Brief report

Urgent Call for Action: Bridging Gaps in Asia-Pacific Laboratories' Transition to ISO 15189:2022

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Abstract

ISO 15189:2022 introduces key updates to medical laboratory standards, emphasizing risk management, ethics, and technical competence. With the December 2025 deadline for ISO 15189:2012 to 15189:2022 transition nearing, a cross-sectional survey was conducted during the Asia-Pacific Federation of Clinical Biochemistry and Laboratory Medicine webinar on February 21, 2025, to assess readiness. On 303 total responses, awareness was high, with 85% familiar with the revised standard and 92% recognizing its stronger focus on risk management. Most (78%) viewed the transition as highly important, and 82% expected improvements in quality and patient care. Major barriers included financial constraints (65%), insufficient training (72%), and resistance to change (45%). Preparation efforts reported were gap analyses (68%), training programs (75%), and policy updates (70%). While optimism is strong, resource limitations and skills gaps threaten timely adoption. The findings highlight the urgent need for structured training, financial support, and expert guidance to help laboratories, particularly in resource-limited settings, meet the new requirements. Collaboration among laboratories, professional bodies, and regulatory authorities will be crucial to ensure a smooth and effective transition to ISO 15189:2022, enabling more accurate, reliable, and patient-centered diagnostics.

Brief Report

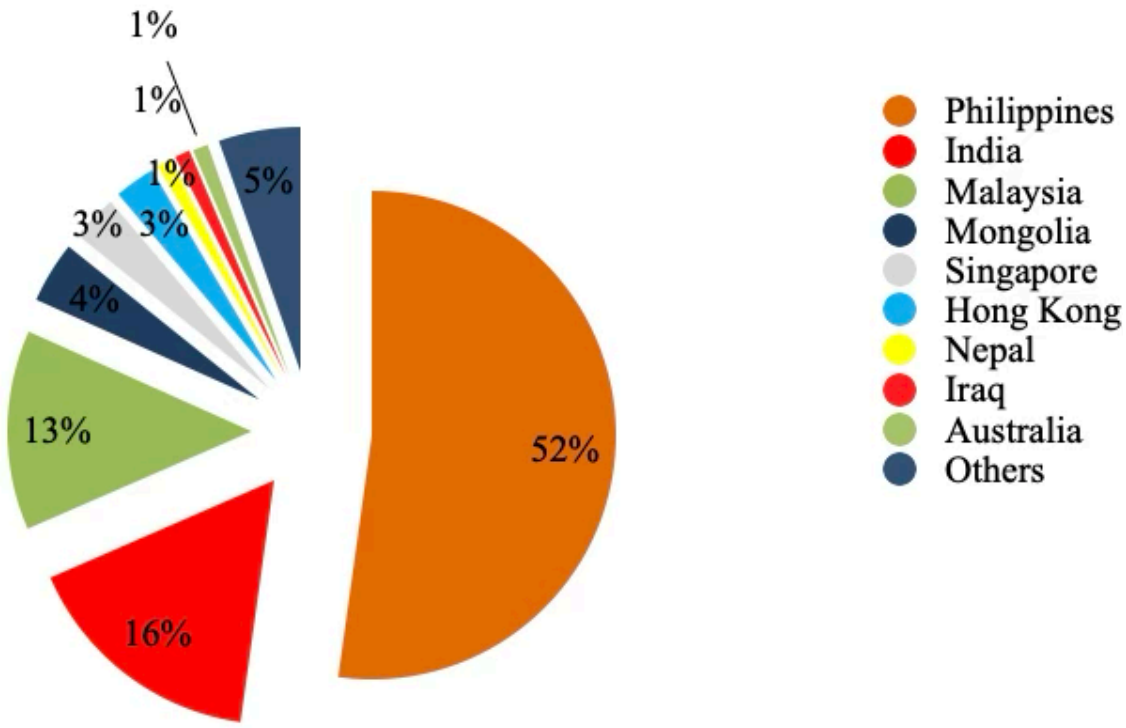
The impending December 2025 deadline for ISO 15189:2022 accreditation presents both an opportunity and a challenge for medical laboratories worldwide [1]. The December 2025 deadline refers to the end of the three-year transition period set by the International Laboratory Accreditation Cooperation (ILAC) for laboratories to move from ISO 15189:2012 to the 2022 version [1]. Our recent survey of 303 laboratory professionals across the Asia-Pacific region reveals critical gaps between awareness and implementation that threaten to leave many laboratories behind, particularly in resource-constrained settings. With 85% of respondents aware of the updated standard but only 20% in low-income countries having begun implementation, these findings demand immediate attention from accreditation bodies, professional organizations, and policymakers.

The transition to ISO 15189:2022 represents a significant evolution in quality management for medical laboratories. Building upon the 2012 version, the new standard emphasizes risk-based thinking, integrates point-of-care testing requirements previously covered under ISO 22870, and aligns more closely with ISO 17025 [2]. These changes aim to create a more robust, patient-centered approach to laboratory medicine. However, as our survey conducted during a February 2025 APFCB webinar demonstrates, many laboratories are struggling to translate these requirements into practice.

A cross-sectional, web-based survey was developed by the APFCB Communication and Publications Committee to assess regional readiness for the ISO 15189:2022 transition and its implementation. The questionnaire, validated for content by a multi-national panel of laboratory experts with no conflict of interest. It captured data across three core domains: awareness of the standard's changes, perceived implementation challenges, and current transition activities (Table 1). It was administered via the online One24 platform on February 21, 2025 following a webinar conducted for laboratory professionals and decision makers involved in accreditation [3]. Participants were instructed that only one response per institution from the primary decision-maker for accreditation (e.g., Quality Manager or Lab Director) should be submitted. From the 1,673 webinar attendees, this yielded 303 complete responses, each representing a unique institution, from professionals across 12 Asia-Pacific countries, with strong representation from India (n=48), Malaysia (n=39), Mongolia (n=12), and the Philippines (n=154) (Figure 1). Participants were allowed to select more than one response for relevant questions. Data were analyzed using descriptive statistics.

What emerged was a picture of uneven progress that correlates strongly with national economic resources. While high-income countries like Australia and Japan report 100% transition completion, laboratories in developing nations face multiple barriers.

Figure 1: Geographic Distribution of Participants across the Asia-Pacific.



Others: Pakistan, Indonesia, Macau, Japan, Thailand, Vietnam, UAE, China

Table 1: Summary of Survey Results on Knowledge, Perspective, and Practices regarding ISO 15189:2022 Transition.

Category	Key Findings	Percentage (number)
Awareness of ISO 15189:2022	Yes	**85% (258)**
	Somewhat aware	**10% (30)**
	No awareness	**5% (15)**
Key Changes Recognized	Enhanced focus on risk management	**92% (279)**
	New requirements for POCT	**78% (236)**
	Revised technical requirements	**65% (197)**
Sources of Information	Training sessions/workshops	**55% (167)**
	Professional associations	**25% (76)**
	Online resources	**20% (61)**
Perceived Importance	Very important	**78% (236)**
	Important	**18% (55)**
	Neutral/Not sure	**4% (12)**
Overall Attitude	Positive (will improve quality and patient care)	**82% (248)**
	Neutral (unsure of impact)	**15% (45)**
	Negative (unnecessary challenges)	**3% (9)**
Major Challenges	Financial constraints	**65% (197)**
	Lack of staff training	**72% (218)**
	Resistance to change	**45% (136)**
	Difficulty in updating procedures	**60% (182)**
	Limited access to expert consultation	**50% (152)**
Transition Steps Taken	Conducted gap analysis	**68% (206)**
	Provided staff training	**75% (227)**
	Updated policies and procedures	**70% (212)**
Tools Used for Transition	Internal quality teams	**50% (152)**
	Online training modules	**30% (91)**
	Consulting services	**20% (61)**
Additional Support Needed	More training for staff	**60% (182)**
	Increased budget allocation	**40% (121)**
	Access to expert consultants	**35% (106)**
	Clearer guidance documents	**30% (91)**

Financial constraints emerged as the most significant obstacle, cited by 65% of respondents. The costs associated with updating quality management systems, purchasing new equipment for compliance, and funding accreditation processes pose particular challenges for public laboratories in low-resource settings [4].

Even more concerning is the training gap, identified by 72% of participants as a major implementation barrier. The survey revealed that many laboratory professionals, while aware of the standard's existence, lack detailed understanding of specific requirements. A common misconception observed during post-webinar discussions was that risk management requires expensive software, whereas the standard intends a practical, patient-focused approach [5]. This misunderstanding highlights the need for clearer guidance and education about the standard's actual requirements.

Resistance to change within organizations presented another significant hurdle, mentioned by 45% of participants. This resistance is compounded by the fact that 60% of respondents reported difficulties in updating their procedures to meet new requirements, often due to limited access to expert consultation. The survey also examined current transition activities, revealing that most laboratories are relying on internal quality teams (50-70% across countries) rather than external consultants. While this approach may reduce costs, it potentially limits exposure to best practices. Common implementation steps included gap analyses (68%), staff training (75%), and policy updates (70%), though the depth and quality of these activities varied widely. Online training modules, which could offer scalable solutions, were underutilized (only 30-50% adoption), suggesting either lack of awareness or concerns about effectiveness.

Perhaps most responses were the regional disparities in

implementation progress. While 100% of participating Australian and Japanese laboratories had completed their transition, rates in other countries told a different story [Table 2]. The Philippines reported 70% of laboratories in planning stages, India 65%, Malaysia 60%, and Mongolia 80%. These numbers correlate closely with both national laboratory accreditation histories and healthcare funding levels, underscoring the economic dimensions of standards implementation [6-8].

Table 2: Country-Specific Challenges, Transition Progress, Tools Utilized, and Support Needs.

Country	Top Challenges	Transition Progress	Tools Used for Transition	Requested Support
Philippines (n=154)	Lack of staff training (75%, n=116), Budget constraints (70%, n=108)	Ongoing/Planning (70%, n=108)	Internal Quality Teams (50%, n=77), Online Training (40%, n=62), Consulting Services (30%, n=46)	Staff Training (80%, n=123), Budget Increase (60%, n=92)
India (n=48)	Staff training (65%, n=31), Resistance to change (50%, n=24)	Ongoing/Planning (65%, n=31), Completed (20%, n=10)	Internal Quality Teams (60%, n=29), Online Training (50%, n=24)	Staff Training (70%, n=34), Clearer Guidelines (40%, n=19)
Malaysia (n=39)	Limited understanding (60%, n=23), Budget (50%, n=20)	Ongoing/Planning (60%, n=23)	Internal Quality Teams (70%, n=27)	Budget Increase (50%, n=20)
Mongolia (n=12)	Budget constraints (80%, n=10), Staff training (60%, n=7)	Ongoing/Planning (80%, n=10)	Internal Quality Teams (70%, n=8), Online Training (60%, n=7)	Staff Training (90%, n=11)

The consequences of uneven implementation could be significant. Laboratories that fail to meet the 2025 deadline risk losing accreditation, potentially compromising patient care and international recognition of test results. This is particularly concerning for countries where laboratory medicine is still developing, as accreditation serves as a crucial quality benchmark. Moreover, the disparities may widen existing gaps in healthcare quality between high-income and developing nations in the region.

Our findings suggest several urgent interventions. First, targeted training programs must address both technical requirements and change management strategies. Second, accreditation bodies should consider developing tiered implementation pathways for resource-constrained settings. Third, regional professional organizations like the APFCB could establish mentoring programs pairing advanced laboratories with those earlier in their transition journey. Finally, clearer, simplified guidance documents with practical examples could help dispel common misconceptions about the standard's requirements.

This study has limitations inherent to its design. The use of convenience sampling from a webinar audience may introduce self-selection bias and limit the generalizability of findings, despite the event being targeted at senior laboratory professionals who are the decision makers for accreditation. Furthermore, the sample size varied significantly between countries, and the lack of specific demographic data on professional roles prevents analysis of how perspectives may differ by responsibility. Nonetheless, as an APFCB initiative, this brief report provides a crucial first assessment of the regional transition landscape, identifying key challenges to enable rapid dissemination and prompt further, more extensive research. The time for action is now. With few months remaining until the December 2025 deadline, laboratories across the Asia-Pacific need coordinated support to ensure no institution is left behind. This transition represents more than compliance, it's an opportunity to elevate the quality of laboratory medicine across the region. By addressing the identified gaps in training, resources, and guidance, we can turn this challenge into a catalyst for improved patient care and strengthened health systems throughout the Asia-Pacific.

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Ethical Approval

Participation in the survey was voluntary, and informed consent was obtained from all respondents before they proceeded with the questionnaire. Data confidentiality and anonymity were maintained throughout this survey study. This survey study was

conducted in compliance with the ethical principles for medical research involving human subjects, in accordance with the Declaration of Helsinki.

Author Contributions

VP, PKD: Conceptualization. VP: Formal analysis, Writing original draft. DP, PKD, MU: Data curation, Writing-Review and Editing. RO, MLS: Writing-Review and Editing.

Conflict of interest

None.

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