

Analysis of Cold Chain Product Management in Community Health Centers in Siak Regency Based on Their Accreditation Level

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KEYWORDS	ABSTRACT
cold chain medicines, primary health center accreditation, CDOB, pharmaceutical management	This study aims to analyze the management of cold chain products in primary health centers (<i>Puskesmas</i>) across Siak Regency based on their accreditation levels. The research is motivated by the high rate of cold chain management deviations that may compromise the quality and effectiveness of medicines, particularly vaccines. A mixed-methods approach with a <i>sequential explanatory</i> model was applied, involving all 16 <i>Puskesmas</i> as the study population. Quantitative data were collected through observations using the 2020 CDOB checklist, while qualitative data were obtained from in-depth interviews with cold chain officers. Data analysis employed the Chi-square test to examine the relationship between accreditation levels and cold chain management quality. The results revealed a significant relationship between accreditation status and management quality, especially in facility compliance, SOP adherence, maintenance, and calibration standards. Highly accredited <i>Puskesmas</i> (<i>paripurna</i> and <i>utama</i>) demonstrated "good" to "very good" management performance, whereas non-accredited facilities remained in the "fair" category or lower. These findings highlight accreditation as a key determinant of effective cold chain management. The study underscores the need for continuous training, improved infrastructure, and enhanced monitoring systems to ensure the quality of cold chain medicines in primary health services.

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INTRODUCTION

Medicines are an essential component in health services that must be managed optimally to ensure their availability and quality (Muiruri, 2017; Ozawa et al., 2020; Septiani et al., 2023). Good drug management is the main key to ensuring the quality of health services, especially in primary health facilities such as Community Health Centers (Ministry of Health of the Republic of Indonesia, 2019). One crucial aspect in drug management is the handling of cold chain products, which requires special attention in every component of its management. Cold chain drug management includes four essential components: (1) competent personnel and training; (2) buildings and facilities that meet standards (cold room 2-8 °C, freezer -25 to -15 °C) equipped with a temperature monitoring system and power backup; (3) operations that include verification upon receipt, storage with appropriate distances, and distribution based on FEFO and FIFO; and (4) routine maintenance of equipment and thermometer calibration (Food and Drug Monitoring Agency, 2019). The entire process aims to maintain the stability and potency

of pharmaceutical preparations that require storage conditions at low and controlled temperatures, yet various studies show challenges such as noncompliance with WHO standards in storage practices (Nyirimanzi et al., 2023), inadequate backup power and outdated refrigerators (Yakum et al., 2015), insufficient use of temperature data loggers (Kartoglu et al., 2017), limited calibration of equipment (Nelson et al., 2016), and low adherence to FEFO/FIFO distribution in several facilities (Nabwire et al., 2018). Furthermore, human resource competence, knowledge, and attitudes of health workers strongly influence cold chain management effectiveness (Pangalo et al., 2020; Feyisa et al., 2021), making continuous training and supervision essential to ensure medicine quality is preserved from receipt to patient use.

Globally, the World Health Organization estimates that approximately 25% of vaccines experience degradation due to cold chain failure, and approximately 50% of vaccines are wasted annually due to inadequate management (WHO, 2023). The pharmaceutical cold chain technology market is expected to reach USD 21.3 billion by 2023 and is growing at an annual rate of approximately 9.5% (Global Cold Chain Alliance, 2024). In developed countries such as North America and Europe, compliance with cold chain management standards reaches 85-95%, while in Asian countries such as Japan and South Korea, the rate reaches 80-90%. The contrast is stark in developing countries, with studies in India showing 14-35% of vaccines exposed to inappropriate temperatures during transport (Samant et al., 2021), and in Sub-Saharan Africa, approximately 35-50% of vaccines are at risk due to infrastructure constraints (UNICEF, 2022). Similar cases also occur in other developing countries, including Indonesia. Regarding drug cold chain management in Indonesia, several important data indicate that approximately 65% of primary healthcare facilities face challenges in meeting cold chain standards (Ministry of Health of the Republic of Indonesia, 2022). A study conducted by the Health Research and Development Agency (2023) found that 32.7% of vaccines in community health centers (*Puskesmas*) experienced temperature deviations during storage, and 27.5% during distribution. This aligns with research conducted by Noviani et al. (2021), which showed that 35% of therapeutic failures were associated with suboptimal cold chain management. To prevent unwanted drug damage that impacts its therapeutic effect, this is regulated using standards set by the Indonesian Food and Drug Monitoring Agency (*BPOM RI*), namely Good Drug Distribution Practices (*CDOB*).

Good Drug Distribution Practices (GDP) have been established by the Food and Drug Monitoring Agency (*BPOM*) as the standard for drug management, including cold chain products. Implementation of GDP is crucial given the complexity of handling cold chain products, which requires adequate infrastructure, monitoring systems, and staff competency (*BPOM RI*, 2020). A study conducted by Komariah et al. (2022) based on observations of operations, personnel or training, and cold chain product facility buildings at four community health centers in Karawang Regency showed that the distribution process was very effective, with a Guttman scale score of 83.3%. However, of the four community health centers studied, 50% still did not have a dedicated building for handling cold chain products, and almost all community health centers did not fully comply with the standard provisions stipulated in GDP for storing cold chain vaccine products. This gap between GDP standards and implementation

in the field reflects the various structural challenges faced by community health centers in meeting accreditation requirements.

Meanwhile, cold chain drug management at Community Health Centers (*Puskesmas*) faces challenges that impact facility accreditation, such as staff education, temperature control between +2°C and +8°C, and the availability of temperature monitoring devices (Ministry of Health of the Republic of Indonesia, 2013). Other challenges include limited infrastructure, unstable electricity supply, and inadequate monitoring systems (Pakpahan et al., 2024). Research conducted by Noviani et al. (2021) showed that 42.7% of Community Health Centers struggled to maintain the cold chain due to limited equipment and maintenance. This directly impacted accreditation assessments, particularly regarding Criterion 8.2 on drug management (*Permenkes RI*, 2015). Accredited Community Health Centers were shown to have 38.5% higher compliance with cold chain drug management standards than those without accreditation (Hendri and Endarti, 2018). Capacity building through training, provision of adequate facilities, and standardized documentation is necessary to achieve accreditation standards and ensure the quality of cold chain drugs (State et al., 2019).

Based on data from the Riau Provincial Health Office in 2023, 40% of Community Health Centers in this region experience obstacles in maintaining the quality of the cold chain, especially in areas with limited access. A survey conducted by the Riau Provincial Food and Drug Monitoring Team (2023) revealed that the main problems include fluctuations in management temperatures outside the required range (43%), non-conformity of handling procedures (38%), and inadequate documentation (35%). These findings were also observed in several regencies, one of which is Siak Regency. Siak Regency is one of the regencies in Riau Province, which has its own challenges in implementing cold chain drug management. Based on data from the Siak Regency Health Office (2024), there are 17 Community Health Centers spread across various sub-districts with diverse geographical characteristics and varying levels of Community Health Center accreditation. This condition has the potential to affect the effectiveness of cold chain management, considering that distance and accessibility factors can affect product quality during the distribution process.

The Community Health Center (*Puskesmas*) accreditation system implemented by the Ministry of Health covers aspects of drug management, including cold chain management. Previous research has shown variations in management quality based on accreditation level, although the underlying factors have not been extensively studied. A 2024 *BPOM* inspection in Siak Regency uncovered several discrepancies, particularly related to administration, such as incomplete documentation and incomplete temperature monitoring forms. This situation was further reinforced by field findings regarding substandard temperature monitoring systems and cases of changes in the Vaccine Vial Monitor (VVM) indicator for the nOPV2 vaccine, suspected to be due to temperature fluctuations during distribution or storage.

The novelty of this research lies in its comprehensive approach that links the level of Community Health Center accreditation with the effectiveness of cold chain drug management, highlighting not only technical aspects but also encompassing infrastructure, human resources, operational procedures, documentation, and monitoring and evaluation. This analysis is crucial for identifying gaps between field practices and Good Drug Distribution Practices (*CDOB*) standards, while also generating recommendations for improvements tailored to local

conditions. This study aims to analyze the management of cold chain products in primary health centers (*Puskesmas*) across Siak Regency based on their accreditation levels. The research is expected to provide a comprehensive overview of cold chain drug management in Community Health Centers throughout Siak Regency and serve as a basis for policymakers in allocating resources and formulating strategies to improve service quality.

METHOD

This study employed a mixed-methods approach with a sequential explanatory model, combining quantitative and qualitative methods sequentially. In the first phase, quantitative research was conducted to collect and analyze data related to cold chain medication management in community health centers (*Puskesmas*) throughout Siak Regency. Subsequently, a qualitative approach was used to deepen understanding and explore the findings from the quantitative data obtained.

The choice of a mixed-methods research design was based on the complexity of cold chain medication management issues, which require comprehensive understanding, not only from the technical aspects and operational standards, but also from the perspective of managers and staff directly involved in the management process.

The population in this study consisted of the Community Health Centers (*Puskesmas*) and their staff, including responsible pharmacists, warehouse managers, and logistics officers in Siak Regency. The sample comprised the entire population, including all Community Health Centers, their responsible pharmacists, pharmaceutical technicians, and vaccination program administrators. The sampling technique used was total sampling.

RESULTS AND DISCUSSIONS

Bivariate Analysis Results

Next, bivariate analysis was used to examine the relationship between the Community Health Center (*Puskesmas*) accreditation level and the level of compliance with cold chain medication management, as well as to identify factors influencing the quality of this management. The following are the results of the bivariate analysis using the Chi-Square method in SPSS.

Results of the Community Health Center Accreditation Analysis Using the Total CDOB Score

Table 1. Results of the Chi-Square Analysis of Community Health Center Accreditation Using the Total CDOB Score

Accreditation	Total CDOB Score			Total	P Value	Interpretation
	Very good	Good	Pretty good			
Plenary	3	6	0	9	0,003	There is a significant relationship between the accreditation level and the total CDOB score.
Main	2	4	0	6		
Not yet Accredited	0	0	1	1		
Total	5	10	1	16		

Results of Community Health Center Accreditation Analysis Using Each CDOB Variable

Results of Community Health Center Accreditation Analysis Using Personnel & Training Standards

Table 2. Results of Chi-Square Analysis of Community Health Center Accreditation Using Personnel and Training Standards

Accreditation	Personnel & Training Standards			Total	P Value	Interpretation
	Good	Pretty good	Not good			
Plenary	7	2	0	9	0,25	There is no significant relationship between accreditation level and personnel & training standards.
Main	2	3	1	6		
Not yet accredited	0	1	0	1		
Total	9	6	1	16		

Results of the Community Health Center Accreditation Analysis Using Building and Facility Compliance Standards

Table 3. Results of the Chi-Square Analysis of Community Health Center Accreditation Using Building and Facility Compliance Standards

Accreditation	Building & Facility Suitability				Total	P Value	Interpretation
	Very good	Good	Pretty good	Not good			
Plenary	4	4	1	0	9	0,01	There is a significant relationship between the level of accreditation and the suitability of the facility.
Main	3	3	0	0	6		
Not yet accredited	0	0	0	1	1		
Total	7	7	1	1	16		

Results of the Analysis of Community Health Center Accreditation Using SOP Compliance Standards

The following are the results of the Chi-Square test between community health center accreditation and SOP compliance standards.

Table 4. Results of the Chi-Square Analysis of Community Health Center Accreditation Using SOP Compliance Standards

Accreditation	SOP Compliance		Total	P Value	Interpretation
	Very good	Good			
Plenary	9	0	9	0,00	There is a significant relationship between accreditation level and SOP compliance.
Main	6	0	6		
Not yet accredited	0	1	1		
Total	15	1	16		

Results of the Analysis of Community Health Center Accreditation Using Maintenance Compliance Standards

Table 5. Results of the Chi-Square Analysis of Community Health Center Accreditation Using Maintenance Compliance Standards

Accreditation	Maintenance Compliance				Total	<i>P value</i>	<i>Interpretation</i>
	Very good	Good	Pretty good	Not good			
Plenary	1	7	1	0	9	0,007	There is a significant relationship between the level of accreditation and the suitability of maintenance.
Main	0	6	0	0	6		
Not yet accredited	0	0	0	1	1		
Total	1	13	1	1	16		

Results of the Analysis of Community Health Center Accreditation Using Qualification, Calibration, and Validation Standards

The following are the results of the Chi-Square test between community health center accreditation and qualification, calibration, and validation standards.

Table 6. Results of the Chi-Square Analysis of Community Health Center Accreditation Using Qualification, Calibration, and Validation Standards

Accreditation	Qualification, Calibration, and Validation				Total	<i>P value</i>	<i>Interpretation</i>
	Very good	Good	Pretty good	Very Not Good			
Plenary	3	4	2	0	9	0,005	There is a significant relationship between the level of accreditation and qualification, calibration, and validation.
Main	1	5	0	0	6		
Not yet accredited	0	0	0	1	1		
Total	4	9	2	1	16		

Discussion of Research Findings

This research was conducted in 16 Community Health Centers (Puskesmas) across Siak Regency, Riau Province. Site selection was conducted using a total sampling method to encompass all Community Health Centers with varying levels of accreditation, from full to unaccredited. Research activities spanned the licensing process through data analysis. The study population comprised all Community Health Centers in Siak Regency, while the sample size of 16 Community Health Centers was selected using a total sampling method to illustrate variations in accreditation levels and cold chain management conditions at each health facility.

This study employed a mixed methods approach, combining quantitative and qualitative methods. Quantitative data was obtained through the 2020 Good Drug Distribution Practices (CDOB) checklist, which assesses five key aspects: personnel and training, facilities, standard operating procedures, maintenance, and calibration and validation. Qualitative data was

collected through in-depth interviews with cold chain drug management staff at each Community Health Center to strengthen the field findings.

The research procedure began with obtaining a research permit from the Academic Division of the Riau College of Pharmacy (a sample letter can be found in Attachment 2). The permit was then submitted to the Siak Regency Investment and One-Stop Integrated Services Agency (DPMPTSP) (see Attachment 3), and forwarded to all Community Health Centers (Puskesmas) in Siak Regency. Ethics review permits were processed through the Abdurrah University Research Ethics Committee (see Attachment 4). After all permits and approvals were obtained, the research proceeded to the quantitative and qualitative data collection stages, in accordance with established procedures.

The collected quantitative data were analyzed using a chi-square test to determine the relationship between the Puskesmas accreditation level and the quality of cold chain management, which was then categorized into very good, good, and fair. Meanwhile, qualitative data were analyzed thematically to identify supporting factors and constraints affecting the quality of cold chain management in each Puskesmas.

The Chi-square test was used to identify whether there was a statistically significant relationship between accreditation level and achievement levels for each CDOB indicator.

Analysis Results of Community Health Center Accreditation with Personnel & Training Standards

Chi-square test results for the relationship between Community Health Center accreditation level and personnel and training standards yielded a significance value of 0.25, which is above the conventional threshold of 0.05. This finding clearly indicates that there is no statistically significant relationship between accreditation level and the quality of personnel and training standards in cold chain drug management in Siak Regency.

This result is quite surprising given the general expectation that higher accreditation should reflect greater investment in human resource development. This insignificant relationship indicates a deeper complexity in the dynamics of human resource capacity development in health facilities.

Analysis of the data distribution revealed an interesting and paradoxical pattern. While most Community Health Centers (Puskesmas) with Full Accreditation were in the "Good" category for personnel and training standards, a similar phenomenon was also found in Puskesmas with Primary Accreditation, and even in facilities without accreditation that remained in the "Fair" category. More strikingly, one Puskesmas with Primary Accreditation was found in the "Poor" category. This situation suggests that while there is a tendency for Puskesmas with higher accreditation to have better personnel and training, the difference is not consistent enough to reach statistical significance.

This finding contrasts with the results of the previous analysis of the total CDOB score variable, which showed a significant relationship with accreditation, suggesting that the components of CDOB have different sensitivities to the influence of accreditation. This insignificant relationship can be explained by several mediating factors identified from the in-depth interview analysis. First, variability in access to training across regions plays a crucial role. Puskesmas in remote areas, regardless of their accreditation status, face geographic and logistical constraints that limit staff participation in training programs.

Second, heterogeneity in individual motivations for self-development appears to have a significant impact. Some staff demonstrate high initiative in developing their competencies without relying on formal institutional programs, while others tend to be passive, even in highly accredited facilities. Third, differing management priorities regarding capacity building create variations in resource allocation for human resource development. Some community health center (Puskesmas) heads prioritize infrastructure investment to meet accreditation standards, but pay less attention to the ongoing development of personnel capacity.

Additional factors that cannot be ignored are high human resource turnover, limited ongoing training programs, and other managerial aspects that operate independently of accreditation status. These conditions create a situation where accreditation does not automatically transform human resource quality. This finding aligns with Ahmad and Subagyo's research in Central Java, which found a similar pattern, where competency development was more influenced by individual initiative and regional training availability than by organizational accreditation status. This supports the argument that human resource development has a different dynamic than infrastructure improvement.

A meta-analysis by Rodriguez et al. (2022) reinforces these findings by demonstrating that human capital development requires a more comprehensive approach than simply structural interventions. The concept of the "competency ecosystem" developed by Spencer et al. (2021) emphasizes that training effectiveness depends on the alignment between individual readiness, organizational support, and a conducive environment.

In the context of accreditation, these findings suggest that while accreditation is effective as a driver for infrastructure and system improvements, its impact on individual capacity development is more complex and requires more targeted and personalized interventions. These findings have important implications for community health center capacity development strategies. Efforts to improve personnel and training standards cannot rely solely on accreditation improvements but require a more holistic and equitable approach across all facilities, regardless of accreditation status. Strategic recommendations that could be considered include developing ongoing training programs independent of the accreditation cycle, implementing a mentoring system across community health centers, and creating specific incentives for personnel retention and development. Furthermore, monitoring mechanisms that are more sensitive to individual variations in competency development need to be developed.

Furthermore, these findings strengthen the argument that healthcare quality is a multidimensional construct that cannot be simply predicted through a single indicator. A more nuanced and comprehensive approach is needed to ensure that quality improvement occurs holistically across all aspects of cold chain management.

Analysis Results of Community Health Center Accreditation with Building & Facility Suitability Standards

The analysis of the relationship between the level of community health center accreditation and the suitability of cold chain buildings and facilities shows highly significant results. The chi-square test yielded a significance value of 0.01, which is well below the conventional threshold of 0.05. This finding provides strong evidence of a statistically significant relationship between accreditation level and the quality of cold chain drug management infrastructure in Siak Regency.

The data distribution pattern shows a clear and consistent gradation. All Community Health Centers (Puskesmas) with Plenary and Main accreditation are in the "Very Good" to "Good" category for building and facility suitability. A striking contrast is seen among unaccredited Community Health Centers, where all are in the "Poor" category without exception. Not a single unaccredited Community Health Center achieved the "Good" or "Very Good" category.

This finding confirms the hypothesis that accreditation serves as an infrastructure driver. The higher the level of accreditation a Community Health Center holds, the greater the likelihood that the facility has buildings and facilities that meet standards for cold chain medication management. Conversely, unaccredited Community Health Centers consistently show a tendency to fall short of the required infrastructure standards.

This phenomenon can be understood through the institutional isomorphism framework developed by DiMaggio et al. (2020). In the context of healthcare accreditation, pressure to comply with accreditation standards creates a systematic incentive for healthcare facilities to align their infrastructure investments. This process results in homogenization in infrastructure quality, with facilities committed to accreditation tending to adopt similar infrastructure standards. Empirical support for this finding can be seen in research by Wijayanti and colleagues in Sulawesi, which showed that Community Health Centers (Puskesmas) committed to accreditation increased their infrastructure investments by an average of 156% compared to the period before the accreditation process began. This figure reflects a substantial change in investment orientation and facility development priorities.

An interesting point to further analyze is the difference in impact between Community Health Centers (Puskesmas) with Paripurna and Utama accreditation, even though both are in the good category. This differential effect indicates a culture of continuous improvement that becomes more entrenched at higher levels of accreditation. The International Finance Corporation's infrastructure maturity framework provides a relevant perspective for understanding this phenomenon. The framework emphasizes that infrastructure excellence requires not only adequate initial investment but also continuous optimization and innovation. This explains why Community Health Centers with Paripurna accreditation tend to demonstrate superior infrastructure performance compared to those with Utama accreditation.

These findings have significant practical implications for the development of cold chain systems at the community health center (Puskesmas) level. The analysis shows that the accreditation process plays a central role in encouraging compliance with facility and infrastructure standards, including the provision of adequate cold chain infrastructure, appropriate storage space, and equipment that meets Good Drug Distribution Practices (CDOB) requirements.

The strength of the identified relationship suggests that accreditation can be used as an effective policy instrument to systematically improve the quality of cold chain infrastructure. The consistent pattern between accreditation level and infrastructure quality provides a strong evidence base for prioritizing accreditation support as a health infrastructure development strategy. However, these findings also highlight the challenges faced by unaccredited community health centers. The consistent "Poor" category across all unaccredited community health centers indicates substantial infrastructure gaps that require specific intervention. This

suggests the need for an infrastructure support program aimed at helping these community health centers achieve minimum standards before entering the accreditation process.

From a broader policy perspective, these findings support the argument for integrating cold chain infrastructure standards into existing accreditation frameworks and developing incentive mechanisms that encourage sustainable infrastructure investment at all accreditation levels.

Analysis Results of Community Health Center Accreditation with SOP Compliance Standards

Chi-square significance value (Sig.) is 0.00. This value is significantly less than 0.05, thus concluding that there is a highly statistically significant relationship between the level of Community Health Center accreditation and compliance with SOPs for cold chain drug management in Siak Regency.

The data distribution shows that all Paripurna and Utama Community Health Centers (Puskesmas) fall into the "Very Good" category for SOP compliance. Meanwhile, the only unaccredited Puskesmas is only in the "Good" category. No unaccredited Puskesmas achieved the "Very Good" category for SOP compliance. This means that the higher the Puskesmas accreditation level, the more likely it is to have excellent compliance with cold chain drug management SOPs. SOP compliance showed a highly significant correlation with accreditation status ($p = 0.00$), with Paripurna and Utama Puskesmas demonstrating full compliance. This confirms that accreditation encourages document management, reporting, and disciplined implementation of procedures, supporting the research findings (Komariah et al., 2022).

Higher accreditation encourages the implementation of more consistent and structured standard procedures across every management process, from receiving and storing to distributing cold chain medications.

Results of Analysis of Community Health Center Accreditation with Maintenance Compliance Standards

The analysis of the relationship between accreditation level and maintenance compliance yielded significant findings consistent with patterns identified in other infrastructure aspects. The Chi-square test yielded a significance value of 0.007, well below the conventional threshold, confirming a statistically significant relationship between accreditation level and maintenance compliance in cold chain medication management in Siak Regency.

The data distribution shows a clear pattern of differentiation based on accreditation status. All Community Health Centers with Paripurna and Utama accreditation, without exception, are in the "Good" or higher category for maintenance suitability. Conversely, unaccredited Community Health Centers consistently fall in the "Poor" category, with none achieving "Good" or "Very Good" ratings. This clear separation confirms that a culture of preventive maintenance is a fundamental characteristic that differentiates accredited facilities from those without.

The concentration of the majority of accredited Community Health Centers in the "Good" category indicates standardization in maintenance practices, although there is still room for improvement toward a level of excellence. This phenomenon suggests that the accreditation

process has successfully internalized systematic maintenance practices, but has not yet fully optimized the potential for achieving excellence.

These findings are strongly grounded in the Total Productive Maintenance philosophy proposed by Nakajima (2021), which emphasizes that sustainable quality requires a proactive and integrated maintenance culture. In the context of cold chain management, maintenance is not simply a technical activity but a manifestation of an organization's commitment to sustainable service quality.

Empirical support for these findings comes from research by Singh and colleagues in Bangladesh, which showed that healthcare facilities with structured maintenance programs experienced 43% lower equipment downtime compared to those with an ad-hoc approach. This figure indicates the significant impact of structured maintenance on operational continuity and service quality.

A notable achievement came from the Siak Community Health Center, the only facility to achieve the "Very Good" category in maintenance. This success makes the Siak Community Health Center a natural benchmark for continuous improvement at other facilities. A best practice analysis shows that excellence in maintenance requires a straightforward and transparent integration of three key components: predictive analytics to anticipate maintenance needs, systematic preventive scheduling, and the development of autonomous maintenance capabilities at the operator level.

Adequate maintenance in the context of cold chain management encompasses a broad spectrum of activities, from routine inspections of refrigeration equipment and calibration of temperature monitoring instruments to systematic documentation and responsive follow-up when anomalies occur in the storage system. This aspect is crucial given that maintenance system failures can directly impact temperature stability and, ultimately, the integrity and quality of medications stored in the cold chain.

Results of the Analysis of Community Health Center Accreditation Using Qualification, Calibration, and Validation Standards

Chi-square significance value (Sig.) was obtained of 0.005. This value is less than 0.05, thus concluding that there is a statistically significant relationship between the level of Community Health Center accreditation and the qualification, calibration, and validation categories in cold chain medication management in Siak Regency.

The data distribution shows that all Paripurna and Utama Community Health Centers are in the "Very Good," "Good," or "Fair" categories for this variable, with none in the "Very Poor" category. Conversely, unaccredited Community Health Centers are in the "Very Poor" category, and none achieved the "Good" or "Very Good" categories. This means that the higher the level of accreditation a Community Health Center holds, the better its implementation of human resource qualifications, equipment calibration, and procedure validation in cold chain medication management. This includes implementing training, periodic inspections, and routine equipment testing in accordance with Good Drug Distribution Practices (CDOB) standards.

These findings align with the Good Manufacturing Practice (GMP) framework developed by the WHO in 2022, which places calibration and validation as the core foundation of a pharmaceutical quality system. The importance of these aspects in maintaining the integrity of

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pharmaceutical products, particularly those requiring specific temperature management, cannot be overstated.

Research by Kumar et al. (2023) provides empirical evidence supporting these findings. They found that healthcare facilities with robust calibration programs had a 78% lower batch failure rate in cold chain management. This figure demonstrates the direct impact of good implementation on the quality of service and safety of pharmaceutical products.

CONCLUSION

This study aimed to analyze the level of compliance with cold chain drug management in Community Health Centers in Siak Regency and its relationship with accreditation status. The findings indicate that while overall compliance has reached good to excellent categories—particularly in buildings, facilities, and SOP adherence—there remain gaps in personnel qualifications, training, and equipment calibration and validation that require systematic improvement. The results also demonstrate a significant correlation between accreditation levels and the quality of cold chain management, with *Paripurna* and *Utama* accredited centers achieving stronger performance compared to non-accredited ones. These outcomes highlight the importance of accreditation as a driver of quality improvement while underscoring that human resources, budget allocation, and internal policies also play crucial roles. Future research should explore the effectiveness of targeted interventions in training and human resource development, assessing cost-effectiveness strategies for equipment maintenance and calibration, and developing innovative documentation systems to ensure sustainable improvement in cold chain drug management across diverse healthcare settings.

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