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## **PHARMACOETHICS: DEVELOPMENT AND VALIDATION OF INSTRUMENT TO MEASURE KNOWLEDGE, PERCEPTION AND AWARENESS OF GRADUATING PHARMACY STUDENTS ON PHARMACY CODE OF CONDUCT IN MALAYSIA**

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### **Abstract**

*Pharmacoethics has not been fully explored in Malaysia. This study aimed to create a psychometric instrument based on the Malaysian Code of Conduct for Pharmacists (PCC) for the measurement of its knowledge, perception and awareness among graduating pharmacy*

*students in Selangor and KL, Malaysia, and to test its validity and reliability. Instrument was designed and refined via an expert group discussion and statistical analysis. It contains three sections; personal information, knowledge on PCC and perceptions and awareness on PCC. The instrument was administered randomly to 260 students among 6 institutions that offers undergraduate pharmacy course. Exploratory factor analysis was for validity of the instrument and reliability was measured via Cronbach's alpha value. Two factors were extracted from 30 items in the knowledge on PCC section and two main factors were extracted from 14 items in perception and awareness on PCC section, classified as General-Knowledge, Practical-Knowledge, Awareness and Perception. After deletion of total of thirteen unstable items, Cronbach's alpha values were 0.80 (General-Knowledge), 0.63 (Practical-Knowledge), 0.85 (Awareness) and 0.53 (Perception). The scores were: General-Knowledge=53±33(satisfactory), Practical-Knowledge=86±14(good), Awareness=50±19 (moderate) and Perception=46±17(low). These results indicated early evidence of the instrument's validity and reliability for use in Malaysia and can be used in future studies.*

**Keywords**

Pharmacoethics, KAP, Malaysia, Pharmacist, Code of Conduct

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**1. Introduction**

Pharmacist is a health professional who assists individuals in making the best use of medications. The profession requires high ethical standards and integrity. A pharmacist needs to have these qualities toward the patients as well as other healthcare providers in order to gain their trust so that mutual benefits can be achieved by all parties. Integrity is essential in both learning and practice. If there is lack of integrity in the learning (education) process, integrity during practice may suffer adversely (Chukwuemeka et al., 2013).

Pharmacoethics is the study of the ethics as applied to pharmacy practice including drug counselling , sales, prescription screening, and the application of pharmaceuticals (Sazrina et al., 2014). In this profession, the health and welfare of the public has always been the highest concern among practitioners. Hence, to ensure that this principle is consistently maintained, a minimum standard of proper conduct and professionalism was established as guidelines for practitioners. It is called as pharmacy code of conduct. These standards also serve as a reference

when the Board considers cases of misconduct in a professional sense (University of Charleston School of Pharmacy, 2013).

Code of Conduct for Pharmacist and Bodies Corporate (PCC) in Malaysia was published by Pharmacy Board of Malaysia. It consists of three parts including part one which is introduction, code of conduct as the second part and final part is the disciplinary jurisdiction and procedure. The first part includes preamble, use of terms and statement on infamous or disgraceful conduct in a Professional Sense and Misconduct. The second part consist of four articles which are professional responsibility, abuse of professional privileges and skills, conduct derogatory to the reputation of the profession and finally is the advertising, canvassing and related professional offences. The final part includes disciplinary jurisdiction of the board, procedure of inquiry, punishments and finally is the appeal (Pharmacy Board of Malaysia, 2009).

Questionnaires are defined as measurement tools (Giesen et al., 2012). Development of questionnaires requires reliability and validity test. The further mentioned that Reliability shows how closely the results of repeated tools of the same concept. Reliable tools will produce the same result when they were tested on the same person for two times at different intervals. Cronbach's alpha is one of the statistical techniques (Christmann & Aelst, 2006), that was used to determine the reliability in this study.

## **2. Literature Review**

Pharmacists in Malaysia are employed by many organizations, majorly hospitals, retail pharmacies, pharmaceutical companies, clinical research organizations, universities and government regulatory bodies. According to National Pharmaceutical Control Bureau (NPCB), they are required to be registered with the Pharmacy Board and have an annual certificate (<http://portal.bpfk.gov.my/>, accessed on April 2, 2015).

The number of registered pharmacists including both provisional and fully registered have been increasing from 799 in 2005 to 1856 in 2011 (<http://www.pharmacy.gov.my/v2/ms/content/pendaftaran-lembaga-farmasi-tahun-2005-2014.html>, accessed on April 2, 2015). The pharmacist to population ratio in 2014 was 1:2,437. However, this number is still not sufficient and the Malaysian government target is approximately 1:2000. Hence, the job prospects for pharmacists are quite good in Malaysia, and there are still shortage of pharmacists in both the public and private sectors.

Graduating bachelors of pharmacy students which are third and final year students are compulsory to be exposed with law of pharmacy educations. One of the requirements set by Pharmacy Board of Malaysia to become a fully registered pharmacist is by passing the forensic examination. The examination consists of 100 Multiple Choice Questions (MCQ) in an open book format. The questions encompass pharmacy law, Code of Conduct and aspects of pharmacy practice such as National Medicines Policy (DUNas) and Good Governance of Medicine (GGM).

### **3. Objectives of the Study**

#### **3.1 General Objective**

To develop an instrument to study knowledge, perception and awareness of graduating pharmacy students on the Pharmacy Code of Conduct for Pharmacist and Bodies Corporates by Pharmacy Board of Malaysia (PCC) in Selangor and Wilayah Persekutuan Kuala Lumpur.

#### **3.2 Specific Objectives**

1. To validate and test the reliability of the newly developed instrument to study knowledge, perception and awareness of graduating pharmacy students on PCC in Selangor and Wilayah Persekutuan Kuala Lumpur.
2. To evaluate the knowledge, perception and awareness of graduating pharmacy students on PCC in Selangor and Wilayah Persekutuan Kuala Lumpur.

### **4. Research Methodology**

This study was a cross sectional study by using questionnaire as the instrument. It was conducted in Selangor and Wilayah Persekutuan Kuala Lumpur. 6 institutions were chosen for this study due to high potential benefit and limited ethical studies were done. They consist of public institution of higher education (UKM, UM, UiTM) and private institution of higher education (CUCMS, IMU, TAYLORS UNIVERSITY). The study started in February 2015 and ended in December 2015. Data collection was made starting April 2015 and finished early September 2015. Subjects were the graduating pharmacy students which consist of third and fourth year Bachelor of Pharmacy students. Simple random sampling majorly via online survey and systematic random sampling was applied in this study. The sample size needed for development of psychometric instruments is determined by the number of items. Rouquette &

Falissard (2011) published that the ratio of respondent per item varies from 1:3 to 1:10 is widely used and accepted. Meaning that, for the ratio 1:3, for each item developed, sample size needed is three (3). This study applied ratio of 1:5. The total respondents targeted in this study were 260. It was done in three phases: Pilot Study Phase I: Development of Instrument and Initial Validity Test (Face and Content Validity), Pilot Study Phase II: Construct Validity and Reliability and Phase III: Data Analysis.

#### **4.1 Pilot Study Phase I: Development of Instrument and Initial Validity Test (Face and Content Validity),**

The questionnaire was constructed manually according to The Code of Conduct for Pharmacist and bodies corporate (PCC) by Pharmacy Board of Malaysia. The preliminary questionnaire was constructed in English Language assuming that all pharmacist students in Malaysia have adequate English competency and understanding. The post Phase I questionnaire had a total 51 questions was divided into three different sections which are demographic background (7 items), Knowledge on PCC (30 items) and Perception and Awareness on PCC (14 items). The questions were formulated in both negative and positive constructs to avoid stereotype answers. The questionnaire was ideally constructed by searching relevant real ethical issues including frequently asked questions on the websites.

In this phase, after the questionnaire was constructed, an expert group discussion was held. After corrective action was taken, the items were further tested for its face validity. During face validity, a comments or suggestion box was provided and was distributed randomly to 10 respondents that met the inclusion criteria in order to allow them to comment and give their suggestion on each question. All 10 respondents during face validity were excluded from the real research study. Corrections were done according to the comments and suggestion during face validation. A cover letter with an introduction of the researcher and the researcher background was attached to the questionnaire.

#### **4.2 Pilot Study Phase II: Construct Validity and Reliability**

After Phase I was executed, next stage was the Pilot Study Phase II. During this phase, construct validity and reliability testing were carried off. Exploratory Factor Analysis (EFA) was used as construct validation. This EFA method helps to reduce the number of variables by grouping the variables into specific domain and construct high factor loadings indicating strong relation with each other.

Reliability test was carried out for each domain by using Cronbach's alpha method. This test was carried out after the data from pilot study were obtained. Correlation between items as a group was identified after Cronbach's alpha was run (Tavakol & Dennick, 2011).

#### **4.3 Phase III: Data Analysis**

All the tests were run by using Statistical Package for the Social Sciences (SPSS). Data analysis and discussion of the result was carried out.

#### **4.4 Scale for Data Analysis**

Three scales were adopted and adapted for the interpretation of the results of this study. The scale for Level of Knowledge was adopted from Perera et al.,(2013) and as presented in Table 4.1.

**Table 4.1:** *Level of Knowledge based on percentage of score*

<b>Percentage Score (%)</b>	<b>Level of Knowledge</b>
80-100	Good
50-79	Satisfactory
0-49	Poor

The scale for Level of Perception was adopted from Coban and Yurdagul, (2014), and as presented in in table 4.2

**Table 4.2:** *Level of Perception based on percentage of score*

<b>Percentage Score (%)</b>	<b>Level of Perception</b>
60-100	Acceptable
0-59	Low

The scale for Level of Awareness was adopted from Thakrar et al., (2014) and as presented in Table 4.3

**Table 4.3:** *Level of Awareness based on percentage of score*

Percentage Score (%)	Level of Awareness
70-100	Highly aware
40-69	Moderately aware
0-39	Lowly aware

## 5. Results

### 5.1 Demographic Frequency

From 260 respondents, there were 205 female respondents and 55 male respondents where majority of the respondents age were between 22 and 23. There were variety of ethnicity where majority of the respondents were Malay then followed by Chinese and Indian. Besides that, the majority of total respondents were from third year (58%) compared to final year students (42%). Among the responses, the highest respondents were from CUCMS students and lowest were from TAYLOR'S UNIVERSITY and UM. Most of the respondents were funded by Jabatan Perkhidmatan Awam (JPA) following Majlis Amanah Rakyat (MARA) and others. They all preferred English language as the medium of study.

### 5.2 Exploratory Factor Analysis (EFA) for Construct Validity

Initial EFA on 30 items to test knowledge of students on PCC were based on eigenvalue more than 1, extracted 4 domains from the total items. Further analysis was done and 4 domains were set. The result for 4 domains showed that the highest factor loading for items in the fourth domain was less than 0.5. The domains were then set from 4 to 3 and the result showed that the highest factor loading for the items in third domain still less than 0.5. Lastly the domains were reduced from 3 to 2 and finally the result showed that the highest factor loading for the items in second domain was higher than 0.5. Items with higher factor loadings are more acceptable which showed that they correlated strongly with each other in the domain and that represent a valid domain. A total of 9 items were removed from the questionnaire due to very low factor loadings and they did not belong to any of the domains. The rest of items were grouped into domain 1 and 2. The domains were then named as General knowledge of PCC (domain 1) and Practical knowledge of PCC (domain 2).

EFA on 14 items to test Perceptions and Awareness on PCC at first were based on eigenvalue more than 1 and 3 domains were extracted from total items. Further analysis was done, and 3 domains were set. The result showed that the highest factor loading for items in the third domain was higher than 0.5. Only one item was removed (PA5) in this analysis. Since the third domain only contained 2 items, 2 domains were set and further analysed. The result showed that the highest factor loadings for second domain was higher than 0.5. The domains were then named awareness on PCC (domain 1) and perception towards PCC (domain 2).

### **5.3 Cronbach's Alpha for Reliability Test**

For the knowledge section, the Cronbach's alpha for total 9 items in domain 1 (General Knowledge on PCC) was 0.48. However after removing item K5, the Cronbach's alpha value increased from 0.48 to 0.56. Further Analysis was done, item K17 was removed, and the Cronbach's alpha value was increased from 0.56 to 0.68. When item K6 was removed, the Cronbach's alpha was increased from 0.68 to 0.80. Therefore, items K5, K7 and K6 were removed from domain 1. The Cronbach's alpha for total 12 items in domain 2 (Practical Knowledge on PCC) was 0.63. Further Analysis was done, however if any item was removed, the highest possible alpha value is still 0.63. Therefore, all 12 items were remained in domain 2.

In the perception and awareness section, the Cronbach's alpha for total 10 items in domain 1 (Awareness on PCC) is 0.85 and for total of 3 items in domain 2 (Perception towards PCC) was 0.53. Further analysis was done for domain 2 but the alpha will not be increased if any of the 3 items was deleted. Therefore, final items in domain 1 (Awareness on PCC) were 10 items and 3 items in domain 2 (Perception towards PCC).

Even though value of 0.53 for Cronbach's alpha can considered as weak reliability, researcher decided to proceed with it in this study due to its importance and time limitation factor.

### **5.4 Evaluation of Knowledge, Perception and Awareness on PCC**

The response were further analyzed to measure the student's knowledge, perception and awareness on the PCC and then interpreted by using the scales. The result is presented in table 5.1 below.



**Table 5.1:** *Mean level of knowledge, awareness and perception based on percentage of score and the interpretations*

<b>Domains</b>	<b>Mean Percentage of Score</b>	<b>Interpretations</b>
General Knowledge on PCC	53 ± 33	Satisfactory
Practical Knowledge on PCC	86 ± 14	Good
Total Knowledge on PCC	75 ± 15	Satisfactory
Awareness on PCC	50 ± 19	Moderate
Perception towards PCC	46 ± 17	Low

## **6. Discussion**

### **6.1 The evaluation of level of total knowledge on PCC of graduating pharmacy students**

The mean and standard deviation of level of knowledge score of graduating pharmacy students in this study was 75% and 15 respectively, indicating satisfactory level of knowledge referring to the adopted scale by Perera et al., (2013).

The score obtained from the finding was compared with a study conducted by Pattanshetti (2010), which evaluated the knowledge, attitude and practice on healthcare ethics and law among doctors and nurses in Barbados, North America. The paper analyzed 159 responses from doctors and nurses comprising junior doctors, consultants, staff nurses and sisters-in-charge. The frequency with which the respondents encountered ethical or legal problems varied widely from 'daily' to 'yearly'. 52% of senior medical staff and 20% of senior nursing staff knew little of the law pertinent to their work. 11% of the doctors did not know the contents of the Hippocratic Oath whilst a quarter of nurses did not know the Nurses Code. Nuremberg Code and Helsinki Code were known only to a few individuals. 29% of doctors and 37% of nurses had no knowledge of an existing hospital ethics committee. Physicians had a stronger opinion than nurses regarding practice of ethics such as adherence to patients' wishes, confidentiality, paternalism, consent for procedures and treating violent/non-compliant patients ( $p = 0.01$ ). In another study by Maros & Abdul Rahman (2017) on the youths' knowledge and practices of the palm oil industry in Malaysia found that majority (82.2%) of the respondents' knowledge on palm oil were satisfactory and below satisfactory levels. They opined that youths should be exposed to the job opportunities in oil palm industry in order to improve their knowledge.

In contrast with a study conducted in the West Bengal, India to evaluate the students' knowledge of the code of conduct. It was a descriptive cross-sectional study which was carried out from July to November 2009 among the 322 medical undergraduates of different batches, from second year MBBS to the final year, of a medical college in West Bengal, India. The total achieved score shows that more than half of the respondent students had a "good" score [61 - 70)], in which the proportion of final year students was low, and 37.26% students achieved a "fair" score [51 - 60] (Chatterjee & Sarkar, 2009).

This study outcome was different from the study in Barbados which showed low level of knowledge in healthcare ethics which was targeted for medical doctors and nurses which might be due to the different in learning medium used during their undergraduate studies such as traditional didactic approach. Conversely, study in India showed majority of good level of knowledge on healthcare code of conduct maybe due to different learning approach .However, more studies on relationship between the learning approach and ethical code of conduct is needed to justify this problem. Reason of satisfactory level of knowledge on pharmacy code of conduct of graduating pharmacy students in this study might be due to the adequate expert-oriented learning medium that was implemented in majorly school of pharmacy in Malaysia. A study by Roberts et al, (2004) among medical students at a New Mexico school found that respondents preferred clinical and expert-oriented learning like case conferences, and workshops involving a multidisciplinary approach over the traditional didactic approach which was also shown as significantly ( $p < 0.001$ ) effective.

## **6.2 The evaluation of level of perception towards PCC of graduating pharmacy students**

The mean and standard deviation of level of perception score of graduating pharmacy students towards PCC in this study were 46% and 17 respectively. Referring to the adopted scale in 2.9, the level of perception was low.

A cross-sectional survey was performed by Sharif et al (2011) on a sample of Iranian pharmacists attended in continuous education programs in 2010. Based on the pharmacists' perception and attitude toward common ethical problems, 9 Likert-type scale scenarios were designed. A thousand pharmacists were surveyed and 505 questionnaires were filled. For the whole questionnaire the strongly disagree answer was the most ethical answer. On a scale from 1-5 on which 5=strongly disagree, the total score of pharmacists ethical attitude was  $17.69 \pm 3.57$ . For easier analysis the researcher considered the score of 1 for agree and strongly agree

answers, score of 2 for neutral answers and score of 3 for disagree and strongly disagree answers. The total score in autonomy for all participants was  $6.25 \pm 1.85$  out of 9, in non-maleficence  $5.14 \pm 1.17$  out of 6 and in justice was  $2.27 \pm 0.89$  out of 3. The level of perception based on this result was acceptable.

A study was conducted in Calgary, Alberta, Canada by Oberle & Hughes (2001) in order to identify and compare doctors' and nurses' perceptions of ethical problems. In this qualitative study a total of seven doctors and 14 nurses working in acute care adult medical-surgical areas, including intensive care, were asked to describe ethical problems that they frequently encounter in practice. Interviews were taped and transcribed. The result showed that all participants experienced ethical problems around decision making at the end of life. The core problem for both doctors and nurses was witnessing suffering, which engendered a moral obligation to reduce that suffering. Uncertainty about the best course of action for the patient and family was a source of moral distress. Competing values, hierarchical processes, scarce resources, and communication emerged as common themes. The key difference between the groups was that doctors are responsible for making decisions and nurses must live with these decisions. Each group, therefore, asked different questions when encountering and interpreting sources of moral distress.

Perception level towards PCC in this study was at low level might be due to the low exposure on the ethical issues and low interest to study the pharmacy code of conduct. Based on study above, the Iranian pharmacist showed an acceptable perception level might be because of working pharmacist are dealing with real patients and real situations where they must implement the pharmacy code of conduct during their working. Their exposure on current ethical issues and interest may be high by practicing the ethical value. In contrast, pharmacy students did not implement any of the code of conduct yet and because they just receive the theory education in the class. However, not all working pharmacist can be assumed to practice real ethical value during their working. For example, study at Canada above shows that even medical doctors and nurses were facing ethical problems during working. Hence, more studies should be done to identify the real problems when dealing with perception and awareness of ethics in pharmacy and other healthcare professionals.

### **6.3 The evaluation of level of awareness on PCC of graduating pharmacy students**

The mean and standard deviation of level of awareness score of graduating pharmacy students on PCC in this study were 50% and 19 respectively. Referring to the adopted scale, the level of awareness was moderate.

In contrast to another cross-sectional study to assess the level of awareness of nurses on patient right teaching in hospital that was conducted in Turkey by Nejad et al., (2011). In this study 156 nurses were randomly selected. Two-part questionnaire was used for data collection. The validity and reliability of questionnaire was determined and then it was distributed between subjects. Results showed that the level of awareness was majorly high with a statistic of 58.33%, 39.10% and 2.56% of nurses have good, medium, and poor levels of awareness respectively. The most of the nurses (%95.51) were aware of “right to privacy protection and ensure confidentiality of information”.

Besides that, Makhani et al., (2011) had conducted a study in Indore city, India to assess the level of awareness of various ethical and legal issues and code of conduct amongst medical professionals. A total of 75 physicians, including general practitioners, specialists of various specialties practicing in Indore were selected and were given a standardized questionnaire to answer. Results showed moderate awareness on medical ethics level.

Generally, graduating pharmacy students in this study had a moderate awareness on PCC. The possible reasons of these results might be that the students had high self-initiative to concern on the current misconduct and unethical issues regarding health related problems. This study was supported by both studies in Turkey and India where level of awareness on bioethics were higher than moderate.

## **7. Limitation and Conclusion**

One of the limitation for this study was time factor where the study was performed only within a year. Another limitation was that the low response rate, even though the sample size obtained was 260 but it could be higher.

In conclusion, despite of the limitations, a psychometric instrument was developed by validation procedures using EFA and reliability tested by using Cronbach’s alpha. Further analysis was done to investigate the level of knowledge, perception and awareness on PCC of graduating

pharmacy students in six different institutions located in State of Selangor and Wilayah Persekutuan Kuala Lumpur. The outcomes from this study showed that General Knowledge =  $53 \pm 33$  (satisfactory), Practical Knowledge =  $86 \pm 14$  (good), Awareness =  $50 \pm 19$  (moderate) and Perception =  $46 \pm 17$  (low). Hence, students should have adequate level of knowledge, perceptions and awareness on PCC in order to holistically reduce the number of ethical issues. As an example, a study on engineering students from Mexican State University by Tinajero-Villavicencio and Perez-Fraguso (2015) published that students perceived that engineer training should be improved starting from beginning of their university studies, and not in later years. Thus, further studies are required to identify specifically the reasons for the significant different and further actions will be taken to improve the level of knowledge, perceptions and awareness on PCC of the study population. Future research should be able to capture the level of knowledge, perception and awareness on PCC of graduating pharmacy students in the whole Malaysia since this research had already developed a validated tool to measure it. Research can even be more elaborated by comparing the graduating pharmacy student population with the practicing pharmacist population.

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