Developing, validating and using a quality of care indicator for pharmacy enforcement: Special Operations for Controlled Substances (SOCS)

Country: Malaysia

Authors: Diana Tan Ai Hsin - Pharmacy Enforcement Division, Pharmaceutical Services Programme, Ministry of Health
Saidatul Sheeda Ahmad Shukri - Pharmacy Policy & Strategic Planning Division, Pharmaceutical Services Programme, Ministry of Health
Samsiah Awang, Nur Ezdiani Mohamed, Izzatur Rahmi Mohd Ujang - Centre for Health Quality Research, Institute for Health Systems Research, National Institutes of Health, Ministry of Health

Country snapshot

Pharmacy enforcement plays an essential role in Malaysia's efforts to prevent diversion and misuse of controlled substances, uphold regulatory requirements and protect communities. This learning brief outlines Malaysia's experience in developing, validating and using a national Quality of Care (QoC) indicator for enforcement activities conducted through Special Operations for Controlled Substances (SOCS). The indicator is monitored at the national level and operationalized at subnational levels through routine enforcement processes and the Electronic Data Pharmacy Enforcement System (eDPF), to guide ongoing performance monitoring and improvement. Here, the national level refers to the federal Ministry of Health headquarters, while subnational levels encompass the state-level pharmacy enforcement branches and their localized operational units.

Why was this quality of care indicator needed?

Diversion of controlled substances poses significant risks to public health, patient safety and regulatory integrity. SOCS are conducted to detect diversion elements, such as sales not for medical treatment purposes, failure to justify stocks/ records discrepancies, stocks not being purchased/ received by targeted premises, falsified recording/ document, and other suspicious activities for the purpose of initiating appropriate enforcement actions. However, prior to the development of this indicator, enforcement responses following detection of diversion elements varied considerably across states, with a heavy reliance on warning letters that had limited deterrent effect.

There was a clear need for a standardized national indicator to assess whether the detection of diversion elements was followed by appropriate investigative actions. The indicator was developed to strengthen

deterrence, improve consistency and accountability in enforcement practices, and support evidence-informed oversight of SOCS activities.

Key motivations included alignment with national regulatory and enforcement priorities, the availability of routine enforcement data within eDPF, and the need for a feasible indicator that could be embedded within the existing operational systems without adding reporting burden.

What was developed: overview of the indicator

Malaysia developed a national QoC indicator with a process focus, defined as **Percentage of cases with investigative actions taken following the detection of diversion elements during Special Operations for Controlled Substances (SOCS)**.

Rather than measuring clinical outcomes, the indicator focuses on whether identified diversion elements are followed by appropriate investigative action and the extent to which enforcement responses are consistent, effective and deterrent. Quarterly data are captured through the eDPF, where pharmacy enforcement officers document activities using individual accounts. Centralized review supports continuous monitoring of enforcement performance across all states.

How the indicator was developed

Governance and leadership

The Pharmacy Enforcement Division of the Pharmaceutical Services Programme, Ministry of Health Malaysia, led the indicator development process. Pharmacy Policy and Strategic Planning Division provided the strategic input with technical and secretariat support from the Institute for Health Systems Research.

Stakeholder management

Engagement with stakeholders was structured around operational realities and continuous feedback. The Pharmacy Enforcement Division first examined enforcement challenges using field experience and input from subnational units, then maintained ongoing dialogue with pharmacy enforcement officers at national and state levels to test implementation feasibility, clarify definitions and refine the indicator. Review through national quality assurance committees ensured that enforcement, policy and quality perspectives were jointly considered and that expectations for investigative actions were standardized nationwide.

Methodological approach

Development followed Malaysia's National Indicator Approach and applied the **SIFA** criteria to assess **S**cientific soundness, **I**mportance, **F**easibility and **A**ctionability. A problem analysis chart was used to identify gaps in enforcement responses following SOCS detections, including variation in the interpretation of diversion elements and investigative actions.

Baseline data from SOCS enforcement activities conducted between 2022 and 2024 were reviewed to understand existing performance and inform the selection of an achievable and meaningful standard. Literature review and internal policy analyses further informed definition and specification, while the feasibility of

measurement was ensured by relying on enforcement data already routinely captured through the Electronic Data Pharmacy Enforcement System (eDPF).

Following endorsement by the Deputy Director General of Health (Pharmaceutical Services), the proposed measure was reviewed and approved through the national quality assurance processes and subsequently adopted for routine monitoring under Malaysia's National Indicator Approach.

Validation of the indicator

Formal validation was embedded within national quality assurance processes. All newly proposed indicators undergo expert review by the Quality Assurance Technical Committee at the national level, which assesses relevance, feasibility, clarity of definitions, and alignment with enforcement objectives.

For this indicator, validation was supported by the fact that the required data were already being systematically collected through eDPF. Expert review focused on ensuring consistent interpretation of key terms, particularly "diversion elements" and "investigative actions". Following refinement, the indicator was approved by the National Quality Assurance Programme and implemented nationwide.

Integration into routine health information systems

The indicator is fully integrated into the eDPF. Following approval, a comprehensive manual and a Shortfall in Quality (SIQ) guide were developed and disseminated. Indicator monitoring is conducted centrally by the Pharmacy Enforcement Division, enabling regular review of performance trends and identification of enforcement gaps.

Capacity-building activities

Capacity-building was central to improving the consistency and effectiveness of indicator implementation. A Quality Assurance Programme (QAP) manual was disseminated to all pharmacy enforcement officers in January 2025. An online continuous professional development (CPD) session was conducted nationally in February 2025 to strengthen understanding of the indicator and enforcement expectations.

Further capacity-building included presentations during the Operational Work Committee Meeting (JKKO 1/2025) to heads of intelligence and operations at the state level, as well as targeted workshops for SOCS coordinators. These workshops focused on SWOT analysis, stakeholder analysis, review of SOCS workflows and the application of risk assessment tools.

Together, these activities helped harmonize understanding of diversion elements, investigative actions and enforcement standards across jurisdictions.

From measurement to use: applying the indicator in practice

The indicator is used at national level for monitoring enforcement performance, with data generated at operational and subnational levels. Integration within eDPF has enabled routine, systematic monitoring without additional reporting burden.

Indicator data are reviewed to identify variation in enforcement responses, guide supervisory discussions and inform revisions to SOCS guidelines and workflows. The indicator has strengthened accountability and supported more deterrent and standardized enforcement actions.

What changed: early results and observed value

Following implementation, a marked improvement was observed in enforcement performance. The percentage of investigative actions taken following detection of diversion elements increased from 68% (January–August 2024) to 90% (January–June 2025). This improvement suggests stronger deterrence, more consistent investigative follow-up and enhanced effectiveness of pharmacy enforcement actions against controlled substances diversion.

Challenges and how they were addressed

Key challenges included inconsistent interpretations of diversion elements and investigative actions, as well as variation in enforcement practices across officers and states. These challenges were addressed through standardized definitions, dissemination of updated manuals, targeted training and hands-on workshops for SOCS coordinators. Validation challenges related to differing interpretations were mitigated through national workshops held in July and September 2025, which aligned understanding and reinforced SOCS guidelines.

Key lessons for other countries

Malaysia's experience highlights several transferable lessons:

- Standardization of definitions and enforcement expectations is foundational,
- Capacity-building and training are essential for consistent implementation,
- Embedding indicators within routine operational systems strengthens sustainability,
- Risk-based and evidence-informed enforcement improves deterrence, and
- Iterative validation and analytical tools strengthen the relevance and actionability of indicators.

> ***What would you do differently?***
>
> *Looking back, conducting more hands-on, state-level workshops earlier in the process could have accelerated shared understanding of investigative actions and strengthened early buy-in among enforcement officers.*

Acknowledgment: The authors would like to thank the Director-General of Health, Malaysia, for his approval to publish this work. The authors declared no potential conflicts of interest regarding the conduct of this write-up.