

## Accessing and Improving Testing, Calibration and Validation Management of Hospital Equipment in Nepal

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### Abstract

*This article has examined the current state of testing, calibration, and validation (TCV) management of hospital equipment in Nepal. It has highlighted the role these processes play in ensuring patient safety and healthcare quality. Nepal faces numerous challenges in managing medical devices, including resource limitations, insufficient training, and lack of standard regulatory frameworks. These issues, particularly in rural and under-resourced healthcare facilities, lead to inconsistent equipment performance and increased risks to patient safety. Through a detailed literature review and field-based analysis, the study compares Nepal TCV practices with global standards. It is identified key gaps and opportunities for improvement. Findings exposed that while some urban hospitals have access to modern equipment and trained personnel. Rest many rural facilities lack the necessary infrastructure and expertise to maintain reliable medical devices. The study emphasized the need for a national regulatory body, enhanced training programs for biomedical technicians, and improved access to advanced calibration technologies. Drawing on international best practices, the article recommends policy reforms, investments in technical capacity building, and further research to create a more robust and standardized TCV system in Nepal.*

**Keywords:** Testing Calibration Validation (TCV), hospital equipment management, patient safety biomedical engineering, regulatory frameworks

### Introduction

Hospital equipment effectiveness and safety are essential to provide good healthcare. Developing countries, like Nepal, are facing the problems managing medical devices. This includes testing, calibrating, and checking if they work right. These issues come from several sources such as not having enough money, not enough training, and no clear rules to follow (Karna & Jain, 2023). The effectiveness and safety of hospital equipment have a significant impact on the quality of healthcare. Managing medical devices, including their testing, calibration, and validation often faces obstacles in developing countries like Nepal (Lama et al., 2020). These obstacles trunk from various factors such as limited resources insufficient training, and a lack of standard procedures.

In the context of Nepal, healthcare facilities range from well-equipped city hospitals to rural clinics with few resources. Despite this variety, all facilities need reliable and accurate medical equipment (Gupta et al., 2015). The calibrated devices can cause diagnostic mistakes, put patients at risk, and increase healthcare costs. For this reason, a strong system to test, calibrate, and validate hospital equipment is essential. Testing, calibrating, and validating hospital equipment is important role in managing healthcare. These steps make sure medical tools work right and, which protects patient's health and increases the quality of healthcare (Huang et al., 2020). Good testing and calibrating can stop equipment from breaking down cut down on wrong diagnoses, and lead to better treatment results. Also, checking equipment meets

international safety rules. It builds trust between patients and healthcare workers (Gupta et al., 2015). In a country like Nepal it is still growing and often doesn't have much healthcare stuff. It is important to keep medical equipment precise and reliable.

The current state of testing, calibration, and validation management of hospital equipment in Nepal shows a mixed picture. Some modern hospitals in cities might have access to advanced equipment and trained staff, but many rural and under-resourced healthcare facilities deal with old and maintained devices. Often, there is no standard approach to regular maintenance. It leads to uneven equipment performance and possible risks to patient safety (Sharman et al., 2020). Also limited access to specialized training and poor regulatory oversight make these problems worse. To find specific ways to improve equipment management practices, it's essential to understand the existing gaps in Nepali healthcare system.

### Objective of the Study

This article has explored into how hospitals in Nepal manage their equipment right now. It needs to find out what's missing and what problems they face. It also suggests ways to make things better. The main aim is to offer advice that can help doctors, government officials, and other important people put good solutions into action. The main objectives are:

- To emphasize how crucial regular testing and calibration are to ensure hospital equipment stays safe and works well.
- To explore a thorough picture of how healthcare facilities in Nepal handle equipment and what problems they face.
- To make healthcare providers, policymakers, and stakeholders more aware of how good equipment management systems can improve healthcare in Nepal.

### Literature Review

Hospitals need to test, calibrate, and validate (TCV) their equipment to keep patients safe and ensure accurate medical diagnoses and treatments. Around the world, groups like the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) have set up rules to guide the TCV of medical equipment (Reimerdes et al., 2022). ISO 17025 lays out the basic requirements for testing and calibration labs to be competent making sure they work. In the same way many people recognize the IEC 60601 series as the go-to standard for the safety and performance of medical electrical equipment (Arandia et al., 2022).

In the US and Germany that have advanced economies, following these rules isn't optional - it's required. Hospitals in these nations go through regular checks to make sure they're doing what they must (Claben et al., 2021). They use a mix of their own staff and outside companies to keep their equipment in good shape. What's more, they're starting to use computer programs that handle calibration. This helps cut down on mistakes people might make and makes things run smoother. Many nations have put into action reliable TCV management systems providing useful insights that Nepal could adopt. Take India, for example. The National Accreditation Board for Testing and Calibration Laboratories (NABL) has played a key role in setting up guidelines to accredit medical labs (Rao, 2021). Indian hospitals that follow NABL rules have seen better performance from their diagnostic tools. This has boosted patient confidence and safety.

In Brazil, the National Institute of Metrology, Quality, and Technology (INMETRO) has created a thorough plan to handle TCV. This plan makes technicians attend required training and go through tough regular checks. Because of this, the quality of healthcare services has gotten much better (Stano,

2022). What Brazil has done shows how important it is to have rules and keep learning to manage medical equipment well. There is limited research in how hospitals in Nepal manage their equipment's total cost of value (TCV), but the studies have shown great problems. Research of Lama et al. (2020) stated that many Nepali hospitals don't have what they need to handle TCV well. Gupta et al. (2015) study found out that very few hospitals have biomedical engineers or technicians who know how to do TCV. Also, because there's no national rule book different healthcare places do things their own way.

Karna and Jain, (2023) highlights the scarcity of calibration and testing labs in Nepal. This shortage forces many hospitals to use outside services often at high costs. Using these external agencies slows down the TCV process and raises concerns about how reliable and accurate these services are. The while worldwide standards and practices provide a guide to manage TCV, Nepal faces unique problems that need custom solutions. The next sections explore the methods used in this study to evaluate the current TCV situation in Nepalese hospitals and suggest practical ways to improve.

## Methods and Materials

To assess and improve how hospital equipment in Nepal is tested, calibrated, and validated, the study used several different methods. For data collection the study talked in depth with key people involved such as doctors, government officials, and medical equipment suppliers. These conversations gave us quality insights. For the data collection, visited to hospitals in different parts of Nepal to see how things work on the ground. During the visits, the study observed how they test and adjust equipment, checked the state of the tools, and spotted any problems and things that could be better. It has also use document analysis including hospital files, upkeep records, and government rules. The study

compared the data from Nepal with global standards and practices the study found in the literature review. This comparison helped us measure Nepal's current state against international best practices and spot gaps and chances to improve.

## Discussion

Data gathered from multiple hospitals across Nepal shows a worrying lack in testing, calibration, and validation (TCV) of medical devices. Many hospitals don't have standard TCV management protocols, which leads to inconsistent practices and possible risks to patient safety. Observation and interviews with the participate show that most of the hospitals have a team dedicated to TCV. It is even fewer can access advanced calibration tools and tech. Also, how often equipment gets tested varies a lot, with some hospitals doing checks, while others check when something breaks down.

Nepal TCV management falls far short of global best practices. Advanced nations follow strict rules and have strong systems to test and calibrate equipment hospitals in the US and Europe must stick to detailed standards from groups like the International Organization for Standardization (ISO) and the Joint Commission (Stano, 2022). These rules make sure medical gear is checked, calibrated, and validated often to keep safety and performance high.

On the other hand, Nepal's lack of required rules leads to a scattered approach to TCV. Also, places like Japan and Germany put a lot of money into training programs for technicians and engineers. This ensures they have a workforce that can handle the complex nature of modern medical equipment (Karna & Jain, 2023). Using cutting-edge tech, like automated calibration systems and digital record-keeping, makes TCV processes in these countries even more productive and precise.

Nepal can learn a lot from what other countries are doing. Adopting standard guidelines investing in

training and tech, and changing how organizations view TCV's importance, the country can improve how it manages hospital equipment. The literature shows vast gaps and problems in how Nepali hospitals manage their equipment's TCV. But there are clear ways to make things better. By tackling these issues and following what works best around the world, Nepal can make its medical gear more reliable and safer. This will lead to better care and results for patients.

The discussion has brought together what the study found showing the many challenges that make it hard to manage testing, calibration, and validation well in Nepal. These include poor infrastructure, money problems, and not enough training for healthcare workers. When it compares this to what's done around the world, see that while Nepal has its own unique problems. There are some strategies that work everywhere and can be adapted to make things better in Nepal.

### **Challenges Identified**

The study spotted several main challenges in managing TCV for hospital equipment in Nepal. It is observed that there is lack of proper set of nationwide guidelines for TCV. This causes hospitals to do things. Such differences make it hard to keep safety and performance at the same level everywhere. Many hospitals in country areas, don't have what they need. They are short on skilled workers, lack good facilities, and don't have enough money to keep up with regular checks and fixes.

It is observed that most of hospital the workers don't get enough training on TCV methods. This gap in know-how and abilities makes it tough to put good TCV practices in place and keep equipment working well. Many parts of Nepal can't get their hands-on top-notch calibration tools and tech. This makes it tough to test equipment (Lama et al., 2020). The problem gets worse because this fancy tech costs a lot putting it out of reach for many hospitals. The

awareness and attitudes, often, hospital managers and staff don't realize how crucial regular TCV is (Lama et al., 2020). This means TCV tasks don't get the attention they need, and not enough money or resources are set aside for them.

### **Recommendations**

To improve how hospital equipment in Nepal is tested, calibrated, and validated big changes in policy are needed. Setting up a central regulatory body to watch over and enforce standards for medical equipment is key. This body should have the power to require regular testing and calibration schedules and to certify institutions that meet these standards. New rules should make sure all imported medical equipment meets international standards before it's allowed to be used in the country.

The government should think about helping pay for testing and calibration services for healthcare facilities in rural and underfunded areas, to make sure everyone has access to good healthcare. The problem for good testing and calibration management in Nepal is not having enough trained people. To fix this, it is need to start a full training program. There should aim to build local know-how in biomedical engineering and medical equipment upkeep. Working with international groups and schools can help set up training workshops, give out certificates, and create exchange programs to boost the skills of local techs and engineers.

### **Future Research Directions**

Future studies should on creating strategies tailored to the specific issues Nepali healthcare facilities face. This means doing thorough field work to grasp the particular needs, limits, and abilities of different healthcare places across various areas. Studies should also look into how cost-effective different testing and calibration tech is to find the most doable options for widespread use. What's more, looking at how regular testing and calibration affects patient results can give solid data to push for

needed policy shifts and resource sharing. Teaming up with international research groups can also help to adapt global best practices to the local scene.

To improving how Nepal manages the testing, calibration, and validation of hospital gear needs a wide-ranging plan. This plan should change policies, build skills, and focus on key research. By tackling these areas head-on, Nepal can make sure its health centers have trustworthy and precise medical tools. In the end, this will boost patient care and health results across the country.

## Conclusion

To managing the testing, calibration, and validation of hospital equipment in Nepal has a crucial impact on healthcare infrastructure, but remains underdeveloped. The article has explored why these practices matter showing how they ensure medical devices are safe, accurate, and reliable, which in turn affects how patients fare. Looking at the current scene for testing and calibration in Nepal brings to gaps and hurdles such as weak regulatory systems, not enough technical know-how, and a lack of standard methods. The study highlights how sticking to worldwide standards and learning can help Nepal improve its equipment management.

It has suggested several steps to take: change policies to set up strict rules, the allocation of the budget into training and growth programs, and encourage research to keep up with new tech. These suggestions to create a strong system that makes sure hospital equipment is reliable and safe, which would make healthcare in Nepal better overall. Nepal needs to tackle the issues linked to testing, calibrating, and validating hospital equipment to boost its healthcare system. As using worldwide proven methods and adapting them to fit local requirements, Nepal can make the best practices to enhance the safety and effectiveness of its medical tools. This will not improve patient care quality but

also help reach the bigger aim of creating a strong and productive healthcare system.

## References

- Arandia, N., Garate, J. I., & Mabe, J. (2022). Embedded sensor systems in medical devices: Requisites and challenges ahead. *Sensors*, 22(24), 9917.
- Claben, J., Krysmen, S., Dorscheidt, F., Sterlepper, S., & Pischinger, S. (2021). Real driving emission calibration: Review of current validation methods against the background of future emission legislation. *Applied Sciences*, 11(12), 5429.
- Gupta, S., Shrestha, S., Ranjit, A., Nagarajan, N., Groen, R. S., Kushner, A. L., & Nwomeh, B. C. (2015). Conditions, preventable deaths, procedures and validation of a countrywide survey of surgical care in Nepal. *Journal of British Surgery*, 102(6), 700-707.
- Huang, Y., Li, W., Macheret, F., Gabriel, R. A., & Ohno-Machado, L. (2020). A tutorial on calibration measurements and calibration models for clinical prediction models. *Journal of the American Medical Informatics Association*, 27(4), 621-633.
- Karna, P. K., & Jain, P. J. (2023). Hospital Equipment Maintenance Management for Reliable and Effective Health Care Services in Nepal. *A Bi-annual South Asian Journal of Research & Innovation*, 10(1), 103-109.
- Lama, T. P., Munos, M. K., Katz, J., Khatry, S. K., LeClerq, S. C., & Mullany, L. C. (2020). Assessment of facility and health worker readiness to provide quality antenatal, intrapartum and postpartum care in rural Southern Nepal. *BMC Health Services Research*, 20, 1-12.
- Rao, D. D. (2021). ISO/IEC 17025: Accreditation standard for testing and calibration laboratories. *Radiation Protection and Environment*, 44(3&4), 121-122.
- Reimerdes, H., Agostini, M., Alessi, E., Alberti, S., Andrebe, Y., Arnichand, H., & Moret, J. M. (2022). Overview of the TCV tokamak experimental programme. *Nuclear Fusion*, 62(4), 042018.
- Sharman, J. E., O'Brien, E., Alpert, B., Schutte, A. E., Delles, C., Olsen, M. H., & Stergiou, G. (2020). Lancet Commission on Hypertension group position statement on the global improvement of accuracy standards for devices that measure blood pressure. *Journal of Hypertension*, 38(1), 21-29.
- Stano, P. H. S. (2022). *Implementation of a technique for measuring the level of damage to vehicles through digitization, applicable to vehicle insurance companies* (No. 2021-36-0016). SAE Technical Paper.