African Journal of Laboratory Medicine
ISSN: (Online) 2225-2010, (Print) 2225-2002

A comparative framework for regulatory oversight in Malawi's medical laboratory professionals: Lessons from Kenya and Nigeria

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Dates:
Received: 10 July 2025
Accepted: 11 Oct. 2025
Published: 29 Nov. 2025

How to cite this article:
Chipofya E. A comparative framework for regulatory oversight in Malawi's medical laboratory professionals: Lessons from Kenya and Nigeria. Afr J Lab Med. 2025;14(1), a2941. https://doi.org/10.4102/ajlm.v14i1.2941

Robust professional regulatory oversight is crucial for ensuring the competence of healthcare practitioners and maintaining high-quality health systems.[1,2] This is particularly vital for medical laboratory professionals, whose work underpins most clinical decisions, directly impacting diagnostic accuracy, treatment efficacy, and, ultimately, patient safety.[3] When professional oversight is weak or violated, patient safety is directly compromised, leading to inconsistent care, an erosion of public trust, and potentially catastrophic outcomes.[4] In healthcare, regulation is a policy that sets external rules for medical practice and administration, representing a sustained form of control by a public agency. Regulatory oversight, a related but distinct concept, is the policy-driven mandate that translates these regulations into practical application.[5] Its practical application is seen in the structured processes that govern the education and professional development of health professionals. The primary mandates of regulatory oversight, including accreditation, licensure, and certification, are the key mechanisms for ensuring the initial and ongoing competence of medical practitioners.[6]

Until the late 1960s, comprehensive global regulation for healthcare professionals, specifically in laboratory medicine, was limited. Today, however, countries such as Canada and the United Kingdom demonstrate the immense value of professional oversight.[2,7] This trend has extended to many African low- and middle-income countries, which have established formal regulatory frameworks for medical laboratory practice. For instance, the Kenya *Medical Laboratory Technicians and Technologists Act of 1999* established the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), responsible for the regulatory oversight of training, registration, and licensing to ensure professional standards and quality control.[8] Similarly, the Medical Laboratory Science Council of Nigeria (MLSCN), established by the 2003 *Medical Laboratory Science Council of Nigeria Act*, holds responsibility for the regulatory oversight of its professional community.[9] While these formal frameworks are vital for public health, robust oversight is often lacking in many low- and middle-income countries, where regulators are frequently resource-constrained, and oversight may be perceived as weak.[10]

Malawi's foundational medical regulation dates to the Registration of Medical Practitioners Ordinance, No. 9 of 1906, which first governed medicine in the British protectorate of Nyasaland (now Malawi) and established the Nyasaland Medical Council.[11] This was later superseded by the *Medical Practitioners and Dentists Act* of 1987, which created the Medical Council of Malawi (MCM).[12] The Act, outlined in Part IV, section 10, gives the MCM a broad mandate for regulatory oversight, including registering practitioners, overseeing training, and exercising disciplinary control.[12,13] Despite these foundational regulations, Malawi's healthcare system faces a significant regulatory oversight gap that endangers patient safety. The *Medical Practitioners and Dentists Act* of 1987 in Malawi is critically deficient, failing to establish a dedicated framework for the professionalisation, training, and continuing development of medical laboratory professionals. This oversight deficiency means this vital workforce lacks the robust, consistent oversight found in countries such as Kenya and Nigeria, which consequently compromises diagnostic accuracy and professional growth. This article addresses the gap by comparatively analysing the regulatory frameworks of Malawi, Kenya, and Nigeria. The analysis identifies key weaknesses in Malawi's approach, demonstrating the 1987 Act's need for substantial revision to meet modern international standards. The resulting evidence-based recommendations aim to strengthen professional governance, ultimately improving patient safety and public health outcomes in Malawi.

The regulatory process for healthcare professionals is a cohesive system with six interconnected components. It begins with (1) the accreditation of pre-service education, ensuring training institutions meet established curriculum standards.[14] This is followed by (2) a thorough competency assessment

to officially certify that individuals can effectively apply their skills and knowledge, which is vital in a rapidly evolving field like laboratory medicine.[7,15] These competencies are then formalised through (3) a comprehensive system of registration, certification, and licensing.[15,16] Concurrently, (4) a clear scope of practice is defined and enforced to clarify authorised tasks, prevent patient safety risks, and improve efficiency.[16] To ensure competence is maintained, (5) mandatory continuous professional development (CPD) requires lifelong learning in response to rapid scientific advances.[2,17] Finally, (6) the system upholds professionalism, which includes a commitment to public service and ethical behaviour. Unprofessional conduct is the most common reason for disciplinary measures, and can significantly undermine public trust, directly affecting public health.[18]

Malawi has a long and notable history of training medical laboratory professionals, with its first reputable programme established in 1968 at Malamulo College of Health Sciences. This programme was so well regarded that it attracted students from across Africa, including Zambia, Lesotho, Uganda, Zimbabwe, Botswana, the Democratic Republic of Congo, Eswatini, Sierra Leone, Ghana, Sudan, Ethiopia, and Rwanda.[19,20] This legacy is further evidenced by the MCM having registered 65 diplomas (3 years of training) and 79 certificates (2 years of training) from both Malamulo and Malawi College of Health Sciences between 1988 and 1999.[13]

Despite this rich history, the medical laboratory profession's growth is now hindered by a legislative gap in the *Medical Practitioners and Dentists Act* of 1987, a stark contrast to the dedicated statutory frameworks found in neighbouring countries such as Kenya, Nigeria, and South Africa. This gap in the primary regulation is, to some extent, mitigated but not eliminated by the MCM's active regulatory oversight (a policy-driven mandate). This oversight is evidenced by recent formal policy tools, such as the comprehensive Undergraduate and Postgraduate Curriculum Standards, the corresponding Assessment Checklists, the Initial Inspection Checklist for Training Institutions, and the Standard Operating Procedures for curriculum approval.[21,22,23,24,25,26]

The persistent challenge confronting medical laboratory professionals in Malawi is a regulatory misalignment that originated in 2004. At that time, key academic institutions (the Malawi College of Health Sciences and Malamulo College of Health Sciences) sought to modernise their training and align it with global benchmarks by proposing to rename the qualification from Medical Laboratory Technology to Biomedical Sciences. Crucially, this academic modernisation shift was not formally recognised by the MCM. Instead, the MCM maintained the outdated, traditional professional registration titles: Medical Laboratory Assistants (for certificate holders) and Medical Laboratory Technicians (for diploma holders).

This initial regulatory discrepancy continues to pose a significant problem. For example, the Kamuzu University of Health Sciences (KUHeS) later renamed its undergraduate programme (introduced in 2006) from Medical Laboratory Technology to Medical Laboratory Sciences. Despite the curriculum having undergone multiple important reviews in 2009, 2014, and 2016, KUHeS graduates face the identical regulatory hurdle: the MCM still mandates the use of the older title, Medical Laboratory Technologists, for official professional registration.

Furthermore, KUHeS introduced a similar, separate Bachelor of Science in Biomedical Sciences programme in 2021. This creates a further complication, as the existence of different curricula for related disciplines at the same institutions, which can lead to internal competition for limited resources and negatively affect educational quality.

These educational challenges are supported by a survey of African laboratory professionals by Maruta, Mataka and Moyo, which provides empirical evidence of core training issues. The most common problems identified were a significant lack of resources and equipment (37.5%), limited clinical exposure (19.0%), insufficient curriculum coverage (9.5%), and inadequate faculty (7.7%).[27]

The issue is further complicated by the MCM's public notice of 23 September 2024, formally acknowledging Medical Laboratory Sciences at the KUHeS as a regulated profession. However, the same notice concurrently indicated that the similar Bachelor of Science in Biomedical Sciences falls outside its regulatory scope. This disparity is starkly contrasted by the programme's establishment timeline: the Bachelor of Science in Biomedical Sciences was established by Mzuzu University in 2007, while KUHeS introduced its similar, separate programme in 2021. Graduates of the Mzuzu University programme can register as medical laboratory technologists under the statutory regulatory body.

This demonstrates a critical inconsistency: while the MCM regulates one title, the similar Biomedical Sciences title is not consistently protected across institutions, leading to varying registration eligibility. Since the MCM regulates practice, not the universities, these inconsistencies in the programme curricula under the MCM's purview cause significant confusion with regard to employment criteria.

The root cause of these regulatory disparities is not the absence of a framework, but rather the MCM's use of a principles-based standards framework. This approach, adopted in the revised standards for undergraduate and postgraduate education, prioritises programme rationale, learning outcomes, and format compliance over mandated, uniform content and titling across equivalent allied health disciplines, including the medical laboratory profession. This regulatory flexibility unintentionally permits the non-uniformity observed in equivalent titles across institutions, despite the MCM's mandate to regulate practice.[21,22]

This failure in regulatory clarity is mirrored by the varied landscape of professional training across the African region.

A previous expert study, drawn from an analysis of the region, demonstrated that although most professionals were trained at public institutions (82%), qualifications lacked uniformity. The bachelor's degree (53%) was the most common first qualification, but qualification names were non-uniform, with Medical Laboratory Sciences (43%) being the most prevalent title, followed by Medical Laboratory Technologist (20%) and Medical Technology (19%). Furthermore, while most qualifications included curriculum content such as genetics, molecular biology, cytology, laboratory management, histology, blood transfusion, haematology, immunology, chemistry, and microbiology, a standardised framework is still necessary to ensure consistency across all training institutions.[27]

The consequences of this regulatory confusion are starkly evident in the workforce. A literature review on standard occupation classifications by Koo confirmed a wide range of global titles for the same roles, including medical laboratory scientist, medical technologist, clinical laboratory scientist, biomedical scientist, biomedical analyst, and medical laboratory technician.[28]

The absence of a clear, national title in Malawi allows these different terms to be used interchangeably for the same roles. This lack of a defined professional identity and consistent regulation directly jeopardises diagnostic quality and patient safety by permitting unqualified individuals to assume critical roles.[12,29] It also hinders career progression by creating confusion in employment criteria and contributing to the paradox of a high number of unemployed professionals, despite a significant national personnel gap. Ultimately, the absence of a defined identity and consistent regulation for these vital medical laboratory professions directly jeopardises diagnostic quality and patient safety, while also hindering career progression.

The governance structure for medical laboratory professionals in Malawi, defined by the *Medical Practitioners and Dentists Act* of 1987, embodies a model of subordination and indirect oversight. While the MCM attempts to define Allied Health Professions, including medical laboratory professionals, via its Code of Ethics, the primary legislation fails to formally recognise them.[12,13,29] Crucially, the profession suffers a significant systemic disadvantage because of its limited and indirect representation on the MCM.[20] As stipulated in Section 4 of the Act, the council's membership is dominated by medical practitioners and dentists, explicitly excluding a dedicated seat for the medical laboratory profession. The Act reserves positions for: the Chief of Health Services, a medical practitioner and a dentist from the public service, a medical practitioner from the Christian Health Association of Malawi, five members from the Medical Association of Malawi, a medical practitioner representing KUHeS, the Secretary for Justice and Solicitor General, and at least three members from the general public (one being a medical practitioner or dentist in private practice).[12,13] This lack of direct involvement of medical laboratory professionals inherently impedes their capacity to effectively shape their own professional regulation, ethical oversight, quality assurance, and accreditation.[20,30] Furthermore, Malawi's broad, centralised framework is vulnerable to political influence because the MCM's council members and chairman are appointed directly by the Minister.[12,13] This political entanglement frequently undermines effective regulatory oversight, leading to deflected accountability and the bypassing of professional protocols.[10,31]

This Malawian model stands in stark contrast to the frameworks established in regional counterparts such as Kenya and Nigeria, which operate under a paradigm of dedicated professional self-regulation. Establishment of separate, dedicated statutory councils is done by both the Kenya *Medical Laboratory Technicians and Technologists Act* (Cap 253A, 1999; the KMLTTB) and the *Medical Laboratory Science Council of Nigeria Act* (2003; the MLSCN). These bodies are explicitly empowered as independent entities to supervise, control, and regulate all facets of the profession, from prescribing training courses and approving institutions to professional licensing and ethical conduct. Significantly, their governing boards are composed predominantly of practising medical laboratory professionals, often elected by their own associations. This model ensures that regulatory standards and policy development are driven by specialised expertise and professional ownership.[8,9] This structure directly addresses Malawi's challenge of political entanglement by creating independent, profession-specific corporate bodies.

The operational deficiencies confronting the Malawian model, where the MCM faces a critical challenge rooted in a widespread misunderstanding of its roles among both the public and practitioners, further emphasise the benefits of autonomous regulatory frameworks.[13,32] This internal confusion is severely compounded by persistent underfunding, as insufficient government budgetary allocations have consistently failed to support the MCM's rigorous oversight and disciplinary actions for over a decade.[13] This financial constraint aligns with broader concerns that limited resources hinder regulators' capacity for high-quality, policy-relevant research,[33] forcing the MCM to rely on fragmented, small-scale studies that impede evidence-informed policy development.[17,34] By contrast, the dedicated statutory bodies in Kenya (KMLTTB) and Nigeria (MLSCN) are structurally better positioned, by virtue of their focused mandate and professional governance, to minimise operational confusion, manage public awareness, and advocate for sustainable, profession-specific funding models.[8,9]

The critical divergence concerns professional standardisation and quality assurance. Malawi's regulatory framework for medical laboratory staff, from assistants to post-graduate scientists, suffers from a fundamental lack of clearly defined roles and a structured scope of practice. This deficiency is in sharp contrast to established models, such as that for laboratory medicine consultants, which mandate a precise definition of competencies and job descriptions.[35] Indeed, since the scope of practice defines the necessary tasks, titles,

and qualifications associated with medical laboratory science,[15] its absence critically compromises professional clarity and quality control. Compounding this issue is the absence of requirements for external verification of qualifications, statutory professional accreditation, and competency assessments.[17] This collectively results in a severe lack of professional consistency, where numerous titles can be applied to identical roles, compromising the profession's identity and mirroring issues found in unregulated systems that lack a protected title for medical laboratory professionals.[36] These systemic failures significantly degrade service quality, lead to poorer patient outcomes, impede professional development, and heighten the threat of brain drain.[37] Conversely, models in Kenya (KMLTTB) and Nigeria (MLSCN) successfully mitigate these problems by establishing independent, profession-specific corporate bodies with governing boards primarily composed of practising professionals. This self-governing mandate ensures rigorous control over entry and quality, while structurally positioning them to minimise political interference, manage public awareness, and effectively enforce the precise competency requirements that Malawi's multi-disciplinary, politically entangled system fails to maintain.

Professionalism encompasses a high level of intellectual and technical expertise, the ability to practise independently, and a strong commitment to public service.[38] Regulatory oversight requires that practitioners consistently demonstrate a high standard of professional conduct, including probity and ethical behaviour. Unprofessional or unethical conduct is the most common reason for disciplinary action taken by regulatory agencies and professional organisations.[18] The MCM frequently receives allegations regarding issues such as illegal drug possession, operating unregistered premises, professional negligence, and practitioners providing services they are not competent to deliver.[13] The MCM's Code of Ethics and Professional Conduct explicitly outlines these as professional misconduct for which practitioners can face disciplinary action.[13,29] Beyond tracking these punitive actions, a more objective measure of whether regulatory oversight delivers a competent workforce and enhances patient safety is to compare data on pathology-related errors.[15,39] However, these data are unavailable in Malawi. The lack of a reliable error repository stems from systemic failures: frequent pre-analytical errors occur because of extreme delivery delays that deteriorate samples, and severe supply shortages (reagents, correct tubes, stationery) that force inadequate data recording.[39] Together, these factors create operational instability, making the collection of systematic errors impractical for directly assessing the regulatory impact on patient safety.

The Medical MCM operates with a policy-driven mandate for regulatory oversight of its CPD programme, a core component of its overall regulatory framework. This programme, initiated in 2008 under the *Medical Practitioners and Dentists Act* of 1987, serves to ensure practitioners maintain competence and uphold ethical obligations, a requirement reinforced by the MCM's *Code of Ethics and Professional Conduct*.[17,29,34] However, several critical issues undermine the programme's practical implementation. First, the required annual point total saw an adjustment: the initial mandate of 50 CPD points for license renewal was later deemed unrealistic and revised to 30 points annually, which is the minimum explicitly stated in the official Malawi CPD Diary that practitioners must present for certification renewal.[34] Second, while the CPD Diary explicitly provides detailed CPD codes (A through I) and rules for point calculation across nine distinct categories (e.g., specific caps on clinical meetings and conferences, or a point range for publications), this intricate, manual system is criticised in the academic literature for its inherent complexity and administrative burden, leading to a lack of operational clarity and practical consistency in its application and verification.[17,34] Finally, this issue of consistency is compounded by the fact that CPD activities are often confined to medical officers in the urban areas, thus creating a problem of professional isolation for practitioners in rural settings who lack access to necessary resources and electronic services.[17] This is compounded by limited published information on the programme and generally low compliance rates in the country. A major barrier is the association of CPD activities with financial incentives such as *per diems* (daily allowances or payments provided to individuals, specifically healthcare workers, for attending training sessions, workshops, or seminars).[17,40] This system prioritises monetary gain over genuine learning, leading to a lack of motivation when payments are absent, and has even resulted in training boycotts and pressure to share allowances with supervisors.[40] Additionally, the MCM's regulations create a significant loophole, as CPD is not mandatory for all healthcare cadres, particularly the medical laboratory profession. This regulatory gap can lead to outdated skills, directly impacting diagnostic accuracy and delaying the adoption of new technologies.[41] Furthermore, many medical professionals, especially those in rural areas, face limited access to CPD opportunities because of a lack of essential resources such as computers and internet access.[34] The programme is also perceived as being primarily for senior urban medical personnel, and some staff believe that skills are best updated through long service rather than formal training.

By contrast, countries such as Nigeria and Kenya offer more effective models for regulatory oversight, particularly for specialised cadres. Nigeria (MLSCN) and Kenya (KMLTTB) have both implemented specific, targeted CPD frameworks for medical laboratory professionals.[42,43] These frameworks detail how points are awarded for activities, from degrees to publications, ensuring clarity and accountability, which addresses a key challenge in Malawi. While Nigeria's system has faced issues with sponsorship,[41,44] Kenya stands out with strict sanctions for non-compliance, including licence suspension.[43] This directly contrasts with Malawi's problem of financial incentives (*per diems*) driving CPD participation, often causing training boycotts when payments are absent.[17,40] The structured, profession-specific regulations in Nigeria

and Kenya thus offer concrete models for Malawi. By improving its administration, mitigating the reliance on financial incentives, and ensuring equitable access, Malawi could align its policy-driven mandate with more effective practical implementation.

Based on the current landscape and international best practices, the following key recommendations are proposed to strengthen the medical laboratory profession:

- Enact a dedicated medical laboratory professionals Act (specialisation)
  - **Action:** Legislate a new, profession-specific Act to replace the current broad, multidisciplinary council model.
  - **Goal:** Establish an independent or highly autonomous regulatory body to define and regulate all cadres, including postgraduates.[20,30] This model must be consistent with Kenya's KMLTTB and Nigeria's MLSCN, ensuring professional duties align with their education and authority.[35]
- Reform the *Medical Practitioners and Dentists Act* (Chapter 36:01 of the Laws of Malawi)
  - **Action:** If a dedicated Act is not feasible, the 1987 Act requires significant reform.
  - **Goal:** The Act's governance must be reformed to mitigate political influence.[20] This requires a merit-based appointment process and mandatory dedicated council representation for medical laboratory and paramedical staff to counter dominant professional bias.[45] This revised structure should align with multi-professional bodies such as the Health and Care Professions Council (United Kingdom) and the Health Professions Council of South Africa.[46,47]
- Implement mandatory, competency-based continuous professional development
  - **Action:** Make mandatory, competency-based CPD a prerequisite for the annual re-registration of all regulated professionals.
  - **Goal:** Ensure consistent standards and diagnostic accuracy through mandatory, verifiable competency assessments.[41,46] Continuous professional development must cover gaps in pre-service training, specifically laboratory accreditation and quality management systems.[41] The MCM must ensure that the CPD is well-structured and tailored.[27] Competency frameworks should be developed by the MCM, training institutions, or professional working groups, including the Malawi Association of Medical Laboratory Scientists.[16,48]
- Establish a rigorous accreditation and licensing system for training
  - **Action:** Develop and strictly enforce a rigorous, independent accreditation system for all medical laboratory training programmes and institutions.
  - **Goal:** Address major challenges: lack of resources/equipment, limited clinical exposure, and inadequate faculty.[27] A standardised national curriculum and classification framework is crucial to end the discrepancy between academic and regulatory titles, which causes inconsistent registration eligibility. Licensing and inspection must be robust, and accreditation should be transparent and independently evaluated.[14] Accreditation must mandate minimum content, including microbiology, biosafety/biosecurity, and laboratory management.[27]
- Enhance transparency and accountability mechanisms
  - **Action:** Significantly enhance the transparency and accountability of regulatory operations.
  - **Goal:** Enhance enforcement and public trust by publishing regular, publicly accessible reports on regulatory activities, finances, and performance. Clear, robust, and independent processes for public complaints and professional appeals are essential.
- Foster professional engagement and ownership
  - **Action:** Strengthen professional engagement and foster a sense of shared ownership amongst healthcare practitioners.
  - **Goal:** Counter political influence by establishing formal dialogue platforms between the MCM and professional bodies (e.g. the Malawi Association of Medical Laboratory Scientists), to ensure shared regulatory responsibility. Prioritise empirical research to ensure regulations are feasible and effective. Supporting local regulation empowers professionals and fosters ownership.[10]
- Delineate scopes of practice and establish career progression pathways
  - **Action:** Develop and implement clearly delineated scopes of practice for each distinct professional grade.
  - **Goal:** Address ill-defined scopes of practice and limited career progression.[20,30] The MCM, training institutions, and the Malawi Association of Medical Laboratory Scientists must formally define the scopes of practice, aligning them with competency principles.[35] Establish attractive career pathways, including formal designation of managerial/non-managerial posts and laboratory-specific post-graduate training (up to PhD level) with defined, compensated career paths.[27,41] This is crucial for professional retention and improving job satisfaction.

In conclusion, Malawi's laboratory services are severely compromised by a confluence of deeply entrenched and interconnected challenges. By addressing these issues, Malawi can not only safeguard its own public health but also serve as a crucial case study for how a targeted and profession-specific regulatory approach can fundamentally transform healthcare governance and outcomes in similar resource-constrained environments.

Acknowledgements

The author thanks Dr Graham Beastall and Dr Mike Hallworth for their valuable insights and guidance during the conceptualisation and development of this opinion paper.

Competing interests

The author declares that no financial or personal relationships inappropriately influenced the writing of this article.

CRediT authorship contribution

Elias Chipofya is the sole author of this article.

Ethical considerations

This article followed all ethical standards for research without direct contact with human or animal subjects.

Sources of support

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Data availability

No new data were generated or analysed for this opinion paper. All information synthesised is derived from publicly available literature and reports, as detailed in the references.

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