

Evaluation of Vaccine Storage and Quality in Independent Midwives Practice

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Abstract

Purpose: A vaccine is a biological product that contains microorganisms that have been weakened or inactivated, but still have intact parts, or that have been modified into recombinant proteins, which are then combined with other substances. Vaccine storage involves the proper handling of received vaccines to ensure their safety and protect them from physical damage, thereby maintaining their quality according to established requirements until they are used. This study aimed to evaluate vaccine storage and quality in independent midwife's practice.

Methodology: This study was a cross-sectional quantitative study. It was conducted at the Independent Midwife Practice (IMP) of the Muntilan 1 Public Health Center in the period of July 2024. Vaccine storage and quality were evaluated based on vaccine management guidelines in healthcare facilities.

Results: Vaccine storage at several Independent Midwives' Practices (IMPs) in the working area of Muntilan 1 Public Health Center was inadequate. Based on the study results, the average storage compliance percentages at several IMPs were 83.3%, 50%, and 33.3%, respectively. Meanwhile, the average vaccine quality percentages were 100%, 96.8%, and 100%.

Conclusions: Vaccine storage practices at independent midwives' practices were not fully compliant with national guidelines, although overall vaccine quality remained good based on VVM status, expiration checks, and shake tests. Strengthening monitoring and improving storage procedures are needed to ensure consistent vaccine safety.

Limitations: Some indicators are not relevant to each IMP; therefore, the indicators are not included in the research criteria.

Contributions: This study can help people in charge of storage, especially midwives in independent practices, improve vaccine quality.

Keywords: *Vaccine, Vaccine Storage, Vaccine Quality*

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1. Introduction

A public health center (*Puskesmas*) is a primary healthcare facility responsible for providing basic health services, including promotive, preventive, curative, and rehabilitative efforts, to the community. *Puskesmas* play an important role in the implementation of the national immunization program as a preventive measure against various infectious diseases. Immunization services, especially in remote or rural areas, are carried out by midwives (Kemenkes, 2016). According to the Indonesian Ministry of Health Regulation No. 28 of 2017 on the License and Practice of Midwives, midwives have the authority to provide health services for mothers and children, including prenatal, childbirth, postnatal services, and administering immunizations. In the implementation of immunization, vaccination is conducted (Kemenkes, 2017b).

Vaccines are a form of pharmaceutical preparation used to prevent infectious diseases. In pharmaceutical preparations, vaccines are classified as biological products, which are different from synthetic chemical drugs because they originate from living organisms or biological components ([Yuliana, 2022](#)). Administering a vaccine can stimulate the body to produce active immunity against certain diseases; therefore, the quality of vaccines must be maintained through proper vaccine management ([Yunilia, 2021](#)). In vaccine management, midwives face various challenges regarding vaccine storage and handling ([Pongsituru, Adam, & Sanuddin, 2024](#)). Common challenges include limited storage facilities, inconsistent temperature monitoring, and a lack of training on proper vaccine handling. These conditions can affect the quality of vaccines provided to the community ([Djamaludin, Hartati, & Trismiyana, 2022](#)).

An important aspect of vaccine management involves several processes, such as storage, distribution, and quality monitoring. Vaccine storage must adhere to standards to maintain the appropriate temperature (2–8 °C) to ensure the stability and potency of the vaccine. Vaccines must also be distributed in a manner that prevents significant temperature changes ([Girsang, Martini, & Yuliawati, 2020](#)). Proper vaccine storage is crucial for maintaining its quality and effectiveness. The storage method is chosen based on the need to maintain temperature stability and prevent exposure to excessive heat or freezing. The use of appropriate refrigerators or freezers, along with continuous temperature monitoring, is important in the vaccine storage process ([Safitri, Setyorini, & Fajri, 2023](#)).

According to several previous studies, the vaccine storage process in some *Puskesmas* in Bantul Regency showed that the Standard Operating Procedures (SOPs) for facilities and infrastructure have not been implemented. The responsibility for vaccine management is delegated to midwives, and quarantine between vaccines in use and those not in use has not been carried out. Additionally, in terms of storage, the proper placement of vaccines in refrigerators has not been applied ([Safitri et al., 2023](#)). Meanwhile, previous research indicates that the responsibility for vaccine monitoring is still delegated to non-pharmaceutical personnel, and the vaccine distribution equipment still relies on the Health Office (Dinkes).

Vaccine storage should be carefully monitored until it is used. If vaccine storage is not properly managed, the vaccine will lose its potency and antigens, making it ineffective for treatment ([Astuti, Prabandari, & Maulida, 2021](#)). Considering the importance of maintaining vaccine quality, this research is expected to provide input for those responsible for vaccine storage, especially in Independent Midwife Practices. Vaccine management monitoring in terms of storage is usually limited to *Puskesmas* and pharmacy installations, whereas in Independent Midwife Practices, monitoring is not conducted ([Purwantini & Yuniar, 2021](#)). This study aims to evaluate the storage and quality of vaccines in Independent Midwife Practices within the working area of the Muntilan 1 Public Health Center.

2. Literature Review and Hypothesis Development

2.1 Public Health Center

A public health center (*Puskesmas*) is a healthcare service facility that carries out public health efforts and individual health services at the primary level. *Puskesmas* are responsible for providing basic health services, including promotive, preventive, curative, and rehabilitative efforts, to the community within its working area ([Kemenkes, 2016](#)). *Puskesmas* play an important role in the implementation of the national immunization program as a preventive measure against various infectious diseases.

2.2 Midwifery Practice

According to the Regulation of the Minister of Health of the Republic of Indonesia Number 28 of 2017 concerning Licensing and Implementation of Midwifery Practice, midwifery practice is a service activity carried out by midwives in the form of midwifery care. Independent Midwife Practice is a place where a series of midwifery service activities are implemented individually by a midwife. Midwives have the authority to provide services, including maternal health, child health, women's reproductive health, and family planning services ([Wee et al., 2021](#)). As authorized medical practitioners, midwives play an important role in the implementation of immunization. The main duty of midwives in this context is not only to administer vaccines to individuals who need them but also to ensure that the

processes of vaccine storage, handling, and administration are carried out properly to maintain the quality and efficacy of the vaccines ([Kemenkes, 2017a](#)).

2.3 Vaccines

In the implementation of immunization, the effort carried out is vaccination. Vaccines are biological products that contain antigens in the form of microorganisms or parts thereof, or substances produced by them, which have been processed in such a way that they are safe; when administered to a person, they will induce specific active immunity against certain diseases. All vaccines are biological products that are fragile and therefore require special handling. Several conditions that affect vaccines include temperature and sunlight ([Kemenkes, 2021](#)).

a. Classification of Vaccines

- 1) Based on the origin of antigens (immunization essential), vaccines can be divided into two types: live attenuated (weakened live bacteria or viruses) and inactivated (bacteria, viruses, or their components that have been rendered inactive).
- 2) Classification based on sensitivity to temperature is divided into two types: vaccines sensitive to cold temperatures and vaccines sensitive to heat. Vaccines sensitive to cold temperatures below 0°C are Freeze-Sensitive (FS) vaccines, including hepatitis B vaccine (in vial packaging or Pre-Filled Injection Device (PID) packaging), DPT, DPT-HB, DT, and TT. Vaccines sensitive to excessive heat (>34°C) are Heat-Sensitive (HS) vaccines, such as BCG, polio, and measles vaccines ([Kemenkes, 2021](#)).

b. Conditions Affecting Vaccines

1) Temperature effect

Temperature is a critical factor in vaccine storage because it can reduce vaccine potency and efficacy if vaccines are stored at inappropriate temperatures.

2) Sunlight effect

All vaccine derived from biological materials must be protected from direct or indirect exposure to sunlight. This is because vaccines are susceptible to damage and can deteriorate in a short time. Vaccine packaging is currently equipped with a Vaccine Vial Monitor (VVM) label, which functions as an indicator of heat exposure, allowing health workers to easily identify vaccines that have been exposed to high temperatures by observing changes in the VVM label.

2.4 Vaccine Management

Vaccine management is similar to cold chain management, which is a procedure used to maintain vaccines at specified temperatures to retain their potency from production until administration to the target population. Vaccine cold chain management as a monitoring system has components consisting of inputs, processes, and outputs ([Kairul, Udiyono, & Saraswati, 2016](#)).

a. Input

Vaccine management involves human resources, money, materials, and methods. Human resources at the *Puskesmas* level must include personnel assigned as immunization officers and cold chain managers with a minimum qualification of senior high school or vocational high school graduates who have attended cold chain training. Hospitals, maternity hospitals, and immunization services in other private practices are, in principle, similar to those in *Puskesmas*. Immunization services are carried out by trained personnel ([Kemenkes, 2021](#)).

To improve the knowledge and/or skills of vaccine management personnel, training should be conducted to prevent errors. Money in vaccine management refers to the availability of operational funds for routine maintenance of vaccine cold chain equipment as well as for emergency conditions in case of equipment damage or operational costs. Materials in vaccine management include cold chain supporting equipment such as refrigerators, vaccine carriers, thermometers, temperature cards, and report forms. Methods include procedures, methods, or guidelines for receiving and storing vaccines ([Safitri et al., 2023](#)).

b. Process

Vaccine management encompasses all activities related to vaccines, including requests, receipt/collection, storage, usage, and recording and reporting.

1) Request

Requests for vaccine needs are based on the number of targets to be immunized, while considering vaccine storage capacity. Vaccine requests at all levels are made when the vaccine stock has reached the minimum stock level; therefore, each vaccine request must include the remaining stock available ([Girsang et al., 2020](#)).

2) Receipt

Vaccine collection must use designated cold chain equipment, such as cold boxes, vaccine carriers, or thermoses. Before placing vaccines into the carrier, officers must check the Vaccine Vial Monitor (VVM). Vaccines may only be used if the VVM is at levels A or B; if the VVM is at levels C or D, the vaccine is not accepted because it can no longer be used. Subsequently, cool packs are placed in the vaccine carrier, and a thermometer is placed in the center. Vaccine carriers containing vaccines must not be exposed to direct sunlight during transport ([Girsang et al., 2020](#)).

3) Storage

Vaccine storage involves arranging the received vaccines to ensure safety, prevent physical and chemical damage, and maintain quality according to established requirements until use. To ensure good vaccine potency at the time of administration, vaccines must be stored at specific temperatures for predetermined storage durations at each administrative level. Proper vaccine storage is important because it affects vaccine potency and antigenicity ([Lumentut, 2015](#)).

4) Use

The principle used in providing immunization services with vaccines is “Earliest Expired First Out (EEFO),” meaning that vaccines are used based on the earliest expiration date. However, with the Vaccine Vial Monitor (VVM) in place, EEFO becomes a secondary consideration. The VVM greatly assists health workers in rapid vaccine management by observing changes in the indicator color ([Astuti et al., 2021](#)).

5) Recording and Reporting

Vaccine stock must be reported monthly to ensure sufficient and adequate vaccine availability. Detailed records of vaccine inflow and outflow, including quantity, batch number, VVM condition, and expiration date, must be recorded on stock cards ([Amin, Muhtar, Sumardiawan, & Yulianingsih, 2024](#)). The remaining or available vaccine stock must always be calculated at each receipt and issuance. Each type of vaccine has its own stock card. The VVM condition at the time of vaccine receipt must also be recorded on the Goods Release Evidence Letter ([Amin, Hurry, Sumantri, & Fauzi, 2024](#)).

c. Output

Vaccine quality is the output of the vaccine cold chain management system. Vaccine quality can only be maintained if vaccines are stored and handled properly from production to use. Monitoring vaccine quality can be carried out quickly by observing VVM indicators and freeze tags or freeze watches ([Astuti et al., 2021](#)). Freeze tags and freeze watches are tools used to monitor exposure to cold temperatures below 0°C. These tools are used to monitor refrigerator performance when storing freeze-sensitive vaccines. If a vaccine is suspected of freezing, a shake test must be conducted using the updated procedure ([Astuti et al., 2021](#)).

3. Research Methodology

This study is a descriptive study using a cross-sectional design with a quantitative approach. It was conducted to evaluate vaccine storage and quality based on vaccine management guidelines in healthcare service facilities. It was conducted at independent midwife practices within the working area of the Muntilan 1 Public Health Center during July 2024. The variables in this study were vaccine storage, which included refrigerator placement, storage in the ice-lining refrigerator [Khodjayeva \(2022\)](#), storage in the freezer, and vaccine quality, which included the Vaccine Vial Monitor (VVM) test, vaccine expiration status, and shake test results. The data used were primary data obtained through direct observation. The instrument used in this study was an observation sheet in the form of a checklist.

The data were analyzed using univariate analysis to describe the frequency distribution of the characteristics of each variable.

4. Results and Discussion

The results of the evaluation of vaccine storage, which included refrigerator placement, vaccine storage in the ice lining refrigerator ([Khodjayeva, 2022](#)), and vaccine storage in the freezer at independent midwife practices within the working area of the Muntilan 1 Public Health Center using the 2021 Vaccine Management Guidelines in Healthcare Service Facilities, are shown in Table 1.

Table 1. Vaccine storage

No	Indicator	Suitability of Vaccine Storage		
		PMB A	PMB B	PMB C
Refrigerator placement				
1	Minimum distance between the refrigerator and the back wall is approximately 10–15 cm or until the refrigerator door can be opened	Yes	Yes	Yes
2	The room has adequate air circulation	Yes	Yes	No
3	Each refrigerator/freezer unit uses only one electrical outlet	Yes	Yes	No
Vaccine storage in Ice Lining Refrigerator (Khodjayeva, 2022)				
1	Temperature between 2–8°C	Yes	No	No
2	The bottom part of the refrigerator is not used to store vaccines	Yes	No	No
3	Cool packs are placed at the bottom of the refrigerator to maintain cold retention and temperature stability	Yes	No	No
4	Placement of vaccine boxes has a distance of 1–2 cm or one finger width	Yes	No	No
5	Heat-sensitive vaccines (OPV, BCG, Measles, MR) are placed near or attached to the refrigerator wall	Yes	No	No
6	Freeze-sensitive vaccines (TT, DT, Hep B, DPT-H, DPT-HB-Hib, Td, IPV) are not placed against the refrigerator wall	Yes	No	No
Vaccine storage in freezer				
1	Freezer temperature between –15°C to –25°C	No	Yes	Yes
2	Cold packs are placed at the bottom of the freezer to maintain cold retention and temperature stability	No	Yes	Yes
3	Placement of vaccine boxes has a distance of 1–2 cm or one finger width	No	No	No
4	Polio vaccine is stored in the freezer	No	No	No

Table 1 shows that the results of the study on refrigerator placement with measured indicators, including minimum distance from the wall, room air circulation, and use of electrical outlets, showed that PMB A and PMB B met all indicators with a percentage of 100%, whereas PMB C only met the indicators with a percentage of 33.3%. This was based on observational results indicating that two indicators did not meet the standards: the absence of adequate room air circulation and the use of electrical outlets shared with other electronic devices ([Thielmann, Puth, & Weltermann, 2019](#)). These results are in line with a study at the Ahmad Yani Public Health Center on Ende Island, which showed that vaccine storage conditions related to refrigerator placement met the standards ([Pambudi, Sarifudin, Gandidi, & Romadhon, 2022](#)).

The physical aspects of the refrigerator and proper positioning according to standards reached 81% compliance, while 19% did not meet the standards ([Yunus, 2018](#)). Meanwhile, research conducted in earthquake-affected public health centers in Lombok showed that 60–70% of public health centers in

East Lombok did not meet the indicators for refrigerator condition assessment. This was due to limited space availability as a result of the earthquake ([Anjani, Rahmawati, Nurbaety, Qiyaam, & Ittiqo, 2023](#)). Proper refrigerator placement ensures that vaccines remain in optimal condition until use. Proper placement also aims to ensure the success of immunization programs and public health efforts ([Kemenkes, 2016](#)).

The results of the study on vaccine storage in the ice-lining refrigerator [Khodjayeveva \(2022\)](#) revealed differences in vaccine storage among the three Independent Midwife Practices (PMB). Vaccine storage at PMB A was in accordance with the 2021 Healthcare Facility guidelines by using an Ice Lining Refrigerator ([Khodjayeveva, 2022](#)). Of the six indicators for vaccine storage in the ILR, PMB A complied with all six indicators (100%), which included maintaining a temperature of 2–8°C, placement of cool packs, spacing between vaccine boxes, and placement of heat-sensitive and freeze-sensitive vaccines. Meanwhile, PMB B and PMB C did not meet any of the indicators because vaccine storage was still using a single-door table refrigerator, resulting in nonspecific vaccine placement and temperatures that could not be regulated according to the indicators ([Amin, Heryanto, Athaya, & Fitri, 2025](#)).

These results are in line with a study at the Ahmad Yani Public Health Center, Ende Island, which showed that vaccine storage in terms of vaccine management met the standards. The aspects of vaccine placement in refrigerators (placement of heat-sensitive and freeze-sensitive vaccines, spacing between vaccines, and vaccine monitoring) were carried out properly according to standards, with 88% meeting the standards and 12% not meeting the standards ([Yunus, 2018](#)). In addition, research conducted in public health centers in the Maros Regency, South Sulawesi, showed that all public health centers in the Maros Regency met the requirements of the Ministry of Health Regulation Number 12 of 2017, with a storage compliance percentage of 100% ([Mufliha, Hendrarti, Muslimin, & Guntur, 2024](#)).

Vaccine storage in an ILR is important to provide optimal temperature stability and protect vaccines. The use of an ILR can also ensure that the vaccines administered remain effective and safe ([Santoso, Anggriani, & Suryaman, 2020](#)). The results of the study on vaccine storage in freezers with measured indicators, including freezer temperature, placement of cool packs, placement of vaccine boxes, and storage of polio vaccines in the freezer, showed that out of the three PMBs, only two PMBs met two indicators (50%) out of four indicators, while one PMB did not meet the requirements because vaccine storage at PMB A used an ice lining refrigerator [Khodjayeveva \(2022\)](#), resulting in no vaccines being stored in the freezer. PMBs B and C performed better in maintaining freezer temperature but were less compliant in spacing between vaccine boxes. These results are consistent with a study conducted by [Santoso et al. \(2020\)](#) at the Garut Regency Health Office, which showed that 77% of the infrastructure used to store vaccines, including refrigerators, cold rooms, and freezers, met the standards.

Additionally, a study conducted in five public health centers in Semarang City showed that vaccine storage in public health centers using vaccine freezers complied with the Indonesian National Standard (SNI) and Performance Quality and Safety (PQS) at a rate of 20%. Storage using vaccine freezers can reduce contamination and the growth of microorganisms ([Lloyd, Lydon, Ouhichi, & Zaffran, 2015](#)). Furthermore, freezer storage allows vaccines to be stored longer without losing effectiveness and ensures safety during administration ([Mustika & Prakasiwi, 2021](#)). The results of observations on vaccine quality, which included the Vaccine Vial Monitor (VVM) test, expiration dates, and shake test results at Independent Midwife Practices (PMB) within the working area of the Muntilan 1 Public Health Center based on the 2021 Vaccine Management Guidelines in Healthcare Service Facilities are shown in Table 2.

Table 2. Vaccine quality

Indicator	Category	Number of Vaccines		
		PMB A	PMB B	PMB C
Vaccine Vial Monitor	A	95 (100%)	30 (93,75%)	1 (14,28%)
	B	0 (0%)	2 (6,25%)	6 (85,71%)
Vaccines Not Expired	Expired	0 (0%)	1 (3,12%)	0 (0%)
	Not expired	95 (100%)	31 (96,8%)	7 (100%)
Shake Test Results	Usable	95 (100%)	31 (96,8%)	7 (100%)
	Not usable	0 (0%)	1 (3,12%)	0 (0%)

Table 2 shows results of the study on vaccine quality based on the VVM indicator showed that one PMB had vaccines in the VVM A category at 100%, including polio (OPV), DPT-HB-Hib, DT, BCG, measles, Td, IPV, hepatitis B, and rotavirus. Meanwhile, the other two PMBs had vaccines in category A at 93.75% and 14.28%, including DPT-HB-Hib, IPV, BCG, hepatitis B, rotavirus, and PCV, and categories B at 6.25% and 85.71%, including DPT-HB-Hib, IPV, and BCG. This study is in line with research conducted at public health centers and independent midwife practices in East Lampung Regency, which showed that the quality of vaccines at *Puskemas* and PMBs was still good, as indicated by the absence of expired vaccines and VVM conditions remaining at A or B, signifying that the vaccines were still suitable for use, with a percentage of 100% ([Purwantini & Yuniar, 2021](#)).

The VVM indicator is used to assist health workers in identifying which vaccines should be prioritized for release and use first. If vaccines are exposed to excessive temperatures and become damaged, their effectiveness can be reduced. The VVM indicators for vaccines that can be used are VVM categories A and B ([Purwantini & Yuniar, 2021](#)). The results of the study on non-expired vaccines showed that in two PMBs, no expired vaccines were found (100 %), while in one PMB, there was one expired vaccine, namely DPT-HB-Hib, amounting to 3.12%. This study is in line with research conducted at public health centers and independent midwife practices in East Lampung Regency, which showed that no expired vaccines were found in all public health centers and PMBs in South Lampung Regency (100 %), thus considered sufficient to meet the needs ([Purwantini & Yuniar, 2021](#)).

Meanwhile, research conducted at the Helvita Public Health Center showed that there were still expired vaccines, amounting to 36.7%. This occurred due to the unutilized distribution of available vaccines ([Sembiring, Panjaitan, & Febriyanti, 2016](#)). Vaccines contain active ingredients that can degrade over time. After passing the expiration date, the effectiveness of vaccines in stimulating an adequate immune response may decrease; thus, they may fail to provide the expected protection against disease ([Langi & Winarti, 2023](#)). The results of the shake test study showed that in two PMBs, no frozen vaccines were found (100 %), while in one PMB, one vaccine that could not undergo the shake test was noted: DPT-HB-Hib (3.12 %). This study is in line with research conducted at the Sleman Health Office, which showed a vaccine damage percentage of 0%, indicating good vaccine management and compliance with guidelines ([Shafa, 2017](#)).

Meanwhile, research conducted at the Helvita Public Health Center showed that vaccine conditions categorized as not damaged were 63.3%, while damaged vaccines accounted for 36.7%. Vaccine damage occurred due to sediment in vaccine bottles (26.7%), thick sediment in clear vaccines (36.7%), and visible thick sediment moving when the bottle was shaken (26.7%) ([Sembiring et al., 2016](#)). The shake test aims to ensure that vaccines remain homogeneous and stable after shaking. Vaccines are considered damaged if their components are not well mixed. Such instability can cause inconsistent doses to be administered, thereby reducing vaccine effectiveness ([Kairul et al., 2016](#)).

5. Conclusions

5.1 Conclusion

The evaluation of vaccine storage and quality at Independent Midwife Practices (PMB) within the Muntilan 1 Public Health Center's area shows that while most vaccine quality indicators were met, the storage conditions were not entirely in line with the 2021 Vaccine Management Guidelines. Issues in storage included improper placement of refrigerators, inadequate storage in ice-lining refrigerators and inconsistencies in freezer storage. Although vaccine quality indicators such as the Vaccine Vial Monitor (VVM) test, expiry dates, and shake test results were generally followed, more attention is needed to meet all storage standards for optimal vaccine preservation.

5.2 Research Limitations

This study faced limitations in its evaluation, particularly because some storage and quality indicators were not applicable to all PMB practices. As a result, these indicators were excluded from the research criteria. Furthermore, the study was limited by the availability of resources and the ability to evaluate storage conditions comprehensively across all PMB practices within the scope of the Muntilan 1 Public Health Center.

5.3 Suggestions and Directions for Future Research

Future studies should focus on identifying and refining relevant indicators for vaccine storage and quality that can be applied universally across different PMB practices. Additionally, a more in-depth evaluation of each PMB's storage infrastructure, as well as its adherence to all aspects of the 2021 Vaccine Management Guidelines, is needed. Researchers should consider conducting longitudinal studies to monitor the impact of improved storage practices on vaccine efficacy and patient outcomes.

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Author Contributions

AWDS contributed to the conceptualization, study design, data collection, analysis, and manuscript drafting. NL was responsible for the study design, data collection, manuscript drafting, and revision. AAR provided supervision, supported the analysis, and reviewed and revised the manuscript. All authors participated in the final approval of the manuscript.

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