NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Evidence generation plan

Digital technologies to support asthma self-management

1 Purpose of this document

NICE's early value assessment of digital technologies to support asthma self-management recommends that Asthmahub, Asthmahub for parents, AsthmaTuner, BreatheSmart/Respi.me (RDMP), Digital Health Passport, Luscii, myAsthma and Smart Asthma can be used in the NHS during the evidence generation period.

This plan outlines the evidence gaps and what data needs to be collected for a NICE review of the technologies 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 companies are responsible for ensuring that data collection and analysis takes place.

Guidance on commissioning and procurement of the technologies will be provided by NHS, which is developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the companies do not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years), the companies 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 technologies 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 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

Clinical outcomes

Data in clinical outcomes related to the condition are important to help understand whether changes in management or self-management lead to meaningful improvements in asthma control. Current evidence on exacerbations, medication use and lung function is limited and mostly non-comparative, so it is difficult to assess the real clinical effect of the technologies. It would be useful to collect information on the impact of the technologies on quality of life, as this is an important component of the overall effectiveness of asthma care.

Uptake and attrition rates

Quantitative evidence on uptake and attrition is considerably lacking across technologies. This limits the understanding of how people engage with the technologies, specifically across people with different levels of asthma control. This data is essential for the economic modelling, which is sensitive to the technologies' use. Information on how much people engage and sustain engagement with the technologies is key for future assessments.

Impact on condition management

Qualitative evidence suggests that it is possible to improve symptom awareness and understanding of the condition, but the evidence is still limited. More research is essential to determine whether the technologies can help improve people's

knowledge, self-management and appropriate use of their personalised asthma control regimens.

Healthcare resource use

Evidence on healthcare resource use is limited across technologies. Few studies reported outcomes such as GP consultations, specialist reviews, emergency department visits, hospital admissions or changes in service utilisation related to asthma control. More information on healthcare use is needed to help understand the potential system benefits and inform the economic modelling.

2.2 Evidence that further supports committee decision making

Generalisability to NHS practice

A substantial level of evidence was generated outside of the NHS or lacked details about the clinical pathway, medications and baseline asthma severity. This limits the confidence in how these findings can be generalised to NHS practice and NICE recommended management of asthma. Studies that can collect data on how the technologies fit into UK practice would improve clarity in their applicability.

Barriers and facilitators to using apps

Existing qualitative evidence highlights the potential benefits and practical challenges, including reduced engagement over time, limited digital confidence and mixed user experience with the technologies. A clearer understanding of barriers and facilitators across different demographic and clinical groups would support more realistic implementation planning and reduce the uncertainty in their adoption.

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 group's (EAG's) report; evidence not meeting the scope and inclusion criteria is not included. The table shows the evidence available to the committee when the guidance was published.

Table 1 Evidence gaps and ongoing studies

Evidence gap	Asthmahub	Asthma hub for parents	AsthmaTuner	BreathSmart /Respi.me (RDMP)	Digital Health Passport	Luscii	myAsthma	Smart Asthma
Clinical outcomes	Limited evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence
Uptake and attrition rates	Limited evidence (Ongoing study)	No evidence	Limited evidence (Ongoing study)	Limited evidence (Ongoing study)	Limited evidence (Ongoing study)	No evidence	Limited evidence (Ongoing study)	No evidence
Impact on condition management	Limited evidence (Ongoing study)	Limited evidence	Limited evidence (Ongoing study)	Limited evidence (Ongoing study)	Limited evidence (Ongoing study)	Limited evidence	Limited evidence (Ongoing study)	Limited evidence
Healthcare resource use	Limited evidence	No evidence	Limited evidence (Ongoing study)	Limited evidence	Limited evidence (Ongoing study)	No evidence	Limited evidence	No evidence
Generalisability	Good evidence (Ongoing study)	Limited evidence	Limited evidence	Limited evidence	Limited evidence (Ongoing study)	No evidence	Limited evidence (Ongoing study)	No evidence
Barriers and facilitators	No evidence	No evidence	Limited evidence (Ongoing study)	Limited evidence (Ongoing study)	Limited evidence (Ongoing study)	No evidence	Limited evidence (Ongoing study)	Limited evidence

The EAG identified multiple ongoing studies across the technologies, summarised in Table 17 of the EAG's report. These may provide additional evidence on asthma control, medication use, adherence and quality of life. But the studies will not address all the uncertainties, such as the lack of robust comparative evidence, limited UK data and the absence of reliable information on uptake, engagement and attrition.

3.2 Data sources

Most of the data needed for this evaluation, particularly outcomes about engagement or attrition patterns, is best collected as primary data within the technologies themselves. Some additional outcomes may be available through existing NHS data sources, but generally these will need to be linked to the primary dataset to ensure completeness and accuracy.

Several data collections have different strengths and weaknesses that could potentially support evidence generation. 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. Potential data sources include:

- Clinical Practice Research Datalink (CPRD)
- Hospital Episode Statistics (HES)
- Hospital Admitted Patient Care Activity data
- Hospital Accident and Emergency Activity data (covering acute asthma presentations)
- the UK Severe Asthma Registry, which provides detailed clinical information for people with severe asthma managed in specialist centres
- National Respiratory Audit Programme (NRAP).

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

Prospective real-world comparative cohort study

A prospective real-world comparative cohort study should be done across NHS sites where the digital technologies for supporting asthma self-management are offered and compared with similar sites where they are not yet in use. People with asthma in both groups should be followed from the point when they would typically be offered the technology, reflecting routine referral pathways in primary and secondary care. This includes groups of people with different levels of asthma control (controlled, partly controlled and uncontrolled).

The comparison group should include people from similar services with comparable asthma pathways, clinical structures and patient populations without access to the digital technology. Ideally, the study should be done across multiple centres to reflect the diversity of the NHS service provision.

Non-random assignment to interventions introduces a risk of confounding bias. So, appropriate methods, such as matching or adjustment (for example, propensity score methods), should be used to minimise selection bias and balance confounding factors between groups. High-quality data on patient characteristics will be essential to support these methods. The identification of key confounders should be informed by expert input during protocol development.

Qualitative survey

A qualitative study should be undertaken to understand the experiences of people using the technologies to support asthma self-management, as well as the views of parents or carers (for children) and relevant clinicians. Evidence should be collected through semistructured interviews, structured feedback and focus groups with a diverse sample of users across different NHS sites and clinical severity groups. The robustness of the findings will depend on:

- broad and inclusive recruitment across eligible users

- the sample of respondents being representative of the population of potential users (for examples, variation in asthma control, socioeconomic status or ethnicity)
- capturing and documenting the reasoning for usability, barriers and facilitators, changes in asthma regimens and perceived benefits.

3.4 Data to be collected

Demographic and baseline characteristics

- Age, sex and ethnicity
- Asthma severity and control
- Long-term conditions (such as COPD, anxiety or depression)
- Postcode deprivation index

Clinical outcomes

- Exacerbations (mild, moderate, severe, emergency department visits)
- Lung function measurements, ideally using spirometry (for technologies that offer external devices to measure lung function, data on cost effectiveness and impact on quality of life is expected to be submitted)
- Asthma control
- Rescue versus controller medication use
- Number of asthma attacks
- Time to exacerbation
- Treatment step-up or step-down
- Smoking status
- Quality of life questionnaire (EQ-5D-5L or EQ-5D-Y for children) at baseline and at 3, 6, 12 or 18 months or, ideally, up to 2 years
- Adverse effects (such as anxiety)
- Asthma Quality of Life Questionnaire (AQLQ)
- Ideally, missed school or work days

Uptake and attrition rates

- Date the technology was first used

- Number of logins per month
- Duration of use (days between logins and inactivity periods)
- Discontinuation date and reason
- Completion rates of app tasks or information material
- Percentage of active users at 1, 2, 3, 6, 12 or 18 months or, ideally, up to 2 years
- Engagement reported by asthma control at baseline

Impact on condition management

- Understanding inhaler technique steps
- Changes in symptom recognition scores
- Completing and updating personalised asthma action plan
- Self-reported ability to interpret triggers, warning signs and deterioration
- Adherence to preventative medication
- Qualitative findings on improved understanding or self-management

Healthcare resource use

- Number of GP visits
- Number of specialist visits
- Number of emergency department attendances
- Number of hospital admissions and length
- Use of out of hours services
- Courses of corticosteroids prescribed in primary or secondary care

Generalisability to UK guidelines

- Setting (UK or outside UK)
- Baseline asthma severity data (controlled, partly controlled or uncontrolled)
- Reporting of medication regimen
- Reporting of alignment with NHS care pathway

Barriers and facilitators

- User-reported technical issues
- Qualitative data on satisfaction and acceptability
- Patient and clinician views on usefulness of modules

- Accessibility needs (support with visual, cognitive or language needs)
- Reporting barriers and facilitators when used in clinical practice

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

3.5 Evidence generation period

This will be 3 years to allow for setting up, implementing the test, data collection, analysis and reporting.

3.6 Following best practice in study methodology

Following best practice in conducting studies is paramount for 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. The NICE real-world evidence framework details some key considerations.

Within the context of an early value 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 guidance about shared decision making.

4 Monitoring

NICE will contact the companies:

- 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 companies 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
- the technologies significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the companies 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 minimum evidence standards for this topic were informed by company submissions, the external assessment group (EAG) report and the committee discussions. Together, these sources provided an overview of the current clinical and economic evidence for digital technologies supporting asthma self-management in the NHS.

The committee noted that, although evidence was available across some outcomes, such as asthma control, quality of life and user experience, there were important limitations. Comparative evidence was limited, follow-up periods were short and there was a lack of reliable data on uptake, sustained engagement and attrition. Evidence on exacerbations, medication use and service utilisation was inconsistent, and the small incremental benefits reported created uncertainty in the economic modelling. Several studies were done outside the UK or lacked sufficient detail on clinical pathways, so generalisability to NHS practice was uncertain.

Future studies will help to address key uncertainties, strengthen understanding of clinical outcomes and support future decision making on whether these technologies should be routinely used in the NHS.

6 Implementation considerations

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

- The companies should provide training for staff in using the technologies, when support is needed. The training and implementation period should be before the data collection period and be sufficient to account for potential learning effects.
- Evidence generation should be overseen by a steering group that includes researchers, commissioners, practitioners and people with lived experience.
- The evidence generation process is most likely to succeed with dedicated research staff, to reduce the burden on NHS staff.
- Sites should be carefully selected to maximise data collection, when appropriate, and ensure that services representative of those in the NHS are included.
- Careful planning of the approach to information governance is vital. The companies should have appropriate structures and policies in place to ensure that the data is handled in a confidential and secure manner and in line with appropriate ethical and quality standards.

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

- the availability of research funds for data collection, analysis and reporting, as well as NHS funding to cover the costs of implementing the technologies in clinical practice
- lack of expertise and staff to collect data
- burden on clinical staff, such as needing training before implementation, data collection and follow up
- variable levels of digital literacy, affecting uptake and use of the technologies
- support for languages other than English, affecting the uptake and use of the technologies.

The committee also highlighted practical considerations for implementation:

- Some outcomes (such as lung function indices) have different relevance across age groups. For example, in children, forced expiratory volume in 1 second (FEV1) is less reliable, but symptom patterns and exacerbation history may be more informative for decision making.
- Technologies may be used for routine day-to-day management or to support remote clinical assessment. These 2 use cases have different implications for cost effectiveness, safety monitoring and staff workload.
- Improving adherence is not an end in itself; the focus should remain on downstream clinical outcomes, such as reducing exacerbations, steroid use, emergency department visits and symptom improvement.
- Automatic data collection is preferable. Manual entry may decline over time, reducing data quality and completeness.

ISBN: [to be added at publication]