

EUnetHTA JA3 WP4 - Other technologies, OTCA09
Review by dedicated reviewers of the draft Project Plan for HIFU in prostate cancer



Comments should be submitted not later than *Weekday 23/12/2017*

Please use this form for submitting your comments

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.

The draft Project Plan of the Rapid Assessment on HIFU in prostate cancer is open to review between 18/12/2017 and 23/12/2017.

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 <ul style="list-style-type: none"> • '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
Roberto Llarena	7	2.1	<p>In the objectives, specifically in 2, the indication of the HIFU for recurrences of Radical Prostatectomy is discussed.</p> <p>I do not understand that indication given the lack of tissue to treat unless local recurrence is demonstrated.</p> <p>In principle, the HIFU is an experimental ablative technique (as stated in the European guidelines EAU 2018) for the treatment of localized prostate cancer.</p> <p>Quite rightly, Van der Poel (Eur of Urol 2018 in press) positions the different focal therapies in the treatment of prostate cancer.</p>	major	<p>Yes, the indication is locally recurrent PCa.</p> <p>We are aware that HIFU is experimental and this is outlined in the assessment report.</p>

Please add extra rows as needed.

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c"linguistic": grammar, wording, spelling or comprehensibility

EUnetHTA JA3 WP4 - Other technologies, OTCA09
Review by dedicated reviewers of the draft Project Plan for HIFU in prostate cancer



eunetha

Comments should be submitted not later than *Weekday 23/12/2017*

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 <ul style="list-style-type: none"> • '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
			<p>2751 patients (Valerio 2017) have been treated with HIFU to date.</p> <p>There is a worldwide consensus when it comes to treating localized prostate cancers avoiding surgery or radiotherapy, trying to avoid side effects.</p> <p>A fundamental premise is to demonstrate the significant index injury that shows a Gleason score of at least 3 + 4. That is, the previous biopsy and the labeling of all the samples with their corresponding report is necessary.</p> <p>Other essential indications are: prostates less than 50 cc, asymptomatic patients, and with less than 25% of the affected prostate volume, no limit being placed on the age of the patient.</p> <p>The technique is performed transrectally, so that the lesions have to be localized in the peripheral and basal area, with apical or anterior lesions not being suitable.</p> <p>Although hemiablations with HIFU of an entire prostatic lobe are also performed.</p>		<p>Does this mean that patients are indicated for HIFU who are not suitable for surgery or radiotherapy or do not want to undergo surgery or radiotherapy?</p> <p>Yes, we outline this in the assessment report. The EAU guideline suggested the intervention in low-and intermediate risk patients.</p> <p>We will add these indications to the description of the target group in the report.</p> <p>According to the literature anterior lesions are also treated, although it is discussed that they are difficult to reach.</p>

Please add extra rows as needed.

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c"linguistic": grammar, wording, spelling or comprehensibility

EUnetHTA JA3 WP4 - Other technologies, OTCA09
Review by dedicated reviewers of the draft Project Plan for HIFU in prostate cancer



eunethta

Comments should be submitted not later than *Weekday 23/12/2017*

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
			So far there are 7 types of energy and / or focal therapy methods, from cryotherapy indicated in anterior-section tumors, focused laser, electroporation, photodynamic therapy, TOOKAT with the intention of maneuvering the patient's immune system, and high-rate brachytherapy with indication in apical tumors, adding or not external radiotherapy.		
	10	2.2.2	A fundamental premise is to demonstrate the significant index injury that shows a Gleason score of at least 3 + 4. That is, the previous biopsy and the labeling of all the samples with their corresponding report is necessary. In this section it is also indicated in low risk patients, with Gleason 6, breaking the fundamental premise of treating patients with significant Gleason cancer lesions at least 7 (3-4)		Yes, we outline this in the assessment report. The EAU guideline suggested the intervention in low-and intermediate risk patients.
	10	2.2.2	I believe it is important that the project should indicate the lesions to be treated, in terms of degree of development, size and location, in order to be able to compare the different treatments afterwards, homogenizing the tumor types and categories.		We will add these data in the extraction table and collect if available. If data is available we will stratify the results.
	10	2.2.2	I think it is important, in addition, to differentiate the different methods and machines that are intended to be used in the study, such as Ablatherm,		Yes, we extracted this data and stratify the results if possible.

Please add extra rows as needed.

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c"linguistic": grammar, wording, spelling or comprehensibility

EUnetHTA JA3 WP4 - Other technologies, OTCA09
Review by dedicated reviewers of the draft Project Plan for HIFU in prostate cancer



eunethta

Comments should be submitted not later than *Weekday 23/12/2017*

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
			Sonablate, Exablate and Tulsa Pro, among others.		
	11		Right objectives		

Please add extra rows as needed.

^a "major": the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)

^b "minor": the comment does not necessarily have to be answered in a detailed manner

^c"linguistic": grammar, wording, spelling or comprehensibility