Optimal Temperature of Cold Chain and its Associated Factors among General Practitioners in Kelantan, Malaysia

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Abstract

Objectives: To determine the prevalence of optimal temperature of cold chain and its associated factors among general practitioners.

Method: Cross sectional study was conducted between April and November 2010 among general practitioners in Kelantan. Refrigerator inspection and recording of temperature after 24-hours using minimax thermometer were done. Sample size calculated using single proportion formula was 115. Data was analyzed by Simple and Multiple Logistic Regression using SPSS 12.0.

Results: There were 89 general practitioners involved with response rate of 80.9%. A total of 14 (15.7%) refrigerators were within optimal temperature. Total working experience and duration of working as general practitioners were significant associated factors for acquiring optimal. For every 1 year increase in total working experience, there will be 0.78 times at odds of optimal temperature and for every 1 year increase in the duration working as general practitioners there will be 1.22 times at odds of optimal temperature.

Conclusion: The difference in working experience does not contribute to optimal temperature as cold chain management in health clinics was performed by paramedics such as staff nurses. Quality improvement activities such as educational material, having dedicated person in charge of vaccine and distribution of thermometer may improve cold chain management.

Key words: optimal temperature, cold chain, associated factors, general practitioners.

Running Title: Optimal Temperature of Cold Chain and its Associated Factors

Introduction

Vaccine is a biological product,[1] thus it is thermo sensitive and needs to be properly stored and distributed within efficient cold chain.[2] The Cold Chain system introduced by World Health Organization (WHO) 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° C.[1] Although all vaccines are sensitive to heat, some vaccines are extra susceptible to heat compared to another.[3] Some vaccine did not change in appearance even when potency is vanished.[4] A comprehensive laboratory test is the sole way to be sure whether vaccine has lost its potency due to heat exposure unlike the shake test that can be used for freezing sensitive vaccine.[4]

Exposure to heat can shorten vaccine's shelf life.[5] For example, exposure of measles vaccine to temperature above 37°C will reduce its vaccine potency within one hour[6] and exposure to temperature above 8°C for more than 80 hours will its decrease potency and caused vaccine failure.[7] Although most of the vaccine could potentially be affected by high temperature, these problems are usually more predictable and occurred in a small scale compared to exposure to cold temperatures.[8]

A number of vaccines are susceptible to extreme cold. However, freezing or exposure to temperature below 0°C can cause loss in potency and effectiveness. [9-11] Aluminium adjuvant in some freeze-sensitive vaccines may precipitate when exposed to cold temperatures resulted in missing adjuvant effect and reduce vaccine potency.[1] Freezing occurs at almost every level of cold chain during storage especially at district and health center and during transportation to the province and district.[12-14] The incidence of exposure to freezing temperature during storage was 13.5% in urbanized countries compared to 21.9% in developing countries,[14] while, exposure throughout shipments were between 75-100%.[14]

Temperature monitoring is a very crucial part in cold chain management. It starts from proper thermometer selection, placement of thermometer, recording of temperature and use of temperature chart for daily monitoring. Various types of thermometers can be used, including alcohol or mercury thermometer, dial thermometer, liquid crystal thermometer and recording thermometer.[11] Alcohol or mercury thermometer are recommended to be used in refrigerator/ freezer and it is able to detect current, minimum and maximum temperature.[11] Liquid crystal and dial thermometers are suggested for cold boxes because they are only able to record current temperature .[15] Recording thermometers are able to read temperature continuously for 7 days and useful for cold rooms at primary or intermediate vaccine store [11]. Studies found that lack of thermometer in the refrigerator occurs in many parts of the world ranging from 0-13.6%.[16-20]

Not much is known on cold chain among general practitioners (GPs) although they contributed 20-30% of vaccination services in Malaysia.[21] This is important to ensure patients obtain maximum benefit with regards to vaccination. Hence, the objectives of this study are to determine the prevalence of optimal temperature of cold chain and its associated factors among GPs in Kelantan, Malaysia. Optimal temperature is defined as temperature between 2-8°C and suboptimal temperature is defined as temperature <2°C and >8°C.

Materials and Methods

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.

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 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.

Research tools

Research tool consist of refrigerator inspection form and recording of temperature using minimax thermometer. 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.

Statistical analyses

Data was entered and analyzed using SPSS 12.0. Simple and Multiple Logistic Regression analysis were used to identify the associated factors for optimal temperature of cold chain. The dependent variable was optimal temperature. The independent variables were socio-demographic data, refrigerator type, dedicated refrigerator for vaccines, presence of thermometer and daily temperature monitoring. Suitable refrigerator type is defined as two door refrigerator or top loading refrigerator. Dedicated person is defined as a person (paramedic or clinic staff)

responsible for vaccine storage and maintaining optimal refrigerator temperature. *P* value <0.05 was used as a cut-off for statistical significance.

Result

A total of 171 GPs were available in Kelantan. However, after the clinic visits, 61 did not practice vaccination, 21 refused to participate and finally, 89 from 110 eligible clinics were involved giving a response rate of 80.9%.

A total of 14 (15.7%) refrigerators were within optimal temperature. Table 1 showed the characteristics of respondents. Majority (26.9%) aged between 46-50 years with maximum age of 65 years and minimum age of 28 years old and mean (SD) of 47.2 (8.32) years. Mean (SD) of total working experience was 20.5 (8.32) years and duration of working as GP was 14.1 (8.63) years. Sub-analysis of the suboptimal temperature showed most clinics (73.5%) were exposed to temperature >8ºC and 26.5% were exposed to temperature < 2ºC (Table 2).

Simple Logistic Regression shows no significant associated factor for optimal temperature (Table 3) but Multiple Logistic Regression shows that total working experience and duration of working as GP were significant associated factors for acquiring optimal temperature (*P* <0.05) (Table 4). Statistical assumptions showed that Hosmer and Lemeshow goodness of fit was not significant (*P* value 0.117), indicating that the model was fit. The high overall percentage (85.4%) in the classification table and area under the curve towards one (0.658) in the receiver operating characteristic curve showed that the model was fit.

Interpretations of final model indicate that: (1) For every 1 year increase in total working experience, there will be 0.78 times at odds of optimal temperature. Thus, for every 1 year increase in total working experience, the likelihood of achieving optimal temperature is 12% lower; (2) For every 1 year increase in the duration working as GP, there will be 1.22 times at odds of optimal temperature. Thus, for every 1 year increase in the duration working as GP, the likelihood of achieving optimal temperature is 22% higher.

Discussion

Optimal temperature

The low percentage of GPs able to maintain optimal temperature could be explained that they did not perceive recording temperature is essential as 41.6% do not bother to record temperature every day. The finding is consistent with others where optimal temperature was achieved only in 7.4%[22] and 31.4%.[20] Both studies were performed in GPs offices. The study design by Woodyard was similar with present study as they placed minimax thermometer in the middle compartment and reading was taken after 24 hours.[22]

Current finding on optimal temperature was not supported by majority of previous studies. Generally, the compliance ranged from 62-93%.[19,23] In a study by Ortega, 93% of GPs

maintained optimal temperature; however, the reading was taken from minimax thermometer which was already present in the refrigerator.[23] This may cause bias as there was no uniformity or standardization in the usage of thermometers. High percentage (86.7%) of compliance to optimal temperature was reported following Expanded Program on Immunization training.[24]

Another small study involving 20 from 232 clinic refrigerators reported 70% of GPs were able to maintain optimal temperature within 2-8ºC.[25] With small sample size and wide confidence interval, the study will be not précised enough and representative of all GPs in the region. Use of strip type thermometer (reversible liquid crystal) with ability to only detect current temperature from 0-20ºC (±0.5ºC) and its placement in refrigerators for only 10 minutes before the reading was taken might influence the result. In contrast, minimax thermometer was able to detect temperature range from minus 30-50ºC (±0.5ºC) and it was left for 24 hours. Thus, the optimal temperature obtained in the present study was more accurate and may represent the actual temperature problem. Study among urban dispensaries and medical store depots along with the use of guidelines have reported 56.2%[26] compliance of optimal temperature. In contrast, GPs in the present study were from urban and rural areas with only 47.2% usage of guideline.

In the current study, 20.2% refrigerators were exposed to freezing temperature and this is supported by results of systemic literature review where the occurrence of exposure to freezing was 21.9% in developing countries and 13.5% in developed countries.[14] This reflects that vaccine exposure to sub zero temperature in cold chain is a worldwide problem. It occurs in resource rich countries as well as in a country with limited resources such as Malaysia. Damage from accidental freezing can result in potency loss for freeze sensitive vaccines.

However, most of refrigerators in this study were exposed to warm temperature compared to freezing temperature. It is consistent with a study in Thailand where researchers found temperature more than 8ºC commonly occur at storage level.[8] Exposure to heat can shorten vaccines shelf life.[5] Measles (heat sensitive) vaccine loses its potency during storage at elevated temperature [6] If the vaccines were exposed to temperatures above 37^{0}C, inactivation will occur within one hour[6] and if kept at 22-25ºC, it will remain potent for four.[5] In contrast, exposure of measles vaccine to temperature above 8ºC more than 80 hours caused decrease in potency to about 3.0 $\log_{10}$ and showed vaccine failure.[7]

Fortunately, there was good evidence that many of the immunization schedule vaccine are stable at temperature less than 25ºC.[5, 27] Hepatitis B vaccine and DTP are susceptible to freezing and they are resistant to storage for several months to temperature 22-25ºC.[5,27] In our study, only 7% of refrigerators were kept at temperature more than 25ºC. Hence, vaccines in our study would have shorter half life due to exposure to temperature greater than 8ºC. Even though the potency of majority of vaccines can be seriously affected by extreme warm storage temperature, these effects are usually more predictable and in lesser scale compared to losses from temperatures that are too cold.[8] Among general practitioners in Kelantan, heat exposure is a more important problem than freezing temperature which is similar to the findings in Thailand [8] but differs from a study in Indonesia where storage of vaccine at health centre was more exposed to freezing temperature.[12]

Regarding the type of refrigerators, domestic refrigerator for home use is appropriate if it has separated door for refrigerator and freezer compartment.[11, 15] A study in Bolivia found that the

use of small domestic–type refrigerators contributes to the freezing temperature.[13] In another study, old refrigerators (more than 12 years) may have higher temperature because of detectable seal breaks on the doors[18] and modification of domestic refrigerator by removing single door insert can lead to local warming of vaccines and reduce vaccines potency.[28]

Majority of GPs did not use recommended refrigerators due to probably storage of smaller number of vaccine. Only 28% used two doors or top loading refrigerators which was much lower than that reported (65.6%).[26] Almost half of GPs keep vaccines in a dedicated refrigerator which is similar to other developing country,[26] whereas, developed country reported a much higher prevalence.[29] The apparent contradictory findings may reflect methodological differences and quality improvement activities such as educational material and written feedback.[29] Lack of thermometer in refrigerators occurs in many parts of the world with the highest prevalence of 13.6%.[16-18] However, current study found that two third of clinics had minimax thermometer inside refrigerator which was consistent with systematic review finding of 54.9% with individual prevalence ranging from 8-100%.[19]

Temperature documentation is equally important. Temperatures must be documented twice daily, once when the clinic opens and once at the end of the day.[5, 15, 30] Generally, numerous studies found that the above recommendation was difficult to adhere.[18, 20, 31-33] In this study, 58.4% of clinics had daily temperature monitoring at least once a day, higher than the overall prevalence according to systematic review which was only 26.8%.[19] However, higher prevalence of 60-71.8% was reported.[26,34] These can be explained by the in-depth training received and appointment of dedicated person in each cold chain point.

Associated factors for optimal temperature

In this study, duration of working as general practitioner and total working experience were significantly associated with optimal temperature. This indicate that six years difference in working experience does not contribute to optimal temperature as cold chain management in health clinics was performed by paramedics such as staff nurses which was also reported by other study[24] who found that working experience was significantly associated with practice on cold chain. However, study among midwives in Turkey found no difference in knowledge of the optimal temperature for vaccine storage based on midwives' years of employment.[35]

In this study, adherence to recommended guideline in terms of dedicated person responsible, use of appropriate refrigerator, dedicated refrigerator, presence of thermometer, temperature charting were not significantly associated with optimal temperature. One study too found no association with dedicated person and refrigerator.[20] However Page *et al.,* found significant association between type of refrigerator and optimal temperature[36] and another study involving public health officers and nurses found significant association between training and knowledge regarding Expanded Programme on Immunization.[24] The differences might be due to difference study design and different target population.

Lack of thermometer in refrigerator, refrigerator without temperature log and use of freezer compartment in small cold storage unit were 2.5 to 7 times more likely to have suboptimal

temperature.[37] The contradictory findings of previous research may reflect methodological differences compared to the current study as the respondents received guideline on vaccine storage at least two months before the site visit and vaccine storage temperature were taken at a single time.[37] This may cause bias where actual practices would be worse than what has been observed. Furthermore, it is possible that single time temperature may show lower overall incidence of vaccine storage outside the recommended temperature range.

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 temperature recording is based on 24-hour reading during the clinic visit. The used of continuous monitoring by electronic refrigerator temperature logger over 30 days for temperature monitoring is ideal. However, studies have shown that 24 hour data by minimax thermometer is adequate and able to reflect the temperature of given refrigerator.

Lastly, suboptimally stored vaccine does not permit any inference about the potency. However, many studies have proven that ambient temperature (> 8^{o}C) will shorten vaccine shelf life while freezing temperature (< 2^{o}C) will lead to irreversible loss of potency.

Conclusion

Only 15.7% of refrigerators were within optimal temperature. Total working experience and duration of working as general practitioners were significant associated factors for optimal temperature. Quality improvement activities such as educational material, having dedicated person in charge of vaccine and distribution of thermometer may improve cold chain management.

Conflict of Interest Statement: The authors declare that there are no conflicts of interest.

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Table 1: Characteristics of respondents

Variables	Total (n=89)	Optimal temperature (n=14) n(%)	Suboptimal temperature (n=75) n(%)
Age(years)[a]	47.2 (8.32)	48.1(7.64)	47.0(8.48)
Total working experience (years) [a]	20.5(8.22)	22.3(7.51)	20.21(8.35)
Duration working as GP (years) [a]	14.1(8.63)	14.6(9.03)	14.0(8.61)
Sex			
Male	61 (68.5)	8(13.1)	53(86.9)
Female	28 (31.5)	6(21.4)	22(78.6)
Education level			
Basic	79 (88.7)	11(13.9)	70(86.1)
Post Grad	10 (11.2)	3(30.0)	7(70.0)
Using guideline			
Yes	42(47.2)	6(14.6)	35(85.4)
No	47(52.8)	8(16.7)	40(83.3)
Dedicated person			
Yes	38(42.7)	6(15.8)	32(84.2)
No	51(57.3)	8(15.7)	43(84.3)
Training			
Yes	11(12.4)	1(9.1)	10(90.9)
No	78(87.6)	13(16.7)	65(83.3)
Awareness of cold chain act			
Yes	42(47.2)	8(19.0)	34(81.0)
No	47(52.8)	6(12.8)	41(87.2)
Two doors / top loading refrigerator			
Yes	25(28.1)	1(4.0)	24(96.0)
No	64(71.9)	13(20.3)	51(79.7)
Dedicated refrigerator for vaccine			
Yes	48(53.9)	9(18.8)	39(81.3)
No	41(46.1)	5(12.2)	36(87.8)
Presence of thermometer (minimax/dial)			
Yes	59(66.3)	10(16.9)	49(83.1)
No	30(33.7)	4(13.3)	26(86.7)
Daily temperature monitoring			
Yes	52(58.4)	8(15.4)	44(84.6)
No	37(41.6)	6(16.2)	31(83.8)

[a] Expressed as mean (SD)

Table 2: Temperature reading

Refrigerator(s) temperature	Number of refrigerators	Percentage (%)
Optimal temperature	14	15.7
Suboptimal temperature	75	84.3

Table 3: Associated factors for optimal temperature using Simple Logistic Regression

Variables	Crude OR[a]	(95% CI [b])	Wald stat[c]	*P* value
Age(years)	0.98	(0.92,1.05)	0.19	0.656
Total working experience (years)	0.94	(0.90,1.03)	0.75	0.386
Duration working as GP (years)	0.83	(0.93,1.06)	0.47	0.827
Sex				
Male	1.00			
Female	0.55	(0.17,1.78)	0.98	0.321
Education level				
Basic	1.00			
Post Grad	2.65	(0.59,11.81)	1.63	0.201
Using guideline				
Yes	1.00			
No	0.86	(0.27,2.71)	0.06	0.793
Dedicated person				
Yes	1.00			
No	1.00	(0.31,3.19)	0.00	0.989
Training				
Yes	1.00			
No	0.50	(0.05,4.25)	0.40	0.520
Awareness of cold chain act				
Yes	1.00			
No	1.61	(0.50,5.08)	0.65	0.419
Two doors / top loading refrigerator				
Yes	1.00			
No	6.11	(0.75,49.5)	2.88	0.090
Dedicated refrigerator for vaccine				
Yes	1.00			
No	1.64	(0.50,5.42)	0.70	0.400
Presence of thermometer				
Yes	1.00			
No	1.33	(0.37,4.64)	0.19	0.659
Daily temperature monitoring				
Yes	1.00			
No	0.96	(0.29,2.97)	0.011	0.915

[a] Odds Ratio
[b] Confidence Interval
[c] Wald statistic

Table 4: Associated factors for optimal temperature using Multiple Logistic Regression

Variables	Adjusted OR[a]	(95% CI [b])	Wald statistic	*P* value
Total working experience (years)	0.78	(0.63,0.98)	4.45	0.035
Duration working as GP (years)	1.22	(1.00,1.49)	3.92	0.048

[a] Odds Ratio
[b] Confidence Interval
[c]There was no interaction between the variables and no multicollinearity problem; model assumption met