A novel approach for Medical E-Consent: Leveraging Language Models for Informed Consent Management

Mouncef Naji[1], Maroua Masmoudi[1], and Hajer Baazaoui Zghal[1]

ETIS Laboratory UMR 8051, CY Cergy Paris University, ENSEA, CNRS, F-95000 Cergy, France

Abstract. In the context of healthcare, the issue of informed and voluntary consent stands a matter of paramount concern. Despite its stringent regulation within the medical field, the process of obtaining informed consent is frequently hindered by systemic, clinician-related, and patient-related factors, necessitating interventions at various levels. Notably, studies have shown that these factors often result in uninformed decisions, particularly in the context of hospitalization or intervention. This paper introduces a novel approach for enhancing the medical e-consent process by leveraging Large Language Models (LLMs) and knowledge graphs. The objective is to provide support during the consent process. Our proposal deal with 1) legal validation of consent documents for content clarity and comprehension verification; 2) personalization of content and interactions based on patient preferences and medical history; and 3) semantic reasoning integration into healthcare system information using knowledge graphs and ontologies. The overarching architectural objective of our proposal is to ensure a well-informed, adaptable, and legally valid consent process. Scenarios explaining the process based on data provided by our collaborators, is also detailed. The results show an improvement in the process and confirm the interest of the proposed LLM for informed consent management.

Keywords: E-consent · Large Language Models · knowledge graphs · Healthcare Information Systems

1 Introduction

The issue of informed and voluntary consent is a highly topical subject that triggers ongoing philosophical and legal reflections. It debates the individual freedom carrying significant implications, especially in the medical field, concerning the informed and voluntary consent of patients. This ethical and legal concept acts as a safeguard, ensuring that patients are fully informed about the nature of the medical interventions they will undergo. Regulations and guidelines governing the conduct of clinical interventions or hospitalizations require informed consent essentially to be obtained from each patient.

However, patients may require special attention influenced by factors like age, socio-economic status, or health. Ongoing technical advancements in medicine

necessitate a reevaluation of patient care, particularly regarding informed consent challenges. In today's evolving societal and medical landscape, the issue of patient consent remains central. Obtaining voluntary patient consent for a healthcare intervention is a complex and intricate process. In fact, it involves many challenges, including the lack of healthcare provider's training on patients' health issues, such as genetic and mental disorders. Additionally, the limited time available during patient consultations, coupled with the low health literacy within the population, further compound the intricacy of this process [11].

In compliance with the 'Kouchner Law' (Law No. 2002-303, March 4, 2002) [1], patients, in collaboration with healthcare professionals, autonomously make voluntary health decisions, including accepting or declining treatment. Healthcare professionals must respect and adapt treatment choices accordingly. No medical procedure can proceed without the patient's informed and revocable consent, allowing ongoing and adaptable treatment decisions throughout care.

In this paper, we propose a novel approach for medical e-consent that aims to enhance the efficiency of the consent process in the medical field, enhance patient understanding and ensure legal compliance, all while taking into account the vulnerability of patients who are unable to make decisions. By analyzing the conditions for informed and voluntary consent and examining the reasons for vulnerability in certain patients, we aim to facilitate the collection of consent as defined by the law. In alignment with this, the study draws its foundation from artificial intelligence. Our primary aim is to showcase the extent to which AI techniques can simplify and support the consent acquisition process and decision-making. Our work will primarily focus on the semantic aspect through the use of knowledge graphs and LLMs, along with the decision-making aspect.

This article is organized as follows: Section 2 presents an overview of related work on current solutions existing in France, the works related to LLMs for consent, and the use of knowledge graphs in that aspect. In section 3, we introduce the architecture of our proposal. Section 4 presents a use case example demonstrating the applicability of our proposal. The paper is concluded by a summary of contributions and research perspectives.

2 Related Work

As applied researchers, our state-of-the-art review has a dual focus. Firstly, it explores existing solutions in the French market for informed consent in the paramedical field. Simultaneously, it examines the issue of informed and voluntary consent in the healthcare system. Legislation and healthcare practices have accommodated these principles adeptly, as outlined in the Kouchner law (2002). However, implementing them has proven challenging, particularly in light of the mentioned difficulties.

Today, with the advancement of technology and the need for digitalization, several companies offer solutions to meet the demand for consent without compromising patient autonomy. We explored the French market to identify the

[1] Article L1111-4 CSP, https://www.legifrance.gouv

latest trends addressing this issue. *Je consens (Tessi)* [2]: is a solution focused on obtaining informed consent in the medical field. Designed for any healthcare institution, it offers an informative and interactive approach. Patients receive detailed information sheets and have the opportunity to participate in question-and-answer sessions with healthcare professionals to clarify all aspects of their treatment or intervention. This solution aims to ensure that patients fully understand the medical procedures to which they are consenting. *Easy consent (Calimed sante)* [3], transforms medical documents into interactive questionnaires, accompanied by reformulations and visual illustrations. Through a video demonstration, *Easy consent* shows how to make the consent process more understandable for patients using visual aids and accessible wording. *Ordoclic* [4], offers digitalization of documents and enables secure document transmission by SMS and email, with the ability to collect electronic signatures for the returned document. This solution simplifies administrative management by eliminating constraints related to physical documents and automating signature processes. *Docaposte* [5], solution relies on online signatures and digital archiving. By allowing electronic signature of consents and secure digital storage of medical documents. Docaposte facilitates future access to medical information and reduces dependence on paper documents. *Mind health (Frontline Media*): define the features of the Docaposte solution. While specific details are limited, this solution appears to offer a similar approach tailored to the specific needs of healthcare institutions to enhance the efficiency of consent and medical document management. Upon analyzing these solutions, we observed that each of them emphasizes digitization and consent collection but fails to specify their approach to effectively communicate with patients. Additionally, they seem to overlook the varying capabilities of patients based on their medical conditions, level of understanding, literacy, and more. Thus, the need for informed and voluntary consent remains unaddressed as a comprehensive solution in the market. However, in terms of digitization, they offer a promising foundation that we believe requires a semantic layer from both a modeling and substantive perspective. Therefore, we aim to delve into this semantic aspect, drawing upon knowledge graphs and LLMs. In this context, many works have introduced the need for summarizing and clarifying information in healthcare practices. These concerns are observed especially in clinical trials [1]. Indeed, the medical records provided to patients seem unrelated to their general understanding, which increases time and satisfaction [2]. This influences badly the healthcare system, shifting the attention far from patient care [3]. The emergence of LLMs recently, have raised research interests towards the healthcare domain, in order to overcome the previously mentioned problems. Many attempts have been made, to match the capabilities of the LLMs to the healthcare field. The work of [4] demonstrates how LLMs can be you used in medicine, and how being trained on medical data can outperform

[2] https://www.tessi.eu/fr/
[3] https://sante.easy-consent.fr/
[4] https://www.ordoclic.fr/
[5] https://www.docaposte.com/

human explanations. The proposed works in contrast to this, focus solemnly on domain specific applications, and thus, in medical domain, they have shown intresting results in terms of understanding [5, 6]. Some medical specific tasks have also been envisioned, this is the case of summarizing radiology reports [7], which have been well handled by the LLMs [8]. These LLM solutions indeed show promising results in terms of clarifying information for patients, serving well the "informed consent" request. But being domain specific, requires a high cost, and expertise to meet the requirements aspired. Moreover, patient's consent is not limited on medical/clinical records. In fact, many institution admit patients based more on legal data than medical, even if it's part of the healthcare system [9]. The informed consent rely both on the patient's pathology, on his personal and social capabilities, environment, economical features, etc, And all the determinants described by the OMS [10]. Moreover, the information system (SI) and the different types of data used; the complexity of the system makes it difficult to reach a consistent system able to handle these aspects. Furthermore, working on healthcare system, reasoning provides more insights and understanding, which can be provided using knowledge graphs. This is the conclusion of the paper [13], showcasing the importance of knowledge graphs in intelligent medical application. However, we noticed that the proposed approaches suffer from a well-defined semantic connections between critical components, which hinders their capacity to communicate effectively with patients. Moreover, the available solutions do not holistically address the varying capabilities and needs of patients, overlooking the nuances introduced by distinct medical conditions, literacy levels, and other vital factors. The proposed approaches, despite their focus on digitization and consent collection, do not offer a comprehensive solution for addressing these issues. They lack of semantic layer, both in modeling and substantive aspects. Our aim is to propose a knowledge graphs and LLM-based approach to enhance semantic connections and provide more effective patient communication and adaptation within the medical e-consent process.

3 LLM-based E-Consent approach

In this section, we describe our proposed approach for the LLM-based e-consent. The aim is to outline a workflow that empowers potential users, medical personal in our case, to acquire a thoroughly informed consent from patients, all while considering individual vulnerabilities and specific medical conditions. Figure 1 presents the proposed approach. It contains three main components: Data acquisition and processing, Personalized e-consent and Reasoning for decision making.

3.1 Data acquisition and processing:

This component oversees core datasets and associated processing. Comprising two sub-components, the first orchestrates offline mapping of consent documents to legal articles, ensuring validated forms and curating patient data for

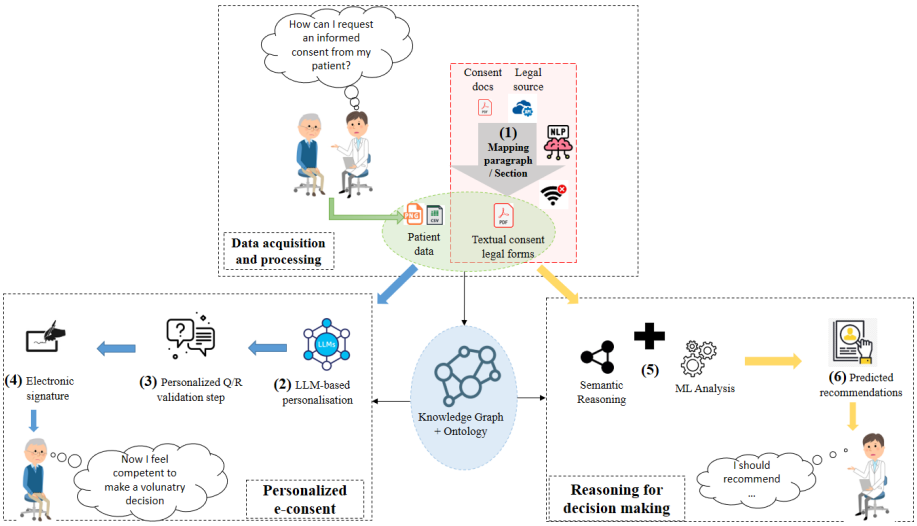


Fig. 1: LLM-based e-consent approach

the knowledge graph. Detailed dataset information is provided in the following subsection. The second sub-component details access modalities and required processing for each dataset, focusing on format and data specifics.

Datasets description: We present in this subsection the various datasets we work with, with a focus on precision and granularity:

- **Patient Dataset:** This dataset encompasses personal details (names, addresses, contact info) and delves into each patient's medical profile, covering medical history, current conditions, medications and allergies. Data is maintained in structured CSV files. The *Dossier Médical Partagé* offers an alternative for compliant data access.
- **Consent Forms:** The consent forms presented to patients are detailed and categorized into various sections, containing textual descriptions. These forms come in two types: (1) Documents to Fill: patients are required to provide precise information in these documents, such as personal information; (2) Documents to Read and Consent to: these documents offer detailed information about medical interventions with legal references.
- **Légifrance API**[6] Employed for legal compliance, this dataset validates consent form content against legal requirements in real-time through secure API integration, ensuring legal compliance for each consent document.

Access process: This subsection provides detailed insights into how each dataset is accessed:

[6] https://www.legifrance.gouv.fr/

- **Patient's Dataset:** Access to patient data is achieved through a multimodal approach: (1) CSV Files: patient data is primarily collected and maintained in structured CSV files, ensuring integration into the system. This mode of access enables efficient data retrieval and management; (2) Shared Medical Folder: the system securely interfaces with the Dossier Médical Partagé using APIs, ensuring up-to-date and compliant patient data. Access to the patient's dataset involves both structured and unstructured data. This structured data includes personal details, medical histories, allergies, and more. In contrast, unstructured data in the form of scanned PDF files contains handwritten notes, medical terminology, and diverse medical documents, all of which are processed within the system.
- **Consent Documents:** Access to consent documents is facilitated through Optical Character Recognition (OCR) technology, paper consent documents are scanned and digitized into PDF files, which are then directly accessed and processed within the system. The consent documents further exemplify the integration of structured and unstructured data. Traditional paper consent documents are scanned and digitized into structured PDF files, which are then directly accessed and processed within the system.
- **Légifrance API:** Accessible through secure digital channels, the system initiates API calls to Légifrance, obtaining relevant legal articles in structured JSON format. The response is processed to ensure legal compliance.

The Access process ensures that all data access modalities are secure, compliant with data protection regulations, and seamlessly integrated into the e-consent approach. Patient data access adheres to strict privacy and consent protocols, safeguarding patient privacy and data security.

Mapping Paragraph/Section: This step (1) ensures legal validation of the consent documents based on the legal source. It is an offline process based on a similarity measure between the documents and legal articles. The access via API to the legal source allows the validation to be updated following each change of law. The result is textual legal consent forms, that are fed to the personalized e-consent component.

3.2 Personalized e-consent :

This component personalizes consent forms by leveraging LLM to refine, rephrase, and summarize content based on the patient's unique information stored in the knowledge graph, including literacy, language, medical history, and health condition. The result is customized questions and answers that assess the patient's comprehension, streamlining the establishment of an electronic signature upon satisfactory responses, confirming well-informed consent.

LLM-based personalisation In step 2 of the architecture, a Large Language Model is used to clarify and summarize consent forms extracted from prior data

acquisition. The process is based on LLM reformulation. The patient's data is extracted from the knowledge graph and included in the context given to the LLM. This sets parameters for the LLM generation (literacy level, language, pathology). In addition, the consent information is extracted from the documents and given as well to the context, which increases accuracy of data generation of the LLM.

Personalised Q&R In step (3), the personalized Q&R module generates questions and answers, verifying the patient's comprehension of the information. Based on the previous content generated from the LLM, we set another context with the same parameters for each patient. This process is based on Langchain, aiming to generate the questions based on the content provided. Ultimately, the LLM generates choice questions to easily confirm the patient's comprehension.

Electronic signature After verifying the patient's understanding, Step (4) enables the establishment of an electronic signature. This signifies the patient's explicit consent and acknowledgment of presented information, reinforcing the legally binding nature of their agreement. It serves as a secure and traceable mechanism for the consent.

3.3 Reasoning for decision making :

This component plays a role in aiding medical professionals in selecting the most suitable interventions for a patient. Its foundation lies in the application of reasoning, ontologies and the pre-established knowledge graph. By taking into account both patient-specific data and domain knowledge, this component offers recommendations for the most fitting decisions concerning patient care.

Semantic reasoning and ML analysis Step (5) relies on ontologies and the comprehensive knowledge graph to fuel its reasoning capabilities. This component is designed to assist medical professionals in making informed and contextually relevant decisions regarding patient care. By leveraging ontologies, which provide structured and domain-specific knowledge, and the knowledge graph, which captures a wealth of information about patients and medical workflows, this step facilitates semantic reasoning. The result is a recommendation system that helps healthcare providers select the most appropriate interventions for each patient, ensuring that the care is medically sound and personalized.

Predicted recommendations In step (6), the E-consent approach offers decision making support for healthcare professionals. The architecture presents a structured hierarchy of recommendations based on individual patient preferences and needs. Serving as a bridge between data-driven insights and practical decisions in patient care, this component considers medical insights, personal choices, and healthcare preferences. The component allows healthcare providers to make decisions aligned with the patient's profile.

4 Examplar use case

The goal of this section is to provide an exemplar use case to illustrate how our proposal would accommodate a LLM and give a decision support for medical e-consent. Our objectives are to obtain well-informed and comprehensible consent from patients. This approach empowers healthcare personals to acquire clear and adaptable consent tailored to individual patient preferences and medical conditions. This process, as illustrated in Figure 2, is driven by two primary components: the information system, modeled as a knowledge graph, which encapsulates interactions within a medical institution and supports information retrieval and reasoning; and the e-consent model, dedicated to obtaining informed consent from patients. It's worth noting that the datasets and scenarios have been supplied by the Léonie Chaptal foundation [7], a socio-medical institution offering in-home nursing care and services to elderly and disabled individuals.

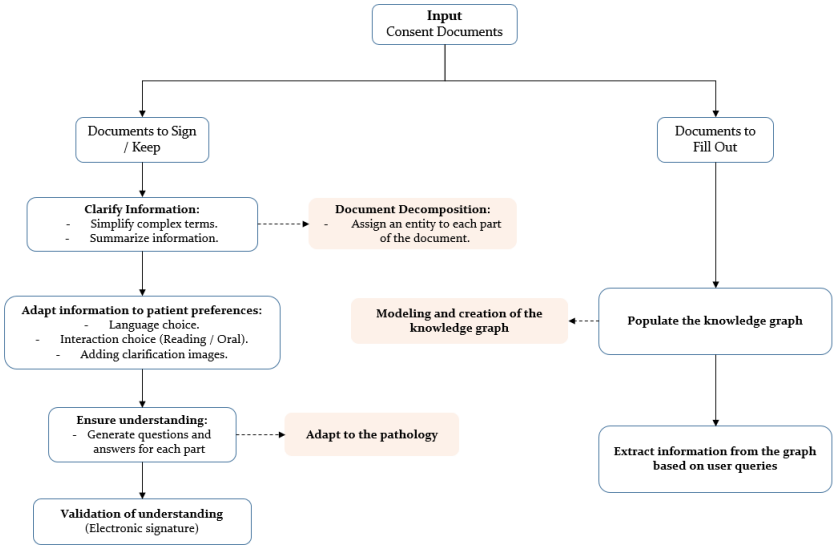


Fig. 2: LLM-based e-consent process scenario

The e-consent approach initiates with its offline component, which involves mapping consent forms to relevant legal articles. Concurrently, patient data is collected to populate the knowledge graph. The subsequent process unfolds through two distinct scenarios. The first scenario revolves around personalized consent, while the second scenario delves into the decision-making process.

Scenario 1: Comprehensive Informed Consent. Within this scenario, a health organization is tasked with obtaining consent from an elderly patient who

[7] http://www.fondationleoniechaptal.fr/

lacks fluency in English, communicates in Spanish, and possesses a low literacy level. Upon acquiring this information, the system condenses the original consent forms and rephrases them using the Language Model (LLM). Subsequently, it translates the reformulated content into Spanish, incorporating visual elements for enhanced clarity. Equipped with these materials, a healthcare professional gives clear, understandable information to the patient, systematically reviewing each section of the consent forms.

Following this, the system evaluates the patient's comprehension by generating multiple-choice questions (QCM) related to the presented content. These questions are also presented in Spanish. After completing the question-answering phase and surpassing a predetermined threshold, the patient is offered an electronic signature option to validate their consent.

Scenario 2: Decision recommendation. In this scenario, the health organisation is tasked with establishing a care plan for a patient having diabetes of type 2. The system starts with analysing the patient's data from the knowledge graph. It analyses the development of his condition, and the adequacy of his historical care. In parallel, the system make connection with medical data sources to get information about diabetes of type 2 (symptoms, treatment, etc). By acquiring this information, the system confronts the historical care plan with the information about the pathology, to predict and suggest different ways to accompany the patient. These recommendations are then presented to the health professional with the pros and cons, assisting him in his decision for the patient.

5 Experiments and results interpretation

This section presents the development tools, evaluation metrics, and discuss experimental results.

5.1 Developed tool and Evaluation metrics

To manage the implementation of our approach, we use the following tools: Google Colab [8], Neo4j [9] and NLP [10].
The evaluation is based on metrics corresponding to the main components of our system: the knowledge graph, the LLM and the prediction phase (Machine learning in the mapping step, as well as the predicted recommendations). Regarding the knowledge graph, we modeled the ontology to match the workflow inside the health institute. Its evaluation is based on the assessment of experts in the field, which measures it's completeness and consistency. For the LLM-generated response, the evaluation of relevance to the text has been measured with the ROUGE and BLEU metrics, and readability was measured by comparing the output with the input [16]. For the prediction models, we will employ standard classification metrics, including accuracy, precision, recall, and the F1 score [17].

[8] https://colab.research.google.com
[9] https://neo4j.com/
[10] https://www.nltk.org/

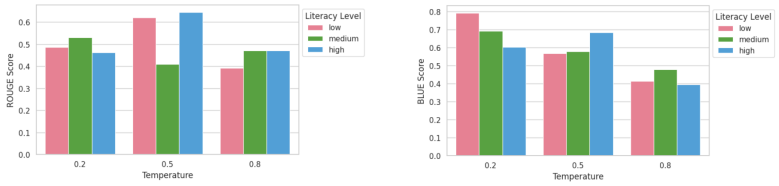
5.2 Experimental results

We initiated the implementation phase of our system by working on the personalized e-consent component. As previously mentioned, the purpose is to clarify the information in the consent documents based on the patient preferences. A priori, we focus on two key factors influencing the understanding of information: literacy and language.

We worked on a sample set of consent documents provided to patients by the health institution. The pre-processing phase involved reading and importing the PDF files, as well as filtering them using regular expressions. Next, we set up the context for the LLM to generate content based on the two factors, and we observed their variations with respect to the temperature change of the LLM. We computed the measures using the ROUGE and BLUE metrics.

ROUGE (Recall-Oriented Understudy for Gisting Evaluation), is designed to evaluate the quality of summaries of text generation. It focuses on recall, measuring how much of the reference text is covered by the generated text. A ROUGE score close to 1.0 indicates a high similarity between the two texts (original and generated). BLEU (Bilingual Evaluation Understudy) on the other hand, is used to evaluate the quality of machine-generated translations. It operates by comparing n-grams (contiguous sequences of n items, typically words) in the generated text with those in the reference text(s). The higher the BLEU score (closer to 1.0) the better.

The figure 3 illustrates the variation of Rouge scores (3a) and Blue scores (3a) in relation to both literacy levels and the temperature setting of the LLM, and their corresponding translation. The experiments are conducted with three different literacy levels (low, medium, high) and three temperature values (0.2, 0.5, 0.8) representing the degree of randomness in the LLM's output.



(a) ROUGE Scores (generated text)

(b) BLUE scores (Translated text)

Fig. 3: Rouge and Blue scores for different literacy levels at different temperatures

The impact of temperature on ROUGE scores (3a) is observable, with lower temperatures yielding more consistent scores across literacy levels. The influence of literacy level on ROUGE scores is not uniform and varies with temperature. In some cases, a higher literacy level correlates with higher ROUGE scores, while in others, the relationship is less straightforward.

As our interest centers around extreme cases—namely, low and high literacy levels — the model exhibits high performance at a temperature of 0.5, having a fine balance between consistency and a deliberate deviation from perfect similarity to the input text. This observation strongly suggests a nuanced customization of the generated text, finely tuned to the user's literacy level.

The results we got imply that the similarity is good but not perfect, which is a good indicator, showcasing that there is a certain similarity between the input and the output, but still personalized on the literacy level.

As for the language factor, the observed variation in BLEU scores (3b) with different temperature settings indicates the degree of randomness in LLM's output. Lower temperatures, such as 0.2, result in higher BLEU scores, indicating more precise and similar text to the reference. In contrast, higher temperatures introduce more variability, leading to lower BLEU scores. We qualify this as reasonable results, since high randomness is used for a high temperature value.

The obtained BLEU scores imply a commendable level of similarity between the input and output texts. However, the scores fall short of perfection, indicating room for personalization. This customization aligns with the user's literacy level, reinforcing the adaptability and customization capabilities of the model.

6 Conclusion

In conclusion, our paper tackles a critical challenge in the healthcare domain: the imperative for a comprehensive and adaptive approach to informed medical consent. Our method capitalizes on knowledge graphs, LLM, and semantic reasoning to elevate patient communication and comprehension, resulting in well-informed and legally valid consent. Our research contributes significantly to overcoming the limitations of existing solutions, often constrained by a lack of robust semantic connections and challenges in accommodating diverse patient needs and conditions. The proposed approach comprehends three components: (1) Data acquisition and processing, (2) Personalized e-consent and (3) Reasoning for decision making. Upon describing each component, this paper focuses mainly on the personalized e-consent component. Indeed, the experiments regarding personalized content and the process of getting informed consent are described throughout the paper. This personalization was based on two factors: literacy level (low, medium, high) and language. During the experiments, we also worked on the variations of the LLM with aspect to these factors. We computed the results using the ROUGE and BLUE metrics, that showcased relatively good results adequate for personalization purposes.

Through the introduction of the described personalized approach, our work ensures that the informed consent process aligns precisely with each patient's unique requirements, thereby enhancing both the quality of care and the protection of patient rights. As perspective, we intend to focus on the decision-making component. The idea is to integrate decision trees and decision transformers to support the recommendation system. Specifically, by training a decision tree model to predict the most appropriate decisions for specific pathologies.

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