EUnetHTA JA3 WP4 - Other technologies, OTCA27
External review by external experts of the 2nd draft project plan on Comparative effectiveness of surgical techniques and devices for the treatment of benign prostatic hyperplasia (BPH)

Comment from *Insert your name and organisation*	**Page number** *Insert 'general' if your comment relates to the whole document*	**Line/ section number**	**Comment and suggestion for rewording** *Please insert each new comment in a new row.*	**Character of comment** • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3 *Please indicate your choice by writing the according number in this field, e.g. for major choose "1".*	**Author's reply**
A.Capizzi	12	Table 2-5	Prostate artery embolization is considered too invasive in the subpopulation with prostate size >35 and <80 g, PVR>100 and peak urinary flow <10 ml and is not recommended.		Thank you, we will take this suggestion into consideration for subgroup analyses
A.Capizzi	12	Table 2-5	TURP is also used in patients with a prostate size >150 g, PVR>100 and peak urinary flow <10 ml.		Thank you, we will take this suggestion into consideration for subgroup analyses although the EAU guidelines considers TURP in case prostate size is between 30 and 80 ml
A.Capizzi	13	Table 2-5	Device related events should be better defined		Thank you. Device related events have been specified and grouped for two technologies (OP and PAE)
A.Capizzi	13	Table 2-5	Urinary tract infection: only clinical		Thank you. We added "clinical"
A.Capizzi	13	Table 2-5	Transient heamaturia should be better defined		Thank you, we have eventually excluded it after the grading survey
A.Capizzi	13	Table 2-5	Blood loss per gram of resected prostate tissue, injury of mucosa and long-term mortality are outcomes, which do not need to be included.		Thank you, we have eventually excluded them after the grading survey
F..Bergamaschi	12	Table 2-5	WAVE and PVP with 80 and 120 W are not used in the suggested subpopulation of patients with prostate size of >35g and <80g, PVR >100 ml and peak urinary flow <10		Thank you, we will take this suggestion into consideration for subgroup analyses. We have eventually excluded PVP 80 and 120 W.
F..Bergamaschi	12	Table 2-5	PVP Green laser 180 with enucleation is an additional technology used in two of the suggested subpopulations: 1, prostate size >80 - <150ml, PVR		Thank you, we will take this suggestion into consideration for subgroup analyses

Please add extra rows as needed.

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			>100 ml and peak urinary flow <10, 2, prostate size >150ml, PVR >100 ml and peak urinary flow <10		
F..Bergamaschi	12	Table 2-5	The comparator in the suggested subpopulation of patients with a prostate size >150ml, PVR >100 ml and peak urinary flow <10 should be prostatectomy or adenomectomy, but not radical.		Thank you, we will take this suggestion into consideration for subgroup analyses. We eliminated the word "radical"
I.Robertson	12	Table 2-5	I don't think PVR and Qmax are as absolute a boundary as depicted in the PICO statement. Patients are being mainly chosen on symptomatic grounds – eg. IPSS + urodynamics to confirm and exclude instability		Thank you. We agree and have taken them out
I.Robertson	12	Table 2-5	This degree of subdivision for this technique (PVP with 80, 120 and 180 W). The iterative development of technologies means this variation likely applies to several other techniques. Eg. for PAE the PEFecTED technique vs standard embolization.		Thank you. We have eventually excluded PVP 80 and 120 W.
I.Robertson	12	Table 2-5	Transurethral enucleation with bipolar energy – B-TUEB: I have no knowledge of this technique		It is mentioned in the AUA guideline, but with a different acronym (BTE)
I.Robertson	12	Table 2-5	Why PAE has not been included in the group of patients with prostate size >80 - <150ml, PVR >100 ml and peak urinary flow <10. There is a reasonable literature for prostate vols > 80.		Thank you, we will take this suggestion into consideration for subgroup analyses
I.Robertson	13	Table 2-5	Blood loss per gram of resected prostate tissue only applies to some interventions, not all of the assessed interventions		Thank you, we have eventually excluded this outcome after the grading survey
I.Robertson	13	Table 2-5	Injury of mucosa : this needs further definition e.g. severity		Thank you, we have eventually excluded this outcome after the grading survey
I.Robertson	13	Table 2-5	Catheterization time : not all techniques require this.		Thanks, we'll retrieve this outcome in

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					studies where it will be available
I.Robertson	13	Table 2-5	Transient heamaturia is almost mandatory with several interventions. Impact?		Thank you, we have eventually excluded this outcome after the grading survey
I.Robertson	13	Table 2-5	Persistent irritative symptoms: needs clearer definition		Thank you. We have now specified that they refer to frequency, urgency, urge incontinence, nocturia
I.Robertson	13	Table 2-5	Device related events: needs clearer definition. Device failure- likely to be very rare.		Thank you. Device related events have been specified and grouped for two technologies (OP and PAE)
I.Robertson	13	Table 2-5	Long-term mortality: I doubt if data is available for most of the techniques other than TURP.		Thank you, we have eventually excluded this outcome after the grading survey
I.Robertson	13	Table 2-5	Inadvertent embolisation of other sites (for PAE): low frequency potentially significant		Thank you, we have eventually included it after the grading survey
I.Robertson	13	Table 2-5	Distal embolization (for PAE): How is this different than inadvertent embolization? If refers to target embolization then distal embolization is desirable.		Thank you. In order to avoid unnecessary duplications, we included only inadvertent embolisation of other sites
I.Robertson	13	Table 2-5	Damage of the perivascular, neural and muscular structures (PAE): I don't really understand this one - some it is a variant of non-target embolization.		Thank you. It was eventually included after the grading survey

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