

Non-Conformance Clearance through an Intensified Mentorship towards ISO 15189 Accreditation: The Case of Jimma and Hawassa Hospital Microbiology Laboratories, Ethiopia

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Abstract : Background: Implementation of a Laboratory Quality Management System (LQMS) is critical to ensure accurate, reliable, and efficient laboratory testing of antimicrobial resistance (AMR). However, limited LQMS implementation and progress toward accreditation in the AMR surveillance laboratory testing setting exist in Ethiopia. By addressing non-conformances (NCs) and working towards accreditation, microbiology laboratories can improve the quality of their services, increase staff competence, and contribute to mitigate the spread of AMR. Methods: Using standard ISO 15189 horizontal and vertical assessment checklists, certified assessors identified NCs at Hawassa and Jimma Hospital microbiology laboratories. The Ethiopian Public Health Institute AMR mentors and IDDS staff prioritized closing the NCs through the implementation of an intensified mentorship program that included ISO 15189 orientation training, resource allocation, and action plan development. Results: For the two facilities to clear their NCs, an intensified mentorship approach was adopted by providing ISO 15189 orientation training, provision of buffer reagents, controls, standards, and axillary equipment, and facilitating equipment maintenance and calibration. Method verification and competency assessment were also conducted along with the implementation of standard operating procedures and recommended corrective actions. This approach enhanced the laboratory's readiness for accreditation. After addressing their NCs, the two laboratories applied to Ethiopian Accreditation Services for ISO 15189 accreditation. Conclusions: Clearing NCs through the implementation of intensified mentorship was crucial in preparing the two laboratories for accreditation and improving quality laboratory test results. This approach can guide other microbiology laboratories' accreditation attainment efforts.

Keywords : non-conformance clearance, intensified mentorship, accreditation, ISO 15189

Conference Title : ICLMCR 2024 : International Conference on Laboratory Medicine and Clinical Research

Conference Location : Washington, United States

Conference Dates : February 26-27, 2024