Comorbidities and Mortality Improvement
New ASMBS/IFSO Guidelines

Systematic Review for the New ASMBS/IFSO Guidelines

Maurizio De Luca

Director Department of Surgery Rovigo,Trecenta and Adria Hospitals– Italy
Vice President Italian Society of Bariatric Surgery and Metabolic Disorders (SICOB)
Treasurer International Federation for Surgery of Obesity and Metabolic Disorders (IFSO EC)
Co-chair Scientific Committee International Federation for Surgery of Obesity and Metabolic Disorders (IFSO EC)
Scientific Committee International Federation for Surgery of Obesity and Metabolic Disorders (IFSO)
Scientific Commitee Italian Society of Obesity (SIO)
Scientific Commitee The Upper Gastrointestinal Surgeons (TUGS)

31st of August, 2023

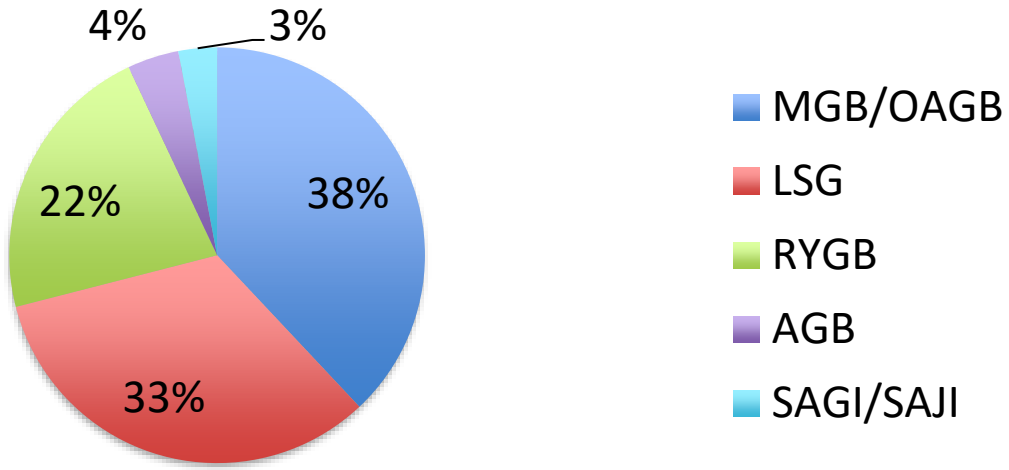
My Bariatric Experience

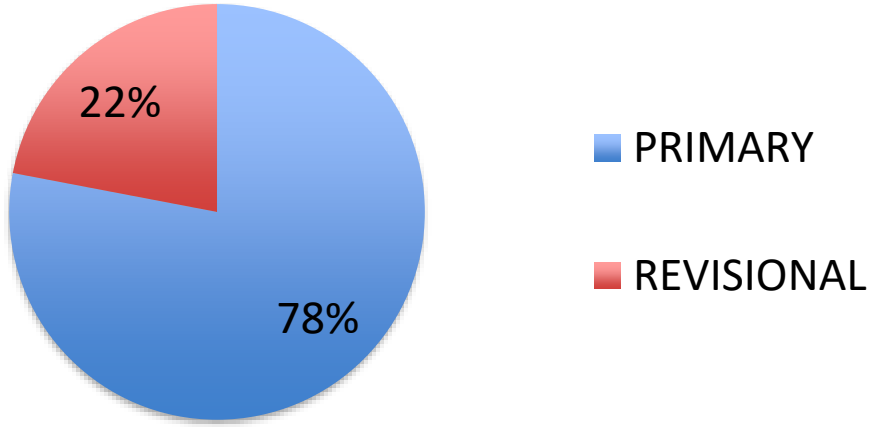
Trained in Mini-invasive Laparoscopic and Thoracoscopic Surgery

First Bariatric Procedure – Gastric Banding, 1993

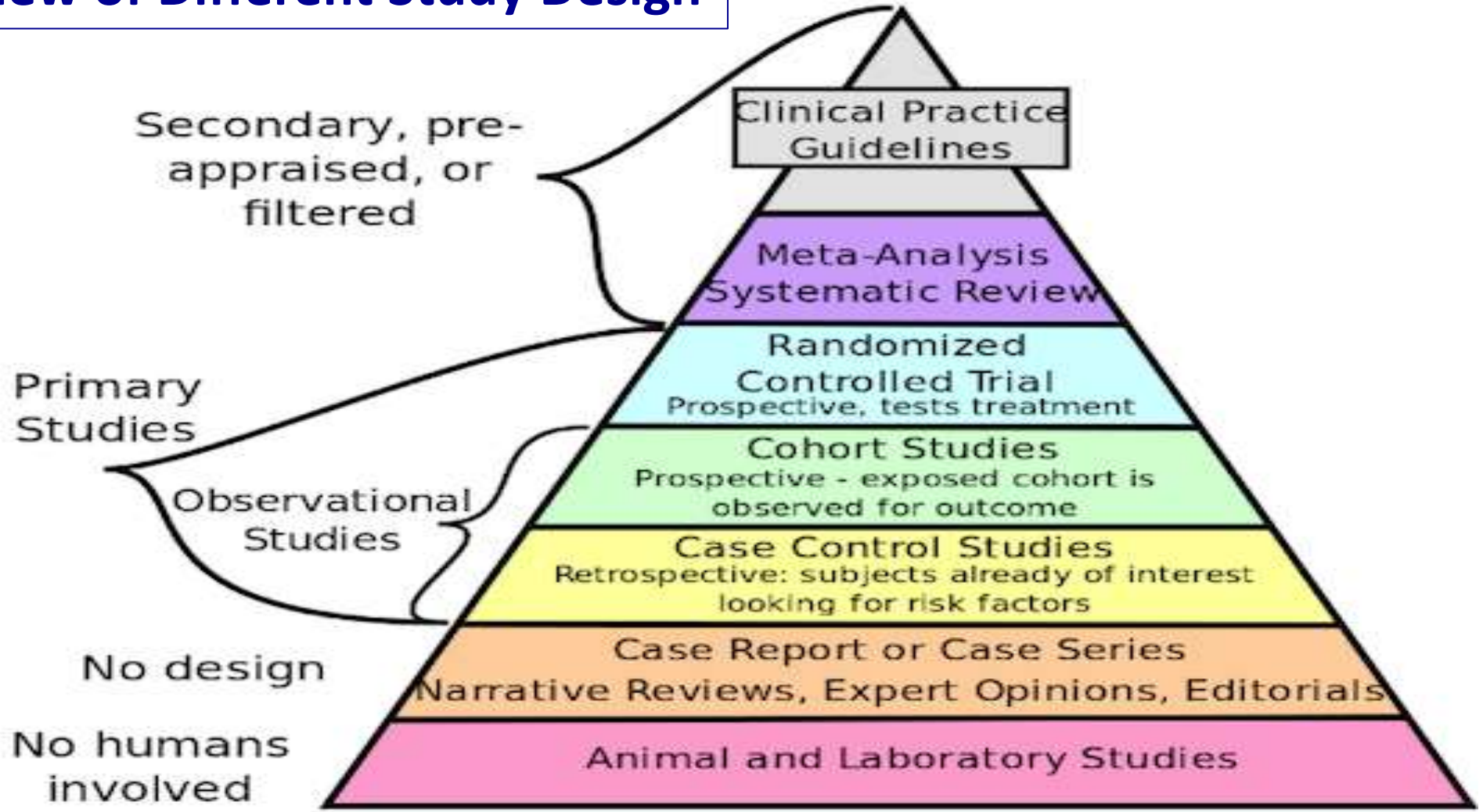
~ 12000 bariatric procedure in 30 years

Last 5 years





Overview of Different Study Design

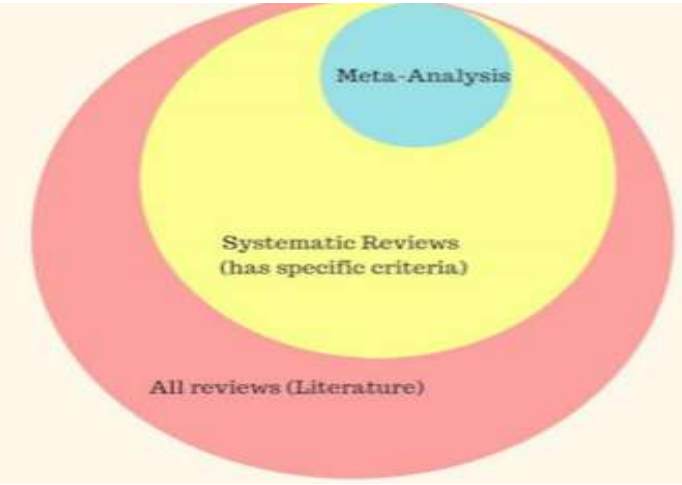


Centre for Evidence-Based Medicine. Study Designs. 2016
https://www.cebm. net/2014/04/study-designs/.

Overview of Different Study Design

Systematic Review and Metanalysis

- **Systematic Reviews and meta-analysis are epidemiological types of studies which do not provide new data but have great importance.**
- They **allow to have a summary picture of the scientific evidence present on a particular topic.**
- They are therefore defined as updated summaries on **the state of art of scientific research in each sector, conducted by experts in the field**, from which us you can get an idea of a certain topic.

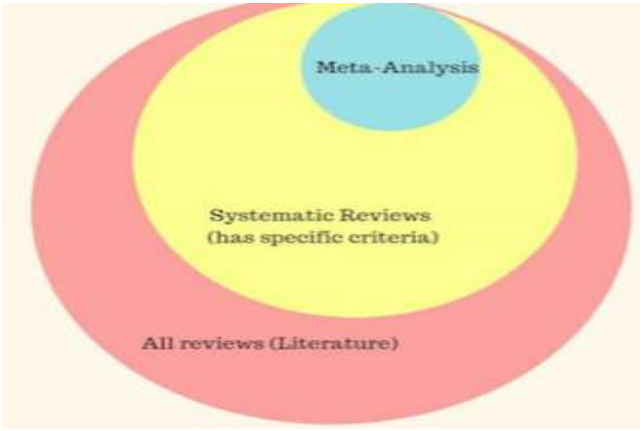


Cochrane Handbook for Systematic Reviews of Interventions.
Retrieved from www.cochrane.org/resources/handbook/index.htm

Overview of Different Study Design

Systematic Review

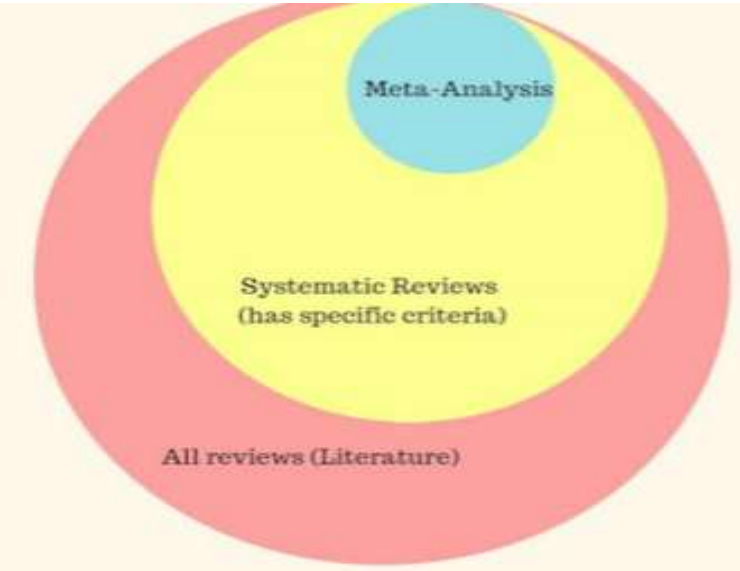
- **The systematic review is a common type of research used in the assessment of literature and studies,** which addresses a particular health-related issue .
- **Systematic reviews can be used *"to summarize", "to collect"* the results of all available medical studies and controlled trials**.
- Systematic reviews **can provide vital information about the effectiveness of an intervention.**
- One of the main disadvantages is that failing to collect and research complicated data may lead to erroneous conclusions.



Cochrane Handbook for Systematic Reviews of Interventions.
Retrieved from www.cochrane.org/resources/handbook/index.htm

Overview of Different Study Design

Meta-analysis



- **Meta-analysis is a study design, which is a powerful research method.**
- **A meta-analysis is the statistical process which "analyzes" and "compares" results from several similar studies.**
- **It's based on data collected from different studies.** Meta-analysis is described as quantitative and epidemiological study design.
- **A rigorous meta-analysis is a great approach to evidence-based medicine**.
- Since this design involves the profound analysis of previous studies, **meta-analysis may have the potential to reveal hidden insights and relationships**, **such as possible health risks related to a new treatment and medical interventions. This particular aspect is one of the main advantages of meta-analyses.**

Peat, J. (2011)
Planning the study
Sage Research Methods

Systematic Review for the New ASMBS/IFSO Guidelines

ELSEVIER

Surgery for Obesity and Related Diseases ■ (2022) 1–12

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): Indications for Metabolic and Bariatric Surgery

Dan Eisenberg, M.D.[a,*], Scott A. Shikora, M.D.[b], Edo Aarts, M.D., Ph.D.[c], Ali Aminian, M.D.[d], Luigi Angrisani, M.D.[e], Ricardo V. Cohen, M.D., Ph.D.[f], Maurizio De Luca, M.D.[g], Silvia L. Faria, Ph.D.[h], Kasey P. S. Goodpaster, Ph.D.[d], Ashraf Haddad, M.D.[i], Jacques M. Himpens, M.D., Ph.D.[j], Lilian Kow, B.M.B.S., Ph.D.[k], Marina Kurian, M.D.[l], Ken Loi, M.B.B.S., B.Sc. (Med)[m], Kamal Mahawar, M.B.B.S., M.Sc.[n], Abdelrahman Nimeri, M.D., M.B.B.Ch.[o], Mary O'Kane, M.Sc., R.D.[p], Pavlos K. Papasavas, M.D.[q], Jaime Ponce, M.D.[r], Janey S. A. Pratt, M.D.[a,s], Ann M. Rogers, M.D.[t], Kimberley E. Steele, M.D., Ph.D.[u], Michel Suter, M.D.[v,w], Shanu N. Kothari, M.D.[x]

Systematic Review for the New ASMBS/IFSO Guidelines

National Institutes of Health Consensus Development Conference Statement: Gastrointestinal surgery for obesity.

National Institutes of Health, Bethesda, MD, March 25-27, 1991

- BMI> 40 kg / m2
- BMI> 35 kg / m2 in the presence of specific comorbidities:
  - Hypertension
  - Ischemic heart disease
  - Type 2 diabetes
  - Obstructive sleep apnea syndrome
  - Obesity syndrome / hypoventilation (Picwick syndrome)
  - Non-alcoholic fatty liver disease and steatohepatitis
  - Dyslipidemia
  - Gastro-oesophageal reflux disease
  - Asthma
  - Venous stasis
  - Severe urinary incontinence
  - Disabling arthropathy
  - Severely reduced quality of life
- Between 18 and 60 years of age
- Proven failure of nutritional and behavioral therapy and longstanding obesity (> 5 years)
- Patients must be motivated and able to provide a valid consent, are willing to undergo periodic inspections and follow an established dietary regime
- Absence of major contraindications (very high operative risk, limited life expectancy due to illness, severe cirrhosis, alcohol abuse / drugs etc.).


ELSEVIER

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Am J Clin Nutr 1992;55615S-19S.

Systematic Review for the New ASMBS/IFSO Guidelines

I) *1991 NIH Consensus described:*

Dominant procedures VBG and RYGB mainly open

II) Currently:

- SG and RYGB mainly laparoscopically and robotically
- VBG is of historical interest and no longer performed
- Other procedures performed include AGB ↓, standard BPD ↓, BPD-DS ↓, OAGB ↑

In light of significant advances in the understanding of the disease of obesity
and in MBS, the leadership of the ASMBS and IFSO have convened to produce this joint statement.

Systematic Review for the New ASMBS/IFSO Guidelines

Criteria for surgery
BMI
BMI thresholds in the Asian population

Extremes of age
Older population
Pediatrics and adolescents

Bridge to other treatment
Joint arthroplasty
Abdominal wall hernia repair
Organ Transplantation

MBS in high-risk patient
BMI>60
Cirrhosis
Hearth failure

Patient evaluation

Outcome
Weight loss and co-morbidity improvement
Cancer risk
Mortality

Revisional surgery

Systematic Review for the New ASMBS/IFSO Guidelines

PRISMA's, Systemat Rieviews and Delphi forIFSO ASMBS Indication for Metabolic and Bariatric Surgery

Maurizio De Luca

Sonja Chiappetta
Angelo Iossa
Giovanni Merola
Salvatore Tolone
Giacomo Piatto
Antonio Vitiello
Mohammad Kermansaravi

ELSEVIER

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Systematic Review for the New ASMBS/IFSO Guidelines

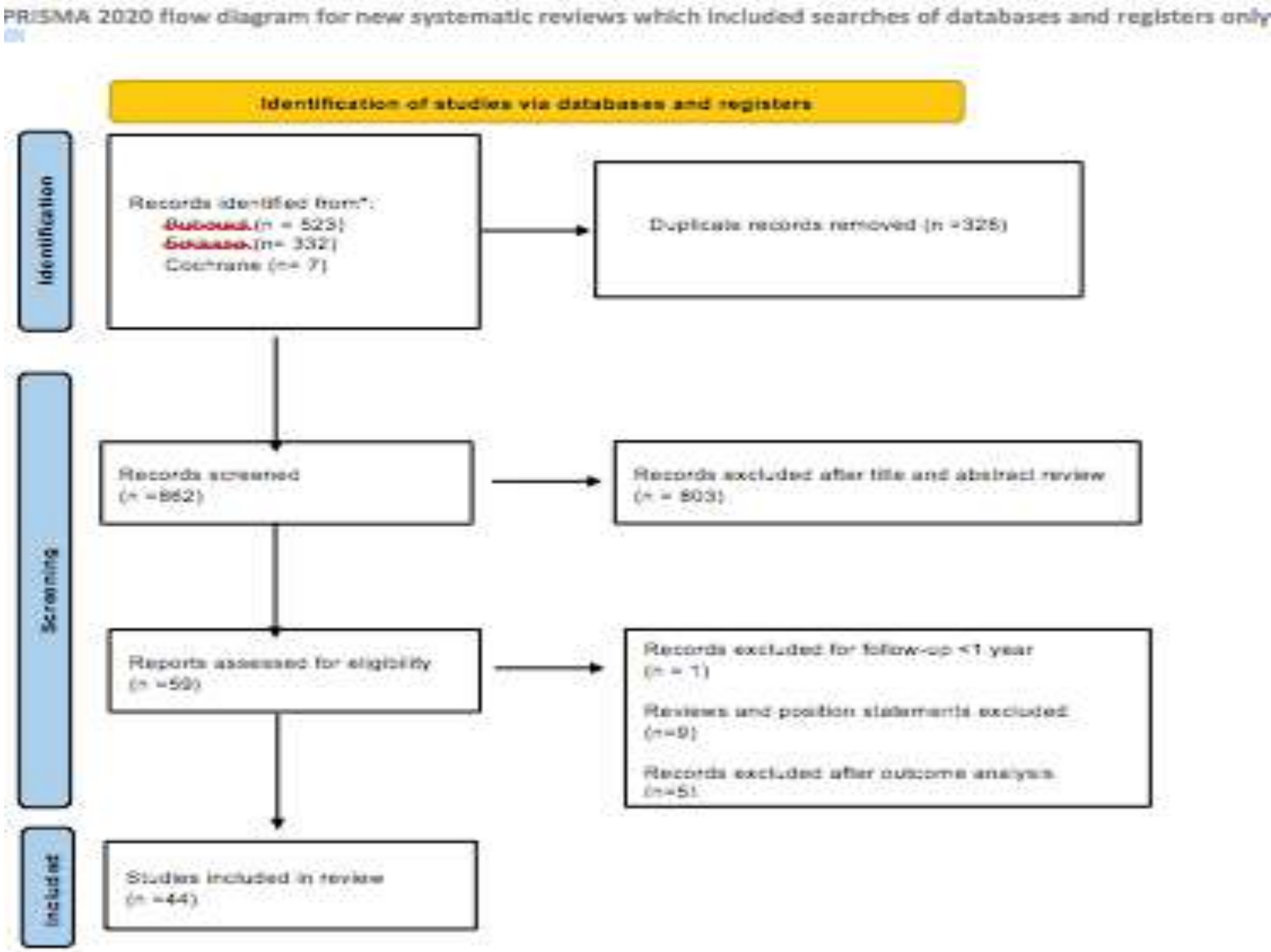
Criteria for surgery

BMI

1) BMI 30-34.9

Pubmed, Cochrane, Embase

OK Systematic Review



Systematic Review for the New ASMBS/IFSO Guidelines

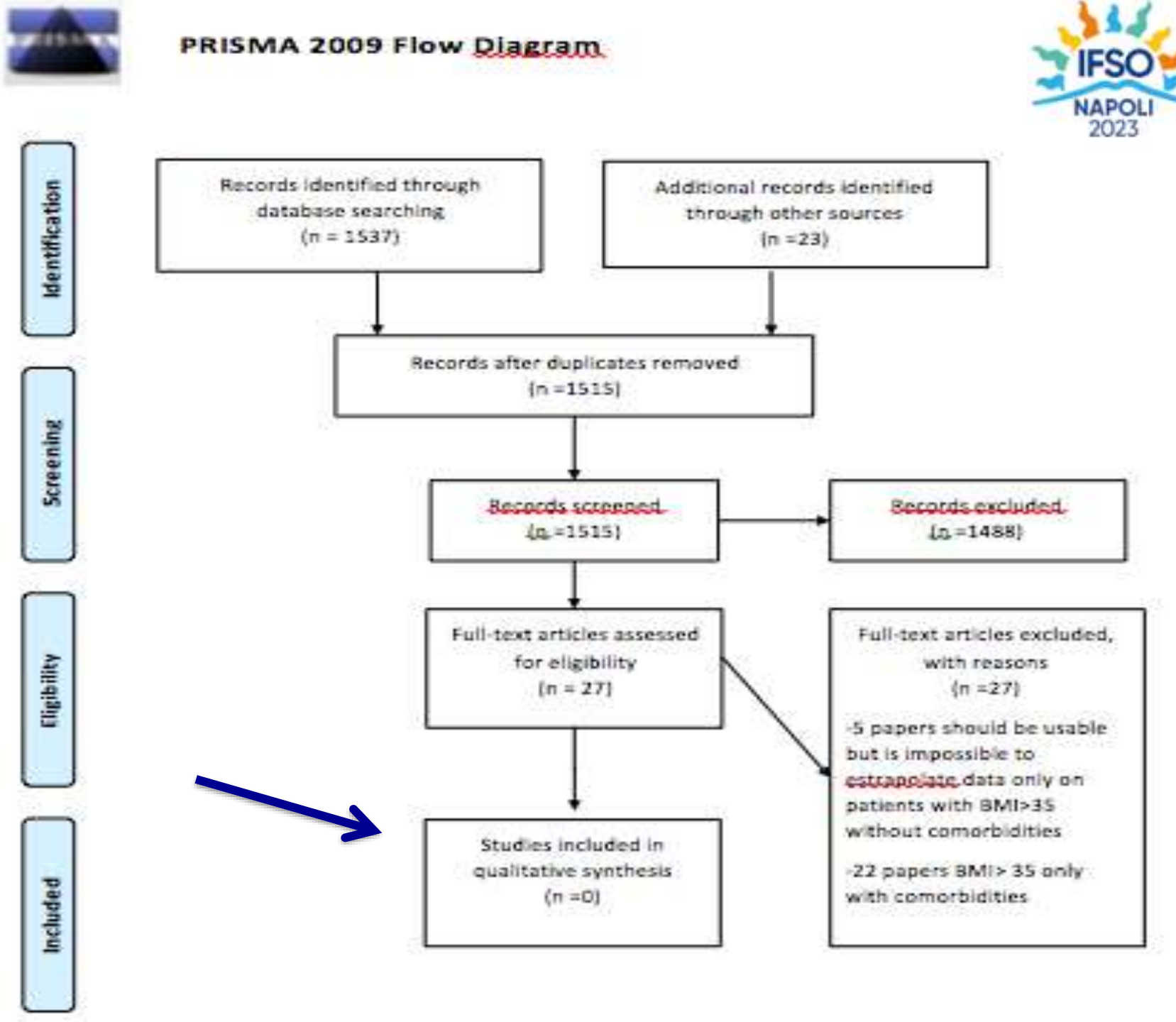
Criteria for surgery
BMI

2) BMI≥35 (no comorbidities)

Pubmed, Cochrane, Embase

NO Systematic Review

DELPHI ROUNDS



Systematic Review for the New ASMBS/IFSO Guidelines

Criteria for surgery

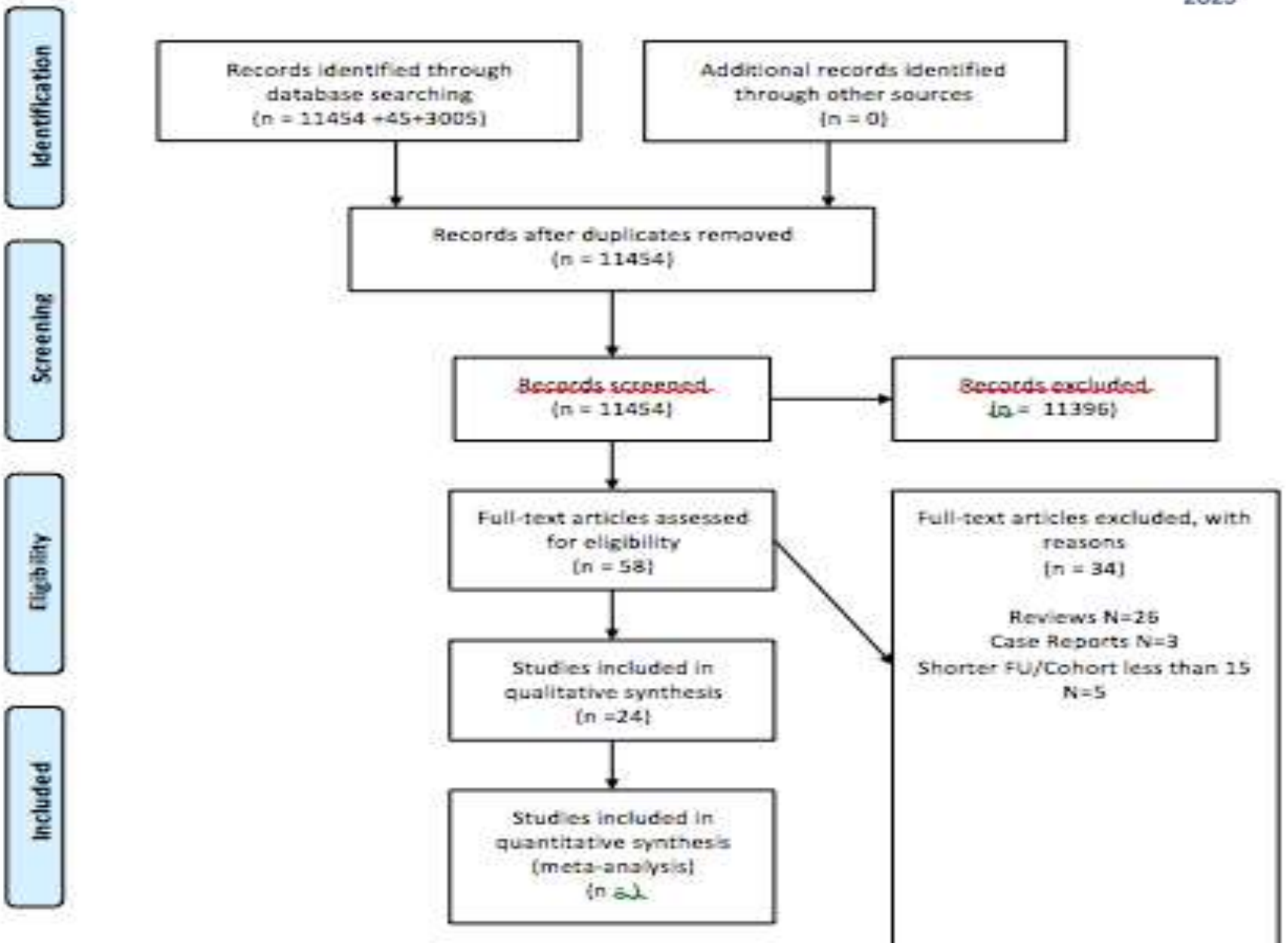
3) BMI thresholds in the Asian population

Pubmed, Cochrane, Embase

OK Systematic Review

PRISMA 2009 Flow Diagram: BMI thresholds in Asian population

IFSO NAPOLI 2023



Systematic Review for the New ASMBS/IFSO Guidelines

Extremes of age

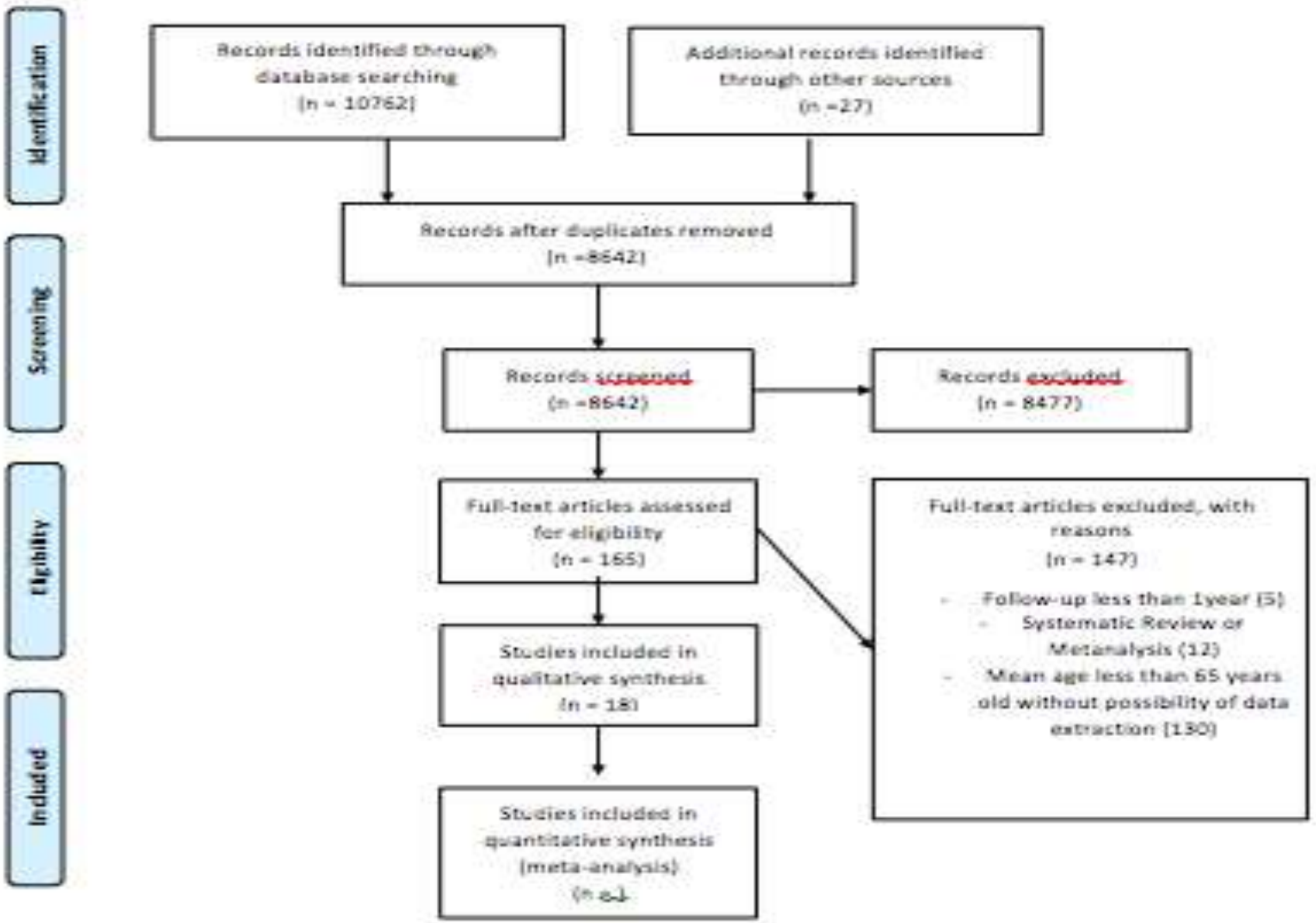
4) Older population

Pubmed, Cochrane, Embase

OK Systematic Review

PRISMA 2009 Flow Diagram for Patients aged more than 65yearsold

IFSO NAPOLI 2023



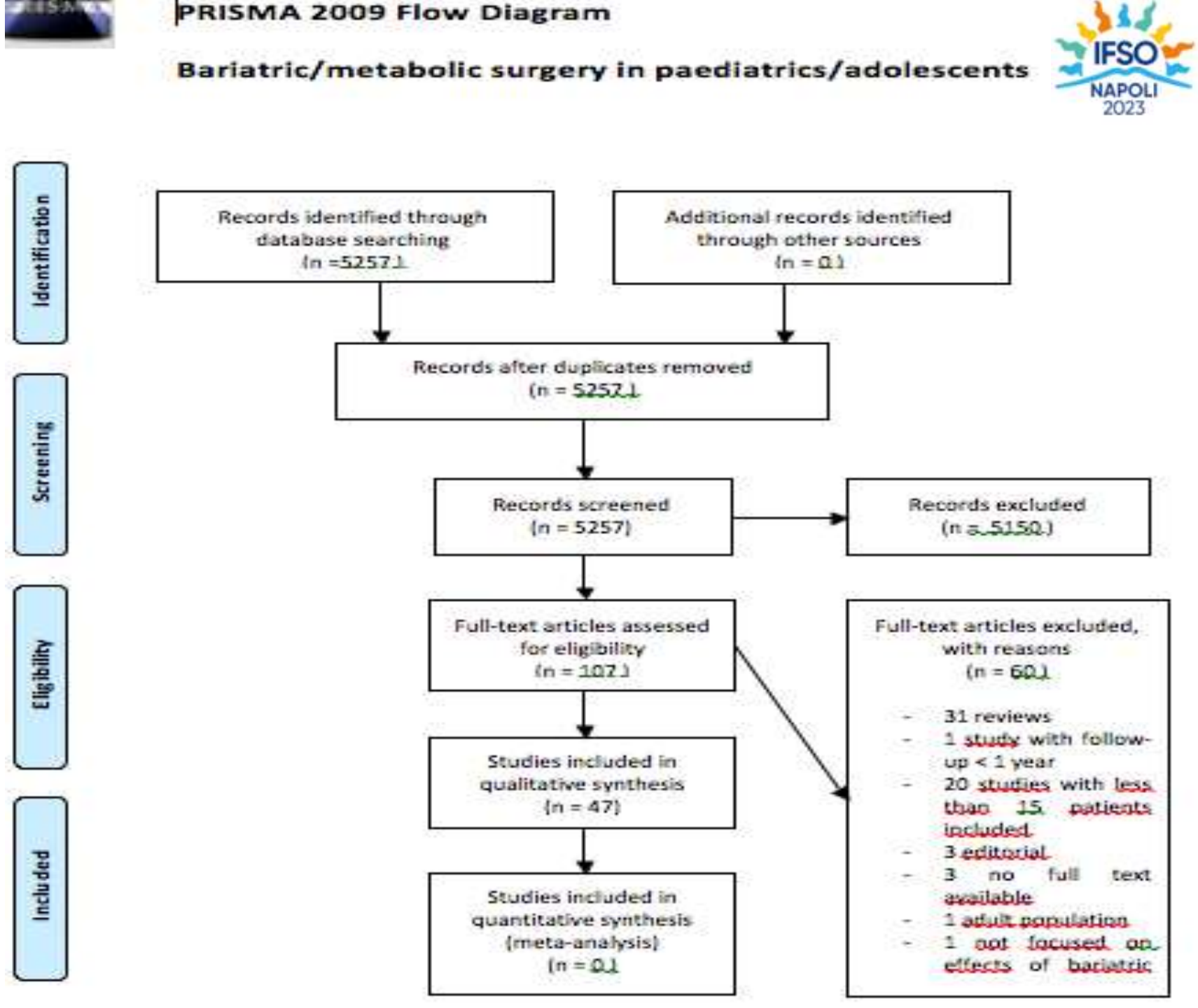
Systematic Review for the New ASMBS/IFSO Guidelines

Extremes of age

5) Pediatrics and adolescents

Pubmed, Cochrane, Embase

OK Systematic Review



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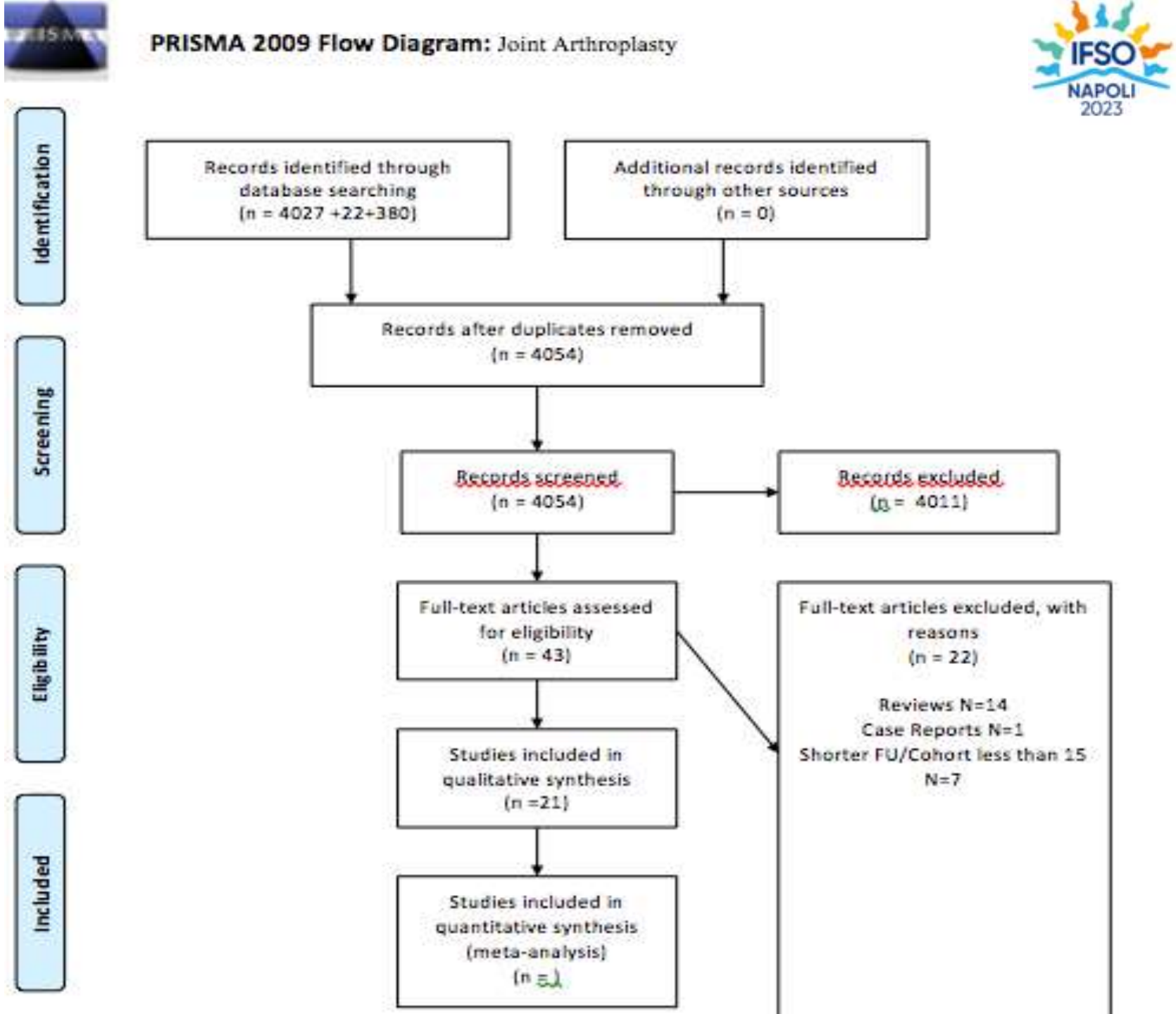
Bridge to other treatment

6) Joint arthroplasty

Pubmed, Cochrane, Embase

Some studies not in favor of MBS before arthroplasty

Systematic Review and DELPHI



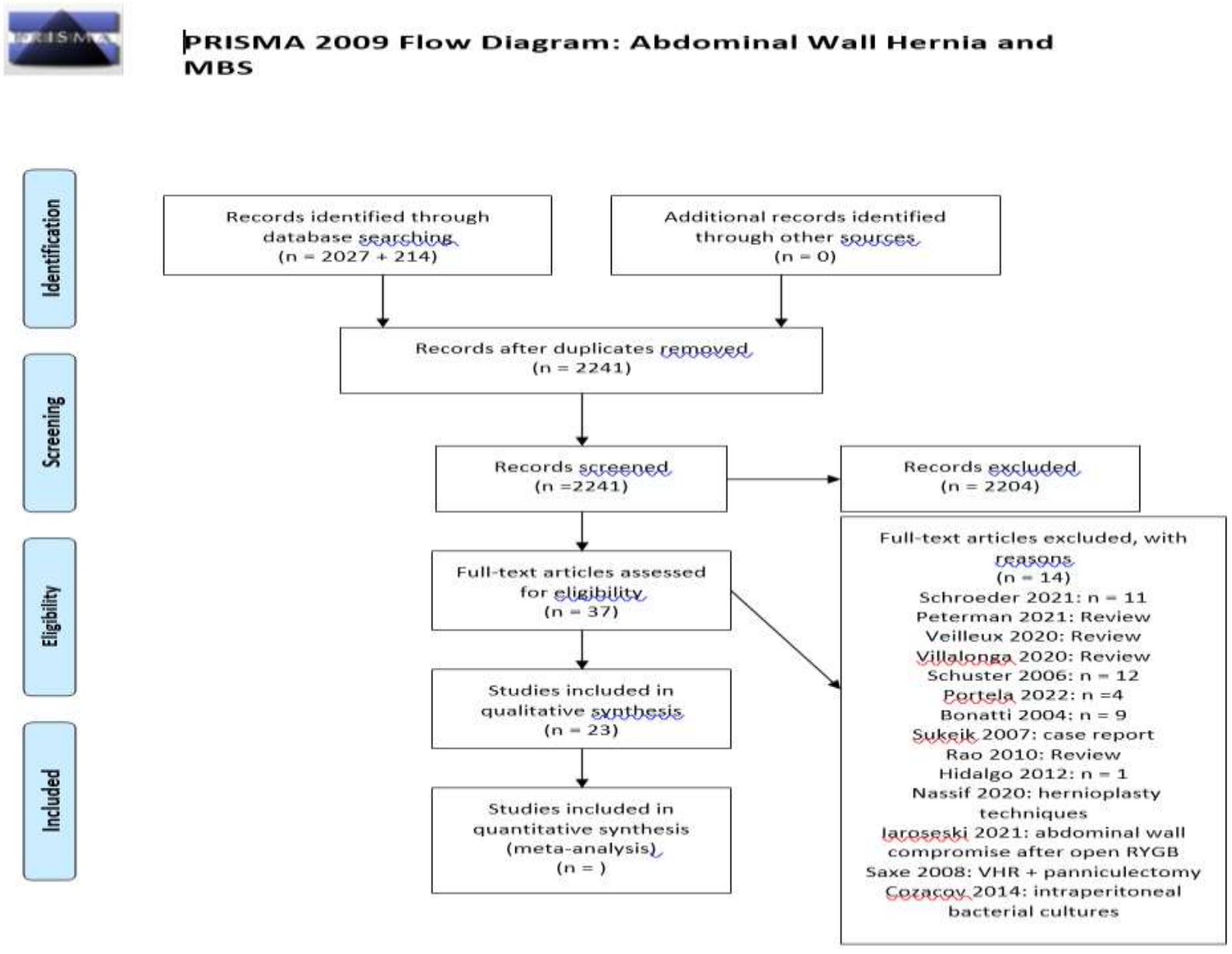
Systematic Review for the New ASMBS/IFSO Guidelines

Bridge to other treatment

7) Abdominal wall hernia repair

Pubmed, Cochrane, Embase

OK Systematic Review



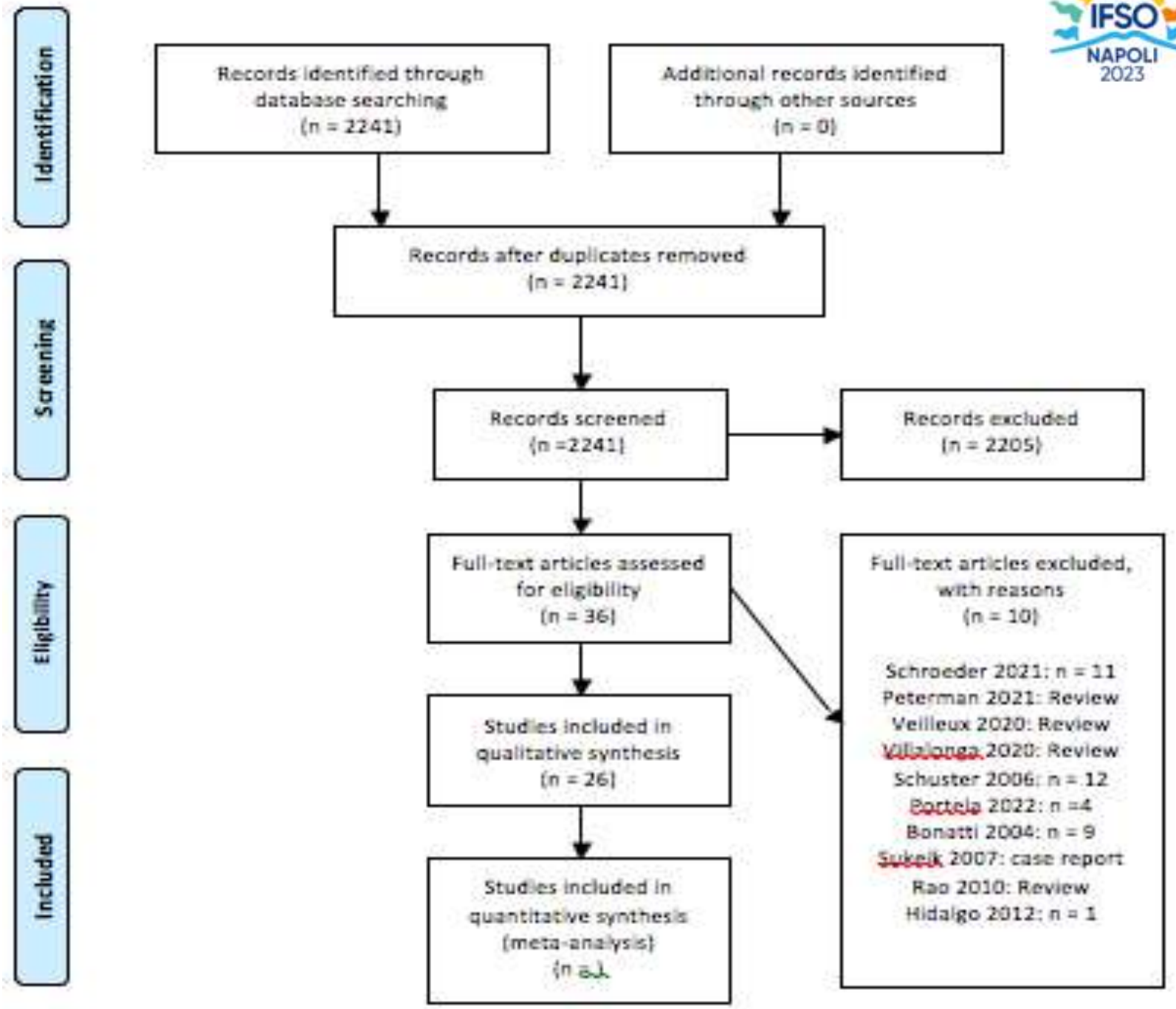
Systematic Review for the New ASMBS/IFSO Guidelines

Bridge to other treatment

8) Organ Transplantation

Pubmed, Cochrane, Embase

OK Systematic Review



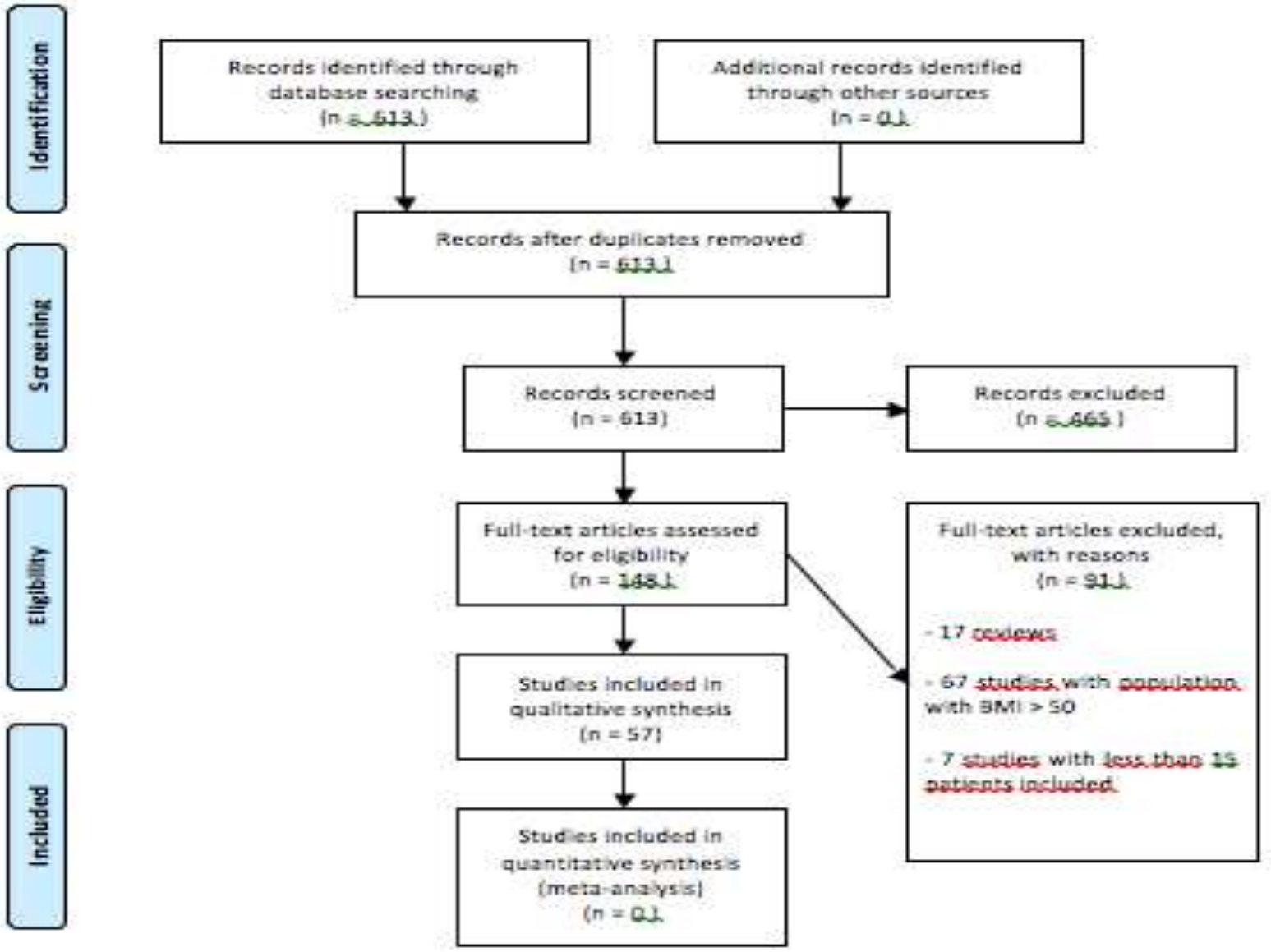
Systematic Review for the New ASMBS/IFSO Guidelines

MBS in high-risk patient

9) BMI>60

Pubmed, Cochrane, Embase

OK Systematic Review



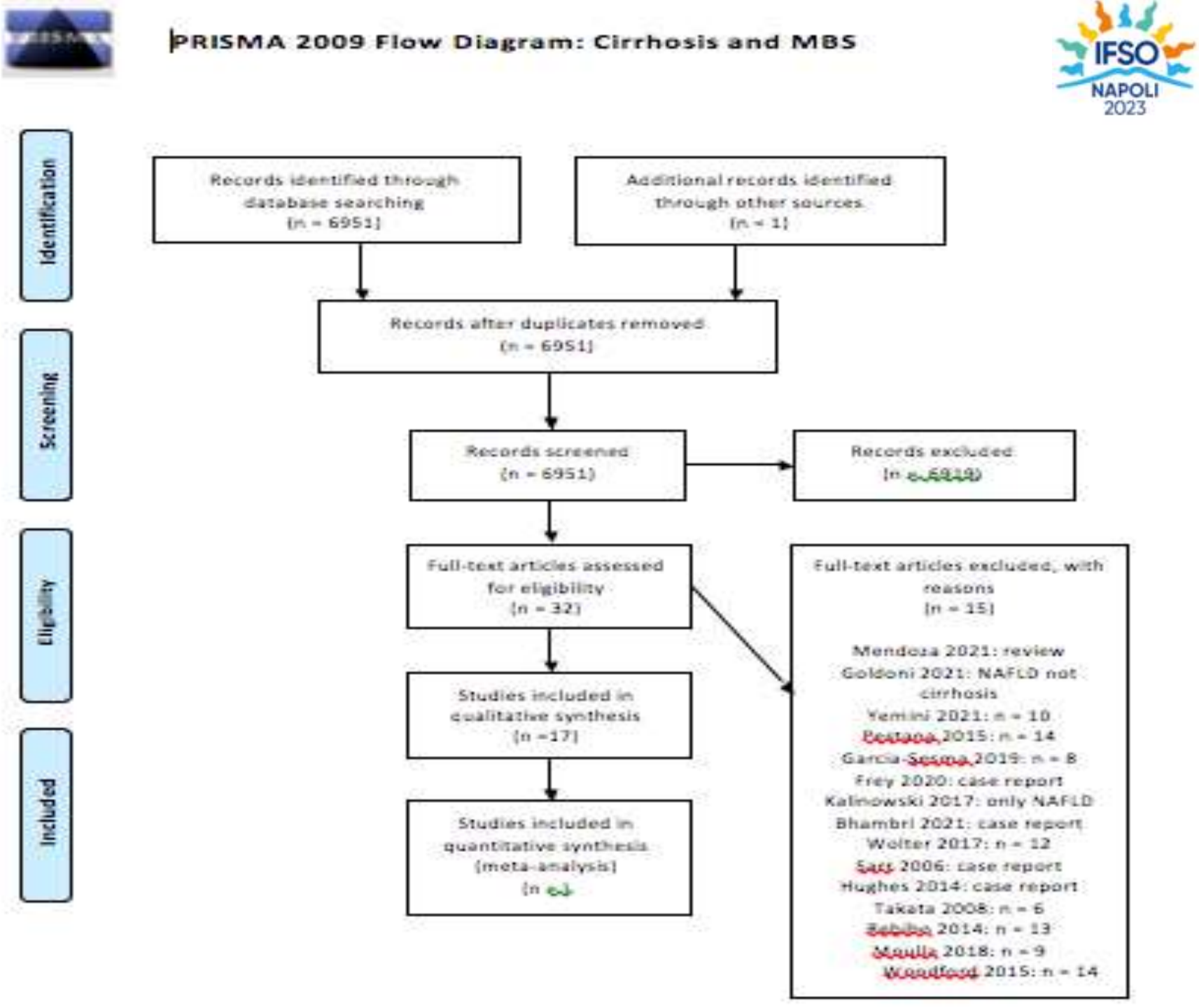
Systematic Review for the New ASMBS/IFSO Guidelines

MBS in high-risk patient

10) Cirrhosis

Pubmed, Cochrane, Embase

OK Systematic Review



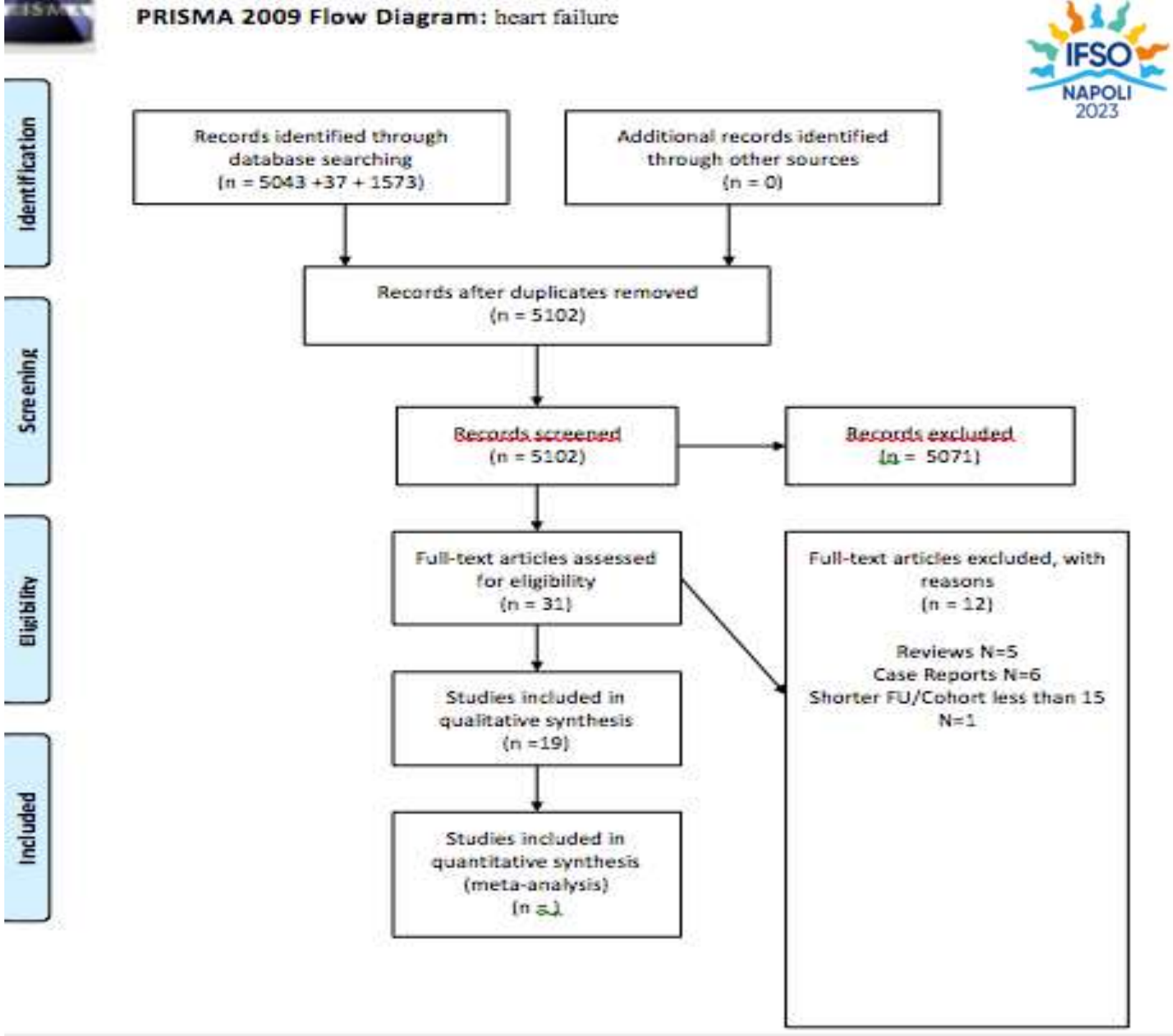
Systematic Review for the New ASMBS/IFSO Guidelines

MBS in high-risk patient

11) Heart Failure

Pubmed, Cochrane, Embase

OK Systematic Review



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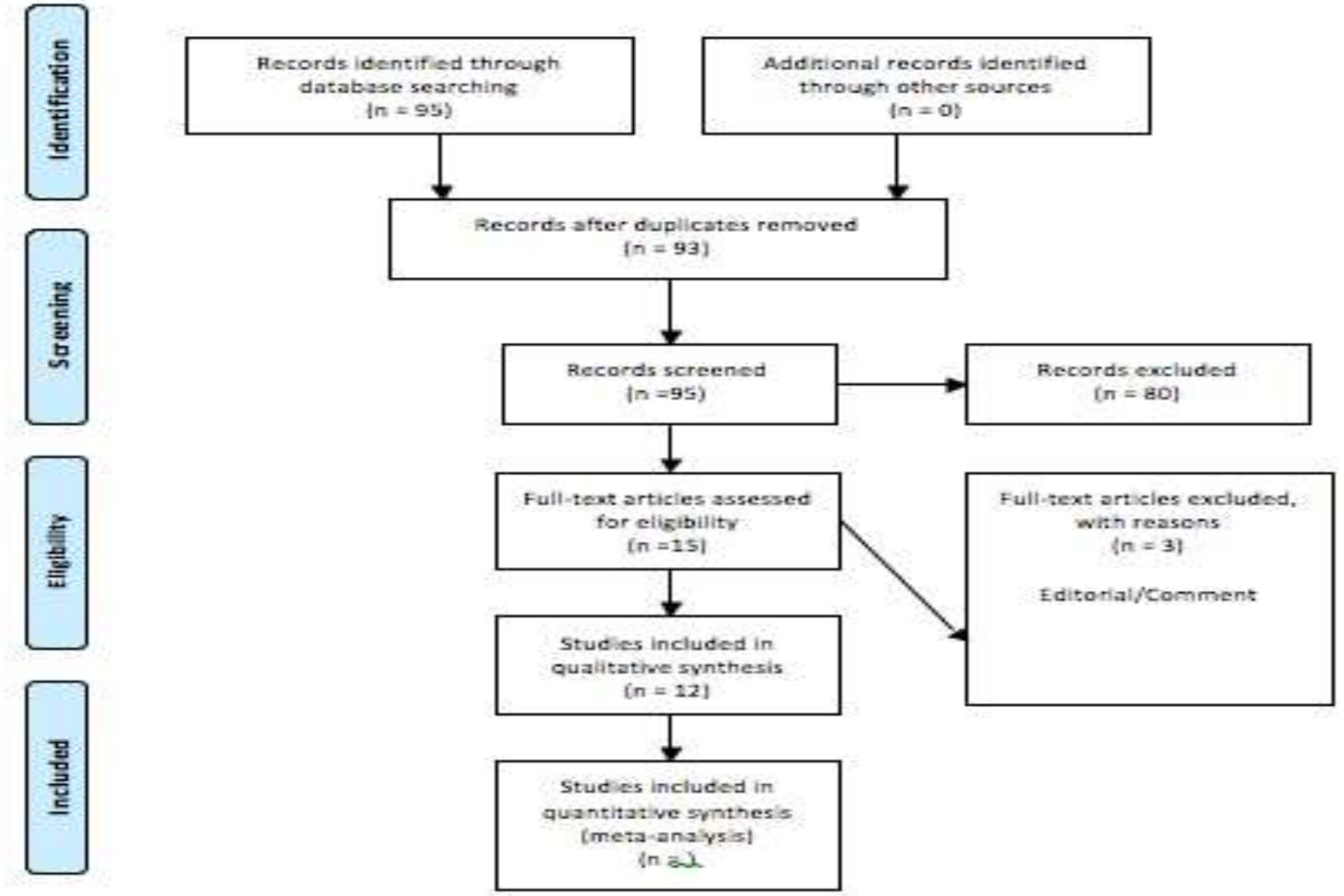
12) Multidisciplinary

Pubmed, Cochrane, Embase

OK Systematic Review

PRISMA 2009 Flow Diagram: Multidisciplinary



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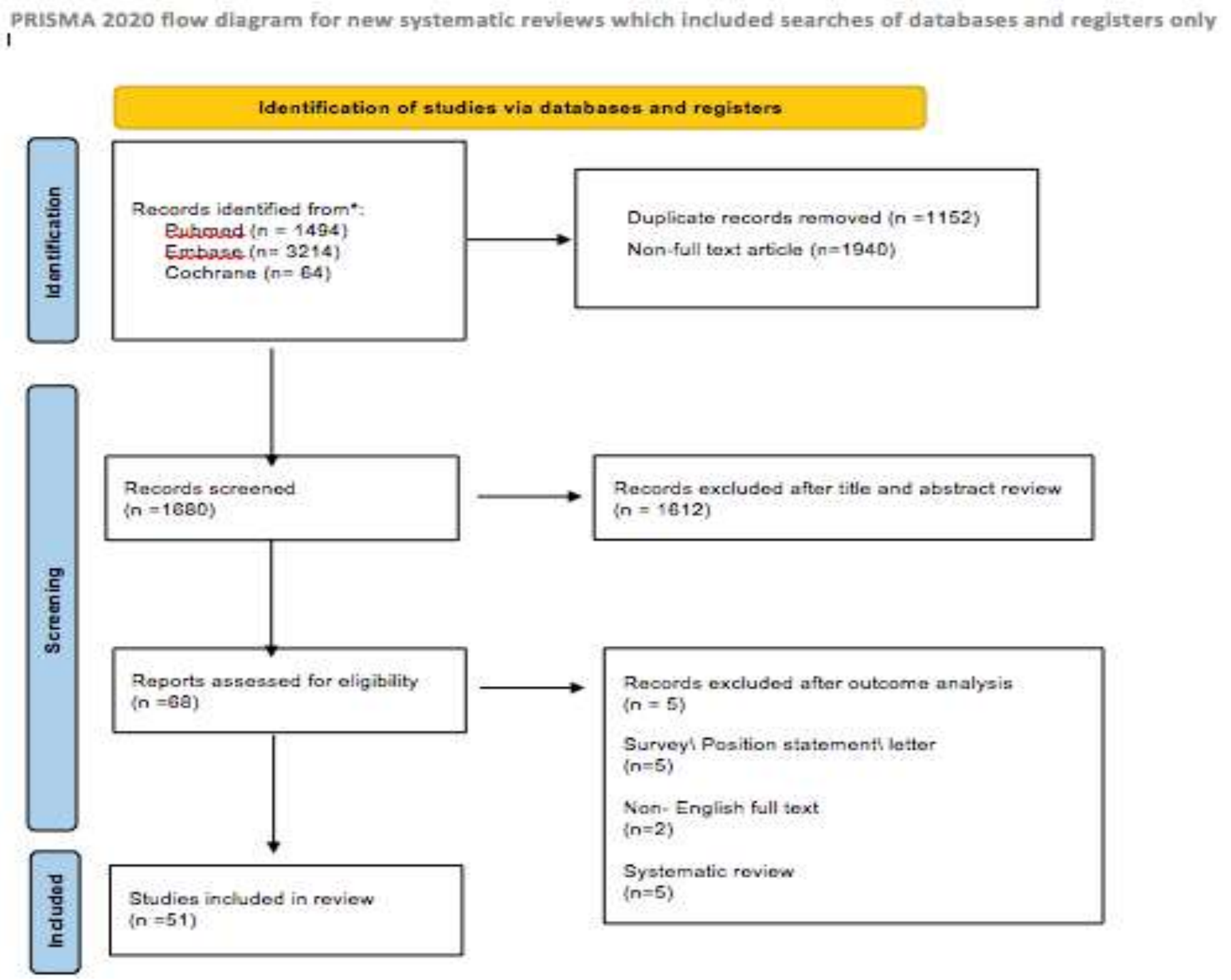
13) Revisional Surgery

Pubmed, Cochrane, Embase

Eterogeneity

OK Systematic Review



Criteria for surgery

1) BMI 30-34.9	OK SR
2) BMI ≥ 35 no comorbidities	***DELPHI (no studies)***
3) BMI thresholds in the Asian population	OK SR

Extremes of age

4) Older population	OK SR
5) Pediatrics and adolescents	OK SR

Bridge to other treatment

6) Joint arthroplasty	***DELPHI Studies non in favor***
7) Abdominal wall hernia repair	OK SR
8) Organ Transplantation	OK SR

MBS in high-risk patient

9) BMI>60	OK SR
10) Cirrhosis	OK SR
11) Hearth failure	OK SR

Patient evaluation

12) Multidisciplinary	***OK SR***	***Patients representative***

13) Revisional surgery	***OK SR***	***Eterogeneity***

Systematic Review for the New ASMBS/IFSO Guidelines

Table 1 – Summary of the recommendations

Population	Recommendation	Grade of Recommendation	Level of Evidence	Type of study
BMI 30-34.9	MBS is recommended in patients with T2D and BMI of 30-34.9 MBS should be considered in individuals with BMI of 30-34.9 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.	B	2a	Systematic review of (homogeneous) cohort studies of "exposed" and "unexposed" patients
BMI ≥ 35 no comorbidities	MBS is recommended for individuals with BMI ≥ 35, regardless of presence, absence, or severity of co-morbidities	D	5	Expert opinion based on non-systematic reviews of results or mechanistic studies
BMI thresholds in the Asian population	Clinical obesity in the Asian population is recognized in individuals with BMI≥25. Access to MBS should not be denied solely based on traditional BMI risk zone.	B	2a	Systematic review of (homogeneous) cohort studies of "exposed" and "unexposed" patients
Older Populations	There is no evidence to support an age limit on patient seeking MBS, but careful selection that includes assessment of frailty is recommended	B	2a	Systematic review of (homogeneous) cohort studies of "exposed" and "unexposed" patients
Pediatric and adolescent populations	MBS does not negatively impact on puberta development or linear growth. MBS is safe in the population younger than 18 years and produce durable weight loss and improvement in co-morbid conditions.	A	1b	Individual randomized controlled trials (with narrow confidence intervals)
MBS prior to Joint Arthroplasty	MBS can be considered as a bridge to joint arthroplasty in patients with Body Mass Index of ≥ 30 kg/m^2.	B	2b+	Individual cohort study / low-quality randomized control studies confirmed by expert opinion (Delphi)

Systematic Review for the New ASMBS/IFSO Guidelines

People with obesity and abdominal wall hernia	Patients with obesity and abdominal wall hernia may benefit from significant weight loss before hernia repair. In patients with severe obesity and an abdominal wall hernia, MBS-induced weight loss should be recommended before ventral hernia repair in order to reduce rate of postoperative complications	B	2b	Individual cohort study / low-quality randomized control studies
Solid Organ Transplantation (SOT)	MBS can be performed post-SOT or concomitantly in order to reduce complications rate and mortality (noting mixed and poor data). Sleeve Gastrectomy before or after SOT seems to be associated with better results and improved safety profile when compared to other MBS.	B	2b	Individual cohort study / low-quality randomized control studies
BMI ≥ 60 kg/m²	MBS is safe and effective in patients with BMI ≥ 60 Although some evidence suggests a higher rate of perioperative complications MBS appears safe in patients with initial BMI ≥ 70 although there is limited literature	B	2a	Systematic review of (hom ge eous) cohort studies of "exposed" a "unexposed" patients
Cirrhosis	MBS has been associated with histologic improvement of NASH and regression of fibrosis in early cases, leading to a reduced risk of hepatocellular carcinoma. MBS is associated with risk reduction of progression of NASH to cirrhosis. Patients with compensated cirrhosis have an acceptable perioperative morbidity and m lity. The patient with obesity and de pens ted cirrhosis is at higher risk for periope tive complications and perioperative mort ity following MBS and patients should be operated after risk assessment and only in high-volume centres. Careful patient selection and consideration of choice of surgical procedure are important to ensure best outcomes.	B	2b	ndi dual cohort study / low-quality andomized control studies

Systematic Review for the New ASMBS/IFSO Guidelines

Heart Failure	MBS can be a useful adjunct to treatment in patients with obesity and hearth failure before heart transplantation or placement of a left ventricular assist device (LVAD) and can be performed with low morbidity and mortality.	B	2b	Individual cohort study / low-quality randomized control studies
Multidisciplinary evaluation	MDT evaluation is at present the unmodifiable core of pre and post operative obesity management.	B	4+	Case series, low-quality cohort or case-control studies. Recommendation upgraded due to expert consensus (non procedural recommendation ranked as a priority by consumers).
Revisional/ conversion surgery	Indication for revisional (or conversion) surgery after MBS vary among individual patients, but may include weight regain, insufficient weight loss, insufficient improvement of co-morbidities, and management of complications (e.g., gastroesophageal reflux). Due to its complexity revisional (or conversion) MBS may be associated with higher rates of perioperative complications. However, revisional (or conversion) MBS induces satisfactory metabolic outcomes with acceptable rates of complications and mortality.	B	2b	Individual cohort study / low-quality randomized control studies

Systematic Review for the New ASMBS/IFSO Guidelines

Thanks!

Maurizio De Luca
nnwdel@tin.it

Systematic Review for the New ASMBS/IFSO Guidelines

Definition and Elements

A systematic review is a comprehensive literature search that tries to answer a focused research question using existing research as evidence.

Elements of a Systemic Review:

1. Research team: including two independent screeners, a tie-breaker, librarian, and statistician
2. Focused research question, including a measurable outcome
3. Written and registered protocol: PROSPERO
4. Inclusion/exclusion criteria
5. Comprehensive literature searches of multiple databases: often *performed by a librarian*
6. Screening and study selection: two independent screeners, conflicts resolved by third reviewer
7. Quality assessment: transparent assessment using validated tools
8. Reporting guidelines: following PRISMA checklist
9. Time: systematic reviews can take at least 12 months to complete

Grant, M.J., & Booth, A. (2009). A typology of reviews: An analysis of 14 review types and associated methodologies. Health Information & Libraries Journal, 26, 91–108.

Higgins JPT, Green S (editors).Box 2.3.b: Timeline for a Cochrane review. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. Available from http://handbook-5-1.cochrane.org. Accessed February 16, 2018.

Systematic Rev

Types of Reviews

Although systematic reviews
time constraints, and types c

Type of Review	Description	Complete	Search Strategy
Narrative/ Literature Review	Collates relevant studies and draw conclusions from them.	2+ months	Not comprehensive which could introduce bias.
Scoping Review	Preliminary assessment of potential size and scope of available research literature. Aims to identify nature and extent of research evidence (usually including ongoing research.	2+ months	Completeness of searching determined by time/scope constraints. Librarian collaboration recommended.
Rapid Review	Assessment of what is already known about a policy or practice issue, by using systematic review methods to search and critically appraise existing research.	2-6+ months	Completeness of searching determined by time constraints. Librarian collaboration recommended.
Integrative Review	Reviews, critiques, and synthesizes representative literature on a topic in an integrated way such that new frameworks and perspectives on the topic are generated.	2-10+ months	Aims for exhaustive, comprehensive search. Librarian collaboration recommended.
Umbrella Review	Reviews other systematic reviews and meta-analyses on a topic. Focuses on broad condition or problem for which there are competing interventions and highlights reviews that address these interventions and their results.	2+ months	Identification of component reviews but no search for primary studies. Librarian collaboration recommended.
Systematic Review	Attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question; using explicit methods aimed at minimizing bias, in order to produce more reliable findings that can be used to inform decision making.	10-12+ months	Aims for exhaustive, comprehensive search. Librarian will develop search strategy and write methodology section of manuscript.
Meta-Analysis	Technique that statistically combines the results of quantitative studies to provide a more precise effect of the results. Contains a forest plot.	10-12+ months	Statistical technique for combining the findings from disparate quantitative studies. Librarian will develop search strategy and write methodology section of manuscript.