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Engineering Report

Healthcare Technology Management in Ethiopia

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ABSTRACT

This document provides an in-depth analysis of healthcare technology management (HTM) in Ethiopia, identifying significant deficiencies and challenges in the management of medical devices (MDs) within the healthcare system. The primary objective of this study is to identify gaps in the lifecycle management of MDs in Ethiopia and to provide recommendations for improvement. The findings reveal a conspicuous absence of a dedicated MD policy and health technology assessment (HTA) institutes, leading to inefficiencies, as MDs are managed under drug policies. Biomedical engineers (BMEs) play a crucial role in managing the entire lifecycle of MDs, which can mitigate risks and corruption associated with these devices. However, the healthcare system faces several challenges, including a lack of quality control measures, inadequate training for BMEs, and poor integration between universities and health facilities, all of which impact the effectiveness of HTM. The document recommends the establishment of a national HTA institute, the formulation of a dedicated MD policy, and the enhancement of links between educational institutions and healthcare facilities to improve the management of MDs. Strengthening the role of BMEs and implementing robust systems for HTM are essential for improving healthcare quality and patient safety in Ethiopia.

Keywords—*Healthcare technology management (HTM), Health technology assessment (HTA), Health technology regulation (HTR), Biomedical engineer (BME), Biomedical technicians (BMT), Regional health bureaus (RHB).*

INTRODUCTION

Health Technology Management in Ethiopia

Health technology management (HTM)—particularly in the realm of medical devices (MDs)[1]—is underdeveloped and underrecognized in Ethiopia's healthcare system. While some progress has been made, current efforts remain narrowly focused on maintenance, failing to establish a comprehensive and system-wide HTM framework. The risk level of medical devices is shown in Figure 1.

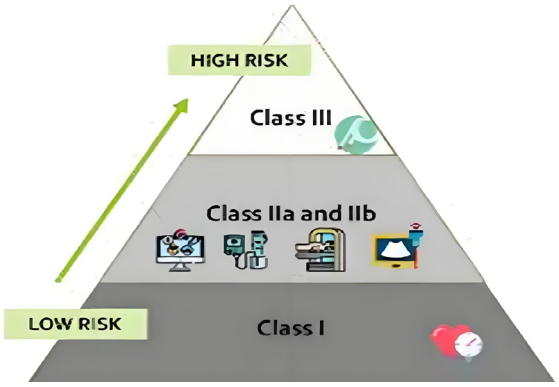

FIGURE 1. Risk level of medical devices.

Systemic Gaps in HTM Implementation

• Ethiopia lacks a full-fledged HTM system. Existing mechanisms do not account for internal and external influencing factors (Figure 2).

• HTM activities are fragmented and often fall under pharmaceutical policies and institutions, resulting in blurred responsibilities.

Marginalization of Biomedical Engineering (BME)

• According to the WHO's role of BME in HTM guidance (Figure 3), BME involvement across the full life cycle of MDs in Ethiopia is invisible or sidelined.

• Most notably, BME professionals are excluded from key processes such as procurement, where pharmacists have assumed authority.

• This is institutionalized through the job description (JD) of pharmacists at all levels of the health system, including in the Ministry of Health-Human Resources (MoH-HR).[2]

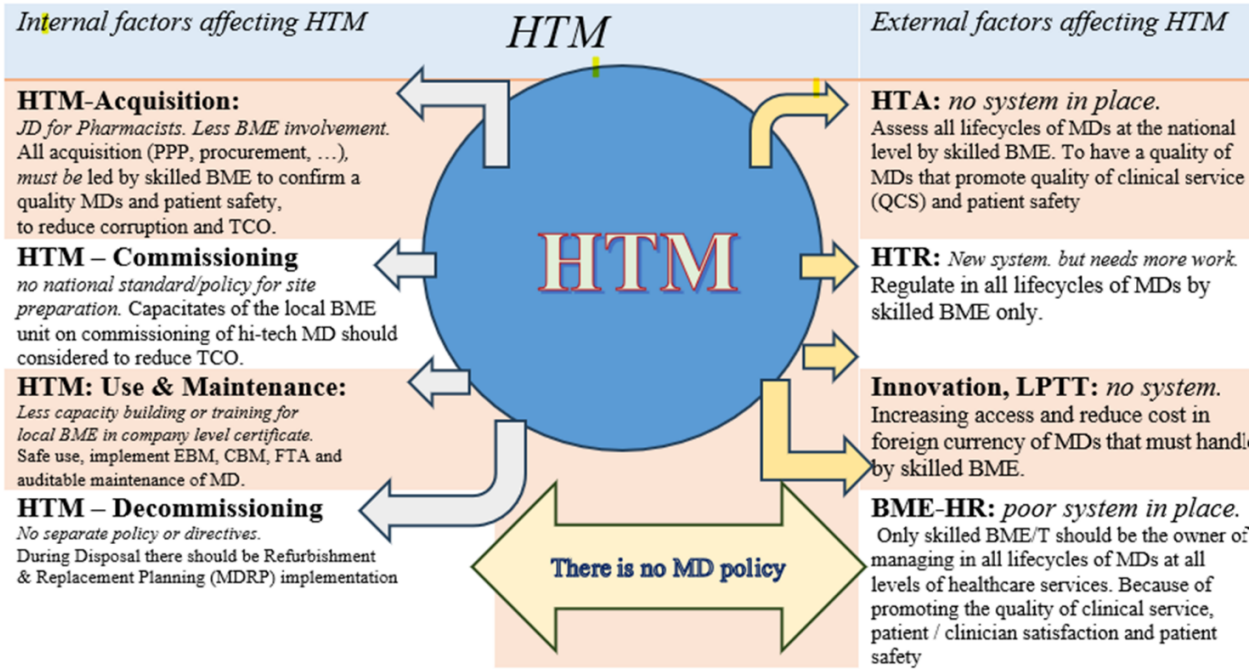

FIGURE 2. HTM determinant factors in the Ethiopian MOH situation.

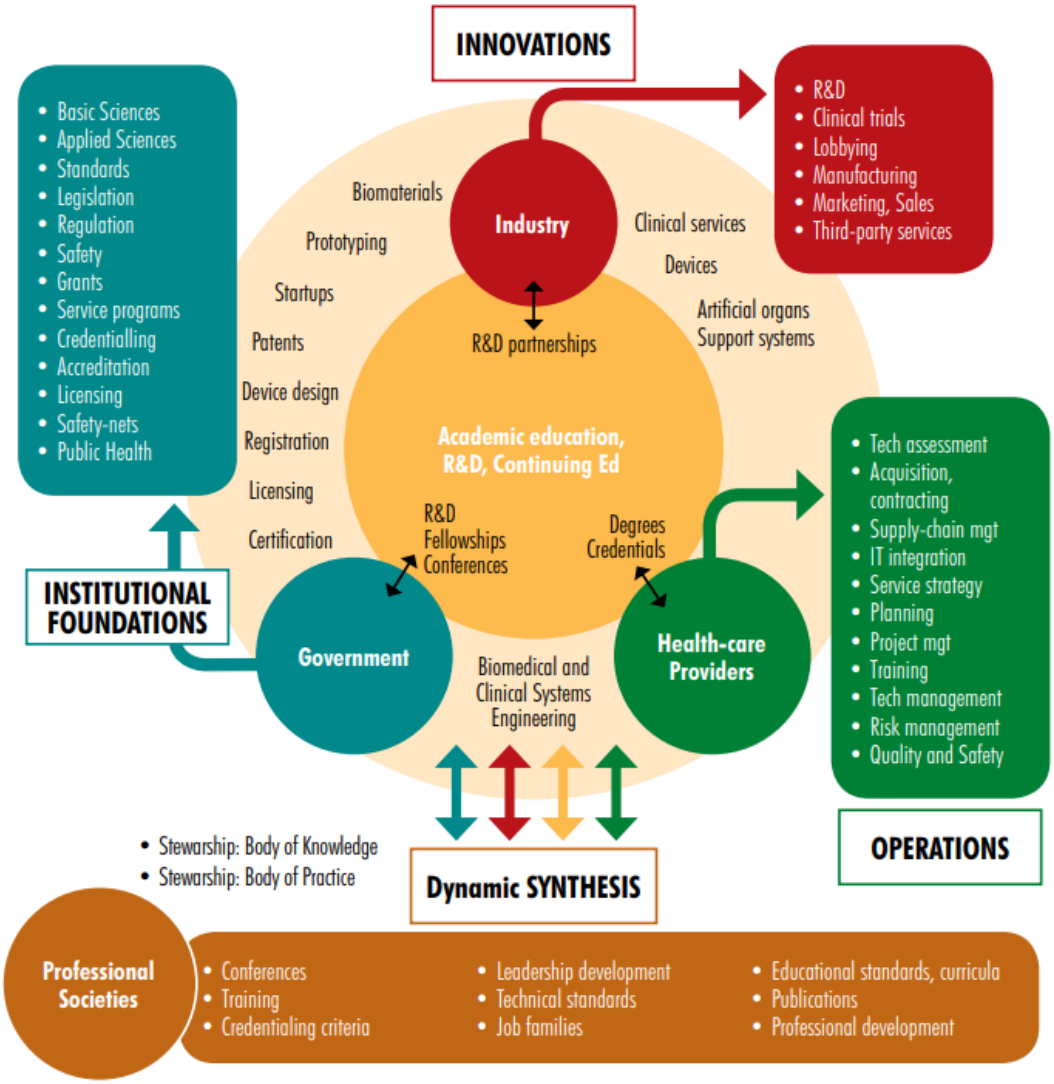

FIGURE 3. Role of BME in healthcare sectors (WHO).

Workforce and Equity Issues

• There exists a salary disparity: A 4-year pharmacy graduate earns significantly more than a 5-year BME graduate, reflecting the undervaluation of BME roles.

• Pharmacists currently lead HTM functions across:

o Regional health bureaus (RHBs)

o Some health facilities

o MoH and its agencies (e.g, Ethiopian Pharmaceutical Supply Service 'EPSS')

Historical Context and Policy Misalignment

• The 1993 drug policy has been the de facto framework for managing MDs, grouping them under medicinal products. Currently, an ongoing revision process is underway.

• The formerly effective techno-center that managed HTM at the national level was disbanded because of decentralization, leaving BME out of leadership roles.

• While the Ethiopian Food and Drug Administration and Control Authority (EFMHACA). Now, the Ethiopian Food and Drug Authority (EFDA) and EPSS were formed

to fill this gap, and pharmacists continue to dominate HTM leadership, sidelining technical experts.

• A new medical and medicine policy (MMP) and roadmap have been drafted, but they conflate medicines and MDs, risking continued mismanagement.

The ACCE leaders are presented in Figure 4, and the chronological order of the gradual growth of the CE/BME field in Ethiopia is shown in Figure 5.

FIGURE 4. From right to left: Jennifer Jackson (Former Chair of ACCE), Mulugeta (Former S&T Commissioner), Dr. Tedros Ghebreyeesus (Former Minister of MoH, now Director-General of WHO), Dr. Ismael Cardero (Former Orbis Eye Foundation engineer), Peter Heiman (Former WHO technical advisor, head of Health Mission in Laos), Andrei Issakov (Former head of Medical Devices Unit at WHO), last person on the left Gebru (Former ESEC-Director). Photo taken during the 6th ACEW in Addis Ababa, Ethiopia, in 2006.[6]

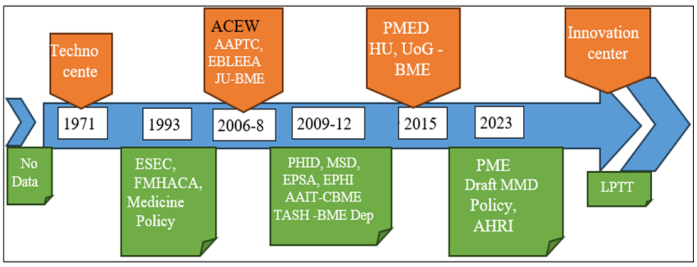

FIGURE 5. The chronological order of the gradual growth of the CE/BME field in Ethiopia.

Historical Evolution and Institutionalization of BME in Ethiopia

The Role of the Ministry of Science & Technology (MoST)

In the absence of a centralized techno-center, the MoST played a pivotal role in sustaining and promoting the field of biomedical engineering (BME) in Ethiopia.

A key turning point was the Sixth American Clinical Engineering Workshop (ACEW) held in 2006 in Addis Ababa, in collaboration with the MoH. This event significantly:

• Raised awareness about the importance of BME.

• Stimulated interest and recognition from the MoH.

• Triggered national-level action to establish BME training and professional development programs.

Institutional Milestones in BME Education & Professionalization

Following the ACEW:

• Addis Ababa Polytechnique College (AAPT) initiated the first formal Biomedical Technicians (BMT) program.

• The Ethiopian Biomedical and Laboratory Equipment Engineering Association (EBLEEA) was established (2007–2009), creating a professional platform for engineers.

Between 2008 and 2015, the BME field expanded to:

• Five universities: Jimma University (JU), Addis Ababa University (AAU), Hawassa University (HU), University of Gondar (UOG), and Bahir Dar University (BU).

• Five polytechnic colleges: Adama, Nekemte, Debre Tabor, Jimma, and Dessie.

Organizational Restructuring at the MoH

In 2008, the MoH was reformed, and **eight directorates** were created. Among these:

• The Public Health Infrastructure Directorate was given the responsibility for MDs and infrastructure, including Information and Communication Technology (ICT) support.

• Simultaneously, BME responsibilities were included within the Clinical Services Directorate, resulting in mandate overlaps and confusion.

To resolve this, the MoH:

• Created a dedicated directorate: the Pharmacy and Medical Equipment Directorate (PMED) under the General Directorate of Clinical Services.

• BME (HTM) has now been downgraded to a desk under the PMED Chief Executive, though it deserves elevation to the level of a parallel chief executive to reflect its importance.

Future Challenges and Opportunities

One emerging mandate overlap is between the PMED and the ICT Chief Executive Office, particularly in medical software, which, according to WHO, is classified as a subset of MDs. This signals the need for:

• Clear role delineation between PMED (MD disk) and ICT leadership.

• Enhanced integration of BME with digital health strategies.

• Greater support for BME, HTM, HTA, and Health Technology Regulation (HTR) in the national health agenda.

The BME sector in Ethiopia has overcome significant challenges and is poised for further growth. With the establishment of training programs, professional associations, and specialized directorates, the foundation is set. The continued recognition of BME as an essential technical and clinical field—alongside medicines, ICT, and infrastructure—will determine its success in supporting safe, effective, and equitable health service delivery.

Statement of the Problem: HTM in Ethiopia

HTM, HTA, and HTR in Ethiopia remain critically underdeveloped. Despite the essential role of MDs in modern healthcare delivery, their governance, evaluation, and lifecycle management are significantly lacking. According to a WHO survey, corroborated by national observations, the following major issues persist:

Key Problems Identified:

• No National HTM Policy

o Ethiopia lacks a dedicated MD policy to guide planning, regulation, acquisition, and lifecycle management of MDs.

• No HTA Institution

There is no national HTA body, limiting evidence-based decision-making in the adoption of technology.

• Weak HTM Structures

The HTM directorates at national, regional, and facility levels are either weak or nonfunctional, leading to fragmented implementation.

• Low Availability of High-Tech MDs

Ethiopia has significantly fewer high-tech MDs per capita than comparable low- and middle-income countries (LMICs), contributing to diagnostic and treatment gaps.

• Disjointed Regulation and Support

While EFDA regulates MDs, technical support is provided by MOH, creating role confusion and inefficiencies.

• Lack of Evidence-Based BME Deployment

No scientific evidence or policy guidance supports the structured deployment of Biomedical Engineers/Technicians (BME/BMT) in health institutions.

• Procurement Gaps

MD procurement focuses almost exclusively on initial (purchase) costs, with no consideration of hidden costs (e.g., maintenance, training, calibration, disposal).

Patient Safety Risks

The lack of a robust HTM system severely compromises patient safety and the quality of care. According to the U.S. FDA, over the past decade:[6,7]

• Seven thousand to nine thousand deaths occur per year because of medical errors.

• Over 80,000 deaths and 1.7 million injuries were linked to MDs.

Given Ethiopia's weak regulatory oversight and near-total absence of calibration, quality audits, and decommissioning systems, the risk of harm is likely even higher.

Systemic Maintenance & Training Deficiencies

• Maintenance practices are limited to corrective maintenance (CM) and planned preventive maintenance (PPM). There is no reverse engineering or reengineering.

• No systematic decommissioning process exists, resulting in unsafe or obsolete devices remaining in use. Patient safety is compromised.

• The lack of ongoing training and regulatory frameworks for BME professionals further weakens patient safety and clinical quality services.

The current state of HTM in Ethiopia presents a critical threat to patient safety, resource efficiency, and health system sustainability. Urgent actions are required to establish a scientific HTA body and empower and properly position BME professionals.

UNICEF reported an average global rate of 17 deaths per 1,000 live births in 2022. Globally, 2.3 million children died in the first month (28 days) of life in 2022—approximately 6,300 neonatal deaths every day. In Ethiopia, there were 27.1 deaths per 1,000 live births. It is above the global average.

UNICEF reported in 2017 that 320,000 babies are born too soon each year, and 23,100 children under five die due to direct preterm complications. Not including stillbirth (> 20 weeks' baby dies in the womb). Because of obstetric complications, 10,000 mothers' deaths occur per year.

General Objective

To assess the gap and recommend the whole life cycle of MD (healthcare technology) management in Ethiopia. The medical device life cycle phases are shown in Figure 6, and the medical devices interconnection phase is presented in Table 1.

• Need for the study: Almost no research has been conducted on HTM and HTA.

• Delimitation of the study: Covers all life cycles of MDs from 1971 to 2024.

• Limitation of the study: Not including pharmaceuticals (Medicines/drugs).

• Operational definitions: HTM, HTA, HTR, MD, BME, BMT.

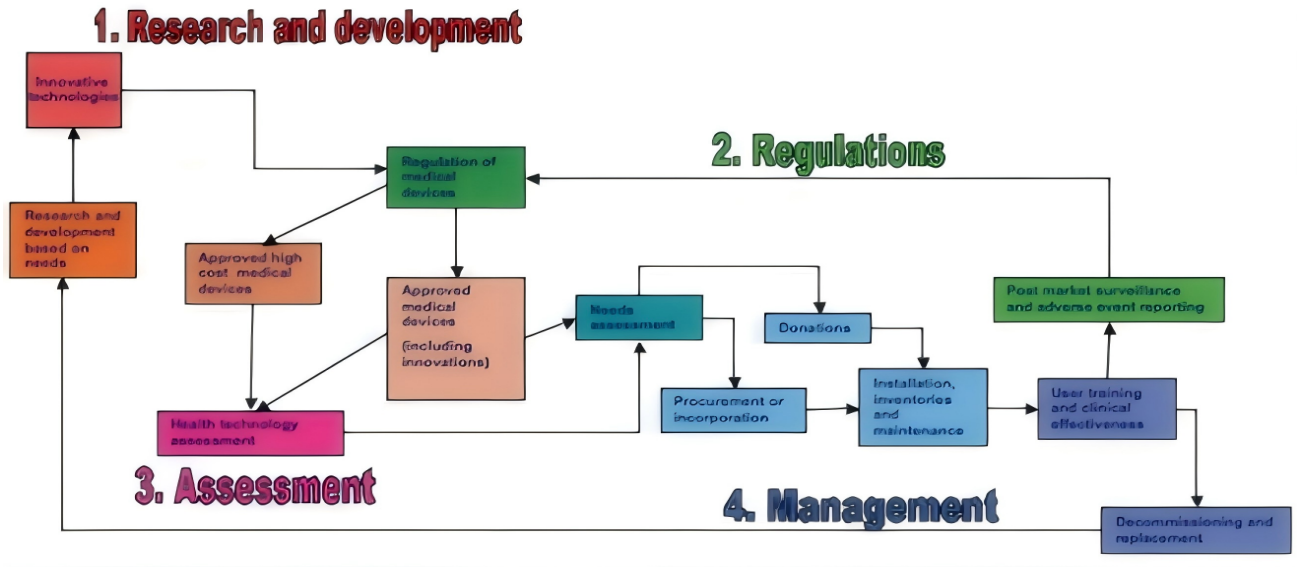

FIGURE 6. The medical device life cycle phases of R and D, HTR, HTA, and HTM (WHO).

METHOD

Sample Size and Sampling Techniques

Research Sampling and Technique

A. For quantitative total population sampling:

• **Total population sampling** is a type of nonprobability sampling—a purposive sampling technique that involves examining the entire population.

Select almost all that is the total population sampling: (five BME Universities, six BMT colleges, six federal Hospitals, thirteen RHB, one MoH, and its three agencies).

B. For a qualitative nonprobability consecutive sampling method:

• **Nonprobability sampling** is a more conducive and practical method for my research to deploy surveys in the real world.

Because of its speed, cost-effectiveness, and ease of availability of the sample.

o To fine-tune my results from a selected group of samples, conduct research over a period, analyze the results, and then move on to another group through a questionnaire, Key Informant interview (KII), Focal Group Discussion (FGD), and site observation.

C. Data analysis or interpretation

The Excel sheets and Google Forms were utilized. The thematic content analysis method was used to analyze the results of the interviews, identifying, analyzing, and reporting on patterns or themes detected in the data. Data obtained from the KII were summarized per category or thematic area.

• Coding: Organizing quantitative data about HTM.

• Editing: Correcting grammatical errors, removing any contradictory information that doesn't have proof, and refining my work into a polished, clear, and impactful document.

• Tabulating: A systematic and logical representation of numeric data in a table format.

TABLE 1. Medical devices interconnection phase of R and D, HTR, HTA, and HTM (WHO).

	R & D	Regulations	HTA	HTM
Perspective	Innovative knowledge, application and tools for health services	Safety & efficacy	Population served	Health services provider
Orientation	Personal health services	Population safety	Population health	Community health services
Requirement (Output)	Improve and/or new tools and services	Mandatory compliance	Recommendation on highly complex technologies	Community health services
Method	Innovation and improvement	Performance testing, safety assessment, and post-market reporting	Systematic analysis, critical review	Operational management of the technology life cycle
Criteria	Market adoption	Safety and quality standards	Epidemiology data, statistics, analysis of efficacy, effectiveness, and appropriateness	Needs analysis, specifications, and reliable device availability for clinical use
Output	Enhanced health service	Risk mitigation and prevention of harm	Responsiveness and maximization of clinical outcome and cost-effectiveness	Improved health delivery; sustainable availability of high-quality and safe devices

FINDINGS, ANALYSIS, AND INTERPRETATION

MD Sector in Ethiopia

Policy & Regulatory Gaps

- **Absence of a Dedicated MD Policy:**

Ethiopia is one of 38 countries globally lacking a standalone MD policy.

The existing drug policy subsumes MDs, treating them as medicinal products, which leads to regulatory ambiguity.

- **Lack of HTA and LPTT Systems:**

No formal HTA institutions.

No structured framework to support MD innovation, and local production and technology transfer (LPTT).

Institutional and Organizational Issues

- **Weak BME Unit Structures:**

No clearly defined BME organizational structure across all government levels (except EFDA).

Lack of mandate clarity for BME functions in the MoH, Regional Health Bureau (RHBs), Zonal Health Bureau (ZHB), Armauer Hansen Research Institute (AHRI), and Ethiopian Pharmaceutical Supply Services (EPSS).

- **Pharmacists' Overreach:**

Pharmacists are authorized under their JDs to engage in MD procurement—a role outside their professional scope and ethically questionable.

- **Workforce Imbalance:**

Approximately 50% of Biomedical engineers and technicians work in public health facilities, indicating a potential human resource bottleneck in rural or underserved regions.

Systemic & Academic Disconnect

- **University—Health Facility Disconnect:**

Minimal collaboration between academic institutions and health facilities, affecting research, innovation, and capacity-building in the MD sector.

Positive Developments

The MD Structure of The Ethiopian Food and Drug Authority (EFDA) is a Benchmark (Figure 7).[8]

The EFDA has a well-established and independent MD regulatory unit.

The new organogram of the EFDA is exemplary and should be benchmarked by other institutions (e.g., MoH, RHBs, ZHBs, and EPSS).

SUMMARY

BMEs graduated from five Universities in BSc = 1,775, MSc = 155, and PhD = 2; BMT completed the Level 4 program from six Polytechnic Colleges, 2,085 BMT in diploma, and Technologist in BSc = 0. Out of them, 147 BMEs are employed in the education sector. 451 BMEs and 571 BMTs are deployed in the health sector. In the next 5 years, Ethiopia will likely get 1,115 BMEs in BSc,

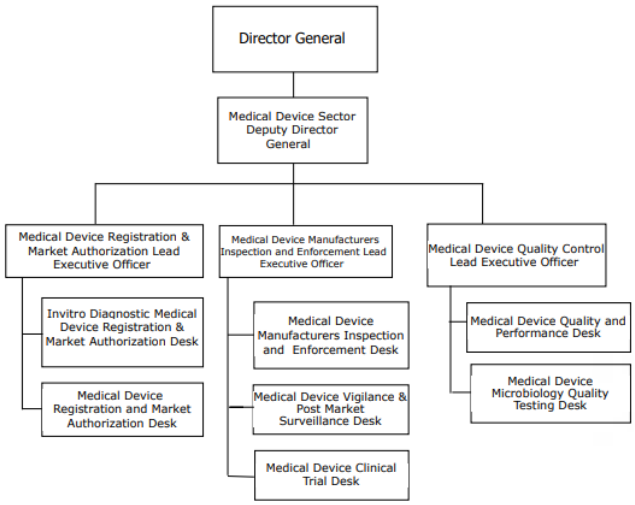

FIGURE 7. The new Ethiopian Food and Drug Authority (EFDA) BME-Director organizational structure.[8]

MSc, and PhD degrees, and 400 BMTs in the Level 4 program. Need a BM-Technologist program to upgrade the Biomedical Technician program and fill the gap between the BMEs and BMTs.

CONCLUSION AND RECOMMENDATION

Conclusion of Strategic Pillars of Effective MD Management

1. HTM (MD Acquisition till Decommissioning)

• Must be handled by Biomedical Engineering (BME) professionals to ensure transparency, reduce corruption, and mitigate risks.

• Multiple acquisition modalities should be utilized:

o Leasing

o Public–private partnerships (PPP)

o Rental

o Loans, etc.

2. HTA, Innovation, LPTT, and Refurbishment

• These are the keys to increasing access to MDs, especially in resource-limited settings (LMIS like Ethiopia).

• Should be supported by a robust national reliability system.

o HTA for informed decision-making.

o Innovation and LPTT to enhance self-reliance.

o Refurbishment programs to extend the life of usable MDs.

3. HTR Ensures the Quality and Safety of MDs

• Encourages clinical trials, particularly in innovation and LPTT phases.

4. BME-HR Development

• Bridging Academic Research and Clinical Practice in the CE/BME field.

• Just as clinicians are embedded in the realities of patient care, biomedical engineers, public health professionals, and health technology experts thrive when academic research and hands-on applications go hand in hand. Here's why that collaboration is so vital:

• Real-World Relevance: Working with health facilities grounds academic training in real needs — whether it's maintaining oxygen systems or implementing HTM strategies.

• Innovation Pipeline: University research can feed directly into practical innovations in medical devices, diagnostics, and system design.

• Capacity Building: Embedding students and faculty in clinical environments trains a workforce that is not only technically skilled but systems aware.

• Co-Development of Solutions: Partnerships foster co-creation of tools and policies that are feasible, scalable, and context-appropriate, especially in LMIS (Like Ethiopia).

• Senior HTM Leaders With their deep expertise in HTM and their commitment to capacity-building, they are uniquely positioned to advocate for and help design these kinds of collaborations, especially where university-based biomedical engineering programs can serve national healthcare goals.

• Would you be interested in sketching out what an ideal university–health facility partnership could look like for Ethiopia or the broader African context? We could co-develop a framework together.

• Critical for managing the entire life cycle of MDs—from planning and acquisition up to decommissioning. Need specialty-focused training.

Without a distinct HTM policy, dedicated BME leadership, and clear delineation of roles, Ethiopia risks continued

inefficiencies, safety issues, and underutilization of medical technologies. Urgent reform is needed to establish a structured, inclusive, and technically led HTM system.

RECOMMENDATION

• **Standardization of MDs**: Implementing standardization through long-term agreement (LTA) holders or other modalities such as leasing, PPP, rental, government procurement, innovation, and refurbishing of MDs is essential.

• **Open System for in vitro Diagnostics (IVD)**: IVD systems should be open and use universal standard reagents and consumables.

• **The Universities should effectively partner with health facilities in practice.**

Here's a structured approach that could turn that vision into an operational reality:

1. Embed Joint Training Programs

• **Clinical Internships**: Embed biomedical engineering, public health, and health economics students in hospitals and clinics for hands-on experience.

• **Residency-Like Models**: Like medical residencies, develop structured rotations where students assist with equipment maintenance, data collection, or health technology assessments.

• **Shared Curriculum Development**: Design modules co-taught by academic faculty and health facility staff that cover both theory and on-the-ground realities.

2. Establish Innovation Hubs and Living Labs

• **Health Tech Incubators**: Set up joint university–hospital innovation centers to develop, test, and iterate context-appropriate technologies (e.g., oxygen delivery systems, remote diagnostics).

• **Real-Time Problem Solving**: Let students and researchers work alongside hospital staff to co-develop low-cost, locally sourced solutions.

• **Device Piloting and Feedback Loops**: Health facilities can act as early adopters, offering feedback to university researchers and developers.

3. Co-Design Research and Policy Initiatives

• **Operational Research**: Tackle system-level challenges like HTM system strengthening, supply chain bottlenecks, or equipment uptime tracking.

• **Joint Grant Writing**: Collaborate on securing funding from donors or ministries for research that serves national health priorities.

• **Policy Advisory Councils**: Include both academic researchers and hospital leaders in national or regional policy formulation.

4. Build Institutional Partnerships and Incentives

• **Memorandums of Understanding (MoUs)**: Formalize collaborations with clear roles, timelines, and outcomes.

• **Dual Appointments**: Encourage shared positions so experts can teach in universities and serve in clinical roles (especially in biomedical engineering and HTM management).

• **Metrics for Impact**: Define joint KPIs such as equipment improvements, reduced turnaround time on diagnostics, or innovations deployed.

5. Anchor the Partnership in Public Health Equity

• Ensure these partnerships prioritize **low-resource settings**, rural hospitals, and marginalized populations.

• Use the collaboration to **decentralize innovation** and build capacity where it's most needed — a mission you've already championed through your global work.

6. Establish the Biomedical Technologist (BMT) Programs:

Establishing Biomedical Technologist (BMT) programs involves several key steps to transition existing Biomedical Technicians into Technologists, enhancing their skills and

qualifications. Here's a structured approach to developing these programs:

• Needs Assessment

Evaluate Current Workforce: Assess the skills, qualifications, and experience of the existing Biomedical Technicians (500–2,000).

Identify Gaps: Determine the knowledge and skills required for Biomedical Technologists that are currently lacking in the technician workforce.

• Curriculum Development

Core Competencies: Develop a curriculum that covers essential topics such as advanced biomedical equipment technology, regulatory compliance, quality assurance, and healthcare informatics.

Hands-On Training: Incorporate practical training sessions with advanced medical devices and technologies.

Interdisciplinary Learning: Include courses on collaboration with healthcare professionals, ethics, and patient safety.

• Accreditation and Standards

Accreditation: Seek accreditation from relevant educational bodies to ensure the program meets industry standards.

Certification Preparation: Align the curriculum with certification requirements for Biomedical Technologists.

• Program Structure

Duration: Determine the length of the program (e.g., 2-3 years) based on the depth of training needed.

Delivery Mode: Offer flexible learning options, including online, hybrid, and in-person classes to accommodate working technicians.

• Partnerships

Healthcare Institutions: Collaborate with hospitals and clinics for internships and real-world training opportunities.

Industry Experts: Engage industry professionals to provide guest lectures and mentorship.

• Funding and Resources

Budgeting: Develop a budget that includes costs for faculty, materials, and facilities.

Grants and Scholarships: Explore funding opportunities to support students transitioning from technician to technologist roles.

• Recruitment and Enrollment

Awareness Campaigns: Promote the program through workshops, webinars, and informational sessions to attract current technicians.

Application Process: Create a streamlined application process for interested candidates.

• Support Services

Advising and Counseling: Provide academic advising and career counseling services to help students navigate their educational journey.

Alumni Network: Establish an alumni network for ongoing support and professional development.

• Evaluation and Feedback

Program Assessment: Regularly evaluate the program's effectiveness through student feedback, job placement rates, and employer satisfaction.

Continuous Improvement: Use assessment data to make necessary adjustments to the curriculum and training methods.

• Certification and Career Advancement

Certification Preparation: Ensure students are prepared for national certification exams upon program completion.

Career Pathways: A Guide to Career Advancement Opportunities within the Biomedical Field.

By following these steps, BMT programs can effectively transition Biomedical Technicians into more advanced roles as Biomedical Technologists, ultimately enhancing the quality of healthcare technology management.

• **Establishing a separate structure for the specialization of the BME directorates**.

Based on clinical services: Imaging, Laboratory, Life support system/devices, Ophthalmic, and Orthopedics/rehabilitation (including assistive technologies)

• **Innovation and Reengineering**:

There should be a system in place for innovation, Local Production and Technology Transfer (LPTT), reengineering, and research and development.

• **HTA Institute**: An HTA institute should be established at the national level.

• **Recruitment of BMEs**: Facilitating and promoting the export of skilled Biomedical Engineering personnel to foreign or neighboring countries can help address the job creation of skilled BME professionals in Ethiopia.

AUTHOR CONTRIBUTIONS

Dr Mulugeta Mideksa Amene is the sole author of this work and is responsible for all aspects of the research and writing.

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In conclusion, I am honored to have been part of this project and am proud of what we have accomplished together. I look forward to the opportunity to collaborate again in the future.

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DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

I declared that I did not have any (potential) conflicts or competing interests with any institutes, organizations, or agencies that might influence the integrity of results or the objective interpretation of their submitted works.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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