Requirements Specification of a Machine Learning-based Medical Software System

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Abstract. *Medicine software systems have increasingly incorporated Machine Learning (ML) models, posing significant challenges for Software Engineering (SE), particularly in dealing with their requirements that could ensure qualities such as reliability and security. In this scenario, the main problem is the difficulty of specifying requirements that often change continuously, including in the context of an large research project in which ML-based medical systems have been developed and this work is part of. Additionally, there is no consensus on better techniques for this. Hence, the main objective of this work was to define techniques for requirements specification and apply them in a real-world ML-based medical system. To this end, we scrutinized the literature to select techniques for specifying requirements; following this, we applied them to a medical system for predicting patient's respiratory health conditions in the context of the large project. As a result, the specified requirements were the key element to the successful development of the system. Hence, these techniques could be helpful for the development of other ML-based medical systems.*

1. Introduction

The use of software systems based on machine learning (ML) (or ML-based software systems) has increased significantly, making it possible to solve a large number of problems that people or other systems were not able to solve so easily [Barrera et al. 2024]. Positioned in the large area of Artificial Intelligence (AI), ML models make use of a large amount of data to learn, predict actions, and support decision-making processes in various fields, including medicine [Nalchigar et al. 2021]. The development of these systems are not trivial, requiring new processes, methods, and techniques from Software Engineering (SE), including those for Requirement Engineering (RE) [Vogelsang and Borg 2019].

RE addresses core activities (e.g., requirements elicitation, specification, analysis, verification, validation, and prioritization) that are the basis for successfully ensuring the development and evolution of software systems [Dick et al. 2017, O'Regan 2017]. Furthermore, in situations where the business environment is continuously changing, new approaches for developing these systems are needed, such as those that enable the continuous specification of requirements [Kirikova 2017]. This contrasts with traditional techniques for specifying requirements, which often adopt static, formalized approaches. In turn, continuous requirements specification is characterized by accepting iteration and flexibility in software development and focuses on continuous delivery and adaptation during the development process [Michailidis et al. 2021]. In this scenario, the main problem addressed in this work is the difficulty in specifying requirements that change continuously in ML-based systems. Additionally, there is no consensus on better techniques for that, given that RE research has only recently begun to investigate the changing requirements of this kind of system. Furthermore, a large research project[1]—which involve a multidisciplinary and large research team, including Computer Science and Medicine—has required ML-based software systems for conducting the research; however, no direction existed to manage the requirements of these systems.

The main objective of this work is to define the techniques to continuously specify (functional and non-functional) requirements of ML-based software systems. Another objective is to specify the requirements of an ML-based medical system that supports a large research project. To this end, suitable techniques were selected; and applied to document the requirements of the medical system. As a result, this work provided an important contribution to that larger project, in particular, to ensure the quality of the software systems. Additionally, our experience (of applying the techniques) could be reproduced in the development of other ML-based medical systems.

The remainder of this work is organized as follows. Section 2 provides a brief background and related work. Section 3 describes the research method. Section 4 presents the results, and Section 5 discusses these results. Section 6 presents the final remarks.

2. Background and Related Work

The integration of ML models into software systems introduces significant challenges for RE, as system's behavior becomes non-deterministic and heavily dependent on data. Traditional RE techniques often fail to address the evolving nature of ML-based systems. The specification of requirements of ML-based systems remains an emerging field with little consensus on standardized activities or detailed techniques. Current research has often focused on adapting existing techniques to these systems. For instance, [Uysal 2023] proposed a four-step approach using use case modeling and textual descriptions to enhance stakeholder communication and validation. Similarly, [Yang et al. 2024] introduced extensions to UML class, state, and sequence diagrams, while also proposing a new specific diagram to capture ML model indicators and data requirements. However, while these and similar initiatives address structural and data-related aspects, there is no consensus of techniques that focus on the continuous changing nature of requirements in ML-based systems. This scenario motivated the conduct of our work.

3. Methodology

The research method encompassed the following three main activities:

Activity 1: Selection of techniques for specifying requirements of ML-based systems: The student conducted a Systematic Mapping Study (SMS) to identify approaches to the specification of (functional and non-functional) requirements of ML-based systems [Breda et al. 2026]. For this, the well-defined three phases outlined in [Kitchenham et al. 2015]—planning, conduct, and results analysis—were performed, and an overview of the state-of-the-art approaches was obtained. In the planning phase, we defined two research questions (RQs): *RQ1 Which are the approaches (methods, techniques, processes, or guidelines) used for the specification of requirements of ML-based systems?*; *RQ2 Are there any tools that could provide support for the specification*

[1]https://bv.fapesp.br/pt/auxilios/113158/spira-bm-biomarcadores-para-condicoes-respiratorias-em-dispositivos-moveis-por-analise-de-audio-com-/

of requirements of ML-based systems?. Our search string was composed of the main keywords addressed in the RQs (e.g., *machine learning*, *requirements engineering*, and *specification*); after calibration and validation, the following search string was defined: *((“deep learning” OR “machine learning”) AND (“requirements engineering”) AND (“modelling” OR “modeling” OR “representation” OR “specification” OR “documentation”))*. The student also selected the most commonly used publications databases in the SE [Kitchenham et al. 2015]: Scopus[2], ACM[3], IEEE Xplorer[4], Science Direct[5] and Wiley[6]. We also defined the following inclusion criteria (IC) and exclusion criteria (EC): IC1: *The study addresses the requirements specification for ML-based systems*. EC1: *The study does not address the requirements specification for machine learning-based systems*; EC2: *The full text of the study is not available*; EC3: *The study is not a primary study*; EC4: *The study is written in a language other than English*; and EC5: *The study is a previous version of an already included study.* In the conduct phase, the student applied the search string to each database, retrieving a total of 519 studies. After deduplication, 439 remained. Each study was examined regarding its title, abstract, keywords, introduction, and conclusion. Applying the IC and EC, the student obtained 48 studies. After reading the full text of all 48 and reapplying the IC and EC, 23 were considered relevant to answer the RQs. After analyzing each study, the most appropriate techniques were selected. Section 4.1 summarizes the results of this SMS.

Activity 2: Specification of Requirements of the ML-based Medical System: The student was responsible for collecting the requirements of the ML-based medical system. In short, this is a cloud-/mobile-based system for predictions of the patient’s respiratory health condition. The system collects patient’s information (e.g., age and medical comorbidities) and recording pre-defined audio sentences. Through the analysis of biomarkers, audio processing techniques, and use of ML models, the system is able to provide predictions regarding smoking issues, severe asthma, and respiratory insufficiency conditions. To collect the requirements, the student conducted several interviews and meetings with researchers of the large project, including medical and speech therapy researchers, computer and data scientists. While collecting the requirements, they were also documented using the techniques previously selected: UML use case diagram and use case descriptions. Still through interviews and meetings, the requirements were continuously validated and refined. As a result, the student produced a document containing the required patient’s data and the refined requirements, including non-functional requirements (such as reliability and usability). Section 4.2 presents such a result.

Activity 3: Implementation of Requirements: Considering the complexity and criticality of the ML-based system to be developed, a large international software company was hired to implement it. The requirements document was used as a key part of the contract with such company. In this activity, the student was responsible for validating the system under development through meetings with company’s team, aiming that the systems matched the researchers’ needs and requirements. Section 4.2 summarizes the results.

[2]https://www.scopus.com
[3]https://dl.acm.org
[4]http://ieeexplore.ieee.org
[5]http://www.sciencedirect.com
[6]https://onlinelibrary.wiley.com

4. Results

4.1. Techniques for Specifying Requirements of ML-based systems

Our SMS revealed the ML-based systems differ from traditional systems, as their behavior is highly dependent on the data used to train ML models. Leading to a non-deterministic behavior, these systems often evolve and change outputs when the models are (re)trained. This characteristic challenges the application of traditional approaches to requirements specification. Another challenge is that the identification of requirements strongly relying on the knowledge and expertise of data scientists to correctly translate concepts, features, and ML metrics to requirements. To overcome these challenges, most studies proposed extensions to existing requirements specification approaches (e.g., i* Framework, GORE, user stories, UML diagrams), whereas other studies proposed new approaches specific for ML-based systems. However, the topic of appropriately addressing requirements specification of such systems is still to be fully matured. Through the conduct of this SMS, the UML use case diagram and use case textual descriptions were selected for the context of this work. They can provide ways to better visualize the system's needs and actor's-system interaction by non-technical stakeholders, while they can also provide deep technical understanding of the requirements.

4.2. Specification of Requirements of a ML-enacted Health System

As a result of Activity 2, the student identified 26 use cases and specified them through the UML use case diagram and textual descriptions. Figure 1 illustrates part of the diagram, outlining the data collection use case and its derived use cases, which are responsible for collecting the patient's data. The use cases were still grouped into application access, application sign out, data collection, and data submission. Additionally, the requirements document also contains the detailed description of each use case. For instance, the description of the use case *"Registrar comorbidades do paciente"* is the following:

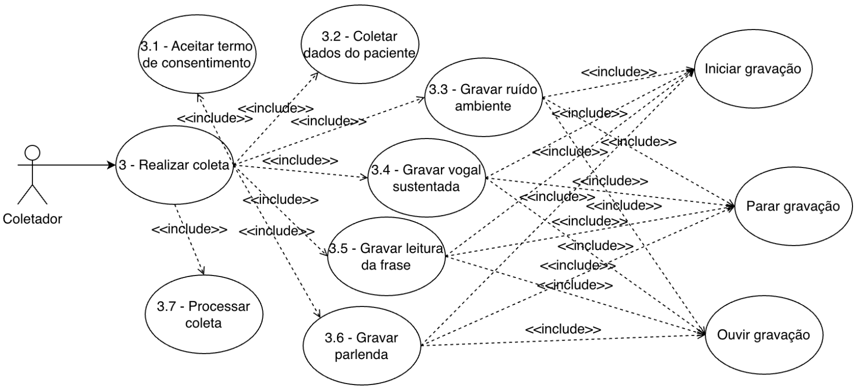

Figure 1. Part of the UML use case diagram

"3.2.6 - Registrar comorbidades do paciente: o coletador deve entrar com as comorbidades do paciente via o número do cadastro internacional de doenças (CID). Dado que o paciente pode possuir nenhuma ou várias comorbidades, devendo todas elas ser inseridas (digitadas manualmente pelo coletador). Exclusivamente no caso de coleta cujo tipo de estudo é "Controle", o preenchimento deste campo não é obrigatório."

As result of Activity 3, the requirements were successfully implemented, as Figure 2 shows. The mobile app that is part of the medical system presents three forms to collect patient's data (Figure 2.a). This app also makes it possible to select the research types, where the patient's respiratory issue is selected (e.g., severe asthma, smoking, or respiratory insufficiency) (Figure 2.b). An important feature of this app is the four high-quality audio recordings, including that the patient must read a pre-defined sentence (Figure 2.c). The patient's data collected and audio recordings collection are then sent to the cloud server and are used to train the ML models, and thus making it possible to perform the predictions on the patient's respiratory health conditions. The implementation of the medical system also ensure qualities, particularly availability and reliability.

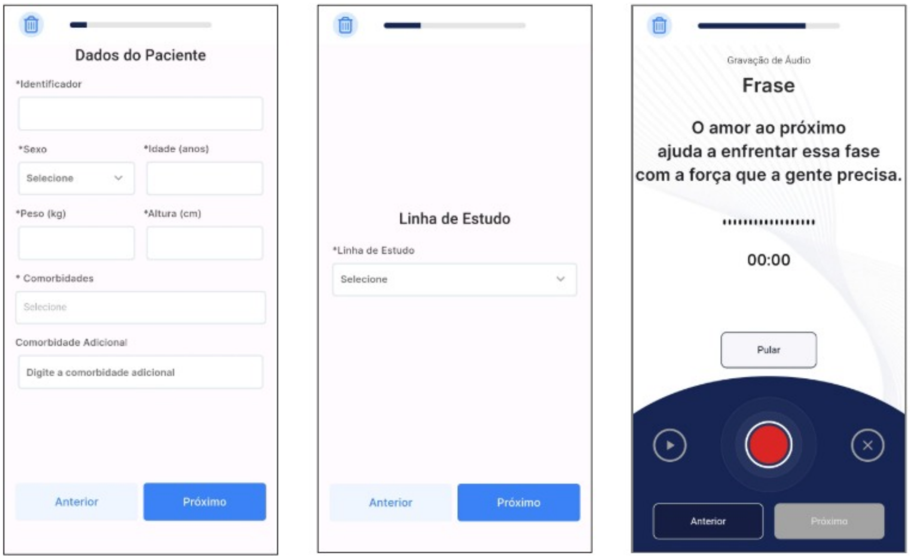

Figure 2. Examples of screens: (a) One of the forms for data collection; (b) Study type selection form; and (c) Pre-defined sentence audio recording

5. Discussion

In the context in which an ML-based medical system needed to be developed, the conduct of this work revealed important insights: (i) **Evolving nature of requirements of ML-based medical systems makes it difficult their specification:** In the development of ML-based medical systems, particularly those in the context of research projects, requirements may not be static, instead, they evolve alongside the research's needs. As observed, requirements initially elicited often shift, as new insights into research objectives emerge. This necessitates an approach flexible enough to accommodate continuous changes without compromising the system's structural integrity or stakeholder expectations. (ii) **Requirements aligned with stakeholders' needs**: A challenge was to ensure that all parties (technical and non-technical stakeholders) remain aligned as requirements evolve. Along with the conduct of this work, it became evident that changing requirements may lead to a lack of alignment if not continuously validated. Additionally, the iterative nature of the meetings (which are essential) with the researchers and the company's team makes it difficult to reach a consensus regarding requirements, particularly when the system's goals and data constraints are in constant evolution. and (iii) **UML use case diagram and textual descriptions for the requirements specification of ML-based medical software systems:** The use of visual techniques like UML diagram facilitated communication to non-technical stakeholders, specially in this context in which the requirements constantly changed, while textual descriptions supported technical teams.

6. Final Remarks

While the current literature lacks consolidated techniques to adequately address the evolving nature of ML-based systems and their requirements, this work experimented with two techniques (UML use case diagram and use case textual descriptions) to perform the requirements specification of an ML-based medical system, which has been essential to conduct the research in a large research project. For the community, the experience reported in this work could be a potential guideline for supporting the development of medical systems, which have increasingly adopted ML models and been adopted in several sectors of the medical area and, therefore, their quality must be ensured.

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