Identifying stakeholders' views on implementation and personalisation of airway clearance devices in primary care for patients with chronic mucus retention: a nominal group technique

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Abstract

Introduction: Chronic mucus hypersecretion in COPD, bronchiectasis, and cystic fibrosis is associated with reduced lung function, increased exacerbations, and higher mortality. Mucus clearance devices (MCDs), including positive and oscillating positive expiratory pressure devices, are guideline-recommended but inconsistently implemented in primary care. This study aimed to identify and prioritise the steps required to implement MCDs in primary care in Belgium, from the perspective of a purposively sampled multi-stakeholder group.

Methods: Two nominal group technique (NGT) sessions were conducted online. Session 1 comprised five participants representing general practice, respiratory physiotherapy, general physiotherapy, and patient advocacy. Session 2 comprised five participants representing general practice, pulmonology, respiratory physiotherapy, and patient advocacy. Each session followed four phases: idea generation, idea sharing, clarification and grouping, and anonymous weighted prioritisation.

Results: Both sessions together yielded 17 distinct implementation steps across six themes. Four themes converged: education and training; device information and standardisation; structured collaboration and care pathway; and financial feasibility and reimbursement. Two themes showed divergence: diagnosis and indication-setting, ranked first in Session 2 with unanimous support, yet absent from Session 1 outputs; and patient experience sharing, identified only in Session 1. Session 2 additionally introduced two structural implementation steps that were absent from Session 1: a formal physiotherapy consultation for device selection and an individualised multimodal COPD care pathway.

Conclusion: Stakeholders identified consistent implementation priorities for MCDs in primary care, with four themes converging across both sessions: education and training; device information and standardisation; structured collaboration and care pathway; and financial feasibility and reimbursement. Diagnosis and indication-setting was identified as an additional priority, suggesting it may serve as a foundational prerequisite not yet explicit in existing guidelines. These findings can inform policy development, professional education, and future research.

Key words: mucus clearance devices; nominal group technique; primary care; implementation; chronic obstructive pulmonary disease; respiratory physiotherapy

1. Introduction

Chronic mucus hypersecretion (CMH) is a clinically significant problem in several chronic respiratory conditions, including chronic obstructive pulmonary disease (COPD), bronchiectasis, and cystic fibrosis.[1–3] CMH is associated with accelerated decline in lung function, increased frequency of exacerbations, reduced health-related quality of life, and higher all-cause mortality, including mortality attributable to mucus plugging in patients with COPD.[1,4] Airway clearance techniques (ACTs), including mucus clearance devices, have been recommended in clinical practice guidelines for patients with symptomatic sputum production, with positive expiratory pressure (PEP) and oscillating PEP (oPEP) devices identified as preferred options.[5–9]

The rationale for mucus clearance devices (MCDs) is based on optimising expiratory airflow to facilitate sputum mobilisation and expectoration.[10] Respiratory physiotherapists are trained to use and teach MCDs to patients as a specific intervention[11], often embedded in a chronic disease management program, like a self-management program or pulmonary rehabilitation, across the healthcare system.[12–15] Short-term clinical benefits of (o)PEP devices in stable COPD have been demonstrated in randomised controlled trials, including improvements in sputum expectoration, health-related quality of life, six-minute walk distance, and exacerbation rates.[16–18]

Despite a clear clinical rationale and documented short-term benefits, the integration of MCDs into routine primary care remains inconsistent. A scoping review identified that no studies have been published with the implementation of MCDs in primary care as a primary objective (see Appendix A). Indirect evidence from clinical studies, audits, and surveys points to barriers at patient, provider, and system levels: an accumulating evidence base that remains insufficiently surfaced in clinical practice, low guideline prominence, non-standardised initiation criteria, and limited perceived usefulness among general practitioners (GPs) (see Appendix A). A qualitative study of Belgian GPs found that difficulty in motivating patients for respiratory physiotherapy was compounded by unclear benefit-mechanism links and by the relative immediacy of pharmacological alternatives.[19] Prescribing data from the United Kingdom confirm this disparity: during 2013 to 2015, oPEP devices accounted for 0.16% of COPD patient-years compared with 13.2% for the mucolytic agent carbocisteine.[20]

Successful implementation of complex non-pharmacological interventions in primary care requires alignment across multiple stakeholder perspectives.[21] No prior study has engaged patient representatives, GPs, respiratory physiotherapists, and respiratory physicians in a structured, consensus-driven process to identify shared priorities for implementing MCDs in primary care. The nominal group technique (NGT) was therefore selected as an appropriate method to elicit and prioritise expert judgements across stakeholder groups, given its capacity to ensure equal participation and reduce the conformity effects of unstructured group discussion.[22–24]

The aim of this study was to identify and prioritise the steps required to implement airway clearance devices in primary care for patients with chronic mucus retention, from the perspective of a purposively sampled multi-stakeholder group.

2. Methods

2.1. Nominal group technique

The nominal group technique (NGT) is a structured qualitative method that facilitates creative problem-solving and judgment-based decision-making through a sequential, facilitated group process. It ensures that all participants have an equal opportunity to contribute and reduces the conforming social pressure characteristic of unstructured group discussions.[22,23] The method involves four sequential phases: 'idea generation', 'idea sharing', 'clarification and grouping', and 'prioritisation'.

NGT was selected because implementing mucus clearance devices in primary care is a conceptually complex problem for which no prior consensus-based prioritisation exists, and for which structured input from across professional groups is essential. The method is particularly suited to generating and ranking actionable priorities in contexts where routine answers are inadequate and expert judgement must be integrated.[22]

NGT sessions were conducted online via Microsoft Teams combined with the GroupMap digital platform (GroupMap, Brisbane, Australia). This online format was adopted to accommodate geographically dispersed participants and to ensure anonymity during the prioritisation phase of the NGT session.

2.2. Selection of experts

Participants were purposively selected to represent a range of six stakeholders relevant to the implementation of mucus clearance devices in Belgian primary care: general practitioners (GPs), respiratory physicians (RPs), (respiratory) physiotherapists working in primary care (PTs), respiratory patient associations for COPD and cystic fibrosis, and public health representatives. We approached 22 potential participants by telephone or email; 11 were willing and received written information about the study's aim and the NGT procedure. We invited them to attend one of two online sessions, resulting finally in five participants per session. The principal reason for declining was prior engagements. Both general and respiratory physiotherapists were contacted, as no legal requirement in Belgium restricts the treatment of patients with chronic mucus retention exclusively to practitioners holding a recognised specialised competency in respiratory physiotherapy. From the contacted respiratory patient associations, only COPD patient representatives were able to attend the sessions.

Participants received written information describing the study aims and the NGT procedure prior to each session and provided written informed consent before participating. No financial compensation was provided.

2.3. NGT sessions

Each session was chaired by an experienced, independent academic moderator (DV or PVR), with one person providing technical support throughout (GL). A session scenario was developed in advance to ensure completion of all four NGT phases.

At the start of each session, participants provided verbal informed consent before the session was recorded. Afterwards, they received a brief presentation on mucus clearance

devices and their role in primary care, followed by an explanation of the NGT procedure and the research question.

In the first phase, 'idea generation', participants had 10 minutes to independently and silently write down what steps they considered required to implement medical devices for airway clearance in primary care, without group discussion. In the second phase, 'idea sharing', each participant contributed one idea per round in sequence. Ideas were recorded in real time directly into GroupMap. Participants could offer a variation on an already-stated idea rather than repeat it. In the third phase, 'clarification and grouping', each idea was reviewed in turn. Brief clarification was invited, and other participants could comment or challenge. Ideas judged to be similar or overlapping were grouped by participant consensus at the end of this phase, with group labels determined collaboratively. In the last phase, 'prioritisation', the participants distributed 15 weighted votes individually across their five most important items: five votes for the highest priority, then four, three, two, and one for the subsequent items. Voting was conducted anonymously via GroupMap. Results were displayed to the group immediately after voting. Afterwards, a brief discussion was held to evaluate the outcome and NGT process: no objections were raised. Group consent to the priority list was formally recorded via the GroupMap platform at the end of each session.

2.4. Analysis

The ranking of implementation steps was determined by total weighted vote count. Both vote totals and the number of individual voters per step are reported to enable transparent interpretation of the voting distribution. Implementation steps that progressed through the clarification and grouping phase, yet were not selected during prioritisation, are retained and reported as valid unranked findings. Each group produced several unique ideas, so the results of the two groups were not entirely comparable. This made that it was impossible to rank all implementation steps across both groups.

3. Results

Two NGT sessions were conducted with five participants. Participant profiles are presented in Table 1.

Table 1: Participants' profiles per NGT session.

Participants	NGT Session 1	NGT Session 2
1	General practitioner (GP)	General practitioner (GP)
2	Respiratory physiotherapist	Respiratory physician (RP)
3	Chairperson of patient association for COPD	Respiratory physiotherapist
4	Respiratory physiotherapist, representative of Belgian professional association for physiotherapy	Respiratory physiotherapist, representative of Belgian professional association for physiotherapy
5	General physiotherapist	Board member of patient association for COPD

3.1. NGT Session 1

Session 1 generated 26 raw ideas, which were consolidated through the clarification and grouping phase to 12 implementation steps for the prioritisation phase (Table 2).

The top-ranked implementation step was education and competencies of the respiratory physiotherapist (18 votes, all 5 voters), encompassing undergraduate training, postgraduate continuing professional development, and hands-on device-specific instruction.

> *'Unknown is unloved. If we have insufficient knowledge of something, it is also difficult to motivate patients towards it.' [GP, session 1]*

The second-ranked implementation step was collaboration and care pathway (15 votes, 4 voters), a broad grouping that encompassed role delineation, multidisciplinary protocol design, a care coordinator function, pharmacist involvement, and the need for GP-accessible guidelines for non-pharmacological management.

> *'There needs to be one story in primary care. Whether it is the pharmacist, the GP, or the physiotherapist telling it, the story must always be the same. If it is clear, then it will be strong.' [PT, session 1]*

Financial feasibility and reimbursement ranked third (11 votes, 4 voters), covering device acquisition costs for both patients and physiotherapists, and geographic access to physiotherapy practices as a structural barrier to patient compliance. Three implementation steps were ranked at equal fifth position: administrative simplicity (5 votes, 3 voters), combination of device use with active exercise therapy (5 votes, 2 voters), and sharing of positive patient experiences via patient associations (5 votes, 1 voter). The last of these is a single-voter implementation step and does not represent group consensus. Two implementation steps received no votes.

3.2. NGT Session 2

Session 2 generated 13 raw ideas, of which 5 were new implementation steps not previously identified in Session 1. After consolidation through the clarification and grouping phase, 7 implementation steps proceeded to prioritisation (Table 2).

The top-ranked implementation step, diagnosis and indication-setting for mucus problems (20 votes, all 5 voters), was unanimous and represented one of the new implementation steps absent from Session 1 ranked outputs. It encompassed a structured diagnostic assessment of mucus impact, a formal indication-setting for airway clearance, and a respiratory physiotherapy consultation as part of the diagnostic pathway.

> *'I receive many patients whom the respiratory physician refers for drainage because of cough or mucus. But the mucus is not always there. The need has to be evaluated, and that is a very important issue.' [PT, session 2]*

A comprehensive list of available devices (14 votes, all 5 voters) was also unanimous and ranked second, with scope expanded relative to Session 1 to include device cost, suppliers, accessories, and cleaning requirements. Specific training for all involved healthcare providers ranked third (13 votes, 4 voters), with the discussion during the clarification and

grouping phase explicitly extending the target audience beyond physiotherapists to include GPs, respiratory physicians, and practice nurses.

> *'Many physicians are not familiar with these techniques and what is available for which patients. That is purely a training issue, and I will be the first to admit it. Many respiratory physicians do not know them well, or at least not very well.'[RP, session 2]*

Session 2 also introduced two structurally distinct implementation steps absent from Session 1: an individualised multimodal COPD care pathway ranked fourth (9 votes, 2 voters), and a formal physiotherapy consultation for device selection ranked fifth (8 votes, 3 voters), described as a discrete billable assessment step distinct from a treatment session.

Table 2: Ranked implementation steps by NGT session, including the total number of votes and voter(s).

Ranking	NGT Session 1	NGT Session 2
1	Education and competencies of the respiratory physiotherapist 18 votes | 5 voters	Diagnosis and indication-setting for mucus problems 20 votes| 5 voters
2	Collaboration and care pathway 15 votes | 4 voters	List of available devices (cost, suppliers, accessories, hygiene) 14 votes | 5 voters
3	Financial feasibility and reimbursement 11 votes | 4 voters	Specific training on COPD and devices for all healthcare providers 13 votes | 4 voters
4	Standardised instructions for use per device 7 votes | 2 voters	Individualised multimodal COPD care pathway 9 votes | 2 voters
5	Administrative simplicity 5 votes | 3 voters Combination with active exercise therapy 5 votes | 2 voters Patient experience sharing via patient associations 5 votes | 1 voter†	Formal physiotherapy consultation for device selection 8 votes | 3 voters
6	-	Conditions and reimbursement for prescribing devices 7 votes | 3 voters
7	-	Reliable list of respiratory physiotherapists (including device experience) 4 votes| 3 voters
8	Centralised list of recognised respiratory physiotherapists 4 votes | 1 voter†	-

Ranking	NGT Session 1	NGT Session 2
9	List of respiratory devices eligible for primary care 3 votes | 2 voters	-
10	Information on the existence of devices for patients 2 votes | 1 voter†	-
N/R	Personalised approach based on socio-economic background and patient profile 0 votes Uniformity of device hygiene and disinfection procedures 0 votes	-

COPD: Chronic Obstructive Pulmonary Disease, †: single voter; does not represent group consensus, N/R: not ranked

3.3. Cross-session comparison

After both sessions, all voted implementation steps were compared and categorised thematically. The two sessions together yielded 17 distinct implementation steps across 6 themes. Four themes showed convergence across sessions; 1 theme showed substantive convergence or appeared in only one session (see Table 3).

Both sessions consistently prioritised education and training, device information and standardisation, structured collaboration and care pathways, and financial feasibility and reimbursement, thereby strengthening these as shared implementation priorities across professional groups.

The most notable divergence was the unanimous prioritisation of diagnosis and indication-setting in Session 2, which was absent from Session 1's ranked outputs. Session 1, by contrast, identified the sharing of patient experiences through patient associations as a ranked implementation step that was not echoed in Session 2.

Table 3: Implementation steps generated across both NGT sessions, grouped by theme and ranked by session priority. Vote totals are shown with the number of individual voters in parentheses.

Theme	Implementation step	NGT Session 1		NGT Session 2		Cross-session agreement
		Rank	Votes	Rank	Votes	
Diagnosis and indication-setting	Diagnosis and indication-setting for mucus problems	-	-	1	20 (5)	Divergence: Ranked first in Session 2 (unanimous); absent from Session 1.
Education and training	Education and competencies of the respiratory physiotherapist	1	18 (5)	-	-	Convergence: Prioritised in both sessions, with Session 2

Theme	Implementation step	NGT Session 1		NGT Session 2		Cross-session agreement
		Rank	Votes	Rank	Votes	
	Specific training on COPD and devices for all involved healthcare providers	-	-	3	13 (4)	broadening the intended audience to all involved healthcare providers.
Device information and standardisation	List of available devices (cost, suppliers, accessories, and hygiene requirements)	-	-	2	14 (5)	Convergence: Identified in both sessions. Session 2 assigns higher priority and expands scope to include cost, suppliers, accessories, and hygiene requirements.
	Standardised instructions for use per device	4	7 (2)	-	-	
	List of respiratory devices eligible for primary care	9	3 (2)	-	-	
	Information on the existence of devices for patients	10	2 (1)†	-	-	
Structured collaboration and care pathway	Collaboration and care pathway	2	15 (4)	-	-	Convergence: Prioritised in both sessions. Session 2 additionally introduces the individualised multimodal COPD care framework and the formal physiotherapy consultation as distinct structural implementation steps.
	Individualised multimodal COPD care pathway	-	-	4	9 (2)	
	Formal physiotherapy consultation for device selection	-	-	5	8 (3)	
	Administrative simplicity	5	5 (3)	-	-	
	Combination with active exercise therapy	5	5 (2)	-	-	
	Reliable list of respiratory physiotherapists (including device experience)	-	-	7	4 (3)	
	Centralised list of recognised respiratory physiotherapists	8	4 (1)†	-	-	
Financial feasibility and reimbursement	Financial feasibility and reimbursement	3	11 (4)	-	-	Convergence: Identified in both sessions, with Session 1 focusing on device cost and Session 2 on prescribing authority and reimbursement criteria.
	Conditions and reimbursement for prescribing devices	-	-	6	7 (3)	

Theme	Implementation step	NGT Session 1		NGT Session 2		Cross-session agreement
		Rank	Votes	Rank	Votes	
Patient experience sharing	Sharing positive patient experiences via patient associations	5	5 (1)†	-	-	Divergence: Identified in Session 1 only; single-voter item.

COPD: Chronic Obstructive Pulmonary Disease, †: single voter; does not represent group consensus

4. Discussion

Using the nominal group technique across two purposively sampled stakeholder groups, this study identified and prioritised the steps required to implement airway clearance devices in primary care for patients with chronic mucus retention. Four of the six identified themes showed convergence across both sessions: education and training; device information and standardisation; structured collaboration and care pathway; and financial feasibility and reimbursement. Two themes showed divergence: diagnosis and indication-setting, ranked first in Session 2 with unanimous support, yet absent from Session 1-ranked outputs; and patient experience sharing, identified only in Session 1. The unanimous prioritisation of diagnosis and indication-setting identifies a foundational clinical prerequisite that implementation frameworks must explicitly address.

Education and training

The consistent priority assigned to education and professional training across both sessions aligns with prior evidence indicating that limited awareness of airway clearance devices and their clinical indications is a major implementation barrier. Alghamdi et al. found that family physicians in Saudi Arabia were least likely to prescribe airway clearance devices, attributing this to limited awareness and perceived benefit of non-pharmacological options.[25] Leemans et al. reported that Belgian GPs remained unconvinced about the effectiveness of respiratory physiotherapy despite growing evidence, and that GPs encountered difficulty motivating patients when the mechanism-benefit link was not apparent.[26] The present findings add specificity to this evidence by identifying what effective training would need to encompass: for physiotherapists, device-specific technical competencies alongside undergraduate and postgraduate courses; for GPs and respiratory physicians, awareness of available devices, clinical indications, and routes to respiratory physiotherapist referral.

Device information and standardisation

Both sessions identified the absence of a comprehensive, accessible, and current device inventory as a barrier to implementation. Session 1 treated the instructions for use (IFU) and a list of primary care-eligible devices as distinct items; Session 2 consolidated them into a single comprehensive resource that includes cost, suppliers, and accessories. This convergence is consistent with findings from the scoping review, which identified low guideline visibility for mucus clearance devices as a contextual barrier (see Appendix A). In the widely used GOLD guideline, information on oPEP therapy is placed under pharmacological management of mucus hypersecretion rather than within non-pharmacological care, reducing its accessibility to non-specialist clinicians.[27] The present

data support the development of a dedicated, multi-professional resource analogous to the European Respiratory Society statement on airway clearance techniques for bronchiectasis[28], however, scoped to the primary care context.

Financial feasibility and reimbursement

Financial feasibility was ranked third in Session 1 and sixth in Session 2, with both sessions identifying it as a structural implementation barrier. Session 1 participants framed the issue more broadly, noting the acquisition cost of devices for patients and for physiotherapists who use devices in clinical practice. Session 2 focused on the reimbursement policy mechanisms: the prescribing authority (whether a device requires a GP or respiratory physician prescription), indication-linked reimbursement criteria, and the absence of a reimbursement pathway for the formal physiotherapy consultation for device selection. Prescribing data from the United Kingdom illustrate the scale of the disparity: during 2013 to 2015, the total expenditure on airway clearance devices across all English primary care practices was approximately £187,000, compared with £73 million for the mucolytic carbocisteine and £483 million for tiotropium.[20] The identification of reimbursement reform as a shared priority across both stakeholder groups aligns with implementation science frameworks that position policy and financing as critical contextual determinants of adoption.[29]

Structured collaboration and care pathway

The need for structured interdisciplinary collaboration was a second-ranked item in Session 1 and was operationalised in Session 2 as the individualised multimodal COPD care framework: a flexible combination of respiratory physiotherapy, exercise, aerosol therapy, and device-based approaches, tailored to disease stage and patient profile and embedded in a formal care pathway. This concept addresses a recognised structural gap in Belgian primary care, where the current reimbursement framework offers a binary choice between individual treatment sessions for chronic diseases in primary care or limited outpatient rehabilitation in hospitals, with no structural provision for a transmural care pathway. Many respiratory disorders with CMH, such as COPD, qualify for higher reimbursement, ranging from 60 treatment sessions per year to unlimited sessions for a maximum of 3 years.[30,31] Additionally, a specific subgroup of patients with severe respiratory conditions may receive health insurance benefits for medical devices such as ventilators and portable oxygen concentrators, or for participation in pulmonary rehabilitation programs, not for the use of mucus clearance devices in the earlier disease stages. These initiatives are coordinated in secondary and tertiary healthcare centres with limited interactions from primary healthcare providers.[32] Furthermore, transmural care pathways, like those for diabetes or chronic kidney disease, do not exist for chronic respiratory disorders. [33] Session 2 additionally introduced the formal physiotherapy consultation as a distinct structural implementation step: a reimbursed assessment visit for device selection and expert clinical opinion, separate from a treatment session. Although the nomenclature code for such a consultation exists within the Belgian healthcare system, it is rarely used. Formalising and incentivising this step would create a referral mechanism that enables GPs to obtain expert advice on device selection for chronic mucus problems, potentially improving the appropriateness of MCDs as a non-pharmacological option. The introduction of the care coordinator concept, the pharmacist's informational role, and the consistent messaging about MCDs across professional groups in Session 1 further reflect the breadth of the collaboration theme. These findings align with the extended FITT framework conceptualisation of

implementation as the fit between individuals, clinical tasks, technology, and the organisational context.[34]

Diagnosis and indication-setting

The unanimous and highest-ranked finding of Session 2, absent from Session 1, was the need for structured diagnosis and indication-setting for mucus problems as a prerequisite for the use of MCDs. Its absence from Session 1 rankings most plausibly reflects the group's professional composition: a physiotherapy-heavy group may reasonably assume diagnostic adequacy, whereas GPs and a respiratory physician (Session 2) identified clarity of diagnostic indication as a foundational step that currently lacks standardisation. Diagnostic thresholds for mucus hypersecretion in COPD vary substantially across clinical practice and between clinical studies, ranging from self-reported daily sputum production to objective scoring tools, with no universal standard (see Appendix A). Guidelines consistently recommend restricting airway clearance to patients with symptomatic sputum but diverge on operationalisation, and no guideline specifies a standardised diagnostic algorithm for primary care.[5,6,9] A dedicated statement on indication-setting for mucus hypersecretion in COPD, analogous to the ERS bronchiectasis statement[28], could address this gap and inform primary care practice.

Strengths and limitations

A methodological strength of this study is that both sessions followed standard NGT procedures, including a formal consent step at the end of each session in which participants confirmed acceptance of the resulting priority list.[23] The divergences between sessions reflect distinct professional vantage points and constitute substantive findings rather than methodological inconsistencies. The two groups differed in professional composition, partly because a participant was unable to attend Session 1 due to a prior engagement, and the priority differences might reflect this variation. As in Stolper et al.[24], in which consecutive groups each contributed new research questions, the second NGT session in the present study introduced concepts that the first did not surface: the individualised multimodal COPD care framework and the diagnostic prerequisite. These are not contradictions of Session 1 findings but additions that emerge from a more clinically diverse group. The combined cross-session dataset, therefore, provides a richer picture of implementation priorities than either session alone would permit.

The following limitations should be considered when interpreting the findings. First, both sessions were conducted online via Microsoft Teams and GroupMap. This departs from the in-person format described in the original NGT methodology.[22] The online format offered practical advantages, including broader geographic recruitment and guaranteed voting anonymity throughout the prioritisation phase. However, it may have affected group dynamics and the depth of idea generation compared with in-person delivery, and it may have prevented the generation of informal exchanges that can enrich face-to-face NGT sessions. Second, data sufficiency cannot be confirmed with certainty. Both sessions drew participants from Belgian primary care contexts, and it remains unclear whether two groups are sufficient to reach thematic saturation across the full range of relevant stakeholder perspectives. The findings should therefore be interpreted as reflecting Belgian stakeholder perspectives and may not capture the full breadth of implementation priorities relevant to other healthcare systems. Participant recruitment also resulted in a higher representation of respiratory physiotherapists than general physiotherapists. Although no legal

requirement in Belgium restricts the treatment of patients with chronic mucus retention to practitioners holding a specialised respiratory physiotherapy competency, all general physiotherapists contacted during recruitment reported referring patients with respiratory conditions to a specialised colleague. The perspectives of general physiotherapists are therefore underrepresented in the dataset, which may limit the transferability of findings to primary care settings where respiratory physiotherapy specialists are less accessible. The absence of a pharmacist from either session is a further gap in stakeholder representation, given that the pharmacist's informational role in device awareness was explicitly identified as important in Session 1 discussions. A further limitation concerns the composition of participating patient associations. Although recruitment aimed to include associations across the range of conditions associated with chronic mucus retention, all participating patient associations represented individuals living with COPD. The findings should therefore be interpreted as reflecting a COPD patient perspective and may not generalise to other conditions associated with chronic mucus retention. Last, vote concentration should be interpreted carefully. Several Session 1 implementation steps received votes from a single voter, and their rankings reflect the individual weighting rather than group consensus. Both vote totals and voter counts are presented in Table 3 to ensure transparency and to make this distinction explicit.

Implications for policy, practice, and research

The findings identify five areas with direct policy and practice implications: (1) the development of multi-professional competency frameworks for MCDs, integrating device-specific content into physiotherapy curricula and GP continuing professional development; patient associations have a complementary role in raising device awareness among patients and supporting informed shared decision-making; (2) the creation of a centralised, regularly updated, and multi-professional device information resource covering clinical indications, available devices, costs, and suppliers; (3) increase awareness about the formal physiotherapy consultation that can used for device selection; (4) the development of a structured, primary care-ready diagnostic algorithm for mucus hypersecretion as a prerequisite for device prescription; and (5) the creation of a flexible, combinable COPD care pathway that accommodates MCDs, combined with other therapy modalities within a single reimbursable framework. Future research should include hybrid effectiveness-implementation studies that combine clinical outcomes data with implementation process evaluation, as well as a quantitative assessment of the impact of reimbursement reform on device uptake in primary care.[35]

5. Conclusion

Using the nominal group technique, this study identified and prioritised the steps required to implement mucus clearance devices in primary care for patients with chronic mucus retention, from the perspective of a purposively sampled multi-stakeholder group. Four themes converged across both sessions: education and training; device information and standardisation; structured collaboration and care pathway; and financial feasibility and reimbursement. The unanimous prioritisation of diagnosis and indication-setting for mucus hypersecretion suggests that structured diagnostic assessment may serve as an antecedent to effective device implementation, a consideration not yet made explicit in existing frameworks and guidelines. These findings provide a basis for policy development, professional education reform, and future implementation research in this field.

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Appendix A: Barriers and facilitators to the implementation of airway clearance devices in primary care for stable patients with Chronic Obstructive Pulmonary Disease: a scoping review

Barriers and facilitators to the implementation of airway clearance devices in primary care for stable patients with Chronic Obstructive Pulmonary Disease: a scoping review

Abstract

Background: Chronic mucus hypersecretion in Chronic Obstructive Pulmonary Disease (COPD) is linked to worse lung function, poorer quality of life, and more exacerbations. While various mucus clearance devices (MCDs) are available, no single device is superior, and their implementation in primary care remains inconsistent. Evidence on integrating MCDs into primary care is limited, with no prior reviews targeting implementation determinants. This scoping review, therefore, maps current MCDs and clinical guidelines and identifies barriers and facilitators to their implementation for people with stable COPD in primary care. **Design**: Scoping review of clinical studies, international and local guidelines on COPD management, audits or surveys published between 2015 and 2025 per the Joanna Briggs Institute methodology. Four electronic databases and grey literature were searched, with hand-searching of eligible records. **Results**: Eleven reports were included in this review, namely four clinical studies, five guidelines and two audits or surveys. MCDs evaluated in clinical studies included Acapella, Aerobika, Threshold PEP, and T-PEP, while audits/surveys revealed broader real-world use of more MCDs with varying frequencies. The five guidelines consistently recommend airway clearance to COPD patients with symptomatic sputum, preferring (oscillatory) positive expiratory pressure devices. No studies were found with implementation as a primary objective. Indirect evidence from clinical studies, audits, and surveys revealed barriers at the patient, provider, and system levels. These include emerging clinical evidence, low visibility in guidelines, non-standardised initiation criteria, and limited perceived utility among general practitioners. Facilitators include reported patient benefits, ease of use at home, a favourable safety profile of the devices, and suitability for telehealth. **Conclusion**: This scoping review provides an overview of MCDs in stable COPD patients in primary care from clinical studies and guidelines, identifying potential implementation barriers and facilitators to support the future implementation and broader adoption of MCDs in primary care. **Registration**: https://osf.io/qngzy.

1. Introduction

Chronic mucus hypersecretion (CMH) in, for example, chronic obstructive pulmonary disease (COPD), is associated with several poor outcomes such as reduced lung function, quality of life and increased frequencies of exacerbations and admissions.[1] Moreover, mucus plugs are associated with higher all-cause mortality for patients with COPD than those without mucus retention.[4] Due to these poor associations, airway clearance techniques (ACT) have been recommended as a non-pharmacological treatment option in clinical practice guidelines for patients with excessive mucus production.[36–39]

The rationale behind these techniques is based on the application of an optimal expiratory airflow velocity, which exerts shearing forces on sputum at the air–liquid interface.[10] Respiratory physiotherapists are trained to execute and teach ACTs to patients as a specific intervention[11], often embedded in a chronic disease management program, like a self-management program or pulmonary rehabilitation, across the healthcare system.[12–15] Self-administered ACTs nowadays include the use of medical devices to assist in mobilising secretions ranging from simple and straightforward devices generating positive expiratory pressure (PEP), through oscillating (oPEP) devices, to high-frequency chest wall oscillation (HFCWO) devices which have significant cost implications.[40] Short-term benefits are reported in the literature regarding improving mucus transport.[41,42] An increasing number of these medical devices continue to infiltrate the market, providing a bewildering choice for healthcare professionals and individuals with CMH. However, systematic reviews have yet to identify any device as more or less efficacious than others.[40,41,43]

Despite a clear clinical rationale and documented short-term benefits, integrating device-assisted airway clearance techniques, also called mucus clearance devices, into routine primary health care remains challenging. Successful adaptation of mucus clearance devices relies on policy considerations, alignment with (integrated) care processes and adherence to clinical practice guidelines (CPGs).[44]

According to the 2023 GOLD guideline, mucus clearance treatments that promote mechanical movement through the airway, such as oPEP therapy, may improve mucus mobilisation, symptoms and quality of life in people with COPD who produce sputum daily or most days.[27] Although considerable research has focused on improving the implementation of CPGs in primary care[45], less specific attention has been given to the transfer from research to the implementation of non-pharmacological treatments, such as mucus clearance devices, within primary care. A preliminary search of PubMed (MEDLINE) on 2 July 2025 found no scoping or systematic reviews on barriers and facilitators to implementing mucus clearance devices in primary care for stable COPD. A scoping review is therefore warranted to fully identify the factors influencing the barriers or facilitators to

implementation, and to map all available mucus clearance devices for people with COPD in primary care.[46]

The main objective of this scoping review was to identify barriers and facilitators that influence the implementation of mucus clearance devices in primary care. The secondary objectives were to map mucus clearance devices used clinically for people with COPD in primary care and identify existing local recommendations and current guidelines for the use of mucus clearance devices.

2. Methodology

The scoping review was conducted in accordance with the Joanna Briggs Institute (JBI) methodology for scoping reviews and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-ScR) extension for scoping reviews.[47,48] The protocol was registered on Open Science Frameworks from the Centre for Open Science.

2.1 Search strategy

The scoping review aimed to address the following research question(s): 1) What are the barriers and facilitators identified for the implementation of mucus clearance devices in primary care? 2) Which mucus clearance devices have been used in research studies for people with COPD in primary care? 3) What are the recommendations of current local, national and international guidelines for the use of mucus clearance devices in patients with stable COPD?

Following these questions, the researchers developed a search strategy using the population, concepts, context (PCC) framework[48] to locate clinical trials, guidelines, audits, and surveys that met our eligibility criteria.

An initial limited search of PubMed was conducted (by GL) to identify relevant articles, using free-text words, keywords and MeSH (Medical Subject Heading) terms found in article titles and abstracts. The search strategy was validated using two articles that met the review eligibility criteria and were identified beforehand by the researchers.[26,49] Medline (Pubmed), Web of Science, Embase and Scopus were searched from 2015 to July 2025. The entire search strategy was tailored to each selected database, utilising a combination of subject headings and keywords to search titles and abstracts (Appendix A). Boolean operators were used to combine search terms. For PubMed, MeSH terms were used when available. In addition, reference lists of relevant articles were hand-searched to expand the search. Grey literature was also searched, including position statements and other practice guidelines related to mucus clearance devices in primary care, retrieved

from national and international healthcare professional association websites. Literature for this review was eligible if published in Dutch, English and French.

2.2 Eligibility criteria

Population

Studies on the use of mucus clearance devices in adults (⩾18 years old) with stable COPD were considered. Studies that included participants with diseases other than COPD were excluded unless the results for patients with the diseases of interest were reported separately.

Concept

Studies that investigated any or multiple mucus clearance devices, i.e., physical strategies specifically developed to promote the mobilisation and removal of excess mucus from the airways and alleviate symptoms associated with mucus retention with the aid of a medical device, were examined. Techniques with different primary objectives, including exercise, non-invasive ventilation, respiratory muscle training, breathing pattern retraining, and improving self-management through educational topics on airway clearance, were excluded. Studies that used mucus clearance devices embedded in other interventions, such as pulmonary rehabilitation, were included. Additionally, humidification and pharmacological approaches, such as hypertonic saline, normal saline, and mucoac,tive agents, were also included, considering their use in real-world practice.

Context

This review encompassed studies that examined the delivery of mucus clearance devices in primary healthcare. In this context, respiratory physiotherapists often require a prescription from a physician to start airway clearance therapy. Such prescriptions may be issued by general practitioners or by respiratory physicians involved in transmural care initiatives. Consequently, both fields of medicine are considered essential to ensure a comprehensive scope of this review, supporting a thorough evaluation of the usage of mucus clearance in primary care. Examples of relevant settings include primary healthcare centres, community services and home care. Studies published before 2015 were excluded because they may have been outdated compared to modern clinical practice.

Type of sources

Quantitative, qualitative and mixed-methods study designs, as well as clinical guidelines, audits and surveys on the use of mucus clearance devices, were considered for inclusion. To prevent duplication, we screened primary studies cited in relevant reviews for eligibility and omitted the reviews themselves from data extraction. Following Pavlic et al.[50], we

selected countries with primary care systems comparable to Belgium based on two dimensions: continuity and comprehensiveness of care relative to healthcare expenditure per capita in purchasing power parity. To maximise relevance and transferability to Belgian primary care, we limited our guideline search to fifteen countries meeting these criteria: Finland, Ireland, Australia, England, New Zealand, Sweden, Germany, Canada, Denmark, the Netherlands, Switzerland, Norway, Luxembourg, Iceland, and Austria. For clinical guidelines or position statements, only the most recent version was included.

In the following stage, we searched the reference lists of included studies and guidelines to locate additional sources. Conference abstracts were not included.

2.3 Study/sources of evidence selection

Search results were stored in Mendeley Reference Manager (version 2.135.0, Elsevier Ltd.), and duplicates were removed with EndNote (version 20.6) and manually. We piloted screening on 25 articles to ensure a shared understanding of eligibility criteria and reduce disagreements, requiring at least 75% agreement before proceeding with screening of the whole database.[48] Title and abstracts were screened independently by two researchers (TG, GL) against the inclusion criteria. Afterwards, the full texts of relevant studies were consulted to determine definitive inclusion. A consensus discussion between all researchers took place after title and abstract screening, as well as after full-text consultation. Disagreements between reviewers were resolved through discussion or by another reviewer (DV).

2.4 Data charting

Two researchers (TG, GL) extracted data from the included papers using a data extraction tool adapted from Peters et al.[48] The extracted data included specifics about the population, concept, context, methods and key outcomes relevant to the scoping review questions, for example, setting (primary healthcare center, home care, …), mucus clearance device applied, duration, frequency and length of intervention, barriers and facilitators to implementation. The main results summarising each study's findings were also extracted. One reviewer (TG) extracted, and another (GL) verified the data. Any disagreements between the reviewers were resolved through discussion or by another reviewer (DV). The extracted data were reported in a narrative summary, as answers to our research questions, and key findings were presented in a table format.

2.5 Deviations from the initial protocol

No deviations were reported; however, the identified and extracted data were refined during the review as the authors' awareness and consideration of the contents of all included sources increased.

3. Results

3.1 Flow of studies through the review

The literature search yielded 4,309 records, including 133 identified by hand-searching of relevant sources. After deduplication and application of the eligibility criteria, 39 articles were selected for a full-text screening. Eleven reports were included in this review, namely four clinical studies[17,51–53] (36%), five guidelines[5–9] (46%) and two audits or surveys[20,54] (18%). The selection process is depicted in a PRISMA-ScR flow diagram (Figure 1).[55,56]

3.2 Characteristics of the included studies

Clinical studies

The characteristics of the clinical studies included are presented in Table 1. Studies were published between 2016 and 2023 and were conducted in the United Kingdom (n=1), Canada (n=1), Egypt (n=1), and Italy (n=1); all mucus clearance devices were used in home care settings. The clinical studies primarily consisted of randomised controlled trials (n=4).[17,51–53] In total, 289 people with COPD were included; study sample sizes ranged from 13 to 55, except for Shamakh et al.[52], which did not report per group numbers. Mean ages ranged from 52.20 to 71.7 years old. All studies, except one study[51], reported participants' severity of airway obstruction, ranging from I to IV in the GOLD classification, with the majority GOLD III and IV.[17,52,53]

Guidelines

The characteristics of the included guidelines are presented in Table 2. There were five guidelines published between 2020 and 2024, in the United Kingdom, the Netherlands, Norway, Sweden, Australia and New Zealand.[5–9] The majority of guidelines was created for the following stakeholders: specialists respiratory medicine, general practitioners, nurses, physiotherapist and dieticians.

Audits and surveys

The characteristics of two included audits and surveys are presented in Table 3. We included two cross-sectional surveys conducted between 2017 and 2023 in Saudi Arabia and the United Kingdom, one of which also incorporated a retrospective cohort audit.[20,54] The retrospective cohort study utilised a database, OpenPrescribing, with anonymised prescribing data issued by general practitioners in England.[57] Cross-sectional studies involved electronic surveys sent to all healthcare professionals managing COPD in Saudi Arabia and respiratory physiotherapist in the United Kingdom. The total number of participating healthcare professionals is 1,304 across a broad spectrum of healthcare settings, including primary care clinics and community services. Healthcare professional's

years of experience were reported in only one study[54], and the response rate was also reported in only one study.[20]

3.3 Research questions

Mucus clearance devices used in primary care

Clinical studies evaluated the effect of oPEP/PEP reported the following MCDs: Acapella, Aerobika, Threshold PEP, and T-PEP (see Table 1). In stable COPD managed in home settings with chronic mucus production, (o)PEP-based airway clearance shows consistent benefit. Active Cycle of Breathing Techniques (ACBT) plus Acapella improves cough-specific and generic Health Related Quality of Life (HRQoL) and reduces fatigue[53]; oPEP enhances sputum expectoration, FVC, QoL, and 6-min walk distance[51]; in moderate COPD, Threshold PEP and Acapella outperform ACBT alone with no difference between the two devices[52]; T-PEP lowers exacerbations versus standard care and improves lung function, dyspnea, and health status in severe COPD, with good adherence and preference for home use.[17] Reporting of MCD session parameters varied across studies. Session duration was expressed as either a breath count (typically 10–12 breaths followed by forced expirations/huffs), a time interval (e.g., 30 min), or not reported. Usage frequency ranged from 2–4 sessions/day, with treatment courses lasting 15 days to 6 months.

Audits and surveys from primary care and community settings indicate real-world use of multiple MCDs, including Acapella and Aerobika, as well as PEP masks, flutters, bubble PEP, and Aerosure. The frequency of usage for these techniques varied greatly. In Saudi Arabia, the most prescribed MCDs were Acapella and Flutter.[54] In the United Kingdom, respiratory physiotherapists were familiar with both and, when asked to choose a single option, most preferred Acapella over Flutter or PEP.[20]

National and international recommendations

Across the five included guidelines, recommendations converge on offering airway clearance only to people with COPD who have symptomatic sputum, with PEP or oPEP as the preferred MCDs and with training focused on enabling independent home use. The Norwegian guideline advises teaching ACTs when mucus is present and tailoring MCDs training so patients can self-manage; for PEP, it specifies a target mid-expiration pressure of 10 to 20 cm H_2O, and suggests considering oPEP for emphysema or hyperinflation, with a preference for devices that can be boiled for cleaning.[7] In the Netherlands, ACTs are recommended for symptomatic COPD patients with hypersecretion in stable disease, adding a device when active techniques alone are insufficient, preferring PEP or oPEP.[5] The Swedish guideline also lists mucus clearance or PEP for COPD with hypersecretion or mucus retention.[8] Moreover, the National Institute for Health and Care Excellence

guideline in the United Kingdom states that before starting prophylactic azithromycin, patients should receive training in ACTs to optimise sputum clearance, and that those with excessive sputum should be taught ACBT and how to use PEP devices.[6] The most recent guideline limits ACTs to patients with sputum, notes that no single technique suits all, and recommends referral to a physiotherapist for assessment, device selection, and education. It is also the only guideline to provide a detailed list of MCDs, spanning PEP (Astra PEP, Pari PEP) and oPEP (Flutter, Acapella, Aerobika).[9]

Barriers and facilitators

No clinical studies were found that had a primary objective of evaluating barriers or facilitators to implementing MCDs for people with stable COPD in primary care.

4. Discussion

Via a broad evaluation of clinical studies, national and international COPD guidelines, local recommendations, and practice audits or surveys, this scoping review is the first to our knowledge to investigate a comprehensive identification of barriers and facilitators to implementing mucus-clearance devices (MCDs) in primary care. Secondarily, it maps the MCDs used clinically for people with stable COPD in primary care and collates existing local recommendations and current guidelines.

Despite the extensive search strategy, no studies were found whose primary objective was to evaluate barriers or facilitators. To address this gap, we extracted implementation-relevant signals reported incidentally in the selected clinical studies, audits or surveys and mapped them to an implementation framework used in implementation studies.[29] We selected the extended FITT (Fit between Individuals, Task, and Technology) framework[34], which conceptualises adoption of new technology as the fit between individuals, clinical tasks/processes, technology, and the organisational/policy context, to collate potential facilitators or barriers for implementation of MCDs for people with stable COPD in primary care (Figure 2). An overview of all identified barriers and facilitators is presented in Table 4.

Firstly, on the individual dimension, included studies and guidelines indicate that COPD patients with mucus retention who use MCDs perceive symptomatic and functional benefits. For example, Alghamdi et al. demonstrated that ACBT plus Acapella reduced nocturnal cough with accompanying improvement in fatigue and cough-specific and generic HRQoL after three months.[53] The reported short and long-term benefits in this review likely facilitate initiation and sustained used, supporting implementation. In a qualitative study, thematic analysis of interviews with 30 Flemish GPs explored COPD management in primary care and views on respiratory physiotherapy, pulmonary

rehabilitation, and interprofessional care. GPs reported difficulty motivating patients for respiratory physiotherapy when the mechanism–benefit link was not evident to patients and when benefits were less immediate than with pharmacological treatment.[19] Secondly, on the task dimension, oPEP devices have a practical advantage over conventional physiotherapy: they are portable and enable self-administered home treatment, though suitability should consider age, independence, and disease severity.[51] In addition, the user-friendly design and patient preference for home use for PEP devices as reported by Mascardi et al.[17] act as potential facilitators for implementation. Clinicians also report a general willingness to recommend MCDs, with or without prescription, given their relatively few contraindications compared with pharmacologic therapies.[54] Furthermore, given their relative simplicity, telehealth is a feasible modality for training patients in MCD use, providing follow-up, and monitoring adherence.[54] During COVID-19, remote demonstration, instruction, and follow-up for COPD patients using MCDs proved practical and effective.[53] Thirdly, at the contextual dimension of the FITT framework, multiple barriers may hinder routine use of MCDs in primary care. An emerging yet still evolving knowledge base, combined with scarce recommendations for ACTs and MCDs in guidelines, has limited the clinical use of mucus clearance devices compared to pharmacological treatments.[29] In the widely used GOLD guideline, information on oPEP therapy is placed under pharmacological management of mucus hypersecretion rather than within non-pharmacological care for stable COPD, which may reduce its visibility.[27] Moreover, prescribing data in the United Kingdom confirmed a marked disparity between pharmacological options and MCDs: 13.2% of COPD patient-years received carbocisteine, versus 0.16% for MCDs. Although phenotype data were not available, many patients who were prescribed carbocisteine likely overlap with those who could benefit from oPEP devices.[20] At the healthcare professional level, recommendations are often driven by medical judgement rather than the guidelines, with wide variation in device preference and in decision making factors to offer a device.[54] Although device choice varied in different countries, clinicians mostly selected Acapella, Aerobika or Flutter. Initiation thresholds for MCDs are not standardised: clinicians agree on prescribing them for daily, difficult-to-clear sputum and withholding them when sputum is minimal or absent, but decisions vary substantially for intermediate phenotypes (e.g., morning-only sputum), resulting in heterogeneous practice.[20,54] A dedicated statement, similar to the European Respiratory Society's statement on airway clearance techniques for bronchiectasis[28], could help standardise practice and clarify indications for managing mucus hypersecretion in COPD. In several countries, healthcare professionals report a limited perceived usefulness of MCDs in the management of COPD.[19,54,58] Alghamdi et al. reported that, in Saudi Arabia, family physicians were least likely to prescribe MCDs for COPD.[54] The authors attributed this pattern to limited awareness and perceived benefit of non-pharmacological options,

including MCDs, as suggested by an online survey of physicians' views on non-pharmacological COPD care.[59] Similar findings were reported by Leemans et al. that some general practitioners remained unconvinced about respiratory physiotherapy's effectiveness, despite the fast-expanding scientific evidence and the recommendations in CPGs. [26] In summary, potential barriers impeding implementation in primary care are a limited clinical evidence base, low visibility in guideline recommendations for MCDs, a non-standardised initiation threshold to offer MCDs and low perceived usefulness among general practitioners.

Strengths and limitations

To the best of our knowledge, this is the first scoping review to map the use of mucus clearance devices for stable COPD in primary care, identify barriers and facilitators to implementation, and collate current local recommendations and guidelines. The methodology was elaborated by using the JBI methodology for scoping reviews and reported following the PRISMA-ScR extension for scoping reviews.[47,48] As a result, the protocol was preregistered on an open science platform, enhancing research transparency and minimising bias. Although we searched grey literature, coverage was limited to four databases, so some studies may have been missed. To mitigate this risk, we thoroughly reviewed the reference lists of relevant sources to identify additional studies. Following Pavlic et al.[50], we focused on countries with primary care systems similar to Belgium, defined by continuity and comprehensiveness of care relative to per-capita health spending. This approach reduces heterogeneity across guidelines but may limit external validity and transferability of our findings to low-income countries. Although this extensive approach yielded 11 reports, the limited number of studies may diminish the significance of this review. Furthermore, because the identified barriers and facilitators were not primary outcomes in the included studies, the certainty of these findings is limited, and they should be interpreted with caution. Nevertheless, these results may offer a solid basis for future reviews or implementation studies with MCDs in primary care. For future research, more phenotype-stratified trials based on mucus-hypersecretion patterns (e.g., morning-only sputum producers) are needed to clarify initiation thresholds and refine guideline recommendations.[20] In addition to more research based in controlled settings, more real-world practice-oriented research is necessary in primary care. Hybrid effectiveness–implementation studies[29], integrating quantitative and qualitative methods, should evaluate both the clinical effectiveness of recommendations guiding MCD use in primary care and the strategies for implementing them. This dual focus will generate actionable evidence to optimise uptake of MCDs and improve outcomes for patients with chronic mucus hypersecretion. Finally, establishing systems for real-time

prescribing/dispensing data on MCDs would enable robust monitoring of uptake and post-market surveillance in routine practice.

5. Conclusion

This scoping review provides the first comprehensive overview of mucus clearance devices (MCDs) in the primary care management of stable COPD, with a focus on identifying implementation barriers and facilitators. Although clinical studies and guidelines support the use of (o)PEP devices for patients with symptomatic sputum, their use in primary care remains highly variable, with Acapella most frequently used, followed by Aerobika and Flutter. All five included guidelines recommend initiating airway clearance only in patients with symptomatic sputum, identifying PEP and oPEP as preferred options. No studies were found with implementation as a primary objective; however, indirect evidence from clinical studies, audits, and surveys revealed barriers at the patient and context levels. These include emerging clinical evidence, low visibility in guidelines, non-standardised initiation criteria, and limited perceived usefulness among general practitioners. Facilitators include reported patient benefits, ease of home use, favourable safety profile of the devices, and suitability for remote support. Future research should prioritise implementation studies in primary care to evaluate both the impact and uptake of MCDs recommendations in current guidelines.

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Figure 1: Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) scoping review flow diagram

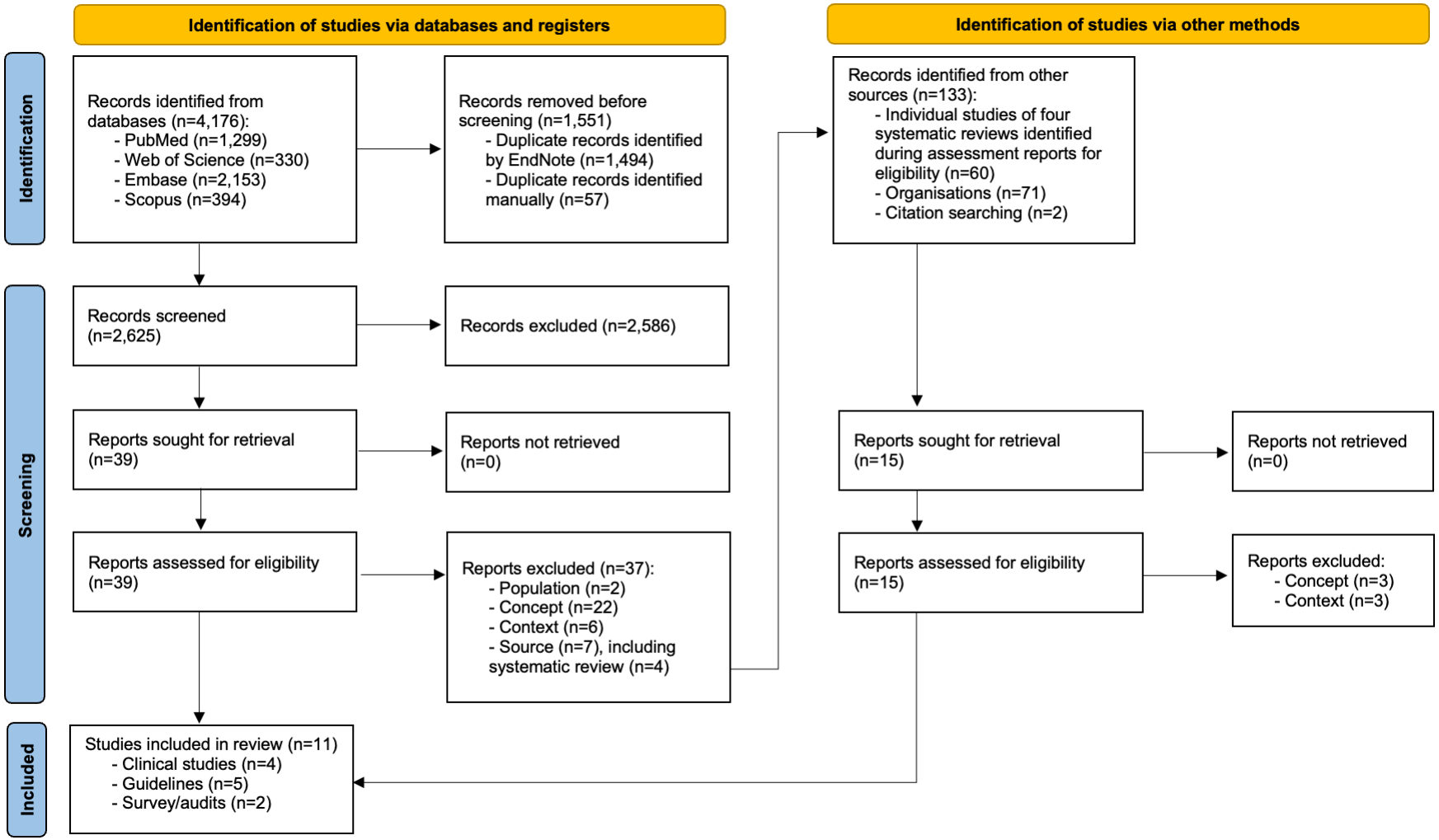
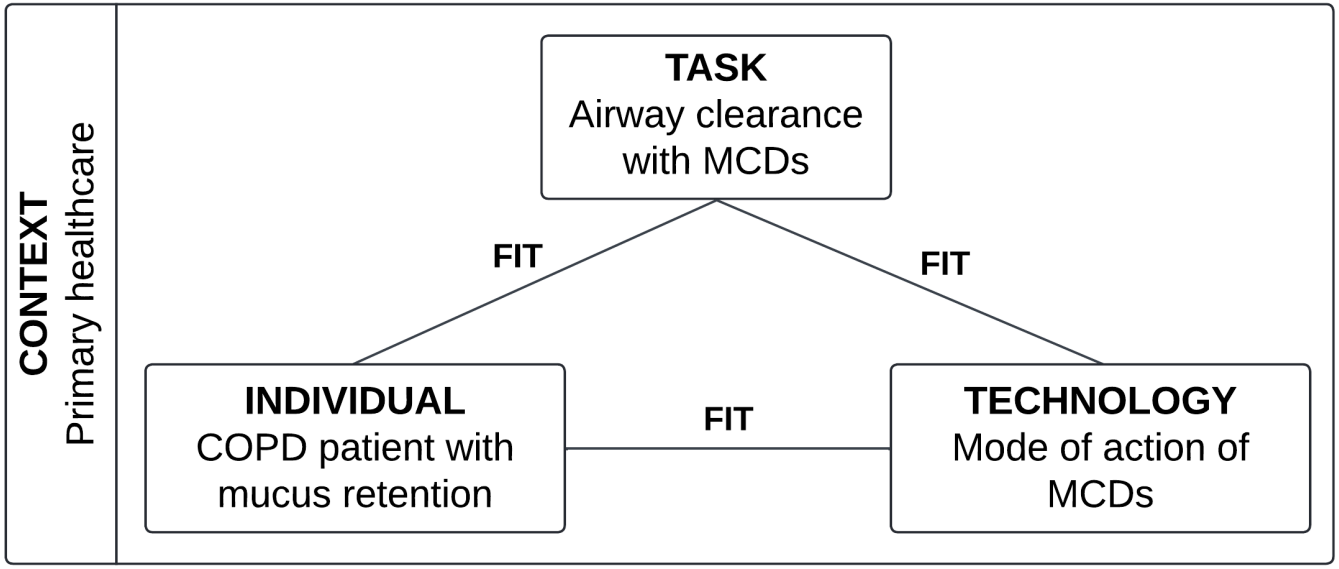


Figure 2: Adapted extended Fit between Individuals, Task, and Technology (FITT) framework for mucus clearance devices (MCDs)



COPD: Chronic Obstructive Pulmonary Disease, MCD(s): Mucus clearance device(s)

Table 1: Summary of clinical studies assessing the effectiveness of mucus clearance devices in stable COPD patients in primary care

Study year, country	**Study design, setting**	**Population**	**Sputum burden threshold in eligibility criteria**	**ACT applied and mucus clearance device**	**Duration, frequency, and length intervention mucus clearance device**	**Outcome measures**	**Summary**
Alghamdi et al.[53] • 2023 • United Kingdom	• Single centre, assessor-blind, parallel-group RCT • Home care	• GOLD I–IV, majority GOLD III (41%) – IV (25.4%), total n=103 • EG: n=55, age=64.24(±10.35), FEV1= 43(26-63) • CG: n=48, age=60.85(±9.99), FEV1= 37(25-46)	• At screening, COPD patients to report sputum production every day, several days a week, or almost every day in the last month • Combined score >5 on the cough and sputum questions in CAT questionnaire	• EG: ACBT with oPEP, Acapella (Smiths Medica, Ohio, USA) • CG: ACBT	• NR • 3 times (not specified beyond ACBT schedule) • 3 months	• Primary: LCQ • Secondary: FACIT, EQ-5D, CAT, Cough VAS, sputum frequency scale, 24-hour cough frequency with LCM and sleep disturbance measured by actigraphy using DynaPort Move monitor Follow-up: 0, 6 weeks and 3 months	Use of ACBT with Acapella supported for COPD with a sputum-producing phenotype, demonstrated significant improvements in cough-related quality of life, generic quality of life, and reduced fatigue. In clinical practice, screening of patients who produce sputum on most days, can identify patients where the Acapella and perhaps similar OPEP devices have a positive impact

Svenningsen et al.[51] • 2016 • Canada	• Unblinded, crossover RCT • Home care	• GOLD stage: NR, total n=27 • Sputum producers: n=14, age=69(±8), FEV1= 59(±19) • Non-sputum producers: n=13, age=69(±8), FEV1= 61(±17)	• Self-identification based upon brough up sputum the month prior to the study: ○ Sputum-producers: several days a week (>2 days), or almost every day ○ Non-sputum-producers: a few days a month, or only with lung/respiratory infects, or not at all	• EG: oPEP, Aerobika (Trudell Medical International, London, Canada) • CG: standard care	• 10–20 breaths followed by 2–3 huffs/session • 4 sessions/day • 21–28±5 days	• Lung function • 6MWT • SGRQ, • PEQ, • RA_{950} • Hyperpolarized ^{3}He MRI VDP Follow-up: 0, 3-4, 6-8 weeks	oPEP device used by COPD patients with chronic sputum production significantly improved ease of bringing up sputum, FVC, quality of life and 6MWD
Shamakh et al.[52] • 2020 • Egypt	• Single-blinded RCT with three groups (A, B and C) • Home care	• GOLD II after acute exacerbation, total n=60 • Group A: n=NR, age=52.20(±6.81), FEV1= 65.89(±4.73) • Group B: n=NR, age=53.65(±5.67), FEV1= 66.27(±4.81)	• NR	• Group A: ACBT • Group B: ACBT and PEP (Treshold PEP, Respironics) • Group C: ACBT and oPEP , Accapella (DHD Healthcare)	• Group B: ○ 10-12 breaths followed by 2-3 forced expiration/session ○ NR ○ 6 months • Group C: ○ Exhalation to FRC followed by	• Lung function • 6MWT • CAT Follow-up: 0, 6 weeks and 6 months	Treshold PEP and Acapella produced greater improvements than ACBT alone in moderate COPD. All groups improved lung function, walking distance, and

		• Group C: n=NR, age=51.25(±5.11), FEV1= 64.68(±4.30)			2-3 huffs/session ○ NR ○ 6 months		quality of life. No significant difference between Threshold PEP and Acapella
Mascardi et al.[17] • 2016 • Italy	• Parallel-group RCT with three groups (T-PEP home, T-PEP hospital and CG) • Hospital versus home care	• GOLD III-IV, total n=99 • Group T-PEP hospital (Hosp-TPEP): n=35, age=71.7.(±4.6), FEV1= 37.9(±10.7) • Group T-PEP home (H-TPEP): n=34, age=70.7(±6.1), FEV1= 35.6(±10.0) • CG: n=30, age=70.7(±6.3), FEV1= 33.2(±11.0)	• Presence of chronic bronchitis	• Group Hosp-TPEP: PEP, UNIKO T-PEP • Group H-TPEP: UNIKO T-PEP, • CG: pharmacotherapy	• Group Hosp-TPEP: ○ 30 minutes/session ○ 2 sessions/day ○ 15 days • Group H-TPEP: ○ 30 minutes/session ○ 2 sessions/day ○ 15 days	• Primary: number of exacerbations at 1 and 3 months • Secondary: lung function, ABG, 6MWT, mMRC Dyspnea scale, BCSS, CAT and inflammatory markers Follow-up: 0, 1 1, 2, 4 8 and 15 weeks	T-PEP significantly reduced number of exacerbations versus standard therapy, improved respiratory function, dyspnea, and health status, and showed similar adherence at home and in hospital, with patients preferring home use

GOLD: Global Initiative for Chronic Obstructive Lung Disease, EG: Experimental group, CG: control group, FEV1: Forced expiratory volume in 1 second (% predicted), CAT: COPD Assessment Test, ACBT: Active cycle breathing techniques, oPEP: oscillatory positive expiratory pressure, NR: Not reported, LCQ: Leicester Cough Questionnaire, FACIT: Functional Assessment of Chronic Illness Therapy, EQ-5D: EuroQol-5 Dimensions, VAS: Visual Analogue Scale, LCM: Leicester Cough Monitor, 6MWT: Six minute walk test, SGRQ: Saint George's Respiratory Questionnaire, PEQ: Patient Evaluation Questionnaire, RA_{950}: Relative area of the parenchyma density histogram with attenuation values ≤ −950 Hounsfield Units, VDP: Ventilation defect percent, FVC: Forced vital capacity, 6MWD: Six minute walking distance, PEP: Positive expiratory pressure, FRC: Functional residual capacity, T-PEP: temporary expiratory pressure, ABG: Arterial blood gasses, mMRC: Modified Medical Research Counsel, BCSS: Breathlessness, Cough and Sputum Scale
.

Table 2: Summary of existing guidelines on mucus clearance devices in stable COPD patients in primary care

Organisation/study, year, country	**Guideline**	**Stakeholders**	**Section**	**Key messages on mucus clearance devices**
Directorate of Health[7] • 2023 • Norway	• COPD–diagnosis and treatment. National professional guidelines	• Specialists respiratory medicine • General Practitioners • Nurses • Physiotherapist	• Section 6 Breathing techniques and mobilisation of secretions	• If the patient produces secretions, training should be provided in mucus clearance techniques and devices • Provide individualised training so patients can perform mucus clearance independently • PEP: ○ Breathing through a mask or valve that provides increased resistance during exhalation. ○ Adjust pressure with a manometer; target a stable mid-exhalation pressure of 10 to 20 cm H_2O • oPEP: ○ consider for patients with emphysema or hyperinflation ○ provides resistance to exhalation and produces positive pressure and vibrations in the airways during exhalation ○ prefer devices that can be boiled for cleaning
Royal Dutch Society for Physical Therapy[5] • 2020 • Netherlands	• KNGF Guideline on COPD	• Specialists respiratory medicine • General Practitioners • Nurses • Physiotherapist • Dieticians • Patients • Others	• C.4.5 Mucus Clearance	• Use mucus clearance techniques for COPD with symptomatic hypersecretion in both stable disease and during exacerbations. • If sputum retention persists after mastering active techniques that the patient can perform independently, add a device. • Preferred devices: PEP or oPEP • Avoid passive techniques such as vibration, percussion, and postural drainage
National Institute for Health and Care Excellence[6] • 2023	• Chronic obstructive pulmonary disease in over 16s: diagnosis and management	• Specialists respiratory medicine • General Practitioners • Nurses • Pharmacists	• 1.2. Managing stable COPD: ○ 1.2.46 Oral prophylactic antibiotic therapy	• Before offering prophylactic antibiotics (azithromycin), ensure that person has training in ACTs to optimise sputum clearance • If people have excessive sputum, teach ACBT and how to use PEP devices

• United Kindom		• Physiotherapist • Dieticians • Patients • Others	○ 1.2.99 Physiotherapy	
Swedish Medical Products Agency[8] • 2023 • Sweden	• Chronic Obstructive Pulmonary Disease (COPD). Treatment recommendation	• Specialists respiratory medicine • General Practitioners • Physiotherapist • Dieticians	• Section 8 non-pharmacological treatment, Table II Effect and recommendation for non-pharmacological treatment	• Mucus clearance/resistance breathing or PEP • Population: COPD with hypersecretion and/or secretion retention. • Effects: increased amount of expectorated mucus, reduced risk of exacerbations, and reduced symptoms.
Yang et al[9] • 2024 • Australia and New Zealand	• The COPD-X Plan: Australian and New Zealand Guidelines for the Management of Chronic Obstructive Pulmonary Disease	• Specialists respiratory medicine • General Practitioners • Nurses • Pharmacists • Physiotherapist • Dieticians	• O6.8 Chest physiotherapy (Airway clearance techniques)	• ACTs indicated only in COPD with sputum, including chronic bronchitis, coexistent bronchiectasis, or exacerbations • Unlikely that one ACT is appropriate or superior for all patients with COPD • Short-acting bronchodilators before treatment may help sputum clearance • Choice of mucus clearance devices: ○ PEP devices (Astra PEP, Pari PEP) ○ oPEP devices (Flutter, Acapella, Aerobika) • Selection of device depends on airflow limitation, dyspnea, sputum volume and consistency, comorbid conditions as bronchiectasis, cognitive status, patient preference, therapist expertise, availability, and cost. • Refer patients with chronic sputum to a physiotherapist for assessment, device choice, and education

PEP: Positive expiratory pressure, oPEP: oscillatory positive expiratory pressure, ACT(s): Airway clearance technique(s), ACBT: Active cycle breathing techniques

Table 3: Summary of audits and surveys of mucus clearance devices in people with stable COPD in primary care

Study, year, country	**Study setting**	**Data collection method**	**Participants**	**Summary**
Alghamdi et al. 2023[54] • 2023 • Saudi Arabia	• Cross-sectional study	• Online survey sent to: ○ professional societies managing respiratory diseases ○ five different medical centres in five different Saudi Arabian provinces • Four themes: ○ demographics, ○ awareness, ○ recommendations ○ clinical practice, for MCDs with COPD patients • Response rate: NR	• Healthcare professionals (HCPs) who manage COPD, total n=1188 ○ General physicians n=135 (11.4%) ○ Family physicians n=229 (19.3%) ○ Pulmonary physicians n=98 (8.2%) ○ Nursing staff n=185 (15.6%) ○ Respiratory therapists n=356 (30%) ○ Physiotherapists n=67 (5.6%) ○ Others n=118 (9.9%) • Healthcare context ○ Governmental/private hospitals n=891 (75%) ○ Rehabilitation centres n= 172 (14.5%) ○ Primary care clinics n=125 (10.5%) • Years of experience: ○ 1–2 years n=271 (22.8%) ○ 3–4 years n=413 (34.8%) ○ 5–6 years n=341 (28.7%) ○ 7–8 years n=76 (6.4%) ○ >8 years n= 87 (7.3%)	• Awareness of MCDs: ○ Knowledge MCDs: Flutter (54.2%), Acapella (23.8), PEP mask (5.4%) ○ Most prescribed: Acapella (40.7%) and Flutter (22.3%) ○ Other options: PEP mask (15.1%) Aerobika (11.5%), Bubble PEP (7.5%) Aerosure (2.6%) • Recommending MCDs for COPD management (threshold) ○ MCD for daily difficulty clearing mucus (75%) ○ MCD for mucus that can be cleared with cough (55.9%) ○ MCD for mucus produced in morning only (63%) ○ MCD for patient with exacerbations: ▪ 0–1/year: 51.6% rarely or sometimes ▪ 2-3/year: 59.7% sometimes or usually ▪ >4/year: 58.7% sometimes or usually • Clinical practice for using MCDs ○ Providing MCDs by HCPs: prescription (32.0%), without prescription (31.8%), do not provide 314 (26.4%), advise only (9.8 %) ○ New MCD in last 6 months: Flutter (37.1%), Acapella (25.0%), Aerobika (24.8%), PEP mask (21.3%) ○ Basis for prescribing or recommending: GOLD guideline (20.1%), STS guideline (20.0%)

Barker et al. 2017[20] • 2017 • United Kingdom	• Retrospective cohort study • Cross-sectional study	• Consultation of a database with English prescription data for carbocisteine and oPEP devices • Online survey to members of ACPRC to assess clinical attitudes to use of MCDs: ○ Awareness MCDs ○ Recommendation MCDs for COPD management (threshold) • Response rate survey: 12%	• Database: NR • Online survey ○ Respiratory physiotherapist, total n=116 ○ Healthcare context: ▪ Hospital (72%) ▪ Community service (28%)	• Prescribing data for 2013-2015: ○ 1.1 million patient-years of tiotropium ○ 422,744 patient-years of carbocisteine ○ 4,989 patient-years of MCDs, almost all Flutter or Acapella. ○ Costs: ▪ Carbocisteine £73 million ▪ Tiotropium £483 million ▪ MCDs £187,000 • Online survey: ○ Awareness MCDs: Acapella (96%), Flutter (95%) ○ Preference if only one MCD available: Acapella (69%), Flutter (24%) and PEP (6%) ○ Recommending MCDs for COPD management (threshold): ▪ Daily, hard-to-clear sputum: 72.9% usually or always ▪ MCD for mucus produced in morning only: 38.7% sometimes ▪ Exacerbations: • 0–1/year: 83.8% rarely or never • >4/year: 35.1% usually or always, even if no sputum produced ○ Providing MCDs to patients: 58% from stock, 13% prescribe, 12% advise patients to buy, 13% do not provide, 5% no response ○ Actual use in preceding year in >5 patients with COPD: Acapella (21.6%), Flutter (14.4%) and PEP mask(1.8%)

MCD(s): Mucus clearance device(s), HCPs: healthcare professionals, GOLD: Global Initiative for Chronic Obstructive Lung Disease, STS: Saudi Thoracic Society, oPEP: oscillatory positive expiratory pressure, ACPRC: Association of Chartered Physiotherapists in Respiratory Care

Table 4: Summary of protentional identified barriers and facilitators for mucus clearance devices (MCDs) for patients with COPD in primary healthcare

Dimension extended FITT framework	Identified barriers	Identified facilitators
Individual	• NR	• Patient's perceived clinical benefit(s)
Task	• Emerging clinical evidence	• Ease of home use • Favourable safety profile • Suitable for remote support with telehealth
Context	• Low visibility in guidelines • Non-standardised threshold criteria to initiate MCDs • Limited perceived usefulness by GPs	• NR

NR: Not reported, MCD(s): Mucus clearance device(s), GP(S): General practitioner(

Appendix B: Study Protocol

Identifying stakeholders' views on implementation and personalisation of airway clearance devices in primary care for patients with chronic mucus retention: a nominal group technique

STUDY PROTOCOL

Protocol Number: WP5_QualR_NGT
Version Number: v. 1.0
Version Date: 27 JUN 2023

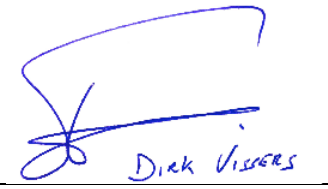
Status: approved

SPONSOR
Department of Rehabilitation Sciences and Physiotherapy
Faculty of Medicine and Health Sciences
University of Antwerp
Universiteitsplein 1
2610 Wilrijk
Belgium

This protocol contains confidential information for use by the Investigators and their representatives participating in this research study. Do not copy or distribute without written approval from the University of Antwerp.

PROTOCOL SIGNATURE PAGE

SPONSOR NAME	University of Antwerp
PROTOCOL TITLE	Identifying stakeholders' views on implementation and personalisation of airway clearance devices in primary care for patients with chronic mucus retention: a nominal group technique
PROTOCOL NUMBER	WP3_QualR_NGT
PROTOCOL VERSION AND DATE	Version 1.0 – 27 JUN 2023

PRINCIPAL INVESTIGATOR NAME	Prof. Dr. Dirk Vissers
SUB INVESTIGATOR NAME	Prof. Dr. Paul Van Royen, MD
I hereby confirm that I have read the above-mentioned protocol and its attachments. I agree to conduct the described trial in compliance with all stipulations of the protocol, any applicable (local) regulations and according to the principles of Good Clinical Practice. I have read this protocol and agree that it contains all the necessary details for carrying out this trial. I will conduct this study as outlined herein and will complete the trial within the time designated. I will discuss this material with all individuals responsible to me who assist in the conduct of this trial, to ensure that they are fully informed regarding the study Intervention, the conduct of the study and the obligations of confidentiality.	
PRINCIPAL INVESTIGATOR SIGNATURE	
SIGNATURE DATE	21/06/2023
SUB INVESTIGATOR SIGNATURE	 **Paul Van Royen**
SIGNATURE DATE	27/06/2023

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1 Schedule of study sessions

Timetable study	**Enrollment**	**NGT Session 1**	**NGT Session 2**
Study Activities	1	2	3
Week (± 1 week)	0	+4	+6
Informed consent	X		
Nominal Group Technique		X	X

1. NGT: Nominal Group Technique.

2 INTRODUCTION

Chronic mucus hypersecretion (CMH) in, for example, chronic obstructive pulmonary disease (COPD), is associated with several poor outcomes such as reduced lung function, quality of life and increased frequencies of exacerbations and admissions (1). Moreover, mucus plugs are associated with higher all-cause mortality for patients with COPD than those without mucus retention (2). Furthermore, persistent respiratory infection, airway inflammation and mucus plugging in Cystic Fibrosis are major contributing factors to severe airway damage and loss of respiratory function over the years (3). Due to these poor associations, airway clearance techniques (ACT) have been recommended as a nonpharmacological treatment option in clinical practice guidelines for patients with excessive mucus production (4–7).

The rationale behind these techniques is based on the exertion of an optimal expiratory airflow velocity that applies shearing forces to sputum at the air–liquid interface (8). Respiratory physiotherapists are trained to execute and teach ACTs to patients as a specific intervention (9), often embedded in a chronic disease management program, like a self-management program or pulmonary rehabilitation, across the healthcare system(10–13). Self-administered ACTs nowadays often include the use of medical devices to help mobilise secretions ranging from simple and cheap devices generating positive expiratory pressure (PEP), through oscillating (oPEP) devices, to high-frequency chest wall oscillation (HFCWO) devices which have significant cost implications (14). Short-term benefits are reported in the literature regarding improving mucus transport (15,16). An increasing number of these medical devices continue to infiltrate the market and provide a bewildering choice for professionals and people with CMH. However, systematic reviews have yet to identify any device as more or less efficacious than others (14,15,17).

Despite the clinical rationale and proven short benefits, their implementation and integration as a recognised respiratory intervention into routine care remain complex in primary care settings (18). Another challenge is the need for more personalisation and patient-centeredness in selecting and using the most cost-effective devices. To address these research gaps, this qualitative study explores the perspectives and preferences of respiratory patients, healthcare professionals, and other relevant stakeholders regarding integrating and personalising airway clearance medical devices in primary care. By utilising a nominal group technique (NGT), we aim to gain comprehensive insights into this multifaceted topic and develop a shared prioritised strategy shared by all critical stakeholders to enhance the utilisation and integration of airway clearance devices within primary care.

3 RESEARCH QUESTIONS

The following research question will be further investigated:

- *Which steps can we take to ensure that the right patient uses the correct medical devices for airway clearance in an affordable and efficient manner within primary care?*

4 STUDY DESIGN

This study will use a qualitative research method, more specifically, the nominal group technique (NGT), because of the intricate nature of the topic. The NGT is a structured, well-established consensus method to facilitate creative problem-solving through judgmental decision-making when routine answers are inadequate (19–21). Van de Ven and Delbecq designed this method, and it comprises four key stages: silent idea generation, round-robin feedback session, clarification of all ideas, and lastly, voting to create a consensus (22). By following this organised process, relevant experts have an equal opportunity to share their personal views before inviting them to build on the reflections of other experts, and finally reach a consensus about the complex topic raised by the researchers (23).

Using existing professional networks, the study will purposively select participants from six stakeholder groups represented in the current primary care: GP, respiratory physicians, physiotherapists working in primary care, patients representatives, public health insurance providers and distributors of medical devices. The patients will be contacted through health professionals. Two NGT sessions of 2 hours with 7 participants will be organised and chaired by experienced facilitators (PVR and DV), assisted by a junior researcher (GL). A scenario is developed (see Annex I) to ensure that all stages (see section 6 Study procedures) will be completed identically per the organised NGT session. An online meeting will be organised for each NGT session. The session will be recorded, and we will use a professional software platform to support the online consensus process.

5 STUDY POPULATION

5.1 Selection of stakeholders

We will purposively select participants from six key stakeholder groups:

1. General practitioners;
2. Respiratory physicians;
3. Physiotherapist working in primary care;
4. Respiratory patients representatives;
5. Public health representatives:
    a. Social health insurers
    b. Health policymakers
6. Distributors of medical devices

We will approach stakeholders by telephone or email, and those willing to cooperate will receive a formal electronic invitation to participate in the NGT. The email will include an information sheet detailing the study goals, research questions and offers the opportunity to ask questions about the study. No financial compensation will be given. These participants will be asked to sign and return the consent form.

5.2 Withdrawal criteria

A participant may withdraw from the study at any time at their request or may be withdrawn at any time at the investigator's discretion for behavioural or administrative reasons. An assessment of the reasons behind their withdrawal will be performed for participants who withdrew from the study.

6 STUDY PROCEDURES

Before the session, each participating expert will receive an information sheet detailing the study goals and research questions in advance. A graphical representation of the study procedures per research question is summarised in Figure 1 at the end of this section.

6.1 Introduction

During the introduction, the facilitators will clarify the group objectives, the member roles, a statement of the importance of the task, mention the importance of each member's contribution and indicate how the expert group's output will be used. The following subsection lists all stages that will be repeated per research question during the NGT session.

6.2 Stage 1: silent idea generation

In silence, the participants are asked to write down what they regarded as their idea per the research question and the corresponding appropriate strategy for implementing their recommendations.

6.3 Stage 2: round-robin feedback session

The facilitator(s) now asks one participant to state a single idea to the group in a round-robin fashion. Each idea will be recorded concisely. Participants can think of new ideas during this process but must wait their turn before sharing them with the group.

6.4 Stage 3: clarification of all ideas

Each recorded idea will be clarified and evaluated by discussion to ensure participant understanding during this stage. Hence, this enables the experts to make an informed decision when they come to vote on ideas in the next step. Similar ideas will be grouped with agreement from all experts.

6.5 Stage 4: prioritisation of ideas by voting

In the last stage, the stakeholders will vote individually to prioritise the ideas, and their votes will be used to arrive at a group decision. Each expert will choose five ideas and specify a number allocated to each item, with larger numbers reflecting greater importance. In this NGT session, for five ideas, the most important idea is scored five points. Finally, the scores for each idea are summed, and a comprehensive, prioritised list will be made up. Afterwards, a brief discussion will be held to evaluate the most favoured group actions to evaluate the procedure and the outcome.

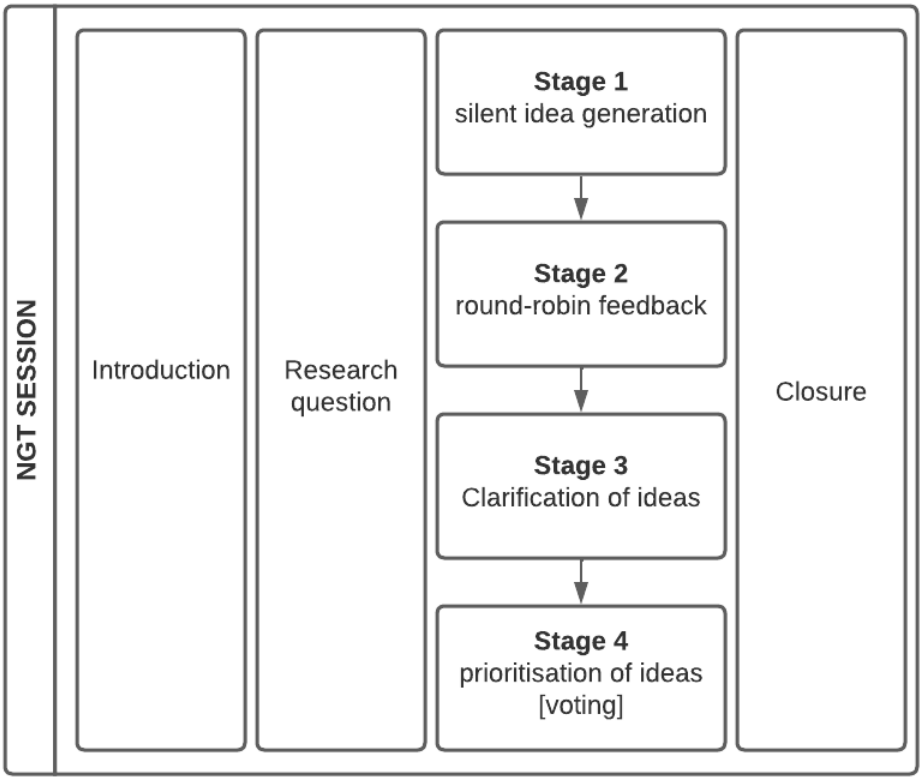

Figure 1 – Overview of process steps during NGT session.

7 DATA ANALYSIS

In this qualitative study, we will use the methods described by Van Breda to identify the most highly prioritised themes when combining data from the two separate NGT sessions into one complete sample. This analysis method uses a combination of qualitative (content analysis) and quantitative (ranking) data analytic techniques (24).

8 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the study protocol, the written scenario, or applicable regulations. The noncompliance may be either on the part of the participant, the investigator, or the study staff.

An investigator must not make any changes or deviate from this protocol, except to protect the rights of a participant in the study. The Sponsor must document all deviations from the protocol,

with the reason for the deviation and the date of occurrence. Sponsors may also be required to report deviations to the IRB/IEC, per local guidelines and government regulations.

Deviations will be reviewed and evaluated on an ongoing basis and, as necessary, appropriate corrective and/or preventive actions will be put into place by the Sponsor.

9 DATA MANAGEMENT

9.1 Source Documents and Data Collection

Source data is all information, original records of study findings, observations, or other activities necessary for the reconstruction and evaluation of the study. Source data are contained in source documents. Examples of these original documents and data records include but are not limited to recorded NGT sessions and related documents with the output of the sessions.

Data collection is the responsibility of the study staff at the site under the supervision of the Principal Investigator. The Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

9.2 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, institution, and regulatory agencies to examine study records for quality assurance reviews, audits, evaluation of the study progress, and data validity. See section 12 for more information regarding the confidentiality of subject data.

9.3 Data Retention

The Principal Investigator or their designee will maintain all essential study documents and source documentation that support the data collected on the study participants in compliance with the applicable regulations and guidelines. Study documents should be retained in compliance with local laws. No records will be destroyed without the written consent of the Sponsor, if applicable.

If for any reason the Principal Investigator or their designee withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility, and the Sponsor must receive written notification of this custodial change.

10 PROTOCOL AMENDMENTS

Neither the investigator nor the sponsor will modify this protocol without a formal amendment. All protocol amendments must be issued by the sponsor and signed and dated by the investigator. Protocol amendments must be implemented with prior IEC/IRB approval. Documentation of amendments approved by the investigator and IEC/IRB must be provided to the sponsor or its designee. When the change(s) involves only logistic or administrative aspects of the study, the IRB (and IEC where required) only needs to be notified.

11 COMPLIANCE

11.1 Statement of Compliance

This study will be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki, pertinent (individual country) laws and regulations (for example EU GDPR 2016/679), and the standards for reporting qualitative research reporting (SRQR) (25,26). The study will not begin until the required approval/favourable opinion from the IRB/IEC. If appropriate, any additional requirements imposed by the IRB/IEC or regulatory authority shall be followed.

11.2 Institutional Review Board (IRB) / Independent Ethics Committee (IEC)

The protocol, informed consent form(s), recruitment materials, and all subject-facing materials will be submitted to the IRB/IEC for review and approval. Approval of both the protocol and the consent form, as well as applicable recruiting materials, if applicable must be obtained before any subject is enrolled.

Any amendment to the protocol (excluding the ones that are purely administrative, with no consequences for participants, data or study conduct) will require review and approval by the IRB/IEC before the changes are implemented to the trial. All changes to the consent form will be IRB/IEC approved and a determination will be made regarding whether previously consented participants need to be re-consented.

The study will be undertaken only after the sponsor has obtained copies of all required approvals.

During the study the investigator (or sponsor where required) will send the following documents and updates to the IEC/IRB for their review and approval, where appropriate:

- Protocol amendments
- Revision(s) to informed consent form and any other written materials to be provided to subjects
- If applicable, new or revised subject recruiting materials approved by the sponsor
- Any other requirements of the IEC/IRB

Where required, the IEC/IRB will be asked to review and reapprove this study. The reapproval should be documented in writing (excluding the ones that are purely administrative, with no consequences for participant, data or study conduct).

At the end of the study, the investigator (or sponsor where required) will notify the IEC/IRB about the study completion.

12 INFORMED CONSENT

Subject participation in this qualitative study is voluntary. Informed Consent is required from each subject or his/her legally authorised representative. The Investigator is responsible for ensuring that Informed Consent is obtained prior to the use of data collection being done specifically for the study.

The ICF must be in a language understandable to the subject and privacy language shall be included in the body of the form or as a separate form as applicable. Approval from the IRB/IEC is necessary before the ICF can be used.

The process of obtaining Informed Consent shall at a minimum include the following steps, as well as any other steps required by applicable laws, rules, regulations and guidelines:

- be conducted by the Principal Investigator or designee authorised to conduct the process
- include a description of all aspects of the study that are relevant to the participant's decision to participate throughout the study
- avoid any coercion of or undue influence of subjects to participate
- not waive or appear to waive the participant's legal rights
- use native language that is non-technical and understandable to the subject or his/her legal representative
- provide ample time for the participant to consider participation and ask questions if necessary
- ensure important new information is provided to new and existing participants throughout the study

The ICF shall always be signed and personally dated by the subject or legally authorised representative competent to sign the ICF under the applicable laws, rules, regulations, and guidelines and by the investigator and/or an authorised designee responsible for conducting the informed consent process.

The original signed ICF will be retained by the Sponsor and a copy of the signed and dated document and any other written information must be given to the person signing the form. Participants may withdraw consent at any time throughout the course of the trial.

The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the subject's research record. Any alteration to the standard consent process (e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

In addition to new significant information during a study, other situations may necessitate revision of the ICF, such as if there are amendments to the applicable laws, protocol, a change in Principal Investigator, administrative changes, or following annual review by the IRB/IEC. The new version of the ICF must be approved by the IRB/IEC, who will also determine the participant population to be re-consented.

13 STUDY DISCONTINUATION AND COMPLETION

13.1 Study Discontinuation

This study may be suspended or prematurely terminated if there is sufficient reasonable cause.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

If the trial is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the IRB/IEC, and the sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to the study schedule.

The study may resume once concerns about protocol compliance and data quality are addressed, and satisfy the sponsor, IRB/IEC and/or Regulatory Authorities.

13.2 Study Completion

The study is considered completed with the execution of the last NGT session in the study.

14 CONFIDENTIALITY AND PRIVACY

Subject confidentiality and privacy are strictly held in trust by the sponsor, investigators, and their research team. Hence, the trial protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without the prior written approval of the sponsor.

The subject will receive all information as required by the EU General Data Protection Regulation, including the identity of the controller, the clinical research purposes, the fair processing of his data, and all his/her data subjects rights. All details are listed in the informed consent form.

15 STUDY-SPECIFIC MATERIALS

15.1 Annex I – Informed Consent Form [Dutch]

15.2 Annex II – Scenario NGT session

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Appendix C: Informed Consent

INFORMATIEFORMULIER
DEELNEMERS

Participant Nummer: ____

Titel studie: Identifying stakeholders' views on implementation and personalisation of airway clearance devices in primary care for patients with chronic mucus retention: a nominal group technique

Vereenvoudigde titel: Opvattingen van belanghebbenden over implementatie en personalisatie van medische hulpmiddelen voor luchtwegklaring in de eerstelijnszorg voor patiënten met chronische slijmretentie: een nominale groepstechniek

U wordt uitgenodigd om vrijwillig deel te nemen aan een onderzoeksproject inzake implementatie en personalisatie van medische hulpmiddelen voor luchtwegklaring in de eerstelijnszorg. Vooraleer u toestemt om aan deze studie deel te nemen, is het belangrijk dat u dit formulier aandachtig leest. In dit informatie- en toestemmingsformulier worden het doel, de onderzoeken, de voordelen, risico's en ongemakken gepaard gaande met de studie beschreven. Ook de voor u beschikbare alternatieven en het recht om op elk ogenblik de studie te verlaten, zijn hieronder beschreven. Er kunnen geen beloften gedaan worden noch waarborgen gegeven worden betreffende de resultaten van het onderzoeksproject. U hebt het recht om op elk ogenblik vragen te stellen over de mogelijke en/of bekende risico's/ongemakken die deze studie inhoudt.

Doel en beschrijving van de studie

Dit is een wetenschappelijk onderzoek waaraan naar verwachting ongeveer 14 deelnemers zullen deelnemen.

Deze studie focust zich op een veelvoorkomend probleem waar mensen met longaandoeningen mee te maken hebben: de overproductie van slijmen. Te veel slijmen kan leiden bij deze personen tot verergering van de klachten, regelmatige opnames in het ziekenhuis, en in sommige gevallen zelfs vroegtijdig overlijden. Het kan ook blijvende schade veroorzaken en de longen na verloop van tijd verzwakken. Daarom stellen artsen vaak behandelmethoden voor om patiënten te helpen het slijm uit hun luchtwegen te verwijderen.

Deze luchtweg klarende technieken worden meestal aan patiënten geleerd door kinesitherapeuten en maken vaak deel uit van een groter behandelprogramma om de longklachten van de patiënt onder controle te houden. Deze luchtweg klarende methoden bestaan uit het gebruik van specifieke ademhalingstechnieken, al dan niet gecombineerd met specifieke hupmiddelen. Deze apparaten helpen om het slijm op te breken zodat het gemakkelijker kan worden uitgehoest.

Er zijn veel medische hulpmiddelen die hierbij kunnen helpen. Ze variëren van eenvoudige en goedkope apparaten tot complexere en duurdere toestellen. Ze zijn allemaal bedoeld om te helpen bij het verplaatsen van slijm, maar we weten nog niet helemaal zeker of het ene hupmiddel beter werkt dan het andere. Hoewel is aangetoond dat deze luchtweg klarende technieken en hulpmiddelen op de korte termijn helpen, worden ze niet altijd zo vaak gebruikt als het zou moeten in de routinezorg. Ook is het de vraag hoe je deze hupmiddelen nog beter kan afstemmen op de noden van de individuele patiënt.

Om deze vragen te beantwoorden, voeren we een onderzoek uit waarin we praten met patiënten, zorgverleners en anderen die een belang hebben in deze kwestie. We willen weten hoe iedereen denkt

over hoe we deze medische hupmiddelen beter kunnen integreren in de reguliere zorg met aandacht voor de individuele noden van de longpatiënt. We zullen hiervoor een nominale groepstechniek gebruiken om een stappenplan te ontwikkelen waar alle betrokkenen zich in kunnen vinden. Op deze wijze hopen we een gedragen advies te creëren die in de toekomst kan leiden tot een betere integratie van medische hulpmiddelen voor de behandeling van longaandoeningen in de eerstelijnszorg.

U werd uitgenodigd om deel te nemen aan deze studie omdat u bent geïdentificeerde als één van de belanghebbenden of ervaringsdeskundigen rond medische hulpmiddelen voor luchtwegklaring.

U kan deelnemen aan deze studie door de onderstaande informatie grondig door te nemen en het toestemmingsformulier te ondertekenen.

Opdrachtgever van de studie

De opdrachtgever van de studie is het departement revalidatiewetenschappen en kinesitherapie van de Universiteit Antwerpen.

Duur van de studie

Er zal u gevraagd worden gedurende ongeveer 2 uren aan de studie deel te nemen.

Onderzoeken in het kader van de studie

Indien u aanvaardt aan de studie deel te nemen en u voldoet aan alle voorwaarden voor deelname aan de studie, dan zal u worden gevraagd om éénmaal aan een online groepsdiscussie deel te nemen met verschillende belanghebbenden en ervaringsdeskundigen. Deze groepsdiscussie zal worden geleid door academische experten.

Er wordt van u verwacht om in eerste instantie uw persoonlijk ideeën naar voren te brengen rond welke stappen we dienen te zetten zodat de juiste patiënt de juiste medische hulpmiddelen gebruikt voor luchtweg klaring en dit op een betaalbare en efficiënte manier binnen de eerstelijnszorg. Vervolgens zullen we alle ideeën van alle deelnemers bespreken in groep en als laatste gaan we deze rangschikken in volgorde van prioriteit volgens een specifieke methode. Het doel is om op het einde van deze sessie een gedragen consensus te bereiken over welke stappen we dienen te zetten rond een betere integratie van medische hulpmiddelen voor de behandeling van longaandoeningen in de eerstelijnszorg.

We maken gebruik van een specifiek softwareplatform waardoor we de ideeën van de groep kunnen tonen en vervolgens rangschikken in volgorde van prioriteit tijdens de online sessie. De sessie zal ook worden opgenomen via Microsoft Teams en indien nodig gebruikt worden als hulpmiddel voor de verdere dataverwerking, bijvoorbeeld het herbekijken van de sessie voor meer informatie omtrent een idee dat u heeft uitgelegd tijdens de sessie.

Vrijwillige deelname

U neemt geheel vrijwillig deel aan deze studie en u hebt het recht te weigeren eraan deel te nemen. U heeft steeds de mogelijkheid om al dan niet aan deze studie deel te nemen of om uw deelname aan de studie stop te zetten.

Indien u aanvaardt om aan de studie deel te nemen, zal u deze informatiefolder krijgen om te bewaren en zal er u gevraagd worden het aangehechte toestemmingsformulier te ondertekenen.

De onderzoeker kan zelf op elk ogenblik een einde stellen aan uw deelname aan de studie, zelfs zonder dat hij/zij hiervoor uw toestemming moet vragen, om één van de volgende redenen:

– u houdt zich niet aan de instructies voor deelname aan de studie;
– er wordt naderhand ontdekt dat u niet aan de studievoorwaarden voldoet;
– de opdrachtgever zet de studie stop wegens andere, momenteel onbekende redenen.

U hebt het recht om uw deelname aan de studie op elk ogenblik stop te zetten, zelfs nadat u het toestemmingsformulier ondertekend heeft. U hoeft geen reden te geven voor het intrekken van uw toestemming tot deelname. Het intrekken van uw toestemming zal geen enkel nadeel of verlies van voordelen met zich meebrengen.

Risico's en ongemakken

Er zijn geen risico's of ongemakken voorzien door deelname aan deze studie

Voordelen

Wij kunnen u niet bevestigen dat, als u toestemt om aan deze studie deel te nemen, u persoonlijk enig rechtstreeks voordeel zal halen uit uw deelname aan deze studie. De uit deze studie bekomen informatie kan bijdragen tot een betere kennis over hoe we een betere integratie kunnen bekomen van medische hulpmiddelen voor de behandeling van longaandoeningen in de eerstelijnszorg.

Vergoeding

De opdrachtgever betaalt de onderzoeker/onderzoeksgroep om deze studie uit te voeren. Er wordt geen vergoeding voorzien voor de deelnemers.

Bescherming van de persoonlijke levenssfeer

Uw identiteit en uw deelname aan deze studie worden strikt vertrouwelijk behandeld. U zult niet bij naam of op een andere herkenbare wijze geïdentificeerd worden in dossiers, resultaten of publicaties in verband met de studie.

Stopzetting van de studie

In geval van stopzetting van de studie zullen wij, de onderzoekers, alle participanten hiervan op de hoogte brengen.

Verwerking van persoonsgegevens

Het is met name de bedoeling om enkel uw persoonsgegevens te verwerken voor de vervulling van een taak voor wetenschappelijke doeleinden zoals beschreven in dit informatieformulier. Gelet dat we daarnaast audio/video opnames maken van de sessie en deze data verwerken, zullen wij u vragen om uw expliciete toestemming hiervoor te geven. In het specifieke geval wanneer u een patiënt met een longziekte bent, zullen we uw zelf-gerapporteerde diagnose aanzien als sensitieve data. We zullen voor deze datacollectie en verwerking specifiek uw expliciete toestemming vragen.

Alle persoonsgegevens, ruwe data en afgeleide data zullen op beveiligde en afzonderlijke plaatsen bewaard worden binnen de IT infrastructuur van de Universiteit Antwerpen en waar mogelijk geëncrypteerd worden.

Om de doeleinden omschreven in dit formulier te bereiken, zullen de volgende personen en/of diensten toegang hebben tot uw persoonsgegevens:

- het onderzoeksteam van de Universiteit Antwerpen met de volgende personen: prof. Dr. Dirk Vissers, Em. prof. Dr. Paul Van Royen en dr. Glenn Leemans.
- Het software plaftorm 'GroupMap' als dienstverlener: naam, voornaam en e-mailadres van de deelnemer zal worden doorgegeven aan de derde partij om de deelnemer toegang te verlenen tot het platform. Daarnaast zal deze dienstverlener uw IP-adres, browser- en apparaatkenmerken, besturingssysteem, taalvoorkeuren, verwijzende URL's, apparaatnaam, land, locatie, informatie over hoe en wanneer u onze deze dienst gebruikt en andere technische informatie automatisch verwerken wanneer u inlogt. Deze informatie is voornamelijk nodig om de veiligheid en werking van Groupmaps's dienstverlening te handhaven en voor hun interne analyse- en rapportagedoeleinden. Indien u wenst kan u steeds de privacyverklaring van deze derde partij opvragen bij de verwerkingsverantwoordelijke voor dit onderzoek, met name Dirk Vissers, hoogleraar Revalidatiewetenschappen en Kinesitherapie, Universiteitsplein 1, 2610 Wilrijk, Universiteit Antwerpen, met telefoonnummer +32 3 265 23 74 en met e-mailadres dirk.vissers@uantwerpen.be

Om de doeleinden omschreven in dit formulier te bereiken, zullen wij uw persoonsgegevens niet doorgeven buiten de Europese Unie aan derde partijen.

Uw persoonsgegevens zullen steeds verwerkt worden onder de verantwoordelijkheid van Dirk Vissers, hoogleraar Revalidatiewetenschappen en Kinesitherapie, Universiteitsplein 1, 2610 Wilrijk, Universiteit Antwerpen, met telefoonnummer +32 3 265 23 74 en met e-mailadres dirk.vissers@uantwerpen.be

U hebt in het kader van de verwerking van persoonsgegevens bedoeld in dit formulier te allen tijde recht om uw persoonsgegevens kosteloos in te zien en om in voorkomend geval alle onjuiste en/of onvolledige persoonsgegevens die op uzelf betrekking hebben, kosteloos te laten verbeteren. Daarbij kan u tevens vragen dat wij uw persoonsgegevens tijdelijk niet verder verwerken (behalve in een aantal wettelijk bepaalde gevallen) totdat wij de juistheid van uw persoonsgegevens hebben gecontroleerd.

U heeft voorts het recht om te vragen dat wij een kopie van uw persoonsgegevens overmaken aan uzelf en/of rechtstreeks aan een andere instelling of persoon van uw keuze in een formaat dat toelaat om deze persoonsgegevens gemakkelijk over te dragen.

Indien u meent dat de Universiteit Antwerpen uw persoonsgegevens niet meer mag verwerken, dan kan u in bepaalde gevallen ook vragen dat uw persoonsgegevens definitief gewist worden. In plaats van wissing kan u als alternatief ook vragen dat uw gegevens wel opgeslagen blijven, maar niet verder worden verwerkt (behalve in bepaalde wettelijk omschreven gevallen).

Uw persoonsgegevens zullen in elk geval niet langer bewaard worden dan nodig is voor de doeleinden omschreven in dit formulier.

Bewaartermijn van de data: De standaard periode voor het bewaren van (persoons)gegevens bedraagt 10 jaar. Indien blijkt dat de bewaring intussen niet meer nodig is voor de doeleinden omschreven in dit formulier, dan zullen uw persoonsgegevens conform deze standaard termijn wel worden bewaard, maar niet meer worden gebruikt voor deze doeleinden.

Voor het uitoefenen van de bovenstaande rechten, kan u contact opnemen met Dirk Vissers, hoogleraar Revalidatiewetenschappen en Kinesitherapie, Universiteitsplein 1, 2610 Wilrijk, Universiteit Antwerpen, en met e-mailadres: dirk.vissers@uantwerpen.be

Voor bijkomende vragen over uw rechten en alle andere aangelegenheden betreffende de verwerking van uw persoonsgegevens binnen Universiteit Antwerpen kan u ook steeds terecht bij onze functionaris voor gegevensbescherming, de Heer Koen Perpermans, Sint-Jacobsstraat 2, 2000 Antwerpen, via het telefoonnummer +32 3 265 52 63 of via het e-mailadres koen.pepermans@uantwerpen.be. Deze

functionaris ziet op onafhankelijke wijze toe op de naleving van de privacywetgeving binnen Universiteit Antwerpen.

Indien u zou menen dat uw persoonsgegevens niet rechtmatig en volgens de wettelijke vereisten worden/werden verwerkt, dan heeft u ook steeds het recht om klacht indienen bij de gegevensverwerkingsautoriteit (contactgegevens beschikbaar via: www.privacycommission.be). In geval van klachten raden wij evenwel aan om eerst onze functionaris voor gegevensbescherming te contacteren. Vaak zullen eventuele problemen of misverstanden zo eenvoudig opgelost kunnen worden.

Indien u niet wenst dat wij uw persoonsgegevens verwerken voor de doeleinden omschreven in dit formulier, dan mag u uiteraard steeds weigeren om uw toestemming te geven zonder dat u daartoe een reden moet opgeven.

Indien u wel uw toestemming heeft gegeven, maar nadien van gedacht verandert, zal u bovendien steeds uw toestemming kunnen intrekken door dit te melden aan Dirk Vissers, hoogleraar Revalidatiewetenschappen en Kinesitherapie, Universiteitsplein 1, 2610 Wilrijk, Universiteit Antwerpen, via het e-mailadres: dirk.vissers@uantwerpen.be zonder dat u daartoe een reden moet opgeven. Indien u uw toestemming intrekt, zal Universiteit Antwerpen uw persoonsgegevens niet verder gebruiken voor de doeleinden omschreven in dit formulier. De intrekking doet echter geen afbreuk aan de rechtmatigheid van de gegevensverwerkingen die reeds plaatsvonden vóór de intrekking van uw toestemming of van gegevensverwerkingen die zonder uw toestemming mogen worden uitgevoerd

Indien u besluit om te weigeren of om uw toestemming in te trekken, dan zal dit geen enkel nadeel met zich meebrengen voor uw huidige en toekomstige relaties met de Universiteit Antwerpen.

Commissie voor ethiek
Deze studie is beoordeeld door een onafhankelijke commissie voor ethiek, nl. de commissie voor sociale en humane wetenschappen die een gunstig advies heeft gegeven (dossiernummer SHW_2023_2023_1).

Contactpersonen in geval van vragen in verband met de studie
Indien u meent studiegebonden schade te hebben opgelopen of indien u vragen heeft over het onderzoek of uw rechten als studiedeelnemer, nu of tijdens of na uw deelname, dan kan u contact opnemen met Dirk Vissers, hoogleraar Revalidatiewetenschappen en Kinesitherapie, Universiteitsplein 1, 2610 Wilrijk, Universiteit Antwerpen, via het e-mailadres: dirk.vissers@uantwerpen.be.

Alvast bedankt om de tijd te nemen dit informatieformulier te hebben doorgenomen. Voor verdere informatie kan u steeds contact opnemen met dr. Glenn Leemans, via het e-mailadres glenn.leemans@uantwerpen.be.

Datum:

Handtekening uitvoerende onderzoeker(s): _____
Contactgegevens: _____

Handtekening Woordvoerder: _____
Contactgegevens:_____

TOESTEMMINGSFORMULIER
DEELNEMERS

Participant Nummer: _____

Titel studie: Identifying stakeholders' views on implementation and personalisation of airway clearance devices in primary care for patients with chronic mucus retention: a nominal group technique

Vereenvoudigde titel: Opvattingen van belanghebbenden over implementatie en personalisatie van medische hulpmiddelen voor luchtwegklaring in de eerstelijnszorg voor patiënten met chronische slijmretentie: een nominale groepstechniek

Deel enkel bestemd voor de deelnemer of de wettelijke vertegenwoordig(st)er:

Hierbij bevestig ik, ondergetekende (naam & voornaam) _____dat ik over de studie ben ingelicht en een kopie van de "Informatie voor deelnemers" en het "Toestemmingsformulier" heb ontvangen. Ik heb de informatie gelezen en begrepen. De uitvoerder van het onderzoek heeft mij voldoende informatie gegeven met betrekking tot de voorwaarden en de duur van de studie, én het effect hiervan. Bovendien werd mij voldoende tijd gegeven om de informatie te overwegen en om vragen te stellen, waarop ik bevredigende antwoorden gekregen heb.

- Ik heb begrepen dat ik mijn deelname aan deze studie op elk ogenblik mag stopzetten nadat ik de uitvoerende onderzoeker hierover heb ingelicht, zonder dat dit mij enig nadeel kan berokkenen.
- Ik ben mij bewust van het doel waarvoor de door mij aangeleverde gegevens verzameld, verwerkt en gebruikt worden in het kader van deze studie en dat zij vertrouwelijk zullen worden behandeld.
- Ik ga akkoord met de verzameling, de verwerking en het gebruik van deze gegevens, zoals beschreven in het informatieblad voor de participant. Ik ga eveneens akkoord met de overdracht en de verwerking van deze gegevens in andere landen dan België.
- Ik stem geheel vrijwillig toe om deel te nemen aan deze studie en om mee te werken aan alle gevraagde onderzoeken. Ik ben bereid informatie te verstrekken i.v.m. mijn achtergrond en eventuele deelname aan andere studies.

- Ik geef de toestemming aan Universiteit Antwerpen mijn persoonsgegevens te verwerken op de wijze en onder de modaliteiten zoals omschreven in het informatieformulier voor de volgende doeleinden:

  ☒ Expliciete toestemming voor video/audio opnames
  ☐ Indien van toepassing, expliciete toestemming voor verwerking van sensitieve data, bijvoorbeeld een zelf-geraporteerde diagnose van uw longziekte.

- Ik geef de toestemming aan Universiteit Antwerpen om audio opnames van mij te maken en te verwerken op de wijze en onder de modaliteiten zoals omschreven in het informatieformulier.
- Ik geef de toestemming aan Universiteit Antwerpen om video opnames van mij te maken en te verwerken op de wijze en onder de modaliteiten zoals omschreven in het informatieformulier.

In deze studie werken we samen met Groupmap. Gelieve op de hoogte te zijn van de privacy policy en de mogelijke recente updates daarvan vooraleer u instemt met deelname aan onze studie. U kan deze informatie hier vinden: https://www.groupmap.com/privacy

Gaat u akkoord met de privacy voorwaarden van Groupmap

- *Ja, ik ben ouder dan 18 jaar, heb de privacy policy van Groupmap gelezen en ga akkoord met de voorwaarden.* ☐
- *Nee, ik heb de privacy policy niet gelezen en/of ga niet akkoord met de voorwaarden.* ☐

Datum: _____

Handtekening deelnemer (of wettelijk vertegenwoordig(st)er):_____

Indien nodig, handtekening onafhankelijke getuige:

_____

Deel enkel bestemd voor de onderzoeker die de studie uitvoert:

Hierbij bevestig ik, ondergetekende (naam & voornaam) _____ dat ik met _____ de procedures zoals beschreven in het inlichtingenblad heb besproken, waarbij ik specifiek heb gewezen op de mogelijke risico's of ongemakken verbonden aan het onderzoek. Ik heb expliciet de vraag gesteld of er nog onduidelijkheden of vragen overbleven en heb deze naar mijn beste vermogen beantwoord. Tevens bevestig ik dat _____ toestemming heeft gegeven om aan de studie deel te nemen.

Datum: _____

Handtekening uitvoerende onderzoeker(s): _____
Contactgegevens: _____

Handtekening woordvoerder: _____
Contactgegevens: _____

Appendix D: Scenario NGT Session

Draaiboek studie WP3_QualR_NGT

Duurtijd	Onderwerp	Wie	Inhoud
[Δ:+10']	**<u>Introductie</u>** (ervarings-) deskundigen en algemene afspraken	Facilitator	*[…] "Hartelijk welkom bij deze groepsdiscussie sessie. Het is de [eerste keer] dat we een bijeenkomst hebben met belanghebbende en ervaringsdeskundingen rond medische hulpmiddelen voor luchtwegklaring in de eerstelijnszorg. Ik wil alvast ieder van jullie bedanken voor uw vrijwillige tijd voor het bijwonen van deze groepsdiscussie.* *Zoals aangegeven in het informatieformulier wordt deze sessie opgenomen met behulp van Microsoft Teams. Mag ik deze opname starten?.* [Facilitator start opname in Microsoft Teams]. *Voordat we beginnen, wil ik graag het team van deskundigen voorstellen dat zich vandaag bij ons heeft gevoegd.* [Facilitator laat slide zien met namen van alle belanghebbenden en ervaringsdeskundingen en hun expertisegebied]. *"Ik stel voor dat we een snelle introductieronde doen zodat we elkaar kennen voordat we beginnen met de groepsdiscussie."* [Facilitator start met zichzelf voor te stellen en kiest de eerste naam op de lijst en vraagt de persoon om hem/haar voor te stellen:] *"Mag ik persoon A vragen om hem/haar kort voor te stellen met naam en voornaam en je rol in de eerstelijnszorg?"* *"Ik zou graag een aantal afspraken willen toelichten, met name […]* [Facilitator laat slide zien met alle afspraken].

			"Als laatste wat informatie rond de technische ondersteuning voor deze sessie. Glenn Leemans, post-doc onderzoeker, mag je contacteren met praktische vragen tijdens deze sessie. *We zullen daarnaast het professionele softwareplatform **GroupMap** gebruiken. Hiervoor kreeg je reeds een link per mail. Glenn zal jullie in het chatkanaal van deze online sessie later een link bezorgen per persoon." […]*
[Δ:+15']	**<u>Inleiding topic</u>**	Facilitator Glenn Leemans	*[…] "Het doel op het einde van deze sessie is een breed gedragen consensus te bereiken over welke stappen we dienen te zetten rond een betere integratie van medische hulpmiddelen voor de behandeling van longaandoeningen in de eerstelijnszorg.* *Glenn Leemans zal nu meer in detail toelichting brengen rond het onderwerp, de onderzoeksvraag en de onderzoeksmethode."* [Glenn Leemans presenteert PowerPoint] *"Bedankt Glenn voor de presentie. Zijn er vragen? Jullie mogen nu allen op de link klikken achter jullie naam in het chatkanaal van deze Teams sessie. Hierdoor krijgen jullie toegang tot het professionele softwareplatform GroupMap. Gelieve Microsoft Teams niet te verlaten. We zullen zowel Microsoft Teams als Groupmap gebruiken tijdens deze sessie om een gedragen concensus te bereiken. " […]*
[Δ:+10']	**<u>Stap 1:</u>** oplijsten persoonlijke ideeën in groep	Facilitator Deelnemers	*[…] "De onderzoeksvraag in het midden van het scherm is het onderwerp voor de sessie van vandaag.* *Ik wil graag dat jullie allemaal **10 minuten de tijd nemen om al jullie antwoorden of ideeën rond deze vraag op een rijtje te zetten.** Schrijf elk idee in een korte zin of een paar woorden op bijvoorbeeld een werkblad.*

			Werk alsjeblieft onafhankelijk van andere leden. Tijdens deze fase vraag ik je om niet met andere leden te praten. Dit is voor ieder van ons een gelegenheid om zijn of haar bijdragen aan de discussie individueel voor te bereiden *Ik zal aangeven als de 10 minuten voorbij zijn zal en voorstellen hoe we verder gaan met het delen van onze ideeën.* *Zijn er vragen? Laten we dan starten gaan met deze individuele actie voor de volgende 10 minuten." […]*
[Δ:+20']	**<u>Stap 2:</u>** delen van persoonlijke ideeën in groep	Facilitator Deelnemers	*[…] "Tijdens de laatste 10 minuten heeft ieder van jullie ideeën opgesomd om onderwerp aan te pakken.* *Nu wil ik jullie vragen om jullie ideeën te delen met de andere leden van de groep. Dit is een **belangrijke** stap omdat onze lijst met ideeën een leidraad zal vormen voor verdere discussie, ons zal helpen begrijpen hoe rijk de ideeën zijn waarmee we moeten werken en eventueel bijkomende ideeën zal stimuleren.* *Om dit doel zo snel en efficiënt mogelijk te bereiken, ga ik **per individu** vragen om mij **één idee** van jouw lijst te geven, samengevat in een korte zin of een paar woorden. Als iemand anders in de groep een idee opnoemt dat jij ook op je werkblad had staan, **hoef je het idee niet te herhalen**. Als je echter van mening bent dat het idee op jouw werkblad een andere nadruk of variatie bevat, dan verwelkomen we dat idee. Variaties op een thema zijn belangrijk en helpen ons om creatief te zijn.* ***Nadat de hele lijst op het bord staat, krijgen we de gelegenheid om de ideeën te bespreken, te verduidelijken en te betwisten in de volgende fase.*** [Facilitator kiest de eerste persoon op de lijst en vraagt:] *Wil je me alsjeblieft één idee van je lijst geven en onthouden, kort en bondig?" […]*

[Δ:+20']	**<u>Stap 3a:</u>** verduidelijking ideeën	Facilitator Deelnemers	*[…] "Nu we onze ideeën op een rijtje hebben gezet, wil ik dat we de tijd nemen om terug te gaan **en elk idee kort te bespreken**. Het doel van deze discussie is om de betekenis van elk item op onze lijst te verduidelijken.* *Het is ook de gelegenheid om ons begrip van de logica achter het idee en het relatieve belang van het item uit te drukken. We moeten ons vrij voelen om verschillende standpunten naar voren te brengen of om het oneens te zijn.* ***Ik stel voor dat diegene die het idee heeft voorgesteld, het nu kort verduidelijkt.** Ik wil erop wijzen dat de bedenker van het idee zich niet verplicht hoeft te voelen om een item uitgebreid te verdedigen.* *Elk lid van de groep kan opmerkingen geven over elk idee!* *We willen het tempo er echter wel in houden, zodat elk item op de kaart de kans krijgt om aandacht te krijgen, dus ik kan de groep soms vragen om verder te gaan met andere items."* [De facilitator wijst naar het eerste item en zegt:] *"Zijn er nog vragen of opmerkingen die de groepsleden willen maken over dit eerste item?"* *[Herhaal dit voor de volgende ideeën.]* *[…]*
[Δ:+10']	**<u>Stap 3b:</u>** groeperen	Facilitator Deelnemers	[De facilitator zegt:] *"**Nu kunnen gelijkaardige ideeën worden gegroepeerd** als jullie het daar allemaal mee eens zijn."* *Heeft er iemand een suggestie om bepaalde items te groeperen onder een overkoepelende titel?* *[…]*
[Δ:+5']	**<u>Stap 4a:</u>** prioritisatie	Facilitator Deelnemers	*[…] "We hebben nu de bespreking van de hele lijst met ideeën afgerond,gegroepeerd, de betekenis van elk idee verduidelijkt, en de punten van overeenkomst en onenigheid besproken.*

			*In de laatste stap van het nominale groepsproces willen we proberen een **volgorde van bruikbaarheid en haalbaarheid** van de voorstellen te maken. Dat doen we door een anonieme stemming via het softwareplatform. Het gaat dus om de bruikbaarheid en de haalbaarheid van elk idee.* *Als eerste stap wil ik dat jullie de vijf belangrijkste ideeën selecteren uit onze ideeënlijst. **Schrijf deze 5 belangrijke ideeën op een stuk papier.** Besteed de volgende paar minuten nu aan het zorgvuldig selecteren van de vijf items. Zijn er nog vragen?* [Facilitor geeft de deelnemer maximaal 5' om hun 5 belangrijkste ideeën te selecteren]
[Δ:+10']	**<u>Stap 4b:</u>** rangschikking en stemming	Facilitator Deelnemers	*Tot slot gaan we nu de door jullie geselecteerde ideeën rangschikken door te stemmen. Ieder van jullie heeft **in totaal 15 stemmen** die jullie moeten toekennen aan **jullie vijf belangrijkste ideeën**. Bepaal aan de hand van jullie vijf ideeën welk idee het belangrijkst is, door 15 stemmen uit te delen:* *het belangrijkste idee krijgt 5 stemmen, het tweede belangrijkste krijgt 4 stemmen, het derde belangrijkste krijgt 3 stemmen, dan 2 stemmen en het minst belangrijkste idee krijgt 1 stem.* *Je geeft stemmen door op de plus te klikken onder het idee.* *[…]* *Mogen we de stemming afsluiten?*
[Δ:+5']	**<u>Stap 4c:</u>** resulaten	Facilitator Deelnemers	*[…] Als alles goed verloopt in deze laatste fase zien we nu de scores voor elk idee bij elkaar opgeteld en krijg we nu een lijst met prioriteiten te zien.*

			Heeft iemand, kijkend naar de rangschikking van nuttige en haalbare ideeën, ***nog aanvullende opmerkingen of suggesties?*** *Heeft iemand nog opmerkingen over de procedure?" […]*
[Δ:+5']	**<u>Akkoord</u>** resulaten en afsluiting sessie	Facilitator	*[…]In deze laatste stap willen we je vragen of* ***je akkoord gaat*** *met de prioriteitenlijst die we samen hebben opgesteld met alle deelnemers. Indien akkoord, gelieve te klikken op* ***de groene knop 'I accept'.*** *Als laatste wil ik jullie allen zeer bedanken voor jullie deelname."* *[…]*

Appendix E: Approval Ethics Committee

