Vaccines Cold Chain Monitoring: A Cross Sectional Study at Three District In Indonesia

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Abstract. Vaccine cold chain is a procedure that is used to keep vaccines at a certain temperature. The aim was to describe the vaccine cold chain management of basic immunization program in health centers district. The study design descriptive observational. The samples was Health Centers (HCs); 12 HCs in Sarolangun Jambi Province, 16 HCs in Brebes Central Java Province, and 24 HCs in Temanggung Central Java Provice. Basic immunization vaccines were BCG, DPT-HB-HIB, Polio, and Measles. The results showed proportion of officers graduated from college in Sorolangun, Brebes, and Temanggung were 66.7%, 81.3%, and 52.0% respectively. Proportion of HC that did not have thermometer and fridge freeze was mostly found in Temanggung (52%) and in Sorolangun (91.7%). The heat-sensitive vaccines arranged near the evaporator mostly found in Temanggung (88%), while freeze-sensitive vaccines prepared away of the evaporator mostly in Brebes (100%). Freezer temperature recording chart is not available mostly found in Sorolangun and Brebes (50%), In Sorolangun 41.7% of the officers monitoring 2 times a day and mostly (91.7%) the refrigerator thermostat tape was not isolated. The officers did not perform daily maintenance (50%), weekly (66.7%), and montly (33.3%) mostly found in Sorolangun. From this study we can conclude there is no vaccine immunization program management in Sarolangun, Brebes, and Temanggung that managed according to Ministry of Health Regulations number 42/2013 on the Implementation of immunization. Improvement oversight, control over management of vaccine and management personal, also managing the temperature of the vaccine were recommended.
Keywords : immunization, cold chain Vaccine, Vaccine, Vaccine Potency

1. Introduction

Immunization is widely acknowledged as one of the most successful and cost-effective public health interventions in history, saving two to three million lives every year [1,2]. Immunization is given by using the vaccine as the main components can improve immunity against disease contagious, for that matter its availability must be guaranteed up to targets and still effective. To achieve immunization targets, there are two important thing must be considered. First is the delivery of potent vaccines to children through properly maintained cold chain systems and other is immunization coverage.

In Indonesia, national immunization programs continue to face delivery challenges in terms of sustainably closing the immunization coverage gap. Today, vaccine storage and handling process are important for immunization programs. Vaccine cold chain and logistics systems are central to addressing some of these challenges [3–5]. Every single process of Vaccine cold chain has potential errors such as maintaining vaccine temperature during storage and handling process. Vaccines

gradually lose their potency, which is permanent and irreversible, when stored out of the recommended range of temperature [6,7] This notice advises vaccine providers of the importance of proper cold chain management practices.

Cold chain is a procedure to maintain vaccine in certain temperature, in order to ensure the vaccine has potent state, from the manufacturer to the person being immunized [8–11]. Infrastructures of cold chain consist of cool room, freezer, refrigerator, cool box, cool pack, vaccine carrier, and generator [12,13]. The cold chain is important for national immunization programs in tropical climates countries. Ideally, high coverage of vaccination resulted in high immunity. So, primary health care must have adequate knowledge to manage the cold chain because vaccine as main component to yield immunogenicity toward program of diseases that can be prevented by immunization need specific cold chain [14–16]. Good practices to maintain proper vaccine storage and handling can ensure that the full benefit of immunization is realized. This study described vaccines cold chain in all primary health care in Sarolangun, Temanggung and Brebes.

2. Method

2.1. Study site

The study was carried out in all primary health cares in three district health offices, namely: Sorolangun, Brebes and Temanggung. There were a total of 128 primary health centre in those districts; 12 in Sorolangun, 16 in Brebes, and 24 in Temanggung.

2.2. Study Design

This was an observational descriptive study, to describe management of cold chain three district health cares. Variables consisted of education level of vaccine manager, training, budget of cold chain, temperature in refrigerator, availability of cool pack in refrigerator, distance between vaccines, distance between heat sensitive vaccine with evaporator, distance between freeze sensitive vaccine with evaporator, availability of thermometer to monitor temperature in refrigerator, availability of freeze tag to monitor expose of cold temperature to vaccine, availability of recording graph, thermostat of refrigerator, number of cool pack in the refrigerator, number of vaccine carrier, maintenance of refrigerator, and test of vaccine potency using shake test.

2.3. Ethic Statement

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors. Ethical approval was obtained from the Committee of Public Health Research Ethics, Diponegoro University (112/EC/FKM/2016). Informed consent was acquired from cold chain officers.

3. Results

There was no differences in Sorolangun, Temanggung and Brebes for percentage of budgeting tools of cold chain (p value 0.0), percentage of source of funding (p value 0.0), percentage of number activities related with cold chain (p value 0.002), percentage of fee management for 1 months (p value 0.0), percentage received funding for cold chain (p value 0.005), p percentage of fee management for 1 year (p value 0.01), temperature monitor (p value 0.0), number of cool pack (p value 0.007), the existence of addition such as box (p value 0.013), the use of soap for laundry of vaccine carrier (p value 0.001), and maintenance for one week (p value 0.008).

There were no differences between three district for percentage of budget cold chain (p value 0.333), temperature of refrigerator (p value 0.342), calibration (p value 0.69), frequency of calibration (p value 0.569), prove of calibration (p value 0.61), position of cool pack (p value 0.926), number of cool pack (p value 0.302), another materials related with cold chain (p value 0.59), space between boxes of vaccines (p value 0.064), vaccine sensitivity (p value 0.302), expired dates (p value 0.302), VVM vaccines (p value 0.302), FIFO (p value 0.302), EEFO (p value 0.302), HS vaccines (p value 0.302), vaccine freeze sensitive (p value 0.302), number of reeze tag (p value 0.07), monitoring of freeze tag (p value 0.332), flag documentation (p value 0.323), temperature graph (p value 0.053), frequencies of recording (p value 0.464), routine (p value 0.489), Thermostat isolator (p value 0.066),

the use of cool pack (p value 0.302), the use of ice cube (p value 0.145), freezing 12 hours (p value 0.138), thermometer (p value 0.394), the laundry of vaccine carrier (p value 0.138), maintenance per day (p value 0,55), maintenance per months (p value 0.138), and the result of shake test (p value 0.302).

Table 1. Description of each Indicator of Cold Chain in Sorolangun, Brebes and Temanggung Sub District

Indicator	Sarolangun	Brebes	Temanggung
All vaccines keeped in temperature + 2˚C s/d 8˚C	The temperature was above 8^0C, it is 21,2^0C and there are 3 primary health care that the temperature was unknown.	The temperature was between 2^0C - 8^0C. So it is suitable with the regulation of Ministry of Health number 42/2013	There was no thermometer inside.
The bottom of refrigerator was put cool pack as cooler resistant	All primary health care have coolpack more than 8	All primary health care have coolpack more than 8	All primary health care have coolpack more than 8
There was cool pack inside of refrigerator	There was cool pack inside refrigerator (100%)	There was cool pack inside refrigerator (100%)	There are no cool pack inside refrigerator
There must be a range for vaccine box inside of refrigerator (1-2 cm)	There was no space inside the refrigerator between 1 box to another	The vaccine was arrange properly inside refrigerator. There was space between 1 box to another	There was no space inside the refrigerator between 1 box to another
Vaccine position didn't arrange by the kind of vaccine (heat sensitive or freeze sensitive)	The vaccine was not arrange based on the sensitivity of the vaccine	All vaccine was arrange properly based on its sensitivity	The vaccine was not arrange based on the sensitivity of the vaccine
There was thermometer inside of refrigerator	there was no thermometer inside	there was no thermometer inside	there was no thermometer inside
There was graphic charts of temperature	50% have graphic charts	50 % have graphic charts	80% have graphic chart
Thermostat taped isolated in order to the temperature of refrigerator		All primary health care in Brebes have isolated thermostat	There are fifteen primary health care that don't have isolated thermostat
There was vaccine carrier			Nine primary health care in Temanggung didn't have vaccine carrier more than 3
There was maintenance of the refrigerator	There were a lot of frost inside the refrigerator. It means the maintenance of the refrigerator didn't do regularly (daily, weekly, or monthly)	There were no frost inside the refrigerator. It means the maintenance of the refrigerator do regularly (daily, weekly, or monthly)	There were a frost inside the refrigerator. It means the maintenance of the refrigerator didn't do regularly (daily, weekly, or monthly)

We also found three vaccines of *Tetanus Toxoid* was suspected freezing from three refrigerator from different health cares, then conducted shake test and founded that vaccines had been freezing before so they might be impotent vaccines. Damage from accidental freezing can result in potency loss

for freeze-sensitive vaccines such as diphtheria, tetanus, pertussis, liquid *Haemophilus influenzae* type b (Hib), hepatitis B, and inactivated polio virus [14–16].

Table 2. Cold Chain Requirements in Sorolangun, Brebes and Temanggung Sub District.

No	Cold Chain Requirements	Percentage (%)		
		Sorolangun	Brebes	Temanggung
1	Minimum Educational Background is senior high school	33,3% cold chain officer, educational background is senior high school, and 66,7% university	18.8% cold chain office is senior high school, 81.3% bachelor degree	48% is senior high school
2	Had been trained about cold chain vaccine	100% officer had been trained minimum one time	62.5% had been trained minimum one time	28% had been trained minimum one time
3	Funding of cold chain	100%	43.8%	84%
4	All vaccines keeped in temperature +2˚C s/d 8˚C	66,7%	100%	4%
5	The bottom of refrigerator was put cool pack as cooler resistant	100%	100%	88%
6	There was cool pack inside of refrigerator	100%	100%	16%
7	There must be a range for vaccine box inside of refrigerator (1-2 cm)	58,3%	100%	72%
8	Vaccine position heat sensitve put nearby evaporator	33,3%	100%	88%
9	Vaccine position freeze sensitive put away form evaporator	75%	100%	88%
10	There was thermometer inside of refrigerator	75%	50%	48%
11	There were graphic charts of temperature	50%	50%	80%
12	Thermostat taped isolated in order to the temperature of refrigerator	8,3%	100%	40%
13	There was vaccine carrier	100% had vaccine carrier > 3 pieces	100% had vaccine carrier > 3 pieces	64% had vaccine carrier > 3 pieces
14	There was maintenance of of refrigerator (Daily)	50%	100%	72%
	There was maintenance of of refrigerator (Weekly)	33,3%	100%	88%
	There was maintenance of of refrigerator (Monthly)	66,7%	100%	80%

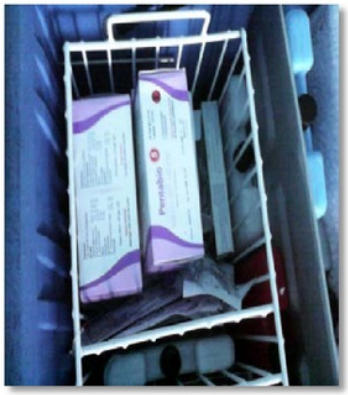

Figure 1(a) There was no thermometer inside

Figure 1(b) Temperature was found 21˚C, contained vaccine.

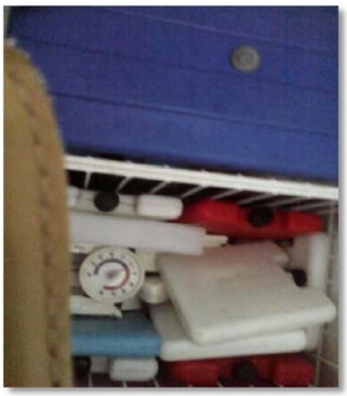

Figure 2(a) A broken thermometer inside

Figure 2(b) Arrangement of vaccine: no space and scrambled

4. Discussion

Vaccines (HB Uniject, BCG, Polio, DPTHB, Measles, DPT-HB-Hib, TT, DT and TD vaccines) taken from the Provincial Health Office then stored in the vaccine storage room, stored in refrigerators and freezers while solvents and dropper (pipette) is stored on a separate rack. In primary health care, the vaccine has been taken from the District Health Office, before it is given to the patient, first stored in the freezer as well as the vault as the storage of solvents and dropper (pipette).

Monitoring of storage temperature vaccine is very important in setting quickly whether the vaccine is still feasible used or not, always pay attention to vaccine vial monitor (VVM) that exist on each one of vaccine to find out if vaccine is still feasible to use. Vaccine potency depends on correct storage temperatures [14,17,18]. This research indicates that the availability of cold chain is not

satisfied and did not meet criteria from Ministry of Health of Indonesia or WHO. For a vaccination program to be effective and provide maximum protection, it is essential for vaccines to be stored in optimum conditions. If vaccines become too hot or too cold, their effectiveness may be compromised. Vaccines naturally biodegrade over time and this process may be accelerated if they are stored outside the recommended temperature range. Vaccines must never be frozen because in addition to vaccine deterioration, this increases reactogenicity by irreversible denaturing of the proteins in the vaccine. This causes the emulsions in the vaccine to become unstable and produces hairline cracks in the ampoule, vial or prefilled syringe, potentially contaminating the contents. Any glass spicules produced may also cause serious local adverse reactions. These factors may result in the failure of the vaccine to stimulate the intended immune response [9,14,15,19,20]. The series of storage locations and transport vehicles needed to get vaccines from manufacturers to vaccine recipients), and can traverse great distances and different climates. Many locations do not have reliable refrigerators or freezers (i.e., cold storage) or reliable means of monitoring temperatures in these devices [10,21–23].

The result of this study similar with studies in India[16,23,24]. Furthermore, it also similar with the result about the capacity of officers in charge to properly monitor the availability of vaccine storage equipment in all health facilities at the North West Region of Cameroon that still limited [25].

Air circulation in the room around the refrigerator should also be good, can be done by spacing between the refrigerators with the back wall and between refrigerators about 10-15 cm and the refrigerator should not be exposed to direct sunlight. Primary health cares some were found not to kept cool packs at the bottom of the storage so that if there is a power outage the temperature in the storage cabinet can immediately change whereas according to the guidelines on the bottom of the refrigerator should be placed cool pack in order to withstand cold and keep the temperature stability in the event of a power outage. The vaccine box has a spacing of at least 12 cm, this is to keep the temperature circulation inside the storage cabinet. According to the guidelines, a heat sensitive vaccine is placed near or attached to the refrigerator wall while the freeze sensitive vaccine is placed not to stick to the refrigerator wall, which if not done can affect the quality of the vaccine and may even cause vaccine damage [10,14].

Optimal immunization programs depend on a mix of stable vaccines used optimally in accordance with their stability, fitted with appropriate temperature monitoring devices on each vial, and by assessing the potential threat of temperature excursions using a risk management approach [10]. One approach of improving the integrity of the vaccine delivery system is to remove the obstacles in maintaining a refrigerated supply chain, which can be approached by a combination of three methods: developing ways to prevent vaccine freezing, for example, by using cold water packs instead of ice for transport; using more effective time–temperature monitors that can go on every vial of vaccine from the time it leaves the manufacturer until it reaches the recipient; and by better control and regulation of the supply chain [10].

The door rubber were not sealed, which should be according to the guidelines of the refrigerator/freezer gate should be tightly closed to prevent exhausted cold air which can affect the temperature of the storage cabinet. Some are known because they do not have internal or external temperature gauges that are damaged so that the temperature record is not done and does not have freeze tags. If it does not have a temperature gauge it can cause the vaccine temperature to be unknown so that if the vaccine is given the vaccine it is not able to stimulate the body's immune optimally, abnormal vaccine temperature is one of the main problems in vaccine storage. According to the Management Guidelines Cold Chain refrigerator/freezer should always be available inside and outside the thermometer in order to control the temperature to record the temperature of the vaccine 2 times a day and at holidays [21, 26].

Recording conditions of cold chain (logbook) were not made by some primary health cares, this is due to negligence of the officers. This logbook report must be made to determine the condition of the cold chain [22].

Vaccine stocks at primary health cares are often damaged due to the fact that no vaccines are taken and the travel time is far away, frequent congestion, no temperature monitoring device in cold box, limited cool pack in cold box so it cannot maintain vaccine temperature during the trip. According to the guidelines, packing of freeze sensitive vaccines should be equipped with a freezing

indicator in order to know whether during the course of the vaccine has clotted or not so that testing can be done immediately [13, 26].

Treatment of cool packs to be used does not conform to the Cold Chain Management Guidelines ie before use should be put into the freezer for 24 hours at 2°C-8°C. This can damage the quality of the vaccine because the cool pack that is inserted into the freezer for 24 hours at 2°C-8°C can maintain the temperature of the vaccine during the trip to the primary health care's [10].

Cold Boxes should be cleaned before and after use and contain 4 pieces of cool pack [10,27] but seen in the field of each cold box there is only 1 cool pack and cold box was never cleaned before or after use but directly stored it on the storage. This is because the limited places in the cold box and cold box are always in a clean state so no need to be cleaned again.

5. Conclusion

There is no cold chain of vaccine in all primary health centers in 3 Districts (Sorolangun, Temanggung, and Brebes) meet the requirement of health ministry (*Permenkes* 42/2013 about immunization). Recommended for DHO to allocate budget for replace the broken tools of cold chain such as freeze tag, thermometer, vaccine carrier, rubber in refrigerator door or else, also budgeting for calibration such as thermometer and electricity of refrigerator.

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PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8

PAGE 9