EUnetHTA Joint Action 3 2016-2020

Surgical procedures for treatment of obesity

Project ID: ***OTCA26***

Project description and planning

The Norwegian Institute of Public Health (NIPH), Norway

The Health Information and Quality Authority (HIQA), Ireland

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Version Log

Version number	Date	Modification	Reason for the modification
V1	21/01/2020	Draft sent to co-authors.	Integration of comments and suggestions from co-authors.
V2	25/03/2020	Feedback on the draft protocol from all dedicated reviewer groups and experts received.	Integration of comments and suggestions from dedicated reviewers and experts.
V3	14/04/2020	Second round of feedback from the co-authors.	Integration of comments, and final version sent to co-authors for approval.
V4	30/06/2020	Third round of feedback from co-authors	Send final version to experts and dedicated reviewers.
V5	11/08/2020	Received final comments on the protocol.	Revised and sent the protocol for publication.

CONTENTS

List of tables

1 Project organisation

1.1 Participants

Table 1-1: Project participants

	Agency	Role in the project	Country	Distribution of work
Assessment team				
1.	Norwegian Institute of Public Health (NIPH)	Author	Norway	Overall responsibility for production and quality of assessment: develop the first draft of the project plan; perform the literature search, carry out the assessment: select and answer assessment elements (for the domains EFF and SAF); fill in the checklist on potential 'ethical, organisational, patient, social, and legal aspects' of the HTA core model for rapid REA; quality check all steps of the production process for the TEC and CUR domain, send 'draft versions' to reviewers for comments, compile feedback from reviewers and incorporate relevant changes to the draft version and the final assessment including an executive summary.
2.	Health Information and Quality Authority (HIQA)	Co-Author, and dedicated reviewer	Ireland	Review the project plan draft, select and answer assessment elements for the domain TEC and CUR. Support the production of the assessment report and quality check all steps of their production (data, information, sources); contribute in answering questions related to potential ethical, organisational, patient, social and legal aspects if needed. Approve/endorse conclusions drawn as well as all draft versions and the final assessment including the executive summary.
3.	Agency for Health Quality and Assessment of Catalonia (AQuAS)	Dedicated Reviewer	Spain	Review of draft project plan, and first draft report with included studies and results.
4.	High Authority of Health (HAS)	Dedicated Reviewer	France	Review of draft project plan, and first draft report with included studies and results.
5.	State Health Care Accreditation Agency (VASPVT)	Dedicated Reviewer	Lithuania	Review of draft project plan, and first draft report with included studies and results.
Contributors				

6.	Dr. Tom Mala, Oslo University Hospital (OUS)	Clinical expert (obesity surgeon)	Norway	Takes part in the scoping of the project and the review of the assessment prior to publication. Answers to clinical questions throughout the project.
7.	Dr. Rune Sandbu, Vestfold Hospital Trust (SIV)	Clinical expert (obesity surgeon)	Norway	Takes part in the scoping of the project and the review of the assessment prior to publication. Answers to clinical questions throughout the project.
8.	Dr. Judith Aron-Wisnewsky, Assistance publique (Paris hospitals) (APHP), Pitié Salpêtrière University Hospital	Clinical expert (endocrinologist/nutritionist)	France	Takes part in the scoping of the project and the review of the assessment prior to publication. Answers to clinical questions throughout the project.
9.	Dr. Laurant Genser, Assistance publique (Paris hospitals) (APHP) , Faculty of Medicine, Sorbonne University	Clinical expert (obesity surgeon)	France	Takes part in the scoping of the project and the review of the assessment prior to publication Answers to clinical questions throughout the project.
10.	TBD	Medical Editor		Text editing.
11.	The Norwegian Institute of Public Health (NIPH)	Project Manager	Norway	Project management

CUR=current use; EFF=effectiveness: HTA= Health Technology Assessment; PICO= population, intervention, comparison, and outcomes framework; REA= rapid effectiveness assessment: SAF= safety; TBD= to be decided; TEC=technical aspects

1.2 Project stakeholders

Table 1-2: Project stakeholders

Organisation	**Role in the project [e.g., manufacturer, patient/ consumer/ citizen (representative)]**
Allergan Inc: adjustable LAP BAND®; Apollo Endosurgery: adjustable gastric band LAP-BAND® Bariatric solutions: Mini Mizer Extra gastric Band; MiiMizer gastric ring; Cousin Biotec: adjustable gastric band ADHESIX® BIORING®; Ethicon: REALIZE® adjustable gastric band; Helioscopic: the Heliogast® gastric band MID- Medical Innovation Development: the MIDBAND® We will reach out to manufacturers and confirm that their product is CE-marked.	Manufacturers of adjustable gastric bands (and gastric rings)

1.3 Milestones and Deliverables

Table 1-3: Milestones and Deliverables

Milestones/Deliverables	**Start date**	**End date**
Project duration	**15/10/2019**	**30/09/2020**
Scoping phase	15/10/2019	28/02/2020
Identification of manufacturer(s) and external experts; *optional: identification of patients*	15/10/2019	24/01/2020

Scoping and development of draft Project Plan incl. preliminary PICO	15/10/2019	28/02/2020
Consultation of draft project plan with co-authors	21/01/2020	10/02/2020
Share the preliminary PICO with external experts *(and patients)* for comments	24/01/2020	24/02/2020
Internal Scoping e-meeting with the assessment team	*07/01/2020*	*07/01/2020*
Consultation of draft Project Plan with dedicated reviewers	17/02/2020	24/02/2020
Consultation of draft Project Plan with external experts	17/02/2020	25/03/2020
Amendment of draft Project Plan & final Project Plan available	26/03/2020	11/08/2020
Assessment phase	17/04/2020	02/04/2021
Writing first draft rapid assessment (including time for QA check by co-authors).	03/08/2020	03/12/2020
Review by dedicated reviewer(s)	23/11/2020	17/12/2020
Writing second draft rapid assessment (including time for QA check by co-authors)	18/12/2020	21/01/2021
Review by ≥ 2 external clinical experts	22/01/2021	4/02/2021
Writing third draft rapid assessment	05/02/2021	24/02/2021
Medical editing	25/02/2021	05/03/2021
Writing of fourth version of rapid assessment	06/03/2021	25/03/2021
Formatting	25/03/2021	02/04/2021
Final version of rapid assessment		- 02/04/2021

2 Project Outline

2.1 Project Objectives

The rationale of this assessment is to collaboratively produce structured (rapid) core HTA information on medical technologies. In addition, the aim is to apply those collaboratively produced assessments in the national or regional context.

Table 2-1: Project objectives

	List of project objectives	Indicator (and target)
1.	To jointly produce health technology assessments that are fit for purpose, of high quality, of timely availability, and cover the whole range of health technologies.	Production of 1 (rapid) relative effectiveness assessment.
2.	To apply this collaboratively produced assessment into local (e.g. regional or national) context.	Production of ≥2 local (e.g. national or regional) reports based on the jointly produced assessment.

This rapid assessment addresses the following research question: What is the relative effectiveness and safety of current bariatric surgery procedures for the treatment of adults with obesity.

This topic was chosen based on a request from The National System for Introduction of New Health Technologies within the Specialist Health Service in Norway, who commissioned The Norwegian Institute of Public Health, to do a HTA on surgical procedures for the treatment of obesity. The relevance of the topic lies in evidence suggesting that bariatric surgery decreases the risk of premature death, and other physical morbidities, but the effectiveness and safety of different surgical procedures may differ.

2.2 Project Method and Scope

2.2.1 Approach and Method

Table 2-2: Project approach and method

Project approach and method
We will within this rapid Relative Effectiveness Assessment, describe the technical characteristics of technology (TEC) under assessment (i.e. type of device, procedure), assess health problem and current use of the technology (CUR) (i.e. target condition, target group), clinical effectiveness (EFF) (i.e. relative health benefits), and safety (SAF) (i.e. unwanted or harmful effects). As results from previous studies suggest that weight regain often may occur two years after surgery (1, 2), we will aim to assess relative effectiveness and safety at both short and long-term follow up. In addition (and as described later on), we will complete the EUnetHTA checklist for potential ethical, organisational, and social and legal aspects. We will use the Core Model for Rapid Relative Effectiveness Assessment Version 4.2 as the reference framework for the selection of the assessment elements per domain (3). We will use the following reports identified in the initial scoping search as a starting point for this assessment: • Colquitt et al. (2014). Surgery for weight loss in adults (4)

- O'Brien et al. (2019). Long –term outcomes after bariatric surgery: a systematic review and meta-analysis of weight-loss at 10 or more years for all bariatric procedures and a single centre review of 20-year outcomes after adjustable gastric banding (5)
- KCE (2019):Bariatric surgery: an HTA report on the efficacy, safety and cost.-effectiveness (6)
- HAS (2019) Surgical treatment of severe and massive obesity by one anastomosis gastric bypass (7)
- ICER (2015) Controversies in obesity treatment (8)

TEC and CUR domains

We will consider information from identified relevant reports (see above), information from current clinical guidelines, and from a general literature search. In addition, we will consider input from clinical experts, patient partners/organisations and information from web-searches.
We will ask manufacturers to provide details of their products to ensure that our description of the product and how it should be used is factually accurate, and also ask for a list on any trials involving their products so that we can cross-check their list against our search to ensure it was comprehensive, and identify any on-going trials of which we should be aware.

EFF and SAF domains

We will consider whether it is appropriate to use the findings from any existing evidence synthesis (i.e. from systematic reviews, or from parts of guidelines or HTA reports) as starting points.
Using existing data syntheses prevents duplication of efforts, i.e. prevents conduct of unnecessary assessments, with all what that entails in terms of waste of time and resources.
Use of findings from existing systematic reviews may include the use of search results, use of extracted data, study level risk of bias assessment and/or synthesis (9, 10). In order to use/include data from existing systematic reviews, the scope of existing and the new assessment must match closely (see Section 2.2.2.). Two reviewers will independently appraise the PICO and the search strategy to see if there is a match, and they will if so, assess the methodological rigor of the existing evidence synthesis (using the AMSTAR 2 instrument (11)). We will based on this assessment decide whether, and how, to use the findings from existing evidence syntheses. We will check identified systematic reviews to ensure that all studies relevant for the review question have been included.

We will, if suitable evidence is available, use this evidence together with evidence from primary studies (as described in section 2.2.2) published after the last search of the latest evidence synthesis. If no suitable evidence is available, we will conduct a completely new systematic review including original studies only. Table 2-3 provides further details on the planned literature search strategy. Original studies will be assessed according to the 'risk of bias' section below.

Selection of (systematic reviews) and individual studies

All references identified from the literature search will after de-duplication in Endnote X8.2 be exported to Covidence (www.covidence.org), after which additional duplicates will be identified and removed by the lead author.Two reviewers will independently use Covidence to screen titles and abstracts, assessing their relevance against inclusion and exclusion criteria. Possible relevant references will be retrieved in full text and assessed independently by two reviewers. In the case of multiple publications from the same RCT, we will use only the most recently published data for that time point. Any disagreements will be resolved by discussion, or if needed by the use of an arbitrator.A flow diagram using PRISMA guidelines will be generated to report the selection process and all results (12). Covidence will be used for reference management. Any systematic review that is identified as relevant through this process will be checked to ensure that no included study relevant to this systematic review has been missed.The co-author team will quality control this process.

Outcome prioritisation

Primary and secondary outcomes will initially be selected on the basis of a prioritisation exercise by the assessment team at the scoping. The project manager will present information on core set outcomes for weight-loss studies derived from the BARIACT study (13) http://www.comet-initiative.org/studies/details/131.

At a later stage, and according to the GRADE (Grading of recommendations, assessment, Development and Evaluation) (14), we will grade the importance of each outcome (as described in Section 2.2.2. Project scope).The project manager will send a form via a web-platform for this process. The outcomes will be assessed as follows: critical (score 9 to 7); important (score 6 to 4), or low importance (score 3 to 1). There will also be a 'do not know' option, in case a team member do not have sufficient information to make a judgement. We will collect the ratings from the clinical experts and patient partners first, then from members of the assessment team (one rating per organisation), while using ratings from the clinical experts as input. The assessment team are expected to take a policy-maker perspective, while clinical experts and patients are providing a clinical and patient perspective, respectively.

Data extraction

One reviewer will use a piloted data extraction form to extract data from the included studies. A second author will check the accuracy of extracted data. Any disagreements will be discussed and solved through discussion, or if needed, by the use of an arbitrator. Table 2.4 gives an overview of the items that will be extracted.
In the case of missing, or unclear information in included studies, we will contact the authors (only once), for clarifications. The response/no response will be noted in the results section, and in additional tables. Also for trial protocols (i.e. terminated, unpublished or ongoing) found, we will contact the authors for further information. Protocols for published studies will be included as companion studies and will be used for the risk of bias assessment in individual studies.

Risk of bias assessment

Two review authors will independently assess the risk of bias of each included RCT study using the Cochrane risk of bias tool for six standard domains (15): adequate sequence generation, concealment of allocation, blinded assessment of objective and subjective outcomes, adequately addressed incomplete outcome data, free of selective reporting, and other potential risks of bias. We will use three additional criteria specified by Cochrane Effective Practice and Organisation of care group (EPOC) (16): similar baseline characteristics, reliable primary outcome measures, and adequate protection against contamination. We will assign an overall risk of bias (high, low, unclear) to each of the included outcomes using the approach suggested in Chapter 8.7 of the *Cochrane Handbook for Systematic Reviews of Interventions* (15). If non-radomised studies are included in the safety review we will use the ROBINS-1 risk of bias tool (17). We will present the results in 'Risk of bias' summary tables and graphs. We will not exclude studies due to a high risk of bias.

Measures of treatment effects

Continous outcomes

We will use the group post-test means and standard deviations to calculate effect sizes (i.e. mean differences).We will if possible calculate the mean difference (MD). If it is not feasible to use the MD (e.g. when different scales have been used to measure the same outcome), we will calculate the standardised mean difference (SMD). We willl for continuous outcomes calculate the absolute benefit of the intervention by subtracting the effect in the control group from the effect in the intervention group, using the original units. The relative difference in the change from baseline will be calculated as the MD divided by the pooled baseline.

Dichotomous outcomes
We will analyse dichotomous data as risk ratios and 95% confidence intervals (CIs). We will calculate the absolute risk difference (ARD), and express the result as a percentage. The relative percentage change will be calculated as the risk ratio (RR), and expressed as a perentage.

We will use intention to treat (ITT) data if available. If studies do not report estimates of effect and measure of dispersion, we will when possible impute values using the methods described in the Cochrane Handbook (15). If different scales have been used to report the same outcome, we will when possible, convert the reported effects to a common scale to permit meta-analysis.

Data synthesis
We will where it is appropriate pool data in a meta-analysis using RevMan software (18). We will use techniques described in the Cochrane handbook (15). Heterogeneity will be investigated using the I^2 statistic. We will base the choice between fixed and random effects meta-analysis on an assessment of the statistical and clinical heterogeneity across studies. Where substantial statistical heterogeneity is observed and sufficient studies are available,we will consider a meta-regression to explore study characteristics that may be potential sources of heterogeneity. If meta-analysis is not feasible we will provide a descriptive summary of the results. When possible we will generate forest plots to display the results and report 95% prediction intervals as well as 95% confidence intervals.

If randomised evidence is included, we will conduct separate meta-analyses for randomised trials and for non-randomised studies, as suggested by Cuello-Garcia (19). Statisitcal methods to manage missing data (see below) or heterogeneity will follow the Cochrane handbook (15).

We may also consider conducting a network meta-analysis if the retrieved data, and our time and resources permit it. If we chose to do a network meta-analysis we will publish an addendum to the project plan.

Sub-group analysis

We will consider the following subgroups:

- People who are obese (20)
  Class I – BMI 30≤35
  Class II – BMI 35≤40
  Class III – BMI ≥40 or higher
- Sex
- Length of follow up (21): Medium term: >1≤5 years (>12≤60 months); Long term: >5≤10 years (>60 ≤120 months), and Very long term: ≥10 years (>120 months)
- Type of surgical procedure (see list of procedures Table 2.5)

Assessment of heterogeneity
Statistical methods to manage missing data (see below) or heterogeneity will follow the Cochrane handbook (15).

Dealing with missing data
If numerical data are missing in an included study, we will contact the authors and request additional data needed for our analysis (i.e. for risk of bias assessment or treatment effects).
If numerical data in an included study are available only in graphical form, we will extrapolate means and standard deviations by digitalising data points on the graphs using Engauge version 5.1 (22). When post-test standard deviations are not available, we will use pre-test score's standard deviations as estimates. When the variance is expressed using other statistics than standard

deviations (e.g. confidence intervals, p-values , or standard errors) we will calculate standard deviations using methods suggested in Chapter 7 of the Cochrane handbook of Reviews of Interventions (15). If studies report median and interquartile range, and the data are scewed, we will use methods suggested by Wan et al to estimate sample means and standard deviations (23). If above mentioned methods cannot be used to derive missing standard deviations, we will impute them using data from other similar studies.

Certainty of evidence for the outcomes

Two review authors will independently assess the certainty of the evidence for each outcome (high, moderate, low and very low), in each comparison, using the GRADE tool (24), and the five GRADE considerations (study limitations/risk of bias, consistency of effect, imprecision, indirectness and publication bias)(24). We will use methods and recommendations described in Section 8.5 and Chapter 12 of the Cochrane Handbook (15) and the EPOC worksheets (25). We will resolve disagreements on certainty of ratings by discussion, or if needed by the use of an arbitrator.

Reporting

We will summarise the results for the main outcomes (i.e. the results data deemed to be of importance for decision- and policy makers) in Summary of findings (SOF) tables. We will use the GRADE worksheets and/or GRADEpro software to produce these tables (https://gradepro.org/). We will present absolute effects. We will provide justification for decisions to down- or up-grade the ratings using footnotes in the tables and provide comments to aid readers' understanding of the results in plain language. We will describe the results for outcomes rated as less important for decision-making in the text of the report. We will, in addition to the included studies, also report ongoing, terminated, and unpublished studies in the report.

Use of software

We will use EndNote (26) for reference management, and Covidence (27) for the screening of titles and abstracts, and selection of studies. We will use Review manager, R or Stata to analyse data, and to graphically present the risk of bias, and GRADEpro to produce summary of findings tables(28). We will also use free software to for example collect votes on the rating of the importance of outcomes (e.g. Google doc), or to extract graphically presented data (e.g. Engauge).

Use of checklist for potential ethical, organisational, patient, social and legal aspects

We will use information from the literature, web-searches, patients, and clinical experts (see also section 3.2 on stakeholder involvement) to answer the checklist (see Appendix A). We are aware of that the checklist usually is completed at the protocol stage, however we feel it is more relevant to complete it during the assessment phase based on the findings of the assessment.

Contact with manufacturers

We will ask manufacturers to submit non-confidential evidence, on the technical characteristics and current use of the technology. The evidence provided will be used in addition to that identified by the literature search. The short version of the EUnetHTA submission file will be used as a starting point to collect these data. We identified the manufacturers listed below on a website https://www.medicalexpo.com/medical-manufacturer/adjustable-gastric-band-6968.html and in reviews found in the scoping search.We plan to contact any other manufacturers that we identify along the way, i.e. when going through the search results.

Patient involvement

We will invite patient engagement and input (e.g. experiences of obesity surgery) through an open call for participation in this project. We will also contact both Norwegian and European patient organisation and ask them to provide input on the PICOs during the scoping phase. We may also

contact representatives for the same organisations at a later stage in the review process to invite them to comment on the readability of the draft review.

Levels of evidence
Study and outcomes validity and level of evidence will be assessed according to the EUnetHTA guidelines, available at: http://www.eunethta.eu/eunethta-guidelines,

Table 2-3: Planned literature search strategy

Literature search strategy
Information specialist Tonje Lehne Refsdal (TLR) will develop the search strategy with the assistance of the project manager. As a starting point TLR will use search terms from relevant papers identified in the scoping search to develop the new search strategy. After peer review of the search strategy by another information specialist Gyri Hval (GH), and a EUnetHTA partner (Emmanuelle Blondet, HAS), the search strategy will be finalised and the searches run. We will not limit the search by language, or publication status. The search strategy will be based on the agreed PICOs. It will contain both index-terms and text-words from as many relevant publications as possible. We will search the following electronic data-bases: • Cochrane Library -Cochrane Database of Systematic Reviews -Cochrane Central Register of Controlled Trials • Epistemonikos • Embase (Ovid) • MEDLINE (Ovid) • ISI Web of Science • Guidelines International Network (G-I-N) • NICE guidance • NIHR-HTA • HTAi vortal • PROSPERO • POP database • Clinical Trials • WHO ICTRP Search Portal • EU Clinical Trials Register We will also search for ongoing and planned systematic reviews in PROSPERO and the POP databases, and for terminated, completed and published, completed and unpublished, and ongoing primary studies in ClinicalTrials.gov, WHO ICTRP, and EU Clinical Trials Register. We will conduct the search in three steps: the first step involve searching for relevant systematic reviews, HTA reports, and clinical guideline or technique procedure standardization consensus/guidelines published after 2013. If we find a more recently published high quality evidence synthesis with similar PICO, we will update this review, and use the search date of this synthesis as a starting point to up-date the search. If no evidence synthesis is found that matches our PICO, the second step will be to search for primary studies in the form of randomised controlled trials. The third step, which is optional and depending on the available time and resources, include searching for non-randomised evidence. We will import the reference lists of identified systematic reviews and original studies from EndNote into Covidence. The references will be screened by two independent researchers against the eligibility criteria (as described in section 2.2.1.). Inclusion/exclusion criteria for studies and other information are described in section 2.2.2. Planned queries to study authors are described in table 2-2, in the section on data extraction.

Search terms to be used in MedlLine
1 Bariatric Surgery/ (9448)
2 Gastric Bypass/ (8944)
3 Gastroplasty/ (4231)
4 Biliopancreatic Diversion/ (978)
5 Anastomosis, Roux-en-Y/ (3444)
6 Jejunoileal Bypass/ (596)
7 or/1-6 [Emneord] (24119)
8 ((bariatric* or metabolic or weight loss or endobariatric* or obes* or superobes* or scopinaro or restrictive) adj3 (surg* or operation* or procedure*)).ti,ab,kf. (24492)
9 gastric bypass.ti,ab,kf. (11135)
10 Roux-en-Y.ti,ab,kf. (10796)
11 RYGB.ti,ab,kf. (2824)
12 LRYGB.ti,ab,kf. (815)
13 distal gastric bypass.ti,ab,kf. (45)
14 distal roux-en-y.ti,ab,kf. (31)
15 mini gastric bypass.ti,ab,kf. (251)
16 LMGB.ti,ab,kf. (35)
17 one anastomosis gastric bypass.ti,ab,kf. (220)
18 single anastomosis gastric bypass.ti,ab,kf. (49)
19 OAGB.ti,ab,kf. (148)
20 OAGB-MGB.ti,ab,kf. (25)
21 SAGB.ti,ab,kf. (121)
22 omega loop gastric bypass.ti,ab,kf. (50)
23 SADI-S.ti,ab,kf. (37)
24 ((sleeve or subtotal) adj3 gastrectom*).ti,ab,kf. (7300)
25 LVSG.ti,ab,kf. (9)
26 LSG.ti,ab,kf. (1966)
27 LISG.ti,ab,kf. (5)
28 ((gastric or stomach) adj (banding or bypass or mini-bypass or minibypass)).ti,ab,kf. (13005)
29 LAGB.ti,ab,kf. (1129)
30 gastroplast*.ti,ab,kf. (2017)
31 gastro-plast*.ti,ab,kf. (2)
32 lap-band*.ti,ab,kf. (279)
33 gastroduodenostom*.ti,ab,kf. (368)
34 gastroenterostom*.ti,ab,kf. (1305)
35 hemigastrectom*.ti,ab,kf. (118)
36 duodenal switch*.ti,ab,kf. (746)
37 BDDS.ti,ab,kf. (51)
38 BPD-DS.ti,ab,kf. (166)
39 ((biliary-pancreatic or biliopancreatic or pancreatobiliary or pancreatic-biliary) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (1175)
40 ((duodenojejunal or duodenal-jejunal) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (294)
41 ((gastroileal or gastro-ileal or gastric-ileal) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (5)
42 ((gastrointestinal or gastro-intestinal) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (126)
43 ((gastrojejunal or gastric-jejunal) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (53)
44 ((ileojejunal or ileal-jejunal or ileal*) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (1174)
45 ((jejunoileal or jejunal-ileal) adj2 (bypass or derivation* or diversion* or shunt* or interposition*)).ti,ab,kf. (883)
46 or/8-45 [Tekstord] (41573)
47 7 or 46 [Emneord OR Tekstord] (45218)
48 Obesity, Morbid/ (18812)
49 Obesity/ (175788)
50 or/48-49 (193387)

51 obes*.ti,ab,kf. (294834)
52 superobes*.ti,ab,kf. (201)
53 or/51-52 (294881)
54 50 or 53 (337727)
55 47 and 54 [UTEN FILTER] (27355)
56 guideline*.ti,ab,kf. (335912)
57 Health Technology assessment.ti,ab,kw. (4566)
58 hta.ti,ab,kf. (3004)
59 systematic review.kw. (15517)
60 meta-analysis.pt. (109937)
61 ((systematic* or literature) adj3 (overview or review* or search*)).ti,ab. (464307)
62 (meta-anal* or metaanal* or meta-regression* or umbrella review* or overview of reviews or review of reviews or (evidence* adj2 synth*) or synthesis review*).ti,ab. (171366)
63 or/56-62 [SR-filter] (863356)
64 55 and 63 [Emne AND SR-filter] (2250)
65 (pretest-posttest study or pretesting or pre-post tests or quasi experimental design or quasi experimental study or quasi experimental study design or repeated measurement or repeated measurements or repeated measures or time series).kw. or non-randomized controlled trials as topic/ or interrupted time series analysis/ or controlled before-after studies/ or randomized controlled trial.pt. or controlled clinical trial.pt. or multicenter study.pt. or pragmatic clinical trial.pt. or (randomis* or randomiz* or randomly).ti,ab. or groups.ab. or (trial or multicenter or multi center or multicentre or multi centre).ti. or (intervention? or effect? or impact? or controlled or control group? or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or time series or time point? or repeated measur*).ti,ab. [Kontrollerte studier] (10431041)
66 55 and 65 [Emne AND Kontrollerte studier] (16010)
67 64 or 66 [MED FILTER] (16757)
68 limit 67 to yr="2013 -Current" (9701)

Overview of already identified most relevant studies that will be included

In the scoping search, we identified one Cochrane systematic review from 2014 (4) that included 15 RCTs reporting head-on-head comparisons of different surgical procedures. The search was from November 2013 (5). We also found a recent HTA report from 2019 (6) on the topic. This report included 17 RCTs that included both overweight and obese adults and adolescents. The review focus was on RYGB, and SG. A number of these studies compared surgery with medication only, i.e. comparisons that would be ineligible for our review. The search was from November 2015. Another HTA report from 2019 (7), which focused on comparing OAMGB with RYGB, included four trials and four systematic reviews. The search was from February 2019. One systematic review from 2019 included only bariatric surgery studies with follow up that was longer than 10 years. This review included 57 datasets (trials and observational studies) of which 33 were eligible for meta-analysis (16 RYGB; 2 OAGB; 11 BPD; 2 SG; 1 LAGB).The search date was December the 17th. We plan to run our search from the search date of the Cochrane review (2013), since their PICO was similar to ours, and up to present.

The EUnetHTA Guideline on Information Retrieval will be consulted to inform the literature search (3).

Table 2-4: Plan for data extraction

Planned data extraction
We will extract the following data from included studies:

- Study information: authors, year of publication, clinical trial identification number/ registry identifier, trial protocol number, declaration of interest/funding source, setting, country of origin, language,
- Methods: study design, type of analysis (e.g. ITT), other trial characteristics needed for the risk of bias assessment
- Participant/patient characteristics: inclusion/exclusion criteria, total number of participants (and participants in each group), baseline characteristics (age, gender, race/ethnicity, socioeconomic status, weight, BMI and BMI class) Disease status: year of obesity, percentage excess weight, comorbidities, first time surgery or prior surgery/revision surgery;
- Intervention and comparator characteristics: description of procedure and comparator procedure, description of technologies/materials used; description of concomitant treatments if any
- Outcomes: primary and secondary endpoints as specified in the PICO table below; type, effect measure, scales, endpoints examined, methods used to analyse outcome data, length of follow up and losses to follow up); reasons for discontinuation of treatment
- Setting: type and size of included hospital/annual hospital volume

2.2.2 Project Scope

The EUnetHTA Guidelines, available at https://www.eunethta.eu/methodology-guidelines/ will be consulted throughout the assessment process.

Table 2-5: Project Scope: PICO (please see HTA Core Model® for rapid REA)

Description	Project Scope
Population	Adults (>18 y) with obesity, including the three groups described below (20) (i) BMI ≥40 kg/m^2, or (ii) BMI ≥35 kg/m^2 and comorbidities (e.g. hypertension, diabetes), or (iii) BMI ≥30 kg/m^2 and type 2 diabetes mellitus (T2DM) who have not achieved durable improvement in glycaemic control with reasonable non-surgical methods. Diagnosis (2020) CD-9-CM 278.00; Obesity, unspecified We will not include subgroups of patients of a certain age (e.g.>65 years), or people with a certain diagnosed disease, e.g. people with chronic kidney disease only, or people with heart failure only. Nor will we include studies of mixed groups that include both patients who has received primary surgery and those undergone revisional (secondary) surgery, unless results for our group of interest are reported separately. MeSH-terms: *Morbid Obesities; Obesities, Morbid; Obesity, Severe; Obesities, Severe; Severe Obesities; Severe Obesity; Morbid Obesity* Intended use of the technology: We will only include first-time bariatric surgery, and exclude studies of revision surgery.
Intervention	Surgical procedures in current use: 1. **Sleeve gastrectomy (SG)**: is a surgical procedure in which the stomach is reduced to about 30% of its original size by removal of a large portion of the stomach along the greater curvature, which results in a sleeve or tube like structure.

	2. **Roux-en-y gastric bypass (RYGB)**: is a surgical procedure that involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, thereby bypassing a large part of the stomach and duodenum. 3. **One anastomosis gastric bypass** (OAGB)(also called single anastomosis gastric bypass (SAGB), omega-loop gastric bypass, or mini gastric bypass): is a procedure that consists of a unique gastro-jejunal anastomosis between a 30–40ml sleeve gastric pouch and a 200cm long jejunal omega loop. 4. **Biliopancreatic diversion with duodenal switch** (BPDDS): a surgical procedure that corresponds to a SG of larger calibration size (up to 52 Fr) with a duodeno-ileal anastomosis thereby bypassing the jejunum and a large part of the ileum. 5. **Distal Roux-en-y gastric bypass (D-RYGB):** is a variant of RYGB where the distance from the small bowel anastomosis to the ileocecal valve is short, giving a short common channel. 6. **Adjustable Gastric banding** (AGB): surgery that involves placing a silicone band around the upper part of the stomach to decrease stomach size and reduce food intake. It is a reversible method. We will in addition to the procedures listed above include available evidence on the effects of two new methods: • Single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S) is a procedure based on the biliopancreatic diversion in which a sleeve gastrectomy is followed by an end-to-side duodeno-ileal diversion. • Single anastomosis sleeve ileal bypass (SASI) procedure is based on Santoro's operation, in which a sleeve gastrectomy is followed by a side-to-side gastroileal anastomosis. Bariatric surgery procedures are always combined with dietary/lifestyle interventions. Gastric rings or banding can be used alone or in combination with a surgical procedure (e.g. banded gastrectomy). We have so far identified the following manufacturers, bands, and rings: • Allergan Inc: the LAP BAND®. • Apollo Endosurgery: adjustable gastric band LAP-BAND® • Bariatric solutions: Mini Mizer Extra gastric Band; MiiMizer gastric ring • Cousin Biotec: adjustable gastric band ADHESIX® BIORING® • Ethicon: the REALIZE® adjustable gastric band, • Helioscopic: the Heliogast® gastric band • MID- Medical Innovation Developpment: the MIDBAND® We still have to verify CE approval, and will only engage with manufacturers of CE approved devices. If a study involve the use of a device that is not CE-marked, we will exclude it from the CUR and TEC domains, but include evidence from any device in the EFF and SAF domains, independently of CE-status, while noting that it was not CE-marked. MeSH terms: Obesity surgery; Bariatric surgery; Bariatric Surgeries; Bariatric Surgical Procedures; Metabolic Surgery

Comparison	Head-to-head comparisons across the different surgical procedures listed above Exclusions We will exclude: • Comparisons of surgical techniques/materials rather than of surgical procedures (e.g. robotic vs. non-robotic surgery, long versus short leg) • Comparisons of open versus laparoscopic surgery (e.g. open Roux-en-y vs. laparoscopic Roux-en-y) • Comparisons involving procedures that are no longer in use: o Jejunoileal bypass o Horizontal gastroplasty o Vertical banded gastroplasty or vertical gastroplasty (not banded) o Non-adjustable banded gastroplasty o Banded gastric bypass (un-adjustable banding) o Biliopancreatic diversion without duodenal switch MeSH-terms: as per above
Outcomes	We will include the core outcomes identified as essential endpoints in all weight loss studies by the BARIACT study (13) (http://www.comet-initiative.org/studies/details/131): Primary outcomes: o Measures of weight change (e.g. % excess weight loss, total weight loss, BMI reduction, % excess BMI reduction; % body fat loss) o Health-related quality of life (HRQOL, assessed using a validated instrument) o Diabetes status: ➢ *reduced need of anti diabetic agents (oral or injected) or reduction of the dosage – potential for substantial improvement in cost-effectiveness if patients on triple therapy with metformin + SGLT inhibitor /GLP analogue /basal insulin can reduce to monotherapy following bariatric surgery* ➢ *improved glycaemic control (reduction in A1C –so to consider the A1C as being on a continuum rather than a binary scale (controlled vs not-controlled)* o Mortality (30-days and long-term) Secondary outcomes: o Cardiovascular risk reduction: ➢ *Reversal or improvement in A1C (e.g. <7.0%),* ➢ *Resolution or improvement of dyslipidemia (e.g. achievement of LDL-C<2.59 mmol/L)*

	➢ *Reversal or improvement of hypertension (e.g. achievement of systolic BP<140mmHG according to the American Diabetes Association standards (ADA)(29)* ○ Patient satisfaction with procedure ○ Adverse events**:** ➢ *Technical complications of specific operation e.g. leaks, fistulas, strictures, and ulcerations at anastomosis, and gastric band problems* ➢ *Any re-operation/re-intervention and classification of its severity* ➢ *Dysphagia/regurgitation/gastroesophageal acid reflux disease (GERD)* ➢ *Micronutrient status (i.e. total number of people with deficiencies in >1 micronutrient)* ➢ *Post-operative morbidity, including adverse events secondary to micronutrient deficiency (i.e. osteopenia and fractures)* ○ Resource use: ➢ *Hospital length of stay (LOS) (if reported with primary outcomes)* ➢ *Readmission to hospital (if reported with primary outcomes)* Due to limitations in time and resources in the project we not consider the following adverse outcomes: cancer, kidney/renal, liver, pancreas, or thyroid function/disease, dental outcomes, or other rare consequences of micronutrient deficiencies (e.g. Beriberi, Wernicke's). Follow up We will consider the following classification of follow up after bariatric surgery as proposed by Mahawar in 2014 (21) o Short term: ≤1 year (≤12 months)* o Medium term: >1≤5 years (>12≤60 months) o Long term: >5≤10 years (>60≤120 months) o Very long term >10 years (>120 months) *This REA will be limited to studies with >12 months follow up after bariatric surgery.
Study design	***Studies of effectiveness***: Inclusion criteria If recent relevant evidence syntheses (i.e. a HTA, or a SR) are available, we will consider including them if they are suitable and comply with our PICO. We will also include original studies published after the search date of the latest evidence syntheses (as described below). If we find no suitable evidence synthesis for inclusion, we will include randomised controlled studies only. ***Studies of safety*** Inclusion criteria: HTA or SRs, and randomised controlled studies. We will if the time and resources allows it also search for and include non-randomised controlled trials or observational studies, single arm trials and single or

	multiple arm prospective registry based data from national, regional, or hospital level registries. Exclusion criteria: Study designs other than those listed above, and with data collected from other sources than registries (e.g. through chart review, electronic health records, or patient surveys).

3 Communication and collaboration

Table 3-1: Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Scoping	To internally discuss and reach consensus on the scoping.	07/01/2020	E-meeting	Author(s), co-author(s), dedicated reviewers, project manager (external experts)
	To discuss the preliminary PICOs with representatives from patient organisations	TBD	*Skype/e-mail*	*Author(s), co-author(s), manufacturer(s), project manager*
	Fact check of the draft project plan by the manufacturers	*TBD*	*E-mail*	*Author(s), Co-author(s), dedicated reviewer(s), project manager*
Feedback on draft project plan	*To discuss comments of dedicated reviewers, clinical experts, manufacturers.*	*TBD*	*E-mail*	*Author(s), project manager, manufacturers*
First draft of the rapid assessment	*To discuss comments of dedicated reviewers*	*TBD*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers*
Second draft of the rapid assessment	*To discuss comments from ≥ 2 external clinical experts and manufacturers*	*TBD*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers; external experts, manufacturers*

3.1 Dissemination plan

The final rapid assessment will be published on the EUnetHTA website: http://eunethta.eu/rapid-reas/ .

All stakeholders and contributors are informed about the publication of the final assessment by the project manager.

We plan to publish the assessment as a journal paper in a peer-reviewed international journal, and present the findings at a conference.

3.2 Collaboration with stakeholders

3.2.1 Collaboration with manufacturer(s)

Manufacturers will be provided the opportunity to review the preliminary PICO. Those manufacturers that have signed a Confidentiality Undertaking will also be provided the opportunity to undertake a fact check of the draft project plan, and of the draft assessment. Only manufacturers with devices that are CE approved will be considered. There will be no further manufacturer involvement in the project.

3.2.2 Collaboration with other stakeholders

We will seek collaboration with patient organisations to get insight into patient experiences of obesity surgery, their input on outcomes selected for this assessment, and possibly also ask patient or patient representatives to comment on the readability of the 2nd draft review, as well as of a brief (1-2 pages) plain language summary of the report. We plan to engage with the newly formed European Coalition of People Living with Obesity, the Norwegian patient organisation for people

living with obesity, as well as the International Federation for the Surgery of obesity and metabolic disorders (IFSO)

3.2.3 Collaboration with EUnetHTA WPs

For the individual rapid assessment, some collaboration with other WPs is planned: WP7 [Implementation] will be informed of the project, in order to prepare activities to improve national uptake of the final assessment. Feedback on the WP4 REA process will be asked from the involved parties by WP6 [Quality Management], and this information will be processed by WP6 to improve the quality of the process and output.

3.2.4 Conflict of interest and confidentiality management

All authors, co-authors, dedicated reviewers, observers, external experts (health care professionals, patients or patient representatives) involved in the production of this assessment have declared they have no conflicts of interest in relation to the technology and comparator(s) assessed according to the EUnetHTA declaration of interest (DOI) form, which was evaluated following the EUnetHTA Procedure Guidance for handling DOI form (https://eunethta.eu/doi).

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5 Appendix A

5.1 Selected Assessment Elements

The table shows the assessment elements and the translated research questions that will be addressed in the assessment. They are based on the assessment elements contained in the 'Model for Rapid Relative Effectiveness Assessment'. Additionally, assessment elements from other HTA Core Model Applications (for medical and surgical interventions, for diagnostic technologies or for screening) have been screened and included/ merged with the existing questions if deemed relevant.

Table 5-1: Selected Assessment Elements

ID	Topic	Topic Issue	Relevance in this assessment [**Yes – critical**, **Yes** or **No**]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
Description and technical characteristics of technology					
B0001	Features of the technology and comparators	What is the technology and the comparator(s)?		M	What are the surgical alternatives for managing obesity?
B0002	Features of the technology and comparators	Whatr are the rsiks and benefits of the different technologies?			What are the claimed benefits, and potential risks, of the different surgical procedures relative to each other?
A0020	Regulatory Status	For which indications has the technology received marketing authorisation or CE marking? [This assessment element can be placed either in the TEC OR in the CUR domain]		M	For which indications has the adjustable gastric band received marketing authorisation or CE marking?
B0002	Features of the technology and comparators	What is the claimed benefit of the technology in relation to the comparator(s)?		M	Combined with B0001
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?		NM	Combined with A0011
B0004	Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?		M	Who undertakes the different bariatric surgical procedures and in what context and level of care are they provided?
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?		NM	
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?		NM	
A0021	Regulatory Status	What is the reimbursement status of the technology? [This assessment element can be placed		NM	Combined with A0011

ID	Topic	Topic Issue	Relevance in this assessment [Yes – critical, Yes or No]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
		either in the TEC OR in the CUR domain]			
Health problem and current use of technology					
A0002	Target Condition	What is the disease or health condition in the scope of this assessment?		M	What health condition is included in the scope of this assessment?
A0003	Target Condition	What are the known risk factors for the disease or health condition?		NM	What are the known risk factors for obesity?
A0004	Target Condition	What is the natural course of the disease or health condition?		M	What is the natural course of obesity and specifically in patients wth BMI≥35 and comorbidities, and in patients with BMI ≥30 and T2DM who have not achieved durable improvement in glycaemic control (with co-morbidities) with reasonable non-surgical methods.
A0005	Target Condition	What are the symptoms and the burden of disease or health condition for the patient?		M	What are the main symptoms or consequences of obesity for patients?
A0006	Target Condition	What are the consequences of the disease or health condition for the society?		NM	What is the burden of obesity and specifically obesity in those with comorbidities including T2DM for society (prevalence, incidence, costs)?
A0024	Current Management of the Condition	How is the disease or health condition currently diagnosed according to published guidelines and in practice?		M	How are obesity and T2DM currently diagnosed in clinical guidelines and in practice?
A0025	Current Management of the Condition	How is the disease or health condition currently managed according to published guidelines and in practice?		M	How are obesity and specifically obesity in those with comorbidities including T2DM managed in clinical guidelines and in practice?
A0007	Target Population	What is the target population in this assessment?		M	What is the target population(s) in this assessment?
A0023	Target Population	How many people belong to the target population?		M	Combined with A0006
A0011	Utilisation	How much are the technologies utilised?		M (NM for diagnostics)	What is the current use and reimbursement status of the different bariatric procedures in Europe?
Clinical effectiveness					
D0001	Mortality	What is the expected beneficial effect of the intervention on mortality?	YES-critical	M	What is the relative effect of the different bariatric surgical procedures on mortality?
D0005	Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?	YES-critical	M	What is the relative effect of the different bariatric surgical procedures on weight loss, and diabetes control?
D0006	Morbidity	How does the technology affect progression (or recurrence) of the disease or health condition?	YES-critical	M	What is the effect of the different bariatric surgical procedures on progression of obesity including the development or worsening of comorbidities?
D0011	Function	What is the effect of the technology on	YES-critical	M	What is the relative effect of the different bariatric surgical

ID	Topic	Topic Issue	Relevance in this assessment [Yes – critical, Yes or No]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
		patients' body functions?			procedures on cardiovascular risk (e.g. diabetes, hypertension, hyper-lipidemia), gastroesophageal acid reflux disease, and micronutrient deficiency)?
D0016	Function	How does the use of technology affect activities of daily living?		NM	
D0012	Health-related quality of life	What is the effect of the technology on generic health-related quality of life?	YES-critical	M	Do the bariatric surgical procedures differ in their effect on generic health related quality of life?
D0013	Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	YES-critical	M	Do the bariatric surgical procedures differ in their effect on disease specific quality of life?
D0017	Patient satisfaction	Were patients satisfied with the technology?		NM	Do the bariatric surgical procedures differ in their effect on patient satisfaction?
Safety					
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	Yes-critical	M	What is the comparative safety of the different bariatric surgery procedures?
C0002	Patient safety	Are the harms related to dosage or frequency of applying the technology?	Yes	NM	Do the harms of the different bariatric surgical procedures relate to by whom they are performed (by high vs. low volume providers (provider level)?
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	Yes	M	Do the frequency or severity of harms with the different bariatric surgical procedures differ depending on when (e.g. different stage of obesity), or where (e.g. low versus high volume hospitals, or private clinics) they are conducted?
C0005	Patient safety	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?	Yes	M	Do the susceptible patient groups that are more likely to be harmed differ between the surgical procedures?
C0007	Patient safety	Are the technology and comparator(s) associated with user-dependent harms?		NM	
B0010	Safety risk management	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	Yes	M for medical devices NM for screening and diagnostics	What kind of data/records and or registry is needed to monitor the use of the different surgical procedures?

5.2 Checklist for potential ethical, organisational, patient and social and legal aspects

[

1. Ethical	
1.1. Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new ethical issues?	No
If answered with 'yes', please provide a short statement explaining why.	

	Example: Routine introduction of prenatal genetic screening tests, which could lead to pregnancy termination, may cause ethical issues for the couple as well as for the health-care provider.	
1.2.	Does comparing the new technology to the defined, existing comparators point to any differences that may be ethically relevant?	No
	If answered with 'yes', please provide a short statement explaining why. *Example: The marketing authorisation holder claims that its product is superior, but has decided to limit the amount of the new medicine, which means that it has to be rationed and not all patients who need it can receive it. The comparator is freely available.*	
2.	**Organisational**	
2.1.	Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) require organisational changes?	No
	If answered with 'yes', please provide a short statement explaining why. *Example: The new intervention requires the establishment of specialised centres for administration.*	
2.2.	Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be organisationally relevant?	No
	If answered with 'yes', please provide a short statement explaining why. *Example: The new technology will replace a surgical intervention, which may lead to excess capacity in relevant areas.*	
3.	**Social**	
3.1.	Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new social issues?	No]
	If answered with 'yes', please provide a short statement explaining why. *Example: A new technology allows patients to return to the workplace, but since the technology can be seen by co-workers, it may lead to stigmatisation.*	
3.2.	Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be socially relevant?	No
	If answered with 'yes', please provide a short statement explaining why. *Example: A technology, which is widely used by persons with abuse problems, colours the tongue blue, thus, immediately identifying the user. Comparators do not have this property.*	
4.	**Legal**	
4.1.	Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) give rise to any legal issues?	No
	If answered with 'yes', please provide a short statement explaining why. *Example: The comparator for the new technology is a pharmaceutical that is not licensed for the indication of concern, but is widely in use.*	
4.2.	Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be legally relevant?	No

If answered with 'yes', please provide a short statement explaining why.

Examples:

- *The comparator for the new technology is a controlled, restricted substance, but the new medicine is not.*
- *The most appropriate comparator for the new technology is available as a pharmacy-compounded medicine, but not as a finished product with marketing authorisation.*

Note: The assessment should not address patent-related issues.

5.3 Human Resources and expenditures

Table 5-2: Anticipated human resources

Role	Total number of person days	Source	
		Staff of participating organisations	Subcontracting
Author	80 person days	80 person days	-
Co-Author	25 person days	25 person days	-
Dedicated Reviewer	5 person days each	5 person days each	-
External expert	5 person days each	-	5 person days each
Patients	1-2 person days each	-	1-2 person days
Medical Editor	10 person days	-	10 person days
Layout	5 person days	-	5 person days

[These numbers are estimations – please adjust as needed.]

In the EUnetHTA timesheet, the deliverable number for this assessment is: [Please include the respective deliverable number in the timesheet].

Table 5-3: Anticipated expenditures

Type of expenditure	Amount in €	Comments
Travel costs	[e.g. for flights to a f2f scoping meeting]	
Subcontracting: • External expert honorarium • Patient honorarium • Medical Editing • Layout	• [200 - 350€ each] • [max. 200€ each for involvement] • [~ 2,000 EUR] • [~ 500 EUR]	The amounts are suggestions and need to be adjusted as needed. All subcontracting costs need to be cleared by 1st authors. Involvement of experts and patients without honorarium is also possible upon approval by the experts/ patients.
Other costs	[e.g., travel costs patients]	

[Please, adjust as needed.]