

DIAGNOSTICS ASSESSMENT PROGRAMME

QAngio XA 3D QFR and CAAS vFFR imaging software for assessing coronary stenosis during invasive coronary angiography

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 5 November 2020

Theme: General comments

Comment number	Name and organisation	Section number	Comment	NICE Response
1	Abbott Medical UK	General	We welcome the draft guidance as it is. We would urge the committee not to make changes. The lack of evidence on clinical effectiveness of QFR and vFFR is particularly relevant and speaks to not making changes to the draft guidance.	Thank you for your comment which the committee considered.
2	British Cardiovascular Society (BCS) in conjunction with the British Cardiovascular intervention Society (BCIS)	1.1	BCS/BCIS note with interest the conclusions from NICE relating to this technology and agree that further research into this promising technology would be welcome	Thank you for your comment which the committee considered.
3	Royal College of Physicians		The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the BCS response.	Thank you for your comment which the committee considered.

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Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 5 November 2020

Theme: Diagnostic accuracy

Comment number	Name and organisation	Section number	Comment	NICE Response
4	Pie Medical Imaging	3.25	User variability was also reported in the study for CAAS vFFR but not taken into account in this document	<p>Thank you for your comment which the committee considered.</p> <p>These details have been added to sections 3.24 and 3.25 of the diagnostics guidance document.</p>
5	Health professional	1.1	<p>“Anything that can increase the level of accurate physiological assessment during angiography, can only be a good thing, especially if it can be done quicker and cheaper.</p> <p>Ultimately, these methods have to provide accurate physiology. The 95% Bland-Altman limits of agreement for QFR and CAAS are similar to other published ‘virtual-FFR’ methods; around ± 0.14. That is quite an interval considering most cases we see in the lab fall into FFR 0.70-0.90, or thereabouts. Although CT-FFR has been approved at a remarkably similar level of accuracy, this acts as gate-keeper to invasive cath. The accuracy ‘bar’ is set higher for QFR and CAAS because these determine definitive management decisions. In my opinion, studies in this area have focused too much on binary outcomes (sensitivity, specificity, PPV, NPV) as markers of accuracy, because these are influenced by study case mix - specifically, the number of cases that happen to lie close to the threshold.</p> <p>What is the accuracy and reproducibility outside of their own development teams, in the hands of general interventionists? i.e. those who will be actually be using them in anger. Data in this context is scant.</p>	<p>Thank you for your comment which the committee considered.</p> <p>The committee agreed that while the previous functional assessments may be used to guide further testing decisions such as whether to do an FFR, the QAngio QFR and CAAS vFFR results would be used to guide high level treatment decisions with substantial consequences. This consideration has been added to section 4.6 of the diagnostics guidance document.</p> <p>The committee’s consideration of test accuracy is described in sections 4.3 and 4.4 of the diagnostics guidance document. No changes were needed in this section.</p>
6	Health professional	1.1	“I share the concern about a test that has fairly significant amount of variability around the cutoff that is significant – we’re not really interested in the test’s accuracy in minimally diseased arteries, nor in 90%+ stenosis/FFR<0.6 disease. It’s the accuracy for the ones in the middle that are the difficult ones.	<p>Thank you for your comment which the committee considered.</p> <p>The committee’s consideration of test accuracy is described in sections 4.3 and 4.4 of the diagnostics guidance document. No changes were needed in this section.</p>

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Theme: Studies in the clinical effectiveness review

Comment number	Name and organisation	Section number	Comment	NICE Response
7	Pie Medical Imaging	3.1 + 3.5	The paper of Jin used the vFFR outside of the instructions for use (the frame rate of the images was too low). And as such should be excluded.	<p>Thank you for your comment which the committee considered.</p> <p>The external assessment group noted that the study was included in order to present all published evidence on CAAS vFFR. The Jin et al. 2019 study was not included in the base case analysis but was included in a scenario analysis. This has been clarified in section 3.5 of the diagnostics guidance document.</p>
8	Pie Medical Imaging	Table 4	<p>The paper of Pizato (ILUMIEN 1) has used incorrect pressure data. This has been stressed out in the FAST Extend publication: https://www.sciencedirect.com/science/article/abs/pii/S1936878X20307233?via%3Dihub and should be excluded</p>	<p>Thank you for your comment which the committee considered.</p> <p>The external assessment group noted that the study was included in order to present all published evidence on CAAS vFFR. The ILUMIEN 1 study was not included in the base case analysis but was included in a scenario analysis. This is summarised in section 3.5 of the diagnostics guidance document.</p>

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Theme: Angiography image quality

Comment number	Name and organisation	Section number	Comment	NICE Response
9	Pie Medical Imaging	3.23	Exclusion of cases were due to the lack of suitable projections or image quality that meet the vFFR analysis requirements not due to angiographic image processing issues as reported in that section	Thank you for your comment which the committee considered. This has been clarified in section 3.23 of the diagnostics guidance document.
10	Medis Medical Imaging	4.9.5	Remarks were made that in retrospective data, there is about a 20% loss of cases that cannot be analyzed due to the fact that the data were not acquired following the QFR acquisition guidelines. Reasons for that may be: no 2 views available about 25 to 40 degrees apart, too much overlap of vessels, not the proper frame speed, poor image quality, etc. Note: in prospective studies the data will be acquired according to the acquisition guidelines, resulting in much less failures. For example, in the Prospective FAVOR II Eu/Jp, only 6 cases out of the total of 302 cases were excluded on these bases, representing only 2% of the cases.	Thank you for your comment which the committee considered. The committee concluded that because all the data considered were from interventional centres, it was not certain what the technical failure rate would be in diagnostic-only centres. An additional paragraph (section 4.5) has been added to describe the committee's considerations on technical failure rates.
11	Health professional	1.1	There also appears to be a high failure rate due to limitations of certain projection angles.	Thank you for your comment which the committee considered. The committee noted that in clinical practice some images may not be of a sufficient quality for the software programs to produce a result. An additional paragraph (section 4.5) has been added to describe the committee's considerations on technical failure rates.
12	Health professional	1.1	"One small point. Whatever system you use, it is crucially dependent upon a good quality angio. In our institution that ruled out 80% of angios - imagine the waste of money and the wrong answers."	Thank you for your comment which the committee considered. The committee noted that in clinical practice some images may not be of a sufficient quality for the software programs to produce a result. An additional paragraph (section 4.5) has been added to describe the committee's considerations on technical failure rates.

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Theme: Care pathway and clinical setting

Comment number	Name and organisation	Section number	Comment	NICE Response
13	Pie Medical Imaging	4.12	Even though ICA is a third line test, what are the current numbers for CT coronary angiography and functional testing for patients who were not referred for an ICA? Furthermore, for PCI procedures ICA procedures are still necessary.	Thank you for your comment which the committee considered. Clinical experts on the committee explained that previous functional assessments can rule out the need for interventional treatment in some people. Therefore, it is likely that the people who do go on to have invasive coronary angiography, have more severe disease than the populations in the diagnostic accuracy studies. Section 4.6 of the diagnostics guidance has been updated to include details of this consideration.
14	Medis Medical Imaging		Physiology class I indications According to the ESC guidelines, FFR physiology is a class I indication, therefore should be used much more than currently done (about 15% of the cases). However, our clinical evidence demonstrates that QFR = FFR, as it provided the same values based on only the X-ray images. Further, with more physiology measurements, patients' pathways using other investigations such as perfusion imaging can be avoided. This is an enormous cost saving to the health care system and decreases the number of patients' visits to the hospital substantially.	Thank you for your comment which the committee considered. Clinical experts agreed that physiological testing using fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) is available but not frequently used in the UK (section 4.1). Clinical experts on the committee explained that previous functional assessments can rule out the need for interventional treatment in some people. Therefore, it is likely that the people who do go on to have invasive coronary angiography, have more severe disease than the populations in the diagnostic accuracy studies. Section 4.6 of the diagnostics guidance has been updated to include details of this consideration.
15	Medis Medical Imaging	3 i)	Diagnostic centers Another point that has been discussed in the Report is the use of the QFR in diagnostic centers. Although diagnostic centers may close down in the future, which still may take a significant time, applying QFR in the diagnostic centers may save 50% of the patients to be sent to a PCI center. If these 50% would be sent to the PCI center, then in a second cath procedure with a guide wire, most likely the same decision will be reached: send home on Optimal Medical Therapy (OMT). Sometimes the patient has to stay over in the diagnostic	Thank you for your comment which the committee considered. A clinical expert explained that according to the 2017 to 2018 data from the National Institute of Cardiovascular Outcomes Research, around 35,000 diagnostic invasive coronary angiography procedures were carried out compared with around 205,000 in interventional centres. The committee concluded that the future role of QAngio QFR and CAAS vFFR

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			<p>center for several days because there is no place in the PCI center, which raises the expenses to the society tremendously plus the anxiety of the patient.</p> <p>Referral of patients for fractional flow reserve using Quantitative Flow Ratio. (A Scholte) EHJ Cardiovasc Imaging, 2018. Doi: 10.1093/ehjci/je187</p>	<p>in a diagnostic-only setting was unclear because diagnostic-only catheter laboratories are likely to decline in number. This has been updated in section 4.13 of the diagnostics guidance document.</p> <p>The committee also concluded that because all the data considered were from interventional centres, it was not certain what the technical failure rate would be in diagnostic-only centres. An additional paragraph (section 4.5) has been added to describe the committee's considerations on technical failure rates.</p>
16	Health professional	1.1	<p>"I strongly believe that this can be a very useful tool, and in particular in the setting where we have still diagnostic only cath labs. This can prevent the need for invasive FFR procedures, repeat procedures and referrals for non-invasive imaging.</p> <p>BCS note however also that there is a more general shift in emphasis by GIRFT to discourage the practice of standalone angiography in favour of angiography in a setting where interventional assessments and procedures can also be performed. That move would diminish the benefit of QAngio and similar technologies.</p> <p>There is also a shift in guidelines and NHS practice towards more non-invasive assessment of coronary anatomy, with CTFFR encouraged (instead of invasive angiography and either FFR or QAngio etc)."</p>	<p>Thank you for your comment which the committee considered.</p> <p>The committee concluded that because all the data considered were from interventional centres, it was not certain what the technical failure rate would be in diagnostic-only centres. An additional paragraph (section 4.5) has been added to describe the committee's considerations on technical failure rates.</p> <p>Clinical experts explained that previous functional assessments can rule out the need for interventional treatment in some people. Therefore, it is likely that the people who do go on to have invasive coronary angiography, have more severe disease than the populations in the diagnostic accuracy studies. This consideration has been added to section 4.6 of the diagnostics guidance document.</p>

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Theme: Clinical benefits of QAngio

Comment number	Name and organisation	Section number	Comment	NICE Response
17	Medis Medical Imaging	3 i)	<p>Clinical Effectiveness. In the Report much emphasis has been placed on the direct comparison of QFR vs the FFR measurements without taking into account the many advantages of the QFR, which will be further detailed in the following sections. However, the basic and prime clinical effectiveness and great advantage to the patient comes from the fact that QFR is obtained from only the available X-Ray angio's of the various vessels, without having to insert a wire into the coronary artery, nor giving adenosine. There is no need for anything additional!</p> <p>That was also the statement by Prof A Baumbach, Prof of Interventional Cardiology at Barts Hospital in London UK in our phone call to the NICE Team, this last Monday Oct 19, 2020: QFR comes with only X-ray angiographic images: no need for anything else!</p>	Thank you for your comment which the committee considered.
18	Medis Medical Imaging	3 i)	<p>Prioritization of narrowings to be treated The QFR solution generates a pressure-drop curve along the analyzed coronary segment. If there are multiple narrowings in a coronary segment (serial lesions), then each narrowing is associated with a delta-pressure drop. By this approach the interventional cardiologist can determine which of the serial lesions should be treated first, being the one with the greatest delta-pressure drop.</p> <p>Residual QFR Moreover, with each of the (serial) lesions a so-called Residual QFR value is presented, which represents the expected QFR value, if that particular stenosis would be treated with a stent. This supports the interventional cardiologist with very essential information about which lesion should be treated first, or even whether a longer stent should be used covering e.g. 2 serial lesions, and thereby realizing a QFR result well above the 0.80 or even 0.90 value for a successful result.</p> <p>Anatomic information</p>	<p>Thank you for your comment which the committee considered.</p> <p>The external assessment group noted that while these may be important considerations, no clinical effectiveness or diagnostic data was presented to demonstrate that these result in meaningful clinical improvements.</p>

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			In addition to the physiologic measure (QFR), the analysis provides accurate anatomic (QCA) information along the coronary segment, which allows to choose the appropriate stent size, based on the measured obstruction length and reference diameters.	
19	Medis Medical Imaging	3 i)	<p>Staged procedure</p> <p>QFR has also great advantages in the so-called Staged procedures. In an acute event the culprit lesion is treated and the decision to possibly treat other narrowings in one or more of the other coronary arteries is often delayed/deferred until a later moment in time, for example the next day. However, such second catheterization and the use of a pressure wire can be avoided, if a few extra X-ray acquisitions according to the QFR Acquisition Guidelines are taken of the other vessels during the primary cath procedure. These other vessels can then be analyzed off-line with QFR, and if each of these vessels has a QFR > 0.80, then the patient can be sent home on optimal medical treatment (OMT) without requiring a second cath procedure.</p> <p>This is an often occurring situation, which saves a lot of distress to the patient, and improves the clinical efficiency in the cath lab, let alone all the costs of extra hospitalizations, wires, cath lab personnel, etc.</p> <p>In addition, all of these analyses can be done during Heart Team discussions where the decisions to treat (PCI/CBAG) or not are taken. Even extra analyses on available data can be done in that session.</p> <p>Quantitative Flow Ratio in myocardial infarction for the evaluation of non-infarct-related arteries. The QIMERA pilot study. (IJ Amat-Santos) REC Interv Cardiol 2019; 1(1): 13-20. Doi.org/10.24875/RECIC.M19000017. Clinical relevance and prognostic implications of contrast quantitative flow ratio in patients with coronary artery disease (KH Choi et al). Int J Cardiol 2020; doi.org/10.106/j.ijcard.2020.09.002</p>	<p>Thank you for your comment which the committee considered.</p> <p>Clinical experts on the committee explained that although potentially useful, these additional benefits of QAngio QFR relating to the assessment in acute events were not applicable to the population being considered and therefore are outside the scope of this assessment.</p>

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20	Medis Medical Imaging		<p>Multiple scenario's Altogether, this means that there are multiple scenario's where the QFR has an enormous advantage over the pressure wire, both in terms of X-ray radiation, workflow in the hospital, less possible complications without the guidewire, less adverse events due the absence of adenosine to the patient, better overall view on the situation of the coronary segment to be treated (both detailed anatomic and physiologic info available). And all of these save money to the healthcare system.</p>	<p>Thank you for your comment which the committee considered.</p> <p>The committee's consideration of these benefits are described in sections 4.1 and 4.2 of the diagnostics guidance document. The committee considered that no further changes to these sections were needed.</p>
21	Medis Medical Imaging	4.6.2.1	<p>IMR applications Remarks have been made in the Report about IMR applications. We would like to mention that we are validating an extension of the QFR, that will allow the assessment of the IMR index (Index of Microcirculatory Disease) within the same workflow as the QFR and essentially require no extra time. This will add a very important clinical tool in the cath lab leading to enormous time and cost savings. This will also solve the differences in results as described in this section 4.6.2.1.</p>	<p>Thank you for your comment which the committee considered.</p>
22	Medis Medical Imaging		<p>Letter of Support [REDACTED] Clinique Axiom, France Please, find attached Letter of Support of [REDACTED]:</p> <p>My team and I have built up over the years a very extensive experience with the Medis' QFR application for the physiologic assessment of coronary narrowings from X-ray angiograms. We use the software on a daily basis in our clinical practice.</p> <p>From a clinical efficiency point of view the following aspects are very important to us and we apply these every day:</p> <ul style="list-style-type: none"> Using the QFR solution, we save a significant amount of time per day, so that we can finish our work on time at the end of the day, and the nurses have less frequent overwork; 	<p>Thank you for your comment which the committee considered.</p>

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			<ul style="list-style-type: none"> Also, assessing the non-culprit vessels in a non-invasive manner without the use of a pressure wire nor of adenosine, helps us tremendously in planning the procedure for the patient and improving the workflow in the department; The Residual QFR helps us also in deciding with lesion or a combination of lesions to be treated with the maximal effect on the PCI procedure; Also, by measuring both anatomy (3D QCA) as well as physiology (QFR) we do not over-stent nor under-stent, but provide the necessary care at the point-of-care; Likewise, the burden on the patients and our team decreases without any negative effect on the quality of care, actually we only see positive effects; From a financial point of view, the QFR has a positive effect on the healthcare system, and therefore should be reimbursed. <p>I do hope that these points are clear to you.</p> <p>Do not hesitate to contact me with further questions.</p>	
23	Medis Medical Imaging		<p>Letter of Support [REDACTED], Altdorf, Germany Please, find attached Letter of Support of [REDACTED]:</p> <p>We have built up over the years a very extensive experience with the Medis' QFR (more than 500 analysis) application for the physiologic assessment of coronary narrowings from X-ray angiograms.</p> <p>We use the software on a daily basis in our clinical practice before we use a wire base system for FFR. Assessing the non-culprit vessels in a non-invasive manner without the use of a pressure wire nor of adenosine, helps massively in planning the procedure for the patient.</p> <p>From a financial point of view, the QFR has a massive positive effect on the healthcare system, and therefore should be reimbursed</p>	Thank you for your comment which the committee considered.

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Theme: Impact on clinical decision making

Comment number	Name and organisation	Section number	Comment	NICE Response
24	Medis Medical Imaging	3.32	<p>Number of revascularizations</p> <p>In the report it was concluded from a simulation study that using the FFR-only strategy 40.2% of people would have revascularization. Using the QAngio QFR-only strategy 42.0% would have revascularization, and using the grey zone strategy 43.2% would have revascularization. Using QAngio QFR therefore moderately increased the revascularization rate, and using it with the grey zone increased it further. However, it should be noted that a FFR-grey zone has not been taken into account, while in reality there is definitely a FFR-grey zone as well. But even more so, with QFR all the necessary info is there in one go based only on standard X-ray angiographic images. QFR allows the assessment of the need for revascularization, but also predicts with the Residual QFR what the post-PCI QFR will be, which should be > 0.90. Furthermore, most likely the use of IVUS pre- and post-PCI will also decrease, as QFR provides a complete picture on both anatomy and physiology!</p> <p>Although it is not only valid for QFR, it is known from the literature, that increasing the use of physiology actually leads to less stent placements, which is also an important cost saving to the healthcare system, and less anxiety to the patients.</p>	<p>Thank you for your comment which the committee considered.</p> <p>The committee noted that the simulation study made numerous assumptions so its results were uncertain. The committee's discussion of this topic is summarised in section 4.7 of the diagnostics guidance document.</p> <p>The external assessment group noted that FFR is included in the NICE scope as the reference standard technology. Therefore, it is assumed to have 100% sensitivity and specificity to aid comparison between results of QAngio QFR (or CAAS vFFR) and FFR.</p>
25	Medis Medical Imaging		<p>Impact of coronary physiology on clinical decision making</p> <p>Below is a very nice overview paper by Kogame et al under the leadership of Prof PW Serruys on the impact of coronary physiology on contemporary clinical decision making, and where also the QFR and other angio-based solution are discussed. It is also indicated that the angio-based solutions may be game changers in the catheterization laboratories</p> <p>Kogame N, Ono M, Kawashima H, Tomaniak M, Hara H, Leipsic J, Andreini D, Collet C, Patel MR, Tu S, Xu B, Bourantas CV, Lerman A, Piek JJ, Davies JE, Escaned J, Wijns W, Onuma Y, Serruys PW The impact of coronary physiology on contemporary clinical decision making. J Am Coll Cardiol Interv 2020; 13: 1617-38</p>	<p>Thank you for your comment which the committee considered.</p>

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Theme: Use of tests post PCI

Comment number	Name and organisation	Section number	Comment	NICE Response
26	Pie Medical Imaging	4.7	<p>Additionally, outcome data is available for vFFR in 800 patients:</p> <p>This information has been removed due to copyright. Please see: Masdjedi K, Ligthart J, Witberg K et al (2019) The prognostic value of angiography-based vessel-FFR after successful percutaneous coronary intervention. Journal of the American College of Cardiology 74 (13_Suppl. B): B110 (https://www.jacc.org/doi/pdf/10.1016/j.jacc.2019.08.156)</p> <p>This study has demonstrated that in case vFFR > 0.9 significantly less target vessel revascularization (TVR) than patients with vFFR < 0.9.</p>	<p>Thank you for your comment which the committee considered.</p> <p>The clinical experts on the committee noted that this is a post-intervention use of CAAS vFFR and reference standard tests in revascularised vessels. This patient population was outside the scope of the assessment.</p>
27	Medis Medical Imaging	3i)	<p>QFR Post-PCI</p> <p>As mentioned above, QFR allows the prediction of the PCI-result on the basis of the calculated Residual QFR, which is not available with the FFR approach. Published data has demonstrated that a post-PCI QFR value > 0.90 indicates that the longer term outcome of that patient is better than if the QFR is in between 0.80 and 0.90. Also with QFR > 0.90 an additional Ivus/OCT investigation is not necessary, nor a post-dilatation, which saves a lot of time, money and stress to the patient. In particular two publications have demonstrated that at several years FU, a QFR < 0.90 post-PCI was associated with significantly higher MACE:</p> <p>Prognostic value of QFR measured immediately after successful stent implantation: The International Multicenter Prospective HAWKEYE Study (Prof G Campo) J Am Coll Cardiol Interv 2019; 12: 2079-2088. Doi.org/10.1016/j.jcin.2019.06.003</p> <p>Clinical implication of Quantitative Flow Ratio after percutaneous coronary intervention for 3-vessel disease (Prof PWS Serruys) J Am Coll Cardiol Interv 2019; 12: 2064-2075. Doi.org/10.1016/j.jcin.2019.08.009</p>	<p>Thank you for your comment which the committee considered.</p> <p>The clinical experts on the committee noted that this is a post-intervention use of QAngio QFR and reference standard tests in revascularised vessels. This patient population was outside the scope of the assessment.</p>

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Theme: Clinical outcomes

Comment number	Name and organisation	Section number	Comment	NICE Response
28	Pie Medical Imaging	4.7	PMI has started an outcome trial called LIPSIA STRATEGY https://clinicaltrials.gov/ct2/show/NCT03497637?term=lipsiastrategy&draw=2&rank=1	Thank you for your comment which the committee considered. Section 4.8 has been updated to include details of this trial.
29	Health professional	1.1	I agree with their statement about clinical effectiveness not being demonstrated yet. I do think however, that future clinical outcomes studies will probably demonstrate non-inferiority to FFR /iFR. The original DEFER and FAME trials were powerful because they reported clinical outcomes, rather than comparing numerical results against another investigation, as has been done in studies of computed FFR so far.	Thank you for your comment which the committee considered.
30	Health professional	1.1	Outcome studies will be important – as with iFR SWEDEHEART or FAME. It could be pretty useful if assessing a non-culprit lesion at time of STEMI or NSTEMI."	Thank you for your comment which the committee considered.

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Theme: Costs and resource use

Comment number	Name and organisation	Section number	Comment	NICE Response
31	Medis Medical Imaging	6.5.8	<p>QFR Training</p> <p>As far as training for the QFR is concerned, which used to be 2 days for a physical training in Leiden. We have further optimized the training and the procedure is now as follows:</p> <ul style="list-style-type: none"> • Remote training to a single or max 2 persons from the same institute by 2 hours of Virtual training by our team at Medis; • Next, the user needs to carry out 10 certification cases, which is all cloud-based and can be done following their own agenda; • Feedback is given by the Medis team on each case, and the user is certified when at least 7 out of 10 are correct. • In Nov 2020 we will have an e-Training module available, so that the initial remote training can be replaced by the e-Training. <p>All in all, a significant simplification of the training without sacrificing quality.</p>	<p>Thank you for your comment which the committee considered.</p> <p>The external assessment group noted that their base-case analysis assumes that training is delivered online (e-training). Therefore, these additional considerations do not change the cost-effectiveness results.</p>
32	Medis Medical Imaging	6.5.8	<p>Cost effectiveness</p> <p>Medis is constantly looking at the best business model for the QFR, and which may also change over time based on further experiences and feedback from the market, but for the UK we would like to propose the following price setting, which is different from the one that we have proposed so far.</p> <p>The basis will be the use of vouchers for a certain number of analyses, or annual licenses for centers that do at least 100 QFR analyses per year. It should also be stressed that such larger centers have usually multiple cath labs per center, and the annual licenses will be available on a server-client basis, that means connected to all the cath labs that require a QFR facility.</p>	<p>Thank you for your comment which the committee considered.</p> <p>The external assessment group provided an addendum which incorporates this update to the price structure in the cost effectiveness analysis.</p> <p>The committee noted that following an update to the price structure during consultation, QAngio QFR using an annual license became slightly cheaper but was less effective compared with the reference standards of FFR or iFR. However, given the small difference in costs and outcomes, the committee reiterated the need for clinical outcome data from studies that directly compare QAngio QFR and CAAS vFFR with FFR (see research</p>

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Theme: Costs and resource use

Comment number	Name and organisation	Section number	Comment	NICE Response
			<div><div><div><div><div><div>Vouchers:</div><div></div></div><div><div></div><div>Voucher price in GBP</div><div></div></div><div><div></div><div>Installation, training &</div><div></div></div></div><div><div>certification</div><div>10 QFR analyses</div><div>50 QFR analyses</div><div>100 QFR analyses</div></div><div><div>GBP 3.833</div><div>GBP 17.259</div><div>GBP 34.518</div></div><div><div>GBP 2.000</div><div>GBP 2.000</div><div>GBP 2.000</div></div></div></div><div><div><div>Annual Licenses:</div><div></div></div><div><div></div><div>Annual license</div><div></div></div><div><div></div><div>Installation, training &</div><div></div></div></div><div><div>certification</div><div>Low volume center (100-500 QFR)</div><div>Mid volume center (500-1000 QFR)</div><div>High volume center (1000-2000 QFR)</div></div><div><div>GBP 43.147,50</div><div>GBP 64.721,25</div><div>GBP 86.295,00</div></div><div><div>included</div><div>included</div><div>included</div></div></div>	recommendation 5.3). The committee concluded that given the uncertainty in clinical utility the cost effectiveness results were also uncertain. Changes were made to section 4.12 to reflect this consideration.
33	Health	1.1	Finally, do they save time? I have heard conflicting reports about this. There has to be a clear reduction in cost and time for them to be attractive against simply passing a pressure wire.	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

QAngio XA 3D QFR and CAAS vFFR imaging software for assessing coronary stenosis during invasive coronary angiography

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 5 November 2020

Theme: Research recommendations

Comment number	Name and organisation	Section number	Comment	NICE Response/EAG considerations
34	Pie Medical Imaging	5	There are some recommendations for further research, the aim of the research is reported but not how much evidence is needed that will support necessary claims.	<p>Thank you for your comment which the committee considered.</p> <p>The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for developing specific research study protocols as appropriate.</p>