Original Paper

Development, Implementation, and Assessment of a Computer Decision Support System for Monitoring and Management of Oral Anticoagulation With Warfarin in Resource-Constrained Settings: Mixed Methods Study

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Abstract

Background: Warfarin remains the mainstay of oral anticoagulation in low- and middle-income countries and in specific clinical conditions, despite its complex management and the risks associated with poor anticoagulation control. In this context, clinical decision support systems (CDSS) have the potential to improve anticoagulation safety and efficacy, particularly in primary care.

Objective: This study aims to develop a CDSS aimed at enhancing anticoagulation management in primary care, to implement it in a resource-constrained region, and to evaluate its usability and satisfaction among health care professionals.

Methods: The study followed a mixed methods, 4-phase design based on the Medical Research Council framework. Phase 1 involved a cross-sectional assessment of primary care units to identify gaps in usual anticoagulation care. In phase 2, a baseline prototype of a secure, web-based application was developed, featuring structured patient data entry and tools for monitoring anticoagulation quality, but without decision-support messages. Formative evaluation was conducted over 8 months through real-world use of the prototype by health care professionals, assessing system functionality, usability, and data entry processes to guide refinement of system features; these professionals assessed 514 patients in 4022 consultations. Phase 3 focused on the development of individualized decision-support messages. Phase 4 consisted of a pilot implementation during routine outpatient consultations, in which trained clinical pharmacists used the CDSS, and usability and acceptability were evaluated through semistructured interviews, and qualitative data were analyzed thematically.

Results: The final CDSS included 210 tailored clinical recommendations addressing anticoagulation indication, dose adjustment, drug-drug interactions, and bleeding management. Internal validation demonstrated the logical consistency of the algorithms and accurate triggering of decision support messages. The system was successfully adopted by all trained pharmacists and integrated into routine workflows. Users reported high usability, intuitive navigation, and perceived usefulness of graphical tools for monitoring international normalized ratio (INR) and time in therapeutic range. The system was perceived

to improve consultation organization, standardize clinical decision-making, enhance patient education, and support longitudinal follow-up. Key barriers included time constraints, competing demands, occasional technical issues, and lack of integration with electronic health records.

Conclusions: This study demonstrates the feasibility and acceptability of a CDSS for anticoagulation management in primary care in a resource-constrained setting. The iterative development process, including extensive real-world formative evaluation prior to implementation of decision-support logic, strengthened system usability and alignment with clinical workflows. Future studies should evaluate its effectiveness on clinical outcomes and explore strategies to enhance integration, scalability, and sustainability.

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Keywords: clinical decision support systems; decision support techniques; anticoagulants; warfarin; quality of health care

Introduction

Stroke is the second most frequent cause of death and the third cause of disability worldwide. The number of individuals affected by ischemic stroke, including survivors, is still increasing [1-3]. Oral anticoagulants are widely used for primary and secondary thromboembolic prophylaxis. Despite the emergence of direct oral anticoagulants (DOACs), warfarin remains a cornerstone in anticoagulation therapy in resource-constrained settings, due to the limited availability and high cost of DOACs. In low- and middle-income countries, access to DOACs remains a significant challenge, largely due to economic constraints and the lack of reimbursement policies [4,5]. As a result, warfarin is often the only viable option for anticoagulation, making effective monitoring and dose adjustment strategies essential for optimizing patient outcomes and minimizing complications [6,7].

Additionally, it is also a cornerstone for anticoagulation therapy for patients with clinical conditions where warfarin has demonstrated superiority over DOACs, such as mechanical heart valve replacement, severe mitral stenosis, and selected patients with antiphospholipid syndrome [8-11].

However, warfarin therapy is complex, requiring careful monitoring of international normalized ratio (INR) levels and frequent dose adjustments to maintain patients within the therapeutic range [6,7]. Poor anticoagulation control is associated with an increased risk of thromboembolic events and bleeding complications, which highlights the need for tools that can assist health care professionals in managing anticoagulated patients more effectively. The number of patients requiring anticoagulation therapy may enhance in the next decades due to better accessibility to health services, technological advances in medical diagnosis, and population aging [12,13].

In this context, clinical decision support systems (CDSS) offer a promising approach to improving the safety and efficacy of warfarin therapy [14], particularly in resource-limited settings. The use of applications for anticoagulant therapy is not a novelty in high-income countries [12,13,15], but is not well explored in low- and middle-income countries. Thus, our aim was to develop a CDSS aimed at enhancing anticoagulation management in primary care, to implement it in a resource-constrained region, and to evaluate its usability and health care practitioner satisfaction. The system was designed for use by primary care physicians, pharmacists, and other health care practitioners involved in anticoagulation care. It is intended to be integrated into routine patient consultations, supporting clinical decision-making such as dose adjustments, monitoring of anticoagulation parameters, and scheduling follow-ups. By facilitating more standardized and evidence-based management, the system has the potential to improve patient outcomes, including safer anticoagulation control and reduced adverse events, while enhancing practitioner workflow and satisfaction.

Methods

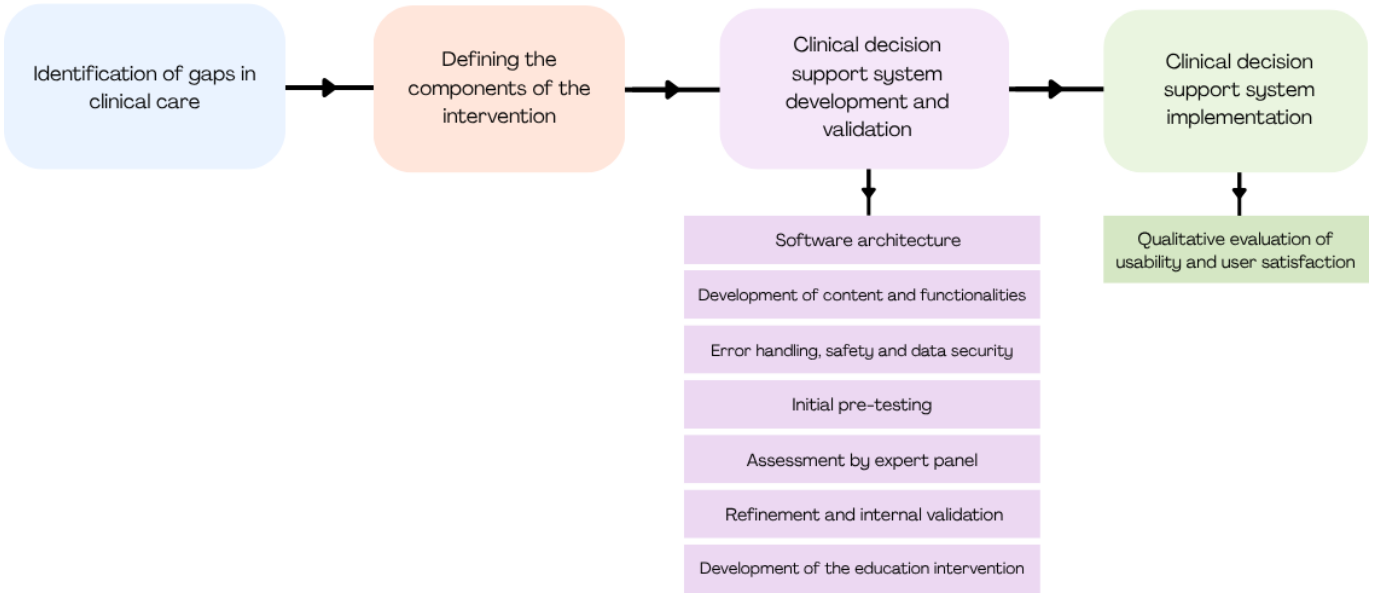
Study Overview

This is a mixed methods study, conducted in 4 sequential phases, following the Medical Research Council (MRC) Framework [16]. System development and evaluation were guided by World Health Organization (WHO) recommendations for digital health interventions, which define evaluation strategies according to application maturity [17]. System development and reporting were conducted in line with recommended principles for digital health interventions (mobile health Evidence Reporting and Assessment [mERA]) and early-stage evaluation of CDSSs (Developmental and exploratory clinical investigations of decision support systems driven by AI [DECIDE-AI]) [18,19]. Although mERA was initially developed for mobile health interventions, its reporting standards are applicable to desktop and web-based systems. Similarly, while DECIDE-AI was originally designed for AI-driven tools, its framework also applies to rule-based decision support systems such as the current application. Specific mERA and DECIDE-AI domains were operationalized across study phases, including intervention description, context of implementation, usability testing, human factors evaluation, safety considerations, and early-stage validation [17,18] (Multimedia Appendix 1 and Checklist 1).

First, gaps in current clinical practice were mapped; second, key intervention elements were defined in consultation with experts and stakeholders; third, the CDSS was developed and validated; and finally, pilot testing was undertaken, during which usability and user satisfaction were formally assessed. Usability was evaluated using complementary quantitative and qualitative approaches, including

a formative expert panel assessment using Likert-scale questionnaires and a postimplementation qualitative process evaluation (Figure 1).

Figure 1. Methodology of the development, implementation, and assessment of the clinical decision support system.



Phase 1: Identification of Gaps in Usual Care

To evaluate which gaps were already known, we performed a cross-sectional study in primary care units in Divinópolis, a medium-sized Brazilian city, and collected data from May 1, 2018, to February 28, 2020. The study has been previously published [20]. In brief, from 162 patients enrolled, in 22 patients (14%) the reason for anticoagulation was not registered in patient records, and the mean time in therapeutic range (TTR) in patients taking warfarin, defined as the proportion of time within the target INR range [21], was 44.0% (SD 28.7%). The complete absence of CHA2DS2-VASc and HAS-BLED scores in medical records was alarming [20].

Phase 2: Identifying the Components of the Intervention Through Discussion With Experts and Stakeholders

Intervention components were defined through an iterative, collaborative process involving health care professionals and key stakeholders. This process comprised the development and review of 3 anticoagulation management protocols, conducted through separate discussion cycles with distinct clinical teams: (1) the Anticoagulation Clinic from the University Hospital of the Universidade Federal de Minas Gerais; (2) primary care teams in Belo Horizonte [22]; and (3) municipal health services in Divinópolis. Key topics discussed within these meetings and formalized in the respective protocols, dose adjustment strategies, management of bleeding events, and care pathways across health care settings were synthesized and directly informed the structure and content of the CDSS. In addition, insights from prior implementation experiences with digital health tools for other chronic conditions, together with user feedback from these initiatives [23], informed refinements to usability features and the expansion of decision-support messages.

Phase 3: Clinical Decision Support System Development and Validation

Software Architecture

System development followed a structured, 3-stage process. First, functional requirements were defined and formalized using use-case and class diagrams to ensure clarity regarding system entities, attributes, and user interactions. Second, the database architecture was designed using a relational model implemented in PostgreSQL (PostgreSQL Global Development Group), with object-relational mapping managed through the Hibernate framework (Red Hat). Third, the application was implemented in Java (Oracle Corporation), with the user interface developed using PrimeFaces (PrimeTek Informatics), Bootstrap (The Bootstrap Core Team), JavaScript (PrimeTek Informatics), and jQuery (The OpenJS Foundation). Secure access control and user authentication were implemented using the Spring Security framework. This architecture was selected to ensure system robustness, data security, and compatibility with existing infrastructure in primary care settings, using widely adopted, open-source technologies.

The system was developed as a standalone web-based application and did not include interoperability or data exchange with other health information systems, such as electronic health records. This design choice was consistent with the early-stage evaluation of the system and the heterogeneous digital infrastructure of the primary care settings in which it was implemented.

No modifications were made to the source code of the publicly available software frameworks used in the system. The application logic and interface were custom-developed by the research team, and the source code is not publicly available.

Although a full economic evaluation was not performed, the system was designed to operate on standard desktop computers with existing internet infrastructure, minimizing additional costs for implementation in primary care settings.

Development of Content and Functionalities

System Overview

A web-based, user-friendly application was developed in Brazilian Portuguese for use by health care professionals, including primary care physicians, nurses, and pharmacists. Access is restricted to authenticated users through a personalized login system, with accounts created and managed by a central administrator. The application is organized into four main modules: (1) patient management, (2) structured clinical evaluation, (3) clinical consultation with decision support, and (4) anticoagulation quality assessment using TTR.

Data Inputs and Acquisition

The system collects structured clinical data for each patient, including demographic information, anticoagulation indication, thromboembolic and hemorrhagic risk scores (CHA_2DS_2-VASc and HAS-BLED) [7], oral anticoagulant type, dose schedules, current and past medications, INR results, treatment adherence, changes in dietary vitamin K intake, tea consumption, and relevant clinical events such as hospitalizations or thromboembolic/hemorrhagic episodes. All data are entered manually by health care professionals during consultations. Previously recorded data are automatically retrieved for review and updating in subsequent visits.

Data Entry Process and Preprocessing

Data entry occurs through structured forms in the web interface. Conditional fields appear only when relevant events or conditions are indicated (eg, subforms for venous thromboembolism [VTE] details if VTE is selected as indication). Default values are prefilled for specific fields to reduce entry errors. The system automatically calculates derived variables such as risk scores (CHA_2DS_2-VASc and HAS-BLED) [7] and TTR, including both the simple fraction-in-range method and Rosendaal linear interpolation method [21]. Auto-generated graphs summarize anticoagulation quality over time.

Handling Missing or Low-Quality Data

Mandatory fields were defined for critical clinical data (eg, INR, anticoagulant type, and weekly dose). Optional fields could be left blank if information was unavailable. Data entry errors or omissions could only be corrected on the same day of entry; the system did not allow modification of records from previous consultations. This restriction was implemented to maintain the integrity of the patient record, preventing post hoc changes that could alter the results of prior analyses and potentially compromise confidence in the system or enable inadvertent or deliberate record tampering.

Decision Support Generation Logic

The CDSS generates individualized recommendations and educational message outputs based on the entered data. The rule-based algorithm integrates patient-specific factors such as INR relative to the therapeutic range, age, sex, bleeding and thromboembolic risk, comorbidities, medication changes, dietary vitamin K intake, and adherence. Recommendations are optional and can be accepted or overridden by the clinician, preserving full clinical autonomy. Core recommendations were derived from international evidence-based clinical guidelines and prioritized according to the highest available level of evidence [24,25]. In cases where guideline recommendations were absent or outdated, evidence-based clinical summaries were consulted.

System Outputs and Presentation

Based on the data entered during each consultation, the system generates several outputs for the user: (1) clinical decision support messages, presented in real-time within the consultation module as pop-up suggestions, alerts, or reminders; (2) patient consultation records, which can be viewed on-screen or printed; (3) quality metrics, including TTR calculations, displayed as numeric values and auto-generated graphs illustrating anticoagulation control over time; (4) reference materials, linked directly to relevant guidelines, accessible from within the interface. All outputs are presented in a structured and intuitive interface to facilitate rapid interpretation and clinical decision-making.

System Error Handling, Safety, and Data Security

Significant system errors or malfunctions were defined as technical or functional issues that impaired system usability, data entry, or the generation of clinical decision support messages. These issues were identified during pretesting phases and through user feedback collected during routine clinical use and expert panel assessment.

Potential risks to patient safety were addressed through system design. The CDSS was intended to support, but not replace, clinical decision-making, and all recommendations were advisory. Final clinical decisions remained under the responsibility of the health care professional, who could accept or disregard system suggestions. Recommendations were derived from evidence-based clinical guidelines, and the system was used as an adjunct to standard care, minimizing the risk of harm.

User access is secured via personalized logins and passwords. Patient data are stored in a secure, relational database, and access is limited to authorized health care professionals. No patient-identifiable information is shared externally.

Initial Pretesting (Baseline Prototype, Without Decision Support Messages)

The initial prototype underwent pretesting prior to the implementation of any decision support logic. This phase focused on verifying core system functionality, interface usability, data entry processes, and system responsiveness. Predefined test cases were used to assess data processing, navigation flow, and overall interface intuitiveness. Identified technical and usability issues were documented and used to guide subsequent system refinements.

Expert Panel Assessment (Formative Evaluation)

An expert panel composed of highly experienced health care professionals from the Anticoagulation Clinic of the University Hospital of the Universidade Federal de Minas Gerais conducted a formative evaluation of the system after 8 months of routine clinical use. At this stage, the application did not yet include automated decision support messages. System performance was assessed using a Likert-scale questionnaire completed by system users. During the evaluation period, 514 patients were included, resulting in 4022 recorded consultations.

Among the 10 health care professionals who participated in the expert panel assessment, usability was rated positively, with 9 (90%) of experts reporting the interface as very easy to use and 1 (10%) as moderately easy. Most experts (9 of 10) indicated that using the application for clinical documentation substantially reduced consultation time, while the remaining expert reported a moderate reduction. Data security was perceived as adequate by 9 (90%) of the respondents, although 1 (10%) expressed some concerns. System stability was identified as a limitation, as 8 (80%) of them reported occasional freezing or failures and 2 (20%) reported frequent issues. The majority of experts (7 of 10) expressed interest in the future inclusion of clinical decision support features, such as dose adjustment recommendations and guidance for perioperative management. Overall satisfaction with the application was high, with 9 (90%) experts reporting being satisfied.

System Refinement and Internal Validation

Insights from the expert panel assessment were used to guide system refinements, including improvements in stability, flexibility in documenting changes in anticoagulation therapy, medication list completeness, and data entry handling. No adaptations were made for other languages, populations, or health care contexts.

Following these modifications and the subsequent implementation of decision support messages, the system underwent additional rounds of internal validation to ensure correct system functionality, absence of software bugs, and alignment of generated recommendations with the prespecified decision tree. Interface usability, intuitiveness, data processing speed, and functionality of system icons were assessed.

Manual data entry using predefined test cases was performed by a multidisciplinary internal team, including one physician (MSM), one pharmacist (João Queiroz Oliveira), one dentist (Amanda Groppi Martins de Oliveira), and 2 medical students (RBC and Lucas Rocha Valle), to verify the accuracy, consistency, and clinical appropriateness of the system's recommendation outputs. Structured test cases were used to verify whether the system's recommendations were generated as expected for each predefined clinical scenario. Identified issues were reported to the project's coordinating researcher (MSM), an internal medicine and cardiology specialist with over 14 years of experience in telehealth and health information systems, who reviewed each issue and, when confirmed, forwarded it to the system development team for correction.

Development of the Educational Intervention

Educational materials were developed for both health care professionals and patients as part of the intervention. For health care professionals, an online training module was created comprising 9 short video lectures covering key aspects of oral anticoagulation therapy, including: introduction to oral anticoagulation, clinical indications, definition of therapeutic range, pharmacological principles, drug-drug interactions, therapy monitoring and control, treatment initiation and dose management, management of bleeding events, and management of anticoagulation during invasive procedures. All video lectures were recorded and edited by the Tele-education team of the Telehealth Network of Minas Gerais, and made available through a dedicated online learning platform. In addition, a recorded webinar entitled "Oral Anticoagulation in Primary Care" was produced and made publicly available on YouTube (Google LLC) to broaden access to educational content [26].

For patients, an illustrated educational booklet was developed focusing on warfarin therapy. The material addressed core topics such as the purpose and interpretation of INR testing, thromboembolic and bleeding risks, factors influencing anticoagulant response, and practical guidance for daily management. Content was written in clear, patient-centered language and supported by visual resources to enhance comprehension.

Phase 4: CDSS Implementation

Overview

This implementation was conducted with clinical pharmacists working in primary health care services of the Brazilian Unified Health System (Sistema Único de Saúde [SUS]) as part of the Implementação do Cuidado Farmacêutico no Sistema Único de Saúde (IMPLANFAR SUS) study [27]. This study aimed to implement and evaluate pharmacotherapeutic follow-up for patients with diabetes mellitus in municipalities of the Central-West region of Minas Gerais, Brazil. Pharmacists were recruited through Municipal Health Departments across participating municipalities. For this study, pharmacists from 7 municipalities (Divinópolis, Pará de Minas, Conselheiro Lafaiete, Carmésia, Virgolândia,

Coroaci, and Diogo de Vasconcelos) who agreed to participate were included. Routine outpatient services in these municipalities had access to electricity, desktop computers, and internet connectivity.

In the Brazilian primary care setting, anticoagulation management is traditionally physician-centered. This pilot implementation was intentionally designed to evaluate the feasibility of using the CDSS among nonphysician health care professionals, specifically clinical pharmacists involved in pharmacotherapeutic follow-up. The IMPLANFAR SUS study provided a structured and pragmatic context to assess this approach in real-world practice.

Training was delivered in 2 sequential phases. The first phase consisted of the asynchronous online course previously described. Pharmacists were also provided with a local clinical protocol for anticoagulation management, developed collaboratively by the research team and the Universidade Federal de São João del-Rei. In the second phase, participants completed a synchronous individual online training focused on the use of the CDSS, after which they were granted secure online access to the system and implemented it during routine outpatient care.

During each outpatient consultation, pharmacists collected clinical and laboratory data, which were entered into the CDSS in real time. The system generated decision support messages during the consultation, informing dose adjustment suggestions, follow-up intervals, and clinical considerations. The final clinical decision regarding anticoagulation management was made by the pharmacist, who could accept or disregard the system's recommendations based on clinical judgment. Patients aged 18 years or older receiving warfarin therapy and monitored in primary care centers were eligible for inclusion.

Qualitative Process Evaluation: Usability and User Satisfaction

The qualitative stage of the study was designed as a process evaluation in accordance with the Medical Research Council framework for the development and evaluation of complex interventions, as updated by Skivington et al [16,28]. This phase aimed to complement the quantitative and formative assessments conducted in earlier stages by exploring, in depth, health care professionals' experiences with the CDSS after its implementation in real-world primary care settings. The process evaluation focused on understanding how the intervention was integrated into routine practice, how users interacted with the system, and which contextual factors influenced its perceived usability, acceptability, and potential sustainability

A total of 7 individual semistructured interviews were conducted with participating pharmacists after the CDSS implementation period (Multimedia Appendix 2). The interviews were conducted online, had an average duration of 40 minutes, and were audio recorded and fully transcribed. The participants' anonymity was guaranteed through alphanumeric identifiers (F1, F2, and F3).

Data were analyzed using thematic content analysis, following 3 stages: preanalysis, material exploration, and interpretation [29]. Initially, transcripts were read in full to achieve familiarization with the empirical corpus. Meaning units were then coded, resulting in 10 codes and 60 subcodes (Multimedia Appendix 3). Codes were grouped according to semantic and conceptual similarity, generating analytical categories related to: (1) experience of CDSS use, (2) professional training and capacity building, (3) reorganization of clinical practice, (4) perceived impacts on care, and (5) barriers and facilitators to implementation (Multimedia Appendix 4).

This analytical approach enabled an in-depth understanding not only of whether the intervention was considered usable and acceptable, but also how and why its effects emerged within specific organizational and clinical contexts, in line with the logic of complex intervention evaluation.

Human Factors Considerations

Human factors considerations were incorporated using an iterative, user-centered development approach. Use cases were based on routine outpatient anticoagulation management in primary care settings. End users included clinical pharmacists working in the Brazilian Unified Health System, while physicians, pharmacists, dentists, and medical students participated in system testing phases. Usability, workflow integration, and clarity of outputs were assessed through hands-on testing and expert panel evaluation.

Patient and Public Involvement

Patients were not directly involved in the development of the research question, study design, or conduct of the study. This early-stage evaluation focused on system development, usability, and integration into clinical workflows from the perspective of health care professionals. Future phases of system evaluation will incorporate patient involvement to assess patient-centered outcomes and user experience.

Ethical Considerations

Ethical approval was obtained from the Universidade Federal de Minas Gerais Research Ethics Committee (number 70135717.0.0000.5149). No specific algorithmic fairness or bias mitigation methodologies were applied, as the system is rule-based and does not rely on data-driven or adaptive algorithms. Ethical considerations were addressed through system design choices, including the use of evidence-based clinical guidelines, transparency of recommendations, and preservation of clinician autonomy, with all final decisions remaining under professional responsibility. Written and informed consent was obtained from all participants. Participants did not receive any type of compensation for participation in the study.

Results

CDSS Development and Validation

An initial bank of 208 reminders and suggestions was created for the clinical decision support functionality. After message content refinement, a final bank of 210 reminders and suggestions was used. The clinical decision support interface provides health care professionals with tailored recommendations generated dynamically based on patient-specific data entered during each consultation, supporting individualized and guideline-concordant care.

The decision logic is organized into 4 main recommendation domains:

1. General guidance on anticoagulation therapy: including adherence, dietary consistency regarding vitamin K, and avoidance of alcohol and herbal products (5 messages);
2. Warfarin dose management: based on INR values and changes in relevant cofactors between consecutive visits (70 messages);
3. Drug-drug interaction risk alerts: triggered by the initiation of new medications (133 messages);
4. Management of bleeding events: stratified by severity (2 messages).

Examples of decision support messages and corresponding algorithms are presented in Table 1, and a representative screenshot of the CDSS interface is shown in Figure 2.

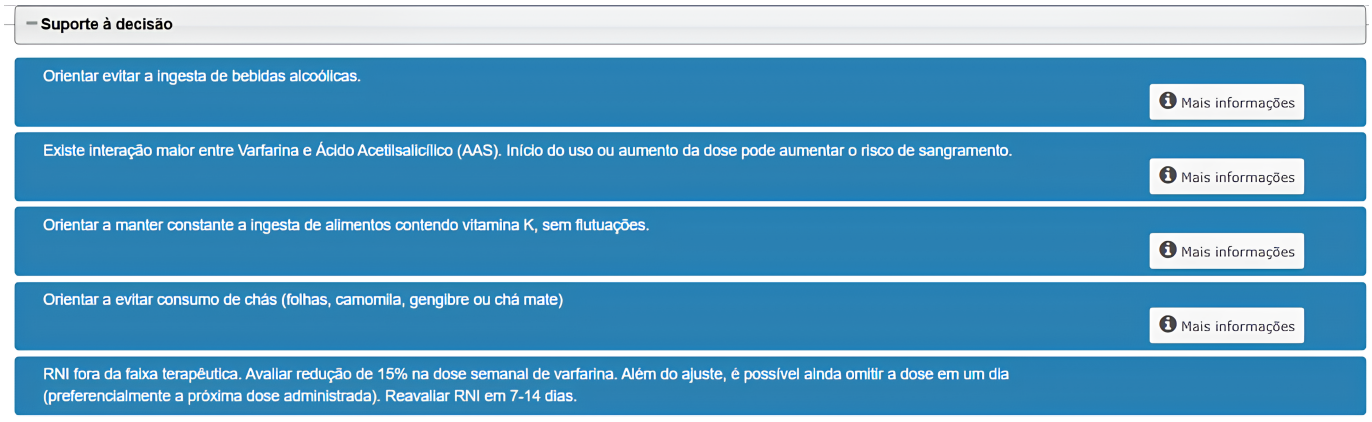
During internal tests, most errors identified were due to misplaced parentheses and connectors in the commands of the decision algorithm and spelling mistakes. The expert panel suggested changes were used to enhance the application. These internal tests confirmed the logical consistency of the decision algorithms and the correct triggering of recommendations under predefined clinical scenarios, supporting the internal validity of the CDSS.

Table 1. Examples of clinical decision support messages.

Approach group	Algorithm	Main message	Additional text
General orientations	{Irregular consumption of vitamin K sources =YES}	Orient to keep the ingestion of food containing vitamin K constant, without fluctuations.	The regular ingestion of food containing vitamin K was found to be associated with a higher stability in the anticoagulation control. When not possible to assure daily intake, orient to keep the same weekly frequency (for example, 3 times a week), the same portion (for example, 2 tablespoons)
Dose management	{[Therapeutic range =2-3] & [all the INRs[a] from the 84 previous days inside the therapeutic range =NO] & [current INR between 1,51-1,79] & [different use than prescribed =NO] & [irregular intake of leafy greens =NO or YES-reduced] & [tea consumption =NO]}	INR outside the therapeutic range. Evaluate a 10% increase in the warfarin weekly dose.	Before deciding on a dose increase, evaluate if there was any difficulty with venipuncture or prolonged tourniquet time, which may have contributed to the test alteration.
Drug interactions	{[Anticoagulant =Warfarin] & [Drug =Carbamazepine] & [Change = ('Dose reduction' OR 'Treatment suspension'] & [Current consultation]	There is a moderate interaction between warfarin and carbamazepine. Treatment suspension or dose reduction can make the INR rise and increase bleeding risk.	Can induce warfarin metabolism and reduce its anticoagulant effect. The mechanism is the induction of isoenzymatic hepatic metabolism by carbamazepine.

[a]INR: international normalized ratio.

Figure 2. Representative screenshot of the computer decision support interface.



CDSS Implementation

The intervention was delivered as planned. All participating pharmacists incorporated the CDSS into routine outpatient consultations after completing the training program. The system was primarily used during scheduled follow-up visits, with real-time data entry and on-screen visualization of INR history and TTR. Engagement and usage were monitored through backend system data, capturing all consultations conducted during the study period. No major deviations from the planned workflow were observed, although occasional system freezes were reported and subsequently addressed in later system iterations.

Qualitative Process Evaluation: Usability and User Satisfaction

Baseline Experience With Anticoagulation Care in Primary Care

Participants reported heterogeneous levels of prior experience with clinical pharmacy services and with the systematic follow-up of patients using oral anticoagulants. For most pharmacists, structured monitoring of patients receiving warfarin was not part of routine practice before the implementation of the CDSS, despite the medication being dispensed in primary care units. Several participants described limited familiarity with anticoagulation management and infrequent clinical involvement with these patients.

> *We work so little with these medications…, the only one available in primary care, … is warfarin, because we don't work with it, …it became really distant* [F4]

Participants also highlighted the multiple responsibilities assumed by pharmacists in primary health care, which often limited the time available for clinical follow-up and longitudinal patient monitoring.

Role of Training and Professional Capacity Building

The prior training program was consistently described as a central element for the adequate use of the CDSS and for the clinical monitoring of patients using oral anticoagulants. Participants emphasized that the training supported not only the technical use of the software, but also the understanding of clinical principles related to anticoagulation therapy, particularly given their limited previous experience with systematic monitoring.

> *I really enjoyed it, both the lesson we had, the initial one from the capacitation, and afterwards the work itself. I thought it was really valid, it was a really important experience for updating knowledge.* [F4]

> *The theoretical basis was really good, without it I think the program wouldn't be of much advantage for me, get it? I wouldn't be able to do analysis if it weren't for this training.* [F3]

In addition to facilitating system use, the training was perceived as an opportunity for professional development, contributing to increased interest in clinical follow-up activities and reinforcing pharmacists' perception of their role in primary health care.

Usability and Integration Into Clinical Workflow

> *...what I enjoyed about the system was its practicality, it is pretty summarized, it condensates information, so when you open the system and search for the patient you want, a summary of the data appears, the appointments, right, in sequence, and the INR value appears.* [F3]

> *Easy, really easy, really smooth, to fill out the data, to go from one screen to another, to understand, and also to include the data, the registrations. It was really easy to register the patient.* [F4]

The organization and sequencing of clinical information were highlighted as differentiating features of the software when compared to other systems already used in primary care, contributing to more agile follow-up consultations.

> *The benefit of this system is that the information is sequenced and organized. You don't have to have access to a spreadsheet, get it? I found it more organized, more straightforward.* [F3]

> *Super practical. The interface is pretty clean, unlike the PEC (Prontuário Eletrônico do Cidadão) your system is intuitive. I found it nice, don't have any complaints.* [F3]

Participants also reported positive perceptions regarding system performance, with no major issues related to speed or responsiveness during routine use. Graphical tools, such as the INR and the TTR visualizations, were considered useful resources for clinical monitoring and decision-making.

> *The software was really quick, I did not have any difficulties, with it becoming frozen, or unresponsive for some time, when I added some information, when I altered something, it always worked out fine.* [F2]

> *...we have these graphs. We have all the TTR here, at hand, easy to calculate. We have all the patient data. This already helps with decision making.* [F2]

Reorganization of Clinical Practice and Perceived Impacts on Care

The implementation of the CDSS supported the organization of pharmaceutical consultations by structuring the collection of clinical, pharmacotherapeutic, and patient routine information. Participants described adaptations in care delivery, including scheduling strategies and changes

in consultation locations, to accommodate patient needs and facilitate data collection.

> *I scheduled an appointment with these patients, right, and from there I kept using the system, I went to the health unit because the first appointment demanded clinical data, so these clinical data I can't obtain in the pharmacy, so the first appointment I scheduled in the health units.For those who preferred to keep going to the health units I would go to the health unit to do the appointment, and the rest preferred to continue in the pharmacy after the first consult, I would go back and do the appointment in the pharmacy, because it was, we could say, more convenient to the patient*. [F2]

Participants perceived that the use of the CDSS expanded access to clinical monitoring for patients receiving oral anticoagulants, particularly those who had not been previously followed in a systematic and continuous manner within primary care.

> *I saw these patients so abandoned by the primary care in our municipality, regarding their follow-up on warfarin*. [F2]

> *This patient I had an appointment with, she hadn't had any follow-up for almost the last three years, she hadn't done the INR since her last appointment* [F3]

The system was also described as facilitating patient education, especially regarding diet, treatment adherence, and understanding of INR results. The organization of information and use of visual resources were perceived as improving communication between pharmacists and patients.

> *So as we brought the patients to orientate them, the patients' quality of life improved, the patients were favored*. [F3]

> *So from the moment we orientated her, we established a day for her to eat, right, to ingest leafy greens, and she started to normalize her diet* [F3]

Participants expressed motivation to engage in the intervention and demonstrated an understanding of the importance of systematic patient monitoring. The CDSS was perceived as an opportunity to strengthen relationships with patients and to expand clinical follow-up activities within primary care.

> *And the patients want, the patients call, the patients give feedback, so my satisfaction is that the patient is actively searching, is looking to do the follow-up* [F2]

However, participants consistently reported that organizational routines, competing demands, and existing work processes limited their ability to engage more closely with clinical practice and to provide longitudinal follow-up. These contextual factors influenced how the intervention was incorporated into daily work and constrained the extent to which its potential could be fully realized within routine primary health care services.

Barriers to the Implementation and Feasibility

The main barriers to implementation were related to organizational and operational constraints within primary health care services. Limited time for clinical appointments, competing administrative demands, and the accumulation of professional responsibilities were consistently reported as challenges to expanding and sustaining patient follow-up.

The first consultation was described as particularly demanding due to the need for comprehensive data collection, especially in the absence of integration with the electronic medical record. Subsequent consultations were reported to be more agile once baseline information had been entered.

> *The first appointment is the worst of all of them, [...] Having to cite the clinical history is what makes it harder, right, checking this initial clinical history data, for me to have the right follow-up of this patient's INR range*. [F2]

> *There, when there is so much information, when you have a professional who is available for that, it is ok, but for a professional that doesn't have much time to input data into the system, it gets a little complicated*. [F5]

Participants highlighted the lack of protected time for pharmaceutical care and the absence of interoperability with existing electronic health records as factors limiting scalability and broader adoption.

> *I think we should have a time slot only for this…* [F4]

> *If your project's system were integrated to the PEC, it would have more adhesion…* [F7]

The absenteeism of some patients was pointed out as a challenge for the continuity of care.

> *Sometimes we call them and the person doesn't go, the same old issue that we have*. [F6]

Despite these challenges, participants described efforts to adapt workflows and strategies to meet patient needs and maintain the feasibility of the intervention within existing service constraints.

Discussion

Main Findings and Interpretation

This study describes the development, implementation, and formative evaluation of a clinical decision support system for warfarin management in primary health care, combined with professional training and continuous implementation support. Using the MRC framework for complex interventions [16,

28], the findings demonstrate that the proposed model is feasible and acceptable in real-world primary care settings, while also revealing contextual constraints that condition how its mechanisms are activated in practice.

The results indicate that the CDSS functioned as a structuring tool for clinical consultations, supporting the organization of clinical and pharmacotherapeutic information, standardizing data collection, and reducing uncertainty in anticoagulation management. When integrated into routine appointments, the system facilitated longitudinal follow-up and supported clinical reasoning, particularly in settings where structured anticoagulation care had previously been limited or absent.

From a program theory perspective, the observed effects were not attributable to the digital tool alone. Rather, they emerged from the interaction between technology, targeted professional capacitation, and ongoing support, highlighting that digital health interventions in primary care operate through combined technological and human mechanisms. This finding aligns with evidence suggesting that digital tools are more likely to qualify clinical practice when embedded within existing workflows and accompanied by capacity-building strategies [30,31].

Reorganization of Anticoagulation Care in Primary Health Care

Prior to implementation, systematic clinical follow-up of patients using oral anticoagulants was not structurally incorporated into routine pharmaceutical practice, despite medication availability. Participants' accounts revealed a gap between dispensing activities and longitudinal clinical involvement, reflecting organizational models centered on administrative tasks rather than structured clinical care.

The implementation of the CDSS combined with targeted training supported a reconfiguration of care processes, enabling pharmacists to assume a more active clinical role in anticoagulation management. By structuring consultations, guiding therapeutic decisions, and systematizing follow-up, the intervention facilitated a form of task shifting from predominantly physician-led anticoagulation management towards shared, team-based care within primary health care. This shift was not merely technological, but professional and organizational, strengthening pharmacists' clinical competencies and expanding their participation in chronic disease management [32]. The opportunity to integrate theoretical training directly into routine consultations promoted experiential learning and increased confidence in clinical decision-making.

The CDSS, combined with training, acted as a catalyst for reorganizing anticoagulation management by guiding consultations, systematizing follow-up, and strengthening clinical knowledge. This practical learning process, directly linked to real-life care situations, facilitated the progressive incorporation of structured anticoagulation care into everyday practice.

These findings are consistent with evidence from the literature indicating that digital interventions integrated into clinical practice, when accompanied by training, continuing education, and user support, can increase professionals' perceived confidence and sense of safety, support the development of competencies, and facilitate the progressive incorporation of more structured clinical practices [33-35]. They also align with broader evidence from low- and middle-income settings demonstrating that digital tools combined with capacity building can support task shifting strategies, improve continuity of care, and optimize workforce use in resource-constrained health systems [35].

Role of Context and Organizational Conditions

Consistent with the MRC framework [28], organizational conditions strongly influenced implementation outcomes. Although participants recognized the clinical value of systematic anticoagulation monitoring, competing demands, limited consultation time, and lack of protected clinical slots constrained sustained follow-up.

These findings highlight that digital innovations in primary care require alignment with service organization, workload distribution, and managerial support. The mere availability of technology is insufficient; institutional prioritization and integration into existing care processes are critical to feasibility and sustainability, as observed in other digital health implementation studies [30,36]. In this context, organizational management plays a structuring role in the feasibility and sustainability of digital interventions by influencing decisions regarding time allocation, prioritization of activities, and institutional support [36].

Human-System Interaction and Workflow Integration

Usability was facilitated by system features aligned with the demands of routine outpatient care, including structured presentation of clinical information and graphical visualization of INR values and time in therapeutic range. These elements reduced cognitive burden and supported clinical reasoning during consultations, contributing to positive user perceptions. The concise presentation of patient history, with rapid access to INR values over time, was identified as a key element contributing to a more efficient follow-up compared with other solutions previously used in the service.

These findings are in line with the literature, which indicates that systems that organize data in a clear, visual, and workflow-integrated manner tend to be perceived as more useful and acceptable by health care professionals, particularly in primary care settings, where time is limited and care demands are multiple [37].

However, the lack of integration with electronic health records increased workload during initial consultations, requiring manual reconstruction of patient histories. While subsequent visits became more efficient, this interoperability gap represents a structural challenge affecting both usability and sustainability.

Overall, user experience emerged as a dynamic process shaped by system design, organizational context, and professionals' adaptive strategies to integrate the CDSS into daily practice. Efforts to adjust routines and make system use feasible within service constraints suggest that CDSS adoption was associated not only with perceived ease of use, but also with local adaptive capacity to integrate the tool functionally into the care provided.

Barriers, Facilitators, and Implications for Sustainability

Several organizational and operational barriers influenced CDSS implementation in the primary care context. Limited time for clinical consultations, competing professional responsibilities, and the absence of integration with existing electronic health records constrained routine use, particularly during the first consultation, which required extensive data collection and manual reconstruction of patients' clinical histories. These demands were perceived as potential obstacles to sustained adoption in settings without protected clinical time or managerial support for workflow reorganization. Patient absenteeism further challenged the continuity of follow-up, reinforcing the influence of contextual factors beyond the digital tool itself.

An additional barrier related to the initial language used in the decision support messages. Participants reported that some recommendations employed overly technical terminology, which limited immediate comprehension and practical application during consultations. In response to this feedback, the messages were iteratively revised and adapted to clearer and more didactic language, improving usability and alignment with routine clinical practice. This process illustrates the importance of user-centered and iterative development approaches in digital health interventions, whereby continuous feedback informs progressive system refinement [38].

Conversely, several facilitators supported CDSS uptake. Perceived usability, structured presentation of clinical information, and the availability of visual tools contributed to positive user experiences after the initial adaptation period. Targeted training and ongoing implementation support were consistently identified as central to building confidence, reducing uncertainty, and enabling routine system use, particularly in a context where systematic anticoagulation management had not previously been embedded in primary care practice.

Taken together, these findings indicate that sustainability depends on the alignment between technical design, professional capacitation, and organizational conditions. Consistent with the digital health implementation literature, continued use and scalability are shaped less by standalone technological availability and more by workflow integration, institutional support, and adaptability to local practice contexts [35-37].

Implications for Scale-Up and Transferability

The findings suggest that scaling up the CDSS to other primary care settings would require attention to the same enabling conditions identified in this study, particularly protected time for clinical consultations, integration with existing health information systems, and sustained investment in professional training and implementation support. Rather than simply replicating the technological tool, successful scale-up would depend on alignment with local organizational structures, workflows, and care priorities. These results reinforce that the effectiveness and acceptability of digital health interventions are constructed through everyday practice and adaptive use over time, rather than being determined solely by initial technical design [28,39].

Intended Use, Safety Considerations, and Early-Stage Evaluation

The CDSS fulfilled its intended formative purpose by supporting clinical organization and decision-making in anticoagulation management. In line with the DECIDE-AI framework and WHO recommendations, evidence of feasibility, usability, and acceptability represents a critical foundation prior to evaluating clinical outcomes or large-scale impact [19,35].

Although the study was not designed to assess patient safety outcomes, internal validation of decision logic supported operational reliability. Verification of the coherence between the generated recommendations and the predefined decision tree follows good practices for early-stage evaluations of decision support systems. These practices emphasize the importance of ensuring logical consistency, predictability, and transparency of recommendations prior to broader clinical adoption [19]. However, this finding does not replace the need for more in-depth assessments of information security and clinical impact, which should be conducted in later phases of development and implementation.

Occasional system freezes were observed during the study period. However, these events did not result in data loss, as the system includes automatic data saving and backup mechanisms. In addition, all clinical decisions were independently verified by health care professionals, and patient care was not compromised during these interruptions.

The lack of electronic health record integration may increase documentation burden and potential for data inconsistencies, particularly in high-demand care settings [40], underscoring interoperability as a key requirement for future implementation phases [37]. Despite this limitation, participants perceived the CDSS as sufficiently useful to support clinical work in the studied context, even with the additional effort required for manual data entry.

Strengths and Limitations

Strengths include the mixed methods design, structured in sequential phases and guided by well-established frameworks for the development and evaluation of complex and digital interventions. The combination of formative

evaluation, internal validation, usability analysis, and qualitative investigation allowed for an in-depth understanding not only of the system's technical functioning but also of how it was perceived and incorporated into routine service practices in the studied context. This approach is particularly relevant for early-stage digital interventions, in which understanding processes, mechanisms, and context is as important as measuring clinical outcomes.

Another key strength was the participatory development of the CDSS, involving health care professionals and specialists from the early stages. This process contributed to the system's alignment with service needs, to the positive perceptions of usability, and to the acceptability observed following implementation.

Limitations include the focus on pharmacists' perspectives, not allowing inferences about how other members of the health care team might perceive or use the system. Although this choice is aligned with the focus of the implementation studied, it limits the understanding of the multiprofessional dynamics involved in anticoagulation management in primary care.

In addition, the study was carried out within a specific organizational context, which restricts the generalizability of the findings to other settings. The sample consisted of pharmacists involved in a structured clinical service, which may represent a group with higher motivation and familiarity with pharmacotherapeutic follow-up. This could have influenced the perceived usability and acceptability of the CDSS, potentially leading to more favorable evaluations. Therefore, the findings should be interpreted with caution, and future studies should include a more diverse group of users to enhance generalizability. Perceptions of usability, acceptability, and feasibility were strongly related to local conditions, including work organization, available infrastructure, and service routines in which the CDSS was implemented. Therefore, transferring these results to other contexts should take into account potential differences in care organization, information systems, and the availability of time and human resources.

The absence of interoperability with existing electronic health records represented a significant operational challenge affecting efficiency. These limitations reflect real-world constraints rather than flaws in the intervention model and highlight areas for adaptation and refinement, consistent with the MRC view of complex interventions as dynamic and evolving processes [28].

Future Directions

As a next step, we are developing an enhanced version of the software that extends its scope beyond anticoagulation monitoring to the broader management of patients with atrial fibrillation, in line with current guidelines [7]. This version will incorporate decision support for anticoagulation initiation, selection of the appropriate anticoagulant, and integrated management of relevant comorbidities.

In parallel, we plan to conduct implementation studies to evaluate the feasibility, usability, and clinical impact of the tool in real-world settings. These studies will assess its effects on adherence to guideline-recommended care, quality of anticoagulation control (including its impact on TTR), and patient outcomes across a broader population.

Building on the present pilot focused on clinical pharmacists, future studies should evaluate a fully integrated, multidisciplinary implementation involving physicians, nurses, and other health care providers.

Conclusion

This study demonstrates that the development and implementation of a web-based clinical decision support system for warfarin management in primary care is feasible and well accepted by health care professionals, even in resource-constrained settings. The CDSS showed good usability and supported the structuring of pharmaceutical consultations, clinical decision-making, and systematic follow-up of patients using warfarin, addressing previously identified gaps in routine anticoagulation care.

The findings highlight that the effectiveness of the CDSS was strongly dependent on professional training, which was essential both for the appropriate use of the system and for strengthening pharmacists' clinical competence in anticoagulation management. Beyond supporting technical decision-making, the intervention contributed to strengthening pharmacist-patient relationships and improving health education, expanding access to longitudinal follow-up in primary care.

Thus, the study provides evidence that CDSSs can enhance the safety and quality of warfarin management in primary care when aligned with professional capacitation and local service realities. Future efforts should prioritize system integration, workflow optimization, and supportive organizational conditions to maximize the impact and scalability of digital decision-support interventions in anticoagulation care.

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Data Availability

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: MSM (lead), ALPR (supporting)
Methodology: MSM (lead), ALPR (supporting), TBCS (supporting), LVRC (supporting)
Software: MSM (lead), ALPR (supporting), TQVS (supporting)
Investigation: MSM (lead), TBCS (supporting), LVRC (supporting)
Data curation: LVRC (lead), TBCS (supporting), LVRC (supporting)
Formal analysis: MSM (lead), LVRC (supporting), LCR (supporting)
Resources: ALPR (lead)
Writing–original draft: MSM (lead), TQVS (supporting), RBC (supporting), LVRC (supporting), LMP (supporting)
Writing–review & editing: All authors
Project administration: MSM (lead)

Conflicts of Interest

None declared.

Multimedia Appendix 1

Developmental and exploratory clinical investigations of decision support systems driven by AI reporting item checklist.
[PDF File (Adobe File), 261 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Semistructured interview guide.
[DOCX File (Microsoft Word File), 3406 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Coding framework derived from thematic content analysis, including main codes and subcodes identified from participants' narratives.
[XLSX File (Microsoft Excel File), 15 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Representation of the analytical categories developed from thematic content analysis, including the main interpretative axes resulting from the semantic and conceptual grouping of codes and subcodes.
[XLSX File (Microsoft Excel File), 63 KB-Multimedia Appendix 4]

Checklist 1

Completed mobile health Evidence Reporting and Assessment checklist.
[DOCX File (Microsoft Word File), 43 KB-Checklist 1]

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Abbreviations

CDSS: clinical decision support system
DECIDE-AI: developmental and exploratory clinical investigations of decision support systems driven by AI
DOAC: direct oral anticoagulant
IMPLANFAR SUS: Implementação do Cuidado Farmacêutico no Sistema Único de Saúde
INR: international normalized ratio
mERA: mobile health Evidence Reporting and Assessment
MRC: Medical Research Council
SUS: Brazilian Unified Health System

TTR: time in therapeutic range
VTE: venous thromboembolism
WHO: World Health Organization

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