KNOWLEDGE, ATTITUDE AND PRACTICE ON COLD CHAIN AMONG GENERAL PRACTITIONERS IN KELANTAN

By

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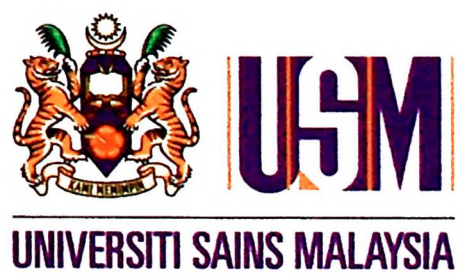

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Acknowledgments

To my dearest husband Almarhum Syukiman Md Daud,
and our children Irfan Khairi, Ikhwan Hafizi and Idlan Syafi
- for love and unconditional support

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LIST OF ABBREVIATIONS

BCG	Bacillus Calmette Guerin
DPT	Diphteria, Tetanus and Pertussis
DTaP	Diphteria,Tetanus and acellular Pertussis
DTwP	Diphteria, Tetanus and whole Pertussis
DT	Diphteria and Tetanus toxoid
GP	General practitioner
Hib	Hemophilus Influenza Type B
IPV	Inactivated polio virus vaccine
MMR	Measles, Mumps and Rubella
MOH	Ministry of Health
OPV	Oral polio vaccine
TT	Tetanus toxoid
WHO	World Health Organization

ABSTRAK

TAJUK : Kajian Tentang Pengetahuan, Sikap dan Amalan terhadap Rangkaian Sejuk Vaksin Di Kalangan Pengamal Perubatan Swasta di Kelantan

PENGENALAN : Bilangan pengamal perubatan swasta di Malaysia meningkat setiap tahun. Dianggarkan 20-30% penduduk Malaysia menerima imunisasi di klinik swasta.

OBJEKTIF : Kajian ini adalah untuk mengenalpasti tahap pengetahuan, sikap, pematuhan dan faktor-faktor yang berkaitan dalam menentukan suhu optima rangkaian sejuk .

METODOLOGI : Kajian keratan rentas dijalankan dari April sehingga Disember 2010 melibatkan pengamal perubatan swasta di negeri Kelantan. Kajian dilakukan melalui borang soal selidik , pemeriksaan dan bacaan suhu peti sejuk.

KEPUTUSAN : Seramai 89 pengamal perubatan swasta telah terlibat dengan kadar respon 80.9%. Purata (SD) markah untuk pengetahuan dan sikap adalah 79.9% (5.43) dan 68.8% (5.48). Hanya 14(15.7%) peti sejuk mengekalkan suhu optima. Dua faktor berkaitan dengan suhu optima iaitu pengalaman bertugas sebagai pengamal perubatan (*p:*0.035) dan tempoh bertugas sebagai pengamal perubatan swasta (p : 0.048).

KESIMPULAN : Walaupun majoriti pengamal perubatan swasta mempunyai pengetahuan yang baik tetapi kebanyakan mereka memiliki sikap yang buruk terhadap rangkaian sejuk. Pematuhan terhadap garis panduan adalah kurang memuaskan. Pengalaman sebagai pengamal perubatan dan tempoh bertugas sebagai pengamal perubatan swasta didapati berkaitan dengan suhu optima.

ABSTRACT

TITLE : Knowledge, Attitude And Practice On Cold Chain Among General Practitioners In Kelantan

INTRODUCTION : In Malaysia, the number of private doctors has been increasing each year. It is estimated that 20-30% of Malaysian population received immunization service from private clinics.

OBJECTIVES : The objectives of the study are to determine the knowledge, attitude, adherence and associated factors for optimal temperature of cold chain.

METHODOLOGY : Cross sectional study was conducted from April to December 2010 among general practitioners in Kelantan. The study used a self administered questionnaire, refrigerator inspection form and recording of refrigerator temperature.

RESULTS : There were 89 general practitioners involved with response rate of 80.9%. The mean(SD) score for knowledge and attitude were 79.9%(5.43) and 68.8%(5.48) respectively. Only 14 (15.7%) of general practitioners were able to maintain optimal temperature. There were two significant associated factors for optimal temperature namely total working experience (p : 0.035) and duration of working as a general practitioner (p : 0.048).

CONCLUSION : Despite high percentage of good knowledge, the majority of respondents have poor attitude on cold chain. The adherence to recommended guideline was unsatisfactory. Total working experience and duration of working as general practitioners were significant associated factors for optimal temperature.

CHAPTER ONE

CHAPTER 1

INTRODUCTION

1.1 : BACKGROUND

Since the introduction of small pox vaccine by Edward Jenner in 1792 and complete eradication of small pox in year 1977[1], the world of medicine has changed . Vaccines are recognized as a powerful public health tool that are able to save around 3 million lives every year[1] . Immunization activity has been identified among the most cost effective health interventions[2]. In 1974, World Health Organization started the initiative to increase coverage of immunization by introducing Expanded Immunization Program[1] which was later adopted by many countries including Malaysia . It was estimated that more than 20 million lives have been saved through this program[1].

Vaccine is a biological product[3], thus it is thermo sensitive and needs to be properly stored and distributed within efficient cold chain. 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° Celcius[4] . Of biological products, the quality control is indispensible because all products must be safe enough for use to immunize a large number of healthy individuals, and all the products must have certain level of potency to confer the immunity to prevent the disease concerned[5]. Biology products will experience potential loss by natural with times change. This process is irreversible and will be defamed if storage practice recommendation is not followed.

Lack of vaccine potency will reduce the response immunity and create inadequate protection against disease[5, 6].

Apart from that, vaccine's price is expensive and immunizer will waste patient's money[5]. Studies have found that vaccine wastage occur around 1-5%[7] and major contributors were refrigerator (cold chain) lapses and product expiration[7] . In another study in Canada, about 4% of all vaccines ordered by clinics expire before they are used and these cost more than 3 million anually[8].

Systematic literature review have shown that vaccine are more exposed to the freezing temperature than heat damage at every level of cold chain[9] . Damage from accidental freezing can cause damage to freezing sensitive vaccine such as diphtheria, pertussis, tetanus, *Hemophilus influenza* type B (Hib) and hepatitis B[3, 10, 11]. Evidence shows knowledge of good vaccine operation and cold chain system is very disappointing[12-15]. This involved not only private practitioners but also doctors who served in government and usually happened in developing countries[16, 17].

Malaysia has a long experience in providing vaccination and immunization services to the public especially to its children. National Immunization Program that has been introducing since 1958 and Expanded Programme for Immunization since 1989 have proven beneficial to prevent against major childhood diseases[18, 19]. Thus, reducing number of morbidity and mortality in children and improvement in quality of life of children[18].

In 1958, Malaysian government has introduced vaccine in health service program which is known as diphtheria-pertussis-tetanus (DPT)[18]. Later in year 1962, the government introduced Bacille Calmette-Guerin (BCG) vaccine, oral poliovirus vaccine (OPV) in 1972, tetanus toxoid (TT) in 1974, measles vaccine in 1983, hepatitis B vaccine in 1989 , Hemophilus influenza type B (Hib) vaccines in 2002 and measles-mumps-rubella (MMR) vaccines also in 2002[18]. The objective of this programme is to reduce the mortality and morbidity due to the identified selected vaccine-preventable diseases (VPD) so that they are no longer pose a public health problem; to maintain quality surveillance on identified vaccine-preventable diseases; to eradicate poliomyelitis; to eliminate neonatal tetanus, measles and reduction of hepatitis B by a certain time frame based on WHO's Regional Plan and to monitor and to also evaluate vaccination strategies in line with current global and national disease control requirements[19]. To achieve these all medical practitioners including private medical practitioners must be skilled in cold chain and good vaccine operation guided act and guidelines provided by Ministry of Health.

The maintenance of vaccine requires enough cold chain infrastructure and compliance to the standard. Previous studies have shown that adherence to recommended guideline is poor[12, 15] and in one study it ranges between 70% to 0% [20]. Various factors contribute to this weakness such as poor knowledge[12, 13, 15, 21], inadequate training[17, 22], types of physicians[23] and not using of guideline in daily practice[24]. However, a more recent study in the United States found that compliance was relatively high, with more than 80% adherence to guidelines[23]. Multivariate analysis indicate that types of physicians,

practice location, using guideline and participation in vaccine programs were significantly associated with compliance[23].

Success of immunization program directly depends on the coverage rate[25] and the effectiveness of the vaccine[5]. Immunization coverage rate of Malaysia ranging from 95% to 98% in 2010[26]. Primary immunization coverage has exceeded 90% of the target population, particularly immunization for measles, which is given in combination with mumps and rubella at one year, exceeded 94 per cent in 2008[27].

In many countries, studies found that improper vaccine storage and handling were cited as possible causes of many measles outbreaks in early 1990's[12]. However, this problem is not only limited to these countries as Malaysia also not exempted. In year 1999 and 2000, measles cases increased drastically with incidence rates of 11.48 (2,608 cases) and 26.59 (6,187 cases) per 100, 000 populations despite wide coverage of immunization in 1999 (86.6%) and 2000 (88%)[28]. In these two years, measles outbreak took place all around the country including urban and rural areas. The Ministry of Health has suggested that the outbreak were due to primary vaccine failure and failure to vaccinate, causing accumulation of susceptible individuals[28].

CHAPTER TWO

CHAPTER 2

LITERATURE REVIEW

2.1 Vaccine types

Since the introduction of Expanded Program in Immunization program by WHO in 1974, vaccine type and availability are changing tremendously. At the initial stage of this program, it only covers 6 types of deadly diseases for children less than one year which are pertussis, diphtheria, polio, tuberculosis, measles and tetanus[1]. Today, with the advancement of technologies, hepatitis B vaccination is also included in immunization schedule for children less than one year in about 171 countries around the world[29].

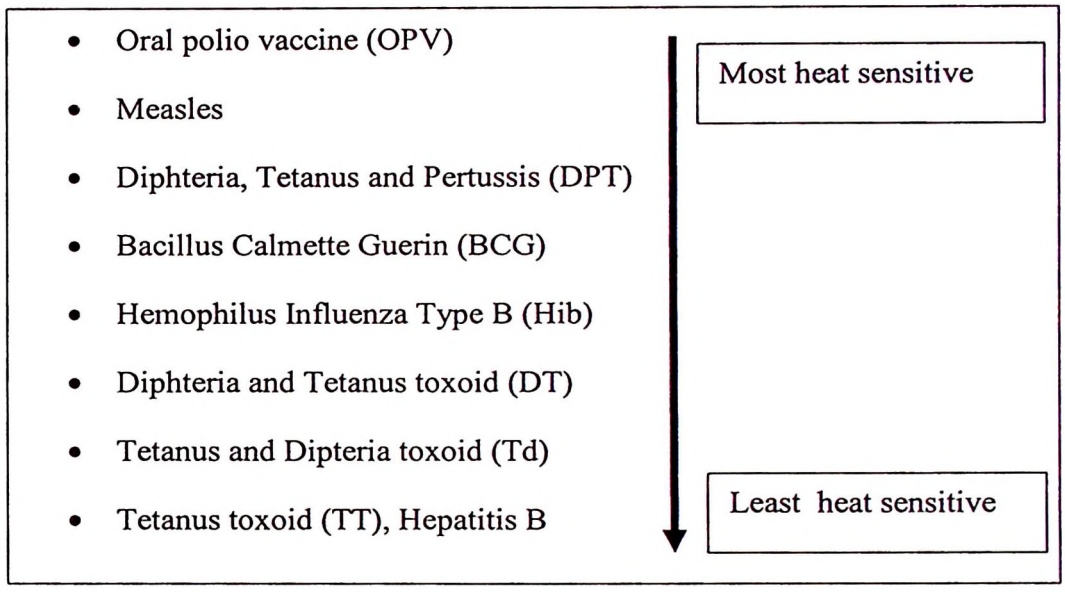
Various new life saving vaccines has been brought in to the public such as vaccine for rotavirus diarrhea, meningitis, pneumonia and human papilloma virus (HPV) infections that cause cervical cancer[30]. More than 80 vaccines are in the late stages of clinical testing, and 30 of them are intended to protect against major diseases including dengue and malaria[30].

2.1.1 Heat sensitive vaccine

Although all vaccines are sensitive to heat, some vaccines are extra susceptible to heat compared to another. Some vaccine did not change in appearance even when potency is

vanished[31]. 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[31]. Following is the list of vaccines according to heat sensitivity[32].

Table 2.1 List of vaccines according to heat sensitivity



Note: These vaccines become much more heat sensitive after they have been reconstituted with diluents.

Oral polio is very sensitive to heat. It must be stored at recommended temperature of 15°C to 20°C especially at primary and intermediate vaccine storage[33]. It has been proven in a study in Taiwan that strict adherence to recommended temperature for polio vaccine ensures its potency[34].

Exposure to heat can shorten vaccine's shelf life[33]. At elevated temperature, measles vaccine loses its potency[35] . Its half-life at 25–30 °C, 37 or 41 °C is 31 days, 16.6 days, or 3.3 days, respectively[35] . If it is exposed to temperature above 37°C, vaccine potency

will be reduced within one hour[35]. The WHO estimates that measles vaccine kept at 22°C to 25°C will remain potent for four weeks[33]. In contrast, research by Qien, has revealed that exposure of measles vaccine to temperature above 8°C more than 80 hours caused decreases in potency and showed vaccine failure[21].

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[36].

2.1.2 Freeze sensitive vaccine

A number of the vaccine is susceptible to extreme cold. For this kind of vaccine, freezing or exposure to temperature below 0°C can cause loss in potency and effectiveness[32]. Therefore, it is very vital to keep the vaccine not only from warmth, but also from cold as well. The vaccines that are sensitive to freezing (as well as heat) are as follows :

Table 2.2 List of vaccines according to freezing sensitivity[32]

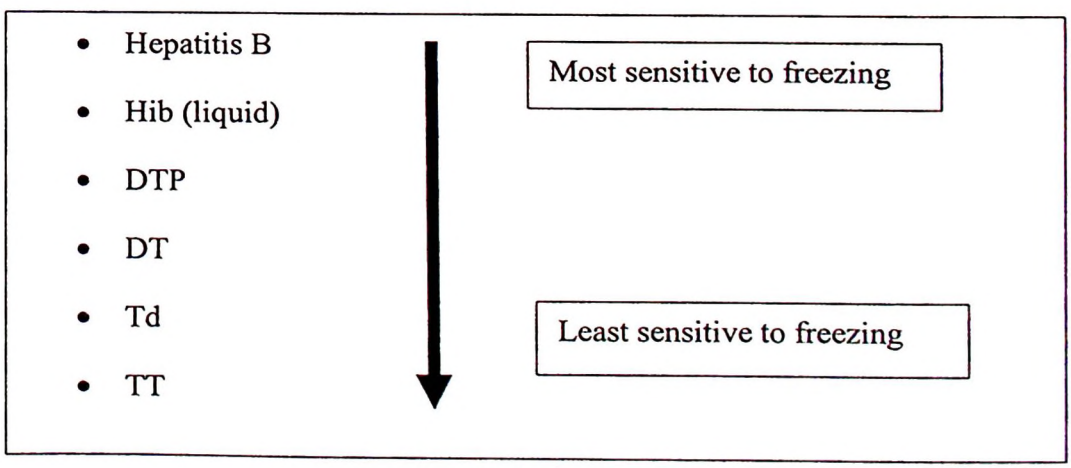


Table 2.3 Sensitivity of vaccines to freezing[32]

Vaccine **damaged** by freezing	Vaccine **unaffected** by freezing
• DPT • DT • Td • TT • Hepatitis B	• BCG * • OPV • Measles * • Mumps

Note: Vaccines freeze at temperatures just below zero.
· BCG and measles vaccines must not be frozen after reconstitution
· Diluents for any vaccine must never be frozen

Temperature less than 0°C can cause a permanent loss of vaccine potency[37, 38]. Aluminium adjuvant in some freeze-sensitive vaccines may precipitate when exposed to cold temperatures[3] . This resulted in missing adjuvant effect and reduce vaccine potency[3].

In recent years, there has been a large increase in research related to freezing effect on cold chain management. Study in Bolivia found that, 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[39]. Another study by Nelson in Indonesia discovered that freezing most likely to occur in three stages namely during transportation from province to district, storage at district and storage at health centers[10]. Other research by Techawat and Qien has revealed that freezing occur more frequently but shake tests for Hepatitis B failed to identify any vaccine damage[21, 36]. Recent study in 2010 funded by WHO shows that, shake test had 100% sensitivity, 100% specificity and 100% positive predictive value, which confirms its validity for detecting freeze damaged vaccine[31].

Freezing is a bigger problem than excessive temperature[36]. Heat contact would shorten vaccine shelf life but freezing temperature spoil vaccine irreversibly[36]. In systematic review published in 2007, accidental freezing occur very frequently and it happened in all cold chain section[9]. The incidence of exposure to freezing temperature during storage was 13.5% in urbanized countries compared to 21.9% in developing countries[9]. Meanwhile, exposure throughout shipments were more alarming , between 75% to 100%[9].

2.1.3 Sensitivity to light

Certain vaccines are very vulnerable towards strong light. For this type of vaccine, exposure to ultraviolet rays would result loss of potency. They have to be protected against sunlight or fluorescent (neon) light. BCG, Measles, Mumps and Rubella (MMR) vaccines are sensitive to light (as well as heat)[32]. These vaccines are supplied in vial made from dark glass to reduce exposure to light[3].

2.2 Cold chain principles

There are few basic principles that must be followed to ensure good vaccine storage and proper maintenance of cold chain. The basic rules are availability of trained staff, appropriate vaccine transport and good vaccine storage [5].

2.2.1 : Trained Personnel

Ideally, in each office which stores vaccine and practice immunization, they should be a well skilled designated person who are responsible for vaccine management starting from ordering, receipt and storage of vaccine[5]. Among the responsibilities is to ensure vaccine cold chain is maintained during shipping and storage; checking deliveries for any leakage or discrepancies, rotating vaccine stocks in which vaccine with shortest expiry date will be used first, maintaining stock, ensuring adequate supply and written guidelines are available at clinics for reference[5].

Researchers have noted that trained personnel in charge of vaccine cold chain are commonly available in developed countries[22-24] compared to developing country[17]. Ortega in the systematic literature review illustrates that 75.2% of vaccine points have dedicated person in charge of vaccines[40]. Ortega in the systematic literature review illustrates that 75.2% of vaccine point have dedicated person in charge of vaccine[40]. Another study by Karen, found that clinics with a dedicated person accountable for vaccine management was two to three times more likely to perform daily temperature monitoring[24]. Interventional study by S Malliks in India found a significant upgrading of interior condition of cold chain equipment with the presence of designated persons[41]. Another interventional study by Andrew showed that educating staff member on minimum and maximum thermometer for monitoring temperature improved storage condition[42]. In contrast, Lewis failed to find the predictable associations between adherence to practice guideline (single person responsible, dedicated fridge) and acceptable storage temperature[22].

2.2.2 : Vaccine transportation

According to WHO recommendation, all vaccine needs to be transported at 2-8^{O}C except for oral polio[3]. These include vaccine transportation from manufacturer up to the end user at health care facilities and further down to outreach sites[3].

Sub zero temperature are more likely to occur compared to exposure to heat[9]. Freezing temperature can take place at transport shipment stage[39, 43] as well as transportation between health amenities. Researchers have noted that freeze-sensitive vaccines are exposed to freezing temperatures during their transport in cold boxes from one facility to another[21, 24, 44-46] , mainly due to deep-frozen ice packs used in the cold boxes[3]. In a recent study conducted by WHO suggests that 'cool life' by maintaining temperature between +2°C to +20°C is harmless for vaccine transportation except for oral polio which needs freezing temperature for transportation[3]. Many countries have successfully adopted this suggestion including Indonesia[10] , Bolivia[39] and Moldova[47] for within country vaccine transport.

2.2.3 Vaccine storage

2.2.3.1. Recommended storage temperature

Most vaccines in the market need to be stored in the storage temperatures of 2°C to 8°C and must not be exposed to sub-zero temperatures[9] . Studies in Indonesia[10], Thailand[36], Cambodia[14], Australia[24] and New Zealand[22] have found extensive freezing at various stages of distribution system . The requirement for storing vaccine is as shown in Table 2.4 .

Table 2.4 WHO recommended vaccine storage conditions[3]

<table>
<tr><td></td><td>Primary vaccine store</td><td colspan="2">Intermediate vaccine store</td><td>Health centre</td><td>Health post</td></tr>
<tr><td></td><td></td><td>Region</td><td>District</td><td></td><td></td></tr>
<tr><td>OPV</td><td colspan="2">-15°C to -25°C</td><td colspan="3" rowspan="11">All vaccines are recommended to be stored at +2°C to +8°C</td></tr>
<tr><td>BCG</td><td colspan="2" rowspan="6">WHO no longer recommends that freeze-dried vaccines be stored at -20°C. Storing them at -20°C is not harmful but is unnecessary. Instead, these vaccines should be kept in refrigeration and transported at +2°C to +8°C.</td></tr>
<tr><td>Measles</td></tr>
<tr><td>MMR</td></tr>
<tr><td>MR</td></tr>
<tr><td>Yellow fever</td></tr>
<tr><td>Hib freeze dried</td></tr>
<tr><td>Meningococcal A&C</td><td colspan="2" rowspan="6">+2°C to +8°C
These vaccines are freeze sensitive and must never be frozen</td></tr>
<tr><td>Hepatitis B</td></tr>
<tr><td>IPV</td></tr>
<tr><td>DT</td></tr>
<tr><td>DTP</td></tr>
<tr><td>DTP-Hep B</td></tr>
<tr><td>Hib liquid</td><td colspan="2" rowspan="3"></td></tr>
<tr><td>Td</td></tr>
<tr><td>TT</td></tr>
</table>

2.2.3.2 Vaccine storage requirement

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[32, 48]. Based on the guidelines, the most appropriate refrigerator that can be used is either two doors or top loading refrigerator[48].

Page SL finds a significant association between refrigerator type and optimal temperature[49]. General practitioners frequently used domestic refrigerator for vaccine storage[50, 51], and are generally of three types: frost free, cyclic defrost and bar refrigerators[49]. Domestic fridges are inappropriate for vaccine storage due to significant temperature difference within the various compartment and more prone to freezing[49]. Purpose built vaccine refrigerator is the best type of refrigerator to store vaccine because it shows the slightest temperature variation and most reading are within 2°C to 8 °C[49]. However, in another study by Yogini et al found a wide variations outside the recommended temperature range were documented in both domestic and specialized storage refrigerator[52].

The use of small domestic–type refrigerators contributes to the freezing temperature and may damage the vaccine[39]. In one systematic population based study in Australia, the use of freezer compartment in small refrigerator and absence of thermometer in refrigerator are the important risks identified for inappropriate vaccine storage in general practice[24]. In another study, Samant finds statistically significant correlation between facility type and cold chain compliance score in terms of refrigerator type, temperature maintenance chart and optimal refrigerator temperature at the

primary/community health centers level[53]. Old refrigerators were likely to perform poorly in preservation of optimal temperature especially if the refrigerators more than 12 years mostly because of detectable seal breaks on the doors[12]. Modification of domestic refrigerator by removing single door insert can lead to local warming of vaccines and reduce the vaccine potency[54].

In addition, a dedicated refrigerator is needed for storage vaccine. Vaccines should not be kept together with laboratory specimens, drugs, food and drinks[32]. Studies examining this matter have found that vaccines are frequently stored with food, laboratory specimen and drugs[15, 20, 55, 56]. WHO has recommended BCG, OPV, measles and MMR to be placed in the top shelf, DTwP, DTaP, combination vaccine, hepatitis B, IPV, HPV, Typhoid, hepatitis A, Hib, influenza, rotavirus vaccines in the middle shelf and diluents in the lowest shelf[4, 48].

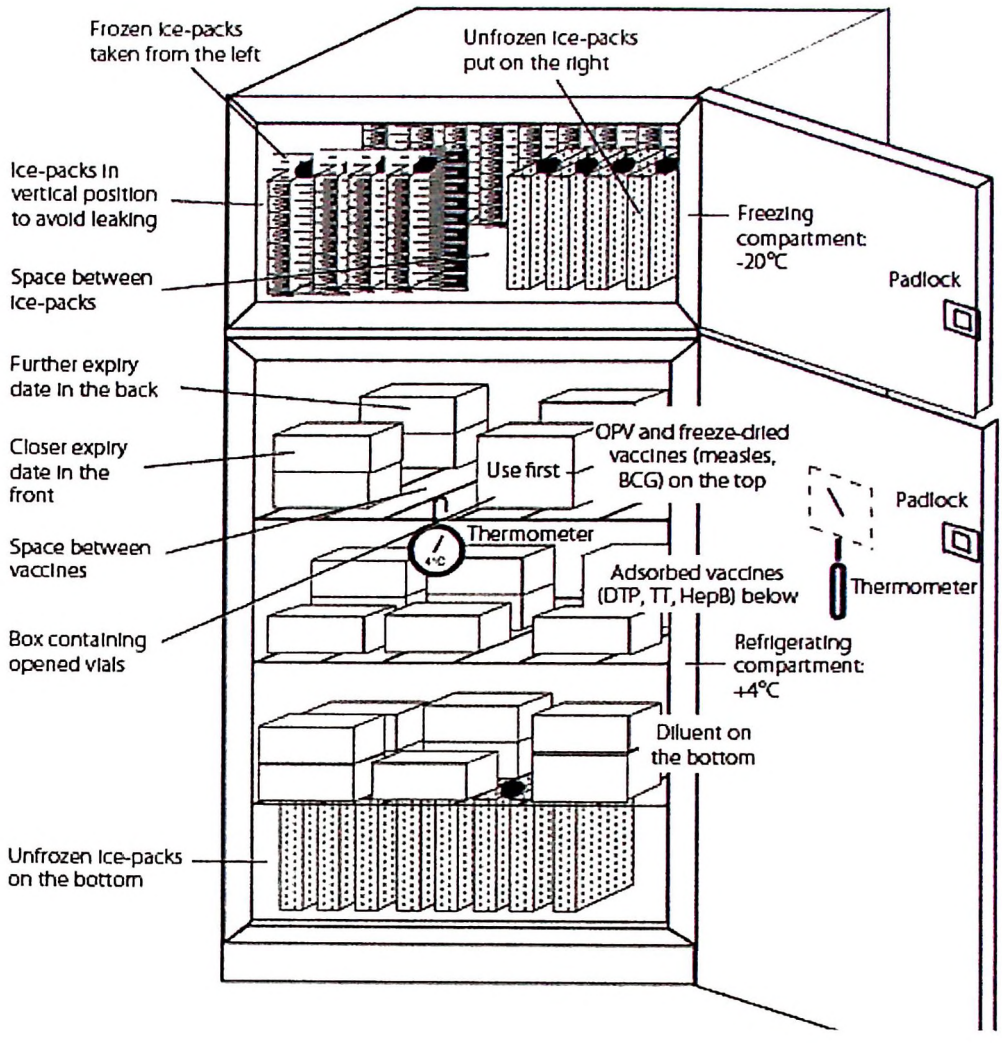


Figure 2.1 Loading a front loading vaccine refrigerator[4, 48]

Vaccines must be kept in perforated tray and space around 1-2 cm between vaccine line to allow air movement[4, 48]. At the same time, vaccines also cannot touch the refrigerator plat because it would result vaccine to solidify[4, 48]. To ensure good ventilation, refrigerator must be located about 40 cm from wall[48]. Refrigerator also cannot be placed under direct sunlight, near stove, microwave or fire to prevent temperature of refrigerator being higher[4, 48].

2.2.4 Thermometer and temperature monitoring

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[32]. Alcohol or mercury thermometer are recommended to be used in refrigerator/ freezer and it is able to detect current, minimum and maximum temperature[32]. Liquid crystal and dial thermometers are suggested for cold boxes because they are only able to record current temperature[48]. Recording thermometers are able to read temperature continuously for 7 days and useful for cold rooms at primary or intermediate vaccine store[32].

In a recent study by WHO in Albania, researchers found that thermometers are not sufficient to monitor refrigerators since they fail to notice the great majority of low and high temperature[57]. The 30 days electronic temperature logger are the best method to measure refrigerator temperature throughout the daytime/nighttime cycle including weekends and holidays and appropriate action can be taken by the health workers to ensure optimal temperature[57].

Various studies found that lack of thermometer in the refrigerator occurs in many parts of the world. Studies in Italy, Canada and Ireland among general practitioners demonstrate low prevalence of 0%[15], 8.1% [12]and 13.6% [58] respectively. In systematic review 2007, provision of maximum and minimum thermometer inside the refrigerator

is only 54.9% (95%CI : 52.5 to 57.4)[40] higher than study by Lewis in which only 13.5% of practices having maximum and minimum thermometer[22].

Thermometers are supposed to be placed in a central location in the storage unit, adjacent to the vaccine[33, 48]. Central compartment has the least temperature variation compared to other section in refrigerator[32] and temperatures must be documented twice each day, once when the office or clinic opens and once at the end of the day[48, 59]. Generally, numerous studies found the above recommendation are difficult to adhere. In Australia, researchers found 62.8% of private offices do not have thermometer and temperature log for monitoring[24]. This is proven by Munir in which only 20% practices have thermometer inside refrigerator with no temperature chart for monitoring[60]. Dissimilar results found by Sachdeva in India where temperature charting twice per day maintained in 71.8% of health facilities[51]. In a recent interventional study in India, overall compliance were acceptable with 55% maintained temperature chart and 60% recorded temperature twice daily[41]. Karen finds among major risk factors associated with suboptimal vaccine storage were lack of thermometer in refrigerator and failure to maintain temperature log[24].

2.2.5 Proficient management procedure

In addition to having staff trained and experienced in the handling of vaccine , clinics which provide immunization must have good management procedure in line with the WHO and the Ministry of Health recommendation. Among the procedures to be followed are a) know what action to do if temperature is not optimal b) have a back up

facilities if the refrigerator is damaged c) safeguard electricity supply using plug stickers or switchless socket d) refrigerator is not placed near the heat sources and direct sunlight e) fridge should no more than 50% full to allow air to circulate and prevent freezing f) defrost, clean and calibrate fridge regularly[5]. Unfortunately, not many studies were conducted to evaluate the management procedures except the latest study in India where researchers find that functional voltage stabilizer and backup generator were available in most clinics that provide immunization services in the central of India[41].

In Malaysia, cold chain act (Act 586, Regulation 87 (5)) has been introduced by MOH in 2006, under Private Healthcare Facilities and Services Act 1998 to facilitate proficient management of cold chain. This act was introduced to ensure the vaccine given to patients is safe and comply with standard set. Anyone who contravenes this regulation commits an offence and shall be liable on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both[59].

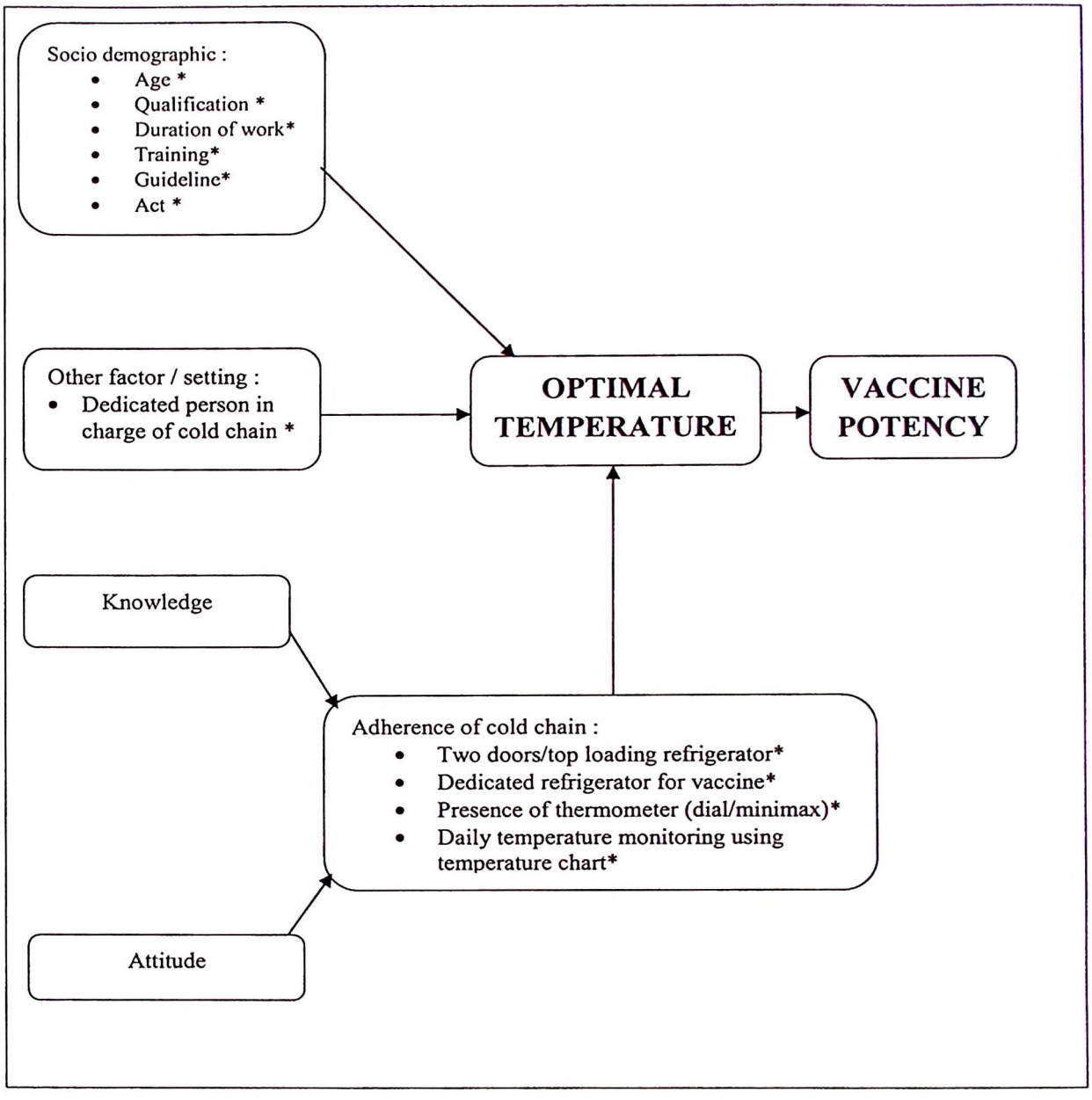
2.3 Justification of the study

A review of the literature has shown that many studies of vaccine cold chain storage and handling, such as respondents' knowledge, practice and observation of refrigerators are not consistent with recommended guideline by WHO. In Malaysia, not much is known about the knowledge, attitude and practice on cold chain among general practitioners although they contribute to 20% to 30% of vaccination services in Malaysia[61]. Apart from that, this study also helps Ministry of Health (MOH) in ensuring vaccination undertaken by general practitioners follow the guideline that was agreed upon. Based on

information obtained from this research, better enforcement and strategy can be organized by MOH in ensuring practitioners to always adhere to the guideline prepared. This would ensure patients who obtain vaccination from general practitioner get the maximum benefit and protect patient's right as consumer with regards to vaccine safety.

2.4 CONCEPTUAL FRAMEWORK

Figure 2.2 shows the outline of conceptual framework. There are various determinants of knowledge, attitude and adherence which are interrelated to each other.



*Associated factors studied for optimal temperature

Figure 2.2 Conceptual framework

CHAPTER THREE

CHAPTER 3

OBJECTIVES AND HYPOTHESIS

3.1 OBJECTIVES

3.1.1 General Objective

This study was conducted with the aim of determining the knowledge , attitude and practice on cold chain based on Ministry of Health (MOH) guideline and the associated factors for optimal temperature among general practitioners in Kelantan.

3.1.2 Specific Objectives

The specific objectives of this study are as follows:

1) To determine the knowledge on cold chain among general practitioners

2) To determine the attitude on cold chain among general practitioners

3) To determine the adherence to cold chain guideline among general practitioners

4) To determine the associated factors for optimal temperature of cold chain

3.2 RESEARCH HYPOTHESIS

Social demographic, refrigerator and thermometer factors are significant associated factors for optimal temperature of cold chain

3.3 OPERATIONAL DEFINITIONS

1. **Cold chain** is defined as vaccine storage and handling

2. **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.

3. **Optimal temperature** is defined as temperature between 2-8^0 Celsius using minimum and maximum thermometer placed in the refrigerator for 24 hours.

4. **Suboptimal temperature** is defined as temperature <2°Celcius and >8°Celcius

5. **Suitable refrigerator type** is defined as two door refrigerator or top loading refrigerator.

6. **General practitioners** is defined as a doctors working in private clinics.

7. **Locum doctor** is defined as a doctor who works in the place of the regular doctor when that doctor is absent.

8. **Dedicated person** is defined as a person (paramedic/staff) responsible for vaccine storage and maintaining optimal refrigerator temperature.

9. **Primary vaccine** is defined as standard vaccination by Ministry of Health Immunization Programme such as BCG, DPT Hib, MMR, Hepatitis B and HPV

CHAPTER FOUR

CHAPTER 4

METHODOLOGY

4.1 Study design

This is a cross-sectional study

4.2 Population and sample

4.2.1 Reference population

The reference population was all general practitioners in Kelantan.

4.2.2 Source population

The source population was all general practitioners in Kelantan

4.2.3 Inclusion and exclusion criteria

We included all the general practitioners who provide vaccination services at the time of data collection. We excluded general practitioners who did not store vaccines in the clinic and locum doctor.

4.2.4 Sample size

The sample size was calculated for all objectives. However, only the one that yielded the biggest sample size was taken as the study sample size.

For objective 1, the sample size calculation to determine the knowledge on cold chain based on MOH guideline among general practitioners in Kelantan was done using single proportion formula.

$$n = \frac{Z^2 P(1-P)}{\Delta^2}$$

n = minimum required sample

Z = value of standard normal distribution = 1.96

Δ = precision = 0.05

P = Prevalence of good knowledge among general practitioner in Ontario, Canada

= 0.06[12] .

Based on the previous study, the prevalence of good knowledge among general practitioners in Ontario Canada was 6.0%[12]. Taking the precision of 0.05 at 95% confidence interval, the minimum required sample was 87. The precision was set at 0.05 after considering its clinical importance and feasibility of the study. However, after considering the non-response rate of 10%, the sample size calculated was 95.

For objective 2, it should be calculated by using single proportion formula. However, there is no data available to calculate the sample size.