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Developing and Validating a Stakeholder-Informed Requirements Framework for a Thrombosis and Anticoagulation Clinical Decision Support System

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ABSTRACT

Aims This study aimed to derive and validate a stakeholder-informed set of requirements for a clinical decision support system designed to support thrombosis and anticoagulant management.
Instrument & Methods This sequential mixed-methods study identified, operationalized, and quantitatively evaluated stakeholder-informed requirements for a thrombosis and anticoagulation clinical decision support system through a targeted literature review, semi-structured interviews, iterative questionnaire development, content validation, and quantitative analysis. Seven experts participated in the qualitative phase, and 35 cardiologists and clinical pharmacists completed the final 48-item questionnaire. Content validity was assessed using the content validity ratio and item-level content validity index; internal consistency was assessed using Cronbach's alpha; and group and age-related differences were assessed using nonparametric tests.
Findings The literature review included 55 studies and indicated that existing clinical decision support systems commonly address venous thromboembolism risk assessment, thromboprophylaxis, anticoagulant prescribing, or atrial fibrillation-related management. Interviews identified six requirement domains and 42 subthemes. All retained items had a content validity ratio of 1.00, and the overall mean item-level content validity index was 0.996. Domain-level mean scores ranged from 4.42 to 4.67 on a five-point scale, and the overall Cronbach's alpha was 0.973. No significant differences were found between cardiologists and clinical pharmacists. Age was positively associated with the Clinical Information Requirements domain (ρ=0.372, p=0.033).
Conclusion The 48-item, six-domain framework provides a stakeholder-informed, content-valid basis for specifying and evaluating thrombosis-focused clinical decision support systems that support individualized anticoagulation decisions while preserving clinician oversight.

Keywords Thrombosis; Anticoagulants; Decision Support Systems, Clinical; Surveys and Questionnaires; Medical Informatics

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[1] 2019 ESC guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS): The Task Force for the diagnosis and management ... [2] Antithrombotic therapy for VTE disease: Second update of the ... [3] Thrombosis: A ... [4] Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with ... [5] 2021 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral ... [6] American Society of Hematology 2020 Guidelines for management of venous thromboembolism: Treatment of ... [7] An overview of clinical decision support systems ... [8] Optimizing clinical decision support system functionality by leveraging specific human-computer interaction ... [9] Designing Clinical Decision Support Systems (CDSS)-A user-centered lens of the design ... [10] Explainability for artificial ... [11] Impact of a clinical decision-support tool on venous thromboembolism ... [12] Computerized clinical decision support to improve stroke prevention therapy in primary care management of ... [13] Universal EHRs clinical decision support for thromboprophylaxis in ... [14] Does involving clinicians in decision support development facilitate system ... [15] Perceived usefulness, perceived ease of use ... [16] Task-technology ... [17] Designing ... [18] Sample sizes for saturation in qualitative research ... [19] Thematic ... [20] Toward good practice in thematic analysis: Avoiding common ... [21] A quantitative ... [22] The content validity index: Are you sure you know ... [23] ABC of content ... [24] Design and evaluation of ACAFiB-APP, a clinical decision support system for anticoagulant ... [25] General practitioners' needs and wishes for clinical decision ... [26] Coefficient alpha ... [27] An analysis of... [28] Task-oriented evaluation of electronic medical records systems: Development and ... [29] A clinical decision support tool for improving venous thromboembolism risk assessment and thromboprophylaxis prescribing compliance within an electronic medication ... [30] Using technology acceptance model to explore physicians' perspectives ...

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Introduction

Thrombotic disease creates a substantial clinical burden, while anticoagulant therapy introduces a second layer of risk because treatment decisions must balance thrombosis prevention against bleeding risk. Venous thromboembolism (VTE), including deep vein thrombosis and pulmonary embolism, is a major component of this burden, and anticoagulants are also central to managing atrial fibrillation and other thromboembolic conditions [1-5].

Anticoagulation decisions are rarely determined by a single clinical parameter. Dose selection and treatment duration may depend on renal and hepatic function, age, interacting medications, pregnancy, bleeding risk, thrombophilia, platelet count, procedural plans, and the indication for therapy. Consequently, clinicians must combine patient-specific information with recommendations that are periodically revised [2, 5, 6].

Clinical decision support systems (CDSSs) are designed to make such information actionable at the point of care. Conventional systems can provide reminders, alerts, risk calculations, prescribing support, and guideline-linked recommendations, while newer approaches incorporate artificial intelligence and machine learning [7-10]. Evidence from thrombosis-related applications suggests benefits in areas such as VTE risk assessment, prophylaxis, and medication management; however, many systems remain limited to a particular decision or patient group [11-13].

User requirements are therefore a central design issue rather than a secondary usability consideration. A technically accurate recommendation can have limited clinical value if required data are unavailable, the system interrupts workflow, explanations are inadequate, or clinicians do not trust the output. The technology acceptance model (TAM) emphasizes perceived usefulness and ease of use, whereas Task–Technology Fit focuses on the match between system capabilities and clinical tasks. User-centered CDSS research likewise supports involving clinicians in development and implementation [9, 14-16].

Despite substantial research on thrombosis-related CDSSs, limited guidance is available on the functions, information, workflow characteristics, usability, and trust requirements to consider when developing a comprehensive thrombosis-focused system. This study aimed to address this gap by integrating evidence from the literature with stakeholder interviews to develop and quantitatively validate a stakeholder-informed requirements framework for a CDSS supporting thrombosis and anticoagulant management. Specifically, we assessed the content validity and internal consistency of the questionnaire, clinicians' ratings of the importance of the requirement domains, differences in these ratings between cardiologists and clinical pharmacists and across levels of professional experience, and the association between age and domain scores

Instrument and Methods

This sequential mixed-methods study was designed to identify, operationalize, and quantitatively evaluate stakeholder-informed requirements for a CDSS for thrombosis and anticoagulation management. It included a literature review, stakeholder interviews and qualitative analysis, questionnaire development, expert review and content validation, and quantitative assessment of the perceived importance and internal consistency of the identified requirements [17].

Interview participants provided verbal informed consent. Participation in the quantitative questionnaire was anonymous and voluntary.

A targeted literature review was conducted to identify existing CDSS applications for thrombosis and anticoagulation management, as well as recurring functions, requirements, and limitations relevant to questionnaire development. Searches were conducted in PubMed, Scopus, Web of Science, and Embase for studies published between January 2020 and March 2026. The search strategy incorporated terms related to clinical decision support systems, computerized provider order entry, artificial intelligence, thrombosis, VTE, deep vein thrombosis, pulmonary embolism, anticoagulants, direct oral anticoagulants, dosing, and drug interactions.

A total of 784 records were identified. After deduplication and screening, 55 studies were retained for evidence mapping. The review examined reported CDSS capabilities, application domains, outcomes, advantages, and limitations relevant to thrombosis and anticoagulation management. Rather than serving as a standalone systematic-review outcome, the findings informed the development of the questionnaire (Table 1).

Stakeholder interviews were conducted to elicit user-informed requirements for a thrombosis and anticoagulation CDSS. Purposive sampling was used to recruit seven participants with relevant clinical or technical expertise: two cardiologists, three clinical pharmacists, and two bioinformatics experts [18]. Interviews were conducted using a semi-structured interview guide developed based on the literature findings and informed by the TAM and task-technology fit (TTF) frameworks [15, 16]. TAM and TTF informed the areas explored during the interviews, particularly those related to perceived usefulness, ease of use, acceptance, and the fit between clinical tasks and technology [15, 16]. However, the final requirement domains and subthemes were not predetermined by these frameworks. Instead, they were derived from the empirical interview data.

Table 1. Evidence-mapping summary of the literature review

Parameter	Summary of findings relevant to questionnaire development
Main clinical applications	Venous thromboembolism (VTE) risk assessment; thromboprophylaxis; anticoagulant prescribing; and anticoagulation management for atrial fibrillation
Technology approaches	Rule-based systems; tools integrated with electronic health records (EHRs); clinical alerts; risk calculators; and systems supported by artificial intelligence or machine learning
Recurring limitations	Narrow application scope; limited support for complex cases; gaps in handling drug interactions and special populations; alert fatigue; and limited explainability or validation
Workflow issues	Fit with clinical workflows; usability; response time; alert burden; and clinician acceptance
Underrepresented needs	Pregnancy-associated thrombosis; thrombophilia; thrombocytopenia; unusual-site thrombosis; and peri-procedural anticoagulation management
Design gap	Need for a comprehensive, stakeholder-informed specification addressing clinical, information, workflow, usability, and trust-related requirements

The interview data were analyzed using thematic analysis [19, 20]. Coding focused on participants' perspectives regarding CDSS functions, clinical and informational requirements, workflow integration, usefulness, usability, acceptance, and trust.

Two researchers independently coded the interview data, and a third researcher reviewed and synthesized the coding outputs. The analysis produced six overarching domains comprising 42 subthemes. TAM and TTF informed the interview guide but were not used as predefined coding categories.

Questionnaire items were developed by integrating requirements and concepts from stakeholder interviews with relevant requirements, gaps, and limitations identified in the literature [24, 25]. The qualitative findings provided the primary structure, while literature-derived requirements were added where they identified further clinically or technologically relevant needs. An item-level traceability matrix linked each questionnaire item to its underlying qualitative theme or subtheme, relevant literature-derived requirements, or both. This process produced an initial pool of 50 items, which was reviewed by five experts—two cardiologists and three clinical pharmacists—for relevance, appropriateness, overlap, wording, and clarity.

The reported domain-level results were as follows: clinical functional requirements (15 items; Cronbach's α=0.956; mean=4.53±0.55), clinical information requirements (6; α=0.944; mean=4.63±0.46), technology and workflow fit (11; α=0.879; mean=4.63±0.37), perceived usefulness (6; α=0.903; mean=4.42±0.61), ease of use, attitude, and behavioral intention (6; α=0.894; mean=4.43±0.56), and trust in CDSS (4; α=0.814; mean=4.67± 0.39). Illustrative requirements included guideline updates and dose adjustment for renal or hepatic impairment; drug, laboratory, patient-specific, and interaction information; system stability and clear recommendations; practical, evidence-based support; ease of interaction; and transparency and scientific references.

Following the expert review, two overlapping items were removed, resulting in a 48-item questionnaire. Content validity was subsequently assessed using the content validity ratio (CVR) and item-level content validity index (I-CVI) [21-23]. For the five experts, a CVR threshold of 0.99 was used as the retention criterion, while an I-CVI greater than 0.78 was considered acceptable [21-23].

All 48 retained items demonstrated a CVR of 1.00, while I-CVI values ranged from 0.93 to 1.00. The final questionnaire therefore comprised 48 items distributed across the six empirically derived requirement domains.

The final 48-item questionnaire was administered electronically using Google Forms to assess clinicians' perceptions of the importance of the identified CDSS requirements. Eligible participants were cardiologists and clinical pharmacists with at least one year of professional experience and direct involvement in thrombosis- or anticoagulation-related clinical decision-making.

Each item was rated on a five-point Likert scale. The quantitative phase assessed the perceived importance of the identified requirement domains and examined whether domain-level ratings differed by professional group or level of professional experience. The association between participant age and domain-level ratings was also examined.

Internal consistency reliability was assessed using Cronbach's alpha for each requirement domain and for the questionnaire as a whole [26].

Statistical analyses were performed using SPSS 27. The distribution of the quantitative data was assessed using the Shapiro-Wilk test [27]. Because the data did not meet the assumptions for parametric analysis, nonparametric statistical tests were used.

The Mann-Whitney U test was used to compare domain-level ratings between cardiologists and clinical pharmacists. The Kruskal-Wallis test was used to examine differences across professional experience groups. Spearman's rank correlation was used to assess associations between participant age and domain-level ratings.

Findings

The literature search yielded 784 records, of which 55 met the study criteria after duplicate and relevance screening. The reviewed systems most often addressed VTE risk assessment, thromboprophylaxis, anticoagulant prescribing, or atrial-fibrillation-related anticoagulation. Recurrent limitations included a narrow clinical scope,

insufficient support for complex anticoagulation decisions, incomplete handling of drug interactions and special populations, alert burden, limited explainability, and inadequate prospective validation.

Seven interviews produced six overarching domains and 42 subthemes. Clinical functional requirements represented the largest theme, with 15 subthemes, followed by technology and workflow fit, with 11. The final questionnaire contained 48 items. All retained items had a CVR of 1.00, while I-CVI values ranged from 0.93 to 1.00, and the overall mean I-CVI was 0.996.

Internal consistency was high across all domains. Cronbach's alpha ranged from 0.814 for Trust in CDSS to 0.956 for clinical functional requirements; the coefficient for the complete 48-item instrument was 0.973. Domain scores were also consistently high, with mean values between 4.42 and 4.67. The most highly rated individual requirements concerned guideline updating, system stability,avoidance of workflow delays, renal and hepatic dose adjustment, and drug-interaction management.

Thirty-five healthcare professionals completed the questionnaire: 19 clinical pharmacists (54.3%) and 16 cardiologists (45.7%). Nineteen participants were women and 16 were men. The mean age was 34.00 ± 5.92 years. Most participants had 1–5 years of professional experience (n=23), and 10 reported previous experience with a CDSS.

Mann–Whitney U tests found no statistically significant differences between clinical pharmacists and cardiologists across the six domains: clinical functional requirements (U=171.0, p=0.533), clinical information requirements (U=159.0, p=0.816), technology and workflow fit (U=182.5, p=0.312), perceived usefulness (U=144.0, p=0.797), ease of use, attitude, and behavioral intention (U=158.5, p=0.839), and trust in CDSS (U=144.0, p=0.791). Effect sizes were negligible to small (r=0.036–0.171). There was also no significant difference across the four experience groups (H=1.162, p=0.762). Age was positively associated with clinical information requirements (ρ=0.372, p=0.033); associations between age and the other domains were not statistically significant (ρ=0.105–0.245, p=0.169–0.560).

Discussion

This study aimed to derive and validate a stakeholder-informed set of requirements for a CDSS designed to support thrombosis and anticoagulant management. The principal result was a validated requirements framework that combines clinical functionality with information availability, workflow fit, usefulness, usability, and trust. Rather than treating thrombosis CDSS design as a problem of algorithm selection alone, clinicians expect a system to support a broad range of anticoagulation decisions while remaining compatible with routine clinical work.

Existing thrombosis-related CDSSs frequently address discrete tasks, such as VTE risk assessment, prophylaxis, prescribing, or atrial-fibrillation management [11–13, 28, 29]. Such systems can improve selected process measures, but the reviewed evidence also revealed gaps in support for complex and less common clinical situations. The stakeholder findings extend this observation by identifying specific functions clinicians would expect from a broader system, including individualized dose adjustment, drug-interaction assessment, bleeding management, pregnancy-related decisions, thrombophilia, thrombocytopenia, and peri-procedural anticoagulation.

Clinical functionality was the largest qualitative domain, with 15 subthemes. This pattern is consistent with the nature of anticoagulant prescribing, in which the same medication may require different decisions depending on the indication, organ function, interacting therapies, and patient characteristics. The high ratings for renal and hepatic dose adjustment and interaction management therefore reinforce the need for patient-specific rather than generic recommendations. These requirements also provide a practical specification for subsequent rule-engine or knowledge-based development.

Trust was the highest-rated quantitative domain. Participants particularly valued guideline-based recommendations, scientific references, transparency, and the retention of clinician judgment. This result is relevant to both conventional and AI-enabled CDSSs. Explainability and accountability have been identified as important issues in clinical AI, particularly when recommendations may influence clinical decision-making [10]. Thus, a thrombosis CDSS should make the evidentiary basis of its recommendations visible and function as an aid to professional judgment rather than as an autonomous decision-maker.

Technology and workflow fit also received a high score. System stability, the absence of workflow delays, and the clarity of recommendations were among the highest-rated individual requirements. This is consistent with evidence that CDSS effectiveness can be undermined when alerts disrupt clinical work or when system design does not adequately meet users' needs [7-9, 30]. For thrombosis care, the practical implication is that integration with the electronic health record, rapid retrieval of relevant clinical parametera, and concise presentation of recommendations should be treated as core functional requirements.

The absence of significant differences between cardiologists and clinical pharmacists suggests substantial agreement between the two professional groups represented in this study. This convergence

is useful for initial requirements engineering because it indicates that the identified domains are not restricted to a single professional perspective. Nevertheless, the sample was small and purposively selected; therefore, the results should be interpreted as stakeholder evidence for specification rather than as population estimates. In addition, the study was conducted within a single national healthcare context. Differences in clinical workflows, healthcare organization, prescribing practices, and digital maturity across countries may influence the applicability of the identified requirements in other settings.

The positive association between age and clinical information requirements was statistically significant, although weak. Older participants tended to place greater importance on information-related support. Because several associations were tested and the sample was limited, this result should be considered exploratory. It may indicate that information integration becomes particularly salient when clinicians manage more complex cases, but this interpretation requires confirmation in larger samples.

The high alpha coefficients demonstrated strong internal consistency, but the overall value of 0.973 should not be interpreted as proof of construct validity. Very high internal consistency can also occur when items overlap conceptually. This study established content validity and internal consistency, but it did not test the factor structure. Future studies should therefore examine the instrument's dimensionality using exploratory and confirmatory factor analyses in larger, more diverse samples.

Taken together, the findings support a user-centered specification strategy for thrombosis CDSS development. A subsequent system should incorporate continuously maintained clinical knowledge, patient-specific data, transparent recommendations, workflow-compatible interactions, and mechanisms for clinician oversight. These requirements can also serve as measurable criteria for evaluating the usability and clinical performance of a future prototype.

The combined quantitative and qualitative results can be translated into a practical specification for a future thrombosis CDSS. First, the clinical layer should accommodate more than prophylaxis or risk scoring. The requirement set indicates a need for decision support that can move from identifying the indication to selecting an anticoagulant, adjusting the dose for the patient, assessing interactions, considering bleeding-related factors, and managing special populations. This broader scope is important because anticoagulation decisions often involve several linked judgments rather than a single prescribing action.

Second, the information layer should make relevant patient data readily available. The Clinical Information Requirements domain received a mean score of 4.63 ± 0.46, and age was significantly associated with this domain. The findings therefore support integrating laboratory results, renal and hepatic function, relevant risk scores, medication lists, and other clinical parameters into the decision-making process. Such integration could reduce the need to search for information across multiple sources, provided that the displayed information remains concise and clinically relevant.

Third, the knowledge layer should support guideline maintenance. The highest-rated individual requirement was the ability to update guidelines. This result is particularly relevant to anticoagulation because recommendations and evidence can change over time. A maintainable knowledge base should therefore allow recommendations to be updated while preserving traceability to the supporting evidence. The related emphasis on scientific references and transparency indicates that clinicians should be able to identify the basis for an important recommendation rather than receive an unexplained output.

Finally, the interaction layer should be designed around the workflow. System stability, the absence of workflow delays, and recommendation clarity were among the most highly rated requirements. These findings suggest that a future prototype should be evaluated not only for technical accuracy but also for response time, information presentation, navigation, alert burden, and compatibility with existing clinical processes. These characteristics should be treated as measurable design requirements during prototype testing rather than as subjective preferences assessed only after implementation.

The study also provides a methodological contribution by linking three sources of evidence during requirements engineering. The literature review established what had already been implemented and where limitations remained; interviews captured requirements that may not be apparent from published system descriptions; and the questionnaire quantified the perceived importance of the resulting domains. The traceability process further connected individual questionnaire items to gaps in the literature or requirements derived from stakeholders. This sequence reduces the risk that the final instrument represents only the researchers' assumptions about what a thrombosis CDSS should contain.

The use of both CVR and I-CVI provided complementary evidence for content validity. CVR addressed whether an item was considered necessary, whereas I-CVI assessed item relevance. The unanimous CVR of 1.00 and overall I-CVI of 0.996 indicate strong agreement among the five content experts. At the same time, these indices should be interpreted in light of the small expert panel. Very high agreement in a small group can

demonstrate strong content agreement without establishing that the questionnaire has the same structure in a larger population.

The reliability findings should similarly be interpreted with appropriate caution. All six domains exceeded the conventional threshold for internal consistency, but the overall alpha of 0.973 is very high. A high alpha can reflect coherent measurement, but it can also arise when multiple items capture closely related aspects of the same construct. The present study therefore supports reliability for the current application but does not justify removing or retaining individual items solely on the basis of alpha. Item-level analysis and factor-analytic testing in a larger sample would be appropriate next steps.

The nonparametric analysis was selected to match the distributional characteristics of the data and the small sample size. The absence of statistically significant differences among professional groups should not be interpreted as evidence that the groups are identical; rather, the observed data did not demonstrate a statistically detectable difference. Likewise, the significant age association was modest and should be regarded as an exploratory finding. A larger, multicenter validation study involving clinicians from diverse geographic regions and practice settings could provide more precise estimates and assess the reproducibility and generalizability of the framework across different healthcare contexts. Such studies could also examine the influence of professional role, clinical experience, practice setting, and prior exposure to CDSSs simultaneously.

Conclusion

The 48-item, six-domain framework provides a stakeholder-informed, content-valid basis for specifying and evaluating thrombosis-focused CDSSs that support individualized anticoagulation decisions while preserving clinician oversight.

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