Integrating Clinical Expertise into Software Development: Evaluating the Use of openEHR Archetypes for Requirements Elicitation in Healthcare Applications

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Abstract: OpenEHR archetypes are standardized frameworks designed to model clinical information in healthcare systems, enabling a consistent and integrated representation of complex data. These models encompass common clinical elements such as symptoms, diagnoses, and treatments, ensuring that information is understood and applied uniformly across different contexts. This paper investigates the use of openEHR archetypes in the requirements elicitation and specification process for clinical systems, highlighting their potential to integrate healthcare professionals' knowledge into software development. The literature review reveals a significant gap in the participation of these professionals during the requirements elicitation phase, especially in studies that apply archetypes. Quantitative and qualitative results positively perceive the methodology used, highlighting clarity, collaboration, and alignment with end-user needs. Statistical analysis using the Wilcoxon test presented significant p-values, indicating that professionals considered the method straightforward, intuitive, and conducive to engagement, with real opportunities for contribution to the validation of requirements. The qualitative data reinforce the importance of a collaborative environment and suggest the need for deeper involvement of healthcare professionals at all process stages. In conclusion, this research indicates that applying openEHR archetypes, combined with more significant interaction with healthcare professionals, is promising for integrating clinical expertise effectively and directly into developing clinical systems.

1 INTRODUCTION

The health sector is vital to society, influencing individuals' quality of life and well-being. With growing population demands and complex care needs, developing efficient, accessible healthcare applications is a priority (Bitkina et al., 2020). Active participation from healthcare professionals throughout development ensures systems address specific needs, prioritizing usability, security, and accuracy while reflecting clinical practices (Barbosa et al., 2021; Maramba et al., 2019).

The openEHR archetype standard supports interoperability and standardization of healthcare data, structuring clinical information consistently across platforms (Badr, 2019; de Araújo et al., 2016). Each archetype represents a clinical concept, such as diagnosis or medication, organizing data in a reusable and extensible way. Academically, openEHR archetypes are studied for improving health data quality and modeling requirements in complex systems (de Araújo et al., 2019; Chen et al., 2009). In industry, they are used to build interoperable applications that integrate data and support patient care continuity (Ding et al., 2023). Their adoption highlights their potential as a robust standard for safe, effective clinical applications (Ferreira and de Souza, 2023).

End-user involvement is critical in software development to ensure requirements reflect the problem domain, particularly in healthcare, where clinical knowledge impacts patient safety (Govella, 2019). Engaging healthcare professionals during requirements elicitation ensures solutions align with clinical realities (Leslie, 2020; Tian et al., 2021; Hak et al., 2020; Silva et al., 2024). While openEHR archetypes are traditionally used for EHR standardization and interoperability during development (Li et al., 2021; Wulff et al., 2021; Arevshatyan et al., 2020), their application in elicitation could formalize specialist knowledge earlier, optimizing development.

This research explores whether using openEHR

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archetypes in requirements elicitation aids in identifying and expressing domain expert knowledge during healthcare application development. We examine if archetypes can effectively capture clinical needs, enhancing communication between developers and specialists while ensuring that the solutions align with healthcare professionals' requirements.

We conducted interviews and practical activities with openEHR archetypes involving healthcare professionals to evaluate their role in bridging communication gaps and accurately representing clinical requirements.

The article is organized as follows: Section 2 introduces openEHR archetypes, their structure, and applications. Section 3 details the study methodology. Section 4 analyzes related work on archetypes in health systems. Section 5 presents our study, methodology, and insights. Section 6 concludes with remarks and future research directions on archetypes in healthcare software development.

2 OpenEHR ARCHETYPE

An archetype is a reusable, structured model that defines clinical concepts and data structures necessary for capturing healthcare information (Palojoki et al., 2024; da Silva et al., 2019). These archetypes rely on two core models: the reference and archetype models (openEHR Foundation, 2024b). The reference model provides foundational structure and data types for interoperability, representing entities, attributes, and relationships consistently in health systems. The archetype model outlines specific clinical content within the reference model, such as diagnoses, treatments, and measurements. This dual modeling approach separates clinical knowledge from technical constraints, facilitating adaptation and maintenance of clinical information across health applications (openEHR Foundation, 2024a).

Archetypes include key elements that enhance adaptability for clinical scenarios (Ferreira and de Souza, 2023). Primary components are data attributes, terminologies, and constraints. Data attributes capture specific clinical data, such as patient identifiers or observations. Terminologies ensure consistent use of clinical vocabularies, linking data to standardized medical coding systems. Constraints limit values or structures, maintaining data quality and consistency across implementations.

Templates combine multiple archetypes into structured forms tailored to clinical workflows (Badr, 2019). These templates customize archetypes for specific use cases, offering flexibility in their application. The Clinical Knowledge Manager (CKM) serves as a repository for openEHR archetypes and templates, enabling access, sharing, and collaboration among healthcare professionals and developers (Foundation, 2023). CKM promotes reuse of standardized archetypes, ensuring consistency and interoperability in healthcare data models.

The Archetype Editor is a tool for creating and specifying openEHR archetypes (Moner et al., 2018). It enables users to define, edit, and validate archetypes by structuring clinical concepts with data attributes, terminologies, and constraints. This tool facilitates precise modeling of clinical concepts, improving interoperability and data accuracy. Users can specify elements such as data attributes, permissible values, terminology bindings, and constraints, ensuring structured clinical models align with the dual-model approach.

The tool supports collaborative development, incorporating clinician feedback to ensure relevance. It plays a key role in the openEHR ecosystem, enabling standardized archetypes for integration into templates and repositories like CKM. Figure 1 illustrates an archetype specified in the Archetype Editor, showing organized sections for data attributes, terminology bindings, and constraints, which ensure data consistency and quality.

3 METHODOLOGY

This section describes the ethical considerations and methodological approach that guided this study. Firstly, institutional and legal regulations describe the ethical aspects guaranteeing participants' protection and privacy. Finally, the methodological path is presented, explaining the stages of reviewing literature and conducting the practical study with health professionals using archetypes.

3.1 Ethical Considerations

The research followed the ethical principles established by the Brazilian resolution, considering the essential pillars of bioethics and human rights. It was ensured that all participants received precise information about the objectives and methods of the research, with emphasis on the voluntary nature of participation and the protection of anonymity and confidentiality of data.

Interactions with the participants only took place after they had signed the Informed Consent Form (ICF). The data processing and confidentiality strategies were detailed, guaranteeing the security of per-

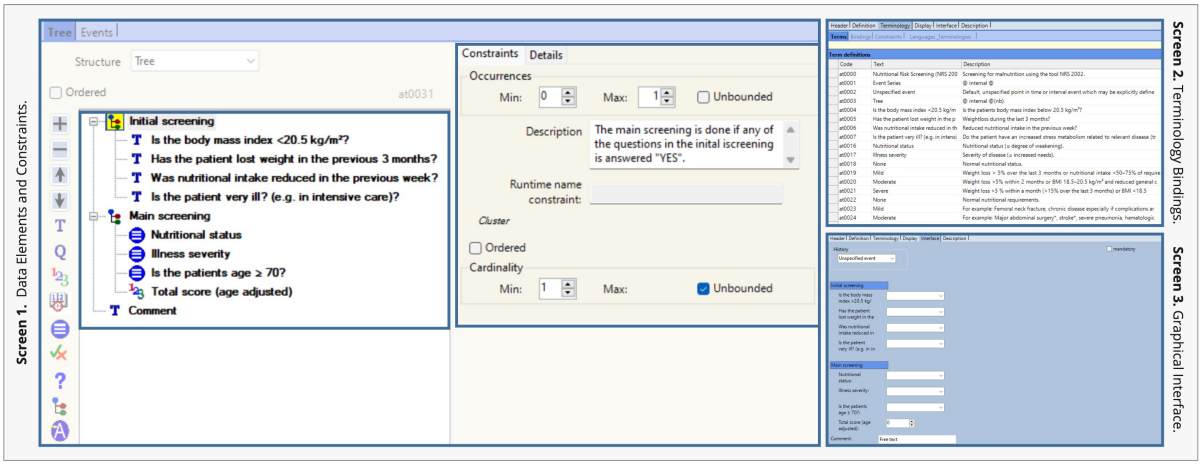

Figure 1: Representation of the elements of an archetype.

sonal data and sensitive information that might arise during the interviews and questionnaires.

3.2 Methodological Approach

The research methodology consisted of a literature review and a practical study using archetypes, as shown in Figure 2. The literature review aimed to analyze studies using archetypes in healthcare software development. This involved reviewing ten studies, synthesizing findings, and discussing them to contextualize the research proposal. Based on this synthesis, the research question for the practical study was formulated.

In the practical study, archetypes were used to simulate a patient anamnesis and follow-up scenario with fourteen healthcare professionals. This aimed to demonstrate and specify requirements, collecting both qualitative and quantitative data. The study explored professionals' perceptions of archetypes in software requirements elicitation for healthcare. After the interviews, a structured form with three Likert-scale questions was administered to capture participants' perceptions. The collected data underwent qualitative and statistical analyses, and the results were discussed in the final stage of the study.

4 RELATED WORK

The related work section is divided into two main parts: a state-of-the-art analysis and a discussion. In the state-of-the-art analysis, we review existing studies on using openEHR archetypes, focusing on their objectives, methodologies, and findings in detail. This analysis thoroughly overviews current approaches and trends in applying openEHR archetypes in healthcare. Following this, the discussion synthesizes the insights gained from the study, highlighting gaps, limitations, and potential areas for further research.

4.1 State of the Art Analysis

In healthcare, clinical data modeling has advanced to better meet the needs and expertise of healthcare professionals. In this context, openEHR archetypes standardize health data and incorporate specific insights and knowledge provided by professionals at various stages of application development. Thus, this section analyzes related works to investigate how each study employs openEHR archetypes, including the level of involvement of healthcare professionals, based on the observations in Table 1.

In the context of clinical standardization, the study (Tian et al., 2021) focused on automating the creation of data quality rules in a Chinese hospital, using archetypes to ensure data consistency and completeness. Meanwhile, the study by (Oliveira et al., 2022) explored the use of archetypes to standardize requests for complementary diagnostics, enabling the creation of indicators to monitor waiting times and test execution. However, neither of the studies specified when the archetypes were modeled, at which phase they were applied nor did they involve end users directly.

The study by (Wulff et al., 2021) aimed to standardize microbiological data for infection control, using archetypes to create a reusable model for different institutions. In contrast to the studies in (Tian et al., 2021) and (Oliveira et al., 2022), (Wulff et al., 2021) actively involved healthcare professionals during the development and validation phases, which was essential to ensure the proposed model's applicability in real-world scenarios.

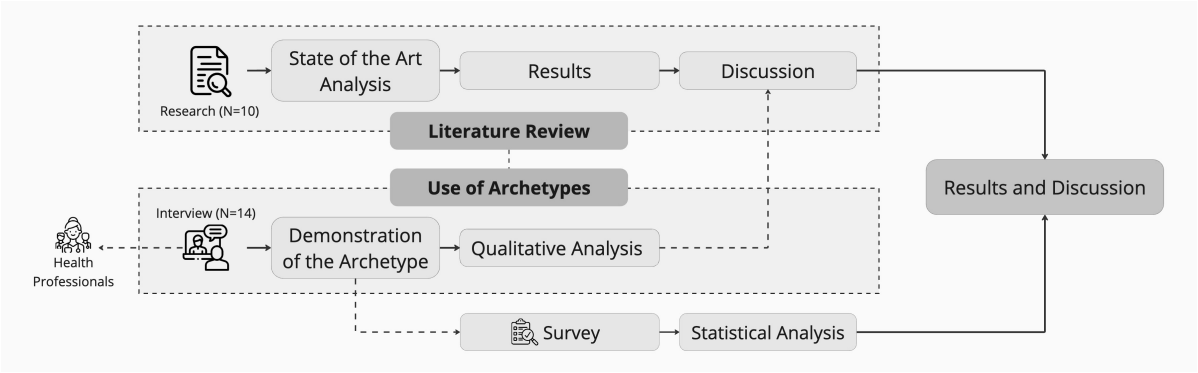

Figure 2: Methodological Approach.

Regarding screening and monitoring, the study (Li et al., 2020) developed a shared model for COVID-19 based on Chinese guidelines, applying archetypes to model clinical data, but without specifying at which stage of the development cycle this was used. This work did not involve direct interaction with healthcare professionals. Similarly, the study (Li et al., 2022) proposed a methodology to measure clinical quality, integrating openEHR with Clinical Quality Language (CQL) in the application development phases, involving doctors directly to provide feedback and adjust quality indicators, improving the system's usability.

In the context of clinical decision support, the study (Silva et al., 2023) focused on rehabilitation medicine and sought to develop a platform for collecting and consolidating clinical data using archetypes during the elicitation and development phases. In this study, healthcare professionals did not participate in archetype modeling but were involved in requirements gathering, which was critical for structuring the platform's standardized data. The study (Hak et al., 2020) discusses the adoption of the openEHR standard with a focus on health information management. In this case, archetypes were applied during validation phases, with engineers and clinical professionals working together to ensure the platform's usability and its impact on clinical practice. The study (Li et al., 2021) developed an openEHR-based screening tool for strokes, applying archetypes during both development and validation phases for eligibility queries in electronic health records (EHRs). The tool was refined with input from healthcare professionals to enhance its accuracy and clinical applicability in medical consultations.

Finally, in the category of clinical use of EHRs, the study (Leslie, 2020) explored the reuse of openEHR archetypes in multilingual COVID-19 clinical data, focusing on symptom tracking. Archetypes were applied without the direct participation of end users, as the development followed international clinical guidelines. Similarly, (Arevshatyan et al., 2020) focused on the integration of clinical and genomic data for cancer treatment in two hospitals in Paraguay, applying archetypes during the development and validation phases, involving oncologists in the process, and ensuring the system met the needs of oncological data analysis.

4.2 Discussion

The analysis of the ten papers listed in Table 1 reveals that all the articles utilize openEHR archetypes in developing their healthcare applications. This approach aims to create standardized, interoperable solutions suitable for clinical contexts. Healthcare professionals are recognized as the end users for all the applications, highlighting that these tools are designed to support their practical activities. However, only six of the ten papers involve healthcare professionals at some point during the development process, primarily for validation purposes, and they do not participate directly in the initial stages.

A standard limitation in the studies is the lack of involvement from healthcare professionals during the elicitation and prototyping phases of archetype modeling. This suggests that clinical requirements are often defined based on external guidelines or technical knowledge rather than through active collaboration with the professionals who will use the applications. Additionally, five studies do not specify at which stage of development archetype modeling occurs, making it challenging to understand how the needs of end users have been translated into technological solutions.

In addition, the studies analyzed are distributed in four focus areas: clinical standardization, screening and monitoring, clinical decision support, and clinical use of EHRs. Each of these areas addresses specific aspects of the needs of healthcare professionals; however, the lack of interaction in the early stages

Table 1: Comparative Analysis of Related Works.

Related Work		[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]	[9]	[10]
Use of openEHR Archetypes		●	●	●	●	●	●	●	●	●	●
Health Professionals	Participation	○	○	○	●	○	●	●	●	●	●
	Considered End-Users	●	●	●	●	●	●	●	●	●	●
Modeling of Archetypes with Healthcare Professionals	Requirements Analysis	○	○	○	○	○	○	○	○	○	○
	Prototyping	○	○	○	○	○	○	○	○	○	○
	Development	○	○	○	○	○	●	○	●	●	●
	Validation	○	○	○	○	○	○	●	●	●	●
	Not Specified	●	●	●	●	●	○	○	○	○	○
Focus Area	Clinical Standardization	○	●	○	○	●	○	○	○	●	○
	Screening and Monitoring	○	○	●	○	○	●	○	○	○	○
	Decision Support	○	○	○	●	○	○	●	●	○	○
	Clinical Use of EHR	●	○	○	○	○	○	○	○	○	●

Note: [1] = (Leslie, 2020); [2] = (Tian et al., 2021); [3] = (Li et al., 2020); [4] = (Silva et al., 2023); [5] = (Oliveira et al., 2022); [6] = (Li et al., 2022); [7] = (Hak et al., 2020); [8] = (Li et al., 2021); [9] = (Wulff et al., 2021); and [10] = (Arevshatyan et al., 2020).

of development can limit the adaptation of tools to the reality of end users. This panorama, evidenced by the analysis of the state of the art, indicates that although openEHR archetypes offer a robust framework for standardization, their effectiveness in representing the specialized knowledge of healthcare professionals is compromised in the absence of a collaborative requirements elicitation process. Thus, the research question highlights the need for more effective strategies for involving domain experts as early as the elicitation phase, ensuring that the knowledge of these professionals is reflected in the applications developed.

5 USE OF ARCHETYPES BY HEALTH PROFESSIONALS

This section explores the use of archetypes by health professionals. It is divided into three stages. The first stage outlines the evaluation scenario, detailing the context and procedures followed during the experiment. The second stage presents a quantitative analysis of the statistical test results, focusing on the responses. The final stage offers a qualitative study, examining key points from the interviews and highlighting professionals' perceptions, challenges, and suggestions for improvement.

5.1 Evaluation Scenario

Our study involved 14 healthcare professionals directly engaged in patient care. We presented a scenario focused on patient anamnesis and follow-up processes. During anamnesis, essential patient information such as medical history, symptoms, and lifestyle is gathered, while the follow-up phase monitors progress and responses to treatment, aiding clinical decisions.

The scenario was introduced to participants, and we discussed the workflow to understand the details. Two archetypes representing anamnesis and follow-up were presented, explaining data attributes, terminologies, and constraints. Each professional was encouraged to share opinions and ask questions, leading to collaborative adjustments to ensure the archetypes reflected the patient care scenario accurately. Afterward, the graphical interface generated from the archetypes was reviewed, and the importance of healthcare professionals' involvement in requirements elicitation was discussed. The professionals also completed a questionnaire, and the results are presented in the next section.

5.2 Analysis of Quantitative Results

After applying the form, the data was analyzed using the Wilcoxon test, which assesses whether a reference value's median differs significantly from zero. Implemented in Python, the responses were compared to the reference point 4, with results shown in the second column of Table 2.

The first question, on method clarity, had a p-value of 0.0005, indicating professionals found the method straightforward. The second, on collaboration, had a p-value of 0.0008, showing participants felt engaged and able to contribute actively. The third, on the archetype reflecting workflow understanding, had a

Table 2: Wilcoxon Test Results for Healthcare Professionals.

Question	P-value
1. I believe that the method used to identify the requirements was clear and easy to follow.	0.0005
2. The method used to identify and validate the requirements allowed me to actively collaborate during the requirements elicitation process.	0,0008
3. The data modeling represented by the archetype facilitates my understanding of the workflow in which I am involved.	0,0013

p-value of 0.0013, demonstrating significant contributions to understanding activity contexts.

These results highlight a positive perception of the method, which is considered transparent, collaborative, and effective, with high satisfaction among professionals, meeting their expectations.

5.3 Analysis of Qualitative Results

During the experiment, various aspects were identified through content analysis to specify functionalities in patient anamnesis and evolution systems using archetypes. Participants' perceptions and researchers' observations provided insights into knowledge gaps and challenges in enhancing understanding and engagement. The analysis was organized into four key moments. The first revealed participants' limited initial knowledge of archetypes and requirements elicitation, leading to the introduction of fundamental concepts. The second emphasized the importance of healthcare professionals' active participation in requirements elicitation, highlighting benefits such as improved clinical needs, efficiency, and risk reduction.

The third addressed limitations in existing systems and professionals' need for tailored solutions, demonstrating how well-designed systems improve efficiency, precision, and satisfaction. Finally, the fourth presented feedback and suggestions for improvement, as detailed in Figure 3.

- **Familiarity with Archetypes and Requirements Elicitation**

A key issue identified was the preconception that healthcare professionals lacked familiarity with software archetypes and requirements elicitation. This was confirmed during interactions, highlighting the need for clearer initial contextualization to explain these concepts and better prepare participants.

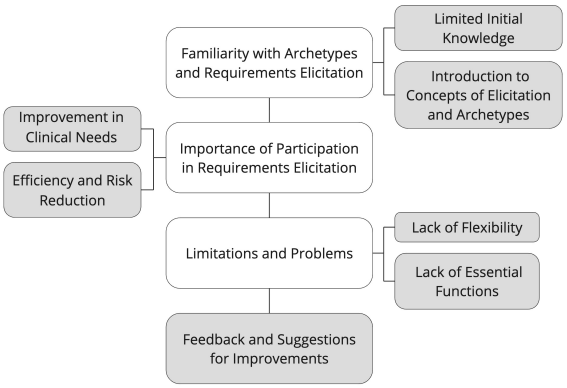

Figure 3: Points of Perceptions and Contributions.

The tool was introduced, and doubts about professionals' involvement were clarified, emphasizing their significant contributions. The fundamentals of openEHR archetypes and the importance of active participation to capture clinical needs were explained, ensuring the elicitation process aligned with actual demands. Professionals must understand their role and development methodologies to avoid gaps in the process.

Limited knowledge also created difficulties in envisioning their role in requirements specification. Without early intervention, this barrier can reduce engagement, as technical terminology often makes participants feel out of place. Addressing this requires accessible language, explanations of fundamental concepts, and practical examples showing how archetypes and the specification process benefit their work.

- **Importance of Participation in Requirements Elicitation**

After participating in the experiment, healthcare professionals emphasized their value in the requirements elicitation process, noting that their input is essential for creating systems that meet clinical demands. One participant stated, "Our presence is essential because although you know very well how to develop the system, you are not in practice to understand what our real needs are," underscoring that developers cannot fully grasp clinical demands without firsthand experience.

The effectiveness of health applications depends on both developers' technical skills and direct feedback from end users. Professionals expressed concern about ensuring the system supports specific tasks, such as documenting essential information, customizing fields for specialties, and recording details like allergies. During prototype analysis, one participant suggested adding an "allergies" field, emphasizing the need for functionalities critical to clinical practice but

easily overlooked in development.

Professionals also noted they often resort to paper or manual processes due to the inflexibility of current tools, which frequently fail to adapt to their needs.

- **Limitations and Problems**

Participants frequently reported challenges with current software systems, which, despite being designed for multi-professional use, rarely meet the specific needs of all specialties. Healthcare professionals highlighted limitations in electronic medical record systems, which often fail to address their unique demands. One participant remarked, "In the public service, we get everything ready-made. [...] There are no tools to open the system and find specific resources for each profession."

The inability to support multiple specialties was a recurring frustration. In hospitals and public health centers, a system equally effective for psychologists, nutritionists, and other professionals is crucial. However, current systems often lack this flexibility, forcing informal adaptations and note summarizations that compromise care quality and patient records. Ethical and data security issues were also noted, particularly regarding privacy and the risk of inappropriate sharing between specialties. Participants stressed the need for systems with controls to limit access to sensitive information based on professional boundaries.

Professionals highlighted that their inclusion in system development could address these issues, ensuring each specialty's needs are integrated from the start. By participating in the requirements elicitation process, they can identify essential functionalities for their practices, creating flexible and practical systems. Additionally, they pointed out that mere training in tool usage is insufficient, as the challenges stem from structural and functional limitations beyond usability.

- **Feedback and Suggestions for Improvements**

After completing the survey, participants shared impressions of the specification process and tool, expressing positive experiences while suggesting improvements. A key observation was the need for more time, ideally available in real environments, as the experiment's simulated context limited time.

A prominent suggestion was improving the graphic interface for a more intuitive and visually organized design. Simpler navigation for locating and filling in fields could enhance efficiency and reduce cognitive load, making the specification process more agile. One participant remarked, "With a prettier interface, it would be much easier to use and even more intuitive."

This is particularly relevant given the technical complexity of openEHR archetypes. While designed to represent clinical data accurately, the current interface can be challenging for users unfamiliar with specific health concepts. A more intuitive design could make openEHR more accessible, enabling professionals to focus on specifying functionalities without unnecessary distractions or difficulties.

6 FINAL CONSIDERATIONS

This article demonstrates that using openEHR archetypes in requirements elicitation and specification effectively integrates healthcare professionals' specialized knowledge into clinical systems development. The literature review revealed a significant gap in involving these professionals during requirements elicitation, particularly in studies incorporating archetypes.

The results indicate a positive perception among health professionals, highlighting clarity, collaboration, and effectiveness. Participants considered the process transparent and engaging, with opportunities to define and validate requirements. Modeling with archetypes facilitated understanding activities, confirming a collaborative approach aligned with professional expectations. These findings show the methodology effectively integrates healthcare professionals' knowledge. However, limitations included healthcare professionals' unfamiliarity with the technology, emphasizing the need for robust educational support on openEHR archetypes and their role. Limited time for demonstrating and specifying functionalities in the simulated environment may have impacted contributions.

Future recommendations include expanding experiments to a diverse healthcare professional sample across specialties and experience levels, enabling comprehensive analyses of challenges and needs. Including varied profiles—doctors, nurses, managers, and technicians—could reveal differences in archetype use, aiding in versatile system development. Formalizing good practices for archetype use through guides, checklists, and manuals is also essential, alongside applying these practices in real development environments to assess effectiveness, observe user-developer interactions, and adjust as needed.

This study's limitations include a small sample size, controlled environment, professionals' unfamiliarity with archetypes, and limited time for specification, which restrict generalization to all clinical contexts or profiles.

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