Feasibility and value of a domiciliary spirometry programme in the assessment of severe asthma: a real-world evaluation

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Shareable abstract (@ERSpublications)
A domiciliary spirometry programme can capture new obstructed lung function and favourably alter the management of individuals with treatment-refractory asthma; further work is needed to address patient-centric issues that lead to poor uptake and adherence. https://bit.ly/3QQvJEr

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Abstract

Background Domiciliary spirometry (DS) is a novel tool that is widely employed in the assessment of respiratory disease. We assessed real-world feasibility, effectiveness and value of a physiologist-led home spirometry programme in patients with treatment-refractory severe asthma.

Methods Patients were referred and provided with a hand-held DS device. Patients completed baseline measurements in a physiologist-led virtual clinic and were instructed to provide further values during any periods of respiratory symptoms. Outcome measures included prevalence of new obstructed events, DS adherence and uptake of this approach.

Results 112 patients were enrolled from November 2020 to January 2023. 102 individuals, mean±SD age 44±13 years (86% female) with median (IQR) forced expiratory volume in 1 s % predicted 88% (77–97%), successfully recorded baseline spirometry values. During follow-up (24 months), 11 (11%) were identified with new obstructive spirometry and were subsequently able to be commenced on biologic therapy. Patient engagement was poor with median (IQR) of 4 (2–6) attempts of contact made before baseline values were recorded, and 2 (1–3) attempts required to record technically acceptable values. Continued DS use was suboptimal; 34% failed to use their device after baseline and only 10% continued at the end of the study period. The cost of DS measurements was greater than a single hospital-based visit but enables multiple event capture.

Conclusion Overall, DS measurement uptake was poor, with a minority of patients continuing to use the device at the end of the study period. However, for those that engage, DS provides an alternative approach to traditional hospital-based spirometry measurements that can alter clinical management.

Introduction

Asthma is a heterogeneous disease that often presents with nonspecific respiratory symptoms [1]. Accordingly, guidelines emphasise the importance of obtaining objective evidence to ensure a diagnosis is secure [2]. These tests include the characterisation of pulmonary physiology to detect variable airflow obstruction [2]. Utilising robust objective tests in assessment and diagnosis is particularly important when evaluating individuals with “difficult-to-treat” or “treatment-refractory” disease. In this context, several differential diagnoses (*e.g.* inducible laryngeal obstruction (ILO)) may act to mimic the diagnosis of asthma, leading to inappropriate use and escalation of asthma medications [3]. Reports indicating that asthma remains frequently misdiagnosed underpin why many guidelines mandate the presence of airflow obstruction, prior to commencement of novel therapies, such as biologic treatments [4].

The ability to undertake objective physiological testing, to reliably capture evidence of airflow obstruction in people with asthma symptoms, can be challenging. Typically, physiological measurement is undertaken

in a clinic or hospital-based setting. The variable nature of asthma, however, means that pulmonary function may be normal during periods of stable disease and abnormalities may only become apparent during a symptomatic period. Thus, undertaking physiological assessment in individuals when they are symptomatic is desirable, but may be limited by the ability to schedule pulmonary function testing in a formal setting and more recently by constraints arising from SARS-CoV-2 pandemic restrictions.

Technological advances have facilitated development of home or domiciliary, self-administered measurement of pulmonary function [5]. Domiciliary spirometry (DS) is now frequently deployed for monitoring chronic pulmonary conditions such as cystic fibrosis and interstitial lung disease [5]. In this setting, DS has been used to detect and characterise pulmonary impact at a time commensurate to exacerbations, evaluate subsequent disease progression and assess response to treatment [5, 6]. Modern devices for DS are light-weight, portable, simple to use and interface with mobile phone technology to allow rapid transmission of data.

In the assessment of asthma, DS was first reported in the 1990s [7], with more recent work evaluating the feasibility and safety of remote spirometry in monitoring asthma control and exacerbations [8, 9]. The cost and accessibility of DS devices has improved over the past 5 years, but to date there is no real-world evidence describing the practical application of a DS approach outside a dedicated research setting. Moreover, many devices now permit recording and subsequent visualisation of the full flow volume loop (FVL), including measurement of forced expiratory volume in 1 s (FEV_1), which presents a distinct advantage over simple peak expiratory flow measurement. This functionality can provide insight regarding the reproducibility of measurements and permits an evaluation of the appearance of the FVL, to detect expiratory flow limitation and attenuation of inspiratory flow, *e.g.* as may be seen in ILO with or without breathing pattern disorder (BPD).

Over the course of the SARS-CoV-2 pandemic we accelerated the use of DS in a home spirometry programme (HSP), with the aim to enable capture of variable expiratory flow limitation and evidence of obstructive pattern spirometry in otherwise treatment-refractory, severe asthma patients. We herein report the effectiveness of this asthma service HSP, focusing on describing uptake, patient experience, safety, data quality and estimated cost impact (*i.e.* both from a financial and environmental/carbon cost perspective). We also report the outcome of monitoring in prompting access to novel asthma therapies.

Methodology

Study design and subjects

This was a pragmatic, real-world, retrospective report of adult patients evaluated in the asthma service at the Royal Brompton Hospital, UK. Patients were enrolled onto a physiologist-led HSP between November 2020 and January 2023. Patients were referred by a respiratory clinician, for HSP clinic review, primarily to undertake DS when symptomatic. This retrospective analysis of HSP outcomes was approved by the Royal Brompton Hospital (Quality and Safety team Project ID: 004611).

Home spirometry protocol

The HSP involved three stages; stage (I) to obtain consent and ensure the use of DS was appropriate; stage (II) to undertake training and validation of measurement; stage (III) to obtain and review results acquired when symptomatic.

Stage I

Following receipt of a referral, a respiratory physiologist contacted the patient *via* telephone, to re-assess eligibility criteria including contraindications to spirometry as per guidelines [10] and patient suitability. The patient completed a consent form and provided demographic details [11]. A hand-held spirometer (MIR Spirobank, Italy) was then posted to eligible patients. The DS device connects to a smartphone *via* Bluetooth, with the mobile application running on either iOS or Android operating systems.

Stage II

Once a patient received a DS device, a virtual physiologist-led clinic appointment time was scheduled (*via* a secure video call service), to help with instruction on device use and to obtain reproducible (as defined by European Respiratory Society (ERS)/American Thoracic Society (ATS) pulmonary function guidelines [12]) baseline spirometry values. During the virtual clinic, the aims of the spirometry were explained to the patient, contraindications to spirometry were assessed again and patients were then asked to perform a minimum of three technically acceptable forced manoeuvres, in a seated position. Spirometry technique was described to the patients prior to commencement of readings and patients subsequently attempted measurements with real-time physiologist instructions. Upon completion, results were transferred directly

via e-mail using the MIR phone application to the physiologist, who reviewed and determined if numerical results met spirometry reproducibility criteria. FVL were also interrogated to ensure a high-quality technique and to determine if they were free from artefact. If deemed technically acceptable and reproducible, results were uploaded to the patient's electronic healthcare record.

Stage III

After baseline DS values were captured, patients were asked to complete measurements during periods of increased symptom burden, *e.g.* during an exacerbation. In this context, the patient was asked to contact the asthma clinical nurse specialist, *via* telephone or e-mail, prior to performing DS. This was not only to re-assess safety of performing spirometry, but also to alert the clinical team to a deterioration in clinical status. Spirometry measures were then performed and transferred to the physiologist for review. If deemed technically acceptable, the FVL and numerical report were uploaded to the patient's record and the clinician alerted. Respiratory clinicians would then retrospectively review spirometry results and where relevant, those who presented with obstructive spirometry pattern were later discussed in a multidisciplinary team (MDT) meeting, to determine onward management.

Outcome measurements

Key outcome measurements evaluated include patient group characteristics, the number of physiologist contact attempts required to schedule an initial virtual clinic appointment (stage I), the number of attempts required to obtain baseline spirometry results of adequate quality and the frequency of DS device use (stage II). Stage III outcomes include identification of obstructive spirometry pattern, classified according to the ERS/ATS guidelines by a FEV_1/FVC (forced vital capacity) ratio less than the lower limit of normal (LLN) (z-score < −1.645) [12] and subsequent initiation of biologic therapy in the appropriate patient. We also report qualitative physiologist and patient feedback, as well as the impact of HSP on healthcare cost and carbon emission offset associated with DS (for additional detail see Methodology in the supplementary material).

Statistical analysis

Data are presented using descriptive statistics including mean±SD, median (IQR) for continuous variables and counts (%) for categorical variables. Group differences and relationships between obstructive and non-obstructive individuals were analysed using the Mann–Whitney U-test and Chi-squared anaylsis, where appropriate. Statistical calculations were completed using GraphPad Prism (GraphPad software, La Jolla, CA, USA). Statistical significance was accepted as a p-value <0.05.

Results

Patient demographics

From the 112 patients who enrolled to the HSP, 102 successfully completed stage I and recorded baseline DS measurements (table 1). Reasons for not recording a baseline DS value are detailed below. Figure 1 illustrates the flow of patients through the HSP.

The demographic of the cohort was in keeping with national severe asthma registry data [13], with a female preponderance (84% female) and 74% classified as being overweight (body mass index (BMI) >25 $kg \cdot m^{-2}$). At the time of referral, the majority of individuals (97%) were using regular high-dose inhaled corticosteroid (in accordance with British Thoracic Society guideline on management of asthma [14]) and the majority (72%) had been prescribed two or more courses of oral steroid in the prior 12-month period or were taking maintenance oral corticosteroid (table 1). Patients resided a median of 20 (11–46) miles from the hospital.

Feasibility and delivery of HSP

Stage I

The median (IQR) contact attempts made before successful stage I was 4 (2–6) (figure 2a). Only 15% of the cohort could be contacted successfully after an initial attempt. There was no difference observed in the number of contact attempts made between individuals with and without the presence of obstructive spirometry identified (p=0.73, median (IQR) 2 (1–8) *versus* 4 (2–6) respectively). 10 patients failed to record baseline DS, most (60%) due to a failure to respond to e-mails. Two individuals were unable to perform technically acceptable spirometry technique, one was hospitalised during the recruitment period and one had no access to e-mail.

Stage II

A median (IQR) of 2 (1–3) virtual clinic sessions were required to achieve technically acceptable and reproducible baseline spirometry, irrespective of obstructive spirometry pattern (p=0.36) (figure 2b). Just

TABLE 1 Patient characteristics (n=102)

Age years	44±13
Sex, female	86 (84)
Weight kg	85±26
BMI kg·m^2	33±13
Ethnicity	
Caucasian	79 (77)
Black	0 (0)
Northeast Asian	1 (1)
Polynesian	1 (1)
Other	21 (21)
Domiciliary spirometry	
Baseline FEV_1 L	2.66 (2.13–3.09)
FEV_1 % pred	88 (77–97)
Baseline FVC L	3.31 (2.58–3.70)
FVC % pred	89 (79–100)
FEV_1/FVC ratio %	81 (76–85)
Patients obstructed at baseline based on FEV_1/FVC<LLN	6 (6)
On a high-dose inhaled corticosteroid (ICS)	99 (97)
On daily maintenance dose of prednisolone	12 (12)
No. of patients who had two or more courses of prednisolone in last 12 months	73 (72)
No. of courses of prednisolone in last 12 months	4 (1–5)
Mean daily prednisolone dose mg	10 (6–13)

Data are presented as n (%), mean±SD or median (interquartile range). BMI: body mass index; FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity; LLN: lower limit of normal; ICS: inhaled corticosteroid; IQR: interquartile range.

under a third (29%) of the cohort successfully recorded baseline spirometry after one virtual clinic (figure 3). Virtual clinic appointments were on average 30 min in duration, although not formally recorded.

Stage III

A second spirometry measurement was performed by ∼50% of the cohort within the first 6 months of their baseline measurement, but only 6% continued to perform DS in the 12 months following baseline and 10% continued to use their device at the end of the study period. Thus, approximately one-third (34%) of the cohort performed DS at baseline only. A median (IQR) of 31 (0–130) days passed before patients performed a secondary DS measurement, with no difference observed in duration for those with or without

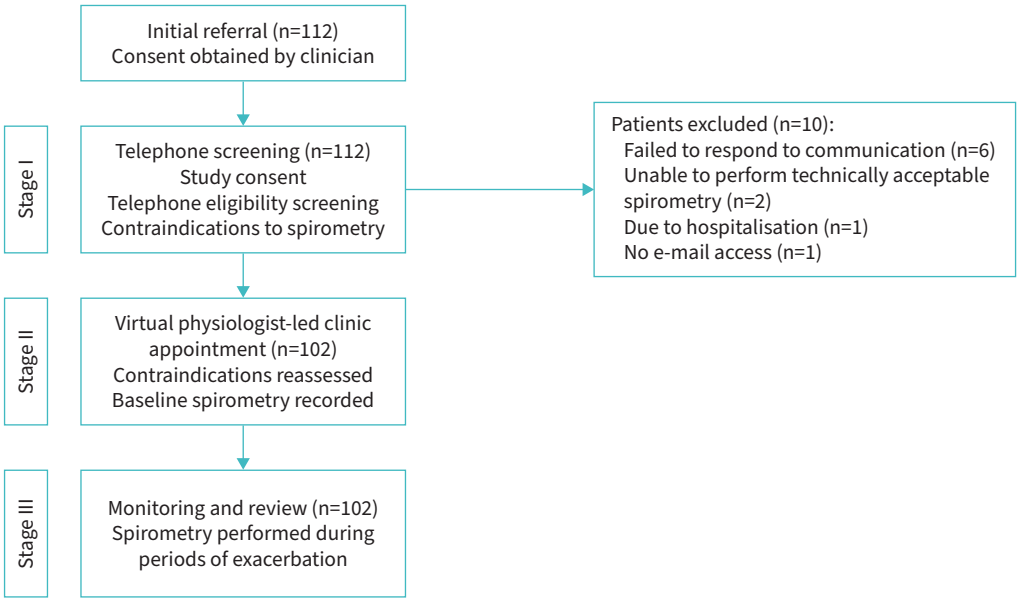

FIGURE 1 Home spirometry programme patient progress.

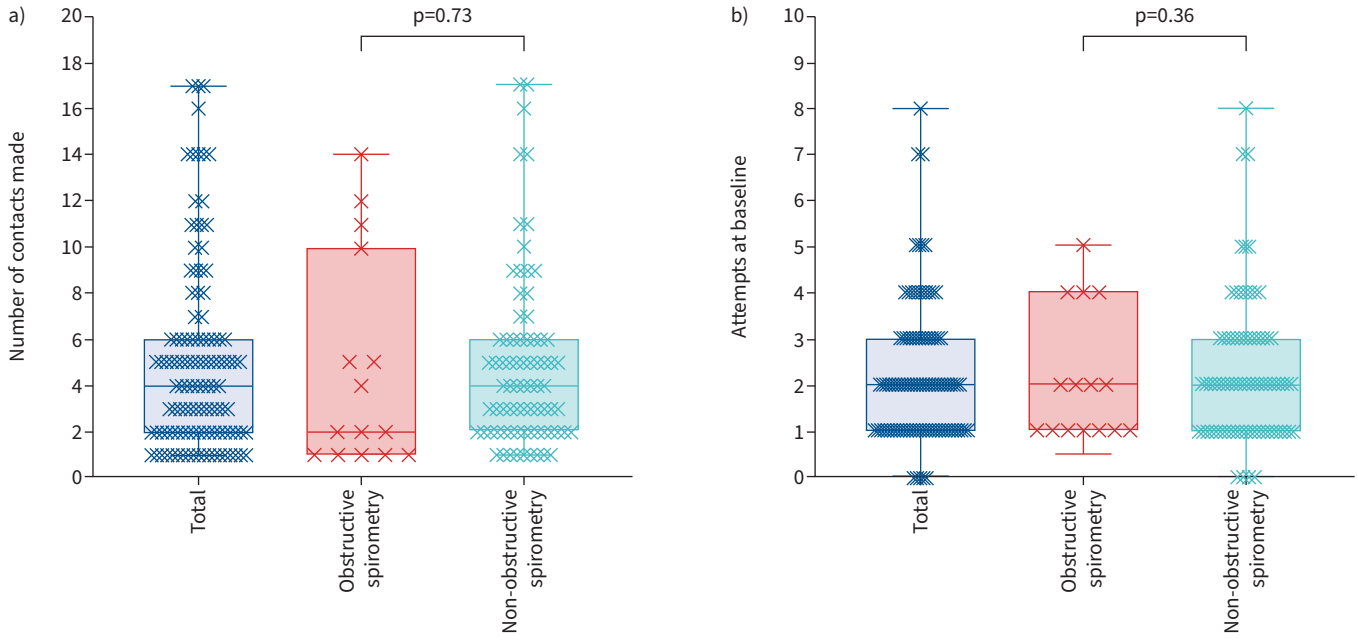

FIGURE 2 Feasibility of home spirometry programme. a) Median (IQR) number of contact attempts made by physiologist before baseline virtual clinic attendance. b) Median (IQR) attempts at baseline before achieving technically acceptable and reproducible spirometry measurement. Data available in 92 patients: obstructive spirometry group n=15; non-obstructive spirometry group n=77.

the presence of obstructive DS (p=0.71, median (IQR): 31 (0–116) *versus* 31 (0–152) respectively). There was no association found between frequency of DS device use during the study period and individuals who presented with obstructive spirometry (table 2). Obstructive spirometry was identified in six individuals at baseline and was a new finding in a further 11 (11%) individuals over the study period (median (IQR) FEV_1/FVC ratio: 69% (65–69)). All of these individuals were subsequently commenced on biologic asthma therapy after discussion of their case at our local severe asthma MDT. There were no findings of inspiratory loop attenuation or reduced peak inspiratory flow.

Outcomes

Physiologist and patient feedback

Key difficulties reported by the physiologist included poor overall uptake and adherence to DS measurements and communication difficulties, *e.g.* ignoring repeated contact attempts and/or patient failure

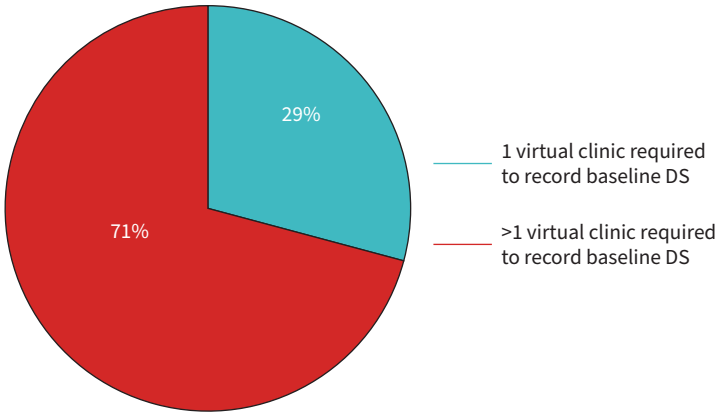

FIGURE 3 Percentage of the cohort (n=102) who required one attempt to successfully complete a baseline spirometry measurement. DS: domiciliary spirometry.

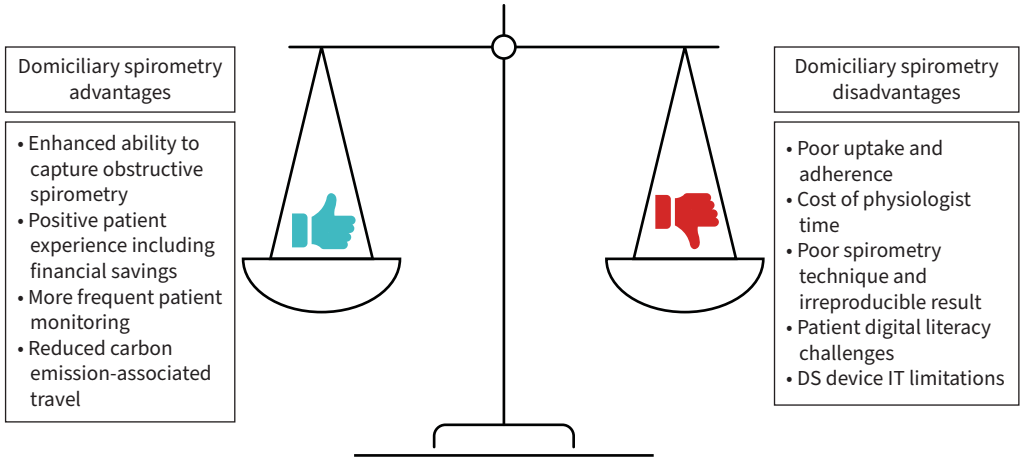

FIGURE 4 Domiciliary spirometry (DS) advantages and disadvantages.

to alert clinical nurse specialists during symptomatic periods. The physiologists also reported difficulties with poor spirometry technique and at stage III sending in physiologically improbable results. Although patient feedback is limited, one patient reported performing DS successfully "changed their life as they were able to commence biologic therapy". Another patient, "found home spirometry incredibly interesting and informative".

Healthcare-related cost

From initial referral by the clinician to completion of stage II the HSP incurs a cost of ~£195 per patient, which includes the initial cost of the DS device (£167), the postage from the hospital to the patient's residence (£2.99) and the physiologist's time spent performing the virtual training clinic and performing administrative duties such as contacting the patient (£25). The cumulative cost to conduct 102 DS device setup and baseline assessments equates to ~£19 900. Comparatively, the cost of 102 hospital-based spirometry measurements is 38% lower at ~£7600. The cost of a single hospital-based spirometry assessment is calculated by the cost of performing a hospital-based spirometry test (£102), the manufacturer equipment and servicing contract cost (£9), the physiologist time conducting the test (£6) and the bacterial filter (£1.50).

Carbon emission costs

A carbon emission cost analysis is reported in the supplementary material.

TABLE 2 Domiciliary spirometry device usage

	Total	Obstructive spirometry identified	No obstructive spirometry identified	p-value (obstructive spirometry *versus* non-obstructive spirometry pattern)
Patients n	102	17	85	
Physiologist contact attempts	4 (2–6)	2 (1–8)	4 (2–6)	0.73
Attempts to achieve baseline	2 (1–3)	2 (1–3)	2 (1–3)	0.36
Time until second domiciliary spirometry measurement performed, days	31 (0–130)	31 (0–116)	31 (0–152)	0.71
Domiciliary spirometry performed at baseline only	35 (34)	6 (35)	29 (34)	>0.99
Domiciliary spirometry performed within 6 months of baseline	51 (50)	9 (53)	42 (49)	0.79
Domiciliary spirometry performed within 12 months of baseline	6 (6)	0 (0)	6 (7)	0.59
Continued domiciliary spirometry use	10 (10)	2 (12)	8 (9)	0.67

Data are expressed as n (%) or median (interquartile range) unless stated otherwise. Number of physiologist contact attempts and attempts to achieve baseline data available in 92 patients: obstructive spirometry group n=15; non-obstructive spirometry group n=77.

Discussion

In a real-world pragmatic scenario, a home monitoring programme using DS appears to provide reliable, objective physiological data that enables capture of airflow obstruction and thus augments an investigative strategy in the assessment of patients with asthma symptoms. In the evaluation of a diagnostic test modality, it is important to determine if the test provides valid results, is safe to conduct and alters clinical management. We report evidence that a physiologist-led HSP satisfies all of these criteria and negates the need for laboratory attendance. Of the total cohort, one in 10 subsequently enrolled had airflow obstruction captured and this altered their management, specifically their workup process for biologic-based asthma treatment. These individuals had non-obstructed spirometry at baseline. Furthermore, this approach was associated with potential beneficial financial and environmental implications, when compared to the traditional clinic or hospital-based approach to measurement.

Nevertheless, it was apparent that successful delivery of an HSP, in this context, is not without considerable patient-focused challenges and is, in our experience, overall evidence of poor uptake and device utility. The strikingly low engagement and uptake after baseline DS measurements may have impacted the prevalence of obstructive spirometry pattern identified within our cohort. There were no obvious patient characteristics detected in the analysis that identified individuals with better adherence or clinical features that alluded to better uptake. Thus, whilst DS is a useful tool, it remains an expensive, time-consuming approach to clinical asthma management that requires future work to refine inclusion criteria and evaluate potential predictors that may improve uptake. Future studies should explore patient characteristics and these features with the aim of improving DS delivery.

It is conceivable that patients could have attended for bronchoprovocation testing (*e.g.* a methacholine or histamine provocation test), but this requires laboratory attendance and mandates a specific period of medication withdrawal to permit interpretation of a valid test. This runs a risk of exacerbating symptoms, and its positive predictive value is dependent on the presence or absence of symptoms at the time of testing [15]. A recent evaluation of DS in the context of symptomatic, athletic individuals found value in the presence of negative bronchoprovocation tests [16]. Further studies are needed to compare the use of DS in patients symptomatic with asthma against bronchoprovocation testing. Similarly, the utility of DS may extend to the assessment and detection of asthma mimics, such as ILO and/or laryngeal dysfunction. Although not formally evaluated, we report no findings of inspiratory loop attenuation or reduced peak inspiratory flow. The application and value of DS to identify these conditions needs to be validated.

Our findings do not eliminate the need to detect and identify other important "biomarkers of asthma", such as those indicating heightened airway inflammation and/or type II asthma biology (*e.g.* serum eosinophil counts or elevated fractional exhaled nitric oxide (FeNO)). Recently, Wang and colleagues [9] reported poor overall measurement adherence as a significant challenge in their assessment of domiciliary FeNO and DS. They note that 40% failed to record a single FeNO measurement and only one-third of the cohort performed twice daily measurements as requested. Suboptimal DS measurement adherence was also reported as low as 33% and 65% to twice and once daily measurements respectively, with 15% failing to record a single DS measurement. In contrast, higher adherence rates of ∼85% have been observed in asthma cohorts who conducted once daily DS measurements [8, 17], and those who performed infrequent readings during a short study period [18]. Some research studies show a higher uptake, but DS performed in the context of a research protocol is likely to be associated with closer scrutiny and support.

In our study, overall measurement adherence was not assessed as patients were requested to perform measurements during symptomatic periods and thus, we did not prespecify the number of measurements required. This may explain the poor device usage findings within this cohort. In a research setting, the optimal required DS measurement frequency and timing of measurements has yet to be determined, which can make the real-world implementation of an HSP challenging. Future research should continue to explore the optimal monitoring frequency over extended periods of time in different disease cohorts.

Some studies have identified concerns regarding data quality and the difference in DS readings with and without direct supervision of a healthcare professional, although the majority report high-quality DS performance and a strong agreement between DS and hospital-based measurements [5]. In contrast, some case series report significant measurement variability, physiologically impossible results and lower DS readings than those from supervised spirometry [19, 20]. We identified similar challenges in respect of irreproducible FVL and spirometric values that required repeat DS attempts. The increased variability and technique breakdown could be attributed to potential BPD, which necessitates specialist respiratory physiotherapy intervention. To circumvent these challenges, a highly skilled physiologist trained patients and both reviewed and identified poor patient technique/results; providing additional support where

required. In addition, appropriate patient selection of individuals capable of performing high-quality, unsupervised spirometry safely at home are key factors when implementing HSP. Improvements in adherence, data quality and mass data interpretation may improve with emergence of novel digital tools such as artificial intelligence (AI) and machine learning [12]. The use of AI may enable rapid DS data acquisition that provides quality assurance and determines measurement acceptability and usability. Furthermore, there may be scope to utilise AI to facilitate interpretation of physiological data, FVL and optimise classification of obstructive *versus* non-obstructive spirometry patterns.

An outcome of the study was to evaluate DS in relation to hospital-based spirometry to determine the impact on cost. The total costs for a one-time hospital-based spirometry assessment were ~40% lower than the cost to perform DS. However, after the initial cost of DS setup, the patient is able to perform multiple DS measurements without incurring additional charges. In contrast, repeat spirometry measurements will incur additional cost per measurement.

The reported carbon footprint benefit of DS is primarily through travel-associated reductions. These findings are in line with Purohit *et al.*'s [21] systematic review, which provided evidence that implementation of telemedicine services leads to a reduction in carbon footprint, particularly as a result of reduction in travel. In this context, there is scope to reduce patient hospital attendance frequency, thus increasing availability of hospital lung function appointments for other clinical circumstances. Environmental and carbon emission impact is multifactorial, and the analysis conducted was limited in scope and detail. Further analysis is required within an HSP setting to fully determine the impact, particularly in relation to emissions produced by device manufacturing, delivery and cost of conducting virtual clinics.

Practical challenges and limitations

We note several limitations to our findings. During the stage I consent process, height and weight were self-reported without formal verification, which may have implications when interpreting predicted values. A further limitation is we cannot precisely report the proportion of individuals who present with mixed obstructive and restrictive spirometry patterns. We recognise a limitation of portable DS devices is the tendency to under read overall lung volumes (*i.e.* FVC measures) in comparison to lab-based results [22]. In our cohort, despite physiologist input, it is likely that FVC measurements may be lower than results performed in a laboratory setting, as we cannot truly verify that full patient effort occurred during the manoeuvre retrospectively. Furthermore, to accurately characterise restrictive patterns, formal measurement of lung volumes including total lung capacity must be performed, using either body plethysmography, helium dilution or nitrogen washout. These measures were not performed in this study but are important when assessing this area, given the context of an elevated BMI, *i.e.* as seen in this cohort [23].

The MIR Spirobank operating system requires patients to manually transfer results upon completion. Manual data input and transfer is prone to errors as well as missed data due to internet failure, equipment failure or patient error. An automation of this service and alerts notifying patients when to perform measurements may potentially improve adherence.

Our approach to the analysis of health-related and carbon emission costs was limited in detail and subject to estimates. To better evaluate this issue, a more robust model is required that uses prospective study design and data collection, that assesses the implications of treatment impact on overall HSP cost and accurately captures the total number of tests performed.

Furthermore, the introduction of DS into clinical services has the potential to widen healthcare and socioeconomic inequalities, primarily for those who are less digitally proficient, have limited internet access and affordability for smart devices. This is an important area to address when considering barriers to DS adherence and successful delivery of an HSP. Fortunately, no patients in our cohort who were put forward for enrolment into the HSP had to be excluded due to limited/no access or poor digital proficiency.

In conclusion, real-world application of DS within a specialist asthma service facilitates the capture of obstructive spirometry, leading to a meaningful impact in the clinical care of some patients. However, there are significant challenges with implementation of an HSP, including primarily the poor uptake and usage rates following baseline virtual clinics and difficulties obtaining reliable measures despite multiple contact attempts (Figure 4). Future research should focus on addressing patient-focused barriers, challenges to help increase accessibility and usability of this valuable tool and identify individuals that will benefit most from use of this diagnostic approach.

Provenance: Submitted article, peer reviewed.

Author contribution: P.H. Patel and J.H. Hull conceived the study idea. J. Ming, C. Roberts and S. Rhamie led the virtual physiologist-led clinics and collected the data. Y. Ge, J. Ming and Z. Williams conducted study analysis. Z. Williams and J.H. Hull contributed to the preparation of the final manuscript. P.H. Patel and J.H. Hull act as guarantors of the paper, taking responsibility for the integrity of the work from inception to published article. All authors approve of final manuscript.

Conflict of interest: Z. Williams, Y. Ge, J. Ming, C. Roberts and S. Rhamie have no conflict of interests to declare. J.H. Hull is an associate editor of this journal. P.H. Patel reports attending advisory boards for AstraZeneca, Celltrion Healthcare and GlaxoSmithKline; he has received speaker fees from AstraZeneca, GlaxoSmithKline, Novartis, and Sanofi/Regeneron; he has attended international conferences sponsored by AstraZeneca.

Ethics statement: This retrospective analysis of HSP outcomes was approved by the Royal Brompton Hospital (Quality and Safety Team Project ID: 004611).

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