

## Knowledge, Attitude and Adherence to Cold Chain among General Practitioners in Kelantan, Malaysia

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### Abstract

**Objectives:** To determine the knowledge, attitude and adherence to cold chain guideline among general practitioners.

**Method:** A cross-sectional study was conducted among general practitioners in Kelantan using questionnaire, refrigerator inspection form and minimax thermometer. The validated questionnaire consists of 10 items on knowledge and 11 items on attitude with Cronbach's alpha of 0.68-0.72. Descriptive analysis was done using SPSS 12.0

**Results:** There were 89 general practitioners involved with response rate of 80.9%. Most respondents 78.7% (95% CI : 71.05, 86.35) have good knowledge but poor attitude towards cold chain 79.8% ( 95% CI;71.76, 87.84). Only 5.6% clinics adhere to the guideline.

**Conclusion:** Despite high percentage of good knowledge, majority of respondents have poor attitude and poor adherence to cold chain guideline. Quality improvement activities such as educational material, having dedicated person in charge of vaccine and distribution of thermometer as well as enforcement may improve adherence on cold chain.

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**Key words:** adherence, knowledge, attitude, cold chain, general practitioners

### Introduction

Cold Chain is a system to transport and store vaccine in the potent condition starting from the time it is manufactured to the time it is administered to patients in specified temperature range of 2-8° Celcius.<sup>1</sup> Vaccine are more exposed to the freezing temperature than heat damage at every level of cold chain.<sup>2</sup> Damage from accidental freezing can cause damage to freezing sensitive

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vaccine such as diphtheria, pertussis, tetanus, *Hemophilus influenza* type B and hepatitis B.<sup>3-5</sup> Evidence shows knowledge of good vaccine operation and cold chain system is very disappointing.<sup>6-9</sup>

The maintenance of vaccine requires adequate cold chain infrastructure and compliance to standard. Studies have shown that adherence to recommended guideline is poor<sup>6, 9</sup> and ranges between 0-70%.<sup>10</sup> Contributing factors were poor knowledge<sup>6, 7, 9, 11</sup>, inadequate training<sup>12, 13</sup>, types of physicians<sup>14</sup> and not using of guideline in daily practice.<sup>14,15</sup> However, study in United States found relatively high compliance with more than 80% adherence to guidelines.<sup>14</sup>

Basic principles to ensure good vaccine storage and proper maintenance of cold chain are availability of trained staff, appropriate vaccine transport and good vaccine storage.<sup>16</sup> Trained personnel in charge of vaccine cold chain are commonly available in developed countries<sup>12, 14, 15</sup> than developing country<sup>13,17</sup> and their presence in clinics accounted for two to three times more likelihood of performing daily temperature monitoring<sup>15</sup> and improved storage condition.<sup>18,19</sup>

Freeze-sensitive vaccines are exposed to freezing temperatures during their transport<sup>11, 15, 20-22</sup> mainly due to deep-frozen ice packs used in cold boxes.<sup>3</sup> Maintaining temperature between +2°C to +20°C is harmless for vaccine transportation except for oral polio which needs freezing temperature for transportation<sup>3</sup> and this has been adopted by many countries.<sup>4,23,24</sup>

Unit for vaccine storage must be selected cautiously and used properly. Domestic refrigerator for home use is appropriate if it has separated door for refrigerator and freezer compartment<sup>25, 26</sup> and the most appropriate is either two doors or top loading refrigerator.<sup>26</sup> Vaccines should not be kept together with laboratory specimens, drugs, food and drinks<sup>25</sup>, however, reverse findings were found.<sup>9, 10, 27, 28</sup>

Ideally, vaccines must be kept in perforated tray and space around 1-2 cm between vaccine line to allow air movement<sup>1, 26</sup> and cannot touch the refrigerator plat because it would result vaccine to solidify.<sup>1, 26</sup> To ensure good ventilation, refrigerator must be located about 40 cm from wall.<sup>26</sup> Refrigerator also cannot be placed under direct sunlight, near stove, microwave or fire to prevent temperature of refrigerator being higher.<sup>1, 26</sup>

In Malaysia, not much is known about knowledge, attitude and adherence to cold chain among general practitioners although they contributed 20-30% of vaccination services.<sup>29</sup> This study will helps Ministry of Health to ensure vaccination undertaken by general practitioners follows the guideline and patients get maximum benefit with regards to vaccine safety.

## **Objectives**

The objectives of this study are to determine the knowledge, attitude and adherence to cold chain guideline among general practitioners in Kelantan, Malaysia. Adherence to cold chain is defined as complying to the Ministry of Health guidelines with regards to type of refrigerator, dedicated refrigerator, presence of thermometer and temperature monitoring.

## **Methodology**

### ***Study design and population***

A cross-sectional study was conducted between April and November 2010. We included all GPs who provide vaccination services in Kelantan and excluded those who did not store vaccines in the clinic and part-time doctors. The list of GPs was obtained from Kelantan State Health Department and Medical Practice Control System. Universal sampling was applied.

### ***Research tools***

Research tool consist of knowledge and attitude questionnaire, refrigerator inspection form and recording of temperature using minimax thermometer. The validated questionnaire consists of 10 items on knowledge and 11 items on attitude with Cronbach's alpha of 0.68-0.72. The respondents should score 75% or more in order to determine that their knowledge and attitude level were good. The cut-off level was decided by consensus among the experts based on each item of what GPs should get minimally to consider satisfactory level. Inspection of the vaccine storage unit were on refrigerator types, dedicated refrigerator for vaccines, presence of thermometer and temperature monitoring using temperature chart. If there is more than one refrigerator or freezer, the one that has the largest number of vaccines was assessed.

Minimax thermometer which record minimum, maximum and current temperature was used. The thermometer was manufactured by GH Zeal Ltd, 8 Deer Park Road, Merton, London SW19 3UU United Kingdom and approved by BS EN ISO 9001:2008 Quality Standard. The thermometer instrument is self-calibrated and do not require calibration before and after use.

### ***Method of data collection***

Appointment with the clinic was made via phone call and those agreed will have to sign the 'Respondent Information and Consent Form'. Self-administered questionnaire was given followed by refrigerator inspection by the researcher. Minimax thermometer was placed in the middle shelf of general compartment during the visit and respondents were advice not to change its location. The temperature reading was taken after 24 hours. Ministry of Health handbook on cold chain guideline was distributed to every clinic involved. Sample size was calculated based on prevalence of good adherence among GPs of 0.16<sup>6</sup> using single proportion formula. Taking the precision of 0.07 at 95% confidence interval, the minimum required sample was 105. The precision was set at 0.07 after considering its clinical importance and feasibility of the study. After considering the non-response rate of 10%, the sample size calculated was 115.

### ***Statistical analyses***

Data was entered and analyzed using SPSS 12.0.<sup>18</sup> Descriptive analysis was used to determine the knowledge, attitude and adherence to cold chain guideline. Suitable refrigerator type is

defined as two door refrigerator or top loading refrigerator. Dedicated person is defined as a person (paramedic/staff) responsible for vaccine storage and maintaining optimal refrigerator temperature. Primary vaccine is defined as standard vaccination in the Malaysian Immunization Programme such as BCG, DPT Hib, MMR, Hepatitis B and HPV.

## **Result**

A total of 171 GPs were invited to join the study. However, after the clinics visit were done, 61 clinics did not practice vaccination and 21 clinics refused to participate and finally, 89 from 110 eligible clinics were involved giving a response rate of 80.9%. Table 1 showed the characteristic of respondents.

Most respondents 78.7% (95% CI : 71.05, 86.35) have good knowledge on cold chain vaccine (Table 2). Mean (SD) for knowledge score was 79.9% (5.43) ranging from 66.7% to 93.3%. Knowledge items that were weak were placement of vaccine at refrigerator door (14.6%), placement of vaccine in the lowest compartment in refrigerator (16.9%) and charting temperature in the temperature chart (6.7%) (Table 3).

Majority of the respondents have poor attitude towards cold chain 79.8% (95% CI;71.76, 87.84) (Table 2). Mean (SD) for attitude score was 68.8% (5.48) ranging from 81.8% to 54.5%. Attitude items that were weak were recording of temperature (12.4%), placement of vaccine (11.2%) and thermometer reading (4.5%) (Table 4).

Only 5 (5.6%) clinics adhere to all four items, 23.5% adhere to three items, 31.5% adhere to two items, 30.3% adhere to one item and 6.7% did not adhere to any item. Sub analysis of the items showed that only 28.1% clinics used two doors or top loading refrigerator, 53.9% have dedicated refrigerator for vaccine, 66.3% of refrigerators have either dial or minimax thermometer and 58.4% monitor daily temperature using temperature chart.

## **Discussion**

### ***Knowledge on cold chain vaccines***

This study showed 78.7% of respondents has adequate knowledge on cold chain operation, which is inconsistent with those of Efa.<sup>30</sup> It is different when compared to a study conducted among midwives at primary care unit in Turkey, where 96.3% had adequate knowledge.<sup>30</sup> In later study, high knowledge on cold chain among midwives was contributed by their total working experience as half of them have already worked at primary health care unit for more than 15 years.<sup>30</sup>

Majority (95.5%) of GPs in the current study knew on optimal temperature although only one-sixth have ever attended training on cold chain and half did not use guideline in their daily practice. Earlier studies reported lower percentage on optimal temperature ranging from 40% to 88.4%.<sup>31,6,7, 17, 13</sup> The lower percentage was possibly due shorter total duration of work<sup>6, 13</sup> which

relates to lesser experience in handling vaccine. The use of guideline among Malaysian GPs was disappointing<sup>32</sup> where only half of respondents used it in their daily practice.

Although 97.8% respondents agree that vaccines cannot be placed with food and beverages, only 14.6% knew that placement of vaccine at refrigerator door and at the lowest compartment (16.9%) are dangerous. These indicate that their knowledge regarding effect of heat and freezing are inadequate. Respondents failed to recognize various refrigerator compartments which have higher temperature and the importance of placing vaccines in an appropriate compartment. Placing the vaccine at the lowest compartment may cause irreversible damage to heat sensitive vaccine such as oral polio and measles vaccine. Fortunately, majority of respondents knew that exposure to heat can cause vaccine damaged as 92% of respondents knew that they need to place refrigerator away from heat source such as microwave, stove and sunlight.

In the present study, majority of respondents knew that vaccine will be spoiled if exposed to heat (98.8%) and frozen state (88.8%). However, other studies have reported that 65.9% and 39% of people responsible for vaccine cold chain did not know that vaccines can be damaged by freezing<sup>6,13</sup> or heat (18%)<sup>20</sup>; most were able to name freezing sensitive vaccine but lack of knowledge regarding its effect on vaccine.<sup>18</sup>

Knowledge on temperature reading was the weakest (6.7%) which could be due to lack of training. Only three-fourth respondents agreed that they need to shift vaccines if power failure occurs more than 72 hours which is consistent with a study among midwives, where two thirds of them knew the exact procedure for protection of vaccines when there is power failure.<sup>30</sup>

### ***Attitude on cold chain***

The success of cold chain management depends very much on the attitude of handlers. The present study showed that the attitude of general practitioners in Kelantan was poor. A majority of the respondents had negative attitude towards cold chain vaccines with only 20.2% perceived cold chain management as crucial. This is inconsistent with the study in China where the health care providers perceived that service delivery of vaccination is important (96.7%)<sup>33</sup> although they believed that it was influenced by hard service delivery (59.9%) due to geographical factors and poor condition of cold chain equipments (87.7%).<sup>33</sup>

About 75-85% respondents agreed to place adequate number of ice packs in the cold box to maintain optimal temperature, need to put an 'Open When Needed' label at every refrigerator door which stores vaccines to minimize exposure to heat, but not bothered if refrigerator is opened > 3 times per day.

For good vaccine care, only 4.5% believed they could place vaccine together with food, drinks and laboratory specimens and majority were concerned with vaccines potency if medicines and specimens are placed together. This shows that respondents have good understanding about potential harm if vaccines are kept in none dedicated refrigerator. Unfortunately, only 11.2% respondents perceived that placement of vaccine in refrigerator door shelf could damage vaccine. Shake test has 100% sensitivity, 100% specificity and 100% predictive value in detecting freeze

damaged vaccine.<sup>34</sup> However, in the present study, only 16.9% respondents perceived that doing shake test is important to determine vaccine potency. This findings were consistent others.<sup>7,6</sup>

Data on daily temperature monitoring was alarming. Most respondents did not attempt to do so although guidelines recommended for charting temperature twice daily.<sup>25</sup> They believed it is important to use special thermometer to measure internal refrigerator temperature but only a few reported that reading should be done without taking thermometer out of the refrigerator.

### ***Adherence to recommended guideline***

Adherence to recommended guideline in the present study was poor despite majority of GPs has good knowledge. It is very likely that this result could be explained by negative attitude of GPs on cold chain management. A study in South India<sup>35</sup> observed 79% compliance at primary health centre using different methodology and scoring parameters. Compliance on temperature monitoring using temperature chart was significantly improved after training and reorganization of cold chain points.<sup>18</sup>

## **Conclusion**

Despite high percentage of good knowledge, majority of respondents have poor attitude and poor adherence to cold chain guideline.

## **Recommendation**

Quality improvement activities such as educational material, having dedicated person in charge of vaccine and distribution of thermometer may improve adherence on cold chain. Research regarding knowledge of general practitioners on the effect of heat and freeze to specific type of vaccine and what needs to be done before giving vaccination should be examined to ensure cold chain is not compromised. Self regulation is the best; however, enforcement is still needed with regards to adherence to guideline by the Private Medical Practice Control Unit.

## **Limitation**

Universal sampling method was applied. Probability sampling are generally preferred because more likely to produce representative samples and provide accurate estimates of a number of the underlying population characteristic. However, the number of sample size calculated exceeds the number of general practitioners available. Hence, it was decided to sample all the available general practitioners.

The questions are solely on cold chain management. It did not assess respondents' knowledge on specific vaccine type and their practice on immunization such as placement of vaccine in the

refrigerator. However, this is not within the scope of current study and the temperature for heat and sensitive vaccine still falls within 2-8°C.

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**Author Contribution:** All the authors have contributed significantly in the supervision, analysis, drafting and revising the article to its completion.

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**Table 1:** Characteristic of the respondents

<b>Variables</b>	<b>Mean (SD)</b>	<b>n( % )</b>
Age (years)	47.2 (8.32)	
Total working experience (years)	20.5 (8.22)	
Duration working as GP	14.1 (8.63)	
Gender		
Male		61 (68.5)
Female		28 (31.5)
Race		
Malay		80 (89.9)
Non Malay		9 (10.1)
Type of vaccine		
Primary only		27 (30.3)
Primary and extended		62 (69.7)
Training		
Yes		11 (12.4)
No		78 (87.6)
Guideline use		
Yes		42 (47.2)
No		47 (52.8)
Dedicated person		
Yes		38 (42.7)
No		51 (57.3)
Awareness about cold chain act		
Yes		42 (47.2)
No		47 (52.8)

**Table 2:** Socio demographic characteristic of respondents according to knowledge and attitude

Variables	Good Knowledge (n=70) n(%)	Poor knowledge (n=19) n(%)	Good attitude (n=18) n(%)	Poor attitude (n=71) n(%)
Sex				
Male	50(82.0)	11(18.0)	14(23.0)	47(77.0)
Female	20(71.4)	8 (28.6)	4(14.3)	24(85.7)
Race				
Malay	62(77.5)	18(22.5)	16(20.0)	64(80.0)
Non Malay	8(85.7)	1(14.3)	2(22.2)	7(77.8)
Post graduation				
Yes	9(90.0)	1(10.0)	2 (20.0)	8(80.0)
No	61 (77.2)	18(22.8)	16(20.3)	63(79.7)
Training				
Yes	8(72.7)	3(27.3)	1(9.1)	10(90.9)
No	62(79.5)	16(20.5)	17(21.8)	61(78.2)
Guideline use				
Yes	33(80.5)	8(19.5)	3(7.3)	38(92.7)
No	37(77.1)	11(22.9)	15(31.3)	33(68.8)
Awareness on cold chain act				
Yes	32(76.2)	10(23.8)	10(23.8)	32(76.2)
No	38(80.9)	9(19.1)	8(17.0)	39(83.0)

**Table 3:** Correctly answered frequency of knowledge items

Knowledge	Items	Correct answers freq (%)
General aspects	K1 2-8°C is an optimal temperature for cold chain	85 (95.5)
	K4 Shifting of vaccine to another refrigerator is required if power failure occurs more than 72 hours	65(73.0)
Good vaccine care	K2 Vaccines will be spoiled if exposed to frozen state	79(88.8)
	K5 Vaccines will be spoiled if exposed to heat	88(98.8)
	K3a Placement of vaccines with food and beverages in the refrigerator	87(97.8)
	K3b Placement of vaccines at refrigerator door	13(14.6)
	K3c Placement of vaccines in the lowest compartment of refrigerator	15 (16.9)

Good refrigerator care	K6	Good refrigerator care is by placing it near to sunlight, stove or microwave	82(92.1)
Temperature readings	K7a	Thermometer is placed in the lowest shelf of general compartment in the refrigerator	59(66.3)
	K7b	Recording of temperature in the temperature chart is not required	5 (6.7)

**Table 4:** Correctly answered frequency of attitude items

Attitude	Items	Correct answer freq (%)	
General aspects about cold chain	A4	I have to place adequate number of ice packs in the cold box to maintain the optimal temperature	66 (74.2)
	A8	I don't bother if refrigerator is opened > 3 times per day	13(14.6)
	A9	I will put ice packs in the freezer to act as a back up in the case of power failure	72(80.9)
	A10	I will put an 'OPEN WHEN NEEDED' label at every refrigerator door which stores vaccines	69 (77.5)
Good vaccine care	A2	I will store vaccine in a dedicated refrigerator	85(95.5)
	A3	I have to do 'shake test' to determine vaccines potency	15 (16.9)
	A6	I need to place vaccine in refrigerator's door shelf	10 (11.2)
	A7	I am not concerned regarding vaccine potency if medicine and specimen are put together in the refrigerator	71 (79.8)
Temperature reading	A1	I don't bother to record temperature everyday	11 ( 12.4)
	A4	It is important for me to use special thermometer to measure internal refrigerator temperature	79 ( 88.8)
	A9	I will read the temperature without taking out the thermometer from refrigerator	4 (4.5)