NICE advice

QbTest for the assessment of attention deficit hyperactivity disorder (ADHD)

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is QbTest. It is used to help assess attention deficit hyperactivity disorder (ADHD) and to evaluate different treatments for people with ADHD when combined with the standard care clinician assessment.
- The **innovative aspects** are that it combines a continuous performance test with an objective and standardised measure of motor (physical) activity. The innovation of this technology is its objectivity compared with potentially subjective neurodevelopmental assessments.
- The intended **place in therapy** would be for people who have been referred for an ADHD assessment. It would be used with the assessments that make up standard care and cannot be used as a separate, independent diagnostic assessment for ADHD. QbTest is also indicated for use as an aid in evaluating treatment effect for ADHD.

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- The **main points from the evidence** summarised in this briefing are from 8 studies (1 randomised controlled trial, 2 objective measure studies, 1 qualitative study of user experience, 1 audit, 1 diagnostic study, 1 national evaluation report and 1 real-world demonstrator project). Studies showed that using QbTest helped with clinical decision making and a more efficient diagnosis, and required fewer consultations.
- **Key uncertainties** around the technology are that studies using QbTest included potentially inappropriate populations and did not use a parallel clinical assessment when diagnosing ADHD.
- **Experts advised** recognising the technology as an addition to routine clinical assessment of ADHD and not as a standalone assessment. All the experts explained that the potential benefits were quicker assessment, and cost savings because of clinician time saving and efficiency of the pathway.
- The **cost** of QbTest is £23 to £96 per assessment (excluding VAT). There is some evidence of cost reduction as well as return on investment.

The technology

QbTest (Qbtech Ltd) can be used to aid the assessment of attention deficit hyperactivity disorder (ADHD) and for evaluating different treatments in people with ADHD. It uses an infrared tracking system and computerised tasks to assess concentration, movement and impulsivity using age- and gender-matched comparisons.

The components of the test include an infrared tracking camera and stand, a flexible headband and reflective ball, a computer and a response button. The person doing the test uses the response button to complete a computerised task, while wearing the headband and reflective ball. The infrared tracking camera records the movement of the reflective ball. The test takes between 15 and 20 minutes. The results are analysed within minutes of the test being completed and are interpreted by a qualified physician.

Innovations

QbTest combines a continuous performance task with an objective and standardised measure of motor (physical) activity. This combination is innovative.

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Current care pathway

ADHD is a neurodevelopmental disorder that is characterised by symptoms of hyperactivity, inattention and impulsivity that interfere with daily and occupational functioning.

ADHD is diagnosed by an appropriately qualified professional, such as a specialist psychiatrist or paediatrician. The diagnosis is made based on all of the following:

- a full clinical and psychosocial assessment of the person, including a discussion about behaviour and symptoms in different settings
- a full development and psychiatric history
- observer reports and assessment of a person's mental state.

The diagnosis process also involves assessing a person's needs, coexisting conditions, social, familial, educational or occupational circumstances and physical health.

A person is diagnosed with ADHD if, after the completion of all assessments, they meet the DSM-5 criteria for ADHD, in that the person presents with symptoms of hyperactivity, inattention and impulsivity that negatively affect their life in 2 or more settings, such as school, work and home, and the symptoms have persisted for 6 months or more. People of any age can be diagnosed with ADHD.

After a diagnosis, people with ADHD and their families are given advice about how the diagnosis could affect them and where they will find useful information. Treatment for ADHD includes pharmacological and non-pharmacological interventions and depends on the person's age, symptoms and preferences.

NICE's guideline on the diagnosis and management of ADHD is relevant to this pathway.

Population, setting and intended user

QbTest is intended for use in people that have been referred for an ADHD assessment. It is used in addition to the assessments that make up standard care. QbTest is also indicated for use as an aid in the evaluation of treatment effect in ADHD.

It is done by a qualified healthcare professional who has been trained in the use of QbTest.

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Costs

Technology costs

The total cost per assessment in England is between £23 and £96 (excluding VAT) depending on the test volume. This is in addition to standard care. No other costs can be provided at this time due to commercial sensitivity.

Costs of standard care

Costs of standard care vary depending on specific local processes for diagnosis. An average cost of £700 per case of standard care was determined from a Kent, Surrey and Sussex cost–benefit analysis and national programme evaluation report.

Real-world evidence demonstrator projects saw a cost reduction of between 9% and 39% depending on model implementation, as well as a return on investment between £14,300 and £93,000 when QbTest was used.

Resource consequences

QbTest is being used at 131 sites across 65 NHS trusts. The use of QbTest could improve the efficiency and speed of ADHD diagnosis as well as reduce assessment costs without loss of diagnostic accuracy. This may lead to an improvement in patient access to treatment.

Despite the test being used in addition to standard care assessments, real-world evidence suggests adoption of the technology in the ADHD assessment pathway reduces clinician assessment time by 20% to 30%. Consultation rooms will need very little adaptation for this technology, and healthcare professionals will need to be trained to use the test.

Regulatory information

QbTest is a CE-marked class I medical device, and there are plans for UK Conformity Assessed (UKCA) marking by 2024.

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Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Attention deficit hyperactivity disorder (ADHD) is most commonly diagnosed in children and young people. ADHD is thought to be under-recognised in girls and women. Age and sex are protected characteristics under the 2010 Equality Act.

The QbTest is not suitable for people aged under 6 years and people who have visual impairment. Age and disability are protected characteristics under the 2010 Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Evidence from 8 studies is summarised in this briefing. The evidence base would benefit from a systematic review.

The studies in this briefing include 1 randomised controlled trial (Hollis et al. 2018), 2 objective measure studies (Edebol et al. 2012, Vogt and Shameli 2018), 1 qualitative study of user experience (Hall et al. 2017), 1 audit (Hall et al. 2016), 1 diagnostic study (Hult et al. 2018), 1 national evaluation report (East Midlands Academic Health Science Network [EMAHSN] 2022) and 1 real-world demonstrator project (NIHR Collaboration for Leadership in Applied Health Research & Care [CLAHRC] and EMAHSN 2017). The size of the population in these studies ranged from 40 to 340 people.

The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

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Overall assessment of the evidence

Hollis et al. (2018)

Study size, design and location

Randomised, parallel, single-blind controlled trial including 267 children evaluating QbTest utility in child and mental health services and community paediatric clinic sites in England.

Intervention and comparators

QbTest combined with standard care attention deficit hyperactivity disorder (ADHD) assessment (QbOpen), standard care ADHD assessment (QbBlind), with 2 experienced child psychiatrists with access to clinician-completed global assessment scores blinded to group allocation.

Key outcomes

Participants whose clinicians had access to QbTest (QbOpen) were 44% more likely during the study period to receive a diagnostic decision compared with those having assessment as usual without a QbTest report (hazard ratio 1.44; 95% confidence interval [CI] 1.04 to 2.01; p=0.029). Clinicians were more likely to make a diagnostic decision about ADHD when they had access to a QbTest report (QbOpen) than when the QbTest report was withheld (QbBlind; 94/123 [76%] compared with 76/127 [60%], odds ratio 2.43; 95% CI 1.35 to 4.49; p=0.003). Compared with the index test, the sensitivity of the QbOpen clinicians' confirmed diagnosis was 86.0%, whereas the QbBlind clinicians' confirmed diagnosis had a higher sensitivity of 96.1%. Specificity was reported to be 39.4% in the QbOpen group and 36.0% in the QbBlind group. Statistical analysis reported no significant differences in sensitivity and specificity between the groups (p=0.64). Cost analysis of using QbTest reports suggested an incremental cost-effectiveness ratio of £1.72. Health economic analysis dominated standard care; however, cost savings were small, suggesting that the impact of providing the QbTest report within this trial can best be viewed as cost neutral.

Strengths and limitations

This is a well-designed comparator study of high methodological quality. The clinical

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setting and population are relevant to the NHS. The outcome measures reported are appropriate. There is limited detail about the method of randomisation; however, the study does reference use of a web-based system. Power calculations are reported. The study reports time to diagnosis as the primary outcome for the economic evaluation; the study does not report the subsequent treatment and clinical outcome after treatment. A limitation is that the health economic analysis was based on a 6-month time horizon and discounting was not applied to costs or outcomes. As such, it was not possible to determine longer-term costs associated with cases awaiting diagnostic determination (which was more common when clinicians did not have access to the QbTest report).

Edebol et al. (2012)

Study size, design and location

Objective measures study evaluating behaviour manifestations in adults with ADHD and in adults with or without other conditions. The study consisted of 306 participants belonging to 4 groups: diagnosed with ADHD (n=53), either bipolar 2 disorder or borderline personality disorder (n=45), assessed for but disconfirmed diagnosis of ADHD (n=29) and the adults without any of these conditions, described in the 'adult normative group' (n=179).

Intervention and comparators

Evaluation of 2 psychometric instruments derived from QbTest, summarised into a Weighted Core Symptoms Scale.

Key outcomes

The Weighted Core Symptoms Scale separated ADHD and normative participants from each other as well as the other 2 clinical reference groups. The highest level of core symptoms reported were in the ADHD group and the lowest level in the normative group. Analyses with prediction of ADHD yielded 85% specificity for the normative group, 87% sensitivity for the ADHD group, 36% sensitivity for the bipolar 2 and borderline group and 41% sensitivity for the group with disconfirmed diagnosis of ADHD. The results of this study helped in the objective assessment of adult ADHD.

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Strengths and limitations

The study has a sufficient study size and provides a combination of prospective design, proper scientific approach and a study hypothesis. It also provides both comparison to a general population and a differential diagnosis. Sensitivity for QbTest was lower in complex clinical groups with other conditions and in those with disconfirmed diagnosis. The study did have some limitations in that most participants had ADHD in combined form, which may have caused generalisation of data. Also, the group with ADHD was tested with QbTest by their clinical contact, which may have created sample biases or affected the generalisation of the study.

Vogt and Shameli (2018)

Study size, design and location

Objective measures study comparing ADHD assessments in 108 children were reviewed, and 46 assessments without objective measurements were compared with 62 assessments with objective measurements (using the QbTest).

Intervention and comparators

Two groups of ADHD assessments were compared: the first group without any objective measures within the assessment and the second group with objective measures included.

Key outcomes

The study showed objective measures improve differentiation between ADHD and other conditions where symptoms overlap with ADHD. The study results stated a reduction in the risk of unidentified ADHD ($p<0.0035$), as measured by subsequent rates of revised diagnosis over a 12-month period. The study states that the introduction of an objective measure into clinical assessment of ADHD will aid in clinical diagnosis and strengthen clinical decision making.

Strengths and limitations

The study is a true reflection of the intended use of the technology and has a retrospective study group. The setting is NHS Children and Adolescent Mental Health Services (CAMHS).

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Hall et al. (2017)

Study size, design and location

A qualitative study of user experience of QbTest to aid ADHD assessment and medication management, including semi-structured interviews with clinicians and families (n=39) and a survey (n=86).

Intervention and comparators

QbTest, no comparator.

Key outcomes

Qualitative findings through semi-structured interviews reported that QbTest was considered valuable and facilitated communication between clinicians, families and schools. In the survey, all clinicians reported that QbTest was helpful to evaluate treatment effects; however, only 39% of families felt it helped them understand the decision.

Strengths and limitations

This study is useful to help understand patient and user perspectives of the test; however, the study does not report diagnostic accuracy outcomes that would be useful in evaluating the effectiveness of the test.

Hall et al. (2016)

Study size, design and location

Audit study on the number of consultations until ADHD diagnosis from case records of 40 people whose ADHD was diagnosed without the QbTest and 40 people whose ADHD was diagnosed with the QbTest.

Intervention and comparators

QbTest, no comparator.

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Key outcomes

Significantly fewer clinician consultations (mean 2.18 compared with 3.05; p<0.02) were required to confirm the diagnosis of ADHD when the QbTest was used to augment assessment in comparison to standard assessment.

Strengths and limitations

One limitation of this study was that ADHD diagnoses were not independently verified, and it is not known whether QbTest helped exclude ADHD diagnosis in non-ADHD cases referred for ADHD diagnostic assessment, limiting the comprehensiveness of the findings. Findings were limited to 1 NHS trust, which is a small sample size. Strengths of this audit include the similar composition of children in each group and the random selection.

Hult et al. (2018)

Study size, design and location

Diagnostic study including 182 children with either ADHD or another clinical diagnosis in a child neuropsychiatry clinic in Sweden.

Intervention and comparators

QbTest in children with ADHD and in children with other clinical diagnoses.

Key outcomes

Only QbTest parameters for inattention and hyperactivity differentiated between ADHD and other clinical diagnoses at the $p \leq 0.01$ level, not for measures of impulsivity. Sensitivity ranged from 47% to 67% and specificity from 72% to 84%. The positive predictive value ranged from 41% to 86%, and negative predictive value from 43% to 86%. Area under the curve varied from 0.70 to 0.80. The study states that analysing QbTest performances in different clinical groups (including ADHD) might give valuable information on clinical presentation that might explain more than the broad diagnostic categories.

Strengths and limitations

Strengths of the study include that the study group was representative of patients who

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would receive the test in practice, and both the study and comparison groups received the same reference tests. A limitation in the study is that, although the ADHD was not based on results from the QbTest, the results were known to some clinicians, whose information could have contributed to the final diagnosis. Also, no inter-rater reliability tests about diagnoses were carried out.

EMAHSN (2022)

Study size, design and location

Focus ADHD national programme evaluation report 2022. A total of 549 pre-implementation cases and 549 post-implementation cases were analysed. Evaluation was carried out in NHS sites across England. The national programme was supported by all 15 regional AHSNs in England and Qbtech Ltd.

Interventions and comparators

QbTest (pre- and post-implementation comparison).

Key outcomes

The evaluation found implementation of QbTest in addition to standard care reduced the number of clinical appointments needed to reach a diagnostic decision. There was a reduction of 17% in the number of school observations that were conducted pre- and post-implementation and a 5% increase in patients having ADHD ruled out as a diagnosis. There was a reduction in the mean number of clinical appointments from 3.22 pre-QbTest to 2.85 post-QbTest implementation, though this is not statistically significant. This change translates to an 11.5% release of clinical consultations. There was an increase in number of days to reach a diagnostic decision (10.3%) and from initial referral to diagnosis (12.2%), with the former being statistically significant.

Strengths and limitations

Sites were responsible for their own audit collection data, so it was difficult to ascertain consistency with what the evaluation requested. Although checked, the evaluation team had no way of determining accuracy of the data. There was also the possibility of non-response bias from sites that did not participate, as well as geographical bias as most responses came from London and South East England. This evaluation was also done

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during COVID-19, which would have limited the generalisability of the findings.

NIHR CLAHRC East Midlands and the EMAHSN (2017) – AQUA randomised controlled trial and the Transforming ADHD Demonstrator Project (2017)

Study size, design and location

ADHD care in the East Midlands. The NIHR CLAHRC East Midlands-funded 10-site, 18-month long randomised controlled trial. The EMAHSN funded and led the 12-month, 7-site real-world demonstrator project. The CLAHRC's 'AQUA' randomised controlled trial explored the clinical use of QbTest for ADHD diagnosis alongside standard practice in CAMHS and community paediatric services. The EMAHSN Transforming ADHD Care Project used the QbTest diagnostic tool across 3 counties to prove the impact on patient experience, efficiency and time to diagnosis.

Intervention and comparators

QbTest, no comparator.

Key outcomes

There was a reduction from the first appointment to diagnosis by an average of 146 to 201 days depending on the model implementation. Eighty-five percent of patients surveyed stated the test helped them better understand their symptoms. There was a release of between 20% and 33% of clinician workforce time. EMAHSN demonstrator projects also saw cost reductions between 9% and 39% depending on model implementation used and a return of investment between £14,300 and £93,000 when QbTest was used in the assessment process. It was also found to maintain clinical accuracy despite speeding up diagnosis. The study found QbTest to be acceptable and feasible for implementation.

Strengths and limitations

There were no comparators, as is common in real-world evidence studies, but the study does provide important evidence on real-world use in the NHS.

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Sustainability

There are no sustainability claims.

Recent and ongoing studies

A nurse-led model of care for ADHD. Status: recently completed. Indication: ADHD. Outcomes: reduced waiting list and prescription costs achieved through using QbTest.

Although there are ongoing studies, the company has suggested they will not conclude for some time and are therefore not appropriate to include.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Five experts commented on this briefing. All experts were familiar with and had used this technology before.

Level of innovation

Three out of 5 experts considered the technology to be novel, with 2 further stating innovation with objectivity through the combination of continuous performance tasks and motor (physical) activity, differing from existing, largely subjective neurodevelopmental assessments. One expert stated that, despite being novel, its efficacy is uncertain. The other 2 experts stated that the technology is already used in established practice and is no longer new. Three experts stated that the technology is the first in a new class of procedures. All experts explained that QbTest is to be used as an addition to standard care and not as a replacement.

Potential patient impact

Four out of 5 experts stated a positive impact on patients with suspected attention deficit hyperactivity disorder (ADHD). The other expert stated there are other symptoms outside

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of the measurements of QbTest and the symptom measurements should not be considered exclusive. One expert described a positive experience for patients and families when using QbTest with regards to objective measurement of ADHD. They also stated it is a more detailed assessment beyond categorical diagnosis. One expert also stated clinicians found value in the ability to assess medication treatment effects using QbTest. Two experts stated that results can be helpful in supporting negative clinical diagnoses of ADHD. Two experts also found use of the technology particularly helpful with young girls where the presentation may be less clear and in those who may 'mask' their symptoms.

Potential system impact

All experts explained the potential beneficial impact of the technology is the reduction in timescale required to reach a diagnostic decision. A reduction in subjective diagnoses and an increase in clinician confidence with regards to diagnostic decision making was found. One expert alluded to the real-world evaluation by an academic health science network (AHSN), which showed a significant reduction in clinician time (20% to 30%) and diagnosis time without loss of diagnostic accuracy. One expert explained that using QbTest allows clinicians to evaluate the impact of medication and make informed decisions about medication. One expert stated the technology is already incorporated within their department in the ADHD pathway.

General comments

All experts stated that the technology is likely to be cost saving due to clinician time saving and efficiency of the pathway. Two experts referred to the real-world demonstrator as evidence. Two experts referred to the regional evaluation by the East Midlands AHSN, where there was a return on investment from 3 trusts adopting the technology. One expert highlighted the economic evaluation of the AQUA trial alluding to both cost saving and cost effectiveness of the technology compared with standard care. Two experts stated this is dependent on how the technology is used.

All experts stated that minimal room adaptation is required, with 4 experts stating that staff training is provided by the company, Qbtech Ltd, with support available anytime. One expert stated that clinicians may mistakenly use QbTest as a standalone tool and that this is not the fault of the technology. Four experts had no experience of adverse effects when using the technology, with 1 expert not commenting.

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Two experts reiterated the importance of recognising the technology as an additional decision aid to routine clinical assessment of ADHD and not a standalone. One expert also raised a concern about whether the technology helps measure ADHD or whether it measures impulsivity, hyperactivity and inattention. One expert also alluded to uncertainty about which QbTest scores and which cut-off points – when adjusting for prevalence of ADHD and type of clinical controls – are most helpful in predicting ADHD diagnosis and treatment response.

Expert commentators

The following clinicians contributed to this briefing:

- Professor Chris Hollis, professor of child and adolescent psychiatry and digital mental health, University of Nottingham. Member of the European ADHD Guideline Group (EAGG). Co-author of EAGG systematic review of QbTest (in preparation).
- Dr Nicola Reynolds, principal clinical psychologist and clinical lead for IND and deputy clinical director for mental health, Health Innovation Network and Oxleas NHS Foundation Trust. Deputy clinical director for mental health at the Health Innovation Network (academic health science network [AHSN]) supporting the Focus ADHD programme.
- Dr Kim Selby, associate specialist in community paediatrics, Medway NHS Foundation Trust. Did not declare any interests.
- Ms Rachel Bullock, nurse consultant, Children and Adolescent Mental Health Services (CAMHS), North Staffordshire Combined Healthcare NHS Foundation Trust. Did not declare any interests.
- Dr Venkat Reddy, consultant neurodevelopmental paediatrician, Cambridgeshire and Peterborough NHS Foundation Trust. Clinical lead at the time of NHS Trust reimbursement for AHSN for the Focus ADHD programme.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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