# A QUALITATIVE AND QUANTITATIVE ASSESSMENT OF STARZ-DRP FOR TRIAGE ACTION PLAN, DETERMINE DRUG-RELATED PROBLEM AND COUNSEL SELF-CARE CUSTOMER IN MALAYSIA COMMUNITY PHARMACIES

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by

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# LIST OF ABBREVIATIONS

Ave	Averages
BMD	Bone Mineral Density
CAP	Consumers' Association of Penang
СР	Community pharmacist
CPEP	Continuing Pharmacy Education Program
CPs	Community pharmacists
CVDs	Cardiovascular diseases
CVI	Content Validity Index
CVR	Content Validity Ratio
DRPs	Drug-Related Problems
et al	and other
GCP	Good Clinical Practice
GP	General practitioner
GPs	General practitioners
HREC	Human Research Ethics Committee
I-CVI	Item-Content Validity Index
MAP	Malaysian Academy of Pharmacy
MCPG	Malaysian Community Pharmacy Guild
МоН	Ministry of Health
MMA	Malaysian Medical Association
MNMP	Malaysian National Medicine Policies
MPS	Malaysian Pharmaceutical Society
NPM	Non-Prescription Medicine

NSAIDs	Non-steroidal anti-inflammatory drugs
PC	Pharmaceutical care
Pc	Probability of chance agreement
PMPS	Penang Medical Practitioner's Society
PSD	Pharmaceutical Services Division
S-CVI	Scale-level Content Validity Index
SPSS	Statistical Package of Social Sciences
UA	Universal agreement
USM	Universiti Sains Malaysia

# PENILAIAN KUALITATIF DAN KUANTITATIF STARZ-DRP UNTUK PELAN TINDAKAN TRIAGE, MENENTUKAN MASALAH BERKAITAN UBAT DAN KAUNSELING PELANGGAN DI FARMASI KOMUNITI MALAYSIA

#### ABSTRAK

Peranan ahli farmasi komuniti (CP) kini berkembang daripada menyediakan perkhidmatan berorientasikan produk kepada menyediakan perkhidmatan berorientasikan pesakit. Tindakan sedemikian berpotensi untuk mungkin meningkatkan imej CP dalam persekitaran perkhidmatan kesihatan. Namun, senario itu mungkin tidak dapat dilaksanakan di Malaysia. Oleh sebab itu, adalah penting untuk meneliti perspektif pihak-pihak berkepentingan yang berkaitan di Malaysia berkenaan peranan tambahan CP. Perkara penting yang paling utama adalah untuk menentukan kemungkinan meletakkan gambaran pendekatan prospektif bagi membantu CP melaksanakan peranan tambahan mereka terutamanya dalam mengatur pelan tindakan saringan dan klasifikasi pesakit serta mengenal pasti masalah berkaitan ubat (DRPs). Objektif utama kajian adalah untuk menjalankan penyelidikan kualitatif bagi meneliti persepsi pihak berkepentingan yang berkaitan berkenaan dengan peranan CP dan STARZ-DRP sebagai instrumen prospektif untuk melaksanakan aktiviti saringan dan klasifikasi serta menentukan DRP. Objektif kedua kajian adalah untuk melaksanakan kajian kuantitatif bagi mendapatkan bukti kesahan kandungan item cadangan dalam STARZ-DRP untuk mengesahkannya sebagai instrumen yang mungkin membantu CP melaksanakan peranan mereka sebagai pelindung ubat. Dalam kajian kualitatif, sekumpulan pihak berkepentingan (n = 12) terlibat dalam temu bual bersemuka. Penemu bual menggunakan soal selidik separa berstruktur untuk

mendapatkan data mengenai idea, perasaan dan persepsi mereka terhadap perkara yang dipersoalkan. Audio kajian direkodkan, ditranskripsikan dan dikodkan untuk menentukan tema kajian. Dalam kajian kuantitatif, sekumpulan pakar kandungan dijemput untuk menyertai ujian kesahan kandungan. Penilaian mereka menentukan nilai Nisbah Kesahan Kandungan (CVR), Indeks Kesahan Kandungan (CVI) dan Kappa Terubah Suai. Seterusnya, sekumpulan pakar dijemput untuk terlibat dalam statistik Kesahan Muka. Seramai lapan orang pihak berkepentingan bersetuju menyertai penyelidikan kualitatif. Lima tema yang baru muncul dikenal pasti: (1) CP lebih fokus kepada amalan yang berorientasikan pengurusan, (2) CP harus melaksanakan perkhidmatan berorientasikan pesakit, (3) Tanggungjawab menyaring dan mengklasifikasikan pelanggan, (4) Pendekatan bersistematik untuk aktiviti saringan dan klasifikasi, (5) STARZ-DRP merupakan pendekatan yang bersistematik untuk membuat keputusan berkaitan saringan dan klasifikasi. Dalam penyelidikan kuantitatif, sekumpulan pakar kandungan (n = 14) bersetuju untuk menyertai kajian. Penilaian mereka digunakan untuk menentukan nilai CVR, CVI dan statistik Kappa Terubah Suai. Dapatan kajian menyatakan bahawa empat elemen dalam STARZ-DRP mempunyai skor kurang daripada 0.51. Elemen-elemen tersebut ialah: (1) Adakah anda berhenti mengambil ubat apabila anda berasa lebih baik? (2) Adakah anda berhenti mengambil ubat apabila anda berasa lebih teruk? (3) Adakah anda mempunyai apa-apa kebimbangan tentang kos terapi ubat? (4) Adakah anda mengandung? Item cadangan yang lain menunjukkan nilai CVI dan statistik Kappa Terubah Suai masing-masing lebih daripada 79% dan 0.74. Hasil kajian mencerminkan kemungkinan untuk menerima item sebagai sesuai dan sangat baik untuk dikekalkan dalam instrumen. Tujuh orang pakar terlibat dalam ujian Kesahan Rupa. Kajian mendapati item-item yang lain dalam STARZ-DRP mempunyai skor

impak item lebih daripada 1.5. Ia menunjukkan penampilan penerimaan item dalam STARZ-DRP sebagai instrumen yang berpotensi untuk menasihati pelanggan jagaan diri. Kesimpulannya, kajian ini mendapati semua pihak berkepentingan berkongsi persepsi yang serupa bahawa CP perlu memperluaskan peranan mereka dalam menyediakan perkhidmatan yang berorientasikan pesakit. Majoriti pihak berkepentingan bersetuju bahawa STARZ-DRP merupakan instrumen prospektif yang membantu CP melaksanakan aktiviti saringan dan klasifikasi serta menentukan DRP. Perkara yang lebih penting ialah kajian menunjukkan bahawa item cadangan dalam STARZ-DRP telah disahkan dan boleh melatih CP untuk melaksanakan peranan mereka dalam persekitaran farmasi komuniti. Kajian ini juga mengakui keperluan melaksanakan ujian kesahan kandungan sebagai cara untuk mengesahkan item cadangan dalam instrumen yang baru dibangunkan.

# A QUALITATIVE AND QUANTITATIVE ASSESSMENT OF STARZ-DRP FOR TRIAGE ACTION PLAN, DETERMINE DRUG-RELATED PROBLEM AND COUNSEL SELF-CARE CUSTOMER IN MALAYSIA COMMUNITY PHARMACIES

#### ABSTRACT

The roles of the community pharmacists (CPs) are currently evolving from providing product-oriented to patient-oriented services. Such course of action might have potential to enhance the image of CPs in the healthcare settings. Nonetheless, the scenario might not be possible to implement in Malaysia. For that reason, it is essential to examine the perspectives of relevant stakeholders in Malaysia regarding CPs' extended roles. Foremost, it is critical to determine the possibility of putting in the picture of a prospective approach to help CPs to perform their extended roles particularly in making a triaging action plan and identifying drug-related problems (DRPs). The primary objective of the study is to perform qualitative research to investigate the perceptions among the relevant stakeholders of CPs' roles and STARZ-DRP as a prospective instrument to perform the triaging activity as well as to determine DRPs. The study's second objective is to execute a quantitative study to generate the content validity evidence for each construct item in STARZ-DRP to substantiate it a possible instrument to assist CPs executing their role as a medication protector. In the qualitative study, a group of stakeholders (n = 12) involved in a face-to-face interview. The interviewer used a semi-structured questionnaire to obtain the data about their ideas, feelings, and perceptions of the matter in question. The study was audio-taped, transcribed and coded to determine the themes. In the quantitative study, a group of lay and content experts was invited to involve in the content validity test. Their assessment determined the value of Content Validity Ratio (CVR), Content Validity Index (CVI), and Modified Kappa. Next, a group of experts was invited to be involved in the Face Validity statistic. A total of eight stakeholders consented to be involved in the qualitative research. Five emerging themes were identified: (1) CPs are focused more on business-oriented practice, (2) CPs shall perform patient-oriented services, (3) The responsibilities to triage customers, (4). A systematic approach for triaging activities, (5). STARZ-DRP as a systematic approach to make triage decision. In the quantitative research, a group of lay and content experts (n = 14) had consented to be part of the study. Their assessments were used to determine the value of CVR, CVI, and Modified Kappa statistic. It was also noted that four elements in STARZ-DRP had the CVR scores of less than 0.51. The elements were: (1) Do you stop taking medication when you feel better? (2) Do you stop taking medication when you feel worse? (3) Do you have any concern about the cost of drug therapy? (4) Are you pregnant? The remaining construct items demonstrated the CVI and Modified Kappa statistics were more than 79% and 0.74, respectively. The outcome reflected the possible to accept the items as appropriate and excellent to maintain in the instrument. Seven experts were involved in the Face Validity test involved. The study found that the remaining items in STARZ-DRP had an item impact score of more than 1.5. They indicated the acceptance appearance of items in STARZ-DRP as a potential instrument to counsel the self-care customers. As a conclusion, the present study finds that all the stakeholders share a similar perception that CPs should extend their roles in providing patient-oriented services. The majority of the stakeholders agree that STARZ-DRP is a prospective instrument to assist CPs in performing the triaging activity and determine DRPs. Most importantly, it reveals that the construct items in STARZ-DRP are validated and it is possible to train CPs to perform the roles in the community pharmacy settings. The study also acknowledges the need to perform a content validity test as the way to validate the construct items in any newly developed instruments.

#### **CHAPTER 1 - GENERAL INTRODUCTION**

#### **1.1 Introduction**

The scope of pharmacy practice has gradually evolved from an ingredient compounder to a dispenser of ready-made products [Allen, 2011]. In the modern era, pharmacists are paying close attention to medication therapy outcome [Ramanath et al., 2012]. Nonetheless, this line of responsibility is most noticeable in the hospital settings where the pharmacists are responsible for working closely with doctors to put into effect the best possible medication therapy plan for each patient [Alhabib et al., 2016].

Similar to the hospital pharmacists, the community pharmacists (CPs) are also responsible for performing an audit, screening out prescriptions inscribed by the general practitioners (GPs). For example, the CPs are supposed to detect an illegitimate instruction written by the GPs such as the wrong dosage regimens or forms, inappropriate selection of medications, or identify the interaction between medications and diseases (Salim and Elgizoli, 2016). Such screening is particularly crucial in the drug-related problems (DRPs) (Cipolle et al., 1998). In most circumstances, the term is noted in the Pharmaceutical Care (PC) concept (Cipolle et al., 1998).

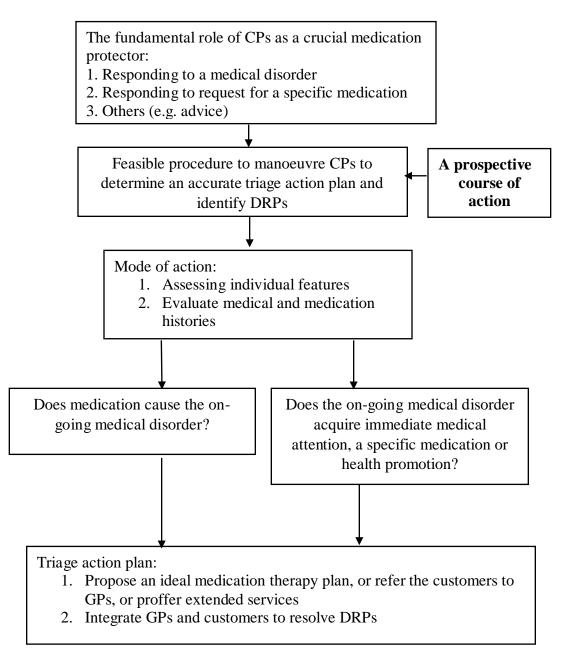
PC concept's main function is way of operating to assist pharmacists in executing a vital role as a medication manager (Cipolle et al., 1998, Cipolle et al., 2004). The concept develops a skill, habit, and quality among pharmacists in the hospital or non-hospital settings in managing medication affairs. The idea ensures that every patient can have access to medications which are safe, of good quality, practical, and cost-effective (Cipolle et al., 1998, Cipolle et al., 2004). This opportunity or ability to act independently and make decisions without authorization magnifies the image of the

CPs in the eyes of other healthcare providers and patients. For that reason alone, the role of CPs is likely to continue to evolve from only focusing on auditing prescriptions to a more demanding responsibility of putting into operation various extended services [Nordin et al., 2017a; Nordin et al., 2017b].

PC situate the vital role of pharmacists in various practices as a medication protector in the healthcare system. Their key task is to identify, prevent, and resolve DRPs [Westerlund and Bjork, 2006; Aguwa et al., 2008; Nordin et al., 2017c]. Nonetheless, it is crucial to remodel the PC concept in order to fulfil the desired expectations of the practice particularly in Malaysia because PC has currently deviated from its fundamental or usual function [Nordin et al., 2017c].

In Malaysia, PC is most effective in hospital settings instead of the non-hospital settings. The main reason is because CPs do not always have the chance to audit written prescriptions [Nordin et al., 2017a]. In the way of operating current practice, GPs have equal legal rights to hand out a wide range of medications to their customers at their practice facilities in the absence of pharmacists. Consequently, CPs need to strive to represent the right image of their profession. In other words, the current line of action might have the potential to indirectly obliterate CPs' accountability as a vital medication manager in the healthcare system. For that reason, it is critical to bring about a current mode of action so CPs can use their knowledge and skills to benefit those involved in the health care system, particularly patients and GPs [Nordin et al., 2017c]. The main strategic formula is to reform the role of CPs so they can exercise their role as a medication protector [Cipolle et al., 1998, Cipolle et al., 2004]. For that line of action, CPs are responsible for superintending each distinctive feature which is

potentially or not potentially associated with medications or the feature needs for a particular drug [Nordin et al., 2017c]. The reason is to ensure every patient is accessible to a wide range of essential medications. The proposed course of action is illustrated in Figure 1.1.



GPs = General Practitioners; CPs = Community pharmacists; DRPs = Drug-related problems

Figure 1.1 A possible course of action as a medication protector

It is crucial to propose an instrument to enable CPs to put into effect their knowledge and skills in managing a real-life operation. STARZ-DRP is introduced into the operation as a possible instrument to guide CPs to identify their vital roles and how these roles mobilised into effective actions [Nordin et al., 2017c]. STARZ-DRP is selected as a suitable instrument after examining other tools thoroughly to discern how they operate or their value [Sarriff et al., 2011]. STARZ-DRP transpires from the concept of PC. Its course of action had been attested in earlier research to discern its feasibility to put into practice in Malaysia [Nordin et al., 2017c]. The findings of the study indicate the potential of STARZ-DRP to guide CPs to construct and manage a triage action plan as well as identify, prevent, and resolve DRPs [Nordin et al., 2017c].

Nonetheless, the primary challenge that motivates the current study is the lack of evidence to validate the construct items in STARZ-DRP. More importantly, it is necessary to obtain the valuable points of view of relevant stakeholders regarding the functionality of the instrument to assist CPs in fulfilling their roles.

#### **1.2** An introduction to the STARZ-DRP template

STARZ-DRP consists of five alphabetical characters (S-T-A-R-Z) which constitutes a methodical approach to guide CPs to discern the individual features comprised in the concept (see Table 1.1). Each alphabetic character stands for a specific course of action as illustrated in Table 1.1. For that reason, CPs have to complete the entire course of action for the concept to be fully functional. Failure to perform a single course of action signified by the alphabetical character might have the potential to misguide the CPs in the executing the triage action plan. Over and above that, the CPs might fail to detect

some critical elements which have the potential to be the origins of the on-going feature disorder.

Table 1.1 Definition of alphabetical characters in STARZ #\*

Letter	Description	
S	Symptom presentation refers to subjective evidence of health problem perceived by	
	the patient.	

- **T Time of onset and duration** of the present symptoms.
- A Associated symptoms refer to patient symptoms explored and determined by the pharmacist during the interview. It does not apply to the symptoms presented earlier by the patient. It is using the graphics documentation form. To aid and ease the pharmacist during the interview, the human body is arbitrarily divided into four regions: (i) Front: the part of the body facing the pharmacist (asking for symptoms like bloating, heartburn, nausea, vomiting, breathlessness, extra), (ii) Back (asking for symptoms like lower and upper back pain, shoulder pain, and neck pain), (iii) Upper (head) (asking for symptoms like headache, dizziness, problems with sleep, extra), (iv) Lower (asking for symptoms like numbness in both legs and hands, constipation, and swollen feet). Perhaps, the method is likened to a filtering or screening process to rule out the presence of severe symptoms.
- **R Recurrence problem** refers to the symptoms have been treated before, precisely when the symptoms recur and persist despite the treatment prescribed.
- Z Zoom into the patient's medication experience refers to information collected by the pharmacist related to any medical problems (example, hypertension, diabetes, hyperthyroid, extra), medication utilization (example, use of prescription and non-prescription drugs, and herbal supplements), immunization history, allergies, drug sensitivities, drug side effects, adverse reactions, and the consumption of alcohol, caffeine and tobacco.

<sup>&</sup>lt;sup>#</sup> This is not a diagnostic tool, rather it is a format with the purpose of organizing a community pharmacist's knowledge in a manner that allows him/her to begin identifying the actual and potential drug-related problems and subsequently referring triage patients to the appropriate health care professionals.

<sup>\*</sup> The patient's vital signs will be measured when necessary. At times, the patient's blood pressure, pulse rate, and body temperature are measured to aid the pharmacist in assessing the appropriateness of symptoms for self-medication.

The first alphabetical characters (S-T-A-R) systematically guide the CPs in determining whether the individual features associated with medications, the individual who is prescribed a drug or whether the individual requires further services to sort out his or her source of trouble. In addition to that, it also guides the CPs to discern the individual features which might require immediate medical attention (see Appendix 1). For that reason, it is necessary to interact face to face with the individual to put into operation the commitment. Over and above that, the individual and the CPs must have a mutual relationship built on trust and respect. Otherwise, it would be difficult for the CPs to complete the entire course of action.

The following sequence (Z) guide the CPs to discern the actual or potential DRPs (see Appendix 2). For that reason, it is necessary for the CPs to examine the medical and medication histories. The facts and figures noted in the thorough examination might have the potential to open the door for CPs to integrate with GPs to prevent and resolve DRPs. Nonetheless, in most circumstances, the individual might not keep a complete data regarding their medical and medication histories for references. For that reason, CPs should be given credit for completing the entire course of action for the benefit of the individual, despite a restricted vital piece of information. Appendix 3 illustrates the whole course of action as noted earlier.

Interestingly, the entire course of action is mapped onto a printed paper (see Appendix 4) to help CPs retain fundamental facts and figures for future review. It might have the potential to help CPs reflect on an earlier triage action plan resulting in the CPs being able to re-evaluate the course of action that needed to be taken. Following the

sequence, CPs might need to initiate a current triage action plan. Such course of action put CPs in the picture as a vital healthcare provider in the healthcare system.

Apart from that, CPs will have the opportunity to advise the individuals to seek their GPs for immediate medical attention, advice or prescription medications. For that reason, it is necessary to integrate the individual and GPs in a construct that can be represented on paper. As a consequence, a referral printed paper is brought to attention as disclosed in Appendix 5. The printed paper has a potential to facilitate CPs in communicating with the relevant GPs regarding the facts and figures recorded in the previous examination. Additionally, it shall also notify GPs regarding an initial triage action plan, particularly in relation to the current medications for GPs to review. As a consequence, the course of action might have the potential to establish a mutual working relationship with GPs for the benefits of the patient.

#### **1.3 Triaging action**

The phrase initially coined during the First World War when the military officers had to decide about the fate of the casualties of war: (1). Able to travel home, (2). Acquire immediate surgery, or (3). Left to die [Keegan, 1976]. In the modern era, the phrase is a common term in the medical practice [Henning et al., 2016] especially noted in the emergency room within a hospital setting [Aacharya et al., 2011]. In most circumstances, the doctors shall discern the most critical individual from a large number of patients who require immediate medical attention. Such line of action might have the potential to save the life of the individual [Aacharya et al., 2011].

Nonetheless, the phrase is unusual in the scope of pharmacy practice as noted in earlier studies [Nordin et al., 2017d]. Interestingly, a solitary stakeholder in previous research pointed out that the phrase was often used in hospital settings, not in the community pharmacies or private clinics [Nordin et al., 2017d]. In another word, the stakeholder placed the responsibility on the GPs, and CPs had limited opportunity to put the line of action into operation. However, the point of view was objected to by another earlier research [Nordin et al., 2017c]. The results noted in the study pointed out CPs have the potential to execute a triage action plan despite their perceived inferiority compared to the GPs. [Nordin et al., 2017c]. CPs shall triage their customers by: (1) Recommending non-prescription drugs, vitamins, or supplements, (2) Referring them to GPs for possible prescription of drugs, or further medical advice, or (3) Giving advice to the patients such as advising them about their diet, healthy lifestyle, or monitoring their blood pressure. The action plan will most likely improve the credibility of the pharmacist. As a consequence, it is necessary to place the course of action as early as in pharmacy practice.

#### **1.4 Preparation to execute a triaging action in community pharmacy settings**

In general, CPs should have the facts, information, and skills obtained through experience, training, or education before putting into operation the triage action plan [Cipolle et al., 1998; Cipolle et al., 2004; Nordin et al., 2017c]. First and foremost, it is critical for the CPs to have an appropriate instrument to help them mobilise the triage action. On top of that, it is necessary to ensure that each construct item in the tool can measure the desired parameters in the real operation. Over and above that, CPs should equip themselves with the theoretical and practical understanding of clinical therapeutic knowledge to put into practice in the triage action [Cipolle et al., 1998;

Cipolle et al., 2004; Nordin et al., 2017c]. It is also necessary for CPs to attain experience from time to time since it might have an influence on the success of the line of action [Nordin et al., 2017c]. The knowledge should guide CPs to identify, prevent and resolve a wide range of DRPs [Cipolle et al., 1998; Cipolle et al., 2004; Nordin et al., 2017c]. Most importantly, it is necessary to introduce the instrument as a fundamental course of action in an actual operation.

Fundamentally, it is necessary that CPs and GPs to have a similar specified relationship with each other before putting into operation the triage action [Donald et al., 2017]. In other words, GPs must understand the theoretical and non-theoretical aspects of CPs' mode of operation, willing to be part of a triage action plan. Otherwise, CPs might not have the chance to work closely with GPs with similar ideas and thoughts, particularly to identify, prevent, and resolve DRPs. As a consequence, it is critical to consolidate GPs in the content validity test to ensure the mode of action is of quality, honest and based on strong moral principles.

#### **1.5 Malaysian National Medicines Policy**

Malaysian National Medicines Policy (MNMP) is also initiating a crucial policy to ensure that all Malaysians have access to medications which are safe, of a high quality, efficient, and cost-effective [Malaysian National Medicines Policy, 2013]. For that reason, it is necessary to integrate all stakeholders on the similar platform to share their facts, information, and experience before constructing a desirable policy. Interestingly, by executing this plan guidance can be provided to healthcare providers, manufacturers, and distributors to put into operation their vital roles according to the standard code of conduct. For example, it is necessary that the healthcare providers to record the facts and figures which corroborate with the evidence-based data as the vital line of action is to ensure that the best possible medication therapy plan can be offered. Also, it highlights the necessity to integrate all healthcare providers to share facts and figures without compromising the confidentiality of their patients. In the end, the policy will have the potential to enhance the quality of medication use among the patients.

#### **1.6 Role of pharmacists**

In general, it has been acknowledged in the policy document that pharmacists are a medication protector in the healthcare system [Malaysian National Medicines Policy, 2013]. They are accountable for superintending all medication affairs with the aim to put into effect safe practices in medication use. Failure to put into operation this line of action might cause adverse medical incidents to occur [Olivier et al., 2009] or causing the medication to become ineffective [Brown and Bussell, 2011]. As a consequence, the policy has outlined the core role of pharmacists in the healthcare system.

#### 1.7 Domestic scenario of community pharmacy practice

CPs are considered as a medication protector in administering all medication matters in the healthcare system [Knudsen et al., 2007]. As mentioned earlier, their key responsibility is to ensure every patient has access to all medications which are not only effective, safe, affordable and of quality [Smith et al., 2010]. For that reason, it is noted that CPs in the developed countries are given the authority to audit the instruction inscribed by GPs to detect a problematic prescription. The accountability may safe patients from consuming ingesting the wrongly prescribed medications. For example, it is noted CPs in Ireland have been given the authorisation to conduct safety inspection of prescriptions at long-term medical facilities [O'Sullivan et al., 2013]. Such recognition could be a good starting point to detect and hinder the likelihood of patients suffering from the undesirable effect of wrongly prescribed medications. Therefore, the role of CPs is accountable as the ultimate medication protector to detect erroneous prescription is crucial in the healthcare way of operating system.

In Malaysia, CPs might not have the chance to put this role into operation with a similar level of accountability [Sing, 2001]. Most of the time, it is noted that GPs are prescribing a wide range of medications to their patients in the absence of CPs to audit their prescribing activities [Nordin et al., 2017a]. The lack of counter check has a possibility of causing to the patient if a mistake is left undetected [Chen et al., 2005]. However, the way of operating is legal as stated in the Poison Act 1952 [Poison Act, 1952]. While acknowledging that this might expose patients to experience a wide range of medications, the safety, effectiveness, quality and cost-effective aspect of the prescription can be doubted [Velo and Minuz, 2009]. Most importantly, this way of operating refuses the essential human rights to have access to medications according to the second point of view particularly the pharmacist [Hestermeyer, 2004].

Instead of low-auditing exercise, CPs in Malaysia have the chance to interact with individuals who prefer to self-medicate. The line of action actively acknowledges throughout the world [Covington, 2006]. The paramount feature inspires the individual to pay attention to self-medicate is that he is accessible to a guidance notice regarding the severe ailments and course of medications noted on the online internet [Murray et al., 2003]. For that reason, the individual shall have a propensity to put into effect the

line of action as a way of behaving [Major et al., 2007]. After everything, the individual is actually in jeopardy to vulnerable experience undesirable effects of medications [Iwamoto et al., 2017]. Therefore, it is crucial to integrate CPs into the line of action to fortify the safe use of medicines [Nunes et al., 2017].

On top of that, CPs should be given a chance to merge into a medical team with an emphasis on the long-term medication therapy programme as the center of interest or activity [Chua et al., 2012; West and Isom, 2014]. Furthermore, it is noted CPs have the potential to superintend a wide range of patients' medication affairs who are currently on long-term treatment [Fera et al., 2008; Chua et al., 2012]. In most cases, CPs are given the accountability to identify, prevent, and resolve DRPs [Brennan et al., 2012; Chua et al., 2012], mainly paying attention to medications which might have potential to cause adverse drug events [Chua et al., 2012]. In short, it is noted the accountability is inherent to keep the people away from the risk of fatal, life-threatening consequences.

As a conclusion, it needed to be pointed out that CPs have the chance to put into practice the extended services side-by-side with the current conservative practices. Nonetheless, it is critical to examine the local context to discern the possibility of incorporating the triaging system and determine DRPs activities into that operation, mainly paying attention to the potential extended services, barriers, and the standpoint of the establishment of a new approach.

#### 1.8 Justification of study

The absence of merit validated instruments to achieve the most effective course of action is a possible barrier which can hinder the possibility of CPs offering the extended services [Nordin et al., 2017a], particularly in the triage action plan [Curley et al., 2016]. For that reason, STARZ-DRP is introduced into the current research based on the following justification: (1). What are the views the relevant stakeholders regarding CPs and STARZ-DRP? (2). Do the construct items in the STARZ-DRP measure the exact elements that needed to be measured? (3). Does each construct item have the potential to be preserved in the original or existing state after incorporating it into the content validity test? (4). Is the remaining construct items essential to the appearance of the instrument?

#### 1.9 Objectives of study

The primarily objective of the study is to perform the qualitative research in order to examine the viewpoints of the relevant stakeholders of CPs' roles and STARZ-DRP as a structured and systematic approach to guide CPs in planning a triage action plan and determine the DRPs.

The secondary objectives of the study are to execute the following actions:

 Determine the Content Validity Ratio (CVR) of each construct item in STARZ-DRP as much as possible to make an accurate triage action plan and determine the DRPs.

- Determine the Content Validity Index (CVI) of each construct item in STARZ-DRP as much as possible to make an accurate triage action plan and determine the DRPs.
- Determine the Modified Kappa calculation to ensure the possible agreement among the expert panels regarding the remaining construct items in STARZ-DRP.
- Perform the Face Validity Test to ensure the quality appearance of STARZ-DRP as a possible model to assist CPs to make a triage action plan and determine the DRPs.

#### **1.10 Rationale of study**

The rationale of the research is the findings have the potential to recognise STARZ-DRP as a course of action to guide CPs in their role as medication protectors. Over and above that, the findings will allow for display of the integrity, credibility, and competency of the instrument. The tool can be proven to be useful despite its application in various cultures, religions, gender, races, and languages.

#### 1.11 Overview of thesis

Chapter 2 is the literature review, discussing global barriers to the introduction of a new practice. Over and above that, it discusses the findings of previous research pertaining to the objectives of the study as well as establishing the viewpoints of CPs, GPs, and patients about the new services offered in the community pharmacy settings. It is hoped that there is a gap of knowledge regarding the role of the CPs and the need of contemporary health care practices to acknowledge the real role of CPs in the healthcare system.

Chapter 3 presents the methodology for accomplishing the objectives of the current study using the qualitative research, indicating the entire process adopted in the study. Over and above that, it provides explanation about the interview methods conducted in the data collection and the sampling methods used in the current study. This section will also explain the data management and analysis process. In other words, it will map the entire line of action in this qualitative research in detail. The section will present the introduction and aims of the recent study, followed by extensive explanation about the materials and method used, the results and discussion.

Chapter 4 the strategies adopted by the current research to determine the right formula in order to ascertain the content validity evidence and potential sampling methods. Next, the data management method and analysis technique are explained in detail pertaining to the current quantitative research. The section provides a practical understanding of the materials, methodology, and results. Inferences are also presented in conclusion.

Chapter 5 is the final chapter of this thesis. It reaffirms the important findings in Chapter 3 and 4. It also discusses the physical or concrete findings noted in the current research in a comprehensive manner. Over and above that, the chapter listed the limitations of the current study and suggestions for future studies.

#### **CHAPTER 2 - LITERATURE REVIEW**

#### 2.1 Background

A review of relevant literature was performed based on previous research found in academic journals to determine the possible perspectives of customers, CPs, GPs, and relevant stakeholders about the CPs' extended roles in the healthcare system. Apart from that, the review determines the possible hurdles that currently restrict the CPs from fully accomplishing their designated roles. The research methods, results, and discussion will be evaluated in this chapter to identify the emerging issues pertaining to the current research. Fundamentally, the review of the previous literature will allow for the appropriate methodology to be chosen to answer all the research objectives stated earlier.

The literature review was also carried out to determine the possibility of constructing a triage action plan and to identify the DRPs in the community pharmacy settings. Foremost, it identifies the recent instruments and their construct items which are able to guide CPs to execute the roles mentioned earlier. Their construct items are evaluated to determine the advantages and disadvantages in order to help CPs in their practice. Subsequently, the outcomes of the literature review will be used to establish the appropriate construct items in STARZ-DRP. Subsequently, the article reviews were performed to determine the validated approach to generate the content validity evidence for each construct item in STARZ-DRP. Such course of action is essential in order to enhance the integrity, competency, and quality of data notified in the recent study.

In short, the literature review is critical to be performed since it assists the researcher to understand the following issues: (1) Other researchers' assumptions about the interest in the current study, (2) Possible methodologies, (3) Earlier findings, (4). Participants should involve in studies, (5) Conflicting theories, results, and methodologies, and (6) Possible findings that evolve over time. Failure to perform the literature review might possibly divert the researcher from focusing on the interest of the recent study.

# 2.2 Determining the selection of the academic papers which reflect the perspectives of the customers, CPs, and GPs about the CPs' extended roles in Malaysia

A systematic search of academic writing papers was conducted using Google Scholar and PubMed as electronic databases, searching for abstracts in English, from January 1, 2006, until May 31, 2017. The search terms used were: (1) Malaysia, (2) CPs, (3) Extended roles, (4) Extended services, (5) Expansion roles, (6) Expansion services, (7) Perception, (8) Perspective, (9) Attitudes, (10) Barriers, (11) Limitation, (12) Customer, and (13) GPs. The abstracts were weighed by a scholar-researcher, by searching for abstracts that integrate with the insertion criterion as illustrated in Table 2.1. At most, the abstracts which merged with the insertion criterion were assessed for the full access printed works. Subsequently, another two academic researchers had taken the following step to discern the published works, searching for contents which satisfied the insertion criterion as illustrated in Table 2.1. These final printed works were accepted to include in this report as shown. Figure 2.1 represented the flow of the published works that uncovered from the searching process.

Population	CPs, customers, GPs, and stakeholders in Malaysia.
Phenomenon of interest	ER performed in community pharmacy settings. Perceptions noted among CPs, customers, stakeholders, and GPs of ER. Discerning barriers to the performance.
Primary outcome measures	<ul> <li>The outcome measures but not restricted to it were:</li> <li>to discern ER in community pharmacies</li> <li>to discern perceptions among CPs, customers, stakeholders, and GPs of ER</li> <li>to discern barriers to the performance of ER</li> </ul>
Types of studies	Quantitative and qualitative academic analysis research, article review

Table2.1. Insertion criterion for literature review

CPs = community pharmacists; GPs = general practitioners; ER = extended roles

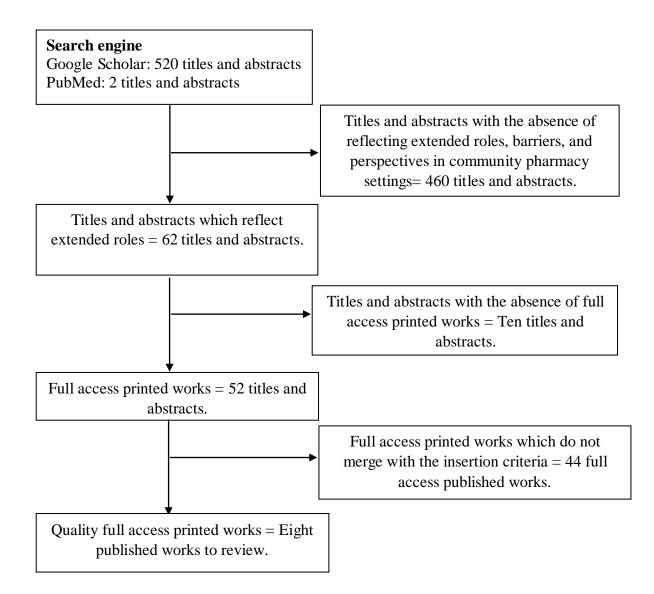


Figure 2.1. Flow diagram of searching process to determine the acceptable printed works

#### 2.2.1 Results notified in the findings

There were eight research papers which were deemed as acceptable materials to review. The first in the sequence is a study which aimed to determine the health promotion services and the obstacles that the community pharmacy services have to overcome in order to fulfil their duties [Hassali et al., 2009a]. It is a cross-sectional survey design based on 100 questionnaires that were distributed to CPs in Penang. It is noted that a total of 80% of the sampling responded to the study, pointing out that they were substantially involved in diabetes counselling (n = 26, 32.5%), followed by weight management counselling (n = 20, 25.0%), traditional and complementary medication counselling (n = 18, 22.5%) and nutrition/physical activity (n = 16, 20.0%). The CPs in the study were least involved in the immunization scheme (n = 5, 6.3%), followed by drug misuse counselling (n = 3, 3.8%), special population (n = 3, 3.8%), and asthma counselling (n = 3, 3.8%). It is noted that there were various obstacles mentioned by the respondents regarding the uncertainty about the CPs' extended role. Among the obstacles included the lack of time, lack of profitability and the absence of a standard approach to follow as a guideline to provide the full range of extended roles.

Another cross-sectional study which aimed to investigate GPs' (n = 80, 50.0%) perspectives of the CPs' roles. The findings indicated that the majority of GPs disagreed when CPs diagnosed minor illnesses (52.5%) and performed the screening test (52.5%) [Hassali et al., 2009b]. However, the GPs agreed if CPs educate the patients about medication safety (52.5%), refer patients to GPs for further medical examination (76.3%) and willingness to collaborate with CPs for the benefit of the patients (77.5%). The GPs (61.3%) agreed that CPs were putting effort to provide the

patient-oriented service and helping their patients to select appropriate nonprescription medications for self-care treatment (46.3%).

The methodology adopted by another study was a face-to-face interview, using a structured questionnaire to determine the CPs' knowledge and perceptions of breast cancer health promotion services [Beshir & Hanipah, 2012]. It was noted that a total of 35 CPs (67.0%) responded to the study. The majority of the respondents answered correctly regarding the prevalence of breast cancer. The CPs pointed out that they could influence patients to perform earlier screening test to detect possible breast cancer (n = 9, 25.7%), CPs should be involved in the breast cancer health promotion (n = 9, 25.7%), and CPs should distribute information to the customers regarding the breast cancer (n = 10, 28.6%). Nonetheless, it was noted in the study that CPs' lack of time (n = 28, 80.0%), knowledge (n = 27, 77.1%) and training (n = 22, 62.9%) were among the obstacles that hindered them from performing these extended roles.

The GPs in the state of Penang were contacted via mail to determine their perception of CPs' specific patient care activities [Azmi et al., 2012]. They are instructed to response to a standard questionnaire. The study pointed out that the majority of the respondents were in favour of the CPs' roles in providing public health education (58.7%), informing GPs about the prescribing and prescription errors (56.0%) and referring patients to GPs who have some medication issues (53.0%). However, the respondents were not in favour of the CPs' roles in conducting smoking cessation programme (34.8%) as well as providing the drug information to GPs (43.0%).

Another cross-sectional study used a self-administered questionnaire to investigate CPs' perception of patient counselling and Continuing Pharmacy Education Program (CPEP) as well as the obstacles they faced in providing the services [Rajiah et al., 2014]. It was noted that a total of 220 CPs responded to the research, they indicated the lack of time (33.0%), patient's interest (27.0%), and knowledge (20.5%) as among the obstacles they faced. The CPs pointed out that it is necessary to promote the public education (52.0%), increasing the number of pharmacists (20.0%) and attending CPEP are the possible strategies to overcome the obstacles.

Sarriff and colleagues performed another cross-sectional research which using a selfadministered questionnaire to investigate the level of knowledge and awareness among people with cardiovascular diseases (CVDs) and expectation of the CPs' role to prevent and manage the disease [Sarriff et al., 2014]. The study found that the respondents had poor (46.0%), moderate (43.0%) and good (9.0%) knowledge of CVDs and their warning symptoms. The public awareness of CVDs' risk factors was better than their knowledge of CVDs and the warning symptoms with poor (37.0%), moderate (35.0%) and good (28.0%) awareness, respectively. The majority of the respondents gave favourable responses on the issue of the CPs' roles to identify and prevent the CVDs' risk factors.

Saw and colleagues, on the other hand, recruited some GPs to participate in a focus group and semi-structured interviews [Saw et al., 2015]. The research aimed to explore GPs' views about integrating pharmacists into the private primary healthcare clinics in Malaysia. The study revealed that thirteen GPs participated in the focus groups and 10 semi-structured interviews. Four major themes were noted which included: (1) Poor

understanding of the pharmacists' roles, (2) Readiness to accept pharmacists in private primary healthcare clinics, (3) Lack of confidence and trust of the pharmacists, and (4) Perceived increased costs with pharmacist integration. Also, the study noted the GPs' views and acceptance were influenced by the GPs' exposure and experience working side-by-side with pharmacists. The study also noted the GPs' view of pharmacists' lack of confidence and the increasing cost associated with employing a pharmacist as the objection to such integration.

Saw and colleagues repeated a similar study with the similar aim and methodology [Saw et al., 2017] involving a total of thirteen GPs in a focus group (n = 3), and semistructured interview (n = 10). The study revealed the GPs had a poor understanding about a pharmacist's role in private healthcare primarily health care clinic. The lack of confidence and trust of the pharmacists, as well as the GPs perceived high cost of the pharmacist's involvement in the clinic. However, the GPs pointed out their readiness to accept the pharmacist's role in the healthcare clinic.

#### **2.2.2 Problem statements**

It is noted that there were five studies which formed the basis of this current research [Hassali et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Rajiah et al., 2014; Sarriff et al., 2014], one studies reflect the quantitative and qualitative research [Beshir and Hanipah, 2012], and two studies demonstrate a qualitative research [Saw et al., 2015; Saw et al., 2017]. The findings revealed it is possible to determine the customers', CPs', and GPs' perspectives about CPs' extended roles via both methods of research. Nonetheless, it is noted that the integrity of the outcomes can be challenged since the findings might not reflect the entire scenario of the practice. The main reason is that the studies [Hassali et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Beshir and Hanipah, 2012; Rajiah et al., 2014; Sarriff et al., 2014; Saw et al., 2015; Saw et al., 2017] involved the public, CPs, and GPs who were not in the right position to represent the larger population. For that reason, it is essential to perform another study to determine the perspectives among the relevant stakeholders regarding the CPs' extended roles. The stakeholders should consist of those who represent the professional associations, consumers, and government agency. Their participation in the qualitative research is vital to provide the right perspectives about the CPs' roles [Lowes et al., 2011]. Foremost, the course of action does not require a great number of participants unlike the quantitative research method [Hassali et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Rajiah et al., 2014; Sarriff et al., 2014].

Also, the findings failed to determine the possible strategic plan to improve the customers', CPs', and GPs' perspectives of the CPs extended roles [Hassali et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Beshir and Hanipah, 2012; Rajiah et al., 2014; Sarriff et al., 2014; Saw et al., 2015; Saw et al., 2017]. In most cases, the studies were paying particular attention to investigate the possible extended roles, obstacles faced to realise the roles, and opinion about the CPs' extended services [Hassali et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Beshir and Hanipah, 2012; Rajiah et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Beshir and Hanipah, 2012; Rajiah et al., 2014; Sarriff et al., 2014; Saw et al., 2015; Saw et al., 2017]. The studies failed to propose a possible approach which has the potential to eliminate the obstacles that hindered the CPs' extended roles [Hassali et al., 2009b; Azmi et al., 2009a; Hassali et al., 2012; Rajiah et al., 2012; Beshir and Hanipah, 2012; Rajiah et al., 2012; Beshir and Hanipah et al., 2014; Saw et al., 2014; Saw et al., 2014; Saw et al., 2009a; Hassali et al., 2009b; Azmi et al., 2009a; Hassali et al., 2014; Saw et al., 2015; Saw et al., 2017]. Most of the studies did not suggest an effective plan to integrate the customers, CPs, and GPs in the same construct to work

side-by-side for the benefit of the customers [Hassali et al., 2009a; Hassali et al., 2009b; Azmi et al., 2012; Beshir and Hanipah, 2012; Rajiah et al., 2014; Sarriff et al., 2014; Saw et al., 2015; Saw et al., 2017]. Such a course of action taken by previous research might not have the chance to enhance the relationship among the customers, CPs, and GPs. For that reason, it is essential to initiate a possible plan that incorporate the ideas of the customers, CPs, and GPs.

Interestingly, it is noted that there is a wide range of extended services which are possible to be incorporated in the triage and to determine the DRPs activities in the community pharmacies. The extended services included monitoring the drug therapy outcome (Azmi et al., 2012), providing drug information to GPs (Azmi et al., 2012), referring customers to GPs (Azmi et al., 2012), treating minor ailments (Azmi et al., 2012), roles in a private healthcare clinic (Saw et al., 2015; Saw et al., 2017), weight management counselling (Hassali et al., 2009a), smoking cessation counselling (Hassali et al., 2009a; Azmi et al., 2012; Sarriff et al., 2014), public health education (Hassali et al., 2009a; Azmi et al., 2012), oral health counselling (Hassali et al., 2009a), nutrition or physical counselling (Hassali et al., 2009a; Sarriff et al., 2014), immunization counselling (Hassali et al., 2009a), drug misuse counselling (Hassali et al., 2009a), diabetes care counselling (Hassali et al., 2009a), breast cancer health promotion (Beshir and Hanipah, 2012), cardiovascular care counselling (Hassali et al., 2009a; Sarriff et al., 2014), and asthma counselling (Hassali et al., 2009a). It brings forward the idea that CPs in Malaysia have so far been put into the operation of patientoriented services for the past few years. In other words, CPs have not failed to magnify the scope of the pharmacy practice in addition to the current conservative service they offer. Nonetheless, the outcomes of the studies might not reflect the entire population because the research was conducted in a specific state. It is essential to execute a nation-wide study in order to obtain the actual scenario of the extended services.

It is noted that the extended services can be evaluated by CPs, GPs, and customers in the literature reviewed. GPs were not in favour of CPs conducting the smoking cessation programme [Azmi et al., 2012], GPs were in favor of CPs determining the DRPs [Azmi et al., 2012], GPs were willing to collaborate with CPs to review the drug therapy outcome [Hassali et al., 2009b; Azmi et al., 2012], GPs were aware of the extended roles of CPs to initiate the patient-oriented services [Hassali et al., 2009b], GPs were not in favor of the CPs keeping patients' profile [Hassali et al., 2009b], GPs were not in favor of CPs to amend the written prescription [Hassali et al., 2009b], GPs were in favor of CPs referring the patients to them [Hassali et al., 2009b; Azmi et al., 2012], CPs were not acknowledged as the best practitioner to advise GPs about a rationale medication use [Hassali et al., 2009b; Azmi et al., 2012], GPs should take into consideration the CPs' advice regarding written prescriptions [Hassali et al., 2009b; Azmi et al., 2012], CPs were not well trained to determine the screening tests [Hassali et al., 2009b], GPs were in favor of CPs treating minor ailments [Hassali et al., 2009b; Azmi et al., 2012], GPs underrated the role of CPs [Hassali et al., 2009b], CPs' knowledge and skills were underutilized [Azmi et al., 2012], CPs were not well trained in clinical therapeutic skills [Hassali et al., 2009b], patients appreciated the extended services [Beshir and Hanipah, 2012; Sarriff et al., 2014], CPs collaborated with GPs, and dieticians [Hassali et al., 2009b; Beshir and Hanapiah, 2014; Saw et al., 2015; Saw et al., 2017], CPs provided counselling about health screening [Beshir and Hanapiah, 2012; Sarriff et al., 2014], CPs were the best to educate about medications [Hassali et al., 2009b; Azmi et al., 2012], CPs recognition would magnify the