

## **Comparison of Medical Device Calibration Compliance Between Paripurna and Utama Accredited Community Health Centers in Palu City**

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### **Abstract**

**Introduction:** Compliance with medical equipment calibration is essential to ensure service quality and patient safety. However, not all medical devices in community health centers (Puskesmas) in Palu City have been calibrated according to standards. **Objective:** This study aimed to analyze differences in calibration compliance between Paripurna-accredited and Utama-accredited Puskesmas. **Methods:** A comparative quasi-experimental study with a posttest-only design was conducted at Kamonji and Lere Health Centers from August to September 2025. Total sampling was applied to all employees, yielding 127 respondents. Data were analyzed using the Independent Sample t-test. **Results and Discussion:** Kamonji Health Center showed higher instrumental compliance, while Lere Health Center demonstrated slightly higher normative compliance. Statistical analysis indicated a significant difference in calibration compliance between the two health centers ( $t = 2.726$ ;  $p = 0.007$ ). **Conclusion:** Calibration compliance was significantly higher at the Paripurna-accredited health center, suggesting that higher accreditation status is associated with better calibration practices. Strengthening supervision and documentation is recommended, particularly for Utama-accredited health centers.

## **Introduction**

Calibration of medical equipment is a crucial aspect in ensuring the quality of healthcare services, diagnostic accuracy, treatment effectiveness, and patient safety (Nielsen & Sahay, 2022; Sivakumar et al., 2020). Along with advances in medical technology, the importance of calibration has been increasingly emphasized globally as part of compliance with international standards and healthcare quality management systems (Gupta & Sarode, 2017; Godwin, 2023; Chow et al., 2023).

Various international reports indicate that uncalibrated medical devices can have serious implications for patient safety. In the United Kingdom, more than 850 incidents related to improperly calibrated medical devices were reported between 2015 and 2020, including cases of medication overdose caused by infusion pump calibration errors (NHS England, 2021). In the United States, approximately 20% of adverse events in healthcare services have been associated with inadequately calibrated medical equipment (The Joint Commission, 2020). In developing countries, more than 50% of medical devices have been reported to function suboptimally due to insufficient maintenance and calibration (WHO, 2021).

In Indonesia, cases of uncalibrated medical equipment are still reported, such as inaccurate blood pressure diagnoses caused by sphygmomanometers that have never been calibrated in several community health centers (Kemenkes RI, 2022). In Palu City, more than 40% of medical equipment in community health centers has reportedly not undergone routine calibration, resulting in measurement inaccuracies and increased patient safety risks (Dinkes Sulteng, 2022). Limited availability of accredited calibration laboratories and qualified technical personnel has been identified as a major barrier to optimal calibration implementation (BPK RI Representative of Central Sulawesi, 2023).

Calibration of medical equipment in community health centers is a mandatory requirement regulated by the Indonesian Ministry of Health Regulation No. 54 of 2015 and constitutes an integral part of quality management systems and patient safety culture (WHO, 2011; Nielsen & Sahay, 2022). Compliance with calibration procedures reflects professional responsibility and contributes to public trust in healthcare services (The Joint Commission, 2020; WHO, 2021). Based on a preliminary study indicating that some medical equipment in community health centers in Palu City has not been calibrated, this study aims to compare the level of staff compliance with medical equipment calibration between a Paripurna-accredited health center (Kamonji Community Health Center) and an Utama-accredited health center (Lere Community Health Center) in Palu City.

## **Method**

This study employed a comparative research design with a quasi-experimental approach, using a posttest-only design. The research was conducted at two community health centers in Palu City, namely Kamonji Community Health Center, which is Paripurna-accredited, and Lere Community Health Center, which is Utama-accredited. The study was carried out from August to September 2025.

The population of this study consisted of all employees working at Kamonji and Lere Community Health Centers. A total sampling technique was applied, whereby all members of the population were included as study participants. Consequently, the total sample size was 127 respondents.

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Data were analyzed using bivariate analysis with the Independent Sample t-test, which aimed to compare the mean levels of medical equipment calibration compliance between two independent groups, namely the Paripurna-accredited and Utama-accredited community health centers.

## Result and Discussion

### 1. Result

#### Univariate Analysis

Table 1 presents the mean scores of medical equipment calibration compliance at Kamonji and Lere Community Health Centers based on two dimensions: instrumental compliance and normative compliance. Instrumental compliance reflects adherence to the physical condition, maintenance, and functional feasibility of medical equipment, while normative compliance represents adherence to regulations, documentation, and standard calibration procedures. The number of respondents was 74 at Kamonji and 56 at Lere Community Health Center.

**Tabel 1**

Average Value of Compliance Rate Community Health Center

Compliance Dimension	Community Health Center	N	Mean	Standard Deviation
Instrumental	Kamonji	74	31.73	4.201
	Lere	56	30.09	4.688
Normative	Kamonji	74	33.96	4.659
	Lere	56	34.11	4.159

*Source: Primary Data, 2025*

Based on the analysis presented in Table 1, the mean score of instrumental compliance at Kamonji Community Health Center was 31.73, slightly higher than that of Lere Community Health Center, which had a mean score of 30.09. This difference indicates that Kamonji demonstrated better instrumental compliance in terms of the physical condition, maintenance, and usability of medical equipment. However, the standard deviation at Lere (4.688) was higher than at Kamonji (4.201), indicating greater variability in compliance levels among respondents at Lere.

Regarding normative compliance, the results showed that Lere Community Health Center had a slightly higher mean score (34.11) compared to Kamonji (33.96). This finding suggests that Lere was more consistent in fulfilling regulatory aspects, including the completeness of calibration certificates, adherence to annual calibration schedules, the availability of equipment fitness labels, and compliance with Ministry of Health Regulation No. 54 of 2015 and Regulation No. 46 of 2015. The standard deviation for normative compliance at Kamonji (4.659) was slightly higher than that at Lere (4.159), indicating more diverse levels of regulatory knowledge or implementation among respondents at Kamonji.

Overall, the findings indicate that Kamonji Community Health Center performed better in instrumental compliance, while Lere Community Health Center showed stronger normative compliance. Lere appeared more compliant with administrative and regulatory requirements, whereas Kamonji demonstrated better technical implementation related to medical equipment. These results reflect differing strengths and weaknesses between the two health centers, highlighting the need for improvements in both the physical condition of equipment and administrative compliance to ensure optimal patient safety and service quality.

### **Independent Sample t-Test**

Table 2 presents the results of the Independent Sample t-test conducted to determine whether the difference in mean medical equipment calibration compliance between the two community health centers was statistically significant. The analysis was preceded by Levene's Test to assess the homogeneity of variances between the groups.

**Table 2**

Independent Sample t-test Results

<b>Variabel</b>	<b>Levene test</b>		<b>T-test for Equality</b>		
	F	Sig	t	Sig	
Compliance	1.195	0.276	5.265	2.726	0.007

*Source: Primary Data, 2025*

Based on the results of the Independent Sample t-test shown in Table 4.2, the Levene's Test yielded an F value of 1.195 with a p-value of 0.276. Since this significance value is greater than 0.05, the variances of the two groups can be considered homogeneous, and the results of the independent t-test were therefore interpreted using the Equal Variances Assumed row.

Under this assumption, the t-test produced a t value of 2.726 with a significance value of 0.007, which is lower than the  $\alpha$  level of 0.05. This finding indicates a statistically significant difference in the level of medical equipment calibration compliance between Kamonji Community Health Center and Lere Community Health Center.

The Mean Difference of 5.265 indicates a clear gap in the average compliance levels between the two health centers, with one center demonstrating higher compliance than the other. This difference suggests that the implementation of medical equipment calibration practices is not uniform across the two facilities and may be influenced by factors such as management quality, staff awareness, availability of facilities, and adherence to regulatory requirements, including Ministry of Health Regulation No. 54 of 2015 and Regulation No. 46 of 2015.

Overall, the results of the t-test confirm that there is a significant difference in calibration compliance between Kamonji and Lere Community Health Centers, indicating that the quality of calibration standard implementation differs between the two facilities and warrants further evaluation and improvement in medical equipment management practices.

## **2. Discussion**

### **Level of Medical Equipment Calibration Compliance in Paripurna-Accredited Community Health Centers**

The results of the study indicate that Kamonji Community Health Center, which holds Paripurna accreditation, demonstrated relatively high average levels of medical equipment calibration compliance across both measured dimensions. The mean score for instrumental compliance was 31.73, while normative compliance reached 33.96. These findings suggest that Paripurna-accredited community health centers have a stronger quality management system in ensuring compliance with medical equipment calibration standards.

This condition is consistent with Regulation of the Indonesian Ministry of Health No. 54 of 2015 on Medical Equipment Testing and Calibration, which mandates that healthcare facilities ensure medical equipment is fit for use through periodic functional testing and calibration. Paripurna accreditation requires stricter implementation of

medical equipment governance, including documentation, standard operating procedures (SOPs), and internal audits. This aligns with Tyler's (1990) theory, which states that organizational compliance is influenced by the consistent application of standards, regulations, and supervision within the organizational structure.

Previous studies support these findings. Research by Putra et al. (2021) found that healthcare facilities with higher accreditation levels demonstrated more consistent calibration practices due to stronger quality monitoring systems. Similarly, Sari and Wibowo (2022) reported that accreditation has a significant effect on staff compliance in medical equipment maintenance. Thus, the higher mean compliance observed in Paripurna-accredited community health centers reflects how a tightly standardized work environment fosters better compliance behavior.

### **Level of Medical Equipment Calibration Compliance in Utama-Accredited Community Health Centers**

At Lere Community Health Center, which holds Utama accreditation, the average level of compliance was lower in the instrumental dimension (30.09), although normative compliance was slightly higher (34.11) compared to the Paripurna-accredited center. This indicates that while regulatory frameworks such as guidelines and SOPs are understood by staff, technical practices related to instrument calibration have not been fully optimized. According to Ministry of Health Regulation No. 46 of 2015 on Community Health Center Accreditation, facilities with Utama accreditation demonstrate good performance but have not yet achieved the highest level of standard fulfillment. This is reflected in several medical equipment management indicators that still require strengthening, particularly in the implementation of technical calibration procedures.

These findings are consistent with Rahmawati (2023), who reported that Utama-accredited community health centers tend to lack optimally functioning facility maintenance units and have insufficient updates to technical SOPs related to medical equipment calibration. Additionally, Hutagalung et al. (2024) found that calibration compliance is influenced by factors such as workload, budget availability, and the level of supervision provided by the head of the community health center.

### **Differences in Compliance Levels Between Paripurna- and Utama-Accredited Community Health Centers**

The results of the Independent Sample t-test revealed a significant difference in medical equipment calibration compliance between Kamonji Community Health Center (Paripurna-accredited) and Lere Community Health Center (Utama-accredited), with  $t = 2.726$ ,  $p = 0.007$ , and a mean difference of 5.265. These findings confirm that community health centers with higher accreditation levels consistently demonstrate better calibration compliance. This supports Tyler's (1990) theory, which emphasizes that individual compliance within organizations is strongly influenced by the legitimacy of rules, organizational structure quality, and consistency in regulatory enforcement. Paripurna-accredited community health centers, having met the highest quality standards, tend to possess stronger documentation systems, SOPs, supervision mechanisms, and safety cultures, resulting in higher compliance levels.

These differences are also aligned with Ministry of Health Regulation No. 46 of 2015, which stipulates that higher accreditation levels require more comprehensive fulfillment of standards related to administration, risk management, and continuous quality improvement. Paripurna-accredited community health centers are required to

maintain internal supervision systems, standardized SOPs, and documented evidence of quality implementation, including medical equipment management. Consequently, this leads to better compliance in calibration practices.

Furthermore, these findings are consistent with Ministry of Health Regulation No. 54 of 2015, which mandates that all healthcare facilities conduct regular testing and calibration of medical devices, maintain documentation, and apply “fit-for-use” labeling. Paripurna-accredited centers generally demonstrate stronger documentation cultures and more intensive audit systems, enabling greater consistency in meeting these requirements. In contrast, Utama-accredited facilities tend to have greater room for improvement in medical equipment management, particularly in record-keeping, labeling, and routine calibration implementation.

The results of this study align with various national and international studies. Research by Setiawan and Ningsih (2020) and Marbun et al. (2025) found that healthcare institutions with higher accreditation levels exhibit better compliance with medical equipment maintenance and calibration due to stricter internal audits and more structured quality oversight. Internationally, Alkhenizan and Shaw (2020) in the International Journal for Quality in Health Care reported that accredited healthcare facilities demonstrate better compliance with medical equipment safety standards, maintenance, and clinical governance. Similarly, El-Jardali et al. (2021) in Lebanon found that accreditation improves staff adherence to standard medical procedures, including equipment use and calibration, by fostering a culture of safety and continuous improvement.

Additionally, Greenfield and Braithwaite (2020) reported that healthcare institutions achieving higher accreditation levels perform better in instrument safety and device management, as accreditation enforces consistency in equipment inspection and calibration. Similar findings were reported by Ojo et al. (2022) in Nigeria, showing a significant increase in compliance with equipment maintenance and calibration following national accreditation. Research by Tanaka et al. (2023) in Japan demonstrated that hospitals accredited by the Japan Council for Quality Health Care showed higher compliance with medical equipment inspections, particularly regarding measurement accuracy and electrical safety. These findings indicate that accreditation promotes strict implementation of technical SOPs through audits and regular reviews of equipment conditions.

Finally, a WHO (2021) study on medical device management in primary healthcare settings emphasized that facilities implementing formal quality standards and accreditation audits exhibit higher compliance with calibration and maintenance practices. Facilities with weaker quality systems are more likely to fail in documentation, calibration scheduling, and quality supervision.

## **Conclusion**

Based on the results and discussion regarding medical equipment calibration compliance in community health centers in Palu City, it can be concluded that the level of calibration compliance differs between Paripurna-accredited and Utama-accredited community health centers. These differences are observed in both instrumental compliance and normative compliance, reflecting variations in the implementation of technical and regulatory standards for medical equipment management.

Kamonji Community Health Center, which holds Paripurna accreditation, demonstrated better instrumental compliance related to the physical condition, maintenance, and usability of medical equipment. This indicates that community health centers with the highest accreditation level have stronger quality management systems and more robust technical medical equipment management. In contrast, Lere Community Health Center, which holds Utama accreditation, showed relatively better normative compliance, associated with understanding and fulfilling regulatory requirements, documentation, and standard operating procedures.

The results of the Independent Sample t-test revealed a statistically significant difference in medical equipment calibration compliance between the two community health centers, confirming that accreditation status influences calibration compliance. Community health centers with Paripurna accreditation consistently demonstrated higher compliance levels compared to those with Utama accreditation.

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