

**MANAGEMENT OF IN-FLIGHT MEDICAL EMERGENCIES:  
A STUDY ON KNOWLEDGE AND CONFIDENCE AMONG  
EMERGENCY DEPARTMENT DOCTORS IN HOSPITAL  
UNIVERSITI SAINS MALAYSIA**

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## **TABLE OF CONTENTS**

ACKNOWLEDGEMENTS	i
LIST OF TABLES	v
LIST OF SYMBOLS AND ABBREVIATIONS	vi
ABSTRAK	vii
ABSTRACT	ix
<b>CHAPTER 1.0 INTRODUCTION</b>	<b>1</b>
<b>CHAPTER 2.0 STUDY PROTOCOL</b>	<b>2</b>
2.1 INTRODUCTION	2
2.2 PROBLEM STATEMENT & STUDY RATIONALE	3
2.3 RESEARCH QUESTION	
2.4 LITERATURE REVIEW	3
2.5 OBJECTIVES	6
<i>General</i>	6
<i>Specific</i>	6
2.6 METHODOLOGY	7
2.6.1 CONCEPTUAL FRAMEWORK	7
2.6.2 RESEARCH DESIGN	8
2.6.3 STUDY AREA	8
2.6.4 STUDY POPULATION	8
2.6.5 SAMPLING FRAME	8
2.6.6 SUBJECT CRITERIA	9
2.6.7 SAMPLE SIZE ESTIMATION	9
2.6.8 SAMPLING METHOD	10
2.6.9 RESEARCH TOOL	11

2.6.10 OPERATIONAL DEFINITION	12
2.7 DATA COLLECTION METHOD	12
2.8 STUDY FLOW CHART	13
2.9 DATA ANALYSIS	14
2.10 EXPECTED RESULTS	14
2.11 STUDY DURATION	18
2.12 GANTT CHART	19
2.13 ETHICS OF STUDY	19
2.14 PRIVACY & CONFIDENTIALITY	20
2.15 CONFLICT OF INTEREST	20
2.16 PUBLICATION POLICY	20
2.17 REFERENCES	20
2.18 ETHICAL APPROVAL LETTER	23
<b>CHAPTER 3.0 MANUSCRIPT</b>	26
3.1 TITLE PAGE	26
3.2 ABSTRACT	28
3.3 INTRODUCTION	29
3.4 METHODS	30
3.4.1 SETTING	30
3.4.2 STUDY CRITERIA	30
3.4.3 SAMPLING METHOD AND SAMPLE SIZE CALCULATION	31
3.4.4 RESEARCH TOOL	31
3.4.5 DATA COLLECTION	31
3.4.6 ETHICAL CONSIDERATION	32

3.4.7 STATISTICAL ANALYSIS	32
3.5 RESULTS	32
3.6 DISCUSSION	35
3.7 CONCLUSION	38
3.8 ACKNOWLEDGEMENTS	38
3.9 DECLARATION OF CONFLICTING INTERESTS	38
3.10 FUNDING	38
3.11 REFERENCES	38
3.12 TABLES	42
3.13 JOURNAL FORMAT	46
<b>APPENDICES</b>	<b>55</b>

## LIST OF TABLES

1. Table 1: Sociodemographic characteristics of patients (N=132)	42
2. Table 2: Confidence of doctors regarding in-flight medical emergencies (N=132)	43
3. Table 3: Participant scores on knowledge of in-flight medical emergencies with mean knowledge score	44
4. Table 4: Confidence level (P2.6) and mean knowledge level between various sociodemographic factors	45

## **LIST OF SYMBOLS, ABBREVIATIONS OR NOMENCLATURE**

BLS	Basic Life Support
ACLS	Advanced Cardiovascular Life Support
ICAO	International Civil Aviation Organisation
KLIA	Kuala Lumpur International Airport
FAA	Federal Aviation Administration
AED	Automated External Defibrillators
CPR	Cardiopulmonary resuscitation
PaO <sub>2</sub>	Partial pressure of oxygen level
CME	Continuing Medical Education
HUSM	Hospital Universiti Sains Malaysia

## **ABSTRAK**

**Pengenalan** Kes kecemasan di dalam kapal terbang sering berlaku dan jumlah kes dijangka bertambah seiring dengan pertambahan populasi dunia yang semakin berumur. Kajian ini bertujuan untuk menilai tahap pengetahuan dan keyakinan para doktor di jabatan kecemasan dalam mengendalikan rawatan kecemasan di dalam kapal terbang.

**Kaedah Kajian** Kaedah yang digunakan dalam kajian ini adalah kaedah keratan rentas atau cross-sectional yang dijalankan di kalangan doktor jabatan kecemasan yang melibatkan pakar perubatan, pegawai perubatan tetap dan pegawai perubatan latihan antara bulan Januari 2019 dan Januari 2020. Borang soal selidik yang sudah disahkan ini diambil dari satu kajian di Amerika Syarikat merangkumi 3 bahagian termasuk data demografi, tahap keyakinan dan pengetahuan dalam rawatan kecemasan di dalam kapal terbang

**Keputusan** Seramai 132 peserta terlibat dalam kajian ini. Majoritinya terdiri daripada pegawai perubatan (53.8%) dan kebanyakannya dibahagikan kepada kumpulan umur 25-30 tahun (43.2%) dan 31-35 tahun (46.2%). Selain itu, majoriti peserta mempunyai pengalaman bekerja dalam bidang klinikal selama 5 tahun dan kurang (47.7%).

Skor min tahap pengetahuan adalah 5.22/9. Hanya 38.6% doktor rasa yakin dalam memberi rawatan kecemasan di dalam kapal terbang. Didapati bahawa terdapat hubungan kait antara jumlah tahun bekerja dalam klinikal dengan tahap pengetahuan ( $P=0.032$ ) dan tahap keyakinan ( $P=0.006$ ). Walaubagaimanapun, tiada hubungan kait antara tahap pengetahuan dan keyakinan dengan latihan kesihatan terdahulu.

**Kesimpulan** Latihan kesihatan sedia ada perlu menyelitkan ilmu rawatan kecemasan dalam kapal terbang untuk meningkatkan pengetahuan dan tahap keyakinan para doktor.



**Kata kunci:** keyakinan, jabatan kecemasan, rawatan kecemasan dalam kapal terbang, pengetahuan

## **ABSTRACT**

**Introduction** In-flight medical emergencies are common and the numbers are expected to rise as the world population ageing. This research is to study on knowledge and confidence among emergency department doctors in the management of in-flight medical emergencies.

**Method** This cross-sectional study used a self-administered questionnaire conducted among doctors in the emergency department of a tertiary hospital in the east-coast of Malaysia from January 2019 to January 2020. The validated questionnaire which was adapted from a study done in the United States (Katzner et al) consists of a total 3 sections on demographic data, confidence and knowledge on the management of in-flight medical emergencies.

**Result** There were a total of 132 respondents. Majority of respondents were medical officers (53.8%) and most of them were divided in the age group 25-30 years (43.2%) and 31-35 years (46.2%). In addition, majority of respondents had working experience of 5 years and less in clinical field (47.7%). The mean knowledge score was 5.22/9. Only 38.6% of doctors felt confident in managing in-flight medical emergencies. There was a significant association between number of years working in clinical field with knowledge level ( $P=0.032$ ) and confidence level ( $P=0.006$ ). However, there was no significant association between knowledge and confidence level with previous healthcare training.

**Conclusion** Our current local training should include management of in-flight medical emergencies to improve the knowledge and confidence level among doctors.

**Keywords:** confidence, emergency department, in-flight medical emergencies, knowledge

## **CHAPTER 1: INTRODUCTION**

Commercial aviation in-flight emergencies are relatively common. Therefore, it is likely that a doctor travelling by air will receive a call for help at some stage in their career.<sup>1</sup>

Health care providers should understand which in-flight medical emergencies occur commonly as well as the roles of the providers can play.<sup>2</sup>

As world population ages and air travel increases, the numbers of in-flight medical emergencies are expected to rise as well.<sup>3</sup>

According to International Civil Aviation Organisation, ICAO, the number of passengers using air transport was only 0.6 billion in 1980 and this number has increased to 1.6 billion in the year of 2000. In 2017, the total number of passengers using air transport reached 4.1 billion people which is an increment of 140% in just 17 years.<sup>4</sup>

Total passenger traffic movements at Kuala Lumpur International Airport (KLIA) was 58.5 million in 2017 as compared to 14.7 million only in 2000, a total jump of 300% in the span of 17 years.<sup>5</sup>

The number of people in the world aged 65 years old and above is 703 million persons and the numbers are projected to double to 1.5 billion in 2050.<sup>6</sup>

In year 2000, Malaysia had 0.9 million population of age 65 years old and above. It was equivalent to 3.9% of entire Malaysia population. In year 2018, we had 2.1 million people age 65 years and above which was equivalent to 6.5 % of entire Malaysia population. It is projected than in year 2040, Malaysia will have 6 million population age 65 years and above which is equivalent to 14.5 % of entire population.<sup>7</sup>

## **CHAPTER 2.0 STUDY PROTOCOL**

### **2.1 INTRODUCTION**

In-flight medical emergencies is reported to occur at a rate of one in 604 to 753 flights.<sup>2,</sup>

<sup>8</sup> Common in-flight medical emergencies encountered include syncope or presyncope, respiratory symptoms and gastrointestinal symptoms such as nausea and vomiting.<sup>2, 9, 10</sup>

The provision of medical assistance to passengers during flights aboard commercial aircraft is a matter of concern to most doctors.<sup>11</sup> Therefore, we are interested in the knowledge and confidence of emergency department doctors in managing in-flight medical emergencies. We believe that emergency department serves as an appropriate venue for this training, and it will equip them with a skillset that is important to serve their communities when the needs arise.

If this study reveals deficit in this particular skillset among emergency department doctors, then a focused training, including simulation, could improve their confidence and knowledge level in the management of in-flight medical emergencies.<sup>12</sup>

Aerospace Medical Association Air Transport Medicine Committee has a guidance document regarding on-board medical supplies, legal and regulatory constraints, training of cabin crew and their role in assisting medical volunteers, liability issues and advice for medical volunteers. The International Civil Aviation Organisation (ICAO), a specialised agency of the United Nations is setting rules and regulations regarding international flight safety including establishment of adequate medical supplies equipment that should be carried in the flight.<sup>13</sup>

## **2.2 PROBLEM STATEMENT AND STUDY JUSTIFICATION**

1. This study is to analyse the knowledge and confidence in management of in-flight medical emergencies among doctors in Emergency Department HUSM
2. Worldwide, 4.1 billion passengers flew on commercial airlines in 2017. When in-flight medical emergencies occur, access to care is limited
3. The steadily increasing number of air travellers, the ageing of the population, and the increasing number of air travellers with acute and chronic illnesses will undoubtedly increase in number of in-flight medical events in the future.
4. Therefore, knowledge regarding management of in-flight medical emergency is needed especially among healthcare providers like doctors.

## **2.3 RESEARCH QUESTION**

What is the knowledge and confidence level in management of in-flight medical emergencies among doctors in emergency department Hospital Universiti Sains Malaysia (HUSM)?

## **2.4 LITERATURE REVIEW**

In-flight medical emergencies are not uncommon in both domestic and international air travels as both the number of air travellers and the number of aging population will increase from time to time. Therefore, healthcare providers like doctors should know which common in-flight medical emergencies will occur as well as the roles the providers can play when such events occur.

There was a study done between 2008 and 2010 reviewing records of in-flight medical emergency calls from five domestic and international airlines to a physician-directed

medical communications center.<sup>2</sup> The research identified most common medical problems encountered and the type of on-board assistance required. The study showed that there were 11,920 in-flight medical emergencies resulting in calls to the center which equivalent to one medical emergency for every 604 flights. The most common in-flight medical problems were syncope or pre-syncope which came up to 37.4% of the cases. It was followed by respiratory problem, 12.1% of the cases and nausea or vomiting, 9.5% of the cases.<sup>2</sup> There was only a few in-flight medical emergencies resulted in diversion of flight or death.<sup>2</sup> One fourth of passengers who had in-flight medical emergency were transported to hospital for further evaluation.<sup>14</sup>

Similar study has been conducted to assess the knowledge and confidence level in management of in-flight medical emergencies but the targets population of the study was fourth year medical students at two United States medical schools. The study showed that fourth year medical students did feel adequately prepared to respond to in-flight medical emergencies and may have sub-optimal knowledge.<sup>8</sup>

It is crucial for doctors to know that environmental and physiological changes that occur during routine commercial flights may lead to hypoxia, which can exacerbate chronic medical conditions or cause acute in-flight medical events. For example, the passenger cabin is pressurised to altitude of 1524-2438 metres while the commercial flights usually cruise at altitude of 7010-12498 metres above sea level. Most healthy individuals are able to tolerate this cabin pressure. However, there is a study showed that the frequency of reported complaints associated with acute mountain sickness symptoms like fatigue, headache, light-headedness and nausea increased with increasing altitude and peaked at 2438 metres.<sup>15</sup> In addition, most of the acute mountain sickness symptoms become

apparent after three to nine hours of exposure. Cabin pressurisation at 2438 metres resulted in a decrease of arterial oxygen partial pressure (PaO<sub>2</sub>) from 95 mmHg to 60mmHg in a normal healthy individual. However, many passengers with pre-existing cardiac, pulmonary and haematological conditions have a reduced baseline PaO<sub>2</sub>. The reduced cabin pressure leads to further reduction in oxygen saturation and eventually causing respiratory distress in these special group of individuals.<sup>16</sup>

Medical volunteers may find assisting with an in-flight emergency stressful, but should acknowledge that they play a vital role in successful outcomes. The medico-legal liability risk is extremely small, and various laws and industry indemnity practices offer additional protection to the volunteer. Doctors often worry whether they will be indemnified if they offer assistance and something goes wrong or there is an unsuccessful outcome. Litigation against Good Samaritans is excessively rare and many jurisdictions protect volunteers against such liability. In the United States of America, there is Aviation Medical Assistance Act 1988 which includes provisions limiting the liability of airlines and volunteer physicians. A lot of airlines indemnify doctors who volunteer and will offer written confirmation from the aircraft captain if the doctor requests it.<sup>1</sup>

There are a lot of challenges that a doctor might face in managing a case of in-flight medical emergency. This includes a limited physical space that is difficult to work in, the emergency medical kit is not immediately available for use, doctor is unfamiliar with the emergency kit contents and last but not least, the absence of flight attendants for much of the event.<sup>17</sup>

A survey of European airlines identified 10,000 in-flight medical emergencies during a 5 year period. The study noted that each airline had its own reporting system and protocol.<sup>9</sup> Even though emergency kits are mandated to contain medications and equipment, the actual kits vary from airline to airline. The US Federal Aviation (FAA) mandates that all flight attendants receive training of proper use of automated external defibrillators (AED) and in cardiopulmonary resuscitation (CPR) at least once every 24 months.

Therefore, management of in-flight medical emergencies is crucial for healthcare providers like doctors.

## **2.5 OBJECTIVES**

### *General objective*

To study the knowledge and confidence level in managing in-flight medical emergencies among doctors in Emergency Department HUSM.

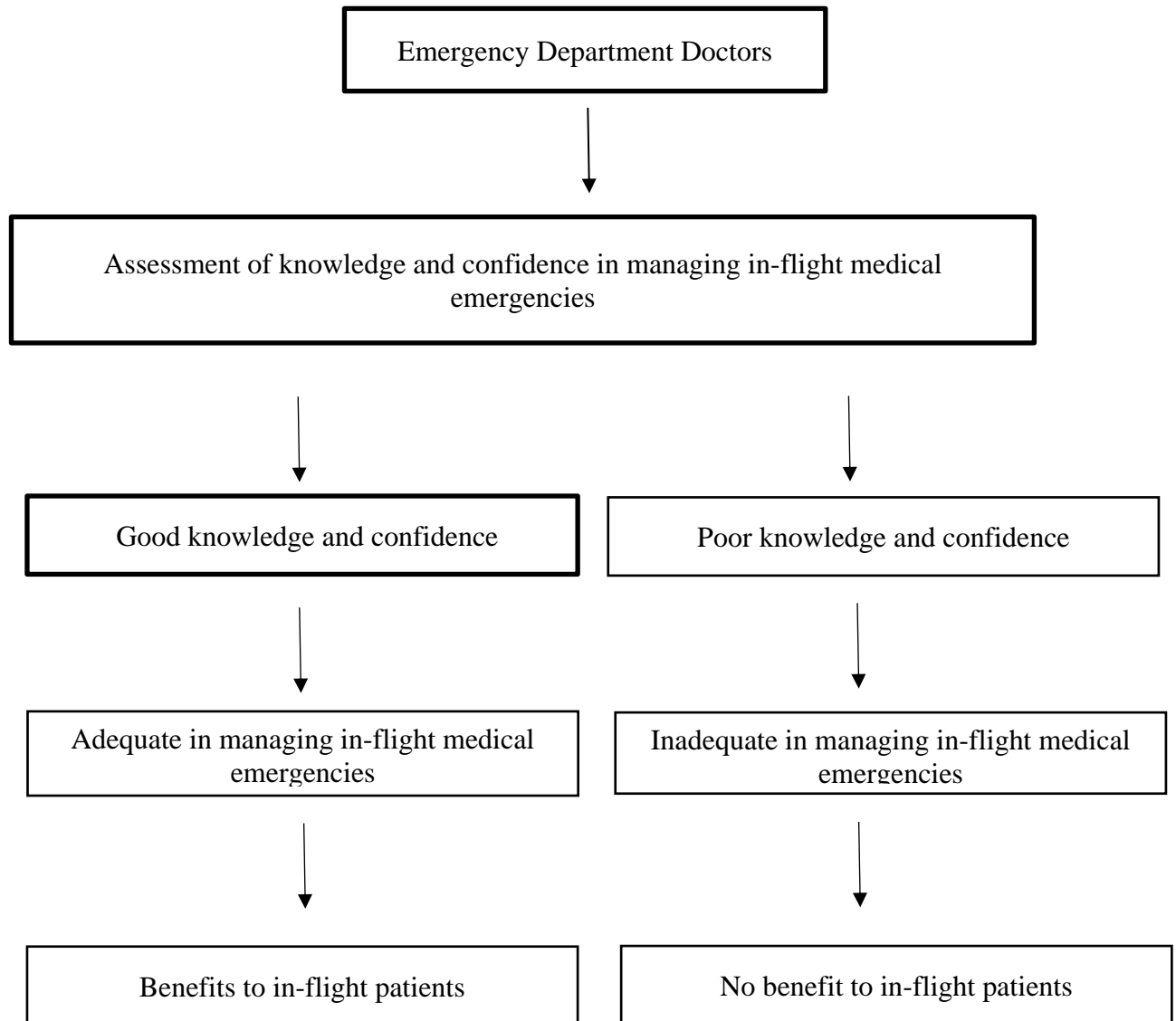
### *Specific objectives*

1. To measure the knowledge and confidence level in managing in-flight medical emergencies among doctors in emergency department HUSM.
2. To determine association of doctors demographic factors (eg: age, gender, years of clinical experience, etc) with knowledge and confidence level in managing in-flight medical emergencies.



## 2.6 METHODOLOGY

### 2.6.1 CONCEPTUAL FRAMEWORK



### 2.6.2 RESEARCH DESIGN

This is a cross-sectional study which includes all doctors that fulfil all inclusion and exclusion criteria and present at the time of study in Emergency Department HUSM

### 2.6.3 STUDY AREA

Emergency Department Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian, Kelantan

### 2.6.4 STUDY POPULATION

#### *Reference population*

All doctors working in Emergency Department in Kelantan.

#### *Source population*

All doctors working in Emergency Department Hospital Universiti Sains Malaysia (HUSM)

#### *Study participants*

All doctors working in emergency department HUSM from January 2019 to January 2020 and fulfil the inclusion and exclusion criteria.

### 2.6.5 SAMPLING FRAME

Medical doctors in Emergency Department Hospital Universiti Sains Malaysia (HUSM) working between January 2019 and January 2020.

## 2.6.6 SUBJECT CRITERIA

### *Inclusion criteria*

Specialists, medical officers and house officers in Emergency Department HUSM at the time of data collection.

### *Exclusion criteria*

Specialists, medical officers and house officers in Emergency Department HUSM who are unwilling to get involve in the study.

## 2.6.7 SAMPLE SIZE ESTIMATION

Sample size is calculated using Raosoft Sample Size Calculator (2004)

The following formula was used:

Sample size,

$$n = \frac{Nx}{((N - 1) * E^2 + x)}$$

$$x = Z \left( \frac{c}{100} \right)^2 r(100 - r)$$

$$E = \sqrt{\left[ (N - n) \frac{x}{n} (N - 1) \right]}$$

N = population size

r = fraction of response

Z(c/100) = critical value for the confidence level c

*(This calculation is based on normal distribution, and assume the samples more than 30 samples)*

**Raosoft** Sample size calculator

What margin of error can you accept? %  
5% is a common choice  
 The margin of error is the amount of error that you can tolerate. If 90% of respondents answer yes, while 10% answer no, you may be able to tolerate a larger amount of error than if the respondents are split 50-50 or 45-55. Lower margin of error requires a larger sample size.

What confidence level do you need? %  
Typical choices are 90%, 95%, or 99%  
 The confidence level is the amount of uncertainty you can tolerate. Suppose that you have 20 yes-no questions in your survey. With a confidence level of 95%, you would expect that for one of the questions (1 in 20), the percentage of people who answer yes would be more than the margin of error away from the true answer. The true answer is the percentage you would get if you exhaustively interviewed everyone. Higher confidence level requires a larger sample size.

What is the population size?   
If you don't know, use 20000  
 How many people are there to choose your random sample from? The sample size doesn't change much for populations larger than 20,000.

What is the response distribution? %  
Leave this as 50%  
 For each question, what do you expect the results will be? If the sample is skewed highly one way or the other, the population probably is, too. If you don't know, use 50%, which gives the largest sample size. See below under **More information** if this is confusing.

Your recommended sample size is **120**  
This is the minimum recommended size of your survey. If you create a sample of this many people and get responses from everyone, you're more likely to get a correct answer than you would from a large sample where only a small percentage of the sample responds to your survey.

This sample size are calculated based on Stratified Sampling Technique calculation to identify the sample size for each group.

$$\text{Stratified Sampling Technique calculation} = \frac{x}{\text{Population Size}} \times \text{Sample Size}$$

Group	Population Size	Sample Size
<b>Specialists</b>	17	$\frac{17}{173} \times 120 = 11.7 \approx 12$
<b>Medical Officers</b>	93	$\frac{93}{173} \times 120 = 72.1 \approx 64$
<b>House Officers</b>	63	$\frac{63}{173} \times 120 = 18.0 \approx 44$
	<b>Total Population Size = 173</b>	<b>Sample Size = 120</b>

Table 1: Sample size based on group using stratified sampling method

## 2.6.8 SAMPLING METHOD AND SUBJECT RECRUITMENT

This study used stratified sampling method.

Recruitment of the subjects was done during department Continuing Medical Education (CME). Data was obtained from eligible and willing participants which includes house officers, medical officers and specialists with no duplications. Each of the participants

was given a questionnaire and expected to complete the questionnaire individually without using any assistance from electronic devices such as mobile phones or laptops. The questionnaire must be completed in the presence of researcher and handover the answered questionnaire to the researcher within half an hour.

#### 2.6.9 RESEARCH TOOLS

A questionnaire was used in this study. The questionnaire was adapted from a previous validated study conducted in University of California, United States of America.<sup>11</sup> Face Validation was conducted among two emergency physicians, four medical officers and four house officers. An email was sent to the author of the study requesting for permission to use the questionnaire.

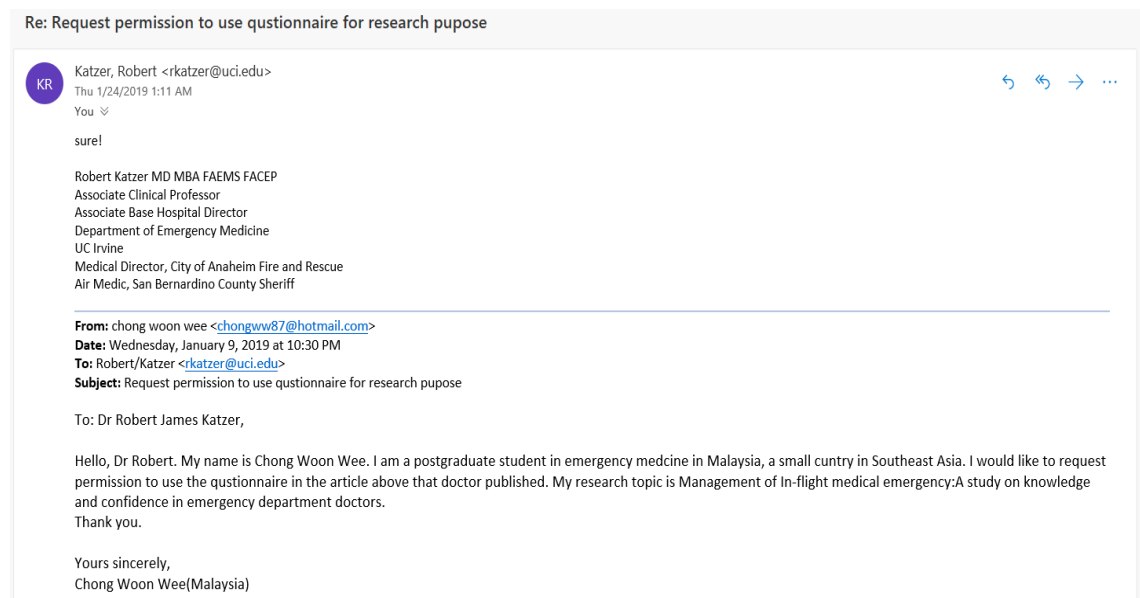
The questionnaire consist of three parts:

Section 1: This section is on sociodemographic data of doctors.

Section 2: This section comprises of 7 questions on confidence level in the management of in-flight medical emergencies in a 5-point Likert Scale ranging from strongly agree to strongly disagree. Participants who answer agree or strongly agree to a statement which correspond to Likert scale 4 and 5 are deemed to have confidence.

Section 3: This section comprises of 9 questions on the knowledge in management of in-flight medical emergencies. It's in the form of single best answer. Each correct answer will be given one mark with maximum score of nine marks.

## Evidence of permission from original author to use questionnaire



### 2.6.10 OPERATIONAL DEFINITION

#### *In-flight medical emergencies*

Medical problems that occur on an individual inside commercial aircraft during a flight that need urgent attention. This does not include helicopters. The medical problems include syncope or pre-syncope, respiratory symptoms, nausea or vomiting, cardiac symptoms, seizures, abdominal pain, infectious disease, agitation or psychiatric symptoms, allergic reaction, stroke, trauma, diabetic complication, headache, arm or leg injury, obstetrical or gynaecological symptoms, ear pain, cardiac arrest, laceration and others (Peterson *et al.*, 2013).

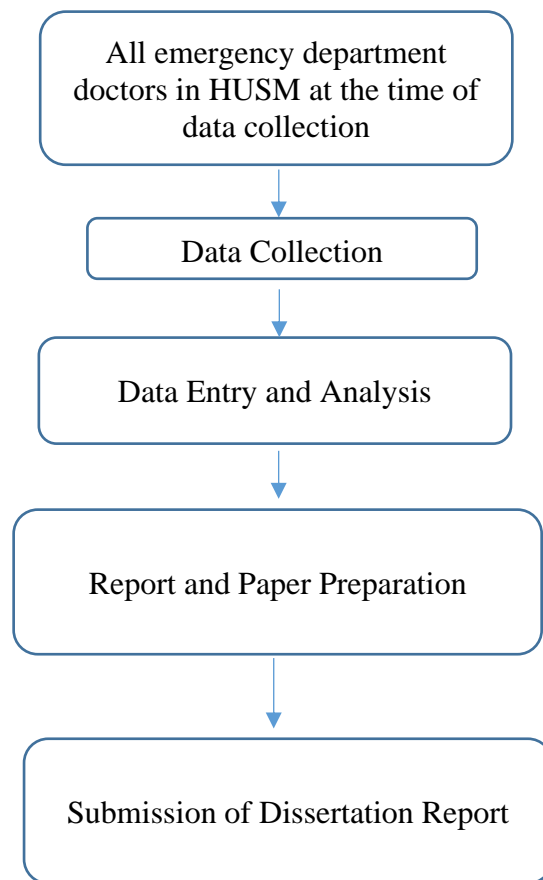
### 2.7 DATA COLLECTION METHOD

Data collection was done during department Continuing Medical education (CME).

Eligible and willing participants which includes house officers, medical officers and specialists would be given questionnaire and expected to complete the questionnaire

individually without using any assistance from electronic devices such as mobile phones or laptops. The questionnaire must be completed in the presence of the researcher and handover the answered questionnaire to the researcher within half an hour.

## 2.8 STUDY FLOWCHART



## 2.9 DATA ANALYSIS

Data will be entered and analysed using Statistical Package for the Social Science (SPSS) for Windows, version 24.0.

For the 1<sup>st</sup> objective, descriptive statistics will be used.

For the 2<sup>nd</sup> objective, frequency analysis, independent T test and analysis of variance (ANOVA) or non-parametric test (Mann Whitney U Test) will be used as deemed appropriate.

## 2.10 EXPECTED RESULTS

### *Specific objective 1*

Confidence level on Likert scale

No	Question	Survey scale: 1=strongly disagree    2=disagree 3=neutral    4=agree 5=strongly agree
1	My medical experience has given me adequate knowledge and skill to give assistance during <i>medical emergency</i>	1   2   3   4   5
2	My medical experience has given me adequate knowledge and skill to give assistance during <i>in-flight medical emergency</i>	1   2   3   4   5
3	I have adequate understanding of what medical supplies required on commercial airplanes	1   2   3   4   5



<b>4</b>	I have an adequate understanding of the level of training of commercial air crew in managing in-flight medical emergency	1 2 3 4 5
<b>5</b>	I have an adequate understanding of the manner in which the air crew, ground based medical control, and on board volunteer healthcare provider work together to manage an in-flight medical emergency	1 2 3 4 5
<b>6</b>	I would currently feel confident responding to an in-flight medical emergency	1 2 3 4 5
<b>7</b>	I would currently provide competent care while responding to an in-flight medical emergency	1 2 3 4 5

*Specific Objective 1:*

Knowledge questions: One best answer

1. The percentage of oxygen in the atmosphere decreases as your altitude or elevation increases

A. True      B. False

2. The humidity in cabin air on commercial airline flight is typically relatively \_\_\_\_\_ when compared to typical ground level building interiors

A. Low      B. High

3. Commercial airplane cabins are typically pressurized to an altitude of \_\_\_\_\_
- A. Sea level
  - B. 2000 feet
  - C. 8000 feet
  - D. 15000 feet
  - E. Not pressurized
4. The most common in-flight medical emergency is
- A. Stroke
  - B. Myocardial infarction
  - C. Seizures
  - D. Vasovagal (syncopal, fainting, dizziness)
5. Licensed physicians are required to respond to in-flight medical emergencies on domestic Malaysian flight.
- A. True
  - B. False
6. Malaysian flight crews are all trained in the use of the automated external defibrillators (AED)
- A. True
  - B. False

7. With respect to the medical kit, flight crew members are required to
- A. Take it out on request
  - B. Always take it out
  - C. Always open it
  - D. Know the indications of the medication
8. Who has the final say on whether the plane will be diverted because of an in-flight medical emergency?
- A. The responding physician
  - B. The pilot in-charge (captain)
  - C. The patient
  - D. Ground based medical control
9. Only a minority of in-flight medical emergencies result in diversion of the plane.
- A. True
  - B. False

*Specific Objective 2*

Sociodemographic factors

Variables	Frequency	Percentage
Gender <ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> </ul>		
Age (years old)		
Years of Working in Clinical Field		

<p>Do you have phobia in taking flight?</p> <ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>		
<p>Frequency of flights you take for last one year</p> <ul style="list-style-type: none"> <li>• None</li> <li>• 1-2</li> <li>• 3-4</li> <li>• 5-6</li> <li>• 7 or more</li> </ul>		
<p>Whether they had been aboard an aircraft during an in-flight medical emergency</p> <ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>		
<p>Previous healthcare training eg basic life support courses (BLS, ACLS)</p> <ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>		
<p>Position</p> <ul style="list-style-type: none"> <li>• Specialist</li> <li>• Medical Officer</li> <li>• House Officer</li> </ul>		

## 2.11 STUDY DURATION

January 2019 to January 2020

## 2.12 GANTT CHART

Project	2018							2019							2020										
	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	
1. Proposal presentation and ethical approval	→																								
2. Data Collection								→																	
3. Data Entry & Analysis															→										
5. Preparation of report																		→							
6. Submission of Dissertation																					→				

## 2.13 ETHICS OF STUDY

During the study, all data involving the samples will be held confidential and will be only accessible to the investigator and his team. The investigator also declared no conflict of interest with regard to this study. Doctors' right will not be jeopardized and will always be prioritized over this study. Participants who are busy attending patients in emergency department will not be asked to join the study. Recruitment of the subjects will be done during department CME. A free pen will be given to each responder when answering the questionnaire as a token of appreciation. Marks of the participants will not be publicly revealed. After the study is completed, a CME regarding management of in-flight medical emergency will be conducted to improve knowledge of medical doctors in emergency department Hospital USM. This study will be beneficial to the community if the knowledge and confidence in management of in-flight medical emergency is increased because in future more in-flight medical emergency events will occur in view of increasing worldwide ageing population and numbers of air travellers.

## **2.14 PRIVACY & CONFIDENTIALITY**

All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually.

## **2.15 CONFLICT OF INTEREST**

The investigators declare that they have no conflict of interests

## **2.16 PUBLICATION POLICY**

No personal information will be disclosed and subjects will not be identified when the findings of the survey are published.

## **2.17 REFERENCES**



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## 2.18 ETHICAL APPROVAL LETTER

 **USM** UNIVERSITI SAINS MALAYSIA 

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)  
Human Research Ethics Committee USM (HREC)

11<sup>th</sup> April 2019

Dr. Chong Woon Wee  
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School of Medical Sciences  
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JEPeM Code : USM/JEPeM/18100586  
Protocol Title : Management of In-Flight Medical Emergencies: A Study on Knowledge and Confidence among Emergency Department Doctors in Hospital USM.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/18100586**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **11<sup>th</sup> April 2019** until **10<sup>th</sup> April 2020**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:

1. Dr. Ariff Arithra

The following documents have been approved for use in the study.

1. Research Proposal


In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

1. Participant Information Sheet and Consent Form (English version)
2. Participant Information Sheet and Consent Form (Malay version)
3. Data Collection Form – Questionnaires

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form**.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form**.

  
**JAWATANKUASA ETIKA  
PENYELIDIKAN MANUSIA**

4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: [www.jepem.kk.usm.my](http://www.jepem.kk.usm.my)

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

**"ENSURING A SUSTAINABLE TOMORROW"**

Sincerely,



**PROF. DR. HANS AMIN VAN ROSTENBERGHE**  
Chairperson  
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM  
Universiti Sains Malaysia