Original Research

Inhalation Innovation: Optimizing COPD Care Through Clinical Pharmacist Integration in a Rehabilitation Hospital's Multidisciplinary Team – A Quality Improvement Study

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Abstract

Inhalation Innovation: Optimizing COPD Care through Clinical Pharmacist Integration in a Rehabilitation Hospital's Multidisciplinary Team – a quality improvement study

Background

Inhalation therapy is the cornerstone of COPD management. However, errors frequently occur since every type of inhalation device has different characteristics, complicating their use. The clinical pharmacist is an expert on these devices and can be involved in the care and education of inhaler use in patients with COPD.

Aim

The feasibility of a pharmaceutical care protocol specifically for patients with COPD in a rehabilitation hospital was assessed in a quality improvement study (mixed-methods).

Method

First, the clinical pharmacist had six contact moments with hospitalized patients between January and April 2022, which contained appropriateness evaluations and educational moments that were focused on inhalation techniques. Subsequently, a focus group discussion with all involved healthcare professionals (HCPs) took place to evaluate the preliminary results of the protocol's implementation.

Results

Nineteen patients entered the study, the protocol results in a decrease of critical device errors (38.5% at baseline, to 7.7% at discharge). The HCPs concluded that it was feasible to implement the protocol given certain adjustments. A multidisciplinary collaboration between pharmacists and nurses is necessary to permit the practical implementation, as well as an individualization

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of the protocol based on the patient's needs. In patient follow-up, transmural care is essential including the HCPs in primary care, and the outpatient clinic.

Conclusion

The evaluation of the protocol by the involved HCPs emphasizes the importance of a clinical pharmacist in the care for patients with COPD as part of the multidisciplinary team, not only in the community or in acute hospital setting, but also in a rehabilitation hospital.

Keywords: Chronic obstructive pulmonary disease, COPD, inhalation therapy, inhalation devices, pharmaceutical care, clinical pharmacy

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Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic respiratory disease, a major health problem worldwide that is frequently diagnosed amongst long-term smokers [1,2]. It is a disease where the patient has airflow limitation due to bronchiolitis and emphysema [3,4]. Patients with COPD often experience exacerbations, characterized by a worsening of the illness, resulting in a lower quality of life [5].

Chronic inhalation therapy is prescribed depending on the stage of the disease, and further finetuned based on individual needs and preferences. Several classes of pharmacological agents can be administered to offer symptom relief and minimize exacerbations [6]. Various devices exist to administer these drugs, such as pressurized metered dose inhalers (pMDI), breath-actuated metered dose inhalers, dry powder inhalers (DPI), soft mist inhalers (SMI), and nebulizers. As there are a variety of devices, and consequently a variety of distinct inhalation techniques, sufficient comprehension of their administration is crucial to assure treatment success [7–10]. Inhalation errors may result in either the absence of drug administration or its improper delivery, potentially exacerbating symptomatic manifestations of the underlying disease [8,11,12]. Moreover, a considerable proportion of individuals face challenges in adhering to inhalation therapy, whether the reasons are intentional or unintentional. Research shows that only 33.6% of patients with COPD are fully adherent to their inhalation therapy [8,13,14].

Different studies have investigated the importance of a structured pharmaceutical care protocol. For example, in the community pharmacy setting the ”Pharmaceutical care for patients with COPD (PHARMACOP)” protocol induced improved adherence and inhalation technique. Community pharmacists provided personalized instructions on correct inhaler use, offered direct feedback, and emphasized the importance of adherence. Additionally, follow-up and monitoring ensured patients remained consistent in their medication use [15].

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In acute care hospitals, clinical pharmacy is already well-established and extensively studied. Research often evaluates the strengths of hospital pharmacists, e.g. to decrease polypharmacy in frail, geriatric patients. However, there has been a growing attention to more specific patient populations and education in pulmonary diseases as well, including COPD [16–19]. These studies have shown that targeted pharmaceutical interventions can enhance medication adherence and improve inhalation techniques, which can lead to better outcomes for COPD patients [20–22].

Patients with a high-risk of pulmonary complications often require more thorough follow-up and are transferred to a rehabilitation service after an acute stay in the hospital. Rehabilitation settings focus on a specific population with longer lengths of stay, presenting a vital opportunity to improve adherence and inhalation techniques. This offers great opportunities for interventions by hospital pharmacists. Despite the well-established role of pharmacists in acute care settings [21], evidence on the benefit of a clinical pharmacist in rehabilitation care remains limited.

Aim

In this study, the feasibility of the implementation of a standardized pharmaceutical care protocol for inhaler therapy in patients with COPD was evaluated in a rehabilitation hospital.

Ethics approval

Ethical approval was obtained with the Committee of Medical Ethics of the University Hospital Brussel (Universitair Ziekenhuis Brussel); EC number: 2021-385. Included patients and the healthcare professionals (HCPs) involved in the focus group signed an informed consent form.

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Methods

Study design and setting

This quality improvement study (mixed-methods) first focused on implementing a pharmaceutical care protocol to optimize inhaler therapy for patients with COPD, managed by a clinical pharmacist. Secondly, the feasibility of routine implementation of the pharmaceutical care protocol was evaluated in a focus group discussion with the HCPs engaged in the intervention.

Setting

The study was carried out at the Queen Elisabeth Institute (KEI - Oostduinkerke, Belgium), a 165-bed hospital with 20 beds specifically for cardiopulmonary rehabilitation. It is a rehabilitation hospital for both residential and outpatient care, located in the same physical location. Patients that are admitted are usually transferred after a stay in an acute hospital. A rehabilitation hospital is comparable to a long-term, acute care center. The hospital pharmacy team comprises a pharmacist trained in smoking cessation techniques, that visits every admitted active smoker, providing personalized counseling and support as part of usual care.

Implementation of the pharmaceutical care protocol

The pharmaceutical care protocol was implemented between January and May 2022. The protocol was an adapted version of the PHARMACOP protocol with more focus on a multidisciplinary approach [15]. A detailed table on the content of the advanced pharmaceutical care program is provided in Appendix 1.

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Patients could be included if they had a COPD diagnosis, were eighteen years or older, used at least one inhalation medication for more than six months and were Dutch speaking. Patients with cognitive impairment or in need of isolation, e.g. due to Methicillin-resistant Staphylococcus Aureus (MRSA) or Severe Acute Respiratory Syndrome - Coronavirus-2 infection (SARS-CoV-2 infection), were excluded from the study.

After obtaining informed consent, each patient had six contact moments with a trained clinical pharmacist (AW or EW), as shown in Figure 1. During these contacts, inhaler therapy was assessed on multiple occasions. A detailed overview of the study protocol and educational moments can be found in Appendix 1. All contacts were executed by a pharmacist. No additional inhaler education from a nurse or other healthcare professional took place. During the admission and counselling visits, the inhalation technique was evaluated using checklists (see Appendix 2). A major error immediately caused a score of zero and was assigned when a crucial step in the inhalation technique was not correctly performed. The patients were also subjected to validated questionnaires: the Modified Medical Research Council (mMRC) for dyspnea severity [23] and the Beliefs About Medicines Questionnaire (BMQ), with necessity and concerns subscale [24]. An evaluation of the appropriateness of inhalation therapy was executed based on the GOLD guidelines. The 'In-Check DIAL' (Flexicare, United Kingdom) was also used to assess the appropriateness of the device since it measures the highest inspiratory flow rate. It can simulate the resistance characteristics of a patient's specific inhaler and can determine if e.g., a dry-powder inhaler (DPI) or pressurized metered-dose inhaler (pMDI) is suited for the patient.

The first therapy optimization session was performed within three days of the baseline evaluation. Several methods were used to teach patients the correct inhaler technique. These included distributing an information brochure, showing instructional videos [25], and providing personalized guidance from the pharmacist to correct any errors in technique. The final visit at

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two weeks after discharge took place by telephone. Patients were asked to explain, step by step, how they used their inhaler.

Focus group discussion

Following the implementation of the care protocol, a focus group discussion was arranged on April 26, 2022, where the HCPs engaged in the project were invited to evaluate the intervention's feasibility. HCPs included two hospital pharmacists, two physicians, the responsible nurse, two reference nurses, the head of the nursing department and the head of the paramedic department. The participants received the questions (Appendix 3) and the protocol a few days prior to the discussion to have time to consider them beforehand.

The focus group discussion was moderated by an independent third person. The moderator used a small degree of control and guidance when there was a risk of getting off topic. The focus group was audio-recorded.

Data analysis

Numeric data were analyzed with Microsoft Excel 365® (Microsoft, Redmond, WA, USA) and IBM SPSS® (Chicago, IL, USA). Descriptive statistics were applied. Counts were presented as frequencies and percentages. Where appropriate, averages with standard deviations or medians with interquartile ranges (IQR) were used depending on if the distribution was normal. Data at admission were compared with those at discharge to evaluate the evolution of the patients during the hospital stay. The Wilcoxon signed-rank test was used to compare the discharge visit with the follow-up interview, assessing whether the evolution achieved during admission continued in the home setting. A per protocol analysis was used and p-values <0.05 were considered significant. The focus group discussion was written out ad verbatim in NVivo 20® (QRS international, Burlington, MA, USA). The texts were evaluated by means of thematic

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analysis. We adhered to the STROBE and SQUIRE guidelines throughout the manuscript writing process to ensure alignment with the publication standards.

Results

1. Implementation of the pharmaceutical care protocol

Out of the 28 patients diagnosed with COPD who were admitted to the hospital, 19 patients with COPD were included in the implementation study. Of the nine excluded patients, only one refused signing the consent form. Thirteen patients (68%) successfully completed the entire protocol, comprising six contact moments. A significant drop-out rate (n=6) was caused by a SARS-CoV-2 outbreak with obligated patient isolation. The implementation process and the characteristics of the included patients are shown in Figure 2 and Table 1.

After the first assessment, a pharmaceutical recommendation was made for nine patients (47.4%), with an acceptance rate of 66.7%. As shown in Table 2, the most common recommendation was to transition patients using two separate devices to combination therapy with a single inhaler. No further adjustments were made during the second therapy evaluation moment. On admission, five out of thirteen (38.5 %) evaluated patients made major errors in their inhaler use, which decreased to one patient (7.7 %) at discharge and zero patients at follow-up. The median score of inhalation device use significantly improved during the patient's hospital stay from 5.7/10 (IQR=7.1) to 9/10 (IQR=2.2) at discharge (p=0.003; z=-2.936). At follow-up, no patients exhibited a major error and their inhaler technique (median score 10/10; IQR=1.4) did not significantly deteriorate (p=0.068, z=-1.826).

Between admission and discharge, there was a significant decrease in median mMRC grade, indicating reduced dyspnea (p=0.047, z=-1.983). The median mMRC grade between these two contacts were respectively 3 (IQR = 1) and 2 (IQR = 1.5). The BMQ score, divided into

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'concerns' and 'necessity' subcategories, showed a significant decrease in 'concerns' at discharge (p=0.011, z=-2.552), while 'necessity' remained unchanged (p=0.419, z=-0.808). The median 'concerns' score shifted from 11 (IQR = 7) to 8 (IQR = 4.5) and the median 'necessity' score shifted from 18 (IQR = 5) to 17 (IQR = 4) between both contacts. At follow-up, no significant changes were observed in dyspnea severity (mMRC grade) or the BMQ scores compared to discharge.

The time needed to execute the visits is represented in Figure 1. The first visit was the most labor intensive (median of 20 minutes, IQR = 8.75).

2. Focus group discussion

HCPs' opinions on the protocol implementation were evaluated during a focus group discussion as shown below.

Theme 1: Multidisciplinary teamwork for patients with COPD

Before discussing the new protocol implemented in this study the standard of care before the study was reviewed. Before the study, two reference nurses educated COPD patients for three hours every two weeks.

Up to the time of the study, the execution of individual educational sessions was considered not feasible. Due to variability in daily workload, mostly depending on the presence of staff members, the daily care of the patients was perceived as the main priority. Also, there were generally insufficient nurses. The COVID-19 pandemic also had a significant influence on usual care.

Subtheme 1: Addition of a clinical pharmacist to the multidisciplinary team

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The study was executed by pharmacists only, so the clinical pharmacist was given a prominent role in COPD care. For the future, the participants were very interested in a partnership between nurses and pharmacists, where the nurses can evaluate the educational needs of the specific patient, as they are the experts of daily patient care and therefore know the patient. Additionally, all HCPs recognized that (clinical) pharmacists are experts on the pharmacotherapeutic aspects of COPD medication since they have a broad knowledge of e.g. adverse events, interactions, therapy adherence.

Subtheme 2: Defining the role of the clinical pharmacist

Pharmacotherapeutic advice on drug-drug interactions, therapy simplification, and related aspects was regarded as a crucial component of this protocol. It was observed that certain patients had been using the same two devices for an extended duration. The period spent in the rehabilitation hospital presented an opportune moment to reassess inhalation medication.

In addition to therapy adjustments, assessing the patient's inhalation capacity in relation to inhalation therapy was considered a very strong aspect of this protocol. Both the nursing and pharmaceutical teams were willing to invest in the 'In-Check DIAL' device[26] during educational sessions. Overall, participants expressed optimism regarding a future multidisciplinary collaboration to implement this protocol.

Theme 2: Necessary adjustments to the pharmaceutical protocol for implementation in daily practice.

The PHARMACOP protocol was intentionally adapted for this study to fit the specific context and needs. Suggestions were made for further adjustments to the adapted protocol to optimize its implementation and ensure its sustainability in a long-term workflow.

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Subtheme 1: Individualization of the protocol

Through the focus group discussion, it was evident that the participants unanimously supported refining the protocol to better suit the individual needs of each patient. All participants reached a consensus that each patient presents unique requirements.

As per the participants, the initial assessment moment was considered the most important, serving as an opportune occasion to estimate the level of assistance or education required by evaluating the inhalation technique. Based on the inhalation technique scores, the staff thought it efficient to determine the frequency of visits required for the individual patient and/or ascertain the specific information desires.

Subtheme 2: Expanding patient education

There were suggestions to involve the patient's family in the education process, and to also broaden the target population as not only patients with COPD can have a need for education about their inhalation device. Other respiratory indications could also qualify.

Subtheme 3: Supplementary training

During the discussion, it was also mentioned that the nursing staff required additional training to make a future multidisciplinary protocol possible.

The current lack of training was mostly be linked to staff shortages. The COVID pandemic also significantly influenced the nurses' training. Training that was planned to be repeated after a few years had been cancelled. This also meant that new nurses were never trained in inhaler use. The multidisciplinary aspect of the pharmaceutical care protocol was highly applauded because knowledge can be shared through educational moments, increasing interprofessional collaboration in the hospital. Aside from this approach, the nursing staff indicated that they would also prefer organized pharmacist-led training days to broaden their knowledge.

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Theme 3: Labor intensity of the pharmaceutical care protocol

An important part of the protocol implementation is also the practical feasibility including the time needed for HCPs to execute the protocol. After evaluating the results of the time investment (Figure 1), the participants were pleasantly surprised by the time required to perform the different assessments and optimizations.

This convinced them that implementing the care protocol with a future multidisciplinary approach, could be achievable. To make the implementation of the protocol even more feasible, an integration in the electronic health record (EHR) was considered necessary to facilitate communication between HCPs and document recommendations for changes in inhalation therapy.

Theme 4: Follow-up after discharge

The participants recognized the major benefit of comprehensive post-discharge follow-up but also identified practical challenges with follow-up calls. The nursing staff expressed concerns about the feasibility of making these calls, leading to the suggestion that pharmaceutical staff take on this responsibility in the future multidisciplinary approach. Furthermore, a proposal was made to integrate inhalation technique follow-up into ambulatory consultations, as all patients are annually invited to visit the outpatient clinic of the rehabilitation hospital.

Alternatively, a monthly group educational session was also mentioned as an educational option, with the expectation that patients could participate annually.

Discussion

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This study highlights the potentially valuable role of a clinical pharmacist in optimizing inhaler use and technique during a rehabilitation hospital stay. As this unique setting has not been previously studied, these findings emphasize the importance of pharmacist-led interventions in improving patient outcomes. Notably, this study is the first to assess the inclusion of a clinical pharmacist in COPD management in a Belgian rehabilitation hospital. During a focus group discussion, a panel of involved HCPs felt that the implementation of a pharmaceutical care protocol for patients with COPD in a rehabilitation hospital would be feasible. The PHARMACOP trial was used as the foundation for the care protocol, as it had previously shown significant benefits to patients with COPD in community pharmacy [15]. The inhalation score and medication adherence were significantly higher in the intervention group compared to the control group. Other studies have also highlighted the positive impact of involving community pharmacists in COPD management [27,28]. The study by Khdour et al. showed that a self-management program led by a clinical pharmacist could add value in improving health outcomes such as quality of life, symptom management and medication adherence [29]. Moreover, the benefit of a clinical pharmacist in an acute hospital setting has been demonstrated extensively in studies evaluating their role on various wards within an acute hospital setting, resulting in, for example, less stress related to therapy, increased clinical efficiency, better pain management, lower utilization of secondary care and higher patient satisfaction [17–19]. Results from research focusing on COPD management in acute hospitals, also indicated the added value of the hospital pharmacist, leading to fewer inhalation errors and increased adherence [30–32]. The systematic review of Lin, Guohua et al. shows the growing evidence of hospital pharmacist' interventions by having an impact on adherence and inhalation technique but also health outcomes, economic outcomes and quality of life. It also addresses the benefit of a multidisciplinary approach and the need for further research.

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This study took place in a rehabilitation hospital which offers advantages such as longer patient stays, allowing more time for patient education and evaluation of inhaler technique [33,34]. This means that the educational process can be more intense compared to the acute hospital setting [35,36]. The study showed an impact on inhaler therapy appropriateness since the clinical pharmaceutical interventions resulted in a reduction in the number of devices per patient or a switch from device type. The protocol included the integration of tools such as an In-Check DIAL, facilitating the choice of the most optimal inhalation device for the patient. The study also had an impact on inhaler use, resulting in an improved inhalation technique, and resolving almost all major device errors. This improvement was influenced by the pharmacist's intervention as no other HCPs were directly involved. Patient cooperation to this study was very high as only one patient refused to participate, indicating that patients were highly motivated and eager to learn how to use their inhalation therapy correctly. During the focus group discussion, participants acknowledged the added value of involving a clinical pharmacist for education about inhaler therapy. Aside from staff shortages, a lack of training and education about inhalation medication for nursing staff was identified, both of which are aspects that can be resolved by pharmacist participation [37,38]. One of the main conclusions of the focus group discussion was that the further adjustment of the protocol with a more multidisciplinary approach would be required, thus significantly benefiting patients with COPD. Additionally, to increase feasibility of implementation of the protocol, adjustments were discussed by the participants of the focus group, to achieve a patient tailored protocol and reduce workload. These adjustments are summarized in table 3.

The integration of the protocol in the EHR is essential as this will facilitate interprofessional communication and assist pharmacists during their follow-up of every patient [39–41]. As supported by literature, the inclusion of family or other caregivers in educational sessions can

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positively impact self-management [42]. When these caregivers are present at the patient's home, they can remind them of the important steps and help with medication adherence.

Further adjustments to the protocol were deemed necessary in the discharge and follow-up period (see appendix 1 – part 7 and 8). A follow-up medication appropriateness screening, and evaluation of the inhalation technique can thus be executed. Studies on transmural care showed that early post-discharge patient contact, intensive follow-up of inhalation techniques, and personalized action plans reduce exacerbations [16,43]. Another study conducted by Farias R et al. showed that telehealth systems improve compliance and reduce exacerbations by providing continuous self-management education and easy access to healthcare providers and prescriptions [44].

Additional aspects considering transmural care optimization are also important tools such as a medication scheme and a discharge letter to inform primary HCPs, which we did not include in this study. Secondly, the pharmacist's follow-up interviews were planned shortly after discharge, patient knowledge could still be very high. In comparison with a telephone follow-up after 2 weeks, a physical follow-up visit after a longer period could be better. An essential partner in the follow-up is the community pharmacist, who can provide information and evaluate inhaler techniques as well [15]. Only 21% of the evaluated patients indicated that they had received an explanation on inhaler use from their community pharmacist. A follow-up consultation with the physician-specialist and nurse in the rehabilitation hospital's outpatient clinic could also be an appropriate moment to perform such an evaluation.

It would be appropriate to make the required changes and run the protocol within a larger population to establish more evidence on the influence of the adjusted PHARMACOP protocol on patients' clinical outcomes such as exacerbation rate, inhalation technique, smoking cessation etc. Although the rehabilitation hospital setting has its advantages, as already

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discussed, an important limitation is the low patient turnover and therefore a low number of patients eligible for inclusion. As a result, an adequately powered cluster-randomized controlled trial in this setting may not be feasible. Based on previous studies, such as the PHARMACOP trial, the addition of a clinical pharmacist in optimization of inhaler therapy can be beneficial and increases quality of care for patients with COPD in different settings, including the rehabilitation hospital. The addition of basic clinical pharmacy services is, however, not financed by the government in rehabilitation hospitals, in contrast to general hospitals in Belgium which plays an important role in importance of workload consideration [45].

Conclusion

In conclusion, the implementation of a pharmaceutical care protocol in a rehabilitation hospital was well-received. All involved HCPs were highly motivated to integrate it in their daily practice, considering several adaptations. The patients' inhalation technique improved significantly during the stay in the rehabilitation hospital after multiple visits involving educational moments, which highlights an important potential role for the clinical pharmacist in the care of these patients.

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Statements & declarations

Informed consent

Informed consent was obtained from all individual participants included in the study.

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All authors contributed significantly to the conception, design, and execution of the research. ET was responsible for the initial idea and design of the study. AW and EW conducted the data collection and analysis. SCMW provided practical guidance, critical revisions and contributed to the interpretation of the results. KDP, SB and KS further assisted with the data collection. All authors reviewed and approved the final manuscript.

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Table 1: Baseline characteristics

Parameter	**n = 19**
Age in years, median (IQR*)	73 (61 – 75)
Sex (male), n (%)	12 (63.2)
COPD duration in years, median (IQR)	7 (2 – 14)
Exacerbation in preceding year, n (%)	12 (63.2)
Pack-years, median (IQR)	48 (34.5 – 60)
Smoking status, n (%)*	
- Current smoker	2 (10.5)
- Passive smoker	4 (21.1)
- Ex-smoker	14 (73.7)
- Never smoked	3 (15.8)
GOLD classification, n (%)	
- A	0 (0)
- B	3 (15.8)
- C	0 (0)
- D	16 (84.2)
Type of inhalers, n (%)	
- (LABA + LAMA + ICS)	11 (57.9)
- LAMA and (LABA + ICS)	4 (21.1)
- ICS and (LABA + LAMA)	1 (5.3)
- (LABA + ICS)	2 (10.5)
- LABA and ICS	1 (5.3)

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Type of inhalation medication, n (%)	
- DPI	7 (36.8)
- pMDI	1 (5.3)
- pMDI + spacer	8 (42.1)
- SMI + DPI	2 (10.5)
- SMI + pMDI + spacer	1 (5.3)

COPD = chronic obstructive pulmonary disease, n = number of participants, IQR = Interquartile range (Q1-Q3), LABA = long-acting bèta$_2$-agonists , LAMA = long-acting antimuscarinic, ICS = inhaled corticosteroids, DPI = dry-powder inhaler, pMDI = pressurized metered-dose inhaler, SMI = soft mist inhaler

* patients may be included in multiple categories

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Table 2: Summary of provided recommendations by the clinical pharmacist

Recommendation	**Recommendation count, n (%)**
No recommendation, appropriate therapy	10 (52.6 %)
Multiple inhalers to single inhaler	6 (31.6 %)
Use short-acting anticholinergics only when necessary, not as a daily standard	1 (5.3 %)
Use of spacer recommended	1 (5.3 %)
Inappropriate frequency for prescribed inhaler	1 (5.3 %)

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Table 3: overview suggested adjustments

Current protocol	**Proposed adjustment**
Pharmacist led protocol	Multidisciplinary approach
Every patient the same protocol	Individualization
Only the patient	Inclusion of family
Separate protocol	Integration in EHR
Follow-up call	After discharge ambulatory consultations

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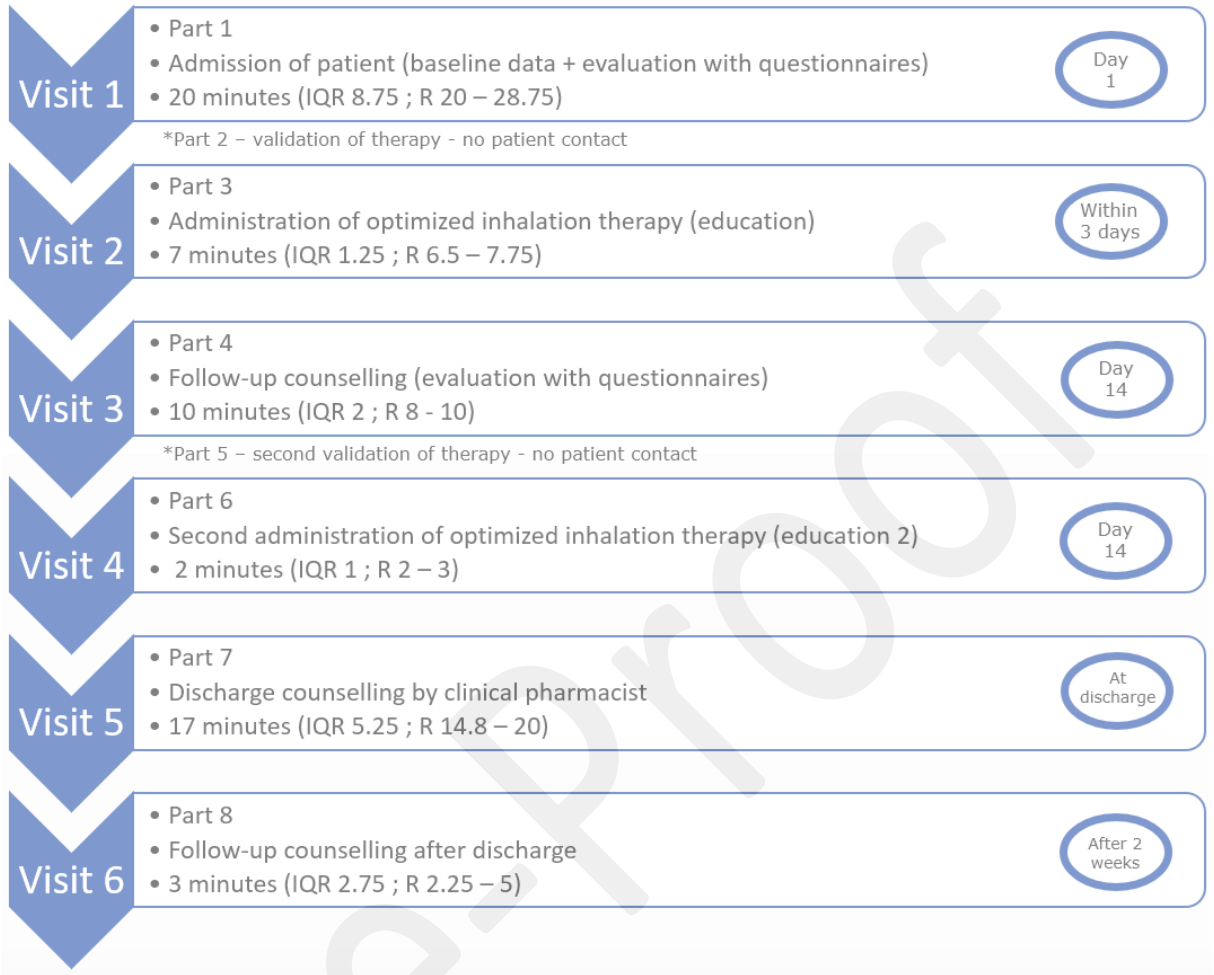
Figure 1: Overview of the different steps in the adapted PHARMACOP protocol, and their median time investment for individual visits (in minutes)



IQR = interquartile range, R = quartile 1 and quartile 3

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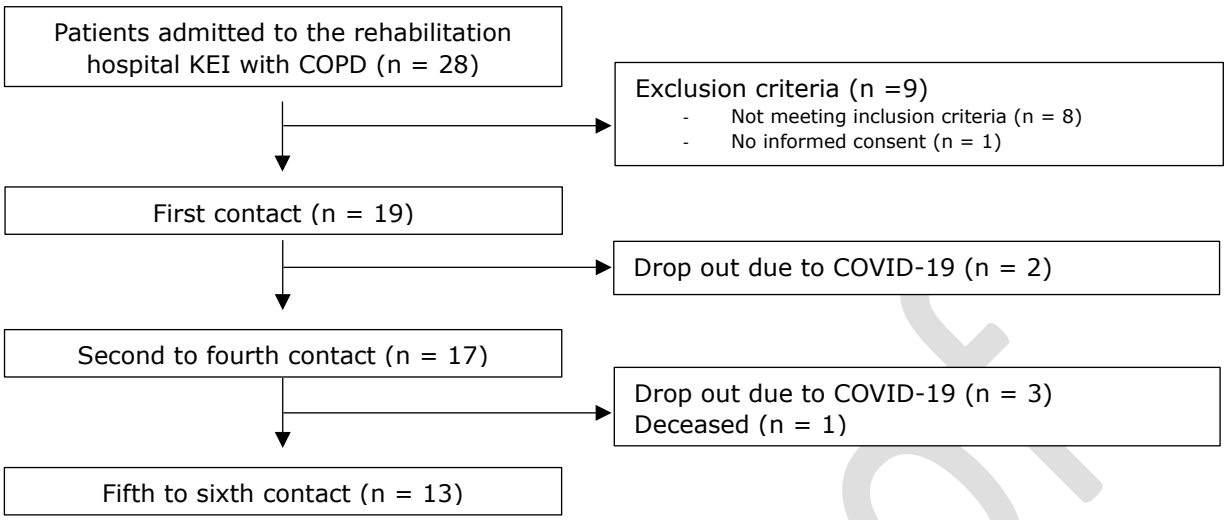
Figure 2: Study patient population: inclusion process



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Online Supplement

Appendix 1

Part 1: Admission of a patient with COPD to the HfR (Patient contact 1)

Evaluation current inhalation technique, medication adherence (if necessary through contact with the family pharmacist), the mMRC (Modified Medical Research Council) Dyspnea Scale, the COPD Assessment Test and the Beliefs About Medicines Questionnaire (BMQ).
Evaluation of smoking behaviour
Evaluation of influenza, pneumococcal and COVID19-vaccination status
Measure of airflow (in case no spirometry is available)

Part 2: First validation of inhalation therapy to a patient with COPD (no patient contact)

Pharmacists' evaluation of pharmacotherapy (GOLD guidelines for pharmacotherapy are followed)
Pharmacists' evaluation of inhalation device is appopriate
→ Discussion with prescribing physician if changes are necessary
→ Discussion of points of attention with nursing staff

Part 3: First administration of optimized inhalation therapy (Patient contact 2)

Structured patient education about
- COPD pathophysiology (if required)
- COPD medication
  - dosing instructions
  - inhalation technique (including physical demonstration with demo inhaler unit and in-check dial)
  - importance of adherence to maintenance therapy and current problems with adherence
  - possible side effects

Short intervention on smoking cessation and referral to smoking cessation counselling (if required)
Provision of a personalized patient information leaflets or medication information sources about COPD or inhalation therapy

Part 4: Follow-up counselling of inhalation medication use for patients with COPD (Patient contact 3)

Evaluation current inhalation technique, medication adherence (if necessary through contact with the family pharmacist), the mMRC (Modified Medical Research Council) Dyspnea Scale, the COPD Assessment Test and the Beliefs About Medicines Questionnaire (BMQ).

Part 5: Second validation of inhalation therapy to a patient with COPD (no patient contact)

Pharmacists' evaluation of inhalation device is appopriate
→ Discussion with prescribing physician if changes are necessary
→ Discussion of points of attention with nursing staff

Part 6: Second validation of inhalation therapy to a patient with COPD (Patient contact 4)

Structured patient education about (if required)
- COPD medication
  - inhalation technique (including physical demonstration with demo inhaler unit)
  - adherence to maintenance therapy

Short intervention on smoking cessation and referral to smoking cessation counselling (if required)

Part 7: Discharge counselling by clinical pharmacist (Patient contact 5)

Evaluation current inhalation technique, medication adherence (if necessary through contact with the family pharmacist), the mMRC (Modified Medical Research Council) Dyspnea Scale, the COPD Assessment Test and the Beliefs About Medicines Questionnaire (BMQ).

Structured patient education about (if required)
- COPD pathophysiology
- COPD medication
  - inhalation technique (including physical demonstration with demo inhaler unit)
  - adherence to maintenance therapy
- Self-management (e.g lifestyle advice, exacerbation recognition, etc)

Short intervention on smoking cessation and referral to smoking cessation counselling (if required)
Provision of information about the need for vaccination (influenza, pneumococcal, COVID19)
Provision of a patient information leaflet about COPD in the home setting
Provision of a discharge letter about inhalation medication to general practitioner and community pharmacist

Part 8: Follow-up counselling of inhalation medication use for patients with COPD after discharge (Patient contact 6)

Evaluation current inhalation technique, medication adherence (if necessary through contact with the family pharmacist), the mMRC (Modified Medical Research Council) Dyspnea Scale, the COPD Assessment Test and the Beliefs About Medicines Questionnaire (BMQ).
Evaluation of smoking behaviour
Evaluation of influenza, pneumococcal and COVID19-vaccination status

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Appendix 2 [15]

PRESSURIZED METERED DOSE INHALER	Score
1. Remove cap*.	.....
2. Shake inhaler*.	.....
3. Hold inhaler upright with mouthpiece down.	.....
4. Breathe out.	.....
5. Put mouthpiece between lips and seal lips tightly around it.	.....
6. Take a slow deep breath at the same time as pressing the canister down.	.....
7. Hold breath for 10 sec.	.....
8. If corticosteroids: rinse mouth with water.	.....

Total score = ... / 8
(If step 1 or 2 are not executed, the patients receives a total score of 0.

PRESSURIZED METERED DOSE INHALER + LARGE-VOLUME SPACER:	Score
1. Remove cap*.	.....
2. Shake inhaler*.	.....
3. Hold inhaler upright with mouthpiece down and place mouthpiece into the spacer.	.....
4. Breathe out.	.....
5. Put spacer between lips and seal lips tightly around it.	.....
6. Press the canister down.	.....
7. Breathe in slowly within 5 sec after pressing down the canister[33].	.....
8. Hold breath for 10 sec.	.....
9. Breathe 5 times in and out in the spacer.	.....
10. If corticosteroids: rinse mouth with water.	.....

Total score = ... / 10
(If step 1 or 2 are not executed, the patients receives a total score of 0.

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DRY POWDER INHALER	Score
1. Load dry powder inhaler correctly (depending on the type) *.	.....
2. Breathe out.	.....
3. Put mouthpiece between lips and seal lips tightly around it.	.....
4. Inhale forcefully and deeply*.	.....
5. Remove dry powder inhaler from the mouth.	.....
6. Hold breath for 10 sec.	.....
7. If corticosteroids: rinse mouth with water.	.....

Total score = ... / 7
(If step 1 or 4 are not executed, the patients receives a total score of 0.

Appendix 3

Interview guide for health care provider

For each part of the advanced pharmaceutical care program as provided in Appendix 1 of the protocol, the following aspects will be discussed with the involved health care providers.

- To what extent do you consider this part of the advanced pharmaceutical care program feasible in your daily routine?
- How much extra effort did this part of the advanced pharmaceutical care program take in comparison to the current protocols?
- To what extent do you feel this part of the advanced pharmaceutical care program is an additional value to the care for patients with COPD?
- Which aspects of this part of the advanced pharmaceutical care program do you consider redundant and why?
- Would you need additional training to provide this part of the advanced pharmaceutical care program in a routine matter? If yes: in which way would you prefer this training?

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Appendix 4

Theme	Subtheme	Participant	Quote
Multidisciplinary teamwork for patients with COPD		Head nurse	*Last year with corona that [the education] wasn't even possible. It could have been once every 18 days, once every 20 days, or even once every 12 days. It really depended.*
	Addition of a clinical pharmacist to the multidisciplinary team	Head of the hospital pharmacy	*I think, indeed, that the full protocol will only be achievable if there is sort of a collaboration with the pharmacy. … It could be a solution to expand our team, so we could execute the full protocol as described.*
		Reference nurse	*The preparatory work, that was performed by the pharmacist in the protocol before the first visit, such as searching information about inhalation medication, vaccination status, weight, smoking status, etc. We don't need to do that since we already have knowledge on the patient.*
		Reference nurse	*Indeed. We know how to prioritize for each patient. We really know the patient and what he/she lacks or needs concerning education.*
		Physician	*The community pharmacists get paid to do an education interview on inhalation medication when a physician prescribes one. Why have we only included nurses in our current practice and not the pharmacists? [rhetoric]*
	Defining the role of the clinical pharmacist	Reference nurse	*I thought that the evaluation of the inhalation device's appropriateness [by the pharmacist] was really good. When the patient used three devices and a switch to one or two could be made, the patient was very happy. This was very well perceived by the patients.*

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Necessary adjustments to the pharmaceutical protocol for implementation in daily practice.	***Individualization of the protocol***	ICT coordinator	*An evaluation of all the patients with COPD with inhalation therapy should happen for every patient. Based on the results [of the evaluation], we need to establish some inclusion and exclusion criteria to determine if the patient will follow the entire education process or maybe requires just one consult from the pharmacy.*
	Expanding patient education	Reference nurse	*We should let the patient know in advance when we will visit. This way we can make sure that they [the family] are present in their room. We can even check if family will visit to include them in the process.*
		Head of paramedics department	*And I think you need to see the bigger picture. I think that every patient on our ward with a respiratory comorbidity can have a need for education concerning their inhaler use.*
	Supplementary training	Nurse	*Everything we do now is actually self-taught. We have never been trained for this particular part. It was all done based on our own checklists and self-study. And yes, I find that a bit unfortunate.*
Labor intensity of the pharmaceutical care protocol		Hospital pharmacist	*I had expected a lot worse. I thought it would have taken a lot longer.*
		ICT coordinator	*It can be implemented in the EHR. You can put everything in the EHR. It is just a matter of in what way, what you need,… We first need to look what is going to be the flow and define the content. We need to have a finished protocol and then we can look further into it.*
Follow-up after discharge		Head nurse	*I also think the ambulatory consultations could [help to] maintain the knowledge of the inhalation medication. Patients come back every so much time, for a consultation. If it [the*

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			educational training] would be repeated there, that could make a difference.

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