

Medical Metrology in the Context of Bangladesh: A Comprehensive Analysis of Calibration Practices, Policy Gaps, and Health Outcomes

*Moktar Hossain; Anila Pasha; Mirola Afroze
Instrumentation and Calibration Division, Bangladesh Reference Institute for
Chemical Measurements (BRICM), Dhaka-1205, Bangladesh

Md. Abu Hasan
Proficiency Testing Division, Bangladesh Reference Institute for
Chemical Measurements (BRICM), Dhaka-1205, Bangladesh

*Corresponding Author

Abstract

Medical metrology, or measurement science for health, is essential for safety, diagnosis and treatment of patients. The health-care sector has made enormous progress in critical care with more than 15,233 registered health-care facilities including hospitals, clinics, diagnostic laboratories, and blood banks [1]. Bangladesh now has around 2,500+ ICU beds, 1,100+ CCU beds, 1,200+ NICU beds, and more than 8,000 operation theater (OT) units [1]. However, the status of medical metrology in Bangladesh is very concerning [2]. This paper provides a comprehensive overview of the medical metrology situation in Bangladesh by reviewing government statistics, institutional reports, reports from medical institutions and international standards [1,2,3]. It assesses the existing metrological laboratories in Bangladesh, especially the Bangladesh Reference Institute for Chemical Measurements (BRiCM) which is the first government institute to start biomedical calibration services in 2021 [2], and the problems of non-implementation of mandatory policies, lack of human resources and awareness among health policy administrators, unethical calibration practices, and in this regard the National Metrology Institute (NMI) of Bangladesh is not visible [3,4,5]. The fundamental concepts of metrology including measurement uncertainty, error analysis and traceability are discussed using simple formulas [6,7,8]. The impact of uncalibrated

medical equipment includes inaccurate diagnosis, unsuccessful treatment, health risks and the cost of healthcare [4,5,9]. The article discusses examples of successful medical metrology practices in countries such as the United States, Germany, and Turkey, which have National Metrology Institutes (NMI) with full capabilities for medical device calibration [10,11,12]. Adopting best practices and international standards from ISO, IEC, BIPM, and WHO [13,14,15], this paper suggests practical recommendations for improving medical metrology in Bangladesh, such as mandatory policies, infrastructure development, training and awareness-raising programs for health administrators [2,16].

Keywords: Medical metrology, biomedical calibration, healthcare quality, patient safety, National Metrology Institute, traceability, measurement uncertainty.

Introduction and Background

Measurements are critical to modern healthcare. Whether it's the sphygmomano-meter in the general practice office or the ventilator in the intensive care unit, the measurements that medical devices produce inform clinical decisions, define treatment options and ultimately impact patient care. When these measurements are not accurate, due to drift, incorrect calibration, or lack of measurement traceability, the results can be

diagnostic failure or death [3,5,6]. Medical metrology, the field of metrology that applies to medical measurement, offers the science and technology to achieve measurement accuracy. This includes calibration, measurement traceability, uncertainty assessment and quality control. Metrological traceability is defined in the International Vocabulary of Metrology (VIM) as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty" [7,8].



Figure 1: Example of medical devices that require regular calibration for accurate patient care

Simple equations for understanding medical measurements

To appreciate the importance of medical metrology, let's first understand a couple of simple relationships that apply to all medical measurements.

What is measurement error? Whenever a medical device makes a measurement, its value will differ from the true value. This difference is called error:

$$\text{Error} = \text{Measured Value} - \text{True Value}$$

If a blood pressure measurement is 123 mmHg but the "true" blood pressure is 121 mmHg, then there's an error of +2 mmHg. Errors may be systematic (bias - always in the same direction), or random (vary in an unpredictable way) [9,10].

What is measurement uncertainty? Even when calibrated, measurements are never perfect. Uncertainty is a measure of how sure we are. For most medical devices:

$$\text{Uncertainty} = 2 \times \text{Standard Uncertainty}$$

The factor 2 is about 95% certain. If a patient monitor display is showing a heart rate of 80 bpm with uncertainty ± 2 bpm, then the true heart rate is between 78 and 82 bpm with 95% confidence [11,12].

How do you calibrate an infusion pump? An infusion pump pumps medication at a desired flow rate. Calibration ensures the flow rate is correct:

$$\text{Flow Rate} = \text{Volume Delivered} \div \text{Time}$$

If the pump is supposed to deliver 100 mL an hour but only delivered 101 mL, then the error is +1%. The accuracy of infusion pumps must be $\pm 1\%$ to meet international standards [6,13].

What is traceability? Traceability means that every measurement can be traced, via a series of comparisons, back to an international standard. This means that a measurement of blood pressure in Dhaka is equivalent to that in London or Tokyo [14,15].



Figure 2: The chain of traceability in medical metrology

The Bangladesh context

The significance of medical metrology has only recently been understood in Bangladesh, with its burgeoning health system. The latest data of the health care facilities for registered hospitals and clinics (government and non-government) has reported 15,233 licensed establishments (hospitals, clinics, diagnostic centers, blood banks etc.) by the Directorate General of Health Services (DGHS) [1]. Currently, Bangladesh has an estimated more than 2,500 ICU beds, around 1,100 CCU beds, approximately 1,200 NICU beds and more than 8,000 operation theater (OT) units [1]. Associated with each of these beds and units are multiple measuring instruments such as patient monitors, ventilators, infusion pumps, defibrillators, incubators, radiant warmers, ECG, lux meters and other devices and equipment that need regular calibration. It is estimated that 70,000-140,000 medical devices need to be calibrated at regular intervals in the country's health care system [2,16].

Methodology

The current study used a qualitative descriptive research design to explore the status, issues and prospects of medical metrology in Bangladesh. Medical metrology is a new field and there is limited primary data available, so documentary analysis and review of institutional reports were chosen as the best possible methodological options [17]. Primary data included government documents, legislation (BRiCM Act 2020, BAB Order 2006) [18,19], and institutional annual reports from BRiCM, BSTI, BAB and DGHS Health Bulletin 2022 [1,2,20,21]. Secondary data

sources included peer-reviewed journal publications (2010-2023) from PubMed, IEEE Xplore and ScienceDirect, and international

standards from ISO, IEC, BIPM and WHO publications [7,8,11,12,13,22]. A structured search was performed using keywords "medical metrology", "biomedical calibration" and "patient safety". Documentary analysis used Bowen's (2009) skimming, reading, interpretation, and coding, focusing on calibration infrastructure, policy gaps and human resource [17]. Comparative analysis reviewed six National Metrology Institutes (NIST, PTB, TUBITAK UME) in terms of institutional framework and calibration capabilities [23,24,25]. Policy, infrastructure, human resources, quality, and awareness were evaluated in gap analysis. Data triangulation was used for validation and draft analysis was reviewed by 12 experts at BRiCM Technical Review Committee (March 2023) [2].

Understanding Medical Metrology

Medical metrology involves measurements, control, verification and calibration of analytical, diagnostic, imaging and therapeutic devices [26,27]. The devices used are of vital importance as they are applied to humans and multifunctional. Karaböce (2020) states that "medical decisions about diseases are usually based on clinical findings including medical examination and the results of statistical studies that have been obtained from patients over the years. Medical measurements are important for creating clinical findings and generating consistent statistical data from large numbers of patients" [4].

Table 1: Key parameter of medical devices and their calibration requirements

Device Type	Parameter Measured	Recommended Calibration Interval	Typical Accuracy Requirement
Ventilator	Tidal volume, pressure, flow	Every 6–12 months	±5%
Infusion pump	Flow rate	Every 6–12 months	±1%
Defibrillator	Energy output	Every 6–12 months	±5%
Patient monitor	ECG, SpO ₂ , NIBP	Every 12 months	±5%
Incubator	Temperature, humidity	Every 6–12 months	±0.5°C
ECG machine	Voltage, time	Every 12 months	±5%

The three pillars of measurement quality

Accuracy is how close to the true value our measurement is. Precision tells us how close each measurement is to all the others. It is possible for a device to be precise (consistently giving the same reading) but inaccurate (consistently giving the wrong reading). Calibration helps ensure both [9,28]. Calibration involves comparing the device's readings to a reference standard. According to Kumar et al. (2023), calibration defines the correlation between the device's reading and the true value of the quantity being measured [6]. Traceability is the ability to trace the reference standard used in calibration back, in a documented chain, to national or international standards. Without traceability, we can't be sure that a "calibrated" device will be accurate [8,29].

Simple equations for medical device calibration

If the device is linear (many medical devices have a linear relationship between input and output):

True Value = (Slope x Reading) + Intercept

The slope is the sensitivity of the device, and the intercept is the zero offset. These two numbers are found during calibration [10,11]. For a defibrillator, the energy delivered to the patient is a function of voltage, time and the patient's chest resistance:

Energy = (Voltage² x Pulse Duration) ÷ Chest Resistance

Calibration ensures the energy delivered is ±5% of the set energy. Insufficient energy may not re-establish the heartbeat; excessive energy can damage the heart's tissue [6,22].

When calibration is required

Calibration is necessary at several points in the life of a measuring device for accuracy, reliability and standard compliance. It should be performed prior to initial use of a new instrument to ensure correct operation and accuracy [30,31]. Every instrument also has a calibration cycle (every 6 months, every year, or as per usage and manufacturer spec) to

ensure that the instrument operates at optimal performance [32,33]. Calibration is also needed after maintenance, servicing or replacement of components as it can impact performance [12]. In fact, when measurements are drifting or showing inconsistencies, the instrument needs to be recalibrated for accurate measurements [10,34]. In essence, calibration is a continuous process which is required on first use, periodically, following maintenance and when there is a question of accuracy to promote consistent, standardized values [2,16].

Why this matters for patient safety

Uncalibrated devices can result in lung damage from ventilators, inaccurate drug doses from infusion pumps, defibrillators that are unable to re-start patient's hearts, patient monitors that fail to detect crucial changes, and incubators that damage babies due to unstable temperatures [5,35]. As Karaböce (2020) stresses, "a simple example is the incorrect blood pressure that is a major risk for health. This example presents a measurement system marked by a technology, where the metrological control has a key role through technical proceedings" [4].

Global and Best Practices

The international medical metrology system is supported by several organizations. The Bureau International des Poids et Mesures (BIPM) defines the International System of Units (SI) [8]. The International Organization of Legal Metrology (OIML) provides international standards for medical devices via its Technical Committee TC 18 [27,36]. The International Organization for Standardization (ISO) is vital with standards such as ISO/IEC 17025 for calibration laboratories and ISO 15189 for medical laboratories [12,37]. The World Health Organization (WHO) offers advice on medical device regulations [16,38]. Table 2: Global NMIs and their medical metrology capabilities

Country	NMI	Medical Metrology Focus
USA	NIST	Ventilators, infusion pumps, MRI phantoms
Germany	PTB	MRI, radiation therapy, electrical safety
Turkey	TUBITAK UME	Patient simulators, defibrillator analyzers, gas

		flow
UK	NPL	Clinical laboratory measurements, imaging
South Korea	KRISS	Biomedical standards, reference materials
France	LNE	Medical electrical equipment, thermometry

National Metrology Institutes worldwide

Developed countries have strong medical metrology programs in their National Metrology Institutes (NMIs). TUBITAK UME (Turkey) has a Medical Metrology Research Laboratory with calibration systems for patient simulators, defibrillator analyzers, infusion pumps and gas flow analyzers [4,25]. NIST (USA) offers traceable calibrations for ventilators and infusion pumps, and reference phantoms for MRI systems [15,23]. PTB (Germany) carries out cutting-edge metrology research for medical technologies such as magnetic resonance imaging [24]. Other prominent NMIs include LNE (France), NPL (UK) and KRISS (South Korea) [4,39].



Figure 3: Countries with National Metrology Institutes for medical metrology

Key lessons for Bangladesh

There are many lessons to be learnt from the global experiences. First, there is clearly identified responsibility for medical metrology by NMI in every advanced economy [5]. Second, NMIs have an established calibration system for all types of medical devices [4]. Third, world-class NMIs supply certified reference materials for clinical measurements [8]. Fourth, NMIs provide training for calibrators. Fifth, they participate in BIPM and OIML to keep up with international standards [39]. Sixth, medical metrology is included in national regulations on medical devices



[16,38].



**Current Situation in Bangladesh
Bangladesh Standards and
Testing Institution (BSTI)**

BSTI, an institute under the Ministry of Industries formed in 1985, is the National Metrology Institute for physical and legal metrology [21]. BSTI's role is to maintain national standards for physical quantities, certify weights and measures used in commerce and trade, develop Bangladesh standards (BDS) and establish the national legal metrology system [21,40]. BSTI has done substantial work in the establishment of metrology infrastructure, and maintains a Central Metrology Laboratory capable of calibrating in the quantities of mass, length, temperature, pressure, and electric [21]. But BSTI's jurisdiction and focus are in physical and legal metrology. However, to date, BSTI has not initiated any major or specific activities in medical metrology, especially for critical care units. There has been no evidence that BSTI is engaged in developing or planning to develop medical metrology standards, calibration procedures, or regulations for life-saving medical devices used in critical care units [2,21].

The emergence of BRiCM

The only major accomplishment to date is the Bangladesh Reference Institute for Chemical Measurements (BRiCM). BRiCM is an

institute under the Science and Technology Ministry, established by the "Bangladesh Reference Institute for Chemical Measurements Act, 2020" [18]. BRiCM has attained the status of Participatory Member of the BIPM (2012), Full Member of the Asia Pacific Metrology Programme (APMP) (2013) and Designated Institute for Chemical Metrology in the National Quality Policy (2015) [2,39]. BRiCM has established considerable expertise in analytical calibrations, such as mass, volume, thermal, electrochemical meter etc. [2].

BRiCM's biomedical calibration initiative

In 2021, BRiCM became the first government institute in Bangladesh to start biomedical calibration services [2]. The equipment calibrations include ventilators, patient monitors, infusion pumps, electrocardiographs (ECG), defibrillators, incubators, radiant warmers, anesthesia machines, electrosurgical units, blood pressure monitors and pulse oximeters. BRiCM has acquired equipment for performance testing, such as defibrillator analyzers, incubator analyzers, gas flow analyzers and electrical safety testers [2].

Figure 4: BRiCM's biomedical calibration: the first government initiative of its kind in Bangladesh

Accreditation framework

The Bangladesh Accreditation Board (BAB), formed in 2006 by the Ministry of Industries, offers the accreditation system for testing and calibration laboratories [19,20]. BAB has the mandate to accredit laboratories to the standards of ISO/IEC 17025, ISO/IEC 17043 and other standards [20]. But the number of accredited calibration laboratories that service the health sector is limited [2].

Private sector calibration providers

Seizing the opportunity, two to three private sector organizations have recently started providing medical calibration services in Bangladesh [2]. This is welcome news but also raises serious questions about quality assurance issues such as traceability, accreditation, technical and methodological rigor [2,4].

Critical Gap

Lack of Mandatory Policies

According to the critical gap analysis, there is no policy or regulation from the Government of Bangladesh on the calibration of medical equipment [1,2]. As a result, only the healthcare facilities that seek international accreditation (e.g., JCI or ISO 15189) perform calibration as per the requirements [41]. The rest are reluctant to undertake calibration because of cost, and most importantly, lack of accountability. Lacking any directive from the government, it is regarded as a discretionary cost rather than an integral part of patient safety [2,4].

Repair is the default practice

Currently the practice in health facilities in Bangladesh is that if a medical device fails, biomedical engineers try to repair it. If they cannot, the service provider is engaged for repairs. In both cases, calibration is not performed [2]. This practice of repair without calibration after repair greatly degrades the quality and integrity of medical measurements. This alarming practice is directly supported by the absence of any institutional mandate and national standard on medical metrology [5,35].

No strategic planning and monitoring have been done

The lack of any visible, government or NMI of Bangladesh initiative in medical metrology is also evident in the absence of any strategic planning and monitoring. There is no strategic plan, budget allocation, target setting, and monitoring of medical metrology development [1,2]. Whatever little development has taken place (e.g. BRiCM's biomedical calibration services) has been done in spite of the policy gap. No institution has been made accountable, no plan has been made, and no monitoring system has been put in place [2].

No local master equipment calibration full facilities

There is no master equipment calibration facility (for defibrillator analyzers, ventilator testers, infusion pump analyzers and electrical safety testers) in Bangladesh for calibrating medical devices [2]. This master equipment must be exported to India, China, Turkey, Germany or the USA, and takes 3-6 months to complete [4,24,25]. This includes expensive

export-import transport, customs and export-import formalities and insurance, which is a major bottleneck in the medical metrology process [2].

Consequences for healthcare facilities

The lack of national policy, repair-based practice and strategic planning and monitoring has implications for healthcare facilities in Bangladesh. The absence of routine calibration can lead to inaccurate or unreliable measurements from medical devices, which can impact on diagnosis, therapy and patient

safety [5,6]. This can lead to inaccurate diagnosis, incorrect treatment, and patient harm [4]. It also affects the overall quality and quality assurance of health care, restricting the possibility of international accreditation [41]. Over time, this can degrade confidence in health care systems, increase risks, and ultimately slow the development of a safe and effective medical system in the country [1,16].

Table 3: Gap analysis of medical metrology in Bangladesh

Area	Current Status	Desired Status	Gap Severity
Policy	No national medical metrology policy	Mandatory calibration policy	High
NMI involvement	BSTI (no medical focus), BRiCM (emerging)	Dedicated medical metrology NMI	High
Calibration facilities	Only in Dhaka (BRiCM)	Regional centers nationwide	High
Skilled manpower	<50 trained professionals	500+	High
Accreditation	Few labs accredited	All labs ISO/IEC 17025	Medium
Awareness	Very low among administrators	High awareness	High

Key Challenges

Lack of awareness of healthcare administrators

Lack of awareness of medical metrology among hospital management and clinicians is a key challenge. According to BRiCM's report, "administrators are not familiar with metrology and cannot understand the need for calibrations, and therefore they do not want to calibrate" [2]. This results in risks being undervalued, calibration being seen as a waste of money, confusion of maintenance and calibration, and unwillingness to prioritise budgets [4]. Karaböce (2020) points out this is not just an issue in Bangladesh: "Medical device owners and users are generally medical doctors who are not very familiar with metrology and calibrations" [4].

Cost constraints

Calibration services are expensive: the direct cost of calibration, transport costs, lost productivity, and in some cases replacement equipment [6]. These costs are often seen as

excessive for many health-care facilities, especially the public sector, with limited budgets [16]. Without dedicated funding, calibration is sometimes seen as less of a priority [2].

Unauthorized calibration practices

Lack of awareness, budgetary pressures and enforcement has led to a demand for unauthorized calibration. These include "non-traceable measurement devices," "unauthorized calibration units" and "metrologically incorrect procedures" [2]. Karaböce (2020) observes similar issues worldwide: "non-metrological calibrations/measurements, and thus, production of improper certificates, reports and labels, are still done by secondary calibration laboratories for economic reasons" [4].

Shortage of skilled personnel

There is a shortage of metrologists, biomedical engineers and calibration technicians [42]. The

small number of professionals is based in Dhaka, and facilities elsewhere lack access to expertise [1]. Dhaka University's Department of Biomedical Physics graduates a small number of students each year [43]. Similarly, only a few other universities in Bangladesh are conducting biomedical programs.

Lack of calibration infrastructure beyond Dhaka city

Although the BRiCM facilities in Dhaka are impressive, there is an unequal distribution of opportunities due to the lack of calibration services outside the capital. Other divisional hospitals face challenges such as distance, transport costs, downtime and scheduling [1].

Maintenance culture

In Bangladesh, there are problems beyond calibration of equipment. According to the WHO, "the World Health Organization estimates that 50% to 80% of equipment is non-functional due to the lack of maintenance culture, competency, and a tendency to focus on corrective maintenance rather than preventative maintenance" [6,35].

Impact on Healthcare Quality

Patient safety risks

The major impact is on patient safety. Barotrauma or death can result from uncalibrated ventilators [5]. Uncalibrated infusion pumps can cause medication errors [6]. Uncalibrated defibrillators can raise the death rate from cardiac arrest [22]. Uncalibrated patient monitors can fail to detect patient deterioration [5]. Uncalibrated incubators can kill babies [35].

Diagnostic errors

Diagnostic errors are caused by uncalibrated diagnostic equipment. According to Karaböce (2020), "if blood sugar is measured higher than its true value, medical doctor prescribes insulin. Or if blood sugar is measured lower than its true value, treatment will not be planned. In both cases, patient either will face the risk of injury/death or will consume unnecessary drug and lose money" [4].

Healthcare inequity

Dhaka centralization leads to geographic disparities. Patients in areas with access to

calibration services get treatment based on accurate measurements, while patients in areas without access may be treated based on inaccurate measurements, exacerbating inequities [1,16].

Economic costs

Failing to prioritize calibration has economic consequences: accelerated replacement of equipment, adverse events and malpractice cases, wasted resources from duplicate testing, and currency exchange costs for transporting equipment overseas [6]. Economic impacts have been demonstrated from improvements in measurement accuracy. Karaböce (2020) reports that "improvement in precision in cholesterol measurements since 1969 has been estimated to save US \$100M/year in treatment costs" [4].

Recommendations

Develop and implement a national medical metrology policy

The Bangladesh Government should initiate a national policy or regulation for medical metrology. This policy should outline standards, obligations and requirements of calibrating equipment in all health care institutions which will ensure consistent accuracy and performance of medical equipment throughout the country [16]. Likewise, a suitable institutional arrangement should be set up or enhanced to help implement this policy. This may involve formally establishing an appropriate national body, providing adequate financial support and establishing a medical metrology advisory committee comprising representatives from various stakeholders like DGHS, DGDA, BSTI, BAB and large healthcare facilities [1,2]. This may help ensure coordinated development, regulation and international compliance [16].

Expand BRiCM's capacity

Expansion should include setting up regional calibration facilities in Chittagong, Rajshahi, Khulna, Sylhet, Barisal, Rangpur, and Mymensingh to serve non-Dhaka-based facilities [2]. Investment in equipment should cover ventilator test systems, infusion pump analyzers, defibrillator analyzers, electrical

safety testers, temperature calibrators, and gas flow analyzers [25]. Human resource development should engage and train more biomedical engineers, metrologists, and calibration technicians, and build capacity through training initiatives in collaboration with universities [2,43].

Establish mandatory calibration requirements

The Directorate General of Health Services (DGHS) and Directorate General of Drug Administration (DGDA) should establish regulations requiring regular calibration of all medical devices used to treat patients, calibration intervals, based on risk classification (every year for high-risk devices), calibration by laboratories that comply with ISO/IEC 17025, documentation of calibration status with records stored for inspection and enforcement with penalties for non-compliance [12,16,38].

Integrate with healthcare quality systems

Health care facility inspections by the DGHS should include compliance with calibration, which is a requirement for facility licensing and renewal, reimbursement and funding, and monitoring of health care system performance [1,41]. This ensures that calibration is part of the standard quality management practice in health care.

Develop training and capacity building programs

University programs should build capacities for biomedical engineering and metrology programs in universities and expand the BRiCM-Dhaka University partnership [2,43]. Technical training should provide certification training for calibration technicians through BRiCM and technical institutes. In-service training should offer continuing education to hospital technical staff on calibration and equipment maintenance [35]. International co-operation should provide training for Bangladesh professionals at international metrology institutes such as NIST, PTB and TUBITAK UME [15,24,25].

Conduct awareness campaigns

Awareness programs should be conducted for healthcare administrators and clinical leaders to highlight the risks of uncalibrated equipment on patient safety, cost benefit of calibration, how to implement a calibration program and study examples from other countries [2,4]. Campaigns should be in Bengali to ensure broad reach and effectiveness.

Strengthen accreditation infrastructure

The government should allocate funds to increase BAB's capacity to accredit biomedical calibration laboratories as per ISO/IEC 17025 and create a list of accredited biomedical calibration service providers that can be easily accessed by health facilities [12,20]. BAB should also remain a full member of ILAC to allow for international recognition of accredited calibrations done in Bangladesh [29].

Establish public-private partnerships

Mechanisms should be established for public-private partnerships that broaden the geographical reach of calibration services, exploit the market efficiency of private sector while ensuring the quality control of government sector, and ensure the traceability and accreditation of private sector providers [2,16]. Such partnerships can help overcome the infrastructure deficit outside of Dhaka.

Develop national calibration standards

BRiCM should establish national calibration standards for priority medical devices, traceable to international reference materials and take part in international proficiency testing programs and BIPM comparisons for medical measurements [2,8]. This will ensure equivalence of Bangladesh's medical measurement capability [39].

Promote research and publication

Medical metrology research should be promoted by encouraging research grants for studies in medical metrology, working with international researchers, incentives for publication in peer-reviewed journals, and presentation and proceedings at conferences [42]. This will create knowledge and evidence

in Bangladesh and promote medical metrology.

Conclusion

Medical metrology is an essential but covert component of the quality of healthcare which has not been given adequate attention in Bangladesh. Although the country has established the Bureau of Standards and Testing Institute (BSTI) for physical and legal metrology, and the Bangladesh Research Institute for Chemical Metrology (BRICM) has begun a remarkable journey into chemical metrology and biomedical calibration [2,21]. Healthcare institutions aiming for international accreditation have had to export their equipment for calibration [2]. The lack of policy for compulsory calibration of equipment means that devices are not calibrated, which can endanger patients [1]. Insufficient human resource capacity and lack of awareness among health-care management make the situation worse [2,42].

It's time for the Bangladesh Government to act. Bangladesh has the infrastructure, BRiCM (as a member of the BIPM and APMP), biomedical calibration and international connections, on which to establish a medical metrology system [2,39]. A clear designation of BRiCM as the NMI for medical metrology, building on capacity building, regulatory change, training and awareness raising, would finally resolve this medical measurement gap and ensure the accuracy, reliability and international traceability of medical measurements in Bangladesh. Every day in the ICUs, CCUs, NICUs and OTs of Bangladesh, decisions are made on the basis of measurements made using medical devices. The accuracy of those measurements is not only a technical consideration, it is a patient safety consideration [5,16]. As Karaböce (2020) concludes, "low levels of uncertainty in medical measurements are crucial for more accurate diagnosis and treatment and less expenditure in health expenses" [4]. For Bangladesh, building medical metrology is a critical investment in patient safety, health care quality and health systems. The government must act now.

References

1. Asia Pacific Metrology Programme (APMP). APMP Annual Report 2023. APMP, 2023.
2. Badnjević A, Cifrek M, Koruga D, Magjarević R. Post-market surveillance of medical devices: A review. *Technology and Health Care*. 2017;25(2):209-217. <https://doi.org/10.3233/THC-161273>
3. Badnjević A, Pokvić LG, Džidić M, Šehić S. Risks in medical device maintenance and calibration. *IFAC-PapersOnLine*. 2018;51(30):616-620. <https://doi.org/10.1016/j.ifacol.2018.11.250>
4. Bangladesh Accreditation Board (BAB). Annual Report 2022-2023. Ministry of Industries, Government of Bangladesh, 2023.
5. Bangladesh Reference Institute for Chemical Measurements (BRiCM). Instrumentation and Calibration Division: Biomedical & Analytical Calibration Capabilities. Ministry of Science and Technology, Government of Bangladesh, 2023.
6. Bangladesh Standards and Testing Institution (BSTI). Annual Report 2021-2022. Ministry of Industries, Government of Bangladesh, 2023.
7. Bell S. A Beginner's Guide to Uncertainty of Measurement. Measurement Good Practice Guide No. 11. National Physical Laboratory, UK, 2001. <https://doi.org/10.47120/npl.mgpg11>
8. Bowen GA. Document analysis as a qualitative research method. *Qualitative Research Journal*. 2009;9(2):27-40. <https://doi.org/10.3316/QRJ0902027>
9. Bureau International des Poids et Mesures (BIPM). Mutual Recognition Arrangement (MRA). BIPM, 2019.
10. BIPM. BIPM Work Programme 2021-2024. BIPM, 2021.
11. Directorate General of Health Services (DGHS). Health Bulletin 2022. Ministry of Health and Family Welfare, Government of Bangladesh, 2023.
12. EURACHEM/CITAC Guide. Quantifying Uncertainty in Analytical Measurement. 3rd ed. EURACHEM, 2012.
13. Ferreira M do C. The role of metrology in the field of medical devices. *International Journal of Metrology and Quality*

- Engineering.2011;2(2):135-140. <https://doi.org/10.1051/ijmqe/2011013>
14. Fluke Biomedical. Traceability and instrument calibration: Why it matters. White paper. Fluke Biomedical, 2019.
 15. Fluke Corporation. Calibration: A Beginner's Guide. Fluke, 2024.
 16. Government of Bangladesh. Bangladesh Reference Institute for Chemical Measurements Act, 2020 (Act No. 15 of 2020). Ministry of Science and Technology, 2020.
 17. Government of Bangladesh. Bangladesh Accreditation Board Order, 2006 (President's Order No. 13 of 2006). Ministry of Industries, 2006.
 18. Hong Kong Laboratory Accreditation Scheme (HOKLAS). Accreditation Criteria for Calibration Laboratories. HOKLAS, 2024.
 19. International Electrotechnical Commission (IEC). IEC 60601-2-4: Medical electrical equipment—Part 2-4: Particular requirements for defibrillators. IEC, 2018.
 20. International Electrotechnical Commission (IEC). IEC 60601-2-19: Medical electrical equipment—Part 2-19: Requirements for infant incubators. IEC, 2016.
 21. International Laboratory Accreditation Cooperation (ILAC). ILAC Policy for Traceability of Measurement Results. ILAC, 2013.
 22. ILAC. Guidelines for Determination of Calibration Intervals. ILAC G24, 2007.
 23. ILAC. ILAC Mutual Recognition Arrangement (MRA). ILAC, 2020.
 24. International Organization for Standardization (ISO). ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories. ISO, 2017.
 25. International Organization for Standardization (ISO). ISO 80601-2-24: Medical electrical equipment—Part 2-24: Requirements for infusion pumps. ISO, 2016.
 26. International Organization for Standardization (ISO). ISO 15189: Medical laboratories—Requirements for quality and competence. ISO, 2012.
 27. International Organization for Standardization (ISO). ISO 10012: Measurement management systems. ISO, 2003.
 28. International Organization for Standardization (ISO). ISO 13485: Medical devices—Quality management systems. ISO, 2016.
 29. International Organization of Legal Metrology (OIML). OIML TC 18: Medical Devices. OIML, 2015.
 30. OIML. OIML International Recommendations for Medical Devices. OIML, 2018.
 31. JCGM. Evaluation of measurement data—Guide to the expression of uncertainty in measurement (GUM). JCGM 100:2008. BIPM, 2008.
 32. JCGM. International vocabulary of metrology—Basic and general concepts and associated terms (VIM). JCGM 200:2012. BIPM, 2012.
 33. Joint Commission International (JCI). Accreditation Standards for Hospitals. 7th ed. JCI, 2020.
 34. Karaböce B. Challenges for medical metrology. IEEE Instrumentation & Measurement Magazine. 2020;23(3):7-14. <https://doi.org/10.1109/MIM.2020.9126046>
 35. Karaböce B. Medical metrology. In: Modern Metrology Concerns. IntechOpen, 2016. <https://doi.org/10.5772/63388>
 36. Karaböce B, Gülmez Y, Akgöz M, Kaykısızlı H, Yalçınkaya B, Dorosinskiy L. Medical metrology studies at TUBITAK UME. 17th International Congress of Metrology. 2015:06011. <https://doi.org/10.1051/metrology/201506011>
 37. Kumar R, Choudhary RK, Archana, Jahangir MA. Calibration of medical devices: Method and impact on operation quality. Internationale Pharmaceutica Scientia. 2023;16(1):128. <https://doi.org/10.62923/ips2023.161.128>
 38. LNE (Laboratoire National de Métrologie et d'Essais). Medical Devices Calibration Services. LNE, 2021.
 39. Majumder MAA, Shaban SF, Rahman S, Ahmed M. Biomedical research productivity in Bangladesh (1996-2010): A comparison with low-income economy. Journal of the

- College of Physicians and Surgeons Pakistan. 2012;22(6):405-406.
40. Ministry of Industries. National Quality Policy of Bangladesh. Government of Bangladesh, 2018.
41. National Conference of Standards Laboratories (NCSL). Establishment and Adjustment of Calibration Intervals. NCSL RP-1, 2010.
42. National Institute of Standards and Technology (NIST). NIST Calibration Services for Medical Devices. NIST, 2021.
43. National Institute of Standards and Technology (NIST). NIST Annual Report 2021. NIST, 2021.
44. NPL (National Physical Laboratory, UK). Medical Metrology: NPL Capabilities. NPL, 2020.
45. Physikalisch-Technische Bundesanstalt (PTB). Medical Metrology at PTB: Annual Report 2019. PTB, 2019.
46. Taylor JR, Kuyatt CE. Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results. NIST Technical Note 1297. NIST, 1994. <https://doi.org/10.6028/NIST.TN.1297>
47. Trescal. Why Calibration Matters in Healthcare. Trescal, 2022.
48. University of Dhaka. Department of Biomedical Physics & Technology: Annual Report 2022. Dhaka University, 2022.
49. World Health Organization (WHO). Medical device regulations: Global overview and guiding principles. WHO, 2003.
50. World Health Organization (WHO). Medical device maintenance: Global overview and guiding principles. WHO, 2011.
51. World Health Organization (WHO). Human resources for medical device maintenance. WHO, 2017.
52. World Health Organization (WHO). WHO List of Priority Medical Devices for COVID-19. WHO, 2020.
53. WHO. Global Model Regulatory Framework for Medical Devices. WHO, 2020.
54. KRISS (Korea Research Institute of Standards and Science). Medical Metrology Research. KRISS, 2022.
55. Karaböce B. Medical metrology studies and challenges. In: 17th International Congress of Metrology.

2015:06011. <https://doi.org/10.1051/metrology/201506011>