

# Development of a ePRO-Based Palliative Care Intervention for Cancer Patients: A Participatory Design Approach

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**Abstract.** This paper describes a qualitative study conducted in the context of developing a novel ePRO (electronic Patient Reported Outcome) based palliative care intervention for cancer patients. The aim of the study was to elicit end-users' needs, judgements of the MyPal system and recommendations for improvement. A participatory design was chosen as the value of this approach has been well established in eHealth systems' design as well as the development of novel healthcare services. Focus groups with Chronic Lymphocytic Leukemia (CLL) patients were conducted at the Centre for Research and Technology (CERTH) in Greece using specially designed vignettes and discussion guides. Findings revealed that patients saw MyPal offering increased, direct contact with the healthcare team, freedom of physical and psychological symptom reporting as well as valid and reliable information. However, they had concerns about the appropriate use of data collected by MyPal, the efficiency of data analysis and data security adopted for sensitive personal information. The participatory design approach used has been very useful in encouraging the genuine involvement of participants, a factor which over time can empower and promote participants' long-term engagement.

**Keywords.** Palliative care, cancer, electronic patient reported outcome (ePRO), Participatory design, Focus Groups, eHealth

## 1. Introduction

There is a growing body of research demonstrating the value of participatory design in the development of novel healthcare services. In the context of palliative care, namely supportive care aiming to improve the quality of life of patients facing life-threatening illness through the assessment and treatment of psychosocial, physical and spiritual problems [1], participatory design is especially relevant. Considering that the demand for palliative care is increasing, discrepancies between care needs and care arrangements must be noted and rectified [2]. Actively involving patients in the design or development of eHealth tools [3], resources [4,5] or systems [6] for palliative care can provide a unique perspective on user acceptability, system usability as well as insight into the feasibility of the overall effort [7].

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MyPal (<https://mypal-project.eu/>) is a collaborative H2020 research project, funded by the European Commission, aiming to use eHealth technologies, in order to support cancer patients and healthcare professionals (HCPs). The main goal of MyPal is to develop and clinically assess new ePRO-based interventions for the palliation of cancer patients, in order to improve their Quality of Life (QoL) [8]. One group of cancer patients targeted by MyPal includes adults suffering from specific chronic hematologic malignancies. MyPal has committed to both adopting a patient-centered approach and adapting technology in order to cater for fundamentally different profiles of patients of different age groups as well as levels of digital and health literacy. Therefore, during the MyPal intervention design and protocol development, it is imperative to take into account not only the context i.e. current clinical practice for cancer patients, their interaction with healthcare professionals, provision of palliative care etc., but also users' personal needs as they identify and express them. To this end, use case scenarios were defined for the implicated stakeholders (patients and HCPs) to better illustrate the use of MyPal's technological tools appropriately responding to user needs in realistic situations. The aim of the present study has been to elicit the needs of end-users' representatives, their judgements with regards to different aspects (i.e. functionalities, characteristics) of the MyPal system, and finally their recommendations for system improvement.

## 2. Method

This was a cross-sectional study employing a qualitative methodology. Qualitative data were gathered via focus group discussions [9]. Ten focus groups (4-8 participants each) were conducted with: a) adult patients with a diagnosis of either Chronic Lymphocytic Leukemia (CLL) or Myelodysplastic Syndromes (MDS), and b) HCPs working in participating hospital units. Focus groups were conducted in partner sites in Greece (n=5; Italy (n=1); Germany (n=2), and the Czech Republic (n=2). This paper presents our overall methodology and the findings from the two focus groups conducted with CLL patients at CERTH, Greece.

With respect to materials used, two versions of vignettes were prepared: one for HCPs and one for adult patients. The following vignette, prepared for CLL patients, introduces the main character, Mr. Leonard Jones and his journey of managing CLL. The scenario starts with the enrollment of a treatment naïve patient, into the study. On Day 0 he completes the entry questionnaires, signs an informed consent and receives the MyPal smartphone application as well as a smart wristband. On Day 7, Mr. Jones receives a motivational message aiming to keep him engaged to the MyPal system. Two weeks later, he receives a notification to fill in the 1<sup>st</sup> symptom questionnaire via which he reports some fatigue, also is also becoming evident through a reduction in his physical activity. On Day 18, Mr. Jones searches for information in the personalized medical information search. He finds out that symptoms like fatigue combined with swollen lymph nodes can signify CLL progression. On Day 22 he develops rash and reports it via the spontaneous reporting functionality of MyPal app. He uploads a photograph and marks all his symptoms including swollen lymph nodes on a list. As all indicators (spontaneous reporting, symptom questionnaires and wristband data) demonstrate that CLL has progressed, MyPal issues an indication to the treating physician, who contacts Mr. Jones and asks him to undergo blood tests. After verification, on Day 24, Drug D is prescribed to Mr. Jones. He checks for drug

interactions and inserts timing preferences for reminder notifications on the MyPal app. Mr. Jones continues to receive motivational messages and self-report questionnaires to complete on physical and psycho-emotional symptoms. Mr. Jones keeps experiencing diarrhea, so on Day 42 he reports it via the MyPal app and his clinician is notified. As the diarrhea persists, he develops distress, evident in his facial expressions and tone of voice. Due to the distress picked up by the smartphone sensors in conjunction with the spontaneous reporting by Mr. Jones, the clinician is alerted and calls to reassure him. A sample screenshot from the vignette under discussion is presented in Figure 1.

The discussion guides reflected the episodes of the vignettes from enrollment up until the end of the storyline. An example follows: *‘Mr. Jones starts feeling fatigue and searches for info, since he thinks this might indicate disease progression. The information that he finds via MyPal is personalized, i.e. information relevant to him as a CLL patient. How do you judge this feature? How would you feel given the opportunity to access information tailored for you as a patient with CLL? How can it be improved?’*.

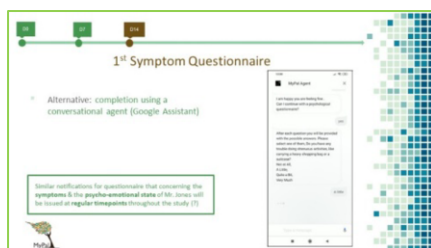


Figure 1. Sample screenshot from the patient vignette.

Concerning data analysis, the framework method was employed [10] for performing thematic analysis. It is an established approach for managing and analyzing qualitative data in applied health research [11]. Ensuring uniformity of the focus group analysis in the different participating sites was a primary concern. The main reasons for choosing this method of analysis included: a) the multi-disciplinary research teams involved, b) the sample with clinical and patient representation, c) the complexity of the collected data pertaining to 4 different countries and languages, and d) the nature of the data consisting of expressed positive and negative judgements as well as concrete recommendations for MyPal system development. The collection of data in diverse cultural contexts and from multiple perspectives contributed to the richness and thickness of data. Codes were developed at a national level and these were grouped into categories at a European level. Researchers are satisfied that data saturation has been achieved per emerging category for both clinical and patient groups.

User acceptance is not only a methodologically major challenge, but also one of significant ethical importance as it aims to enhance patients' autonomy and is directed towards their beneficence [12]. MyPal is indeed tailoring the technological aspects of the intervention to the exact patient needs, rather than requiring patients to adapt themselves to the employed technology. During recruitment participants were informed about the study, gave their consent for participation, recording of the discussion and use of content for the needs of the MyPal program. The information collected did not include any personal data but rather information on the functionality of the system as well as recommendations for better use. It must be noted that in the clinical studies to

follow later in the course of this project, consent forms will be submitted with the actual protocol to the appropriate Research Ethics Committees for approval.

3. Results

Nine patients with CLL, aged 39-73, participated in the two focus groups held at CERTH, Greece. Five were males and four were females. Three participants were receiving treatment at the time of the focus group, four had received treatment in the past, while two were treatment-naïve. CLL patients expressed what they considered to be the most important advantages that the MyPal system has to offer (Table 1), but also voiced important concerns (Table 2). Participants have given recommendations which have led to amendments in the MyPal system design and MyPal intervention delivery. Indicative examples can be found in Table 3.

Table 1. Patients’ positive judgements on aspects of the MyPal system.

Themes	Explanation
Valued contact with the healthcare team	MyPal promotes direct contact with the doctor, instantly updating the medical file and, thus, expediting medical decision-making and initiating supportive treatment following the presentation of an issue the patient is concerned about.
Freedom of reporting	MyPal allows the communication of physical and psychological symptoms attributed to either the disease or its treatment through ePROs or other information difficult for patients to assess. Patients positively perceived MyPal’s capability to record on a scheduled or spontaneous basis, in a structured or unstructured way.
Validity and reliability of information	The MyPal database will relieve them from stress and put a stop to misinformation. It will be safer and much more specialized than most generic databases available on the web since many physicians will be contributing throughout the study.

Table 2. Patients’ concerns regarding aspects of the MyPal system.

Themes	Explanation
Reliability of collected data	The data generated might not provide essential or reliable information (e.g. the data on the quality of sleep might be affected by the use of sleeping aids).
Interpretation of collected data	The data gathered might not be interpreted correctly (e.g. smartphone sensors might not be able to distinguish real distress from happiness and exertion). The need to combine different sources of information, so that data is interpreted in context was stressed.
Privacy and digital safety of collected data	Patients desired transparency over issues such as who will be viewing their personal files, who these data belong to, where data will be stored, etc. Finally, concerns were voiced about safeguarding privacy, e.g. whether the system will be recording information without patient consent and/or awareness (e.g.. smartphone sensors reading facial expressions and tone of voice).

Table 3. Impact of participants’ recommendations on MyPal system design and intervention delivery.

MyPal proposal	Participants’ feedback	Amendment Decisions
MyPal will notify participants that a PRO assessment is due and accept submitted PRO reporting	Patients stressed the need for feedback after submission	The MyPal system will issue a notification to inform the participant that the information has been successfully submitted and that it will be seen by a HCP as soon as possible.
The MyPal system was designed to record spontaneous symptom reporting and scheduled symptom reporting	Patients expressed concerns that the physician will not see the information in real time or that he/she will not be available or not respond	Informed consent will state that MyPal is not an emergency service. During symptom reporting, patients will be informed that in case of emergency they should contact the hospital directly. Participating HCPs will check the system for new information every 72 hours.

#### 4. Lessons learnt

The purpose of this study was to present the vision of the MyPal system to all implicated stakeholders. Findings from the focus groups conducted with CLL patients offered insights into patients' requirements from an eHealth system like MyPal. It was evident that, in order to support patients and their caregivers in getting the most of MyPal, it is necessary to alleviate their concerns about the appropriate use of data and the efficiency of data analysis, while also providing reassurance with high standards of data security adopted for sensitive personal information. End users' valuable contributions are already informing and shaping the MyPal design and the next cycle of iteration has already been planned for preliminary field testing. The employed participatory design approach has been very useful in that it has encouraged genuine involvement of participants, a factor which over time can empower and promote participants' long-term engagement.

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