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**Reinventing vitamin K antagonist therapy management:
an implementation study of a home-based integrated monitoring model**

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Abstract

Vitamin K antagonist (VKA) oral anticoagulant therapies are crucial for preventing thromboembolic complications in cardiovascular diseases; however, their narrow therapeutic range necessitates frequent monitoring of the International Normalized Ratio (INR), posing significant challenges for elderly and frail patients. This article presents the implementation of a new home-based monitoring model for VKA therapy that integrates digital tools with clinical supervision.

Since 2022, the Local Health Authority of Bologna (Italy) has implemented a home-based coagulation diagnostics model to improve VKA management, consisting of an INR PoCT Network that integrates hospital and community services through a digital system that streamlines data collection and oversight. Portable devices, supervised by laboratory personnel, provide home-based results comparable to central laboratory standards, improving workflows and enabling timely clinical decisions.

By 2024, the INR PoCT Network comprises 17 home care units serving 1,701 patients. Approximately 20,000 blood samples are processed each year, with further growth expected. Nurses perform INR testing using the Xprecia Prime™ analyzer (Universal Biosensors Inc.), and results undergo automated self-verification based on algorithms aligned with central laboratory procedures, ensuring accuracy and reliability. A digital report is generated to support timely therapy adjustments and follow-up. This model reduces Turn Around Time for coagulation results from more than three hours to about 20 minutes, improves monitoring effectiveness, decreases hospital visits, and enhances patients' quality of life.

The system demonstrates that investing in home monitoring improves comfort, reduces healthcare burden, and modernizes VKA therapy management through a scalable, accurate, and patient-centered approach.

Key words: digital health, medication therapy management, home care services, INR, point-of-care testing.

Introduction

Vitamin K antagonists (VKAs) such as warfarin, phenprocoumon and acenocoumarol are widely used as long-term anticoagulants, for example to prevent stroke in atrial fibrillation or to treat venous thromboembolism. However, their narrow therapeutic window and numerous drug–drug and drug–food interactions [1] require frequent coagulation monitoring and dose adjustments to maintain the international normalized ratio (INR) within the therapeutic range [2]. VKAs are effective only when the INR remains between 2.0 and 3.0; values outside this range increase the risk of thromboembolism ($\text{INR} < 2.0$) or bleeding ($\text{INR} > 3.0$) [3]. These monitoring needs, together with dietary restrictions, can affect patients' daily lives and reduce their quality of life [4]. Routine INR checks also increase healthcare costs, including testing, travel, nurse visits, missed work, and additional workload for clinical staff.

Data collected outside anticoagulation clinics suggest that the real-world effectiveness of VKAs does not fully replicate the efficacy observed in clinical studies; in fact, although VKAs are often considered less expensive, their true cost goes beyond the lower drug price compared with DOACs (Direct Oral Anticoagulants) and must also include the overall management of therapy—routine monitoring, adverse events, and complications from non-adherence [1].

Over the past decade, the COVID-19 pandemic in Italy has highlighted major challenges in managing more than 24 million chronically ill patients and an ageing population with significant social and healthcare needs [5-6]. In response, the Italian Health System has adopted the "NextGenerationEU" (NGEU) program launched by the European Health Union in May 2020, which allocates over €800 billion to address key public health, technological, environmental and socio-cultural priorities[7-9].As a result, national healthcare strategies now focus on strengthening community-based services, expanding the Electronic Medical Record (EMR), modernizing infrastructure and increasing the use of telehealth. Telehealth refers to delivering healthcare remotely through digital technologies, supporting patients throughout diagnosis, treatment and follow-up [10-13].

Since 2022, the Local Health Authority of Bologna (Italy) has implemented a home-based care model using Point-of-Care Testing (PoCT) for coagulation monitoring, employing the Xprecia Prime™ analyzer (Universal Biosensors Inc.) to meet the needs of the growing number of patients on VKA therapy, which is increasing with population aging. This INR PoCT network uses a digital system that integrates hospital and community services, enabling

efficient data collection and management to optimize VKA monitoring. Portable devices, remotely supervised by qualified laboratory personnel, can provide home-care results comparable to those from the central laboratory, improving workflows and supporting clinical decisions. The model mainly serves elderly or frail patients requiring frequent coagulation tests, as well as those living far from the central laboratory.

The aim of this retrospective implementation study is to describe and evaluate the home-based VKA monitoring model introduced in 2022 in the Bologna metropolitan area, comparing it with the previous system and assessing the relationship between perceived benefits and implementation costs. The conceptual framework assumes that a PoCT-based INR network can improve efficiency, reduce turnaround times (TAT), and optimize resource use while preserving quality and safety. Accordingly, the evaluation focuses on process indicators, reproducibility of results, and the perceived impact on healthcare professionals and patients.

Materials and Methods

Study design and data sources

This retrospective implementation study evaluated the home-based VKA monitoring model introduced in the Local Health Authority of Bologna in 2022. The evaluation was based on routinely collected operational and laboratory data and on aggregated data from previously administered quality questionnaires. Data were extracted retrospectively from the laboratory database, including the number of samples analyzed and the results of centralized quality controls. Perceived quality was assessed using aggregated data derived from questionnaires administered to nursing staff, healthcare professionals, and patients, as reported in published official reports [14]. No individual-level clinical outcome data were collected or analyzed.

Ethical statement

This study does not involve direct collection of clinical patient data. All information concerning patients and healthcare professionals was obtained exclusively from published official reports [14], which are based on anonymized quality questionnaires completed by participants who had provided written informed consent. As no personal data were collected and the analysis focuses solely on aggregated perceived quality outcomes, institutional review board approval was not required. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical analysis

Data were analyzed using descriptive statistics. Continuous variables were summarized using mean and standard deviation (SD), where applicable, while categorical and questionnaire-derived variables were reported as absolute frequencies and percentages. Analytical precision was expressed as coefficient of variation (CV). Turnaround times were reported as mean $\pm$ SD. No inferential statistical tests were performed, as the study was designed as a descriptive implementation evaluation rather than a comparative effectiveness study. Descriptive statistics were calculated using Microsoft Excel, version 2608 (Microsoft Corporation, Redmond, WA, USA).

Home-based management of VKA therapy: description of the previous model

Until 2021, the home-based management of VKA therapy followed a multi-step, resource-intensive workflow involving several healthcare professionals. After the cardiologist prescribed the INR test and issued the required documentation, home care nurses used the computerized anticoagulation management system to print the list of patients scheduled for the next day and prepare the venipuncture materials (test tube, barcode label, and medical record with an adverse events questionnaire), which were organized into dedicated containers and assigned according to geographical sampling routes.

The next morning, nurses visited patients' homes, completed the adverse events checklist, and performed venipuncture. By a predetermined time, they stopped visits and returned to their base to finalize sample acceptance procedures: verifying tube labelling, entering checklist data into the information system, and sending the information to the Prescription Center. Between 9:00 and 9:30 a.m., designated drivers collected the test tubes from home care centers and delivered them to the Central Metropolitan Laboratory (LUM).

Laboratory staff checked the samples on arrival to ensure proper collection (correct labelling, tube type, and filling volume), recorded any non-compliances, and sent them to the appropriate section for processing. Here, samples were centrifuged for 15 minutes at 1500 x g and then analyzed for INR measurement and validation. If the process was successfully completed, the report was generated and automatically uploaded to the patient's EMR. Physicians in the Cardiology and Angiology Units then reviewed the results, adjusted or confirmed the VKA dosage, and scheduled the next follow-up. As expected, this workflow—summarized in Figure 1—presented several critical issues, outlined below.

- Prolonged downtime, including transportation delays, coordination of multiple operators and vehicles for sample transfer, and diversion of time from direct nursing care.
- Substantial back-office workload and significant nursing hours dedicated to home sampling activities.
- Delays in the communication of test results.
- Unsuitable specimens, such as clotted, insufficient, missing, or misplaced samples, requiring repeated nursing visits to the patient's home on the same day or within a short interval.
- Lack of traceability of the healthcare professional performing the collection.
- Inadequate patient identification procedures.
- Increased exposure to biological risk associated with the invasive nature of venipuncture.
- Technical difficulties in blood collection related to venous insufficiency in frail or elderly patients, frequently resulting in patient discomfort.

Implementation of the new model: pilot project

The new INR PoCT network (Figure 2), implemented in 2022, aims to streamline the workflow through a digital system for collecting, integrating, and managing clinical data, ensuring close coordination between hospital and community services. Its originality lies in equipping nurses with portable diagnostic devices that deliver laboratory-quality results, as they are managed, validated, and reported by the reference laboratory. This allows nurses to perform testing without interrupting routine care. The transition from venous to less invasive capillary sampling further simplifies the process: a blood drop is applied to the analyzer, which immediately displays the result and automatically transmits it to the Laboratory Information System (LIS). The project was developed by a multidisciplinary team including laboratory staff, nurses, cardiologists, general practitioners, IT specialists, and administrative personnel. It was initially piloted in three nursing centers after dedicated training by laboratory professionals on the correct use of PoCT devices. In practice, the workflow involves the nurse—equipped with a portable diagnostic device (Xprecia Prime™ analyzer)—identifying the patient at home by scanning the health card, performing capillary sampling, and measuring the INR. The analyzer features a strip-ejection system that

minimizes biological risk, while the barcode reader ensures full traceability of both patient and operator.

The generated data are processed by a validation algorithm: if no errors are detected, the result is automatically sent to the central laboratory, which issues the report and forwards it to the prescribing physician for immediate therapeutic adjustment. If an error is flagged, the nurse receives an instant alert and repeats the test. Data and adverse event checklists are transmitted via GSM (Global System for Mobile Communications) or Wi-Fi, eliminating the need for nurses to return to their service site. All workflows can be monitored in real time by laboratory staff through a web portal, which also provides device status checks, quality control review, measurement tracking, and data export. Data reaching the LUM undergo additional verification algorithms, and results are released only after successful validation.

Operational workflow

The operational workflow is managed through the BeHome software (Siemens Healthineers), which communicates bidirectionally with the LIS. Available also as a mobile app on nurses' tablets, it supports patient identification, data acquisition from PoCT devices, and entry of clinical information.

Self-checking algorithm and digital reporting

Automatic validation algorithms, developed in collaboration with clinicians, identify significant INR deviations and enable nurses—after appropriate training—to follow standardized protocols:

- If $\text{INR} < 1.5$ or > 5.5 : the test is repeated, with only the most recent result transmitted to the LIS and the initial value documented in the notes.
- If $\text{INR} < 0.8$ or > 8.0 : no numerical value is displayed, and a HI/LOW alert appears. The nurse repeats the test, and if the alert persists, a venous sample is collected and sent to the laboratory for urgent analysis.

After validation, the INR report is made available to the cardiologist via the EMR.

Quality control of analytical performance by the central laboratory

Reliability of PoCT INR results is ensured through regular QC checks supervised by the reference laboratory, with devices interfaced to the LIS for real-time monitoring. Devices are automatically locked if QC procedures are missed or results are out of range, requiring

withdrawal and laboratory verification before reuse. Analytical performance is periodically compared with that of the central laboratory, and participation in External Quality Assessment (EQA) programs (e.g., NEQAS) provides continuous quality monitoring across all PoCT sites.

Results

Effectiveness in terms of volumes and turnaround times of INR PoCT

The continuous transmission of data to the LIS enables constant process monitoring and evaluation of effectiveness in terms of volumes and TAT (Table 1). The pilot project, launched in 2022, involved three home nursing units in the Bologna metropolitan area and 1,118 patients. By 2024, the INR PoCT network had expanded to 17 home nursing units—including several in disadvantaged mountain areas—serving 1,701 patients on home-based VKA therapy. Approximately 20,000 blood samples are processed each year, a number expected to rise as the project moves toward full implementation.

A comparison of data from the same period (April) in two consecutive years—2021, when only venous sampling was used, and 2022, after PoCT implementation—showed a marked reduction in mean TAT for coagulation results, measured from sample collection to report availability in the EMR accessed by Cardiologists and Angiologists.

In 2021, the TAT for venous sampling—covering collection, administrative processing, transport to the LUM, and laboratory analysis—was approximately 3 hours and 13 minutes. With the PoCT model introduced in 2022, the TAT was approximately 20 minutes, requiring only capillary sampling and immediate on-site analysis (Table 2).

Impact assessment

To assess the impact of the new model on patients and stakeholders, the Local Health Authority of Bologna conducted a structured evaluation using two complementary questionnaires [14].

Questionnaire 1, an online survey completed by 55 professionals six months after implementation (75% home care nurses using PoCT, 17% prescribing physicians, 8% LUM staff), assessed ease of use, organizational implications, performance, safety, and critical issues. All domains scored above 78%, except *impact on quality of care*, where the item *risk to patient health* received the lowest score (54.2%), possibly due to misinterpretation of the

question. Within *organizational impact*, the lowest ratings concerned spaces/facilities (56.6%) and human resources (54.7%).

Questionnaire 2, a paper-based survey completed by 432 of 448 patients monitored with PoCT one year after implementation, evaluated satisfaction with capillary sampling and perceived benefits compared with venous sampling. Overall, 80% found fingerstick sampling less painful, 1.9% more painful (likely due to comorbidities), and 91.7% considered it more practical. Reported advantages included reduced need for undressing or repositioning (96.5%), absence of bruising (96.1%), and greater ease of sampling (97.2%). Patients showed high satisfaction with PoCT, highlighting improvements in comfort, practicality, and daily disease management.

Cost assessment

Two years after the implementation of the new model, its economic impact and appropriateness were evaluated by comparing the annual costs of venous and capillary blood sampling. Although the laboratory cost per INR test is lower for venous sampling (€1.61) than for PoCT (€4.00), the overall analysis showed an estimated annual saving of approximately €1.55 million (Table 3).

Quality assessment

As already mentioned, the novelty and strength of the model presented in this study—compared with those used in other settings—lie in the central role of the laboratory, which continuously monitors internal and external quality controls performed remotely or on site. In this context, the 2024 internal QC analysis, based on 5,242 tests across two control levels on all INR devices, showed a mean CV below 5.0%, demonstrating the reliability and robustness of the PoCT network and confirming its compliance with internationally accepted quality standards for coagulation testing [15,16].

Internal quality controls

Xprecia Systems PT Controls are provided as a combined package containing both normal (target value = 1.2 ± 0.05 INR; CV = 3.8%) and abnormal (target value = 2.8 ± 0.08 INR; CV = 2.84%) lyophilized plasma. The controls are reconstituted with CaCl₂ diluent for use with Xprecia Coagulation Systems in PT/INR determinations and are analyzed by healthcare professionals following the same procedures as patient samples.

Repeatability testing

Repeatability is assessed by comparing results from capillary samples obtained through multiple fingersticks on the same individual—since a single blood drop cannot be reused—and analyzed with the same instrument. The mean INR, SD, and CV (%) were calculated across three INR ranges (<1.0, 2.0–3.0, and 3.1–4.5). Repeatability testing consistently yielded CV values below 5.0%, confirming the precision of the method. Tests are performed by laboratory staff at device installation, whenever verification is required due to instrument issues, and during routine monthly checks. This systematic approach enables early detection of malfunctions, ensures stable analytical performance over time, and reinforces the overall robustness and reliability of the PoCT network.

PoCT-laboratory comparability

Periodic comparability assessments are performed by analyzing paired samples collected simultaneously from the same individuals using both PoCT and laboratory-based venous INR testing. In all cases, differences remained within ± 0.5 INR units (mean 0.43 ± 0.06), confirming the comparability of PoCT measurements. These assessments cannot be performed for samples with results < 0.8 or > 8.0 , which generate a HIGH/LOW flag without a numerical value. Both PoCT devices and laboratory methods use recombinant human thromboplastin, ensuring consistency of results.

External quality control

Since 2024, participation in the NEQAS External Quality Assessment Scheme has been implemented. However, as only a limited number of centers currently participate, consistent data to verify interlaboratory reproducibility across institutions are not yet available.

Discussion and Conclusions

Current guidelines emphasize that appropriate monitoring of VKA therapy reduces thrombotic and bleeding complications as well as overall mortality [17,18]. Advances in reliable PoCT devices, combined with telehealth solutions and Anticoagulation Management Services (AMS), have further enabled safe home-based INR testing and more timely therapeutic decisions [10-12,19-21]. A 2012 meta-analysis by Heneghan et al. demonstrated that self-monitoring and self-management of oral anticoagulation are safe and effective options for appropriately selected patients across all age groups [22]. In this context, our

study proposes an integrated PoCT–telemedicine model for home-based INR monitoring, primarily focused on process efficiency and large-scale implementation. Compared with other initiatives, such as the telehealth-based Patient Service Center (PSC) model described by Bernstein et al. [6], important differences emerge in objectives and scope. The PSC model mainly targets clinical effectiveness: although patients are still required to attend a collection site, turnaround time is reduced to 15–20 minutes, enabling immediate treatment decisions and resulting in a substantial improvement in anticoagulation control, with mean time in therapeutic range (TTR) increasing from 32% to 77.8%. However, this experience remains limited to a small pilot cohort of eight patients across three PSCs over 40 weeks. In contrast, our study evaluates process efficiency and system-wide performance in a large, real-world population. The transition from venipuncture to nurse-performed, home-based PoCT reduced TAT from over three hours to approximately 20 minutes directly at the patient's home, significantly improving accessibility for elderly and frail patients. Implementation is supported by robust quality assurance procedures, including repeatability testing to verify device precision ($CV < 5.0\%$), centralized internal quality controls, and participation in EQAS programs. The economic evaluation also showed substantial estimated annual cost savings despite higher per-test costs, largely attributable to reduced transportation needs and lower consumable use. Patient comfort and perceived quality were assessed using structured questionnaires, providing insight into organizational and experiential outcomes; fewer hospital visits were associated with improved comfort and quality of life, particularly among patients with limited mobility or complex care needs [23]. From an operational perspective, integration of PoCT devices with the LIS ensures full traceability, standardized data flows, and a marked reduction in pre-analytical errors [24,25]. Overall, the PoCT-based INR monitoring network centered on the reference laboratory represents a reliable, efficient, and scalable solution for the safe management of VKA therapy in home-care settings. Centralized oversight of analytical and organizational processes ensures quality and consistency across the entire care pathway while supporting a decentralized and patient-centered model of care. Unlike approaches primarily based on patient self-management, this model relies on coordinated involvement of local healthcare providers and continuous supervision by the central laboratory, which directly oversees PoCT result quality at the patient's home. Beyond its immediate operational benefits, this model addresses key challenges in home-based anticoagulation management and offers a replicable framework for healthcare systems aiming to modernize service delivery, improve sustainability, and reduce resource

utilization. Although the present study focuses on organizational and managerial aspects rather than clinical effectiveness, the findings are consistent with existing evidence supporting the safety and effectiveness of self-monitoring strategies in eligible patients [22]. Future research should further investigate clinical outcomes to provide a more comprehensive assessment of the model's impact. Limitations include dependence on stable internet connectivity, which may affect performance in remote or underserved areas, and variability in organizational resources across healthcare systems that could influence broader implementation.

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Table 1. Annual implementation of PoCT devices, home nursing care units involved, and patients enrolled in VKA PoCT home monitoring.

Year	PoCT devices implemented	Patients enrolled	Home nursing care units	INR PoCT
2022	27	1118	3	13,054
2023	35	1225	3	13,976
2024	94	1701	17	18,662

Table 2. TAT comparison between venipuncture (April 2021) and PoCT (April 2022).

Month, year (method)	Patients (n)	Total samples (n)	Sampling time	Sample transport: patient home → Nursing Center (avg ± SD)	Sample acceptance/ registration at Nursing Center (avg ± SD)	Sample transport: Nursing Center → LUM (avg ± SD)	TAT: Analysis → EMR (avg ± SD)	Total TAT (avg ± SD)
April, 2021 (Venipuncture)	1014	3008	00:18:00±00:09:09	00:32:50±00:18:08	00:20:00±00:14:14	00:25:00±00:14:14	01:37:31±00:47:28	03:13:21±00:20:39
April, 2022 (PoCT)	925	2,918	00:03:15±00:01:18	n.a.	n.a.	n.a.	00:16:51±00:10:40	00:20:06 00:05:59

Comparison of TAT between April 2021, when all home INR blood samples were collected by venipuncture, and April 2022, after the implementation of PoCT systems. TAT was defined as the total elapsed time from blood collection to final report generation in the EMR. Approximately 1,000 patients from different parts of the metropolitan area, ranging from remote mountain areas to those close to the central laboratory, were included. Each patient undergoes an average of about three INR tests per month. *avg* = average; *EMR*: electronic medical record *SD* = Standard Deviation; *TAT* = Turnaround Time; *n.a.* = not applicable. Time is expressed as *hh:mm:ss*.

Table 3. Comparison of the annual costs of venous versus capillary (PoCT) blood sampling for INR testing.

	Venous blood sampling	Capillary blood sampling
Cost of the material needed to perform the sampling	€ 1.784.185,92	€ 219.897,6
Cost of nurses	€ 41.931,02	€ 138.338,893
Cost of vehicles for sample Transport	€ 360.000	€ 240.000
Total cost	€ 2.150.116,94	€ 598.236,49

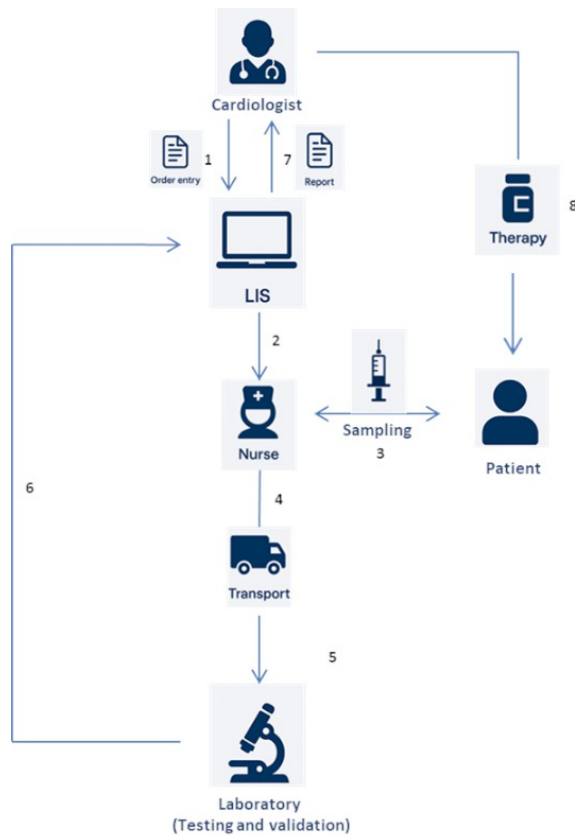
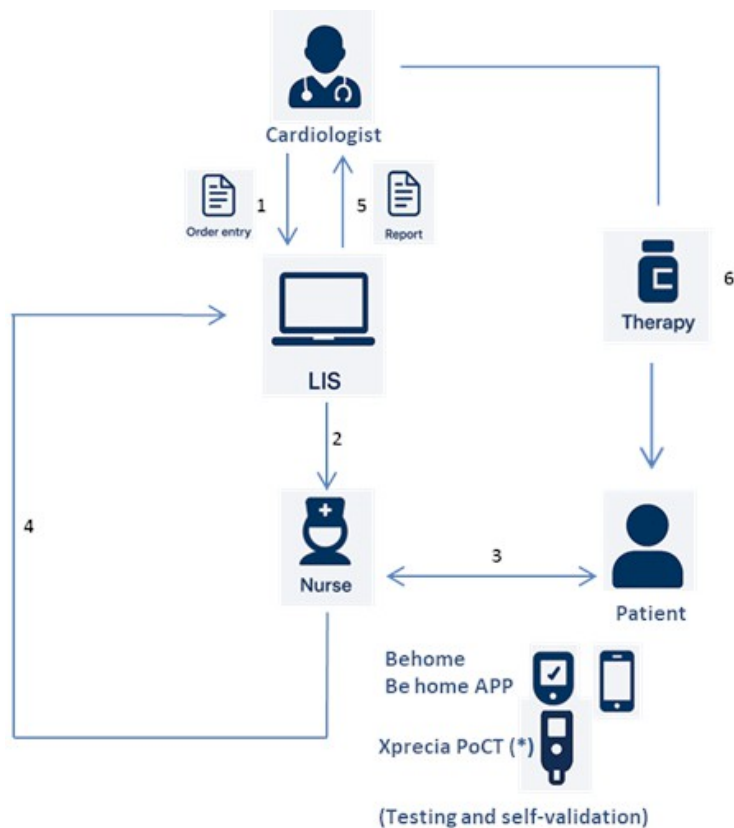


Figure 1. Workflow of the home-based INR Monitoring Model in the metropolitan area of Bologna until 2022.

Step 1 – Test ordering. The cardiologist requests the INR test and issues the patient with the necessary documentation for the scheduled day of the blood draw. **Step 2 – Order management.** The nurse practitioner receives the order through the computerized oral anticoagulant therapy management system. **Step 3 – Home visit and sample collection.** The nurse goes to the patient's home to take the blood sample. **Step 4 – Sample Transportation.** After sampling, the nurse takes the blood tube to the workstation where it will be collected to be transported to the reference laboratory. **Step 5 – Laboratory processing.** In the reference laboratory the sample is processed by the technical staff and, if no errors occur, the result is validated. **Step 6 – Result Reporting.** A report is generated through the LIS. **Step 7 – Clinical review.** The cardiologist receives the INR result. **Step 8 – Therapy and Follow-up.** The cardiologist prescribes the patient therapy and schedules the follow-up, that will be received by the patient via EMR.

LIS: laboratory Information System, INR: International Normalized Ratio, EMR: Electronic Medical Record.



* Daily monitored by the Reference Laboratory

Figure 2. Workflow of the new POCT-based INR Monitoring Network.

Step 1 – Test ordering. The cardiologist requests the INR check and issues the patient with the necessary documentation for the scheduled day of the blood draw. **Step 2 – Order management.** The nurse receives the order entry. **Step 3 – Home visit and sample collection and analysis.** the nurse goes to the patient's home, and, after PoCT CQ is passed, collects the sample and runs the analysis. **Step 4 – Result Validation and Reporting.** Once the auto-checking phase is completed, a report is generated through the LIS. **Step 5 – Clinical review.** the cardiologist receives the INR result. **Step 6–Therapy and Follow-up.** The cardiologist prescribes the patient therapy and schedules the follow up, that will be received by the patient via EMR.

PoCT: Point of care testing, **INR:** International Normalized Ratio, **CQ:** quality control, **LIS:** laboratory Information System, **EMR:** Electronic Medical Record.