DIAGNOSTICS ASSESSMENT PROGRAMME

MRI fusion biopsy systems for diagnosing prostate cancer

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 16 February 2023

THEME: Recommendations

Comment number	Name and organisation	Section number	Comment	NICE response
1	Prostate Cancer UK	1.2	*Further data collection and research is recommended (see the section on further research) to:* • *assess the performance of MRI fusion biopsy systems compared with cognitive fusion biopsies to detect different grades of prostate cancer* Prostate Cancer Uk agrees that further data collection is necessary in this instance. We would reiterate our previous point over our concerns in an increase in detection of clinically insignificant prostate cancer by this modality from the evidence currently available. We, again, would suggest that any evaluation of a biopsy technique should focus on the detection of high grade cancers (ISUP grade 2 and above) and minimising the detection of clinically insignificant	Thank you for your comment which the committee considered. The External Assessment Group (EAG) highlighted that their economic analysis accounts for the implications of overtreatment in individuals whose cancer lesions are 'truly' ISUP grade 1, so any increases in such cancers caused by use of the fusion biopsy systems is captured in the cost effectiveness estimates. Committee agreed that further research is needed to determine the impact of MRI software fusion biopsy compared with cognitive fusion biopsy on the detection of different grades of prostate cancer (see section 4.1 of the diagnostics consultation document). Section 3.11 has been amended to emphasise the point raised in your comment and note that "at consultation on the draft guidance, a stakeholder further highlighted the importance of collecting data on the effect of software fusion technologies on detection of clinically insignificant prostate cancer, as well as higher grade cancers".

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			cancers. The more clinically insignificant cancers detected can lead to a higher rate of overdiagnosis and therefore potentially higher levels of overtreatment in patients with prostate cancer that would otherwise not become symptomatic in their lifetime.	Section 3.1 of the final guidance document has been amended to highlight the potential issue of diagnosis: "At consultation on the draft guidance, a stakeholder further highlighted concerns about any higher rates of overdiagnosis from using software fusion leading to potentially higher levels of overtreatment in patients with prostate cancer that would otherwise not become symptomatic in their lifetime".
2	Prostate Cancer UK	4.2	Further data collection or research is recommended on the impact of implementing MRI software fusion technologies on the rate at which biopsies can be done, capacity resources and waiting times for this procedure. Prostate Cancer UK welcomes this recommendation. Anecdotally, and through our own scoping, we know that biopsy facilities are at capacity or over capacity in some centres and due to the uncertainty around rates of biopsy completion, capacity	Thank you for your comment which the committee considered.

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			resources and waiting times with this procedure we also would recommend further research in this area.	

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3	Medcom	-	We have to be very cautious when comparing cognitive to software-assisted fusion. As shown in most studies there are several bias parameters and drawing conclusions and providing "performance" numbers for individual software systems should not be based on 1 or 2 individual studies with several limitations. Software fusion systems have been proven to be very effective in the latest years and the main reason is the interpretability from operator experience or age but also the convenience and confidence it provides to the users. Of course, there are a lot of skilled doctors who can perform high-quality cognitive fusion biopsies, especially when using a high number of samples in the suspected areas. However we have to consider, for the quality of the health we provide to each individual patient, that in several cases the software-assisted systems will assist all doctors and prevent potential user errors. We have always to take into account that when a user is participating in a comparison study, he/she will most probably be more cautious and try to perform as	Thank you for your comment which the committee considered. The EAG highlighted that in their report they had accounted for a range of sources of uncertainty, including risk of bias, imprecision of diagnostic accuracy estimates, and the limited number of studies for most individual software fusion systems. They also noted that evidence on operator preferences was limited. The EAG's report also included a quality assessment of studies, which was considered by committee in its decision making. In the first meeting, the committee discussed the uncertainties and evidence gaps highlighted in the EAG's report. They acknowledged the potential benefits of the technology (see section 3.8 of the diagnostics consultation document) and agreed that the technology showed promise, but felt there was too much uncertainty to recommend it for routine adoption (see section 3.10). Committee decided not to change the final guidance with regards to this comment.

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			best as possible. Whereas in everyday routine, people would prefer to use a system that makes their life easier for the safety of their patients.	

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THEME: Description of product

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4	Philips	2.23	Please add (or replace) this text to section 2.23: "*The UroNav (Philips) is a mobile workstation using an electromagnetic tracking system for MR/Ultrasound fusion. The system is compatible with a wide variety of third-party ultrasound systems and transrectal probes. UroNav supports transrectal and transperineal biopsies with stabilised stepper and freehand approaches. UroNav fuses pre-biopsy MR images of the prostate with live ultrasound images - in real time. UroNav's unique rigid & elastic registration methods allow the user to create and maintain optimal 3D registration of MR/US images and compensate for patient movement, so that imaging plane restrictions or repeat fusion processes during biopsy procedures can be avoided*".	Thank you for your comment which the committee considered. The product details for UroNav were updated to include this new information in line with the technical descriptions of the other included technologies (see section 2.23 of the final guidance document).
5	Philips	2.24	Please add (or replace) this text to section 2.24: "*UroNav works in conjunction with DynaCAD Prostate which is an image analysis and reporting tool for the radiologist to read and report prostate MR images. UroNav also works with DyanCAD Urology which is a unique tool for the urologist to manage and utilise longitudinal mpMRI and*	Thank you for your comment which the committee considered. The product details for UroNav were updated to include this new information in line with the technical descriptions of the other included

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			fusion biopsy data to support full care cycles, in prostate cancer detection and treatment".	technologies (see section 2.24 of the final guidance document).