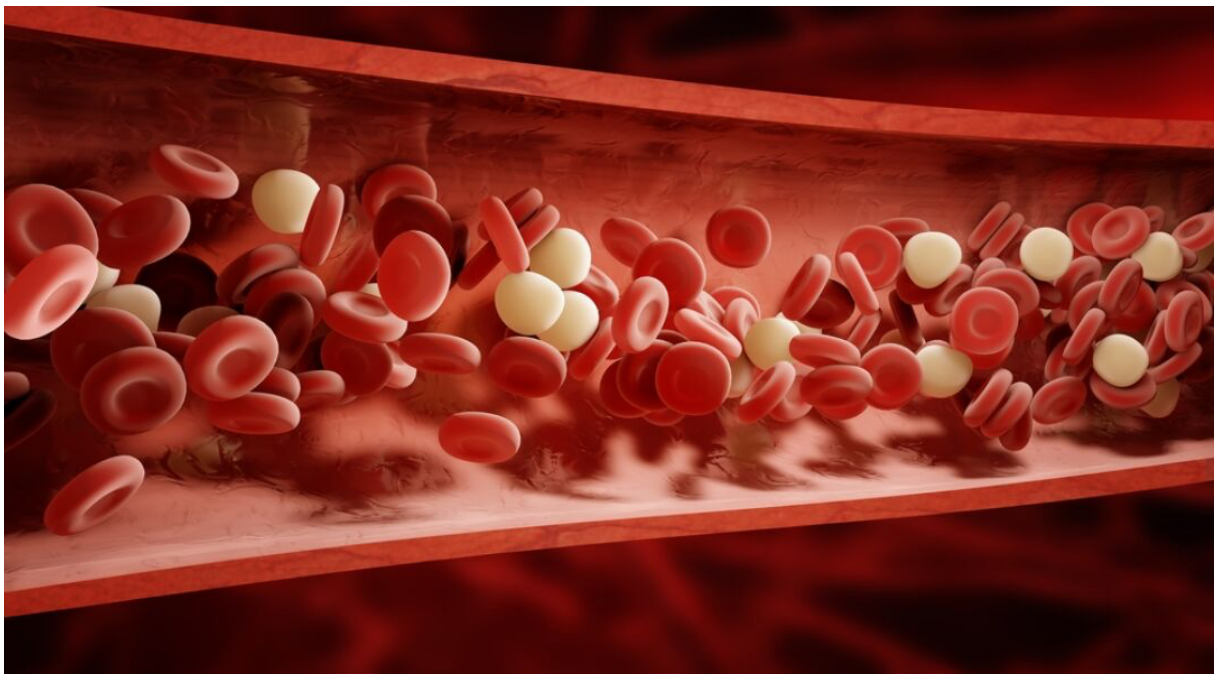
University of Applied Sciences and Arts Northwestern Switzerland
School of Life Sciences

CDSS: AFib DOAC Navigator

 [1]

Team: Andreas Braun Ponce De Leon, Justin Jouwena, Ramon Winkler

Module: Clinical Decision Support Systems

Date: 14.08.2025

[1] Image: https://www.nps.org.au/professionals/anticoagulants

Table of Contents

1. L1: Anticoagulation clinical guideline ... 3

1.1 Problem Statement ... 3

1.2 Target audience ... 3

1.3 Target patient population ... 4

1.4 User scenario ... 5

1.4.1 Scenario 1 ... 5

1.4.2 Scenario 2 ... 6

1.5 Rationale for the CDSS ... 7

2 L2: 'Human Readable' Algorithm ... 9

2.1 Clinical Workflow ... 9

2.2 Data Dictionary ... 10

2.2.1 ... **Error! Bookmark not defined.**

2.3 Decision Logic ... 14

2.3.1 Patient Information & Initial Checks ... 14

2.3.2 Indication Assessment Logic ... 14

2.3.3 Contraindication Assessment Logic ... 15

2.3.4 Drug-Drug Interaction Assessment Logic ... 15

2.3.5 Final Recommendation Logic ... 16

2.4 Challenges in L1 to L2 Translation ... 16

3 L3: Machine-Readable Code ... 18

4 L4: Executable Layer ... 19

5 Quality Assurance and Testing Strategy ... 20

5.1 Logic Testing Approach ... 21

5.1.1 Bugs and Issues ... 21

6 Implementation Plan ... 22

6.1 Delivery ... 22

6.2 User Training ... 22

6.3 Maintenance and Monitoring ... 22

6.3.1 Maintenance ... 22

6.3.2 Monitoring and Evaluation ... 22

7 Expected Impact ... 24

7.1 Benefits ... 24

7.2 Challenges ... 24

8 Vision ... 24

1. L1: Anticoagulation clinical guideline

1.1 Problem Statement

Atrial fibrillation (AF) is a common cardiac arrhythmia associated with a significantly increased risk of stroke, heart failure, and premature death. Its prevalence increases with age, affecting approximately 1–2% of the general population and up to 10% of those over 80 years old. The mainstay of stroke prevention in AF is anticoagulant therapy.

Direct Oral Anticoagulants (DOACs), including Rivaroxaban (Xarelto®), Apixaban (Eliquis®), Edoxaban (Lixiana®), and Dabigatran (Pradaxa®), have largely replaced vitamin K antagonists, like Marcoumar, in many indications because of fixed dosing, fewer food and drug interactions, no need for routine INR monitoring, and faster onset and offset. They are also used for venous thromboembolism treatment and prevention.

However, safe and effective prescribing of DOACs is not straightforward. Dose adjustments depend on renal function (eGFR), age, body weight, and co-medications such as strong P-gp or CYP3A4 inhibitors or inducers. Inappropriate prescribing can lead to catastrophic bleeding events or inadequate stroke prevention.

In clinical practice, these decisions are often made by residents from various specialties such as internal medicine, and emergency medicine, who may not be fully familiar with the latest guidelines or contraindications. Diagnosis of AF and consideration for anticoagulation can happen in diverse healthcare settings, from outpatient clinics to emergency departments, often under significant time pressure.

The result is a high cognitive load, unnecessary delays, and frequent ad-hoc research for what should be a streamlined, evidence-based decision: *Does patient X need anticoagulation, and if so, which DOAC and at what dose?*

A Clinical Decision Support System (CDSS) for DOAC therapy addresses this need by integrating multiple decision points, including patient-specific risk factors, contraindications, and drug interactions, into a single, rapid, guideline-based recommendation. This reduces clinician workload, supports adherence to best practices, and ultimately improves patient safety and outcomes.

The CDSS logic is based on the Direct Oral Anticoagulants (DOAC) comparison table of the Cantonal Hospital of Aarau (KSA) and is aligned with their latest institutional guidelines for anticoagulant therapy in atrial fibrillation.[2]

1.2 Target audience

This Clinical Decision Support System (CDSS) is specifically designed for healthcare providers at the Cantonal Hospital of Aarau (KSA) who are involved in the initiation, adjustment, and monitoring of Direct Oral Anticoagulant (DOAC) therapy for patients with atrial fibrillation. It supports a broad range of clinical roles including junior residents, emergency physicians, internal medicine specialists, and nursing staff who operate in settings where anticoagulation decisions must be made quickly and in alignment with institutional guidelines. By integrating KSA's latest DOAC recommendations into a single, structured

[2] *DOAC selection table, Cantonal Hospital Aarau, KD 023.035, Version 05 (valid 12.05.2023)*

decision-making tool, the CDSS addresses the unique workflow challenges, time constraints, and safety considerations faced by the hospital's multidisciplinary care teams.

Table 1 Target audience

User Group	Role in Care Pathway	Key Challenges	CDSS Support Provided
Junior Residents	Initial assessment and prescribing decisions for patients with atrial fibrillation	Limited familiarity with latest DOAC guidelines; time pressure; uncertainty with contraindications/dosing	Indication and contraindication checks, dosing recommendations, and monitoring guidance
Emergency Physicians	Rapid triage and initiation of anticoagulation therapy in acute settings	Need quick decision-making; high cognitive load	Fast, structured decision flow; default safety checks for high-risk patients
Internal Medicine Specialists	Ongoing management and follow-up of anticoagulated patients	Variability in prescribing habits; complex polypharmacy and comorbidities	Integrated guideline-based dosing adjustments and drug interaction alerts
Nurses	Assess indication and contraindications based on EMR data and present structured decision to the clinician	Lack of quick reference onNeed quick, reliable tools to consolidate EMR information into a decision-ready output DOAC monitoring parameters and patient counselling points	CDSS processes entered data to produce a recommendation with decision logic, enabling nurses to reduce physician workload

1.3 Target patient population

The CDSS is intended for the primary assessment of patients with newly diagnosed atrial fibrillation (AF), focusing on those where a CHA_2DS_2-VASc score is appropriate to guide anticoagulation indication.

The tool supports the initial decision stage prior to dosing selection or detailed bleeding risk assessment.

Included:

- Adults with newly diagnosed AF.
- Patients for whom CHA_2DS_2-VASc scoring is clinically relevant and applicable.

Excluded:

- Patients with AF and a mechanical heart valve.
- Patients with moderate to severe mitral stenosis.
- Patients already on established anticoagulation without a need for reassessment of indication.

- Patients requiring anticoagulation for other primary indications independent of AF (e.g., recent venous thromboembolism).

By defining the scope in this way, the CDSS is applied only in clinical scenarios where it can meaningfully support guideline-based initiation of anticoagulation therapy.

1.4 User scenarios

1.4.1 Scenario 1

A 72-year-old male patient presents to the emergency department with palpitations, shortness of breath, and mild dizziness that began earlier in the day. An ECG confirms paroxysmal atrial fibrillation. His medical history includes hypertension, type 2 diabetes mellitus, and stage 3 chronic kidney disease. Current medications include metformin, amlodipine, and simvastatin. The patient's weight is approximately 65kg.

Laboratory results show:

- Creatinine: **159 µmol/L**
- eGFR: **42 mL/min/1.73 m²**
- INR: **1.0**

The attending physician is a second-year emergency medicine resident. Although familiar with atrial fibrillation management, he is not yet fully confident in making anticoagulation decisions independently and prefers to review guideline-based recommendations before finalising the treatment plan.

He logs into the Clinical Decision Support System (CDSS), enters the patient's demographic data, laboratory values, comorbidities, and current medications. The CDSS processes the information, applies guideline-based logic, and provides:

- CHA_2DS_2-VASc score with calculated stroke risk: 3 points
- Assessment of potential contraindications to DOAC therapy: None
- Recommended DOAC options with appropriate dose adjustments based on renal function and comorbidities
- Relevant warnings regarding possible drug interactions

With this structured, evidence-based recommendation, the resident is able to prepare a complete management proposal and review it with his supervisor before discharging the patient. This ensures the decision is both guideline-concordant and patient-specific, while reducing unnecessary delays in care.

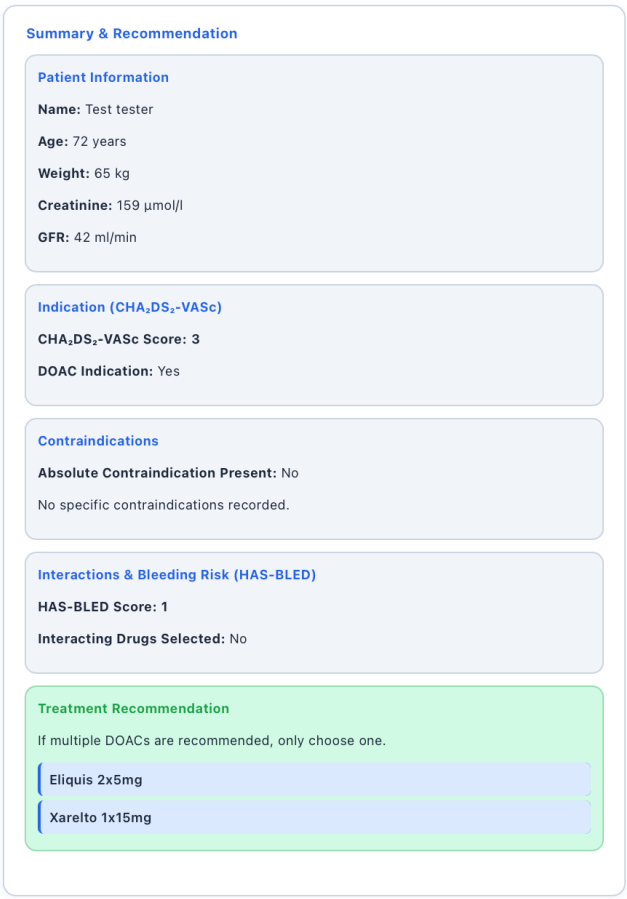


Figure 1 Recommendation Scenario 1

1.4.2 Scenario 2

A 79-year-old female patient presents to the emergency department with new-onset palpitations, fatigue, and mild chest discomfort. An ECG confirms **paroxysmal atrial fibrillation**. Her medical history includes hypertension, prior ischemic stroke, and moderate chronic kidney disease. She is currently taking lisinopril, atorvastatin, and low-dose aspirin. Her weight is 50 kg.

Laboratory results show:

- Creatinine: **185 µmol/L**
- eGFR: **26 mL/min/1.73 m²**
- INR: **1.0**

Her **CHA_2DS_2-VASc score** is calculated at 6, indicating a high annual stroke risk.

The attending physician, a first-year emergency medicine resident, wants to ensure the anticoagulation decision is appropriate given the patient's renal function. She logs into the Clinical Decision Support System (CDSS) and inputs the patient's demographics, comorbidities, laboratory values, and medication list.

The CDSS processes the data and outputs:

- Stroke risk assessment (CHA_2DS_2-VASc score: 6)
- Detection of significant renal impairment (eGFR 26 mL/min/1.73 m^2)
- Warning that DOAC use is restricted or contraindicated at this level of kidney function
- Recommendation:
    - Eliquis 2 x 5 mg
    - Xarelto 1x10mg after hematology consultation.

Armed with this information, the resident promptly prepares the case details and discusses them with her supervisor **before discharging the patient**, ensuring that a specialist consultation is arranged without delay.

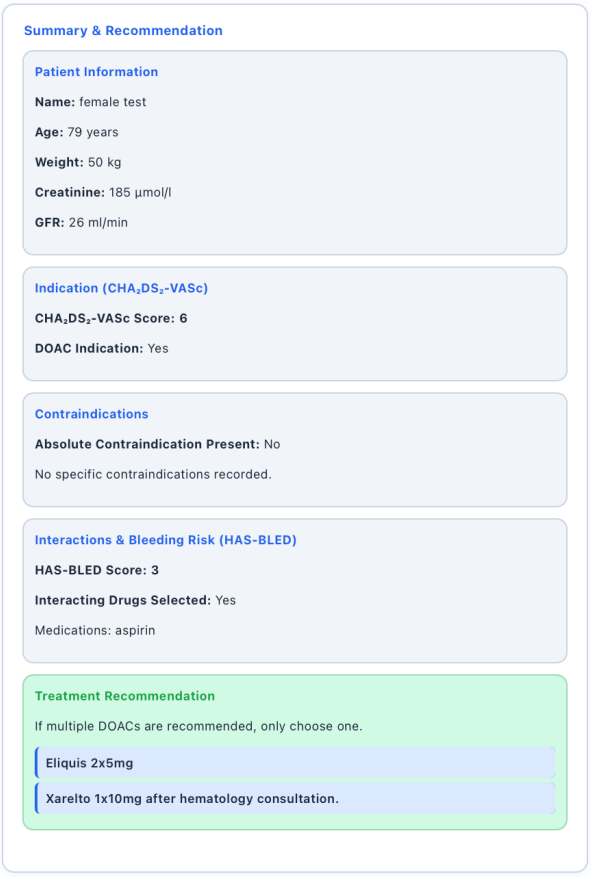


Figure 2 Recommendation Scenario 2

1.5 Rationale for the CDSS

Prescribing DOACs requires careful consideration of multiple patient-specific factors such as age, kidney function, body weight, drug interactions, and clinical indication. In busy clinical settings, these decisions are often made under time pressure, sometimes by residents or physicians from various specialties who may not be fully familiar with the latest guidelines or contraindications.

This CDSS has been developed to make the prescribing process safer, faster, and more consistent. By integrating guideline-based recommendations into a single, easy-to-use tool, it

helps clinicians quickly determine whether a patient is eligible for DOAC therapy and, if so, which medication and dosage is most appropriate.

The system aims to reduce prescription errors, improve consistency across departments, and increase clinician confidence. It also supports patient safety by highlighting contraindications, recommending appropriate dosing, and providing clear explanations for each decision. Ultimately, it reduces time spent cross-referencing guidance and allows clinicians to focus on patient care.

2 L2: 'Human Readable' Algorithm

2.1 Clinical Workflow

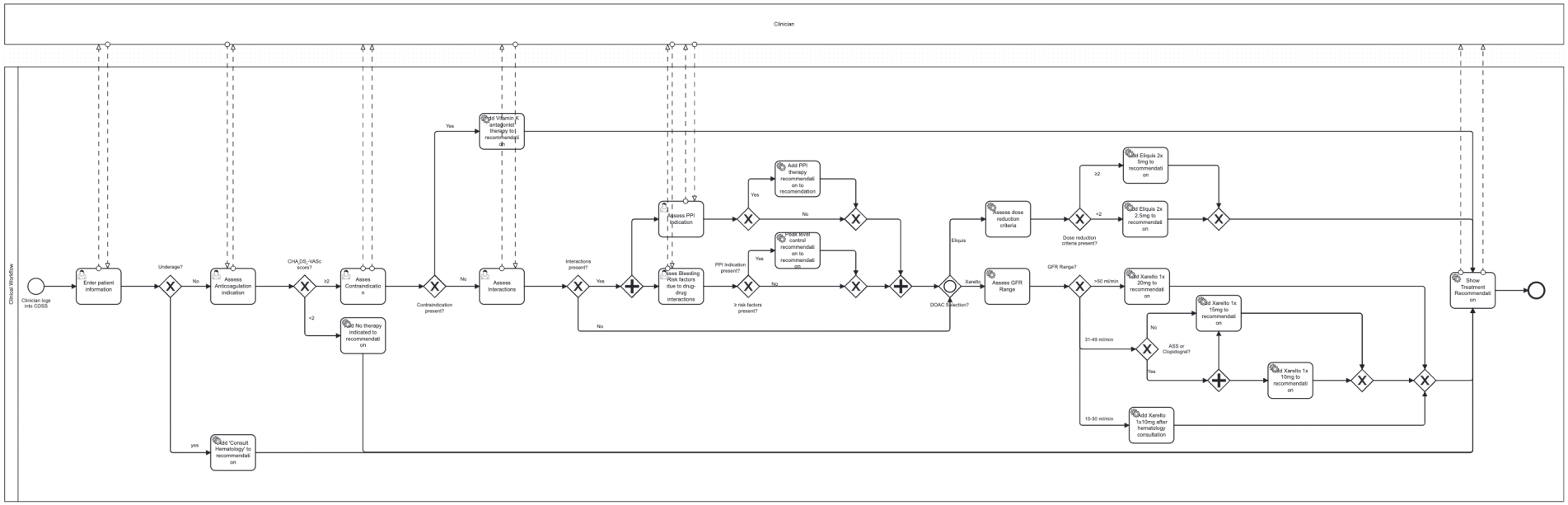


Figure 3 BPMN Clinical Workflow

2.2 Data Dictionary

The data dictionary is a foundational component of the Clinical Decision Support System, providing a comprehensive and standardized description of all data elements used within the system. It defines each variable's name, type, allowed values, units, source, and role in the decision-making process.

In this CDSS, key data elements include patient demographics (e.g., age, weight), clinical parameters (e.g., renal function measured by glomerular filtration rate and creatinin), medication details (e.g., current drugs), and relevant lab results (e.g., INR).

The importance of the data dictionary lies in:

- **Ensuring Data Consistency:** It provides a shared reference for developers, clinicians, and stakeholders to ensure consistent understanding and usage of data elements.
- **Facilitating Accurate Decision Logic:** Clear definitions and constraints help prevent errors in data entry, interpretation, and processing, which is critical for precise dosing recommendations.
- **Supporting System Integration:** Standardized data elements ease integration with electronic health records (EHRs), laboratory systems, and other clinical data sources.
- **Enabling Maintenance and Updates:** A well-documented data dictionary simplifies system updates, audits, and future expansions by clearly outlining the data requirements.

Overall, the data dictionary is essential for the CDSS to function accurately, safely, and interoperably within clinical environment.

Table 2 Data dictionary

Object	Element Label	Type	Response Options	Conditional Logic / Description
patient	first_name	String	User-defined text	Patient's first name.
	last_name	String	User-defined text	Patient's last name.
	age	Number	Integer	Patient's age in years. If patient is underaged, CHADSVASC is not allowed to be used. Consultation with hematology is indicated.
	patient_weight	Number	Integer	Patient's weight in kg.
	patient_kreatinin	Number	Integer	Serum creatinine in µmol/L. May be used to calculate GFR in future versions of the CDSS.
	patient_gfr	Number	Integer	Glomerular Filtration Rate in mL/min. Often calculated with creatinine (direct calculation not implemented in V1.0).
chadsvasc	age_group	String	"<65", "65-74", ">=75"	Determined by patient.age
	agePoints	Number	0, 1, 2	0 if age < 65, 1 if 65-74, 2 if >= 75
	sex	String	"M", "F"	Patient's sex. Adds 1 point to score if female.
	chf	Boolean	true, false	History of Congestive Heart Failure. true adds 1 point.
	hypertension	Boolean	true, false	History of Hypertension. true adds 1 point.
	diabetes	Boolean	true, false	History of Diabetes Mellitus. true adds 1 point.
	stroke_or_tia	Boolean	true, false	History of Stroke/TIA/Thromboembolism. true adds 2 points.
	vascular_disease	Boolean	true, false	History of Vascular Disease. true adds 1 point.
	score	Number	Integer (0-9)	Sum of points from all contributing CHA_2DS_2-VASc risk factors.
	derived_CHADSVASC_Score	Boolean	true, false	True if the score was automatically calculated. This means that score >= 2 and so there is an indication for anticoagulation.
contraindications	ci_active_bleeding	Boolean	true, false	User-defined check for active, clinically significant bleeding.

	ci_endocarditis	Boolean	true, false	User-defined check for acute bacterial endocarditis.
	ci_gi_ulcus_active	Boolean	true, false	User-defined check for an active gastrointestinal ulcer.
	ci_liver_failure...	Boolean	true, false	Check for severe liver disease (Child-Pugh C) or liver disease with coagulopathy.
	ci_pregnant_or_breastfeeding	Boolean	true, false	User-defined check for pregnancy or breastfeeding status.
	ci_drugs	Boolean	true, false	User-defined, indicates contraindication due to other drugs.
	ci_none	Boolean	true, false	true if all other ci_* fields are false. This ensures that at least one of the fields is clicked and the user does not skip this step by accident.
	derived_absolute_contraindication	Boolean	true, false	true if any ci_* field (except ci_none) is true. This means, there is an absolute contraindication for DOAC.
interactions	None_of_the_above	Boolean	true, false	true if no interacting medications are selected. This ensures that at least one of the fileds is clicked an the user does not skip this step by accident.
	Aspirin	Boolean	true, false	Patient is taking Aspirin.
	Clopidogrel	Boolean	true, false	Patient is taking Clopidogrel.
	NSAID	Boolean	true, false	Patient is taking Nonsteroidal Anti-inflammatory Drugs. (e.g., Diclofenac, Ibuprofen)
	SSRI_or_SNRI	Boolean	true, false	Patient is taking SSRI or SNRI antidepressants.
	derived_dual_antiplatelet_therapy	Boolean	true, false	true if Aspirin and Clopidogrel are both true.
	derived_PPI_indication	Boolean	true, false	true if Proton Pump Inhibitor is indicated. This is true if one of following is true: derived_dual_antiplatelet_therapy, NSAID or SSRI_SNRI

	derived_HASBLED_drugs...	Boolean	true, false	true if Aspirin, Clopidogrel, or NSAID is true. This is used in the HASBLED scoring. If one of the three is true, one point is allocated
	interacting_drug_list	Array	Array of strings	A list of other specific interacting drugs (e.g., "ciclosporin").
	interacting drugs	Boolean	true, false	true if interacting_drug_list is not empty. Then HAS-BLED is calculated
hasbled	total_score	Number	Integer (0-9)	Calculated sum of points from HAS-BLED bleeding risk criteria.

	medication_condition_peak_lvl	Boolean	true, false	Set to true if:
				• Interacting drugs = true
				• Risk factors >= 2
				  ○ Age >= 75
				  ○ GFR < 50
				  ○ Weight <= 60
				  ○ NSAID True
				  ○ Total Score >= 3

2.3 Decision Logic

The decision logic of the CDSS translates current clinical guidelines into a structured, step-by-step process for prescribing Xarelto® (Rivaroxaban) and Eliquis® (Apixaban) in patients with atrial fibrillation. It incorporates key patient-specific factors, such as renal function, age, weight, and drug interactions, to generate accurate, evidence-based dosing recommendations. The logic follows a clear sequence from indication confirmation and contraindication screening to dose adjustment and monitoring advice, ensuring that recommendations are both following the clinical guidelines and are transparent for the end user. The output will display recommended DOAC therapy.

2.3.1 Patient Information & Initial Checks

Table 3 Decision Logic Patient Information Assessment

Rule ID	Condition	Action / Result	Next Step
1.1	Any required field is empty or invalid.	Display error: "Please fill out all required fields"	Remain on Patient assessment page
1.2	Age < 18	**Recommendation:** "Consult Hematology"	Go to recommendation page
1.3	Age ≥ 18	Proceed with calculations.	Go to indication assessment

2.3.2 Indication Assessment Logic

Table 4 ChadsVasc Score calculation logic

Condition	Points Awarded
Congestive Heart Failure	+1
Hypertension	+1
Age 65 – 74	+1
Age ≥ 75	+2
Diabetes Mellitus	+1
Stroke / TIA / Thromboembolism	+2
Vascular Disease (e.g., MI, PAD)	+1

Sex is Female	+1

Table 5 Score-based decision logic

Rule ID	Condition	Action / Result	Next Step
2.1	CHA_2DS_2-VASc Score < 2	**Recommendation:** "No anticoagulation indicated"	Go to recommendation page
2.2	CHA_2DS_2-VASc Score ≥ 2 AND GFR < 15	**Recommendation:** "Vitamin K antagonist, e.g. Marcoumar"	Go to recommendation page
2.3	CHA_2DS_2-VASc Score ≥ 2 AND GFR ≥ 15	Proceed to check for contraindications.	Go to contraindication assessment

2.3.3 Contraindication Assessment Logic

Table 6 Contraindication logic

Rule ID	Condition	Action / Result	Next Step
3.1	**ANY** of the following is TRUE: Active Bleeding, Endocarditis, Active GI Ulcer, Severe Liver Failure, Pregnancy/Breastfeeding, Interacting Drugs	**Recommendation:** "Vitamin K antagonist, e.g. Marcoumar"	Go to recommendation page
3.2	**NONE** of the above conditions are true.	Proceed to check for interactions.	Go to interaction assessement page

2.3.4 Drug-Drug Interaction Assessment Logic

Table 7 HAS-BLED Calculation Logic

Condition	Points Awarded
Uncontrolled **H**ypertension	+1
Abnormal Renal or Liver Function (1 point for either)	+1
Stroke	+1
Bleeding History or Predisposition	+1
Labile INR	+1
Elderly (Age ≥ 65)	+1
Drugs (e.g., Aspirin, NSAIDs) or Alcohol (1 point for either)	+1

2.3.5 Final Recommendation Logic

Table 8 Final Recommendation Logic

Rule ID	Medication	Condition	Result / Dose
5.1.1	**Eliquis**	(Age ≥ 80) + (Weight ≤ 60) + (Creatinine ≥ 133) ≥ **2 risk factors**	Eliquis 2x2.5mg
5.1.2	**Eliquis**	Fewer than 2 of the above risk factors	Eliquis 2x5mg
5.2.1	**Xarelto**	GFR is between 15 and 30	Xarelto 1x10mg after hematology consultation
5.2.2	**Xarelto**	GFR is between 30 and 50 AND taking Aspirin or Clopidogrel	Xarelto 1x15mg AND Xarelto 1x10mg
5.2.3	**Xarelto**	GFR is between 30 and 50 AND NOT taking Aspirin or Clopidogrel	Xarelto 1x15mg
5.2.4	**Xarelto**	GFR ≥ 50	Xarelto 1x20mg

These are added to the primary recommendation from the table above.

Table 9 Additional Recommendations

Rule ID	Condition	Added Recommendation
5.3.1	Taking Aspirin AND Clopidogrel, OR taking an NSAID, OR taking an SSRI	"Consider additional PPI therapy."
5.3.2	If one of following = TRUE: Amiodaron, Chinidin, Dronedaron, Diltiazem, Verapamil, Erythromycin, Naproxen, Fluconazol, Ciclosporin, Tacrolimus	Calculate Risk Factors
5.3.3	Risk Factor Count (+1 for each true)	Age >= 75 GFR < 50 NSAID True HAS-BLED >= 3
5.3.2	If Risk Factors COUNT >= 2	"Monitoring of peak plasma level (2–4 h after intake) is recommended."

2.4 Challenges in L1 to L2 Translation

The CDSS was built on the decision table of KSA, developed by the Department of Hematology. This table is based on the evaluation and synthesis of multiple guidelines and provides a clear, well-structured clinical logic. Due to the quality of this pre-existing work, there were no significant gaps that required filling during CDSS development.

Risk scores such as CHA_2DS_2-VASc and HAS-BLED were sourced directly from MedCalc, which offers transparent calculation methods and thorough documentation. The KSA guideline used as the reference is from 2023. No additional literature search was conducted to identify newer guidelines that might contradict the KSA recommendations. Since the CDSS is

intended specifically for use within KSA, incorporating external or newer guidelines was not deemed necessary at this stage.

During the translation of the decision logic into the L2 implementation, the primary challenge was defining the required variables. While some variables could be derived from others, we deliberately kept derived variables to a minimum. This approach ensures that the CDSS remains easy to read and maintain over time.

We also considered grouping related variables so that questions are asked together in a logical sequence. This prevents duplication of data entry and improves the overall user experience. Where appropriate, scores are automatically derived from previously entered variables, further streamlining the process for the end user while maintaining accuracy.

The implications of these decisions are largely positive:

- Consistency with institutional standards by strictly adhering to the KSA guideline.
- Reduced cognitive load for clinicians by avoiding unnecessary or repeated questions.
- Improved maintainability of the CDSS through minimal use of derived variables and clear logic structure.
- Potential limitation in adaptability if future guidelines change significantly, as updates would be required to align with new evidence.

3 L3: Machine-Readable Code

The CDSS decision logic is implemented as structured, machine-readable JavaScript code that directly encodes the clinical rules for anticoagulation therapy in atrial fibrillation. The logic is organized into modular functions corresponding to each decision step, including patient eligibility checks, CHADSVASC score calculation, contraindication assessment, drug–drug interaction evaluation, bleeding risk calculation (HAS-BLED), and final therapy recommendation.

Each rule is defined with explicit conditional statements, standardized variable names, and clear mappings from input parameters to output recommendations. Clinical thresholds (e.g., age, renal function values, weight limits) are parameterized to allow for rapid updates without modifying core logic. The code structure supports traceability between guideline text, decision tables, and executable rules, ensuring consistency and auditability.

Integration with EHR systems can be achieved via JSON structured dataflow that can be translated to FHIR-compatible API calls. Output values can be consumed directly by other clinical applications or displayed within the user interface.

Version control (Git) is used to manage changes to the codebase, with commits documenting the source of clinical updates (e.g., new ESC guidelines). Automated test scripts verify correct behavior for a range of predefined clinical scenarios, ensuring reliability and adherence to current standards.

For project handover the applicant team can access the Readme of the repository. Installation and development can be achieved with npm.

4 L4: Executable Layer

The executable layer implements the operational logic of the clinical decision support process in JavaScript. In this implementation, data persists in workflow step transfer as state object that lives in runtime memory. An actual implementation would profit from a backend and database logic.

Each step in the workflow is designed to capture a specific subset of patient-related data using UI components such as input fields, radio buttons, and checkboxes.

The state (JSON) object serves as the standardized, machine-readable representation of the patient's data at that stage. It is stored with predefined keys. On subsequent pages, the stored object is retrieved, parsed, and used to pre-fill form fields, drive decision logic, or populate recommendation elements.

The executable layer also implements conditional logic for therapy recommendations. For example, renal function thresholds, comorbidities, and potential drug interactions are evaluated to ensure that only recommendations aligned with the encoded decision rules are displayed.

By combining UI event handling, data-based state management, and embedded decision logic, the executable layer ensures that narrative clinical guidelines (L1) and operationalized rules (L2/L3) are executed consistently for the scope of our limited scope of this project.

5 Quality Assurance and Testing Strategy

The quality assurance (QA) process for the CDSS will ensure that the implemented decision logic is accurate, reliable, and aligned with current clinical guidelines for anticoagulation in atrial fibrillation. Testing will follow a multi-layered approach, combining automated verification with clinical expert review.

If the system were to qualify as Software as a Medical Device (SaMD), the QA process would need to be adapted accordingly. In such a case, the V-model would be applied to guide development and verification, recognizing that regulatory bodies such as the FDA do not test the software itself, but rather review the entire development process and its documentation, in accordance with IEC 62304.

Table 10 10 Testing strategy

Testing Type	Description	Key Objective
Unit Testing	Each decision function (e.g., CHADSVASC calculation, contraindication assessment, HAS-BLED scoring, dosing recommendations) will be tested independently using predefined input–output pairs.	Verify individual functions work correctly for normal and edge cases.
Integration Testing	Once individual components are validated, integration tests will ensure correct interaction between decision modules. Test scenarios will follow complete clinical pathways.	Ensure modules work together and decision flow is correct.
Regression Testing	Automated regression tests will be run after each code change to confirm previously validated behavior remains correct.	Detect unintended changes after updates or guideline changes.
Clinical Validation	All test cases and decision outputs will undergo review by a panel of clinical experts.	Confirm alignment with guidelines and best practices.
Performance / Reliability Testing	The system will be stress-tested to ensure responsiveness under typical and peak usage loads.	Guarantee stability, uptime, and acceptable performance.
User Acceptance Testing	Pilot deployment in a limited clinical setting to collect end-user feedback.	Validate usability, clarity, and workflow fit.
Continuous Quality Monitoring	Post-deployment logging and periodic analysis of decision inputs, outputs, and overrides.	Detect anomalies, monitor adherence, and enable continuous improvement.

5.1 Logic Testing Approach

The decision logic of the CDSS underwent both manual code-level testing and scenario-based evaluation to ensure correctness and guideline adherence. At the code level, intensive step-by-step verification was performed for each decision branch, with special attention to edge cases such as borderline GFR values, multiple concurrent contraindications, and rare drug–drug interaction combinations. Although this testing phase was rigorous, it was not accompanied by comprehensive formal documentation due to the iterative and exploratory nature of development.
In parallel, approximately 50 realistic user scenarios were created to simulate clinical workflows and patient presentations. These scenarios covered a wide spectrum of inputs including edge-cases.

However, the additional testing strategies described above, such as automated regression testing, clinical validation, performance testing, and continuous quality monitoring, have not yet been implemented.

5.1.1 Bugs and Issues

During the testing period various issues and bugs have been identified and documented.

Table 1111 Bug Table

Issue_ID	Description
001	When the age was determined during patient information assessment step, it was still possible to change the age group during patient assessment step.
002	Stroke and other variables were overwritten by other events during testing.
003	The system allowed progression to the next selection step even when not all applicable options had been selected.
004	Value ranges of input features are limited.
005	GFR and creatinine variables are not derived from eachother. Therefore it is possible to impute values which are not possible in real life.
006	Imputing an age, weight, GFR, Creatinine of 0 was still possible.
007	Main control flow logic crashed due to vibe coding.
008	Stroke checkbox was not automatically checked in HAS-BLED score when Stroke was True in CHADSVASC
009	Uncontrolled Hypertension could be checked in HAS-BLED even though Hypertension was False in CHADSVASC
010	HAS-BLED calculator was shown on the interactions page, even if there is no indication to calculate the score.
011	Recommendations showed wrong output due to variables having null values.
012	A user can go back in the forms and change information, even if this would not be indicated. E.g., changing interactions could prompt other recommendations, even if age < 18 years old.
013	Form styles did not always render correctly because the CSS was organized in several separate files.
...	...

6 Implementation Plan

6.1 Delivery

The CDSS will be implemented as a JavaScript-based web application to ensure an intuitive and easy-to-use experience for clinicians. In future releases the solution will be implemented as an integrated web component embedded within existing EHR or HIS solutions. This will allow seamless access and use for clinicians. This feature integration will rely on standard API's such as FHIR, to automatically retrieve patient data, autofill questions and ensure safety. Dose recommendations will be displayed within the clinical workflow.

6.2 User Training

The tool will be delivered including detailed documentation. User training will be supported with interactive tutorials. Additional live or virtual training sessions will be conducted for clinicians, focusing on interpreting recommendations, using override options and reporting issues. During implementation phases additional supporting will be implemented if required by the customer. Since the user personas are clinicians in a central Swiss hospital, it is safe to assume that there is a basic familiarity with IT systems, making extensive technical training less critical. However, it is more important to clearly communicate the inclusion and exclusion criteria for using the tool.

6.3 Maintenance and Monitoring

6.3.1 Maintenance

The system will be maintained using version control, such as Git, to manage updates based on new clinical evidence or guideline revisions. API connections will be monitored to ensure uninterrupted data flow and system availability, while a helpdesk or designated support contact will be established for user assistance.

6.3.2 Monitoring and Evaluation

In order to address the different maturity stages of the project, the monitoring and evaluation strategies will be adjusted to the different stages. In the early stages of the project the functionality, stability of the system and the adherence to the clinical guidelines will remain focus of the monitoring and evaluation strategies. During early deployment stages the focus will shift towards monitoring of clinical outcomes in relation to the variety of input variables as well as clinicians feedback. In the mature stage, the system will be assessed for its long-term impact on patient safety, prescribing patterns, and clinician satisfaction.

Maintenance activities will also include proactive adaptation of the system to reflect changes in clinical guidelines, ensuring that decision logic, dosing recommendations, and alerts remain fully aligned with the most current standards of care.

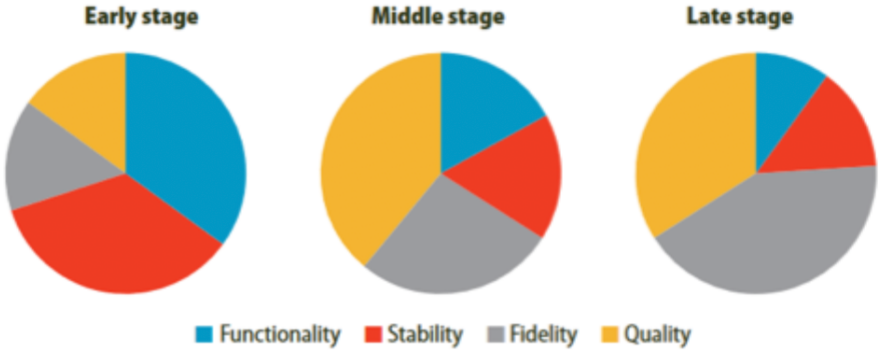


Figure 4 4Monitoring and Evaluation Strategy[3]

[3] Dr. Fenella Beynon, CDSS Module Presentation, FHNW

7 Expected Impact

7.1 Benefits

- Supports evidence-based dosing decisions for Xarelto® and Eliquis® tailored to patient-specific variables.
- Reduces medication errors related to renal impairment, age, weight, and drug interactions.
- Facilitates faster, consistent clinical decisions and enhances guideline adherence.

7.2 Challenges

- Ensuring data completeness and accuracy from integrated systems to avoid false alerts or missed warnings.
- Achieving clinician trust and acceptance, especially around clinical judgment areas.
- Maintaining the system in line with evolving clinical guidelines and drug updates.
- The CDSS aims to improve guideline adherence while educating users, but over-reliance on recommendations could reduce active clinical reasoning. Balancing support with critical thinking is a key challenge.

8 Vision

The long-term vision for this system is to seamlessly integrate the clinical decision support tool into existing Electronic Health Record (EHR) platforms, enabling clinicians to access and use it directly within their daily workflow. This integration will ensure that patient data is captured and utilized without redundant manual entry, reducing administrative burden and minimizing the risk of errors.

A key component of this vision is the adoption of standardized healthcare data exchange protocols such as HL7 FHIR, ensuring that the tool can communicate efficiently and securely with diverse clinical systems. Implementing these standards will enable interoperability across institutions, facilitate real-time data sharing, and ensure compliance with regulatory requirements.

The framework can be extended for other Direct Oral Anticoagulants (DOACs) or adapted to different regional guidelines.