

EUnetHTA JA3 WP4 - Other technologies, OTCA26
External review by external experts of the 2nd draft project plan on Surgical procedures for treatment of obesity



Comments should be submitted not later than *Weekday 25/02/2020*

Please use this form for submitting your comments and please return to Gerd M Flodgren; gerdmonika.flodgren@fhi.no

Please use the [checklist](#) for external experts as guidance for your review.

1. Please put each new comment in a new row.
2. Please insert the page number and section number on which your comment applies. If your comment relates to the document as a whole, please put **'general'** in this column.
3. Please provide a description of your comment as specific as possible and preferably also provide a suggestion for rewording. If you wish to draw our attention to published literature, please supply the full reference.

Comment from <i>Insert your name and organisation</i>	Page number <i>Insert 'general' if your comment relates to the whole document</i>	Line/ section number	Comment and suggestion for rewording <i>Please insert each new comment in a new row.</i>	Character of comment • 'major' ^a =1 • 'minor' ^b = 2 • 'linguistic' ^c =3 <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	Author's reply
Judith Aron-Wisnewsky	7	Projet method	Add this reference https://www.ncbi.nlm.nih.gov/pubmed/28930514 Because it is not in the paper proposed by O'Brien This is one of the longest follow-up after RYGB at 12 years	1	O'Brien reported effects of any type of bariatric surgery, and not only RYGB. The papers that we report here in the protocol are relevant reviews found by the scoping search. The paper by Adams 2017 is an original paper that probably will be included in the full report.
	8	Selection	Selection of (systematic reviews) and individual studies A word is missing to state which software is going to be used for reference	3	Sorted.

Please add extra rows as needed.

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			management will be used for reference management.		
	13	Point 8	What is endobariatric ?? I do not think this is a relevant key word	1	It appears to be a relevant key word (no action)
	13	2	Add gastric banding as a key word if we are also including this surgery type as suggested by gastroplasty	1	Sorted.
	15	Project scope	Add NASH to the comorbidities ?	2	Sorted.
	15	Project scope	Note that although we will not take into account revisional surgery, some studies with longer follow-up might have included patients with a second operation (check into material and method if specified)	2	We have added a sentence stating that "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."
	16	intervention	Although several operation are called bypass, each type should be evaluated in its own category and one should not mix RYGB and distal bypass	3	We will not mix different types of surgical procedures, but assess them separately.
	16		Not all bariatric surgery are non reversible : RYGB can be undone for example Sleeve in non reversible	3	We have removed the sentence about reversible and non-reversible

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					procedures.
	17	Outcomes	% body fat should in fact say: % body fat loss	3	Sorted.
	17	Outcomes	Health related quality of life (validated instrument) ? maybe this should be predefined ? Baros questionnaire for bariatric surgery +/- SF36	2	SF-36 is not a HRQOL, but a general QOL instrument. We will consider any validated instrument.
	17	Outcomes	Diabetes: reduced need of other medications should be replaced by reduced need of anti diabetic agents (oral or injected) or reduction of the dosage Remission status should be evaluated (definition based 2009 ADA)	1	Sorted.
Laurent Genser	14		There is increasing evidence and ongoing RCT on sleeve gastrectomy with transit bipartition, it could be worth including this procedure in the review	1	At the scoping meeting we took a group decision on what procedures to include and not to include (no action).
	16		Why do you include open procedure, Nearly 100% of all primary bariatric procedures are performed laparoscopically	2	Removed ' either laparoscopic or open surgical procedures)
	16		Regarding OAGB, surgeons usually perform a long and narrow gastric tube (30-40French) and a long 150-200 omega loop), please consider these details. Please add: It is a reversible method.	2	This is too detailed for the protocol. In the full review HIQA will provide more detailed descriptions of the procedures. Removed the sentence about reversible and non-reversible methods, as more than one can be reversed.

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	16		Sleeve: the stomach is reduced to 30%of its original size not 15% . It is a non-reversible procedure		Sorted
	16		BPDDS: it is not similar to RYGB; please replace with the following description, BPPDDS 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.		Sorted
	16		Regarding the description of the RYGB, please add: "It is a reversible method."		Sorted
	16		After SASI: please consider Sleeve gastrectomy with transit bipartition	1	See reply above
	17		Comparison groups; Comparisons involving procedures that are no longer in use section: banded procedures (SG/ RYGB) are still performed either in primary and revisional settings!	1	These procedures were excluded in the Cochrane review by Colquitt et al. Colquitt et al.
	17		Primary outcomes settings: please consider % Excess BMI loss as a marker of weight changed commonly reported	1	We include any measure of weight loss, those listed here are only examples.
	17		Please consider as a secondary endpoints <ul style="list-style-type: none"> • 90 days overall morbidity • 90 days morbidity reported according to dindo-Clavien Classifications • readmissions rates 	2	We already have included morbidity under adverse events, and will include any morbidity that is reported, using any classification.
Tom Mala	16		"Suggest removing "is similar to Roux-eny gastric bypass, but the small	2	Sorted.

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			stomach pouch is connected .."		
	16		Statement: "All procedures are none reversible" – the Roux en Y gastric bypass may be reversed	2	Sorted.
	17		Regarding secondary outcome: considering broader evaluation also including HDL and triglycerides (Dyslipidemia HDL cholesterol < 1.0 mmol/L (men) or < 1.3 mmol/L (women), triglycerides > 1.7 mmol/l, total cholesterol/HDL cholesterol ratio > 5 or the use of lipid-lowering medication kan være definsjon for HDL/Triglycerider.) Could also consider abdominal pain as a secondary outcome – may not be adequately defined however.	2	We believe we already have the most important outcomes listed. Abdominal pain would be a subjective outcome, and may, as you say, be poorly/differently defined in different papers. We have included all core-set outcomes described in the BARIACT study.
	17		Include patient satisfaction as a secondary outcome (may not be available)	2	Added.
	17		Include hospital stay/readmission rates?	2	Added.
	18		What system will be used to describe morbidity related to treatment? Accordion? Clavien Dindo? Specify?	2	We will include all reported adverse events/morbidity during or after surgery independently of assessment tool.
	15		Data extraction: annual hospital volume?	2	Added.
	15		Follow up rate porbably included in the broader term "trial characteristics needed for the risk of bias assessment	2	Follow up is also described under 'outcomes'
Rune Sandbu			No specific comments at this point.		No action needed.

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