INCIDENCE OF RHEUMATIC FEVER AND RHEUMATIC HEART DISEASE AND ITS ASSOCIATED FACTORS AMONG PAEDIATRIC PATIENTS IN MALAYSIA

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT

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CHAPTER 1:
THE PRELIMINARIES

Acknowledgement

Firstly, thank you to Allah SWT for his bestowed upon the strength and good health in order to complete this research. I would like to express my sincere gratitude to Dr Mohd Rizal Mohd Zain for his expertise, assistance, guidance and patience throughout the process of making this thesis a reality. I would like to thank Associate Professor Dr Najib Majdi Yaacob for the advice and contribution for this thesis. I am highly indebted to my fellow lecturers, colleagues, supporting staff, friends and family for the encouragement and support along the way. Not to forget, my wife, my children and my family for their sacrifice and relentless support during the thesis journey.

LIST OF TABLES AND FIGURES

LIST OF ABBREBIATION AND NOMENCLATURE

Hospital USM	Hospital Universiti Sains Malaysia
RHD	Rheumatic Heart Disease
ARF/RF	Acute Rheumatic Fever/Rheumatic Fever
ESR	Erythrocyte Sedimentation Rate
CRP	C-Reactive Protein
GAS/GABHS	Group A Streptococcus/Group A-B Haemolytic Streptococcus
ASOT	Antistreptolysin O Titre
PSGN	Post-Streptococcal Glomerulonephritis

ABSTRACT

Introduction: Acute rheumatic fever (ARF) cases are still a significant cause of morbidity and early death in poor and developing countries. In Malaysia, ARF remains the primary cause of acquired cardiac problems, particularly in the East Coast of Peninsular Malaysia and East Malaysia. This study aims to reveal the incidence of ARF and its risk factors to develop better strategies to combat ARF in Malaysia.

Methodology: This cross-sectional study was conducted across 23 centres in Malaysia over a period of one year from July 2021 to June 2022. The study included all new cases of ARF or RHD with a ratio of one case to two control patients. Sociodemographic characteristics such as age, gender, race, parental education, house condition, and monthly income were recorded. Clinical profiles such as clinical presentation, echocardiography findings, complication, management and outcome of the disease were captured. Multivariate analyses were used to determine the associated sociodemographic risk factors.

Result: The incidence of ARF was 34.1 per 100,000 paediatric admissions, with Kelantan and Sabah states recording most of the cases. The most common clinical presentation for ARF patients was carditis (85.7%) and migrating polyarthritis (31.4%), with majority had valve involvement and mitral regurgitation being the most common valvular abnormality. Multivariate analysis showed age, total monthly income and rural population are significant risk factors for ARF.

Conclusion: This study showed that the incidence of the Acute Rheumatic Fever was still high in Malaysia. Factors such as age, low socioeconomic status and rural residential area showed strong correlation of getting the ARF.

Keywords: Rheumatic Fever, Rheumatic Heart Disease, Incidence, Risk Factors

ABSTRAK

Latar Belakang: Kes Demam Rheumatik Akut (DRA) adalah antara penyumbang utama kepada morbiditi dan kematian awal di kebanyakan negara miskin dan negara membangun. Di Malaysia, Demam Rheumatik Jantung (DRJ) adalah antara punca utama kepada penyakit jantung yang diperolehi di beberapa tempat di Malaysia terutamanya di bahagian Pantai Timur dan juga Timur Malaysia. Kajian ini adalah bertujuan untuk mengetahui kejadian sebenar DRA dan juga faktor-faktor risiko untuk merangka strategi yang lebih baik dalam menghadapi masalah DRA.

Kaedah: Kajian ini adalah kajian keratan rentas yang melibatkan 23 pusat di seluruh Malaysia, dalam tempoh 1 tahun bermula Julai 2021 sehingga Jun 2022. Ini melibatkan semua kes baru DRA atau DRJ dengan nisbah 1 kes kepada 2 pesakit sebagai kawalan. Faktor sosiodemografi seperti umur, jantina, bangsa, tahap Pendidikan ibu bapa, keadaan rumah, dan pendapatan bulanan telah direkodkan. Profail klinikal seperti gejala klinikal, penemuan ekokardiografi, komplikasi, pengurusan dan hasil penyakit direkodkan. Analisis multivariat digunakan untuk menentukan faktor risiko yang berkaitan.

Keputusan: Kejadian DRA adalah 34.1 bagi setiap 100,000 pesakit kanak-kanak yang dimasukkan ke wad. Gejala klinikal pesakit DRA adalah karditis (N=30, 85.7%) dan radang sendi yang berpindah (N=11, 31.4%), di mana kebanyakan pesakit mempunyai gangguan pada injap (N=34, 97.1%), dan regurgitasi mitral adalah masalah injap yang paling kerap. Analisis multivariat menunjukkan faktor umur, jumlah pendapatan bulanan dan juga populasi kawasan pedalaman adalah faktor yang signifikan untuk mendapat DRA.

Kesimpulan: Kajian ini menunjukkan bahawa kejadian Demam Rheumatik Jantung adalah masih tinggi di Malaysia. Faktor-faktor seperti umur, faktor sosioekonomi yang rendah, dan populasi kawasan pedalaman menunjukkan kaitan yang jelas dengan risiko penyakit DRA.

Kata kunci: Demam Reumatik, Demam Reumatik Jantung, Kejadian, Faktor Risiko

CHAPTER II:

THE TEXT

2.1 Section A:

Introduction

Introduction

Acute rheumatic fever is one of the most common acquired heart diseases in the paediatric population. Each year, it is estimated around 470,000 new cases and 275,000 deaths are related to Rheumatic Heart disease globally. Most cases occur in low-income and middle-income countries.(1) In Malaysia, it is still the main cause of acquired cardiac problems, particularly in the East Coast of Malaysia, as well as in East Malaysia. However, published data are scarce. Few studies were highlighting the issue, but mainly in a particular centre or area. Gurujaj et al in 1990, recorded 42 patients over 4 years period in a retrospective study describing the clinical, laboratory and echocardiographic profile of children with ARF in a tertiary hospital in Kelantan.(2) In a retrospective study by Omar et al, looking at the incidence of acute rheumatic fever among the patients admitted to Hospital Kuala Lumpur across a 10 years span from January 1981 to December 1990, the incidence of first acute attacks of 15.8 per 100000 hospitalized children per year as compared to 5.4 recurrent attacks per 100000 hospitalized children per year, account 21.2 per 100000 paediatric admission per year.(3) Bulk of cases came from 6-11 years old age group, and low-income family with Indian ethnics had a higher relative risk as compared to Malay.

A study by Chew et al in 2002 which looked for Sydenham chorea in a teaching hospital in Klang Valley over 30 years period (1967 to 1997). They documented 313 cases in the time frame which gave average of 10 cases per year. The actual trend was however reduced from more than 50 cases annually in 1970s to only about 5 cases per year in 1997 .(4) This correlate well with the observation that cases of ARF are seldom seen anymore in Klang Valley area.

However, the other part of Malaysia especially Sabah, Sarawak and Kelantan the cases are still common and become one of the most common acquired heart disease among children. Unfortunately, there is no specific study to date found describing the exact incidence of the disease in Malaysia.

Associated with the disease, there are few risk factors to be considered. According to Baizid et al, a case control study in Bangladesh, they studied 413 patients; women, urban resident, having >2 siblings, offspring of working mothers, illiterate mothers and overcrowding were more likely to develop RF. However, age >19 years old and large family-size appeared as the protective factors for RHD.(5)

Another study in New Zealand, a retrospective study by Jason Gurney et al, the incidence was 4.1/100 000 per year. The burden of ARF was greater among males than females with the median age at diagnosis being 12 years old. Maori and pacific ethnic (aboriginal ethnic in New Zealand) were more likely to be diagnosed with ARF. It also showed that those residing in rural areas were nearly half as likely to be diagnosed with ARF compared to those residing in urban areas.(6)

Jane R oliver et al studied environmental exposures associated with ARF. Common exposures include household crowding, bed-sharing, dampness and mold, cold, and co-habiting with smokers. 62% participants recalled of having sore throat weeks before ARF which quarter of them seek medical attention and 13% received antibiotics.(7)

Thus, this study is determined to reveal the actual incidence of ARF and RHD and its associated sociodemographic risk factors in our population which will help us to form better strategies to overcome the problems. Thus, it will help us identify high-risk

populations, monitoring and preventive measures. The data can be used to create more awareness and hopefully to structure national policy towards the disease in Malaysia.

2.2 Section B:

Study protocol

2.2.1 Documents submitted for ethical approval

Dissertation proposal

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INCIDENCE OF RHEUMATIC FEVER AND RHEUMATIC HEART DISEASE AND ITS ASSOCIATED FACTORS AMONG PAEDIATRIC PATIENTS IN MALAYSIA

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Introduction

Acute rheumatic fever (ARF) cases have remained a major cause of morbidity and early death in many poor and developing countries, despite a dramatic reduction of the incidence of ARF in developed countries since the early 1900s. It is estimated that there are over 15 million cases of RHD worldwide, with 282,000 new cases and 233,000 deaths annually.(1,12)

In Malaysia ARF are still the main cause acquired cardiac problem, rheumatic heart disease (RHD) in certain part of Malaysia especially in east coast of Peninsular Malaysia particularly in Kelantan, as well as in East Malaysia, Sabah and Sarawak. Unfortunately, there are very limited published data regarding the disease. The disease is seldom seen at more urban area of the country, i.e Selangor and Kuala Lumpur. Most of the cases received are the referral from the other state for further management. From the observation most of the surgery involving the valves are due to underlying rheumatic heat disease.

There were a few studies highlighted this issue but most of them only described the situations at their particular center or area. Sadly that some of the studies were presented at international conference but were not later published.

A study by Gururaj et al in 1990 conducted a retrospective study describing the clinical, laboratory and echocardiographic profile of children with acute rheumatic fever in Hospital Universiti Sains Malaysia. They recorded 42 patients over 4 years period.(2) The results reflected the incidence of acute rheumatic fever in Kelantan.

There are few articles highlighted about the issues of ARF in Malaysia but most of them quoted the data from unpublished data such as from proceeding and presentations at medical congress. For instance Wan Ariffin in 1994 stated that RHD constituted 11.2% out of 250 patients attending paediatric cardiology clinic in a large city in Peninsular Malaysia which quoted from Proceedings of the Malaysian Paediatric Association Congress in 1993 held in Kuala Lumpur which presented by Choo HL and Jai Mohan.(3)

A paper in 1993, by Ibrahim A and Rahman ARA highlighted that RHD was the commonest diagnosis among the new case referred to them in Hospital Universiti Sains Malaysia between 1991 and 1992. This was presented in 2nd International Heart Health Conference in 1995, Barcelona. Besides, in the same conference, a study revealed that a prevalence study conducted by the same institution involving 46986 school children between 1998 and 1990 in Kelantan which showed prevalence of 0.11 per thousand (Ibrahim & Rahman,1993).(4)

A paper by A Omar was published in Medical journal of Malaysia in 1995 which was a retrospective study to look for the incidence of acute rheumatic fever among the patients admitted to HKL across a 10 years span from January 1981 to December 1990. It recorded incidence of first acute attacks of 15.8 per 100000 hospitalized children per year as compared to 5.4 recurrent attacks per 100000 hospitalized children per year, account 21.2 per 100000 paediatric admission per

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However the other part of Malaysia especially Sabah, Sarawak and Kelantan the cases are still common and become one of the most common acquired heart disease among children. Unfortunately, there is no specific study to date found describing the exact incidence of the disease in Malaysia.

Associated with the disease, there are few risk factors to be considered. According to Baizid et al, a case control study in Bangladesh, they studied 413 patients **; w**omen, urban resident, having >2 siblings, offspring of working mothers, illiterate mothers and overcrowding were more likely to develop RF. However, age >19 years old and large family-size appeared as the protective factors for RHD.(8)

Other study in New Zealand, a retrospective study by Jason Gurney et al, the incidence was 4.1/100 000 per year. Burden of ARF was greater among males than females with median age at diagnosis was 12 years old. Maori and pacific ethnic (aboriginal ethcnis in New Zealand) were more likely to be diagnosed with ARF. It also showed that those residing in rural areas were nearly half as likely to be diagnosed with ARF compared to those residing in urban areas.(9)

Jane R oliver et al did a study on environmental exposures associated with RHF. Common exposures include; household crowding, bed-sharing, dampness and mould, cold and co-habiting with smokers. 62% participants recalled of having sore throat weeks before ARF which quarter of them seek medical attention and 13% received antibiotics.(11)

Thus, this study is determined to reveal the actual incidence of ARF and RHD and its associated risk factors in our population which will help us to form better strategies to overcome the problems. Thus, it will help us to identify high-risk population, monitoring, and preventive measures. The data can be used to create more awareness and hopefully can be used to structuring national policy towards the disease in Malaysia.

OBJECTIVES

General objective

To determine incidence and associated risk factors of Rheumatic Fever and Rheumatic Heart Disease of paediatric patients population in Malaysia in year 2021.

Specific objectives

1. To determine the incidence of Rheumatic fever And Rheumatic Heart Disease among the Malaysian paediatric population in year 2021.
2. To describe the clinical profile, sociodemographic and environmental factors of patient with Rheumatic fever And Rheumatic Heart Disease in Malaysia
3. To determine the risk factors associated with Rheumatic fever And Rheumatic Heart Disease

HYPOTHESIS

Hypothesis are not applicable to the first and second objective as it involves incidence estimation and description of characteristics for patients with ARF and RHD.

For the third objective, we hypothesize that there is significant association of sociodemographic and environmental factors towards Acute Rheumatic Fever and Rheumatic Heart Disease

MATERIAL AND METHODOLOGY

Study Design

The study will be divided into 2 phases according to the objectives.

Phase 1: For objective 1 and 2, a cross-sectional study will be conducted.

Phase 2: For 3rd objective, a case control study will be conducted, in which the patients in the 1st phase and randomly selected controls will be studied.

Study Area

Major Hospitals in Malaysia with paediatric cardiology service

1. Hospital Universiti Sains Malaysia
2. Hospital Raja Perempuan Zainab II, Kota Bharu Kelantan
3. Hospital Sultanah Nur Zahirah, Kuala Terengganu
4. Hospital Tengku Ampuan Afzan, Kuantan, Pahang
5. Hospital Sultanah Aminah, Johor Bharu, Johor
6. Hospital Serdang
7. Hospital Pulau Pinang
8. Hospital Sultanah Bahiyah, Alor Setar
9. Hospital Likas, Sabah
10. Hospital Umum Sarawak
11. University Malaya Medical Centre
12. Institut Jantung Negara (IJN)

Study Duration

One-year period from **1st January 2021 to 31st December 2021.**

Reference Population

Malaysian paediatric patient population in year 2021.

Source Population

Paediatric patients who are admitted to the paediatric ward of the 13 participating hospitals during the study period.

Sampling Frame

For the first and second objectives (Phase 1 of the study), the sampling frame include all patients (new or recurrent cases) who fulfilled the criteria for diagnosis of ARF and RHD based on Modified Jones Criteria WHO 2003[7].

For the third objective (Phase 2 of the study), patients (ARF and RHD patients) and controls who fulfilled the eligibility criteria listed below will be the sampling frame.

Inclusion and Exclusion Criteria for cases

Inclusion Criteria

- New or recurrent cases of ARF or RHD
- Admitted to one of the 13 participating hospitals
- Admitted between 1st January and 31st December 2021
- Age less than 18 years old on admission

Exclusion Criteria

- Non-Malaysian citizen

Inclusion and Exclusion Criteria for controls

Inclusion Criteria

- Admitted not due to ARF or RHD
- Admitted to one of the 13 participating hospitals
- Admitted between 1st January and 31str December 2021
- Age less than 18 years old on admission and ± 5 years old

Exclusion Criteria

- Non-Malaysian
- Previous history of ARF/RHD
- Having one of the symptoms such as joint pain, subcutaneous nodules, erythema marginatum or chorea, or raised ASOT

Sample Size Calculation

For Objective 1, it will apply single proportion formula:

$n = (z/\Delta)2 \times (p(1-p))$

$= (1.96/0.0001)2 \times 0.00021(1-0.00021)$

= 80654 samples

**p is 0.00021% based on A Omar et al 1996.*

In summary, for the first objective, 80,654 paediatric admission is required for an estimation to 95% level of confidence and 0.01% margin of error.

For Objective 3, sample size is calculated using PS software with α 0.05 and power 0.8, using 2 proportion formula, with M =2. P0 is the probability of exposure in controls. P1 is the expected probability of exposure in cases.

	P0	P1	Calculated sample size	References
Age				
Gender (female)	0.17	0.32	Cases: 93 Control: 186	Baizid et al
Ethnic				No previous study
Underweight				No previous study
Monthly income (low income)	0.18	0.33	Cases: 96 Control: 192	Baizid et al
Family size (≥5 person)	0.18	0.33	Cases: 96 Control: 192	Baizid et al
Persons per room (>3 people)	0.23	0.38	Cases: 108 Control: 206	Baizid et al
Education (illiterate/primary)	0.1	0.25	Cases: 71 Control: 142	Baizid et al
Residence (rural area)	0.4	0.45	Cases: 129 Control: 258	Baizid et al
Water supply (underground water)	0.35	0.5	Cases: 126 Control: 252	Baizid et al
Tobacco exposure				No previous study

In summary, the largest sample size for the third objective is 129 cases and 258 controls. Anticipating 10% dropout rate, the corrected required sample size is 144 cases and 288 controls.

Sampling Method

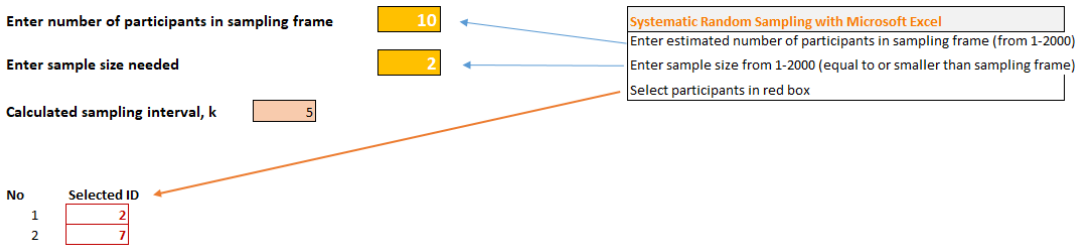
Phase 1:

All the ARF and RHD patients that fulfilled the study criteria will be included. No sampling method will be applied.

Phase 2:

All ARF and RHD patients identified from the first phase of the study will be included as cases in the second phase without any sampling.

For the control group, patients who fulfilled the eligibility criteria for controls will be randomly selected using a systematic sampling method. For each case, 2 controls will be randomly selected from patient who is admitted subsequently after the case was admitted. Using an online systematic sampling calculator, the 1st control is the 2nd patient admitted after the case, and the 2nd control is the 7th patient admitted after the case.



Example

	Admission 1	Admission 2	Admission 3	Admission 4	Admission 5	Admission 6	Admission 7	Admission 8	Admission 9	Admission 10
Case		**Control**					**Control**			

DATA COLLECTION

For the first phase, screening will be made, and final diagnosis will be determined. In each participating hospital a medical officer working along with the in-house cardiologist will be identified to record the patients who fulfill the inclusion criteria. Patients/patients' parents will be interviewed and explained regarding the study. They will be included if consented.

Subjects' information will be recorded into the study proforma (Appendix I) and submitted to the primary researcher. However, they have the right to withdraw from the study if they changed their will. Though, their data will be counted for objective 1 and 2.

The treatment of the patients is solely by the respective teams in the respective hospitals according to the standard treatment for the disease. There are no additional investigation, blood sampling, follow up needed.

Study subjects are labelled by the code of study centre (eg I, II, III), and for case, number(1,2,3,4 etc), for control 1.1, 1.2, 2.1, 2.2 and so on in order to protect the confidentiality. For example, case is from centre A, labelled as I-1 and controlled labelled as I-1.1, I-1.2. A copy of signed-consent will be kept in the patients' tickets.

Secondly, clinical profile for each of the patient will be recorded, based on the symptoms and signs in Modified Jones Criteria for Rheumatic Fever, 2 dimensional echocardiography findings based on WHO echocardiography criteria for diagnosis of RHD. Final diagnosis, its management and the final outcome at the point of discharge will be recorded.

Demographic data such as age, ethnic group, body weight and height, will be recorded. Information such as rurality, number of household members, number of rooms, economical status household income. These information will be recorded and analysed in the phase 2 of the study to look for their associated risk towards the disease.

DATA ANALYSIS

Data entry and analysis will be conducted in IBM SPSS version 26.

For both objective 1 and 2, descriptive analysis will be applied. The incidence rate will be measured with 95% CI. All new and recurrent cases of that year will be counted for the incidence. Incidence will be determine using cumulative incidence.

The numerical data will be presented as mean and SD or medium and IqR subjected to normality of the distribution. The categorical data will be presented as frequency and percentage.

For objective 3, the logistic regression will determine the Odds Ratio (OR) of each identified risk factors. Simple and multiple logistic regression will be conducted. For multiple logistic regression, stepwise, forward and backward LR method will be used for variable selection. Multicollinearity and interaction between the remaining variables will be checked. Model fitness will be examined by checking the Hosmer-Lemeshow test p-value, the classification table and the area under the Receiver Operating Characteristic (ROC) curve. The final model will be presented as Adjusted OR with it's 95% confidence interval, the Wald statistic value and the p-value. The level of significant was set at 0.05.

Expected Results

Table 1: Incidence of the RHD/RHF among pediatric age group in Malaysia (n=?)

		95% CI
Incidence of RF/RHD		

*Incidence = total number of cases in 2021/ total number of paediatric admission in 2021

Table 2: Sociodemographic characteristic of the respondents (n =?)

Variable		**Mean (SD)**	**N (%)**
Sex	male		
	female		
Age			
Weight		*Median	
Races	Malay		
	Chinese		
	Indian		
	others		
	Non Malaysian		
Monthly income	B40		
	T20/M40		
Family size	<5		
	≥5		
Number of rooms			
Area of stay	urban		
	rural		

**The household income and number of occupant was categorized based on the latest available data released by Malaysian Department of Statistic - Key Demographic Statistics Estimates, Malaysia 2017. The categories may change during the time of write up according to updated data.*

**Underweight: weight for age < –2 standard deviations (SD) of the WHO Child Growth Standards median*

Table 3: Clinical presentation of the respondents (n=?)

Variable		**Mean (SD)**	**N (%)**
Major Criteria	Carditis		
	Migrating polyarthritis		
	Chorea		
	Erythema marginatum		
	Subcutaneous nodule		
Minor Criteria	Monoarthritis		
	Fever ≥ 38°C		
	Raised ESR AND/OR CRP		
	Prolong PR interval >200ms		
Throat swab GABHS	Positive		
	Negative		
	Not done		
Complications	Complete heart block		
	other		
UFEME	Positive		
	Negative		

Table 4 : Echocardiography findings (n=?)

Echocardiography findings	N (%)
Mitral stenosis	
Mitral regurgitation	
Aortic stenosis	
Aortic regurgitation	
Tricuspid stenosis	
Tricuspid regurgitation	
Pulmonary stenosis	
Pulmonary regurgitation	

Table 5: The factor associated with RHD / RHF among pediatrics population admitted to hospital in Malaysia (n=?), simple logistic regression

Variable		**Crude OR**	**95% CI**	**Walt Stat**	**P value**
Age					
Weight					
Underweight	Yes				
	No				
Gender	Male				
	Female				
Races	Malay				
	Chinese				
	Indian				
	Others				
	Non Malaysian				
Monthly income	B40				
	M40/T20				
No of person per room	<2				
	≥2				
Number of household	<5				
	>5				
Area of stay	urban				
	Rural				
Education of mothers	Illiterate/Primary				
	Secondary and above				

Note: those variable with p value <0.2 will be included in Multivariate analysis

**Underweight: weight for age < –2 standard deviations (SD) of the WHO Child Growth Standards median*

Table 6: The factor associated with RHD / RHF among pediatric population admitted to hospital in Malaysia (n=?), multiple logistic regression

Variable		**Adjusted OR**	**95% CI**	**Walt Stat**	**P value**
Age					
Weight					
Gender	Male				
	Female				
Underweight	Yes				
	No				
Races	Malay				
	Chinese				
	Indian				
	Others				
	Non Malaysian				
Monthly income	B40				
	M40/T20				
Family size	<5				
	≥5				
No of person per room	<2				
	≥2				
Area of stay	urban				
	rural				