

# Compliance Analysis of Vaccine Storage and Distribution at the Samarinda Pharmacy Installation in December 2024

Asih Rahayu Pamungkas<sup>1</sup>, Muh. Taufiqurrahman<sup>2</sup>, Raymon Simanullang<sup>3</sup>

<sup>1,2,3</sup> Bachelor of Pharmacy Study Program, Dirgahayu College of Health Sciences Samarinda, Indonesia

e-mail:

<sup>1</sup> [asihrahayupamungkas@gmail.com](mailto:asihrahayupamungkas@gmail.com)

<sup>2</sup> [muh.taufiqurrahman@gmail.com](mailto:muh.taufiqurrahman@gmail.com)

<sup>3</sup> [simanullang.raymon@gmail.com](mailto:simanullang.raymon@gmail.com)

## ABSTRACT

Vaccines are very susceptible to damage, so vaccine management requires special handling. Vaccines if handled not according to the provisions can cause damage to the vaccine so that it reduces or eliminates the potential, and can even cause post-immunization adverse events when administered. The objective of this study is to assess the compliance of immunization vaccine storage and distribution at Samarinda Pharmacy Installation with the Good Distribution Practices (GDP) Guidelines of 2020 and Guidelines for Vaccine Management in Healthcare Facilities of 2021 for the period December 2024. This research approach is qualitative research. Qualitative research is presented in descriptive form. Data collection was carried out by observation using a checklist, document observation in 2024 and interviews with the pharmacist in charge. The population in this study were all immunization vaccines stored at the Samarinda Pharmacy Installation. The results obtained will be compared with the guidelines of good distribution practice and the guidelines for vaccine management in health facilities. Based on the results of the study conducted at Samarinda Pharmacy Installation, the compliance of vaccine storage was 67% based on the GDPN Guidelines of 2020 and 94% based on the Guidelines for Vaccine Management in Healthcare Facilities of 2021. The compliance rate of vaccine distribution was 83% based on the GDP Guidelines of 2020 and 100% based on the Guidelines for Vaccine Management in Healthcare Facilities of 2021.

Keywords: compliance, vaccine, storage, distribution

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## Introduction

Efforts to establish immunity or immunization against infectious diseases have long been implemented in Indonesia. The immunization program is one of the primary strategies for preventing diseases, disabilities, and deaths caused by vaccine-preventable diseases in both children and adults. It is a national health priority under the Ministry of Health and serves as a tangible manifestation of the government's commitment to achieving the Sustainable Development Goals (SDGs) (Ministry of Health Republic Indonesia, 2021). Based on their implementation, immunizations are categorized into program-based and optional immunizations. The provision and

implementation of program-based immunization are regulated in accordance with statutory provisions. The Minister of Health Regulation of the Republic of Indonesia No. 12 of 2017 concerning the implementation of immunization governs both program-based and optional immunization services.

Immunization involves the use of vaccines as the primary component to enhance immunity against specific infectious diseases. Therefore, vaccine availability must be ensured up to the point of delivery, with maintained efficacy and usability. Vaccines must be stored at specific temperatures: between 2°C and 8°C for freeze-sensitive vaccines (must not be frozen), and between -15°C and -25°C for heat-sensitive vaccines (WHO, 2015). Vaccines such as polio, *Bacillus Calmette-Guérin* (BCG), and measles can become ineffective when exposed to heat, while hepatitis B and DPT-HB-Hib (diphtheria, pertussis, tetanus, hepatitis B, and *Haemophilus influenzae* type B) vaccines are vulnerable to damage when exposed to freezing temperatures below 0°C. In general, exposure to direct sunlight can degrade the quality of most vaccines (Paluseri, 2024). In this study, the vaccines observed included BCG, Polio (OPV), DPT-HB-HIB (Easy Five and Combe Five), DPT-HB0-Uniject, DT (Diphtheria-Tetanus), TD (Tetanus-Diphtheria), IPV (Inactivated Poliovirus Vaccine), and Hepatitis B Immunoglobulin. These vaccines were selected based on their availability and relevance to the national immunization program during the study period.

Vaccines are biological products that contain antigens in the form of either inactivated or attenuated live microorganisms, whole or partial components of microorganisms, or microbial toxins that have been processed into toxoids or recombinant proteins. These components are combined with other substances, and when administered to an individual, they induce active, specific immunity against particular diseases (Ministry of Health of the Republic of Indonesia, 2017). Vaccines are highly susceptible to degradation, requiring meticulous handling during storage and distribution to maintain their quality. Proper cold chain management from the time of production until administration is essential. Inadequate handling may lead to vaccine deterioration, reducing or eliminating its potency, and potentially causing adverse events following immunization (AEFI). Vaccine damage may also result in significant financial losses for the government, both from the cost of the vaccines and the management of resulting AEFI cases (Utami, 2019).

Indonesia's regulatory framework for vaccine storage has evolved to include increasingly stringent standards. The Good Distribution Practices (GDP) Guidelines of 2020, issued by BPOM, provide comprehensive technical requirements for pharmaceutical distribution, including cold chain management. These are complemented by the Guidelines for Vaccine Management in Healthcare Facilities of 2021, which introduce more detailed operational protocols tailored to public health settings.

Compared to the GDP Guidelines, the 2021 Guidelines emphasize stricter compliance in areas such as continuous temperature monitoring, documentation of maintenance activities, and the use of Vaccine Vial Monitor (VVM) indicators. These enhancements reflect a regulatory shift toward greater accountability and precision in vaccine handling, especially at the facility level. The higher compliance rates

observed in this study under the 2021 Guidelines may be attributed to their clearer operational focus and alignment with routine practices in healthcare facilities.

A study conducted by Dewi et al. (2022) aimed to compare the vaccine cold chain storage system in the health office warehouse and public health center in Salatiga. The results showed good compliance with cold chain standards: 88.88% in the Health Office, 77.77% in Cebongan Public Health Center, 70.37% in Mangunsari Public Health Center, 85.18% in Kalicacing Public Health Center, 81.48% in Tegalrejo Public Health Center, and 81.48% in both Sidorejo Lor and Sidorejo Kidul Public Health Center. Another study by Oktaviani (2022) evaluated the conformity of vaccine storage and distribution practices in the Lamandau District Health Office, Central Kalimantan, and reported 100% compliance for refrigerator condition indicators and vaccine distribution. A similar study by Harsanti (2022) evaluated vaccine storage and distribution in the Manokwari District Health Office and found storage compliance at 64.22% based on GDP 2020 and 72% based on Minister of Health Regulation No. 12 of 2017. Distribution compliance was 70% based on GDP 2020 and 78.5% based on Minister of Health Regulation of 2017. Expired vaccine indicators were at 0.29%, damaged vaccines at 0%, average stockout time was 0.60% for BCG, 1.40% for hepatitis B (HB0), and 6.11% for Td vaccines. Compliance with the First-Expired-First-Out (FEFO) principle, vaccine temperature standards, and Vaccine Vial Monitor (VVM) indicators was 100%. These findings indicate that vaccine storage and distribution practices in the Manokwari Health Office did not yet fully comply with the GDP 2020 and Minister of Health Regulation No. 12 of 2017 guidelines (Harsanti, 2022).

The objective of this study is to assess the compliance of immunization vaccine storage and distribution at Samarinda Pharmacy Installation with the Good Distribution Practices (GDP) Guidelines of 2020 and Guidelines for Vaccine Management in Healthcare Facilities (Fasyankes) of 2021.

### **Methodology**

This study employs a qualitative research design and presents its findings in a descriptive format. Data collection was carried out through observation and interviews. The collected data were then analyzed based on the Good Distribution Practice (GDP) Guidelines of 2020 and the Guidelines for Vaccine Management in Healthcare of 2021.

This study was carried out over a period of one month, specifically in December 2024 at the warehouse of the Samarinda Pharmacy Installation. The sample consisted of routine immunization vaccine stocks available during that period. Specifically, the vaccines observed included BCG, Polio (OPV), DPT-HB-HIB (Easy Five and Combe Five), DPT-HB0-Uniject, DT, TD, IPV, and Hepatitis B Immunoglobulin. These vaccines were selected based on their availability and relevance to the national immunization program. The instruments used in this study included a camera for documenting observation activities in the vaccine storage warehouse and a voice recorder for recording interviews between the researcher and both the Immunization Logistics Officer and the Head of the Pharmaceutical Storage Unit at the Samarinda Pharmacy

Installation. Research materials included an observation checklist and a set of interview questions, both of which were utilized for data collection.

The research procedure began with submitting an ethical clearance request to the Research Ethics Committee (KEP) of STIKES Dirgahayu Samarinda. Subsequently, the researcher obtained permission from the Head of STIKES Dirgahayu to conduct the study at the Samarinda Health Office. After receiving institutional approval, the researcher submitted a formal request to the Health Office to carry out the study. Data were collected through direct observation and interviews with the Immunization Logistics Officer and the Head of the Pharmaceutical Storage Unit at the Samarinda Pharmacy Installation.

The qualitative data obtained were analyzed descriptively to illustrate the actual conditions of the vaccine storage and distribution system at the warehouse of the Samarinda Pharmacy Installation and were compared against the GDP Guidelines of 2020 and Guidelines for Vaccine Management in Healthcare Facilities of 2021. The compliance percentage for vaccine storage and distribution was calculated by dividing the total compliance score obtained through observation by the maximum possible score, then multiplying the result by 100% (Edo, 2018).

## Result and Discussion

### 1. Compliance of Vaccine Storage Based on Good Distribution Practices (GDP) Guidelines of 2020 at the Samarinda Pharmacy Installation

The compliance of vaccine storage at the Samarinda Pharmacy Installation with the 2020 GDP Guidelines was found to be 67%. The remaining percentage is attributed to non-compliance (16.5%) and the absence of a cold room facility (16.5%). Non-compliance was observed in seven aspects, including: two aspects related to temperature monitoring (which was only conducted twice daily), two aspects concerning the absence of thermometers and alarms with specific features, two aspects related to the lack of documentation for daily and monthly maintenance activities, and one aspect regarding the failure to inspect the door hinges during monthly maintenance. Details on the compliance of storage can be found in Table 1.

**Table 1. Compliance of Vaccine Storage Based on Good Distribution Practices Guidelines of 2020**

No	Category Aspect	Compliant	Non-Compliant	Not Available
1	Vaccine storage	5/6 (83%)	1/6 (17%)	0/6 (0%)
2	Daily maintenance	2/3 (67%)	1/3 (33%)	0/3 (0%)
3	Weekly maintenance	3/4 (75%)	1/4 (25%)	0/4 (0%)
4	Monthly maintenance	4/6 (67%)	2/6 (33%)	0/6 (0%)
5	Storage facilities	6/15 (40%)	2/15 (13%)	7/15 (47%)
6	Building	9/9 (100%)	0/9 (0%)	0/9 (0%)
<b>Compliance Percentage</b>		<b>29/43 (67%)</b>	<b>7/43 (16,5%)</b>	<b>7/43 (16,5%)</b>

The 2020 GDP Guidelines define six categories of proper vaccine storage: vaccine storage, daily maintenance, weekly maintenance, monthly maintenance,

storage facilities, and building. Similarly, the Guidelines for Vaccine Management in Healthcare Facilities (Fasyankes) of 2021 also outline six categories, including refrigerator conditions, vaccine storage in Ice Lined Refrigerators (ILR), storage in freezers, and daily, weekly, and monthly maintenance.

Monitoring the storage conditions of vaccine products is crucial for maintaining temperature within the specified range and ensuring product stability. Periodic monitoring of temperature, humidity, packaging integrity, storage equipment conditions, and calibration of monitoring tools is essential. Temperature fluctuations may compromise product quality, potentially reducing efficacy (Sari & Amalia, 2024). According to the 2020 GDP Guidelines, temperature in chillers, cold rooms, or freezers should be monitored and recorded at least three times daily—in the morning, afternoon, and evening—and such records must be evaluated and documented. Any deviations must be addressed and recorded accordingly. However, observations at the Samarinda Pharmacy Installation revealed that temperature monitoring was only performed twice daily, in the morning and evening.

Another observed non-compliance was the lack of thermometers and alarms with specific features. Based on the 2020 GDP Guidelines, pharmacy installations should use thermometers that can continuously record temperature and are equipped with sensors placed at one or more critical points to represent accurate temperature profiles under normal operations. Furthermore, chillers and freezers should be equipped with alarms that trigger when temperature deviations occur. These devices were not available at the Samarinda Pharmacy Installation due to limited budget for procurement.

Adequate maintenance and well-designed monitoring and control systems are vital for ensuring consistent vaccine storage conditions. Routine maintenance ensures proper functioning of equipment such as chillers, cold rooms, and freezers, thereby maintaining stable temperatures. Operational efficiency is also preserved, as regular maintenance and sound control systems reduce the risk of equipment failure, which could disrupt the distribution process. An effective monitoring system allows early detection of potential issues, enabling corrective action before product quality is compromised (Sari & Amalia, 2024).

According to the 2020 GDP Guidelines, weekly maintenance activities should be recorded and documented to ensure that storage equipment such as chillers, cold rooms, and freezers are operating optimally. This practice helps ensure the stability and quality of stored vaccines. Any deviations must be promptly addressed. However, observations revealed that daily and monthly maintenance activities were not recorded or documented at the Samarinda Pharmacy Installation.

The final storage-related non-compliance pertains to the failure to inspect chiller or freezer door hinges during monthly maintenance. According to an interview with the Immunization Logistics Officer, such inspections were never performed. Furthermore, Samarinda Pharmacy Installation lacks a cold room facility. In the observation checklist, there were seven statements related to the cold room, representing 16.5% of all assessed storage aspects. Based on

interviews, the absence of a cold room was due to insufficient electrical capacity, which does not meet the specific requirements for operating a cold room (5–10 kW).

A study by Harsanti at the Manokwari District Health Office reported a 64.22% compliance rate for vaccine storage based on the 2020 GDP Guidelines (Harsanti, 2022), which is lower than the findings of this study. The lower percentage was attributed to limited infrastructure and human resources in vaccine storage management at the Manokwari Health Office.

## 2. Compliance of Vaccine Storage Based on Guidelines for Vaccine Management in Healthcare Facilities of 2021 at the Samarinda Pharmacy Installation

Compliance with vaccine storage at the Samarinda Pharmacy Installation based on the Guidelines for Vaccine Management in Healthcare Facilities of 2021 was 94%. The remaining 6% non-compliance resulted from the lack of recorded and documented weekly and monthly maintenance activities. These two non-compliant aspects were among 31 total aspects assessed. The same discrepancies were also identified in the observation checklist based on the 2020 GDP Guidelines. The compliance details based on the 2021 guidelines can be seen in Table 2.

**Table 2. Compliance of Vaccine Storage Based on Guidelines for Vaccine Management in Healthcare Facilities of 2021**

No	Category Aspect	Compliant	Non-Compliant	Not Available
1	Refrigerator condition	6/6 (100%)	0/6 (0%)	-
2	Vaccine storage in ILR refrigerator	6/6 (100%)	0/6 (0%)	-
3	Vaccine storage in freezer	4/4 (100%)	0/4 (0%)	-
4	Daily maintenance	5/5 (100%)	0/5 (0%)	-
5	Weekly maintenance	5/6 (83%)	1/6 (17%)	-
6	Monthly maintenance	3/4 (75%)	1/4 (25%)	-
<b>Compliance Percentage</b>		<b>29/31 (94%)</b>	<b>2/31 (6%)</b>	<b>0/31 (0%)</b>

The antibodies produced by vaccines are susceptible to degradation and can be compromised under certain conditions. Vaccines are particularly vulnerable to damage when exposed to heat or freezing temperatures. At the public healthcare center, vaccine storage temperature is maintained between 2°C and 8°C (Helmi et al., 2019). Vaccine temperature monitoring must be recorded twice daily, specifically upon arrival in the morning and before leaving in the afternoon or evening. The temperature is documented on a daily temperature monitoring form placed near the refrigerator. This monitoring is conducted every day, including weekends and holidays. Frost accumulation is also checked regularly, and no frost exceeding 0.5 cm in thickness was observed, indicating that the warehouse staff performed routine defrosting. Defrosting is carried out at least once a month or when the frost thickness exceeds 0.5 cm (Syakur et al., 2021).

Risk factors contributing to vaccine deviation include non-compliance with proper vaccine management guidelines, limited knowledge among personnel, the use of refrigerators not specifically designed for vaccine storage, the absence of temperature-monitoring thermometers, and improper methods of transporting vaccines (Ningrum et al., 2022).

A similar study was conducted at the District Health Office of Lamandau, Central Kalimantan, using the Guidelines for Vaccine Management in Healthcare Facilities of 2021. The results showed a compliance rate of 86.6% for vaccine storage (Oktaviani, 2022). This percentage is lower than that found in the current study, primarily due to the limited availability of storage infrastructure and inadequate routine maintenance. Therefore, the development of Standard Operating Procedures (SOPs) and maintenance schedules is essential to ensure the quality of vaccine storage infrastructure and equipment.

### 3. Compliance of Vaccine Distribution Based on Good Distribution Practices (GDP) Guidelines of 2020 at the Samarinda Pharmacy Installation

In addition to improper storage, vaccine damage can also result from inadequate distribution practices (UNICEF, 2020). Temperature-sensitive products must be distributed using transportation systems designed to maintain temperatures within acceptable ranges as per product specifications and protected from external environmental conditions. The Samarinda Pharmacy Installation adheres to the First Expired First Out (FEFO) principle in distributing cold chain products.

**Table 3. Compliance of Vaccine Distribution Based on Good Distribution Practices (GDP) Guidelines of 2020**

No	Category Aspect	Compliant	Non-Compliant
1	Vaccine release follows FEFO (First-Expired, First-Out) rule	✓	
2	Vaccine release follows FIFO (First-In, First-Out) rule		✓
3	Inspection of VVM (Vaccine Vial Monitor) indicators on vaccines	✓	
4	Recording of vaccine release in batch record forms	✓	
5	Invoice / delivery letter for vaccine distribution	✓	
6	Vaccine transport container meets standard	✓	
<b>Compliance Percentage</b>		<b>5/6 (83%)</b>	<b>1/6 (17%)</b>

Various materials and technologies are used to ensure the quality of cold chain products, including dry ice, gel packs, ice packs, liquid nitrogen, and reefer containers, according to required temperature standards. These materials function as Phase Change Materials (PCMs) and passive cooling agents that absorb heat and maintain specific thermal environments needed to prevent antigen degradation and preserve vaccine potency. Vaccine distribution to

healthcare facilities in Samarinda is carried out using cool boxes and cool packs to minimize the risk of vaccine damage during transportation, ensuring the integrity and stability of vaccines during transit. The number and arrangement of cool packs are adjusted according to the distance of the healthcare facility. Additionally, temperature during distribution is monitored using temperature data loggers placed inside the storage containers. Details of distribution compliance based on the 2020 GDP Guidelines are presented in Table 3.

One identified area of non-compliance is that the Samarinda Pharmacy Installation only implements the FEFO principle during distribution, without broader adherence to comprehensive cold chain logistics management. This practice is due to FEFO's effectiveness in minimizing losses from expired vaccines. Prioritizing the distribution of vaccines nearing expiration helps ensure that no doses go to waste and that patients receive high-quality vaccines.

A study by Ningrum et al. at the Salatiga City Health Office found a vaccine distribution compliance rate of 72.72% based on the 2020 GDP Guidelines (Ningrum et al., 2022), which is lower than in this study. The lower percentage was attributed to a shortage of human resources managing vaccine logistics. Similarly, Harsanti's study at the Manokwari Health Office reported a compliance rate of 70% for vaccine distribution based on the 2020 GDP Guidelines (Harsanti, 2022), also lower than in this study. The non-compliance in that setting was primarily due to limitations in infrastructure and human resources

#### **4. Compliance of Vaccine Distribution Based on Guidelines for Vaccine Management in Healthcare Facilities of 2021 at the Samarinda Pharmacy Installation**

Compliance with vaccine distribution based on the Vaccine Management Guidelines at Health Care Facilities of 2021 is presented in Table 4 below. Routine monitoring and documentation of the Vaccine Vial Monitor (VVM) are essential to determine whether vaccines are still suitable for use. A study conducted at Bantul Public Health Center reported that failure to record VVM status can result in the accumulation of unusable vaccines due to the absence of regular inspections. On the other hand, regular VVM checking and documentation help prevent financial losses that may be incurred by the health center as a result of vaccine spoilage (Safitri et al., 2023).

A related study was conducted at the District Health Office of Lamandau, Central Kalimantan, using the 2021 Guidelines for Vaccine Management in Healthcare Facilities as the observation reference. The findings showed 100% compliance with vaccine distribution procedures (Oktaviani, 2022). Maintaining the cold chain during vaccine distribution and storage is essential to ensure the preservation of high-quality vaccines. From the point of receipt to distribution at the next level or point of use, vaccines must be consistently stored at the recommended temperatures (Setyo, 2021).

**Table 4. Compliance of Vaccine Distribution Based on Based on Guidelines**

<b>for Vaccine Management in Healthcare Facilities of 2021</b>			
<b>No</b>	<b>Category Aspect</b>	<b>Compliant</b>	<b>Non-Compliant</b>
1	VVM (Vaccine Vial Monitor) condition is recorded when issuing the vaccine on the Goods Issue Receipt (SBBK) and stock card	✓	
2	Vaccines must be distributed using at least a vaccine carrier filled with cool packs and maintained at the standard temperature	✓	
3	If vaccines are used immediately on the same day as distribution, the solvent must be distributed according to the vaccine cold chain requirements	✓	
4	If the vaccine is not used on the same day as distribution, the solvent should be stored at room temperature, and at least 12 hours before use, the solvent must be stored at the same temperature as the vaccine in the quantity needed for use.	✓	
5	The solvent must be provided in one package with the vaccine, and must be of the same type and from the same manufacturer as the vaccine	✓	
<b>Compliance Percentage</b>		<b>6/6 (100%)</b>	<b>0/6 (0%)</b>

The most common side effects associated with the vaccines analyzed (BCG, DPT-HB-HIB, Polio) include local reactions (pain, redness, swelling at the injection site) and mild systemic reactions (fever, irritability). It is important to note that while heat exposure primarily reduces potency, accidental freezing of aluminum-adjuvanted vaccines (like DPT-HB-HIB) can cause irreversible adjuvant agglomeration, potentially increasing the risk of sterile abscesses and local reactions. Therefore, strict adherence to storage protocols is essential for both efficacy and patient safety (Haber, 2021).

## **Conclusion**

The observed vaccines included BCG (Bacillus Calmette–Guérin), Polio (OPV), DPT-HB-HIB (Easy Five and Combe Five), DPT-HB0-Uniject, DT (Diphtheria-Tetanus), TD (Tetanus-Diphtheria), IPV (Inactivated Poliovirus Vaccine) and Hepatitis B Immunoglobulin. Based on the results of the study conducted at Samarinda Pharmacy Installation, the compliance of vaccine storage was 67% based on the Good Distribution Practices (GDP) Guidelines of 2020 and 94% based on the Guidelines for Vaccine Management in Healthcare Facilities of 2021. The compliance rate of vaccine distribution was 83% based on the GDP of 2020 and 100% based on the Guidelines for Vaccine Management in Healthcare Facilities of 2021. For further research, we suggest that future studies investigate the correlation between storage compliance and actual vaccine potency using laboratory titration methods. Additionally, research should be expanded to include the Community Health Centers/Puskesmas in Samarinda, where the risk of cold chain breaks is typically higher due to infrastructure challenges.

### Declaration of Competing Interest

The authors declare that they have no competing interests

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