PATIENT FACTORS INFLUENCING INAPPROPIATE ANTIBIOTIC PRESCRIBING FOR UPPER RESPIRATORY TRACT INFECTION (URTI) IN EMERGENCY DEPARTMENT, HOSPITAL UNIVERSITI SAINS MALAYSIA

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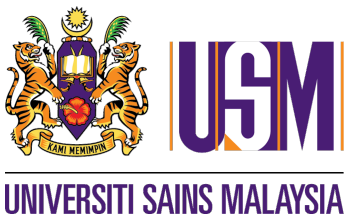
DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE (EMERGENCY MEDICINE)



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LIST OF SYMBOLS, ABBREVIATIONS OR NOMENCLATURE

URTI	Upper respiratory tract infection
RFE	Reason for encounter
GABHS	Group A Beta haemolytic Streptococcus
DDD	Defined daily doses
AMR	Antimicrobial resistance
ED	Emergency department
SD	Standard deviation
SPSS	Statistical Package for the Social Sciences
ESAC-Net	European Surveillance of Antimicrobial Consumption Network
KKM	Kementerian Kesihatan Malaysia
HRPZ2	Hospital Raja Perempuan Zainab 2
AM	Morning
PM	Evening
ON	Night
NAMCS	National Ambulatory Medical Care Survey
NHAMCS	National Hospital Ambulatory Medical Care Survey
OPD	Outpatient Department

ABSTRAK

Pengenalan

Gejala jangkitan saluran pernafasan merupakan salah satu aduan yang kerap dinyatakan oleh pesakit yang hadir di jabatan kecemasan untuk mendapatkan rawatan. Kebanjiran pesakit-pesakit yang bukan kes kecemasan di jabatan kecemasan akan meningkatkan risiko pemberian antibiotik yang tidak sesuai. Tujuan kajian ini adalah untuk melihat faktor-faktor pesakit yang mempengaruhi pemberian antibiotik secara tidak sesuai terhadap penyakit jangkitan saluran pernafasan di Jabatan Kecemasan Hospital USM.

Kaedah Kajian

Kajian ini dijalankan secara pemerhatian. Kajian ini meliputi semua pesakit yang didiagnosa sebagai *upper respiratory tract infection* (URTI) di zon hijau di sebuah hospital pengajian tinggi di pantai timur Malaysia. Data yang diperolehi adalah seperti sosiodemografi pesakit (umur, jantina, bangsa), jangka masa penyakit, hari bekerja, syif kerja dan gejala penyakit. Pesakit dibahagikan kepada dua kategori: positif McIsaac (skor ≥ 2) dan negatif McIsaac (skor <2). Faktor-faktor yang mempengaruhi pemberian antibiotik secara tidak sesuai dari kategori negatif McIsaac akan dianalisa.

Keputusan

Sejumlah 261 kes telah dikenalpasti. Terdapat 127 kes positif McIsaac dan 134 kes negatif McIsaac. Gejala demam (85%) dan batuk (76%) merupakan simptom utama bagi pesakit URTI yang hadir di Jabatan Kecemasan Hospital USM. Kadar pemberian antibiotik yang tinggi dilihat bagi pesakit yang mempunyai diagnosa *acute tonsillitis* (42%) dan *acute pharyngitis* (36%). Kedua-dua kategori menunjukkan kadar pemberian antibiotik yang tinggi bagi jenis antibiotik amoxicillin/clavulanate acid (34%) diikuti

amoxicillin (33%). Secara keseluruhannya kadar pemberian antibiotik secara tidak sesuai dalam kohort negatif McIsaac adalah 29%. Kajian juga menunjukkan tempoh gejala, simptom merasa sejuk dan diagnosa *acute tonsillitis* mempengaruhi pemberian antibiotik yang tidak sesuai.

Kesimpulan

Doktor di jabatan kecemasan hendaklah mengambil tahu tentang simptom-simptom pesakit dan diagnosa yang spesifik dalam mempengaruhi pemberian antibiotik untuk penyakit URTI. Risiko pemberian antibiotik yang tidak sesuai bagi penyakit URTI dapat dikurangkan dengan menganjurkan pendidikan dan latihan kepada para doktor di jabatan kecemasan dengan menekankan kepentingan penggunaan sistem skor permakahan selari dengan amalan penilaian klinikal yang tepat.

Kata Kekunci

URTI, McIsaac skor, pemberian antibiotik

ABSTRACT

Introduction

Upper respiratory tract infection (URTI) is a common clinical presentation for non-emergency cases in the emergency department. Increased numbers of the non-emergency cases such as URTI may contribute to inappropriate antibiotic prescribing. Most of the study done in Malaysia regarding URTI was done in the outpatient department. The objective of this study is to determine patient factors associated with inappropriate antibiotic prescribing for URTI in emergency department Hospital USM.

Methods

This was an observational, cross sectional study involving patients diagnosed as URTI admitted in the green zone in the emergency department of a tertiary teaching hospital in the east coast of Malaysia. Data collected included patient's demography (age, gender, race), duration of illness, working days, working shift, frequency of health visit, patient's symptom and signs. Patients were categorized into two groups: positive McIsaac (score ≥ 2) and negative McIsaac (score <2). Factors associated in influencing antibiotic prescribing in the negative McIsaac group (inappropriate prescription) were determined.

Results

A total of 261 subjects were included. There were 127 positive and 134 negative McIsaac score. From the total, most common URTI symptoms presented were fever (85%) and cough (76%). Highest antibiotic prescriptions were for acute tonsillitis and acute pharyngitis (42% and 36% respectively). Both groups showed higher prescription of amoxicillin (33%) and amoxicillin/clavulanate acid (34%). The overall inappropriate

antibiotic prescribing based on negative McIsaac score was 29%. Duration of symptoms, symptoms of chill and specific diagnosis of acute tonsillitis were associated with inappropriate antibiotic prescription.

Conclusion

Emergency doctors should be aware of the influence of patient's symptom and specific final diagnosis in prescribing antibiotic for URTI. The occurrence of inappropriate antibiotic prescribing in the emergency department can still be improved with intervention to re-educate, retraining and academic detailing which address prescribers regarding the importance of scoring system coupled with good clinical assessment in managing URTI.

Keywords

URTI, McIsaac score, antibiotic prescribing

CHAPTER 1.0 INTRODUCTION

Upper respiratory tract infections (URTIs) or common cold defined as infections that affect the nose, sinuses, pharynx, and larynx with associated cough with no proof of pneumonia. URTI is the commonest reason for patients to visit primary health care including the emergency department with estimated prevalence of 6% to 15%.[1] The etiology for URTI can vary from viral pathogen to bacterial pathogen.

The risk of complication post Group A Beta Hemolytic Streptococcus infection such as carditis, endocarditis, glomerulonephritis and rheumatic fever causing an increased number of inappropriate antibiotic prescriptions even the commonest causative agent is viral in origin. This inappropriate antibiotic prescription will lead to an increased number of antibiotic resistance organisms. Thus, it will threaten our ability to successfully treat the on growing infectious diseases.

Several determinants of inappropriate antibiotics prescribing have been highlighted in previous study including social-cultural, knowledge, economic status, prescriber factors and patient factors but their importance varies from each center.

Hospital Universiti Sains Malaysia is a tertiary university hospital in Kubang Kerian, Kelantan, Malaysia offering 24 hours emergency services in an academic and suburban city setting. There was no study regarding inappropriate antibiotic prescription in emergency settings in this center.

The objective of this study was to determine patient factors in influencing antibiotic prescription for URTI in negative McIsaac score.

CHAPTER 2.0 STUDY PROTOCOL

2.1 INTRODUCTION

Upper respiratory tract infections (URTIs) are the commonest condition presented to healthcare facilities including emergency department despite the condition is categorized as non-emergency (G3) in Malaysia triage scale. Study by national medical care statistic show reason for encounter (RFE) were respiratory conditions that accounted for 26.8% of all RFEs, about 49.2 per 100 patient encounters.[2] Overcrowding of this non-emergency cases such as URTIs in emergency department lead to increase in patient mortality.[3]

Upper respiratory tract infections include nasopharyngitis, pharyngitis, tonsillitis and otitis media. Most common presenting complaints of patients with URTI are sore throat, cough, and runny nose. It can be caused by many etiologies including infection due to viral pathogen or streptococcal infection, but viral agent representative >80% of the cases, while Group A Beta Hemolytic Streptococcus (GABHS) is responsible for 15%.[4] Since GABHS causing severe complication such as acute rheumatic fever, peritonsillar abscess and rheumatic disease which may lead to death, medical practitioners prone to prescribe antibiotic to reduce the morbidity and mortality. However, as most of URTIs are caused by viral pathogens, antibiotics are not needed in most cases.

Inappropriate antibiotic prescribing in URTI patients will significantly increase healthcare cost and result in rapid emergence of new resistant strains that contribute to antimicrobial resistance. Malaysia is still not free from antibiotic resistance issue despite antibiotic utilization in the country (10.87 defined daily doses (DDD) / 1000 population / day) is low compared to the western country such as Finland (30.85), France (21.56), Denmark (17.8) and Norway (16.6).[5]

The causes of this antibiotic abuse is a result from complex interplay of economic, social-cultural and cognitive factors at multilevel including patients, prescribers and drug industry.[6] A study done in Taiwan show 30% of URTI patients was been irrationally prescribed with antibiotic.[7] Failure in prescribing antibiotic to appropriate URTI patient will not only led to the rising healthcare costs, but has also increase mortality, morbidity and health utilization.

2.2 PROBLEM STATEMENT & STUDY RATIONALE

Inappropriate antibiotics prescription will cost a big burden to our healthcare system, as well as promoting antibiotic resistance. At least 30% of antibiotic courses prescribed are unnecessary.[8] Most of this unnecessary prescription is for acute respiratory conditions, such as colds, bronchitis, and sore throat which are caused by viruses. As this upper respiratory tract infection is one of the most common presentations in our healthcare, this problem would affect a large portion of our resources. Therefore, it would be appropriate to study on this matter and its relation with inappropriate antibiotic prescription in our population.

Although the emergency department caters for emergencies, it is frequently flooded with non-emergency cases such as upper respiratory tract infection. Usually treated in the outpatient department, URTI patients often misuse the emergency department since it is operating 24-hours a day. Because of this, we decided to do our study in the emergency department, since the findings may be different compared to other studies in the outpatient department due to the difference in the working environment.

Many factors may contribute to inappropriate antibiotic prescription. In the emergency department, due to its hectic and unpredictable nature, the medical practitioners are required to make quick decisions while treating their patients. Thus, certain patient factors

may affect the decision in antibiotic prescription, although the antibiotics are not needed. Therefore, in this study we would like to identify the patient factors influencing inappropriate antibiotic prescribing in URTI cases presented to the emergency department.

2.3 RESEARCH QUESTIONS

1. What is the sociodemographic pattern for URTI patients presented in Emergency Department Hospital Universiti Sains Malaysia?
2. What is the practice of antibiotic prescription for URTI patients in Emergency Department Hospital Universiti Sains Malaysia?
3. What are the patient factors influencing antibiotic prescription in URTIs with negative McIsaac score in Emergency Department Hospital Universiti Sains Malaysia?

2.4 OBJECTIVES

General

To study on inappropriate antibiotic prescription for upper respiratory tract infections in Emergency Department HUSM.

Specific

1. To identify sociodemographic patterns of URTI patients presented in emergency department Hospital USM.
2. To study the practice of antibiotic prescription for URTI patients presented in Emergency Department Hospital USM.

   (type of antibiotic use, percentage of case prescribed with antibiotic in positive and negative McIsaac score)

3. To determine the patient factors associated with antibiotic prescription in negative McIsaac score for URTIs.

2.5 LITERATURE REVIEW

Antimicrobial resistance (AMR) is a natural occurring phenomenon whenever antimicrobials are used due to the process of bacterial adaptation. The overuse and misuse of antimicrobial drugs however does expedite this phenomenon. Frequent antibiotic usage over long periods of time puts selective pressure on bacteria by killing susceptible bacteria, allowing antibiotic resistant bacteria to survive and multiply.[9]

About 80% of antibiotics used in humans occurs in the community, with the bulk of it contributed either by prescription from medical practitioners or self-medication. Despite predominantly viral in origin and evidence shows lack of clinical benefit with antibiotic usage, the irrational antibiotic prescribing in URTIs are still reported to be high.[10] In emergency department setting, a study done in western country showed that about 30% of antibiotic prescription were inappropriate and the most common indication was URTI.[11]

A variety of factors affect prescribing behaviour, including the sociodemographic of patients, clinical characteristics of patients, physician training and local pattern of practice. In this study, we focus on patient factors that contribute to antibiotic prescribing.

A systematic review study done in 2016 showed that a patient's age contributes a higher significant factor in influencing antibiotic prescribing.[12] Younger aged patients are more frequently prescribed with antibiotics because younger patients are more likely to be infected with GABHS.

Women are more likely to be prescribed antibiotics than men during their lifetime because it may be driven by social and behavioural factors. Women consult medical practitioners

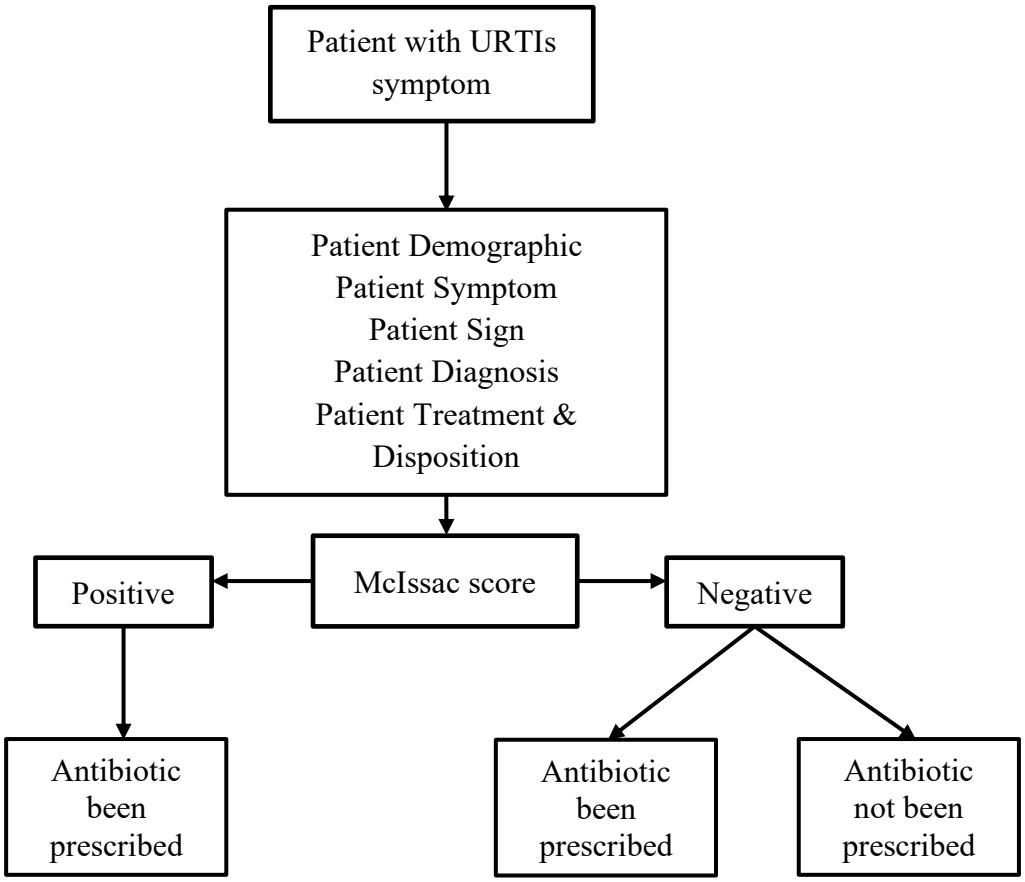
more frequently than men do. It is noteworthy to emphasize that there was a strong association between URTIs and increased antibiotic prescription in younger woman in a study done in United State which analysed the rate of inappropriate antibiotic prescribing for acute respiratory infection in ambulatory care.[13]

In addition, the factors that influence antibiotic prescription in emergency department settings may vary from the outpatient department. Staffing in the emergency department and the availability of other supporting services are limited especially during non-daylight. Therefore, time pressure due to overcrowding and fear of missed diagnosis may contribute to inappropriate antibiotic prescribing. A study done in emergency department showed that presentations to emergency department during evening and night were associated with a higher frequency of antibiotic prescribing for URTI.[14]

The results of patient symptoms and physical examination also contribute to antibiotic prescribing. A study done showed purulent green or yellow nasal discharge, symptom of green phlegm and physical examination of tonsillar exudate have strongly associated with antibiotic use.[12]

2.6 METHODOLOGY

2.6.1 CONCEPTUAL FRAMEWORK



2.6.2 RESEARCH DESIGN

This is a 6-month cross-sectional observational study conducted from November 2018 till April 2019.

2.6.3 STUDY AREA

Emergency and Trauma Department Hospital Universiti Sains Malaysia, Kelantan.

2.6.4 STUDY POPULATION

Reference population

All URTI patients treated in the emergency department, Kelantan.

Source population

All patient who are treated for URTIs in emergency department Hospital Universiti Sains Malaysia, Kelantan.

Study Participant

All patients who are treated for URTIs in green zone emergency department Hospital Universiti Sains Malaysia, Kelantan during the study period who fulfilled the inclusion and exclusion criteria.

2.6.5 SAMPLING FRAME

All patients who are treated for URTIs in green department Hospital Universiti Sains Malaysia, Kelantan who fulfilled inclusion and exclusion criteria from November 2018 to April 2019

2.6.6 SUBJECT CRITERIA

Inclusion

URTIs cases that had been treated in green zone emergency department Hospital Universiti Sains Malaysia.

Exclusion

1. Age less than 3 years old

   Cases with age less than 3 years old were excluded from using this McIsaac score as strep throat is very rare in this population.
2. Cases treated for URTIs in yellow and red zone

Based on Malaysia Triage Category 2011, sore throat not having respiratory symptoms, fever more than 38°C for adults and children age between 2 years old to 12 years old has been classified as green non-critical. Most of the target study participants will be treated in this area. For URTI patients that have been treated in yellow and red zones, most of the patients are semi-critical or critical ill patients that require intravenous intervention or antibiotic administration.

2.6.7 SAMPLE SIZE ESTIMATION

This sample size calculation is based on the available data using 2 portion estimation form a practical guide on determination of sample size in health sciences research.[15] Data was extracted from previous literature.

Objective 1: To identify sociodemographic patterns of URTI patients presented in emergency department Hospital USM.

Variable	P0	P1	m	n	N(+10%)
Gender					
Male	57%	37%	1	94	105
Female	56%	36%	1	94	105
Age					
0-4	48%	67%	1	103	115
5-17	57%	38%	1	105	117
18-59	58%	38%	1	95	106
Ethnicity					
Malay	53%	71%	1	111	**124**
Chinese	60%	35%	1	59	66
Indian	56%	20%	1	25	28

P0 = literature review with sociodemographic predictor of overall and broad spectrum antibiotic prescribing.[10]

P1 = expert opinion, sociodemographic pattern in URTI patient in HUSM.

M = ratio between 2 groups.

N = sample size per group.

Sample size for this objective will be 248 samples.

Objective 2: To study the practice of antibiotic prescription for URTI patients presented in Emergency Department Hospital USM.

(type of antibiotic use, percentage of case prescribed with antibiotic in positive and negative McIsaac score)

Variable	P0	P1	m	n	n(+10%)
Type of antibiotic	34%	55%	1	84	**94**
Penicillin	27%	48%	1	80	89
Cephalosporin	19%	5%	1	81	90
Macrolide					

P0 = literature review with frequency antibiotic prescription in primary care units in Taiwan.[7]

P1 = expert opinion, frequency antibiotic prescription in HUSM.

m = ratio between 2 groups.

n = sample size per group.

Sample size for this objective will be 188 samples.

Objective 3: To determine patient factors associated with antibiotic prescription with negative McIsaac score for URTIs.

Variable	P0	P1	m	n	n (+10%)
Gender					
Woman	47%	65%	1	116	129
Men	40%	60%	1	95	106
Symptoms					
Cough	25%	42%	1	118	132
Rhinitis	21%	40%	1	89	99
Pharyngitis	22%	40%	1	100	112
Dyspnoea	44%	65%	1	85	95
Fever	40%	58%	1	118	**132**
Signs					
Wheezing	47%	25%	1	71	79
Non-tender cervical lymph node	29%	10%	1	65	73
Sputum production	34%	55%	1	84	94
Non-exudative tonsil	34%	15%	1	77	86

P0 = literature review with antibiotic prescription for presumed nonbacterial acute respiratory tract infection.[14]

P1 = expert opinion, antibiotic prescription with positive McIsaac score.

M = ratio between 2 groups.

N = sample size per group.

Sample size for this objective will be 264 samples.

2.6.8 SAMPLING METHOD & SUBJECT RECRUITMENT

Sample will be identified based on cases presented with URTIs symptom at triage in Emergency Department Hospital USM. Simple random sampling will be used.

From November 2018 to January 2019, samples will be taken on Sunday and Monday (weekdays) every shift.

From February 2019 to April 2019, samples will be taken on Friday and Saturday (weekends) every shift.

Samples will be collected until the sample size is achieved.

2.6.9 RESEARCH TOOL

	Research tool
Specific objective 1 To identify sociodemographic patterns of URTI patients presented in emergency department Hospital USM.	A data collection form was created to record information from emergency clerking sheet (Appendix A) (patient sociodemographic including age, gender, race, employment, frequency of health visit and duration of illness)
Specific objective 2 To study the practice of antibiotic prescription for URTI patients presented in Emergency Department Hospital USM. (type of antibiotic use, percentage of case prescribed with antibiotic in positive and negative McIsaac score	A data collection form was created to record information from emergency clerking sheet (Appendix A) (percentage of type antibiotic use) Based on the data collection form, McIsaac score will be used to identify patients with positive and negative score. McIsaac score 0 or 1 are considered as negative McIsaac scores while McIsaac score 2 to 4 considered as positive McIsaac score.
Specific objective 3 To determine patient factors associated with antibiotic prescription with negative McIsaac score for URTIs.	A data collection form was created to record information from emergency clerking sheet (Appendix A) (sign and symptom of URTIs)

	Based on data collection form, McIsaac score will be used to identify cases with negative McIsaac score. This instrument is chosen as it has been tested for validity and reliability to estimate probability of streptococcal pharyngitis (bacteria) in patients with URTIs. A large-scale validation study was done for McIsaac score with data over 140000 samples with multicentre over a year provide precise interpretation of risk for each score category that still lie within 95% CI and show that it was valid and useful score for diagnosing and managing patient with pharyngitis[15] For local setting such as tropical country (Malaysia), a study done show McIsaac score can be used efficiently to reduce misuse of antibiotic and help to tackle in diagnosing aetiology of URTIs[16]. McIsaac score is also used in clinical practice guidelines for managing sore throat.

2.6.10 OPERATIONAL DEFINITION

1. Upper respiratory tract infection

   An infection of the upper part of the respiratory system which is above the lungs. An upper respiratory infection can be due to any number of bacterial or viral infections. These infections may affect the throat (pharyngitis), nasopharynx (nasopharyngitis), sinuses (sinusitis), larynx (laryngitis), trachea (tracheitis) or bronchi (bronchitis). Symptoms of upper respiratory tract infection include cough, sneezing, sore throat, nasal discharge, nasal congestion, running nose and fever.

2. Inappropriate antibiotic prescribing

In this study, we will calculate the McIsaac score of the patient based on the data in the data collection form to determine the probability of streptococcal pharyngitis. McIsaac scores of 0 or 1 are considered as McIsaac score negative and do not require antibiotics. Inappropriate antibiotic prescribing is considered when a patient with a negative McIsaac score is prescribed an antibiotic.

3. McIsaac Scoring scale

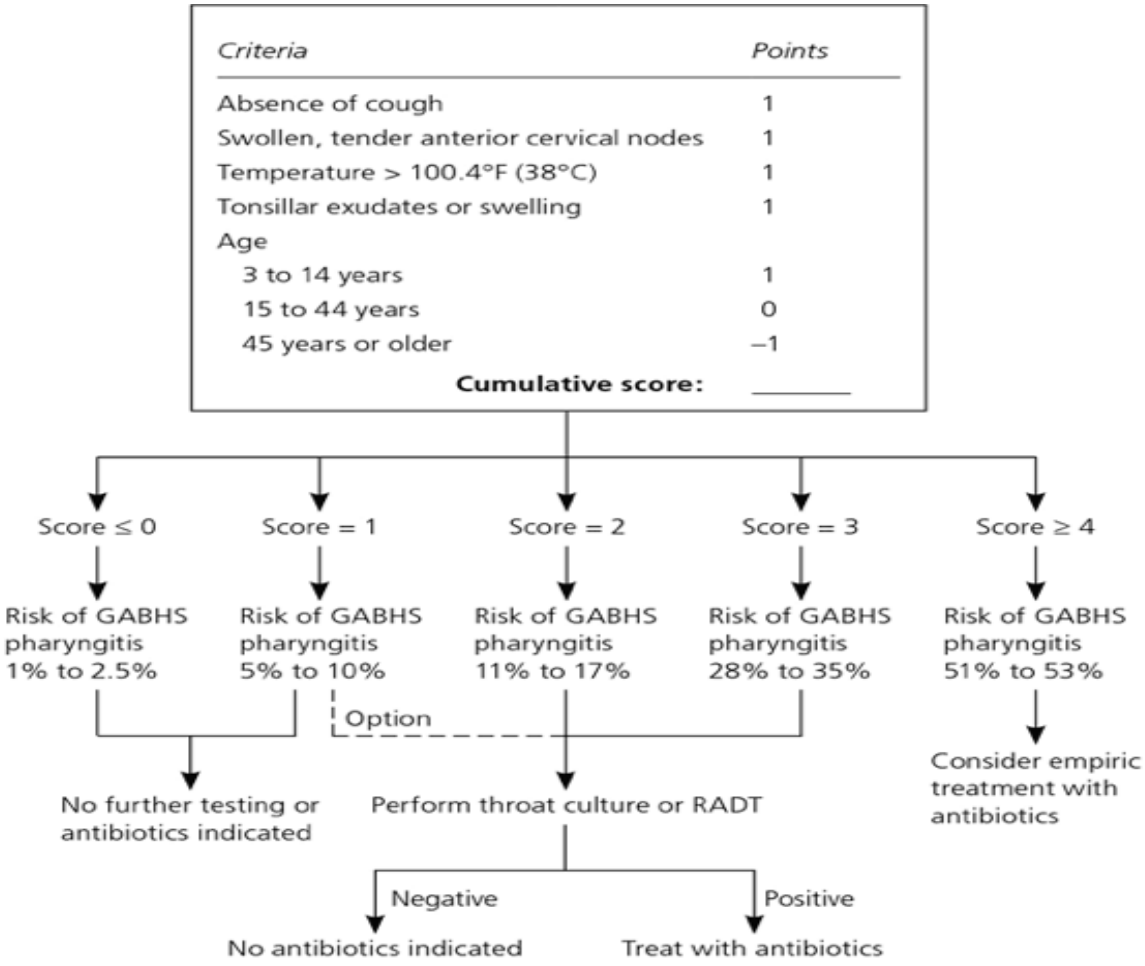
McIsaac score is a scoring to estimate probability of streptococcal pharyngitis and suggests a management course. It also can increase the accuracy of the clinical diagnosis. It is based on the age of the patient and four clinical symptoms, i.e. tonsillar swelling/exudate, fever > 38°C, swollen anterior cervical nodes and lack of cough.

Even if a patient has all four classic symptoms, there is a significant probability that it is not Group A streptococcal sore throat. However, presence of certain clinical symptoms such as cough, rhinitis, hoarseness, conjunctivitis, diarrhea and oropharyngeal ulceration may suggest a likely viral etiology.

A large-scale validation study was done for McIsaac score show that it was valid and useful score for diagnosing and managing patient with pharyngitis.[16] For local setting such as tropical country (Malaysia), a study done show McIsaac score can be used efficiently to reduce misuse of antibiotic and help to tackle in diagnosing aetiology of URTI. [17]

Based on a study done, there was no significant difference in sensitivity and specificity between adult and children population in detecting Group A Streptococcus in sore throat patient.[18]

For negative McIsaac score which is score 0 or 1, no further testing required or antibiotic needed for URTI patients. (refer diagram).

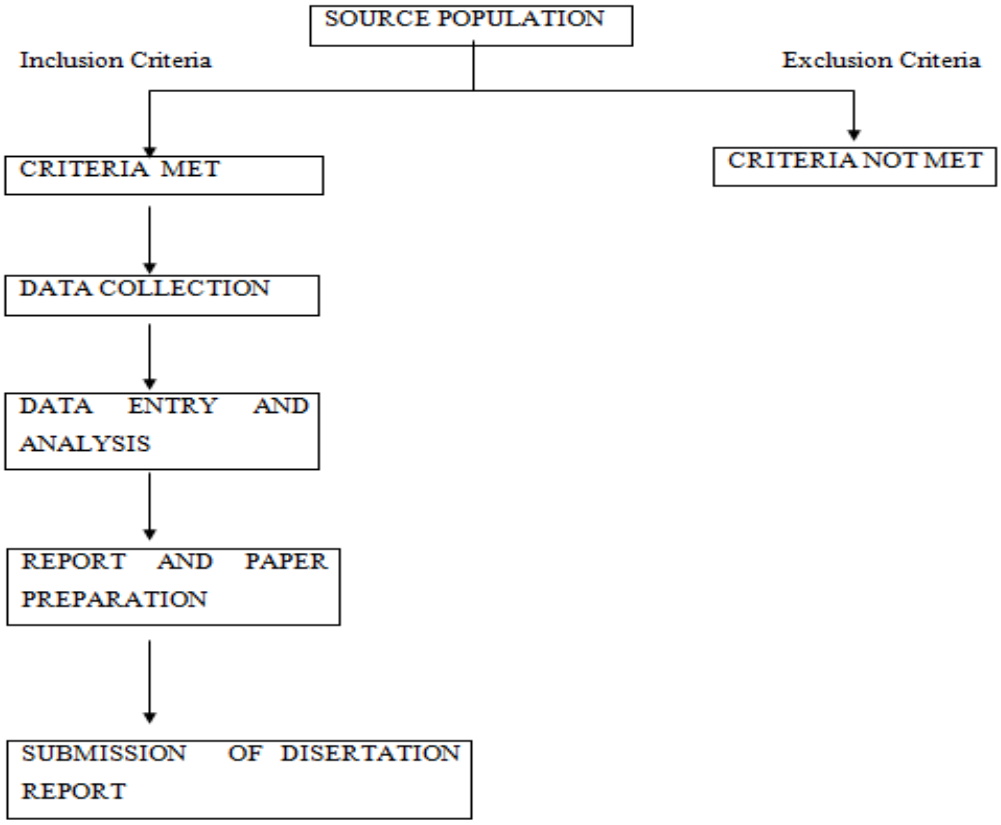


2.7 DATA COLLECTION METHOD

Sample will be identified based on cases that attend to the green zone emergency department Hospital USM with symptoms of URTI. Researcher team will fill up the data collection form based on the patient's emergency clerking record and McIsaac score will be calculated.

No consent will be taken from the patient or attending doctor. Permission and approval from the hospital director will be asked to collect data from Hospital USM emergency clerking sheet. Each of the samples will be assigned with a unique study ID to maintain patient’s confidentiality.

2.8 STUDY FLOWCHART



2.9 DATA ANALYSIS

Data will be entered and analysed using SPSS version 22.

Specific objective No. 1 and No. 2 will utilise descriptive statistics to summarise the socio-demographic characteristics as well as the type of antibiotic prescribed among subjects. Numerical data will be presented as (SD). Categorical data will be presented as frequency (percentage).

Specific objective No. 3 will be analysed via multiple logistic regression to determine association between patient factors with antibiotic prescribing in negative McIsaac score.

2.10 EXPECTED RESULTS

Specific Objective 1

Table 1: Sociodemographic pattern of URTI patients in emergency department Hospital USM

Variables	Categories	Frequency (n)	Percentage (%)
Age	3-14		
	14-45		
	>45		
Gender	Male		
	Female		
Race	Malay		
	Chinese		
	Indian		
	Others		
Employment	Working		
	Not working		
Duration of Illness	1 day		
	1-2days		
	> 2 days		
Frequency of health visit	1st visit		
	2nd visits		
	≥ 3rd visits		

Specific Objective 2

Table2 : Proportion of type of antibiotic prescription for URTI patients in Emergency Department Hospital USM

Variables		**Positive McIsaac**	**Negative McIsaac**
		n (%)	**n (%)**
Type of antibiotic			
	Amoxicillin		
	Erythromycin		
	Amoxicillin/Clavunate acid		
	Ampicillin		
	Penicillin V		
	Cloxacillin		
	Bactrim		
	Cephalexin		
	Cefuroxime		

Specific Objective 3

Table 4 : Patient factors associated with antibiotic prescription in URTI patient in emergency department Hospital USM.

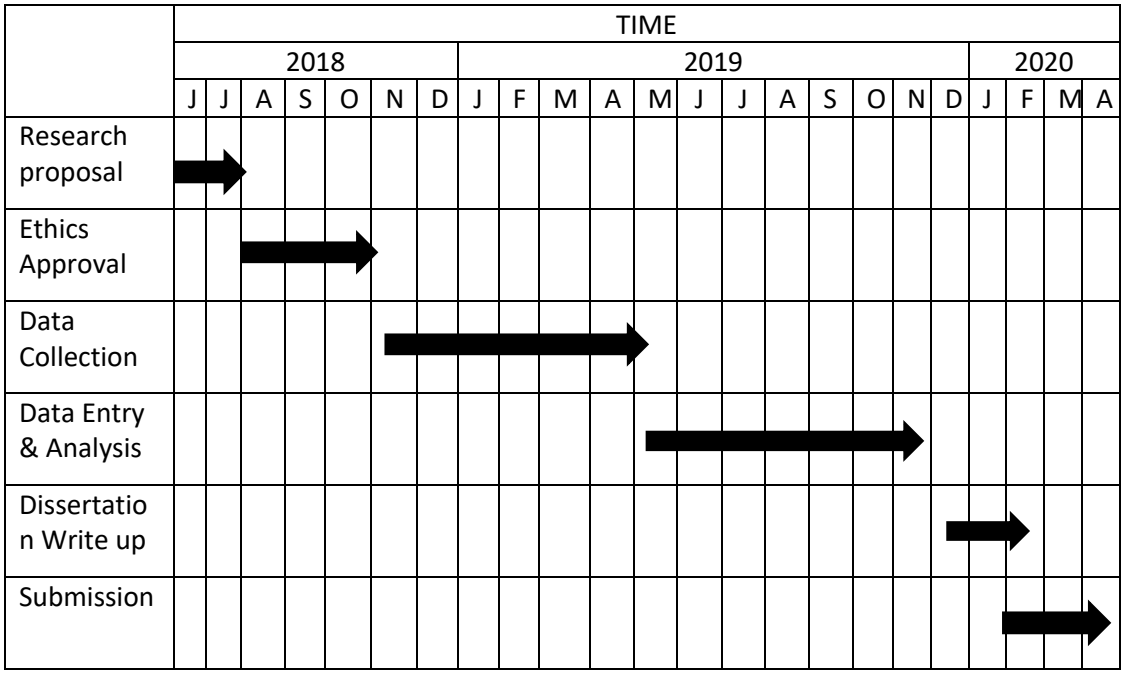
VARIABLES	STUDY FACTOR	SIMPLE LOGISTIC REGRESSION		MULTIPLE LOGISTIC REGRESSION	
		OR (95% CI)	p-value	OR (95%CI)	p-value
PATIENT FACTOR					
AGE, Mean ± SD					
Working Shit	AM				
	PM				

	ON				
Patient Presentation	Fever >38∘C				
	Cough				
	Rhinitis				
	Wheezing				
	Dyspnea				
	Tachypnoea				
	Palpable cervical lymph node				
	Exudative tonsillar				
Patient Disposition	Observation ward				
	Discharge				
	Admit				

2.11 STUDY DURATION

November 2018-November 2019

2.12 GANTT CHART & MILESTONES



No	Milestones	Date	Semester
1.	Draft research proposal to supervisor	April 2018	Semester I 2017/2018
2.	Present research proposal to department	May 2018	
3.	Submit proposal to ethics committee	June 2018	
4.	Anticipated date for Ethics approval	November 2018	
5.	Data collection commencement	November 2018	Semester II 2018/2019
6.	Data collection complete	April 2019	
7.	Data entry & analysis commencement	May 2019	
8.	Data entry & analysis complete	December 2019	Semester III 2019/2020
9.	Review findings with supervisor	January 2020	
10.	Dissertation report write up	January 2020	
11.	Review draft final report with supervisor & corrections	March 2020	
12.	Submit final report	April 2020	

2.13 ETHICS OF STUDY

Study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline. Approval to conduct the study will be obtained from the institutional ethics committee; Human Research Ethics Committee USM (HREC) and the hospital management.

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

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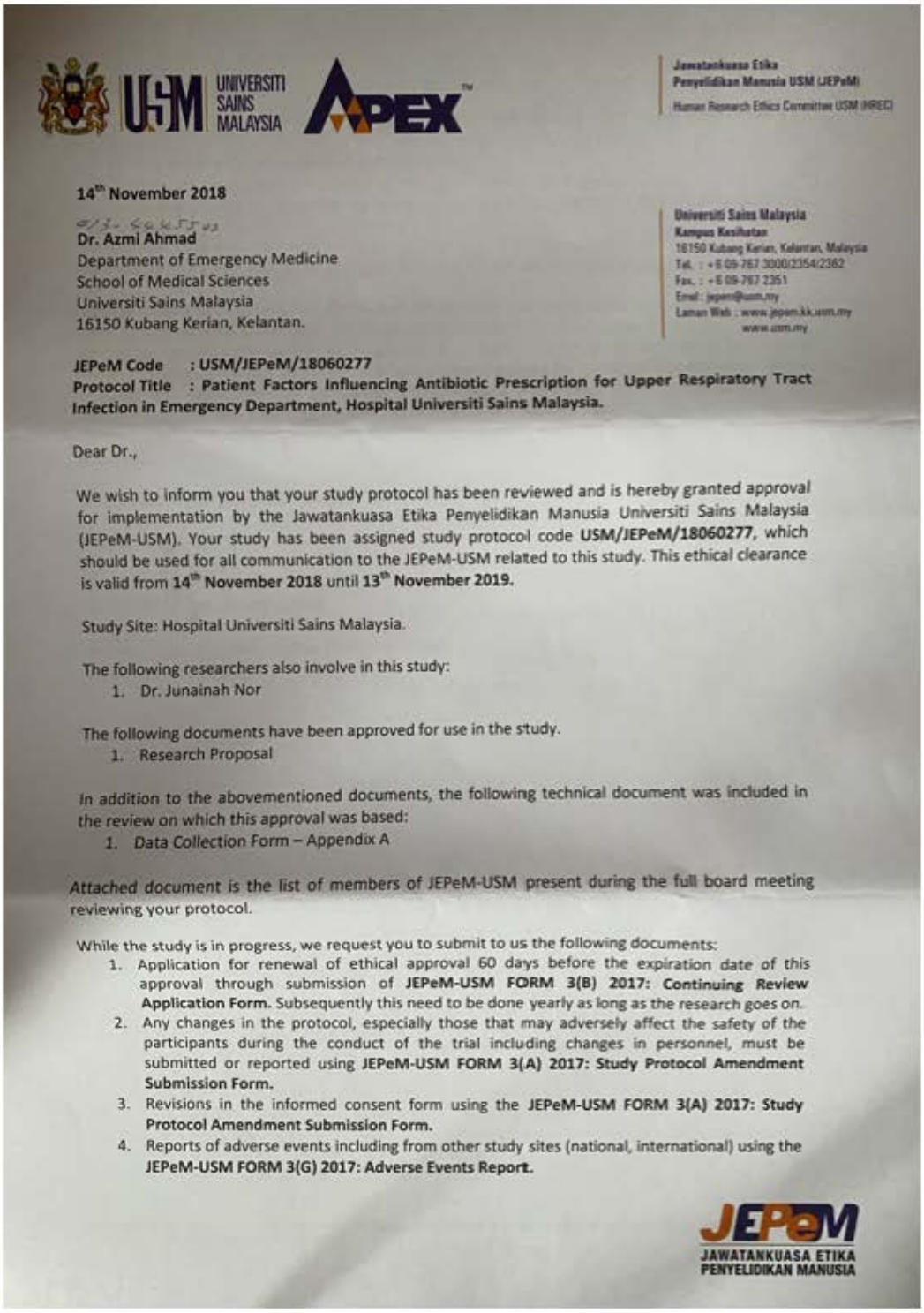
2.18 ETHICAL APPROVAL LETTER



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

14th November 2018

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JEPeM Code : USM/JEPeM/18060277
Protocol Title : Patient Factors Influencing Antibiotic Prescription for Upper Respiratory Tract Infection in Emergency Department, Hospital Universiti Sains Malaysia.

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/18060277**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **14th November 2018** until **13th November 2019.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:
1. Dr. Junainah Nor

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. Data Collection Form – Appendix A

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) 2017: Continuing Review Application Form.** Subsequently this need to be done yearly as long as the research goes on.
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) 2017: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2017: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2017: Adverse Events Report.**

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PENYELIDIKAN MANUSIA