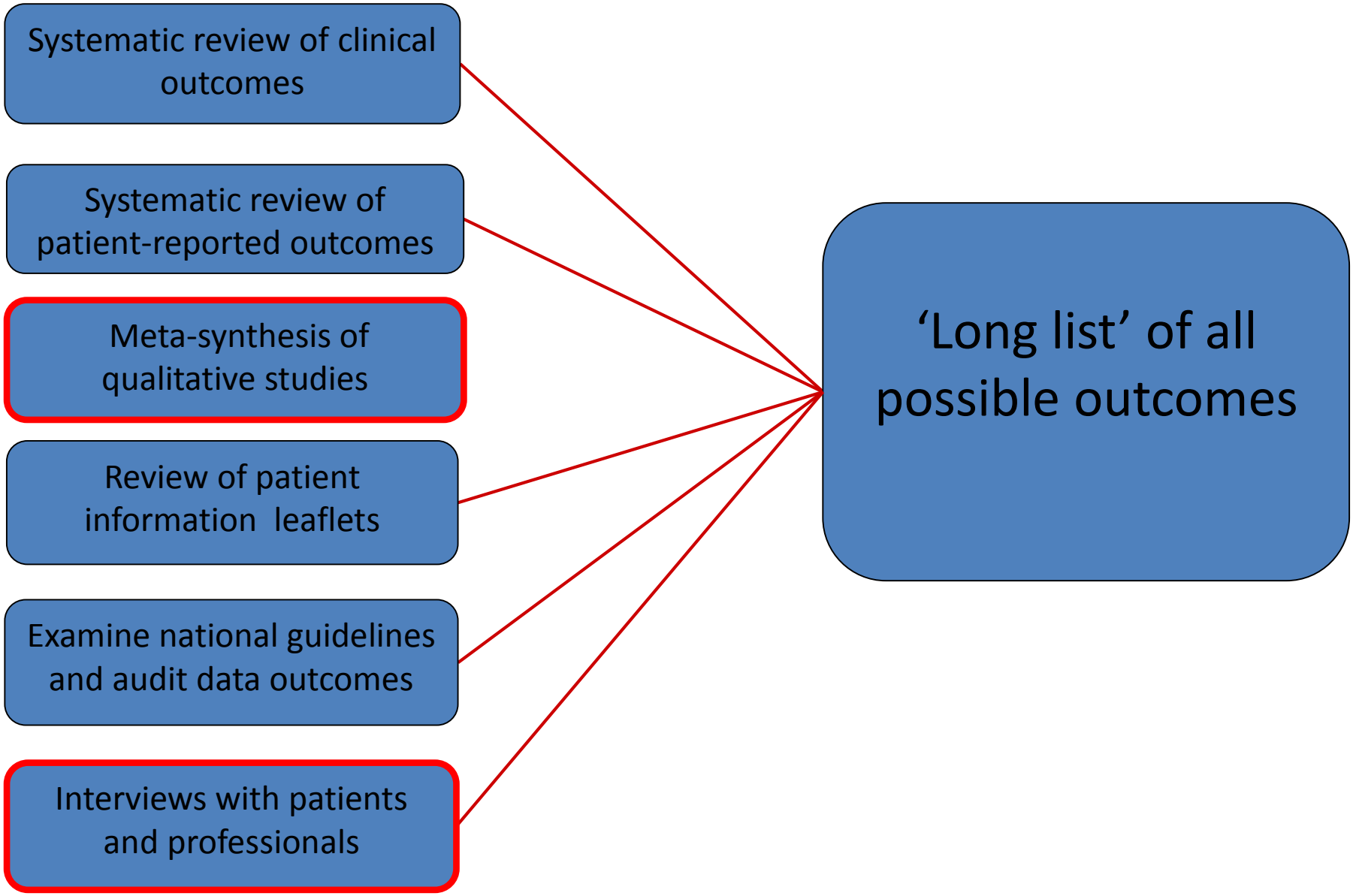
TRIALS

METHODOLOGY Open Access

Developing core outcomes sets: methods for identifying and including patient-reported outcomes (PROs)

Rhiannon C Macefield[1*], Marc Jacobs[2], Ida J Korfage[3], Joanna Nicklin[4], Robert N Whistance[1], Sara T Brookes[1], Mirjam AG Sprangers[2] and Jane M Blazeby[1,4]

Identify outcomes (e.g. Bariatric surgery)



Meta-synthesis & qualitative interviews

Themes from published qualitative research

Themes from interviews

→ Outcome domains

obesity reviews

doi: 10.1111/obr.12518

Obesity Treatment/Outcomes

Patient experiences of outcomes of bariatric surgery: a systematic review and qualitative synthesis

Karen D. Coulman,[1] Fiona MacKichan,[1] Jane M. Blazeby[1,2] and Amanda Owen-Smith[1]

Results: meta-synthesis

2603 abstracts,

33 qualitative studies

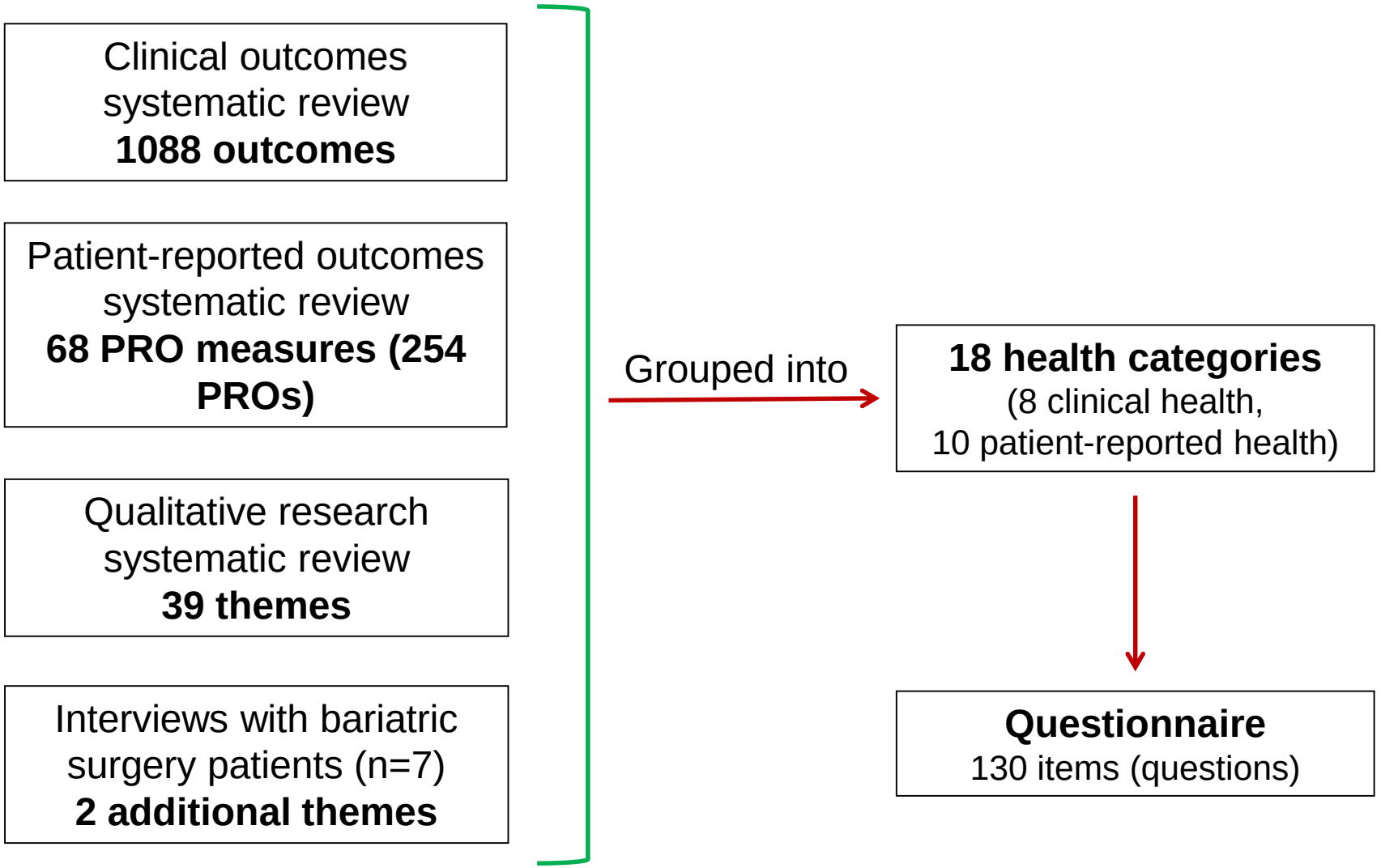
39 themes
(36 overlap with PROs)

"The development of new addictions after surgery"

"Excess skin"

"Stigma"

Identifying and grouping the information



PLOS | MEDICINE

GUIDELINES AND GUIDANCE

A Core Outcome Set for the Benefits and Adverse Events of Bariatric and Metabolic Surgery: The BARIACT Project

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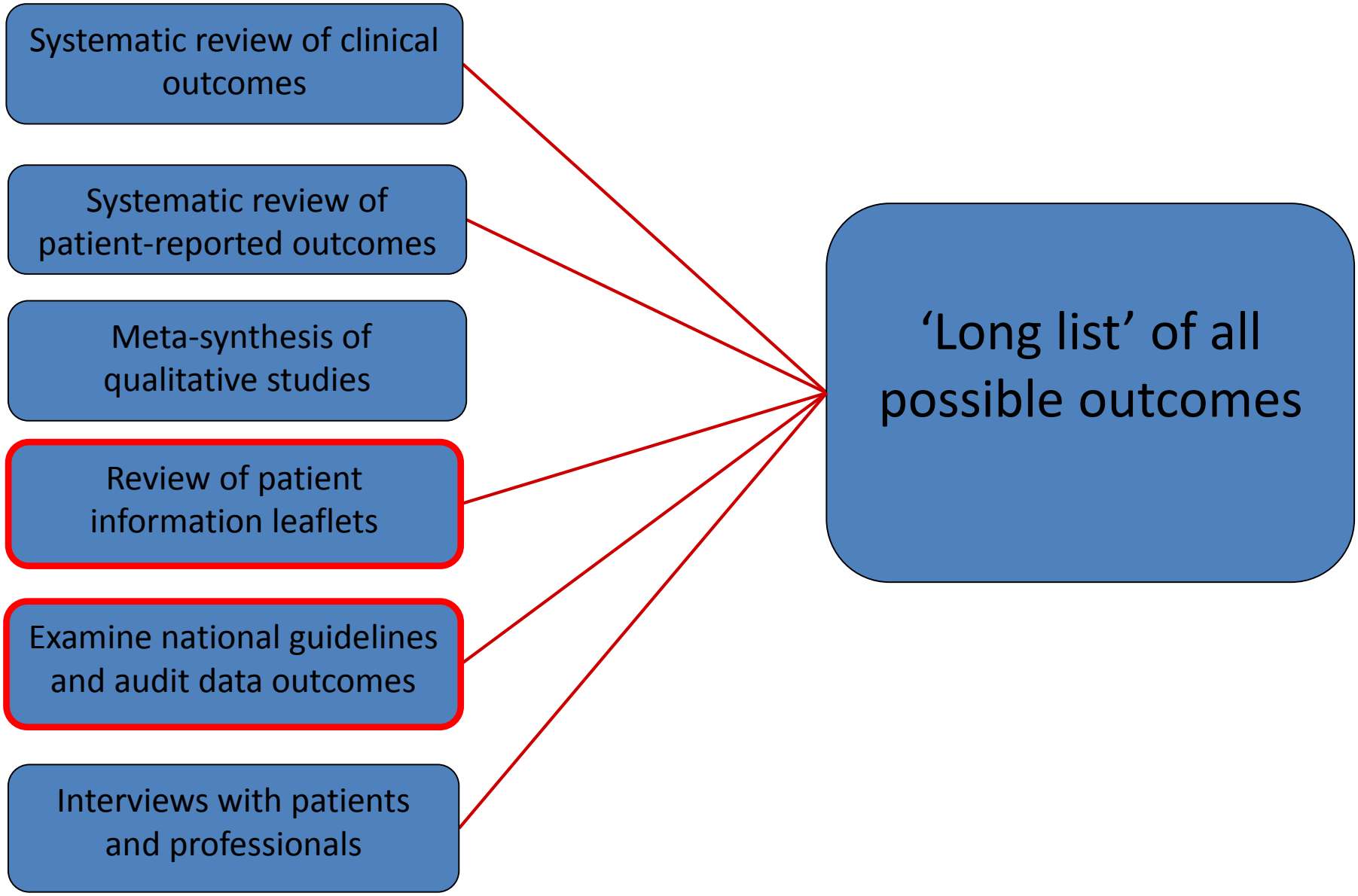
Abstract

Background

Identify of possible outcomes



BMJ Open

Assessing the quality of written information provision for surgical procedures: a case study in oesophagectomy

N S Blencowe,[1,2] S Strong,[1,2] A G K McNair,[1,2] N Howes,[1,2] J Elliot,[3] K N Avery,[1] J M Blazeby[1,2]

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ABSTRACT

Objective: To examine the content and quality of written information provided by surgical centres for patients undergoing oesophagectomy for cancer.

Design: Cross-sectional study of the content of National Health Service (NHS) patient information leaflets (PILs) about oesophageal cancer surgery, using a modified framework approach.

Data sources: Written information leaflets from 41 of 43 cancer centres undertaking surgery for oesophageal cancer in England and Wales (response rate 95.3%).

Eligibility criteria: All English language versions of PILs about oesophagectomy.

Results: 32 different PILs were identified, of which 2 were generic tools (Macmillan 'understanding cancer of the gullet' and EIDO 'oesophagectomy'). Although most PILs focused on describing in-hospital adverse events, information varied widely and was often misleading. Just 1 leaflet described survival benefits of surgery and 2 mentioned the possibility of disease

Strengths and limitations of this study

- Excellent response rate.
- In-depth analysis of written information for patients prior to major cancer surgery.
- Makes a strong case to address this issue with future work (eg, development of nationally agreed patient information leaflets (PILs) informed by 'core information sets').
- Verbal communication of information was not assessed, and it is therefore possible that 'missing' written information was discussed during clinical consultations.
- Provision of written patient information does not guarantee if it has been read or understood; assessment of the comprehensibility of PILs was beyond the scope of this study.

McNair et al. BMC Cancer (2016) 16:258
DOI 10.1186/s12885-016-2292-3

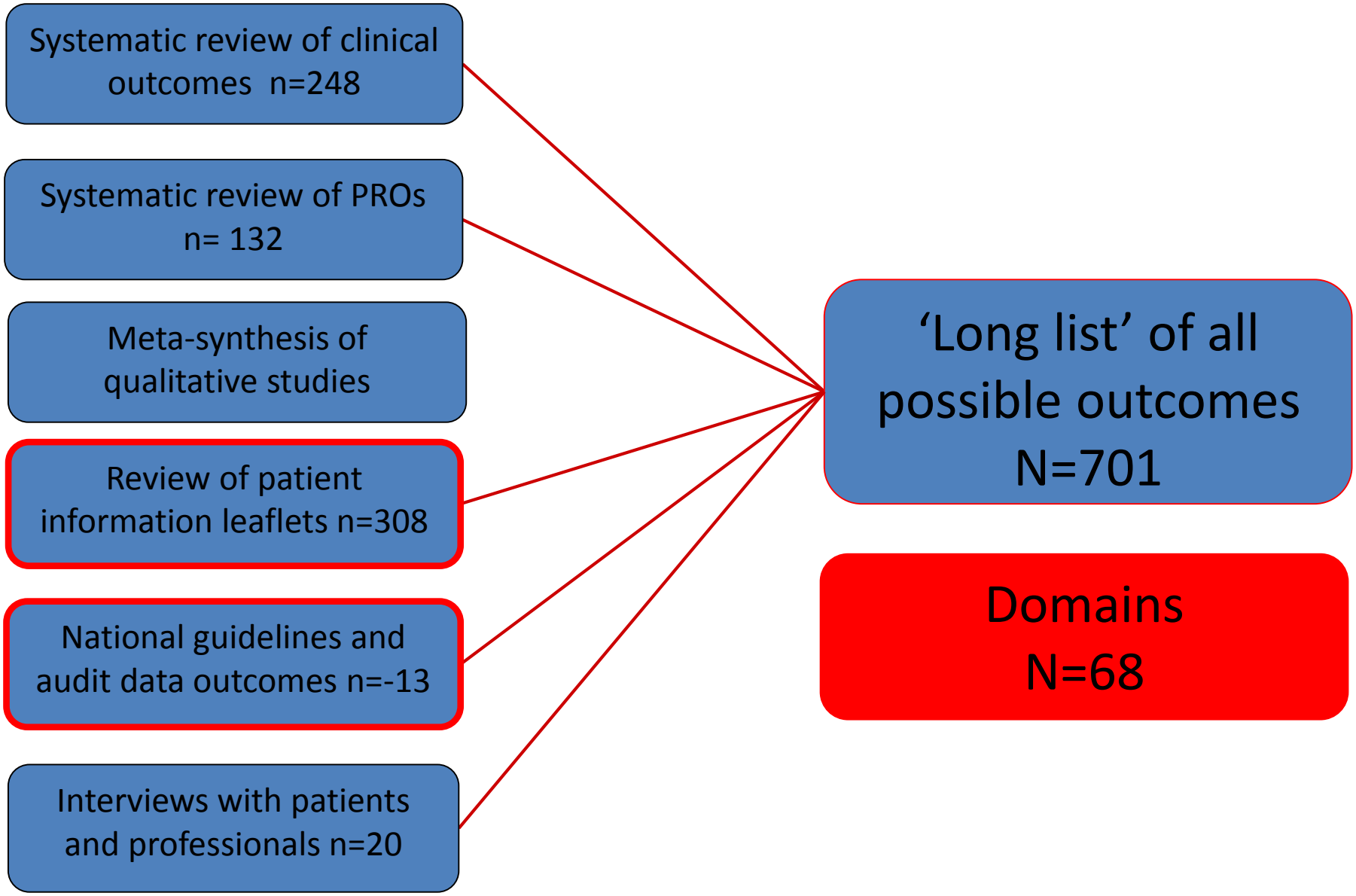
BMC Cancer

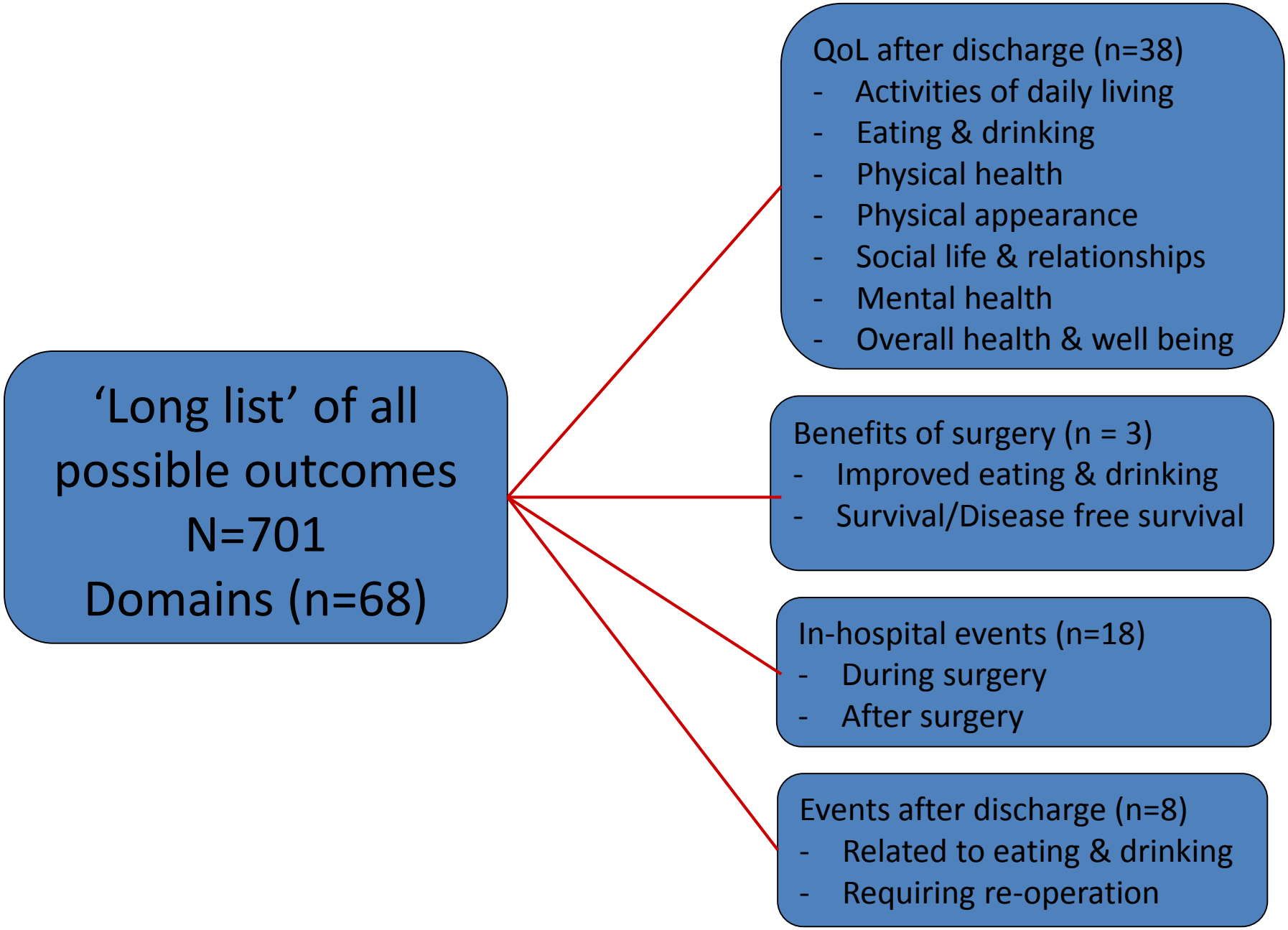
RESEARCH ARTICLE Open Access

What surgeons tell patients and what patients want to know before major cancer surgery: a qualitative study

Angus G. K. McNair[1,2*], F MacKichan[1], J. L. Donovan[1], S. T. Brookes[1], K. N. L. Avery[1], S. M. Griffin[3], T. Crosby[4] and J. M. Blazeby[1,5]

Identify of possible outcomes




'Long list' of all possible outcomes N=701 Domains (n=68)
QoL after discharge (n=38)
- Activities of daily living
- Eating & drinking
- Physical health
- Physical appearance
- Social life & relationships
- Mental health
- Overall health & well being
Benefits of surgery (n = 3)
- Improved eating & drinking
- Survival/Disease free survival
In-hospital events (n=18)
- During surgery
- After surgery
Events after discharge (n=8)
- Related to eating & drinking
- Requiring re-operation

How to classify domains?

- Remember the scope of your COS
- Use independent views
- Multi-disciplinary approaches
  - Patient benefit
  - Adverse events
  - Specific issues related to scope

Summary

- Can be very detailed, lengthy process (more to it than apparent - get advice)
- Possible to simplify the process
- Domains critical to the consensus process – try to avoid overlap


The Author(s) *Trials* 2017, **18**(Suppl 3):280
DOI 10.1186/s13063-017-1978-4

Trials

REVIEW Open Access

The COMET Handbook: version 1.0

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