IEEE Access
Multidisciplinary ⋮ Rapid Review ⋮ Open Access Journal

Date of publication xxxx 00, 0000, date of current version xxxx 00, 0000.

Digital Object Identifier 10.1109/ACCESS.2017.DOI

Design of an Electronic Health Record for Treating and Monitoring Oncology Patients in Chile

CARLA TARAMASCO[1 2], DIEGO RIVERA[3], CAMILO GUERRERO[4], and GASTÓN MÁRQUEZ[5]
[1]Centro para la Prevención y Control del Cáncer (CECAN), Chile.
[2]Instituto de Tecnología para la Innovación en Salud y Bienestar, Facultad de Ingeniería, Universidad Andrés Bello, Quillota 980, Viña del Mar, 2520000, Valparaíso, Chile (e-mail: carla.taramasco@unab.cl)
[3]Instituto de Sociología, Pontificia Universidad Católica de Chile, Vicuña Mackenna 486, Santiago, 7820436, Chile (e-mail: dirivera1@uc.cl)
[4]Escuela de Enfermería, Universidad de Valparaíso, Angamos 655, Viña del Mar, 2540064, Valparaíso, Chile (e-mail: camilo.guerrero@uv.cl)
[5]Departamento de Ciencias de la Computación y Tecnología de la Información, Universidad del Bío-Bío, Chillán, 3780000, Chile (e-mail: gmarquez@ubiobio.cl)

Corresponding author: Carla Taramasco (e-mail: carla.taramasco@unab.cl).

This work was funded by the ANID FONDAP 152220002 (*Centro para la Prevención y Control del Cáncer (CECAN))*

ABSTRACT Identifying the clinical needs to evaluate and manage the treatment and monitoring of cancer patients is a multidimensional challenge in healthcare institutions. In this regard, electronic health records (EHRs) are beneficial for managing clinical information; however, EHRs focused exclusively on patients with cancer have not been sufficiently adopted. In Chile, the need for oncology EHR has only been briefly addressed, resulting in insufficient updated and systematized information on oncology patients. In this paper, we propose the design of an oncology EHR that manages critical variables and processes for the treatment and monitoring of patients with cancer in Chile. We used a systematic methodology to design a software architecture oriented to focus groups and interviews to elicit the requirements and needs of stakeholders. We created and described an EHR design that considers four modules that group and manage the main variables and processes that are critical for treating and monitoring oncology patients. Enabling and designing a treatment and monitoring registry for cancer patients in Chile is essential because it allows for the evaluation of strategic clinical decisions in favor of patients.

INDEX TERMS Cancer, Oncology, Electronic Health Record, Attribute-Driven Design, Chile

I. INTRODUCTION

Cancer causes millions of deaths each year, generating high economic and social costs both in terms of the cost of treatment and the compromise it generates in the work productivity of those directly affected and their families and/or caregivers [1]. According to the World Health Organization (WHO) [2], cancer is associated with social determinants of health, such as socioeconomic status; educational level; working conditions; the quality of basic resources such as water and various health services; risk factors such as poor nutrition or unhealthy lifestyles; and structural conditions associated with public, socioeconomic, cultural, and environmental policies. In this way, it is possible to show marked inequalities in the distribution of this pathology, which makes it more complex to address, given that it is possible to observe regions with higher mortality from certain types of cancer as well as differences between men and women [3].

Health institutions worldwide have defined their mechanisms for treating and monitoring cancer patients. These mechanisms range from clinical processes, government policies, and health campaigns, to the development of monitoring care plans. Monitoring aims to evaluate the effectiveness of treatment, its duration over time, to detect complications of the disease or associated diseases, and to monitor the possible long-term adverse effects of treatment [4]. In addition, monitoring is appropriate for diseases with a course tending towards chronicity or recurrence, whose potential complications are of sufficient severity, and whose early management would be of benefit to the patient to be monitored.

Although treatment and monitoring strategies for cancer patients have proven successful in some countries, the increasing number of cancer patients, the inclusion of technologies in healthcare, and the need for fast, accurate, real-time, and quality data to evaluate new treatment and monitoring strategies force healthcare institutions to digitize their processes, including the cancer patient registry [5]. In this regard, electronic health records (EHR) are real-time, personalized, and digital versions of a patient's history that make information instantly and securely available to authorized users. While an EHR contains patients' medical and treatment histories, an EHR system is designed to go beyond the standard clinical data collected in a provider's office, and can include a broader view of a patient's care [6].

Clinical information systems (including EHRs) are composed of software that meet the needs of both patients and stakeholders. The development and deployment of clinical information systems involve several stages that depend on the type of development methodology selected by the teams [7]; however, there are basic stages that consider software development: (i) requirements identification, (ii) analysis and design, (iii) construction, (iv) testing, (v) integration, and (vi) maintenance. Requirements identification, system analysis and design are the most fundamental stages of the systems, as they are the inputs for the following stages. The requirements describe the main needs of stakeholders as well as the fundamental and critical characteristics of the system [8]. The design, on the other hand, reflects the vision of the system, which conceptualizes, encapsulates, and implements the system's functionalities. In turn, design analysis allows the analysis of which qualities or systemic properties are satisfied in the system [9].

In Chile, several public and private institutions have proposed initiatives to create a source of information on patients with suspected, diagnosed, treated, and monitored cancer for disease surveillance, data collection, and support scientific research to assist in public health decision-making and in the management of care for people with the disease [10]. Nevertheless, these institutions do not have the capacity to manage such initiatives systematically and digitally, which leads to several problems with the interoperability, structure, standardization, speed, and interpretation of patients' cancer data. Furthermore, health institutions do not have sufficient capacity to automatically share information with Chilean health authorities, resulting in biases in national treatment plans and monitoring of patients with cancer. The challenges described are not limited to the clinical setting. Because the treatment and monitoring of oncology patients must satisfy many different views of different stakeholders, there is insufficient information on which qualities attributes an oncology EHR must satisfy stakeholders' views. This implies that there is insufficient input for designing a technological architecture that meets the needs of cancer patients and clinical staff, which makes the construction, testing, integration, and maintenance of oncology EHR extremely difficult.

This study addressed the technical design of a national oncology EHR in Chile that aims to store high-quality clinical information and generate knowledge from variables related to cancer patient treatment and monitoring. Through the use of a systematic system design and appropriate stakeholder identification, we identified both clinical and technological needs to be met by oncology EHR. These needs translate into the identification of clinical variables and processes related to the monitoring and treatment of oncology patients in Chile, which are then mapped into an oncology EHR design. The contributions of this study are as follows:

- The design of an oncology EHR for the treatment and monitoring of cancer patients in Chile, obtained from a methodological process that includes stakeholder perspectives.
- A microservices-based architecture that is capable of supporting clinical processes related to the treatment and monitoring of clinical patients.
- The identification of eight quality attributes required by stakeholders to characterize oncology EHR.
- The characterization of the main clinical variables to record the process of treatment and monitoring of cancer patients in an EHR.
- The identification of the relevant actors in the treatment and monitoring of cancer patients in Chile.
- The description of key clinical processes related to the treatment and monitoring of people with cancer is necessary for the management of health centers through an EHR.

The remainder of this paper is structured as follows: Section II describes related work; Section III details the methodology used in this study; Section IV shows the results; Section V describes the design of the oncology EHR; Section VI details the discussion; And Section VII describes the conclusions of the study.

II. RELATED WORK

Several studies have reported research related to cancer registries in different countries. Some studies have described the experience of using and implementing integrated software systems to assess and monitor cancer patients in countries such as China [11], Nigeria [12], Iran [13], Denmark [14], North America [15], Egypt [16], Japan [17], Malaysia [18] and Ukraine [19]. The common denominator of these proposals is that the use of interoperability and both national and international standards for cancer patient registration is relevant for successful cancer registration systems. Although each country reports evidence based on its population and culture, these studies converge on the critical need for software systems that assist in managing the treatment and monitoring of cancer patients and in making early decisions.

Duggan et al. [20] discuss the US National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) program. The authors noted that approaches to cancer surveillance are evolving from enumerating the development of cancers by organ location in populations to monitoring the occurrence of cancers by histopathological and molecular subtypes, which opens up new possibilities for clinical research. In turn, the authors conducted a review that aimed to provide a brief overview of SEER and highlight opportunities and challenges for pathologists to benefit from and enhance the value of SEER data.

Bianconi et al. [21] propose a management system for the Umbria Cancer Registry (S.G.RTUP) based on AMPAX technology (Apache, Mysql, PHP, Ajax and XML) and object-oriented programming following the ISO/IEC 27001:2005 standard to guarantee the security of access to information. In addition, the authors defined and characterized a modular and extensible architecture. Furthermore, the location, topology, morphology, and behavior of cancer were described according to the International Classification of Diseases.

Pardamean et al. [22] describe the implementation of CANREG 5, which is a oncology EHR software used in Indonesia. The authors used empirical research methods and validated their approach in two cancer hospitals: the National Cancer Center (NCC) and the Cancer Registration Center (HCRC). To develop and deploy the proposal, the authors propose three phases: analysis of current technology, implementation, and system testing.

In terms of oncology EHR design challenges, Kechagioglou [23] mentioned that there are several challenges related to the collection of data generated by oncology EHRs. These challenges mainly point to linking the data to create structured and meaningful databases that are able to represent the general population, are unbiased, and are of good quality in order to draw meaningful conclusions. On the other hand, Strachna et al. [24] reported that remote monitoring programs based on the collection of patient-reported outcome data are increasingly being adopted in oncology clinical processes. This implies that when designing and implementing oncology EHRs, a module or component should be considered that allows alerts to be warned when an oncology patient experiences adverse events.

Other initiatives proposed by corporations such as International Agency for Research on Cancer (IARC[1]) , European Network of Cancer Registries (ENCR[2]), Spanish Network of Cancer Registries (REDECAN[3]) and Australasian Association of Cancer Registries (AACR[4]) aim to propose standardized information systems whose main function is to register cancer patients using interoperable data formats to share information between national health institutions.

The proposals described in this section demonstrate the benefits of oncology EHR systems for oncology patients. Each study addressed the development and implementation of software systems to register cancer patients in different countries. Our study aims to expand the body of knowledge on electronic cancer registries by describing the experience of designing clinical cancer registries in Chile. In addition, our study use systematic techniques to design software based on stakeholder satisfaction and the systemic properties represented by quality attributes.

III. METHODS

A. MOTIVATION

Like other countries, Chile has undergone a significant change in its population structure, and unhealthy behaviors and lifestyle habits have had an impact on the increase in morbidity and mortality from non-communicable diseases, both acute and chronic. Within the latter, cardiovascular diseases and cancer have been identified as the first and second leading causes of death [25]. In terms of mortality projections, more people die from cancer every year, and it is expected that by 2023, cancer will be the leading cause of death in the country (see Figure 1).

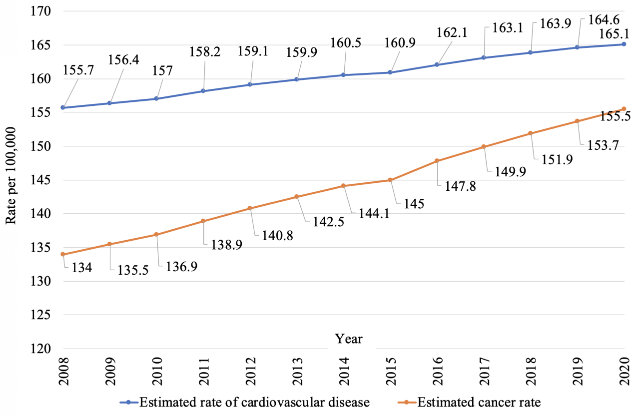

FIGURE 1. Cancer and cardiovascular disease mortality rates between 2008 and 2020 in Chile [25]

Even more so if one considers that around 40% of cancers are related to unhealthy lifestyles and modifiable risk factors, such as tobacco consumption and exposure to tobacco smoke, obesity, alcohol consumption, exposure to toxic substances and agents. These factors are common to other chronic diseases and are, therefore, amenable to common coping strategies. In this context, it is of utmost importance to strengthen the monitoring and treatment of cancer in the health system at the local level, both in the promotion of protective factors and self-care of the population, in order to favor healthy lifestyles, and in the protection of the environment, protecting the population from external agents that cause or could cause health problems [26].

In 2011, the Chilean government launched the National Health Strategy 2011-2020, which defined nine strategic objectives for the decade, including cancer monitoring and treatment, with the intention of making the strategy sustainable over time and guaranteeing a focus on national health actions with an intersectoral approach and a budget that supports the proposed objectives and goals. For the period 2021-2030, the lessons learned from the first period are being used to improve the proposed new strategy, which will focus on a more direct approach to cancer patients. One of the lessons learned is to identify the variables that are related to the suspicion of diagnosis, treatment, and monitoring of patients with cancer. This involves the collection of data directly from

---

[1] https://www.iarc.who.int

[2] https://www.encr.eu

[3] https://redecan.org/en

[4] https://ghdx.healthdata.org/organizations/australasian-association-cancer-registries

existing electronic clinical records in Chile, whether primary, secondary, or tertiary care, through coding and integration in compliance with international standards. Only in those cases where these records are not available in health centers will we propose the entry of data into the treatment and monitoring registry module for cancer patients. Therefore, our study focused on systematically designing a system that allows the process of registering the treatment and monitoring of cancer patients to be performed, considering the definition of the set of key variables, responsible actors, and registration events inspired on national and international practices, such as minimally invasive image-guided procedures [27], expansion in the depth and variety of databases [28], and others.

B. RESEARCH OBJECTIVES AND QUESTIONS

An overview of our study is shown in Figure 2. We identified stakeholders and requirements to characterize (i) oncological clinical variables, (ii) clinical processes related to oncological treatment and monitoring, and (iii) potential properties that oncological EHR should have. Subsequently, we used the information obtained to define and propose the design of oncological EHR. We also describe the technologies that will be used to implement oncological EHR. Finally, we will proceed with the development and deployment of oncology EHR. Because this last step considers several standardized activities, coding, processes, and tests, it will not be addressed in this study.

Our research objective is twofold. Clinically, we aim to identify and characterize the clinical variables that allow us to treat and monitor oncology patients, as well as the clinical processes that enable the above. Additionally, we aim to identify milestones that allow for reconstruction of the patient path, specifically at the treatment and monitoring stages. On the other hand, concerning the design of oncology EHR, we aim to describe the quality attributes that define the main characteristics that oncology EHR must have to enable the treatment and monitoring of patients. Consequently, the research questions are as follows:

- *Which clinical variables define and characterize the treatment and monitoring of cancer patients?* Rationale: This research question aims to systematize the treatment and monitoring of cancer patients through the identification of clinical, social, and demographic variables that will be considered in the oncology EHR.
- *Which clinical processes characterize the treatment and monitoring of cancer patients?* Rationale: The goal of this research question is to identify the relevant clinical processes that should be implemented in the oncology EHR, whose mission is to address events related to the notification of health institutions regarding the treatment and monitoring of cancer patients.
- *Which systemic properties should be satisfied in the registry to treat and monitor patients with cancer?* Rationale: This research question aims to identify the systemic qualities a oncology EHR should have to satisfy the needs of the different stakeholders involved in treating and monitoring cancer patients.

C. STAKEHOLDER AND REQUIREMENTS IDENTIFICATION

Identifying the needs and requirements of different stakeholders in a system is key to understanding the system's different views and expectations. Properly identifying requirements can influence the success or failure of a project. Consequently, if requirement identification is conducted incorrectly, it can lead to clinicians' rejection of the system as well as poor software development management. Studies such as [29] [30] claim that incorrect requirement identification causes clinical software to fail to meet the needs of stakeholders and, consequently, not to be considered in clinical processes. Given that the clinical care of oncology patients in Chile considers both the government and social operations, identifying and capturing meaningful requirements related to oncology EHRs is a critical task. Therefore, we designed a clinical study oriented towards intra-method triangulation [31] (see Figure 3), based on two mutually nurturing techniques, namely focus group identification and in-depth interviews.

This design allows us to obtain relevant and strategic information to design a system that addresses all the viewpoints described by the stakeholders. In addition, we used health implementation science techniques [32] [33] to identify evidence-based methods for implementing clinical interventions in oncology patients. Health implementation sciences focus on bridging the gap between research and clinical practice with the aim of promoting the effective adoption of evidence-based interventions in healthcare settings. These sciences offer approaches and methodologies to facilitate consideration of patient and stakeholder requirements during the implementation of health interventions. Consequently, we used the following implementation strategies [32] in our study:

- Capture and share local knowledge: It aims to elicit knowledge from the places where it is implemented and how implementers and clinicians do their work and share it with their peers.
- Conduct local consensus discussion: Suppliers and stakeholders are included in discussions that address issues affecting clinical process innovation.
- Involve executive boards: Involve government structures and institutions in process implementation efforts.
- Involve patients/consumers and family members: Encourage or include patients, consumers, and family members in process implementation efforts.
- Obtain and use patients/consumers and family feedback: Develop strategies to increase patient, consumer, and family feedback on process implementation.

The activities to obtain requirements focused on ten types of stakeholders, who signed an informed consent document validated by the Scientific Ethics Committee of the Chilean Ministry of Health. Table 1 presents the stakeholder profiles.

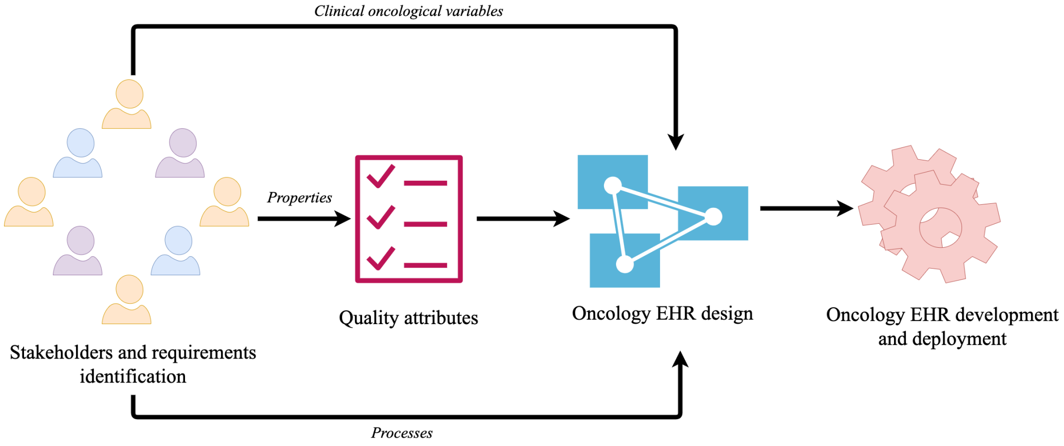

FIGURE 2. Overview of our study

TABLE 1. Description of the main stakeholders of the oncology EHR

Profile	Description
Health Authority	Representatives of the official institutions in charge of directing the health system at the national, intermediate, and local levels, with expertise in the areas of population-based cancer registries, among others.
Clinical Experts in Oncological Treatment	Clinical staff with at least five years of work experience in the area, who develop their professional practice in the treatment of neoplastic processes, both in the diagnostic suspicion, admission, monitoring, and completion of treatment.
Staff related to Care Management	Professionals with at least three years of experience in the area who work in the management of patients affected by oncological pathologies, particularly in the administrative processes of admission, the trajectory of people, and their treatment.
International Cancer Referrals	The experience with international referrals provides a global perspective on the necessary aspects to be integrated into a cancer treatment registry.
Scientific Society Representatives	Members of scientific societies are involved in the fields of medicine/public health and cancer. The participation of these societies will enrich the registry, as they develop comprehensive views in terms of research and social value in this type of issue.
Representatives of Oncology Patient Societies or Groups	The participation of these groups will favor the integration of elements from the experiences and meanings of the families in relation to this type of pathology.
Director of Oncology Services and/or Deputy Medical Director of Health Centres	The experience of directing oncology services or highly complex care centers is relevant given the overall management of waiting lists, inclusion of patients in the treatment process, resource management, and coordination at the level of clinical units, health facilities, and health authorities.
Expert in Health Economics	Professional in public health and/or health management, who develop analytical lines involving health economics. Including a health expert economics perspective will favor the inclusion of a perspective on the importance of having a cancer treatment registry based on cost-effectiveness analyses and the social relevance of this clinical/administrative management tool.
Reference person from the Institute of Public Health of Chile	Professional members of the Institute of Public Health know the expectations, experiences, and analysis of the treatment of patients with cancer. In this regard, at least one professional from the National Medicines Agency with expertise in pharmacological treatment of cancer patients is expected to participate.
Representatives of Pharmaceutical Associations	Professionals have extensive experience in the pharmaceutical industry at national and international levels, particularly in the management of cancer and in accessing the population.

1) Focus group

To execute the focus group technique, we constructed a list of relevant representatives per profile and created five focus groups, in which at least one representative was randomly selected from each group. Each focus group had a weekly meeting lasting approximately 90 min for two weeks. The meetings included participants, a professional moderator trained in qualitative techniques, faithful witness, and oncology EHR expert. In addition, the meetings had an initial stimulus and thematic guidelines to facilitate dialogue and

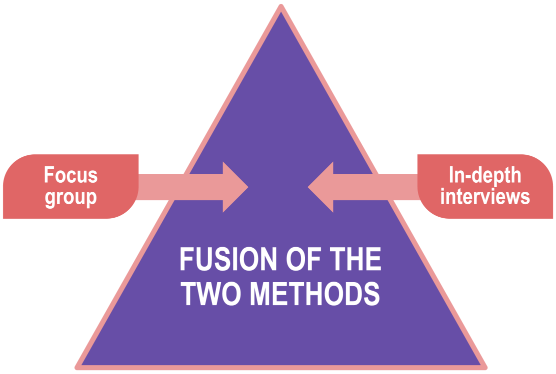

FIGURE 3. Intramethod triangulation

group listening. All meetings were conducted using a digital platform due to access and socio-sanitary conditions.

This technique assumes a dynamic and flexible structure in its application as it seeks a conversational process to generate information, and its objective is to bring together the main stakeholders to identify and analyze the primary needs to be addressed by the system.

In this activity, we conducted a preliminary survey to obtain the following information:

- The processes (internal/external) involved in cancer treatment, both in the public and private sector.
- The specific needs of key users and stakeholders.
- The applicable/current norms, protocols, ethical issues, regulations and standards for cancer treatment registration.
- International policies and best practices for cancer registries and registrars.
- Definition of functional and non-functional requirements of the cancer treatment registry.

Appendix B describes the questions asked in the focus group.

2) Interviews

In-depth interviews provide the possibility of studying the discursive trajectories of stakeholders to complement the information obtained in the focus groups. To conduct the interviews, we selected a relevant group of stakeholders based on the following criteria:

- Widely acknowledged national or international references/experts.
- Stakeholders who participated in the focus groups and/or made relevant proposals in the previous stage.

The interviews lasted 60–90 minutes to deepen the components addressed in the focus groups to obtain information. Thirteen interviews were conducted with key actors and experts from stakeholders' profiles. The initial guideline presents semi-structured interviews with questions aimed at identifying new elements and deepening those identified in focus groups. In the interviews, we addressed the following topics.

- General relevance of national cancer treatment and monitoring registry.
- Registry variables.
- Impacts of the national cancer treatment registry.
- Facilitators and barriers to the implementation of a national cancer treatment registry.
- Personnel in charge of the registry.
- Integration with other systems.

Appendix C describes the questions asked in the interviews.

D. ATTRIBUTE DRIVEN DESIGN

Because several actors and stakeholders are related to our proposal, the software architecture and selection of appropriate technologies become key artifacts for a successful and quality oncology EHR.

Although software development methodologies have well-defined phases that allow a system to be built, software architecture groups the design decisions that allow a system to respond to stakeholders' needs [34]. From a software perspective, quality is related to the satisfaction of requirements that point to the systemic properties of the software, such as availability, security, and scalability. In most cases, the qualities that a system must possess are described in terms of the extra-functional requirements. These requirements describe how a system must satisfy the needs of its users and stakeholders [35]. Moreover, these requirements describe the system constraints (e.g., security, availability, and scalability).

Given that each stakeholder has different aspirations regarding these properties (for example, software security for a physician is different from that for a cancer patient's family member), it is necessary to use methodologies that bring together different stakeholder views to define the software architecture that will be part of the oncology EHR development process. If we omit different stakeholder perspectives, the software architecture may not adequately meet the needs and objectives of the business. On the other hand, from a clinical point of view, a poorly designed software architecture can lead to resistance to change by those who feel excluded or disregarded. This can lead to conflict, lack of acceptance of the system, and difficulties in the implementation and adoption of software. Therefore, we used Attribute-Driven Design (ADD) methodology (see Figure 4) to define the architecture of the oncology EHR [36].

ADD is a software architecture design method that provides steps for designing software systems over a series of iterations. It focuses on satisfying the quality attributes by selecting and instantiating different types of structures. The inputs to this process are summarized as follows:

- Design purposes describe the design intent to be achieved in the system.
- Primary functional requirements are those functionalities that the system must provide.

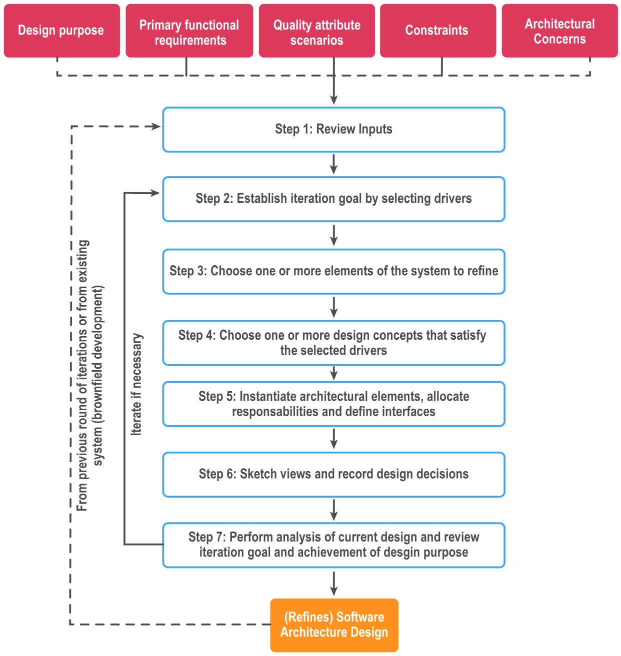

FIGURE 4. The Attribute-Driven Design method [36]

- Quality attribute scenarios are specifications that describe and detail how and where system properties will be satisfied.
- Constraints are software decisions with little control over the design (e.g., governmental constraints).
- Architectural concerns are more general issues that the system must address. These issues generally point to technologies and software specifications.

With the inputs already established, ADD executes seven steps that allow the iterative design of a software architecture considering the different dimensions described in the inputs (Appendix A details the steps of ADD). Each step has its own complexity and corresponding internal processes. As a result, the ADD generates an output corresponding to the software architecture design that is used in the subsequent phases of software development.

ADD also allows for the definition of scenarios that enable the development and implementation of software. The quality attributes obtained by the ADD define the drivers of the software architecture of the system. These drivers are based on design decisions that will be implemented in the system, either as architectural patterns or through the use of technologies. Architectural patterns are systematic solutions to recurring problems in software design [9]. These patterns help represent software design and guidelines for selecting the technologies that implement them.

IV. RESULTS

A. VARIABLES FOR TREATING AND MONITORING ONCOLOGICAL PATIENTS

We identified 19 relevant stakeholder requirements from focus groups and interviews. Although the list of requirements is generally extensive, we identified the requirements that are essential for developing and implementing the national oncology EHR. The details of these requirements are presented in Appendix D.

Regarding requirements, stakeholders emphasize that the system should contain a cancer treatment-only module to identify potentially ill patients. In addition, stakeholders need to have a history of changes in cancer patient treatment and monitoring records.

On the other hand, stakeholders mentioned that including clinical staff in the system is relevant and strategic for accessing patient characterization data and their respective historical information. Similarly, clinical staff should have access to download patient information anywhere in the country, and should be empowered to extend the clinical characteristics of the patient if necessary.

From quantitative and qualitative points of view, it is important for stakeholders to have an analysis module that allows them to make decisions regarding the treatment and monitoring of patients. This information is relevant, as it allows them to make indicators, reports, and patient risk maps, as well as to apply data science to the information.

From a clinical point of view, stakeholders expressed that it is essential to systematize, under the framework of social determinants of health, a demographic characterization of cancer patients to guide the production of better health indicators. The data relevant for this purpose and those identified by the stakeholders are as follows:

- Sex (registered at birth)
- Gender
- Date of birth
- Age at cancer diagnosis
- Date of death
- State
- County
- Nationality
- Social priority index
- Type of housing (rural or urban)
- Ethnicity
- Religious belief
- Level of school education
- Occupation
- Occupational exposure
- Health insurance
- Existence or non-existence of supplementary insurance
- Risk factors and access to health centres
- Type of cancer
- Date of diagnosis
- Type of institution in diagnosis, treatment and monitoring
- Type of treatment
- Date of indication for treatment

- Name and dose of drug
- Weight
- Size

The data described above not only allow for the characterization of the demographics of cancer patients but also for the standardization of therapeutic strategies. Therefore, stakeholders also request that the national oncology EHR be able to recommend data and information on three aspects relevant to the monitoring of patients with cancer:

- Type of treatment and timing: This need points to the therapeutic intention according to the type of cancer and intervention advised for the patient's health status. This information, which comes from the clinical resolution stage of the oncology EHR, will make it possible to characterize the institution of origin, diagnosis, access to therapies, their sequence, and the start/end times for each of them.
- Origin of patient referral: This functionality refers to registering the care centers involved in the different therapeutic strategies for access to treatment for people with cancer.
- Registration of medication and dosage: This need points to information on the medication used in cancer patients. Therefore, it is proposed that each medicine's generic name or active ingredient be registered, as well as the dosage indicated by the specialist, to establish a relationship with the treatment cycles. In addition, stakeholders express the need for a drug database to acquire more and better data for monitoring national policies, health management, and efficiency of public resources.

Stakeholders also mentioned the need to incorporate monitoring information into the registry. Currently, in Chile, the monitoring of patients with cancer is the responsibility of secondary and tertiary care to monitor possible complications of the disease (metastasis, thrombosis, dysphagia, etc.) and treatment (myopathies, neuropathies, others). One of Chile's significant public health priorities is to make patient registration compatible between public and private systems and between the different levels of care provided by clinical institutions. In this regard, it is essential to identify monitoring strategies according to the type of institution, interventions performed, and information integration. This monitoring should include criteria related to current indicators of the quality of healthcare provision, evaluation of care, and management, considering the minimum variables collected at the international level to compare the evolution of this type of disease and their treatments with those of other countries.

B. CLINICAL PROCESSES

Although the oncology EHR encompasses several types of clinical processes, we identified two critical processes for stakeholders: suspicion of a patient with cancer (see Figure 5) and the staging and treatment process (see Figure 6).

The suspicion process spans from receiving a suspected cancer diagnosis to the histological confirmation of cancer and the clinical notification of the patient for their diagnosis. The process begins when the treating physician receives a patient with a suspected cancer diagnosis from a non-cancer care center. If the patient's data do not contain sufficient biopsy results or history for diagnosis or require new details, the process continues with the Anatomical Pathology department. Otherwise, if the patient's data come with the biopsy or the patient is not susceptible to analysis, the process continues with the Preparation Committee. The physician prepares the patient's presentation to the oncology committee, organizing the available background for diagnostic confirmation, staging, and treatment resolution. Finally, during the medical consultation, the physician notifies the patient of his or her cancer diagnosis (whether suspected, histological, or cytological) and his or her future presentation to the committee.

The physician will then refer the case to the Committee until the Committee's therapeutic decision, including cancer staging. During this process, the physician determines whether tests are required for cancer staging. For this, the physician may consider: (i) not requiring tests, as the patient has arrived with a history from another health center; (ii) requiring laboratory or imaging tests to complement the histological diagnosis provided by the pathological anatomy for tumor cancer; (iii) requiring laboratory or imaging tests to complement the cytological diagnosis provided by the laboratory for non-tumor cancer; or (iv) requiring laboratory or imaging tests to provide a history for patients who cannot undergo a biopsy. Subsequently, the physician incorporates the patient's history, which is necessary for the Committee's evaluation, and requests the patient's review.

The oncology committee analyzes the medical history and determines whether a therapeutic decision can be made. If necessary, the histological diagnosis is updated. In case of insufficient background information, the treating physician is requested to order further examinations before the therapeutic decision is made. After the therapeutic decision, the patient may undergo one or more treatments and be monitored by a physician.

Monitoring can be (i) during a treatment, (ii) after completion of one of several treatments assigned to the patient, or (ii) after completion of the last treatment. If the treating physician identifies the need to present the patient to the committee, he or she will continue with Committee Preparation. Otherwise, if the patient has any remaining treatment, he or she will return for a new check-up. If no more treatments are left, and the patient does not need to be evaluated by the committee, the patient will undergo strict oncological monitoring.

C. QUALITY ATTRIBUTES

Stakeholders mentioned different types of needs and qualities of the national oncology EHR. Consequently, we identified

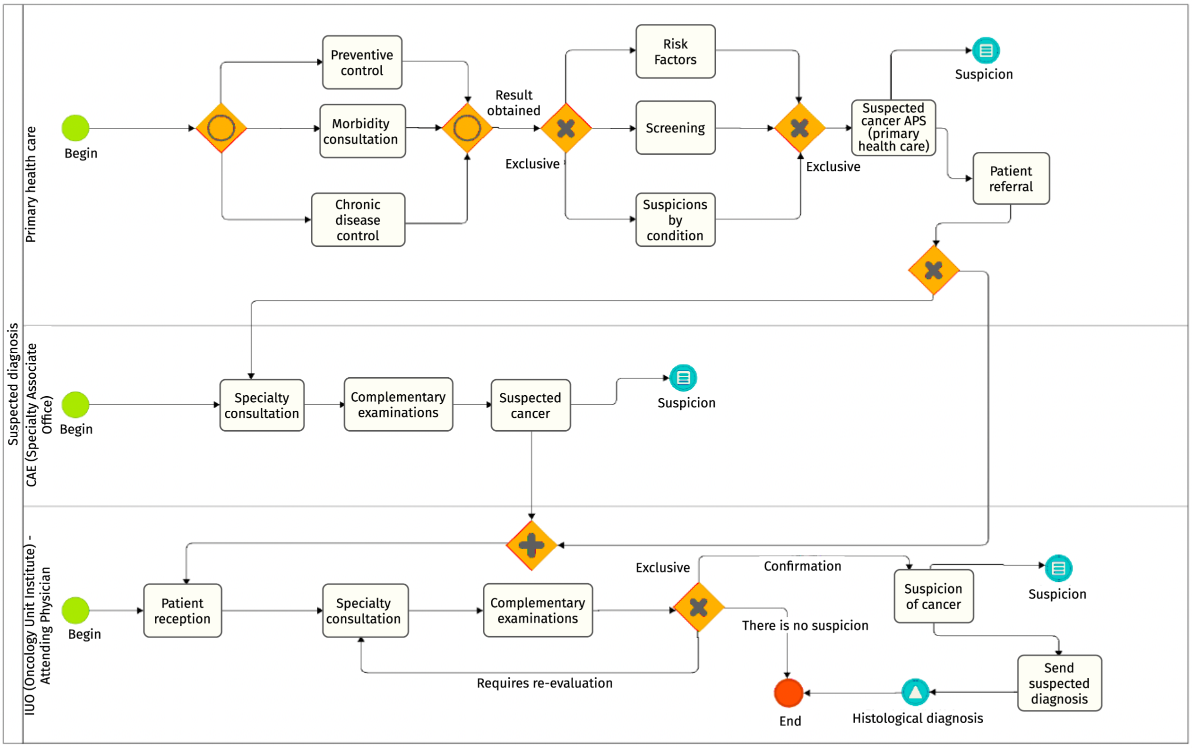

FIGURE 5. The suspicion diagnosis process

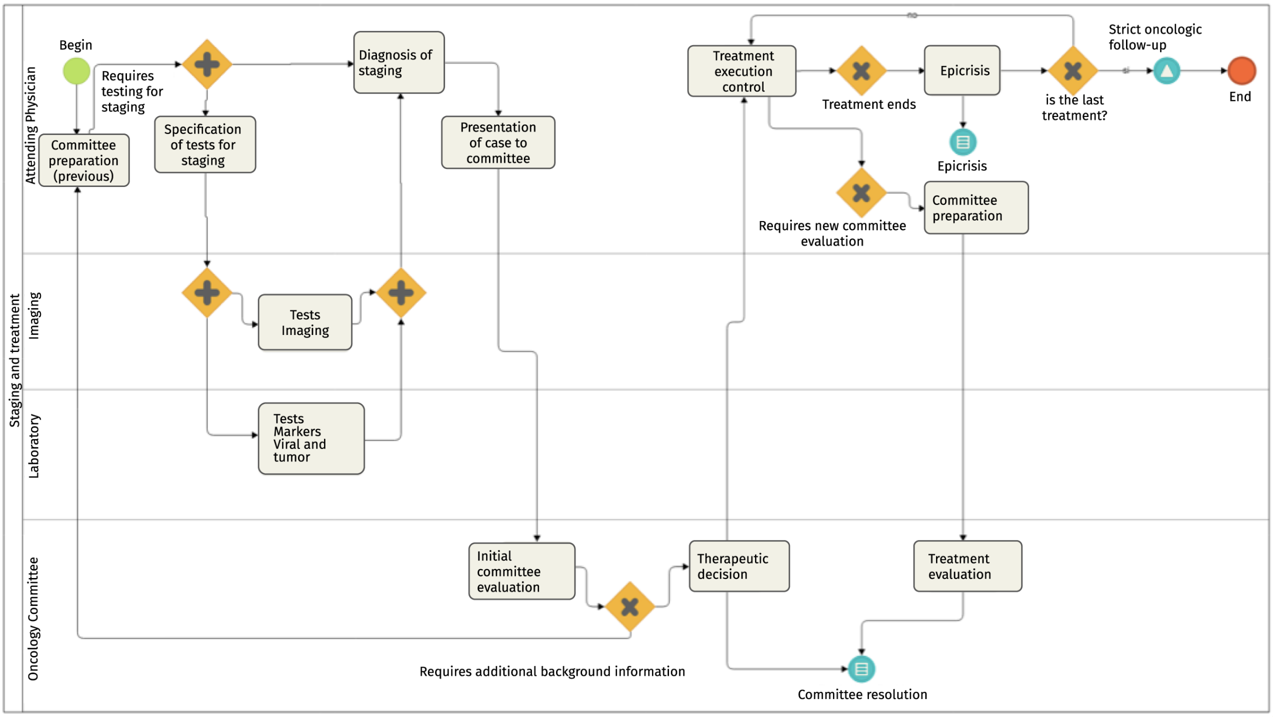

FIGURE 6. The staging and treatment process

14 extra-functional requirements characterized by eight quality attributes (based on ISO 25010 [37]) as follows:

- *Compatibility*: Stakeholders expressed significant concern regarding the interoperability and coexistence of data. From an operational and clinical point of view, it is relevant that data can be communicated between different systems.
- *Reliability*: Regarding this attribute, stakeholders mentioned that the system must have a robust ability to be fault tolerant because, if data is unavailable, it can compromise the quality of patient care.
- *Security*: This attribute was the most important for stakeholders. Privacy, confidentiality, accountability, non-repudiation, and authenticity are imperative qualities of the clinical record. Additionally, the Chilean Ministry of Health's security policies require all clinical information systems to have security standards.
- *Performance*: For the stakeholder, the system must perform optimally at certain moments of high workflow, specifically in creating reports and patient monitoring.
- *Maintainability*: From the point of view of adapting to new requirements, the stakeholders requested that the system should be modular in order to be able to add modules whenever a new need is required.
- *Usability*: Given that the national oncology EHR will be used by a variety of users with different profiles and technical knowledge, it is essential for stakeholders that the system has a policy of protection against user errors, as well as a minimalist and functional aesthetic.
- *Portability*: It is important to stakeholders that the system can be used on different operating systems, browsers, and mobile devices.
- *Interoperability*: Patients' clinical data must be exchanged between different clinical processes while maintaining the integrity and availability of information.

V. DESIGN OVERVIEW

We used the answers to the research questions as inputs to define the high-level design of the oncology EHR. To describe the design, it is important to select the most relevant actors in the oncology EHR from stakeholders. Additionally, the second research question provided background information on the most important modules that the oncology EHR should have. Finally, the ADD methodology revealed the potential architecture of cancer registries. Figure 7 presents an overview of the proposed system.

The main actors in the oncology EHR and its modules are described as follows.

- Physician: This actor can view, record and edit the information of patients under their care.
- Nurse: This actor has the same powers as the Physician actor, as long as it is pre-authorised by the corresponding physician.
- Healthcare Professional: This actor has the same attributes as the Nurse actor, also requiring prior authorisation from the Physician actor. This user can be an external professional who is not directly related to the patient but focuses on data recording.
- MINSAL (Chilean Ministry of Health): This actor has a central role which allows him/her to have access to the information of all patients, without being able to edit the record, and to the analysis module.

Consequently, the modules of the oncology EHR are as follows:

- Treatment Module: This module allows the entry of the treatment associated with the patients registered in the oncology EHR and the monitoring carried out during this period. Different treatments may be entered manually by platform users or obtained through interoperability with external sources or other MINSAL systems.
- Monitoring Module: This module allows the entry of monitoring actions performed on patients registered in the oncology EHR after the completion of their treatments in order to verify the results, side effects and general health status of the patient. Different actions must be entered manually by platform users.
- Characterisation Module: This module allows extending the information of patients registered in the oncology EHR, with the aim of having data that detect those factors that are relevant to the impact of patients' health, such as, for example, social determinants.
- Analysis Module: This module allows the generation of indicators and valuable information from monitoring data, demographic data and the epidemiological characterization of patients. Among the functionalities to be incorporated are different types of data analysis (surveillance indicators, care/management evaluation, survival analysis, and social determinants) and the generation of reports, dashboards, and risk maps.

Table 2 summarizes the operationalization of the design for the implementation of oncology EHR. Broadly speaking, we used a technology stack based on Spring Boot[5] and Angular[6] to implement most of the attributes. Some of these quality attributes are implemented in patterns, such as the Circuit Breaker pattern. Although the pattern describes an overview of the solution to be used, it will be implemented using Spring Boot technology. In contrast, the predominant architecture style in our oncology EHR is the microservice architecture style [39] [41]. Microservices architecture is an architectural style that structures an application as a set of independent and autonomous services. Each service focuses on a specific functionality of the system and can be individually developed, deployed, and scaled. Instead of building a monolithic application, where all functionality is contained in a single block of code, the microservice architecture divides the application into smaller cohesive services. These services communicate with each other through well-defined interfaces, such as Application Programming Interfaces (APIs), to perform complex tasks.

---

[5] https://spring.io

[6] https://angular.io

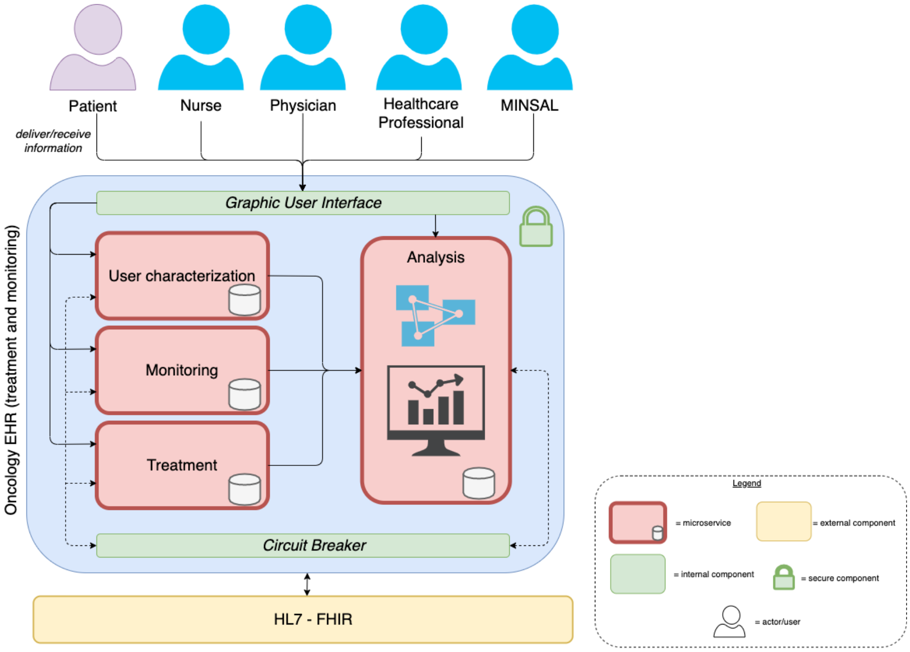

FIGURE 7. High-level design of oncology EHR system

TABLE 2. Decisions and implementation of quality attributes

Quality attribute	Decision	Architectural pattern/technology	Rationale
Compatibility	Architecture with independent modules	Spring boot	Application development in the Java language is required
Reliability	Prevent a system from constantly trying to execute an operation that tends to fail	Circuit Breaker pattern [38]	This pattern detects faults and encapsulates the logic to prevent faults
Security	Use authorization and authentication mechanisms. In addition, data must be protected	Spring boot security	This Spring boot component provides robust security libraries to the back-end
Performance	Acceptable clinical consultation time in the oncology EHR	Using indexes in databases	Adjustments to the database and queries are required, applying the necessary indexes
Maintainability	Architecture with independent modules	Microservices architecture [39]	Stand-alone backend applications are required
Usability	System error handling	Angular and Angular Material	Angular Material technologies offer front-end libraries that users widely accept
Portability	Use of the system on different platforms and browsers	Angular	Angular technology supports multiple web browsers
Interoperability	Use clinical data exchange standard	HL7 and FHIR [40]	HL7 (Health Level Seven) is a set of standards that facilitate the electronic exchange of clinical information. On the other hand, Fast Healthcare Interoperability Resources (FHIR) define a set of resources that represent granular clinical concepts.

Our design also considered the ability to exchange, interpret, and use patient oncology data effectively. Therefore, we consider HL7 (Health Level Seven) and Fast Healthcare Interoperability Resources (FHIR) in the interoperability component. HL7 is a set of international standards for the exchange of clinical and administrative information in health care systems. These standards facilitate communication and interoperability between different healthcare systems and applications, allowing data to be shared securely and consistently. HL7 defines a set of messages, structures, and protocols that specify how health data should be exchanged [40]. These standards cover a wide range of areas such as electronic health records, appointment management, laboratory management, and billing. In addition, HL7 provides a framework for the development of interfaces and integration of health information systems. On the other hand, FHIR is a standard for clinical data interoperability that is based on modern web principles and uses data exchange formats such as JSON and XML [42]. FHIR was developed with the aim of being easier to implement and use than the previous HL7 standards. FHIR focuses on resources that represent logical units of clinical information, such as patients, appointments, medications, and laboratory results. These resources can be exchanged individually and combined to form more complex documents or messages. It is worth mentioning that the quality attributes of compatibility, performance, and portability are not described in Figure 7, as they are qualities that are implemented in the oncology registry programming code.

The microservice-based design proposed in our study opens up the possibility of including emerging techniques and technologies to obtain the maximum value from the data managed by the oncology EHR. According to studies such as [43] [44], artificial intelligence can be a great ally for the detection of different types of cancers, such as breast cancer. The techniques used in artificial intelligence to classify and predict data are relevant for supporting medical decision-making. The oncology EHR is designed to have large datasets in the form of images and health records. With artificial intelligence, the system may be able to analyze such data to discover patterns and relevant information that even a team of highly skilled clinicians would not be able to detect. Our previous studies on data analysis using artificial intelligence [45] provided us with guidelines for including data classification and prognostication techniques in oncology EHR.

A. VALIDATION

We conducted a pilot plan for the treatment registry and monitoring of cancer patients, focusing preferably on breast cancer, highlighting the development of a pilot that includes clinical pathways, divided by treatment, with the aim of moving towards a comprehensive and integrated development of health policies in Chile. Thus, oncology EHR views related to patient characterization, oncology treatment entry, and patient monitoring have been deployed. In this pilot study, we gathered critical stakeholders to evaluate the functionalities and qualities of oncology EHRs through acceptance testing of the main functionalities. Given the good results obtained in the pilot study and based on our analysis of stakeholder feedback, we plan to expand the pilot experience to six additional cancer types: breast, lung, cervical, colon, gastric, prostate, and leukemia (if we add children and adolescents).

B. LIMITATIONS

The main limitation of our proposal is that it aims to define specific views on cancer types. According to feedback from users and stakeholders, it is necessary to have specific information on different types of cancer, as each type of cancer requires specific treatment and monitoring decisions. This requirement can make the oncology EHR a complex system as each cancer has its own way of being treated. On the other hand, another limitation we identified in the study is the identification of who is responsible for the registry, that is, who will take responsibility for entering the data and following the patient's progress. In our proposal, the physician defines the clinical actions regarding treatment; however, since monitoring is not a medical responsibility, care management professionals (e.g., nurses) must take responsibility. Given this scenario, the system must have specific functionalities and views that can be used by professionals when monitoring patients.

VI. DISCUSSION

The experiences we gathered with the implementation of the oncology EHR reveal that it is important for the treatment and monitoring of cancer patients to identify and characterize who is responsible for the monitoring. With regard to our study, we identified that the physician (and the corresponding team) is essential for the oncology EHR to be successful for patients, as the physician must account for interventions, strategies by institution, characterization of the health provider according to the population and portfolio, and integration with other databases. Since the oncology EHR uses HL7 standards, the data added by physicians are used by various institutions that study cancer in Chile. They are also used to create new and better-quality indicators for patients with cancer.

On the other hand, the proposed oncology EHR has served as a mechanism to integrate different institutions that contribute data with the aim of extending the potential of the oncology EHR by extracting and exchanging a subset of records to which they can add new variables to be observed. This will allow the oncology EHR to be used as an initial source of cases to allow the system to evolve towards the registration of specific aspects of other varieties of cancer and for the development of cancer-related research, enhancing the significant contribution of knowledge both at the level of novel treatment proposals and for the validation of already developed treatments that require a patient base with well-defined characteristics.

According to the feedback gathered from users and stakeholders who have used the oncology EHR, our proposal has great potential in terms of creating indicators to measure the impact of cancer in Chile. Feedback suggests that the oncology EHR can act as a producer of inputs for various outcomes related to the completeness of cases or the completeness and accuracy of the details of cancer patients in Chile. In other words, in the opinion of stakeholders, the dimension of treatment and monitoring provided by the oncology EHR includes criteria related to minimum variables proposed at the international level, with the purpose of comparing the evolution of cancer and its treatment in other countries.

From the perspective of oncology EHR development and deployment, using a methodology focused on system properties and stakeholder needs allowed us to better manage expectations about the system. Given that the need to create a oncology EHR is relevant to health services in Chile, each relevant stakeholder has different needs and aspirations. These must be reflected in the system; therefore, using familiar software development processes is not sufficient. The ADD methodology allows us to identify the main stakeholder needs early and translate these needs into quality attributes. Using the steps of the methodology, we were able to characterize and describe the main stakeholder needs through quality attributes to select technologies and patterns in a more informed and systematic way. Thus, we created a common vision of the system among stakeholders based on a software architecture that primarily meets the needs of all stakeholders involved in cancer monitoring and treatment.

VII. CONCLUSIONS

In this study, we proposed a national electronic oncology EHR to treat and monitor patients with cancer in Chile. By systematically identifying relevant variables for the treatment and monitoring of patients, we identified a set of variables that allow us to fulfill the different needs expressed by stakeholders that aim to provide quality patient care. On the other hand, to build an electronic registry that meets stakeholders' expectations, we used a systematic approach to design the software architecture of the registry to satisfy stakeholders' concerns and thus conduct appropriate development of the registry. As a result, we identified twenty-six variables critical to the treatment and monitoring of cancer patients. In addition, we identified two clinical processes relevant to the stakeholders that the oncology EHR should consider. Finally, we identified eight systemic properties that the oncology EHR must satisfy to provide quality care for patients and families.

To further our research, we will proceed to explore the data collected by the registry with the aim of implementing tools for data visualization and mining by analyzing the information collected by the oncology EHR. More precisely, we will proceed to study the needs of different actors in the public sector to take advantage of the information in the registry through information views with different levels of grouping according to their needs and the possibility of exporting (anonymous) data for more specific requirements that institutions can use for their own research purposes.

ACKNOWLEDGMENTS

We thank Michelle Pacheco for her support and contribution to our study. Additionally, we want thanks Millennium Nucleus on Sociomedicine (ANID - MILENIO - NCS2021_013) and the Centro Nacional en Sistemas de Información en Salud (CENS).

.

APPENDIX A THE ATTRIBUTE DRIVEN DESIGN STEPS

The ADD steps [36] are described as follows:

- Step 1 - Review inputs: The architect reviews the inputs provided, including the requirements, constraints, and stakeholder concerns. These inputs allow architects to understand the context of the system and its desired outcomes.
- Step 2 - Establish iteration goal by selection drivers: The architect identifies and selects the key drivers that guide design iterations. These drivers are often quality attributes that are critical to the success of a system.
- Step 3 - Choose one or more elements of the system to refine: The architect identifies elements of the system that require further refinement to address the selected drivers. Often, these elements are specific components, modules, or features that play an important role in achieving the desired quality attributes. At this point, it is important to identify key stakeholders to discuss the critical elements of the system.
- Step 4 - Choose one or more design concepts that satisfy the selected drivers: In this step, the architect generates and evaluates the design concepts that respond to the selected drivers. The different views that the system has (e.g., physical view, infrastructure view, logical view) are inputs for the architect to make decisions.
- Step 5 - Instantiate architectural elements, allocate responsibilities, and define interfaces: An architect instantiates the chosen design concepts by assigning them to specific architectural elements.
- Step 6 - Sketch views and record design decisions: The architect creates specific architectural views, such as component diagrams, deployment diagrams, or sequence diagrams, to illustrate the structure and behavior of the system. Additionally, all design decisions made during the process were documented, providing a clear record of the fundamentals of the chosen design.
- Step 7 - Perform analysis of the current design and review iteration goal and achievement of design purpose: In the last step, the architect conducts an analysis of the current design to assess its effectiveness in addressing the selected drivers and achieving the goal of iteration. Deviations or deficiencies are identified and adjustments are made to refine the design and align it with the overall design intent. In addition, alternative scenarios are analyzed to detect potential problems in the proposed design.

APPENDIX B FOCUS GROUP QUESTIONS

The questions for the preliminary survey are as follows:

1) What are the main objectives of a cancer treatment registry?
   - Focus of the discussion: Participants are invited to describe, from their point of view, the main objectives that a cancer treatment registry should address in order to advance the definition of requirements (in a general way) that a cancer treatment registry system should have and its possible impact at the national level. It is also expected to open the discussion on international experiences and to learn what each par-

ticipant highlights about cancer treatment registries.

2) How can a registry respond to the proposed objectives?
    - Focus of the discussion: The aim is to determine the wishes of each participant about the cancer registry, in order to detect early on what expectations the registry will and will not be able to meet.
3) If we consider people starting and completing cancer treatment, what are the main variables or criteria for a oncology EHR?
    - Focus of the discussion: Identify the main variables that should be addressed in the implementation of a oncology EHR.
4) What are the steps in implementing the cancer treatment registry implementation strategy? Identifying weaknesses and strengths at the local level.
    - Focus of the discussion: Identify different strategies for implementing a national cancer treatment registry, identifying local weaknesses and strengths.
5) What are the perceived barriers to and facilitators of oncology EHR?
    - Focus of the discussion: Identify the main barriers and facilitations that need to be addressed in the implementation of oncology EHR.

APPENDIX C LIST OF STAKEHOLDER INTERVIEW QUESTIONS

Table 3 describes the questions we asked stakeholders.

APPENDIX D STAKEHOLDERS REQUIREMENTS

Table 4 describes the main functionalities to be performed by oncology EHR.

REFERENCES

[1] R. Yancik and L. A. Ries, "Cancer in older persons: an international issue in an aging world," in Seminars in oncology, vol. 31, pp. 128–136, Elsevier, 2004.
[2] J. Ferlay, M. Colombet, I. Soerjomataram, D. M. Parkin, M. Piñeros, A. Znaor, and F. Bray, "Cancer statistics for the year 2020: An overview," International journal of cancer, vol. 149, no. 4, pp. 778–789, 2021.
[3] F. Merletti, C. Galassi, and T. Spadea, "The socioeconomic determinants of cancer," Environmental Health, vol. 10, no. 1, pp. 1–7, 2011.
[4] A. S. Walker, N. P. Zwintscher, E. K. Johnson, J. A. Maykel, A. Stojadinovic, A. Nissan, I. Avital, B. L. Brücher, and S. R. Steele, "Future directions for monitoring treatment response in colorectal cancer," Journal of Cancer, vol. 5, no. 1, p. 44, 2014.
[5] C. A. Caligtan and P. C. Dykes, "Electronic health records and personal health records," in Seminars in oncology nursing, vol. 27, pp. 218–228, Elsevier, 2011.
[6] N. Menachemi and T. H. Collum, "Benefits and drawbacks of electronic health record systems," Risk management and healthcare policy, pp. 47–55, 2011.
[7] N. B. Ruparelia, "Software development lifecycle models," ACM SIGSOFT Software Engineering Notes, vol. 35, no. 3, pp. 8–13, 2010.
[8] A. Aurum and C. Wohlin, Engineering and managing software requirements, vol. 1. Springer, 2005.
[9] L. Bass, P. Clements, and R. Kazman, Software architecture in practice. Addison-Wesley Professional, 2003.
[10] Y. A. Bernal and I. Delgado, "Multimorbidity among patients with digestive cancers patients in chile: a nationwide database study," The Lancet Oncology, vol. 23, p. S30, 2022.
[11] W. Wei, H. Zeng, R. Zheng, S. Zhang, L. An, R. Chen, S. Wang, K. Sun, T. Matsuda, F. Bray, et al., "Cancer registration in china and its role in cancer prevention and control," The Lancet Oncology, vol. 21, no. 7, pp. e342–e349, 2020.
[12] E. E. Jedy-Agba, E. A. Oga, M. Odutola, Y. M. Abdullahi, A. Popoola, P. Achara, E. Afolayan, A. A. F. Banjo, I.-O. Ekanem, O. Erinomo, et al., "Developing national cancer registration in developing countries–case study of the nigerian national system of cancer registries," Frontiers in public health, vol. 3, p. 186, 2015.
[13] V. Haghpanah, B. Soliemanpour, R. Heshmat, A. Mosavi-Jarrahi, S. Tavangar, R. Malekzadeh, and B. Larijani, "Endocrine cancer in iran: based on cancer registry system," Indian journal of cancer, vol. 43, no. 2, pp. 80–85, 2006.
[14] M. L. Gjerstorff, "The danish cancer registry," Scandinavian journal of public health, vol. 39, no. 7_suppl, pp. 42–45, 2011.
[15] J. E. Seiffert, "Development and use of the north american association of central cancer registries standards for cancer registries.," Topics in health information management, vol. 17, no. 3, pp. 35–44, 1997.
[16] A. S. Ibrahim, H. M. Khaled, N. N. Mikhail, H. Baraka, and H. Kamel, "Cancer incidence in egypt: results of the national population-based cancer registry program," Journal of cancer epidemiology, vol. 2014, 2014.
[17] T. Higashi, F. Nakamura, A. Shibata, Y. Emori, and H. Nishimoto, "The national database of hospital-based cancer registries: a nationwide infrastructure to support evidence-based cancer care and cancer control policy in japan," Japanese Journal of Clinical Oncology, vol. 44, no. 1, pp. 2–8, 2014.
[18] S. M. Jeffree, O. Mihat, K. A. Lukman, M. Y. Ibrahim, F. Kamaludin, M. R. Hassan, N. Kaur, and T. Myint, "Surveillance evaluation of the national cancer registry in sabah, malaysia," Asian Pacific Journal of Cancer Prevention, vol. 17, no. 7, pp. 3123–3129, 2016.
[19] A. Ryzhov, F. Bray, J. Ferlay, Z. Fedorenko, L. Goulak, Y. Gorokh, O. Soumkina, and A. Znaor, "Evaluation of data quality at the national cancer registry of ukraine," Cancer Epidemiology, vol. 53, pp. 156–165, 2018.
[20] M. A. Duggan, W. F. Anderson, S. Altekruse, L. Penberthy, and M. E. Sherman, "The surveillance, epidemiology and end results (seer) program and pathology: towards strengthening the critical relationship," The American journal of surgical pathology, vol. 40, no. 12, p. e94, 2016.
[21] F. Bianconi, V. Brunori, P. Valigi, F. La Rosa, and F. Stracci, "Information technology as tools for cancer registry and regional cancer network integration," IEEE Transactions on Systems, Man, and Cybernetics-Part A: Systems and Humans, vol. 42, no. 6, pp. 1410–1424, 2012.
[22] B. Pardamean and T. Suparyanto, "Hospital-based cancer registry application," in 2017 International Conference on Information Management and Technology (ICIMTech), pp. 44–48, IEEE, 2017.
[23] P. Kechagioglou, "Big data in oncology: The electronic patient record transformation program," in Seminars in Oncology Nursing, p. 151430, Elsevier, 2023.
[24] O. Strachna, O. Asan, P. D. Stetson, et al., "Managing critical patient-reported outcome measures in oncology settings: System development and retrospective study," JMIR Medical Informatics, vol. 10, no. 11, p. e38483, 2022.
[25] Department of Integrated Management of Cancer and other Tumours, "National cancer plan 2018-2028," Chilean Ministry of Health, 2018.
[26] S. Mundnich and M. M. Saba, "Cardio-oncology in chile: The future of an emerging discipline," Cardio Oncology, vol. 4, no. 4, pp. 555–558, 2022.
[27] M. Elsayed and S. B. Solomon, "Interventional oncology: 2043 and beyond," Radiology, vol. 308, no. 1, p. e230139, 2023.
[28] J. T. Shreve, S. A. Khanani, and T. C. Haddad, "Artificial intelligence in oncology: Current capabilities, future opportunities, and ethical considerations," American Society of Clinical Oncology Educational Book, vol. 42, pp. 842–851, 2022.
[29] R. N. Charette, "Why software fails [software failure]," IEEE spectrum, vol. 42, no. 9, pp. 42–49, 2005.
[30] M. D. Cabana, C. S. Rand, N. R. Powe, A. W. Wu, M. H. Wilson, P.-A. C. Abboud, and H. R. Rubin, "Why don't physicians follow clinical practice guidelines?: A framework for improvement," Jama, vol. 282, no. 15, pp. 1458–1465, 1999.
[31] I. Buchanan, Assemblage theory and method: An introduction and guide. Bloomsbury Academic, 2020.
[32] R. C. Brownson, G. A. Colditz, and E. K. Proctor, Dissemination and implementation research in health: translating science to practice. Oxford University Press, 2017.

TABLE 3. Table of questions asked in the interviews categorized by perspective

Perspective	Questions
Importance of the cancer registry	From your perspective, what is the importance of the national cancer treatment registry?
	Who are the key actors or institutions in the development of the National Cancer Treatment Registry?
Variables of the cancer registry	In your expertise, what elements should the National Cancer Treatment Registry in Chile contain? Of these, which are essential and why?
	What importance do you attach to the inclusion of variables related to social determinants?
	What importance do you attach to including variables related to treatment type and timing?
	What relevance do you attach to the inclusion of drugs and doses in the registry?
Impact of the cancer registry	What is the relevance of a national cancer treatment registry to the health system?
	What is the relevance of a national cancer treatment registry for networking different levels of healthcare (PHC, secondary, and tertiary care)?
	What is the relevance of the national cancer treatment registry for health management and administration?
	What is the relevance of such a registry in the clinical setting (e.g., case tracking and type of treatment)?
	What is the relevance of a national cancer treatment registry for research and technology transfers?
Barriers and facilitators	In your expertise, what are the enablers of the implementation of the National Cancer Treatment Registry?
	And the barriers?
Integration	From your perspective, what is the relevance of integrating the new cancer patient treatment registry with other health information systems?
	What is the feasibility of its integration with other systems?

[33] G. Márquez and C. Taramasco, "Using dissemination and implementation strategies to evaluate requirement elicitation guidelines: A case study in a bed management system," IEEE Access, vol. 8, pp. 145787–145802, 2020.

[34] P. Kruchten, H. Obbink, and J. Stafford, "The past, present, and future for software architecture," IEEE software, vol. 23, no. 2, pp. 22–30, 2006.

[35] M. Glinz, "On non-functional requirements," in 15th IEEE international requirements engineering conference (RE 2007), pp. 21–26, IEEE, 2007.

[36] R. Wojcik, F. Bachmann, L. Bass, P. Clements, P. Merson, R. Nord, and B. Wood, "Attribute-driven design (add), version 2.0," tech. rep., Carnegie-Mellon Univ Pittsburgh Pa Software Engineering Inst, 2006.

[37] M. Haoues, A. Sellami, H. Ben-Abdallah, and L. Cheikhi, "A guideline for software architecture selection based on iso 25010 quality related characteristics," International Journal of System Assurance Engineering and Management, vol. 8, pp. 886–909, 2017.

[38] F. Montesi and J. Weber, "Circuit breakers, discovery, and api gateways in microservices," arXiv preprint arXiv:1609.05830, 2016.

[39] S. Li, H. Zhang, Z. Jia, C. Zhong, C. Zhang, Z. Shan, J. Shen, and M. A. Babar, "Understanding and addressing quality attributes of microservices architecture: A systematic literature review," Information and software technology, vol. 131, p. 106449, 2021.

[40] D. Bender and K. Sartipi, "Hl7 fhir: An agile and restful approach to healthcare information exchange," in Proceedings of the 26th IEEE international symposium on computer-based medical systems, pp. 326–331, IEEE, 2013.

[41] N. Alshuqayran, N. Ali, and R. Evans, "A systematic mapping study in microservice architecture," in 2016 IEEE 9th International Conference on Service-Oriented Computing and Applications (SOCA), pp. 44–51, IEEE, 2016.

[42] R. Saripalle, C. Runyan, and M. Russell, "Using hl7 fhir to achieve interoperability in patient health record," Journal of biomedical informatics, vol. 94, p. 103188, 2019.

[43] D. Zheng, X. He, and J. Jing, "Overview of artificial intelligence in breast cancer medical imaging," Journal of Clinical Medicine, vol. 12, no. 2, p. 419, 2023.

[44] L. K. Singh, M. Khanna, and R. Singh, "Artificial intelligence based medical decision support system for early and accurate breast cancer prediction," Advances in Engineering Software, vol. 175, p. 103338, 2023.

[45] P. Ormeño, G. Márquez, C. Guerrero-Nancuante, and C. Taramasco, "Detection of covid-19 patients using machine learning techniques: A nationwide chilean study," International Journal of Environmental Research and Public Health, vol. 19, no. 13, p. 8058, 2022.

• • •

CARLA TARAMASCO received the B.Eng. degree in computer engineering from the Universidad de Valparaíso, Chile (1996–2001), the M.Sc. degree in cognitive science from the Ècole Normale Supèrieure (2005–2006), and the Ph.D. degree (summa cum laude) from the Ècole Polytechnique, France (2006–2011). She is a full professor at the Faculty of Engineering of the Andrés Bello University and Director of the Institute of Technology for Innovation in Health and Wellbeing (ITiSB). She is also a member of the executive committee of the National Centre for Health Information Systems. Her main academic interests are health and complex social systems.

TABLE 4. Requirements description

Id	Requirement
R1	Incorporate a new treatment module that allows the entry of data related to the treatment of patients registered in the cancer registry.
R2	Allow the clinical user to enter data regarding the treatment of patients registered in the cancer registry by accessing different forms that should be available for both entering and editing information.
R3	Maintain a history of changes (editing or deletion) in the patient monitoring and treatment records. This history should contain at least the following information: (i) type of change (edit or delete), (ii) user making the change, (iii) old value (before the change), (iv) new value (after the change), (v) date and time of the change, (vi) IP number from which the change is made, and (vii) user agent
R4	The treatment record should incorporate the following variables: (i) treatment intention: curative or palliative; (ii) type of treatment, divided into radiotherapy, palliative care, surgical and oncological; (iii) start date of treatment; (iv) end date of treatment; (v) institution/provider; (vi) scheme; (vii) date of last control; (viii) date of relapse; (ix) reactions and adverse effects; (x) toxicity; (xi) evolution; (xii) surgical milestones; (xiii) complementary medicines; and (xiv) rehabilitation.
R5	Clinicians can access patient characterization data recorded in the cancer registry and historical treatment information.
R6	Allow the clinician to download all treatment data from patients registered in the cancer registry in different formats.
R7	Incorporate a monitoring module to record post-treatment control and health status.
R8	Clinicians can enter data regarding the monitoring of patients registered in the cancer registry by accessing different forms, which should be available for both entering and editing information.
R9	The monitoring record should incorporate the following variables: (i) treatment timing (before, in parallel, or after treatment), (ii) symptomatic/asymptomatic, (iii) dose reduction (yes/no), (iv) tests and examinations, (v) outcome, and (vi) observation.
R10	Clinicians can access the historical monitoring information of the patients registered in the cancer registry.
R11	Allow the clinician to download all monitoring data of patients registered in the cancer registry in different formats.
R12	Extend patient data from the cancer registry by incorporating characterization variables.
R13	Enable the clinician to extend the data regarding the characterization of patients registered in the cancer registry by accessing different forms, which should be available for both entering and editing information.
R14	Patient data should incorporate the following variables: (i) gender, (ii) type of housing, (iii) nationality, (iv) ethnicity, (v) religious beliefs, (vi) level of schooling, (vii) occupation, (viii) occupational exposure, (ix) foresight, (x) insurance, and (xi) access to health facilities.
R15	Consider the analysis module, which allows clinical users and decision makers to access a dashboard of relevant information that considers the information entered in the monitoring, treatment, and characterization data modules for the generation of indicators, and reports.

CAMILO GUERRERO is Nurse from the University of Valparaíso and holds a Master's degree in Public Health from the University of Chile. He is currently a Ph.D. student in Public Health at the University of Chile. His research is in the field of health inequities and timely diagnosis of cancer. He has published papers related to health care in several journals and conferences.

DIEGO RIVERA is a Sociologist, Master in Philosophy and PhD student in Sociology. He is a research secretary at the Center for Interdisciplinary Studies in Social Theory and Subjectivity (CEITESyS) at the University of Valparaíso. During the last few years, he devoted himself to studying the processes of subjectivation and governments of the life of Chilean authoritarian neoliberalism.

GASTÓN MÁRQUEZ is Ph.D. in Informatics Engineering (Federico Santa María Technical University, Chile). He is professor at the Bío-Bío University, Chile. He is working in the research fields of architectural tactics, patterns, microservice architectures, technical debt, and security in telehealth systems. He has published in several international conferences and has participated in international software architecture schools. He participated as a Research Visitor at the Rochester Institute of Technology (RIT), Rochester, NY, USA, and the Université de Technologie de Compiègne (UTC), Compiègne, France. Before becoming a Ph.D. student, he worked in financial companies for five years.