

Risk Evaluation Under Various Speculations of Antibiotic Usage; A Cohort Survey Among Outpatients of Pinang, Malaysia

Gillani Wasif Syed¹, Azhar Sulaiman Syed², Ling Ai Oh³

¹Department of Clinical Pharmacy, Universiti Sains Malaysia.

²School of Pharmaceutical Sciences, Universiti Sains Malaysia.

³School of Pharmaceutical Sciences, Universiti Sains Malaysia.

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Correspondence: Syed Wasif Gillani
MClin. Pharm, Lecturer & Researcher,
Department of Clinical Pharmacy, Universiti Sains Malaysia, 11800 Gelugor, Pulau Pinang, Malaysia
Phone: 60174203027, Office: 6046532205
Fax: +604-6570017
Email: wasifgillani@gmail.com

ABSTRACT

Aim: The study aim was to provide baseline information against the contradictory evaluations done in the public health sector, by enlighten the risk evaluation or identification by means of controlling irrational use in the society.

Method: A cross sectional survey using self administered questionnaire was conducted starting from February to March 2009 at outpatient pharmacy department of Penang Hospital and from April to September 2009 from twenty difference pharmacy stores across whole Pulau Pinang. Data analysis was made against the theoretical framework of the study by using Statistical Package of Social Sciences 13®.

Result: Study respondents were 1139 with 99.0% response rate. Almost equal distribution was made between man (53.9%) and female (46.1%). Majority of them were Malay (46%) next to Chinese (35.8%). Age group between 18 - 30 years largely (36.7%) responds to negative behavior of incomplete course of antibiotics. Marital status (married) three times more likely to irrational use of antibiotics as to single. The only predictor for statement 'the effectiveness of treatment is reduced if a full course of antibiotic is not completed' was significantly associated with more respondents having chronic medical condition getting the correct response (65.2% vs 58.9%, $p=0.025$). It has been found that knowledge level has less likelihood towards the sources of antibiotics and people taking antibiotics from different retail pharmacy are 200 percent more likely to develop or adopt irrational use pattern as to out-patient pharmacy of Penang hospital (RR 3.34, 95% CI 1.95 - 4.60).

Conclusion: It is concluded that respondents to retail pharmacy were at high risk and more likely to be indulge in irrational antibiotic use as to Out-patients of Penang hospital.

Key words: Antibiotic usage, irrational prescription, knowledge, antibiotic resistance.

Antibiyotik Kullanımının Çeşitli Spekülasyonları Altında Risk Değerlendirmesi; Malezya, Pinangdaki Poliklinik Hastalarında Bir Kohort Çalışması

Amaç: Çalışmanın amacı kamu sağlık sektöründe yapılan çelişkili değerlendirmelere karşı, risk tespit ve değerlendirmeyle bilgilendirme yaparak toplumdaki irrasyonel kullanımı kontrol için temel bilgiler sağlamaktır.

Metod: Kendi kendine anket yöntemi kullanılarak Şubat-Mart 2009 tarihleri arasında Penang Hastanesi Eczacılık bölümü polikliniğinde ve Nisan-Eylül 2009 tarihleri arasında tüm Pulau Pinangdaki yirmi farklı eczanede bir kesitsel araştırma yapılmıştır. Çalışmanın veri analizi Statistical Package of Social Sciences 13® kullanılarak yapılmıştır.

Bulgular: Araştırmaya katılanlar 99,0 % yanıt oranı ile 1139 idi. Erkek (53.9%) ve kadınlar (46.1%) arasında hemen hemen eşit dağılım mevcuttu. Katılanların büyük çoğunluğu (% 46) Malay, ikinci sırada Çinli (35.8%) idi. 18-30 yaş grubundakiler çoğunlukla (36.7%) antibiyotiğin eksik kullanımı yönünde negatif cevap bildirdiler. Evlilik durumu (evli onlar) bekarlara göre üç kat irrasyonel antibiyotik kullanımına meyilli idiler. "Eğer tam bir antibiyotik kürü tamamlanmazsa tedavinin etkinliği azalır" cümlesi için tek belirleyici belirgin olarak daha fazla doğru cevap elde edilen (65.2% vs 58.9%, p=0.025) kronik medikal durumu olan katılımcılardı. Antibiyotiğin kaynağıyla ilgili daha az olasılıklı bilgi düzeyinin mevcut olduğu ve farklı eczanelerden antibiyotik elde eden kişilerin Penang hastanesi poliklinik eczanesinden elde edenlere göre 200% daha fazla irrasyonel antibiyotik kullanımına sahip olduğu bulunmuştur (RR 3.34, 95% CI 1.95 - 4.60).

Sonuç: Sonuç olarak perakende eczaneden antibiyotik alan katılımcıların Penang hastanesi poliklinik eczanesinden alanlara göre daha fazla riskte olduğu ve irrasyonel antibiyotik kullanımına daha fazla meylettikleri tespit edilmiştir.

Anahtar kelimeler: Antibiyotik kullanımı, irrasyonel reçeteleme, bilgi, antibiyotik direnci

INTRODUCTION

Worldwide escalation of antibiotic resistance poses a significant global threat to human health. The World Health Report 2007 has highlighted the issue of microbial evolution and antibiotic resistance as one of the major threat to public health security in the 21st century which has contributed to the emergence and re-emergence of infectious diseases (1). The resistance phenomenon is resulting in the increased morbidity, mortality and healthcare cost (2,3). This trend is expected to continue unless the problem of antibiotic resistance can be curbed. Antibiotic consumption is a key driver of resistance although the relationships are complex (4). According to the Malaysian Statistics on Medicine 2005, antibiotics accounted as the most commonly anti-infective prescribed by public and private healthcare sector in Malaysia with 9.55 DDD/1000 population/day (5).

The pattern of antibiotic usage in six general hospitals in Malaysia was showing about two thirds of prescriptions were for therapeutic purposes and the most common infections treated were for lower respiratory tract infections (31%) (6-7). In the public primary care setting, it was found that half of all the antibiotic prescriptions were for upper respiratory tract infections (URTIs) (8-9). Misuse of antibiotic is a result of complex socioeconomic, cultural and behavioral factors (10,11). Patient as an ultimate consumer play an important role in the antibiotic utilization pathway. In year 2000, the World Health Organization (WHO) report with the topic Overcoming Antimicrobial Resistance has identified three key issues

for public involvement: improving access to medical services, reducing unnecessary use of antimicrobial drugs and taking a full course of treatment, not sharing medication with other people or keeping part of the course for another occasion (11).

Several studies have revealed the patient expectation as important determinant of antibiotic prescribing (18-21). However, inaccurate and overestimation of patient expectation is often resulting in unnecessary prescribing (19). Besides, considerable evidences also point to widespread problems in knowledge, attitudes, beliefs and behavior among consumers which influence the antibiotic usage (16-22). The misguided beliefs and expectations are associated with a lack of awareness of the dangers of antibiotic use (16). Therefore, changing public attitudes and expectations regarding antibiotic use will be an important first step to preserve antibiotic effectiveness in the era of resistance (23). These have led to the implementation of educational initiatives directed at public with the aim of promoting rational and appropriate use of antibiotic (24,25).

The study aim was to provide baseline information against the contradictory evaluations done in the public health sector, by enlighten the risk evaluation or identification by means of controlling irrational use in the society. Therefore a theoretical frame work was prepared on the initial stages of protocol development. Study design was then selected in accordance to the need of analysis.

Table 1. Summary of demographic characteristics

Characteristics	n (1139)	(%)
Age		
18-30	260	22.8
31-40	254	22.3
41-50	260	22.8
51-60	232	20.3
>60	133	11.8
Race		
Malay	533	46.8
Chinese	407	35.7
Indian	179	15.7
Others	20	1.8
Marital Status		
Single	301	26.4
Married	807	70.9
Widowed/Divorced/ Separated	31	2.7
Highest Educational Status		
Primary or lower	37	3.2
Secondary	583	51.2
College/University	519	45.6
Employment Status		
Employed for wages	558	49.0
Self employed	134	11.8
Housewife	132	11.5
Retired/Unemployed	315	27.7
Monthly Income		
None	285	25.0
<RM1000 (<US\$ 295 approx.)	145	12.7
RM1000-2000 (US\$ 295-591)	329	28.9
RM2001-4000 (US\$ 593-1181)	288	25.2
>RM4000 (US\$ 1184)	92	8.1
Occupation related to health care		
Yes	207	18.2
No	932	81.8
Smoking		
Yes	207	18.2
No	932	81.8
Drinking Alcohol		
Yes	79	6.9
No	1060	93.1
Chronic Medical Condition		
Yes	561	49.3
No	578	50.7
Number of Clinic/Pharmacy Visit		
None	126	11.0
1-4 times	634	55.7
5-10 times	262	23.0
>10 times	117	10.3

MATERIALS AND METHODS

Study design

A cross sectional survey using self administered questionnaire was conducted starting from February to March 2009 at outpatient pharmacy department of Penang Hospital and from April to September 2009 from

Table 2. Relative risk ratio(s) of socio-demographics against antibiotics use.

Characteristics	Risk Ratio	CI 95% range
Age	1.35	1.00 - 1.97
Gender	1.76	1.12 - 2.07
Races	2.35	1.22 - 3.01
Marital Status	3.14	1.90 - 4.20
Educational level	1.98	1.28 - 2.46
Occupation status	0.87	0.23 - 1.10
Socioeconomic status	2.10	1.31 - 2.41

twenty (20) difference pharmacy stores across whole Pulau Pinang. The targeted subjects were general public/ patients who visited outpatient pharmacy department at Penang Hospital and retail pharmacy buyers without prescription or at incompliance state. Cluster Random sampling method was used in against both cohorts. Study population of Penang state is 1.546 million with Different ethnic groups inhabiting the state are Malays (41.73%), Chinese (41.71%), Indians (9.76%), and other minorities/non Malaysian citizen (6.81%) (29). So in contrast to the above mention statistics our study accredited subjects with Malay (46.8%) followed by Chinese (35.8%), Indian (15.7%) and others (1.7%). There are only 37 pharmacy stores at the Pulau Pinang study population area. So our study emphasize on 20 pharmacies by using convenient type of access.

National antibiotic policy

There are very few infections for which the duration of treatment has been precisely defined. This reflects the fact that the end-points for assessing treatment are largely clinical rather than microbiological. Clinical features that are driven by the inflammatory response usually subside after microbial elimination. Clinicians should assess the time frame for discontinuing antibiotics after careful review of the clinical response, guided by microbiological clearance of the pathogen whenever appropriate. Antibiotic prescribing should be made after careful consideration of the underlying infective process, the likely etiologic agents, local susceptibility pattern, known spectrum of a chosen antibiotic, host factors and comorbidities. Rational antibiotic prescribing can minimize development of antibiotic resistance and reduce costs of healthcare. Broad-spectrum initial therapy does not appear to result in the emergence of antibiotic resistance as long as the duration of use was limited. The choice of the initial antibiotic regimen

Table 3. Risk ratio (s) between Knowledge domain and Health assurance against irrational use of antibiotics.

Knowledge*	HA**	Risk Ratio	CI 95%	Irrational ***
Knowledge level	Source of Ab	1.25	0.75 - 1.54	Public of retail
Reason Ab use	Visit & Behaviour	4.76	2.56 - 6.13	Pharmacy to
ADR of Ab	Chronic Med.	2.05	1.79 - 2.45	Out-patient
Course completion	Smoking & alcohol	1.87	1.31 - 2.29	Penang (3.34)
Awareness attitude	Neg. Act	2.43	1.33 - 3.10	

*Knowledge level and awareness domain, **Health Assurance, ***Irrational use of antibiotics suspected outcome, Ab: Antibiotic, ADR: Adverse drug reactions, Med: Chronic Medical condition, Neg. Act: Negligence Act (irresponsible behaviour towards antibiotic use)

should be based on the local microbiological surveillance data (28).

Questionnaire development and Reliability

The questionnaire was adapted from previous study and modified to suit the local population in Penang (22,26,27). It was divided into three parts which were Part 1: Demographic characteristics, Part 2: Usage of antibiotic against Knowledge of antibiotic and Part 3: Health assurance towards antibiotic usage. Complete detail against each domain represented in the theoretical frame work of the irrational antibiotic use to risk assessment in Figure 1, given below. The questionnaire was designed in two language versions (English and Malay). English version of the questionnaire was developed initially which was then translated into Malay language. Face and content validation of the questionnaire was done. The Malay version was also counterchecked to ensure correct and appropriate translation was made. Pilot study was conducted with 20 subjects randomly selected from the study site. Reliability testing was carried out for the Part 2 statements regarding knowledge towards antibiotic usage based on the responses from pilot testing. The results showed internal consistency of the items tested with the Cronbach's α value 0.85.

Study population and sample size

On monthly basis the sample was analysed by using Raosoft ® web, the minimum of 380 sample size was needed with CI 95% from Penang Hospital. While 670 with different distribution pattern was collected from 20 different retail pharmacies across whole Pinang by using cluster random sampling technique with CI 95%. Total sample size was 1050, a total of 1150 questionnaires were distributed in account of 20% non response rate. The randomly selected individuals must fulfill the following criteria: inclusion criteria; adults more than

18 years old. Ability to read or understand English and Malay. Ever heard of the term 'antibiotic'. Exclusion criteria; physically unfit, significant cognitive impairment or psychiatric problem.

Ethical Consideration

Approval had been granted by the Clinical Research Centre (CRC) under National Institute of Health (NIH), Ministry of Health Malaysia to conduct this survey in Penang Hospital. The registration ID was NMRR-09-6-3235. Ethical approval was also obtained from Ministry of Health Research and Ethics Committee (MREC) with the reference (2) KKM/NIH SEC/08/0804/P09-21.

Data collection procedure

The investigator was around while waiting for the participants to complete the questionnaire. A thorough checking of returned questionnaire was done and participants were requested to fill in the missing information shall there be any incomplete questionnaire detected. Help was given especially to the elderly participants to complete the questionnaire including reading the questions and filling in the answer. However, no further explanation was provided which might contribute bias to this study.

Statistical analysis

Study analysis was made by using inferential as well as descriptive statistic techniques by using Statistical Package for Social Sciences (SPSS 13®). Demographic part was analysed by using descriptive statistics and Chi-square was employed to identify the significant values by using Pearson correlation value, later hypothesis evaluation was made by using Risk ratios/Odd ratios against the expected outcome of the study.

RESULTS

A total of 1150 questionnaires were distributed to the general public. However, 11 of the questionnaires were found incomplete and therefore excluded from the analysis. This ended up with a total sample of 1139 for this study.

As shown from the summary of demographic characteristics in Table 1, there was almost an equal distribution for most of the age groups except those >60 years old were around half as less compared to the others. The mean age of the respondents was 43±14 years. Majority of the respondents were male (53.9%) as compared to female (46.1%). From the distribution of races, it was shown that Malay accounted for the highest (46.8%) followed by Chinese (35.8%), Indian (15.7%) and others (1.7%). A high proportion (70.8%) of the respondents was married. Almost all of the respondents (96.8%; n:1102) had completed secondary school and above.

As for the employment status, there was almost half of them were employed for wages (49%), followed by retired/unemployed including students (27.7%). There was an equal distribution between self employed and housewife. The majority of the respondents had monthly income ranged from RM1000-2000 (US\$ 295 - 591 approx) (28.9%), with the least group >RM4000 (US\$ 1184 approx.) (8.1%). Only a minority of the respondents' and family members' occupation were related to health care with 18.1% and 21.3% respectively. Most of them were non smoker (85.8%) and non alcoholic (93.1%). There was almost an equal distribution between respondents who were healthy or having chronic medical condition. Those having chronic illness were suffered from hypertension (19.4%), followed by diabetes (13.5%), heart problem (8.6%), respiratory illness (5.9%) and kidney disease (4.2%). Other diseases (15.9%) reported were for example systemic lupus erythematosus (SLE), cancer, skin problem and thyroid disorders. The most frequency of clinic/pharmacy visits for the last 12 months among the respondents was between 1 to 4 times (55.7%).

There was 28.9% (n:329) of the respondents had the experience of using antibiotic within one month before the survey was conducted. Statistically significant differences were noted between age group ($p=0.027$), race ($p=0.014$), and frequency of visit to clinic/pharmacy in the last 12 months ($p<0.001$) in response to the use of antibiotic within prior one month to the survey. Those who took antibiotic varied among age group with the

highest use among the younger generation of 31-40 years old (36.3%) and 18-30 years old (32.3%). The elderly (>60 years old) was the least group who used the antibiotic recently (10.4%). Among the different races in Malaysia, Indian constituted for the highest usage of antibiotic (39.1%) followed by Malay (31.9%) and Chinese (21.9%). Respondents who had the most frequent visit (>10 times) to clinic/pharmacy over the previous 12 months accounted for the highest usage of antibiotic (40.5%), while those visited 5-10 times and 1-4 times were 39.4% and 28.2% respectively.

Respondents providing incorrect responses with the statement 'you can stop taking a full course of antibiotic if your symptoms are improving' were significantly more likely to be younger (18-30 years old) (37.6% vs others <22%, $p=0.009$) and having primary or lower education level (53.8% vs others <26%, $p=0.004$). The only predictor for statement 'the effectiveness of treatment is reduced if a full course of antibiotic is not completed' was significantly associated with more respondents having chronic medical condition getting the correct response (65.2% vs 58.9%, $p=0.025$).

Ratio analysis provided significant amount of information regarding the risk assessment of different confounding and subseries generated factors against the outcome of irrational use of antibiotics. Values are mentioned in table 2 and 3. It has been found that knowledge level has less likelihood towards the sources of antibiotics and people taking antibiotics from different retail pharmacy are 200 percent more likely to develop or adopt irrational use pattern as to out-patient pharmacy of Penang hospital (RR 3.34, 95% CI 1.95 - 4.60).

DISCUSSION

Current findings identified a unique pattern of risk development against the irrational use of antibiotics among the society members. It was found that socio-demographic section of the study has individual significant effect on both 'Behaviour to antibiotic resistance' (RR 4.53, CI 95% 3.12 - 5.31) and 'Irrational use of antibiotics' (RR 3.67, CI 95% 2.29 - 3.95). but the flow was seem to be unidirectional in both cases (refer to fig. 01). Whilst among socio-demographic the 'Marital status (married)' was 3 times more likely towards irrational antibiotic behaviour. Socio-economic status (RR 2.10) with moderate economic status against high and

low economic status and Race (RR 2.35) with Malays as compared to Chinese and Indians. Occupation showed no intermediate behaviour to adapt irrational antibiotic use (17-19).

In our theoretical framework second uni-directional subseries were initiated with 'behaviour modification to antibiotic resistance', gone through two dependent domain 'knowledge & awareness' and 'health assurance'. At this level of analysis our findings diverted to two different pathways, i.e., Knowledge level and antibiotics resistance. Complete outlet analysis was done in Table 3. But we would like to generate a hypothesis at this point that: either individual behavior has any influence on knowledge and lead to antibiotic resistance?.. Therefore we come across with some discussions regarding the compliance and antibiotic course completion etc. against the level of knowledge on responsive behaviour on antibiotic usage (16, 18, 20). Our study showed that responsive behaviour and high level of knowledge towards antibiotics less likely to adopt antibiotic resistance as to non-responsive low-level of knowledge (RR 0.76, 95% 0.10 - 1.10), while irresponsible attitude towards antibiotics use and altered perception towards antibiotic course completion responds were five (5) times more likely to develop antibiotic resistance as per irrational use of antibiotics as to responsible attitude respondents (RR 5.12, CI 95% 3.37 - 7.89) (15, 17, 27).

At this point of discussion, we found that only 'knowledge & awareness' was not reflecting the final outcome of irrational use but moving through by another articulate subseries and so-named 'Health assurance' according to sub-items involved (3). Detail findings were presented in table 03, but major findings showed that each sub-domain of knowledge and awareness series had a subsequent effect on other side of Health assurance sub-domains. It was found that reasons of antibiotic use (fever and cough) more likely to drop clinical visits and produce irrational behavior (RR 4.76, CI 95% 2.56 - 6.13) as compare to clinical manifestations (like UTI's, STD's, Lungs infections etc) (17,27). Similarly our estimations reflect that low level of knowledge with irresponsive behavior three (3) times more likely to evolve least Health assurance calculation (like chronic medical conditions, smoking, alcohol etc) and thus with such perimeters responds were two (2) times at risk of irrational use (RR 2.21, 95% 1.40 - 2.79); regardless to the matter of fact either non-compliance or knowledge induced behaviour change.

Our study identified a direct proportional pattern of relationship between knowledge & awareness with Health assurance, so as if knowledge level and awareness increases in the community will cause a direct increase in health assurance values to upper limits and less likely to develop irrational behaviour of antibiotic use (16-20).

Although our research theoretical framework provides a comprehensive overview against all the associated risk in the community to identify and evaluate the extend of risk(s) but still we need to identify some psychological issues concerning irrational use of antibiotics at community level. It is concluded that respondents to retail pharmacy were at high risk and more likely to be indulge in irrational antibiotic use as to Out-patients of Penang hospital.

Our research work was a comprehensive work among the diversity of research against this topic. We find out the risks and extend of risk(s) to which a person or community member least likely to identify the irrational use of antibiotics. This research provides a idea that how we can produce a therapeutic plan or health policy against the irrational or non-compliance use of antibiotics in the society. Last but not least through this lead of research we concluded that current policies or control measure are ineffective against the human behaviour and least effective against the treatment compliance. While human behaviour and addition to certain community practices cause a irrational antibiotic use, cause non-compliance with antibiotics.

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