Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

From Values to Requirements: Co-creating Remote COPD Monitoring Solutions

Atena Mahboubian

a.mahboubian@lumc.nl

Leiden University Medical Center

Mirjam WM Biemond

Leiden University Medical Center

Hannah F van Bruggen

Leiden University Medical Center

Sophie Harding

King's College London

Elizabeth A Steed

Queen Mary University of London

Niels H Chavannes

Leiden University Medical Center

Richard Russell

King's College London

Marise J Kasteleyn

Leiden University Medical Center

Jiska J Aardoom

Leiden University Medical Center

Research Article

Keywords: COPD, co-creation, participation research, value specification, remote patient monitoring, development process

Posted Date: November 1st, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10904764/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Preventing COPD exacerbations is essential for patient well-being and reducing healthcare burden. A non-invasive breath analysis device is being co-created with patients and healthcare professionals (HCPs) to support the early recognition of exacerbations through remote patient monitoring (RPM). This study aimed to identify key values related to this device and the associated COPD care process, and translate these into specific requirements.

Patients (n = 63) and HCPs (n = 42) from the Netherlands and United Kingdom participated in three qualitative research activities: interviews, focus groups, and patient and public involvement (PPI) sessions. These aimed to : 1) explore and identify values; 2) validate values; and 3) translate them into requirements.

Participants highlighted 38 device- and care process related values, these were grouped into nine categories; 1) Patient-centred care and patient outcomes, 2) User-friendliness and inclusivity, 3) Agreements on RPM responsibilities, 4) Patient empowerment, 5) Information provision and guidance, 6) Optimizing care delivery, 7) Implementation process, 8) HCP care provision, 9) Safety and reliability. Patients and HCPs translated the 38 values into 142 concrete products (e.g., device blocks after frequent use) and process (e.g., yearly personal check-in) requirements.

This study demonstrates the active involvement of patients and HCPs in the early stages of development, supporting the alignment of RPM solutions with their values as well as existing COPD care processes. The findings provide a strong foundation for the development of digital innovations in COPD and other chronic pulmonary care, and offer transferable insights for co-creating patient-centred technologies beyond the breath analysis device.

Take home message

This study provides practical requirements for co-creating chronic care innovations with end-users and stakeholders supporting continuous involvement and implementation in real-world setting.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is the third leading non-communicable disease worldwide and is often characterized by exacerbations. Exacerbations involve persistent symptom worsening, causing irreversible pulmonary impairment, psychological distress, increased risk of hospitalization, and higher healthcare costs(1–4). However, early exacerbation recognition remains challenging, as symptoms often resemble daily fluctuations of COPD, yet timely identification and treatment is crucial to minimize their impact on patients' well-being(2, 5, 6).

Existing care approaches, including remote patient monitoring (RPM), aim to facilitate early exacerbation recognition by increasing patients' awareness of their symptoms via physical measurements and

patient-reported outcomes, while providing healthcare providers (HCPs) with better insight into patients' health status(6–8). This can support earlier treatment, prevent excessive deterioration, and ultimately reduce hospitalization risk(6, 9, 10). While some studies show that RPM has the potential to reduce the duration of exacerbations (9, 10) most studies still lack significant evidence on reducing the number of exacerbations or hospitalizations(11, 12). This highlights the inconsistency in evidencing its effectiveness(6, 10). Additionally, patients report limited perceived value of existing RPM approaches for early exacerbation recognition(13, 14). These experiences and outcomes might be caused by a misalignment between existing interventions and the needs, values, and perspectives of stakeholders, including patients and HCPs(13, 15, 16).

Actively engaging key stakeholders in a collaborative manner throughout product or service development (i.e., co-creation) can help bridge this misalignment(17, 18), enhancing the likelihood of innovation acceptance and effective integration into existing care processes(18–20). Therefore, the European project BreathSense uses co-creation to develop a breath analysis device for RPM and the corresponding care process for COPD exacerbation management. The development process is guided by the Centre for eHealth Research and Disease Management (CeHRes) roadmap, a stakeholder-driven framework for developing and implementing eHealth technologies, consisting of five iterative phases: contextual inquiry, value specification, design, operationalization, and summative evaluation(18). The first phase was a contextual inquiry, a systematic exploration of the current care context and stakeholder perspectives, which provided insights into existing COPD exacerbation care and patients' and HCPs' experiences and expectations regarding RPM(14, 18).

This study focuses on the second phase, the value specification, and aims to inform the development of a novel RPM device and its corresponding care process by identifying stakeholders' values (i.e., what people consider important), building on data from the preceding contextual inquiry phase, and translating those into product and process specific requirements (i.e., concrete elements or features of an innovation). To achieve this we plan to, 1) develop a value list including product- and process-related values for RPM in COPD care; and 2) develop a product- and process-related requirement list based on these values.

Textbox 1: Explaining values and requirements as part of co-creation

Values

Concepts reflecting what stakeholders consider important (e.g., personal contact with HCPs). These values can relate to a wide range of aspects including practical, social, behavioural, economic, or healthcare-related issues. Fictional end-users (i.e., fictive personas) are often used to support the translation of values into design requirements[21]. Personas are a fictive profile of a representative user, described through a short life story, accompanied by a photo, background information, and key personal values[21]. In this study fictive personas were used to capture diverse end-users' perspectives and guide design from multiple viewpoints.

Requirements: Elements that a digital healthcare-related intervention should include or enable (e.g., specific features, functionalities, and content). Requirements are value-driven; one value often leads to multiple specific requirements by asking the guiding question: '*How can this value be translated into practice?*' (e.g., 'speaking to a HCPs at least once a month either physically or virtually')(22).

Methodology

Study design

This qualitative co-creation study comprised three participatory activities designed to meet the research objectives: 1. Exploring and identifying values based on previously collected data in the Contextual Inquiry phase (18) (contributed to objectives 1 and 2); 2. Validating these values (contributed to objective 1); and 3. Translating them into requirements (contributed to objective 2). Figure 1 visualizes the study objectives and corresponding activities described above. Furthermore, this study is reported in accordance with the consolidated criteria for reporting qualitative research (COREQ)(23).

* hard-and software of the product, including physical device, application, dashboard. **the process for remote patient monitoring in COPD exacerbation care (e.g., communication between HCPs and patients). *PPI = public and patient involvement*; HCP: healthcare professional

Recruitment

Patients for all activities were recruited from the Dutch Lung Health Organization's (Longfonds) database using their newsletter and two COPD-Facebook groups using a flyer. Additionally, HCPs from various healthcare organizations and coordinators of patient meetings from the Lung Health Organization assisted with patient recruitment.

HCPs were contacted by phone or email to invite them to participate. Additionally, a flyer was posted on LinkedIn to recruit non-end-users (e.g., other HCPs, policy advisors in primary and secondary care, IT staff, and managers) for the last activity.

Data collection

Exploring and identifying values

The value list was derived from previously collected data (i.e., 34 interviews and 4 focus groups with patients and HCPs) from the contextual inquiry phase. Detailed information about the data collection procedure have been described elsewhere(14). Interviews lasted 40–90 minutes and focus groups 90–120 minutes and were conducted using a semi-structured guide and continued until saturation was reached.

Validating values

Two project group meetings, each lasting 30–60 minutes, were conducted with patients and secondary care HCPs to discuss the initial draft of the value list. Concurrently, the list was shared with patient and HCPs participants from the previous contextual inquiry phase (14) for further feedback.

Additionally, two in-person PPI sessions were held with patients and their informal caregivers to discuss the COPD management process and the needs and values of patients in the UK context (N = 8) to assess applicability within that country. The sessions lasted 90–120 minutes and were guided by the developed value list.

Translating values into requirements (dup: abstract ?)

Focus groups with patients and HCPs were held and lasted approximately two hours. Values were systematically translated into requirements using mind maps (Fig. 2) including fictive personas (Appendix A), to incorporate multiple perspectives and ensure the requirements reflected diverse end-user needs (24). Participants worked in small groups (2–4 people) moderated by at least one researcher (AM, MB, HB, JA, MK, JS). During this process, researchers asked: '*How can this value be translated into practice?*, thereby translating the values (e.g., "personal contact with HCPs") into practical requirements (e.g., "speaking to an HCP at least once a month, either in person or virtually")*'*. Each mind map covered two to three value categories and was discussed for 30 to 50 minutes, after which they received a new mind map. The focus groups continued until saturation was reached. Lastly, participants completed a demographic questionnaire covering their age, sex, profession, and for patients clinical characteristics such as years of COPD and classification.

The sessions with non-end-users focused on better understanding the procedural requirements for developing, implementing, and evaluating eHealth innovations. The sessions were performed online and lasted 60–90 minutes. Before the session, participants completed a characteristics questionnaire covering their age, sex, and profession.

Data analysis

Exploring and identifying values

Figure 3 *Value list development process. The seven steps visualize the analysis and development process of a value list, starting with the interviews and focus groups conducted in the previous co-creation step (contextual inquiry)[14].* Consensus meetings with the research team until consensus was reached.

Validating values

The project group participants and previous study participants – both patients and HCPs - provided feedback on the value list, which enabled the researchers to improve its clarity.

The PPI sessions with patients and their informal caregivers were audio recorded and transcribed. A female researcher in the UK (SH) analysed the transcripts by allocating quotes to the existing values in the list developed by the Dutch research team. Where needed, additional values were added.

Translating values into requirements

Thematic analysis was used to analyse the data from the translating exercise sessions(24). First, researchers familiarized themselves with the data by transcribing the focus groups and interviews verbatim. Thereafter, the validated value list was used to deductively code data into product- and process requirements, based on the CeHRes roadmap definitions. This approach involved assigning data segments to predefined categories based on the validated value list and the CeHRes roadmap framework.

For the sessions with non-end-users, requirements related to the procedural development, implementation, and evaluation of an innovation were identified using the semi-structured interview guide (Appendix B).

All transcripts were independently coded by one to three female researchers of (AM, MB, or HB and JS) using Atlas.ti (version 24), followed by consensus meetings to finalize the coding scheme. The next steps encompassed compiling the identified requirements iteratively reviewing for overlap and duplications, resulting in a final requirement list. Finally, the requirements were labelled at micro (individual), meso (organizational) and macro (contextual) level. No additional field notes were made or analysed during the focus groups.

Reflexivity

All researchers were female, two were PhD candidates (SH and AM), two were assistant professors (JA and MK), and four were Master's students in Medicine. AM supervised the Master's students during the preparation and facilitation of the focus groups. The Master's students' medical background and familiarity with COPD facilitated communication with participants but may also have influenced the interpretation of participants' accounts by shaping expectations regarding COPD care and digital health. The PhD candidates and assistant professors had prior experience conducting qualitative interviews and focus groups. AM had previously conducted interviews and focus groups with patients with COPD and HCPs involved in COPD care and was therefore familiar with some participants in the value translation session. While this familiarity may have fostered trust and open discussion, it may also have influenced participants' responses through social desirability or shared assumptions. Participants were therefore informed about the purpose of the study and the researchers' roles before participation.

Results

Table 1 summarizes participant characteristics included in all three research activities. For the PPI and non-end user sessions, limited demographic information was available or applicable. Additionally, eight participants (5 females) participated in the PPI sessions in the United Kingdom of which 6 patients and 2 informal caregivers, aged 60–80 years. Eight non-end-users participated (5 females) aged 29–63, with professions varying from project leader, primary care nurse eHealth, senior policy advisor innovation, healthcare insurers, and IT managers/specialists.

Table 1
Characteristics table of all participants, patients, healthcare professionals, and non-end-users

Characteristics	Patients	HCPs
N	51	39
Mean age (SD)	68.4 (8.4)	44.6 (10.5)
Female, n (%)	26 (51.0)	30 (76.9)
Ethnicity, n (%)		-
Dutch	49	-
Iranian	1	-
Turkish	1	-
Years of COPD diagnosis, mean (SD)	12 (7.9)	-
COPD classification, n (%)		-
GOLD 2	6 (11.8)	-
GOLD 3	18 (35.3)	-
GOLD 4	20 (39.2)	-
Unknown	7 (13.7)	-
Comorbidities, n (%)	24 (47.1)	
Education patients, n (%)		-
Senior general secondary education or pre-university education	21 (41.2)	-
Secondary vocational education	17 (33.3)	-
University of applied sciences	11 (21.6)	-
University	1 (2.0)	-
Unknown	1 (2.0)	
Employment status, n (%)		-
Incapacitated or sickness benefit for work due to COPD	14 (27.5)	-
Part-time job	4 (7.8)	-
Retired	29 (56.9)	-
Volunteering	3 (5.9)	-
Self-employed	1 (2.0)	
Profession, n (%)		

Characteristics	Patients	HCPs
General practitioner	-	4 (10.3)
Pulmonologist	-	9 (23.1)
Nurse	-	14 (35.9)
Primary care	-	*8 (20.5)*
Secondary care	-	*6 (15.4)*
PA or NS		6 (15.4)
Physiotherapist	-	5 (12.8)
Speech therapist	-	1 (2.6)
Work experience (y), mean (SD)	-	18.3 (11.3)
Experience in COPD-care or innovation (y), mean (SD)	-	13.4 (7.2)

HCP: Healthcare professional; SD: standard deviation; COPD: Chronic Obstructive Pulmonary Disease; GOLD: Global Initiative for Chronic Obstructive Lung Disease; PA: Physician Assistant; NS: Nurse Specialist.

The value list including product and process related values consisted of 38 values that were grouped into nine categories (Fig. 4). Patients and HCPs translated these values into 142 concrete products (e.g., easy to clean)- and process (e.g., group training before use) requirements (Appendix C). All requirements have been colour coded based on their applicability to micro (n = 54), meso (n = 47), or macro (n = 9) level. This provides an overview of the multi-level efforts required to successfully develop and implement a novel remote patient monitoring process at scale.

Rather than being strictly device-specific, the identified requirements varied in their level of specificity. Some were more closely related to device-based solutions such as breath analysis systems, while others reflected broader needs for RPM and telemonitoring in COPD care. Examples of requirements more closely related to a breath analysis device are; ‘The device is durable (i.e., robust and water resistant), easy to maintain, has a detachable mouthpiece, and washable parts.’ (category: User-friendly and inclusive device) or ‘The device does not explicitly alert patients to a predicted exacerbation within X days and does not display prediction results to patients, in order to avoid unnecessary stress and burden.’ (category: Improving patient empowerment).

Each value category has been summarized below to describe the overarching features and focus. A detailed overview of the entire requirement list is presented in Appendix C and an interactive visual of the value *categories*, *values*, and *requirements* can be found on the National eHealth Living Lab website (https://rpm-values.nell.eu).

Patient-centred care and improved patient outcomes

This category focuses on enhancing the quality of care by ensuring rapid, accessible communication and maintaining a strong personal bond between patients and their HCPs. It emphasizes a holistic approach where patients feel "looked after" through the monitoring of both objective clinical data, their own subjective well-being, and needs. An example of a value in this category is *personalized and continuous HCP-patient contact.* This was translated into a key requirement of a yearly in-person check-up that is advised to maintain personal contact, with the option to schedule digital sessions in between if needed.

User-friendly and inclusive device

This category prioritizes the usability and accessibility of the physical and digital components of the RPM system for all patients, regardless of their literacy or digital skills. It covers requirements for portability, low-burden data entry, and inclusive features such as multilingual support and visual aids to accommodate diverse needs. An example of a value is *easy-to-use*, with a requirement that the device should be compact, handy, easy to grab, not too heavy, and capable of fitting into a handbag.

Clear agreements on responsibility of care

This category establishes the organizational framework and interdisciplinary agreements necessary to coordinate care between patients, general practitioners, pulmonologists, and nurses. It defines specific roles for data monitoring, clarifies clinical decision-making responsibilities, and ensures patients know when and how to raise an alarm. An example of a value is *well-defined care process between patients and HCPs*, which was, amongst others, translated into the requirement that contact with HCPs must be personalized, with agreements on which specific HCP to contact and who acts as a backup.

Improving patient empowerment

This category focuses on enabling patients to take an active role in managing their own disease by increasing their understanding and sense of control. It utilizes user-friendly dashboards to visualize health trends and encourages the involvement of the patient's relatives to support patient' engagement and provide additional support when needed. A value within this category was *raising understanding of the patient's own disease*, which in practical terms meant that the app should include a questionnaire to monitor whether patients can perform daily activities to make them more aware of their well-being.

Providing good information and guidance

This category ensures that patients receive tailored feedback and guidance based on real-time monitoring data. It supports self-management through personalized thresholds, clear action plans and educational materials, helping patients understand their condition and respond to changes in their health status. An example of a value is *guidance and feedback for patients tailored to the RPM data*, which was translated into, amongst others, the requirement that the app must include a clear, color-coded exacerbation plan outlining specific steps and responsibilities in case symptoms worsen.

Optimizing care delivery

This category focuses on optimizing healthcare resources by balancing the workload of HCPs with the long-term benefits of improved patient outcomes and reduced hospital admissions. It promotes early detection of symptom changes to prevent acute events and aims to make consultations more efficient using RPM insights. A value within this category is *the benefits outweigh the burden of RPM*. A requirement complying with this value is that earlier detection results in fewer visits and exacerbations, thereby reducing overall healthcare costs.

Comprehensive implementation process

This category details the strategic integration of RPM into existing healthcare pathways, emphasizing the need for broad staff support and standardized procedures. It covers the training of both patients and staff, the onboarding process, and the use of RPM during transition periods like hospitalization. One of the main things to achieve this is having *widespread support for RPM among HCPs*, which can be fostered by ensuring they 'consistently introduce RPM, supported by supervisors and agreements, reinforced through recurring evaluation moments, daily huddles, and attention rules'.

Better (or more adequate) care provided to patients by HCPs

This category focuses on using RPM data to improve clinical decision-making and interventions, such as timely initiating treatment or better managing post-hospitalization recovery. It also highlights the ability of HCPs to use data to differentiate between COPD symptoms and potential comorbidities like heart failure. An example value is *accelerated start of treatment* which can be achieved through the requirement that 'the app automatically notifies a physiotherapist when a patient returns home following an exacerbation to enable rapid re-engagement of care'.

Safe and Reliable

This category ensures the technical integrity, accuracy, and security of the RPM system to protect patient data and provide trustworthy results. It addresses the need for robust technology that functions without delays and sensors that are accurately calibrated to minimize false alerts. An example value is *reliable results, based on objective and patient-reported data*, which was translated into the requirement 'Short questions pop up about patients' well-being using visuals such as scales and icons. Patients must understand the importance of filling out these questions to ensure thoughtful and accurate responses'.

A broader perspective on innovation development and implementation

Firstly, non-end-users experienced that HCPs are often reluctant to use innovations due to concerns about patient readiness and the potential impact on workload and workflow. They indicate that key factors to support adoption include the involvement of a clinical lead to engage and inspire teams,

having a clear goal for the innovation (e.g., improving job satisfaction, reducing workload, or minimizing administrative tasks), and continuous involvement of end-users.

Secondly, clear agreements, roles, and responsibilities are crucial for the use of the innovative device. Furthermore, complex processes, such as contracting, data transfer and ownership are often overlooked in early development stages and the initial implementation phase. As data processing is often performed by commercial parties, while healthcare organizations aim to retain ownership and control, these arrangements should be explicitly defined. Similarly, technical integration frequently remains challenging due to incompatibility with existing information technology (IT) systems, emphasizing the importance of early involvement of the organization's internal IT team.

Lastly, successful widespread implementation of innovations such as RPM depends on regional and national factors. Policies supporting collaboration between healthcare organizations and commercial partners can facilitate sustainable partnerships, simplify implementation, and encourage adoption. This is closely linked to the importance of involving insurers early in development to assess resource allocation and identify funding opportunities. Certain funding structures, such as transformation funds, provide temporary support but do not offer a sustainable solution for long-term reimbursement. Consequently, according to the healthcare insurer and IT specialists implementation following a pilot often fails.

Discussion

This study identified a broad range of values related to both a future RPM device and the COPD care process, categorized into 9 categories, amongst which, *user-friendly and inclusive device, providing good information and guidance* and *safe and reliable)*, which were translated into concrete product and process requirements. These findings highlight the importance of addressing both technological and care-related aspects across micro-, meso-, and macro-levels when developing an intervention.

Previous studies that gathered input from patients and HCPs on digital health interventions - outside a co-creation context - identified needs similar to those found in our study(20, 25, 26). These include combining objective and subjective data, providing digital action plans, enabling progress tracking, and granting family access. However, these studies primarily describe participant needs without translating them into concrete requirements. Our study extends this work by translating the needs and values into specific product- and process related requirements – with prospective end-users – allowing others to adopt them to their innovation and setting. This translation is an important step for the systematic operationalization of product and process development and facilitates greater reproducibility in pulmonary health innovations, uniformity across development practices, and more effective collaboration among developer(18, 22). Although some requirements might be idealistic, ambitious, and from some perspectives considered unrealistic, all identified requirements were included to reflect the diversity in participants' perspectives and facilitate transparency.

The requirements highlight several distinct areas of disagreement between and among stakeholder groups. The main areas of conflict concerned the level of inclusivity, the roles and responsibilities related to monitoring and follow-up, and the diversity in patients' needs and preferences regarding RPM. With regard to inclusivity, HCPs indicated that patients lacking basic digital or language skills, such as the ability to use WhatsApp, should not be included in the use of RPM. In contrast, patients suggested practical ways to make the innovation more inclusive, thereby widening accessibility to a broader range of patients. The mismatch between patients' and HCPs' perspectives, as well as HCPs' concerns regarding patients' ability to engage with digital care, has previously been described in other healthcare contexts(27–29). Moreover, within constraints of time and responsibility for eligibility decisions, HCPs may tend to exclude patients rather than provide training(13, 25). To address these barriers, shared decision making (SDM) could serve as an approach for facilitating a more collaborative assessment of RPM eligibility(30). Shared decision making is traditionally utilized to navigate treatment choices and enhance patient empowerment(31), however, given the increasingly important role of RPM in chronic disease management, its principle may also be relevant for care delivery decisions regarding the adoption of such digital health processes. Applying SDM in this context may support patient involvement in decisions regarding RPM use, empower patients throughout the care process, and facilitate implementation that aligns with patients' preferences and health literacy levels.

Regarding responsibility, most HCPs prefer patients to be responsible for monitoring and taking action. However, in practice, healthcare professionals (HCPs) often remain primarily responsible for monitoring patients and initiating contact, except in acute care settings where patients are expected to contact the HCP themselves(12, 32). This suggests a persistent mismatch between the intended level of patient autonomy and its implementation in current clinical practice. Evidence indicates that applying SDM to treatment decisions enhances patient satisfaction and adherence(33). A similar approach during the RPM enrolment phase may facilitate explicit discussions regarding the division of monitoring responsibilities between patients and HCPs, allowing these roles to be aligned with patients' preferences, capabilities, and expectations.

The results of this study demonstrated considerable heterogeneity in patients' needs and preferences regarding the operationalization of RPM. While some patients preferred weekly contact with HCPs and daily device use, others favoured symptom-triggered monitoring and only initiating contact with HCPs when feeling unwell. These findings suggest that a one-size-fits all in developing and implementing innovations is non-existent and hampers successful widespread adoption, highlighting the importance for a more personalized approach to better match with patients' and HCPs' diverse needs, preferences, skills, and workflows. Health recommender systems could facilitate this tailored approach by prioritizing features based on individual user profiles, which enhances both usability and engagement(34). For instance, these systems have shown to deliver personalized treatment programs that help patients with COPD manage their symptoms and improve their quality of life(35). This suggests that integrating health recommender systems into RPM may be a promising strategy to optimize adoption and sustainable use amongst patients with COPD.

In COPD care, many health interventions and RPM processes have been studied, piloted, and in some cases even implemented in various hospitals(9, 12, 36). However, widespread (national) adoption or implementation in both primary and secondary care often remains absent(36). Based on the insights of the non-end-user participants in this study, this mismatch may be attributed to factors operating at the micro, meso, and macro levels. In line with findings from other healthcare contexts, highlighting the broader need for integrated care approaches, participants confirmed that interprofessional and cross-organizational collaboration is essential for improving COPD care and facilitating successful RPM implementation (20, 25, 37). However, certain needs and requirements ask for regional or national legislation changes(22), and often require an involved lead driver from the beginning. Furthermore, societal barriers in the implementation of eHealth in chronic lung disease often concern the lack of global privacy standards, cost-effectiveness, maintenance of infrastructure, and high training demand(38). Additionally, a practice-based report from a Dutch governmental organization (Zorg instituut Nederland) evaluated the digital care process and concluded that establishing successful cross-organizational implementation of RPM depends on cost-effectiveness evidence, which is crucial for broad acceptance and adoption(39). Taken together, these findings suggest that successful implementation of health innovations, including RPM, in COPD care requires early involvement of non-end-user stakeholders, such as organizational decision-makers members and healthcare insurers, alongside clinical stakeholders.

Strengths and limitations

The main strength of this study is the detailed execution and reporting of the value specification phase, particularly the systematic and iterative approach of three reproducible research activities, the involvement of a large group of various stakeholders throughout these activities, and the development of a concrete product and process requirements list. To our knowledge, this is the first co-creation study in chronic care that provides such a comprehensive overview. Unlike previous studies, which often included a limited number of participants or focused on a single stakeholder group, our study actively engaged patients, HCPs, and non-end-users throughout the development process. This enabled a more comprehensive understanding of the implementation context and may enhance the technology’s acceptability and uptake by ensuring close alignment with the needs and requirements of end-users and the contexts in which it will be implemented(18).

Given our co-creation and multi-stakeholder involvement approach it is considered a limitation that no organizational board members and regional or national policy advisors were involved. Additionally, despite the importance of inclusivity in co-creation, it remained challenging to include individuals who did not speak Dutch. This could significantly influence the generalizability of the design requirements, potentially resulting in a final product that lacks inclusivity and further widens the gap in healthcare equality. This risk was somehow mitigated by using different personas during the translation phase. Finally, although some requirements reflected idealistic or, in certain cases, unrealistic expectations, the identified requirements were not prioritized by the research team. This may limit their direct applicability in practice and highlights the importance of involving end-users throughout the development process

while also managing expectations to ensure that the resulting requirements remain feasible and actionable(40).

Conclusion

This study provides insight into the heterogeneous values, needs, and requirements of a broad range of stakeholders, highlighting the importance of inclusivity, responsibility, and diversity in the development and implementation of digital care processes for chronic care. The identified requirements span the micro, meso, and macro levels, emphasizing the need for a holistic co-creation approach that considers the multifaceted nature of care processes.

Our findings suggest that a one-size-fits-all approach to RPM development and implementation may not adequately capture the diversity of user needs and preferences and may contribute to widening the inequalities in care provision. Sustainable implementation of digital care processes requires alignment with the needs, preferences, and capabilities of end users. In this context, approaches such as SDM in RPM eligibility decisions may support more sustainable adherence and implementation. Continuous involvement of diverse stakeholders, including end users, insurers, and IT specialists, is therefore essential to support sustainable and scalable implementation, while bridging the gap between pilot initiatives and national adoption. The multi-level requirements identified in this study may also inform the development of other patient-centred digital health technologies.

Abbreviations

CeHRes
Centre for eHealth Research and Disease Management
COPD
Chronic obstructive pulmonary disease
COREQ
Consolidated Criteria for Reporting Qualitative Research
HCP
Healthcare professionals
IT
Information technology
PPI
Public patient involvement
PRM
Remote patient monitoring
SDM
Share decision making
UK
United Kingdom

WMO
Medical Research Involving Human Subjects Act

Declarations

Ethical approval and consent to participate

In the Netherlands, studies outside the scope of the Medical Research Involving Human Subjects Act (WMO) do not require full review by a Medical Ethical Review Committee (METC) but must be assessed by local non-WMO committees. This study received a declaration of no objection from the non-WMO review board of Leiden University Medical Centre (reference number 25-3002). The study complied with the General Data Protection Regulation (GDPR) and the Dutch Implementation Act (UAVG). All participants provided written informed consent prior to participation in the focus groups and participants were informed of their right to withdraw at any time without consequences. As the UK value validation sessions worked with PPI members, formal ethical approval was not required, but all PPI members provided written informed consent for session recording and for output to contribute to published work. This study was conducted in accordance with the principles of the Declaration of Helsinki.

Consent for publication

Not applicable.

Funding

This publication is part of the Breath-Sense project, which has received funding from the European Union's Horizon Europe European Innovation Council research and innovation program under grant 101115028. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Innovation Council. Neither the European Union nor the granting authority can be held responsible for them. Clinical trial number: not applicable.

Competing interests

Not applicable.

Author Contribution

M.K., J.A., and N.C. contributed to funding acquisition. A.M., M.B., M.K., J.A., H.B., S.H., and E.S. contributed to the conceptualization and methodology. A.M., M.B., H.B., M.K., J.A., and S.H. contributed

to the data gathering and analysis. A.M. drafted and edited the manuscript. M.K., J.A., M.B., H.B., S.H., E.S., R.R., and N.C. contributed to reviewing the manuscript.

Acknowledgement

We would like to thank all the participants who contributed to the development of such an encompassing value and requirement list. A special thanks to all the patients in the Netherlands and UK who actively participated in the sessions and were motivated to provide input. Furthermore, they would like to thank the partners in the Breath-Sense consortium for their participation and contributions.

Data Availability

The datasets generated and/or analysed during the current study are not publicly available due to the privacy of the participants who have participated in this study and signed an informed consent. However, specific sections could be made available from the corresponding author on reasonable request.

References

1. Monteagudo M, Rodriguez-Blanco T, Llagostera M, Valero C, Bayona X, Ferrer M et al (2013) Factors associated with changes in quality of life of COPD patients: a prospective study in primary care. Respir Med 107(10):1589–1597
2. Hurst JR, Skolnik N, Hansen GJ, Anzueto A, Donaldson GC, Dransfield MT et al (2020) Understanding the impact of chronic obstructive pulmonary disease exacerbations on patient health and quality of life. Eur J Intern Med 73:1–6
3. Anzueto A (2010) Impact of exacerbations on COPD. Eur Respir Rev 19(116):113–118
4. Hurst JR, Han MK, Singh B, Sharma S, Kaur G, de Nigris E et al (2022) Prognostic risk factors for moderate-to-severe exacerbations in patients with chronic obstructive pulmonary disease: a systematic literature review. Respir Res 23(1):213
5. Lareau SR, MS, Moseson EM, Slatore MA (2018) Exacerbation of COPD. Am J Respir Crit Care Med 198:21–22
6. Voulgareli I, Antonogiannaki EM, Bartziokas K, Zaneli S, Bakakos P, Loukides S et al (2025) Early Identification of Exacerbations in Patients with Chronic Obstructive Pulmonary Disease (COPD). J Clin Med. ;14(2)
7. Lenferink A, van der Palen J, van der Valk P, Cafarella P, van Veen A, Quinn S et al (2019) Exacerbation action plans for patients with COPD and comorbidities: a randomised controlled trial. Eur Respir J. ;54(5)
8. Hallensleben C, Meijer E, Biewenga J, Kievits-Smeets RMM, Veltman M, Song X et al (2020) REducing Delay through edUcation on eXacerbations (REDUX) in patients with COPD: a pilot study.

Clin eHealth 3:63–68

9. van Buul AR, Derksen C, Hoedemaker O, van Dijk O, Chavannes NH, Kasteleyn MJ (2021) eHealth Program to Reduce Hospitalizations Due to Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Retrospective Study. JMIR Form Res 5(3):e24726
10. Nagase FI, Stafinski T, Avdagovska M, Stickland MK, Etruw EM, Menon D (2022) Effectiveness of remote home monitoring for patients with Chronic Obstructive Pulmonary Disease (COPD): systematic review. BMC Health Serv Res 22(1):646
11. Janjua S, Carter D, Threapleton CJ, Prigmore S, Disler RT (2021) Telehealth interventions: remote monitoring and consultations for people with chronic obstructive pulmonary disease (COPD). Cochrane Database Syst Rev 7(7):CD013196
12. van der Burg JMM, Aziz NA, Kaptein MC, Breteler MJM, Janssen JH, van Vliet L et al (2020) Long-term effects of telemonitoring on healthcare usage in patients with heart failure or COPD. Clin eHealth 3:40–48
13. Korpershoek YJG, Vervoort S, Trappenburg JCA, Schuurmans MJ (2018) Perceptions of patients with chronic obstructive pulmonary disease and their health care providers towards using mHealth for self-management of exacerbations: a qualitative study. BMC Health Serv Res 18(1):757
14. Mahboubian A, Kasteleyn MJ, Basic E, Chavannes NH, Aardoom JJ (2025) Patients' and Health Care Professionals' Perspectives on Remote Patient Monitoring in Chronic Obstructive Pulmonary Disease Exacerbation Management: Initiating Cocreation. J Med Internet Res 27:e67666
15. Schrijver J, Effing T, Brusse-Keizer M, van der Palen J, van der Valk P, Lenferink A (2023) Facilitators and Barriers of Adherence to Multi-Disease Exacerbation Action Plans in COPD Patients - A Qualitative Study. COPD 20(1):262–273
16. Coutu FA, Iorio OC, Ross BA (2023) Remote patient monitoring strategies and wearable technology in chronic obstructive pulmonary disease. Front Med (Lausanne) 10:1236598
17. Poberezhets V, Kasteleyn MJ (2023) Telemedicine and home monitoring for COPD - a narrative review of recent literature. Curr Opin Pulm Med 29(4):259–269
18. Kip H, Beerlage-de Jong N, van Gemert-Pijnen L, Kelders SM (2025) The CeHRes Roadmap 2.0: Update of a Holistic Framework for Development, Implementation, and Evaluation of eHealth Technologies. J Med Internet Res 27:e59601
19. Vargas C, Whelan J, Brimblecombe J, Allender S (2022) Co-creation, co-design, co-production for public health - a perspective on definition and distinctions. Public Health Res Pract. ;32(2)
20. Ekstedt M, Kirsebom M, Lindqvist G, Kneck A, Frykholm O, Flink M et al (2021) Design and Development of an eHealth Service for Collaborative Self-Management among Older Adults with Chronic Diseases: A Theory-Driven User-Centered Approach. Int J Environ Res Public Health. ;19(1)
21. van Velsen L, van Gemert-Pijnen L, Nijland N, Personas (2012) The Linking Pin in Holistic Design for eHealth. The Fourth International Conference on eHealth, Telemedicine, and Social Medicine
22. Van Velsen L, Wentzel J, Van Gemert-Pijnen JE (2013) Designing eHealth that Matters via a Multidisciplinary Requirements Development Approach. JMIR Res Protoc 2(1):e21

23. Tong A, Sainsbury P, Craig J (2007) Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 19(6):349–357
24. Ahmed SK, Mohammed RA, Nashwan AJ, Ibrahim RH, Abdalla AQ, Ameen M (2025) Using thematic analysis in qualitative research. J Med Surg Public Health 6:100198
25. Biset N, Rosiere A, Lartigue V, Pochet S, De Vriese C (2024) Patients and healthcare practitioners' perspective on the development of a digital interprofessional intervention for COPD. Digit Health 10:20552076241288317
26. Alwashmi MF, Fitzpatrick B, Davis E, Farrell J, Gamble JM, Hawboldt J (2020) Features of a mobile health intervention to manage chronic obstructive pulmonary disease: a qualitative study. Ther Adv Respir Dis 14:1753466620951044
27. Borge CR, Larsen MH, Osborne RH, Engebretsen E, Andersen MH, Holter IA et al (2022) Exploring patients' and health professionals' perspectives on health literacy needs in the context of chronic obstructive pulmonary disease. Chronic Illn 18(3):549–561
28. Lee PY, Khoo EM, Low WY, Lee YK, Abdullah KL, Azmi SA et al (2016) Mismatch between health-care professionals' and patients' views on a diabetes patient decision aid: a qualitative study. Health Expect 19(2):427–436
29. Oudbier SJ, Souget-Ruff SP, Chen BSJ, Ziesemer KA, Meij HJ, Smets EMA (2024) Implementation barriers and facilitators of remote monitoring, remote consultation and digital care platforms through the eyes of healthcare professionals: a review of reviews. BMJ Open 14(6):e075833
30. Vaseur RME, te Braake E, Beinema T, d'Hollosy WON, Tabak M (2024) Technology-supported shared decision-making in chronic conditions: A systematic review of randomized controlled trials. Patient Educ Couns 124:108267
31. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P et al (2012) Shared decision making: a model for clinical practice. J Gen Intern Med 27(10):1361–1367
32. Korpershoek YJG, Hermsen S, Schoonhoven L, Schuurmans MJ, Trappenburg JCA (2020) User-Centered Design of a Mobile Health Intervention to Enhance Exacerbation-Related Self-Management in Patients With Chronic Obstructive Pulmonary Disease (Copilot): Mixed Methods Study. J Med Internet Res 22(6):e15449
33. Granados-Santiago M, Valenza MC, López-López L, Prados-Román E, Rodríguez-Torres J, Cabrera-Martos I (2020) Shared decision-making and patient engagement program during acute exacerbation of COPD hospitalization: A randomized control trial. Patient Educ Couns 103(4):702–708
34. Sun Y, Zhou J, Ji M, Pei L, Wang Z (2023) Development and Evaluation of Health Recommender Systems: Systematic Scoping Review and Evidence Mapping. J Med Internet Res 25:e38184
35. Cai Y, Yu F, Kumar M, Gladney R, Mostafa J (2022) Health Recommender Systems Development, Usage, and Evaluation from 2010 to 2022: A Scoping Review. Int J Environ Res Public Health. ;19(22)
36. Metting E, Dassen L, Aardoom J, Versluis A, Chavannes N (2021) Effectiveness of Telemonitoring for Respiratory and Systemic Symptoms of Asthma and COPD: A Narrative Review. Life (Basel). ;11(11)

37. Poot CC, Meijer E, Kruis AL, Smidt N, Chavannes NH, Honkoop PJ Integrated disease management interventions for patients with chronic obstructive pulmonary disease. Cochrane Database Syst Reviews. 2021(9).
38. Salmi EM, Basile FW, Khan FA, Watt L, Song R, Bijker EM (2025) Facilitators and barriers affecting the implementation of e-health for chronic respiratory diseases in remote settings: a qualitative evidence synthesis. BMC Health Serv Res 25(1):19
39. Nederland Z (2025) Evaluatie Passende zorg verbetertraject COPD. Zorginstituut Nederland, Zorginstituut Nederland
40. An Q, Sandlund M, Agnello D, McCaffrey L, Chastin S, Helleday R et al (2023) A scoping review of co-creation practice in the development of non-pharmacological interventions for people with Chronic Obstructive Pulmonary Disease: A health CASCADE study. Respir Med 211:107193

Figures

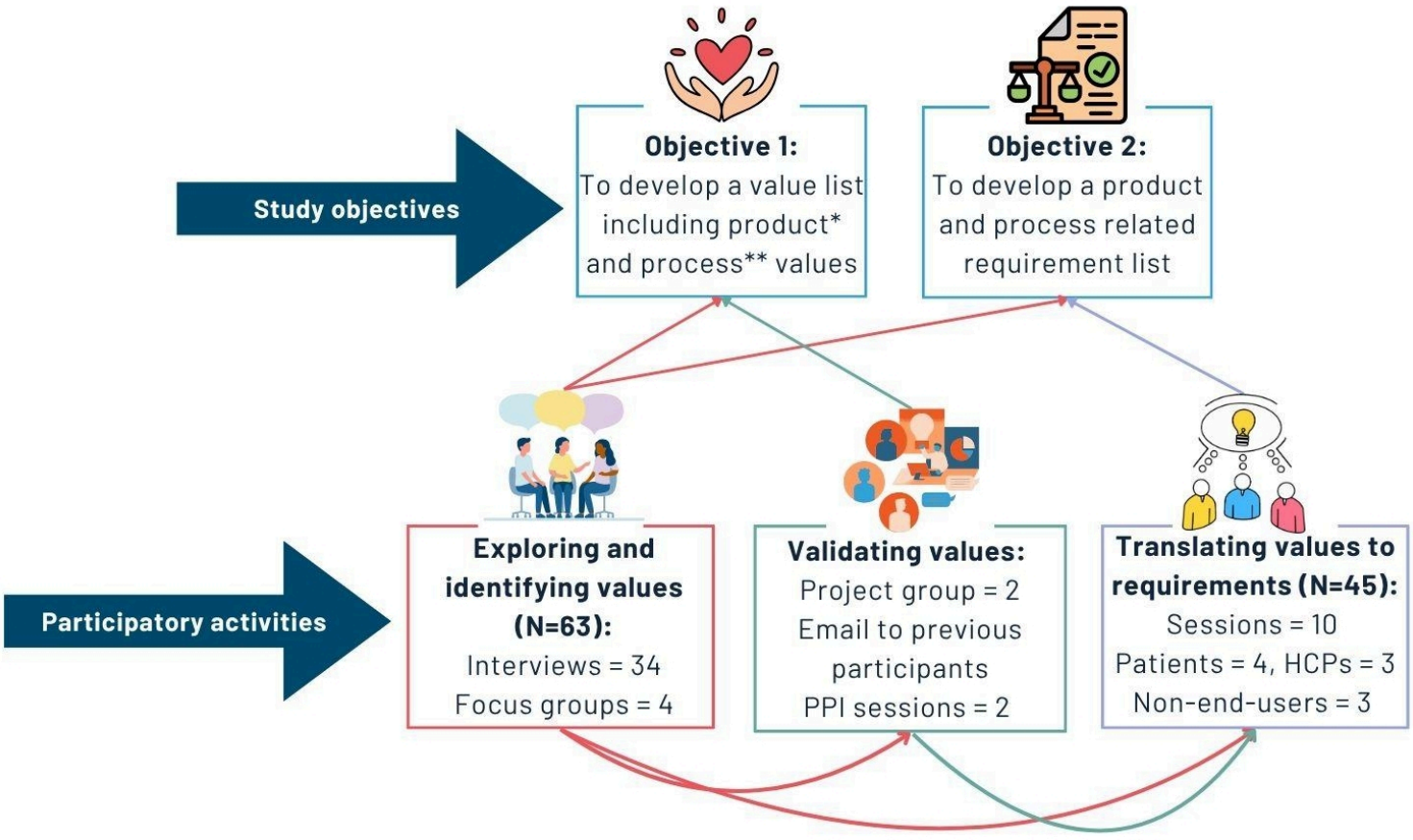


Figure 1

Overview of value specification activities and their contribution to the study objectives. Arrows between activities indicate the interdependencies in terms of input and contribution to achieving the study's objectives.

* hard-and software of the product, including physical device, application, dashboard. **the process for

remote patient monitoring in COPD exacerbation care (e.g., communication between HCPs and patients). *PPI = public and patient involvement*; HCP: healthcare professional

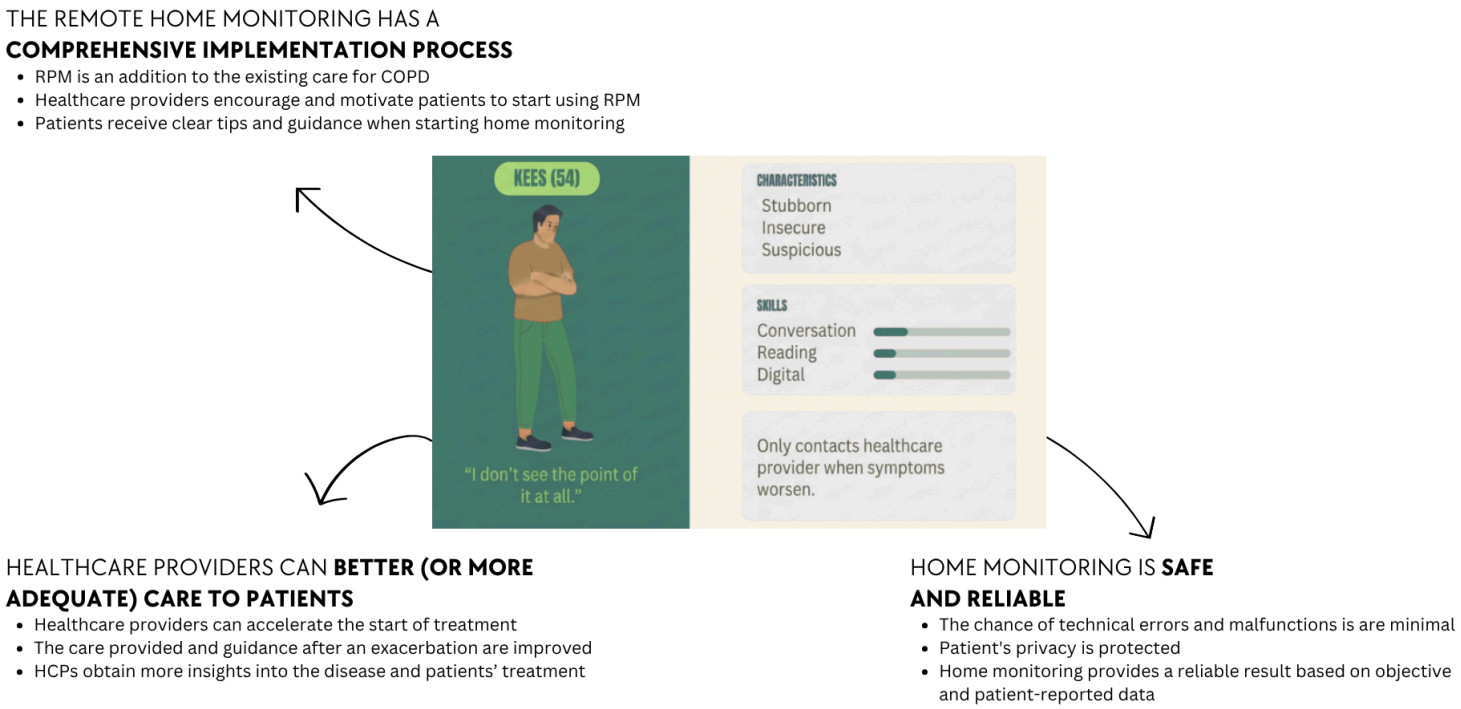


Figure 2

Mind maps used during the focus group sessions with HCPs. The centre shows two personas. Two to three value categories were included on the mind map. Requirements were added during the sessions by participants. This figure was translated from Dutch to English using the AI function of Canva.

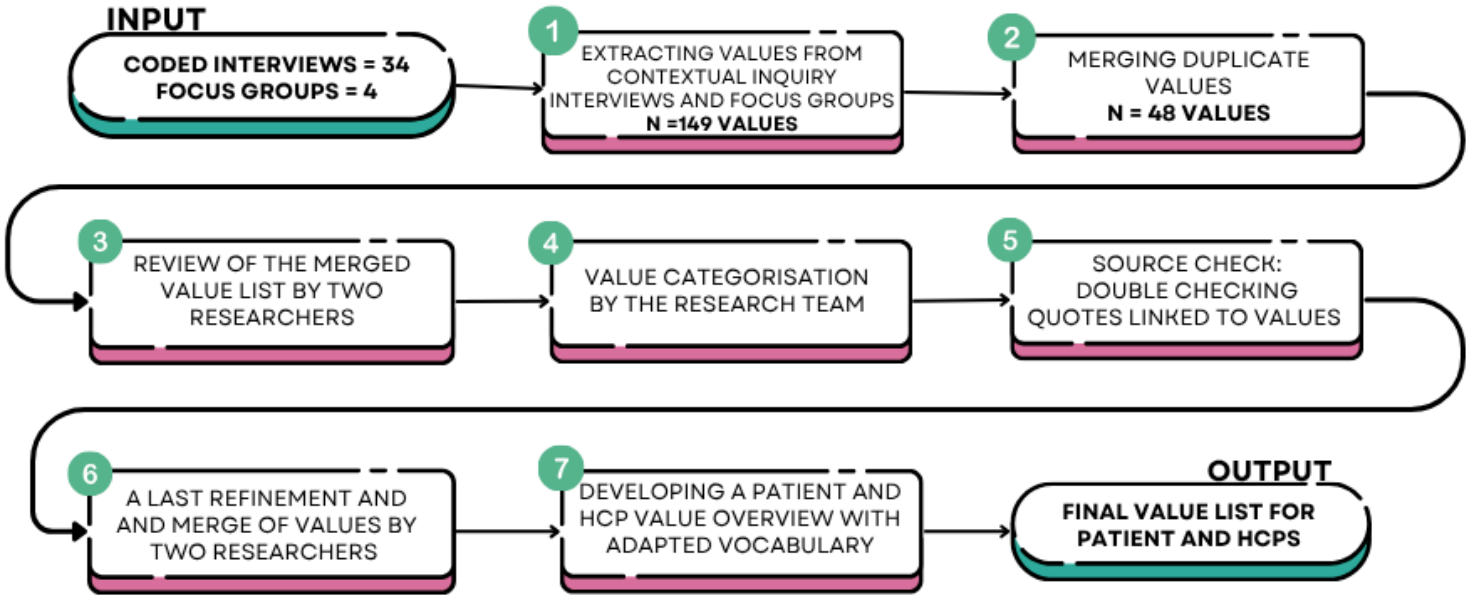


Figure 3

Value list development process. The seven steps visualize the analysis and development process of a value list, starting with the interviews and focus groups conducted in the previous co-creation step (contextual inquiry)[14]. Consensus meetings with the research team until consensus was reached.

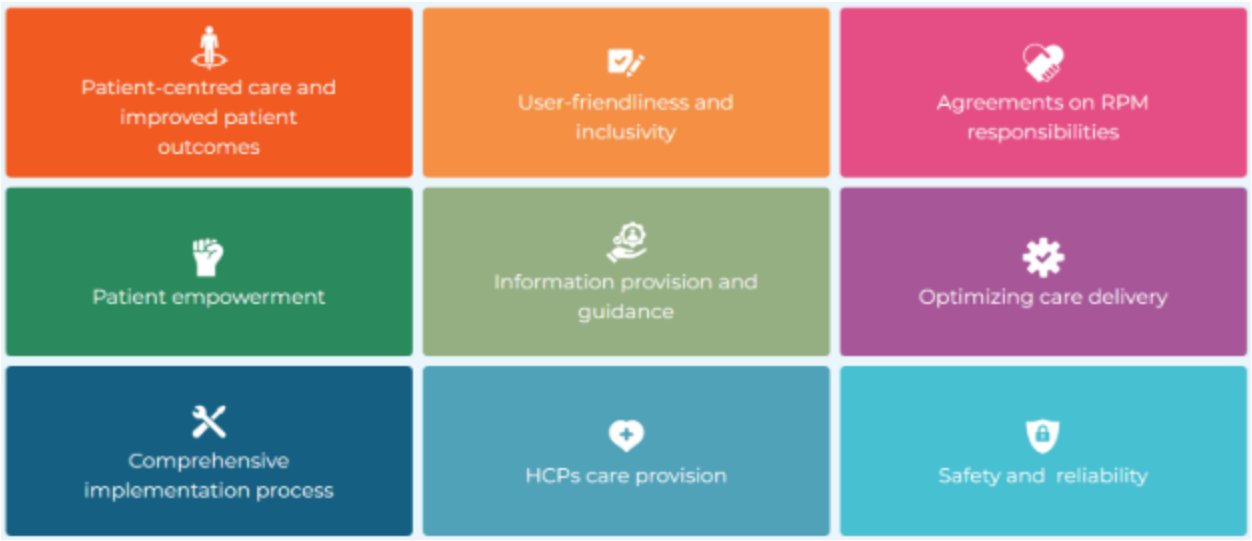


Figure 4

Overview of the 9 value categories in which the 38 values and 142 requirements have been subdivided. The entire list of the values and requirements including a summary can also be found on the website: https://rpm-values.nell.eu/

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendixBSemistructuredinterviewguidenonendusers.docx
- AppendixA.PatientandHCPspersonas.pdf
- AppendixC.Finalrequirementlist.pdf