

**NICE - HealthTech Programme (Diagnostics)**

**Digital technologies for assessing attention deficit hyperactivity disorder**

**Draft Guidance collated comments**

<b>Comment number</b>	<b>Name and organisation</b>	<b>Section number</b>	<b>Comment</b>	<b>Response</b>
1	Consultee 1	1.1	<p>Recommendation 1.1 aligns with previous research from our group (which I see cited in committee papers, page 179):</p> <p>30. Bellato AH, Charlotte L. Groom, Madeleine J. Simonoff, Emily Thapar, Anita Hollis, Chris Cortese, Samuele. Practitioner Review: Clinical utility of the QbTest for the assessment and diagnosis of attention-deficit/hyperactivity disorder - a systematic review and metaanalysis. Journal of child psychology and psychiatry, and allied disciplines 2023; <a href="https://dx.doi.org/10.1111/jcpp.13901">https://dx.doi.org/10.1111/jcpp.13901</a></p> <p>I suggest reporting this citation in final guidance, if possible.</p>	<p>Thank you for your comment which NICE considered.</p> <p>NICE guidance does not include citations as it is a summary of the committee's decision-making. The paper is cited in the External Assessment Report.</p>
2	Consultee 1	1.3	<p>Besides (or instead of) "effectiveness", would you consider adding "response" or "effects", to make it more easily interpretable and in line with challenges in determining when a treatment is considered "effective" (and by whom)?</p>	<p>Thank you for your comment which NICE considered.</p> <p>Treatment effectiveness has been replaced with response to treatment throughout for clarity.</p>
3	Consultee 1	1.5	<p>Looking at the narrative, it looks like last bullet point should be under "the impact of the digital technologies in section 1.3 for people with a diagnosis of ADHD when used:" (second level) and not first-level?</p>	<p>Thank you for your comment which NICE considered.</p>

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				This was a web formatting error, which has now been amended.
4	Consultee 1	3.12	As per previous comment, I suggest considering changing "effectiveness" to "response" or "effects".	<p>Thank you for your comment which NICE considered.</p> <p>Treatment effectiveness has been replaced with response to treatment throughout for clarity.</p>
5	Consultee 2		I am concerned about the research framework within which all our understanding of ADHD is based. I cannot see it framed within the kinetic chain of child development and normal, correctable barriers to development to good motor sensory integration i.e. the point at 7/8yo when a child should be able to work calmly with all senses and motor skills.	<p>Thank you for your comment which NICE considered.</p> <p>Specialist committee members with expertise in ADHD are involved in considering the evidence and making recommendations. A list of <a href="#">Specialist committee members</a> can be found on the NICE Website.</p>
6	Consultee 2		I do not believe that the people studied were screened for their (a) integration of primitive reflexes and hence bi-lateral integration of motor skills - if primitive reflexes are present they can cause a person to be hyper-alert (b) sound processing skills - these impact on all areas of development; if a child has a lot of disruption to their sound processing from say inner ear infection that can cause them to function quite chaotically. (b) binocular vision, the ability to focus with both eyes and not to suffer flickering vision. All of the above are correctable, but no-one checks them or supports them properly in all	<p>Thank you for your comment which NICE considered.</p> <p>The inclusion and exclusion criteria for study participants is listed in Appendix 3 Table 31 of the External Assessment Report.</p>

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			<p>children.</p> <p>So the sample was not assessed for other factors that might have produced similar issues but are correctable.</p>	
7	Consultee 2		<p>No there are huge costs associated with diagnosing lots of people as having ADHD and not having a programme to prevent the problems in the first place.</p> <p>Why do we not have health and education systems that support excellent development that minimise risk of other factors dysregulating child development?</p> <p>If we diagnose lots of youngsters as having ADHD and therefore needing extra support in the education system then how is that paid for?</p> <p>The system is already creaking under the pressure of SEN diagnoses; yet most of the clients I see have entirely correctable conditions.</p> <p>My more extreme clients e.g. Downes Syndrome and children in Care with extreme trauma do not get the support that they genuinely need on a timely basis. Consequently, many go on being challenging for for life. They are long term dependent either in community care homes or in prisons. That is a cost of flooding the SEN system with lots of children diagnosed as ADHD, it crowds out those with greater long-term needs.</p> <p>There is also the cost to the families and carers of these individuals who fight desperately for years for help which they deserve as of right. They often suffer from huge levels of stress.</p> <p>We have to be realistic we do not want to automate diagnosis of</p>	<p>Thank you for your comment which NICE considered.</p> <p>The resource use and costs associated with diagnosis of ADHD are accounted for in the cost-effectiveness estimates, including healthcare professional time and costs associated with the technologies (section 5.3.8 of the <a href="#">External Assessment Report</a>).</p> <p>The purpose of this NICE guidance is to determine whether the technologies set out in the <a href="#">scope</a> for assessing ADHD are clinically and cost effective for use in the NHS. Changes to the educational system is beyond the scope of this assessment.</p> <p>In section 3.7 of the Guidance the committee stated that the technologies should not be used as standalone tools</p>

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			<p>ADHD, the aim ought to be to prevent or remediate such issues as far as possible.</p> <p>Problems in the UK are made worse for many factors:</p> <ul style="list-style-type: none"> <li>(a) poor diets &amp; high levels of ultra processed foods</li> <li>(b) early start to formal education which stunts development</li> <li>(c) no physical education curriculum which supports the kinetic chain of child development (Contrast to Slovenia &amp; the Slofit programme - it is not perfect, but it is a lot better than the UK).</li> <li>(d) Tomatis sound therapy and the work of Dr Alfred Tomatis are barely recognised. Yet sound is our first myelinated sense and if it is blocked it can impact on global development.</li> <li>(e) The Behavioural Optometrists have no standard and recognised methods of working to ensure that cognitive visual processing is established in all. The profits are in the sales of visual aids. We need to sort out our understanding of how visual skills develop.</li> </ul> <p>Automating diagnosis of ADHD seems like IBM being asked to automate Ford Motor Companies Mismatched Invoice Department in the early 1980's.</p> <p>IBM sent Ford to Japan to see how Japanese companies operated. When Ford returned they solved the problem by not letting it arise in the first place - there was thus no need to automate.</p> <p>Let's design systems to maximise child development and if there is a genuine issue then let's ensure that we have the resources and knowledge in place to address those issues.</p>	<p>without a full clinical assessment from a trained healthcare professional, to prevent the situation of automated diagnosis occurring as highlighted in the comment. Experts highlighted the need for healthcare professionals to make diagnoses and decide on best care for people with suspected ADHD. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.</p>
8	Consultee 2		<p>No as I have noted in my other comments we need to go back to basics in all areas of child Health and Education and prevent problems or remediate them on a timely basis.</p> <p>That can for the most part be done more cheaply and effectively</p>	<p>Thank you for your comment which NICE considered.</p>

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			<p>within the education system if we reformed primary education and a bit of secondary to screen regularly as youngsters grow or experience trauma.</p> <p>Labels do not offer specific solutions.</p> <p>The SEN systems at a school and local authority level will be further swamped by demand, but no real solutions.</p> <p>Let's make our nation fit to learn, calmly.</p>	
9	Consultee 2	1.2	<p>No more research is need in new technologies to monitor gross motor skill development + sound processing + dynamic binocular vision and integrated motor sensory problem solving.</p> <p>We would then have a far better understanding of the root causes of issues and be able to monitor interventions to increase neural development.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The purpose of the NICE guidance is to determine whether the technologies set out in the <a href="#">scope</a> for assessing ADHD are clinically and cost effective for use in the NHS. Wider aspects of ADHD research are beyond the scope of this assessment.</p>
10	Consultee 2	1.4	<p>We need to be careful that commercial schemes are not more expensive and convoluted than basic solutions which can be easily implemented in any school environment. For example I have just screened 300+ 11/12 year olds in the North East using simple tests 95% had problems with some aspects of motor skills, sound and vision processing. It was easy to see just looking at bi-lateral movement, using the Tansley Figure Ground Test and the Thomson Software Solutions Eye Tracker using a Tobii eye tracking bar.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The setting for ADHD assessment outlined in the <a href="#">scope</a> is Secondary Care, rather than schools.</p>

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			Actually seeing the children was important we also picked up one child with cancer in the eye and others with a myriad of issues.	
11	Consultee 2	1.5	But honestly what is ADHD? Our current Health systems do not have a robust enough understanding of basic child development to 7/8 years old to identify what is a real "neurodiversity" and what is a correctable developmental delay.	Thank you for your comment which NICE considered.
12	Consultee 2	1.5	Mmm this seems a splendid computer programme to push people towards medication rather than dealing with the root causes of the issues and remediating as far as possible. Why would a Healthcare professional want to do that? Last week one of my adult autistic clients raved about how exciting it was to understand direction for the first time: left and right; and which direction buses were moving in - why do we not want to skill people up?	Thank you for your comment which NICE considered.  The <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> states that both diagnosis of ADHD and medication initiation for ADHD should only be made by a healthcare professional with training and expertise in diagnosing and managing ADHD. The technologies have been assessed to support decisions made by healthcare professionals, not replace them as decision makers. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.

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13	Consultee 2	2.1	<p>Is it? The brain is connected to the body. I find when I do specific motor skills exercises, sound therapy and visual exercises with clients I can significantly improve their concentration skills.</p> <p>Modern environments have changed dramatically in the last few decades. Life is vastly more passive. We need to design childhood to maximise skills development for a hunter-gatherer i.e. the stage to which we have evolved.</p> <p>Humans are neuroplastic they can effect change at any stage in life if they so wish.</p>	Thank you for your comment which NICE considered.
14	Consultee 2	2.9	<p>It seems an expensive way to go through basic exercises which could be part of every child's education. If there are then still problems then a skilled professional needs to see the child and assess in detail.</p> <p>I have videos on Youtube which many people use for free.</p>	Thank you for your comment which NICE considered.
15	Consultee 2	3.1	<p>In my experience many families in the long-term are disappointed when it dawns on them that there is no strategy to sort out the problems.</p> <p>Diagnosis is just pushing the problem down the line to local authorities and schools who do not have the resources.</p> <p>We need a better plan to support good development for all. The scale of the problems related to basic child development in the UK are such that it needs to be part of the school curriculum.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The purpose of this NICE guidance is to determine whether the technologies set out in the <a href="#">scope</a> for assessing ADHD are clinically and cost effective for use in the NHS. Changes to the educational system is beyond the scope of this assessment.</p>

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16	Consultee 2	3.1	<p>Which is why child development should be a central part of the UK education system so that all aspects of development are supported and assessed throughout the school years and issues are adessed as soon as possible at a low cost. Problems are not allowed to drift on for years unidentified until there is a crisis.</p> <p>All health professionals should also be trained in the basics of child development which they are not currently. For example, Opticians are not trained in visual processing (I know my own son was blinded by my local hospital Optometrist, I sorted the mess out); Audiologists are not trained in sound processing, nor are Speech &amp; Language Therapists; PE professionals and Occupational Therapists are not routinely trained in primitive reflexes and how they impact on higher level skills development.</p> <p>Currently our Health and Education systems are not fit for purpose in this area. Automating ignorance seems yet more dangerous.</p>	<p>Thank you for your comment which NICE considered.</p> <p>Please see response to comment 15.</p>
17	Consultee 2	3.8	<p>technologies with headsets are not suitable for anyone without good steopsis of vision. I bet no-one checked this. Vision is our last sense to develop fully and if there are problems with motor skills or sound it will not be properly established. i.e. no-one with ADHD is likely to have good visual development. So the equipment is not suitable.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee noted in section 3.8 of the Guidance that the technologies may not be suitable for some people with visual impairments and other learning or physical disabilities.</p>
18	Consultee 2	3.14	<p>It might be cheaper for the NHS but diagnosing larger numbers of people with ADHD is just posting problems down to Local Authorities and Schools who do not have the resources to deal with them as individual cases.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The resource use and costs associated with diagnosis of ADHD are accounted for in the cost-effectiveness estimates, including healthcare</p>



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				<p>professional time and costs associated with the technologies (section 5.3.8 of the <a href="#">External Assessment Report</a>).</p>
19	Consultee 2	6	<p>Is there anyone on this committee who has actually moved a child on from ADHD using non-invasive therapies? <a href="https://www.fit-2-learn.com/_webedit/uploaded-files/All%20Files/Research/Case-Study-Year-7-girl-with-ADHD.pdf">https://www.fit-2-learn.com/_webedit/uploaded-files/All%20Files/Research/Case-Study-Year-7-girl-with-ADHD.pdf</a></p>	<p>Thank you for your comment which NICE considered.</p> <p>Specialist committee members with expertise in ADHD are involved in considering the evidence and making recommendations. A list of <a href="#">Specialist committee members</a> can be found on the NICE Website.</p>
20	Consultee 3	3.7	<p>The committee acknowledges that most evidence investigated the diagnostic accuracy of digital tools compared to clinical assessment. However, it fails to comment on this (instead, commenting on the higher accuracy of combined digital and clinical assessment). If standalone digital assessment is shown to be equal in accuracy to clinical assessment then it should still be acceptable clinical practice. The committee states that the AQUA trial combines QbTest information in a way that better matches real-world practice, pre-supposing what real-world practice should be. It may well be that the accuracy of standalone digital tools vs clinical assessment was discussed but has been omitted from the consultation. If so, can this discussion be recorded.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The marketing authorisation for the technologies are based on the indication for use which states that they should be used to support healthcare professional decision making, not to replace it. The committee stated in section 3.7 of the Guidance that the technologies should not be used as standalone tools without a full</p>

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				<p>clinical assessment from a trained healthcare professional. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.</p> <p>The committee does not normally make recommendations on using a technology outside the terms of its regulatory approval (<a href="#">NICE health technology evaluation manual</a> section 6.1.11).</p>
21	Consultee 4 Qbtech	1.2	<p>Given the significant challenges for the NHS in providing the capacity needed to meet demand, QbCheck offers services the opportunity to realise the benefits described for QbTest with a reduced need for clinic appointments. This could be especially valuable for treatment evaluation were the baseline test for each patient serves as their control for tests completed on treatment initiation, titration or change. QbCheck has the same licensed indications as QbTest, an identical test construct and equivalence data necessary for FDA clearance. A recent paper (June 2024) concluded that QbCheck can be a useful objective measure that could be incorporated in guiding treatment decisions, remote monitoring of ADHD medication, tracking of ADHD symptom regulation, and optimizing treatment outcomes for those with ADHD.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee noted in the guidance section 3.12 that little evidence was available for QbTest or QbCheck for the evaluation of treatment response.</p> <p>The EAG have reviewed the paper shared and concluded that it would not meet the criteria for their review as it</p>

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			<p><a href="https://www.scivisionpub.com/pdfs/utilizing-remote-objective-adhd-testing-to-monitor-symptom-improvement-following-medication-treatment-3330.pdf">https://www.scivisionpub.com/pdfs/utilizing-remote-objective-adhd-testing-to-monitor-symptom-improvement-following-medication-treatment-3330.pdf</a></p>	<p>does not report any information on accuracy, impact on patient outcomes or process measures. The inclusion criteria for the EAG's review can be found in the <a href="#">Protocol</a>. The guidance has not been changed.</p>
22	Consultee 5 Braingaze		<p>Dear EAG Committee, Thank you for the comprehensive report on the Diagnostic Assessment Programme. The Diagnostic Assessment Report, commissioned by the NIHR Evidence Synthesis Programme on behalf of the National Institute for Health and Care Excellence, aims to evaluate whether new technologies can improve ADHD diagnosis. The objective of the report is to know whether using new technologies will mean that more people are correctly told whether or not they have ADHD.</p> <p>After careful review, we would like to provide the following comments:</p> <p>Has All of the Relevant Evidence Been Taken into Account?</p> <p>The NICE Diagnostics Programme aims to evaluate technologies for the assessment of ADHD. The primary inclusion criteria focus on technologies that combine measures of cognition and motor (physical) activity. The technologies selected for evaluation are QbTest, QbCheck, EF Sim, EF Sim Web Version, Nesplora Kids, and Nesplora Adults.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The technologies included in the assessment are specified in the <a href="#">scope</a> published on the NICE website. This was generated based on discussions with healthcare professionals working in this area, and a scoping workshop held for the topic. The <a href="#">NICE health technology programme manual</a> section 2 describes the scoping process in more detail.</p> <p>Section 3.13 of the Guidance notes how the manufacturers emphasised that their tests were considerably different in their mechanisms of action and output to the QbTest. The committee</p>

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			<p>It is unclear why the scope was restricted to these specific technologies, especially considering the broader goal of digital technology in healthcare: to enhance diagnostic accuracy, expedite the diagnostic process, reduce patient waiting lists, and optimize NHS resources. There are other technologies on the market that not only quantify ADHD traits but also provide markers of these traits captured via sensors.</p> <p>Encompassing a wider range of digital technologies would better support the overarching aims of improving diagnostic accuracy, speeding up the diagnostic process, reducing patient waiting lists, and freeing up NHS resources. A more inclusive evaluation process would foster innovation and competition, ultimately benefiting patients and the healthcare system.</p> <p>Are the summaries of clinical and cost-effectiveness reasonable interpretations of the evidence?</p> <p>The EAG has focussed on tools for which health economics data is available, which led in practice to the exclusion of all but QbTest being considered.</p> <p>The relevant data for modelling cost-effectiveness of QbTest is primarily derived from the AQUA trial. The results indicate that in real-world clinical settings, QbTest does not significantly improve diagnostic accuracy. To us, it seems that the health economics case that could be made for QbTest is fundamentally linked to the positive impact on speed and confidence of the clinical ADHD diagnostic process caused by a visual report providing objective measures for cognition and activity.</p>	<p>therefore concluded that the data generated using QbTest was not generalisable to any other technologies in this evaluation and that there was limited data for the other technologies considered.</p>

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			<p>If the presence of an objective report is the main identified driver of positive health economics, it is fair to assume that similar reports being produced by other tools (some of which show better specificity) would yield similar health economics benefits.</p> <p>Therefore, in our opinion, a crucial aspect of determining cost-effectiveness in the AQUA trial is confidence in the diagnostic reports produced by QbTest, leading to shorter diagnostic times and reduced costs. Since the evaluated technologies provide objective measures of cognition and motor activity, the cost-effectiveness results of QbTest could be generalized to other technologies.</p> <p>Are the recommendations sound, and a suitable basis for guidance to the NHS?</p> <p>We appreciate the thorough evaluation of the selected digital technologies for ADHD assessment. Digital technology is indeed a novel approach to mental health care, and we anticipate that new and improved technologies will continue to emerge.</p> <p>In that sense, we applaud the conclusions formulated around the need for broader assessment of a broader range of tools in future studies. We emphasize that this should not pre-select any (combination of) sensor and support approaches, focusing entirely on the support function provided by the tool, not on the specific technologies or parameter classes covered by it.</p> <p>We are concerned that the guidance document in its present form could in practice cause NHS clinicians and other decision makers to focus their consideration of support tools on QbTest thereby increasing the risk of a monopoly for QbTech in the UK market. By not explicitly acknowledging the likely similar health economics</p>	

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			<p>impact that other tools providing objective measures for key aspects of ADHD will have, there is a risk of it stifling rather than stimulating innovation and competition, achieving the opposite of the UK's intended goals.</p> <p>It is our opinion the EAG should go beyond the methodically sound assessment of a very stringent selection of specific types of sensor and CPT data and studies. It should provide the NHS with realistic guidance that facilitates the adoption of clinically useful, efficient, and economically positive solutions, thereby helping the NHS to evaluate all viable alternatives.</p>	
23	Consultee 6 NHS England		<p>There appears to be an absence of data as to whether the disciplinary background of the ADHD assessor makes a difference to how effective or not QbT is in assisting speed of diagnosis. In AQUA study, the published paper groups assessors together - only dividing them into paediatric teams and CAMHS teams. However, looking at the backgrounds of the individual assessors, these were very diverse covering a wide range of disciplines. There is also a lack of detailed information about individual levels of ADHD expertise/experience.</p> <p><a href="https://emahsn.org.uk/component/rsfiles/download-file/files?path=our-work%252Ffour-innovations%252FADHD%2BFOCUS%2Bevaluation%2Breport%2B-%2BFINAL%2Bv.1.0%2B18.10.22.pdf&amp;Itemid=1457">https://emahsn.org.uk/component/rsfiles/download-file/files?path=our-work%252Ffour-innovations%252FADHD%2BFOCUS%2Bevaluation%2Breport%2B-%2BFINAL%2Bv.1.0%2B18.10.22.pdf&amp;Itemid=1457</a></p> <p>Exploring the widely touted finding that QbT reduces the number of clinical appointments needed before a diagnosis is made, it seems QbT makes more of a difference to speed of ADHD diagnosis for community paediatric teams than for CAMHS teams.</p> <p>Findings from the Focus ADHD Programme National Evaluation (October 2022) Number of clinical appointments saved 11.5% (18.9% saved for Paediatric services and 9.2% saved for CAMHS Services)</p>	<p>Thank you for your comment which NICE considered.</p> <p>The AQUA trial did not provide any data to allow the external assessment group (EAG) to explore the impact of background of the ADHD assessor on the diagnosis rate. In section 3.5 of the Guidance, the committee noted that there could be variation in clinical practice for ADHD assessment across the NHS and was unsure whether the impact of QbTest would be the same everywhere. But it noted that the AQUA trial was done across 10 non-academic sites across the UK in both child and adolescent mental health services and community</p>

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			<p>It seems this is a non-significant reduction in number of clinical appointments for CAMHS but a significant reduction in number of clinical appointments for Paediatrics.</p> <p>Do Paeds teams and CAMHS teams see the same children? Are CAMHS teams seeing more complex cases, older children?</p> <p>There seems a lack of data regarding age of the child at diagnosis with and without QbT. Is there an age effect, making QbT more useful in speeding diagnoses in certain age groups?</p> <p>Blanket support for QbT in ADHD assessment of children does not seem to be supported by the current findings.</p> <p>In AQUA the follow up period was only 6 months and so it is not known whether those who were undiagnosed at 6/12 went on to get ADHD diagnoses, ADHD + comorbidities or another diagnostic conclusion. This also seems to have important implications</p>	<p>paediatric clinics, which provided reassurance. Scenario analyses were also run by the EAG, and considered by the committee, that reduced the size of benefit from using the QbTest as reported in the AQUA trial. This included an analysis that explored the impact of a reduced benefit in the proportion of people diagnosed at 6 months using the QbTest, using the lower 95% confidence interval from the AQUA trial (see scenario 15, section 5.4 of the <a href="#">External Assessment Report</a>). The cost effectiveness estimate from this scenario still indicated that QbTest was cost effective.</p> <p>The comment notes that the FOCUS study indicated that there was an increase in the number of clinical appointments saved for paediatric services (albeit less than for CAMHS Services) with QbTest use. However, it should be noted that the EAG highlighted that this study was severely impacted by the Covid</p>

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				<p>pandemic (section 4.2.3 of the <a href="#">External Assessment Report</a>).</p> <p>The participants in the AQUA trial had a mean age of 9.5 years in both QbOpen and QbBlind arms, and ranged from 6 to 17 years. The committee considered subgroup data by age (6 to 12 years and over 12 years) from the AQUA trial where this was reported, however as highlighted by the EAG there was minimal such evidence. The committee considered that the overall analysis which involved both younger children and adolescents was suitable to recommend the QbTest for use in all under 18s.</p>
24	Consultee 6 NHS England		<p>1. Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? There is the issue of training time (not sure how long training takes, says initial, 3 month update and annual training available) – which would have a negative impact on service/staff capacity and costs associated.</p> <p>2. re cost effectiveness has the cost of training been included?</p> <p>3. cost effective reduction in diagnostic decision time seems like a desirable outcome. What is not clear is how this is achieved - which component of diagnostic decision time was reduced by deployment of the tool?</p>	<p>Thank you for your comment which NICE considered.</p> <p>Training materials are provided by the company and included in the cost of QbTest, and so are included in the model (as noted in section 5.3.8 of the <a href="#">External Assessment Report</a>). The results of the cost-effectiveness</p>



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			<p>4. Slight concern that rather than necessarily be useful it is possible that we will introduce an additional cost into the diagnostic pathway. This may ironically play out particularly in the Independent Sector (with further burden on parents) even if the hope is that more rapid diagnosis will decrease the pressure to seek Independent Sector Assessments.</p>	<p>analysis was robust to changes in cost of the QbTest. The QbTest strategy remained cost-effective in all scenario analyses in which the cost of a test was varied, including doubling the cost of the test.</p> <p>The resource use and costs associated with diagnosis of ADHD are accounted for in the cost-effectiveness estimates, including healthcare professional time and costs associated with the technologies (section 5.3.8 of the <a href="#">External Assessment Report</a>).</p> <p>In the cost-effectiveness model, including QbTest alongside standard clinical assessment increased the rate of receiving a diagnostic decision. This was based on data from AQUA reporting fewer appointments until diagnostic decision was reached (See also section 5.3.2 and 5.3.3 of the External Assessment Report). The EAG explained that they did not have data from any of the studies</p>

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				<p>included in the review on what component of the diagnostic decision time was reduced by use of the tests. However, there is data on the reduction in the number of appointments and also on the time-ratio for consultant time from the AQUA study (reported in section 5.3 of the <a href="#">External Assessment Report</a>), and this was used in the cost-effectiveness model.</p>
25	Consultee 6 NHS England		<p>Are the recommendations sound, and a suitable basis for guidance to the NHS?</p> <p>1. The evidence for the effectiveness of any digital technology in either the diagnosis arm or treatment effectiveness arms is weak-if NICE applied their usual scoring of level of evidence, would it even pass the mark?</p> <p>Whilst explicitly stating there is no good evidence of any digital tech in the ongoing assessment of the effectiveness of treatment, the paper than confuses by mentioning it as an option</p> <p>If the point of using digital tech is to "speed up " the diagnosis and support diagnostic uncertainty in clinical assessment alone, then not sure how making qb testing simply part of the normal diagnostic pathway, will make any difference? Perhaps suggesting it as an option where there is diagnostic uncertainty following clinical assessment, it may help-but this will not reduce waiting lists or speed up the diagnostic process-which was the initial point of this appraisal. What is the specificity/sensitivity of a negative QB test? The helpful bit -if it can screen out large numbers of CYP waiting for a clinical</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee considered the evidence for the use of QbTest in children and young people from the AQUA trial. The EAG's quality and risk of bias assessment using the RoB2 tool noted that only time-to-event outcomes were at a high risk of bias. However, the EAG explained that this was not an issue for outcomes for people who had received a diagnosis in the study period. Despite some limitations of the AQUA trial, the committee considered</p>

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			<p>diagnostic assessment it becomes a very helpful tool as long as its sensitivity and specificity are high for a negative result.</p> <p>2. Looks like diagnostic accuracy is uncertain from information provided.</p> <p>3. It seems there are questions over the diagnostic accuracy hence confusing why being suggested as an option. Maybe a role in triage rather than diagnosis (however not sure whether evidence would support this).</p> <p>4. If its helpful it was trialled at Tees, Esk and Wear Valley NHS Trust – however the feedback is that it did not significantly reduce the need for a full assessment – so did not work as a triage tool or as a “screening tool” but instead was a diagnostic aid.</p>	<p>it was suitable for decision making (section 3.5 of the guidance).</p> <p>Section 1.3 of the guidance, which refers to using technologies to evaluate the effectiveness of treatment, is part of the committee research only recommendations. These state (in section 1.2 and 1.3) that more research is needed before these technologies can be used for this purpose in the NHS. The committee noted in sections 3.12 and 3.18 that little evidence is available on whether any technologies are clinically or cost effective for evaluating treatment effectiveness.</p> <p>The committee considered evidence from the AQUA randomised controlled trial which used the QbTest in addition to the normal diagnostic process (section 3.5 of the Guidance). The committee concluded that the evidence suggested that when used with standard clinical</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>assessment by a healthcare professional, QbTest was likely to allow diagnostic decisions to be made quicker. The AQUA trial findings were supported by data from 5 before-and-after studies which found that using QbTest resulted in fewer consultations being needed to reach a diagnostic decision (section 4.2.3 of the Guidance). Qualitative evidence suggested that this was in part due to healthcare professionals being more confident in their decisions when using QbTest.</p> <p>The committee noted that the AQUA trial showed very similar specificity when incorporating QbTest into clinical assessment, to standard assessment alone. The committee concluded that there was some uncertainty about the impact on accuracy of using the tests to detect ADHD. But it recalled that the tests should only be used to supplement healthcare professional judgement, not to replace it (section 3.9 of the Draft</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>guidance). Scenario analysis varying the diagnostic accuracy parameters demonstrated no large impact on cost effectiveness estimates (section 5.5.2 of the <a href="#">External Assessment Report</a>).</p> <p>The committee stated in section 3.7 of the Guidance that the technologies should not be used as standalone tools without a full clinical assessment from a trained healthcare professional, including that it should not be used for triage assessments without appropriate healthcare professional input. Use of the technologies as standalone tools for screening or triage is not in line with its indication for use.</p>
26	Consultee 6 NHS England		<p>Could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology</p> <p>1. BAME children and girls are not recognised, referred and diagnosed with ADHD compared to general population. Qb Test addresses this situation as the test is objective compared to most of the evidence for current diagnosis is subjective.</p>	<p>Thank you for your comment which NICE considered.</p> <p>Information on the included populations is reported in the appendix tables of the <a href="#">External Assessment Report</a>. Table 42 reports specifically on patient</p>

Comment number	Name and organisation	Section number	Comment	Response
			<p>2. Do we know if the population these were tested on was representative of the population. Were some groups underrepresented? (quite common). Did they see any disparities across eg ethnic groups?</p>	<p>demographics related to equalities.</p> <p>For the AQUA study, 21% of participants were female. Of the participants where ethnicity data were available, 11% were described as “mixed or other”.</p> <p>The EAG did not identify any accuracy or impact data stratified by sex or ethnicity subgroup, however, qualitative findings highlighted that clinicians felt that objective tests may help to differentiate ADHD subtypes (particularly subtle presentation, common in girls), and supported diagnosis in the presence of comorbidities (see section 4.2.4 of the <a href="#">External Assessment Report</a>). This was considered by the committee in its decision making as described in section 3.3 of the Guidance.</p>

27	Consultee 6 NHS England		<p>Could have any adverse effect on people with a particular disability or disabilities.</p> <p>1. In terms of the EQIA questions-the paper answers that itself-it suggests it will increase disparity for those who will struggle to use the technology or interact with its commands including some CYP with LD and Autism, or other visual or sensory impairments</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee did acknowledge in section 3.8 of the guidance that the technologies may not be suitable for all people. However, the committee also raised that the technologies should not be used without a full standard assessment, and that that people for whom the technologies are unsuitable or are not tolerated should still receive a full clinical assessment during diagnosis.</p>
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Comment number	Name and organisation	Section number	Comment	Response
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28	Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust		<p>Overall, we consider that these tools are, as yet, of unproven value. Hence, we agree with the draft, it is too early to adopt them for the adult population.</p> <p>We identified the following concerns:</p> <ol style="list-style-type: none"> <li>1. Over time, busy or inexperienced clinicians may potentially place too much emphasis on these tools and cut back on history taking, in an effort to save time and “get through the waiting list”.</li> <li>2. NHS Trusts are at risk of becoming dependent on the one and only company who make the product (eg. Qb test). That company can then charge whatever they like. Such a reliance would not be cost-effective.</li> <li>3. As yet it is not clear what the purpose of these tools would be for the adult population? We wondered what new information they provide and whether that information could be obtained by other methods? None of these tools are diagnostic tests and their reliability is unclear.</li> <li>4. As with any investigation, the key question is “How will this test influence my management? For example, if the Qb concurs with clinical judgement, then it hasn’t told the clinician anything that they didn’t already know. If the Qb contradicts clinical judgement; then surely, clinicians will prioritise their own judgement over the “IT tool”. Either way; the Qb result has not altered the patient management, so what was the point of it? We believe that there is a danger of being blinded by the “promise of new technology” and clever marketing. We have all had experience of technology making big promises within the NHS, however in practice, it rarely delivers. When dealing with patients, there is no substitute to taking a careful history.</li> </ol>	<p>Thank you for your comment which NICE considered.</p> <p>The committee agreed that no technologies had sufficient evidence to be considered for use in the adult population (section 3.10 of the Guidance).</p> <p>The committee stated in section 3.7 of the Guidance that the technologies should not be used as standalone tools without a full clinical assessment from a trained healthcare professional. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.</p> <p>The QbTest is only recommend as cost-effective on the basis of the test cost as stated in the Guidance section 2.10 Table 1. The committee noted that all technologies other than QbTest have much less</p>
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Comment number	Name and organisation	Section number	Comment	Response
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				<p>evidence. Manufacturers emphasized that the technologies were considerably different, and therefore the committee concluded that data for QbTest was not generalizable to other technologies. As such, cost effectiveness could not be estimated, and these technologies were not recommended (section 3.13 of the guidance).</p> <p>The committee has recommended that all technologies can only be used in research in the adult population (section 1.2). The committee concluded that there is limited evidence for all of the technologies when used for adults, and the evidence from people under 18 is not generalisable to adults. So, more research is needed in this group. Regarding what information is provided by the test, please see the <a href="#">scope</a> which describes the test and its outputs.</p>
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Comment number	Name and organisation	Section number	Comment	Response
				<p>Please see response to comment 25 regarding the evidence considered for the use of QbTest alongside standard clinical assessment.</p> <p>The committee stated in section 3.7 of the Guidance that the technologies should not be used as standalone tools without a full clinical assessment (as outlined in <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a>) from a trained healthcare professional. This includes a full clinical and psychosocial assessment as well as a full developmental and psychiatric history. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.</p>
29	Consultee 7 Tees, Esk and Wear Valleys NHS	1.1	Agree could be used “as an option” in children and young people but would question whether there is sufficient evidence that it is cost-effective to do so.	<p>Thank you for your comment which NICE considered.</p> <p>The committee considered that economic modelling using data</p>

Comment number	Name and organisation	Section number	Comment	Response
	Foundation Trust			from the AQUA randomised controlled trial was suitable for decision-making, and this showed that including QbTest in addition to standard assessment is cost effective compared with standard clinical assessment alone for children and young people (section 3.14 of the Guidance). The finding that QbTest is cost- effective in children and young people was robust to the range of scenario and sensitivity analyses performed.
30	Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust	1.1	Agree that more research is needed on all of the tests for adults to evidence cost-effectiveness of NHS care provision.	Thank you for your comment which NICE considered.
31	Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust	1.5	Agree that more research is needed. It is unclear how “additional information from digital technologies may help people to get diagnostic decisions quicker and help healthcare professionals be more confident in their decisions”, particularly as these are in addition to standard assessment processes. If the test result does not align with the clinical judgement of the trained specialist, it is unlikely that their confidence as a diagnostician would improve. Is this statement within the draft guidance, based on an assumption that the test would be more accurate than clinical judgement?	Thank you for your comment which NICE considered.  Please see response to comment 25 regarding the evidence considered for the use of QbTest alongside standard clinical assessment.

Comment number	Name and organisation	Section number	Comment	Response
				<p>The economic model base case did not assume a difference in accuracy between standard clinical judgement and the QbTest. Scenario analyses which varied diagnostic accuracy parameters were run, but showed no large impacts on cost effectiveness estimates (section 5.5.2 of the <a href="#">External Assessment Report</a>).</p>
32	<p>Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust</p>	3.7	<p>It is clear that there is no replacement for the clinical judgement of trained healthcare professionals, which remains necessary in all cases. This section suggests that all of the standard assessment processes will still need to be undertaken and that these tests are in addition to these. Therefore, as opposed to shortening the assessment, this is an additional step in the process that may add additional time to the duration of the assessment period – and with significant additional financial implications. It is possible therefore that waiting lists could further increase as a result as opposed to reducing waiting times.</p>	<p>Thank you for your comment which NICE considered.</p> <p>Please see response to comment 25 regarding the evidence considered for the use of QbTest alongside standard clinical assessment.</p> <p>In the cost-effectiveness model, including QbTest alongside standard clinical assessment increased the rate of receiving a diagnostic decision. This was based on evidence from the AQUA trial which showed a reduction in number and length of appointments until a diagnostic decision was reached (See also section 5.3.2 and 5.3.3 of the</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>External Assessment Report). The committee also considered the qualitative evidence identified that highlighted that healthcare professionals found the information from tests increased their confidence in decision making (section 3.3 of the guidance).</p>
33	<p>Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust</p>	3.8	<p>It is estimated that around 75% of adults with ADHD will have one or more comorbidities and that there are a number of factors that could impede performance whilst undertaking such tests (for example, physical illness, taking sedating medications, being under the influence of illicit or other substances, other mental health conditions, intellectual disabilities, emotional distress, anxiety, Autism Spectrum Disorders, visual or hearing impairment etc.). Many of these are commonly comorbid for people with ADHD (both children and adults), which could severely influence the usage / reliability of such technologies in the ADHD population.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee noted in section 3.8 of the Guidance that technologies may not be suitable for people with existing learning disabilities, visual and physical impairments.</p> <p>In section 3.11 of the Guidance, the committee noted that it may be difficult to reach a diagnosis in people with co- existing conditions that overlap with symptoms of ADHD using standard clinical assessment. They noted that the additional information provided by technologies may have benefits for diagnosis in such complex cases (see further details in</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>response to comment 34 below).</p> <p>The committee considered the results from the AQUA study which included patients with additional diagnoses and comorbidities (see further details in response to comment 34 below).</p> <p>The committee concluded that there is limited evidence for the use of any of the technologies in adults, and the evidence from people under 18 is not generalisable to adults and that further research is needed. Section 3.10 of the guidance has been amended to emphasise the need for further data collection in adults representing the population with comorbidities.</p>

34	Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust	3.11	<p>In the most complex cases i.e., usually those people with multiple physical or mental health comorbidities, performance in such tests is potentially more likely to be impaired, as a result of the comorbidities.</p> <p>As opposed to such tests being used in complex cases, these results could potentially be the least accurate. The job of a diagnostician is to determine that presenting symptoms and functional difficulties are directly attributable to an ADHD (and not other causes). Whilst these tests would give a value on “performance”, they may not be able to discriminate between ADHD and other causes that may be impeding performance and in such complex cases, would question both the clinical value and cost-effectiveness.</p>	<p>Thank you for your comment which NICE considered.</p> <p>In section 3.11 of the Guidance, the committee noted that in instances of co-existing conditions with overlapping traits with ADHD and cases where substantial information is missing, the QbTest may provide additional information to inform clinician’s diagnostic decisions as part of the entire diagnostic process.</p> <p>Included in the AQUA study were patients with the following diagnoses (n=241; allows more than one diagnosis per patient): 71% ADHD; 35% oppositional defiant disorder/conduct</p>
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Comment number	Name and organisation	Section number	Comment	Response
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				<p>disorder; 20% any anxiety disorder; 17% chronic tic disorder/ Tourette syndrome; 9% autism spectrum disorder; 3% depressive disorder; 11% learning difficulties; 0.4% attachment disorder; 19% no psychiatric diagnoses. The committee considered the AQUA trial to be a good representation of the population who would be having the test in the NHS. Section 3.11 of the guidance has been amended to include more information on the population in the AQUA trial.</p>
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35	Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust	3.14	The Qb test would be in addition to standard diagnostic processes - it is another source of assessment data, however, does not replace the need for thorough holistic assessment nor clinical judgement. It is unclear how cost-effectiveness has been demonstrated (limited evidence), particularly as there is a need for commitment to ongoing staff training regarding the interpretation of results. In the context of national recruitment / retention issues, training is likely to come at significant resource cost when there is a high staff turnover. This applies to those working with both children and adult ADHD populations, as well as the cost of the technology itself. This comment also applies to section 3.16.	Thank you for your comment which NICE considered.  A full description of the cost effectiveness model and results are described in section 5 of the <a href="#">External Assessment Report</a> .  Training materials are provided by the company and included in the cost of QbTest, and so are included in the model (as noted in section 5.3.8 of the <a href="#">External Assessment Report</a> ). The cost-effectiveness of the QbTest strategy remained cost-effective in all scenario analyses in which the cost of a test was
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Comment number	Name and organisation	Section number	Comment	Response
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				<p>varied. The resource use and costs associated with diagnosis of ADHD are accounted for in the cost-effectiveness estimates, including healthcare professional time and costs associated with the technologies (section 5.3.8 of the <a href="#">External Assessment Report</a>).</p> <p>In the cost-effectiveness model, including QbTest alongside standard clinical assessment increased the rate of receiving a diagnostic decision. This was based on evidence from the AQUA trial which showed a reduction in number and length of appointments until diagnostic decision was reached (see also section 5.3.2 and 5.3.3 of the External Assessment Report).</p>
36	<p>Consultee 7 Tees, Esk and Wear Valleys NHS Foundation Trust</p>	3.17	<p>ADHD is a 'differential diagnosis' and consideration of ADHD is undertaken as part of a wider bio-psychosocial assessment of the person - meaning that all other potential causes of symptoms (including Autism, medical causes, other mental health issues, substance use, other neurological conditions), need to be fully considered prior to concluding a diagnosis of ADHD. The 'idea' or suggestion that this assessment can be undertaken safely and effectively over two sessions (particularly in complex</p>	<p>Thank you for your comment which NICE considered.</p> <p>This guidance does not suggest the number of sessions necessary to make a diagnostic decision.</p>

Comment number	Name and organisation	Section number	Comment	Response
			<p>cases i.e., most adults and some children) is a concept that is misleading (particularly to those commissioners of services and stakeholders) and must be strongly challenged.</p> <p>Assessments should be longitudinal and multi-faceted, involve gathering data from several sources and in complex cases involve multi-disciplinary team oversight. These ‘tests’ could be one data source (however, comorbidities may impede performance in this complex patient group), but other data sources are also necessary to improve robustness and diagnostic reliability.</p> <p>Unfortunately, there have been examples where diagnoses of ADHD have been formed following a failure to consider other comorbidities, vulnerabilities, and without gathering information from other agencies / data sources (often one or two 60-minute remote / video consultations via some providers), with tragic adverse patient outcomes.</p> <p>Diagnosing ADHD should be in line with diagnosing any other mental health or neurodevelopmental disorder. The time taken to conclude a diagnosis will vary based on the needs and circumstances of the individual. If the “two hours” time frame is portrayed as the norm within guidance, this is likely to adversely affect the quality and reliability of diagnostic assessments. Mainstream Mental Health Services should be appropriately commissioned to support person-centred, holistic, need- focussed assessments (inclusive of consideration of neurodevelopmental related needs) as part of routine practice in primary, secondary and tertiary care services (akin to the stepped-care model of depression with similar prevalence). Diagnostically aligned services / assessments can lead to assessor bias and failure to adequately consider the impact of other conditions and disorders. In line with Community Transformation principles, this requires a paradigm shift and huge change in culture. The components of an ADHD assessment mirror the components of a standard high quality mental health assessment</p>	<p>The cost-effectiveness model assumed a distribution for the number of appointments until either ADHD is ruled out or a diagnosis is made. The model does not assume that there are only 2 appointments, but the distribution of the number of appointments was based on the FOCUS ADHD study which found an average number of appointments to be 3.22, although this was very variable across individuals with a skewed distribution. In those who had not yet received a diagnosis by 6 months the average number of appointments was approximately 15. These figures were used in the model.</p> <p>For scenario analysis which modelled the use of QbTest for complex cases only, the EAG assumed that a “simple case” (where diagnosis is straightforward) would occur after 2 appointments, and that complex cases would take longer than 2 appointments. The 2 appointment cut-off was</p>

Comment number	Name and organisation	Section number	Comment	Response
			(a two-hour time frame would not be applied when assessing for any other mental health, physical health or neurodevelopmental disorder, so why specify this within the assessment of ADHD?). Continuing to “silo” ADHD and the assessment of ADHD as a “specialism” away from mainstream mental health services is damaging to the quest of ensuring equitability of mental health support for this population at all levels of the care system.	used as a proxy to define a point after which QbTest could be used if a diagnosis isn’t reached yet, in the absence of data on this, rather than a suggestion about the number of appointments that should happen. Section 3.17 of the guidance has been amended to clarify that this was a modelled scenario used for exploratory purposes.
37	Consultee 8 PeiliVision	1	We would like to thank the committee for their feedback and we will ensure to have further research validating our technology as a diagnosis support tool. We also would like to emphasise the importance of analyzing other underlying neurological conditions like prospective memory and autism spectrum related deficits. Comorbidity is known to be high in ADHD patients, so the earliest possible detection of a more holistic view of executive functions would have a direct implication of reducing unnecessary ADHD diagnosis appointments. Our technology as a real life simulation tool facilitates analysis of multiple root causes, not just ADHD, and we hope to bring this modern technology into current practises jointly with the NHS.	Thank you for your comment which NICE considered.
38	Consultee 9 British Association for Neurodiversity		Only the QB test has sufficient data to be included in the consideration.	Thank you for your comment which NICE considered.

Comment number	Name and organisation	Section number	Comment	Response
39	Consultee 9 British Association for Neurodiversity		<p>Its use has been evaluated in the AQUA trial whose endpoint was time to diagnostic assessment within a 6 month timeframe. The conclusions of the study were that:</p> <p>a) 'clinicians were more confident in a diagnosis when using a QB test'</p> <p>b) 'the use of a QB test as an adjunct reduced the time to diagnosis'</p> <p>c) the specificity of the QB test in the Aqua trial was found to be very low.</p> <p>We would normally judge the effectiveness of an intervention on the basis of an improvement in sensitivity/specificity which this study does not show. The study seems to suggest that the test should be used as it is "cost effective" on the basis that an earlier diagnosis can be made as clinicians are more confident in their diagnoses. However, there was no difference in sensitivity and specificity when compared with diagnostic assessments without the use of the QBTest. In addition experts feel there will be a reduced number of complaints. We do not feel this is sufficient reason for endorsing this test.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee considered evidence from the AQUA randomised controlled trial which used the QbTest in addition to the normal diagnostic process (section 3.5 of the Guidance). The committee concluded that the evidence suggested that when used with standard clinical assessment by a healthcare professional, QbTest was likely to allow diagnostic decisions to be made quicker. The AQUA trial findings were supported by data from 5 before-and-after studies which found that using QbTest resulted in fewer consultations being needed to reach a diagnostic decision (section 4.2.3 of the Guidance). Qualitative evidence suggested that this was in part due to healthcare professionals being more confident in their decisions when using QbTest.</p> <p>The committee noted that the AQUA trial showed very similar</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>specificity when incorporating QbTest into clinical assessment compared to standard assessment alone. The committee concluded that there was some uncertainty about the impact on accuracy of using the tests to detect ADHD. But it recalled that the tests should only be used to supplement healthcare professional judgement, not to replace it (section 3.9 of the Guidance). Scenario analysis varying the diagnostic accuracy parameters demonstrated no large impact on cost effectiveness estimates (see section 5.5.2 of the <a href="#">External Assessment Report</a>).</p>
40	<p>Consultee 9 British Association for Neurodiversity</p>		<p>We know that ADHD is more difficult to diagnose in females - this study does not provide gender information</p>	<p>Thank you for your comment which NICE considered.</p> <p>Please see response to comment 26.</p>
41	<p>Consultee 9 British Association for Neurodiversity</p>		<p>We know that ADHD is more difficult to diagnose/ differentiate from other comorbid conditions- this study does not include/ differentiate between those with other conditions.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The participant demographics for those recruited in the AQUA</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>trial are reported in the appendix tables of the <a href="#">External Assessment Report</a>.</p> <p>Included in the study were patients with the following diagnoses (n=241; allows more than one diagnosis per patient): 71% ADHD; 35% oppositional defiant disorder/ conduct disorder; 20% any anxiety disorder; 17% chronic tic disorder/ Tourette syndrome; 9% autism spectrum disorder; 3% depressive disorder; 11% learning difficulties; 0.4% attachment disorder; 19% no psychiatric diagnoses. The committee considered the AQUA trial to be a good representation of the population who would be having the test in the NHS.</p>
42	<p>Consultee 9 British Association for Neurodiversity</p>		<p>There is the time delay from initial clinical assessment to final diagnosis. Is this true in practise? What is defined as initial clinical assessment? It is hard to see what this test adds in the context that it is suggesting being used. The majority of patients within an NHS or private setting are seen and diagnosed at the first assessment, so it is unclear what is meant by "reduced time to diagnosis from first assessment". What does this test add apart from another hurdle through which patients have to jump?</p>	<p>Thank you for your comment which NICE considered.</p> <p>The standard assessment in the AQUA trial included an interview with the child and their family and the completion of at least one standardised</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>informant-based behavioural assessment measure.</p> <p>The EAG's quality assessment judged the AQUA trial to have no concerns regarding the applicability of the QbTest. The committee considered it was suitable for decision making (section 3.5 of the Guidance).</p> <p>The assumptions for time to diagnostic decision included in the modelling conducted by the EAG was based on evidence from the AQUA trial, which reported the mean number of appointments until diagnostic decision was reached with and without the use of QbTest (See also section 5.3.2 and 5.3.3 of the External Assessment Report). The distribution of the number of appointments in the model was based on the FOCUS ADHD study which found an average number of appointments for the standard assessment to be 3.22.</p>



Comment number	Name and organisation	Section number	Comment	Response
				<p>The cost-effectiveness modelling showed that using QbTest as an adjunct to standard clinical assessment was cost effective. This benefit was gained from people diagnosed with ADHD receiving treatment faster, which led to an increase in quality adjusted life years (QALYs).</p>
43	<p>Consultee 9 British Association for Neurodiversity</p>		<p>Several of the NICE committee members were also authors in the AQUA trial</p>	<p>Thank you for your comment which NICE considered.</p> <p>The published declarations of interest registers for both standing committee members and specialist committee members can be found here:</p> <p><a href="#">Standing Committee</a></p> <p><a href="#">Specialist Committee Members</a></p> <p>NICE's declaration of interest policy can be accessed from a link within these documents.</p>
44	<p>Consultee 9 British Association for Neurodiversity</p>		<p>There is anecdotal evidence from BAND members (either personal or family members) of a negative Qb test but diagnosed ADHD, with some having a more tumultuous time 'convincing' the ADHD assessor of the validity of their diagnosis as a direct result of a</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee stated in section 3.7 of the Draft</p>

Comment number	Name and organisation	Section number	Comment	Response
			negative Qb result. This results in risk of harm for an already stigmatised group	guidance that the technologies should not be used as standalone tools without a full clinical assessment (as outlined in <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> ) from a trained healthcare professional. This includes a full clinical and psychosocial assessment as well as a full developmental and psychiatric history. Diagnostic decisions should not therefore be made on the outcome of the test itself alone. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.
45	Consultee 9 British Association for Neurodiversity		This appears to be a distraction from the real issue that which is lack of capacity to do assessments, and QbT has not been shown to increase throughput of assessments for same staff- if it had, we would be much keener. QbTech (online) is quite a bit more expensive than QbTest (licenced in clinics)- that might also affect the conclusions about cost effectiveness.	Thank you for your comment which NICE considered.  The committee considered data from the AQUA trial which showed that using the QbTest reduced the number of appointments to make a diagnostic decision. The economic model assumes that

Comment number	Name and organisation	Section number	Comment	Response
				<p>the appointments saved during assessment period, could be offered to those on the waiting list, increasing the overall throughput of cases.</p> <p>The QbTech online, marketed as QbCheck, was not recommended as an option by the committee (section 1.2 of the Guidance). Higher costs of the QbTest were explored in scenario analyses, which showed no large impacts on cost effectiveness estimates (section 5.5.2 of the <a href="#">External Assessment Report</a>).</p>
46	Consultee 9 British Association for Neurodiversity		<p>After 30 years use the data is scarce that it offers much more than clinical assessment alone. "Economic modelling using data from this trial suggests that QbTest is cost effective compared with standard clinical assessment" for those aged 6 to 17. This is assuming a QbT cost £31.20, and a couple of other assumptions are made, noting that the savings are from earlier diagnosis and because expert opinion suggests a QbT seems to reduce the number of complaints/appeals about whether the diagnosis is correct.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee considered the evidence for the use of QbTest in children and young people from the AQUA trial. Despite some limitations of the AQUA trial, the committee considered it was suitable for decision making (section 3.5 of the guidance). In the cost-effectiveness model, including QbTest alongside standard</p>

Comment number	Name and organisation	Section number	Comment	Response
				<p>clinical assessment increased the rate of receiving a diagnostic decision. This was based on fewer appointments until diagnostic decision was reached (See also section 5.3.2 and 5.3.3 of the External Assessment Report). The cost effectiveness estimates are based on impacts on people's health as well as impact on costs.</p>
47	<p>Consultee 9 British Association for Neurodiversity</p>		<p>There is a real risk that clinicians will use the test to screen people out of a diagnosis and rely upon a negative finding to exclude ADHD.</p>	<p>Thank you for your comment which NICE considered.</p> <p>The committee stated in section 3.7 of the Guidance that the technologies should not be used as standalone tools without a full clinical assessment from a trained healthcare professional. Section 3.7 has been amended to clarify that a full clinical assessment as outlined in section 1.3 <a href="#">NICE Guideline on ADHD diagnosis and management NG87</a> should still be carried out.</p>