

Co-design of a mobile application for engaging breast cancer patients into reporting health experiences: Qualitative case study

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Abstract

Background: In the world cancer is the leading cause of death. To ensure care processes, the World Health Organization recommends incorporating the Patient Reported Experience Measure and the Patient-Reported Outcome Measure. New technologies allow large volumes of data to be converted into useful information. Considering that many cancer patients have adverse effects and doubts during their treatment, the development of technologies can be a viable alternative for reporting and monitoring, which must be in accordance with the needs of people.

Objective: to present the results of a qualitative study, aimed at identifying the needs of cancer patients and health personnel during the breast cancer treatment process to design a mobile application that allows the reporting of adverse symptoms and impact and improving the quality of life.

Methods: with focus groups, the information needs of breast cancer patients and health professionals were raised. The patients were those who were undergoing chemotherapy treatment and those who had finished it between 3 months and 1 year. The group of health professionals was involved in the care of patients and belonged to the cancer committee of the cancer center where the study was conducted. A written survey was incorporated into this group.

Results: Patients mention four areas of information: general description of the disease; treatment; normal and abnormality meters in response to treatment; symptoms to report. Professionals consider it necessary to provide guidance in the administrative-financial process and require prior clinical information when patients have consulted other professionals. Categorized four areas of information needs: (1) knowledge regarding the disease in general, (2) feedback for symptom reporting, (3) support in administrative processes, and (4) complementary information. The solution proposal consists of a mobile application, called +Contigo, with four modules, whose functionality is different, depending on the actors involved (patient, caregiver, moderator, professional and administrator).

Conclusions: the information needs are specified in the design of +Contigo with four modules: (1) Clinical information, which offers multimedia information about the disease, treatment and tests; (2) Report and assistance to report symptoms with notification to a health professional, who can respond, depending on the severity of the reported symptom; (3) Assistant administrator to deliver information and help record the necessary information of the process and (4) Community, to share with other patients data on activities, clothing, food and complementary therapies. The technical design of the mobile application has three-layer architecture, based on microservices with portable technologies, whose most important functional feature is its high flexibility.

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Co-design of a mobile application for engaging breast cancer patients into reporting health experiences: Qualitative case study

Abstract

Background: The World Health Organization recommends incorporating the Patient Reported Experience Measure (PREM) and the Patient-Reported Outcome Measure (PROM) to ensure care processes. New technologies, such as mobile applications, could help report and monitor patients' adverse effects and doubts during treatment. However, engaging patients in the daily use of mobile applications is a challenge that must be addressed in accordance with the needs of people.

Objective: This article presents a qualitative case study documenting the process of identifying the information needs of breast cancer patients and healthcare professionals during the treatment process in a Chilean cancer institution. The study aims to identify the patients' information requirements to be integrated into a mobile application that accompanies patients throughout their treatment while also providing features for reporting adverse symptoms.

Methods: We conducted focus groups with breast cancer patients undergoing chemotherapy (n=3) or completed chemotherapy treatment between 3 months and one year (n=1). We also surveyed healthcare professionals (n=9) involved in patient care and belonging to the oncology committee of the cancer center where the study took place. Content analysis was applied to the responses to categorize the information needs and the means to satisfy them. A user interface was designed upon the findings of the focus group and assessed by three trained information system and user interaction design experts from two countries, using heuristic evaluation guidelines for mobile applications.

Results: Patients' information needs were classified into four areas: an overview of the disease, treatment and day-to-day affairs information, assistance on the normality and abnormality of symptoms during the treatment, symptoms relevant to report. Healthcare professionals require the patients to be provided with information on the administrative-financial process. The active involvement of four main actors is required to satisfy the information needs: patients, caregivers, social network moderators, and health professionals. Seven usability guidelines were extracted from the heuristic evaluation recommendations.

Conclusions: A mobile application that seeks to accompany breast cancer patients to report symptoms require the involvement of multiple participants to handle the reports and day-to-day information needs. User interfaces must be designed having mindful consideration of the patient's social conventions and emotional load of the disease information.

Keywords: Cancer; Registration systems; PROM; PREM; Software analysis and design; cancer patient report; adverse event reporting; quality of life; eHealth; mHealth

Introduction

Background

Cancer is a disease characterized by an accelerated multiplication of abnormal cells which are able to spread, being able to spread to different organs (metastasis), becoming the main cause of death worldwide with almost 10 million deaths in 2020, being breast, lung, colorectal, prostate, dermal and gastric cancer, being the most common [1]. The situation in Latin America is worrying because survival after five years of diagnosis is lower than that registered in OECD countries [2]. In Chile, as

in other countries of the world, there has been an increase in morbidity and mortality from acute and chronic Noncommunicable Diseases (NCDs). Specifically, at the national level between 2009-2019, NCDs were the main cause of death, where cancers ranked first, displacing cardiovascular diseases in second place in 2019, which places Chile in a worrying second place in South America [3]. In addition, although the disease can affect people throughout their life cycle, data from the beginning of the second millennium showed that the number of new cases in both sexes increases with advancing age [4].

In Chile in recent years, certain milestones have been achieved that, together, are aimed at improving the detection, care and monitoring of people with cancer, among which is the National Cancer Plan of 2018 [4], the National Cancer Law (Law 21 258) [5] and the National Cancer Registry (NCR) [6]. Within the first, five strategic areas are proposed, three of which are considered transversal and fundamental, among which is the strengthening of registration, information and surveillance systems [7]. Additionally, the Cancer Law states that the disease is considered mandatory notification [5], in this way, the creation of the NCR provided health authorities with a national information system that collects, stores, processes and analyzes continuously and systematically data on all cases and types of cancers that occur in the country, which includes public and private health patients, where more than 20 establishments in the country are taxed, with a total of records that exceeds 5 000 cases of cancer [2].

The NCR is a technological tool that helps monitor cancer trends over time, guides the planning and evaluation of cancer control programs and shows cancer patterns in different populations and identifies high-risk groups, enabling decisions to be made with specific needs in mind and, overall, information from the NCR contributes to prioritizing resource allocation and promoting research activities in specific areas [3]. However, the World Health Organization now recommends that to guarantee health care processes it is important to incorporate the Patient Reported Experience Measure (PREM) and the Patient-Reported Outcome Measure (PROM) [8]. The health entity mentions that quality assurance and improvement are important components of the development and sustainability of services that must consider cultural characteristics. Thus, outcome measures reported by patients and health professionals and measures of experience provide valuable data on the person's centrality and effectiveness in the services provided, bestowing information on a person's self-perception of their health, which may include quality of life, functioning and self-efficacy or reveal a person's perception of their experience of a service of health or social care, which may include experience in terms of access, waiting times and the possibility of participating in shared decision-making [8]. Therefore, it is necessary to incorporate information directly from patients into the NCR.

Mobile apps for collecting and managing adverse symptoms have been designed [9- 10], and experimental evidence confirms their positive effect on breast cancer patients, leading to significantly less symptom prevalence and symptom burden [11]. However, engaging patients into the daily use of apps for reporting health experiences is challenging, as presented [12]. One strategy to introduce a tool for reporting adverse symptoms into the daily life of breast cancer patients and simultaneously impact their quality of life is to leverage positive experiences with accompanying applications [13,14]. While there is evidence that functionalities such as discussion and learning forums are highly used by patients, adherence to use depends on various factors, requiring a tailored design [15].

This article presents a study that aims to identify the information needs of patients and healthcare professionals in order to integrate them into a mobile application that accompanies patients throughout their treatment and, at the same time, offers functions for reporting adverse symptoms. The following subsections present evidence on the benefits of reporting adverse symptoms through

PREM and PREM surveys, and existing technological tools to support this process.

Use of PROM and PREM in Cancer

The clinical follow-up of cancer patients is an interdisciplinary activity that aims to control side effects and detect early possible relapses and relapses, which varies depending on the type of cancer and characteristics of the person [16]. In Chile, follow-up is part of the treatment of cancer patients and is carried out through secondary and tertiary care [17] to monitor possible complications of the disease (metastasis, thrombosis, dysphagia, etc.) and treatment (myopathies, neuropathies, etc.). [18]. However, such information, which focuses on estimating incidence and types of cancer, is not collected in the NCR or used in nationwide statistics. The NCR collects information from 4 population-based cancer registries in the country [19]. In this regard, the OECD's recommendations indicate that Chile should develop more systematic monitoring for cancer control: a) extending the registry to more regions; b) expanding the information collected from screening and diagnosis, similar to childhood and cervical cancer where data are linked to public and private sector providers and c) using PREM and PROM to improve the quality of cancer care and care [20].

The Patient-Reported Outcome Measure (PROM) are standardized and validated surveys that measure the results reported by patients, during the perioperative period to know perceptions of health status, level of perceived deterioration, disability and health-related quality of life, and can be classified as generic or specific to a disease [21], for example, the QLQ-C30 questionnaire is generic for cancer, is available in more than one hundred languages, including Spanish [22] and is the most widely used [23]. QLQ-PAN26 [24] is specific for pancreatic cancer. The two questionnaires mentioned can be used together. The use of PROM in clinical practice is associated with a) reduction of emergency care; b) improved doctor-patient communication, quality of care, quality of life and experience with providers; c) better survival compared with usual care in patients with metastases who are undergoing chemotherapy [25]. Other studies suggest that routine PROM collection may improve quality of life and outcomes for pelvic cancer patients [26] identify undetected symptoms [27], and aid in clinical management and intervention of adverse effects [28].

However, not only the complications of the disease impact on the quality of life of people with cancer, but also the consequences of treatment with high cost [29], therefore, it is also possible to include the measurement of financial toxicity in PROMs, an example being the COST - FACIT survey [30], which has 12 questions divided by themes: affect, coping, family, financial and resources [31].

In general, the use of standardized surveys allows comparative studies to be carried out, however, it is also possible to create surveys that adapt to the local reality. For this it is recommended to follow the ISOQOL PROM measurement standard [32-33] which states: 1) Conceptual model: description and framework; 2) Confidence: Degree to which the measurement of the Patient-Reported Outcome (PRO) is error-free; 3) Validation: The degree to which the instrument measures the PRO concept it intends to measure; 4) Interpretability: Ease of understanding the meaning of the score of a PRO measure; 5) Minimum important difference: minimum score difference that patients or guardians perceive as important, beneficial or harmful; 6) Load: time, effort and other demands on those who administer the instrument or those who administer the instrument (investigator or administrative).

The collection of PROM through digital means is known as ePROM. Authors point out [34] that these have greater acceptance and preference by patients, lower costs, similar or faster completion times, better data quality and response rates, and patient management of symptoms is more appropriate. The disadvantages identified, meanwhile, are related to privacy, large initial financial investment, and the digital divide in the case of some people.

In relation to Patient-Reported Experience Measures (PREM), which are surveys of patients to collect information regarding lived experiences during care, analyzing the impact of the care process [35] such as waiting times and doctor-patient communication, can be classified as a) relational: regarding the relationship with those who provide care, an example of a questionnaire is CARE [36]; b) functional: with respect to practical situations such as availability of care [21].

The National Cancer Program of the UK's National Health Service developed a PREM to monitor its progress in cancer care, drive quality improvements, support cancer care commissioners and providers, and inform the work of the various charities and stakeholders supporting cancer patients [37]. In Chile, the PROM QLQ-ELD 14, Spanish version, which measured the quality of life in older adults with cancer, was validated, concluding that the instrument in the applied population presented psychometric properties suitable for survivors of breast, colorectal, gastric, hematologic, lung, gynecological, head and neck, prostate, skin and other cancers and found that gynecologic cancer survivors have the worst mobility [38]. Other investigators [39] used the QLQ-C30 and QLQ-STO22 questionnaires for stomach cancer, concluding that a significant proportion of patients showed an improvement in global health and perception of pain, despite the worsening of some symptoms that could be related to therapy, indicating that research is required on a large scale to confirm the observation.

The advantages of data collection using PROM and PREM justify the need for their continuous collection to increase the impact of a national cancer registry. However, challenges need to be addressed regarding the need to collect indicators at a time when patients are comfortable (ideally at home [21]), and to design user-centered tools that enable user engagement to overcome digital divides [34].

Technological tools for the collection of PROM and PREM

In the market there are PROM and PREM collection tools that can be divided into generic and specific applications.

a) FORM BUILDER: These are applications that allow the creation and distribution of generic surveys that, due to their functionality, can be used for PROM and PREM, namely Teamscope [40]; Survey CTO [41]; Beaver [42]; KoBo Toolbox [43]; RED Cap [44]; ODK [45].

b) ePROM and ePREM applications: These are tools that have standardized surveys, including Pro-CTCAE Patient Symptom Reporter, which corresponds to a web application for the registration of adverse events, following the CTCAE criterion [46]; Buddy Care Platform that allows automatic sending of surveys, reminders and incorporates instructions and educational material to patients [47], although it is only available for Germany, Finland and the United States; Patient IQ [48] captures PROMs, identifies predictors of clinical outcomes and improves the patient experience, available only in the United States; My Clinical Outcomes is a web application that allows you to regularly collect information on diagnosis, treatment and any clinical condition [49]; Philips Quest Link integrates with external medical records, uses validated questionnaires to collect, process and align PROM and clinical information [50]; Heartbeat, is a German web application that allows the collection and analysis of PROM, can be integrated with external clinical records through the FHIR clinical message exchange standard [51]; Zedoc PROM, platform for the integral management of PROM, has integration with external systems through FHIR and with support of LOINC and SNOMED CT, available for New Zealand, Singapore and Australia [52]; Force Therapeutics, has integration with AJRR and other records. reserving the right to use the information registered on the platform [53].

However, Form Builder applications are useful for the development of surveys, however, they are designed for projects in which it is not necessary to have an integration. On the other hand, the

specific applications provide more functionalities than necessary, have associated payment for their use, are not available in Chile and, currently, some reserve the right to use the data collected.

It can be said that from the technical point of view there are advances that allow the development of technological tools for the collection of PROM and PREM, but from a patient-centered approach it is essential that this development contemplates the needs of primary users, that is, patients and cancer professionals.

Research Goal

This work aims to present the results of a qualitative case study, aimed at identifying the needs of cancer patients during the breast cancer treatment process, to design a mobile application that allows the reporting of adverse symptoms and impact and improving the quality of life. In particular, the research questions addressed in this study are:

- What information does patients need during the breast cancer treatment process?
- What information does healthcare professionals need from patients during the breast cancer treatment process?
- What are the user roles that must interact with the application, so information needs are met?

To address these questions, we involved patients and healthcare professionals into a co-design process.

Methods

Design and sample

A qualitative case study was conducted to address the research questions. The research protocol was reviewed and approved by the Scientific Ethics Committee CEC Med-UC in Minute No. 3/2019. Participants were informed about the study and voluntarily signed the consent document. The study was carried out between June-July 2019. Data was collected through focus groups and a survey. The methodology of focus groups was used to survey the needs of two types of users: breast cancer patients and health professionals. Below, we report the qualitative study following the guidelines in [54].

The focus group was conducted by the first author, PhD (female), principal investigator of the research project with more than 15 years of experience in eHealth research. No relationship with the participants prior to the study were established. Participants have knowledge about the goals of the research and acknowledge the researcher and the research team as participants of the NCR project. The methodological orientation of the research is content analysis, since we aimed to identify common information need themes across the participants.

The participants for the focus groups (both with patients and healthcare professionals) were selected by convenience and were the patients and professionals of the Chilean health institution. In all the focus group, the participants were approached face-to-face. Two focus groups were conducted with cancer patients (n=4). One participant dropped out, without giving further reasons. All participants were women, aged 34-53 years. The group of health professionals corresponded to those who participated in the care of patients and belonged to the cancer committee of the cancer center where the study was conducted (n=9). No healthcare professionals dropped out from the focus group, though just four surveys were collected after the activity.

Data was collected in the clinic, and nobody else besides the participants and the researchers were present during the activity. Cancer patients were divided into two groups, one consisting of stage I, II

or III patients who were undergoing chemotherapy treatment (n=3) and another consisting of patients in stage I, II or III who had finished chemotherapy treatment between 3 months to 1 year (n=1).

For the patient's focus group, four guiding questions were used: 1) *What information about your disease would you like to have?* 2) *What information regarding your treatment would you like to have?* 3) *In what instances would you have liked to have feedback from a health professional during your treatment?* 4) *What symptoms have you reported to your doctor that have been caused by an adverse effect?* Field notes were taken by the first author. The first focus group with patients lasted 55 minutes and the second one, 33 minutes; in the two cases, data saturation marked the end of the interviews.

For the healthcare professionals' focus group, the guiding question was *What is the information needs of cancer patients during treatment?* At the end of the group session, a written survey form was delivered, which was to be sent later to the research team, which inquired about the information that professionals required from patients and how important and feasible observed providing the information requested by patients through a digital tool.

Two researchers analyzed the collected data. The data were analyzed following the content analysis method with an inductive approach [55]. One of the researchers coded the transcripts of the focus groups to obtain the subcategories. The abstraction process, i.e., the grouping of the categories around less numerous and higher-level categories, was carried out jointly by the two researchers. The main categories emerged from grouping the generic categories into functional groups, which are then considered in the design process as modules of the system. In Figure 1, we provide an example of the content analysis process.

Figure 1: An example of the analysis process.

Next, the results are presented as answers for each of the research questions.

Results

Cancer patients

This group corresponds to patients with stage I, II or III breast cancer being treated with chemotherapy or who have completed it. The information obtained from the guiding questions is summarized in Table 1.

Table 1. Summary of the information required by cancer patients.

Question	Scope of Information Required	Aspects pointed out by patients
1	Disease overview	What is disease. Symptoms.

		Tests.
		Treatments.
		Procedures.
		Aftermath.
2	Treatment Information	What's going to happen next?
		What is marking the tumor?
		How is the effect of the treatment determined?
		What can be done and what can't?
		How much exercise can be done?
		Can other diseases affect cancer?
		How do I know if what I prepare to eat corresponds to a light regime?
		Are the sensations and consequences I have normal?
		Positive and negative effects of complementary therapies.
		Activities focused on people who have overcome the disease or are in the same process.
		Other domestic aspects that impact quality of life (Where to buy turbans? How to cut your hair? How to put on a bra?).
3	Parameters of normality and abnormality in response to treatment.	Help to identify what is expected and unexpected in the face of chemotherapy.
		What are the symptoms in which the professional should be notified.
		What medicines to use in case of dizziness or discomfort?
4	Symptoms to report.	What is the difference between adverse effects and those of the treatment?
		Symptoms that affect quality of life.
		Vomiting.
		Allergies.

Questions: (1) What information about your illness would you like to obtain? (2) What information regarding your processing would you like to obtain? (3) In which instances would you have liked to have feedback from a health professional during treatment? (4) What symptoms have you reported to your doctor that have been caused by an adverse effect?

Health professionals

The group corresponds to health professionals who care for cancer patients participating in the study. One aspect that stood out in the focus groups with professionals was that they considered it necessary to provide patients with guidance on the administrative and financial process in which they are immersed. They also mentioned the need to have the clinical information of other professionals that patients consult in the process of research, diagnosis and treatment of the disease. In addition, all professionals who responded to the survey pointed out that it was important to provide patients with generic information on symptoms and intensity that should be reported by the patient with different levels of urgency and provide information on daily activities for well-being (diets, physical exercise). Most professionals pointed out that it was important to respond to private clinical questions (chat, private message) and public (forum or social networks) of patients through a digital means of communication and deliver non-clinical data for the well-being of cancer patients (activities, data on turbans, bras and others). On a scale of 1 to 5 (where 1 disagrees little and 5 strongly agrees), the importance of providing information on complementary therapies to clinical treatments was rated at level 5 by a professional, the remaining three rated it at level 3. In the responses, the majority of respondents indicate (level 4 and 5) that actions qualified as important are feasible, except for the item of answering private clinical questions, where all professionals rated it at level 2 or 3. On the other hand, among twelve symptoms presented to determine adverse effect of a treatment, all professionals agreed on one, pain, as an important symptom to report. Likewise, all the professionals who responded to the survey agree that in the adverse effects it is necessary to know the temporality, severity, and intensity.

Proposal for design of the application

From the collection of information with patients and cancer professionals, four areas of information needs were detected: (1) knowledge regarding the disease in general, (2) feedback for the reporting

of symptoms, (3) support in administrative processes and (4) complementary information. The solution proposal consists of a mobile application, called *+Contigo* (+ Whit you, Spanish name remains), whose functionality will be described considering the four modules that compose it, according to the actors involved. Based on this, the prototype design for the main user interfaces and the design of the system architecture, including its components and deployment, will be shown.

Modules

The solution in *+Contigo* proposes four modules with different modalities of use (1) Clinical information; (2) Report and assistance; (3) Administrative guide and (4) Community, which are oriented to different actors or types of users. It is considered that a large part of the actions will be carried out during the process of implementation of the solution (pilot period and white gear).

Figure 2: *+Contigo* application diagram

Actors can access the four functional modules of *+Contigo*. Both users are required to register in the system and, in the case of the caregiver, register the patients under their care. Although the system will know your identity, it will be protected for any interaction with other actors in the registry, unless the user explicitly authorizes its use.

The mobile actor will be involved only with the module and complementary information unit and will be able to contribute information to the discussions of the patients and caregivers' community, as well as edit or delete published information that may be considered harmful to users from a clinical or quality of life point of view.

The professional actor of the avalanche will be directly related to the reporting and assistance module and will receive notifications from patients, which will be classified by priority and severity, being able to deliver online responses (audios, texts, images, videos, reference links) or other types of actions outside the system (telephone contact, schedule regular control, schedule urgent control attention).

The administrator has a central role in the *+Contigo* management process consisting of configuring the system and providing multimedia content, being able to define the different levels in the clinical information module; configure different types of symptoms, degrees of severity with their description and alert priority in the module of support and system; Upload multimedia content, add questions, answers and checklist items in the module of administrative support and generate discussion topics in the module of the community.

By downloading the application on mobile, users will be able to recognize *+Contigo*, as shown in figure 3, with the logo on the screen of the mobile device.

Figure 3: Main page *+Contigo*

When entering the application, the user finds the login (figure 4) to start a secure session, protected by password and the chosen username.

Figure 4: *+Contigo* login

The following figures (5, 6, 7 and 8) will present the domain model of each module. This conceptual modeling represents the vocabulary of the system, as well as the relationships allowed between these concepts, with dependence (black rhombus) or without dependence (white rhombus), with many relationships (1...*) or with possible relationships (0...*). Added text boxes with appended notes (dotted lines) that complement the information delivered to clarify how the model will respond to certain functional requirements.

The clinical care process assistant module (figure 5) provides information to the patient regarding the level of care in which he is, using questions and answers that allow him to internalize the disease, the phases of the process, treatments and in particular chemotherapy.

Figure 5. Clinical information module.

The report and assistance module (figure 6) allows the user to consult detailed information on chemotherapy symptoms, indicating levels within expected ranges and those that are out of normality, also allowing symptoms to be reported based on a scale of type and severity. This module enables healthcare professionals to interact with patients via text, audio, or video messages, or initiate a phone call to the patient's mobile.

Figure 6. Report and assistance module

The administrative guide module (figure 7) is an informative module with a focus of questions and answers, together with a checklist to guide the patient regarding the eventual and possible main procedures to be carried out in the process of his disease, which is associated with the different stages and substages of the care process.

Figure 7. Administrative guide module

The community module (figure 8) provides practical and everyday information for non-clinical aspects. This module is aimed at supporting the quality of life (for example, where to find clothing or clothing, support groups, information and dissemination activities and others), posing as a social network, where users can use a fictitious or real name, whose objective is that the community shares the information it considers necessary and relevant, providing links to external resources, comments, photographs and/or audio or video messages.

Figure 8. Community module

Interface

A prototype design for the main user interfaces and the design of the +*Contigo* architecture are presented, including its components and deployment to finally propose the data model.

With the main version of the first level of the clinical information module (figure 9) you can access information on the whole process, patient diagnosis, multidisciplinary case analysis, cancer staging,

treatment, and case tracking. From the bottom menu you can quickly access information and the other modules such as port, administrative guide, and community. The selected section is identified by the color change.

Figure 9. Main view clinical care process (first level)

The sublevel of the clinical information module (figure 10) displays multimedia information (text, audio and video) of the stage of the clinical care process selected in the main view (in this case Treatment), where the active section of the interface in which the user is located is identified through color change.

Figure 10. Clinical care process assistant module (sublevel)

The report and assistance module (figure 11) are accessible directly from Report in the bottom menu. Here the patient can choose what aspects they want to report (health outcomes, care experience, symptoms, or financial burden).

Figure 11: Report and Support module parameters

The report of symptoms related to the disease or treatment (figure 12) is made by indicating severity through a scale represented in a set of five selectable faces (radio button), which can be accompanied by complementary information through a voice message, by pressing the microphone icon, which activates this function on the phone.

Figure 12. Symptom report and assistance module.

Answers to frequently asked questions in the Administrative guide module (figure 13) are available directly from Assistant in the menu below. Here administrative information is provided using the approach questions, response, and checklist to guide the patient regarding the main procedures to be carried out. When you select a question from the list, the answer is displayed and when you select it again, it collapses, hiding the answer.

Figure 13. Administrative guide module (assistant questions)

Regarding the recording of voice notes of the patient in the administrative guide module (figure 14) it is accessible directly from Assistant in the lower menu, showing in this case the answer to a selected question, which corresponds to a list of steps, among which the patient can identify those that were fulfilled or not. In addition, an audio can be incorporated into each response by pressing the microphone icon.

Figure 14. Administrative guide module (record of patient voice notes)

The figure 15 exemplifies some possible topics of conversation in the community module, which is accessible directly from the bottom menu. The interface groups several categories and each has different conversation topics that can vary, renew, and expire, depending on the interests of the participants. The functionality of this section is like a conversation chat, but the intervention of a moderator, health professional, has been added in charge of reviewing the material before its publication to ensure that the suggestions and recommendations to be discussed in the community do not affect the quality of life of the participating patients.

Figure 15. Community module

Architecture

A three-layer architecture is proposed for the development of the application, considering microservices, that is, monolithic applications (with their self-contained server), and with scope limited to a subset of the data model (consistent with the concepts of the domain model). To ensure portability, the development of a progressive application (PWA) compatible with different mobile operating systems (Android, iOS) is proposed, with development in Angular 8. You propose to use the same server and database management system that your organization already has to implement the data tier.

Table 2. Definitions of High-Level Architecture

Identify	Solution
Type of Application	Stand-alone Web Application
Relevant Technologies	Ionic 4, Angular 8, Postresql (or available), Java 7
Deployment Strategy	Containerization
Cross-cutting concerns (optional)	
Styles and Patterns of Architecture	Microservices, MVC
Reuse, Purchase or Construction	Construction

The following table 3 shows the quality attributes that the application must have.

Table 3. Quality attributes of the application.

Traceability Matrix			
Quality Attribute	Decision	Element	Justification
Compatibility	Monolithic java application	Spring boot	Development of self-contained monolithic applications on java framework (spring boot), for server independence.

	API REST	REST consumption of patient identification and contact information.	API of and	Interoperability standards are not implemented due to not sharing clinical information.
Reliability	<i>Circuit Breaker Design Pattern</i>	Using <i>Circuit Breaker Pattern</i>	<i>Circuit Design</i>	The <i>Circuit Breaker</i> pattern is used to detect faults and encapsulates the logic of preventing a failure from constantly repeating, during maintenance, a temporary system failure or unexpected system difficulties.
Safety	Spring boot	Spring Security	Boot	The security component of the development framework will be used to provide security to the back end.
	Angular 8	Angular Security		The security component of the development framework will be used to provide security to the front end.
Maintainability	Microservices	Microservices Architecture		Minimum data models will be defined for each module and separate back end applications for each.
Portability	Ionic 4 - Angular 8	Angular utilization 8		The use of Ionic 4 allows you to port the application to different mobile operating systems. Angular 8 supports multiple browsers (Chrome, Firefox, Edge, Opera)
Performance Efficiency	Query tuning	Make query adjustments. Use of indices.		Make adjustments to the database and queries, applying the necessary indexes.
Usability	Angular 8 Angular Material	Use of Angular 8 and Angular Material		The use of these technologies allows users to achieve their goals effectively, efficiently and with satisfaction in a specific context of use.

Discussion

While various applications for reporting health experiences and outcomes are available, some are general [40-35], which can be adapted for PREM and PROM purposes, but do not allow integration. Other applications are specific [46-53], but provide more functionality than necessary, have associated payment, are not available in many countries and, additionally, some reserve the right to use the collected data. In this sense, the study carried out managed to identify four categories of requirements, generating a mobile application design based on the responses of primary users (patients and cancer professionals). Although the sample corresponded to patients with breast cancer, it is estimated that +*Contigo* proposal would be useful for patients with other types of cancer.

On the other hand, it is currently recognized that cancer is not only a public health problem but a socio-health, social and economic problem, which affects the patient, family, and community [4]. Therefore, it is necessary to know the demands and needs of patients and carry out all actions that tend to reduce waiting and ignorance of this disease, given that many patients have delayed diagnosis (23.57%), being largely the cause of the health system (79.03%) [56]. New technologies can be a means to bridge inequity gaps [57], being a means to access the information that patients and clinicians need, and safeguarding the methods, standards, processes, and tools that have been reported in the literature to assess the quality of health information systems [58, 59].

Threats to Validity

According to Wohlin [60], we analyze the threats to the study's internal, construct, and external validity. Internal validity refers to the existence of other elements affecting the observed results. As in any case study, the specific context, in this case, the cancer center, might affect the results. Nevertheless, our approach is not explanatory but exploratory, so the results are meant to be interpreted in the context of the case study provided in the Introduction. Construct validity deals with the degree to which the measurements reflect what the researchers have in mind and help answer the research questions. We addressed this threat by designing the questions for patients and health professionals beforehand and explaining them to the subjects during the focus groups. The survey questions were designed to answer research questions 1 and 2, while the third research question came up from the requirements analysis. External validity addresses to what extent it is possible to generalize the findings. The sample size and the scope of the study certainly limit the generalizability of the results. However, as in other case studies, we intend to provide enough detail for the audience to extend the results to cases with common characteristics and hence for which the findings are relevant [61]. Finally, the conclusion validity in case studies mainly deals with the reliability of the measures. We addressed this threat by providing details of the content analysis and the categorization of the findings; however, different researchers might come up with different categories by following the same analysis procedure.

Usability Evaluation

We evaluated the application's design through a heuristic evaluation [62], where trained evaluators identify potential usability problems by reviewing the application or prototypes by applying a set of design best practices called heuristics. Three information systems and user interaction design experts from Chile and Spain performed the assessment. The evaluators reviewed the front end of the patient and caregiver mobile application and mockups of the applications for the health professional and

social network moderator. The evaluators received a high-level description of the application features (the same described in the Modules section of this paper) and the application prototypes. The evaluators were asked to base their review on the heuristics for mobile applications by Berini, Gabrielli, and Kimani [63]. The reported problems indicated the feature and user role with issues, the heuristics compromised in the problem, and the severity, graded in low, medium, and high. The evaluators were asked to provide improvement recommendations for each problem.

A total of 62 usability problems were identified by the experts, 18 of them having high severity. Among the most severe issues, the more compromised heuristics were *"Ease of input, screen readability, and glanceability"* (7 issues), *"7. Aesthetic, privacy, and social conventions"* (6 issues), and *"Consistency and mapping"* (5 issues). The features with more severe issues were patients' symptoms and experience reporting. Table 4 presents the features with high-severity problems.

Table 4. Features with high severity issues.

User	Feature	Issues (high severity)
Patient	home	2
Patient	disease information	2
Patient	report symptoms	4
Patient	report mental health	2
Patient	report quality of life	1
Patient	report experience	3
Health professional	home	1
Health professional	reports	1
Health professional	alert	1

Some of the most severe issues regard patients' home screen and the disease information features, which in the app was named *"My journey."* The *"journey"* feature name and metaphor were directly elicited from the focus groups since patients wanted to avoid seeing cancer or disease in a daily-use app. Reviewer (R1) from Spain commented that the *"My Journey"* feature was not intuitive for finding information about the disease and treatment. We think this is due to idiosyncratic differences between Chile and Spain and consistent with the heuristic *"Aesthetic, privacy, and social conventions"* in [63], which enforces taking into account the social and emotional aspects of the system. Regarding the results and experience reporting features, both Reviewer 2 (R2) and Reviewer 3 (R3) reported issues related to the heuristic *"Ease of input, screen readability, and glanceability"*. Given the length of the questionnaires, the reviewers recommended separating them into subsections, providing visibility on the questionnaire's completion status, and autosaving the responses to avoid information loss. Regarding providing assistance for patients' queries on the normality of their symptoms, R1 and R3 reported that the system should clearly separate when interacting with an automatic assistant or a health professional.

After the evaluation process, the researchers analyzed the problems graded with high severity. The evaluators' recommendations for these problems were studied and grouped by the compromised heuristics and the associated features. From the information requirements identified in the case study and the heuristic evaluation, we present the set of guidelines for designing a mobile app for self-reporting results and experiences for breast cancer patients. The guidelines consider the information requirements which must address the app and the usability considerations.

Table 5. Proposed guidelines for designing a mobile app for self-reporting results and experience for breast cancer patients.

Information Requirement Guideline	Usability Guideline
Disease overview information	1. Name the features that provide information about the disease matching patients' social conventions.
Treatment information	2. Consider the actual treatment and status of the patient to avoid cognitive and emotionally overwhelming. 3. Organize the information matching the timeline and flow of actions for the patient.
Treatment information (Day-to-day affairs – community)	4. Provide interaction mechanisms for patients and community moderators to avoid disinformation and inappropriate social behavior.
Parameters of normality and abnormality in response to treatment.	5. Patients should know whether their queries will be addressed by an automatic assistant (chatbot or other) or by a health professional.
Symptoms Report	6. Apply best usability practices for questionnaires: Break up questionnaires into multiple steps, provide completion status feedback, and autosave. 7. Provide prioritized notifications with contact information for health professionals to reach patients reporting abnormal symptoms.

Conclusions

The study carried out has allowed to characterize the needs of the primary actors involved (patients and cancer healthcare professionals). The findings show that main information needs regard generic information on symptoms and intensity, which should be reported according to different levels of urgency; guidance on the administrative process; non-clinical data that contribute to the well-being and daily comfort of patients (activities, data on turbans, brass, and others) and daily activities for well-being (diets and physical exercise). The satisfaction of the needs must be supported by different mobile application features: multimedia information on the disease and treatments, interactive forms and query mechanisms to reporting symptoms, experiences and for requiring assistance, and a social network for enabling community support for day-to-day affairs. The information needs require the collaboration of the community of patients, caregivers, healthcare professionals and social network moderators. The heuristic evaluation of the user interfaces reveals that app must consider delivering disease and treatment information taking into account the emotional effect on patients as well as their social conventions, and to address the length of some questionnaires (particularly symptoms and experience) with usability best practices.

Future research will focus on empirically assessing the effects of the study on patients' symptoms and experience reporting. We aim to evaluate how using the app's features correlates with patients' reporting behavior. Results from the heuristic evaluation suggest that more research is needed to underpin the cultural nuances of providing information about the disease considering patients' social conventions.

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Conflicts of interest

The authors declare that they have no conflict of interest

Abbreviations

AJRR: American joint replacement registry

CTCAE: Common terminology criteria for adverse events

FHIR: Fast healthcare interoperability resources

LOINC: Logical observation identifiers names and codes

NCR: National cancer registry

NCD: Non communicable disease

OECD: Organization for economic cooperation and development

PREM: Patient reported experience measure

PROM: Patient reported outcome measure

SNOMED CT: Systematized nomenclature of medicine – clinical terms

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 - 64.

Supplementary Files

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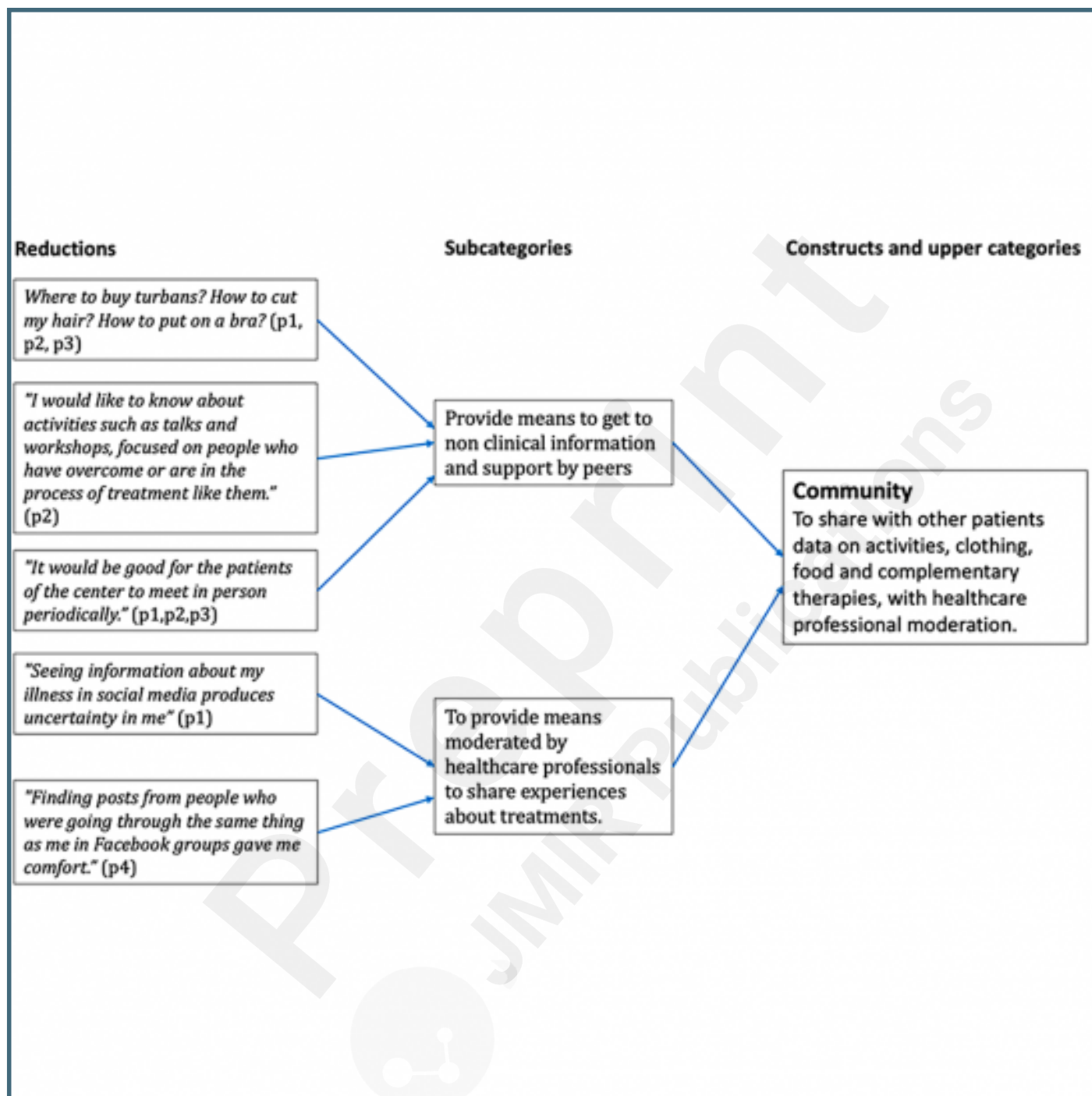
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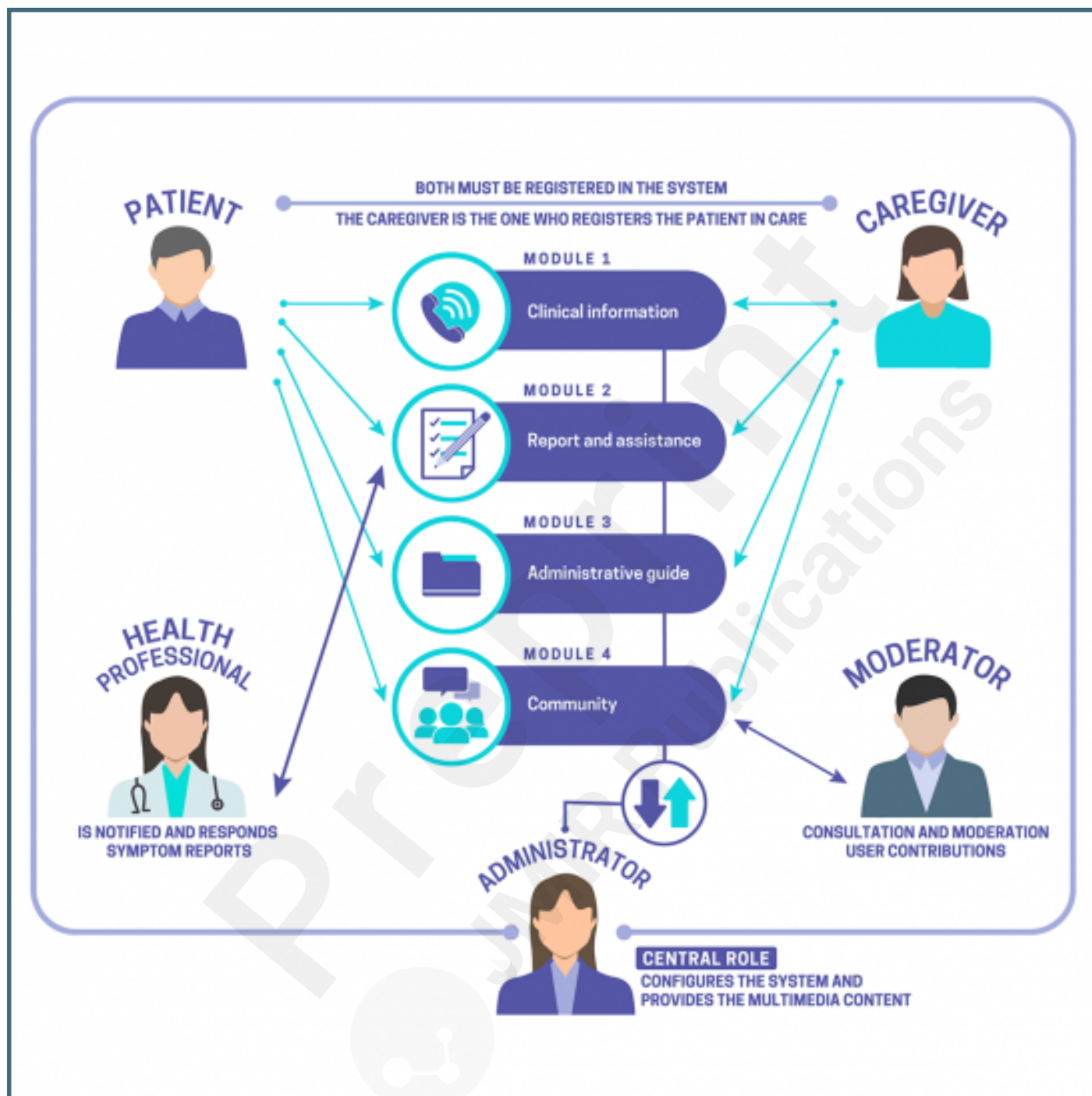
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Figures

An example of the analysis process.



+Contigo application diagram.



Main page +Contigo.



+Contigo login.



The image shows a login form for 'contigo'. At the top, there is a logo consisting of a red and blue cross-like shape with a white circle in the center, followed by the word 'contigo' in a sans-serif font. Below the logo is a white rounded rectangle containing the login fields. The title 'Login' is centered at the top of this rectangle. There are two input fields: 'EMAIL' and 'PASSWORD', both with placeholder text. Below the 'PASSWORD' field is a checkbox labeled 'Remember Password' and a link 'Forgot Password'. At the bottom of the white rectangle is a blue button labeled 'Enter'. The background of the form is a light blue gradient with a faint network diagram icon at the bottom.

contigo

Login

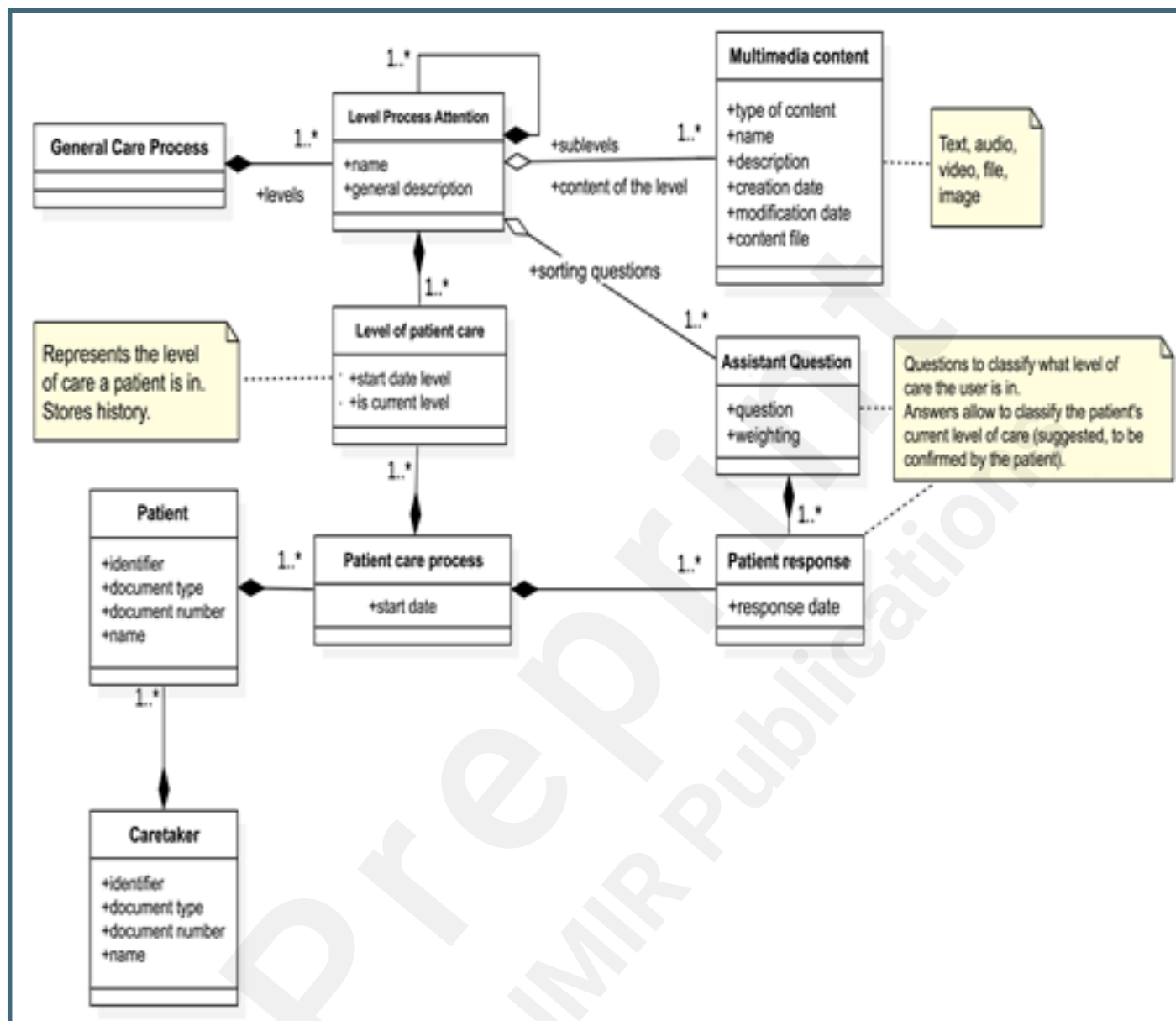
EMAIL

PASSWORD

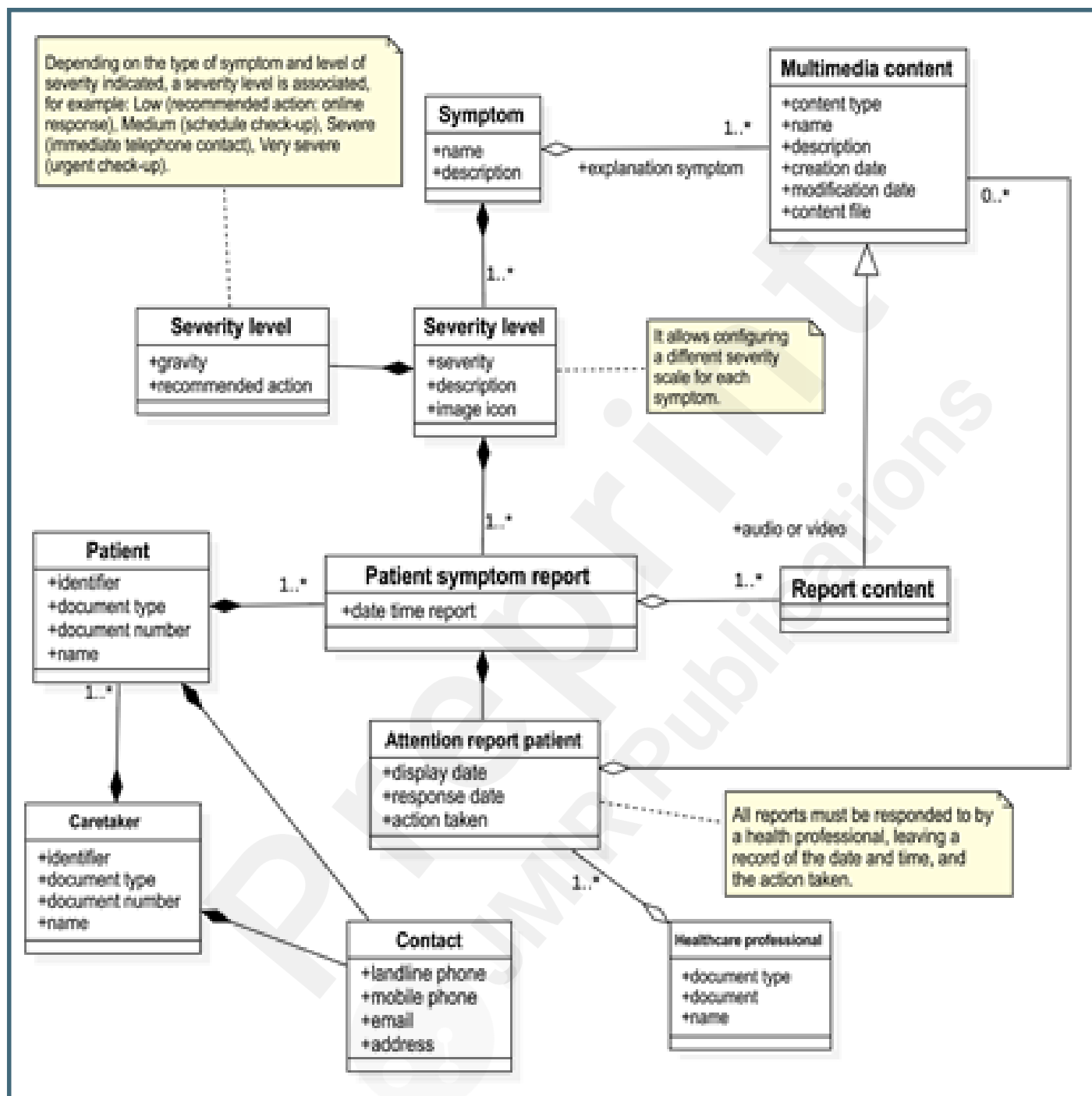
☐ Remember Password [Forgot Password](#)

Enter

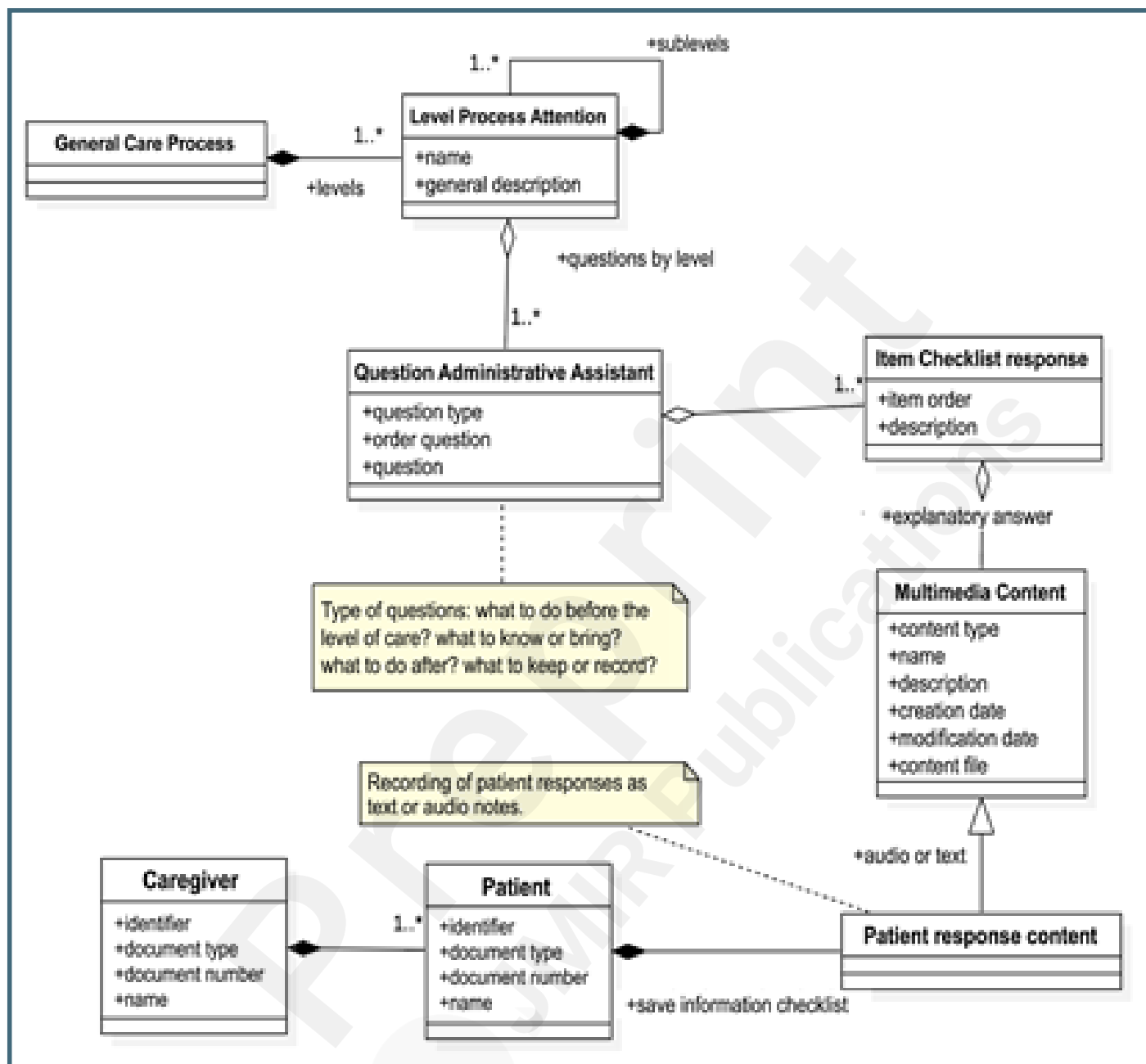
Clinical information module.



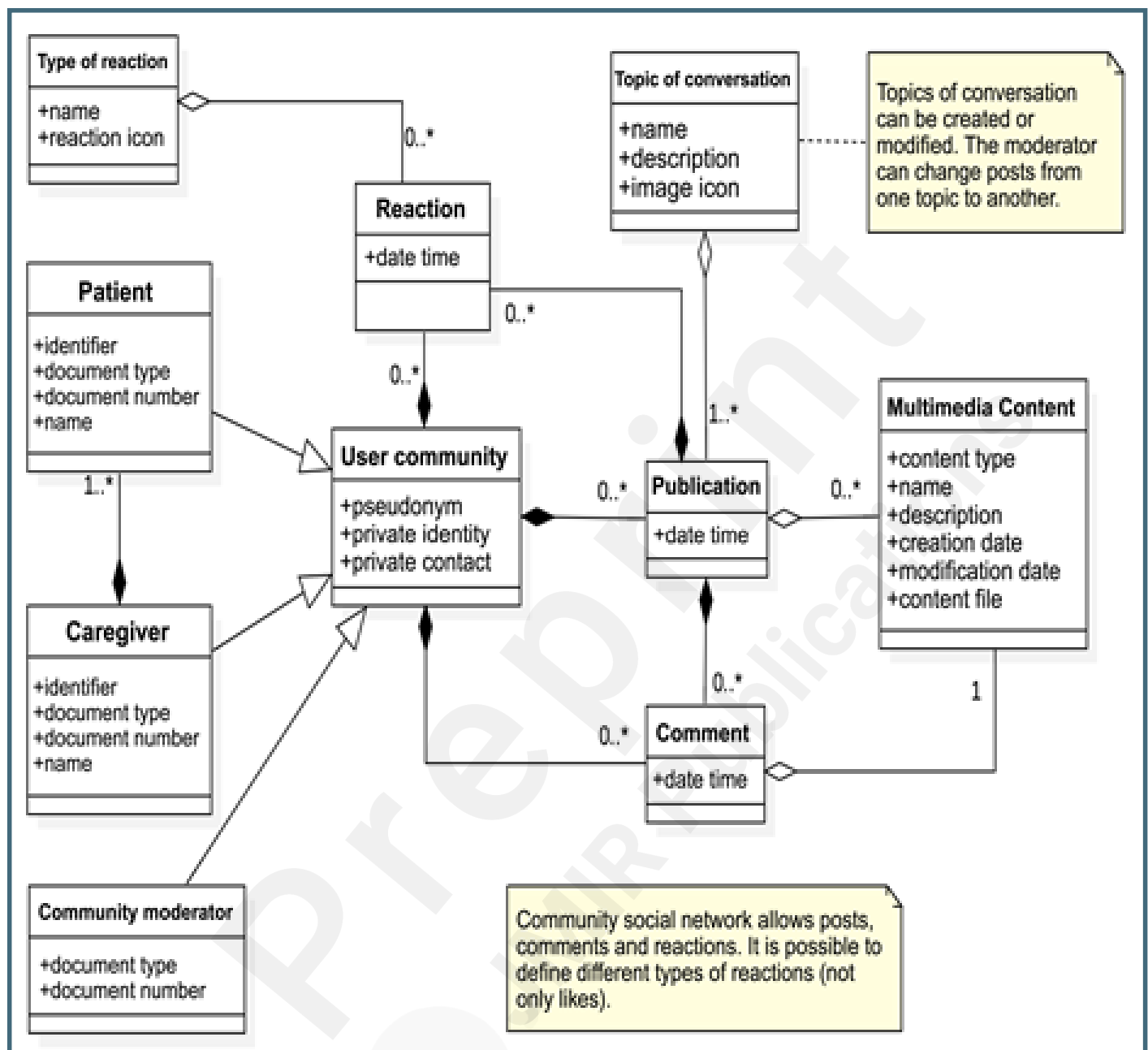
Report and assistance module.



Administrative guide module.



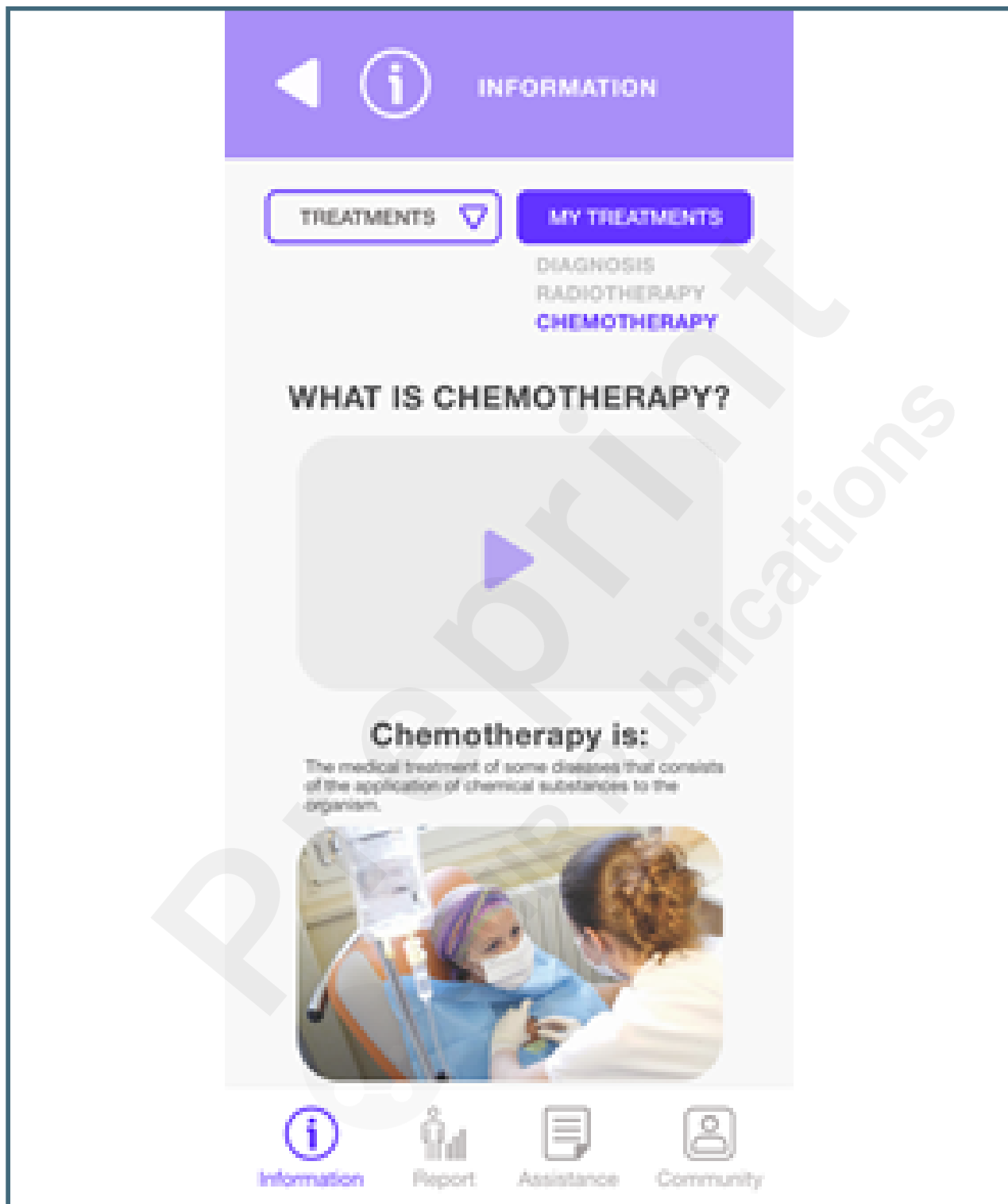
Community module.



Main view clinical care process (first level).



Clinical care process assistant module (sublevel).



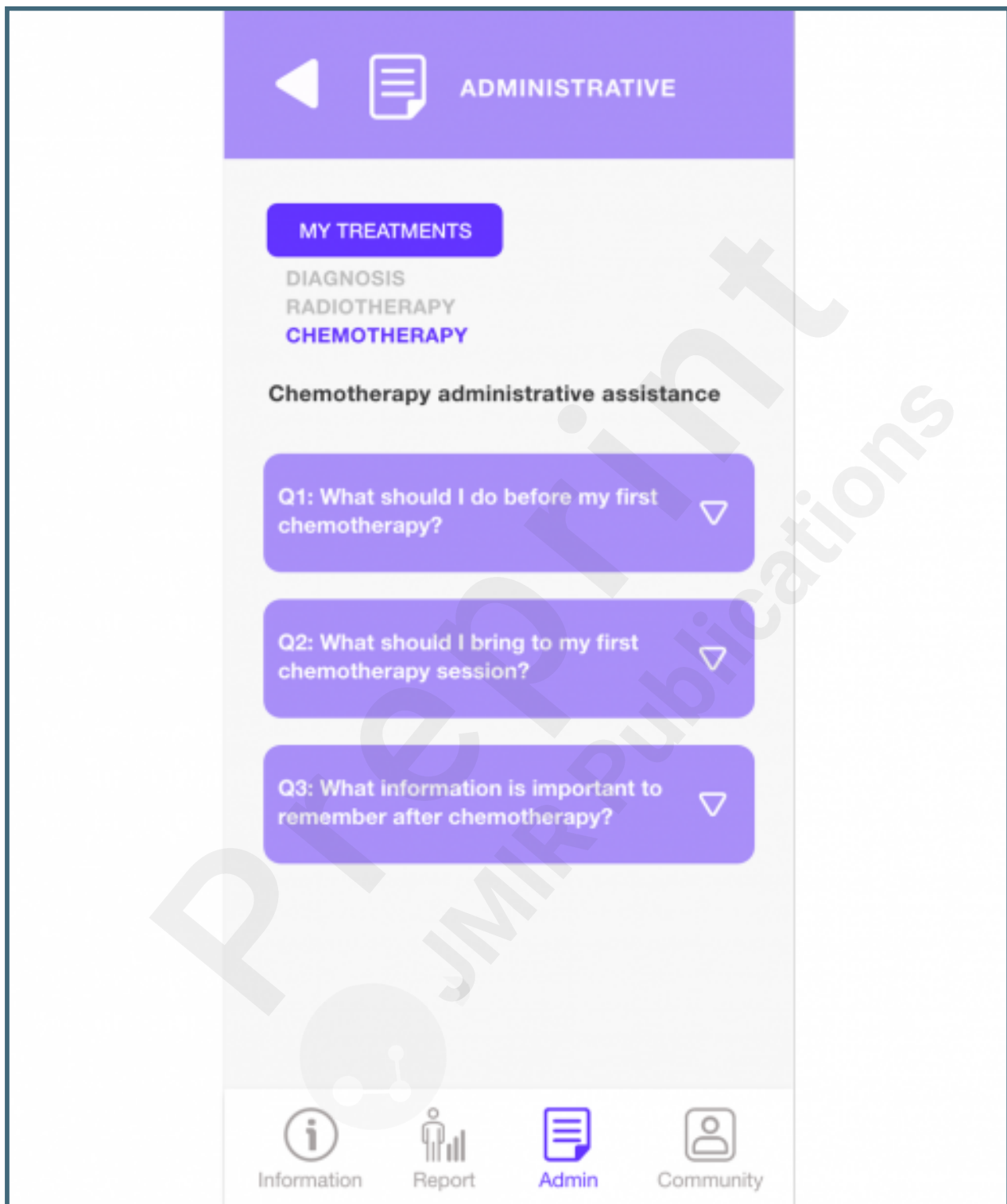
Report and Support module parameters.



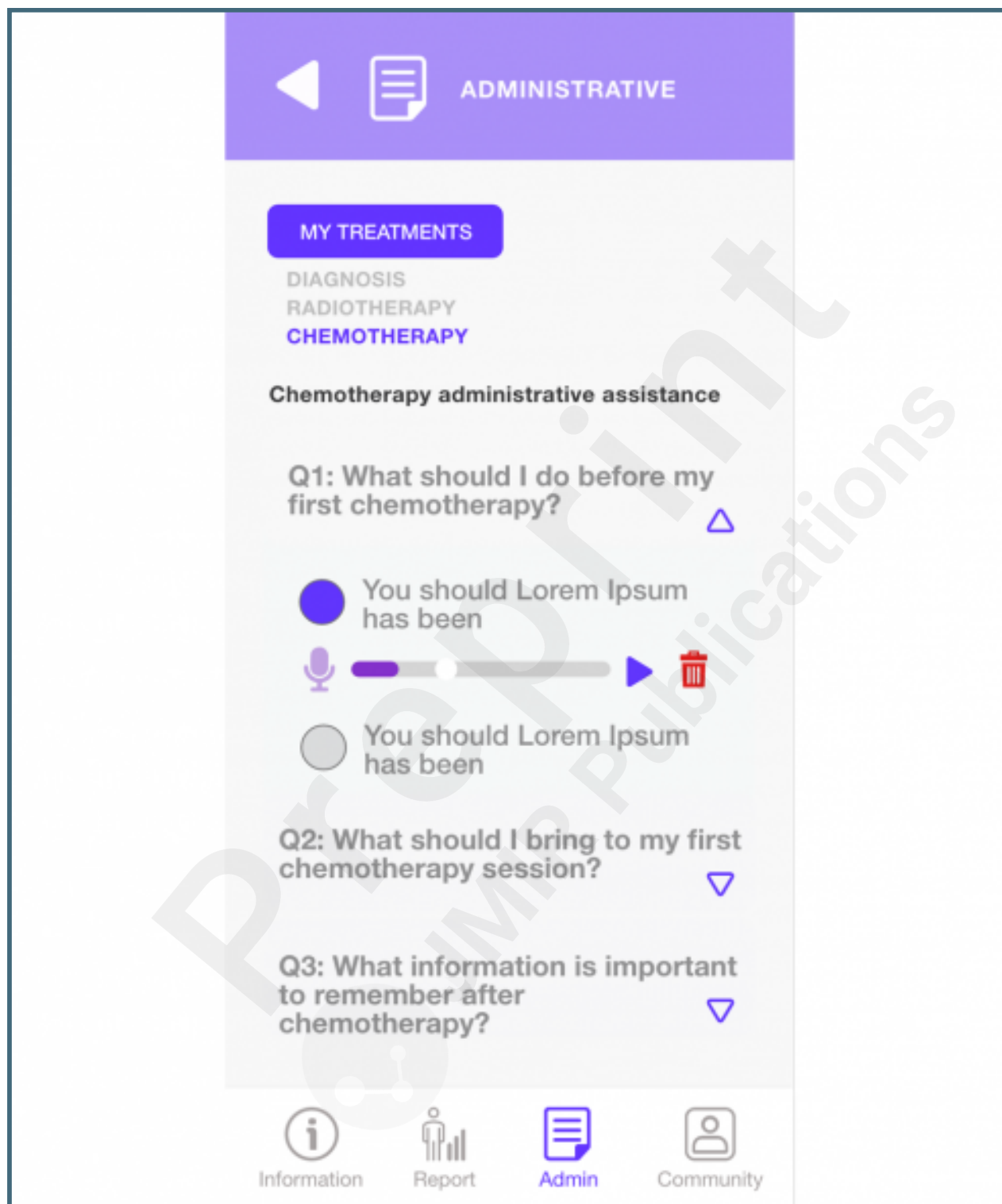
Symptom report and assistance module.



Administrative guide module (assistant questions).



Administrative guide module (record of patient voice notes).



Community module.

