Patients and Healthcare Providers’ Experiences and Expectations in Chronic Obstructive Pulmonary Disease Exacerbation Management and Remote Patient Monitoring: Initiating Co-Creation

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Submitted to: Journal of Medical Internet Research
on: October 17, 2024

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Abstract

Background: Chronic Obstructive Pulmonary Disease (COPD) exacerbations worsen lung function and cause psychological distress, affecting overall health and quality of life (QoL). Early diagnosis and prevention of exacerbations are crucial for preserving lung function, improving QoL, preventing hospitalizations, and reducing mortality and healthcare costs. While remote patient monitoring (RPM) offers the potential for early exacerbation detection, challenges remain in recognizing symptoms early. A non-invasive breathalyzer is being developed to monitor COPD patients and detect exacerbations before symptoms arise. This study encompasses the initial co-creation phase to align the breathalyzer and corresponding care process with current COPD exacerbation management and user needs.

Objective: This study aims to understand COPD care processes, exacerbation management, and RPM in the Netherlands, through three objectives: 1) Explore stakeholders involved in COPD exacerbation care, 2) Understand current COPD care, and 3) Assess stakeholder experiences and expectations regarding RPM in COPD care.

Methods: Following the CeHRes roadmap, four research activities were conducted between March and September 2024 for the initial co-creation phase: 1) desk research, 2) interviews, 3) project group meeting, and 4) co-analysis focus group. Desk research involved reviewing literature and COPD (exacerbation) care guidelines. Semi-structured interviews (n=34) were conducted with 18 patients, 14 healthcare professionals, one caregiver, and one hospital policy advisor. Topics included COPD diagnosis processes, exacerbation management, stakeholder roles in COPD (exacerbation) care, and RPM experiences or expectations. The project group meeting between interviews and the focus group verified interim findings and guided the focus group content. Six patients participated in a co-analysis focus group to review interview quotes on exacerbations and RPM. The Framework Method was used to analyze the interviews and the focus group through inductive and deductive coding.

Results: Objective 1 identified seven key stakeholders in COPD care, patients, pulmonologists, general practitioners, nurse practitioners, nurse specialists, physiotherapists, and informal caregivers. Objective 2 found a lack of uniformity in COPD care, exacerbation management, and information provision across providers. Patients reported struggling to recognize exacerbations. Regarding objective 3, although patients with experience in RPM generally reported positive experiences, they questioned the added value in early detection of exacerbations. Those without RPM experience were receptive to its use for symptom tracking but were concerned about reduced in-person care and overreliance on data. Healthcare providers reported seeing value in RPM for monitoring between visits and efficiently allocating resources but stressed the need for clear guidelines and noted barriers such as language proficiency and usability of technology.

Conclusions: This study highlights opportunities to improve COPD exacerbation management by optimizing effective and efficient RPM usage and integrating it into clinical practice. Future research should refine RPM processes, balance objective data with patient-reported symptoms, enhance communication amongst HCPs and between HCPs and patients, provide clear

exacerbation management guidelines, and ensure inclusivity.

(JMIR Preprints 17/10/2024:67666)
DOI: https://doi.org/10.2196/preprints.67666

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Patients And Healthcare Providers' Experiences And Expectations In Chronic Obstructive Pulmonary Disease Exacerbation Management And Remote Patient Monitoring: Initiating Co-Creation

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Introduction

Chronic Obstructive Pulmonary Disease (COPD) is characterized by a gradual deterioration of pulmonary functionalities [1]. It is the third leading cause of death worldwide, with a prevalence of 391.9 cases and an incidence rate of 3.23 million [2-4]. The global financial burden is estimated to be $4.5 trillion between 2020 and 2050 [5]. Symptoms like persistent cough, (exertional) dyspnea, wheezing, and sputum production, along with comorbidities, characterize COPD and impact patients' quality of life (QoL) [6]. Typically, COPD exhibits an unpredictable course, with sudden symptom worsening, clinically identified as exacerbation, which increases the risk of irreversible lung function deterioration [7,8].

Annual exacerbation rates for COPD range between 22% and 47%, with hospitalization rates varying from 5% to 25% [9,10]. Moreover, in the Netherlands, a considerable proportion of patients are readmitted; 15% within 30 days and 30% within one year post-discharge [11]. Exacerbations strongly predict future exacerbations, significantly affecting QoL through worsened lung function and psychological distress [10,12]. Therefore, early exacerbation diagnosis and prevention are pivotal for preserving lung function, enhancing QoL, preventing hospitalizations and readmissions, reducing mortality rates, and associated healthcare costs and burden [12-16]. However, identifying exacerbations remains challenging [17-19]. Most patients experience regular symptom variability, with about 40% of exacerbations developing gradually, making it difficult to distinguish them from typical COPD fluctuations [8,20,21]. As a result, patients may struggle to recognize exacerbations and seek timely care, leading to acute symptom worsening, such as severe dyspnea, and potential Emergency Room visits or hospitalization [8,15,19,22].

Existing exacerbation management processes, including identifying personalized exacerbation indicators and corresponding tailored actions (i.e., COPD action plan) or Remote Patient Monitoring (RPM) to monitor parameters such as oxygen saturation and physical activity, may facilitate early recognition of exacerbations [23-25]. These approaches can transition COPD care from reactive to proactive by increasing patient engagement and empowerment [26,27]. Some exacerbation management processes show promise in reducing delays in symptom recognition and response, as well as in decreasing exacerbation frequency, hospitalization duration, and readmissions [23,25,28]. Nevertheless, most exacerbation management processes focus on early symptom recognition yet fail to adequately predict exacerbations pre-symptomatically, possibly due to the lack of clear objective predictors and cut-off measures [23,29-31]. Furthermore, usability issues in exacerbation management processes persist, largely due to the lack of trust and labor-intensive tasks faced by end-users. These challenges include frequent questionnaires, difficulty in expressing their feelings, and the need to manage false alarms by monitoring staff [26,31,32]. Additionally, healthcare professionals (HCPs) may also view RPM processes as unsuitable for more vulnerable patients or those perceived as unable to engage with the system, despite potential benefits [32-35]. This leads to continuous challenges in ensuring comprehension and inclusivity, particularly regarding literacy barriers and digital skills [26,30,32]. These challenges may hinder adherence and widespread adoption, potentially limiting their benefits for a substantial portion of the COPD population, specifically the more vulnerable [28,30,31,36]. This highlights the disparity between the needs of exacerbation management processes, such as RPM, and existing processes [26,29,30].

A novel non-invasive RPM device (i.e., the breathalyzer) in COPD exacerbation management is being developed to objectively predict exacerbations pre-symptomatically by detecting specific exacerbation-indicative volatile organic compounds [37]. Ensuring the device's compatibility with existing exacerbation management requires a thorough understanding of current COPD care and RPM processes, alongside the diverse end-users' needs regarding both the device and the care process [30,31]. Research recommends involving relevant stakeholders and end-users in early product development, as co-creation can improve user experience and promote successful adoption [31,38]. Therefore, this study encompasses the initial co-creation phase (i.e., *contextual inquiry*), per the CeHRes roadmap (Figure 1) [39], for developing the novel RPM device and corresponding care process. This initial phase is crucial for understanding the context in which the device will be adopted and serves as the foundation for the entire co-creation process [39]. This study aims to thoroughly understand COPD care processes, exacerbation management, and RPM in the

Netherlands, through three objectives: 1) Explore stakeholders involved in COPD exacerbation care, 2) Understand current COPD care with an explicit focus on exacerbations, and 3) Assess stakeholder experiences and expectations regarding RPM in COPD care.

Methods

Study design

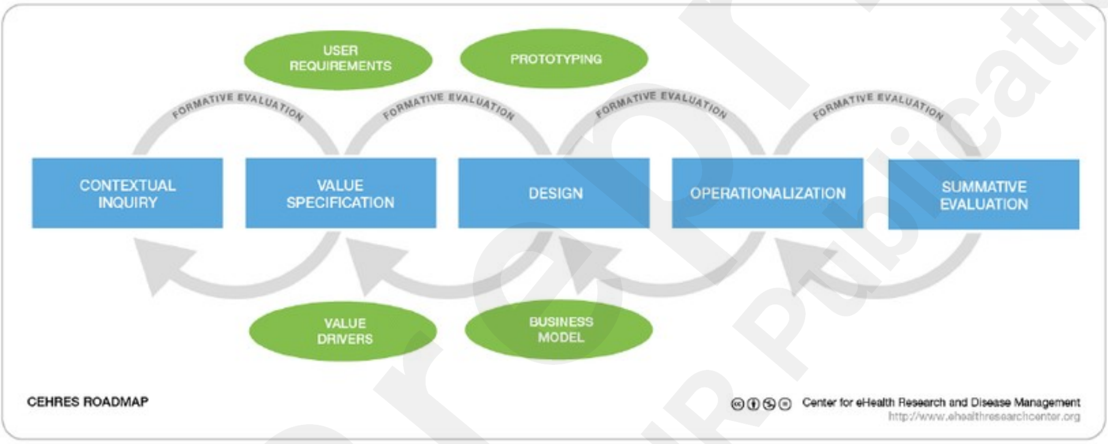
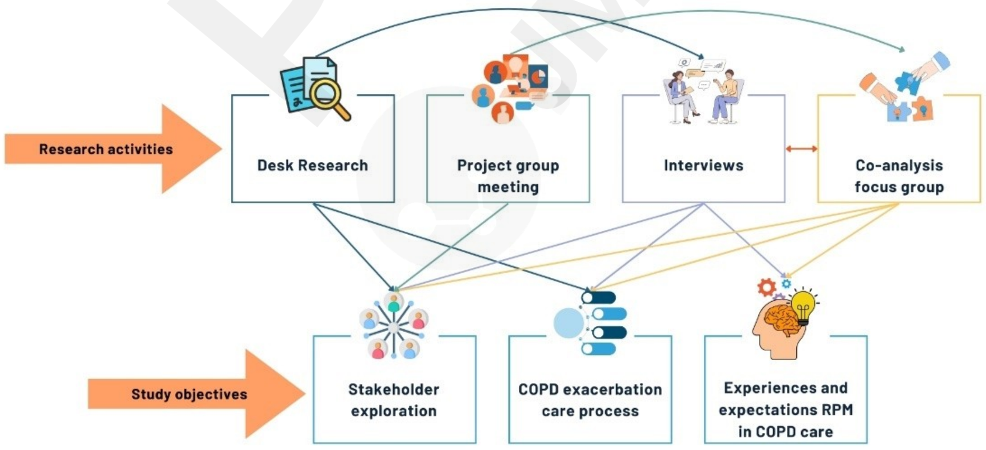


Figure 1. CeHRes Roadmap for the development of eHealth technologies. Derived from van Gemert-Pijnen et al., (2011).

This qualitative co-creation study encompasses the contextual inquiry, which is the initial co-creation phase according to the CeHRes roadmap (Figure 1). During this phase, as shown in Figure 2, four research activities were conducted iteratively to achieve the research objectives: 1. *Desk research*, 2. *In-depth interviews*, 3. *Project group meeting*, and 4. *Co-analysis focus group*.

This study did not fall under the scope of the Dutch Medical Research Involving Human Subjects Act (WMO) and has been approved by the non-WMO review board of LUMC (reference number 24-3015). This study is compliant with the General Data Protection Regulation (GDPR) and the Dutch Act on Implementation of the General Data Protection Regulation (Uitvoeringswet AVG, UAVG). All participants provided written consent before participating in an interview or focus group.

Figure 2. Overview of research activities in the contextual inquiry phase, and the corresponding contribution to the study objectives



Desk Research

The *Desk Research* focused on a grey literature search (e.g., COPD guidelines and recommendations), and scientific literature concerning COPD care, exacerbation management (i.e., COPD action plan[1]), and existing RPM processes. This offered an initial overview of stakeholders and their relative importance based on a general understanding of COPD exacerbation management and RPM processes. Additionally, during a COPD care conference, HCPs were asked to identify key stakeholders in COPD care. These insights were added to the stakeholder overview.

Interviews

Semi-structured *interviews* were conducted with preliminarily identified stakeholders, mainly prospective end-users, to obtain in-depth information concerning the perspectives and experiences of stakeholders regarding general COPD care, living with COPD, COPD exacerbation management, and RPM experiences or expectations, as well as to verify the preliminary stakeholder overview [40].

Project group meeting

A *project group* of key COPD stakeholders, including patients and HCPs, was formed to integrate co-creation throughout the entire research. The *project group* enabled stakeholders to participate in decision-making for subsequent research activities.

Co-analysis focus group

In a *co-analysis focus group*, we engaged patients to verify the preliminary stakeholder overview and information obtained from the interviews. Subsequently, participants were enquired to participate in the thematic analysis of interview quotes related to the following research topics, experiencing exacerbations, care received during exacerbations, and RPM expectations and experiences. *The co-analysis focus group* provided deeper insights into the interview data, helping researchers address their own biases by incorporating patient perspectives [41,42].

Recruitment and participants

For the *interviews*, *project meeting*, and *co-analysis focus group*, purposeful sampling

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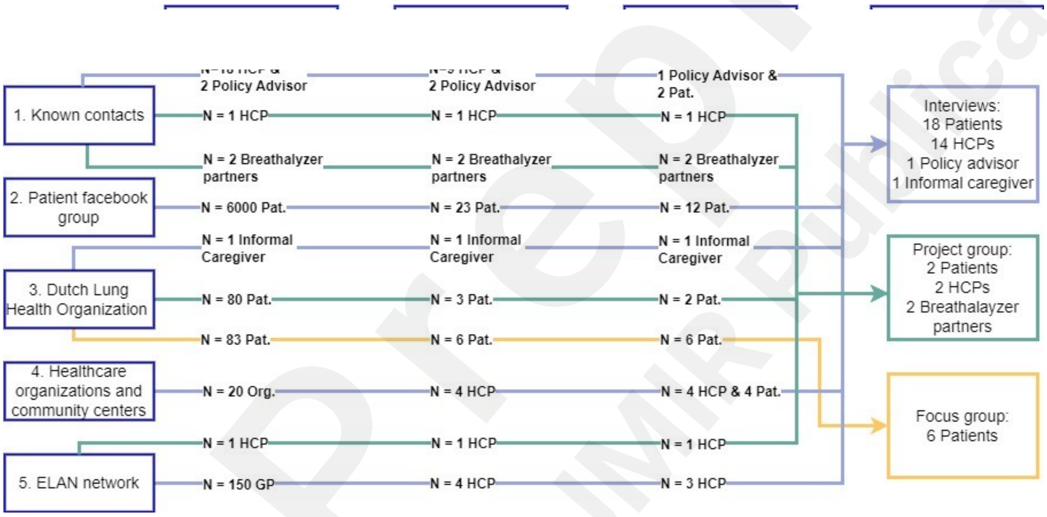
[1] A COPD action plan for COPD patients is a personalized guide that helps them recognize worsening symptoms early and provides specific steps for managing flare-ups to prevent further worsening.

was employed to strive for a diverse population, based on characteristics such as age, sex, ethnicity, profession (for HCPs), and living situation (urban or rural) [43]. The target population comprised identified stakeholders such as patients and HCPs involved in COPD exacerbation care. Patients were eligible if they had experienced or feared an exacerbation within the past three years, while HCPs needed to be actively working in COPD care. Two non-end-users (i.e., hospital policy advisor for patient care and informal caregiver) were also included. Sampling continued until saturation was reached, with no new themes emerging from the *interviews*, with the *co-analysis focus group* further confirming data saturation. Five main recruitment approaches were used. Figure 3 illustrates the various approaches and their contributions to the final number of participants in each research activity.



Interviews

All recruitment strategies were used. Familiar contacts were emailed or called accordingly. Healthcare organizations were emailed and called in cases of no response. The recruitment flyer and text were distributed in a Facebook group for pulmonology patients. The Extramural LUMC Academic Network for Primary Care Facilities database was targeted through a newsletter [44]. Lastly, a *co-analysis focus group* participant's partner was recruited as an informal caregiver (Figure 2). After prospective participants showed interest, they received a detailed information letter and informed consent form to formally consent to their participation. In total, 14 HCPs, 18 patients, one hospital policy advisor, and one informal caregiver were interviewed.

Project group

The Lung Health Organization inquired a database of patients interested in contributing to COPD-related projects (recruitment strategy 3). Additionally, two specialized COPD nurses from both primary and secondary care were recruited via strategy 1 and 5 (Figure 3). Lastly, two breathalyzer partners participated as senior management and engineer. Three LUMC researchers (JA, MK, AM) initiated the meeting.

Co-analysis focus group

Researcher AM contacted the Lung Health Organization in Utrecht (the Netherlands) to request assistance with recruiting participants for the focus group (recruitment strategy 3). Their existing contacts were approached to gauge interest, leading to a *co-analysis focus group* session with six participants, including the coordinator.

Data collection

Interviews

Interviews lasted approximately 60 minutes and were performed physically or through Microsoft Teams. Interview topics concerned the COPD diagnosis process, experiences with COPD, exacerbations, exacerbation management, the roles, and responsibilities of different stakeholders in COPD exacerbation management, and their possible experiences or expectations with RPM processes. Participants filled out a demographic characteristic questionnaire. Patient *interviews* were mostly conducted in person, while HCP interviews were typically done digitally due to their time constraints. *Interviews* were conducted between April and September 2024. Ten *interviews* were conducted with two researchers (AM and EB), the remaining *interviews* were conducted either by researcher AM or EB.

Project meeting

The participants were asked to verify the preliminary stakeholder overview developed based on the *desk research* and *interviews.* Thereafter, the content of the *co-analysis focus group* was discussed with the participants to obtain their feedback. This led to significant changes in the *co-analysis focus group* content, particularly in the explanation and exercises designed to familiarize participants with thematic analysis.

Co-analysis focus group

Three researchers (MK, JA, AM) led the *co-analysis focus group*, consisting of three phases. *Phase 1*: participants created a stakeholder overview of key stakeholders in COPD care and a word cloud reflecting words associated with their experiences or expectations of RPM. *Phase 2*: Participants were introduced to co-analysis through a coding exercise, creating a word cloud from their COPD care experiences, grouping related terms, and assigning overarching themes (i.e., brain mapping). These two phases were moderated by AM and were conducted with the entire group. During *phase 3*, participants read quotes, identified keywords (codes), and were encouraged by the moderators to group these codes under overarching themes, as practiced in phase 2. Simultaneously, the quotes prompted discussions about their own experiences with COPD care, exacerbation management, and RPM often confirming interview findings and introducing new insights. This phase was moderated by JA and MK. Afterward, participants completed a questionnaire gathering their socio-demographical information.

Data analyses

The *interviews* and *co-analysis focus group* data were audio recorded, transcribed verbatim and pseudonymized. Furthermore, descriptive analyses (e.g., M ± *SD, N*, percentages) of interview and focus group participants were performed in Microsoft Excel 365 to summarize participants’ socio-demographic characteristics.

The Framework Method was deemed most applicable to the explorative nature of this study and allowed for codes and themes to emerge inductively and deductively [45,46]. The first two interviews with patients and HCPs were individually coded by two independent researchers (AM and EB). Consequently, the codes were compared during consensus meetings to develop a comprehensive code tree and to improve inter-coder reliability [47]. Once consensus was reached, the remaining transcripts were coded by one researcher (AM). A consensus meeting was conducted if any new codes emerged. The entire coding procedure was supervised by two researchers (JA and MK) and the final set of codes and subcodes was reviewed. If required, consensus meetings were scheduled with the senior researchers. The analysis of the interview data was performed using the Atlas.ti software (version 23).

Co-analysis focus group

The input from *phase 1* was summarized and resulted in a final overview of key stakeholders in COPD exacerbation management and an overview of their first associations with RPM in COPD care. The thematic coding exercise of *phase 2* was summarized in a handwritten overview developed during the focus group. The new codes identified by the participants during *phase 3* were added to the existing code tree and applied to relevant quotes. The discussions between participants while reading the quotes were recorded, transcribed, summarized, and coded using the existing code tree. Any new themes that emerged from the *co-analysis focus group* were used to further contextualize the results.

Results

The results aimed to address the study's objectives: 1) identifying stakeholders in COPD care, 2) understanding current COPD care processes, and 3) assessing stakeholder experiences and expectations regarding RPM in COPD care. During this process, three overarching themes emerged, providing a comprehensive summary of the contextual inquiry phase: (i) The diagnosis and daily impact of COPD, (ii) The regular COPD care process, and (iii) The exacerbation management process. Themes two and three also cover experiences and expectations related to RPM.

Population characteristics

An overview of key stakeholders in COPD exacerbation care was determined based on all research activities. The stakeholders prominently involved are, patients, partners, or informal caregivers, primary, secondary, and rehabilitation care nurses, (rehabilitation) physiotherapists, (rehabilitation) pulmonologists, GPs. Less frequently mentioned stakeholders, such as home care nurses, pharmacists, and breathing coaches were excluded from the interviews for clarity.

Table 1 presents a summary of the demographics of the interview and co-analysis focus group participants. Patients' ages varied between 50 and 86 years and their COPD GOLD classification ranges from stage 2 to 4. Most patients had at least experienced one exacerbation in the last 12 months, except for one. The HCPs' ages varied from 33 to 60 and their professions were pulmonologist, nurse specialist (secondary care), rehabilitation nurse, general practitioner (GP), nurse practitioner (NP) (primary care), and physiotherapists. Participants were mainly from the central and southern regions of the country.

Table 1. Interview and co-analysis focus group participants; patients and informal caregiver characteristics (n=25)

Characteristic	Value
Age in years, mean (SD)	68.9 ± 9
Male gender, n (%)	14 (58.3%)
Nationality, n (%)	*N =25*
Dutch	22 (88%)
Dutch-Moluccan	1 (4%)
Dutch-Iranian	1 (4%)
Dutch-Turkish	1 (4%)
Years COPD, mean (SD)	10 ± 7.1
n (%) ***Unknown***	3 (12.5%)
GOLD classification, n (%)	*N = 24*
2	3 (12.5%)
3	9 (37.5%)

4	7 (29.2%)
Unknown	5 (21%)
Education , n (%)	*N = 25*
Low (no education – high school)	10 (40%)
Intermediate (intermediate vocational education)	7 (28%)
High (BSc, MSc, doctorate)	8 (32%)
Profession, n (%)	*N = 25*
Disabled for work	7 (29.2%)
Pensionado	15 (60%)
Volunteer	3 (12.5%)

*18 patients participated in interviews and 6 patients in the co-analysis focus group.

Table 2. Interview participants; HCPs and policy advisor characteristics (n=15)

Characteristic	**Value**
Age in years, mean (SD)	43.7 ± 9.5
Male gender, n (%)	4 (26.7%)
Profession, n (%)	
Pulmonologist	6 (40%)
GP (primary care)	1 (6.6%)
NS (secondary care)	1 (6.6%)
Rehabilitation nurse	1 (6.6%)
NP (primary care)	3 (20%)
Physiotherapist	2 (13.3%)
Policy advisor	1 (6.6%)
Years experience, mean (SD)	15.6 ± 10.4
Years experience in COPD, mean (SD)	10.3 ± 5.5

Diagnosis and the daily impact of COPD

According to interviews with secondary care HCPs, there are three main pathways for COPD diagnosis: 1) Diagnosis by a GP, 2) Diagnosis in the emergency room due to acute dyspnea, often with patients unaware of a COPD exacerbation, and 3) Referral from other specialties, such as cardiology, where COPD may be misidentified as cardiac issues. While the diagnostic process varied among patients, most interviewees reported receiving a diagnosis from their GP after experiencing a persisting cough and sudden worsening of stamina or dyspnea. Depending on the diagnosis, patient's medical status, and COPD classification, they either continued treatment with their GP or, in more complex cases, were referred to secondary care. Although many found it difficult to recall details, most patients noted that the information they received at diagnosis was limited, typically consisting of a brief explanation of COPD and instructions on how to use their inhalers.

> ***“The initial diagnosis made by a GP was ‘you have COPD, good luck living with it and there is nothing we can do’” – Patient 10***

According to the HCPs, the initial conversation for diagnosis is typically conducted by the GP or pulmonologist, covering the COPD basics, progression, and management, with smoking cessation as a key topic. Some pulmonologists indicated that due to time constraints, follow-up conversations are conducted by nurses. Two interviewed NPs indicated that they serve as the primary point of contact from the initial diagnosis onward, only consulting the GP when unfamiliar situations arise.

The patients interviewed reported feeling restricted in their daily lives and during routine activities like grocery shopping, cooking, cleaning, and sometimes even eating. They feel reliant on others, such as their partners, and struggle with the rapid decline in their well-being compared to their initial diagnosis. Many are frustrated by the invisibility of their disease and misunderstanding of others. Patients indicated that the impact of COPD extends to patients’ friends and family. Those living alone initially felt embarrassed to ask for help but recognized its necessity, particularly as their rehabilitation process taught them the importance of distributing their energy throughout the day and after an exacerbation. HCPs observed that patients often struggle to understand the progressive nature of COPD, leading to ongoing frustration as they adapt to life changes caused by their worsening condition.

> ***“When we’re out and I need to use the restroom, I need to take breaks frequently and end up occupying the restroom for a while. I often try to anticipate going to the restroom before leaving, which adds more stress to the situation.” – patient 1***

Regular COPD care process

Patients with stable symptoms typically attend consultations with their GP or pulmonologist once or twice a year. Despite regular interactions, ambiguity often exists among patients regarding their primary point of contact. When available, patients may also have (bi-)annual appointments with a NP or NS. Physician visits often last between 10 to 15 minutes, covering medication management and their health status. Some patients expressed doubts about the value of pulmonologist visits, citing limited time for in-depth discussions and a lack of understanding of their needs and preferences concerning medication and aids such as oxygen. Some even felt their concerns and questions were overlooked or ignored, leading to dissatisfaction and the decision to change physicians. Others report high satisfaction, valuing effective communication and prompt responses. Some could easily contact their HCPs whenever they felt anxious or experienced symptoms worsening. An illiterate interviewee received information verbally, which met his needs. However, despite repeated explanations, he had difficulty retaining detailed information about his condition but was proactive in seeking assistance when needed.

HCPs report that they strive to deliver optimal and equitable care, but experience challenges in providing optimal care to patients facing information or language barriers. Although NPs and NSs often have more time to address disease-related needs and employ supporting tools such as the ABC-tool[2] or the “topic overview” (in Dutch: ‘spreekkaart’)[3] to guide discussions, they also acknowledge and encounter these barriers.

“Low literacy and limited digital skills present a challenging situation where communication frequently lacks because it just does

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[2] The ABC-tool integrates the Clinical COPD Questionnaire, allowing patients to complete it during each consultation. It uses color-coded balloons, green, amber, and red for recent responses and gray for previous ones, to visualize changes per topic.

[3] The “spreekkaart” is a placemat featuring images on various topics such as "healthy eating," "smoking," "finances," and "what is COPD". This placemat enables patients to select discussion topics for their consultations, thereby empowering them to guide the focus of their meetings with the NS or NP.

> ***not get through. When a patient relies on a young child to translate, it further hinders effective interaction and creates personal resistance from my end." – NP***

Experiences and expectations of RPM during regular COPD care

Some patients were familiar with RPM for COPD, using apps with daily, weekly, or monthly questionnaires that became more frequent when they indicated an increase in symptoms. While they valued the reassurance of ongoing monitoring, motivation was often external and depended on HCP's recommendations or perceived benefits for HCPs. Despite a generally positive view, many questioned RPMs' specific benefits for their health or COPD management and struggled with vague or ambiguous questions and unhelpful automatic responses like "refer to your COPD action plan" or "call your GP". Additionally, some patients noted that the repetitive nature of the questions could lead them to respond automatically, without consciously reflecting on their feelings and answers. A system that could objectively measure their status was therefore considered beneficial to them.

> ***The question, "Do you feel normal?" can be answered with the option, "I feel normal" or "I feel better". But better? That hasn't been the case for a long time. I find it a bit suggestive, and the other possible answer implies something much worse, making it difficult questions to interpret and answer" – Patient 8***

Patients unfamiliar with the concept of RPM had varying expectations. Some were enthusiastic about sharing their status with HCPs, believing it would enhance communication and disease management. Others worried that RPM might reduce human interaction and limit consultations to even lesser frequent intervals. Additionally, patients questioned whether RPM systems could fully capture their well-being through standalone data. Some worried that HCPs unfamiliar with their medical history might misinterpret data and therefore miss crucial insights. Others were open to interacting with new HCPs but emphasized the need for evidence or trust that the system would positively impact their well-being. Generally, most patients did not foresee technical barriers to using RPM but stressed the need for comprehensive in-person training to aid adoption and empower them. A patient with a migration background, fluent in Dutch but with a history of addiction and lower education, reported difficulties with tasks like emailing and online banking. Despite this, he expressed a positive attitude toward using RPM for health monitoring and regular HCP assessments. He felt confident in his ability to use RPM effectively, provided he received thorough introductory training.

> ***"Yes, I find it challenging to send emails and manage online banking for instance, but an app like that [RPM] sounds great. It would allow me to keep track of my disease and health status, and I wouldn't need to bother my nurse as much. They could simply guide me through the app on what to do. I think that would be really helpful." – Patient 18***

Among the interviewees, RPM was solely implemented in secondary care, hence from the HCPs only one NS and some pulmonologists were familiar with these processes within COPD care. Two pulmonologists from the same hospital had recently changed RPM systems due to technical system changes but had positive experiences with the previous system as it showed a reduction of exacerbation-related Emergency Room visits and hospitalization. The NS with RPM experience was optimistic about the future of RPM. He foresaw that through RPM time and resources could be allocated more efficiently, but also noted challenges related to digital and language barriers and some patient populations' eligibility. HCPs generally indicated asking patients if they were interested in participating in RPM processes. However, they also reported that, in many cases, they would assess patients' eligibility. According to the participant whose mother tongue is Farsi, language should not pose a significant barrier in today society. He suggests that tools like Google Translate effectively eliminate communication obstacles, enabling individuals like himself to participate more in such interventions.

> ***“You don’t notice much of it [effect of RPM] yet, but I think in the long term, as more people participate and we all become more familiar with this population, it [RPM] will help reduce the workload. We’ll see patients less frequently, maybe only once every year and a half. That’s where the real benefit should come from.” – Nurse specialist***

Healthcare professionals without RPM experience were generally open to its benefits, noting that regular insights into patients’ well-being could prompt timely interventions and reduce unnecessary visits. However, they expressed concerns about the frequency of use, the inclusion of patients who may benefit from RPM but are currently perceived as ineligible, and the distribution of roles across different HCPs and the patient. They also reported that having insight into patients’ medication use, especially changes that might not be communicated until a regular consultation, would be very beneficial. This information is considered crucial for understanding a patient’s disease trajectory.

> ***“There are situations where a patient repeatedly falls ill with varying symptoms, and after several rounds of treatment, both the doctor and the patient start to wonder, ‘Are we on the right path?’ A home monitoring app could add significant value here, providing insights that the patient might struggle to recall.” – Pulmonologist***

Exacerbation care process

Experiencing and recognizing exacerbations

Most patients reported being unaware of what an exacerbation was until they had experienced it one or more times, a finding that was confirmed by some HCPs. Many did not recall detailed information about exacerbations at diagnosis or during following consultations, aside from possibly receiving information in brochures. Some HCPs reported that they intentionally avoid discussing exacerbations during the initial consultation to prevent overwhelming patients. Instead, they may briefly mention that symptom fluctuations are inherent to COPD or choose to introduce the topic only after the patient has experienced an exacerbation. A patient during the co-analysis focus group, coded quotes regarding this topic as “feeling ignorant” and “confused” due to a lack of understanding about what was happening to him and the implications of worsening symptoms.

> ***“I couldn’t come back; it just kept getting worse. I should have called for help sooner, but I was inexperienced and overwhelmed. I felt completely out of breath, struggling to stay afloat, and genuinely feared it was the end.” – Patient 9***

Overall, patients reported experiencing certain exacerbations as traumatic, characterized by sensations of suffocation, a state of disorientation, and feeling deadly ill. When asking patients how they would describe an exacerbation, the definitions and recognition varied greatly among patients. Some described an exacerbation as persisting and extreme illness-like symptoms such as fever, extreme fatigue, and/or breathlessness, while others described them as short episodes of extreme breathlessness sometimes leading to a panic attack or having a “bad day”. Almost all patients admitted struggling at times with distinguishing a “normal” cold from an exacerbation. Additionally, patient responses indicated that terms like exacerbations and pneumonia are sometimes used interchangeably by HCPs. As one nurse clarified, while every pneumonia is an exacerbation, not every exacerbation is pneumonia.

> ***“I: ‘You mentioned earlier that you have experienced exacerbations.’***
>
> ***R: ‘Yes, yes. Quite a lot actually. I’ll have three good days, and***

then I feel worse. That's essentially another exacerbation. Although, for many patients, it's very difficult to recognize what an exacerbation really is.'" – Patient 1

HCPs define an exacerbation as a worsening of symptoms for at least two to three days, with increased coughing and green sputum. They noted that patients often have difficulty recognizing an exacerbation promptly, even with a COPD action plan designed to guide early symptom identification and management.

Acting upon exacerbations

Delays in seeking help and contacting HCPs remain a concern in COPD care, confirmed by both patients and HCPs. Most of the participants, both patients and HCPs, were familiar with the COPD action plan or had heard of something similar. Nevertheless, some HCPs acknowledged that usage of the plan is not integrated into their standard care process. Most patients reported becoming acquainted with the COPD action plan during rehabilitation, where they received practical tips and theoretical information on effective exacerbation recognition and daily energy management. All patients who underwent rehabilitation were highly enthusiastic and felt they gained significant insights into their condition.

"It's usually introduced to people who experience frequent exacerbations, and then the pulmonary nurse is involved to develop such a plan with them. Ideally, we would provide it to everyone, but we simply don't have enough resources for that." – Pulmonologist

The use of the plan varies significantly, some patients follow it diligently, while others use it inconsistently or still face challenges in seeking timely help due to uncertainty about symptom severity or underestimation and trivialization of symptoms. Additionally, friends, family, and physiotherapists often alert patients to worsening shortness of breath or other physical changes, prompting them to contact their HCP.

Some patients in secondary care indicated that they often consult their GP first for advice and medication. While pulmonologists generally have no objections to patients contacting their GP, they prefer to be informed about any exacerbation treatment to monitor disease progression. The interviewed physiotherapists mentioned occasionally contacting patients' GPs to inform, advise, or discuss the patients' conditions, given their frequent contact with patients. However, this interaction is often perceived as one-way communication and generally lacks a well-established multidisciplinary collaboration.

"I don't use it [COPD action plan]. No, I don't really need it. It's intended for situations where someone is with me and I might have an exacerbation. So my friends know they can refer to the plan because that's what it's for. At least, that's how I understood it. Or isn't it?" – Patient 2

In some cases, patients have a clear protocol for managing symptom worsening, such as contacting their HCP for medication advice or scheduling a physician visit. Some patients had established agreements with their physicians, allowing them to initiate treatment independently when suspecting an exacerbation. For instance, an illiterate patient used a designated phone number to reach an NS during specific hours, to address his worsening symptoms. One GP recommended patients to call if coughing persisted two days, despite the clear guidance, they still experienced delays in patients seeking medical help. Furthermore, many patients felt the general definition of an exacerbation did not match their symptoms, such as lack of persistent coughing, green sputum, or fever, confusing whether to contact their HCP.

"I have a card with the phone numbers and names of the nurses. You can call them during specific hours if it seems like things are worsening, like a telephone consultation for COPD." – Patient 13

Experiences and expectations of RPM during exacerbations

Patients experienced with RPM often had a well-established process in place already for managing symptom worsening. Consequently, they questioned the app’s value in addressing exacerbations. They often did not consider using the app for worsening symptoms if they had already completed their weekly questionnaire, as it might have been sent on Monday, while symptoms began on Wednesday. Although some patients received advice from nurses monitoring the app varying from, “wait and see” to “increase medication usage”, or “visit your HCP for a check-up”, when reporting worsened symptoms. The majority did not find it effective in preventing or identifying exacerbations earlier. One patient specifically mentioned not feeling more secure or empowered by the app. Yet, most patients viewed it positively, appreciating the continuous insights into their well-being over a longer timeframe, its visibility for HCPs, and the ability to easily contact HCPs when needed. Although they rarely use the chat functionality for urgent medical support.

> ***“You would naturally get a sense of whether things were improving or worsening. And if things weren’t going well, I would automatically receive a message from the nurses saying, ‘It seems like you’re not doing well, maybe you take more medication’ or ‘Be cautious and if it worsens contact your GP’. Overall, I was quite pleased with it.” – Patient 3***

> ***“They rely on the information I provide. And that time the exacerbation happened on Wednesday, not on a Monday or Sunday. In such cases, I don’t think about it [name of application]. I don’t consider calling my pulmonologist, I call my GP first. I’m not saying they wouldn’t have helped if I had called, but the app wouldn’t have been useful in that situation.” – Patient 9***

The interviewed patients unfamiliar with RPM processes had varied perspectives and expectations regarding its use in exacerbation management. Some felt it could enhance their understanding of COPD and enable earlier detection of exacerbations. These patients, who often already monitored their saturation, blood pressure, or heart rate, were open to using an objective measurement system for predicting exacerbations. Conversely, others expressed skepticism, emphasizing the importance of physically observing patients and evaluating their overall presentation, even if conducted virtually. Furthermore, most patients felt it would be more convenient to interact with HCPs familiar with their health status to avoid repetitive discussions, reduce data misinterpretation, and foster trust.

“It would be great if there would be something that could detect it [exacerbation] before I do. It would feel like having a buddy that helps keep an eye on me.” – Patient 5

“Last time I mentioned over the phone that I wasn’t feeling well, but she said, ‘the data showed I was fine’, and, in those situations, I shut down, because I think to myself, I’m not a machine. No, I can’t say I have much confidence in home monitoring.”– Patient 10

Most HCPs, regardless of their experience with RPM, believed that RPM could aid in the earlier identification of exacerbations, with a system incorporating both objective and subjective measurements being the most beneficial. HCPs generally preferred patients to proactively notify them through the RPM system. Healthcare professionals should intervene only if the system indicates concerning outcomes without the patient initiating contact. One physiotherapist suggested that HCPs should be responsible for monitoring the data and contacting patients, as patients might not be skilled to interpret medical data.

“I think a questionnaire and some form of objective

> ***measurements could add even more value, where the breathalyzer could anticipate an exacerbation for instance. But it would need to be combined with the symptoms a person is experiencing." – Pulmonologist***

Overall, the majority of the patients and HCPs were receptive towards RPM and anticipated benefits in early exacerbation detection. However, various participants noted that successful implementation requires clear guidance, logistics, defined roles, and responsibilities between different HCPs and patients, and careful consideration of RPM's content and frequency of use. Additionally, maintaining a human element in COPD exacerbation management is crucial, as exacerbation presentations can strongly vary among patients.

> ***"Clear agreements need to be made about responsibilities, and if I'm not the primary caregiver, I don't think I am the right person to handle it. Other arrangements can be made, but they need to be clear at the regional level. Otherwise, it becomes unmanageable for the pulmonologist, especially with agreements involving multiple general practitioners. It's best to coordinate such arrangements regionally to avoid overwhelming the hospital." – General practitioner***

Discussion

Principal Findings

This study encompasses the initial stage of co-creation, a contextual inquiry, to develop a novel RPM device and corresponding care process for COPD exacerbation management. The study's aim was subdivided into three objectives, 1) Explore stakeholders involved in COPD exacerbation care, 2) Understand current COPD exacerbation care, and 3) Assess stakeholder experiences and expectations regarding RPM in COPD care. These objectives were addressed by three themes identified in the results, (i) The diagnosis and daily impact of COPD, (ii) The regular COPD care process, and (iii) The exacerbation management process, and RPM's role in these processes.

Seven main stakeholders were identified as prominently involved in COPD care: patients, pulmonologist, GP, NP, NS, physiotherapist, and informal caregiver. Our findings revealed a lack of national uniformity in COPD care and exacerbation management. Information provision about COPD and exacerbations differs per HCP and the recognition of COPD exacerbations remains challenging mainly for patients.

Patients with RPM experience generally expressed positive attitudes about the concept of RPM, but many questioned its effectiveness for early recognition of exacerbations. Most patients without RPM experience were receptive towards its use for symptom tracking and improved communication with HCPs, though some expressed concerns about reduced in-person care and for decision-making to rely more on data rather than patient evaluation.

HCPs were overall receptive to its use because it offers insights into patients' health status in between visits and might help in allocating resources more efficiently. However, they indicated that RPM process requires clear guidance, defined roles and responsibilities between HCPs and patients to ensure effective usage. Furthermore, they did not expect all patients to be eligible for RPM as language and technical barriers still pose challenges.

Comparison to Previous Work

State-of-the-art literature was compared to our findings based on themes identified in the results. Despite the patients in this study repeatedly highlighted the lack of information regarding exacerbations at diagnosis and throughout their COPD care, which is also reflected in earlier qualitative research [32,48]. Hayes et al.[49] conducted a questionnaire among UK patients to assess their perspectives on COPD care, where 23% reported either missing information about their COPD diagnosis or not understanding the information provided. Additionally, 33% of hospitalized patients indicated they had not received any medication or information upon discharge [49]. Furthermore, a review exploring patients’ needs in advanced stages of COPD concluded that information about the implications of the disease is often insufficient [50]. These findings suggest a lack of information provision experienced by patients throughout various stages of their disease [48-51].

The implications in the daily lives of patients with COPD found in our study were in line with existing literature where patients often address their forced reliance on others due to their physical impairments and their inability to even conduct simple tasks and domestic chores [51]. Furthermore, COPD is often linked to mental health challenges as patients cope with accepting their diagnosis, declining health, daily adjustments, and exacerbations [52].

For their general COPD care, patients typically visit their GP or pulmonologist (bi)annually to review test results, discuss their health status, and adjust medication. However, some patients repeatedly mentioned a lack of communication and information from their physician. Previous research showed that open communication and information sharing strengthen the patient-HCP relationship [50]. This aligns with our findings, where some patients felt overlooked by their pulmonologist when their questions were ignored or when there was a lack of transparency about their health status. According to literature, chronically ill patients are curious and value information provision about their health [53]. Our study, along with previous research, confirms that COPD patients are eager to learn more about their condition [54]. In some cases, patients see the NP or NS in addition to or instead of their physician, as they often provide more detailed and practical information and have more time to address patients' questions. However, the British Lung Foundation reported that only 41% of patients felt confident in their understanding of COPD and that their HCP had explained where to find information and advice [55]. Additionally, approximately 75% of the respondents did not receive clear support to manage their care and missed an agreed written plan on managing their COPD [55]. Furthermore, HCPs noted that language barriers often diminish the quality of care and information provision. Borge et al.[56] highlight this gap, noting that there is a disparity between the needs of COPD patients with low health literacy and the ability of HCPs to address those needs [56]. This lack of understanding of patients' needs may reflect situations where language barriers impact the quality of care provided and received, suggesting that training and enhanced communication are necessary to bridge this gap [56].

The gaps and inequities in healthcare appear to widen with technical processes like RPM [57]. HCPs who participated in this study acknowledged that they gauge patients' suitability for processes such as RPM, a finding consistent with existing literature [58]. Studies on HCPs' views of RPM adoption, identify patients' lack of digital and health literacy as a major barrier. They also highlight that providers often hesitate to offer RPM to their most vulnerable and ill patients, limiting participation among those who could benefit the most [19,33,34]. These factors may unintentionally widen the gap within the Dutch COPD population by favoring patients who are more engaged with their disease or more willing to participate in such processes [33]. Despite the anticipated inequities in RPM and the skepticism reported in the literature regarding the effectiveness of wearables in COPD RPM, the interviewed HCPs remained optimistic about RPM’s future [58,59]. This optimism is in line with the positive responses of HCPs to telemonitoring during COVID-19 [60]. The discrepancy in experiences and expectations might be due to the differences in RPM devices and processes such as questionnaires or telemonitoring communication platforms compared to wearables. Previous studies highlight a preference for insights into vital parameters of COPD patients, such as oxygen saturation, heart rate, and physical activity. They also emphasize the positive complementary effect of measuring objective data alongside patients' subjective experiences [30,58].

Most patients in this study who used RPM questioned its added value for exacerbation management and overall well-being. These patients were often knowledgeable about their condition and had already established clear communication or agreements with their HCPs regarding exacerbation management, potentially leading them to perceive RPM processes as redundant or cumbersome, which is in line with literature [32]. The absence of perceived added value aligns with findings from a study assessing the app used by some of our participants, which found no significant reduction in exacerbation-related hospitalizations, although it did report decreased COPD-related healthcare costs [29]. Nevertheless, the review by Nagase et al.[27] highlights that RPM can lead to better disease control, reduced anxiety, and a decreased burden on family members. These benefits were not frequently mentioned as experienced benefits by participants in this study, but they mainly expressed feeling more secure due to easier communication with their HCPs and the benefit of continuous insights in their well-being. However, most patients did not experience or believe that the app they used contributed to earlier recognition or action in case of an exacerbation. Conversely, most patients without RPM experience believed that RPM could aid in early recognition of exacerbations, aligning with a qualitative study in which patients felt it could enhance their awareness of symptom deterioration [32] . This highlights a clear discrepancy between the perceived and experienced added value of RPM in COPD care and exacerbation management among patients. Nevertheless, patients without RPM experience also expressed concerns about the lack of human interaction and the excessive data reliance without in-person contact, which is also reflected in the literature, where patients frequently prefer hospital visits over brief video consultations [19,61]. Yet, literature also suggests that patients may feel empowered by the available data, as it allows them to compare their subjective experiences with objective data, thereby enhancing their understanding of their disease [27,30].

There is no standardized care process for managing exacerbations as it largely depends on the agreements between patients and HCPs as well as patients' ability to recognize when action is required, which aligns with our findings [22]. Many patients continue to struggle with distinguishing between disease-related fluctuations, common colds, and exacerbation symptoms [8,21]. A widely known tool for early exacerbation recognition is the COPD action plan, aiding patients in identifying deteriorating symptoms early and providing personalized guidance, such as adjusting medication or contacting HCPs [25,36]. Most interviewed patients were familiar with this plan, although HCPs acknowledge that they do not introduce this to every patient. However, some patients familiar with the plan, continued struggling with recognizing exacerbation-related symptoms, which is line with previous findings [26]. Schrijver et al.[26] also reported other barriers such as disliking daily symptom monitoring and the complexity of symptom diaries and action plans [26]. Participants in this study expressed a willingness to monitor daily symptoms through RPM if they believed it would enhance their COPD care or overall health status. The literature offers no clear consensus on the efficacy of RPM in preventing exacerbations. Some studies suggest that RPM aids in early exacerbation detection, reduces exacerbation frequency, and lowers hospitalization rates, while others find little significant evidence [23,62,63]. Studies demonstrating beneficial outcomes typically focus on measuring vital parameters, such as saturation, forced expiratory volume, forced vital capacity, temperature, and weight. They may also incorporate questionnaires like the Clinical COPD Questionnaire and assess physical activity through step counting, which could account for differences in experiences and study results [23,28,62]. The literature shows a wide variety of existing RPM devices and processes, yet this study emphasizes the variety in experienced and perceived added value. It pinpoints the need to refine existing RPM devices and processes to accommodate efficient, effective, and inclusive COPD exacerbation management for the individual patient.

Strengths and limitations

An important strength of this study is its uniqueness in which this study has performed the initial co-creation phase, guided by the CeHRes roadmap, with such detail within this population. We have systematically performed various iterative research activities which strengthened the co-creative nature of this study and the final findings. In line with this, the analyses of the interviews were partly conduced in co-analysis with patients with COPD, which, to our knowledge, is the first study to have performed co-analysis with this population. The co-analysis allowed for the involvement of prospective end-users throughout all the aspects of this first co-creation phase, and to move beyond the researchers' perspective during analyses [42]. Furthermore, studies often focus solely on either patients or HCPs, neglecting to address both perspectives in COPD care, exacerbation management, and RPM processes, or fail to include caregivers and other relevant stakeholders hampering the comprehensiveness of co-creation in this respective field [38,64]. This study addressed this limitation by incorporating a variety of stakeholders and perspectives. Lastly, co-creation processes frequently involve knowledgeable patients who have adequate technical or language proficiency, potentially increasing health disparities [65]. In contrast, this study involved individuals with diverse migration backgrounds, educational levels, and digital and literacy proficiencies from the outset of the co-creation process. This approach established a strong foundation for future co-creation phases and ensured inclusivity from the start, aiding to develop a novel RPM device and corresponding care process to accommodate a broad range of end-users' needs and requirements.

One of the limitations was that patients unfamiliar with RPM might have found it challenging to envision the processes and articulate their expectations, particularly those with language barriers or lower educational levels. In these cases, researchers attempted to explain RPM by using an example of an existing process, providing limited details to avoid biasing their responses. Nevertheless, it is possible that patients' responses about their ideal RPM device and process were biased, as their creativity may have been hampered after hearing the researcher’s explanation. This could limit the extent to which their answers reflected original, imaginative thinking and restricted out-of-the-box ideas. Furthermore, their perceived expectations may have been skewed by the way potential RPM processes were presented, leading to the possible idealization of RPM's added value to their COPD care and overall well-being. Furthermore, most participants were from the mid-south of the Netherlands, which may limit the generalizability of the findings to the northern regions, as differences were observed even between adjacent areas. Given the greater remoteness and longer distances to hospitals in the northern Netherlands, the perceived and experienced added value of RPM processes may differ significantly from the findings of stakeholders in the central and southern regions of the country.

Implications

This study provides a solid foundation for the subsequent co-creation steps (value specification, design phase, operationalization, and evaluation) in developing a novel RPM device and corresponding care process for COPD exacerbation management. It allows for the extrapolation of values and needs during the value specification phase and their translation into product and process requirements during the design phase to develop a prototyped novel RPM device and blueprinted corresponding care process blueprint, such as the breathalyzer. Additionally, the methodology of this study can serve as a guide for other co-creation efforts, whether in similar or different populations or conditions. The findings also offer several opportunities to enhance clinical practice in COPD exacerbation management and RPM processes. Future research should focus on further developing and improving RPM devices and especially corresponding processes. This involves striking the right balance between collecting objective measurements and subjective patient-reported symptoms through RPM, improving communication amongst HCPs and between HCPs and patients in both primary and secondary care, providing clear information and transparency on COPD, medication usage, health aids, exacerbation management, and improving inclusivity. It also involves refining how HCPs evaluate patients' eligibility for exacerbation management processes, such as RPM, to ensure that all patients can benefit from new interventions rather than only those deemed sufficiently skilled.

Conclusion

This paper provides a detailed overview of the context in which a novel RPM device and its corresponding care process may be implemented. It offers insights into key stakeholders, regular COPD care processes, the variation in exacerbation management, information provision, and experiences and expectations regarding RPM processes. Improving the information and transparency provided to patients about COPD and exacerbations is essential for optimizing COPD care. The overall willingness to use RPM presents opportunities to enhance COPD exacerbation management. However, this study highlights the need to identify and target appropriate patients for RPM, particularly those often perceived as ineligible due to technical or language barriers. Additionally, the perceived value of RPM must be demonstrated to patients and HCPs to facilitate acceptance and uptake. The findings highlight opportunities to refine COPD exacerbation management and RPM processes by improving devices, balancing objective data with patient-reported symptoms, strengthening communication between patients and providers, and ensuring inclusivity by involving key stakeholders throughout the entire co-creation process starting from the initial phase.

Acknowledgements

First and foremost, we would like to express our gratitude to all the participants in this study, both patients, HCPs, informal care giver, and policy advisor. Furthermore, a special thanks to the employees of the Dutch Lung Health Organization for their support in recruiting patients with COPD for the interviews. A special thank you goes to Nicole, who coordinates the Dutch Lung Health Organization sessions in Utrecht and organized the co-analysis focus group. We also extend our thanks to Piet van Eck, Gert Otter, Michelle de La Roij, and Fleur Heijermans for their participation in the project group meeting. Additionally, we appreciate the administrator of the Lung Patients Facebook group for their trust and posting the recruitment flyer within the group. Lastly, we would like to thank our partners in the Breath-Sense consortium for their participation and contributions, as well as the European Innovation Council for funding this study through the EU Pathfinder Grant for the Breath-Sense project. Furthermore, ChatGPT was utilized to improve sentences grammatically.

Conflicts of Interest

All authors declare that they have no conflict of interest. Two employees of the Breathalyzer developing company were involved in the Project Team meeting to ensure all stakeholders are involved throughout the development to serve the co-creation element. However, no employees were involved in the execution, analysis, or reporting of the study.

Abbreviations

CeHRes: the centre for eHealth research roadmap
COPD: Chronis Obstructive Pulmonary Disease
GDPR: General Data Protection Regulation
GP: general practitioner
HCP: healthcare professional
RPM: remote patient monitoring
NP: nurse practitioner
NS: nurse specialist
UAVG: Dutch Act on Implementation of the General Data Protection Regulation
WMO: Dutch Medical Research Involving Human Subjects Act

Data Availability

The datasets analyzed during the study are not readily available because participants did not consent to share the data with other parties.

Authors’ Contributions

JJA and MJK contributed to funding acquisition, conceptualization, methodology, data gathering and analysis, and reviewing the manuscript. AM contributed to the conceptualization, methodology, data gathering and analysis, transcribing, draft preparation, and editing the manuscript. EB contributed to data gathering and analysis, transcribing and reviewing the manuscript. NHC contributed to funding acquisition and reviewing the manuscript.

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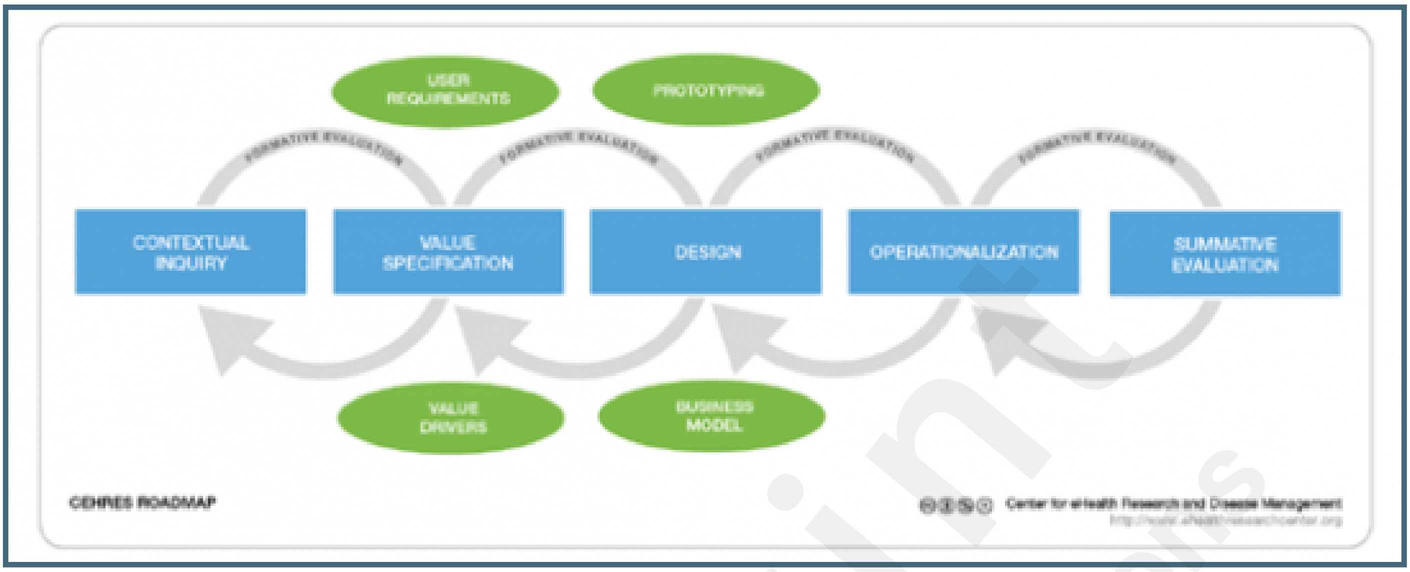
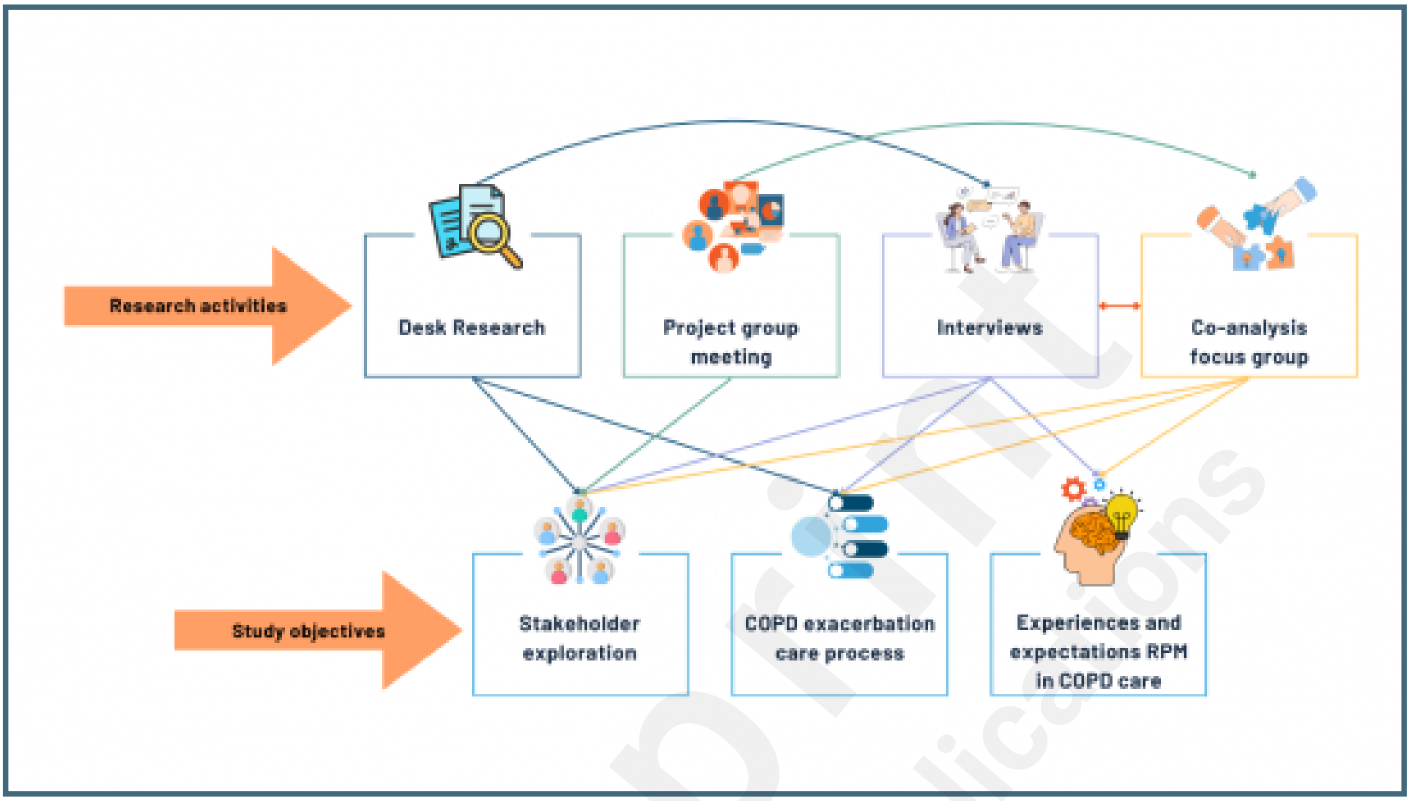
Supplementary Files

Figures

CeHRes Roadmap for the development of eHealth technologies. Derived from van Gemert-Pijnen et al., (2011).



Overview of research activities in the contextual inquiry phase, and the corresponding contribution to the study objectives.



Recruitment flowchart elucidating the different recruitment and inclusion streams to corresponding research activities. HCP = healthcare professional, Pat. = Patient, GP = General Practice.