Development and evaluation of a tool to optimise inhaler selection prior to hospital discharge following an exacerbation of COPD

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Abstract

Introduction Rates of mortality and re-admission after a hospitalised exacerbation of COPD are high and resistant to change. COPD guidelines do not give practical advice about the optimal selection of inhaled drugs and device in this situation. We hypothesised that a failure to optimise inhaled drug and drug delivery prior to discharge from hospital after an exacerbation would be associated with a modifiable increased risk of re-admission and death. We designed a study to 1) develop a practical inhaler selection tool to use at the point of hospital discharge and 2) implement this tool to understand the potential impact on modifying inhaler prescriptions, clinical outcomes, acceptability to clinicians and patients, and the feasibility of delivering a definitive trial to demonstrate potential benefit.

Methods We iteratively developed an inhaler selection tool for use prior to discharge following a hospitalised exacerbation of COPD using surveys with multiprofessional clinicians and a focus group of people living with COPD. We surveyed clinicians to understand their views on the minimum clinically important difference (MCID) for death and re-admission following a hospitalised exacerbation of COPD. We conducted a mixed-methods implementation feasibility study using the tool at discharge, and collated 30- and 90-day follow-up data including death and re-admissions. Additionally, we observed the tool being used and interviewed clinicians and patients about use of the tool in this setting.

Results We completed the design of an inhaler selection tool through two rounds of consultations with 94 multiprofessional clinicians, and a focus group of four expert patients. Regarding MCIDs, there was majority consensus for the following reductions from baseline being the MCID: 30-day readmissions 5–10%, 90-day readmissions 10–20%, 30-day mortality 5–10% and 90-day mortality 5–10%. 118 patients were assessed for eligibility and 26 had the tool applied. A change in inhaled medication was recommended in nine (35%) out of 26. Re-admission or death at 30 days was seen in 33% of the switch group and 35% of the no-switch group. Re-admission or death at 90 days was seen in 56% of the switch group and 41% of the no-switch group. Satisfaction with inhalers was generally high, and switching was associated with a small increase in the Feeling of Satisfaction with Inhaler questionnaire of 3 out of 50 points. Delivery of a definitive study would be challenging.

Conclusion We completed a mixed-methods study to design and implement a tool to aid optimisation of inhaled pharmacotherapy prior to discharge following a hospitalised exacerbation of COPD. This was not associated with fewer re-admissions, but was well received and one-third of people were eligible for a change in inhalers.

Introduction

Hospitalised exacerbations of COPD are among the most common reasons for emergency hospital admission in the United Kingdom (UK) [1] and are associated with significant mortality [2] and risk of re-admission. UK national audit data highlight that 23.9% of people surviving to discharge will be re-admitted within 30 days, and 43.2% will be re-admitted in 90 days [3]. Most of these re-admissions are respiratory-related; for example, because of recurrent exacerbation or pneumonia [3]. An additional 6% of people will have died at 30 days and 12% at 90 days [3]. Therefore, optimisation of care at the point of hospital discharge is an important part of care, often delivered as part of a "discharge bundle" [2].

There are many pharmacological and nonpharmacological interventions that reduce the risk of COPD exacerbations [4]. Effective pharmacological interventions include inhaled long-acting β-agonist (LABA) and long-acting muscarinic antagonist (LAMA) bronchodilators, with or without inhaled corticosteroids (ICS), dependent on the risk–benefit profile in individual patients [4]. There are a number of factors that might affect the risk–benefit profile of ICS in people with COPD, including the presence of characteristics typical of "asthma", the blood eosinophil count and a past history of pneumonia [4]. In addition to selecting the optimal combination of inhaled drugs, it is vital that there is an appropriate selection of delivery devices that includes dry powder inhalers (DPI), pressurised metered-dose inhalers (pMDI) and soft mist inhalers (SMI). A potential concern with DPI, especially in people hospitalised for an exacerbation, is that patients may not be able to achieve sufficient peak inspiratory flow (PIF) to activate the device [5]. Lower PIF at discharge is associated with increased risk of re-admission [6]. Critical inhaler errors are observed in >50% of people with COPD and are associated with an increased risk of hospitalisation [7, 8].

Despite the importance of selecting the optimal combination of inhaled drugs and device, practical advice for clinicians is lacking, particularly around the risk–benefit profile of ICS and appropriate device selection. The standard UK discharge bundle does not give practical advice on selection of inhaled drug or device. UK National Institute for Health and Care Excellence (NICE) guidance advises consideration of ICS when there are "asthmatic features" or "higher blood eosinophil count", but does not provide explicit, practical guidance [9]. The international Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy document does include specific criteria for the use of blood eosinophils to guide ICS use in COPD, but not an overall structure to assess risks and benefits [4].

We hypothesised that a failure to optimise inhaled drug and drug delivery prior to discharge from hospital after an exacerbation of COPD would be associated with a modifiable increased risk of re-admission and death. To address this, we designed a study to 1) develop a practical inhaler selection tool for clinicians to use at the point of discharge and 2) implement this at three pilot sites to understand the potential impact on modifying inhaler prescriptions, clinical outcomes, acceptability to clinicians and patients of using the tool, and the feasibility of delivering a definitive trial to demonstrate benefit.

Methods

Designing the inhaler selection tool and consensus on outcome measures

The trial management group prepared an online survey using SurveyMonkey that sought the views of multiprofessional clinicians involved in the care of people with hospitalised COPD exacerbations. We included questions on how inhaled drugs and devices are selected prior to discharge following exacerbation, and asked participants to prioritise selections using a five-point Likert scale covering the importance of various selection criteria (not important; slightly important; moderately important; important; very important), how commonly they were able to implement each criterion in clinical practice (never; seldom; about half the time; usually; always) and how they delivered that (free text). Free-text comments were used to collect any additional items that clinicians considered when selecting inhaled drugs and devices. The survey also sought views on the minimum clinically important difference (MCID) for outcome measures of 30- and 90-day re-admissions and mortality following a hospitalised COPD exacerbation. Qualitative analysis was completed from the free-text responses. Survey dissemination was supported by the Association of Respiratory Nurse Specialists, the Association of Chartered Physiotherapists in Respiratory Care, the British Thoracic Society and the National Asthma and COPD Audit Programme (all in the UK). The survey was open from 25 April to 31 May 2022.

Qualitative and quantitative results together with 2019 NICE [9] and GOLD [4] COPD guidance was used to design a first iteration of an inhaler selection tool that we call "Optihale". The tool was discussed at the trial management group and an agreed revised version went out to consultation with survey respondents who had agreed to be re-contacted (2–16 August 2022). The tool content and use of the tool to guide inhaler selection, as well as the concept of changing regular inhalers during a hospital admission was discussed with a four-person expert patient panel, recruited by Asthma + Lung UK, to ensure the tool was aligned with the priorities of people living with COPD. Based on feedback from the patient panel and clinicians, a final version of the tool was developed for clinical testing.

Pilot implementation of the Optihale inhaler selection tool

We ran an implementation feasibility study at three UK hospitals between 14 November 2022 and 30 June 2023. Patients with COPD hospitalised for an exacerbation and close to the point of discharge were approached to take part. The inclusion criteria were all patients eligible for entry into the UK national COPD audit programme (hospitalised and treated for an exacerbation of COPD, excluding those with pneumonia, and with no requirement for confirmatory spirometry at the time of study entry). The only additional criterion was to exclude those with an expected survival of <90 days, which we operationally defined as being in receipt of palliative care services at the point of discharge. Those providing written informed consent then had an assessment of inhalers made by a member of their clinical team using the Optihale tool, which the clinician had been trained to use. We recorded the number of times this resulted in a change in inhaled drug, device or both.

Information on re-admissions and death was collected at 30 and 90±7 days from the hospital records and phone calls with participants. We assessed if any changes to inhalers made at the point of discharge were continued in the community. Participants were asked about satisfaction with their inhalers using the Feeling of Satisfaction with Inhaler (FSI-10) questionnaire [10] consisting of 10 questions on a five-point Likert scale with a maximum score of 50 and minimum score of 10, with a higher score representing greater satisfaction with the inhaler. Where people were on more than one preventative inhaler, we used the mean of the two scores. In addition, we asked about community-treated exacerbations.

Quantitative data were collected and managed using Research Electronic Data Capture (REDCap) hosted at University College London (London, UK) [11, 12]. This included the severity of the initial exacerbation using the Rome criteria [13] and the COPD Assessment Test score [14]. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. Summary statistics are reported as mean±SD, median (interquartile range (IQR)) or n (%), as appropriate.

Qualitative work was conducted with 17 multiprofessional clinicians and two patients (at 30 days) to understand more about tool implementation and resulting changes to inhaled prescriptions. This included direct observation of delivery of the tool by clinicians on three occasions. Qualitative data collection comprised hand-written notes and transcribed audio recordings. They were analysed thematically using a coding framework derived from normalisation process theory.

The trial received ethics approval from the Health Research Authority (IRAS309854) and all participants provided written informed consent. The trial was registered as ISRCTN16732324.

This was a feasibility study and not powered on clinical end-points. There was no *a priori* power calculation. An outcome of the work was to be able to power a definitive study were we to show benefit. We originally intended to approach 300 people to take part.

Results

Designing the inhaler selection tool

The completed Optihale inhaler selection tool is illustrated in supplementary figure S1. In brief, the first step of the tool considers the current use, preference and adherence to inhalers (as a change would only be recommended where there was good reason to change). The second step considers the need for ICS, and the third considers choice of device. Criteria for the second and third steps (selection of drugs and device), were informed by our clinician survey and patient focus group as outlined later. The fourth step is to teach inhaler technique and demonstrate effective use, and the fifth and final step is to communicate changes with the patient and their usual care team.

94 multiprofessional clinicians took part in our initial clinician survey, with representation from all 10 UK National Health Service regions. The mean±SD age of the participants was 41.0±8.5 years; 69% were female; and the proportion of doctors, nurses, pharmacists and physiotherapists was 45%, 30%, 6% and 17%, respectively.

44% strongly agreed and 48% agreed that patients should receive a dual long-acting bronchodilator with or without ICS at hospital discharge. On a scale of 0 (not important) to 4 (very important), the factors to assess when considering an ICS, in rank order, were blood eosinophil count (mean±SD 3.38±0.72), a previous diagnosis of asthma (3.35±1.02), a history of frequent exacerbations (3.17±0.99), variation in forced expiratory volume in 1 s (FEV_1) (2.55±1.30), history of pneumonia (2.52±0.98) and history of nontuberculous mycobacterial infection (2.39±1.13). Qualitative responses were used to inform the "how-to" notes on the tool. The most frequently cited blood eosinophil cut-off to support ICS use was >300 cells·μL^{-1} in 20 out of 24 responses to this question. There was a general preference for fixed *versus* open triple inhaled therapy (3.24±0.89).

In terms of device selection, demonstration of correct use was ranked highest (3.83±0.47). Environmental concerns (2.39±1.05), concerns related to involvement of the tobacco industry in producing inhalers (2.28±1.36) and cost (1.77±1.09) were considered less important. At the level of the individual patient, environmental concerns were considered less important than supporting that patient to have well-controlled disease. The key decision was considered to be between a pMDI with spacer *versus* DPI, with only one participant preferring SMI first-line. Qualitative responses were used to guide the "how-to" section, which centres on a demonstration by the patient of a quick and deep inspiration (necessary for DPI) *versus* a slow and steady inhalation (suitable for use with pMDI and SMI).

The patient focus group emphasised that patients wanted to be involved in decisions about changing inhalers, and noted that hospitalisation is a vulnerable time, with some anxiety about changes recommended by a new hospital team with whom a patient may not have an ongoing relationship. This emphasised the importance of discussing any proposed change with the patient's regular clinicians. Patients said they were most likely to accept a switch when it was associated with greater efficacy, easier availability, fewer side-effects and greater convenience.

An initial version of the tool was circulated to the original clinician participants who had agreed to be re-contacted. Feedback was received from 17. All agreed or strongly agreed that the tool was easy to use. 13 definitely or probably would use it to guide inhaler selection. Feedback informed development of the final version of the tool (supplementary figure S1), which went forward to implementation testing.

MCID for outcome measures

We asked clinician participants what they felt was the MCID for an intervention designed to reduce 30- and 90-day all-cause re-admissions, and 30- and 90-day all-cause mortality. A minimum of 66 participants responded with results reported in table 1. Taking >50% as majority consensus, the MCIDs of these outcomes are as follows, expressed as a reduction from baseline: 30-day re-admissions 5–10%, 90-day re-admissions 10–20%, 30-day mortality 5–10% and 90-day mortality 5–10%. Smaller reductions in mortality were seen as more important than smaller reductions in re-admissions.

Pilot implementation of the inhaler selection tool

Figure 1 shows the flow of participants through the implementation pilot. In brief, 118 participants were assessed for eligibility, and 30 agreed to participate. The commonest reason for a participant not to be

TABLE 1 Minimum clinically important difference for key outcome measurements following a hospitalised exacerbation of COPD (minimum n=66 participants)

	⩾5%	⩾10%	⩾20%	⩾30%	⩾40%
30-day all-cause re-admissions	24	57	79	89	100
90-day all-cause re-admissions	18	48	79	97	100
30-day all-cause mortality	41	62	77	94	100
90-day all-cause mortality	34	64	83	96	100

Data are presented as cumulative %, rounded to the nearest integer, and representing the percentage reduction from baseline.

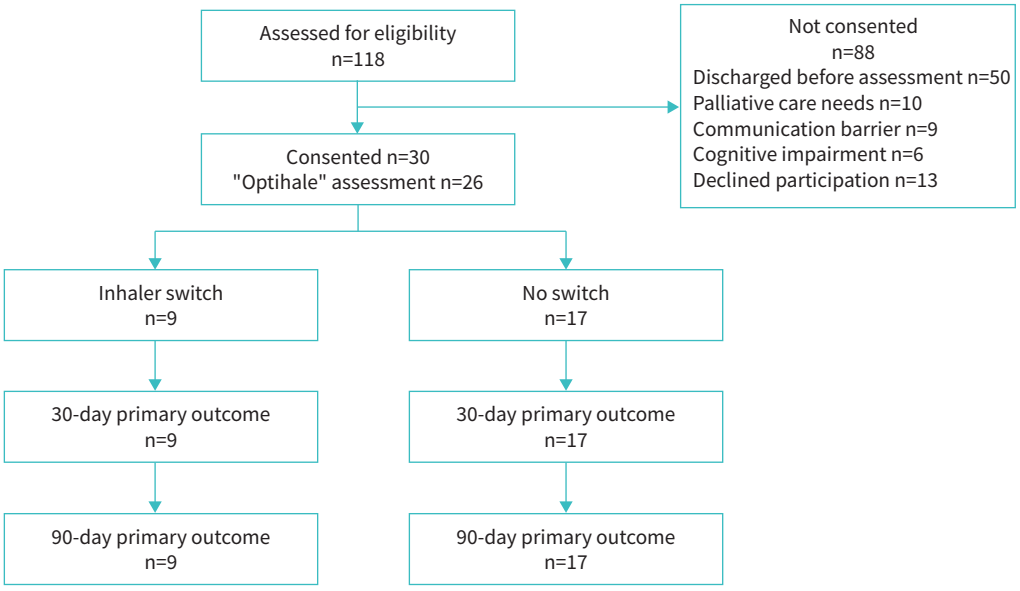

FIGURE 1 Participant flow.

recruited was discharge prior to consent, emphasising the challenge of research aiming to assess patients close to the point of discharge with a hospitalised exacerbation of COPD. 60% of participants were women (table 2) with a mean±SD age of 67.8±12.2 years and FEV_1 45.4±17.7% predicted (those for whom the information was available).

Of those enrolled, four were discharged before the tool could be completed, leaving 26 assessed using Optihale. A change in inhaled medication was recommended in nine (35%) out of 26. The nature of the inhaler switches made are summarised in table 3. A change to the inhaled drug(s) alone was recommended in one out of 26; a change to the recommended device alone was recommended in four out of 26; and a change to both inhaled drug class(es) and device was recommended in four out of 26. Where a change was recommended, this was always achieved. For the 17 not deemed eligible for a switch, 14 were on a fixed triple inhaler (n=4 DPI, n=10 pMDI) and three were on LABA/LAMA (all DPI).

The characteristics of the included participants, in those with and without an inhaler switch recommended are reported in table 2. The two groups appear generally similar in terms of demographic characteristics, severity of COPD and severity of the index exacerbation.

Table 2 reports the 30- and 90-day outcome measures in those with and without an inhaler switch. The proposed primary outcome measure of a definitive trial, combined death or re-admission was met by nine (35%) out of 26 at 30 days (33% of the switch group and 35% of the no-switch group at 30 days), and 46% at 90 days (56% of the switch group and 41% of the no-switch group at 90 days).

Where a switch was made, this was maintained in 71% of people at 30 days and 50% at 90 days. In general, baseline satisfaction with inhalers was high with a mean±SD FSI score of 43.9±4.2 from a maximum score of 50. Where a switch was made, the median increase in score was 3 units.

Qualitative evaluation of inhaler selection tool implementation

Qualitative work with multiprofessional clinicians highlighted the diversity in resources available to COPD teams across the three sites which was associated with variable delivery of the discharge bundle. In general, there was a positive response to the tool, working as an “aide memoire” to more experienced members of the team, and helping to structure decision making for those less experienced. The importance of assessing existing patient preferences was emphasised. There was divergent opinion about the best time to optimise inhalers, although clinicians often concurred that just prior to discharge was the most appropriate time, in line with our original intentions. Although specifically designed to be used prior to discharge, some clinicians felt that use in community and specialist outpatient settings would be preferable. Barriers to effective use included staff time, staff turnover, variable information-technology systems, and

TABLE 2 Participant characteristics and outcome measures

	Consented	Inhaler switch	No switch
Participants n	30	9	17
Age years	67.8±12.2	67.3±14.3	69.1±10.8
Gender			
Female	18 (60)	8 (89)	10 (59)
Male	12 (40)	1 (11)	7 (41)
Ethnicity			
White British	25 (83)	7 (78)	14 (82)
Any other	5 (17)	2 (22)	3 (18)
Smoking status at admission			
Current smoker	18 (60)	6 (67)	9 (53)
Ex-smoker	12 (40)	3 (33)	8 (47)
Last FEV_1 % predicted	45.4±17.7 n=15	44.6±8.0 n=6	49.0±21.9 n=8
COPD hospitalisation past year			
No	10 (33)	4 (44)	6 (35)
Yes	20 (67)	5 (56)	11 (65)
CAT score pre-discharge	24.4±7.7 n=25	25.8±7.3	22.7±8.7 n=12
Length of stay days	6.0 (4.25–11.75) n=26	5.0 (7.0–26.0)	6.0 (4.75–11.25) n=16
Rome exacerbation severity on admission			
Mild	0 (0)	0 (0)	0 (0)
Moderate	25 (83)	8 (89)	14 (82)
Severe	5 (17)	1 (11)	3 (18)
Outcomes at day 30		n=9	n=17
Inhaler switch maintained[#]		5/7 (71)	Not applicable
Alive		8 (89)	17 (100)
Re-admitted		2 (22)	6 (35)
Combined re-admission/death		3 (33)	6 (35)
Community-treated exacerbation		0/7 (0)	2/9 (22)
Change in FSI-10 from baseline[¶]		3 (−2.3–9) n=3	Not applicable
Outcomes at day 90		n=9	n=17
Inhaler switch maintained		4/8 (50)	Not applicable
Alive		8 (89)	17 (100)
Re-admitted between days 30 and 90		2 (22)	5 (29)
Combined re-admission/death		5 (56)	7 (41)
Community-treated exacerbation		1/8 (13)	5/12 (42)
Change in FSI-10 from baseline[+]		3 (2–10) n=3	Not applicable

Data are presented as mean±SD, median (interquartile range) or n (%). FEV_1: forced expiratory volume in 1 s; CAT: COPD Assessment Test; FSI: Feeling of Satisfaction with Inhaler questionnaire. [#]: in those alive; [¶]: for those on a previous inhaler regime and when switch maintained; [+]: 26 with primary outcome data.

access to training materials such as placebo inhalers. Facilitators may include automated use on an electronic record, although the risk of "click fatigue" was raised by others.

With regard to qualitative work informing feasibility of a definitive study, the challenges of recruiting people when admitted with an exacerbation and who are therefore sick, and often with other physical and mental health comorbidities, was noted, as was the unpredictability of discharge day.

Discussion

We report the design and pilot implementation of a tool to guide the optimal selection of inhaled drugs and device at the point of discharge from a hospitalised exacerbation of COPD. 35% of people were considered not to be on optimal inhaled therapy when assessed using the Optihale tool, with the majority requiring a change in device with or without a change in drug(s). Qualitative feedback from clinicians using the tool was positive, but in those switching inhalers the 30- and 90-day re-admission and death rates of 33% and 56% do not appear lower than the national average data of 30% and 55%, or the data in

TABLE 3 Inhaler switches made

Case	Drug prior to switch	Device prior to switch	Drug post-switch	Device post-switch
1	Open triple	DPI	Closed triple	DPI
2	No therapy		Dual	DPI
3	Closed triple	DPI	Closed triple	MDI
4	No therapy		Dual	DPI
5	Open triple	Mixed	Dual	DPI
6	Dual	DPI	Open triple	DPI
7	Dual	SMI	Closed triple	MDI
8	Open triple	DPI	Closed triple	MDI
9	Open triple	DPI	Closed triple	MDI

Triple: inhaled corticosteroid/long-acting β-agonist (LABA)/long-acting muscarinic antagonist (LAMA), closed when delivered in a single device, open when in more than one inhaler; DPI: dry powder inhaler; dual: LABA/LAMA; MDI: metered dose inhaler; mixed: more than one inhaler device used; SMI: soft-mist inhaler.

our population who were not switched at 35% and 41%. By 90 days, only 50% of those switched remained on the new inhaler regime. We have also provided consensus on the MCID for reductions in 30- and 90-day re-admission and death. Significant challenges were encountered in conducting research with people hospitalised with a COPD exacerbation, notably rapid and unpredictable discharge prior to assessment for eligibility and consent.

Reducing COPD exacerbations, particularly hospitalised exacerbations, is a major goal of COPD therapy given that people living with COPD find exacerbations the most difficult component of their disease [15], and that exacerbations are a major driver of healthcare costs [16]. While there are an array of pharmacological and nonpharmacological interventions that can reduce COPD exacerbations, reducing re-admission to hospital following a hospitalised COPD exacerbation has proved particularly difficult to change. Illustrating the complexity of the problem, when evidence-based interventions, each of which have a strong evidence base for improving outcomes in COPD, such as support for smoking cessation and referral to pulmonary rehabilitation, are included as a package called a discharge bundle, there is no evidence that implementation of a bundle improves re-admissions [17]. This may be because the wrong outcome measures have been chosen (it may take longer, for example, to accrue benefit from smoking cessation), and/or because of a failure of proper implementation of the discharge bundle. Only ∼50% of re-admissions are respiratory-related, making it more challenging for an intervention to affect this unless it is holistic.

Despite the absence of robust evidence to support the use of a discharge bundle, the 2023 UK COPD quality standards recommend a discharge bundle which includes optimisation of inhaled medicine [18]. To the best of our knowledge there is no tool designed to support clinicians in optimising inhaled medicines at this time and we have addressed this deficit. We have gone on to show that the tool was well received by clinicians. One in three of the people that were assessed were considered in need of a change in inhalers, suggesting an important opportunity to optimise care by hospital-based teams whose primary focus is often on treating the acute event. Despite that opportunity, and the change being implemented at discharge, we did not see a suggestion that this resulted in fewer re-admissions and by 90 days only 50% of the switches had been maintained. A lower proportion of people switched had community treated exacerbations over this time. Overall, patient satisfaction with inhalers was high, and switching was associated with only a small improvement, on average. We note that our tool, and implementation of a post-exacerbation care bundle, could also be valuable in community settings where the greater proportion of exacerbations are managed. Our tool might also be valuable when considering reviews in routine outpatient settings, including at assessment for pulmonary rehabilitation.

We have provided, for the first time, consensus on the MCID for reduction in 30- and 90-day re-admissions and death. UK national audit data suggest a 30-day readmission rate of 43%. Our consensus on 90-day re-admissions was a minimum of a 20% reduction. If optimising inhalers reduced the rate by 20%, that would suggest a re-admission rate in the switch arm of 35%. At 80% power and $p<0.05$, this would require 580 people per arm to demonstrate benefit, before considering dropouts and the number of people screened to identify the one in three eligible for switch. In addition, many would consider that there may not be sufficient clinical equipoise to deny switching a patient's inhaled regimen where the need for a change has been identified.

There are strengths and weaknesses to our research. We were careful to seek wide views on the design of the tool, including the opinions of people living with COPD, and the Optihale tool was well received in qualitative work. However, only four people living with COPD took part in our focus group, which means that we may not have captured a diversity of experience. We have provided the first consensus MCID for reductions in 30- and 90-day all cause re-admission and death following a hospitalised exacerbation of COPD. However, we encountered significant challenges in implementing the tool. Chief among these were short stays and unpredictability around the discharge timing of people admitted with exacerbations of COPD. There are now many ways to manage COPD exacerbations alongside traditional admission, for example hospital at home and virtual wards. Deploying an intervention in an acute setting needs to be adapted to local services and be able to adapt as these services are evolve. We found no suggestion, compared to national data, that switching inhalers was associated with fewer re-admissions (although there was a small improvement in patient satisfaction, and numerically fewer people experiencing community exacerbations). This was not a randomised trial, and we did not have a control group without a switch. We did not collect data on enrolment in pulmonary rehabilitation in the immediate post-discharge period, which may affect re-admission risk, although this would currently be unusual in UK settings.

In summary, we have completed a mixed-methods study to design and implement a tool to aid optimisation of inhaled pharmacotherapy prior to discharge following a hospitalised exacerbation of COPD. This was not associated with fewer re-admissions, but was well received and one-third of people appear eligible for a change in inhalers at this time.

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