Evaluation of Covid-19 Vaccine Management in Indonesian Health Facilities: A Nationwide Cross-Sectional Study

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Abstract. The Indonesian government is vaccinating all Indonesians against Covid-19. Covid-19 vaccine required a cold chain system to maintain the recommended storage and distribution temperature range. The study was conducted to describe the compliance of the vaccine management in Indonesia with Guidelines for Vaccine Management in Health Service Facilities, Minister of Health Republic Indonesia Regulation No. 12 of 2017. It was adapted from the instruments of Effective Vaccine Management UNICEF. This descriptive study with a facility-based cross-sectional design, involves multistage sampling. It was carried out in two selected *Puskesmas* / Public Health Centers (PHCs) in every two (urban-rural) districts in each of twelve provinces, namely Aceh, South Sumatera, Jakarta, West Java, Banten, Yogyakarta, Central Kalimantan, Central Sulawesi, East Nusa Tenggara, Bali, North Maluku, and Papua. For a period of July to October 2021, 517 PHCs that support Covid-19 vaccination services filled out the Covid-19 vaccine self-administered questionnaire form. The study found that the proportion of PHCs was 98,1% applied temperature monitoring, 31,5% had adequate vaccine storage, 83,6% had a standard refrigerator, 97,8% had constant electricity, 93,4% had good stock management, 54,9% had thermometers in their storage equipment, 91,3% had vaccine carrier, 70,1% had a cold box for distribution, 75,9% had implemented vaccine management, and 93,0% had implemented SMILE (*Sistem Monitoring Imunisasi dan Logistik Elektronik*) information system. Several criteria that need special attention were storage and transport capacity, vaccine distribution, and vaccine management. This evaluation demonstrates more than half of PHCs need more storage capacity and infrastructure. Meanwhile, the majority of PHCs have implemented standard temperature control and stock management.

Keywords: cold chain management · Covid-19 · health facilities

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1 Introduction

The cold chain systems are striving to effectively support Covid-19 national immunization programs. Many factors have influenced cold chain management in developing countries, even though effective vaccine management and well-functioning equipment are critical to vaccine distribution and storage [1, 2]. Monitoring for cold storage is insufficient in health facilities' storage equipment, and vaccine cold chain management guidelines are not being followed [3–6]. The common problems associated with vaccine storage such as lack of standard-compliant cold chain equipment for storing and transporting vaccines [7], a lack of systems for monitoring thermosensitive vaccine temperatures [8], and insufficient cold chain storage capacity. The availability of adequate vaccine storage capacity was 43% in low and lower-middle-income countries [9], with poor access to electricity [10], weak management of vaccine inventory and logistics information systems also contribute to poor vaccine cold chain management.

Based on the Minister of Health's Decree HK.01.07/MENKES/4638/2021 concerning Technical Instructions for Vaccination Implementation of Corona Virus Disease 2019 (COVID-19) Pandemic Management [11], the immunization program manager, and/or logistics of the Provincial and District Health Offices must inventory the number and condition of cold chain facilities (vaccine refrigerators, cool packs, cold boxes, vaccine carriers, etc.), as well as their distribution at the provincial, district/city, Puskesmas/PHC, and other health service facilities. One of the keys to the readiness of COVID-19 vaccine supply and logistics is the availability of adequate cold chain storage and transportation capacity [12].

Some Covid-19 vaccines must be stored at temperatures less than -20 degrees Celsius. Most existing vaccines do not require an ultra-cold chain, thus many countries must develop their ultra-cold chain infrastructure to store vaccines [13]. Even if vaccines were properly stored and distributed, a system that must be assessed and rated is satisfactory in Effective Vaccine Management (EVM) [6]. EVM criteria for a satisfactory vaccine supply chain include (i) vaccine arrival procedures, (ii) temperature monitoring, (iii) storage and transport capacity, (iv) buildings and equipment, (v) maintenance, (vi) stock management, (vii) vaccine distribution, and (viii) vaccine management practices, and (ix) information systems, and supportive management functions [6, 14–16].

The long distribution chain of the COVID-19 vaccine necessitates special logistics and handling to preserve the vaccine's potential until it is administered to the vaccine's subject/target. As a result, research on COVID-19 vaccination activities is required, beginning with planning and progressing through logistics management, implementation, recording and reporting, monitoring, and program evaluation systems. In Indonesian health facilities, data on cold chain management is critical. This data supports the successful implementation of the government's interventions in dealing with Covid-19, namely, vaccinating all Indonesians so that herd immunity against COVID-19 disease was formed. The purpose of this research was to describe the suitability of the vaccine cold chain system and the quality of vaccine management in Indonesia during the Covid-19 pandemic. The description of the cold chain system in Indonesia has been adjusted in full compliance with Ministry of Health RI Regulation No. 12 of 2017 on Immunization Implementation [17, 18].

2 Material and Methods

This evaluative research was carried out in a facility-based cross-sectional design. The research subjects are PHOs, DHOs, and health service facilities which distributed vaccines from the national level to the service location following the vaccine distribution flows. It was carried out in two selected PHCs in every two (urban-rural) districts in each of the twelve provinces, namely Aceh, South Sumatera, Jakarta, West Java, Banten, Yogyakarta, Central Kalimantan, Central Sulawesi, East Nusa Tenggara, Bali, North Maluku, and Papua. For the period July to October 2021, 517 PHCs that support Covid-19 vaccination services collected data by filling out the Covid-19 vaccine questionnaire form. The self-administered questionnaire was adapted from the instruments of EVM UNICEF. The questionnaire components include general information, facilities, equipment, recording and reporting, cold chain management, logistics, and information system. All immunization program managers were instructed to complete the questionnaire using the self-assessment method. They were given instructions on how to complete the questionnaire on their own and then email the completed form to the NIHRD researcher. The researcher repeatedly called, texted, and emailed the subjects to remind them to complete the survey in order to reach the desired response rate. In addition, the collected data were descriptively analyzed.

3 Results

According to the current study, the EVM criteria for the vaccine arrival process are only applicable at the national (primary) level, not at the PHC level. The Indonesian government still depends on vaccines in collaboration with many producers in several countries until 2021. Meanwhile, in 2022 Indonesia will produce its own vaccines. The majority of vaccines received by the Indonesian government are managed by PT Bio Farma, except for the Pfizer Global brand, which is distributed by Pfizer Indonesia and the Ministry of Health. Indonesia only has one domestic vaccine producer, PT Bio Farma, which is a government-owned business. PT Bio Farma takes raw vaccine materials from Sinovac, packages them, and distributes them to the public. PT Bio Farma's main business is producing vaccines and antisera, with its management focusing on the sector as an operating holding. Thus, it's not surprising if the government appoints PT Bio Farma to manage the research and development of the Covid-19 vaccine, which is urgently needed right now.

EVM the maintenance criteria for storage buildings, cold-chain equipment, and vaccine distribution vehicles is can not be analyzed. Almost all PHCs can not assess that their preventive and curative maintenance systems are standard and operational. In general, criteria for a satisfactory vaccine supply chain are temperature control, infrastructure, stock management, and information system. Several criteria that need special attention were: storage and transport capacity, vaccine distribution, and vaccine management (Table 1).

Table 1. The cold chain system's infrastructure and practices in the PHCs of Indonesia, 2021.

EVM criteria	The cold chain system's infrastructure and practices have been evaluated.	Percentage
Temperature control	Temperature monitoring	98,06%
	Temperature record	96,89%
Storage capacity	Adequate vaccine storage	31,46%
Infrastructure	Standard vaccine refrigerator	83,60%
	Electricity infrastructure	98,45%
Stock management	No damaged and expired vaccines	93,43%
Distribution	Cold box	70,10%
	Vaccine carrier	91,26%
	Thermometer	54,85%
	Freeze tag	37,42%
	Log tag	29,45%
Vaccine management	Implement Good vaccine management	75,92%
Information systems	Implement P-CARE	98,22%
	Implement SMILE	93,02%

4 Discussion

The COVID-19 vaccine used in Indonesia is a combination of four platform types: inactivated, protein, mRNA, and viral vector [1]. Storage requirements differ between the four types. In terms of capabilities up to the PHC level, Indonesia is already used to a storage temperature of 2–8 degrees Celsius as well as basic immunization vaccines. The inactivated and protein vaccine groups met the criteria for a freeze-sensitive vaccine, whereas the mRNA vaccine group was more stable when frozen. Vaccine management policies will be influenced by variations in storage temperature categories.

Vaccine storage facilities will differ at each administrative level, according to Permenkes No. 12 of 2017. At the national level, vaccine storage facilities are cold rooms. This room is completely insulated to keep heat out. There are two cold rooms with temperatures ranging from 2 °C to 8 °C and −20 °C to −25 °C. This facility has a backup generator in case of a power outage. At the provincial level, there must be a cold room, a freezing room, a vaccine refrigerator, and a freezer. A cold room, vaccine refrigerator, and freezer must be available at the district/city level, while a sufficient vaccine refrigerator must be available at the PHCs.

It was recorded that at 98.0% PHCs perform daily temperature monitoring and recording where vaccines were stored. This finding is in contrast to one from Ethiopia, where 46% of health facilities and 23% of PHCs were found to have storage that a non-standard daily temperature range [19]. Temperature monitoring issues have also been identified in India [20], the Philippines [10], Cameroon [21], and Nigeria [22]. The vaccine potency is lost much faster and may be destroyed due to cumulative damage when

exposed to temperatures outside the recommended storage range. This could be caused by the lack of a thermometer control in the storage, insufficient/small cold storage units, failure to keep a freezer temperature log works, refrigerator type, lack of alternative power sources, and intense workload. In this study, 96.9% of the PHCs recorded vaccine storage temperature monitoring. This finding is higher than in Egypt [23]. These disparities are the result of knowledge gaps, poor attitudes, professional negligence, and loose follow-up. It is critical to maintain complete and accurate records to ensure vaccine quality.

It was discovered that only 31.5% of PHCs could accommodate peak stock levels. The key informant noted that it was due to a lack of refrigerator storage space. This result was better than in Nigeria, which is only 30% of health facilities were equipped with adequate vaccine storage equipment [22]. This could be due to differences in the refrigerator quantity and storage capacity, as well as vaccine vial sizes. Vaccine storage requirements varies greatly. Meanwhile, the introduction of new vaccines will necessitate increased cold storage capacity. When calculating cold storage capacity, it required considering the vaccine expiry date, additional immunization activities, and cold chain reliability.

The WHO advises using vaccine refrigerators and freezers that comply with Performance, Quality, and Safety standards. A contingency plan must be in place and communicated to all staff in the event of a power outage or interruption if regular/domestic refrigerators and freezers are the only options for vaccine storage. It is also crucial to monitor and record the storage temperature of all equipment twice daily. Domestic refrigerators and freezers may offer sufficient cooling, but they lack the holding time needed to maintain the proper temperature for vaccine storage and are more susceptible to temperature changes. During power outages, they may freeze or expose the vaccines to higher temperatures. Indonesian health systems need more optimal fridges to store COVID-19 vaccines, especially in PHCs and rural communities. Almost all PHCs have electricity, and the vast majority operate 24 h a day. Electricity is reported in 98.5% of PHCs, with the remainder in PHCs suffering from the unreliable electricity supply. Qualitative research also reveals frequent and lengthy power outages. Out-of-standard temperature occurs at nearly almost the level of the cold chain distribution system, particularly in facilities that use a single power source. In Cameroon, 26.9% of vaccine refrigerators were overheated and 12% were exposed to cold [21]. Although solar refrigerators have a 132% higher annual cost than electric refrigerators, solar refrigerators can save money on the total cost per dose when compared to electric refrigerators [24].

Almost all PHCs, 93.4%, kept vaccines in good condition. The PHCs were found to have damaged and/or expired vaccines, according to the rest of the findings. This could be due to a lack of a refrigerator, a staff's heavy over workload, a lack of knowledge, a negative attitude, or professional negligence. This is consistent with findings from Ethiopia [25], Cameroon [21], and Nigeria [22]. It could be due to a broken cold chain, a lack of storage space, a bad attitude, or professional negligence. The key informant also stated that the medicines, drinking water, and laboratory samples were stored in the same refrigerator as the vaccine.

PHCs' most popularly used vaccine distribution equipment in Indonesia is vaccine carriers and cold boxes. When distributing vaccines, a small number of these PHCs have equipped their vaccine carriers with thermometers, freeze tags, and log tags. According to the WHO, up to 50% of vaccine doses are wasted before or after a vial is opened, which is primarily due to supply chain and logistics issues [6]. Studies from both developing and developed countries have identified errors to both extremes, the lower and higher temperature ranges [26–28]. Other non-electronic temperature monitoring methods include Vaccine Vial Monitors (VVM), which are labels attached to vaccine vials that warn of potential storage failure in the recommended temperature range through a color change. Vaccine vial monitors (VVMs) on the vials indicate whether or not the vaccine is usable. In the absence of temperature stability data, the COVID-19 vaccines have been approved for use without VVM, complicating the tracking of temperature excursions. Without a continuous temperature monitoring mechanism, this poses an operational challenge for the immunization system in LMICs.

According to the findings of this study, 75.9% of PHCs have effective cold chain management. Inefficient vaccine management systems, such as poor stock management as well as poor vaccine handling and storage quality, contribute to high wastage, resulting in revaccination and financial losses [29]. Thus, effective vaccine management and storage can reduce program costs, reduce wastage and stockouts, and improve immunization safety.

Three applications are used in all ministries and agencies to support a single Covid-19 vaccination data set, namely *PeduliLindung*, PrimaryCare, and SMILE. Those applications are used to improve the efficiency of the Covid-19 vaccine data system and develop a comprehensive system for vaccination registration, distribution, implementation, and monitoring. The Ministry of Communications and Informatics and the Ministry of SOEs' *PeduliLindung* application is useful for re-registering people who have received the Covid-19 vaccine. While BPJS Health's PrimaryCare will be used to record vaccination results. MoH RI developed information systems namely SMILE. A platform called SMILE (*Sistem Monitoring Imunisasi dan Logistik secara Elektronik*) contains real-time information about the cold chain of vaccine distribution, including the quantity, batch number, and expiration date of vaccines received from distributors at every level and storage locations from the provincial level to PHCs. In order to update receipts and the entry and exit of vaccines at their respective facilities, officers in charge of logistics for vaccines must use mobile phones.

We acknowledge that this study has some limitations, such as the fact that all participants were government funded PHCs, which restricts the results' external validity and limits their applicability to the population of healthcare facilities. Second, using self-descriptive methods to evaluate the EVM may produce biased results, but this is common for such evaluations in this area of study. We are also limited by the study's cross-sectional design, which can be enhanced by longitudinal analysis to assess vaccine administration.

5 Conclusion

This study found that more than half of health facilities need to improve their storage capacity and infrastructure, while the majority of health facilities have implemented standard temperature control and stock management. An in-depth understanding of the infrastructure and practices of the cold chain of health facilities will have implications for improving the immunization program's supply chain. The health facilities should have sufficient cold chain equipment and manage the vaccine cold chain system effectively.

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