[GID-HTE10065] Digital technologies for asthma self-management

Protocol

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Plain English Summary

Asthma is a common long-term condition that affects people's breathing. It cannot be cured but there are different treatments that can help improve how well the lungs work and control the symptoms people get, such as wheezing, coughing, shortness of breath and the chest feeling tight. Although there are guidelines about how to treat the condition, uncontrolled asthma is still very common and can lead to emergency visits to hospital and sometimes to death. Digital health technologies, such as apps, could potentially help people to keep their asthma under control by giving them the ability to track their own symptoms, reminding them to take medications, and by giving educational content (such as the best way to use an inhaler).

As an External Assessment Group for the National Institute of Health and Care Excellence (NICE), we have been asked to bring together the current evidence about digital health technologies that might help people manage their asthma. We want to find out if there is evidence that using digital technologies to support people to manage their asthma works, and whether it might be good value for money for the National Health Service (NHS).

To do this, we will bring together published and unpublished evidence about how well different digital technologies work for both children and adults. We will be looking at the evidence for nine digital technologies: Asthmahub; Asthmahub for parents; AsthmaTuner; Digital Health Passport; Luscii; MyAsthma; NuvoAir Home; Smart Asthma; and the Respiratory Disease Management Platform.

As well as bringing together evidence on how well these technologies might work, we will also be creating an "economic model", which is a type of statistical research that helps us make predictions about whether these digital technologies might be good value for money for the NHS. We will also be looking at research that has collected information on peoples' opinions on the different technologies, so that we have a better idea of what people who have used them think about how well they work and if there are any challenges when using them.

Once completed, we will send our report to NICE, who will use it to make a decision about whether these digital technologies could be used for helping people manage their asthma in the NHS.

1. Decision problem

The scoping document highlights that asthma is a long term health condition which requires self-management.[1] However, structured self-management support guidance is still lacking. Digital technologies may be able to aid in the self-management of asthma. The decision problem question is therefore: does the use of digital technologies to support self-management of asthma have the potential to be clinically and cost-effective in the NHS?

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the published scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description	EAG comments
Population(s)	People with a confirmed diagnosis of asthma, their families, or carers	No comment
Subgroups	Where data allows, we will consider the following: • Adults (aged 17 years and over) • Young people/adolescents and children (aged 5 to 16 years) • Families or carers of children under 5 years • People newly diagnosed • Severe asthma • uncontrolled asthma/at risk of poor outcomes	Where data allows we will attempt to stratify patient risk using the criteria suggested by Couillard et al (2022), which includes number of asthma attacks in the last 12 months, FeNO values, blood eosinophils, and Global Initiative for Asthma (GINA) risk factors (e.g. mean ACQ score ≥1.5, low FEV, obesity)[2] We will also consider families or carers for people of any age, where necessary
Intervention(s)	• Asthmahub • Asthmahub for parents • AsthmaTuner • Digital Health Passport • Luscii	For the RDMP it must be used in conjunction with the application Respi.me or BreatheSmart.

	• MyAsthma • NuvoAir Home • Smart Asthma • Respiratory Disease Management Platform (RDMP)	
Comparators	Standard care which could include self-management without digital support	No comment
Setting	Community, primary or secondary care, tertiary specialised centres	No comment
Outcomes eligible for inclusion (organised by outcome type)	Intermediate outcomes: • Inhaler technique (using checklists or standardised scoring tools like 'inhaler technique assessment tool') • Medication use (including use of rescue/reliever medication and type of inhaler) • Adherence/attrition rates • Number of referrals to specialists Clinical outcomes: • Changes in symptoms/symptomatic improvement • Lung function (FEV1, FVC, PEF or FeNO) • Asthma control (measured using validated tools such as C-ACT, ACT, ACQ or SGRQ) • Symptom free days • Exacerbations or attacks • Mortality • Adverse events (such as respiratory infection) Patient reported outcomes: • Time off work (adults/parents/carers)/school (children/young/people) – number of work/school days missed	For medication use, we will consider the reduction of a reliever a positive result. An increase in preventer use will be a positive result. For adherence/attrition rates we will consider both medication and application use separately. For exacerbations or attacks, the definitions may vary and we will extract author definitions where reported. Additionally, we will consider the implication of oral corticosteroid use, which can become long term and lead to adverse events. Mortality will be considered as a serious adverse event and identified separately within these. Respiratory infections are likely to be linked with treatment adherence, where possible this will be reported. For quality of life outcomes we will consider asthma specific (e.g. AQLQ) and general quality of life measures (e.g. EQ5D).

	• Quality of life
	• Ease of use and acceptability
	• Patient perception of technology
	
	Costs and resource use:
	• Cost of the technologies including software, device, license fees, staff training, patient education, implementation, and ongoing operational costs
	• Costs and healthcare resource use associated with managing asthma and exacerbations such as:
	  ○ Unscheduled hospital presentations, e.g. emergency department visits, urgent consultations, adverse events or complications
	  ○ Healthcare appointments/visits in all settings (community, primary, or secondary care) including tertiary asthma services
	  ○ Length of hospital stay
	  ○ Number of treatments and extent of treatments
	  ○ Staff time (including remote care).
		These will be reported separately in the report.

Time horizon	The time horizon for estimating the clinical and cost effectiveness should be sufficiently long enough to reflect any differences in costs or outcomes between the technologies being compared.	The EAG recommend a time horizon of 12 months for the base case, which may be extended in sensitivity analysis
Gap analysis	Evidence gaps in clinical evidence and cost modelling should be identified to help direct further evidence generation.	No comment

1.1 Objectives

The purpose of this evidence assessment is to summarise the evidence for the digital technologies included in the Final Scope. The aim is to evaluate the clinical-effectiveness and cost-effectiveness, identify evidence gaps, and highlight any risks associated with the potential use of these digital technologies in the NHS while further evidence is generated. It should be noted that the purpose of the review is not to compare the technologies with each other. Based on the scope developed by NICE, the following specific primary objectives are proposed:

- To identify, review and summarise evidence of the clinical effects and safety of digital technologies as an aid or adjunct, when compared with the standard of care.
- To identify, review and summarise the economic evidence of digital technologies as an aid or adjunct, when compared with standard of care.
- To develop an early economic model to provide an initial assessment of the potential cost-effectiveness of digital technologies when compared with standard of care.
- To summarise information on the capacity, capabilities and practicalities of implementing digital technologies.
- To identify important evidence gaps for each digital technology in scope and outline what data could be collected to address them.

2. Evidence review methods

The EAG will review the standard request for information forms and instructions for use (IFU) submitted to NICE for each digital technology within scope in order to develop a technology summary. This will be supplemented by information from company websites and from peer-review publications. Indications and

contraindications listed in each IFU will be considered, any evidence identified which has been undertaken in a contraindicated population will be excluded by the EAG. Any missing or incomplete information may be supplemented from information found in the public domain, for example from company websites, as appropriate.

The EAG will search for relevant national guidelines (from NICE, other HTA organisations and professional societies) and any routine data collection (for example from NHS England list of national clinical registries, databases and audits) relevant to this topic. This will be supplemented by asking the Clinical Experts if any additional national guidance or data collection is relevant to this topic. Relevant sources will be summarised in the clinical context section.

Clinical and economic evidence provided by companies in scope will be supplemented by an independent literature search undertaken by the EAG.

2.1 Inclusion criteria

The inclusion and exclusion criteria are outlined in Table 2. In instances where no evidence directly relevant to the scope is identified for a technology from the literature searching, the EAG may expand the elements of the scope and will consult with clinical experts to determine the generalisability of the included evidence and findings to the UK NHS.

The population of interest is patients diagnosed with asthma, this definition may vary between geographical location and study date. We will therefore extract the authors' definition of confirmed asthma were reported. While systematic reviews will be excluded from the main report, we will assess their reference lists for potentially relevant includes. To accomplish this, we will use CitationChaser, which will automate the collection of potentially relevant records.[3] We will also consider any data found regarding health equality (e.g. those with neurodiverse conditions, learning disabilities, visual, hearing or cognitive impairment or problems with manual dexterity, or who are less used to using digital technologies in general).

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Population	Patients with diagnosed asthma (may be suspected asthma in under 5 years)	Undiagnosed asthma (including exercise induced asthma)
Intervention	Any of the following technologies: • Asthmahub • Asthmahub for parents • AsthmaTuner • Digital Health Passport • Luscii • MyAsthma • NuvoAir Home • Smart Asthma • Respiratory Disease Management Platform (RDMP)	Any other technology not named; for the RDMP this must be used in conjunction with the Respi.me or BreatheSmart application..
Comparators	Any form of standard care which could include self-management without digital support	Any comparator that is not a form of standard care
Setting	Community, primary or secondary care or tertiary care	Any care setting that may fall outside those mentioned
Outcomes	Any outcome as listed in Table 1	Outcomes outside of the scope which are not included in Table 1
Study design	Randomised controlled trials Comparative observational studies (including before-after studies) Qualitative studies Mixed-method studies	Single arm observational studies with no comparative data Case studies/series Systematic reviews
Other	Studies must be available in English	Studies reported in languages other than English

2.2 Search strategy

A pragmatic search strategy will be developed based on the literature search strategy shared by the NICE Information Specialist team during scoping (see Appendix) and identified published literature reviews in the topic area (for example

Belisario et al. 2013; Hodkinson et al. 2020)[4, 5]. The strategy will be optimised for the decision problem (for example including company and technology names listed in the Final Scope, and older device names as advised by the companies in their completed request for information). Searches will supplement information provided by the companies. The search strategy will be applied to the following electronic databases:

- MEDLINE, EMBASE, CINAHL, Cochrane CDSR and CENTRAL for clinical evidence,
- INAHTA, RePEc/IDEAS, PEDE for economic evidence,
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) for ongoing studies,
- MHRA Field Safety Notices for adverse events.

Filters will be applied, as appropriate, to identify economic evaluations. The EAG will consider applying limits to the literature search (for example date of publication) where appropriate.

Published and unpublished studies provided by companies and other stakeholders will also be considered and included if relevant to the decision problem.

2.3 Study selection

Titles and abstracts will be screened using online software (Rayyan).[6] Two reviewers will initially screen 20% of the studies, blinded. Once agreement has been met between the two reviewers the remaining studies will be assessed individually by the reviewers. For those deemed relevant to the scope, full papers will be retrieved and reviewed in the same manner as the title and abstracts (i.e. 20% initially double screened). Any exclusions of full papers will have the reason for exclusion tabulated.

If a large amount of relevant evidence is identified, the EAG will prioritise evidence it considers most relevant to the decision problem; this may be based on study location/setting, study design, and sample size.

2.4 Data extraction strategy

A tailored data extraction form will be created in Microsoft Excel and piloted. Once piloted, any adaptations necessary will be made. Two reviewers will extract data into the form. One reviewer will extract data and another will check for accuracy. Data points to be extracted include information about the study reference, setting, design, population characteristics, medication characteristics (including delivery method), intervention characteristics and results of relevant outcomes as listed in the Final Scope. For qualitative studies, we will also extract the method of data collection (e.g. focus group, interviews), analysis method (e.g. thematic or framework analysis) and relevant information relating to the outcomes listed within the Final Scope. Any additional outcomes reported in the included evidence will be extracted, if time permits. Results will be summarised by technology, outcome and age group (where applicable).

2.5 Quality assessment strategy

Formal risk of bias assessment will not be completed. Discussion will be included in the EAG report on potential biases in included studies and how the risk of bias could affect key outcomes. The report will explicitly detail the potential sources of bias such as the main confounding factors and will comment on the generalisability of the results to clinical practice in the NHS.

2.6 Methods of synthesis and analysis

Clinical evidence will be narratively synthesised by technology, outcome, and age (subgroups will be considered within this framework as appropriate/where applicable). Qualitative data will be synthesised using a framework analysis according to outcomes listed within the Final Scope and summarised narratively alongside clinical evidence. Methods and findings from included published economic evidence will be summarised in a tabular format and synthesised in a narrative review.

For the economic evidence, economic modelling results will be summarised separately from economic evaluations of published randomised trials using technologies listed in the scope. Economic evidence from the perspective of the UK NHS and Personal Social Services will be presented in greater detail.

3. Economic analysis methods

The primary aim of the economic analysis is to work out whether it is plausible that using digital technologies to support self-management of asthma is cost-effective in the NHS. It will consider people with a confirmed diagnosis of asthma, and their families or carers, where appropriate, and may further consider specific subgroups, as detailed in the Final Scope. The secondary aim of the analysis is to identify the key drivers of the model and highlight the evidence gaps that could be filled with further evidence generation. It is expected that a simple model with a time horizon of 1 year will be enough to meet these aims. Clinical experts will be asked to comment on the validity of the model structure, its inputs, and assumptions, to make sure they are appropriate. It is unlikely that there will be a published economic evaluation that fully meets the scope of this assessment. Therefore, it is likely that a de novo model will be developed and will use the relevant features of available models where appropriate.

3.1 Model development

The EAG will develop a cost-utility model to estimate the costs, including for resource use, and quality-adjusted life years (QALYs) between treatment arms. The proposed time horizon of 1 year has been chosen because it is likely to be long enough to reflect differences in costs or outcomes between the technologies being compared, and should account for seasonal variation in asthma symptoms. It is possible that the only outcomes with enough evidence to be modelled will be health related quality of life, and number of asthma exacerbations resulting in emergency treatment or hospital admission. If evidence exists for other outcomes, these may also be included. Modelling will be from the perspective of the NHS and personal

social services, and cost-effectiveness will be evaluated against a threshold of £20,000 per QALY, in line with the NICE reference case.

The EAG will describe the appropriate characteristics of the model (for example structure, setting, input parameters, sources of data, assumptions). The structure of the model and parameters used to populate it will be informed by clinical evidence and economic evidence identified from the EAG review and advice sought from Clinical Experts regarding assumptions and parameter values where evidence is lacking. Targeted searches for economic model inputs may be considered where appropriate.

The EAG will explore the impact of different cost options supplied by companies on the economic model. Where appropriate, and if data and time allow, sensitivity analysis will be undertaken to explore uncertainty. These may include deterministic and probabilistic sensitivity analysis, scenario analyses and subgroup analyses focused on what are believed to be the key characteristics and population subgroups identified in the Final Scope. Costs will be considered from an NHS and Personal Social Services perspective, consistent with the reference case framework (NICE Health Technology evaluations manual, 2022).

3.2 Conceptual modelling

The EAG will construct an economic model built in either Microsoft Excel or R Programming Language, which will be informed by published economic evaluations describing the asthma management pathway. This may include learnings from published economic studies. The EAG expects that a Markov model would be most suitable to address the decision problem. This is in line with the combined NICE, SIGN and BTS guidance on diagnosis, monitoring and management of chronic asthma. However, if there is not enough data available to populate this model, the EAG may develop a simple cost comparison model, taking a similar approach as York Health Economics Consortium took in their early value assessment of digital technologies to support management of COPD, or use other approaches if appropriate, and if data allow.

3.3 Cost of reversing a decision

The EAG will consider the costs of reversing a decision to implement the technologies. In particular, up-front costs, such as for staff training, and integration of the digital technologies into current NHS services will be explored. These will also be considered in sensitivity analysis, if appropriate.

4. Evidence gaps analysis

Evidence gaps identified pertaining to the intermediate, clinical, and patient reported outcomes from the scope and those pertaining to the economic modelling will be summarised in tabular and narrative form. Key areas for evidence generation will be summarised in tabular form. Narrative text will also address missing clinical evidence for other parts of the scope, such as population, setting and comparators. The EAG will outline potential study designs to address specific research questions to address identified evidence gaps.

5. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by **24 September 2025**. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any 'academic in confidence' data provided by company(s), and specified as such, will be highlighted in yellow and underlined in the assessment report. If confidential information is

included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values).

6. Additional information sources

NICE will recruit experts and specialist committee members for this assessment. Specialist committee members are recruited in accordance with NICE's appointments to advisory bodies policy and procedure.

7. Competing interests of authors

None.

8. References

See the NICE style guide:
https://www.nice.org.uk/corporate/ecd1/chapter/referencing-and-citations.

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Appendix A: Literature search developed by NICE (Medline)

Database: Ovid MEDLINE(R) ALL <1946 to June 13, 2025>

Search Strategy:

1 ("Respiratory Toolkit" or Myasthma* or "Digital Health Passport" or "Asthma?me" or "Smart Asthma" or "Propeller Health" or "Asthma MD").af. (125)

2 asthma*.ti. (113803)

3 (app or apps).ti,ab. (53661)

4 (online or web or internet or digital*).ti. (166128)

5 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti. (31326)

6 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti. (10553)

7 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab. (27304)

8 or/3-7 (264220)

9 2 and 8 (735)

10 (self-manag* or home* or communit* or self-direct* or patient led).tw. (1535114)

11 9 and 10 (268)

12 1 or 11 (385)

13 limit 12 to yr="2015 -Current" (319)

14 limit 13 to english language (316)

15 animals/ (7682799)

16 exp Animals, Laboratory/ (1000854)

17 exp Animal Experimentation/ (10718)

18 exp Models, Animal/ (684634)

19 exp Rodentia/ (3721320)

20 (rat or rats or mouse or mice or rodent*).ti. (1531716)

21 or/15-20 (7815678)

22 21 not humans/ (5437851)

23 14 not 22 (316)

Appendix B: Literature search draft developed by EAG (Medline)

Database(s): **Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions** 1946 to August 21, 2025
Search Strategy:

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=1nBM9VcsDHwufa5uENX6ZTbUsBNC1C3fl7itgGllo43H4hKZvgE8CoDB18suVDhop

#	Searches	Results
1	exp Asthma/	149603
2	(asthma or asthmatic or "chronic respiratory" or wheez*).ti,ab,kw.	210252
3	((reduc* or inflammation or narrow*) adj2 airway*).ti,ab,kw.	24549
4	or/1-3	241296
5	Self-Management/	7064
6	((self or personal) adj2 (manag* or regulat* or care or help or aid or govern* or organi*)).ti,ab,kw.	124904
7	or/5-6	125534
8	Digital Technology/ or Digital Health/	2488
9	((medical or digital or automated or personal* or cyber*) adj2 (technolog* or device*)).ti,ab,kw.	56278
10	(phone* or telephone* or smartphone* or cellphone* or smartwatch* or "mobile health" or mhealth or m-health or ehealth or e-health or emental or e-mental or online or web or internet).ti,ab,kw.	723866
11	((apple or google or mobile*) adj2 (play or store or based or application* or intervention* or device* or technolog*)).ti,ab,kw.	27196
12	(MedTech or app or apps).ti,ab,kw.	55505
13	or/8-12	815927

14	(mHealth or "Institute of Clinical Science & Technology" or "Tiny Medical apps" or "Smart respiratory products Ltd" or "Smart respiratory products limited" or "Imperial I-Hub" or Luscii or Nuvoair or MediTuner or "aptar digital health").ab,in,go,ci.	7194
15	4 and 7 and 13 and 14	61
16	(MyAsthma or Asthmahub or "Digital Health Passport" or "Smart asthma system" or "Smart asthma app" or Luscii or AsthmaTuner* or "Asthma Tuner" or "NuvoAir home" or " aptar digital health respiratory disease management platform" or "ADH RDMP" or "respi.me" or "respi me" or breathesmart).ti,ab,kw.	22
17	or/15-16	81