NICE National Institute for Health and Care Excellence

Evidence generation plan for digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres: early-use assessment

Implementation support

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1 Purpose of this document

NICE's early-use assessment of digital technologies for applying algorithms to spirometry to support asthma and chronic obstructive pulmonary disorder diagnosis in primary care and community diagnostic centres recommends that ArtiQ.Spiro can be used in the NHS during the evidence generation period. The other technologies that were assessed can only be used in research and are not covered in this plan.

This plan outlines the evidence gaps and what data needs to be collected for a NICE review of the technology again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. Evidence generated through other study approaches will also be considered. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence.

The company is responsible for ensuring that data collection and analysis take place. NICE will withdraw all or part of the guidance if a company does not meet the conditions in section 4 on monitoring.

At the end of the evidence generation period (3 years), the company should submit the evidence to NICE in a format that can be used for decision making. NICE will review all the evidence and assess whether the technology can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The company can strengthen the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Diagnostic accuracy

The committee noted that information about diagnostic accuracy, including the number of false-positive and false-negative results when the technology is used as part of NHS care pathways, was not reported adequately. More evidence is needed on the sensitivity and specificity of the technology, ideally compared with current NHS care. This is particularly important in an undiagnosed population.

Impact on the NHS care pathway

A key part of the committee discussion was around the impact on the NHS care pathway for asthma and chronic obstructive pulmonary disorder (COPD). For example, spirometry algorithms could improve access to diagnosis of asthma and COPD in primary care and community diagnostic centres. Collecting evidence on this will help the committee understand how using the technology will affect care in the NHS.

Long-term resource-use data

More information is needed on how using the technology would affect resource use during and after implementation, to help the committee understand its long-term resource use impacts. Key areas that will help to address this evidence gap are:

- long-term resource-use costs, such as staff time, band and accreditation of healthcare professionals using the spirometry algorithms to support asthma and COPD diagnosis
- technology cost per patient of implementing the technology in the primary or community care diagnostic pathway.

2.2 Evidence that further supports committee decision making

Health-related quality of life

The committee asked for more information about how the technology affects health-related quality of life. The EQ-5D is the preferred tool for measuring this outcome. This information can be easily included in health economic evaluations, for which quality of life is an important driver.

Effectiveness in different subgroups

The committee noted that the current evidence comparing the technology's effectiveness in some subgroups is limited. It recommended that evidence be generated in subgroups who may benefit more from the technology, such as those for whom access to spirometry is currently limited or lacking altogether.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them. Information about evidence status is derived from the external assessment report. More information on the studies in the table can be found in the supporting documents.

Table 1 Evidence gaps and ongoing studies

Evidence gap	ArtiQ.Spiro
Diagnostic accuracy of the spirometry algorithm ideally compared with standard care	Limited evidence Ongoing study
Impact of using spirometry algorithms on the NHS care pathway	No evidence
Long-term resource-use data	Limited evidence
Health-related quality of life	No evidence Ongoing study
Effectiveness in different subgroups	No evidence

3.2 Data sources

NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question.

The National Respiratory Audit Programme (NRAP) is a clinical audit dataset that collects information about people with respiratory disease in England and Wales. It includes some data needed to address the evidence gaps, such as standard care in the NHS, hospital admissions, and exacerbations because of asthma or chronic obstructive pulmonary disorder (COPD). NRAP can be linked to other datasets such as NHS Digital's Hospital Episode Statistics (HES) dataset, and this combined dataset could be used to estimate

resource use. HES can be accessed through NHS England's Secure Data Environment service. NRAP can be amended to support additional data collection where necessary.

The quality and coverage of real-world data collections are of key importance when used in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach to ensure good-quality data with broad coverage.

3.3 Evidence collection plan

Real-world prospective comparative cohort study

The study should enrol a representative population and compare people with an asthma or COPD diagnosis made using the technology with a similar group who had standard care. The population should include young people (aged 5 to 16 years) where possible and adults. Eligibility for inclusion, and the point of starting follow up, should be clearly defined and consistent across comparison groups to avoid selection bias.

Data should be collected in all groups from the point at which a person would become eligible for standard care. The data from both the intervention and comparison groups should be collected at appropriate time intervals and for a minimum of 12 months.

Data could be collected using a combination of primary data collection, suitable real-world data sources, and data collected through the technology itself (for example, engagement data).

The technology developer could initially do a 'silent evaluation' (see Kwong et al. 2022) before full deployment into services. This approach allows the technology to be used in a real-world setting without any influence on clinical decision making until it is fully deployed. This approach can be used to:

- understand whether the technology can be deployed safely (including in subpopulations)
- understand how the technology might have influenced decision making (for example, onward referrals and care pathway)
- collect some relevant data items (for example, failure rate or number of indeterminate findings).

3.4 Data to be collected

The following information has been identified for collection:

- patient demographics, including age, sex and ethnicity
- diagnostic accuracy, including false-positive and false-negative results
- accuracy when used by different healthcare professionals
- health-related quality-of-life data, ideally collected with the EQ-5D questionnaire
- resource use, including staff time, band, level of experience and accreditation of healthcare professionals using the technology (for example, Association of Respiratory Technology and Physiology accreditation), and time taken to do and interpret spirometry
- details of the technology (cost, software name, version and configuration settings)
- impact on the NHS care pathway of using the technology, for example, waiting lists, time to accurate diagnosis, and setting in which diagnosis was made.

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies.

3.5 Evidence generation period

The evidence generation period will be 3 years, to allow for enough time to set up and implement the technology, collect the necessary data, analyse and report it.

3.6 Following best practice in study methodology

Following best practice when conducting studies is paramount to ensuring the reliability and validity of the research findings. Adherence to rigorous guidelines and established standards is crucial for generating credible evidence that can ultimately improve patient care. NICE's real-world evidence framework details some key considerations.

Within the context of an early-use assessment, a key factor to consider as part of the

informed consent process is to ensure that patients (and their carers, as appropriate) understand that data will be collected to address the evidence gaps identified in section 2. Where applicable this should take account of NICE's guidance on shared decision making.

4 Monitoring

NICE will contact the company:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm that the data is being collected and analysed as planned.

The company should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- if the technology significantly changes in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the company should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Minimum evidence standards

During the evidence generation period, new technologies may become available. This section summarises the minimum evidence requirements that a new technology would need to meet to be considered in the NICE evaluation after the evidence generation period.

The technology that has been recommended for use in the NHS during the evidence generation period has some clinical evidence suggesting that, compared with standard care, it has:

- comparable diagnostic accuracy results in populations suspected to have either asthma or COPD
- some evidence on spirometry performance quality assessment and spirometry pattern interpretation for example using American Thoracic Society and European Respiratory Society standards
- some costs and resource-use data showing plausibly cost-effective scenarios for diagnosis of asthma or COPD.

But, more information is still needed to fully understand the benefits it may provide. More evidence is needed on:

- diagnostic accuracy of the technology, ideally compared with standard care
- the impact of the technology on the NHS care pathway
- long-term resource use
- effectiveness in different subgroups.

This evidence is essential to future NICE decision making. It will also potentially inform the optimum use and implementation of technologies that apply algorithms to spirometry to support asthma and COPD diagnosis in the NHS.

6 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

Equalities

- It was noted that the NHS has regional variation in access to diagnostic spirometry. The technology may increase the number of primary care settings and community diagnostic centres that are able to offer spirometry as part of their services, addressing this variation.
- The company should collect evidence from important subgroups who may benefit more from the technologies and for whom access to spirometry is limited or lacking all together. These are subgroups such as:
  - people who are less familiar with using digital technologies or have limited access to equipment or the internet
  - people living the most deprived areas
  - neurodivergent people
  - people with learning disabilities
  - people with visual, hearing or cognitive impairments
  - people who have problems with manual dexterity
  - people who have difficulties reading, writing or understanding health-related information (including people who cannot read English).

Evidence generation

- Diagnosis of asthma and COPD in addition to patient history is needed to access necessary treatment from the NHS. The company should consider testing the technology at varied points in the NHS care pathway to identify where it could best support early diagnosis.

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