

The analysis of Covid-19 vaccine storage management at the pharmacy installation of the S.K. Lerik Hospital Kupang City

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ABSTRACT: The COVID-19 pandemic poses a vast morbidity and mortality burden and disrupts communities and economies globally, including Indonesia. Vaccination is an essential prevention. Vaccine storage must be maintained to preserve its potency and safety. This study determined the suitability of the storage and COVID-19 vaccine preparations at the Pharmacy Installation of RSUD S. K. Lerik Kupang City, based on the 2020 Good Drug Distribution Method (Cara Distribusi Obat yang Baik or CDOB) standard and the 2021 Ministry of Health regarding Technical Instructions for Vaccination Implementation in Combating the Corona Virus Disease 2019 (COVID-19) Pandemic. This study used a qualitative, non-experimental observational method, data collection, structured interviews, and documentation. The storage management assessment for the COVID-19 vaccine is carried out using Zuhroh's checklist tool. The results show that the COVID-19 vaccine storage system at the RSUD S. K. Lerik needs development to follow CDOB 2020 and Kepmenkes 2021 rules fully. Indicators results that are below the standard: training and evaluation, the unavailability of a hygiene schedule, air ventilation, Vaccine Vial Monitor (VVM) images, expiration places, quarantine places, destruction of damaged vaccines, weekly and monthly recording maintenance, and also unavailability of replacement equipment during the implementation, repair, maintenance, and calibration of equipment.

KEYWORDS: CDOB 2020; COVID-19 vaccines; hospital; Kepmenkes 2021; vaccine storage.

INTRODUCTION

The infectious disease known as the SARS-CoV-2 causes COVID-19, a member of the coronavirus family. The onset of this illness can be traced back to a pneumonia case in Wuhan, China, in 2019, the cause of which was first unknown [1]. The authorities have officially classified the COVID-19 pandemic as a non-natural disaster. As of May 2022, more than 515,547,168 people globally have been exposed to COVID-19 [2]. Announcement of confirmed cases in Indonesia for the first time on March 2, 2020; all provinces have reported confirmed cases within one month [3]. Since it was first announced in Indonesia, cases of COVID-19 have increased in number from time to time, requiring attention. The spread of COVID-19 in Indonesia alone until May 2022 reached 6,048,431 people, while in East Nusa Tenggara (NTT), it reached 93,814 people [4].

Efforts to tackle COVID-19 continue to be carried out with various strategies. The rapid spread of COVID-19 has caused that simply complying with the health protocol is not enough. Practical and fast steps are needed to minimize the potential they can cause [5]. Hence, the government must be adequately prepared to guarantee widespread and fair access to the COVID-19 vaccination, provided that a secure and effective vaccine becomes available. Adequate health system capacity and strategies are needed to increase trust and acceptance of vaccines for those who vaccinate [4]. Vaccine management is a significant part of health services in hospitals. Accuracy and thoroughness in vaccine management will positively impact hospitals medically, socially, and economically [6].

Vaccination is an attempt to actively induce a person's immunity by administering an antigenic substance that aims to stimulate antibodies so that it is hoped that they will be immune to the disease or only experience mild illness [7]. History has recorded the massive role of vaccination in saving the world community from illness, disability, and even death due to Immunization Preventable Diseases (*Penyakit*

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yang Dapat Dicegah Dengan Imunisasi or PD3I) [8]. The primary objective of vaccination is to deliberately stimulate or augment an individual's immune response to a particular disease. This proactive approach is intended to prevent the occurrence of illness or, in the event of exposure to the disease, minimize its severity and reduce the likelihood of transmitting it to others. To deal with the COVID-19 pandemic, the government is organizing the administration of the COVID-19 vaccine in the hope of reducing the transmission rate of COVID-19 in Indonesia [9]. Vaccines are biologically derived substances that consist of antigens, either in the form of attenuated or inactivated microorganisms, intact or fragmented, or as toxins from microorganisms converted into toxoids or recombinant proteins. These antigens are combined with other components and, upon administration, elicit an immune response, leading to the development of immunity tailored to specific disorders [10].

Vaccines are biological elements that are susceptible to damage and sensitive to changes in environmental temperature, so they require special treatment. It is necessary to be supported by quality vaccine management; one of the vaccine management is vaccine storage. How vaccines are stored is very important because vaccine quality must be maintained so as not to lose potency, be safe, and avoid physical damage [11]. Vaccine storage must also meet cold chain requirements to ensure quality. Vaccine chain equipment is all equipment used in administering vaccines according to procedures. The primary function of the vaccine chain equipment is to bring the vaccine to a predetermined temperature so that the vaccine is preserved [3].

The publication, which is based on Zuhroh's sheet, examines the Management Evaluation of Storage of COVID-19 Vaccine Preparations in the Pharmacy Installation Warehouse of the Mataram City Health Office. The findings indicate that the storage practises for the COVID-19 vaccine at the Mataram City Health Office do not comply with the guidelines outlined in the Good Drug Distribution Methods 2020 and the Decree of the Director General of Disease Prevention and Control Number HK.02.02/4/1/2021, which pertain to general disease prevention and control. The overall accuracy rate for storing the COVID-19 vaccine was determined to be 67% [6]. Another publication concerning the Storage and Distribution of Vaccine Preparations at the Garut District Health Office shows that facilities are categorized as good, infrastructure as sufficient, implementation as good, and vaccine storage and distribution profile needs to be improved [12].

▪ MATERIALS AND METHODS

Materials

The assessment of storage management for the COVID-19 vaccine is carried out using Zuhroh's checklist tool.

Methods

This research is a qualitative, non-experimental observational study with a descriptive design. The data were collected retrospectively and analyzed to understand the storage management of COVID-19 vaccine preparations at the S. K. Lerik Hospital, Kupang City. This study was conducted through observation, interviews, and documentation. Analysis of the management overview of COVID-19 vaccine storage at SK Lerik Hospital, Kupang City, using Zuhroh's checklist [6] with appropriate or inappropriate assessment categories based on the 2020 CDOB guidelines on how to distribute drugs properly and the 2021 Minister of Health Decree on technical guidelines for implementing vaccinations in the context of tackling the coronavirus pandemic disease 2019 (COVID-19).

▪ RESULTS AND DISCUSSION

The proper storage of vaccines plays a crucial role in the effective implementation of a vaccination programme. Inadequate storage practises can lead to the failure of the immunisation programme [13]. Vaccine storage involves implementing measures to ensure the safety and preservation of received vaccinations, safeguarding them against potential physical and chemical harm. Their quality is maintained per the specified requirements until they are used. Storage is carried out to maintain the quality of the vaccine so that it does not lose potency, is safe, and avoids physical damage [3]. The regulation of vaccine

quality assurance has been addressed in the 2020 Good Drug Distribution Method (Cara Distribusi Obat yang Baik or CDOB) and the 2021 Minister of Health Decree (Keputusan Menteri Kesehatan or Kepmenkes) with regards to the administration of vaccinations in the context of combating the COVID-19 pandemic. These regulations encompass six distinct components: personnel and training, infrastructure, facility amenities, storage procedures, maintenance of storage facilities, and qualification, calibration, and validation.

Officers and training on storage of COVID-19 vaccines at the S. K. Lerik Hospital, Kupang City

In the officers and training components, two indicators are needed to follow the CDOB 2020 and Kepmenkes 2021 regulations: training and evaluation (Table 1).

Table 1. Officers and training on storage of COVID-19 vaccines.

No	Indicator	Conformity		Condition description
		Yes	No	
1.	The person in charge of the COVID-19 vaccine warehouse is a Pharmacist.	√		
2.	Cold Chain training for staff managing the COVID-19 vaccine in a systematic and periodic manner		√	One time only
3.	Evaluation is carried out regularly (once every six months)		√	Once a year

Cold Chain training for staff managing the COVID-19 vaccine during the period from January 2021 to August 2022 has only been carried out once online, so it is not following CDOB 2020 and Kepmenkes 2021 regulations, which need to be carried out systematically and periodically to improve the capability and quality of staff managing the vaccination program. The pandemic period, which has been running for almost three years, has made almost all activities carried out online (online). Online learning is learning remotely or using technology or internet networks [14]. The COVID-19 epidemic has necessitated a shift from traditional face-to-face instruction to remote learning methods, significantly modifying various activities, particularly in education and training [15]. They were shifting the implementation of training activities for workers, including health workers, to improve the quality of human resources (HR) and maximize existing potential. Distance learning methods such as online training are a solution because health workers can easily access the activities provided by the organizers [16]. The assessment is conducted annually, utilizing data obtained from observations, interviews with officers, and training indicators at RSUD S. K. Lerik, located in Kupang City. These discrepancies need to be input for the hospital to adjust training evaluations and staff according to the 2020 CDOB and Kepmenkes 2021 rules, which must be carried out every six months to improve control over the quality of COVID-19 vaccine services.

This result is per the research conducted by Pratama regarding the evaluation of vaccine storage in the pharmaceutical warehouse of the Jambi Provincial Health Service, showing that officers are responsible for managing vaccines and attending regular training. The purpose of holding the training is to ensure the quality of the vaccine is following distribution or distribution that meets the requirements and intended use, starting from procurement storage to distribution. This training is carried out systematically and periodically [17].

The COVID-19 vaccine storage building at the S. K. Lerik Hospital, Kupang City

In the vaccine storage building components, two indicators were not following the CDOB 2020 and Kepmenkes 2021 regulations, namely the availability of a schedule for cleaning the room and the availability of air ventilation (Table 2).

Table 2. The COVID-19 vaccine storage building.

No	Indicator	Conformity		Condition description
		Yes	No	
1.	Availability of drains	√		
2.	Availability of floors that are easy to clean and in good condition	√		
3.	The availability of ceilings is always in good order.	√		
4.	Warehouse free from insects and pests.	√		
5.	Availability of separate and locked areas	√		
6.	Availability of cleaning schedule		√	There is no cleaning schedule in the room
7.	Availability of air ventilation		√	Use an air conditioner to regulate room temperature
8.	Sufficient lighting to carry out activities safely and correctly	√		

Based on the results of the interviews, there is no schedule for cleaning the room for IFRS warehouse staff. However, room cleanliness is always in good condition because there are sanitation workers who are divided into two shifts, namely morning at 06.30 - 16.00 WITA and evening at 16.00 - 06.30 WITA who ensure the cleanliness of the room in the IFRS warehouse using equipment such as brooms, mops, dusters, and wastebaskets. According to the 2020 CDOB, buildings and storage facilities must be clean and free of trash and dust. Therefore, written procedures, cleaning programs, and documentation of cleaning operations must be available. The cleaning equipment used must be suitable so as not to become a source of contamination.

The vaccine storage room attempts to minimize the content of dust particles, germs, and spores by maintaining humidity and air exchange [18]. The ventilation system is designed to provide fresh air so that sunlight can enter and illuminate the room. Adequate ventilation will reduce humidity. The main principle of the ventilation system is to increase the rate of fresh air in the room to dilute (decrease the concentration) pollutants. Increase the exhaust rate of dirty air outdoors and replace dirty or infected air with clean and fresh air. When the change of fresh air, two things happen. First, the collected particles will be diluted so that the risk of transmission is negligible. Second, virus particles will leave the room, reducing the number of virus particles. In rooms with air conditioning, there is no change of air with fresh air. On the other hand, there will also be air circulation in the room, which can spread the virus [8].

The research results by Pondaag showed that many factors influence the quality of a stored drug. One of the elements that influence storage conditions is temperature. Temperature and environmental controls in the medicine storage room must always be maintained. The storage room at the UPTD Pharmacy Installation is equipped with air conditioning and a temperature measuring device so that the room temperature can be maintained stably and temperature stability can be monitored from a temperature meter installed in the medicine storage room, significantly influencing the quality of medicines [19]. Storage areas with temperature conditions that do not comply with pharmaceutical dosage labels can cause product damage; therefore, products must be stored at appropriate storage temperatures, and monitoring of storage temperatures is carried out so that when discrepancies occur, they can be handled immediately [20].

Storage Facility for COVID-19 Vaccine Preparations at the S. K. Lerik Hospital, Kupang City

One indicator in the building facility components must follow the CDOB 2020 and Kepmenkes 2021 regulations. Based on the interview results, it was found that in the Pharmacy Installation of the SK Lerik Hospital, Kupang City, there were no Vaccine Vial Monitor (VVM) images for the COVID-19 vaccine (Table 3).

Table 3. Building facility for storage of COVID-19 vaccine preparations.

No	Indicator	Conformity		Condition description
		Yes	No	
1.	Availability of electric generators	√		
2.	Availability of fire extinguishers	√		
3.	Availability of room temperature gauges	√		
4.	Availability of wastebasket/ trash	√		
5.	Cold room availability	√		
6.	Cold pack availability	√		
7.	Special refrigerator availability	√		
8.	VVM image availability		√	Do not have VVM for COVID-19 Vaccine
9.	Availability of an alarm indicating the occurrence of a temperature deviation	√		
10.	Thermometer availability in the refrigerator	√		

VVM is an indicator of exposure to heat attached to vaccines that are used to monitor vaccines while in transit or storage but is not used to measure vaccine potency directly; it only provides information on whether or not vaccines are suitable for use and have different characteristics for each vaccine [21]. According to CDOB, in 2020, the vaccine storage warehouse was equipped with illustrations of VVM color changes accompanied by explanations. This equipment makes it easier to check each routine vaccine in the storage and distribution process to other health facilities [22]. Based on the description above, it is necessary to procure a VVM tool for the COVID-19 vaccine at IFRS S. K. Lerik, Kupang City.

According to the findings of Pratiwi's study on the assessment of storage management for COVID-19 vaccines, it was observed that the utilized vaccine storage equipment demonstrated compliance. To ensure the preservation of vaccine quality, the utilization of Vaccine Vial Monitors (VVM) as a heat exposure monitoring instrument is imperative. VVMs effectively monitor the temperature of vaccines throughout transportation and storage. The VVM is attached to each vaccine vial and is round-shaped with a rectangular shape inside [23].

COVID-19 vaccine preparations operational storage at the S. K. Lerik Hospital, Kupang City

In the operational storage components, three indicators were not following the CDOB 2020 and Kepmenkes 2021 regulations, namely the availability of quarantine places, the indicator for the availability of unique places for COVID-19 vaccines that do not meet the requirements because they are damaged or expired, and the indicators for destroying damaged vaccines are not following CDOB 2020 and Kepmenkes 2021 (Table 4).

Table 4. Operational storage of COVID-19 vaccine preparations.

No	Indicator	Conformity		Condition description
		Yes	No	
1.	The volume of vaccine orders never exceeds the storage capacity	√		
2.	Availability of quarantine area		√	There is no quarantine area
3.	<i>Stock opname</i> is done regularly	√		<i>Stock opname</i> taking is carried out once a month, and reporting to the Kupang City Health Office is carried out daily
4.	Availability of a special place for COVID-19 vaccines that do not meet the requirements because they are damaged or expired		√	There is no particular place for damaged or expired vaccines
5.	Vaccine storage at 2-8°C	√		
6.	No temperature drift	√		
7.	The storage and placement system for the COVID-19 vaccine takes into account the FEFO and FIFO systems.	√		
8.	When the vaccine is taken out of Styrofoam, it immediately moves to the refrigerator.	√		

No	Indicator	Conformity		Condition description
		Yes	No	
9.	Damaged vaccines are destroyed		√	The destruction of the COVID-19 vaccine has never been carried out, but the damaged COVID-19 vaccine was withdrawn to the Kupang City Health Office
10.	Place the vaccine far from the evaporator	√		
11.	The distance between the vaccine boxes is about 1-2 cm.	√		
12.	A minimum distance of 15 cm between the refrigerator and the building wall	√		
13.	Availability of one plug for each refrigerator for COVID-19 vaccines	√		

Based on the interview results, no quarantine place is available because the transfer process is direct. Suppose the vaccine has arrived from the Kupang City Health Office. In that case, it will be immediately taken and arranged in their respective places, and the transfer time is at most 30 minutes after checking the temperature because the officer will ask other officers to put it into the refrigerator. The availability of quarantine places at the S. K. Lerik Hospital Pharmacy Installation in Kupang City must follow the regulations. The 2020 CDOB states that places used for drugs or medicinal ingredients require special temperature handling, and product temperature checks must be carried out at the time of receipt. If it is found that the temperature does not meet the requirements, then the product must be quarantined in a separate particular storage area with an appropriate temperature. In order to determine whether the product can be distributed further or must be returned to the supplier, written verification is required from the principal.

Based on the results of the interviews, there was no particular place for damaged vaccines at the SK Lerik Hospital, Kupang City. They were still in a refrigerator, but the expired COVID-19 vaccines were separated on the shelves at the bottom with the COVID-19 vaccines, which were in good condition at the top. Storage of the COVID-19 vaccine in good condition apart from the refrigerator requires a damaged vaccine storage area as written in CDOB 2020; the quarantine area must separate product returns, damaged, and recalls awaiting follow-up. So, one way to anticipate this is to do the separation. If there is no separation between good and damaged vaccines, there is a fear of contamination or mishandling [22]. The Pharmacy Installation at the S. K. Lerik Hospital, Kupang City, does not have a special storage place for COVID-19 and other vaccines that have been damaged or do not meet the requirements. The destruction of damaged vaccines was not carried out at the SK Lerik Hospital because the hospital only collected them, which would then be withdrawn by the Kupang City Health Office for destruction. The destruction of the COVID-19 vaccine at the Pharmacy Installation of the SK Lerik Hospital, Kupang City, did not follow the regulations because the destruction was not carried out at the S. K. Lerik Hospital, Kupang City. However, an official report was made for the recall and destruction of the COVID-19 vaccine carried out by the Kupang City Health Office because the COVID-19 vaccine is the newest, and the number of expired vaccines be small; if it were carried out at the SK Lerik Hospital, Kupang City, it would require quite a lot of money, so the hospital made an official report on the recall of expired vaccines. The destruction of immunization waste must be proven by an official report on handling damaged or expired vaccines [10].

The findings of Sari's research indicated that RSD Madani in Pekanbaru City adhered to the prescribed guidelines for preserving COVID-19 vaccines, as evidenced by the provision of a dedicated facility for storing damaged vaccines. At the time of observation, apart from the refrigerator to store vaccines in good condition, there was also a place for vaccines that did not meet the requirements because they were damaged and expired, namely in the expired warehouse [11].

Maintenance of COVID-19 vaccine preparations storage at the S. K. Lerik Hospital, Kupang City

In the maintenance of storage components, the overall storage maintenance components follow the 2020 CDOB and Kepmenkes 2021. Thirteen indicators follow the rules and are carried out but cannot be demonstrated by officers or documented (Table 5).

Table 5. Maintenance of storage of COVID-19 vaccine preparations.

No	Indicator	Conformity		Condition description
		Yes	No	
Daily				
1.	Examination of liquid at the bottom of the refrigerator	√		Done but not shown to the researcher
2.	Refrigerator temperature monitoring three times a day	√		Done but not shown to the researcher
Weekly				
3.	Plug check	√		Done but not shown to the researcher
4.	Refrigerator wall cleaning	√		Done but not shown to the researcher
5.	Remove the plug when cleaning the body of the vaccine refrigerator	√		Done but not shown to the researcher
6.	Use of a wet cloth/soft brush/foam sponge and soap in cleaning the body of the vaccine refrigerator	√		Done but not shown to the researcher
7.	Use a dry cloth to dry the body of the vaccine refrigerator	√		Done but not shown to the researcher
8.	Do the opening of the refrigerator door while cleaning the body of the vaccine refrigerator.	√		Done but not shown to the researcher
9.	Recording of weekly maintenance activities		√	No records
Monthly				
10.	Cleaning the condenser in the vaccine refrigerator with a brush/air pressure	√		Done but not shown to the researcher
11.	Check the density of the vaccine refrigerator door with paper	√		Done but not shown to the researcher
12.	Recording of monthly maintenance activities		√	No records
13.	Examination of the temperature monitor card by the head of the warehouse/person in charge of vaccines	√		

Two indicators are unsuitable: the indicator for recording weekly maintenance activities and the indicator for recording monthly maintenance activities. According to the results of interviews with officers, information was obtained that the thirteen indicators carried out daily, weekly, and monthly storage maintenance activities. Researchers cannot do documentation, so when researchers come, the maintenance component has likely been completed, and when the researcher finishes conducting research, the maintenance component will be carried out. Periodic maintenance must be carried out to ensure the storage facility is always in good condition. Maintenance of the COVID-19 vaccine storage facilities referred to in the 2020 CDOB and 2021 Kepmenkes is the maintenance of a refrigerator for storing the COVID-19 vaccine and a thermometer for temperature monitoring. To ensure the preservation of vaccine quality, it is imperative to uphold the integrity of cold chain equipment facilities through the diligent documentation of maintenance operations on the vaccine refrigerator maintenance card, encompassing daily, weekly, and monthly intervals [24].

Hikmarida conducted a study examining the correlation between storage and recording practices and the integrity of the DPT vaccine cold chain within Community Health Centres. The findings of this research also indicated a potential association between the documentation of the DPT vaccine cold chain and the features of data quality surveillance. Data quality reflects the completeness and validity of the recorded data. Systems that have high-quality data can accurately describe reported events. Likewise, if records regarding the DPT vaccine cold chain are complete and accurate, this can be used to monitor whether the quality of the DPT vaccine is in good condition. Routine recording of the vaccine cold chain is also related to the stability attribute. If data is recorded regularly, when data about the vaccine cold chain is needed, the data can be immediately available. Stability encompasses two key aspects: reliability, which pertains to the capacity to accurately gather, manage, and deliver data without encountering any errors or malfunctions, and availability, which relates to the ability to function as required whenever necessary [25].

Qualification, calibration, and validation of COVID-19 vaccine storage at S. K. Lerik Hospital, Kupang City

In the qualification, calibration, and validation components, one indicator is not following the CDOB 2020 and Kepmenkes 2021 regulations (Table 6).

Table 6. Qualification, calibration and validation of COVID-19 vaccine storage.

No	Indicator	Conformity		Condition description
		Yes	No	
1.	A competent and certified party calibrates the equipment (thermometer, refrigerator).	√		Conducted by PT. Famed Calibration
2.	The availability of spare equipment when equipment is repaired, maintained, and calibrated.		√	No replacement available

The indicator for replacement equipment is unsuitable because no replacement equipment is available when carrying, repairing, maintaining, and calibrating equipment. Based on the results of the interviews, it was said that there were no replacement tools when the equipment was calibrated because the calibration system was directly carried out at the S. K. Lerik Hospital by PT. Famed Calibration. Qualification, calibration, and validation of tools used to support the storage of COVID-19 vaccine preparations must be carried out. Thermometers and refrigerators need to be qualified, calibrated, and validated. The purpose of qualification, calibration, and validation is to ensure product quality following established procedures and guarantee and document that the system or equipment is used per the provisions or specifications regulated in the applicable CDOB provisions. The qualification must be carried out to ensure that all equipment used runs according to the specified qualifications and is also well maintained. Equipment maintenance is crucial to prevent cross-contamination of all products [26]. Calibration should be carried out using standards that have been tested and validated. The temperature in the storage room must comply with predetermined storage standards to guarantee the quality of goods stored in the room [22].

According to the findings of Wijaya's study, it is imperative to calibrate health equipment to ensure the accuracy and consistency of measures or exams conducted, aligning them with other instruments. Because medical equipment will not work optimally without calibration, routine maintenance and calibration will affect the accuracy of the medical device to avoid early misdiagnosis [27].

CONCLUSION

Based on the findings of the study conducted on the management analysis of COVID-19 vaccine preparations storage at the S. K. Lerik Hospital in Kupang City, it can be concluded that the overview of the storage system for COVID-19 vaccine preparations is still not fully following the 2020 CDOB rules and Kepmenkes 2021, namely: The staff and training components are not following cold chain training indicators for staff managing the COVID-19 vaccine and evaluation indicators that are carried out routinely (once every six months). In building components, it still needs to follow the indicators of availability of cleaning schedules and indicators of availability of air ventilation. The building facility component does not match the VVM image availability indicator. In the operational storage component, the indicator for the availability of a special place for expired vaccines is unsuitable for the availability of a quarantine place and the indicator for destroying damaged vaccines. The storage maintenance component must still be per the indicators for recording weekly and monthly maintenance activities. In the qualification, calibration, and validation components, the indicators for the availability of replacement equipment are unsuitable when carrying out, repairing, maintaining, and calibrating equipment.

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