Developing, validating, and using a quality of care indicator for anticoagulation monitoring

Country: Malaysia

Authors: Aliza Alias, Chuah Sim Mei - Pharmaceutical Care Subdivision, Pharmacy Practice & Development Division, Pharmaceutical Services Programme, Ministry of Health (MoH)
Saidatul Sheeda Ahmad Shukri - Pharmacy Infrastructure Development & Quality Subdivision, Pharmacy Policy & Strategic Planning Division, Pharmaceutical Services Programme, MoH
Nur Ezdiani Mohamed, Izzatur Rahmi Mohd Ujang, Samsiah Awang - Centre for Health Quality Research, Institute for Health Systems Research, National Institute of Health, MoH

Country snapshot

Malaysia has made sustained investments in strengthening pharmaceutical care as part of its broader health system quality agenda. Within the Ministry of Health, clinical pharmacy services play an increasingly important role in optimizing medication use, improving patient safety, and supporting quality improvement initiatives at scale.

This learning brief documents Malaysia's experience in developing, validating, and using a national quality of care (QoC) indicator for anticoagulation monitoring. The work was led by the Pharmacy Practice and Development Division, Pharmaceutical Services Programme, Ministry of Health Malaysia, with technical support from the Institute for Health Systems Research (IHSR) and oversight provided through national quality assurance governance.

Anticoagulation therapy, particularly with warfarin, requires careful and continuous monitoring to maintain effectiveness while minimizing the risk of adverse events such as bleeding or thromboembolism. Internationally, time in therapeutic range (TTR) is recognized as a robust and clinically meaningful measure of anticoagulation quality, reflecting how consistently patients' International Normalized Ratio (INR) values remain within the target range.

The indicator focuses on anticoagulation care delivered through Anticoagulation Medication Therapy Adherence Clinics (AC-MTAC), established in selected hospitals and health clinics nationwide. Data is monitored nationally and used locally to support continuous quality improvement. AC-MTAC service provision follows MTAC recognition criteria set by the Pharmacy Practice and Development Division, which include minimum requirements for pharmacist staffing and patient recruitment.

The indicator is currently used at the national level to monitor anticoagulation service quality, with data generated and reviewed at the facility and state levels. Importantly, data collection has evolved from a standalone reporting

activity into an embedded component of routine clinical documentation and service delivery. Standardized templates and guidance have reduced reporting burden and improved consistency across facilities. Indicator data are reviewed within professional and technical committees, where they are used to:

- Identify performance gaps,
- Share best practices across facilities,
- Inform revisions to clinical protocols, and
- Support targeted quality improvement initiatives.

This integration has strengthened the indicator's practical utility beyond compliance reporting.

Why was this indicator needed

In Malaysia, AC-MTAC services were already well established and delivered collaboratively by pharmacists and doctors. However, despite the availability of clinical data and established protocols, there was no–national indicator to systematically assess the quality of anticoagulation management across facilities.

Several needs motivated the development of the indicator:

- The need for a nationally agreed benchmark to assess service performance,
- The desire to align clinical pharmacy services with existing national quality assurance and indicator frameworks,
- The opportunity to leverage routinely collected clinical data rather than introduce parallel reporting systems,
- The importance of supporting evidence-informed quality improvement within AC-MTAC services.

Developing a national outcome-oriented QoC indicator defined as the percentage of patients achieving TTR was therefore seen as a pragmatic and policy-relevant solution to strengthen measurement while remaining feasible within routine service delivery. The indicator was set to≥ 65% of patients in AC-MTAC achieving TTR ≥ 60%.

The indicator measures anticoagulation control by assessing the proportion of time patients' INR values remain within the therapeutic range. While it does not directly measure care processes, performance is influenced by clinical management and follow-up practices, as well as patient-level factors such as adherence and comorbidities.

Data is collected at the facility level by pharmacists providing AC-MTAC services, using information from patients' clinical notes and/or during clinic encounters. Data may be compiled manually or extracted from electronic medical records, and TTR is calculated for enrolled patients using the Rosendaal linear interpolation method. This method estimates daily INR values between recorded measurements. Facilities submit indicator reports using a standardized template (e.g. an Excel form) to their respective State Pharmaceutical Services Divisions according to reporting schedules set by individual states. State-level data are then consolidated and submitted to the Pharmaceutical Services Programme, which consolidates the information annually for national-level monitoring and analysis.

Indicator development process

Leadership and stakeholder engagement

The indicator development process was led by the Pharmaceutical Services Programme, Ministry of Health Malaysia, with IHSR serving as the Technical Secretariat. Oversight and approval were provided through established national quality assurance governance, ensuring institutional ownership and sustainability.

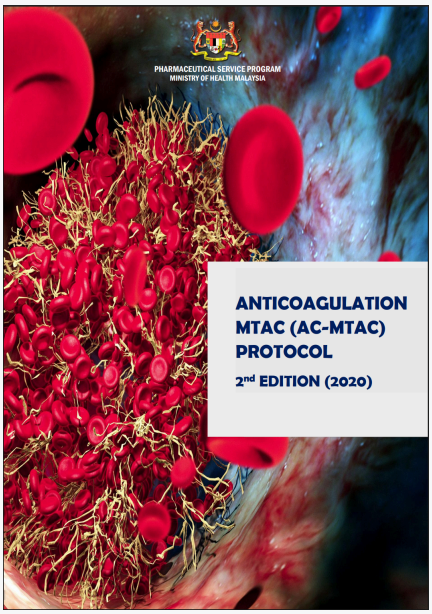
Stakeholder engagement was purposeful and technically focused, rather than broad-based. Continuous engagement was maintained throughout the indicator development process with a subject matter expert pharmacist specializing in anticoagulation from the Cardiology Centre, Hospital Sultan Idris Shah, Serdang. This expert contributed to the conceptualization, definition, feasibility assessment, and refinement of the indicator, ensuring strong clinical relevance and methodological appropriateness.

Engagement also extended to institutional stakeholders within the Ministry of Health. The Pharmaceutical Services Programme led the process and worked closely with ministry leadership and national quality assurance governance to align the indicator with existing policy, quality improvement mechanisms, and reporting systems. The National Quality Assurance Technical Committee conducted iterative technical reviews of the proposed indicator, allowing clinical, methodological, and implementation considerations to be examined and strengthened before approval.

This focused engagement model ensured depth of expertise, institutional ownership, and smooth transition from development to national implementation.

Methodological approach

The indicator was developed using a structured quality assurance and quality improvement (QA/QI) problem-solving cycle. Candidate indicators were first assessed and prioritized using the SMART criteria (Seriousness, Measurable, Appropriateness, Remediable, and Timeliness) and further evaluated against the SIFA criteria (Scientific Soundness, Importance, Feasibility, and Actionability)[1]. This ensured that the selected indicator was not only clinically meaningful but also practical for routine monitoring.



A problem analysis chart was then used to systematically examine factors influencing TTR achievement. Based on this analysis, the relevant process of care was defined in line with the national AC-MTAC Protocol (2nd edition, 2020), providing a clear clinical and operational foundation for the indicator.

Standard setting and feasibility assessment were grounded in empirical evidence. Baseline TTR data from facilities providing AC-MTAC services in 2020 and 2021 were analyzed to understand existing performance and inform the selection of a national performance threshold (TTR ≥ 60%).

Data availability and measurement feasibility were further confirmed by applying inclusion and exclusion criteria and establishing a standardized data collection mechanism.

Following refinement, the indicator was formally discussed and reviewed by the Pharmaceutical Services Programme. After incorporating recommended improvements, it was submitted to the National Quality Assurance Committee for approval and subsequently adopted for routine monitoring under Malaysia's National Indicator Approach (NIA). Finally, the indicator was integrated into national monitoring systems through:

- Development of a comprehensive indicator manual,
- Standardized reporting templates,
- A Shortfall in Quality (SIQ) guide, and
- Dissemination through existing pharmaceutical services reporting channels.

Indicator implementation process

Capacity-building was integral to implementing and sustaining the anticoagulation quality indicator, with a focus on strengthening both technical competence and routine data use at the facility and subnational levels.

- A comprehensive indicator manual was developed and disseminated nationally, providing standardized definitions, calculation methods, data collection procedures, and reporting requirements. This manual served as a key reference for pharmacists and state-level teams, supporting consistent interpretation and application of the indicator across facilities.

- Structured training activities complemented the written guidance. National-level anticoagulant workshops and cardiology pharmacy updates were conducted to strengthen clinical and technical capacity in anticoagulation monitoring, TTR result interpretation, and the use of indicator data for quality improvement. These activities reinforced alignment between clinical practice and measurement expectations.

- Mentorship and peer-learning mechanisms were also used to support implementation. Facilities with established AC-MTAC services and strong indicator performance were engaged to share practical experiences, workflows, and lessons learned with other sites. This peer-to-peer approach helped build confidence, address operational challenges, and support adaptation in facilities with varying levels of experience and system readiness.

- In addition, regular committee meetings and stakeholder consultations provided an ongoing platform for feedback, problem-solving, and tool refinement.

- A standardized reporting template, informed by successful implementation practices, was introduced to streamline data submission, reduce administrative burden, and improve data completeness.

Together, these capacity-building efforts strengthened the reliability of indicator data and supported its effective use for quality monitoring and improvement.

Early results and observed value

Following national implementation, improvements in anticoagulation control were observed. The percentage of patients achieving TTR ≥ 60% increased from 59.8% in 2023 to 63.0% in 2024, and further increased to 66% in 2025, representing a 6.2 percentage-point improvement. While multiple factors may contribute to this trend, the indicator has helped:

- Reinforce adherence to monitoring protocols,
- Support more consistent clinical decision-making, and
- Encourage systematic follow-up of patients receiving anticoagulation therapy.

Beyond numerical gains, the indicator has improved transparency, accountability, and peer learning within AC-MTAC services nationwide.

Challenges faced and how they were addressed

Several challenges were encountered during the development and validation of the indicator:

- First, tight reporting timelines initially limited facilities' ability to conduct thorough data cleaning and internal review. This was addressed by revising the submission deadlines in response to stakeholder feedback.

- Second, patient-related factors such as comorbidities, socioeconomic conditions, and medication adherence influenced TTR outcomes and were not fully within provider control. Refinement of inclusion and exclusion criteria helped reduce confounding and improve interpretability.

- Third, variability in documentation practices and data infrastructure across facilities affected consistency. National manuals, standardized calculation guidance, and peer-learning sessions helped harmonize practices and strengthen data quality.

Together, these responses improved both technical robustness and stakeholder confidence in the indicator.

Key lessons learned

Malaysia's experience highlights several transferable lessons:

- Sustained stakeholder engagement is critical to ensure relevance and feasibility

- Routine clinical data can support meaningful QoC indicators when standardized effectively

- Piloting in real-world settings strengthens indicator design and acceptability

- Simplicity and clarity are essential for uptake and use

- Alignment with national quality frameworks accelerates institutionalization.

What would you do differently?

In hindsight, Malaysia would have explicitly designed and documented a formal validation framework from the outset. Although validation occurred through multiple mechanisms, a clearly articulated validation plan and documentation could have further strengthened credibility, transparency, and alignment with international measurement standards. To further enhance oversight, monitoring would have been conducted at both 6- and 12-month intervals to ensure closer tracking and timely identification of any shortfalls. These combined strategies would reinforce Malaysia's commitment to continuous quality improvement in line with international standards.

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