Assessing the cost-effectiveness of Smartinhaler technology in primary care: a health economic decision Model in school-Aged children (SMART-MOD)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000556

Study ID

1000000556

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study aims to evaluate whether digital interventions, such as Smartinhalers, are cost-effective tools for improving medication adherence and reducing unscheduled medical contacts (UMCs) among school-aged children with asthma.
Poor adherence to maintenance therapy is a known contributor to exacerbations and emergency care use in paediatric asthma, causing a significant financial burden to the NHS.

This study will be conducted in three key phases:

Phase 1 involves a secondary analysis of a retrospective cohort of school-aged children with asthma using NHS primary care data. This phase will examine patterns of ICS adherence (e.g. via Medication Possession Ratio), the frequency and nature of UMCs, and estimate mathematical relationships such as risk ratios and average treatment effects. Seasonal variation in adherence and UMCs will also be analysed.

Phase 2 introduces a Quality Improvement (QI) programme in collaboration with GP practices. This phase aims to identify and extract uncoded UMC data from free-text entries and discharge summaries in electronic health records to strengthen the accuracy and completeness of healthcare utilisation data.

Phase 3 will integrate the findings into a health economic model using a Individual-Level Simulation approach. The model will simulate patient pathways over time, accounting for adherence, asthma control, seasonal effects, and intervention uptake. Cost and outcome estimates will be analysed from an NHS perspective.

The ASTHMA study will generate evidence to support national policy and commissioning decisions regarding digital adherence technologies for asthma in

children in primary care.

Study status

Planned

Research institutions and networks

Institutions

University of Sheffield

Asthma UK Centre for Applied Research

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Optimum Patient Care (OPC) Network

United Kingdom (Northern Ireland)

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Network ENCePP partner

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/09/2022

Study start date

Planned: 01/06/2025

Data analysis start date

Planned: 01/06/2025

Date of final study report

Planned: 30/09/2026

Sources of funding

- EU institutional research programme

More details on funding

This research is funded by the University of Sheffield as part of the Wellcome Trust Public Health Economics PhD programme.

Study protocol

Research Protocol.pdf (161.93 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Study Design: Retrospective secondary analysis using cohort of school-aged children with
asthma aged 5-16 from 2022-2024.

Main study objective:

Research Question
What interventions are effective, and cost-effective towards achieving optimal adherence to inhaled medication in school-aged children with asthma?

Aim
To evaluate the effectiveness, and cost-effectiveness of interventions aimed at achieving optimal
adherence to inhaled medication among school-aged children with asthma.

Objectives
i) To describe and characterise the extent of medication adherence among school-aged children with
asthma.
ii) To extract and define unscheduled medical contacts from NHS primary healthcare records
iii) To analyse the relationship between asthma medication adherence and

unscheduled medical
contacts by: assessing (1) the association between adherence levels and the frequency of
unscheduled medical contacts, (2) the causal impact of adherence on reducing asthma-related
exacerbations and healthcare utilisation, and (3) the influence of seasonal variations on the
adherence-outcome relationship.
iv) To develop a health economic decision model to represent the relationship between asthma
medication adherence and unscheduled medical contacts.
v) To simulate the effects of one or more interventions that improve medication adherence using
this decision model, and identify those that are cost-effective towards achieving optimal levels

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Health economic evaluation (based on secondary data)

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

School-aged children (5 to 16 years) with a clinical diagnosis of asthma who have been prescribed inhaled corticosteroids (ICS) as maintenance therapy. The study population is derived from routinely collected UK primary care electronic health records.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

112.949

Study design details

Setting

The study is a secondary analysis of longitudinal United Kingdom primary care data collected between 2022 and 2024, using routinely recorded electronic health records that include information on prescriptions, clinical diagnoses, and healthcare use.

The study population includes school-aged children aged 5 to 16 years with a coded diagnosis of asthma who have received at least one prescription for inhaled corticosteroids as maintenance therapy during the study period. Children are included if they have sufficient follow-up data to calculate medication adherence and to identify unscheduled medical contacts.

Medication adherence is measured quarterly using the medication possession

ratio and categorised into three levels:

Optimal adherence: 80% or higher

Intermediate adherence: 50 to 79%

Poor adherence: below 50%

Patients are stratified by adherence level to examine differences in outcomes. Model-based comparisons are conducted between usual care and intervention scenarios, such as the implementation of digital adherence technologies like Smartinhalers. These scenarios are evaluated within a individual-level simulation model to estimate the clinical and economic impact of improved adherence.

The model includes the following covariates:

Baseline covariates: age, sex, socioeconomic status, baseline asthma severity
Time-varying covariates: medication adherence as Medicines Possessions Ratio, asthma control, asthma symptom severity, previous unscheduled medical contacts, healthcare use

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Comparators

The study uses an individual-level simulation model to compare the clinical and economic outcomes of different adherence strategies in school-aged children with asthma.

The model will compare:
Standard care, where children are prescribed inhaled corticosteroids without

additional adherence support

Digital adherence interventions, such as Smartinhaler technology, which monitor inhaler use and aim to improve adherence through feedback or reminders

Comparisons will also be made across adherence levels defined by quarterly medication possession ratio:

Optimal adherence (80% or higher)

Intermediate adherence (50 to 79%)

Poor adherence (below 50%)

The simulation will estimate the impact of these comparators on unscheduled medical contacts and routine asthma management costs over time. The analysis will assess which strategies are cost-effective from the perspective of the UK National Health Service and Personal Social Services.

Outcomes

The adherence outcome variable will be defined by the Medicines Possession Ratio (MPR). MPR is
calculated as the ratio of the number of days' supply of medication obtained by a patient over a
specific period, to the total number of days in that period. The total days covered will be sourced through the summation of asthma medication prescriptions within the dosage table of the patient’s EHR. It is anticipated that prescriptions for first-line, low dose ICS maintenance therapy in children, such

as 100-200 mcg/daily of Beclomethasone dipropionate and Budesonide, will be used to calculate the MPR initially.
The dependent variable of this analysis are unscheduled medical contacts. Within the NHS,
unscheduled medical contacts are those that occur without a pre-arranged appointment. These
types of contacts cater to immediate or urgent healthcare needs.

Annual Unscheduled Care Frequency
The unscheduled medical contacts that form this variable include asthma-related Emergency
Department (A&E), inpatient and outpatient attendances including urgent care centres, walk-in
centres, out-of-hours GP services, and home visits by GPs. The total frequency of unscheduled
medical contacts will be calculated by totalling each individual event for each patient over the year, thereby providing a single measure of the frequency of unscheduled care utilisation for each patient.

Data analysis plan

A longitudinal person-period dataset will be constructed using quarterly intervals, capturing changes in adherence and healthcare use over time. Medication adherence will be measured using the Medication Possession Ratio and categorised into good, intermediate, or poor. These adherence profiles will be tracked across time and linked to unscheduled medical contacts and healthcare costs.

To account for time-varying confounding, inverse probability of treatment weighting (IPTW) will be used to estimate causal effects. Stabilised weights will

be applied at each time point to create a pseudo-population where adherence is independent of prior covariates. Weighted regression models will estimate the average treatment effect of adherence level on both unscheduled contact rates and healthcare costs, providing a measure of relative and absolute risk over time.

These results will be used as inputs in an individual-level simulation model. The model will project patient-level outcomes over time and simulate the effects of different adherence scenarios, including standard care and adherence-enhancing interventions such as Smartinhalers. Comparative analysis will estimate the incremental costs and outcomes of each strategy.

Internal validity will be strengthened through the use of IPTW and sensitivity analyses testing alternative assumptions. While external validity is limited to the UK primary care context, real-world data enhances generalisability. Cost-effectiveness will be assessed from the NHS and Personal Social Services perspective using standard decision modelling techniques.

Summary results

The model will produce estimates of the impact of adherence-improving interventions on unscheduled medical contacts and healthcare costs in children with asthma. Results will include comparative outcomes between standard care and Smartinhaler-based intervention scenarios. Primary results will include incremental costs, reductions in unscheduled contacts, and incremental cost-effectiveness ratios (ICERs) from the UK NHS and Personal Social Services perspective.

Where applicable, quality-adjusted life years (QALYs) and cost-effectiveness acceptability curves will also be reported to support decision-making.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after creation of study variables

Data characterisation details

To characterise the cohort of school-aged children with asthma, a structured approach was
employed using the NHS Digital SNOMED CT Browser to identify and extract relevant codes for
various specifications (NHS Digital, 2017).
This process involved searching for codes associated with QOF-published medication lists; unscheduled care, including out-of-hours care, hospital admissions, and emergency department visits; and severity levels of asthma. Additionally, codes were sought for control measures, including validated questionnaire scores such as ACT, and ACQ; lung function indicators such as Peak Flow and FEV; societal aspects like school absenteeism; and patient/practice-level characteristics, including age, sex, ethnicity, and deprivation level (IMD).
The extracted codes were recorded in a spreadsheet to facilitate data extraction from the OPCRD dataset. A feasibility test was then conducted to estimate the cohort size and verify the practicality of the criteria.