NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Draft guidance

Digital technologies for assessing attention deficit hyperactivity disorder

The National Institute for Health and Care Excellence (NICE) is producing guidance on using digital technologies that combine measures of cognition and motor activity for assessing attention deficit hyperactivity disorder (ADHD) in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the external assessment report).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- 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
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on technologies for assessing ADHD. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document, and comments from the consultation. After considering the comments, the committee will prepare its final recommendations, which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see NICE health technology evaluations: the manual.

Key dates:

Closing date for comments: 6 August 2024

Second diagnostics advisory committee meeting: 20 August 2024

1 Recommendations

Use as an option

1.1 Use QbTest as an option to help diagnose attention deficit hyperactivity disorder (ADHD) in people aged 6 to 17 years. It should only be used with standard clinical assessment by a healthcare professional.

Can only be used in research

1.2 More research is needed on using the following digital technologies to help diagnose ADHD:

- QbTest in people 18 years and over
- EFSim Test
- EfSim Test Web Version
- Nesplora Attention Adults Aquarium
- Nesplora Attention Kids Aula
- QbCheck.

1.3 More research is needed on using the following digital technologies to evaluate treatment effectiveness:

- EFSim Test
- EfSim Test Web Version
- Nesplora Attention Adults Aquarium
- Nesplora Attention Kids Aula
- QbCheck
- QbTest.

1.4 Access to the digital technologies for the uses described in sections 1.2 and 1.3 should be through company, research, or non-core NHS funding, and clinical or financial risks should be appropriately managed.

More research

1.5 More research is needed on:

- how the digital technologies are used in, and their impact on, decision making in ADHD diagnosis, including for more complex cases
- the impact of the digital technologies in section 1.2 when used to help diagnose ADHD
- the impact of the digital technologies in section 1.3 for people with a diagnosis of ADHD when used:
  - during dose titration
  - as part of longer-term treatment monitoring.

Why the committee made these recommendations

The diagnostic process for ADHD requires a lot of clinical judgement. Healthcare professionals need training on and experience in the process to apply the criteria correctly. Waiting lists for an ADHD assessment can be long, and the process of reaching a diagnostic decision can take a long time. Additional information from digital technologies may help people to get diagnostic decisions quicker and help healthcare professionals be more confident in their decisions.

The clinical trial evidence suggests that information from QbTest helps to reduce the time it takes for people aged 6 to 17 years to get a diagnostic decision compared with standard clinical assessment by a healthcare professional. Economic modelling using data from this trial suggests that QbTest is cost effective compared with standard clinical assessment for these people.

For people under 18, there is limited evidence for technologies other than QbTest. The other technologies are different to QbTest in how they measure ADHD traits, so it is unclear whether they would have a similar impact. So, it was not possible to assess the cost effectiveness of the technologies other than QbTest when used to help diagnose ADHD for people aged 6 to 17 years, and further research is needed.

For adults, there is limited evidence for any of the technologies, and the evidence from people under 18 is not generalisable to adults. So, more research is needed in this group.

After a diagnosis with ADHD, the technologies could also be used to help evaluate treatment effectiveness, which may aid decisions about changing or continuing current treatment. This can help make sure people are having the best possible medication and dosage to manage symptoms and reduce side effects, and reduce overprescribing. Little evidence is available on whether any technologies are clinically or cost effective for evaluating treatment effectiveness. More research is needed to help assess this.

2 The diagnostic tests

Clinical need and practice

ADHD

2.1 Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental condition characterised by a persistent pattern of hyperactivity, impulsivity, and inattention that interfere with daily and occupational functioning.

2.2 This may manifest as: wandering off-task; having difficulty sustaining focus; being disorganised; excessive motor activity when it is not appropriate; excessive fidgeting, tapping and talkativeness; social intrusiveness; and making important decisions without considering the long-term consequences. People with ADHD may take hasty actions that occur in the moment without forethought and that have high potential for harm to the individual.

2.3 The global prevalence of ADHD in children is estimated to be around 5%. In the UK, prevalence of ADHD in adults is estimated at 3% to 4%. It is more commonly diagnosed in boys than girls.

2.4 ADHD is associated with psychiatric disorders including oppositional defiant disorder, conduct disorder, substance abuse, and mood disorders such as depression and mania. Autism spectrum disorder, dyslexia, dyscalculia, and dyspraxia commonly co-occur in people with ADHD. Overall prognosis may depend on the severity and management of any comorbid disorders.

2.5 Treatment for ADHD may be non-pharmacological, including psychoeducation, ADHD coaching, parent training, or environmental changes. Pharmacological treatment may include stimulant or non-stimulant medication. Medication doses are titrated against symptoms and adverse effects until dose optimisation is achieved.

Care pathway and clinical need

2.6 The NICE guideline on attention deficit hyperactivity disorder: diagnosis and management describes the care pathway. People presenting to primary care with behavioural or attention problems that suggest ADHD are referred to secondary care for assessment.

2.7 A clinical assessment for ADHD by a specialist healthcare professional involves gathering information about a person's symptoms and behaviours. This includes the person's developmental, medical, educational and mental health history, and ADHD-specific history. Information may come from the person themselves, a parent or carer, school teachers (for children), or employers (for adults). Information can be collected using interviews, observer reports and standardised rating scales.

2.8 Standard clinical assessment for ADHD is based on diagnostic criteria that require training and experience to apply correctly and can be somewhat subjective, relying on information obtained from a range of sources. Information from these sources may often be incomplete or contradictory, requiring multiple clinic visits or observations to reach a

diagnostic decision. Diagnosis of ADHD is further complicated by similarities in presentation and overlap with other neurodevelopmental disorders and mental health conditions, which may lead to difficulties and delays in decision making.

2.9 Digital technologies that combine measures of cognition and motor (physical) activity may help healthcare professionals when considering a diagnosis of ADHD, by providing additional objective information. This could reduce the number or length of clinical appointments needed to reach a diagnosis, reducing patient waiting lists and freeing up NHS resources. It may also provide people with quicker access to appropriate further care or assessment.

The interventions

2.10 The intervention is any of the digital technologies that combine measures of cognition and motor activity listed in table 1, when used as part of the standard clinical assessment for ADHD by a healthcare professional. See section 1.3 of the external assessment report for further information on the technologies. The tests may not be suitable for everyone.

Table 1 Technology specifications

Technology (manufacturer)	Technology description	Test cost
EFSim Test (Peili Vision Oy)	A game-like virtual reality (VR) test suitable for people aged 8 to 16 years. The simulation includes a home-like environment where the user performs everyday life tasks. Neurological performance measures, and head and hand movement are compared to data from a typically developing population to identify deficits in executive function associated with ADHD. There is a web version of the EFSim Test that does not need a VR headset. It is designed for remote testing that can be done without a healthcare professional present.	Proposed delivery model in which a dedicated healthcare professional travels to each practice 1 day per month to provide assessments. Cost per 7.5-hour working day of £197.05 including VAT.

Technology (manufacturer)	Technology description	Test cost
Nesplora Attention Kids Aula **Nesplora Attention Adults Aquarium** (Giunti Nesplora)	VR continuous performance test suitable for people aged 6 to 16 years (Kids Aula) and 17 to 90 years (Aquarium). It measures auditory and visual attention, impulsivity, motor activity and reaction time in a real-life setting. It provides a score calculated by comparing to a normative data set of people without ADHD of the same sex and age.	£21.03 single use (plus a one-off registration fee of £84.12), £75.70 for 7 uses (monthly), £227.11 for 22 uses (quarterly) or £1,345.85 per year for unlimited use. Costs exclude VAT.
QbCheck (QbTech)	Web-based continuous performance test with a webcam motion-tracking system suitable for people aged 6 to 60 years. Measures 3 core symptoms of ADHD: attention, impulsivity, and hyperactivity. Results from the test are compared to a normative data set of people without ADHD of the same sex and age. It is designed for remote testing that can be done without a healthcare professional present.	£69 per test excluding VAT.
QbTest (QbTech)	Continuous performance test with a high-resolution infrared motion-tracking system suitable for people aged 6 to 60 years. There are 2 versions for different age groups. They vary in the computer-based task. Measures 3 core symptoms of ADHD: attention, impulsivity, and hyperactivity. Results from the test are compared to a normative data set of people without ADHD of the same sex and age.	£31.20 per test excluding VAT.

The comparator

2.11 The comparator is standard clinical assessment by a healthcare professional without using digital technologies that measure cognition and motor activity. This assessment uses a variety of information sources, including a developmental and psychiatric history, psychosocial assessment, and observer reports.

3 Committee discussion

The diagnostics advisory committee considered evidence on digital technologies for assessing attention deficit hyperactivity disorder (ADHD) from several sources, including an external assessment report and an overview of that report. Full details are in the project documents for this guidance.

Quicker access to appropriate support

3.1 Patient experts explained how important a diagnosis of ADHD was for people and their families. It can help them better understand their behaviour, including strengths and needs, and help them access the right support. They described the diagnosis as life changing. A diagnosis can also help get access to support in schools and to reasonable adjustments in the workplace. Long waiting times, running to many years, were highlighted as a significant issue, causing anxiety and even suicide. Many people are having private care to get a diagnostic assessment, but this is not an option for everyone. Any technology that could increase speed of assessment was highlighted as having potentially large benefits.

Impact on the diagnostic experience

3.2 Digital technologies to support diagnosis may help to communicate diagnostic decisions with patients and families. The committee noted qualitative evidence from 4 studies, in which healthcare professionals and families (including input from children having an assessment) reported that the test results helped to communicate the diagnostic decision. The test results helped people to better understand their symptoms and they were more likely to accept the diagnostic decision. The external assessment group (EAG) also noted that clinical experts had suggested that test results may reduce appeals about diagnostic decisions. The committee also noted that the tests may be of particular benefit for people with language or communication difficulties.

3.3 The committee also considered the qualitative evidence that had highlighted that healthcare professionals found the information from tests increased their confidence in decision making. This was helpful when assessing people with subtle presentation (common in girls and women) and supporting a diagnosis when there are comorbidities. This was also raised by patient experts, who noted that tests may help diagnosis in groups in which symptom masking is prevalent, such as particular ethnic backgrounds and cultures.

3.4 The qualitative evidence also highlighted that families felt that tests may be beneficial in shortening the diagnostic process, which can be an emotionally overwhelming process for those having the assessment. Evidence from children surveyed after using EFSim Test reported that the tasks were interesting, and the children were enthusiastic to participate. But the EAG judged that this evidence was at high risk of bias. The patient experts described how testing may be frustrating or emotionally difficult for people with ADHD and emphasised the importance of suitable support being provided throughout the process. Evidence from the qualitative studies also reported that some families and young people still felt the results were not properly explained and did not help them to understand how diagnoses were made. The committee was mindful of the importance of communicating the purpose and outcomes of the tests with people having an assessment.

Clinical effectiveness

Impact on the ADHD diagnostic process in children and young people

3.5 The committee concluded 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 was the only randomised controlled trial identified in the EAG's review. It showed that a diagnostic decision had been made for a larger proportion of people within 6 months of baseline when QbTest results were available, compared with

when they were not. 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. Unfortunately, the largest implementation study (FOCUS) was severely affected by the COVID-19 pandemic and so was judged to be at serious risk of bias. The EAG also said that AQUA time-to-event outcomes were judged as being at a high risk of bias. This was because a large proportion of participants were censored from the analysis because they did not have a diagnosis at 6 months. This assumed that censored participants would have the same diagnosis rate as those for whom a diagnosis was reached at 6 months. But the EAG explained that this was not an issue for outcomes for people who had received a diagnosis in the study period. 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 paediatric clinics, which provided some reassurance. Despite some limitations of the AQUA trial, the committee considered it was suitable for decision making. The committee recalled that the process of diagnosing ADHD is complex, and so valued having direct data on the impact of test use on outcomes related to the diagnostic process.

3.6 The committee also concluded that when used with standard clinical assessment, QbTest was likely to provide healthcare professionals with higher confidence in their decisions. The clinical experts noted that diagnosis could be particularly difficult when information was missing (for example, observer reports from school or family members) and the test could provide further information in these scenarios. The committee considered qualitative and quantitative evidence from the AQUA trial that reported an increase in confidence in diagnostic decisions when QbTest results were available. In addition, the AQUA trial reported that clinicians

were able to rule out ADHD in more cases when using QbTest than when using standard assessment alone.

Standalone use

3.7 Most evidence identified by the EAG investigated the diagnostic accuracy of the technologies as a standalone tool, compared with standard clinical assessment. The EAG highlighted that estimates of accuracy evaluated in isolation were generally lower than when evaluated in combination with clinical judgement. The EAG stated that the AQUA trial was the only study to combine QbTest information with clinical assessment in the same way that it would be used in practice. The clinical experts were concerned that the tests could be used inappropriately in practice. That is, to make decisions about whether further assessment was needed, or even to make diagnostic decisions based on triage assessments, without appropriate healthcare professional input. The indications for use for the tests state that they should be used to supplement healthcare professional decision making, not to replace it. The committee emphasised that the standalone use of any of the technologies was not appropriate and not in line with their intended use.

3.8 The committee raised that the technologies may not be suitable for use in people with existing learning disabilities, visual impairments or physical disabilities. Technologies with wearable components such as a headband or headset may not be suitable for all people, such as those with anxiety and sensory difficulties associated with autism spectrum disorder.

Diagnostic accuracy

3.9 The committee noted that although the AQUA trial showed low specificity when incorporating QbTest into clinical assessment, the standard assessment arm of the trial also showed low specificity. The EAG stated that this may have been because of the limited information available for the reference standard, which may have resulted in the diagnosis being too stringent, leading to an underestimate of specificity. The committee

noted that the sensitivity to detect ADHD was lower when the QbTest result was available in the AQUA trial. Although the EAG commented that this difference was not statistically significant, this could be because the size of the population tested was not large enough. The EAG highlighted concerns about the accuracy data from the AQUA trial. This included that the diagnostic accuracy data was only from people who received a diagnosis, but that a large proportion of people did not receive any diagnostic decision in either arm of the study by 6 months. The committee concluded that there was 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 (see section 3.7). The EAG had also run scenario analyses in its economic model which reduced the diagnostic accuracy of the test compared with standard assessment alone. So, any possible negative impact of adding the test to clinical practice had been explored in the cost-effectiveness analyses.

Limited evidence in adults

3.10 The committee concluded that there was not enough evidence to support using the tests in adults. No studies were identified in the EAG's review that used any of the tests with standard clinical assessment in the diagnosis of ADHD in adults. The clinical experts stated that the data obtained from studies in children and young people was not appropriate to show how the tests would work when used for adults. This is because of differences in the clinical presentation and information available to make a diagnosis in adults compared with children and young people. For example, observer reports of behaviour are less commonly available for adults and there are more differential diagnoses. But the clinical experts did highlight the considerable potential benefits of the tests if they can help diagnose ADHD in adults. So, the committee decided that although there were potential benefits for the tests in adults, more research was needed.

Limited evidence in complex cases

3.11 The committee considered the targeted use of tests in complex cases. That is, for people for whom standard clinical assessment by a healthcare professional does not typically lead to a diagnosis. This may be because of co-existing conditions, some of which have a large overlap in traits with ADHD, such as autism spectrum disorder, trauma, mental health conditions, learning disorders or behavioural conditions. It may also be complex because there is substantial missing or conflicting information, or because of medication or substance use. It was noted that some centres already use QbTest in this way. The committee concluded that although there may be potential benefits in the targeted use of tests only in complex cases in which standard assessment could not reach a diagnosis, more data is needed.

Limited evidence in evaluating treatment effectiveness

3.12 The technologies under consideration are also indicated for evaluating treatment effectiveness for people diagnosed with ADHD who are having treatment. The EAG identified 1 accuracy study and 1 randomised controlled trial feasibility study evaluating QbTest in this population. The EAG considered both to be at high risk of bias. The committee concluded that there was insufficient evidence to recommend any technology for evaluating treatment effectiveness.

Limited evidence for technologies other than QbTest

3.13 The committee concluded that there was insufficient evidence to assess the cost effectiveness of any technology other than QbTest to aid in the diagnosis of ADHD:

- No studies were identified for EFSim Test Web Version or Nesplora Attention Adults Aquarium.

- Studies were available for EFSim Test, Nesplora Aula and QbCheck, but the EAG highlighted that none of them used the test with standard clinical assessment in line with their intended use (see section 3.7).
- No studies for any of the technologies reported on the impact of the test on diagnostic process outcomes.

The manufacturers of the EFSim and Nesplora technologies emphasised that their tests were considerably different in their mechanisms of action and outputs to QbTest. QbCheck, although it has the same outputs as QbTest, uses a different motor activity sensor, and is designed for remote use without the presence of a healthcare professional. The committee concluded that the data generated using QbTest, such as from the AQUA trial, was not generalisable to any other technologies in this evaluation and that there was limited data for the other technologies considered. So, the committee did not consider the potential cost effectiveness of the other technologies for detecting ADHD. The outcomes used by the EAG in modelling to assess the cost effectiveness of QbTest, such as the impact on waiting time and time to diagnosis, gave an indication of potentially relevant outcomes. Any assessment of test accuracy should be done as the tests are intended to be used; that is, alongside healthcare professional judgement.

Cost effectiveness

Cost effectiveness of QbTest to help diagnose ADHD in children and young people

3.14 The committee concluded that using QbTest alongside standard clinical assessment was likely to be a cost-effective use of NHS resources for assessing ADHD in children and young people. In the EAG's base case analysis, the QbTest strategy incremental cost-effectiveness ratio was £6,184 per quality-adjusted life year gained. QbTest was cost effective in almost all scenario analyses run by the EAG. The impact of QbTest was

largely modelled using data from the AQUA trial, which the committee considered was suitable for decision making (see section 3.5). The committee concluded that QbTest was likely to be cost effective when used alongside standard clinical assessment by a healthcare professional to help diagnose ADHD for children and young people.

3.15 The committee also noted the importance of suitable training for healthcare professionals in interpreting the results of the test alongside other clinical information. Manufacturer submissions confirmed that initial training to administer and interpret QbTest reports is provided. This is supplemented by a 3-month update training, and annual training is also offered.

Cost effectiveness of tests to help diagnose ADHD in adults

3.16 Because of the limited available data, the EAG did not provide cost-effectiveness estimates for using the technologies to help diagnose ADHD in adults. The committee recalled its conclusion that it was not appropriate to use data from studies of children and young people to show performance in adults (see section 3.10) and agreed that further evidence was needed for this population.

Cost effectiveness of tests to help diagnose ADHD in complex cases

3.17 The committee was uncertain if targeted use of the tests in complex cases only (when standard assessment does not lead to a diagnosis) was likely to be cost effective compared with using the test in all ADHD assessments. Because of limited data for this population, the EAG was only able to explore the cost effectiveness of QbTest when used for complex cases by making the strong assumption that QbTest would only be used if a diagnosis was not made in 2 appointments (including the initial appointment). This analysis also made the strong assumption that the test impact on the diagnostic process and diagnostic accuracy would be the same in complex cases. The results of the exploratory analysis suggested that this strategy could be cost effective compared with testing

everyone. The committee recalled that diagnosing ADHD is a complex process, and exactly how the tests affect this process could be variable (see section 3.5). The committee noted that further evidence on exactly how the tests are used in clinical decision making could be beneficial to help identify if there may be particular benefit for more complex cases.

Cost effectiveness of tests for evaluating treatment effectiveness

3.18 The EAG did not provide cost-effectiveness estimates for using the tests to help evaluate treatment effectiveness for people with ADHD. It considered there was insufficient data to populate an economic model for dose titration or long-term monitoring. The committee agreed that further evidence is needed to show the impact of the tests on people with ADHD and the healthcare system when used by a healthcare professional to help make decisions about treatment.

4 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition, NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered for developing specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 1 into its guidance research recommendations database and highlight these recommendations to public research bodies.

5 Review

NICE will regularly monitor its published technology guidance to check for any new evidence or information that could affect the recommendations. Guidance will not have a fixed review date.

Brian Shine

Chair, diagnostics advisory committee

July 2024

6 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions for this topic:

Specialist committee members

Samuele Cortese

NIHR research professor and professor of child and adolescent psychiatry, University of Southampton

Chris Hollis

Professor of child and adolescent psychiatry, University of Nottingham

Nicole Horwitz

Consultant neurodevelopmental paediatrician, Whittington Health NHS Trust

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Emily Simonoff

Professor of child and adolescent psychiatry and head of department, Institute of Psychiatry, Psychology and Neuroscience, King's College London

Mauline Vernon

Specialist lay committee member

NICE project team

Each diagnostics evaluation is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Jessica Wilcock

Topic lead

Thomas Walker

Technical adviser

Toni Gasse

Project manager