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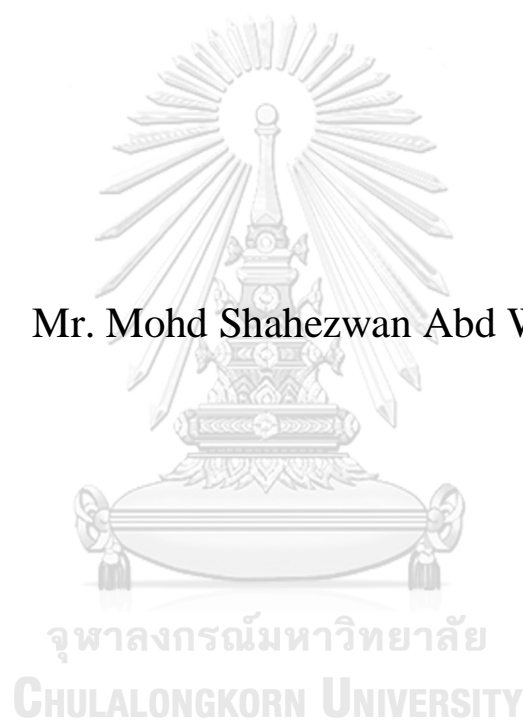
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DEVELOPMENT OF A DETERMINANT SCALE OF  
PHARMACIST'S CARE FOR HERBAL AND DIETARY  
SUPPLEMENT USERS

Mr. Mohd Shahezwan Abd Wahab



A Dissertation Submitted in Partial Fulfillment of the Requirements  
for the Degree of Doctor of Philosophy in Pharmaceutical Care  
Department of Pharmacy Practice  
Faculty of Pharmaceutical Sciences  
Chulalongkorn University  
Academic Year 2018  
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การพัฒนามาตรวัดการตัดสินใจของเกษตรกรในการบริหารผู้ใส่สมุนไพรรและผลิตภัณฑ์เสริมอาหาร



นายโมหิต ชาญวาน อับดี วาฮับ

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาเกษตรศาสตรดุษฎีบัณฑิต

สาขาวิชาการบริหารทางเกษตรกรรม ภาควิชาเกษตรกรรมปฏิบัติ

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ปีการศึกษา 2561

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Thesis Title	DEVELOPMENT OF A DETERMINANT SCALE OF PHARMACIST'S CARE FOR HERBAL AND DIETARY SUPPLEMENT USERS
By	Mr. Mohd Shahezwan Abd Wahab
Field of Study	Pharmaceutical Care
Thesis Advisor	Associate Professor PHANTIPA SAKTHONG, Ph.D.
Thesis Co Advisor	Associate Professor Win Winit-Watjana, Ph.D.

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CHULALONGKORN UNIVERSITY

โมหัด ชาเอชวาน อับด์ วาฮับ : การพัฒนามาตรวัดการตัดสินใจของเภสัชกรในการ  
 บริบาลผู้ใช้สมุนไพรและผลิตภัณฑ์เสริมอาหาร. ( DEVELOPMENT OF  
 A DETERMINANT SCALE OF PHARMACIST'S  
 CARE FOR HERBAL AND DIETARY  
 SUPPLEMENT USERS) อ.ที่ปรึกษาหลัก : รศ. ภญ. ดร.พรรณทิพา  
 ศักดิ์ทอง, อ.ที่ปรึกษาร่วม : รศ. ภก. ดร.วิน วินิจวัญนะ

วัตถุประสงค์ : เนื่องจากยังขาดเครื่องมือที่มีความตรงและความเที่ยงในการประเมินการตัดสินใจของเภสัชกรในการบริบาลผู้ใช้อาหาร  
 เสริมและสมุนไพร ดังนั้นในการศึกษานี้จึงมีวัตถุประสงค์เพื่อพัฒนาเครื่องมือในการตัดสินใจสำหรับการบริบาลดังกล่าว โดยใช้ทฤษฎีพฤติกรรมที่  
 ได้รับการวางแผน

วิธีการศึกษา : ประกอบด้วย 3 ระยะ คือ ระยะที่ 1 เป็นการศึกษาเชิงคุณภาพเพื่อสำรวจการปฏิบัติและความเชื่อของเภสัชกรชุมชนใน  
 การบริบาลผู้ใช้อาหารเสริมและสมุนไพร ระยะที่ 2 สร้างกลุ่มข้อคำถาม และ ระยะที่ 3 การประเมินการวัดทางจิตวิทยาของเครื่องมือ

ผลการศึกษา : ผลการศึกษาเชิงคุณภาพในระยะที่ 1 และ 2 พบว่า ประกอบด้วย 3 เครื่องมือ คือ เครื่องมือประเมินพฤติกรรมที่ได้รับ  
 การวางแผนทางตรง เครื่องมือประเมินพฤติกรรมที่ได้รับการวางแผนทางอ้อม และเครื่องมือการบริบาลผู้ใช้อาหารเสริมและสมุนไพร ซึ่งได้ผ่านการ  
 ทดสอบความตรงเชิงเนื้อหาจากกลุ่มผู้เชี่ยวชาญ และความตรงแบบผิวเผินกับกลุ่มเภสัชกรชุมชน พบว่า ข้อคำถามมีความชัดเจนและสามารถเข้าใจได้  
 สำหรับระยะที่ 3 ซึ่งเป็นงานวิจัยเชิงปริมาณได้ทำการสำรวจแบบภาคตัดขวางกับเภสัชกรชุมชนในเขตกรุงเทพมหานคร โดยแบ่งกลุ่มตัวอย่างเป็น 2  
 กลุ่ม กลุ่มที่ 1 เพื่อสำรวจโครงสร้างปัจจัยและตัดข้อคำถาม และ กลุ่มที่ 2 เพื่อทำการทดสอบความเที่ยงและความตรงของโครงสร้างดังกล่าว พบว่า  
 เครื่องมือทั้งสามมีความตรงเชิงโครงสร้างที่เป็นไปตามทฤษฎีโดยใช้ทั้งการวิเคราะห์ปัจจัยเชิงสำรวจและเชิงยืนยัน สำหรับความตรงเชิงผู้เข้า ความตรงเชิง  
 ผู้ออก และความตรงตามเกณฑ์สัมพัทธ์อยู่ในระดับที่ดีพอสมควร รวมทั้งมีความเที่ยงของความสอดคล้องภายในอยู่ในระดับที่ดีถึงดีเลิศ นอกจากนี้ยังม  
 การวิเคราะห์แบบบราซซ์ พบว่า ข้อคำถามและตัวเลือกตอบมีความเหมาะสม

สรุป : เครื่องมือประเมินการตัดสินใจของเภสัชกรในการบริบาลผู้ใช้อาหารเสริมและสมุนไพรมีความตรง ความเที่ยง และสามารถ  
 นำมาใช้ได้ การศึกษาต่อไปสามารถทดสอบความตรงของเครื่องมือในกลุ่มตัวอย่างเภสัชกรชุมชนตามภูมิภาคต่าง ๆ ของประเทศไทย เช่น ภาคเหนือ และ  
 ภาคใต้

จุฬาลงกรณ์มหาวิทยาลัย  
 CHULALONGKORN UNIVERSITY

สาขาวิชา การบริหารทางเภสัชกรรม

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ปีการศึกษา 2561

ลายมือชื่อ อ.ที่ปรึกษาหลัก

ลายมือชื่อ อ.ที่ปรึกษาร่วม

# # 5776555633 : MAJOR PHARMACEUTICAL CARE

KEYWORD: Pharmacist's care, Herbal and dietary supplement, Community pharmacist

Mohd Shahezwan Abd Wahab : DEVELOPMENT OF A DETERMINANT SCALE OF PHARMACIST'S CARE FOR HERBAL AND DIETARY SUPPLEMENT USERS.

Advisor: Assoc. Prof. PHANTIPA SAKTHONG, Ph.D. Co-advisor: Assoc. Prof. Win Winit-Watjana, Ph.D.

**Objective:** There is a lack of instrument that is valid and reliable to measure the determinant of pharmacist's care (PCare) for herbal and dietary supplement (HDS) users. The present study aimed to develop scales to measure the determinant of PCare for HDS users and to quantify the practices. The study utilized qualitative and quantitative approaches.

**Methods:** Three scales were developed: Direct TPB scale based on a modified Theory of Planned Behaviour (m-TPB) framework, Indirect TPB scale based on the m-TPB and beliefs elicited from community pharmacists (CPs), and PCare-HDS scale based on findings from the qualitative study. This study involved three phases: (1) qualitative study to explore CPs' salient practices of PCare for HDS users, and the beliefs associated with the practices; (2) generation of item pools; and (3) psychometric evaluation of the scales.

**Results:** The qualitative study identified eight domains of PCare for HDS users, divided into two dimensions of direct and non-direct customer/patient care activities, and identified relevant beliefs underlying the practices. Item generation procedures produced pools of items for the scales. These items were examined and refined by a group of pharmacy experts in a content validity study. A face validity study established the clarity and comprehensibility of the items. For the third phase, a cross-sectional survey was carried out among CPs in Bangkok. The sample was divided into two datasets: sample 1, to explore the factor structures and to refine the scales; and sample 2, to cross-validate the factor structures. Additionally, Rasch analysis and criterion validity tests were performed on the entire sample of CPs. Exploratory factor analysis (EFA) supported the factor structures of the Direct TPB and PCare-HDS scales, and identified an additional factor for the Indirect TPB scale. Both the EFA and a preliminary confirmatory factor analysis (CFA) guided the refinement of the scales. Data from the second dataset for all three scales fitted well with the models using CFA. Discriminant and convergent validity were shown for the scales. Rasch analysis showed no substantial misfit and the category functioning followed monotonic increases in mean and step measures for all domains of the scales. All constructs of the scales had good to excellent internal consistency reliability. The scales had criterion validity to some extent.

**Conclusion:** The scales were shown to have validity and reliability and can be of interest to researchers aiming to understand PCare for HDS users. Further study can validate the scales in different sample of CPs such as in the Northern and Southern regions of Thailand.

Field of Study: Pharmaceutical Care  
Academic Year: 2018

Student's Signature .....  
Advisor's Signature .....  
Co-advisor's Signature .....

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Mohd Shahezwan Abd Wahab



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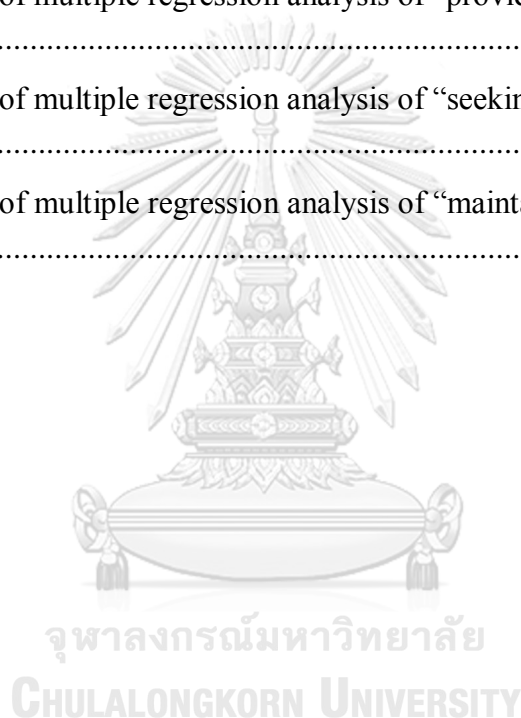
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## **CHAPTER 1: INTRODUCTION**

This chapter presents the overview of the thesis. The background of research discusses the area being studied. The specific aims, research questions and hypotheses relevant to the research are also outlined. The significance of the study is also discussed in this chapter. Finally, key definitions pertinent to the research are introduced.

### **1.1. Research background**

The involvement of community pharmacists (CPs) with herbal and dietary supplements (HDS) is apparent through the sale of these products at community pharmacies (1-3). However, as healthcare professionals, CPs should extend their roles beyond selling the products in manners that should differ from non-healthcare professional retailers. In this regard, CPs should ensure quality and safe use of HDS by holding to the highest standards of pharmacist professional responsibilities, and by integrating consumer- or patient-centered care in their services (4).

It is more important than ever for CPs to involve with HDS due to the fact that the use of the products is highly prevalent in the current society (5). For example, a survey in Thailand showed that the prevalence of HDS use among the general population in Bangkok city was 52%. Among those who were HDS users, 58.4% of them were consuming herbal medicines, whereas the other 65.3% were using dietary supplements (5). In general, people are willing to spend a significant amount of money to purchase HDS, and perceived the products as natural and safe (6-8). Nevertheless, similar to conventional pharmaceutical products, HDS may in fact produce adverse effects, interact with other medicines and thereby may impair health (9-11).

These issues can potentially be prevented by CPs through conducting specific pharmacist's care (PCare) activities such as assessing HDS use and providing sufficient information to the users at the point of HDS sale or dispensing. Many studies have been carried out to investigate the extent to which pharmacists provide PCare for HDS users. In many of these studies, pharmacists have been shown to hold

the belief that it is part of their responsibilities to provide PCare for HDS users (12). However, previous studies have also reported that CPs did not regularly engaged in PCare activities related to HDS. In this regard, pharmacists were less proactive in evaluating, monitoring, or communicating with customers or patients about HDS use (1-3, 12).

At present there is limited information about the beliefs and practices of Thai CPs regarding their involvement in PCare for HDS users. In a qualitative study carried out in the Northeast region of Thailand, the provision of professional services to support quality and safe use of HDS was not optimum. The CPs admitted that the assessment of risks and benefits of HDS use for their customers, were performed at a lesser standards than they normally practiced with conventional medicines (13). In a cross-sectional survey which was also carried out in the same region, Thai pharmacists (community and hospital) endorsed various roles of pharmacists about the use of HDS such as evaluating the appropriateness of HDS use, and providing counseling to the users (14). However although the endorsement for the activities were favourable, it was not known to what extent the pharmacists surveyed actually performed the activities.

Based on the existing information, similar to that reported by studies in other countries, it appeared that the engagement of Thai pharmacists in PCare for HDS users were not satisfactory (13, 14). More studies have been suggested to investigate pharmacists' practices related to HDS, and to facilitate the understanding of factors that promote or impede pharmacists to provide PCare for HDS users in Thailand. However, research in this area is challenging mainly due to the lack of consensus on what constitutes PCare for HDS users and the absence of an ideal practice model (15).

Additionally, at present there is no acceptable survey instrument that is valid and reliable to measure PCare for HDS users. The disparity in the national situation regarding pharmacy practices and legal pharmacist obligation among countries limits the adaptation of survey instruments of other studies in the context of Thailand. In this regard, certain pharmacy practices related to HDS may not be applicable in community pharmacy settings in Thailand. Therefore the salient practices of PCare

for HDS users among CPs in Thailand should be further investigated and a tool to measure PCare for HDS users that is relevant to the local culture should be developed.

Likewise, the determinants (influencing factors) of PCare for HDS users reported in previous studies may not be relevant for Thai CPs. The generalizability of findings from those studies is therefore limited. There is a need to carry out a study to explore salient beliefs of CPs regarding PCare for HDS users so that facilitators and barriers for the provision of PCare for HDS users that are relevant to the local CPs can be recognized. However, the identification of factors for the provision of PCare for HDS users should be based on a valid theoretical reasoning. The use of a theory can assist researchers to explain, predict, and understand a phenomenon, which in this case, the provision of PCare for HDS users (16).

There are many existing psychosocial theoretical models such as the Social Cognitive Theory (SCT), Theory of Reasoned Action (TRA) and Theory of Planned Behavior (TPB) that have been applied to explain various healthcare professionals' behaviour (17). However, among the psychosocial theories, the TPB framework has been found to be the most useful due to its ease of application and good explanatory power (17). In the pharmacy practice context, the TPB has been utilized to explain factors influencing pharmacists' engagement in various activities such as the provision of support for secondary prevention of cardiovascular disease (18), reporting of adverse drug events (19), and provision of medication therapy management (20). To date, a study to investigate relevant factors influencing the provision of PCare for HDS users using the TPB is lacking. Due to the efficacy of the TPB in explaining pharmacists' behaviour in previous studies, a modified TPB (m-TPB) framework was used to underpin the exploration of CPs' beliefs regarding the provision of PCare for HDS users in this study. Additionally, the m-TPB formed the foundation for the development of the scales to measure the determinants of PCare for HDS users.

## **1.2. Specific aims, research questions and hypotheses**

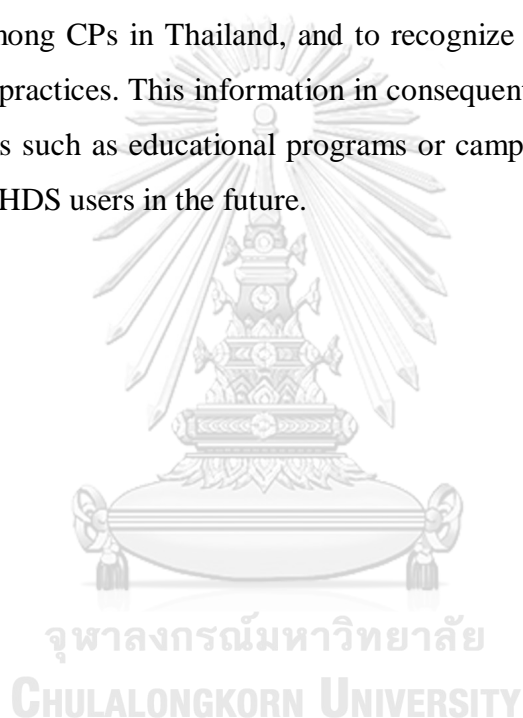
The purpose of this study was to identify salient practices and beliefs regarding PCare for HDS users among CPs in Bangkok, Thailand. Additionally, this study aimed to develop survey instruments to quantitatively measure PCare for HDS users and the determinants of the practice. The study was conducted in three phases to meet the study purposes. In Phase 1 of the study, a qualitative study was carried out to elicit CPs' opinions about PCare for HDS users, and to identify salient behavioural, normative, control and professional normative beliefs about the provision PCare for HDS users. In Phase 2 of the study, two scales for the determinant of PCare for HDS users were developed in the study (Direct and Indirect TPB scales). The Direct TPB scale was developed based on major constructs of the m-TPB framework and the Indirect TPB scale was based on both the m-TPB framework and beliefs elicited from CPs. Additionally, a tool to quantify PCare for HDS users namely PCare-HDS scale was developed based on findings from the qualitative study. In Phase 3 of the study, the assessment of the psychometric properties was conducted to establish content, face, construct, convergent, and discriminant validity, and internal consistency reliability of the scales. The specific aims of the study (A), research questions (RQ) related to the development of the scales, and the hypotheses (H) to be tested are outlined in Table 1.

## **1.3. Originality of study**

The present study incorporated a qualitative study based on the m-TPB framework that included a professional norm construct in addition to the original TPB constructs to identify salient beliefs of CPs about PCare for HDS users. To date, there is a lack of study that utilises such framework to uncover beliefs and factors influencing the provision of PCare for HDS users. The qualitative study also explored various practices of PCare for HDS users that are relevant and applicable in the local community pharmacy settings. The present study also developed three scales to measure determinants and practices of PCare for HDS users. These scales are the first measures developed for the purposes mentioned.

#### 1.4. Significance of study

The significances of this study included the development of scales that was based on an established theoretical framework, and the application of both classical test theories and Rasch analysis for the psychometric evaluation of the newly developed scales. Additionally, the use of the qualitative study to inform the development of the scales through the application of a mixed-method approach provided a pragmatism perspective in achieving the goals of the present study. The development of the scales can provide a means for future researchers to understand the current PCare practices related to HDS among CPs in Thailand, and to recognize the important barriers and facilitators for the practices. This information in consequent can be used to inform the design of strategies such as educational programs or campaigns to encourage CPs to provide PCare for HDS users in the future.



**Table 1. Specific aims (A), research questions (RQ) and hypotheses (H) of the study**

<b>Aim</b>	<b>Research question</b>	<b>Hypothesis</b>
<b>Phase 1: Elicitation study using qualitative interview</b>		
A1. To describe the practices of PCare for HDS users among CPs in Bangkok, Thailand.	<ul style="list-style-type: none"> <li>• RQ1. What are the meanings of PCare for HDS users from the perspectives of CPs in Bangkok, Thailand?</li> </ul>	-
A2. To describe the behavioural, normative, control and professional normative beliefs of CPs about the provision of PCare for HDS users.	<ul style="list-style-type: none"> <li>• RQ2. What are the beliefs of the CPs about the consequences of providing PCare for HDS users?</li> <li>• RQ3. Who are the individuals that support the CPs to provide PCare for HDS users?</li> <li>• RQ4. What are the facilitators and barriers for the CPs to provide of PCare for HDS users?</li> <li>• RQ5. What are the beliefs about professional responsibility among the CPs regarding PCare for HDS users?</li> </ul>	- - -
<b>Phase 2: Development of scales</b>		
A3. To develop the Direct TPB, Indirect TPB, and PCare-HDS scales based on the theoretical framework and qualitative study findings from Phase 1 study.	-	-
<b>Phase 3: Quantitative study</b>		
<b>Stage 1: Exploratory analysis and refinement of scales</b>		
A4. To examine the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales as hypothesized from the theoretical framework and qualitative study findings from Phase 1	<ul style="list-style-type: none"> <li>• RQ6. What are the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales?</li> </ul>	-

study.		
A5. To refine the item pools of the Direct TPB, Indirect TPB and PCare-HDS scales using the EFA and CFA.	-	-
A6. To examine the internal consistency reliability of the Direct TPB, Indirect TPB and PCare-HDS constructs.	<ul style="list-style-type: none"> <li>• RQ7. Do the Direct TPB, Indirect TPB and PCare-HDS constructs have internal consistency reliability?</li> </ul>	-
<b>Stage 2: Validation of scales</b>		
A7. To confirm the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales as identified in Stage 1 data analysis using the second half of the sample.	<ul style="list-style-type: none"> <li>• RQ8. Are the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales identified in Stage 1 data analysis confirmed by the CFA?</li> </ul>	-
A8. To examine the convergent and discriminant validity, and construct reliability of the Direct TPB, Indirect TPB and PCare-HDS scales.	<ul style="list-style-type: none"> <li>• RQ9. Do the Direct TPB, Indirect TPB and PCare-HDS scales have convergent and discriminant validity, and construct reliability?</li> </ul>	-
A9. To examine the internal consistency reliability of the Direct TPB, Indirect TPB and PCare-HDS constructs of the final models.	<ul style="list-style-type: none"> <li>• RQ10. Do the Direct TPB, Indirect TPB and PCare-HDS constructs of the final models have internal consistency reliability?</li> </ul>	-
<b>Stage 3: Additional analyses</b>		
A10. To further examine the items of the Direct TPB, Indirect TPB and PCare-HDS scales based on the Rasch model.	<ul style="list-style-type: none"> <li>• RQ11: Do the subscales of the Direct TPB, Indirect TPB and PCare-HDS scales map on to a common underlying construct based on the Rasch model?</li> </ul>	-
	<ul style="list-style-type: none"> <li>• RQ12. Do the structure of rating scales of the Direct TPB, Indirect TPB and PCare-HDS scales appropriate</li> </ul>	-

based on the Rasch model?

- RQ13. Do items of the Direct TPB, Indirect TPB and PCare-HDS scales contain Differential Item Functioning (DIF) in terms of gender according to the Rasch model?

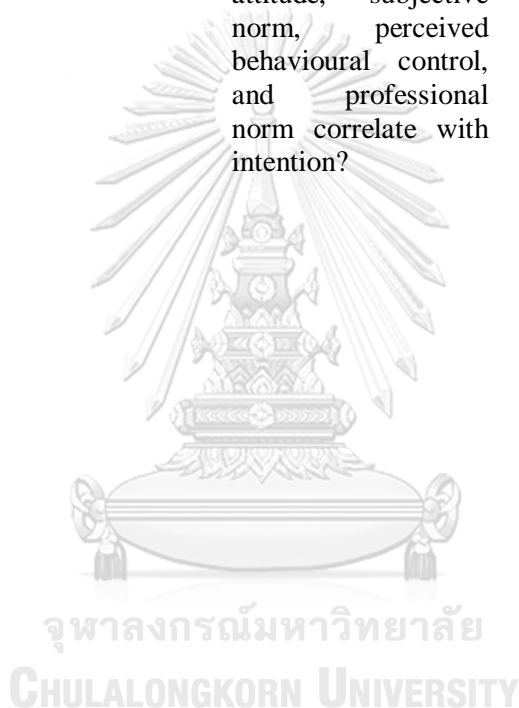
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A11. To examine the concurrent validity of the Direct TPB scale.

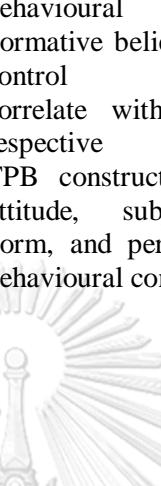
- RQ14. Do the Direct TPB constructs i.e., attitude, subjective norm, perceived behavioural control, and professional norm correlate with intention?

- H1. There are associations between the attitude, subjective norm, perceived behavioural control, and professional norm mean scores with the intention mean score.

- H<sub>1.1</sub>. Intention mean score would have a positive correlation with attitude mean score.
- H<sub>1.2</sub>. Intention mean score would have a positive correlation with subjective norm mean score.
- H<sub>1.3</sub>. Intention mean score would have a positive correlation with perceived behavioural belief mean score.
- H<sub>1.4</sub>. Intention mean score would have a positive correlation with





- 

professional norm mean score.

  - RQ15: Do the Indirect TPB constructs i.e., behavioural belief, normative belief, and control belief correlate with their respective Direct TPB constructs i.e., attitude, subjective norm, and perceived behavioural control?
  - H2. There are associations between the attitude, subjective norm, and perceived behavioural control mean scores with the behavioural belief, normative belief, and control belief mean scores, respectively.
    - H<sub>2.1</sub>. Attitude mean score would have a positive correlation with behavioural belief mean score.
    - H<sub>2.2</sub>. Subjective norm mean score would have a positive correlation with normative belief mean score.
    - H<sub>2.3</sub>. Perceived behavioural control mean score would have a positive correlation with control belief mean score.
  - RQ16. Does the total mean score of the PCare-HDS scale correlate with the total mean score of the Direct TPB scale?
  - H3. There is an association between the total mean score of the PCare-HDS scale with the total mean score of Direct TPB scale.
    - H<sub>3.1</sub>. The total mean score of the PCare-HDS scale would have a positive correlation

- RQ17. Does the total mean score of the PCare-HDS scale correlate with the total mean score of the Indirect TPB scale?

with the total mean score of the Direct TPB scale.

- H4. There is an association between the total mean score of the PCare-HDS scale with the total mean score of Indirect TPB scale.

H<sub>4.1</sub>. The total mean score of the PCare-HDS scale would have a positive correlation with the total mean score of the Indirect TPB scale.

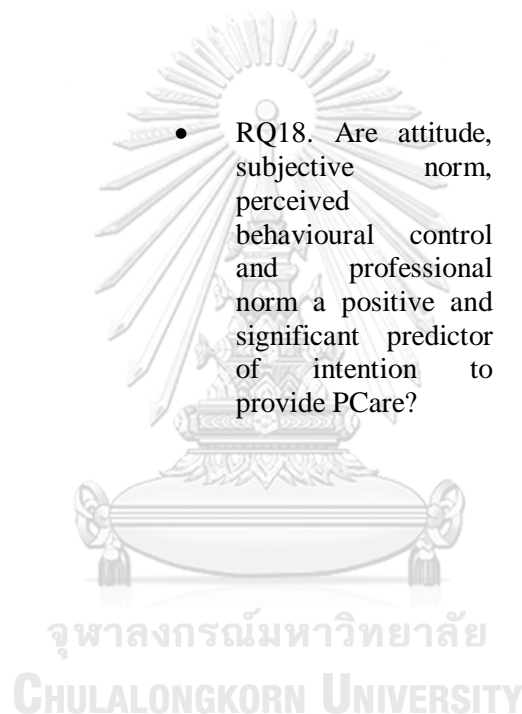
- RQ18. Are attitude, subjective norm, perceived behavioural control and professional norm a positive and significant predictor of intention to provide PCare?

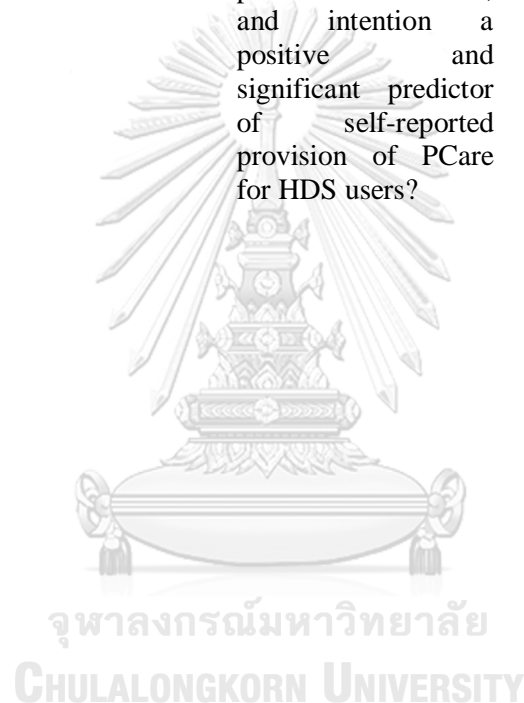
- H5. There are relationships between the attitude, subjective norm, perceived behavioural control, and professional norm mean scores with the intention mean score.

- H<sub>5.1</sub>. Attitude is a positive and significant predictor of intention to provide PCare for HDS users.

- H<sub>5.2</sub>. Subjective norm is a positive and significant predictor of intention to provide PCare for HDS users.

- H<sub>5.3</sub>. Perceived behavioural control is a positive and significant predictor of intention to provide PCare for HDS users.





- RQ19. Are attitude, subjective norm, perceived behavioural control, professional norm, and intention a positive and significant predictor of self-reported provision of PCare for HDS users?

- H<sub>5.4</sub>. Professional norm is a positive and significant predictor of intention to provide PCare for HDS users.

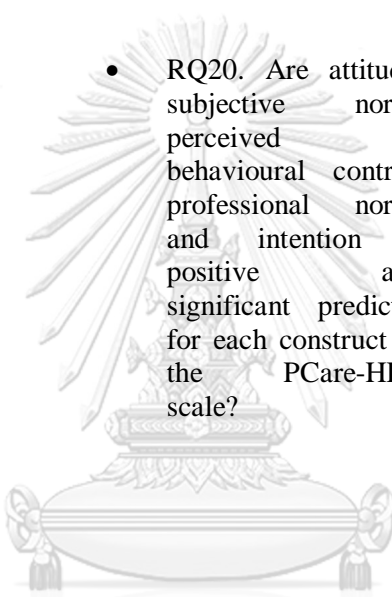
- H6. There are relationships between the attitude, subjective norm, perceived behavioural control, professional norm, and intention mean scores with the self-reported provision of PCare for HDS users mean score.

- H<sub>6.1</sub>. Attitude is a positive and significant predictor of self-reported provision of PCare for HDS users.
- H<sub>6.2</sub>. Subjective norm is a positive and significant predictor of self-reported provision of PCare for HDS users.
- H<sub>6.3</sub>. Perceived behavioural control is a positive and significant predictor of self-reported provision of PCare for HDS users.
- H<sub>6.4</sub>. Professional norm is a

positive and significant predictor of self-reported provision of PCare for HDS users.

- H<sub>6.5</sub>. Intention is a positive and significant predictor of self-reported provision of PCare for HDS users.
- H7. There are relationships between the attitude, subjective norm, perceived behavioural control, professional norm, and intention mean scores with the mean score of each construct of the PCare-HDS scale mean score.

- RQ20. Are attitude, subjective norm, perceived behavioural control, professional norm, and intention a positive and significant predictor for each construct of the PCare-HDS scale?



จุฬาลงกรณ์มหาวิทยาลัย

CHULALONGKORN UNIVERSITY

### 1.5. Definition of terms

***Herbal and dietary supplements (HDS).*** HDS refers to products containing plant-derived materials, or containing dietary ingredients e.g., vitamins, minerals, amino acids and substances such as enzymes, organ tissues, glands, metabolites, extracts and concentrates in the form of pills, capsules, tablets, powder, or liquids that are taken to treat and/or prevent diseases or maintain health (21, 22).

***Pharmacist's care (PCare).*** In this study, all professional activities carried out by pharmacists when dealing with HDS users e.g., the collection of HDS users' medication and medical history, and the provision of counselling were referred to as "pharmacist's care". This term was chosen to avoid confusion with the term "pharmaceutical care" that concerns on the optimization of medication use (23). Moreover in Thailand, pharmaceutical care has been frequently associated with activities such as advice about medicines, home medical care, and lifestyle modification, and rarely incorporate the aspects of HDS use (24). The term PCare has been used in previous published studies (25).

***Community pharmacist (CP).*** CPs are pharmacists working in community pharmacies or drugstores who generally supply medicines in accordance with a prescription or supply OTC medicines that do not require a prescription (26). In Thailand, CPs work in various type of community pharmacies such as independent, franchise, chain or university-affiliated community pharmacies.

## 1.6. Chapter summary

This chapter described the importance of the provision of PCare for HDS users by CPs. The safe and appropriate use of HDS among the users can be assured by CPs through various PCare activities. There is a need to investigate the facilitators and barriers to the provision of PCare for HDS users so that appropriate strategies to promote CPs to become more proactive in the activity can be devised. At present there is no quantitative instrument exists that can measure the determinant of PCare for HDS users. Moreover, a tool that can quantitatively measure the practice is presently unavailable. Therefore, the main purpose of this thesis was to develop such instruments. The following chapter reviews literature related to PCare for HDS users.



## CHAPTER 2: REVIEW OF LITERATURE

This section reviews previous studies that justify the need for the present study. This section begins with discussion about the common usage of HDS among the public and chronic disease patients. A special attention was given to the pattern of use of HDS by consumers and patients in Thailand. The high prevalence of HDS use and the potential adverse outcomes associated with HDS justified the need for CPs to be more proactive in providing PCare for HDS users. The recommended roles of CPs in caring for HDS users and the relevant tools to measure such activities are also discussed. The strengths as well as limitations of these tools are outlined. Subsequently, findings from previous studies about CPs' activities related to PCare for HDS users are provided.

### 2.1. Pattern of use of herbal and dietary supplements

The HDS falls under the broad term of complementary and alternative medicine (CAM). The other category of CAM is the “mind and body practices” (such as acupuncture, massage, and meditation). By this definition, HDS are considered as complementary medicine when used alongside conventional medicines to prevent and treat diseases, or to promote general well-being. HDS when used instead of conventional medicines are termed as “alternative medicine”. Over the past several years, the use of CAM has increased dramatically throughout the globe. The prevalence of use of at least one CAM could be as high as 74.8%, depending on the population and study settings (27-29). Among CAM modalities, HDS was found to be among the most commonly used.

In the United States (U.S.), based on the country's national survey carried out in the years 2002, 2007 and 2012 that encompassed almost 89,000 American adults who used CAM, HDS was found to be the type of CAM being most commonly used in each time point (30). In the survey, about 19% of the respondents were HDS users in 2002, and approximately 18% used the modalities in both 2007 and 2012. The survey findings showed that HDS such as fish oil, glucosamine, chondroitin, garlic supplements and Echinacea were the most commonly used. Comparably, findings

from another U.S. national survey showed that American adults frequently used HDS such as Echinacea, ginseng, ginkgo biloba, and garlic supplements (31). Similarly, the survey also showed HDS as the most common type of CAM used by American children in 2007 (32). The types of the most common HDS this population included Echinacea, fish oil and herbal pills of unspecified types.

Previous reports also showed that the Americans were willing to spend a substantial amount of money for purchasing HDS. In 2007 alone, it was estimated that American adults spent USD14.8 billion out-of-pocket for HDS. This amount was approximately 31% of the amount Americans spent for prescription medicines in 2007 (6). The willingness to pay for HDS was also observed among the Thai people. In a survey carried out among diabetic patients residing in the province of Ubon Ratchathani, the respondents were willing to spend USD8.6 for herbal medicine and USD30 for dietary supplements monthly despite earning only USD93.8 every month. This means that they were willing to spend approximately 9% to 32% of their monthly income to purchase HDS (33). In another survey among cancer patients in Bangkok, the average spending for CAM was even higher. These patients were willing to spend USD10 to USD1,000 for HDS (average = USD200) (7). The high prevalence of use of HDS and the willingness of HDS consumers to pay for these products indicate general acceptance of HDS in the society.

Previous reports also showed that not only the use of HDS is common among healthy people but it is also widely used among patients with chronic diseases who are using prescribed medicines. For an example, in a U.S. study, approximately 30% of HDS users used the products concomitantly with prescribed medicines. Those who had concomitant diseases were also found to be frequent HDS users (34). Other studies also showed that HDS are widely used by the elderly (35, 36) and pregnant women (37) that are known to respond differently to medications and perhaps HDS, due to an altered pharmacokinetics.

Apart from that reported in the U.S., similar trend of high HDS usage among the public had been observed in other countries such as Australia, Germany, and South Korea (28, 29). Thailand, as a multicultural nation in Southeast Asia, with more than



60 million citizens, the use of HDS by the Thai people is common. The following section reviews several studies about the use of HDS among Thais especially in those with chronic diseases.

## **2.2. The use of herbal and dietary supplements among Thai people**

In Thailand, based on the purpose for which the HDS are intended, as well as the availability of evidences for safety, efficacy, and quality, HDS products can be classified as “food” or “medicine” by the Thai Food and Drug Administration (FDA) (38). These products are widely available over the counter in community pharmacies in Thailand (13). In a survey in Bangkok, the prevalence of HDS use among the Thai general population in the city was 52% (5). Of these HDS users, 58.4% consumed herbal medicines to treat illnesses, whereas 65.3% used dietary supplements to enhance their well-being.

Additionally, in Thailand, various types of CAM have been reported to be used among chronic kidney disease (39), rheumatoid arthritis (40), diabetic (33), cancer (7), and HIV-infected patients (8, 41, 42). The prevalent of use of CAM among these patients ranged from 34% to 95%. Similar to findings from international studies, HDS appeared as the most common type of CAM being used by chronic disease patients in Thailand (8, 41, 42). These patients generally used the products to improve health, maintain health, improve emotional well-being, prevent illness, and/or reduce symptoms (7, 8). In several studies, chronic disease patients were influenced by their family and friends to use HDS (33, 39, 40). Apart from social influences, factors such as income (7, 33), career type (33), types of diseases (7), and general perceptions about CAM (8) have been found to influence the use of CAM among Thai patients.

### **2.3. The need to care for herbal and dietary supplement users**

It is a common notion that HDS are “natural” and therefore are entirely safe (9). However, similar to conventional medicines, HDS may potentially produce untoward effects. Nevertheless, due to the low reporting of adverse effects of HDS, the incidence for the adverse events may be misleadingly low (9, 43). Moreover, since the HDS are normally marketed as combinations or mixtures, and come in different strengths, the causal relationship between HDS and adverse effects is hard to establish (10). Even that so, mortality (10) and hospitalizations due to HDS-associated adverse effects have been reported and should not be overlooked (43).

In a study in the U.S., an estimated average of 23,000 emergency department (ED) visits yearly was associated with adverse effects of dietary supplements. Dietary supplements, in this study were defined as orally administered herbals, vitamins and minerals. Of all the ED visits, about 2,000 cases resulted in hospitalizations. Common nutrient products such as multivitamin, iron and calcium were found to be responsible for 31.8% of all ED visits. In the study HDS-associated adverse effects included cardiac symptoms such as palpitations, chest pain and tachycardia; gastrointestinal symptoms such as nausea, vomiting and abdominal pain; and mild-to-moderate allergic reactions (43). The authors of the study argued that the incidence of HDS-related adverse effects could be underestimated since the use is not often disclosed to the healthcare providers.

As a matter of fact, the rate of disclosure of HDS use to the healthcare providers among patients has been found to be low (44-46). This should be a cause for concern because prescribed medicines may potentially interact with HDS, and thus may cause treatment failure or toxicity (47). Moreover, since healthcare providers are unaware of the use of HDS by their patients, the identification of HDS-drug or HDS-disease interactions, together with the resultant adverse effects, may not be possible (7, 39). Ginseng, for example, has been shown to decrease the international normalized ratio, and if used concurrently with warfarin, the blood-thinning effect of the medication may be reduced (9). This may put patients who need anticoagulant effect of warfarin

to be at risk of developing blood clots, which can consequently result in life-threatening conditions such as stroke.

The occurrence of HDS-drug interactions, as a matter of fact, is common. In a cross-sectional study in Hungary, the researchers found that among 197 patients with a cumulative amount of 1,563 prescribed medicines and 490 types of HDS, as many as 365 and 718 HDS-drug interactions as indicated by Lexi-Interact and Medscape databases were identified, respectively. Among these HDS-drug interactions found, 130 and 21 interactions were considered as serious or contraindicated by the Lexi-Interact and Medscape databases, respectively (48).

Despite the recommendation to avoid certain HDS in chronic disease patients, this recommendation was not fully observed. For example, HDS products such as Java tea, roselle, *Ya Hom* and *Ka Sai*, that are not recommended to be used by chronic kidney disease patients as indicated in the Thai National List of Essential Medicines, were still reportedly used by these patients (39). It is possible that the patients who were using HDS were not aware of the potential danger of such products. It is also possible that the patients had the perceptions that HDS are beneficial. For instances, in two Thai studies, HDS were believed to produce positive effects in 51% of cancer patients (7) and 74% of chronic kidney disease patients (39).

Nevertheless, although many patients hold the belief that HDS may improve their health, studies that examined the quality of life of patients using HDS showed that the benefits may not necessarily achieved as expected. In a study among HIV-infected patients who used CAM, the assessment of their health-related quality of life (HR-QOL) as determined by the *Medical Outcomes Study-HIV Health Survey* indicated that there was no difference in terms of physical functioning among users and non-users of CAM (42). In another study, HR-QOL of diabetic patients who used CAM was compared to those of non-users, using the 36-item *Short Form Health Survey* (SF-36). The study found no difference of scores of all eight domains of the SF-36 among users and non-users of CAM. Similarly, health assessment and visual analog scale scores among rheumatoid arthritis patients who used CAM were found to be indifferent to those of non-users. Moreover, self-reported joint swelling and

tenderness among CAM users and non-users were similar (40). These findings showed that although many claims indicated that HDS may improve health, this outcome may not be necessarily observed in patients.

Concerns should arise if patients rely heavily on HDS to manage their disease and forgo standard treatment for the preference of HDS. In fact, a study among chronic disease patients in Thailand showed that CAM users were more likely to have poorer adherence to prescribed medicines compared to the non-users. The study also showed that 70% of CAM users were considered as low to medium adherers to prescribed medicines based on the *Thai 8-item Medication Adherence Scale* (39). This finding may indicate that some patients may prefer to use HDS over conventional medicine. This preference may be shaped by many external influences such as family and friends and the media. The obtainment of HDS information from family members and friends, and media such the Internet, radio and television should be a reason to worry about (8, 39, 41). The information gathered from these sources of information may not be reliable or valid, and may only be anecdotal in nature.

Given that there are several potential risks with HDS use, the use of HDS among the public, especially those with chronic diseases or using prescribed and OTC medicines, should not be overlooked. The CPs, more than ever should play a role in caring for HDS users given the high prevalence of HDS use and the increased reporting of its associated adverse effects. The following section reviews the roles of CPs in caring for HDS users and the rationales for them to provide PCare for HDS users.

#### **2.4. Community pharmacists' roles related to herbal and dietary supplement use**

In the joint International Pharmaceutical Federation (FIP) and World Health Organization (WHO) Good Pharmacy Practice (GPP) guideline (49), GPP is defined as the “*practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care*”. The guideline outlined four main roles for pharmacists to perform in pharmacy practice. Although, the guideline was written specific for medicines, several of the recommended practices can be adopted in the context of HDS. For examples, CPs should procure

and store quality products, provide assessment for patient needs, and monitor patient progress or outcomes. In addition to these general practices, the GPP guideline specifically mentioned that pharmacists should maintain and improve their knowledge and skills about HDS. Moreover, among the four roles of pharmacists mentioned in the joint FIP/WHO GPP guideline, pharmacists are expected to involve in activities related to self-care. Since HDS use is normally aimed to establish and maintain health, and to prevent and treat illnesses, it is considered as self-care. In a FIP/WHO report published in 1998, several roles of pharmacists in related to self-care are outlined (50). Table 2 summarizes these activities.

The White Paper on Herbal Medicine (51) published by the American College of Clinical Pharmacy (ACCP) in 2000 corresponds to the list of roles of pharmacists in self-care. The White Paper emphasizes that CPs should only stock herbal products that are produced by certified facilities that conformed to good manufacturing practices (GMP) guidelines. CPs are recommended to only stock, recommend and sell those HDS with proven efficacy and safety.

During encounters with customers using or planning to use HDS, CPs are recommended to talk about HDS use in a non-judgmental manner. This in consequent would allow the CPs to obtain drug and disease histories from the customers. Information obtained from the interview can help CPs to assess the appropriateness of HDS use and identify HDS-related problems. CPs should also assist customers in making informed decision about using HDS by supplying them with available evidences of efficacy and safety of HDS they are planning to use. Additionally, CPs are recommended to make recommendation about HDS use without conflict of interests and at standards similar to when recommending conventional medicines.

**Table 2. Roles and activities of pharmacists related to self-care**

Role	Activity
<b>As a communicator</b>	Initiate dialogue with patients to obtain a sufficient medication history. Ask patients key questions and provide relevant information to them. Perform proper screening for specific conditions and diseases. Provide objective information about medicines. Use and interpret additional sources of information to satisfy the needs of the patient. Help patients undertake appropriate and responsible self-medication. Refer patients for medical advice.
<b>As a quality drug supplier</b>	Ensure that the products are from reputable sources and of good quality. Ensure the proper storage of these products.
<b>As a trainer and supervisor</b>	Participate in continuing professional development activities such as continuing education. Ensure that the services rendered by non-pharmacist staff correspond to established standards of practice. Promote the training and supervise the work of non-pharmacist staff.
<b>As a collaborator</b>	Develop quality collaborative relationships with other healthcare professionals; national professional associations; the pharmaceutical industry; governments (local/national) and patients and the general public.
<b>As a health promoter</b>	Participate in health screening to identify health problems and those at risk in the community. Participate in health promotion campaigns to raise awareness of health issues and disease prevention. Provide advice to individuals to help them make informed health choices.
<b>The roles and activities are based on the 1998 FIP/WHO recommendation for “Role of Pharmacist in Self-Care and Self-Medication” (50)</b>	

Patient education about HDS use is another important aspect of CPs' roles mentioned by the white paper. Since CPs have received extensive formal education in medication and HDS use, and in the management of diseases/ailments, they should be held responsible in educating customers who are using or planning to use the products. CPs should advise HDS users about the risks, efficacy and safety of the products, and advise them to inform their doctors about using HDS.

CPs are also recommended to document the information presented to patients and to record patients' informed decision about using HDS to avoid liability issues. Apart from these direct patient care activities, CPs are also encouraged to be vigilant for adverse event associated with the HDS and report such event to the authorities. In

addition, CPs should update and maintain their knowledge about HDS and share the information with patients and other healthcare professionals.

In summary the White Paper by the ACCP calls for pharmacists to be more engaging with people using or planning to use HDS. The report outlined several activities that can be exercised by pharmacists in ensuring quality and safe use of HDS. Among these practices are direct care activities that are consistent with the pharmaceutical care (PC) practice. The following section describes PC practice and the processes that come with it.

## **2.5. The pharmaceutical care practices**

Hepler and Strand (52) introduced the PC philosophy as a patient-centered approach in caring for patients in 1990. At present, PC is defined as a practice in which pharmacists accept to be responsible for patient's drug related needs (23). According to the PC philosophy, pharmacists are considered to "professionally care" if they assess patients' needs, mobilize all resources to meet those needs, and evaluate the outcomes of the patients. The provision of PC is aimed at accomplishing positive patient outcomes through the identification, resolution and prevention of the drug therapy problems (DTPs). Although the word "pharmaceutical" is used in PC concept, other products that patients use for therapeutic purposes including HDS must also be taken into account in all PC processes.

PC processes can be divided into three stages i.e., assessment, development of care plan and evaluation. In the assessment stage, pharmacists seek to understand patients' medication experience in order to determine whether patients are receiving indicated, effective and safe therapy, and to identify DTPs. Using information gathered from patients, pharmacists can subsequently develop a care plan to assist patients achieving their therapeutic goals.

The care plan includes interventions such as starting a new drug therapy, ceasing or adjusting the dosages of existing medications, or providing patients with relevant education. In PC, patients are scheduled for a follow-up to allow the assessment of the established care plan. At follow-up pharmacists evaluate whether the treatment

regimen given is effective and safe, and whether the patients are adherent to the regimen. Pharmacists will also identify new possible DTPs that need resolution.

Additionally, it is recommended for pharmacists to record or document the PC plan that has been developed. The documentation of PC plan will provide a means of reference to patients and other healthcare practitioners about the decisions and interventions made during PC processes. In the context of HDS, PC if committedly performed may benefit customers or patients who are using HDS through the prevention of HDS-related problems such as adverse effects and HDS-drug interactions.

## **2.6. Measuring pharmacist's care for herbal and dietary supplement users**

Review of the literature showed that a limited number of validated tools are relevant for measuring PCare for HDS users. Previous studies either used a self-developed scale with limited (or lack of) evidence for validity (3, 53-55) or only utilized specific questions to investigate certain activities. As for examples, to measure counselling, the items, “*Do you advise consumers on safe use of herbal medicine?*” and “*Do you counsel your customers about using of herbal drugs?*”, have been used (56, 57). Additionally the previous studies only included a limited number of activities to represent PCare for HDS users with most focusing on counselling for (3, 54, 55, 57-62), or recommendation (1-3, 44, 60-65) of HDS.

In 1996, Odedina and Segal (66) developed the “*Behavioural Pharmaceutical Care Scale (BPCS)*” to measure various pharmacists’ activities based on the philosophy of PC mentioned earlier (23, 52). The scale contained 34 items distributed among 14 domains: (1) documentation; (2) patient assessment; (3) implementation of therapeutic objectives and monitoring plans; (4) patient record screening; (5) patient consultation; (6) verification of patient understanding; (7) referral and consultation; (8) counselling location; (9) filled-prescription validation; (10) informational support; (11) evaluation of patient satisfaction; (12) competency improvement; (13) performance evaluation; and (14) provision of medical information.



The strengths of the BPCS included the strong foundation of scale development based on the PC philosophy, and the coverage of a breadth of activities related to PC. Additionally, the scale was also found to be valid and reliable. However, several activities listed by the BPCS are specific to prescribed medicines and may not be relevant to the context of HDS. For examples, items: *“Double-checked each prescription prepared by other personnel before giving the medication to the patient”*, and *“Referred patients with social problems, such as inability to afford medications, to appropriate agencies for help”*, are not relevant to the HDS context.

In addition, several activities listed in the BPCS, such as the “documentation of patients’ information and intervention made on patients’ file”, and “provision of written copies of patients’ information to other healthcare professionals”, may not be applicable to community pharmacy practice in Thailand. Furthermore, several aspects of pharmacists’ roles in self-care such as ensuring quality products being stored at the community pharmacies, ensuring proper storage for these products, and ensuring informed decisions to use self-care products were not included in the BPCS. Moreover, only 2 out of 34 items of the BPCS were related to counselling or provision of information to patients.

Kemper *et al.*, (53) in their study to examine expertise about HDS among health professionals, utilized a communication scale that consisted of 11 items. Nine of the items asked the respondents to indicate their engagement in various communication activities related to HDS from 0% to 100% (e.g., *“In the past 30 days, in what percentage of your clinical encounters have you discussed with a patient or family about the use of HDS?”*). Another two questions utilized yes/no response: *“In the past 30 days, have you cautioned any patient about the potential hazards associated with the use of any herbal products (other than tobacco)?”* and *“In the past 30 days, have you discussed with a colleague a clinical question related to the use of herbs or dietary supplements?”*. The scale was found to have internal consistency reliability with a Cronbach’s alpha value of 0.84.

The main strength of the communication scale for HDS by Kemper *et al.*, (53) involved the inclusion of several crucial aspects of PCare for HDS users such as

gathering information from HDS users, providing HDS information, and documenting patients' HDS use and associated issues (such as adverse events and HDS-drug interactions). However, being a communication scale for HDS use, the scale was limited to items relevant to communication practice only. In addition, information regarding the validity of the scale was lacking limiting its use as a valid measure.

In 2010 Lin *et al.*, (67) published an instrument to measure the provision of counselling with respect to HDS. Although the main aim of the study was to measure patient counselling for HDS, the authors also included a development of a general patient counselling measure (8 items). The patient counselling measure for HDS included 7 items that were distributed among two main dimensions: (1) assessment (content and process) and (2) plan/follow-up (recommendation and monitoring). The instrument was found to be psychometrically valid, and was recommended by the authors to be used as a means of self-assessment by pharmacists, evaluation of students' competencies or as a measure for quality improvement in quality assurance programs. The instrument by Lin *et al.*, although found to be valid, only included a limited number of advice that should be given to HDS users. Only two specific items representing advice were available in the instrument: (1) *explain the pros and cons of HDS use*; and (2) *provide written information*. The other 5 items were representing assessment process, recommendation or monitoring for HDS use. Since the instrument were fundamentally developed for measuring patient counselling for HDS, other activities that are important in the context of HDS such as assisting informed decisions, maintaining HDS product quality and maintaining knowledge about HDS were lacking.

In a cross-sectional study in Australia, CPs were surveyed to investigate their attitudes towards, perceptions about, confidence in and practices related to various aspects of complementary medicines (CM), defined as products that are orally administered e.g., vitamins, minerals, amino acids, herbs, concentrates, metabolites, constituents, botanical, and animal extracts (54). The "practices" section of the survey comprised of 5 items representing comprehensiveness of an evaluation for appropriateness of CM use, and 1 item representing pharmacists' decision to sell CMs to customers when the product is consider inappropriate.

The questionnaire was found to have construct validity and reliability as determined using the confirmatory factor analysis approach. One main limitation of the Australian study was that the behavior in focus was “*the selling of CMs that is not appropriate*”. The researchers used a 5-point Likert-type scale: 1=almost never to 5=almost always, to assess the CPs’ responses to the item. The result showed that less than 5% of the CPs responded to the highest two responses (almost always and always). Since “*the selling of CMs that is not appropriate*” is an unfavorable behavior, the authors noted that this result may be influenced by “social desirability”. Moreover, the other 5 practice items were only limited to evaluation of CMs only, thereby limiting a full understanding of CPs’ behavior in respect to CM. Additionally, although the “perception” section of the survey consisted of 10 items asking CPs their perceptions about their responsibilities of CPs in regard to CMs, the CPs were not asked to indicate their level of engagement in these activities.

In a study performed in Iran, the knowledge, attitude and practice model was used to understand Tehran CPs’ practices in regard to dietary supplements (55). The study used 10 items to represent various activities related to dietary supplements. The authors only provided evidences for content and face validity, and internal consistency reliability of the practice scale. Other aspects of validity namely construct, convergent, and discriminant validity were not reported by the authors. Additionally, among the 10 “practices” items used in the survey, the researchers also included an item written as, “*I have self-confidence for recommending supplement*”. This item may not accurately signify a practice but essentially representing self-efficacy or self-confidence.

The review of the literature showed that previous studies in attempts to investigate pharmacists’ activities related to HDS had utilized a set of questions or instruments that were only limited to certain type of activities, not validated or not relevant to the context of HDS or to the context of community pharmacy practice in Thailand. These instruments therefore did not satisfy the measurement goals in the present study i.e., PCare for HDS users. Mapping of the items from five relevant tools (53-55, 66, 67) to measure pharmacists’ activities to the pharmacists’ roles in self-care framework by

the FIP/WHO (50) showed that there is a need for a valid and reliable to measure a comprehensive set of activities of PCare for HDS users (Table 3).

## **2.7. Pharmacist engagement in pharmacist's care for herbal and dietary supplement users**

Despite having no ideal scale to measure a whole range of PCare for HDS users. Many studies have reported the extent to which pharmacists engage in several activities relevant to PCare for HDS users. These activities included communicating with customers or patients, performing assessment on HDS use, providing counselling to HDS users, documenting HDS use, and recommending HDS.

### **2.7.1. Communicating with customers or patients**

Eliciting information about HDS use from those who are using or planning to use HDS is an important aspect in PCare for HDS users. The information collected during this process allows CPs to assess the appropriateness of HDS use, and enable them to evaluate potential HDS-related issues (such as the occurrence of adverse events or HDS-drug interactions). This in consequence allows CPs to take further action such as by ceasing the HDS use, referring patients to physicians, or providing them with education.

However, previous studies have shown that pharmacists did not actively communicate with customers or patients about HDS use (59, 61, 64). For instance, in a survey conducted in England among 818 CPs (64), only less than 5% of the respondents asked their patients about HDS use when dispensing regular medicines. Similarly, in another survey in the U.S., CPs estimated that only 20% of patients have been inquired about their HDS use (44). A similar trend of practice was observed in other countries such as Australia (68), Saudi Arabia (59), and Nigeria (61).

In an Australian study, 95% of CPs reported that communication about HDS only occurred when customers or patients brought up the issue (1). The low level of engagement of pharmacists in communicating with customers or patients about HDS use should be a cause of concern since HDS users may be using HDS inappropriately,

developed adverse effects or being exposed to HDS-drug or HDS-disease interactions without being noticed by healthcare providers. Among the reasons for not communicating with customers or patients about HDS use included the reliance on patients to provide HDS information, lack of time, and the lack of HDS information resources (59, 68).

### **2.7.2. Assessing use**

Pharmacists generally agreed that regular assessment of HDS use among patients is part of a standard patient care (69). The assessment of HDS use is critical to ensure that the use of the products is appropriate in relation to patients' conditions. Inconsistent findings were found in the literature in regard to the extent of involvement of pharmacists in regard to this activity mainly due to the different questions or focuses used to represent "assessment of HDS use". Based on previous studies, it appeared that pharmacists were more active in assessing the safety of HDS products compared to assessing the indication.

In a study in the U.S., only 40% of pharmacists examined the appropriateness of HDS relative to patients' medicine and disease (44). In a study in Australia, only 3.5% of the respondents agreed that they "always" identified the potential adverse effects of HDS. On the contrary, in another Australian study, pharmacists were noted to be proactive in assessing the safety of HDS products (79.3%) (54). Pharmacists in studies in Jordan and Iran were also found to be proactive in checking the presence of interactions between HDS and patients' regular medicines (3, 55). Studies that report the extent to which pharmacists monitor customers or patients who are using HDS are limited. In one Australian study only approximately 40% of the respondents claimed that they monitor or follow-up HDS-related problems in their patients (44).

**Table 3. Mapping of content of previous scales to the framework of the Role of Pharmacist in Self-Care and Self-Medication**

	Odedina and Segal (1996)	Kemper <i>et al.</i> , (2006)	Lin <i>et al.</i> , (2010)	Kanjanarach <i>et al.</i> , (2010)	Mehralian <i>et al.</i> , (2014)
Components are specific to HDS	No	Yes	Yes	Yes	Yes
Provide evidence of validity	Yes (construct, convergent, discriminant, and nomologic validity)	No	Yes (content, construct, and convergent validity)	Yes (content, face, construct, and convergent validity)	Yes (only face and content validity)
Provide evidence of reliability	Yes (item to total correlation and internal consistency reliability)	Yes (internal consistency reliability)	Yes (internal consistency reliability)	Yes (construct reliability)	Yes (internal consistency reliability)
Included the following aspects of pharmacist's roles in self-care <sup>a</sup>					
As a communicator					
• Initiate dialogue with patients to obtain a sufficient medication history.	Yes	Yes	Yes	No	No
• Ask patients key questions.	Yes	Yes	Yes	No	Yes
• Provide relevant information to patients.	Yes (general and not specific)	Yes (mainly in the forms of reference materials)	Yes	No	Yes
• Perform proper screening for specific conditions and diseases.	Yes	No	Yes	Yes	Yes
• Provide objective information about medicines.	No	No	Yes (but not specific and not comprehensive)	No	Yes (but not comprehensive)
• Use and interpret additional sources of information to satisfy the needs of the	Yes	No	Yes	No	Yes



<ul style="list-style-type: none"> <li>• Provide advice to individuals to help them make informed health choices.</li> </ul>	No	No	No	No	No
<sup>a</sup> As described in the “Role of Pharmacist in Self-Care and Self-Medication” endorsed by the FIP and WHO.					





### 2.7.3. Providing counseling

It is important for CPs to counsel patients on the use of HDS so that patients are informed about the benefits and limitations of HDS use, the direction for use, and the possible adverse effects that are associated with the products (51). Counseling for HDS use will promote quality and safe use of both HDS. The rate for counselling for HDS use varied in previous studies due to the inconsistent use of survey items to measure the activity. In general when pharmacists were asked in a general manner about the extent to which they provide counselling for HDS use, the majority admitted that they did not actively provide the activity (56-60). However, when pharmacists were presented with specific aspects of counselling such as the direction of use (3, 55) and lifestyle changes (3, 54), they rated their involvement in the activity as high.

In a few studies pharmacists were shown to be proactive in advising patients about the side effects of HDS (3, 55) whereas in one study, only about 20% of the pharmacists engaged in this activity. Having limited knowledge about HDS, lack of time, and insufficient HDS evidences have been suggested as barriers for pharmacists to provide counselling for HDS users (67). Additionally, inadequate information in HDS package leaflets, and public misunderstanding about HDS have also been cited as barriers (70).

### 2.7.4. Documenting use

Documentation of HDS use can provide a means of reference to the patients, pharmacists and other healthcare providers about the indication of HDS use or any other information such as the interventions made related to HDS use (such as patient education, ceasing of HDS, and referrals). The rate of documentation of HDS use by pharmacists has been found to be low in previous studies. The reported proportions of pharmacists who documented patients' HDS use range from 0.4% to approximately 30% (44, 59, 64, 71-73). In one study, the majority of pharmacists (60%) was reported to perform documentation of patients' HDS use in "patient history" but just about 30% of them recorded the information in patients' medication chart (68).

### **2.7.5. Recommending and dispensing**

Although the majority of previous studies showed that the involvement of pharmacists in various activities of PCare for HDS users was suboptimal (12), many studies reported that pharmacists were active in recommending HDS. For example, in an Australian survey, 95% of the pharmacists agreed that they have recommended their patients to use CAM in the past one year (1). In Jordan and England, approximately 80% and 50% of the pharmacists, respectively, prescribed HDS products to their patients (3, 64). Additionally pharmacists were also found to be active in recommending HDS to their own family and friends (2, 65).

Despite the different level of HDS recommendation reported in previous studies, consistent results were noted in regard to the extent to which pharmacists sell HDS products. The proportions of pharmacists selling HDS reported in previous surveys range from 65% to 99% (1, 59, 62-64, 72, 74, 75). It should be noted that many pharmacists generally believed that stocking and recommending HDS did not have negative implications on pharmacists' profession (63, 72, 76).

### **2.8. Factors influencing pharmacist's engagement in activities related to pharmacist's care for herbal and dietary supplement users**

Previous sections of the literature review have shown that pharmacists although regularly recommend and sell HDS to their customers, they did not regularly provide PCare for HDS users. Information about the factors that may influence pharmacists to provide PCare for HDS users is limited. Several studies have suggested that education history, environmental factors, and pharmacists' characteristics as factors influencing pharmacists' practices in regard to HDS. Table 4 shows the contextual factors that have been associated with the provision of PCare for HDS users. Unfortunately, these contextual factors are not modifiable, and therefore are not suitable to be targeted in strategies to promote CPs to become more proactive in providing PCare for HDS users.

Previous studies have shown that psychosocial factors such as beliefs and attitudes may influence pharmacists to be more proactive in several pharmacy-related activities

(18, 20, 77, 78). Therefore, these cognitive aspects can be potential targets to change CPs' behavior in respect to HDS. Pharmacists' beliefs about the provision of PCare for HDS users therefore, should be explored further so that salient beliefs about the facilitators and barriers for the provision of such care can be identified. Findings from such study can be valuable to guide behavioral change strategies in promoting CPs to provide PCare for HDS users. These strategies may include the provision of educational programs or launching of campaigns to promote the provision of the service by CPs.

Review of the literature showed that the majority of previous studies reported the beliefs and attitudes of pharmacists towards the HDS, and not towards the behaviour of providing PCare for HDS users. Survey findings on pharmacists' beliefs about providing PCare for HDS users are limited. The majority of available studies focused on pharmacists' beliefs about their confidence in counseling (60, 68, 69), discussing (1, 79) and providing information (44, 73, 80) about HDS to patients. In these studies, pharmacists rated their confidence in the three aspects of PCare for HDS users as inadequate. Additionally in several studies, pharmacists perceived their knowledge in HDS as insufficient (65, 72, 81). However, despite being unconfident in counseling, discussing and providing information about HDS to patients, and perceived themselves as unknowledgeable in HDS, pharmacists in general agreed that providing PCare for HDS users is indeed one of their responsibilities (3, 14, 54). In this regard, pharmacists believed that they have the responsibility to advice (14, 54, 63), ask (1, 79) and provide information (3, 74, 81) about HDS to their patients.

**Table 4. Factors associated to pharmacist's care for herbal and dietary supplement users**

Categories	Subcategories	Factors	Association	References
<b>Pharmacists</b>	Previous use of AM	Asking patients about AM	Pharmacists who used AMs were more likely to ask patients about AM	Dolder <i>et al.</i> , (2003) (73)
<b>Pharmacists</b>	Previous use of DS	Recommending DS	Pharmacists who used DS were more likely to recommend DS	Howard <i>et al.</i> , (2001) (2)
<b>Pharmacists</b>	Previous use of HNP	Recommending HNP	Pharmacists who used HNP were more likely to recommend CAM	Welna and Hadsall (2003) (65)
<b>Pharmacists</b>	Gender	Recommending CAM	Male pharmacists are more likely to recommend CAM	Welna and Hadsall (2003) (65)
<b>Pharmacists</b>	Gender	Recommending CAM	Male pharmacists are more likely to recommend CAM	Bouldin <i>et al.</i> , (1999) (72)
<b>Pharmacists</b>	Position	Recommending CAM	Pharmacy owners are more likely to recommend CAM	Welna and Hadsall (2003) (65)
<b>Environment</b>	Access to herbal medicine information	Discussing with patients about HM	Pharmacists who had access to herbal medicine information were more likely to 'sometimes' discuss with patients about HM	Al-Arifi (2013) (59)
<b>Environment</b>	Access to herbal medicine information	Documenting HM use by patients	Pharmacists who had access to herbal medicine information were more likely to 'sometimes' document HM use by patients	Al-Arifi (2013) (59)
<b>Environment</b>	Place to document	Asking patients about CAM	Pharmacists who had a place to document in the pharmacy were more likely to ask patients about their CAM use	Brown <i>et al.</i> , (2005) (44)
<b>Environment</b>	Practice settings	Documenting AM use	Pharmacists who work in the inpatient settings were more likely to document AM use by patients	Dolder <i>et al.</i> , (2003) (73)
<b>Environment</b>	Practice settings	Providing advice	Pharmacists who	Abahussain

		about HM	work in the private sector were more likely to provide advice about CAM to patients than those who work in the government sector	<i>et al.</i> , (2007) (58)
<b>Education</b>	Previous training	Asking patients about AM	Positively associated with asking patients about AM use	Dolder <i>et al.</i> , (2003) (73)
<b>Education</b>	Previous training	Documenting AM use	Positively associated with documenting AM use by patients	Dolder <i>et al.</i> , (2003) (73)
<b>Education</b>	Previous training	Asking patients about CAM	Positively associated with asking patients about their CAM use	Brown <i>et al.</i> , (2005) (44)
<b>Education</b>	Previous training	Asking patients about CAM	Positively associated with asking patients about CAM	Barnes and Abbot (2007) (64)
<b>Education</b>	Previous training	Discussing with patients about HM	Pharmacists who had previous training in HM were more likely to ‘sometimes’ discuss herbal medicine use by patients	Al-Arifi (2013) (59)
<b>Education</b>	Previous training	Documenting HM use by patients	Pharmacists who had previous training in HM were more likely to ‘sometimes’ document herbal medicine use by patients	Al-Arifi (2013) (59)
<b>CAM = complementary and alternative medicine; AM = alternative medicine; DS = dietary supplement; HM = herbal medicine; HNP = herbal and natural products</b>				

## 2.8. Theory of the planned behavior

The theories of behavior can be used to understand the factors underlying a particular behavior. The social-cognitive, “Theory of the Planned Behavior” (TPB) is one of the most comprehensively tested social-psychological models (17). The efficacy of the TPB to predict behavioral intentions and behaviors of healthcare professionals including the pharmacists has been demonstrated (17, 82). In a systematic review by Godin *et al.*, the predictive power of studies utilizing the TPB to predict healthcare professionals’ behaviors was superior compared to studies using other theoretical

frameworks (17). The other social cognitive models such as the SCT and the Theory of Interpersonal Behavior (TIB) have been shown to have less efficacy in predicting behaviors of healthcare professionals (17).

In general, the psychosocial theoretical models put the focus of perceived advantages and barriers to performing a particular behavior (17). However in addition to these factors, the TPB also emphasizes on social influences for a behavioral performance. Previous studies have shown that social influences are important determinants for CPs' intention to engage in various pharmacy-related activities such as the delivery of medication disposal education (83), utilization of a prescription drug monitoring program (77), adjustment of medication regimens (84), and provision of cardiovascular disease care (18). Given the importance of social influences for CPs' behavioral intentions, and due to the efficacy of the TPB constructs as predictors for behavioral intentions and behaviors in general, and among healthcare professionals, the TPB model has been selected as the theoretical framework to underpin the present study.

The TPB states that intention is the antecedent or predictor of a given behavior (85). The ability of behavioral intention to predict behavior has been shown in a systematic review by Eccles *et al.*, (86). In the context of pharmacy practice, Odedina and Segal showed that pharmacists who intended to carry out general PC activities were significantly more likely to provide the service (66). The intention is determined by three constructs namely attitude towards the behavior (overall evaluation of a behavior including the advantages and disadvantages), subjective norm (pressure from important or significant people to perform a given behavior) and perceived behavioral control (perceived ability of individuals to perform the target behavior). These three components of the TPB model are referred to as the direct measure that can be directly derived from the TPB domains. Antecedents to each of the three constructs are corresponding salient beliefs (behavioural belief, normative belief, and control belief) that are unique to the given behavior and target group (87). These constructs are called the indirect measure.

It is worth noting that all three constructs underlying the behavioral intention in the TPB model should correspond to the behavior in context, and not to a specific “object”. For example, a CP’s intention to provide PCare for HDS users can be influenced by his or her positive attitude towards the practice (e.g., beliefs that PCare for HDS users may ensure rational use of HDS or ensure safety of HDS users). On the other hand, a positive attitude towards the HDS itself (e.g., beliefs that HDS can cure disease or HDS is safe) may or may not influence the provision of PCare for HDS users. To date no study has ever reported a full set of beliefs based on the TPB to explain the provision of PCare for HDS users among CPs.

Apart from the original constructs of the TPB framework, a construct for “professional norm” was included in the theoretical framework to explore CPs’ beliefs about the provision of PCare for HDS users in this study. This norm although is not part of the original TPB framework, the construct is a pivotal determinant of behavioural intention in the Triandis’ TIB (88). In previous studies, this element has been shown to be an important determinant for pharmacists’ intention to engage in various pharmacists’ activities (19, 77). Furthermore, in a systematic review of the studies that predict healthcare professionals’ intentions and behaviours based on social cognitive theories, the “professional role/identity” was found to be a significant determinant in 8 out of 14 studies (17). The professional norm therefore is deemed important in the present study. Figure 1 shows the theoretical framework based on the m-TPB that underpinned the investigation of CPs’ beliefs about the provision of PCare for HDS users. The definition of each construct of the theoretical model in the context of present study is as the following:

**Attitude.** The attitude refers to the degree to which a CP has a favorable or unfavorable evaluation about the provision of PCare for HDS users. Attitude is determined by behavioural beliefs about the provision of the service (85, 87, 89, 90).

**Behavioural belief.** Behavioural belief of the provision of PCare for HDS users includes thoughts of what would happen if the service is offered (e.g., PCare for HDS users may ensure rational use of HDS or ensure safety of HDS users) or the outcomes

of the service (e.g., attract more customers or enhance CP professional image) (85, 87, 89, 90).

**Subjective norm.** Subjective norms refer to the extent to which CPs feel pressure from the society to provide PCare for HDS users (85, 87, 89, 90).

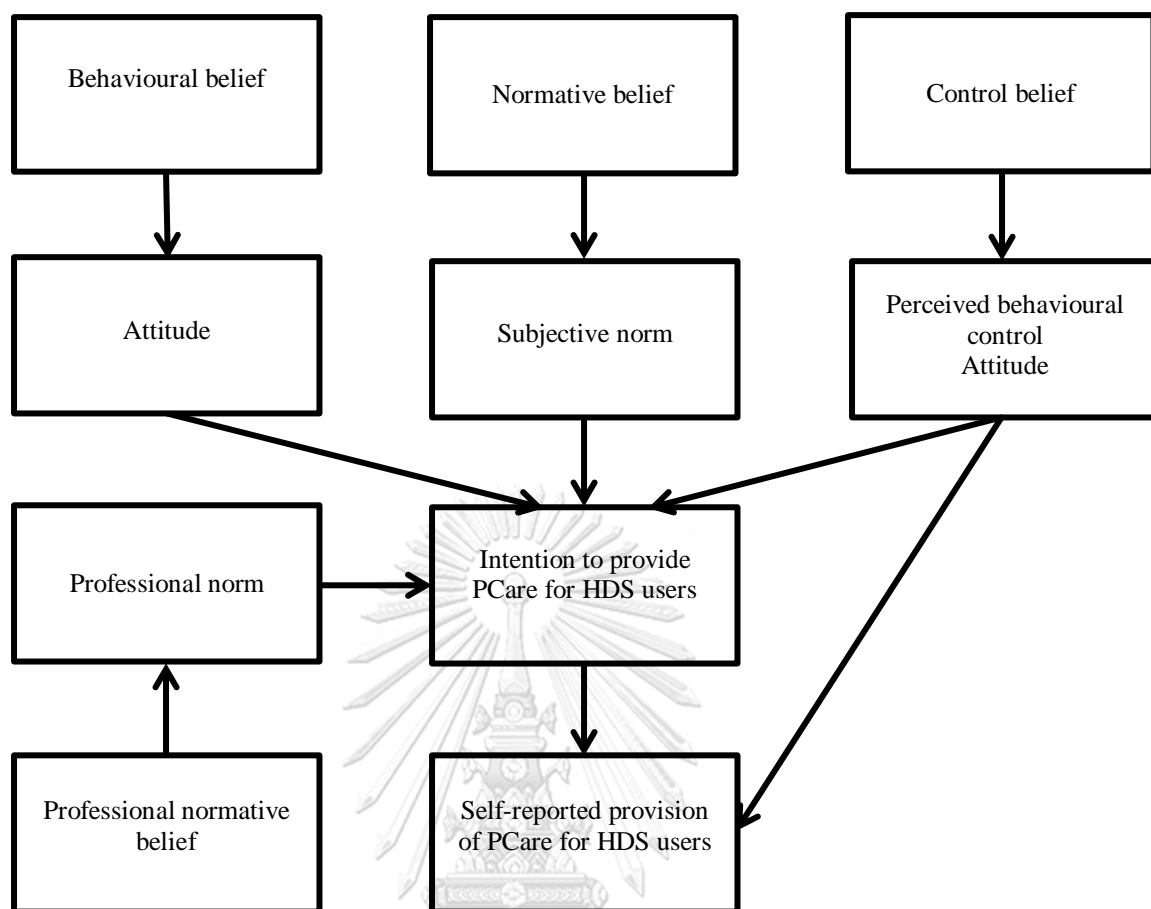
**Normative belief.** Normative belief involved the belief that important or significant people (e.g., family, colleagues, spouse, close friends, pharmacy owners, or supervisors) would like them to provide PCare for HDS users (85, 87, 89, 90).

**Perceived behavioral control.** Perceived behavioral control (PBC) is defined as the perceived ability of CPs to provide PCare for HDS users. PBC also includes the extent to which the CPs feel confident that they can enact the behavior (85, 87, 89, 90).

**Control belief.** Control beliefs included the situational and internal factors that inhibit (e.g., having inadequate knowledge in HDS or limited source of information) or facilitate (e.g., professional training or having more time) the CPs to provide PCare for HDS users (85, 87, 89, 90).

**Professional norm.** The professional norm refers to the extent of which CPs felt it is their professional obligation to provide PCare for HDS users (19, 77).

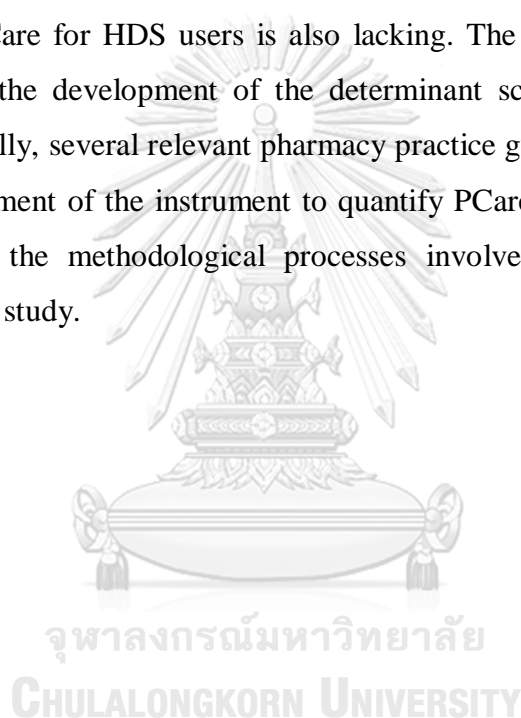




**Figure 1. Conceptual framework guided by the modified Theory of Planned Behaviour**

## 2.9. Chapter summary

This chapter discussed previous studies related to the provision of PCare for HDS users. Results from previous studies showed that many pharmacists were not proactive enough in providing PCare for HDS users, warranting the investigation of the factors underlying the behaviour. Additionally, the information about the extent to which CPs in Thailand provide PCare for HDS users is scarce. Existing tool that are relevant to pharmacy practice related to the HDS are not satisfactory with many lack of acceptable psychometric properties. A theory-based instrument to measure the determinant of PCare for HDS users is also lacking. The modified TPB framework that underpinned the development of the determinant scale was discussed in this chapter. Additionally, several relevant pharmacy practice guidelines were reviewed to guide the development of the instrument to quantify PCare for HDS users. The next chapter discusses the methodological processes involved in the development of instruments in this study.



## CHAPTER 3: METHODS

This chapter describes the study designs and methods to develop the Direct TPB, Indirect TPB and PCare-HDS scales, and to establish the psychometric properties of the instruments. The development of the scales in this study was carried out in three phases – Phase 1: qualitative study to elicit CPs’ opinions about PCare for HDS users; Phase 2: development of Direct TPB, Indirect TPB and PCare-HDS scales; and Phase 3: quantitative studies to refine and validate the scales. In this study, the development of the scales utilized both the qualitative and quantitative research methods. The use of mixed method design can provide a better understanding of a research topic than either quantitative or qualitative alone (91, 92). Mixed method design offer additional benefits in answering complex research questions by combining the strengths of both qualitative and quantitative research approach (92). In this study a sequential exploratory design that is characterized by an initial qualitative study (Phase 1) that informs the quantitative study (Phase 3), was utilized (92). In this regard, the qualitative study identified potential variables to be tested in the subsequent validation phase of the study. A mixed method study design can produce study scales that centered on the “voice” of participants through the incorporation of their opinions and vocabulary (93, 94).

### 3.1. Phase 1: Elicitation study using qualitative interview

The qualitative study was aimed to explore and identify the salient practices of PCare for HDS users, and the behavioral, normative, control and professional normative beliefs underlying the practices. The qualitative study allowed the elicitation of informants’ perspectives in their natural settings and permitted immediate clarifications and elaborations from the informants during data collection thus allowing deeper understanding of the topics (95). Consequently, the most commonly held beliefs about the behavior that are relevant and culturally appropriate for CPs in Bangkok can be compiled (85). These compiled modal salient beliefs are crucial requirement for a TPB questionnaire, and undergirded the development of the Direct and Indirect TPB scales. In addition, CPs’ salient practices of PCare for HDS users

can be explored and investigated, and a valid scale to quantitatively measure such practices that is constructed in the CPs' own voice can be constructed.

### **3.1.1. Study design**

The descriptive qualitative study was carried out from December 2016 to June 2017. Through this approach, interviewer obtained understanding of the meaning of the phenomena (PCare for HDS users) from the interviewees who describe their experiences from their own social context (96). The present qualitative study imposed both the deductive and inductive approaches to identify salient practices of PCare for HDS users, and the behavioral, normative, control and professional normative beliefs underlying the practices.

The qualitative study was guided by the m-TPB framework (please refer section 2.9.). In addition, the study was also open to new and unanticipated answers from the interviewees to uncover new insights about the phenomenon outside the imposed framework (97). In this study, the CPs were interviewed face-to-face by using a semi-structured guide. The one-to-one interview was preferred over a focus-group as the qualitative methodology in this study as to allow informants to freely express their opinions without being influenced by other people, or being deferred to more dominant individuals.

This method therefore, can reduce responses that are due to group norms. In addition, because the present study mainly centered on CP's PCare behaviors, study informants may have concerns about disclosing their behaviors to peers or discussing their personal practices in public (97). Therefore, the one-to-one interview may provide a more private and comfortable environment for the CP informants to express their dissenting opinions (98). In addition, a one-to-one interview may ease clarification of questions, correction of misconceptions and encouragement of participants to co-operate (99).

### 3.1.2. Study tool: semi-structure interview guide

A semi-structured interview guide was used to elicit CPs' practices and commonly held beliefs about PCare for HDS users. The semi-structured interview guide contained open-ended questions based on the m-TPB framework (85, 87, 98) and included probing questions to seek detailed clarifications and elaborations from the informants (97). Table 5 lists questions included in semi-structured guide:

**Table 5. Interview guide for the qualitative interview**

Category		Question
PCare for HDS users		In your opinion, what is PCare for HDS users? Can you provide examples?
Behavioural belief	Positive	In your opinion, what are the benefits (or advantages) of PCare for HDS users?
	Negative	In your opinion, what are the disadvantages (or drawbacks) of PCare for HDS users?
Normative belief	Approval	Who do you believe would encourage you to provide PCare for HDS users?
	Disapproval	Who would discourage you to provide PCare for HDS users?
Control belief	Facilitator	What are the factors that help (or facilitate) you to provide PCare for HDS users?
	Barrier	What are the factors that make it difficult for (or prevent) you to provide PCare for HDS users?
Professional normative belief		As a pharmacist do you think you have to provide PCare for HDS users? Why or why not?
Other factors		Would you like to provide any other opinions or information about PCare for HDS users?
<b>HDS, herbal and dietary supplement; PCare, pharmacist's care.</b>		

The guide also contained an open-ended question, “*Would you like to provide any other opinions or information about PCare for HDS users?*” to provide opportunity for the interviewees to express their opinions about the topic that they regarded as important and meaningful. The use of the semi-structured guide allowed the application of consistent thematic approach for all informants during the interview and helped to uncover not only themes within the TPB context but also new insights outside the imposed framework. This provide advantages over using structured and unstructured interview guides that may not able to evoke sufficient narratives from the informants (97).

In addition to the semi-structured interview guide, a demographic questionnaire was developed and used to collect relevant study informants' information such as age, gender, type of community pharmacy, location of workplace, etc. The demographic questionnaire also contains a question that asks the informants to approximate the number of pharmacy customers (out of 10 customers) who requested for a HDS products and to estimate the number of HDS customers (out of 10 HDS customers) that had been provided with "PCare" by the CPs. The inclusion of the question was to ensure that the sample varied somewhat in the level of engagement of PCare for HDS users (Appendix A).

The semi-structured interview guide and the demographic questionnaire was examined by a group of pharmacy professors from the Faculty of Pharmaceutical Sciences, Chulalongkorn University, and a senior community pharmacist to check for its face validity using a set of criteria purposely devised for this study. The purpose of the face validation study was to ensure that the semi-structured interview guide and the demographic questionnaire are clear, relevant to the study objectives and culturally acceptable. The face validity study was also aimed to ensure that the researchers have included all necessary questions to answer the research questions. The questions used to assess the face validity of the semi-structured interview guide included:

1. Is the question in line with the theoretical framework of the study?
2. Is the question clear and understandable?
3. Is the language use easy to understand?
4. Will informants be able to provide a sufficient response without possessing a specific expertise?
5. Is the question culturally acceptable?

The semi-structured interview guide was then piloted to two post-doctoral students with community pharmacy practice experience, two CPs affiliated with the university, and one final year PharmD student. Interviews carried out in the pilot studies were done using procedures similar to the actual study. The purposes of the pilot study were to ensure that the questions used in the qualitative study are comprehensible to

the interviewees and were able to elicit adequate responses. The pilot studies also ensure that the interviews were carried out within an appropriate duration. In addition, the processes also allowed the interviewer to become accustomed with the recording device, questioning and probing, and note taking. Recommendations obtained from the pharmacy experts (face validation study) and the pilot study participants were used to improve the interview guide.

### **3.1.3. Qualitative study informants**

The informants in the qualitative study consisted of a sample of CPs working in Bangkok, Thailand. A CP could be included in the study if he or she is a fully registered CP working full- or part-time in a community pharmacy in Bangkok; able to understand and communicate in the English language; and willing to participate in the study. The CP should also be working in a community pharmacy that allows direct contact with customers or patients. A CP therefore was not eligible to participate in the study if his or her job scopes confined to administrative work or drug procurement exclusively.

### **3.1.4. Sampling of informants**

The qualitative study utilized the non-probabilistic purposive sampling scheme to recruit the study informants. This type of sampling scheme are deemed appropriate for the qualitative phase of the study since its main goal is not to provide an external statistical generalizations but to acquire insights of CPs' perspectives about PCare for HDS users (100). Therefore in this qualitative study, the informants were purposively chosen using: (1) maximum variation sampling; and (2) snowball purposive sampling approaches.

The maximum variation purposive sampling method is considered appropriate for this study as it allowed the selection of informants with a wide range of characteristics and experiences (101). This sampling approached allowed a compilation of a multitude, complex and information-rich perspectives of CPs, thus avoiding results that are one-sided (102). In order to achieve information-rich cases, sampling for a qualitative study should not only guided by socio-demographic units (e.g., gender, or age), but

also settings (e.g., locations, or organizations) and identities (103). Additionally, in developing a survey instrument using findings from a qualitative study, it is recommended to include a sample of informants that are closely similar to the population for future studies (104).

Therefore, during the recruitment of the CPs, the following pharmacist characteristics were aimed: male and female (gender); having less and more than five years of community pharmacy practice experiences (age or experience); full- and part-timers (identities/positions); chain/franchise and independent community pharmacies (organization); and inner and outer Bangkok community pharmacies (location). In addition to the purposive sampling method, the snowball sampling technique was also used by asking the study informants to identify and refer other CPs in their network to the researchers (91). This method of sampling was useful in identifying potential informants since a sampling list was not available.

Initially, five CPs from the researchers' network were contacted by phone and subsequent informants were recruited using the maximum variation and snowball sampling technique. During the initial contact, the principal investigator briefly described the study purposes and procedures, and screened the CPs for the inclusion criteria. If the CPs did not satisfy the inclusion criteria they were excluded from the study. The CPs were also informed that their identities will be kept anonymous except to the researchers, and all data will be confidential. In cases where the CPs were referred to the researchers but they did not wish to participate in the study, they were allowed to do so without any further questions asked. An appointment for a meeting was made with the CPs if they met the inclusion criteria and if they confirmed their interest in participating in the study. The location and time of the interview were decided upon mutual agreement between the principal investigator and the informants. Figure 2 shows the workflow for the recruitment of informants for the qualitative study.

The sample size for a qualitative study cannot be derived from quantitative sample size estimations algorithms, nor it can be calculated using power calculations (98). Instead, the sample size of this study was dependent on theoretical saturation in which



the recruitment of the CP informants were continued until data redundancy and research questions were answered (105). At this stage of data collection, it was expected that additional interviews were unlikely to provide new and valuable information (98).

### **3.1.5. Interview process**

All interviews were carried out either at the principal investigator's site (Faculty of Pharmaceutical Sciences, Chulalongkorn University) or at the workplaces of the informants, depending on mutual agreement. Interviews at the principal investigator's site were performed in the discussion room at the faculty library that is free from noise and other distractions. Interviews at the workplaces of the informants occurred in the counseling room or the CPs' office. In order to minimize interruptions during the interviews at the informants' sites, each informant was conveyed with the importance of uninterrupted interview before the interview session. All interviews were performed at a time convenient to the informants. The principal investigator performed all interviews as to maintain the consistency in interview techniques, elicitation of informants' responses and the understanding of the issues (98).

The interviewer introduced himself as a postgraduate student carrying out a study about PCare for HDS users. The informants were briefed about the study at the beginning of the meeting. Consequently the informants were provided with a participant information sheet and an informed consent form for them to read through and scrutinize (Appendix B and C). The informants provided their consent to participate in this research project by providing their signature on the informed consent form prior to the interview. Permission to audio record the interviews using a digital audio recorder was sought from each informant. All interviews were conducted face-to-face, guided by the semi-structured interview guide mentioned earlier. Each informant was interviewed only once using the English language.

During the interview, each informant was asked to describe their practices and opinions about PCare for HDS users. Probing questions were used to elucidate or clarify the meaning of the informants' responses and to gain deeper understanding of

the topic being discussed. The interviewer while listening to the interviewees took field notes to capture important answers or responses. At the end of the interviews, all informants were de-briefed. In each interview, the principal investigator refrained from providing his own opinions, and maintained consistency in interview techniques, and interactions. Each interview lasted approximately one hour. All informants were given THB200 as a token of appreciation for their time. However if the informants preferred to have the interview at the investigator's site, they were provided with an additional of THB200 to cover for their travel expenses.

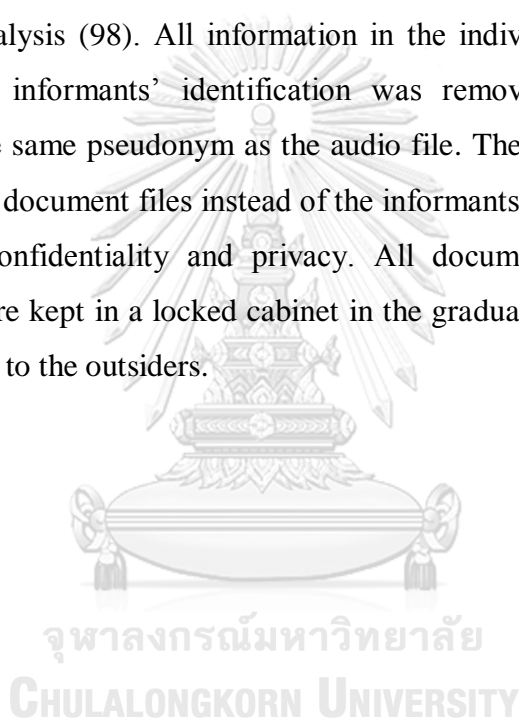
### **3.1.6. Researcher positionality**

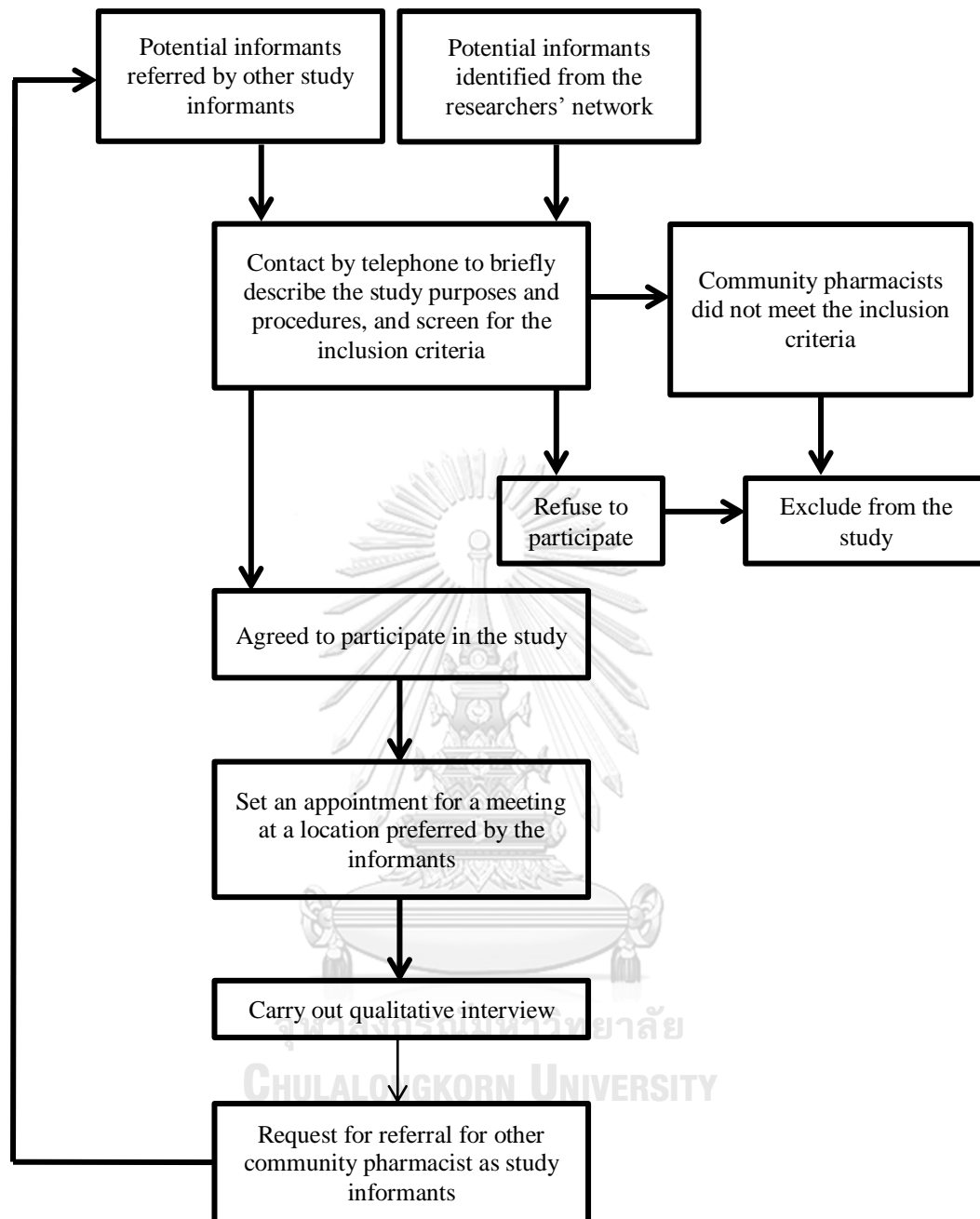
MSAW who is the principal investigator of the study is a pharmacist and a post-graduate student in the PhD in Pharmaceutical Care program at the Faculty of Pharmaceutical Sciences, Chulalongkorn University. Prior to his enrollment in the PhD program, MSAW has worked in hospital pharmacy, health clinic and in the academia in Malaysia. MSAW has received training in community pharmacy and had completed a community pharmacy attachment during his undergraduate studies. He has attended multiple seminars, workshops and lectures in both community pharmacy practices and qualitative research methodology throughout his career and while attending graduate school.

His past training in and exposure to community pharmacy practices may assist in executing interviews, and in interpreting and analyzing qualitative data. MSAW has been trained to be unbiased, systematic and thorough while conducting the interviews, analyzing data and reporting research findings. However, there may be possibilities that the procedures may be influenced by his experiences and perspectives. Nevertheless, multiple strategies have been employed throughout the study to enhance the trustworthiness of the qualitative research findings. These strategies include using contact summary form (Appendix D), audit trail, and peer debriefing.

### 3.1.7. Data management

All interviews carried out in the qualitative study were audio recorded. All recordings of the interview were uploaded into the principal investigator's password-protected personal computer and each audio file was issued a pseudonym as identification. In addition, the field notes and contact summary form that the interviewer used to record and summarize important points and opinions brought up by the interviewees during the interview, as well as the demographic questionnaire were kept in a file. All the audio recordings and field notes offered transparency for data collection and facilitated data analysis (98). All information in the individual informant's file that may lead to the informants' identification was removed. Documents for each informant used the same pseudonym as the audio file. The use of the pseudonym for both the audio and document files instead of the informants' real names was to protect the informants' confidentiality and privacy. All document files pertinent to the qualitative study are kept in a locked cabinet in the graduate student room. The room provides no access to the outsiders.





**Figure 2. Workflow for selecting study informants**

All audio recordings of informants' interviews were transcribed by the principal investigator. In the transcription process, the principal investigator listened to each of the informant's interview recording and converted them into written form by typing the conversation using the Microsoft Word in the computer. All transcripts were reviewed for accuracy by comparing the texts with the audio files after each audio transcription. The transcription of the interviews into the written form permitted a more convenient and systematic data analysis. In addition, the transcription process allowed the researcher to familiarize with the qualitative data and facilitated realizations and understanding of salient opinions brought up by each of the interviewee during the interview (106, 107).

Transcriptions of an hour of audio recording took approximately two hours to complete. In order to ensure the accuracy of the procedure, the principal investigator read the final transcription for each informant while listening again to the respective audio file. The transcriptions of all interviews were then loaded into ATLAS.ti, a computer assisted qualitative data analysis (CAQDAS) software package. The ATLAS.ti was chosen due to its features that simplify organization, classification, and categorizing qualitative data, thus facilitated and expedited qualitative content analysis (QCA). The use of the CAQDAS also provided a more visible audit trail in the qualitative data analysis (98). In addition, ATLAS.ti allowed the identification of complex relationships and links among data, thereby enhance the thoroughness of data handling and analysis.

### **3.1.8. Qualitative content analysis**

The transcripts that were loaded in the CAQDAS were then analyzed line-by-line using QCA. The QCA is a strategy to analyze qualitative data by systematically and rigorously categorize data to identify patterns or themes and to provide meanings or interpretations in the content (108). QCA not only enables a phenomenon to be qualitatively analyzed but also allows data quantification (109). The QCA is considered an appropriate qualitative analysis approach due the descriptive nature of the present study that was aimed to explore and identify the salient practices, and behavioral, normative, control and professional normative beliefs related to PCare for

HDS users, and not to provide a higher level of interpretation of the phenomenon under study, such as in the interpretative phenomenological analysis and grounded theory (108).

The QCA is also deemed suitable for analyzing a multifaceted phenomenon such as the provision of PCare for HDS users that are influenced by many factors (108, 110). Moreover the QCA is flexible, and could be used with any theoretical framework (111). The use of QCA has also been recommended to analyze elicitation study data to draw out the most commonly held beliefs that would be used to form the Indirect TPB scale (87).

QCA in the present study focused on both the latent and manifest content to identify and describe the commonly held beliefs of the informants about PCare for HDS users. In this regard, the apparent meanings of the content as well as those that are not immediately obvious were described and interpreted (112). The unit of analysis or the data corpus (the major entity being analyzed) in this study was the whole interviews with the CPs. In this study, both the deductive and inductive QCA were performed. The deductive or concept-driven content analysis allowed the identification of themes (or category) based on the m-TPB framework, whereas the inductive or data-driven analysis gathered themes outside the m-TPB context from the raw qualitative data (97, 108). The procedures to carry out the content analysis in the present study were guided by several QCA guidelines (110, 112, 113). In this study data analysis was carried out simultaneously with the data collection described earlier to permit the comparisons of the informants' responses in a continuous manner thus increasing the understanding of data content and enhancing quality of data analysis (98, 108). In addition, the analytical procedures in the study (describing, classifying/categorizing, and connecting data) did not occur in a linear manner but instead involved a cyclic (back and forth) movement through the content (98, 112). The procedures to carry out the QCA include preparation and familiarization, and organization and coding of data.

***Preparation and familiarization with data.*** The principal investigator started to familiarize himself with the qualitative data beginning from the transcriptions of the audio recordings of the interview. Consequently the investigator immersed himself in the data by reading and rereading the interview transcripts, field notes and contact summary forms. During this process, the investigator attempted to make sense of the collected data (114). To assist data analysis and interpretations in the later stage, the investigator wrote down any important and relevant analytical points about the interview during the data familiarization.

***Organizing and coding of data.*** In this QCA phase, the investigator identified the meaning units (MU) which are the constellations of words or statements (e.g., ideas, opinions and points put forward by the interviewees) that have similar central meaning (112). These MUs can denote PCare for HDS users practices; the advantages and disadvantages of providing PCare for HDS users; important or significant people who put pressure on the informants to perform PCare for HDS users; the facilitators and barriers to provide the care; or other factors associated with the behavior. Each MU was condensed into a description which meaning is close to the text. The condensed MUs were then abstracted and assigned with a specific code. This process of sorting and categorizing qualitative data with the similar is called “coding” (102).

In the deductive part of the QCA, the analysis was viewed through the lens of the m-TPB in which the broad m-TPB constructs were used as the general themes. Identified codes were then classified into an explicit sub-theme of the m-TPB theoretical framework (102, 112). In the inductive QCA, data that were coherent and relevant to the research questions especially for the practices of PCare for HDS users, were subjected to open coding. Data that were coded in this way were then organized and grouped together based on their central meaning under a similar theme (110).

In this study, all data coding and organization were performed using the ATLAS.ti software program. Condensation of MUs and data coding occurred iteratively in which the condensed MUs and coded data were re-examined throughout the course of the study. During the re-examinations of MUs, condensed MUs were improved, and initial codes were revised, combined or split when necessary. In addition, the mapping

of codes into the m-TPB themes, and the additional “inductive” themes were reviewed for coherence and plausibility. The codes and themes were checked if they were consistent, correct and logical and if they captured the salient and essential data in relation to the research questions. In this phase the codes and themes were also revised or renamed necessarily. Codes and themes that were considered lacked of coherence with the research questions or had limited data were discarded.

The principal investigator reviewed all coding after the completion of the first coding, guided by a coding frame (113). This review was performed in order to check for coding consistency. The identification and condensation of MUs, and the decisions in coding and categorizing codes were all discussed with the other co-researchers. This procedure helped to ensure that the interpretations done by the principal investigator were not based on “individual understanding” and but are founded by understandings that are shared, and consensual among others with similar pharmacy practice background. Relevant contextual, methodological, analytic and personal response documentation (e.g., field notes, contact summary forms, audio files, and analytical outputs) provided a means of audit trail and were frequently referred to in the decision process (115). Multiple meetings and discussions that occurred throughout the course of the study resulted in agreement of data coding, categorization and interpretations. Finally, the investigator calculated the number of MUs reported by the community pharmacist informants in each theme. This quantification of MUs in the QCA allowed the investigators to compile the most commonly held beliefs of the CPs about PCare for HDS users. This in consequent assisted the investigator to determine the selection of items for the intended TPB scales (87).

### **3.1.9. Measures to enhance the quality of qualitative data analysis**

The methods of quality determination of qualitative data analysis are different than that observed for quantitative data analysis. In general qualitative studies had different methodological, epistemological and ontological stances compared to quantitative studies. In addition, qualitative researches often analyze data in a flexible non-standardized way (116). It is therefore unsuitable for qualitative researchers to adopt quantitative study criteria of quality such as validity and reliability.



In this qualitative study, various strategies were employed to meet the quality criteria as recommended in the literature (112, 117). The face validation and pilot studies that were carried out before the main qualitative study, and peer debriefing throughout the study processes may enhance the credibility of the research findings (118). In addition, the mutual agreement on the data analysis among the principal investigator and the co-investigators strengthened the credibility of study findings (112).

The purposively selected informants from a diverse backgrounds not only assisted in the understanding of intra-group variation (116) but also enhancing the credibility (119) and transferability of the study findings (120). Two research team members who did not involve in the data collection and analysis processes continuously monitored and examined data collection and analysis by the principal investigator. This processes ensured the dependability of study findings (112). Confirmability of data analysis was achieved by means of contact summary forms and field notes (108, 121). These two documents provided a means for the principle investigator to reflect on each interview session, and to assist data analysis at the later stage of the qualitative study. Reflexivity was achieved through continual evaluation of research process, continuous data recheck and the reflection of how the principal investigator's knowledge, experiences and position affect data analysis and interpretation (see researcher's positionality) (122).

### **3.1.10. Ethical considerations**

Ethical practices to manage all study information were observed. The participation of informants in this study was entirely voluntary and they had the right to refuse from participating or withdrawing from the study at any time even after providing their consent of participation. The informants also had the right to refuse answering any questions asked by the interviewer. All information obtained from this study were remained confidential and kept in a private locked cabinet. Each informant was issued a pseudonym (code), and therefore the real names of the study informants were not disclosed. Moreover the identity and personal details of the study informants would not be appearing in any publications or presentations of the study findings. As participants in this study, CPs did not receive any personal benefits. However,

findings from this study can be useful to the researchers in better understanding the practices of PCare for HDS users among CPs and their beliefs about the practices. There were no physical risks associated with this study. However, discussion about practices in pharmacy and some issues such as those regarding pharmacist's skills or confidence may cause discomfort to some CPs. However, informants in this study were assured that they may decline to talk about any topics that cause them uneasiness. This qualitative study obtained approval from the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (COA: 189/2016) (Appendix E).



### **3.2. Phase 2: Development of scales**

Three scales were developed for the present study: (1) Direct TPB scale; (2) Indirect TPB scale and (3) PCare-HDS scale. The scale development in this study followed the following framework recommended by DeVellis (123):

- Specify what to measure.
- Generate item pool.
- Determine measure format.
- Submit item pool for experts review (content validity study).

#### **3.2.1. Specify what to measure**

The development of the Direct and Indirect TPB scales was underpinned by the m-TPB framework (please refer section 2.9.). The Direct TPB scale is meant to measure attitude, subjective norm, perceived behavioural control, professional norm and intention in regard to the provision of PCare for HDS users. The Indirect TPB scale on the other hand measures behavioural beliefs, normative beliefs and control beliefs for the provision of PCare for HDS users. For operational definitions of the components of the Direct TPB and Indirect TPB scales, please refer to section 2.9. The PCare-HDS scale is aimed to measure practices or efforts of CPs to provide PCare for HDS users. The development of this scale was guided by previous literatures and findings from the qualitative study as described in Chapter 4 (Phase 1 study).

#### **3.2.2. Generate item pool**

The generation of items for the Direct and Indirect TPB scales followed the standard recommendation for constructing questionnaire in the context of TPB with some modifications (85, 87). Items for the Indirect TPB scale were developed based on the findings from our qualitative study (Phase 1 study). For the PCare HDS scale, two approaches were utilized for the generation of items. First, the literature was reviewed to search for relevant information and existing scales that can be adapted for the new scale. Secondly and most importantly, findings that were obtained from our

qualitative study were used to generate items for the scale. Generation of items for the Indirect TPB and PCare-HDS scales utilized the mixed methods item generation matrix. Table 6 shows several examples of items generated using this matrix. The use of this mixed methods procedure to produce the item pool can result in a collection of survey items that was close to the language, cultures and experiences of the respondents (124).

**Table 6. Item generation for the scales**

Scale / subscale	Sample quote	Sample scale item
<b>Indirect TPB scale</b>		
<b>Behavioural belief</b>	When I talk to the patients I can get new knowledge. Customers talk about their beliefs, about traditional Thai herbs... new knowledge for me.	If I provide care for the HDS users, my knowledge about the HDS will be improved.
<b>Normative belief</b>	I think the customers... they want to consult with the pharmacists because we are (the) experts in this field.	The HDS users want me to provide care for them.
<b>Control belief</b>	When my drugstore received new HDS products, the company provided me with leaflets so that I can learn about the products... In my drugstore we have many leaflets so I will provide these to my customers... because even I have advised (them) on how to use the HDS... customers may forget, so these leaflets will remind them.	I think I have enough informational materials (e.g., leaflets, posters, booklets, etc.) about the HDS at my drugstore.
<b>PCare-HDS scale</b>		
<b>Foster Relationship</b>	I will listen to them to the end and later provide them with the correct information.	I listen carefully to the customers' inquiries or requests for the HDS.
<b>Gather Information</b>	What are the medicines they are using at the moment?	I ask the HDS users if they are using any medicines.
<b>Assess HDS Use</b>	First of all ask the purpose. Is the purpose of the patients match with the HDS?	I assess whether the HDS has any indication for the customers.
<b>Assist Informed Decision</b>	We have to give the exact information to the customers so that they can decide whether to use or not to use the supplements.	I provide unbiased information about the HDS to help the customers decide on whether or not to use the HDS.
<b>Make Professional Decision</b>	If not necessary I will tell them 'no, no', not necessary.	If the use of the HDS is not appropriate (not indicated, not

		appropriate, or contraindicated), I advise the customers not to use the HDS.
<b>Provide Advice or Information</b>	Tell them, 'If you take it with medications, it will decrease your blood sugar level and cause you to feel dizzy', just tell them the symptoms that might happen to them.	When dispensing HDS, I tell the HDS users about what they can expect from the HDS (positive effects and side effects).
<b>Seek HDS Information</b>	Pharmacists must learn all the time because new products come out all the time.	I make sure I know the indications of common HDS.
<b>Maintain HDS Product Quality</b>	If you come to my drugstore you will see that the products are not many like in other drugstores because I only choose products that are good and can be trusted.	I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice (GMP).

**Direct TPB scale.** The direct measures include items that directly ask respondents about their self-reported attitudes, subjective norms, perceived behavioral control, professional norms, and behavioural intentions for the provision of PCare for HDS users. The standard guideline to develop direct TPB scale recommends researchers to adapt the items and format indicated in the guideline (85, 87). This resulted in 15 items for the Direct TPB scale: 3 items for the attitude subscale; 3 items for subjective norm subscale; 6 items for the perceived behavioural control subscale; and 3 items for the behavioural intention (Appendix F). All items used a 5-point Likert-type scale (1 = strongly disagree, to 5 = strongly agree) and a non-applicable (N/A) response. Although the N/A responses do not provide information about the degree of agreement of the respondents toward each item, the item was included as means to evaluate the practicality of each item of the scale.

**Indirect TPB scale.** Findings from our qualitative study (Phase 1 study) were used to develop items for the Indirect TPB scale which consists of behavioural, normative and control belief subscales. The items for the Indirect TPB scale were written in a way to reflect the voice of the informants in the Phase 1 study. The initial pool of items for the Indirect TPB scale covered all aspects of behavioural, normative and control beliefs mentioned by the CPs to account for the wide range of CPs beliefs about the provision of PCare for HDS users. The initial item pool for the Indirect TPB scale consisted of 28 items: 9 items for behavioural belief subscale; 6 items for normative

belief subscale; and 13 items for control belief subscale (Appendix F). All items in the Indirect TPB scale used a 5-point Likert-type scale (1 = strongly disagree, to 5 = strongly agree) and a N/A response. Even though the N/A responses do not provide information about the degree of agreement of the respondents toward each item, the item was included as means to evaluate the practicality of each item of the scale.

**PCare-HDS scale.** The purpose of the PCare-HDS scale was to quantitatively measure PCare for HDS users. The findings from our qualitative study (Phase 1) provided theoretical foundation for the development of the PCare-HDS scale (please refer Chapter 4 for complete analysis of the qualitative study). The qualitative study indicated eight factors for the PCare-HDS scale: (1) fostering relationship; (2) gathering information; (3) assessing HDS use; (4) assisting informed decision; (5) making professional decision; (6) providing advice and information; (7) seeking HDS information; and (8) maintaining HDS product quality. The items for the PCare-HDS scale were written in a way to reflect the voice of the informants in the Phase 1 study. The initial item pool for the PCare-HDS scale contained 54 items (Appendix F). All items in PCare-HDS scale used a 5-point Likert-type scale (1 = never, to 5 = always).

**Socio-demographic.** Various socio-demographic data were included in the survey such as gender, type of previous undergraduate education, history of a postgraduate education, number of years as a registered pharmacist, type of community pharmacy, number of years working in a community pharmacy, history of participation in HDS-related training, positions (e.g., owner, manager, full-/part-time, etc). A question to seek the level of perceived provision of PCare for HDS users among CPs was also included in the survey (*For the past two weeks, how often have you provided care for the HDS users?*). The 1-item self-reported provision of PCare for HDS users used a 5-point Likert-type scale (1 = never, to 5 = always). This item, although was subjected to content and face validity assessment, it was not included in the EFA and CFA in the quantitative phase of the study.

### 3.2.3. Submit item pool for experts review

**Content validity.** All items of the three scales were submitted to experts review in the content validity study. Content validity of each item of the Direct TPB, Indirect TPB and PCare-HDS scales was assessed by a panel of four experts in pharmacy practices, consisting of two Professors from the Faculty of Pharmaceutical Sciences, Chulalongkorn University. One of the Professors is also an expert in questionnaire development and psychometric validation of survey instruments. The other two panelists were two registered full-time CPs from *Osot Sala*, a community pharmacy that is affiliated with Chulalongkorn University. The panel was asked to rate 1 = not relevant; 2 = items need some revision; 3 = relevant but need minor revision; and 4 = very relevant, for each item to assess the relevance of the items. In addition to the relevance rating of the items, the panel also provided comments regarding the format, clarity, style, adequateness and social desirability of the items of the Direct TPB, Indirect TPB and PCare-HDS scales.

**Face validity.** The Direct TPB, Indirect TPB and PCare-HDS scales were also administered to a convenient sample of five CPs and five final year pharmacy students. In this procedure, the scales were examined to confirm the readability, clarity and comprehensibility of the items. Wordings and format of the scales were changed according to the respondents' comments and suggestions when deemed appropriate.

### 3.3. Phase 3: Quantitative study

This was a cross-sectional quantitative study among CPs in Bangkok. The quantitative study was aimed to explore and refine the Direct TPB, Indirect TPB and PCare-HDS scales, and consequently validate the scales. Various procedures were undertaken to establish the psychometric properties of the three scales. The main statistical procedures in this quantitative phase involved exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). Additional statistical analyses included Rasch analysis and multiple regression analysis (MRA).

#### 3.3.1. Population

The participants in the quantitative phase of the study were CPs working in Bangkok. CPs can be recruited in the study if he or she is: (1) a fully registered CP; (2) working in a community pharmacy as a full- or part-time pharmacists; (3) working in an environment that allows direct contact with customers or patients; (4) working in a community pharmacy located in Bangkok; and (5) able to read and understand the English language.

#### 3.3.2. Data collection

A mixed-mode data collection was utilized in the study. Data were collected from December, 2017 – April, 2018. The main method of data collection was through distribution of questionnaires by mail to 4,194 community pharmacies in Bangkok based on a list obtained from the Thai FDA. Additionally, the questionnaires were distributed online using *Survey Monkey*, disseminated to CPs attending two pharmacy seminars, and distributed by hand by two research assistants to CPs at conveniently selected community pharmacies around Bangkok.

The postal mailing of the survey package to CPs was initiated in the second week of December, 2017 and was completed in the second week of January, 2018. Each survey package contained an invitation letter for CPs to complete the survey, a survey instrument (Appendix G), and a stamped-envelope for the CPs to return the survey. A



reminder postcard was sent to all community pharmacies in the second week of March, 2018 (approximately 2 months after the completion of the mailing).

The distribution of the questionnaires during the two pharmacy seminars organized by the CPA, were done by placing the questionnaires on the conference table that were occupied by participants. The first seminar was held in December, 2017, and was attended by 120 CPs, whereas 200 CPs attended the second seminar that was held in January, 2018. The master of ceremony of the two seminars briefly explained the purposes of the survey and the eligibility criteria. Consequently, he invited all eligible attendees to participate in the survey, and provided a few reminders for them to fill up the questionnaire. The principal investigator collected all completed survey at the end of the seminars.

For the online survey, a list of 713 e-mail addresses of CPs affiliated with the CPA was obtained from the association. The 713 CPs were invited to complete the questionnaires online using *Survey Monkey* in the fourth week of December, 2017. E-mail reminders were sent two and four weeks after the first e-mail invitation.

In addition, two research assistants distributed the questionnaires at conveniently selected community pharmacies that are located nearby the Bangkok Mass Transit System (Sky train) and Metropolitan Rapid Transit stations over a period of two and a half months. Approximately 5 to 6 community pharmacies were approached daily. At the end of the data collection period, 404 community pharmacies were visited.

In attempt to enhance response rate, the CPs were offered an opportunity to win a book voucher (worth of THB 1,000) by returning the survey. In this study, survey non-response were assessed by comparing early to late responders (125).

### **3.3.3. Sample sizes**

For the purpose of data analysis, all samples collected from the four methods of data collection were combined and randomly split into two datasets of approximately equal size using the random sample selection function of the SPSS (version 23). The first dataset was used in the first stage of data analysis to explore the factor structures of

the scales and to refine the item pool whereas the second dataset was used in the second stage of data analysis to validate the scales. Additionally, the total sample was used for additional statistical analysis such as Rasch analysis and MRA. The adequacy of sample sizes for Stage 1 and 2 data analysis was determined primarily based on the assumptions for conducting factor analysis.

### 3.3.4. Statistical analysis

#### 3.3.4.1. Stage 1: Exploratory analysis and refinement of scales

The first half of the total sample was used for data analysis in this stage. The assessment of construct validity or the exploration of the factor structures of the scales utilized the EFA whereas both the EFA and a preliminary CFA assisted the refinement of scales. The main purposes of the analysis were to answer the following research questions:

**RQ6.** What are the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales?

**RQ7.** Do the Direct TPB, Indirect TPB and PCare-HDS subscales have internal consistency reliability?

Prior to conducting the EFA and CFA, consideration for the sample size, missing data, normality, linearity, level of data, outliers, and inter-items correlations were undertaken. The following measures for assessing the assumptions for factor analysis are relevant for both the EFA and preliminary CFA in this stage of data analysis.

- **Sample size.** For conducting factor analysis, 300 cases were considered acceptable (126, 127). Alternatively, the adequacy of sample size for the factor analytic study can be guided by the minimum ratio of respondents to the number of variables. The recommended ratio is in the range of 5 – 10 respondents for each variable (128-130). Since the highest number of items among the Direct TPB, Indirect TPB and PCare-HDS scales was 33, at least 330 CPs (by using a ratio of 10:1), were required for factor analysis in Stage 1.

- **Missing values.** Missing values for each item was assessed. A variable with more than 10% missing values were marked for deletion (131). Since N/A responses do not provide information about the degree of agreement of the respondents toward each item, the N/A responses were treated as missing. In this study, a respondent who did not respond to 15% of items in each scale were removed from analysis. Missing data for the main items of the three scales were not imputed. Missing data for demographic details were handled by replacing missing values with the mode for categorical data, whereas continuous data were replaced using the expectation maximization technique (130).
- **Univariate and multivariate outliers.** Assessment of the presence of univariate outlier was performed by inspecting the standardized value (z-score) of each item of the scales (129). A variable having a z-score of more than the absolute value of 3.29 is considered a source of univariate outlier. The assessment of the presence of multivariate outliers were also performed since the EFA is sensitive to this type of outliers (126). The identification of the multivariate outliers was performed by using the linear regression analysis in which the Mahalanobis distance for each case was identified (129). The maximum Mahalanobis distance for each case is the critical chi-square ( $X^2$ ) values for “n” degrees of freedom ( $df$ ) at  $\alpha < 0.001$  (132).
- **Normality.** The EFA could provide a better factor solution if variables are normally distributed (129). Moreover other statistical analysis such as the Pearson correlation test that underlies factor analysis, require the assumptions of normality (133). The datasets therefore, was checked for the normality assumptions. For this purpose, the preliminary mean score for each subscale of the Direct TPB, Indirect TPB and PCare-HDS scales was computed, and the skewness and kurtosis values for the mean scores were obtained and inspected.
- **Level of data and linearity.** The response format for both of the Direct and Indirect TPB scales use a 5-point Likert-type scale, ranging from 1 = strongly disagree to 5 = strongly agree. Meanwhile the PCare-HDS scale uses a 5-point Likert-type scale, ranging from 1 = never to 5 = always. All variables in the scales were considered interval data for the purpose of data analysis (134). Linearity of the data was

examined using the scatterplots (129, 133). In this procedure, the absence of curvilinearity was required to assume linearity of data.

- ***Factorability of factors.*** The correlation matrix of the items of the Direct TPB, Indirect TPB and PCare-HDS scales were examined to determine the factorability of items of the three scales for EFA (129). An EFA is appropriate if there is a sizable number of correlations exceed  $\pm 0.30$  (130). Additionally, the Kaiser-Meyer Olkin (KMO) measure for sampling adequacy, and the Barlett's test of sphericity were referred as to provide objective evidences for the suitability of the data for EFA. A KMO value that is  $\geq 0.70$  is desirable (135), and a significant Bartlett's test of sphericity indicates that factor analysis is appropriate for the data (136).

***Exploratory factor analysis.*** To answer RQ6, data was first analyzed using the EFA. The aim of the EFA was to examine the factor structures of the scales. In addition, the EFA allows researchers to identify latent dimensions within the datasets, and guide the reduction of items to ensure each factor is parsimonious and meaningful (129). The three scales, despite being developed from the m-TPB theoretical framework or from the qualitative study findings (Phase 1) may benefit from the EFA. In this regard, the EFA can ascertain whether a similar number of factors for the scales were formed as theoretically informed. The EFA was performed separately for the Direct TPB, Indirect TPB and PCare-HDS scales. The conduct of EFA for the present study followed several guidelines to ensure best factor analytic practice (135, 137).

- ***Model of factor analysis extraction.*** Principal axis factoring (PAF) was used as the extraction method for the EFA analysis. PAF which also known as the common factor analysis seeks the least number of factors which can account for the common variance (correlation) of a set of variables (135). The decision to choose PAF as the extraction method for the EFA in the present study was based on the recommendation by factor analysis methodologists to use this method when the purpose of analysis is to identify latent constructs responsible for the variation of measured variables (138).

- ***Rotation of factors.*** The oblique rotation (direct oblimin) was utilized as the rotational method (139). This rotational method was used because the factors of the three scales are expected to correlate with each other to some extent (140). As indicated by measurement specialists, the oblique rotation may provide a more realistic representation of data, and produce a solution that is easier to interpret.
- ***Number of factors to retain and removal of problematic items.*** Two important aspects that should be observed when retaining factors in EFA are parsimony and comprehensiveness (135). This means that an ideal factor solution should have just enough factors to account for the covariation among variables. Traditionally, the retention of factors with an eigenvalue greater than 1 has been recommended (141). However the reliance to this criteria when retaining factors in EFA is not recommended since it can be misleading (138, 139). Therefore, apart from inspecting the eigenvalue of each factor, relevant theory and information from prior research were taken into consideration when determining the number of factors to retain in the present study (135). In addition, the total variance explained and the interpretability of the factor solution (i.e., factor solution represents a meaningful underlying dimension) were included as evidences for the number of factor being retained (142). In the present study, an item was considered problematic if the factor loading is less than 0.40 or is cross-loading on two or more factors at 0.40 or higher (129, 130). Items that fall into these categories were removed from further analysis. After removal of problematic items, the EFA were re-run.

***Preliminary confirmatory factor analysis.*** The preliminary CFA that was conducted in this stage of data analysis was aimed to further examine the factor structure of the scales, thus strengthen the evidence to answer RQ6. The CFA is a confirmatory technique in which the analysis is based on the theoretical relationship among variables. Since the Direct and Indirect TPB scales development were grounded on the TPB framework, and the PCare-HDS scale from the findings from the qualitative study in Phase 1, CFA is deemed appropriate for the present study (143). The decision to include a preliminary CFA in this stage of data analysis and another CFA in the next stage of data analysis was based on the recommendation by Pohlmann (144) to

randomly split data in half and estimate the model twice to provide evidence of stability of parameter estimates (145). The use of CFA in this stage of data analysis could also guide the deletion of items that would impair the model fit, thus provide a means to refine the scales further. However, deletion of items from the scales should not exceed 20% or else the models to be tested would be considered invalid (146).

- **Assessment of model fit.** Numerous goodness-of-fit indices are available to assess the model fit. Researchers are recommended to use several model-fit indices to evaluate the goodness-of-fit of measurement models rather than using one index. CFA results that showed good fit for a variety of indexes suggest that model has a good fit (147). Table 7 shows the model-fit indices that were used in the present study. In addition to the model-fit indices, the factor loading of each item was observed. An item with a factor loading of less than 0.6 were considered for deletion (130, 146). Additionally, the standardized residual covariances matrix for each model was inspected to identify items with significant residual values (values exceeding 2.58). The items with residual values in excess of 2.58 are considered large and are suggestive for model misfit (148). These items were evaluated and were considered for removal (149). The removal of items if necessary, began with the most problematic ones i.e., lowest factor loading or highest residual value. After the items were deleted, the revised models were submitted for another CFA. This process was continued until a model with adequate fit was achieved.

**Table 7. Model fit indices and cut-off criteria**

<b>Goodness-of-fit indices</b>	<b>Shorthand</b>	<b>Cut-off value (reference)</b>
<b>Absolute / predictive fit</b>		
Relative Chi-square to $df$	$X^2/df$	< 3.00 (150)
<b>Comparative fit</b>		
Normed fit index	NFI	> 0.90 (151)
Tucker–Lewis index (also known as non-normed fit index, NNFI)	TLI	$\geq$ 0.95 (147)
Comparative fit index	CFI	$\geq$ 0.90 (152)
<b>Others</b>		
Root mean square error of approximation	RMSEA	< 0.08 (153)
Goodness-of-fit index	GFI	> 0.90 (151)
Standardized root mean square residual	SRMR	< 0.09 (147)

**Internal consistency reliability analysis.** To answer RQ7, the internal consistency reliability of each factor or subscale of the Direct TPB, Indirect TPB and PCare HDS scales was assessed by reviewing the Cronbach's alpha reliability coefficient. The interpretations of the Cronbach's  $\alpha$  coefficient are as the following: > 0.9 = excellent, > 0.8 = good, > 0.7 = acceptable, > 0.6 = questionable, > 0.5 = poor, and < 0.5 = unacceptable (154). A factor or subscale with good to excellent internal consistency reliability means that the subscale is measuring the same construct. In addition, the "Cronbach's alpha if item deleted" was also examined. This value represents the Cronbach's alpha value if the item is removed from the scale. An item that would increase the Cronbach's alpha upon its deletion would be marked for removal.

### 3.3.4.2. Stage 2: Validation of scales

The second half of the total sample was used for data analysis in Stage 2. The CFA was the main statistical analysis for this stage of the study. The purposes of the analysis were to answer the following research questions:

**RQ8.** Are the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales identified in Stage 1 of data analysis confirmed by the CFA?

**RQ9.** Do the Direct TPB, Indirect TPB and PCare-HDS scales have convergent and discriminant validity, and construct reliability?

**RQ10.** Do the Direct TPB, Indirect TPB and PCare-HDS constructs of the final models have internal consistency reliability?

*Assessment of assumptions for factor analysis.* Prior to conducting the CFA, consideration for the sample size, missing data, normality, linearity, level of data, outliers, and inter-items correlations were undertaken. The approaches used to assess the assumptions for CFA were similar to that in Stage 1 analysis (please refer section 3.3.4.1.1.). For the sample size to carry out CFA, 10 observations for each variable have been recommended as the sample size (143). After the refinement processes mentioned earlier, the highest number of items among the three scales was 30. This means 300 samples were required to conduct the CFA. This number was consistent with the recommendation to have at least 300 cases for CFA (126, 127).

*Confirmatory factor analysis.* The CFA was used in order to answer RQ8. The purpose of the CFA was to confirm the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales as identified by the EFA and preliminary CFA in Stage 1 of data analysis (155). Construct validity of the scales are established if the recommended values for the model-fit indices in Table 7 are met. The factor loading of items were observed to ensure that none of the items had factor loadings of less than 0.6 (130). Additionally the standardized covariances matrix of each model was checked to ensure the absence of items with standardized residual value of more than 2.58 (148). The assessment of convergent and discriminant validity, and construct



reliability of the scales described in the following sections were aimed to answer RQ9.

**Convergent validity.** Convergent validity is part of construct validity (156). Convergent validity refers to the extent to which a scale correlate with another scale that has similar measurement purpose. If a scale has convergent validity, the score of the scale should correlate highly with the score of another scale that measured the same constructs. At present, there are no valid scales similar to the Direct and Indirect TPB scales. Additionally, although there are a few scales that have been developed that are similar to the PCare-HDS scale, the inclusion of an additional scale into the survey would increase respondents' burden and could reduce response rate. Therefore, the calculation of convergent validity using this approach for the three scales was not possible.

Alternatively, convergent validity can be determined by examining the item factor loadings and their statistical significance. Items that have factor loading higher than  $\geq 0.60$  and  $P < 0.05$  are considered to have convergent validity (130). Additionally, a more stringent approach of establishing convergent validity is by having the average variance extracted (AVE) for each construct exceeding 0.50 and construct reliabilities of  $\geq 0.70$  (157).

**Discriminant validity.** Discriminant validity refers to the extent of a scale differs from another scale having similar constructs. Discriminant validity can be assessed by comparing the square root of AVE to the correlations between constructs. In order for a scale to have discriminant validity, the square root of AVE should be greater than the inter-construct correlations (157).

**Construct reliabilities.** CR is used to report the reliability of a latent construct. CR provided a better means to assess reliability of a construct compared to the Cronbach's alpha value due to its less biased estimate (157). For a construct to have CR, the CR value should exceed 0.70 (130).

**Internal consistency reliability analysis.** RQ10 was answered by examining the Cronbach's alpha reliability coefficient of each subscale of the Direct TPB, Indirect

TPB and PCare HDS scales. The interpretations of the Cronbach's alpha coefficient are as the following:  $> 0.9$  = excellent,  $> 0.8$  = good,  $> 0.7$  = acceptable,  $> 0.6$  = questionable,  $> 0.5$  = poor, and  $< 0.5$  = unacceptable (154). A construct having good to excellent Cronbach's alpha means that the construct has good internal consistency reliability and therefore it is measuring what it should be measuring.

### **3.3.4.3. Stage 3: Additional analyses**

The total sample was used for data analysis in Stage 3. The analyses in this stage of data analysis and their respective research questions are as the following:

**RQ11:** Do the subscales of the of Direct TPB, Indirect TPB and PCare-HDS scales map on to a common underlying construct based on the Rasch model?

**RQ12.** Do the structure of rating scales of the Direct TPB, Indirect TPB and PCare-HDS scales appropriate based on the Rasch model?

**RQ13.** Do items of the Direct TPB, Indirect TPB and PCare-HDS scales contain Differential Item Functioning (DIF) in terms of gender according to the Rasch model?

**RQ14.** Do the Direct TPB constructs i.e., attitude, subjective norm, perceived behavioural control, and professional norm correlate with intention?

**RQ15:** Do the Indirect TPB constructs i.e., behavioural belief, normative belief, and control belief correlate with their respective direct TPB constructs i.e., attitude, subjective norm, and perceived behavioural control?

**RQ16.** Does the total mean score of the PCare-HDS scale correlate with the total mean score of the Direct TPB scale?

**RQ17.** Does the total mean score of the PCare-HDS scale correlate with the total mean score of the Indirect TPB scale?

**RQ18.** Are attitude, subjective norm, perceived behavioural control and professional norm a positive and significant predictor of intention to provide PCare for HDS users?

**RQ19.** Are attitude, subjective norm, perceived behavioural control, professional norm, and intention a positive and significant predictor of self-reported provision of PCare for HDS users?

**RQ20.** Are attitude, subjective norm, perceived behavioural control, professional norm, and intention a positive and significant predictor for each construct of the PCare-HDS scale?

**Rasch analysis.** To address RQ11 – RQ13 the Rasch analysis was utilized. Rasch analysis was employed to provide additional psychometric evidence for the Direct TPB, Indirect TPB and PCare-HDS scales. Rasch analysis provided an additional means to assess the quality of the scales by testing model-data fit through the assessment of whether the pattern of response observed in the data match to the theoretical pattern expected by the model.

- **Sample size.** Previous simulation study showed that under the assumption of Rasch model fit, sample sizes around  $N = 250$  to  $N = 500$  could provide a good balance for the interpretation of fit statistic. Therefore the sample size for the Rasch analysis was deemed adequate (158).
- **Assessment of item fit.** The item fit statistics i.e., Infit and Outfit mean square (MNSQ) were used as the criteria to examine the model-data fit. In this study, Infit and Outfit MNSQ between 0.5 and 1.5 are considered as satisfactory model-data fit (159).
- **Assessment of response category functioning.** For studies using Likert-type scale response format, it is imperative to assess the response category structure as to determine whether such structure is functioning well (160). In this study the Rasch analyses of the five-point Likert-type scales for each domain of the Direct TPB, Indirect TPB and PCare-HDS scales were conducted. The response category

functioning was assessed by analyzing category frequencies, mean measures, Outfit MNSQ and thresholds (161). Satisfactory response category functioning should follow monotonic increases in mean and step measures for all domains of the scales. Additionally the Outfit MNSQ should be less than 2.0 and each category should have 10 observations (161).

- **Assessment of differential item functioning for gender.** In previous surveys, female pharmacists had shown more favorable responses towards PC attitudinal items compared to their male counterparts (162). Similarly, female physicians had provided higher endorsement to survey items in regard to patient-centered activities compared to the male physicians (163, 164). On the other hand, male pharmacists had been shown to be more likely to endorse survey items in regard to HDS recommendation (65, 72). These findings raised questions to whether such differences in the endorsement for patient-centered care practices and HDS recommendation were true differences related to gender or due to measurement bias.

Therefore in this study, DIF analysis will be carried out to assess possible gender-related measurement bias of the items using Rasch analysis. The DIF analysis using this approach examines construct equivalence across groups. The presence of DIF may provide a negative impact on the credibility of the scales since different individuals with different gender may respond differently to the item. A substantial DIF is considered present if the difference of item difficulty across gender was equal to or larger than 0.5 logits (165).

**Criterion validity.** To answer RQ14 – RQ20, two types of criterion validity tests were run for the data namely concurrent validity and predictive validity.

- **Concurrent validity.** First, the mean score of each factor of the Direct and Indirect TPB scales was computed. Consequently, concurrent validity test was performed using the Pearson correlation test. The test was aimed to examine if the mean score of attitude, subjective norm, perceived behavioral control and professional norm correlate with the mean score of intention. Additionally, the test was performed to

assess the correlation of the Indirect TPB factors with their respective direct measures in the Direct TPB scale (166). The total mean scores of the Direct TPB, Indirect TPB and PCare-HDS scales were also computed. The Pearson correlation test was performed to see if the total mean score of the PCare-HDS scale correlate with both the total mean scores of the Direct and Indirect TPB scales.

The interpretation of the correlation coefficients followed the convention by Guilford as the following:  $< 0.19$  = slight or almost no relationship;  $0.20 - 0.39$  = low correlation or definite but small relationship;  $0.40 - 0.69$  = moderate correlation or substantial relationship;  $0.70 - 0.89$  = high correlation or strong relationship;  $0.90 - 1.00$  = very high correlation or very dependable relationship (167). Additionally, a correlation coefficient of  $\geq 0.30$  implies practically significant relationship (168).

- **Predictive validity.** Prior to conducting the predictive validity test, the independent samples *t*-test was carried out on dichotomous independent variables to find significant differences in the mean of intention and the mean of self-reported provision of PCare for HDS users. The independent variables included in this test were gender (male/female), type of undergraduate education (PharmD/other than PharmD), having a postgraduate qualification (yes/no), number of years as a registered pharmacists ( $\leq 10$  years/ $> 10$  years), type of community pharmacy (chain or franchise/independent), number of years working at the community pharmacy ( $\leq 5$  years/ $> 5$  years), position (full-time/part-time), being a manager (yes/no), being an owner (yes/no), having attended a HDS-related training in the past 6 months (yes/no), and having used HDS in the past 6 months (yes/no). For the type of community pharmacy, the survey included a third option which was “others”. However, only less than 3% of the respondents chose this option. Therefore for this question, the independent samples *t*-test was only performed to compare the mean of scores for the first two types of community pharmacy (chain/franchise and independent). For each variable, the homogeneity of variance was assessed using Levene’s test of equality of variances. Variables with violation of the assumption of homogeneity of variance were compared by adjusting the

degrees of freedom using the Welch-Satterthwaite method that is embedded in the SPSS system.

Several regression models were tested in the predictive validity test. First the MRA was conducted with constructs of the Direct TPB scale (i.e., attitude, subjective norm, perceived behavioural control and professional norm) as the independent variables and intention as the dependent variable. The second model involved testing attitude, subjective norm, perceived behavioural control, professional norm and intention as the independent variables and the self-reported provision of PCare for HDS users as the dependent variable. The rest of the models involved using each PCare-HDS scale construct as the dependent variable and the constructs of the Direct TPB scale (i.e., attitude, subjective norm, perceived behavioural control, professional norm and intention) for the independent variable. Demographic variables that influenced the mean scores of the dependent variables as identified by the independent sample *t*-test were included in the model. Through this analysis, the determination of the best fitting and most parsimonious model can be achieved (169). This means that the model could achieve a desired level of prediction with the fewest predictor variables possible.

Prior to running the MRA, data was screened to check for the adequacy of sample size, and presence of univariate and multivariate outliers. Data was also assessed for normality, linearity, and multicollinearity. Multicollinearity was assessed by inspecting the correlation matrix, Tolerance and VIF values (130). Normality for the intention and self-reported provision of PCare for HDS users mean score was checked by computing the skewness and kurtosis values. Data was assumed normal if the values did not exceed  $\pm 1$ . Multivariate outliers were determined by referring to the Mahalanobis distance from the residual statistics.

### 3.3.5. Statistical software

Three main statistical analysis software were used in the quantitative phase of the study: (1) Statistical Package for the Social Sciences (SPSS) version 23 (for descriptive statistics, EFA, correlation tests, and MRA); (2) Analysis of a Moment Structures (AMOS) software version 23 (for CFA, convergent and discriminant validity, and construct reliability tests); and (3) Winsteps Rasch version 4.2 (for Rasch analysis).

### 3.3.6. Ethical consideration

For the quantitative study, completion and the return of survey instrument by CPs indicated consent to participate in the survey. Response to the survey was voluntary. Respondents were offered anonymity and confidentiality. All returned questionnaires were kept securely by the researchers. The quantitative study obtained approval from the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (COA: 224/2017) (Appendix H).

## 3.4. Chapter summary

Chapter three outlined the methodological processes undertaken in the present study. In summary, the study was conducted in three phases. The study began with a qualitative study that allowed the elicitation of response from CPs about PCare for HDS users. In this regard the most relevant activities pertinent to PCare for HDS users were compiled. Additionally CPs' salient beliefs about the provision of PCare for HDS users (i.e., behavioural, normative, control, and professional normative beliefs) were elicited. Subsequently, the findings from the qualitative study together with the theoretical framework underpinning the study formed the initial item pools. These item pools were then examined in content and face validity study to refine the scales further. Finally, the scales were subjected to several stages of psychometric evaluation to ensure that the scales are valid and reliable. The subsequent chapter discussed results obtained from all phases of the study.

## CHAPTER 4: RESULTS

This chapter presents findings from the three phases of the study. Phase 1 was a qualitative study aimed to identify the salient practices of PCare for HDS users among CPs in Bangkok and to explore the behavioural, normative, control and professional normative beliefs of CPs associated with PCare for HDS users. Phase 2 was aimed to generate item pools for the Direct TPB, Indirect TPB, and PCare-HDS scales based on the theoretical framework and qualitative study findings from Phase 1. Phase 3 of the study was a quantitative study that was carried out in three stages to establish the psychometric properties of the scales.

### 4.1. Phase 1: Qualitative study results

#### 4.1.1. Informant characteristics

For the qualitative study, 22 CPs were interviewed. Saturation of themes was achieved after conducting 20 interviews. At this stage of data collection, no new and valuable information emerged from the interviews (98, 105). Additional interviews sessions with two CPs, one male and one female, confirmed data saturation. Data collection was concluded thereafter. The informants' ages ranged from 24 to 65 years old, with a mean age of 32 years old. The sample was 59% (13/22) female. The average working year of the informants was 4.32 (range: 1 – 33 years). Half of the informants (50%, 11/22) were working in independent community pharmacies while the other half were working in chain community pharmacies. The majority of the CPs interviewed (14/22, 63.6%) were working full-time, whereas the other 36.4% (8/22) were part-timers. The estimated number of customers among the interviewed CPs ranged from 20 – 1300 people daily. The informants estimated that 1 – 8 out of 10 of their customers purchased HDS daily. Only two CPs (9.1%) claimed that they provided PCare to all HDS users at their community pharmacies. On the other hand, 40.9% (9/22) of the informants estimated that out of 10 HDS users, they were only able to provide PCare to 5 or fewer. Table 8 summarizes the demographic characteristics of the study informants.



Table 8. Characteristics of community pharmacists in the qualitative study

Informant code	Age	Gender	Years working at current pharmacy	Pharmacy type	Employment status	Approximate daily number of customers	Daily number of customers requesting for HDS <sup>a</sup>	Number of HDS users provided with PCare <sup>b</sup>
CP01	28	Female	3	Chain	Full-time	1300	3	7
CP02	32	Female	3	Independent	Full-time	30	3	3
CP03	28	Male	3	Chain	Part-time	100	5	5
CP04	29	Female	5	Chain	Part-time	100	7	10
CP05	35	Female	5	Independent	Full-time	20	6	6
CP06	29	Male	3	Chain	Full-time	100	2	6
CP07	33	Female	1	Independent	Full-time	70	1	5
CP08	29	Male	3	Chain	Full-time	150	5	8
CP09	34	Female	7	Independent	Full-time	150	6	8
CP10	32	Male	1	Independent	Full-time	60	2	10
CP11	29	Female	5	Chain	Part-time	60	2	8
CP12	26	Female	1	Chain	Full-time	80	5	2
CP13	26	Male	1	Chain	Part-time	50	3	8
CP14	24	Female	1	Chain	Full-time	500	2	7
CP15	26	Male	1	Chain	Full-time	500	3	8
CP16	65	Male	33	Independent	Full-time	100	3	7
CP17	34	Female	1	Independent	Full-time	30	5	5
CP18	27	Female	4	Chain	Part-time	400	7	4
CP19	30	Male	6	Independent	Part-time	300	8	5
CP20	26	Female	4	Independent	Part-time	50	7	7
CP21	42	Male	2	Independent	Part-time	400	2	1
CP22	37	Female	2	Independent	Full-time	30	4	2

HDS, herbal and dietary supplements; PCare, pharmacist's care

<sup>a</sup> Estimated for daily customers requesting for the HDS based on 10 customers.

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<sup>b</sup> Estimated for HDS users provided with PCare based on 10 HDS users.



#### 4.1.2. Qualitative study findings

Table 9 shows the summary of themes and frequencies of practices for PCare for HDS users, and the behavioral, normative, control and professional normative beliefs associated with the behaviour.

**Table 9. Main themes of pharmacist's care for HDS users, and the underlying beliefs and factors**

Main theme / Subtheme	Frequency <sup>a</sup>
<b>PCare for HDS users</b>	
<i><b>Direct customer/patient care activities</b></i>	
Giving advice or counselling on HDS use	18
Gathering relevant information from HDS users	17
Making a professional decision or suggestion for HDS use	15
Assessing HDS use	12
Assisting informed decisions	12
Fostering pharmacist-customer relationship	8
<i><b>Non-direct customer/patient care activities</b></i>	
Seeking HDS information	13
Maintaining HDS product quality	5
<b>Underlying beliefs and factors influencing the provision of PCare for HDS users</b>	
<i><b>Behavioural beliefs: advantages</b></i>	
<b>Related to HDS users</b>	
Ensuring the rational use of HDS	16
Ensuring the safety of HDS users	14
<b>Related to pharmacists</b>	
Improving pharmacists' own knowledge	8
Making pharmacists more trustworthy	5
Providing pharmacists with self-satisfaction	5
<b>Related to community pharmacies</b>	
Promoting loyalty among customers	9
Attracting customers	2
Enhancing the image of community pharmacy	2
<i><b>Behavioural beliefs: disadvantage</b></i>	
Time-consuming	1
<i><b>Normative beliefs: approval</b></i>	
HDS users	13
Co-workers	4
Doctors	2
Thai Food and Drug Administration	1
Pharmaceutical companies	1
<i><b>Normative beliefs: disapproval</b></i>	
Family members of HDS users	1
<i><b>Control beliefs: facilitators</b></i>	
<b>Related to HDS users</b>	
Conversation on HDS initiated by HDS users	15
HDS users with characteristics that are perceived as easy to provide PCare	6

for	
HDS users who showed trust in pharmacists	5
Willingness of the HDS users to spend time for receiving PCare	4
<b>Related to pharmacists</b>	
Professional training	11
Perceived expertise in HDS	11
Having supporting staffs or assistants	6
Having more time allocation	5
Having sufficient education of HDS from the undergraduate program	4
<b>Related to community pharmacies</b>	
Availability of reference materials about HDS	14
Access to the Internet	10
Access to scientific evidence for HDS	7
<hr/> <b>Control beliefs: Barriers</b>	
<b>Related to HDS users</b>	
Reluctance to accept pharmacists' opinions about HDS use	14
Unwillingness of HDS users to communicate with pharmacists	12
HDS users with characteristics that are perceived as difficult to provide PCare for	8
Unwillingness of HDS users to spend time for PCare	3
Inadequate information offered by HDS users	3
<b>Related to pharmacists</b>	
Busyness	6
Insufficient education in HDS from the undergraduate program	5
Limited knowledge about HDS	5
Lack of professional training	2
<b>Related to community pharmacies</b>	
Limited sources of information for HDS in the pharmacy	5
Limited access to the scientific evidence for HDS	3
Restrictive space available	1
<hr/> <b>Professional norm</b>	
Job description of pharmacists	12
Pharmacist as a healthcare professional	9
<hr/>	
<sup>a</sup> Frequencies used to quantify categories reflect the presence of beliefs for a CP and not the number of times that a single CP expressed the same belief	
HDS, herbal and dietary supplements; PCare, pharmacist's care	
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#### 4.1.2.1. Pharmacist's care for herbal and dietary supplement users

The CPs mentioned various pharmacist activities that they regarded as PCare for HDS users. The activities can be categorized into direct and non-direct customer/patient care activities. The direct customer/patient care activities included six domains: (1) fostering relationship; (2) gathering information; (3) assessing HDS use; (4) assisting informed decision; (5) making professional decision; and (6) providing advice and

information. The non-direct customer/patient care activities included two domains: (1) seeking HDS information; and (2) maintaining HDS product quality.

Direct customer/patient care activities:

***Fostering pharmacist-customer relationship.*** The CPs opined that it is important for them to be ready to listen attentively to customers inquiring about or requesting the HDS. Most informants believed that CPs in general should aware that many customers prefer the HDS and they should deal with the users in an open and non-judgmental manner:

- “They prefer natural products... they ask me for the best products... they ask my recommendations. When they get sick and it’s not severe they want natural products and not drugs... I can talk with them” (CP08, 29 year-old male).
- “I will listen to them to the end and later provide them with the correct information” (CP10, 32 year-old male).

***Gathering relevant information.*** The CPs also emphasized the need to ask various questions during encounter with HDS users. These questions are generally aim to elicit information (e.g., the purpose of HDS use, medical illnesses/conditions, and existing medicines) that can allow them to assess whether or not the use of HDS is appropriate, and to identify any HDS-related problems. The CPs provided some examples:

- “Some customers have chronic diseases... some customers are on warfarin. Warfarin has many interactions. I ask ‘Do you use any drug at the moment?’ Important question to prevent interaction” (CP08, 29 year-old male).
- “I try to ask a lot of questions to the customers, ‘Do you have any allergies? What is the purpose of using the HDS?’ This can help the patients... I will ask if they are taking warfarin when they are buying ginkgo biloba or garlic supplements” (CP 13, 26 year-old male).

***Performing assessment on herbal and dietary supplement use.*** Two main aspects the CPs paid attention in the assessment of HDS use were related to the indication and safety of HDS. The CPs mentioned that in many occasions, HDS use can be unreasonable and users are even using HDS for the wrong indication. The CPs said:

- “Sometimes they use for the wrong indication. I have some cases where patients use fish oil for diabetes and their blood glucose levels went out of control” (CP16, 65 year-old male).
- “They are using many medicines but still ask for fish oil, calcium or something else... I have to analyze (assess) first whether there are problems or not” (CP19, 30 year-old male).

Therefore, the CPs mentioned that they should evaluate whether the requested HDS are suitable for their health problems or needs. Regarding safety issues of HDS, many CPs reported that they often check for HDS-drug interactions. A few CPs mentioned that they checked for HDS-disease interactions and potential adverse effects of the HDS. One CP mentioned:

- “If the customers have chronic diseases, and are using medications daily, we have to check if there are any interactions” (CP16, 65 year-old male).

***Assisting customers to make informed decision.*** Before the customers decide on using HDS, the CPs mentioned that they should provide sufficient and unbiased information to the customers to ensure that the customers are using the products based on an informed-decision. In this regard, the customers are ensured that they understand the limitations and possible risks of using HDS before deciding on using it:

- “We have to give the exact information to the customers so that they can decide whether to use or not to use the supplements” (CP06, 29 year-old male).
- “Some HDS can have interactions with drugs... so as pharmacists, it is our duty to provide the information” (CP04, 29 year-old female).

One CP said if there is no evidence that a HDS can cure a particular disease, this should be informed to the customer:

- “Some people have misunderstanding about the HDS. They believe HDS can treat their disease, but no... I will just tell them” (CP13, 26 year-old male).

***Making professional decisions or suggestions about herbal and dietary supplement use.*** This activity involved various form of actions that require CPs’ professional judgment. These include a recommendation or non-recommendation of HDS use. CPs highlighted that professional decisions should derive from the information gathered from HDS users and all available evidences. Additionally, CPs mentioned that they should make a professional judgment to refer HDS users to physicians when necessary, and to suggest them for more laboratory and physical examinations before using HDS. One CP mentioned that CPs should be able to judge if an adverse event from HDS use occurs, and report it to the authority.

- “If there is no problem and if it is appropriate for the customers to use... it is OK for me to sell” (CP19, 30 year-old male).
- “I make decisions from the problems of the customers” (CP15, 26 year old-male).

Nonetheless, in many occasions, the CPs reported that their customers still insisted on using HDS even when it is not important, or if it has limited evidence for the intended purposes. Unless major safety issues exist, the CPs usually resorted to the customers’ final decisions about using a particular HDS. Nevertheless, in cases where HDS is found to be harmful to the users, CPs normally maintain their stance in discouraging the use. One CP said:

- “If not necessary I will tell them *no*” (CP02, 32 year-old female).

***Providing advice or information about herbal and dietary supplement use.*** Almost all CPs mentioned that they should counsel HDS users about HDS use. The CPs put attention on advising about the direction of use of HDS and the common side effects associated with its use. In addition, CPs also normally advice about the importance to comply with prescribed medicine. The CPs mostly agreed that HDS are only suitable to complement existing medications and should not be used as a substitution to conventional therapy.

- “I always remind them to take the medications that the doctors gave them... the supplements are just complementing the therapy” (CP06, 29 year-old male).
- “Tell them, ‘If you take it with medications, it will decrease your blood sugar level and cause you to feel dizzy’, just tell them the symptoms that might happen to them” (CP11, 29 year-old female).

Non-direct customer/patient care activities:

***Seeking herbal and dietary supplement information.*** The CPs also highlighted the importance of seeking HDS information. This is because new products are being launched frequently. In addition, many CPs mentioned that many customers were influenced by advertisement of HDS products and they regularly come to the community pharmacy to inquire about these products. CPs therefore, should keep updated with latest HDS information so that they can provide professional feedback to the customers.

- “Pharmacists must learn all the time because new products come out all the time” (CP05, 35 year-old female).



***Maintaining herbal and dietary supplement product quality.*** One important aspect that the CPs highlighted as part of PCare for HDS users was ensuring HDS product quality at the community pharmacy. The CPs mentioned that at present there are many products that are marketed, are not at standards. These products may not be approved by the FDA and may be produced at facilities that do not adhere to good manufacturing practices. However since these products are heavily advertised in social media and by prominent public figures such as celebrities and television personalities, these products are being sought after by the public.

- “You can see there are many products being advertised in *Facebook* with excessive claims. I don’t have these products. This is to protect the customers... In my drugstore I only have HDS products that are approved by the FDA. Other drugstores may keep it (unapproved products), but for me... I can’t. I am a pharmacist I can’t do like that” (CP05, 35 year-old female).
- “I am very selective and careful in choosing products (to be sold at community pharmacy) because people trust me... If I don’t care about the quality of the products, it means I am cheating the people” (CP16, 65 year-old male).

#### **4.1.2.2. Behavioral beliefs**

The informants saw the values of PCare as not only beneficial to HDS users, but also to themselves, and their community pharmacies. In general, positive behavioral beliefs were elicited from CPs regardless of their level of involvement in PCare activities, and the type of community pharmacy. The most salient advantages of providing PCare for HDS users were: ensuring rational use of HDS (72.7%, 16/22); ensuring safety of HDS users (63.6%, 14/22); and promoting loyalty among customers (40.9%, 9/22).

In this study, the CPs believed that ensuring the rational use of HDS is very important because many customers often request or use HDS that are inappropriate for their health concerns. Additionally, in many cases, the use of HDS is unnecessary for them. The CPs believed this irrational use of HDS often stemmed from misleading information about HDS from the Internet, advertisements, and family and friends that

can be unreliable. The CPs opined that PCare can result in rational use of HDS by making sure the users are receiving products that are appropriate to their needs, in suitable doses, for an adequate period of time, and at the lowest cost to them. The CPs mentioned:

- “They will get the most out of pharmacist’s actions... get the best thing” (CP03, 28 year-old male).
- “The customers can use the best product. Suitable for their symptoms and their budget” (CP07, 33 year-old female).

Additionally many CPs mentioned “safety” when asked for the benefits of PCare for HDS users. In general, the CPs mentioned that the safety of the HDS users can be assured through PCare by avoidance of HDS-drug interactions, identification of adverse effects, and prevention of overdosing. A few CPs mentioned that PCare can prevent the use of HDS that are harmful in pregnancy, and patients with kidney or hepatic problems. In addition, HDS users who are dismissing their prescribed medicine in favor for HDS can be identified through PCare. These HDS users can be educated about the importance of adherence to proven therapy, thereby ensuring their safety from disease worsening.

The CPs also identified advantages of providing PCare that can benefit them personally. For an example, some CPs reported that while providing PCare, they gain new knowledge about HDS (36.4%, 8/22). The CPs mentioned that they usually obtain new information when the users shared their experiences about using HDS. Additionally the CPs often “forced” to look up for more information about HDS when they received inquiry about the products or when being asked to validate the information that the customers received from other sources. Two CPs shared their experiences:

- “When I talk to the patients I can get new knowledge. Customers talk about their beliefs, about traditional Thai herbs... new knowledge for me” (CP08, 29 year-old male).

- “A customer asked for a HDS for (increasing) lactation. I don’t know. Then when I check... there are some HDS for it!” (CP13, 26 year-old male).

Other advantages of providing PCare that may benefit the CPs included making them more trustworthy (22.7%, 5/22), and provides satisfaction (22.7%, 5/22).

- “If pharmacists do it (providing PCare for HDS users)... it makes pharmacists more trustworthy” (CP19, 30 year-old male).
- “When I can provide care for them, they will trust me and I will be happy... I feel proud of my profession” (CP02, 32 year-old female).

Several other benefits identified by the CPs are for their community pharmacies. For example some CPs opined if they provide PCare for HDS users, these customers will be more loyal to their community pharmacies (40.9%, 9/22). A small proportion of the CPs believed that it can attract more customers due to word-of-mouth (9.1%, 2/22), and may enhance the image of community pharmacy (9.1%, 2/22). One CP said that:

- “My drugstore only opens in the evening, with short opening hours, but my customers wait for me. They like to receive my advice and like to consult me... when patients received my care, they feel good. These patients will tell friends and family about my service and I will get more customers” (CP05, 35 year-old female).

The majority of the informants did not associate the provision of PCare for HDS users with any disadvantage. One CP however suggested that PCare for HDS users can be time-consuming.

- “Customers spend 30 minutes with me. Some people spend about one hour with me, they have many questions. They want to know the good, the bad, side effects, efficacy...” (CP08, 29 year-old male).

#### 4.1.2.3. Normative beliefs

The most often mentioned individuals that encourage the CPs to provide PCare for HDS users are the customers (59.1%, 13/22). Only a few informants (18.2%, 4/22) mentioned that their co-workers provide such encouragement. External entities that approve the CPs to provide PCare for HDS users such as the doctors (9.1%, 2/22), Thai FDA (4.5%, 1/22), and pharmaceutical companies (4.5%, 1/22) were only mentioned by the minority of the informants. The majority of the informants reported that there is no individual or entity that disapproves PCare for HDS users. One female CP mentioned that sometimes her effort to engage with and to provide PCare for HDS users was disapproved by the family members.

#### 4.1.2.4. Control beliefs

The CPs described facilitators and barriers for the provision of PCare for HDS users that can be customer-, pharmacist- or community pharmacy-related. The most common customer-related factor that motivated the CPs to provide PCare was the initiation of conversation by HDS users (68.2%, 15/22). One CP said:

- “Some customers come and tell me their symptoms, asking for help to solve symptoms. When I know the symptoms, I can advise something ... if they come and don’t want the advice it is hard, but if they want it, it’ll be easy. It’s up to the customers” (CP09, 34 year-old female).

Consistently many CPs (54.4%, 12/22) mentioned that the unwillingness of HDS users to communicate with them, demotivate them to provide PCare. The CPs believed that this group of HDS users is already using the products for a long time, or they simply do not want CPs’ advice. The following are two situations where PCare was not offered by the CPs due to customers’ refusal to talk to them:

- “Some patients just pick up and don’t want any advice. ‘Don’t talk to me, I just want to buy. You just sell’. So these customers I can’t provide care. They come and buy and go” (CP05, 35 year-old female).

- “When the customers ask, I will give them the information but if they don’t ask, it means that they don’t want to know or they want to make their own decision. So I won’t force myself” (CP18, 27 year-old female).

Many CPs also reported to be less motivated in providing PCare when encountering HDS users who are reluctant to accept CPs’ opinions about HDS (63.6%, 14/22). It was noted that all part-timer CPs mentioned this barrier during the interview. Many CPs mentioned that those HDS users who refused to accept CPs’ opinions about HDS are generally assertive, can be aggressive and had the perceptions that they are knowledgeable or experienced:

- “They have some walls to receive any information, because they think they know the best... they don’t listen to the pharmacists” (CP19, 30 year-old male).
- They trust their own knowledge and don’t trust me... if I suggest a product that is more suitable for them... they refuse to receive it because they think they know what is the best product” (CP03, 28 year-old female).

It was also noted that some CPs have inclination to stereotype the type of customers that will be easy (27.3%, 6/22) or more difficult (36.4%, 8/22) to be provided with PCare. The characteristics of customers that are thought to be easier or harder to be provided with PCare were not consistent. The HDS users who are educated, having middle to high incomes, and health professionals were proposed as the group that is easy to be provided with PCare. To some CPs, it is easier to provide PCare to the young customers whereas to some CPs the middle-aged and older adults are easier. On the other hand, for two CPs, it was more difficult to provide PCare to the older customers, whereas another two thought that providing PCare to the youngsters is harder. Those who are uneducated, office workers and foreigners (non-Thais) were also suggested as difficult to be provided with PCare. It was observed that CPs who are younger than 30 years old, working in chain community pharmacy, having less than five year experience in community pharmacy practice, and having more than 100

customers daily appeared to be more inclined to stereotype their HDS users as either easier or harder to provide PCare.

Many CPs identified professional training as an important facilitator for them to provide PCare for HDS users (50%, 11/22). CPs reported that such training provides and updates them with HDS information, making them more confident in providing PCare for HDS users. Professional training as a facilitator was more salient among CPs who are less than 30 years old, full-timers and having less than five year experience in community pharmacy practice. One CP mentioned:

- “The company provides training for us every month where we learn new HDS product in the market. I also have attended courses on pharmaceutical care for the HDS supported by the company. We learn how to provide proper care” (CP01, 28 year-old female).

Additionally, many CPs (50%, 11/22), usually in enthusiasm mentioned that they are the experts in PCare for HDS users. They often stated that their integrated knowledge in pharmaceutical products, human diseases, and HDS motivated them to provide PCare for HDS users. CPs who believed that they are experts in HDS tend to be younger than 30 years old, having community pharmacy experience of less than 5 years, working in chain community pharmacy and working as part-timers. Several CPs also highlighted that they are more knowledgeable in this area compared to the other healthcare professionals:

- “We provide care for them because we know about the HDS... I think pharmacists know the best” (CP15, 26-year old male).
- “I think we know about this more than other healthcare professionals” (CP13, 26 year-old male).

Nevertheless, although many CPs identified themselves as the experts in providing PCare for HDS users, some CPs reported that they had insufficient knowledge about HDS (22.7%, 5/22), and had insufficient coverage of HDS information in their previous undergraduate education (22.7%, 5/22).

- “Sometimes I don’t know everything about the HDS. When the customers ask me, I said ‘I don’t know. I am sorry’. Sometimes we cannot give advice because we don’t know” (CP14, 24 year-old).
- “We learned for five years. We learn about drugs and not the HDS. Although we learned pharmacognosy... that’s all. It’s just one subject” (CP11, 29 year-old female).

Some CPs (22.7%, 5/22) mentioned that it would be more feasible for them to provide PCare for HDS users when they are less busy especially during off-peak hours. Consistently, busyness was identified as a barrier for several CPs to provide PCare for HDS users (27.3%, 6/22). Some CPs mentioned that they are under pressure to execute multiple roles at their community pharmacies especially during busy hours. This resulted in CPs not being able to provide attention to HDS users:

- “Sometimes we have five people come at the same time and we cannot provide advice for all. They lined up so we just can’t” (CP20, 26 year-old female).
- “I cannot pay attention to my customers properly during the rush hour. Sometimes you only have one or two minutes for each customer” (CP18, 27 year-old female).

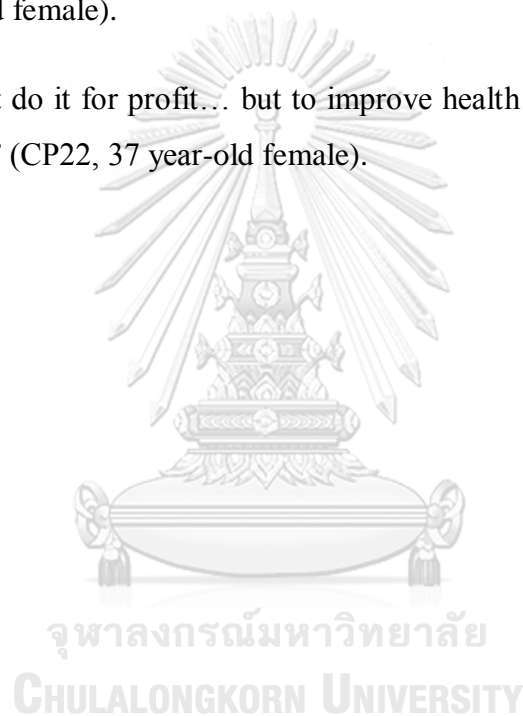
In general, the CPs believed that the availability of printed materials about HDS such as leaflets, posters, booklets, etc., (63.6%, 14/22) can support them when providing PCare for HDS users. These materials were predominantly supplied by HDS manufacturers. The CPs mentioned that they not only use these materials as a guide while educating HDS users, but also provide these materials to the customers:

- “The company (manufacturers) provided me with leaflets. I will provide these to my customers, because even I have advised on how to use the HDS, customers may forget so these leaflets will remind them” (CP03, 28 year-old male).

#### 4.1.2.5. Professional norm

Professional normative beliefs related to the provision of PCare for HDS users include the beliefs that it is the “job description of CPs”, and that they are “health professionals” whose actions should be distinguishable from those of salespersons, or the cashiers. The CPs said:

- “We are pharmacists and not just sellers... You can’t just come and get what you want and go out. Otherwise we are not different from the cashiers” (CP11, 29 year-old female).
- “We don’t do it for profit... but to improve health and for the benefits of the customers” (CP22, 37 year-old female).





## **4.2. Phase 2: Development of scales**

The development of the Direct TPB, Indirect TPB and PCare-HDS scales has been discussed in detail in section 3.2. This section provides the results of the content and validity studies.

### **4.2.1. Results for content and face validity studies**

In the content validity study, the relevance of the items of the Direct TPB, Indirect TPB and PCare-HDS scales was reviewed by a panel of experts. Since only four experts were included in the content validity study, only items that have a content validity index (CVI) of 1 were retained in the scales (114). Items that have a CVI value of less than 1 were deleted. Several items were combined accordingly due to having very similar meanings. At the end of the content validity study, the items of the Direct TPB, Indirect TPB and PCare-HDS scales were reduced to 12, 16 and 33, respectively.

Results from the face validity study showed that the scales were readable, clear and easily comprehensible. In addition, the response formats for the scales were also considered as appropriate. Appendix F shows the initial pool of items, item CVI and comments from the reviewers, and the revised items. The list of items for each scale that were submitted for further analysis in the next phases of the study is outlined in Table 10 - 12.

**Table 10. List of items for the Direct TPB scale**

<b>Attitude</b>	
1.	I think pharmacist care for the HDS users can bring many benefits to the customers, pharmacists and the drugstores (ATT1).
2.	I enjoy providing care for the HDS users (ATT2).
3.	If I provide care for the HDS users, I feel satisfied (ATT3).
<b>Subjective norm</b>	
4.	The public wants me to provide care for the HDS users (SN1).
5.	I have to provide care for the HDS users because this is what the society wants me to do (SN2).
<b>Perceive behavioural control</b>	
6.	I am confident that I can provide care for the HDS users (PBC1).
7.	Providing care for the HDS users is easy (PBC2).
<b>Professional norm</b>	
8.	As a community pharmacist, I believe that providing care for the HDS users is something I should do (PN1).
9.	It is my professional responsibility as a community pharmacist to provide care for the HDS users (PN2).
<b>Intention</b>	
10.	I am ready to provide care for the HDS users on a regular basis during the next two weeks (INT1).
11.	I will try to provide care for the HDS users on a regular basis during the next two weeks (INT2).
12.	I have intention to provide care for the HDS users on a regular basis during the next two weeks (INT3).

**Table 11. List of items for the Indirect TPB scale**

<b>Behavioural belief</b>	
13.	If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions (BB1).
14.	If I provide care, I can ensure the HDS users are using the most suitable products (BB2).
15.	If I provide care for the HDS users, my knowledge about the HDS will be improved (BB3).
16.	If I provide care for the HDS users, I will be trustworthy (ethical / honest) (BB4).
17.	If I provide care for the HDS users, they will come back to my drugstore in order to consult me (BB5).
<b>Normative belief</b>	
18.	The HDS users want me to provide care for them (NB1).
19.	Those who work with me (e.g., other pharmacists, drugstore assistants, healthcare consultants, etc.) think that I should provide care for the HDS users (NB2).
20.	The doctors think that I should provide care for the HDS users (NB3).
<b>Control belief</b>	
21.	I think I have received enough training to provide care for the HDS users (CB1).
22.	I think I can manage my time so that I can provide care for the HDS users (CB2).
23.	I believe I have received sufficient education about the HDS in my previous undergraduate studies (CB3).
24.	I think my knowledge about the HDS is good (CB4).
25.	I think the HDS users are happy to talk with me about their HDS use (CB5).
26.	I think the HDS users would like to receive advice and suggestions about the HDS from me (CB6).
27.	In my opinion I have access to information about the HDS including the scientific evidences at my drugstore (CB7).
28.	I think I have enough informational materials (e.g., leaflets, posters, booklets, etc.) about the HDS at my drugstore (CB8).

**Table 12. List of items for the PCare-HDS scale**

<b>Foster relationship</b>	
1.	I listen carefully to the customers' inquiries or requests for the HDS (FR1).
2.	I develop a good relationship with the HDS users (FR2).
3.	I respect the customers' intentions to use the HDS for treating diseases, or maintaining their health (FR3).
<b>Gather information</b>	
4.	I ask the reasons why the customers want to use the HDS (GI1).
5.	I ask the HDS users if they are using any medicines (GI2).
6.	I ask the HDS users if they have any other illnesses or medical conditions (e.g., pregnancy, allergies, etc.) (GI3).
<b>Assess HDS use</b>	
7.	I assess whether the HDS has any indication for the customers (AU1).
8.	I identify any HDS-related problems associated with the use of the HDS (AU2).
9.	I identify disease– or drug–HDS interactions if the HDS users have medical illnesses or are using medicines (AU3).
<b>Assist informed decision</b>	
10.	I provide unbiased information about the HDS to help the customers decide on whether or not to use the HDS (AID1).
11.	To help the customers decide on whether or not to use the HDS, I explain both the potential benefits and limitations of the products (AID2).
12.	I tell the customers if there is no scientific evidence for the HDS use (AID3).
<b>Make professional decision or suggestion</b>	
13.	I recommend the customers to have physical or laboratory examinations (e.g., blood glucose test or blood pressure test) before using the HDS (MPD1).
14.	If there is no contraindication to HDS use, I recommend HDS that is appropriate to the customer's needs, in a suitable dose, for an adequate period of time, and at a suitable cost (MPD2).
15.	If the use of the HDS is not appropriate (e.g., not indicated, not appropriate, or contraindicated), I advise the customers not to use the HDS (MPD3).
16.	I suggest using Western (modern) medicine if it is more appropriate than using the HDS (MPD4).
17.	I refer the customers to the physicians if I found out that they actually need medical treatment (MPD5).
18.	I report to the authority if the HDS users experience adverse events from HDS use (MPD6).
<b>Provide advice or information</b>	
19.	When dispensing HDS, I tell the HDS users about what they can expect from the HDS (positive effects and side effects) (PAI1).
20.	When dispensing HDS, I advise how to use the HDS (e.g., directions for use and dose per day) (PAI2).
21.	When dispensing HDS, I advise the HDS users to avoid other OTC medications, and HDS that can cause interactions (PAI3).
22.	When dispensing HDS, I advise the HDS users to monitor their symptoms (e.g., improvement or worsening of health) (PAI4).
23.	When dispensing HDS, I advise the HDS users to seek medical attention if their symptoms worsened (PAI5).
24.	When dispensing HDS, I tell the HDS users the importance of adherence with the prescribed medicines, if they are using prescribed medicine (PAI6).

25. When dispensing HDS, I advise the HDS users to tell their physicians about their HDS use (PAI7).
26. I provide the HDS users with relevant HDS informational materials (e.g., brochures, pamphlets, or booklets, etc.) (PAI8).

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**Seek HDS information**

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27. I use reliable sources of information when providing information to the HDS users (SI1).
28. I seek information about the indications of common HDS (SI2).
29. I seek information about disease– and drug–HDS interactions (SI3).
30. I seek information about signs and symptoms of adverse effects of common HDS (SI4).

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**Maintain HDS product quality**

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31. I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice (MPQ1).
  32. I make sure that the HDS in my drugstore do not have non-logical claims (e.g., curing cancer, whitening skin in few days, etc.) (MPQ2).
  33. I make sure that the HDS in my drugstore are stored properly (MPQ3).
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### 4.3. Phase 3: Quantitative study results

This was a descriptive cross-sectional study carried out among CPs in Bangkok. The main aims of the quantitative study were to examine and validate the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales. The quantitative study consisted of three stages. This section discusses the characteristics of the respondents, response rates, and comparison of the characteristics of early and late responders. Finally this section discusses results from the three stages of data analysis.

#### 4.3.1. Community pharmacist participation and response rate

Out of 4,194 survey packages mailed to community pharmacies in Bangkok, 74 were returned undelivered. Two hundred and seventy CPs returned the questionnaires in the stamped envelope enclosed in the survey packages. Out of these 270 questionnaires, 16 were blank leaving 254 useable questionnaires for data analysis. The useable response rate for the mail survey was therefore 6.2% (254/4120). For the online survey, approximately 11% (79/713) of the invitations were undelivered. Out of 634 delivered e-mail invitations to complete the questionnaire, 96 responded, giving a response rate of 15.1% (96/634). Data collection during two seminars resulted in 85 questionnaires being returned. Of these returned questionnaires, 13 were answered by CPs from other provinces: one each from *Yala*, *Phuket*, *Phetchabun*, *Phitsanulok*, *Chiang Rai*, *Maha Sarakham*, *Prachinburi*, *Chachoengsao*, and *Chonburi*; and two from *Surat Thani* and *Samut Sakhon*, respectively. These questionnaires were discarded resulting in 72 useable questionnaires for data analysis (useable response rate: 22.5%, 72/320). Common reasons for CPs not completing the survey during the seminars included lack of time, not interested to participate or had responded the mail survey. The data collection by hand carried out by two research assistants yielded a relatively higher response rate compared to the other data collection methods (69.6%, 281/404). Out of 404 community pharmacies visited, CPs at 150 community pharmacies declined to answer the questionnaires. Some reasons for refusing to answer the questionnaires included busyness, not interested, had already answered, concern about confidentiality or had other questionnaires to fill up.

#### 4.3.2. Assessment of missing values

For the Direct and Indirect TPB scales, the response format used a 5-point Likert-type scale (1 = strongly disagree, to 5 = strongly agree) and a N/A response. All items of the two scales had at least one N/A response. However, the percentage of the N/A response for each of the item was small, ranging from 0.1% – 1.4% for the Direct TPB scale, and 0.1% - 1.3% for the Indirect TPB scale. The PCare-HDS scale did not use N/A as one of the response choices. Since N/A responses do not provide information about the degree of agreement of the respondents toward each item, the N/A responses were treated as missing. After treating N/A as missing, the Direct TPB scale had missing values that ranged from 0.3% - 2.0%. For the Indirect TPB scale, missing values ranged from 0.1% – 1.8%. Meanwhile, missing values ranged from 2.7 – 3.0% for the PCare-HDS scale. The percentage of missing values for each item of the Direct TPB, Indirect TPB and PCare-HDS scales is shown in Appendix I. All items for the three scales were retained for further analysis since no item had a percentage of missing values of more than 5%.

Further assessment of missing values for each case (respondent level) revealed that out of 703 respondents, 25 (3.57%) cases for the Direct and Indirect TPB scales had a percentage of missing value of more than 15%. These cases were removed, leaving 678 cases eligible for subsequent analysis. On the other hand, out of 703 respondents, 21 cases for the PCare-HDS scale had a missing value of more than 15%. These cases were removed. As a result, 682 cases were available for subsequent analysis. Removal of the cases with 15% missing values resulted in all cases having no missing value.

For the demographic data, the following data had missing values: type of previous undergraduate education (2.1%); number of years registered as pharmacist (3.3%); number of years working in community pharmacy (0.9%); type of further education obtained (2.6%); history of HDS training (3.1%); history of use of HDS (2.3%); employment position (1.8%); type of community pharmacy (2.3%); number of customers received daily (3.6%); and number of customers purchase HDS daily (3.6%). Missing data for categorical variables were handled by replacing missing values with mode, whereas continuous data were replaced using the expectation

maximization technique. Missing data for each scale were not imputed to maximize the validity of the item selection during the refinement phase of the scales. Since there are no differences in the demographic characteristics of completers and non-completers, this is considered appropriate (Appendix J).

The low percentage of missing values and responses for N/A option indicated that the items used in the survey were practical. The time taken for answering the survey was not collected in the study. However, in the face validity study among a small sample of CPs and pharmacy students, the time taken to complete the survey ranged from 30 – 45 minutes.

#### **4.3.3. Comparison of early and late responders' characteristics**

For the mail survey, mailing of all questionnaires to 4,194 community pharmacies began in the second week of December, 2017 and was completed in the second week of January, 2018. A reminder postcard was sent to all community pharmacies approximately 2 months after the first mailing, in the second week of March, 2018. CPs who responded within the first two months of the survey (65%, 166/254) were considered early responders whereas those who responded after the two-month period were categorized as late-responders (34.6%, 88/254). The characteristics of the late respondents were similar to the early responders for all the socio-demographic information. Appendix K shows the comparison of the characteristics of the early and late responders for the mail survey.

The online survey was started in the fourth week of December, 2017 and followed by two e-mail reminders. The e-mail reminders were sent two and four weeks after the first e-mail invitation. Approximately 60% (57/96) of the respondents responded to the online survey within the first month of the survey and about 40% (39/96) responded thereafter. The respondents were classified as early and late respondents, respectively. Comparison analysis of the characteristics of the early and late respondents of the online survey showed no significant difference for each of the socio-demographic variable. Appendix L shows the comparison of characteristics of the early and late respondents for the online survey. The comparison of the



characteristics of early and late responders for the surveys distributed by hand and during the pharmacy seminars was not feasible and therefore was not performed.

#### 4.3.4. Sample characteristics of total sample

Out of 703 CPs who responded to the survey, 469 were female (66.7%). Most of the CPs had a BPharm/BSciPharm degree as their undergraduate education (80.1%, 563/703) with most of them (86.5%, 608/703) had no postgraduate education. At the time of survey, majority of the CPs were working at an independent community pharmacy (63.9%, 449/703) and were working full time (74.8%, 449/703). Most of the CPs had been registered as pharmacists for 11 – 20 years (42.5%, 299/703) but the majority of them had been working in their current workplace for  $\leq 5$  years (50.2%, 353/703). Approximately 70% of the CPs (484/703) were HDS users. Although almost half of the respondents received 6 – 15 HDS customers daily (48.5%, 341/703), almost 60% of them had not received any HDS-related training in the past six months of the survey. The distribution of respondents based on their socio-demographic characteristics for the total sample of the study is presented in Table 13.

**Table 13. Characteristics of community pharmacists in the quantitative survey (n = 703)**

Demographics	Total sample n (%)
Gender	
Male	234 (33.3)
Female	469 (66.7)
Previous undergraduate education	
PharmD	92 (13.1)
BPharm / BSciPharm	563 (80.1)
Others e.g., MPharm (UK) <sup>a</sup>	48 (6.8)
Having a postgraduate qualification	
Yes	95 (13.5)
No	608 (86.5)
Number of years as a registered pharmacist	
$\leq 10$	247 (35.1)
11 – 20	299 (42.5)
21 – 30	132 (18.8)
> 30	25 (3.6)
Type of community pharmacy	
Chain / franchise	234 (33.3)
Independent	449 (63.9)
University-affiliated	20 (2.8)

Number of years working in community pharmacy	
≤ 5	353 (50.2)
6 – 10	230 (32.7)
> 10	120 (17.1)
Position at community pharmacy	
Full-time	526 (74.8)
Part-time	177 (25.2)
Number of hours working in a week	
≤ 20	122 (17.4)
21 – 40	133 (18.9)
> 40	448 (63.7)
HDS users <sup>b</sup>	
Yes	484 (68.8)
No	219 (31.2)
Have attended HDS-related training <sup>b</sup>	
Yes	297 (42.2)
No	406 (57.8)
Holding a managerial post at community pharmacy	
Yes	45 (6.4)
No	658 (93.6)
Owner of community pharmacy	
Yes	216 (30.7)
No	487 (69.3)
Number of pharmacist coworkers	
None	496 (70.6)
1	171 (24.3)
2	26 (3.7)
> 2	10 (1.4)
Number of co-workers including pharmacists	
None	409 (58.2)
1	168 (23.9)
2	78 (11.1)
> 2	48 (6.8)
Number of customers daily	
≤ 50	315 (44.8)
51 – 100	307 (43.7)
> 100	81 (11.5)
Number of HDS customers daily	
≤ 5	229 (32.6)
6 – 10	178 (25.3)
11 – 15	163 (23.2)
> 15	133 (18.9)

<sup>a</sup> In the past 6 months

<sup>b</sup> In the United Kingdom, Master in Pharmacy is considered as an undergraduate program  
HDS, herbal and dietary supplements

#### 4.3.5. Descriptive statistics

Table 14 shows the mean score and standard deviation for each item of the Direct TPB, Indirect TPB and PCare-HDS scales. For the Direct TPB scale the highest endorsed item was in regard to professional norm: item PN2 (*It is my professional responsibility as a community pharmacist to provide care for the HDS users*) with a mean score of  $3.789 \pm 1.081$ , followed with an item related to attitude: item ATT1 (*I think pharmacist care for the HDS users can bring many benefits to the customers, pharmacists and the drugstores*) with a mean score of  $3.693 \pm 1.113$ . Item with the lowest mean score was a perceived behavioural control item: item PBC2 (*Providing care for the HDS users is easy*) with a mean score of  $2.891 \pm 1.163$ .

For the Indirect TPB scale, the two most endorsed items were related to control belief, item CB6: *I think the HDS users would like to receive advice and suggestions about the HDS from me*, and item CB5: *I think the HDS users are happy to talk with me about their HDS use*, with mean scores of  $3.588 \pm 1.037$  and  $3.555 \pm 1.027$ , respectively. Item CB8 (*I think I have enough informational materials about the HDS at my drugstore*) had the lowest mean score of  $2.637 \pm 1.066$ , followed by item CB4 (*I think my knowledge about the HDS is good*) with a mean score of  $2.687 \pm 0.946$ .

For the PCare-HDS scale, the item with the highest mean score was item PAI8 (*I provide the HDS users with relevant HDS informational materials*) with a mean score of  $3.742 \pm 0.958$ , followed by item MPQ1 (*I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice*) with a mean score of  $3.726 \pm 1.037$ . Item with the lowest mean score was item MPD6 (*I report to the authority if the HDS users experience adverse events from HDS use*) with a mean score of  $3.106 \pm 1.132$ . Additionally, it was noted that all three items under the “Seeking HDS information” domain had low mean scores ranging from 3.353 – 3.415.

**Table 14. Mean score, standard deviation, skewness and kurtosis value for each item of the scales**

Subscale / item		Mean	SD	Skewness	Kurtosis
Direct TPB scale <sup>a</sup>					
<b>Attitude</b>					
1.	I think pharmacist care for the HDS users can bring many benefits to the customers, pharmacists and the drugstores (ATT1).	3.693	1.113	-0.799	-0.071
2.	I enjoy providing care for the HDS users (ATT2).	3.606	1.079	-0.740	-0.060
3.	If I provide care for the HDS users, I feel satisfied (ATT3).	3.608	1.126	-0.656	-0.359
<b>Subjective norm</b>					
4.	The public wants me to provide care for the HDS users (SN1).	3.236	1.149	-0.101	-0.843
5.	I have to provide care for the HDS users because this is what the society wants me to do (SN2).	3.118	1.131	-0.012	-0.902
<b>Perceive behavioural control</b>					
6.	I am confident that I can provide care for the HDS users (PBC1).	3.174	1.080	-0.068	-0.661
7.	Providing care for the HDS users is easy (PBC2).	2.891	1.163	0.287	-0.711
<b>Professional norm</b>					
8.	As a community pharmacist, I believe that providing care for the HDS users is something I should do (PN1).	3.608	1.066	0-.745	-0.058
9.	It is my professional responsibility as a community pharmacist to provide care for the HDS users (PN2).	3.789	1.081	-0.897	0.328
<b>Intention</b>					
10.	I am ready to provide care for the HDS users on a regular basis during the next two weeks (INT1).	3.348	1.150	-0.136	-0.944
11.	I will try to provide care for the HDS users on a regular basis during the next two weeks (INT2).	3.353	1.150	-0.163	-0.928
12.	I have intention to provide care for the HDS users on a regular basis during the next two weeks (INT3).	3.227	1.127	-0.117	-0.878
Indirect TPB scale <sup>a</sup>					
<b>Behavioural belief</b>					

1.	If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions (BB1).	3.529	1.103	-0.556	-0.540
2.	If I provide care, I can ensure the HDS users are using the most suitable products (BB2).	3.501	1.048	-0.765	0.032
3.	If I provide care for the HDS users, my knowledge about the HDS will be improved (BB3).	3.512	1.065	-0.837	-0.052
4.	If I provide care for the HDS users, I will be trustworthy (ethical / honest) (BB4).	3.456	1.031	-0.691	-0.228
5.	If I provide care for the HDS users, they will come back to my drugstore in order to consult me (BB5).	3.350	1.131	-0.336	-0.767
<b>Normative belief</b>					
6.	The HDS users want me to provide care for them (NB1).	3.156	1.002	-0.255	-0.711
7.	Those who work with me (e.g., other pharmacists, drugstore assistants, healthcare consultants, etc.) think that I should provide care for the HDS users (NB2).	3.156	1.021	-0.191	-0.746
8.	The doctors think that I should provide care for the HDS users (NB3).	2.929	1.049	0.419	-0.498
<b>Control belief</b>					
9.	I think I have received enough training to provide care for the HDS users (CB1).	2.888	1.088	0.037	-0.785
10.	I think I can manage my time so that I can provide care for the HDS users (CB2).	3.289	1.085	-0.225	-0.833
11.	I believe I have received sufficient education about the HDS in my previous undergraduate studies (CB3).	2.693	1.033	0.261	-0.438
12.	I think my knowledge about the HDS is good (CB4).	2.687	0.946	0.702	0.464
13.	I think the HDS users are happy to talk with me about their HDS use (CB5).	3.555	1.027	-0.776	0.054
14.	I think the HDS users would like to receive advice and suggestions about the HDS from me (CB6).	3.588	1.037	-0.835	0.151
15.	In my opinion I have access to information about the HDS including the scientific evidences at my drugstore (CB7).	3.127	1.168	-0.053	-0.938

16.	I think I have enough informational materials (e.g., leaflets, posters, booklets, etc.) about the HDS at my drugstore (CB8).	2.637	1.066	0.418	-0.265
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PCare-HDS scale <sup>b</sup>					
<b>Foster relationship</b>					
1.	I listen carefully to the customers' inquiries or requests for the HDS (FR1).	3.689	1.146	-0.681	-0.402
2.	I develop a good relationship with the HDS users (FR2).	3.559	1.132	-0.530	-0.467
3.	I respect the customers' intentions to use the HDS for treating diseases, or maintaining their health (FR3).	3.694	1.122	-0.703	-0.238
<b>Gather information</b>					
4.	I ask the reasons why the customers want to use the HDS (GI1).	3.504	1.110	-0.470	-0.511
5.	I ask the HDS users if they are using any medicines (GI2).	3.548	1.128	-0.505	-0.513
6.	I ask the HDS users if they have any other illnesses or medical conditions (e.g., pregnancy, allergies, etc.) (GI3).	3.573	1.135	-0.578	-0.428
<b>Assess HDS use</b>					
7.	I assess whether the HDS has any indication for the customers (AU1).	3.589	1.016	-0.813	0.257
8.	I identify any HDS-related problems associated with the use of the HDS (AU2).	3.551	0.986	-0.691	0.165
9.	I identify disease- or drug-HDS interactions if the HDS users have medical illnesses or are using medicines (AU3).	3.491	1.004	-0.561	-0.076
<b>Assist informed decision</b>					
10.	I provide unbiased information about the HDS to help the customers decide on whether or not to use the HDS (AID1).	3.488	1.095	-0.559	-0.290
11.	To help the customers decide on whether or not to use the HDS, I explain both the potential benefits and limitations of the products (AID2).	3.457	1.086	-0.632	-0.290
12.	I tell the customers if there is no scientific evidence for the HDS use (AID3).	3.477	1.136	-0.594	-0.531
<b>Make professional decision or suggestion</b>					

13.	I recommend the customers to have physical or laboratory examinations (e.g., blood glucose test or blood pressure test) before using the HDS (MPD1).	3.576	1.041	-0.712	0.077
14.	If there is no contraindication to HDS use, I recommend HDS that is appropriate to the customer's needs, in a suitable dose, for an adequate period of time, and at a suitable cost (MPD2).	3.597	1.055	-0.704	0.026
15.	If the use of the HDS is not appropriate (e.g., not indicated, not appropriate, or contraindicated), I advise the customers not to use the HDS (MPD3).	3.669	0.984	-0.718	0.214
16.	I suggest using Western (modern) medicine if it is more appropriate than using the HDS (MPD4).	3.614	1.029	-0.795	0.216
17.	I refer the customers to the physicians if I found out that they actually need medical treatment (MPD5).	3.630	0.996	-0.946	0.622
18.	I report to the authority if the HDS users experience adverse events from HDS use (MPD6).	3.106	1.132	-0.294	-0.558
<b>Provide advice or information</b>					
19.	When dispensing HDS, I tell the HDS users about what they can expect from the HDS (positive effects and side effects) (PAI1).	3.592	1.003	-0.755	0.203
20.	When dispensing HDS, I advise how to use the HDS (e.g., directions for use and dose per day) (PAI2).	3.579	1.045	-0.679	0.016
21.	When dispensing HDS, I advise the HDS users to avoid other OTC medications, and HDS that can cause interactions (PAI3).	3.567	1.062	-0.613	-0.269
22.	When dispensing HDS, I advise the HDS users to monitor their symptoms (e.g., improvement or worsening of health) (PAI4).	3.462	1.045	-0.460	-0.387
23.	When dispensing HDS, I advise the HDS users to seek medical attention if their symptoms worsened (PAI5).	3.540	1.125	-0.552	-0.413
24.	When dispensing HDS, I tell the HDS users the importance of adherence with the prescribed medicines, if they are using	3.632	1.060	-0.724	0.073

	prescribed medicine (PAI6).				
25.	When dispensing HDS, I advise the HDS users to tell their physicians about their HDS use (PAI7).	3.664	1.088	-0.669	-0.185
26.	I provide the HDS users with relevant HDS informational materials (e.g., brochures, pamphlets, or booklets, etc.) (PAI8).	3.742	0.958	-0.612	0.102
27.	Seek HDS information				
28.	I use reliable sources of information when providing information to the HDS users (SI1).	3.607	1.088	-0.920	0.253
29.	I seek information about the indications of common HDS (SI2).	3.415	0.989	-0.485	0.007
30.	I seek information about disease- and drug-HDS interactions (SI3).	3.356	0.995	-0.536	-0.126
31.	I seek information about signs and symptoms of adverse effects of common HDS (SI4).	3.353	1.005	-0.595	-0.174
<b>Maintain HDS product quality</b>					
32.	I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice (MPQ1).	3.726	1.037	-0.686	0.004
33.	I make sure that the HDS in my drugstore do not have non-logical claims (e.g., curing cancer, whitening skin in few days, etc.) (MPQ2).	3.644	1.076	-0.581	-0.326
34.	I make sure that the HDS in my drugstore are stored properly (MPQ3).	3.724	1.020	-0.694	0.080

<sup>a</sup> Response format: 1 = Strongly Disagree; 2 = Disagree; 3 = Neutral; 4 = Agree; 5 = Strongly Agree, <sup>b</sup> Response format: 1 = Never; 2 = Seldom; 3 = Sometimes; 4 = Often; 5 = Always



#### 4.3.6. Sample sizes for data analysis in Stage 1

For the analysis of the Direct and Indirect TPB scales, 339 cases each were assigned for Stage 1 and 2 data analysis, respectively. Meanwhile, for the analysis of the PCare-HDS scale, 343 and 339 cases were assigned into Stage 1 and 2 data analysis, respectively. Appendix M shows the comparison of the socio-demographic characteristics of Stage 1 and Stage 2 samples for the Direct and Indirect TPB scales. Appendix N shows the comparison of the socio-demographic characteristics of Stage 1 and Stage 2 samples for the PCare-HDS scale. There was no significant difference in the characteristics of the samples from both phases of data analysis for all the three scales.

#### 4.3.7. Stage 1: Exploratory analysis and refinement of scales

The purpose of this phase of data analysis was to explore the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales, and to refine the item pool for each scale. The EFA and CFA were used in this stage of data analysis.

##### 4.3.7.1. Assessment of assumptions for factor analysis

**Sample size.** The sample size for the Stage 1 data analysis was 339 each for the Direct and Indirect TPB scales, and 343 for the PCare-HDS scale. These sample sizes were greater than the recommended number of cases ( $n = 300$ ) to carry out factor analysis, and therefore deemed adequate (126). Moreover since the Direct TPB, Indirect TPB and PCare-HDS scales have 12, 16 and 33 items, respectively, the number of observations for each item for analysis was more than sufficient (128, 129).

**Missing data.** For missing values, as discussed previously (please refer section 4.3.2.), after the removal of cases with 15% of missing data, the dataset do not have any missing value for all three scales.

**Univariate and multivariate outliers.** Inspection of the standardized value for each item of the scales showed that none of the item had a z-score of more than the absolute value of 3.29 indicating an absence of univariate outliers. (129). The Mahalanobis distance for each case was calculated to determine the presence of

multivariate outliers (129). The maximum Mahalanobis distance for each case is the critical chi-square ( $X^2$ ) values for “n” degrees of freedom ( $df$ ) at  $\alpha < 0.001$ . The Direct TPB scale has 12 items. Using the criterion of  $\alpha < 0.001$  with 12  $df$ , the critical  $X^2$  is 32.910. Nine cases were found to have exceeded the Mahalanobis distance and therefore were excluded from the EFA. The Indirect TPB scale on the other hand has 16 items. Using the criterion of  $\alpha < 0.001$  with 16  $df$ , the critical  $X^2$  is 39.252. Three cases surpassed the critical  $X^2$  and were not included during the EFA. For the PCare-HDS scale, since it has 33 items, the critical  $X^2$  for 33  $df$  at  $\alpha < 0.001$  is 63.870. Nine cases exceeded the value and therefore were removed from the dataset. After the removal of cases with multivariate outliers, 330 and 336 valid cases were available for each of the Direct and Indirect TPB scales, respectively, and 334 for the PCare-HDS scale. These sample sizes were still adequate for EFA.

**Normality.** Inspection of the skewness and kurtosis for the mean score of each of the subscale showed that the values were not exceeding  $\pm 1$ , indicating that the variables were reasonably normally distributed and appropriate for EFA (129). Additionally each item of the scales also has skewness and kurtosis values of less than  $\pm 1$ . It should be noted that previous simulation studies have shown that EFA will only be disrupted when the univariate skewness and kurtosis values are  $\geq 2$  and  $\geq 7$ , respectively (170). Table 15 shows the skewness and kurtosis values for each of the subscale’s mean score of the Direct TPB, Indirect TPB and PCare-HDS scales.

**Level of data and linearity.** All variables in the scales were considered interval data for the purpose of data analysis (134). Linearity of the data was examined using the scatterplots. Examination of the swarm revealed that the data were linearly related to some extent. Furthermore there was no presence of curvilinearity. Linearity was therefore assumed for the datasets.

**Table 15. Assessment of normality for the exploratory and refinement sample**

Scale / subscale	Skewness	Kurtosis	Sample size <sup>a</sup>
<b>Direct TPB</b>			
Attitude	-0.846	0.298	330
Subjective Norm	-0.098	-0.940	
Perceived Behavioral Belief	0.300	-0.565	
Professional Norm	-0.875	0.049	
Intention	-0.361	-0.629	
<b>Indirect TPB</b>			
Behavioural Belief	-0.773	-0.065	336
Normative Belief	-0.076	-0.760	
Control Belief	-0.172	-0.579	
<b>PCare-HDS</b>			
Foster Relationship	-0.808	-0.018	334
Gather Information	-0.900	0.003	
Assess HDS Use	-0.910	0.719	
Assist Informed Decision	-0.675	-0.384	
Make Professional Decision	-0.908	0.389	
Provide Advice or Information	-0.858	-0.165	
Seek HDS Information	-0.855	0.338	
Maintain HDS Product Quality	-0.849	0.495	
<sup>a</sup> Sample size after removal of cases with multivariate outliers			

**Factorability of factors.** The correlation matrixes were inspected to determine the factorability of items of the three scales (129). It was found that the correlation matrixes have several sizeable correlations ( $> 0.30$ ), indicating substantial relationships (171). Based on the inter-item correlations, our data were deemed factorable. The KMO values for the Direct TPB, Indirect TPB and PCare-HDS were 0.889, 0.905 and 0.894, respectively, exceeding the minimum recommended value of 0.70 (135). Furthermore, for all three scales, the results for Barlett's test of sphericity were statistically significant, indicating that the data were suitable for factor analysis (136) (Table 16).

**Table 16. KMO and Barlett's test for the exploratory factor analysis**

Scale	KMO measure for sampling adequacy	Bartlett's test of sphericity
Direct TPB	0.889	$X^2_{66} = 2477.012; P < 0.001$
Indirect TPB	0.905	$X^2_{120} = 3545.796; P < 0.001$
PCare-HDS	0.894	$X^2_{528} = 6952.377; P < 0.001$

#### 4.3.7.2. Direct TPB scale

##### Exploratory factor analysis Direct TPB scale

PAF was used as the extraction method for the EFA analysis. The oblique rotation (direct oblimin) was utilized as the rotational method since the factors are expected to correlate with each other. The factor analysis was performed by fixing the number of factors to five based the m-TPB framework as discussed in Chapter 2 (please refer 2.9.). The produced 5-factor solution explained 83.474% of variance. There was no item with communalities of less than 0.40. The item communalities range from 0.604 to 0.850. Furthermore, none of the items had a factor loading of less than 0.4 or cross-loaded on different factors. The KMO value for this analysis was 0.889. Bartlett's test of sphericity was significant at  $P < 0.001$  ( $X^2_{66} = 2477.012$ ). However, by fixing the number of factors to five resulted in three factors having an eigenvalue of  $< 1.0$  (SN, PBC and PN).

The EFA was then rerun to extract factors based on eigenvalues greater than 1.0. This resulted in two factors that explained 64.015% of variance. However, the extracted 2-factor solution did not make a theoretical sense. In this regard, items of the scales were grouped together in one domain and two items cross loaded onto the second factor. Due to these reasons, the initial 5-factor solution was determined to be most appropriate, as well as theoretically and statistically sensible. Since item communalities and factor loadings of the 5-factor solution were within acceptable values, no item was reduced or removed at this stage (Table 17).

**Table 17. Principal axis factoring of the Direct TPB scale (n = 330)**

Item <sup>a</sup>	Factor <sup>b</sup>				
	INT	ATT	PN	SN	PBC
<b>INT2:</b> I will try to provide care for the HDS users on a regular basis during the next two weeks.	<b>0.961</b>				
<b>INT3:</b> I have intention to provide care for the HDS users on a regular basis during the next two weeks.	<b>0.627</b>				
<b>INT1:</b> I am ready to provide care for the HDS users on a regular basis during the next two weeks.	<b>0.591</b>				
<b>ATT2:</b> I enjoy providing care for the HDS users.		<b>0.913</b>			
<b>ATT1:</b> I think pharmacist care for the HDS users can bring many benefits to the customers, pharmacists and the drugstores.		<b>0.814</b>			
<b>ATT3:</b> If I provide care for the HDS users, I feel satisfied.		<b>0.641</b>			
<b>PN1:</b> As a community pharmacist, I believe that providing care for the HDS users is something I should do.			<b>0.861</b>		
<b>PN2:</b> It is my professional responsibility as a community pharmacist to provide care for the HDS users.			<b>0.818</b>		
<b>SN1:</b> The public wants me to provide care for the HDS users.				- <b>0.855</b>	
<b>SN2:</b> I have to provide care for the HDS users because this is what the society wants me to do.				- <b>0.761</b>	
<b>PBC2:</b> Providing care for the HDS users is easy.					<b>0.849</b>
<b>PBC1:</b> I am confident that I can provide care for the HDS users.					<b>0.747</b>
Eigenvalue	6.307	1.374	0.905	0.772	0.657
% of variance	52.561	11.454	7.544	6.437	5.478

<sup>a</sup> Arranged in descending order based on factor loading<sup>b</sup> Rotation method: Direct oblimin

ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention

### Preliminary confirmatory factor analysis of Direct TPB scale

A preliminary CFA was conducted to further examine the factor structure of the Direct TPB scale based on the m-TPB framework. It can be seen from Table 18 that the model fits the data well. The values for all the goodness-of-fit indices met the cut-off values. The factor loadings were acceptable, ranging from 0.800 to 0.889 for attitude, 0.820 to 0.916 for subjective norm, 0.766 to 0.886 for perceived behavioural control, 0.833 to 0.892 for professional norm, and 0.791 to 0.833 for intention. Inspection of the standardized residual covariances matrix showed none of the value exceeding 2.58, indicating an absence of significant misfit. Based on the results from the EFA and the preliminary CFA, all items from the Direct TPB scale were retained at this stage.

**Table 18. Goodness-of-fit indices for the Direct TPB scale (n = 330)**

Goodness-of-fit indices	Final model: 12 items	Cut-off value
$X^2/df$	2.422	< 3.00
RMSEA	0.066	< 0.08
GFI	0.950	> 0.90
SRMR	0.037	< 0.09
TLI	0.962	$\geq 0.95$
NFI	0.958	> 0.90
CFI	0.974	$\geq 0.90$

### Internal consistency reliability analysis of Direct TPB scale

The internal consistency reliability of each factor or subscale of the Direct TPB scale was assessed by reviewing the Cronbach's alpha value. The reliability of each of the subscale was generally good with all factors had Cronbach's alpha values of > 0.80. Review of the "Cronbach's alpha if item deleted" values showed none of the value was higher than the original value. Based on the internal consistency reliability results, all items were retained for further examination (Table 19).

**Table 19. Internal consistency reliability of constructs of the Direct TPB scale**

Subscale / item	Corrected item-total correlation	Cronbach's alpha if item deleted
<b>Attitude: Cronbach's <math>\alpha = 0.877</math></b>		
ATT1	0.743	0.844
ATT2	0.813	0.782
ATT3	0.737	0.852
<b>Subjective Norm: Cronbach's <math>\alpha = 0.858</math></b>		
SN1	0.751	-
SN2	0.751	-
<b>Perceived Behavioural Control: Cronbach's <math>\alpha = 0.807</math></b>		
PBC1	0.679	-
PBC2	0.679	-
<b>Professional Norm: Cronbach's <math>\alpha = 0.851</math></b>		
PN1	0.743	-
PN2	0.743	-
<b>Intention: Cronbach's <math>\alpha = 0.855</math></b>		
INT1	0.713	0.812
INT2	0.768	0.759
INT3	0.702	0.821
ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention		

#### 4.3.7.3. Indirect TPB scale

##### Exploratory factor analysis of Indirect TPB scale

Similar to the Direct TPB scale, PAF was used as the extraction method for the EFA analysis for the Indirect TPB scale. Since the factors of the Indirect TPB scale are expected to correlate with each other, the oblique rotation (direct oblimin) was utilized as the rotational method. Although the Indirect TPB scale was hypothesized to have 3 factors, extraction of factors based on eigenvalues of greater than 1.0 produced a 4-factor solution. Two items, CB5 and CB6 that were expected to be under the control belief domain loaded on a separate factor. Upon inspection of the two items, both items describe the facilitators that come from the customers (CB5: *I think the HDS users are happy to talk with me about their HDS use*; and CB6: *I think the HDS users would like to receive advice and suggestions about the HDS from me*).

Meanwhile, the other five items in the control belief domain were related to CPs. The two items in a separate factor therefore, can be an additional important latent factor.

The additional factor produced by the EFA was named: “Control Belief: Facilitators Related to Customers (CBC)”. The original control belief domain was renamed as: “Control Belief: Facilitators Related to Pharmacists (CBP)”. The 4-factor solution explained 74.627% of variance. KMO value was 0.905 and Barlett’s test of sphericity value was significant at  $P < 0.001$  ( $X^2_{120} = 3545.796$ ). Item communalities range from 0.491 to 0.819. All items had a factor loading of  $> 0.4$  (Table 20).

**Table 20. Principal axis factoring of the Indirect TPB scale (n = 334)**

Item <sup>a</sup>	Factor <sup>b</sup>			
	CBP	BB	NB	CBC
<b>CB3:</b> I believe I have received sufficient education about the HDS in my previous undergraduate studies.	<b>0.848</b>			
<b>CB4:</b> I think my knowledge about the HDS is good.	<b>0.846</b>			
<b>CB1:</b> I think I have received enough training to provide care for the HDS users.	<b>0.780</b>			
<b>CB8:</b> I think I have enough informational materials (e.g., leaflets, posters, booklets, etc.) about the HDS at my drugstore.	<b>0.775</b>			
<b>CB7:</b> In my opinion I have access to information about the HDS including the scientific evidences at my drugstore.	<b>0.594</b>			
<b>CB2:</b> I think I can manage my time so that I can provide care for the HDS users.	<b>0.449</b>			
<b>BB4:</b> If I provide care for the HDS users, I will be trustworthy (ethical / honest).		<b>0.837</b>		
<b>BB3:</b> If I provide care for the HDS users, my knowledge about the HDS will be improved.		<b>0.831</b>		
<b>BB2:</b> If I provide care, I can ensure the HDS users are using the most suitable products.		<b>0.773</b>		
<b>BB5:</b> If I provide care for the HDS users, they will come back to my drugstore in order to consult me.		<b>0.600</b>		
<b>BB1:</b> If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease-		<b>0.591</b>		



or drug-HDS interactions.

**NB1:**

The HDS users want me to provide care for them.

**0.832**

**NB2:**

Those who work with me (e.g., other pharmacists, drugstore assistants, healthcare consultants, etc.) think that I should provide care for the HDS users.

**0.823**

**NB3:**

The doctors think that I should provide care for the HDS users.

**0.683**

**CB6:**

I think the HDS users would like to receive advice and suggestions about the HDS from me.

**0.941**

**CB5:**

I think the HDS users are happy to talk with me about their HDS use.

**0.716**

Eigenvalue	7.443	2.118	1.271	1.108
% of variance	46.520	13.236	7.944	6.927

<sup>a</sup> Arranged in descending order based on factor loading

<sup>b</sup> Rotation method: Direct oblimin

BB = behavioural belief; NB = normative belief; CB = control belief; CBP = control belief: facilitators related to pharmacists; CBC = control belief: facilitators related to customers

### Preliminary confirmatory factor analysis of Indirect TPB scale

Firstly, the 3-factor model that was informed by the theory was used as a rival model to that was produced by the EFA. This model was tested using the CFA to see if it provided fit for the data. Results from the CFA showed that the model fit was poor with  $X^2/df$  was higher than 5.0, RMSEA of more than 0.08 and all other values of goodness-fit indices were greater than the cut-off values. The 3-factor model was therefore, rejected. To confirm whether the proposed model from the EFA was more appropriate, the 4-factor model produced by the EFA, starting from the one containing all 16 items was tested using the CFA.

Results from the CFA showed that the model provided a poor fit for the data but performed much better than the 3-factor model. Goodness-of-fit indices such as  $X^2/df$ , RMSEA, GFI, TLI and NFI were not at satisfactory values. Factor loadings of the items were acceptable ( $> 0.60$ ) with item BB1 was noted to have the lowest factor loading at 0.65. Upon inspection of the standardized residual covariance matrix, several items were noted to have significant standardized residual covariances, providing an evidence of source of misfit. Since item CB2 had the highest number of

significant standardized residual covariances, the item was removed and the CFA was again run to test the fit of the second model.

The second model containing 15 items performed slightly better than the full model. However, indices namely  $X^2/df$ , RMSEA, GFI, and TLI were still not satisfactory. At this stage, item BB1 had the highest number of significant standardized residual covariances, and therefore was removed. Consequently, the third model was tested. The removal of item BB1 improved the goodness-of-fit indices. All indices were now at acceptable values except for RMSEA that slightly exceeded the cut-off value of  $< 0.08$  and  $X^2/df$  of  $> 3.0$ . At this stage, item CB7 was noted to have two significant standardized residual covariances and were removed to improve the model fit.

Re-specification of the model with 13 items provided a good fit for the data. Although the value of TLI for the final model was slightly lower than the recommended cut-off point of  $\geq 0.95$ , this was acceptable since it was close to the recommended value (149). The factor loading for each item was satisfactory and no item had a standardized residual covariance of more than 2.58. Based on the findings from the CFA, the 4-factor model with 13 items was deemed the most acceptable. The removal of 3 items resulted in retention of 81.3% of items from the original model. This is considered appropriate since not more than 20% of items were deleted (Table 21).

**Table 21. Goodness-of-fit indices for the Indirect TPB scale (n = 334)**

Goodness-of-fit indices	Rival model	Model 1: 16 items	Model 2: 15 items <sup>a</sup>	Model 3: 14 items <sup>b</sup>	Final model: 13 items	Cut-off value
$X^2/df$	5.661	4.196	3.722	3.335	2.832	$< 3.00$
RMSEA	0.118	0.098	0.090	0.083	0.074	$< 0.08$
GFI	0.812	0.863	0.886	0.910	0.928	$> 0.90$
SRMR	0.086	0.700	0.616	0.054	0.048	$< 0.09$
TLI	0.840	0.890	0.911	0.929	0.947	$\geq 0.95$
NFI	0.842	0.886	0.906	0.923	0.940	$> 0.90$
CFI	0.865	0.910	0.929	0.944	0.960	$\geq 0.90$

<sup>a</sup> Item CB2 was removed

<sup>b</sup> Item CB2 and BB1 were removed

<sup>c</sup> Item CB2, BB1 and CB7 were removed

### Internal consistency reliability of Indirect TPB scale

All factors of the Indirect TPB scale had a Cronbach's alpha value of more than 0.80, indicating good internal consistency reliability. Review of the "Cronbach's alpha if item deleted" values showed none of the value was higher than the original value (Table 22).

**Table 22. Internal consistency reliability of constructs of the Indirect TPB scale**

Subscale / item	Corrected item-total correlation	Cronbach's alpha if item deleted
<b>Behavioural Belief: Cronbach's <math>\alpha = 0.885</math></b>		
BB2	0.688	0.876
BB3	0.785	0.839
BB4	0.809	0.831
BB5	0.727	0.864
<b>Normative Belief: Cronbach's <math>\alpha = 0.873</math></b>		
NB1	0.769	0.810
NB2	0.787	0.793
NB3	0.715	0.859
<b>Control Belief – Related to Pharmacists: Cronbach's <math>\alpha = 0.897</math></b>		
CB1	0.772	0.867
CB3	0.798	0.858
CB4	0.790	0.861
CB8	0.730	0.883
<b>Control Belief – Related to Customers: Cronbach's <math>\alpha = 0.811</math></b>		
CB5	0.682	-
CB6	0.682	-
BB = behavioural belief; NB = normative belief; CB = control belief		

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#### 4.3.7.4. PCare-HDS scale

##### Exploratory factor analysis of the PCare-HDS scale

For the PCare-HDS scale, the PAF with oblique rotation (direct oblimin) was used to extract factors. Inspection of the factor correlation matrix showed that the factors were correlating with each other thus justifying the use of oblique rotation as the rotational method. The EFA produced an 8-factor solution that explained 72.334% of variance. Items MPD6, SI1 and PAI8 had unacceptable values for item communalities after extraction at 0.243, 0.323 and 0.364, respectively (137). These items; MPD6 (*I report to the authority if the HDS users experience adverse events from HDS use*), SI1

(*I use reliable sources of information when providing information to the HDS users*) and PAI8 (*I provide the HDS users with relevant HDS informational materials*) also had factor loadings of  $< 0.4$ . Based these results, the three items were removed and the EFA was re-run.

Removal of the three problematic items produced an 8-factor solution that explained 76.266% of variance. The new EFA run produced a KMO value of 0.890 and a significant Barlett's test of sphericity value ( $X^2_{435} = 6554.948$ ;  $P < 0.001$ ). Item communalities range from 0.457 to 0.812. No factor loading of less than 0.4 and cross-loading were observed in the result (Table 23).



Table 23. Principal axis factoring of the PCare-HDS scale (n = 336)

Item <sup>a</sup>	Factor <sup>b</sup>							
	MPD	PAI	AID	FR	MPQ	SI	AU	GI
<b>MPD4</b> I suggest using Western (modern) medicine if it is more appropriate than using the HDS.	<b>0.941</b>							
<b>MPD3</b> If the use of the HDS is not appropriate (e.g., not indicated, not appropriate, or contraindicated), I advise the customers not to use the HDS.	<b>0.855</b>							
<b>MPD2</b> If there is no contraindication to HDS use, I recommend HDS that is appropriate to the customer's needs, in a suitable dose, for an adequate period of time, and at a suitable cost.	<b>0.739</b>							
<b>MPD5</b> I refer the customers to the physicians if I found out that they actually need medical treatment.	<b>0.717</b>							
<b>MPD1</b> I recommend the customers to have physical or laboratory examinations (e.g., blood glucose test or blood pressure test) before using the HDS.	<b>0.700</b>							
<b>PAI3:</b> When dispensing HDS, I advise the HDS users to avoid other OTC medications, and HDS that can cause interactions.		<b>0.853</b>						
<b>PAI2:</b> When dispensing HDS, I advise how to use the HDS (e.g., directions for use and dose per day).		<b>0.825</b>						
<b>PAI5:</b>								

When dispensing HDS, I advise the HDS users to seek medical attention if their symptoms worsened.	<b>0.754</b>
<b>PAI1:</b> When dispensing HDS, I tell the HDS users about what they can expect from the HDS (positive effects and side effects).	<b>0.729</b>
<b>PAI4:</b> When dispensing HDS, I advise the HDS users to monitor their symptoms (e.g., improvement or worsening of health).	<b>0.713</b>
<b>PAI6:</b> When dispensing HDS, I tell the HDS users the importance of adherence with the prescribed medicines, if they are using prescribed medicine.	<b>0.702</b>
<b>PAI7:</b> When dispensing HDS, I advise the HDS users to tell their physicians about their HDS use.	<b>0.688</b>
<b>AID1</b> I provide unbiased information about the HDS to help the customers decide on whether or not to use the HDS.	<b>0.908</b>
<b>AID2</b> To help the customers decide on whether or not to use the HDS, I explain both the potential benefits and limitations of the products.	<b>0.885</b>
<b>AID3</b> I tell the customers if there is no scientific evidence for the HDS use.	<b>0.780</b>
<b>FR2</b> I develop a good relationship with the HDS users.	<b>0.894</b>
<b>FR3</b> I respect the customers' intentions to use the HDS for	<b>0.825</b>

treating diseases, or maintaining their health.

**FR1**

I listen carefully to the customers' inquiries or requests for the HDS.

**0.786**

**MPQ3**

I make sure that the HDS in my drugstore are stored properly.

**-0.858**

**MPQ2**

I make sure that the HDS in my drugstore do not have non-logical claims (e.g., curing cancer, whitening skin in few days, etc.).

**-0.737**

**MPQ1**

I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice.

**-0.733**

**SI4**

I seek information about signs and symptoms of adverse effects of common HDS.

**0.825**

**SI3**

I seek information about disease– and drug–HDS interactions.

**0.768**

**SI2**

I seek information about the indications of common HDS.

**0.698**

**AU1**

I assess whether the HDS has any indication for the customers.

**0.845**

**AU2**

I identify any HDS-related problems associated with the use of the HDS.

**0.821**

**AU3**

I identify disease– or drug–HDS interactions if the

**0.659**





### **Preliminary confirmatory factor analysis of the PCare-HDS scale**

Initially a model with all 33 items for the PCare-HDS scale was submitted for the CFA testing. This was performed in order to confirm whether the original hypothesized model fit the data better than the model obtained from the EFA. The CFA of the model with all 33 items showed that although the  $X^2/df$ , RMSEA and CFI values were acceptable, values for several fit indices such as GFI, TLI and NFI were not satisfactory. Observation of the factor loadings showed that item PAI8 had the lowest loading of 0.249. Additionally the item had 21 significant standardized residual covariances with other items. This item was then removed and a new model with 32 items were specified and tested with the CFA.

The second 32-item model still had several unsatisfactory values of goodness-of-fit indices namely GFI, TLI and NFI. Item MPD6 was noted to have a low factor loading of 0.25 and 17 significant standardized residual covariances with other items. This item was consequently deleted, and a new 31-item model was tested. The model with 31 items fit the data better than the previous model. Values for the GFI, TLI and NFI were closer to the cut-off values.

Inspection of the standardized residual covariances matrix showed that item SI1 had six significant standardized residual covariances with other items. Furthermore, the item had an unacceptable factor loading of 0.493 (146). Based on these findings, item SI1 was removed and a new model with 30 items was tested.

The new model had better fit indices than the previous models. Except for GFI, the 30-item model had model fit indices that exceeded the recommended values. Additionally no item had a factor loading of less than 0.6 and none having standardized residual covariance of more than 2.58. Based on the goodness-of-fit indices, item factor loadings and standardized residual covariances, the 30-item model was deemed acceptable. The identification of the three problematic items (PAI8, MPD6 and SI1) resonated well with findings from the EFA. Deletion of 3 items from the original scale resulted in elimination of only 9.1% of items (Table 24).

**Table 24. Goodness-of-fit indices for the PCare-HDS scale (n = 336)**

Goodness-of-fit indices	Model 1: 33 items	Model 2: 32 items	Model 3: 31 items	Final model: 30 items	Cut-off value
$X^2/df$	2.045	1.817	1.753	1.691	< 3.00
RMSEA	0.056	0.050	0.048	0.046	< 0.08
GFI	0.854	0.871	0.879	0.887	> 0.90
SRMR	0.743	0.575	0.482	0.039	< 0.09
TLI	0.917	0.938	0.946	0.953	≥ 0.95
NFI	0.868	0.887	0.897	0.906	> 0.90
CFI	0.927	0.945	0.953	0.959	≥ 0.90

<sup>a</sup> Item PAI8 was removed

<sup>b</sup> Item PAI8 and MPD6 were removed

<sup>c</sup> Item PAI8, MPD6 and SI1 were removed

### Internal consistency reliability analysis

All factors of the PCare-HDS scale were found to have good to excellent internal consistency reliability. Cronbach's alpha values for the PCare-HDS subscales range from 0.835 to 0.914. Out of eight subscales, four had a Cronbach's alpha value of ≥ 0.90. Except for the subscale "Assess HDS Use", no deletion of item would increase the Cronbach's alpha value for the subscales. For the "Assess HDS Use" subscale, the deletion of item AU3 would increase the Cronbach's alpha value from 0.837 to 0.848. However, due to the negligible increase in Cronbach's alpha value and to maintain the theoretical structure of the subscale, item AU3 was kept. Therefore, except for the three items that were removed during the initial EFA, all other items were retained for further analysis (Table 25).

**Table 25. Internal consistency reliability of constructs of the PCare-HDS scale**

Subscale / item	Corrected item-total correlation	Cronbach's alpha if item deleted
<b>Foster Relationship: Cronbach's <math>\alpha = 0.902</math></b>		
FR1	0.786	0.877
FR2	0.819	0.849
FR3	0.812	0.855
<b>Gather Information: Cronbach's <math>\alpha = 0.892</math></b>		
GI1	0.788	0.848
GI2	0.793	0.844
GI3	0.786	0.850
<b>Assess HDS Use: Cronbach's <math>\alpha = 0.837</math></b>		
AU1	0.730	0.743
AU2	0.751	0.724
AU3	0.622	0.848
<b>Assist Informed Decision: Cronbach's <math>\alpha = 0.900</math></b>		
AID1	0.823	0.840
AID2	0.816	0.848
AID3	0.772	0.886
<b>Make Professional Decision: Cronbach's <math>\alpha = 0.914</math></b>		
MPD1	0.775	0.896
MPD2	0.776	0.896
MPD3	0.804	0.890
MPD4	0.841	0.883
MPD5	0.711	0.909
<b>Provide Advice or Information: Cronbach's <math>\alpha = 0.910</math></b>		
PAI1	0.704	0.898
PAI2	0.735	0.895
PAI3	0.800	0.888
PAI4	0.724	0.896
PAI5	0.747	0.894
PAI6	0.701	0.899
PAI7	0.682	0.901
<b>Seek HDS Information: Cronbach's <math>\alpha = 0.835</math></b>		
SI2	0.660	0.806
SI3	0.699	0.769
SI4	0.731	0.736
<b>Maintain HDS Quality: Cronbach's <math>\alpha = 0.854</math></b>		
MPQ1	0.703	0.817
MPQ2	0.723	0.799
MPQ3	0.752	0.772
FR = foster relationship; GI = gather information; AU = assess HDS use; AID = assist informed decision; MPD = make professional decision; PAI = provide advice or information; SI = seek HDS information; MPQ = maintain HDS product quality		

#### 4.3.8. Stage 2: Validation of scales

The purpose for the validation phase was to cross validate the factor structure of the Direct TPB, Indirect TPB and PCare-HDS scales that were identified in Stage 1 of data analysis.

##### 4.3.8.1. Assessment of assumptions for factor analysis

**Sample size.** The sample size for the validation phase of this study was 339 each for the Direct TPB, Indirect TPB and PCare-HDS scales. For the purpose of CFA, the sample sizes were considered sufficient for each scale (126). The number of observations for each item for CFA was also adequate (i.e., Direct TPB: approximately 28 cases per item; Indirect TPB: approximately 26 cases per item; and PCare-HDS: approximately 11 cases per item) (128, 129, 149).

**Missing data.** As discussed previously (please refer section 4.3.2.), after the removal of cases with 15% of missing data, there was no missing value in the datasets.

**Univariate and multivariate outliers.** Examination of the z-score of each item showed none of the item had a value greater than  $\pm 3.29$ , indicating an absence of outliers (129). In addition to the assessment of the presence of univariate outliers, the datasets were also checked to for the presence of multivariate outliers. The linear regression analysis was used to identify the Mahalanobis distance for each case (129). Each case should not exceed the maximum Mahalanobis distance or the critical chi-square ( $X^2$ ) value for “n” degrees of freedom ( $df$ ) at  $\alpha < 0.001$ . Using the criterion of  $\alpha < 0.001$  with 12  $df$ , the critical  $X^2$  is 32.910 for the 12-item Direct TPB scale. Three cases exceeded the Mahalanobis distance and therefore were removed from the dataset. For the 13-item Indirect TPB scale, the critical  $X^2$  is 34.528 ( $\alpha < 0.001$ ,  $df = 13$ ). Three cases exceeded this value and therefore were excluded from further analysis. For the 30-item PCare-HDS scale, the critical  $X^2$  for 30  $df$  at  $\alpha < 0.001$  is 59.703. Eight cases were removed as they exceeded the critical  $X^2$  value. The exclusion of cases with multivariate outliers resulted in 336 for the Direct and Indirect TPB scales, and 331 for the PCare-HDS scale. These sample sizes were deemed adequate for CFA (Direct

TPB: approximately 28 cases per item; Indirect TPB: approximately 26 cases per item; and PCare-HDS: approximately 11 cases per item).

**Normality.** The datasets was then checked for the normality assumptions. In this procedure, the mean score for each subscale of the Direct TPB, Indirect TPB and PCare-HDS was computed, and the skewness and kurtosis values were obtained. Values exceeding  $\pm 1$  for skewness and kurtosis, signify a violation of normality. The results showed that the skewness and kurtosis values of each of the subscale were less than  $\pm 1$ , suggesting that the variables were approximately normally distributed (129). In addition, the skewness and kurtosis values for each item from the three scales were also not greater than  $\pm 1$ . Normality was therefore assumed for the data in the validation study. Table 26 shows the assessment of normality for each of the subscale of the Direct TPB, Indirect TPB and PCare-HDS scales for the validation study.

**Table 26. Assessment of normality for the validation sample**

Scale / subscale	Skewness	Kurtosis	Sample size
<b>Direct TPB</b>			
Attitude	-0.751	0.147	336
Subjective Norms	-0.014	-0.878	
Perceived Behavioral Beliefs	0.219	-0.446	
Professional Norm	-0.888	0.388	
Intention	-0.361	-0.636	
<b>Indirect TPB</b>			
Behavioural Belief	-0.611	-0.343	336
Normative Belief	-0.121	-0.795	
Control Belief: Facilitators Related to Pharmacists	0.228	-0.042	
Control Belief: Facilitators Related to Customers	-0.987	0.351	
<b>PCare-HDS</b>			
Foster Relationship	-0.817	-0.091	331
Gather Information	-0.780	-0.188	
Assess HDS Use	-0.923	0.694	
Assist Informed Decision	-0.669	-0.557	
Make Professional Decision	-0.885	0.407	
Provide Advice or Information	-0.860	-0.143	
Seek HDS Information	-0.850	0.200	
Maintain HDS Product Quality	-0.920	0.480	
<sup>a</sup> Sample size after removal of cases with multivariate outliers			

**Level of data and linearity.** For the purpose of data analysis in the present study, all variables in the scales were considered interval data (134). Linearity of the data was examined using the scatterplots. Examination of the swarm revealed that the data were linearly related to some extent. Furthermore there was no presence of curvilinearity. Linearity was therefore assumed for the datasets.

#### 4.3.8.2. Direct TPB scale

##### Confirmatory factor analysis of Direct TPB scale

The CFA was carried out on data of the second sample ( $n = 336$ ). Assumptions of univariate and multivariate normality have been assessed as discussed previously. Due to assumption of normality, the maximum likelihood estimation was chosen in the analysis. The hypothesized 5-factor model is depicted graphically in Figure 3. Latent variables are depicted in circles while measure variables are represented in rectangles. Several fit indices were used to assess the model-data fit (Table 27). The values of the goodness-of-fit indices CFA showed that there was a good fit between the model and the observed data. All model fit indices exceeded the cut-off points. No item had a standardized residual covariance of  $> 2.58$ . Post-hoc modifications were not performed since the goodness-of-fit indices, and the residual analysis did not indicate any problems. The measurement model for the Direct TPB scale was therefore considered to have construct validity.

**Table 27. Goodness-of-fit indices for the Direct TPB scale ( $n = 336$ )**

Goodness-of-fit indices	Final model: 12 items	Cut-off value
$X^2/df$	2.092	$< 3.00$
RMSEA	0.057	$< 0.08$
GFI	0.959	$> 0.90$
SRMR	0.034	$< 0.09$
TLI	0.969	$\geq 0.95$
NFI	0.961	$> 0.90$
CFI	0.979	$\geq 0.90$

### Convergent and discriminant validity

To assess for the convergent validity of the scale, the factor loadings of observed variables, AVE by each construct and CR were observed. Table 28 shows the standardized and unstandardized loadings of the observed variables. None of the factor loading of the observed variable had a value of less than 0.6. The factor loadings for the items range from 0.768 to 0.931. The AVE and CR for each construct were calculated and are shown in Table 29. AVE for each construct was found to exceed 0.5 and CR exceeding 0.7, providing an evidence of convergent validity for the scale.

**Table 28. Standardized and unstandardized coefficients for the Direct TPB scale**

Observed variable	Latent construct	SMC	$\beta$	B	SE
ATT1	Attitude	0.611	0.781	1.000	-
ATT2	Attitude	0.752	0.867	1.061	0.064
ATT3	Attitude	0.678	0.823	1.020	0.065
SN1	Subjective Norm	0.745	0.863	1.000	-
SN2	Subjective Norm	0.675	0.822	0.960	0.060
PBC1	Perceived Behavioural Control	0.854	0.924	1.000	-
PBC2	Perceived Behavioural Control	0.589	0.768	0.894	0.069
PN1	Professional Norm	0.868	0.931	1.000	-
PN2	Professional Norm	0.661	0.813	0.836	0.105
INT1	Intention	0.658	0.811	1.000	-
INT2	Intention	0.767	0.876	1.096	0.064
INT3	Intention	0.672	0.820	1.006	0.064

SMC = squared multiple correlations;  $\beta$  = standardized estimates; B = unstandardized estimates; SE = standard error

ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention

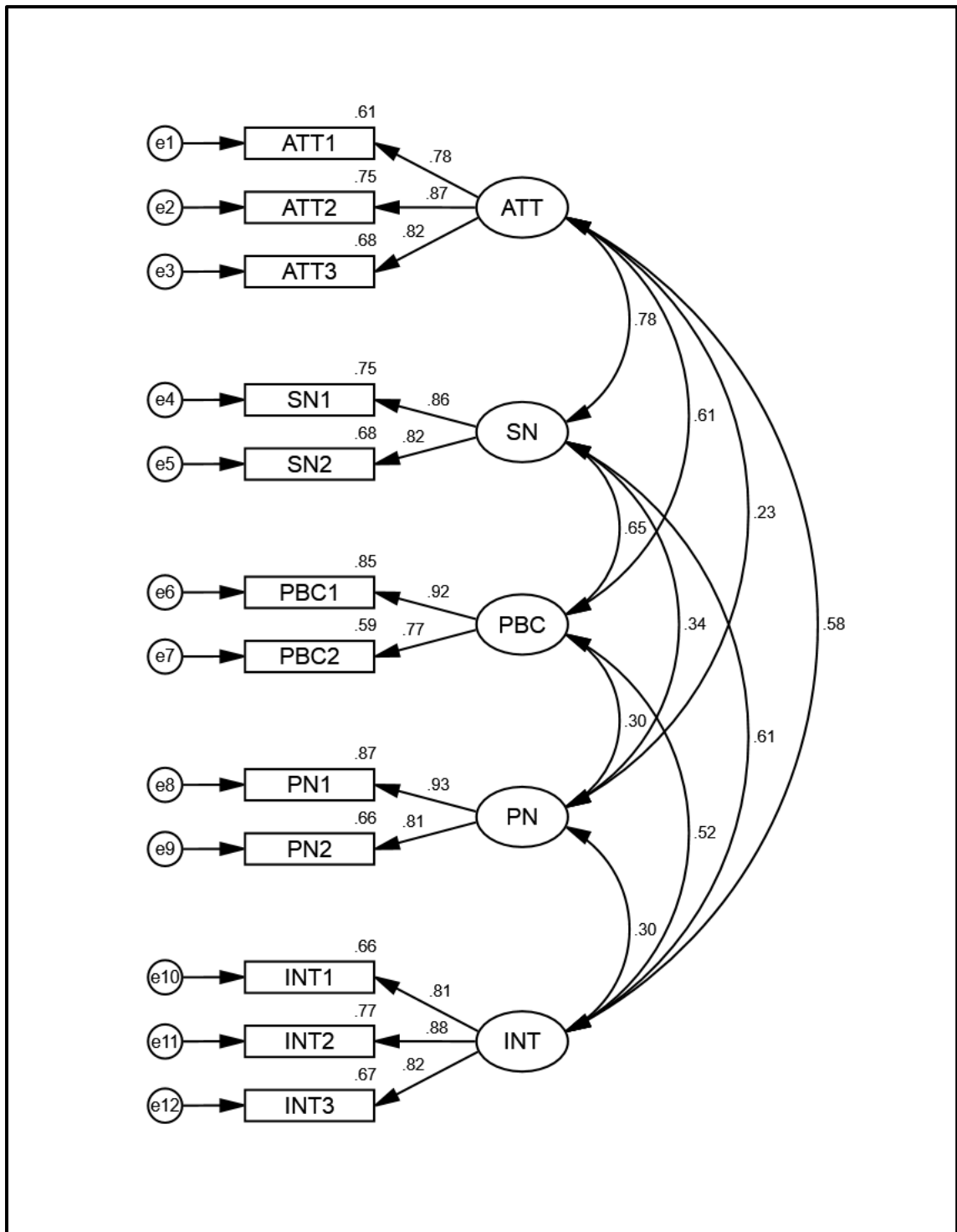
For discriminant validity, the square root of AVE for each construct were calculated and compared to the correlation among constructs. A square root of AVE value that is lower than any inter-construct correlations, showed a violation of discriminant validity. Our results showed that none of the correlation among constructs was higher than the square root of AVE for each construct, indicating good discriminant validity.

**Table 29. CR, AVE and inter-correlations of constructs for the Direct TPB scale**

Construct	CR	AVE	ATT	SN	PBC	PN	INT
ATT	0.864	0.680	<b>0.824*</b>				
SN	0.830	0.710	<u>0.775</u>	<b>0.843*</b>			
PBC	0.837	0.722	<u>0.610</u>	<u>0.655</u>	<b>0.850*</b>		
PN	0.866	0.764	<u>0.229</u>	<u>0.338</u>	<u>0.304</u>	<b>0.874*</b>	
INT	0.874	0.699	<u>0.576</u>	<u>0.610</u>	<u>0.519</u>	<u>0.302</u>	<b>0.836*</b>

\*Square root of AVE for each construct  
 Underlined numbers indicate inter-correlations of constructs  
 CR = construct reliability; AVE = average variance extracted; ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention





**Figure 3. Confirmatory factor analysis of the Direct TPB scale**

ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention

#### 4.3.8.3. Indirect TPB scale

##### Confirmatory factor analysis of Indirect TPB scale

Data of the second sample ( $n = 336$ ) for the Indirect TPB scale was analyzed using the CFA. The maximum likelihood estimation was chosen in the analysis since data was assumed to be normal. Figure 4 shows the graphical representation of the hypothesized 4-factor model where latent variables are depicted in circles and measure variables in rectangles. Several fit indices were referred to examine the goodness-of-fit of the model and to confirm the hypothesized model. (Table 30). It was evident from the results that there was a good fit between the model and the observed data. All values of the goodness-of-fit indices exceeded the cut-off recommendation. Inspection of the standardized residual covariance showed none of the value was greater than 2.58. Since the goodness-of-fit indices were acceptable and there was no issue with the residual analysis, post-hoc modifications were not performed. The measurement model for the Indirect TPB scale was therefore considered to have construct validity.

**Table 30. Goodness-of-fit indices for the Indirect TPB scale ( $n = 336$ )**

Goodness-of-fit indices	Final model: 13 items	Cut-off value
$\chi^2/df$	2.689	< 3.00
RMSEA	0.071	< 0.08
GFI	0.932	> 0.90
SRMR	0.047	< 0.09
TLI	0.952	$\geq 0.95$
NFI	0.944	> 0.90
CFI	0.964	$\geq 0.90$

### Convergent and discriminant validity

The factor loadings of observed variables, the value of AVE and CR for each construct were observed to assess for the convergent validity of the scale. None of the factor loading of the observed variable had a value of less than 0.6. The standardized and unstandardized loadings of the observed variables are summarized in Table 31. The factor loadings range from 0.755 to 0.958. The computed AVE and CR for each construct are shown in Table 32. AVE for each construct was found to exceed 0.5 and CR exceeding 0.7. Since there was no factor loading lower than 0.6 and AVE for each construct exceeding 0.5, an evidence for convergent validity of the scale was established.

**Table 31. Standardized and unstandardized coefficients for the Indirect TPB scale**

Observed variable	Latent construct	SMC	$\beta$	B	SE
BB2	Behavioural belief	0.594	0.771	1.000	-
BB3	Behavioural belief	0.660	0.813	1.062	0.067
BB4	Behavioural belief	0.712	0.844	1.045	0.065
BB5	Behavioural belief	0.751	0.867	1.156	0.07
NB1	Normative belief	0.679	0.824	1.000	-
NB2	Normative belief	0.785	0.886	1.103	0.061
NB3	Normative belief	0.624	0.790	1.017	0.064
CB1	Control belief: CBP	0.779	0.882	1.000	-
CB3	Control belief: CBP	0.629	0.793	0.828	0.048
CB4	Control belief: CBP	0.571	0.755	0.679	0.043
CB8	Control belief: CBP	0.629	0.793	0.831	0.048
CB5	Control belief: CBC	0.918	0.958	1.000	-
CB6	Control belief: CBC	0.641	0.801	0.842	0.068

SMC = squared multiple correlations;  $\beta$  = standardized estimates; B = unstandardized estimates; SE = standard error

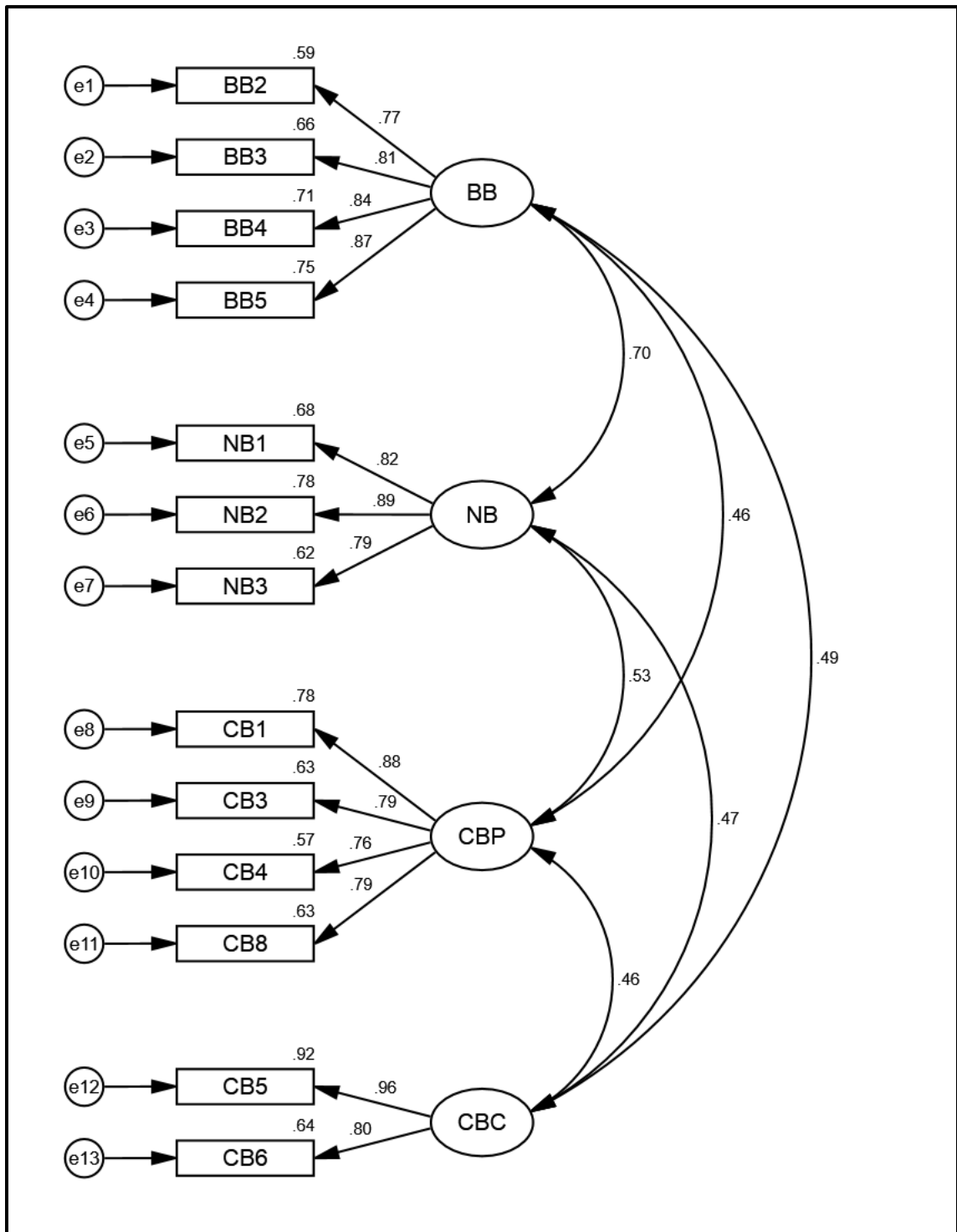
BB = Behavioural belief; NB = normative belief; CBP = control belief: facilitators related to pharmacists; CBC = control belief: facilitators related to customers

The square root of AVE for each construct were also calculated and compared to the correlation among constructs to assess for the scale's discriminant validity. The results showed that there was no violation of discriminant validity since none of the correlation among constructs was higher than the square root of AVE (Table 32). This finding proved that the scale has discriminant validity.

**Table 32. CR, AVE and inter-correlations of constructs for the Indirect TPB scale**

Construct	CR	AVE	BB	NB	CBP	CBC
<b>BB</b>	0.894	0.680	<b>0.825*</b>			
<b>NB</b>	0.873	0.696	<u>0.697</u>	<b>0.834*</b>		
<b>CBP</b>	0.882	0.651	<u>0.465</u>	<u>0.528</u>	<b>0.807*</b>	
<b>CBC</b>	0.875	0.780	<u>0.490</u>	<u>0.468</u>	<u>0.464</u>	<b>0.883*</b>

\*Square root of AVE for each construct  
 Underlined numbers indicate inter-correlations of constructs  
 CR = construct reliability; AVE = average variance extracted; BB = Behavioural belief; NB = normative belief; CBP = control belief: facilitators related to pharmacists; CBC = control belief: facilitators related to customers



**Figure 4. Confirmatory factor analysis of the Indirect TPB scale**

**BB = Behavioural belief; NB = normative belief; CBP = control belief: facilitators related to pharmacists; CBC = control belief: facilitators related to customers**

#### 4.3.8.4. PCare-HDS scale

##### Confirmatory factor analysis of PCare-HDS scale

For the PCare-HDS scale, data from a sample of 331 respondents was analyzed using the CFA. Since data was assumed to be normal, the maximum likelihood estimation was chosen for the CFA. The graphical representation of the hypothesized 8-factor model for the PCare-HDS scale is shown in Figure 5. Latent variables are depicted in circles and measure variables in rectangles. Hypothesized model was examined for its model fit using several goodness-of-fit indices (Table 33). Except for the value for GFI, all other goodness-of-fit indices met the cut-off values. Despite not exceeding the cut-off value for GFI, the value was close to the recommended value and therefore was deemed acceptable (149). In addition, since the CFA results showed good fit for the majority of indexes, the model was considered acceptable (147). Therefore it was concluded that there was an acceptable fit between the model and the observed data. Inspection of the standardized residual covariances showed none of the value was greater than 2.58. Post-hoc modifications were not performed for the data since goodness-of-fit indices and standardized residual covariance values were acceptable. The measurement model for the PCare-HDS scale was concluded to have construct validity.

**Table 33. Goodness-of-fit indices for the PCare-HDS scale (n = 331)**

Goodness-of-fit indices	Final model: 30 items	Cut-off value
$X^2/df$	1.647	< 3.00
RMSEA	0.044	< 0.08
GFI	0.887	> 0.90
SRMR	0.036	< 0.09
TLI	0.958	≥ 0.95
NFI	0.913	> 0.90
CFI	0.963	≥ 0.90

### Convergent and discriminant validity

Convergent validity of the scale was assessed by examining the factor loadings of observed variables, and the value of AVE and CR for each construct of the PCare-HDS scale. The standardized and unstandardized loadings of the observed variables are summarized in Table 34. The lowest factor loading was 0.690 and the highest was 0.900. Table 35 shows the computed AVE and CR for each construct of the PCare-HDS scale. The AVE for all constructs exceeded 0.5. Each construct had a CR value of more than 0.7. Since the results showed that all factor loadings were more than 0.6 and the AVE for each construct was acceptable, the scale was considered to have convergent validity.

**Table 34. Standardized and unstandardized coefficients for the PCare-HDS scale**

Observed variable	Latent construct	SMC	$\beta$	B	SE
FR1	Foster relationship	0.719	0.848	1.000	-
FR2	Foster relationship	0.745	0.863	0.986	0.052
FR3	Foster relationship	0.761	0.872	0.982	0.051
GI1	Gather information	0.771	0.878	1.000	-
GI2	Gather information	0.758	0.871	1.009	0.048
GI3	Gather information	0.767	0.876	1.025	0.049
AU1	Assess HDS use	0.650	0.806	1.000	-
AU2	Assess HDS use	0.715	0.846	1.016	0.066
AU3	Assess HDS use	0.634	0.796	0.974	0.067
AID1	Assist informed decision	0.743	0.862	1.000	-
AID2	Assist informed decision	0.790	0.889	1.059	0.052
AID3	Assist informed decision	0.745	0.863	1.021	0.052
MPD1	Make professional decision	0.682	0.826	1.000	-
MPD2	Make professional decision	0.564	0.751	0.915	0.061
MPD3	Make professional decision	0.672	0.819	0.932	0.054
MPD4	Make professional decision	0.730	0.854	1.035	0.057
MPD5	Make professional decision	0.545	0.738	0.879	0.060
PAI1	Provide advice or information	0.647	0.805	1.000	-
PAI2	Provide advice or information	0.664	0.815	1.045	0.061
PAI3	Provide advice or information	0.719	0.848	1.138	0.064

PAI4	Provide advice or information	0.586	0.765	0.987	0.064
PAI5	Provide advice or information	0.576	0.759	1.070	0.072
PAI6	Provide advice or information	0.614	0.784	1.026	0.066
PAI7	Provide advice or information	0.529	0.728	0.969	0.068
SI2	Seek HDS information	0.477	0.690	1.000	-
SI3	Seek HDS information	0.769	0.877	1.281	0.093
SI4	Seek HDS information	0.805	0.897	1.322	0.093
MPQ1	Maintain HDS product quality	0.663	0.814	1.000	-
MPQ2	Maintain HDS product quality	0.777	0.881	1.168	0.063
MPQ3	Maintain HDS product quality	0.810	0.900	1.117	0.059

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SMC = squared multiple correlations;  $\beta$  = standardized estimates; B = unstandardized estimates; SE = standard error  
 FR = Foster relationship; GI = Gather information; AU = Assess HDS use; AID = Assist informed decision; MPD = Make professional decision; PAI = Provide advice or information; SI = Seek HDS information; MPQ = Maintain HDS product quality

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It can be seen in Table 35 that none of the correlations among constructs were higher than the square root of AVE. Based on this finding, it can be concluded that discriminant validity of the scale was supported.



Table 35. CR, AVE and inter-correlations of constructs for the PCare-HDS scale

Construct	CR	AVE	FR	GI	AU	AID	MPD	PAI	SI	MPQ
<b>FR</b>	0.896	0.741	<b>0.861*</b>							
<b>GI</b>	0.907	0.766	<u>0.623</u>	<b>0.875*</b>						
<b>AU</b>	0.857	0.666	<u>0.425</u>	<u>0.502</u>	<b>0.816*</b>					
<b>AID</b>	0.904	0.759	<u>0.290</u>	<u>0.433</u>	<u>0.295</u>	<b>0.871*</b>				
<b>MPD</b>	0.898	0.638	<u>0.464</u>	<u>0.502</u>	<u>0.525</u>	<u>0.320</u>	<b>0.799*</b>			
<b>PAI</b>	0.919	0.620	<u>0.368</u>	<u>0.402</u>	<u>0.298</u>	<u>0.401</u>	<u>0.349</u>	<b>0.787*</b>		
<b>SI</b>	0.865	0.683	<u>0.355</u>	<u>0.362</u>	<u>0.399</u>	<u>0.287</u>	<u>0.319</u>	<u>0.335</u>	<b>0.827*</b>	
<b>MPQ</b>	0.900	0.750	<u>0.409</u>	<u>0.374</u>	<u>0.411</u>	<u>0.427</u>	<u>0.423</u>	<u>0.409</u>	<u>0.436</u>	<b>0.866*</b>

\*Square root of AVE for each construct

Underlined numbers indicate inter-correlations of constructs

CR = construct reliability; AVE = average variance extracted; FR = foster relationship; GI = gather information; AU = assess HDS use; AID = assist informed decision; MPD = make professional decision; PAI = provide advice or information; SI = seek HDS information; MPQ = maintain HDS product quality

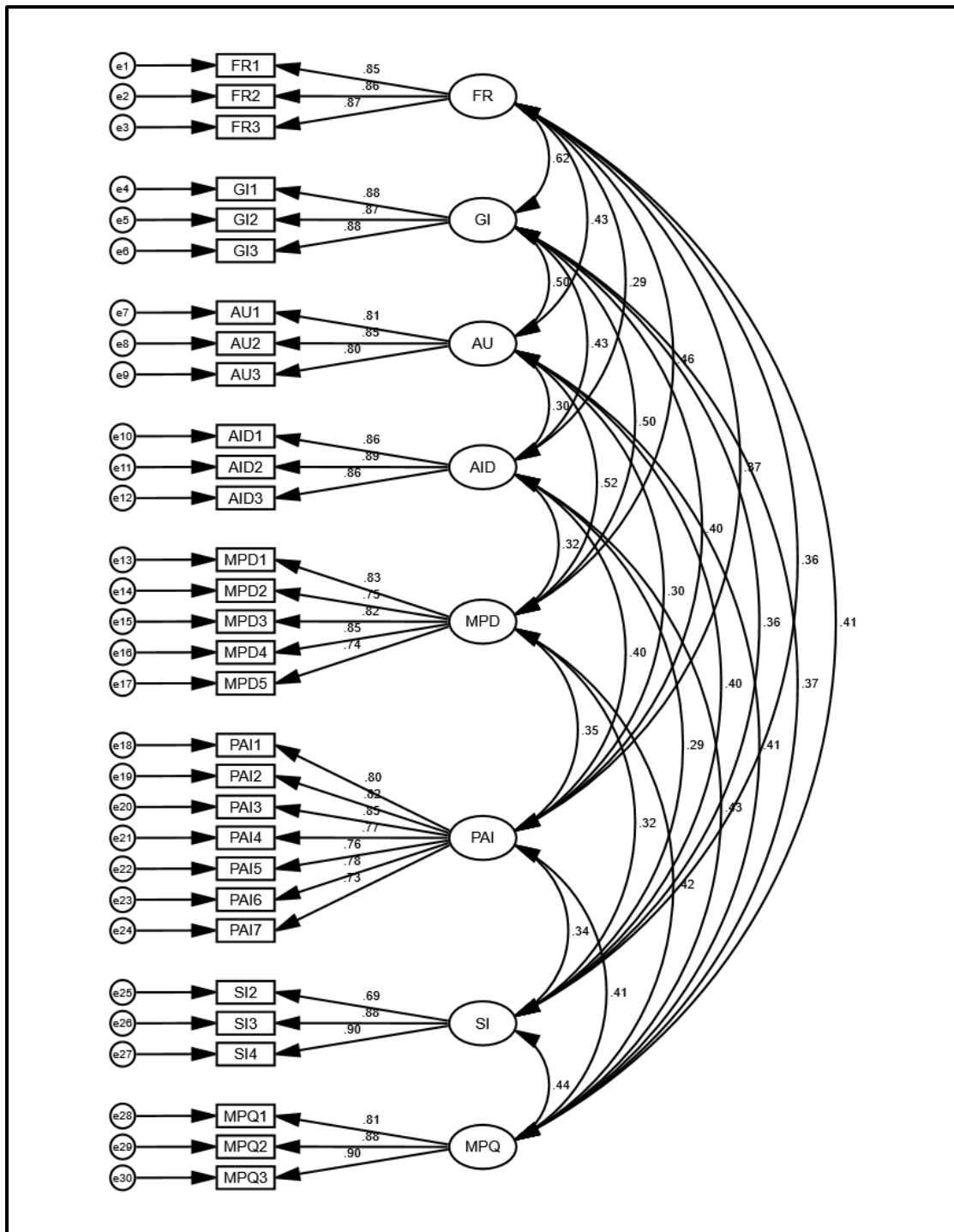


Figure 5. Confirmatory factor analysis of the PCare-HDS scale

FR = Foster relationship; GI = Gather information; AU = Assess HDS use; AID = Assist informed decision; MPD = Make professional decision; PAI = Provide advice or information; SI = Seek HDS information; MPQ = Maintain HDS product quality

### Internal consistency reliability

The internal consistency reliability of each subscale of the Direct TPB, Indirect TPB and PCare-HDS scales for the validation phase was assessed by reviewing the Cronbach's alpha value. The reliability of each of the subscale was generally good with all factors had Cronbach's alpha values of  $> 0.80$ . Except for the subscale "Seeking HDS Information" for the PCare-HDS scale, no deletion of item would increase the Cronbach's alpha value of the subscales. For the "Seeking HDS Information" subscale, the deletion of item SI2 would increase the Cronbach's alpha value of the subscale from 0.860 to 0.880. Since the increased in the Cronbach's alpha value was minimal and the subscale already showed satisfactory reliability, no further deletion was performed. Table 36 shows the internal consistency reliability of the subscales of the Direct TPB, Indirect TPB and PCare-HDS scales.

**Table 36. Internal consistency reliability of constructs of the final models of the Direct TPB, Indirect TPB and PCare-HDS scales**

Subscale / item	Corrected item-total correlation	Cronbach's alpha if item deleted
<b>Direct TPB Scale</b>		
<b>Attitude: Cronbach's <math>\alpha = 0.863</math></b>		
ATT1	0.713	0.833
ATT2	0.772	0.778
ATT3	0.735	0.812
<b>Subjective Norm: Cronbach's <math>\alpha = 0.830</math></b>		
SN1	0.709	-
SN2	0.709	-
<b>Perceived Behavioural Control: Cronbach's <math>\alpha = 0.829</math></b>		
PBC1	0.710	-
PBC2	0.710	-
<b>Professional Norm: Cronbach's <math>\alpha = 0.862</math></b>		
PN1	0.757	-
PN2	0.757	-
<b>Intention: Cronbach's <math>\alpha = 0.872</math></b>		
INT1	0.717	0.851
INT2	0.802	0.771
INT3	0.740	0.831
<b>Indirect TPB Scale</b>		
<b>Behavioural Belief: Cronbach's <math>\alpha = 0.894</math></b>		
BB2	0.724	0.879
BB3	0.774	0.860
BB4	0.783	0.858

BB5	0.783	0.857
<b>Normative Belief: Cronbach's <math>\alpha = 0.870</math></b>		
NB1	0.735	0.833
NB2	0.796	0.777
NB3	0.727	0.841
<b>Control Belief – Related to Pharmacists: Cronbach's <math>\alpha = 0.881</math></b>		
CB1	0.791	0.828
CB3	0.741	0.848
CB4	0.716	0.860
CB8	0.734	0.850
<b>Control Belief – Related to Customers: Cronbach's <math>\alpha = 0.868</math></b>		
CB5	0.768	-
CB6	0.768	-
<b>PCare-HDS Scale</b>		
<b>Foster Relationship: Cronbach's <math>\alpha = 0.896</math></b>		
FR1	0.786	0.859
FR2	0.795	0.850
FR3	0.802	0.844
<b>Gather Information: Cronbach's <math>\alpha = 0.907</math></b>		
GI1	0.813	0.868
GI2	0.816	0.866
GI3	0.815	0.867
<b>Assess HDS Use: Cronbach's <math>\alpha = 0.856</math></b>		
AU1	0.707	0.819
AU2	0.757	0.772
AU3	0.722	0.804
<b>Assist Informed Decision: Cronbach's <math>\alpha = 0.904</math></b>		
AID1	0.799	0.871
AID2	0.824	0.851
AID3	0.805	0.866
<b>Make Professional Decision: Cronbach's <math>\alpha = 0.897</math></b>		
MPD1	0.755	0.873
MPD2	0.714	0.882
MPD3	0.762	0.872
MPD4	0.798	0.863
MPD5	0.704	0.884
<b>Provide Advice or Information: Cronbach's <math>\alpha = 0.919</math></b>		
PAI1	0.749	0.907
PAI2	0.764	0.905
PAI3	0.794	0.902
PAI4	0.733	0.908
PAI5	0.739	0.908
PAI6	0.766	0.905
PAI7	0.701	0.912
<b>Seek HDS Information: Cronbach's <math>\alpha = 0.860</math></b>		
SI2	0.651	0.880
SI3	0.767	0.774
SI4	0.793	0.749
<b>Maintain HDS Quality: Cronbach's <math>\alpha = 0.899</math></b>		
MPQ1	0.767	0.883
MPQ2	0.808	0.850
MPQ3	0.827	0.832

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ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention; BB = behavioural belief; NB = normative belief; CB = control belief; FR = foster relationship; GI = gather information; AU = assess HDS use; AID = assist informed decision; MPD = make professional decision; PAI = provide advice or information; SI = seek HDS information; MPQ = maintain HDS product quality

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#### 4.3.9. Stage 3: Additional analysis

The following sections describe additional statistical tests to further support the validity of the Direct TPB, Indirect TPB and PCare-HDS scales. These tests included Rasch analysis, and criterion validity tests (concurrent and predictive validity tests). For the Rasch analysis, complete cases for each scale i.e.,  $n = 678$  for Direct and Indirect TPB scales, and  $n = 682$  for PCare-HDS scale were used (please refer Appendix M and N). For the concurrent validity test, in the assessment of whether the Direct TPB constructs correlate with intention, and whether the Indirect TPB constructs correlate with their respective Direct TPB constructs, the complete cases for the Direct and Indirect TPB scales ( $n = 678$ ) were used. Additionally, to assess whether the total mean score of the PCare-HDS scale correlate with the total mean score of the Direct and Indirect TPB scales, the total complete cases of both the TPB and PCare-HDS scales were used ( $n = 661$ ).

##### 4.3.9.1. Rasch Analysis of the Direct TPB, Indirect TPB and PCare-HDS scales

The model fit data was assessed by examining the Rasch fit statistics namely Infit and Outfit MNSQ. The Rasch analysis showed that there was no misfit item. All item had an Infit and Outfit MNSQ value of more than 0.5 but less than 1.5 (Table 37). The acceptable Rasch fit statistics achieved in the study showed that all items are productive for measurement. The findings from the Rasch analysis also further verified the validity of the three scales and supported the retention of items as recommended in the psychometric test based on the classical test theory.

DIF analyses across gender showed that the majority of items in the Direct TPB, Indirect TPB and PCare-HDS had no substantive DIF by gender (Table 37). This means that for each item, male and female CPs with the same trait level of beliefs would have similar responses. However, item CB4 (*I think my knowledge about the HDS is good*) and CB8 (*I think I have enough informational materials about the HDS at my drugstore*) from the Indirect TPB scale were DIF for gender with DIF contrasts of 0.52 and 0.55, respectively. No DIF by gender was found for the Direct TPB and PCare-HDS scales.

**Table 37. Rasch fit statistics of the Direct TPB, Indirect TPB and PCare-HDS scales**

Subscale	Item measure <sup>a</sup>	SE	Infit mean square	Outfit mean square	DIF (Gender) <sup>b</sup>	Rasch-Welch, <i>P</i>
<b>Direct TPB scale</b>						
<b>Attitude</b>						
ATT1	-0.21	0.07	1.10	1.05	0.09	0.567
ATT2	0.11	0.07	0.83	0.83	0.00	1.000
ATT3	0.10	0.07	1.03	0.95	0.10	0.519
<b>Subjective Norm</b>						
SN1	-0.31	0.09	0.98	0.90	0.30	0.113
SN2	0.31	0.09	0.98	0.90	0.31	0.102
<b>Perceived Behavioural Control</b>						
PBC1	-0.71	0.09	0.97	0.96	0.00	1.000
PBC2	0.71	0.09	0.97	0.96	0.00	1.000
<b>Professional Norm</b>						
PN1	0.61	0.10	0.97	0.94	0.12	0.584
PN2	-0.61	0.10	1.00	0.96	0.12	0.570
<b>Intention</b>						
INT1	-0.07	0.07	1.09	0.93	0.11	0.491
INT2	-0.09	0.07	0.85	0.75	0.13	0.393
INT3	0.16	0.07	1.04	0.87	0.24	0.124
<b>Indirect TPB scale</b>						
<b>Behavioural Belief</b>						
BB2	-0.16	0.07	1.16	1.11	0.21	0.168
BB3	-0.20	0.07	0.91	0.89	0.00	1.000
BB4	0.00	0.07	0.79	0.73	0.07	0.644
BB5	0.37	0.07	1.05	0.92	0.28	0.061
<b>Normative Belief</b>						
NB1	-0.35	0.08	0.97	0.92	0.02	0.909
NB2	-0.35	0.08	0.84	0.81	0.26	0.151
NB3	0.71	0.08	1.12	1.03	0.30	0.098
<b>Control Belief: Facilitators Related to Pharmacists</b>						
CB1	-0.60	0.07	0.95	0.95	0.08	0.636
CB3	0.12	0.07	0.94	0.90	0.10	0.544
CB4	0.14	0.07	0.91	0.87	<b>0.52</b>	<b>0.001</b>
CB8	0.33	0.07	1.15	1.16	<b>0.55</b>	<b>0.001</b>
<b>Control Belief: Facilitators Related to Customers</b>						
CB5	0.11	0.10	0.99	0.96	0.03	0.893
CB6	-0.11	0.10	0.99	0.96	0.02	0.908
<b>PCare-HDS scale</b>						
<b>Fostering Relationship</b>						
FR1	-0.18	0.08	1.08	1.05	0.06	0.720
FR2	0.38	0.08	0.97	0.92	0.04	0.794
FR3	-0.20	0.08	0.91	0.89	0.00	1.000
<b>Gather Information</b>						
GI1	0.16	0.08	1.00	0.84	0.04	0.829
GI2	-0.03	0.08	0.96	0.81	0.19	0.255
GI3	-0.13	0.08	1.01	0.87	0.14	0.399

<b>Assess HDS Use</b>						
AU1	-0.19	0.08	1.00	0.98	0.42	0.012
AU2	-0.03	0.08	0.83	0.84	0.00	1.000
AU3	0.22	0.08	1.15	1.19	0.43	0.010
<b>Assist Informed Decision</b>						
AID1	-0.07	0.08	0.97	0.92	0.18	0.323
AID2	0.08	0.08	0.88	0.82	0.00	1.000
AID3	-0.01	0.08	1.09	0.97	-0.19	0.293
<b>Make Professional Decision</b>						
MPD1	0.14	0.07	1.00	1.00	0.07	0.643
MPD2	0.07	0.07	1.12	1.14	0.04	0.812
MPD3	-0.18	0.07	0.86	0.90	0.24	0.114
MPD4	0.01	0.07	0.77	0.76	0.15	0.315
MPD5	-0.04	0.07	1.18	1.11	0.12	0.447
<b>Provide Advice or Information</b>						
PAI1	-0.04	0.06	0.93	1.00	0.13	0.304
PAI2	-0.01	0.06	0.92	0.94	0.00	1.000
PAI3	0.02	0.06	0.77	0.77	0.19	0.141
PAI4	0.28	0.06	0.96	1.00	0.17	0.182
PAI5	0.09	0.06	1.11	1.12	0.23	0.074
PAI6	-0.14	0.06	1.05	1.09	0.03	0.825
PAI7	-0.22	0.06	1.18	1.17	0.00	1.000
<b>Seek HDS Information</b>						
SI2	-0.17	0.08	1.21	1.16	0.03	0.857
SI3	0.08	0.08	0.89	0.85	0.06	0.727
SI4	0.09	0.08	0.85	0.82	0.00	1.000
<b>Maintain HDS Product Quality</b>						
MPQ1	-0.12	0.08	1.10	1.06	0.03	0.885
MPQ2	0.24	0.08	1.04	0.99	0.10	0.562
MPQ3	-0.12	0.08	0.84	0.81	0.06	0.726

<sup>a</sup> Item measures are in logits

<sup>b</sup> DIF values for gender are the absolute values in logits of item difficulty differences between males and females

ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention; BB = behavioural belief; NB = normative belief; CBP = control belief: facilitators related to pharmacists; CBC = control belief: facilitators related to customers; FR = Foster relationship; GI = Gather information; AU = Assess HDS use; AID = Assist informed decision; MPD = Make professional decision; PAI = Provide advice or information; SI = Seek HDS information; MPQ = Maintain HDS product quality

Table 38 presents the Rasch analysis of the five-point Likert-type scale of the Direct TPB, Indirect TPB and PCare-HDS scales. It was observed that each category had more than 10 observations. Except for two categories in the Direct TPB scale and another two in the PCare-HDS scale, none of the other categories in the three scales showed misfit because their Outfit MNSQs were less than 2.0. Outfit MNSQs for rating category 3 and 4 for “Intention” (0.39 and 0.40, respectively), category 1 for “Assist Informed Decision” (2.18) and category 4 for “Gather information” (0.42)



slightly violated the recommended criterion. However, the category functioning followed monotonic increases in mean and step measures for all domains of the Direct TPB, Indirect TPB and PCare-HDS scales. The thresholds of the 5 categories for the scales were therefore considered to follow the expected order.

**Table 38. Rasch analyses of the five-point Likert-type scale of the Direct TPB, Indirect TPB and PCare-HDS scales**

Subscale	Observed count (percentage, %)	Mean measures	Outfit mean square	Threshold
<b>Direct TPB scale<sup>a</sup></b>				
<b>Attitude</b>				
1	108 (5)	-3.07	1.23	None
2	247 (12)	-1.11	1.70	-4.01
3	360 (18)	-0.45	0.60	-1.13
4	882 (43)	2.64	0.68	0.34
5	437 (21)	4.25	0.99	4.81
<b>Subjective Norm</b>				
1	89 (7)	-6.83	1.20	None
2	329 (24)	-3.59	0.94	-7.74
3	379 (28)	-0.04	0.71	-1.62
4	371 (27)	4.74	0.71	2.14
5	188 (14)	6.62	1.23	7.22
<b>Perceived Behavioural Control</b>				
1	110 (8)	-5.95	1.31	None
2	352 (26)	-3.54	0.84	-6.56
3	441 (33)	-0.29	0.87	-2.02
4	290 (21)	3.20	0.82	1.72
5	163 (12)	4.50	1.51	6.85
<b>Professional Norm</b>				
1	68 (5)	-4.92	1.40	None
2	131 (10)	-3.73	1.00	-6.24
3	251 (19)	-0.78	0.82	-2.98
4	598 (44)	4.85	0.99	1.31
5	308 (23)	7.70	0.94	7.92
<b>Intention</b>				
1	97 (5)	-7.55	0.61	None
2	450 (22)	-2.85	1.68	-8.11
3	541 (27)	1.76	<b>0.39</b>	0.17
4	584 (29)	3.97	<b>0.40</b>	2.89
5	362 (18)	4.39	1.28	5.05
<b>Indirect TPB scale<sup>a</sup></b>				
<b>Behavioural Belief</b>				
1	155 (6)	-3.79	0.90	None
2	413 (15)	-1.79	1.12	-4.11
3	528 (19)	-0.83	0.87	-1.55
4	1276 (47)	2.74	0.84	-0.01
5	340 (13)	5.54	0.89	5.67

<b>Normative Belief</b>				
1	97 (5)	-9.28	0.60	None
2	555 (27)	-3.27	1.12	-9.25
3	624 (31)	0.87	0.85	-0.77
4	603 (30)	4.56	0.86	2.66
5	155 (8)	7.09	1.06	7.36
<b>Control Belief: Facilitators Related to Pharmacists</b>				
1	283 (10)	-8.38	0.88	None
2	919 (34)	-2.89	1.06	-8.31
3	933 (34)	1.24	1.11	-0.01
4	411 (15)	3.28	0.78	3.02
5	166 (6)	5.08	0.89	5.30
<b>Control Belief: Facilitators Related to Customers</b>				
1	66 (5)	-5.93	0.96	None
2	165 (12)	-3.48	1.13	-7.02
3	245 (18)	0.10	0.91	-2.13
4	688 (51)	4.69	0.90	1.79
5	192 (14)	6.43	1.07	7.36
<b>PCare-HDS scale<sup>b</sup></b>				
<b>Foster Relationship</b>				
1	105 (5)	-4.41	1.51	None
2	254 (12)	-2.07	1.23	-5.49
3	412 (20)	0.19	0.73	-1.37
4	762 (37)	3.78	0.73	1.54
5	513 (25)	4.98	1.15	5.32
<b>Gather Information</b>				
1	110 (5)	-5.11	1.36	None
2	278 (14)	-3.66	1.16	-7.74
3	481 (24)	1.62	0.68	-1.16
4	747 (37)	4.65	<b>0.42</b>	3.02
5	430 (21)	5.38	1.01	5.88
<b>Assess HDS Use</b>				
1	90 (4)	-5.20	1.28	None
2	221 (11)	-2.76	0.94	-5.60
3	504 (25)	0.96	0.83	-1.43
4	948 (46)	3.07	1.21	1.36
5	283 (14)	5.06	1.01	5.67
<b>Assist Informed Decision</b>				
1	128 (6)	-4.79	<b>2.18</b>	None
2	288 (14)	-3.65	0.56	-5.57
3	438 (21)	-0.24	0.75	-2.22
4	870 (43)	4.06	0.97	1.05
5	322 (16)	6.63	0.82	6.74
<b>Make Professional Decision</b>				
1	159 (5)	-3.30	1.18	None
2	327 (10)	-2.07	0.76	-3.66
3	745 (22)	0.52	1.06	-1.67
4	1608 (47)	2.41	0.97	0.76
5	571 (17)	4.32	0.96	4.56
<b>Provide Advice or Information</b>				
1	227 (5)	-2.25	1.33	None

2	556 (12)	-1.14	1.13	-2.79
3	1103 (23)	0.18	1.11	-1.25
4	2013 (42)	2.04	0.68	0.66
5	875 (18)	3.02	0.98	3.38
<b>Seek HDS Information</b>				
1	107 (5)	-5.12	1.45	None
2	258 (13)	-3.57	0.72	-5.81
3	638 (31)	1.03	0.93	-2.14
4	847 (41)	3.41	0.97	2.10
5	196 (10)	4.98	0.92	5.85
<b>Maintain HDS Product Quality</b>				
1	73 (4)	-7.31	0.81	None
2	205 (10)	-2.58	1.33	-7.19
3	465 (23)	1.38	0.98	-1.12
4	827 (40)	4.07	0.77	2.34
5	476 (23)	5.31	0.89	5.97

Misfit values are in **bold**  
<sup>a</sup> Response format: 1 = Strongly Disagree; 2 = Disagree; 3 = Neutral; 4 = Agree; 5 = Strongly Agree;  
<sup>b</sup> Response format: 1 = Never; 2 = Seldom; 3 = Sometimes; 4 = Often; 5 = Always

#### 4.3.9.2. Criterion validity

##### Concurrent validity

To examine whether the mean score of the Direct TPB constructs (i.e., attitude, subjective norm, perceived behavioural control and professional norm) correlate with the intention mean score, and whether the Indirect TPB constructs (i.e., behavioural belief, normative belief, control belief: CBP and control belief: CBC) correlate with their respective direct measures in the Direct TPB scale (i.e., attitude, subjective norm and perceived behavioural control), the Pearson correlation test was performed on the total complete cases for the Direct and Indirect TPB scales (n = 678). The mean score for each factor of the Direct TPB and Indirect TPB scales is summarized in Table 39. Additionally, the total complete cases for both the TPB and PCare-HDS scale (n = 661) was used to assess the correlation of the total mean score of PCare-HDS scale with the total mean score of the Direct TPB and Indirect TPB scales. The total mean score for the Direct TPB, Indirect TPB and PCare-HDS scales is outlined in Table 40.

**Table 39. Mean score and standard deviation of the constructs of the Direct and Indirect TPB scales (n = 678)**

Scale / subscale	Mean (SD)
<b>Direct TPB scale</b>	
Attitude	3.636 (0.978)
Subjective norm	3.177 (1.054)
Professional norm	3.032 (1.028)
Perceived behavioural belief	3.698 (1.001)
Intention	3.326 (1.008)
<b>Indirect TPB scale</b>	
Behavioural belief	3.459 (0.926)
Normative belief	3.081 (0.914)
Control belief: facilitators related to pharmacists	2.726 (0.897)
Control belief: facilitators related to customers	3.572 (0.956)

**Table 40. Total mean score and standard deviation of the Direct TPB, Indirect TPB and PCare-HDS scales (n = 661)**

Scale / subscale	Mean (SD)
Direct TPB scale	3.399 (0.771)
Indirect TPB scale	3.172 (0.707)
PCare-HDS scale	3.565 (0.600)

The results showed that there were positive and significant correlations between attitude and intention ( $r = 0.502$ ,  $P < 0.001$ ), subjective norm and intention ( $r = 0.544$ ,  $P < 0.001$ ), perceived behavioural control and intention ( $r = 0.516$ ,  $P < 0.001$ ), and professional norm with intention ( $r = 0.420$ ,  $P < 0.001$ ). Based on the Guilford's interpretation of the magnitude of significant correlations, these correlations showed moderate but substantial relationship (167). In addition, the results showed that there were positive and significant correlations between behavioural belief and attitude ( $r = 0.445$ ,  $P < 0.001$ ), normative belief and subjective norm ( $r = 0.525$ ,  $P < 0.001$ ), control belief: CBP with perceived behavioural control ( $r = 0.516$ ,  $P < 0.001$ ), and control belief: CBC with perceived behavioural control ( $r = 0.400$ ,  $P < 0.001$ ). Based on the Guilford's interpretation of the magnitude of significant correlations, these correlations showed moderate but substantial relationship (167). Table 41 shows the correlations between the variables from the Indirect TPB scale with the Direct TPB scale.

**Table 41. Correlations between the variables from the Indirect TPB scale with the Direct TPB scale**

Scale / subscale		Direct TPB					Indirect TPB			
		ATT	SN	PBC	PN	INT	BB	NB	CBP	CBC
Direct TPB	ATT	1								
	SN	0.629**	1							
	PBC	0.492**	0.545**	1						
	PN	0.306**	0.427**	0.368**	1					
	INT	0.502**	0.544**	0.516**	0.420**	1				
Indirect TPB	BB	0.445**	0.472**	0.483**	0.336**	0.378**	1			
	NB	0.413**	0.525**	0.381**	0.306**	0.359**	0.586**	1		
	CBP	0.363**	0.411**	0.516**	0.268**	0.441**	0.410**	0.454**	1	
	CBC	0.377**	0.384**	0.400**	0.291**	0.358**	0.419**	0.422**	0.422**	1

\*\* Correlation significant at  $P < 0.01$  (two-tailed)

ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention; BB = Behavioural belief; NB = normative belief; CBP = control belief: facilitators related to pharmacists; CBC = control belief: facilitators related to customers

Assessment of the correlation coefficient between the total mean scores of PCare-HDS scale and Direct TPB scale showed that the scores of the two scales had positive and significant but small relationship ( $r = 0.284$ ,  $P < 0.001$ ). However, the correlation coefficient was close to being a practically significant relationship (168). In addition, the total mean score of PCare-HDS scale had a positive and significant but weak correlation with the total mean score of the Indirect TPB scale ( $r = 0.254$ ,  $P < 0.001$ ).

In summary, the data support the following hypotheses:

- **H<sub>1.1</sub>**. Intention mean score would have a positive correlation with attitude mean score.
- **H<sub>1.2</sub>**. Intention mean score would have a positive correlation with subjective norm mean score.
- **H<sub>1.3</sub>**. Intention mean score would have a positive correlation with perceived behavioural belief mean score.
- **H<sub>1.4</sub>**. Intention mean score would have a positive correlation with professional norm mean score.
- **H<sub>2.1</sub>**. Attitude mean score would have a positive correlation with behavioural belief mean score.
- **H<sub>2.2</sub>**. Subjective norm mean score would have a positive correlation with normative belief mean score.

- **H<sub>2.3</sub>**. Perceived behavioural control mean score would have a positive correlation with control belief mean score.
- **H<sub>3.1</sub>**. PCare-HDS total mean score would have a positive correlation with the total mean score of Direct TPB scale.
- **H<sub>4.1</sub>**. PCare-HDS total mean score would have a positive correlation with the total mean score of Indirect TPB scale.

### **Predictive validity**

- **Prediction of intention**

To identify independent variables that influenced the mean score of intention and mean score of self-reported provision of PCare for HDS users, the independent samples *t*-test was carried out (Appendix O). The independent samples *t*-tests results showed that the mean scores for intention (dependent variable) were significantly different among CPs with the following variables: number of years working at community pharmacy ( $\leq 5$  years vs.  $> 5$  years), type of community pharmacy (chain/franchise vs. independent), position (full-time vs. part-time), being an owner (yes vs. no), and history of participation in HDS-related training in the past six months (yes vs. no). These variables were recoded into “dummy” variables in order to provide valid interpretation for the regression analyses. These independent variables along with the other predictors of intention i.e., attitude, subjective norm, perceived behavioural control and professional norm were included in the MRA analysis for the prediction of intention.

The sample size for the MRA was 678 and was deemed adequate. Inspection of the correlation matrix showed that no correlations exceeded 0.7. In addition, *Tolerance* and VIF values did not exceed 1.0 and 2.5, respectively. Based on these results, absence of multicollinearity was assumed. Normality was assumed for the intention mean score since the skewness and kurtosis values did not exceed  $\pm 1$  (skewness = -0.360 and kurtosis = -0.609). Multivariate outliers were determined by referring to the Mahalanobis distance from the residual statistics. One case exceeded the critical  $X^2$  for 9 *df* of 27.877 and was excluded from the MRA.

Findings from the MRA showed that nine predictors explained 41.7% of the variance ( $R^2 = 0.417$ ,  $F(9, 668) = 31.901$ ,  $P < 0.001$ ). It was found that attitude ( $\beta = 0.194$ ,  $P < 0.001$ ), subjective norm ( $\beta = 0.214$ ,  $P < 0.001$ ), perceived behavioural control ( $\beta = 0.232$ ,  $P < 0.001$ ), and professional norm ( $\beta = 0.182$ ,  $P < 0.001$ ) were contributing significantly to the regression model. These variables had significant positive regression weights, indicating that CPs with higher scores on these subscales were expected to have higher intention to provide PCare for HDS users, after controlling for the other variables in the model. Examination of the beta coefficients showed that perceived behavioural control contributed the most to the overall regression model (Table 42).

**Table 42. Results of multiple regression analysis of intention**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Intention (n = 677)	Attitude	0.194	4.918	< 0.001
	Subjective norm	0.214	5.048	< 0.001
	Perceived behavioural control	0.232	6.263	< 0.001
	Professional norm	0.182	5.458	< 0.001
	Number of years working at community pharmacy <sup>a</sup>	0.022	0.682	0.495
	Type of community pharmacy <sup>b</sup>	0.007	0.229	0.819
	Position <sup>c</sup>	0.005	0.170	0.865
	Being an owner <sup>d</sup>	-0.049	-1.529	0.127
	History of participation in HDS-related training in the past six months <sup>d</sup>	0.041	1.355	0.176

$R^2 = 0.417$ ;  $F = 31.901$ ,  $P < 0.001$

<sup>a</sup> Measured as  $\leq 5$  years and  $> 5$  years; <sup>b</sup> Measured as chain/franchise and independent; <sup>c</sup> Measured as full-time and part-time; <sup>d</sup> Measured as yes and no

- **Prediction of self-reported provision of PCare for HDS users**

For the self-reported provision of PCare for HDS users, the mean score was significantly different among CPs with the following variables: number of years registered as pharmacists ( $\leq 10$  years vs.  $> 10$  years), number of years working at community pharmacy ( $\leq 5$  years vs.  $> 5$  years) and position (full-time vs. part-time) (Appendix O). The three variables were dummy coded and were included in the MRA analysis along with other potential predictors of self-reported provision of PCare for HDS users i.e., attitude, subjective norm, perceived behavioural control, professional norm and intention.

The sample size of 678 was adequate for the MRA. Absence of multicollinearity was assumed for the analysis since there were no correlations exceeding 0.7 for the independent variables, *Tolerance* value did not exceed 1.0 and VIF value did not exceed 2.5. Normality was assumed for the mean score of the self-reported provision of PCare for HDS users since the skewness and kurtosis values did not exceed  $\pm 1$  (skewness = 0.143 and 0.715). Multivariate outliers were determined by referring to the Mahalanobis distance from the residual statistics. One case exceeded the critical  $X^2$  for 8 *df* of 26.125 and was excluded from the MRA.

Findings from the MRA showed that eight predictors explained 47.5% of the variance ( $R^2 = 0.475$ ,  $F(8, 669) = 25.721$ ,  $P < 0.001$ ). It was found that perceived behavioural control ( $\beta = 0.320$ ,  $P < 0.001$ ), professional norm ( $\beta = 0.118$ ,  $P < 0.001$ ), and intention ( $\beta = 0.335$ ,  $P < 0.001$ ) were contributing significantly to the regression model. These variables had significant positive regression weights, indicating that CPs with higher scores on these subscales were expected to have higher self-reported provision of PCare for HDS users, after controlling for the other variables in the model. Examination of the beta coefficients showed that intention contributed the most to the overall regression model (Table 43).



**Table 43. Results of multiple regression analysis of self-reported provision of PCare for HDS users**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Self-reported provision of PCare for HDS users (n = 677)	Attitude	0.073	1.916	0.056
	Subjective norm	0.018	0.439	0.661
	Perceived behavioural control	0.320	8.870	< 0.001
	Professional norm	0.118	3.657	< 0.001
	Intention	0.335	9.083	< 0.001
	Number of years working at community pharmacy <sup>a</sup>	-0.001	-0.04	0.970
	Number of years registered as pharmacists <sup>b</sup>	0.005	-0.187	0.852
	Position <sup>c</sup>	0.001	0.015	0.988
$R^2 = 0.475$ ; $F = 75.680$ , $P < 0.001$				
<sup>a</sup> Measured as $\leq 5$ years and $> 5$ years; <sup>b</sup> Measured as $\leq 10$ years and $> 10$ years; <sup>c</sup> Measured as full-time and part-time				

- **Prediction of each construct of PCare-HDS scale**

The mean score of each construct of PCare-HDS scale was calculated (Table 44). Normality was assumed for the mean score of each of the PCare-HDS construct since the skewness and kurtosis values did not exceed  $\pm 1$ . Absence of multicollinearity was assumed for the analysis since there were no correlations exceeding 0.7 for the independent variables, *Tolerance* value did not exceed 1.0 and VIF value did not exceed 2.5. The independent samples *t*-test was performed to determine the independent variables that may result in a significant difference in the mean of the PCare-HDS scale constructs (Appendix P). The independent samples *t*-test results showed that the mean score of “foster relationship (FR)” was significantly different in CPs with the following variables: number of years registered as pharmacists ( $\leq 10$  years vs.  $> 10$  years), and the number of years working at community pharmacy ( $\leq 5$  years vs.  $> 5$  years).

There was a significant difference in the mean of “gathering information (GI)” in CPs with  $\leq 5$  years and  $> 5$  years of working experience at community pharmacy, and those working in chain/franchise and independent community pharmacy. The mean of “providing advice or information (PAI)” was significantly different in CPs with  $\leq 5$  years and  $> 5$  years of working experience at community pharmacy, among those who

were working as full- and part timers, and among CPs who had used HDS and those who did not. Additionally, those who had  $\leq 5$  years and  $> 5$  years of working experience at community pharmacy, and those who were full- and part timers had significantly different mean score for “seeking information (SI)”. Finally, the mean score of “assist informed decision (AID)” were noted to be significantly different among CPs who were working in chain/franchise and independent community pharmacy, and among those who were working as full- and part-time CPs. None of the independent variables caused a significant difference in the mean scores of the other three constructs of the PCare-HDS scale namely, “assess HDS use (AU)”, “making professional decision (MPD)”, and “maintain HDS product quality (MPQ)”.

**Table 44. Mean score, standard deviation, skewness and kurtosis of the constructs of the PCare-HDS scale (n = 661)**

Scale / subscale	Mean (SD)	Skewness	Kurtosis
Foster relationship	3.644 (1.028)	-0.817	-0.061
Gather information	3.552 (1.011)	-0.887	0.022
Assess HDS use	3.543 (0.868)	-0.913	0.667
Assist informed decision	3.470 (1.001)	-0.668	-0.485
Make professional decision	3.619 (0.869)	-0.996	0.581
Provide advice or information	3.571 (0.859)	-0.859	-0.181
Seeking HDS information	3.378 (0.862)	-0.864	0.186
Maintain HDS product quality	3.695 (0.930)	-0.881	0.508

The sample size for the MRA was 661 and was deemed adequate. MRA was performed with constructs of the Direct TPB scale (i.e., attitude, subjective norm, perceived behavioural control, professional norm and intention) as the independent variables, and each construct of PCare-HDS scale as the dependent variable. Demographic variables were included in the regression model if they caused a significant difference in the mean score of the PCare-HDS scale constructs. Multivariate outliers were determined by referring to the Mahalanobis distance from the residual statistics.

For the “foster relationship (FR)” construct, one case exceeded the critical  $X^2$  for 7 *df* of 24.322 and was excluded from the MRA. Seven predictors explained 9.5% of variance ( $R^2 = 0.095$ ,  $F(7, 652) = 9.755$ ,  $P < 0.001$ ). Perceived behavioural control ( $\beta = 0.136$ ,  $P = 0.005$ ), and intention ( $\beta = 0.105$ ,  $P < 0.032$ ), were the only two predictors that were contributing significantly to the regression model (Table 45).

**Table 45. Results of multiple regression analysis of “foster relationship” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Foster relationship ( <i>n</i> = 660)	Attitude	0.049	0.972	0.331
	Subjective norm	0.013	0.249	0.803
	Perceived behavioural control	0.136	2.797	0.005
	Professional norm	0.080	1.867	0.062
	Intention	0.105	2.150	0.032
	Number of years working at community pharmacy <sup>a</sup>	0.056	1.202	0.230
	Number of years registered as pharmacists <sup>b</sup>	0.013	0.280	0.780
$R^2 = 0.095$ ; $F = 9.755$ , $P < 0.001$				
<sup>a</sup> Measured as $\leq 5$ years and $> 5$ years; <sup>b</sup> Measured as $\leq 10$ years and $> 10$ years				

For the “gather information (GI)” construct, one case exceeded the critical  $X^2$  for 7 *df* of 24.322 and was excluded from the MRA. Seven predictors explained 6.9% of variance ( $R^2 = 0.069$ ,  $F(7, 652) = 6.915$ ,  $P < 0.001$ ). Perceived behavioural control ( $\beta = 0.106$ ,  $P = 0.031$ ) was the only predictor that was contributing significantly to the regression model (Table 46).

**Table 46. Results of multiple regression analysis of “gather information” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Gather information ( <i>n</i> = 660)	Attitude	0.074	1.439	0.151
	Subjective norm	0.036	0.661	0.509
	Perceived behavioural control	0.106	2.161	0.031
	Professional norm	0.056	1.282	0.200
	Intention	0.034	0.688	0.492
	Number of years working at community pharmacy <sup>a</sup>	0.050	1.244	0.214
	Type of community pharmacy <sup>b</sup>	0.054	1.356	0.176
$R^2 = 0.069$ ; $F = 6.915$ , $P < 0.001$				
<sup>a</sup> Measured as $\leq 5$ years and $> 5$ years; <sup>b</sup> Measured as chain/franchise and independent				

For the “assess HDS use” construct, with five independent variables, one case were noted to be a multivariate outlier as it exceeded the critical  $X^2$  for 5 *df* of 20.515. The case was excluded from the MRA. Five predictors explained 4.5% of variance ( $R^2 = 0.045$ ,  $F(5, 654) = 6.122$ ,  $P < 0.001$ ). Professional norm ( $\beta = 0.089$ ,  $P = 0.042$ ) and intention ( $\beta = 0.127$ ,  $P = 0.011$ ) were the only two predictors that were contributing significantly to the regression model (Table 47).

**Table 47. Results of multiple regression analysis of “assess HDS use” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Assess HDS use ( <i>n</i> = 660)	Attitude	0.011	0.206	0.836
	Subjective norm	-0.015	-0.279	0.781
	Perceived behavioural control	0.050	1.010	0.313
	Professional norm	0.089	2.035	0.042
	Intention	0.127	2.555	0.011
$R^2 = 0.045$ ; $F = 6.122$ , $P < 0.001$				

For “assist informed decision (AID)” construct, one case was considered a multivariate outlier (exceeded the critical  $X^2$  for 7 *df* of 24.322) and was removed from MRA. Seven predictors explained 3.7% of variance ( $R^2 = 0.037$ ,  $F(7, 652) = 3.554$ ,  $P < 0.001$ ). Professional norm ( $\beta = 0.093$ ,  $P = 0.035$ ) was the only predictor that was contributing significantly to the regression model (Table 48).

**Table 48. Results of multiple regression analysis of “assist informed decision” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Assist informed decision ( <i>n</i> = 660)	Attitude	-0.052	-0.993	0.321
	Subjective norm	0.077	1.390	0.165
	Perceived behavioural control	0.043	0.863	0.389
	Professional norm	0.093	2.117	0.035
	Intention	0.015	0.292	0.770
	Type of community pharmacy <sup>a</sup>	0.072	1.863	0.063
	Position <sup>b</sup>	0.058	1.482	0.139
$R^2 = 0.037$ ; $F = 3.554$ , $P < 0.001$				
<sup>a</sup> Measured as chain/franchise and independent; <sup>b</sup> Measured as full-time and part-time				

For “make professional decision (MPD)” construct, one case was removed due to being a multivariate outlier (exceeded the critical  $X^2$  for 5 *df* of 20.515). Five predictors explained 2.7% of variance ( $R^2 = 0.027$ ,  $F(5, 654) = 3.598$ ,  $P = 0.003$ ). Professional norm ( $\beta = 0.089$ ,  $P = 0.046$ ) was the only predictor that contributed significantly to the regression model (Table 49).

**Table 49. Results of multiple regression analysis of “make professional decision” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Make professional decision ( <i>n</i> = 660)	Attitude	0.068	1.316	0.189
	Subjective norm	0.002	0.032	0.974
	Perceived behavioural control	-0.017	-0.331	0.741
	Professional norm	0.089	2.002	0.046
	Intention	0.064	1.272	0.204
$R^2 = 0.027$ ; $F = 3.598$ , $P = 0.003$				

For “providing advice or information (PAI)” construct, one case was identified as a multivariate outlier as it exceeded the critical  $X^2$  for 8 *df* of 26.125. The case was therefore removed from the MRA. Eight predictors explained 3.4% of variance ( $R^2 = 0.034$ ,  $F(8, 651) = 2.828$ ,  $P = 0.004$ ). The self-use of HDS ( $\beta = -0.084$ ,  $P = 0.030$ ) was the only predictor that contributed significantly to the regression model, indicating

that CPs who did not use the HDS were more likely to provide advice or information to HDS users, after controlling for the other variables in the model (Table 50).

**Table 50. Results of multiple regression analysis of “provide advice or information” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Provide advice or information ( <i>n</i> = 660)	Attitude	0.027	0.520	0.603
	Subjective norm	0.002	0.036	0.971
	Perceived behavioural control	0.037	0.733	0.464
	Professional norm	0.065	1.465	0.143
	Intention	0.008	0.153	0.878
	Number of years working at community pharmacy <sup>a</sup>	0.067	1.692	0.091
	Position <sup>b</sup>	0.072	1.838	0.067
	Self-use of HDS <sup>c</sup>	-0.084	-2.176	0.030
$R^2 = 0.034$ ; $F = 2.828$ , $P = 0.004$				
<sup>a</sup> Measured as $\leq 5$ years and $> 5$ years; <sup>b</sup> Measured as full-time and part-time; <sup>c</sup> Measured as yes and no				

For “seeking HDS information (SI)” construct, two cases exceeded the critical  $X^2$  for 7 *df* of 24.322. The two cases were removed from the MRA. Seven predictors explained 8.0% of variance ( $R^2 = 0.080$ ,  $F(7, 651) = 8.052$ ,  $P < 0.001$ ). Four predictors namely attitude ( $\beta = -0.147$ ,  $P = 0.004$ ), perceived behavioural control ( $\beta = 0.129$ ,  $P = 0.009$ ), professional norm ( $\beta = 0.115$ ,  $P = 0.008$ ) and position ( $\beta = 0.083$ ,  $P = 0.031$ ) contributed significantly to the regression model (Table 51).

**Table 51. Results of multiple regression analysis of “seeking HDS information” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Seeking HDS information ( <i>n</i> = 559)	Attitude	-0.147	-2.882	0.004
	Subjective norm	0.052	0.949	0.343
	Perceived behavioural control	0.129	2.609	0.009
	Professional norm	0.115	2.659	0.008
	Intention	0.093	1.888	0.060
	Number of years working at community pharmacy <sup>a</sup>	0.069	1.802	0.072
	Position <sup>b</sup>	0.083	2.167	0.031
$R^2 = 0.080$ ; $F = 8.052$ , $P < 0.001$				
<sup>a</sup> Measured as $\leq 5$ years and $> 5$ years; <sup>b</sup> Measured as full-time and part-time				

Finally, for “maintain HDS product quality (MPQ)” construct, one case was identified as a multivariate outlier as it exceeded the critical  $X^2$  for 5 *df* of 20.515 and was excluded from the MRA. Five predictors explained 5.1% of variance ( $R^2 = 0.051$ ,  $F(5, 654) = 7.054$ ,  $P < 0.001$ ). Only professional norm ( $\beta = 0.133$ ,  $P = 0.002$ ) contributed significantly to the regression model (Table 52).

**Table 52. Results of multiple regression analysis of “maintain HDS product quality” construct**

Dependent variable	Independent variable	Beta	<i>t</i>	<i>P</i>
Maintain HDS product quality ( <i>n</i> = 660)	Attitude	0.041	0.808	0.420
	Subjective norm	0.017	0.309	0.757
	Perceived behavioural control	0.016	0.327	0.744
	Professional norm	0.133	3.044	0.002
	Intention	0.083	1.670	0.095
$R^2 = 0.051$ ; $F = 7.054$ , $P < 0.001$				

For all the regression models the absence of multicollinearity was assumed for the analysis since there were no correlations exceeding 0.7 for the independent variables, Tolerance value did not exceed 1.0 and VIF value did not exceed 2.5.

Results from the MRA supported the following hypotheses:

- **H<sub>5.1</sub>**. Attitude is a positive and significant predictor of intention to provide PCare for HDS users.
- **H<sub>5.2</sub>**. Subjective norm is a positive and significant predictor of intention to provide PCare for HDS users.
- **H<sub>5.3</sub>**. Perceived behavioural control is a positive and significant predictor of intention to provide PCare for HDS users.
- **H<sub>5.4</sub>**. Professional norm is a positive and significant predictor of intention to provide PCare for HDS users.
- **H<sub>6.3</sub>**. Perceived behavioural control is a positive and significant predictor of self-reported provision of PCare for HDS users.
- **H<sub>6.4</sub>**. Professional norm is a positive and significant predictor of self-reported provision of PCare for HDS users.

- **H<sub>6.5</sub>.** Intention is a positive and significant predictor of self-reported provision of PCare for HDS users.
- **H7:**
  - Perceived behavioural control is a significant predictor of “foster relationship”, “gather information”, and “seeking HDS information”.
  - Intention is a significant predictor of “foster relationship”.
  - Professional norm is a significant predictor of “assess HDS use”, “assist informed decision”, “make professional decision”, and “seeking HDS information”, and “maintain HDS quality”.





#### 4.3.10. Chapter summary

This chapter presented the results from the three phases of the study. In the first phase of the study, twenty-two CPs were interviewed. The CPs mentioned several pharmacy-related activities that they regarded as PCare for HDS users. Additionally the CPs provided their beliefs associated with the behaviour. Findings from the qualitative study together with the m-TPB framework resulted in a pool of items for the Direct TPB, Indirect TPB and PCare-HDS scales with 15, 28 and 54 items, respectively. Pharmacy experts, who reviewed the items, reduced the item pool to 12, 16 and 33 items, respectively. Face validity showed that the items were clear and comprehensible. In the quantitative phase, 703 CPs returned the survey. Of the entire total sample, 678 CPs completed the Direct and Indirect TPB scales whereas 682 completed the PCare-HDS scale. The EFA supported the factor structures of the Direct TPB and PCare-HDS scales. The EFA identified additional factor of the Indirect TPB scale. Both the EFA and a preliminary CFA guided refinement of the scales. Items for the Indirect TPB and PCare-HDS scales were reduced further to 13 and 30 items, respectively. Data from the second dataset for all three scales fitted well with the models using the CFA. Discriminant and convergent validity were shown for the scales. Rasch analysis showed no substantial misfit and the category functioning followed monotonic increases in mean and step measures for all domains of the three scales. Additionally, all factors of the three scales had good to excellent internal consistency reliability. All scales had acceptable criterion validity. The tools appeared to be valid and reliable in its current form. The next chapter discussed the results.

## CHAPTER 5: DISCUSSION

This chapter presents the summary for each phase of the study and outlines relevant recommendations. Limitations of the present study and suggestions for future research are also discussed.

### 5.1. Phase 1: Elicitation study using qualitative interview

Phase 1, the qualitative study involved 22 CPs working in community pharmacies in Bangkok, Thailand. The study was aimed to answer the following research questions:

**RQ1.** What are the meanings of PCare for HDS users from the perspectives of CPs in Bangkok, Thailand?

**RQ2.** What are the beliefs of the CPs about the consequences of providing PCare for HDS users?

**RQ3.** Who are the individuals that support the CPs to provide PCare for HDS users?

**RQ4.** What are the facilitators and barriers for the CPs to provide PCare for HDS users?

**RQ5.** What are the beliefs about professional responsibility among the CPs regarding PCare for HDS users?

#### 5.1.1. Pharmacist's care for herbal and dietary supplement users

In answering the first research question, the qualitative study identified several pharmacist activities that CPs considered as PCare for HDS users. Essentially PCare for HDS users in the perspective of the CPs can be categorized into two dimensions (1) direct customer/patient care activities consisting of six domains (fostering relationship, gathering information, assessing HDS use, assisting informed decision, making professional decision, and providing advice and information), and (2) non-direct customer/patient care activities consisting of two domains (seeking HDS information, and maintaining HDS product quality). The domains of PCare for HDS

users identified in the present study was consistent to many roles of pharmacists recommended in the joint FIP/WHO GPP guideline for good pharmacy practice (49). Additionally, the domains covered most of the recommended responsibilities of pharmacists related to HDS as stipulated in the FIP/WHO guideline for the “Role of Pharmacist in Self-Care and Self-Medication” (50), and the White Paper on Herbal Medicine published by the ACCP (51).

However, it should be noted that although the FIP/WHO guideline recommended pharmacists to be a “trainer or supervisor” in regard to self-care and self-medication, this role was not mentioned by any of the CPs in our study. Half of our qualitative study informants were working in an independent community pharmacy. It could be likely that those CPs were working alone at their workplaces, and therefore the roles as “trainer or supervisor” were not relevant. However these roles of pharmacists may be pertinent to those CPs working in chain/franchise community pharmacies where many non-pharmacist staffs are employed to work at the premises.

At certain times especially during peak hours, CPs may not be able to consult each customer who is using or planning to use HDS. Therefore training of non-pharmacist staff can be crucial in supporting the safe use of HDS. In this regard, the non-pharmacist staff can be provided with basic knowledge about HDS so that they can provide basic but important information about the products to the customers. The staff should also be trained so that they are able to recognize customers or patients that need special attention from CPs. Customers who are using HDS but at the same time using conventional medicines, are having chronic diseases, or being pregnant can be referred to CPs so that the use of HDS in these customers can be appropriately assessed. Future studies therefore, should aim to explore the extent to which CPs in Thailand ensure their non-pharmacist staff are capable in managing HDS users as recommended.

Additionally, although the White Paper on Herbal Medicine published by the ACCP (51) suggested pharmacists to document patients’ HDS use and other relevant information including patients’ informed decision to use HDS, this activity appeared not to be implemented in practice. This activity, although form an important

component of the PC care processes recommended by Cipolle *et al.*, (23) was not identified as important by CPs in our study. In this regard, none of the CPs mentioned that they perform any documentation related to customers' or patients' HDS use. At present there is no regulation being implemented that obligate CPs to document patients' information at the community pharmacy settings. The Thai-FIP quality indicators for community pharmacies developed by the CPA also does not contain items that require CPs to perform documentation of patient care activities (172). However, it can be argued that in practice, documentation of customers' HDS use by CPs may be impractical. This is because HDS users may visit community pharmacies in a "walk-in" manner to obtain HDS products. It is possible that these HDS users may not be encountered again by the CPs. In this context, such documentation may have little value.

Findings from our study also showed that maintaining or ensuring HDS product quality is an important part of PCare for HDS users. This aspect of PCare for HDS users is not often being discussed in the literature but can be a very important aspect for ensuring rational and safe use of HDS. As shared by a few of our CP informants, in reality there are still unapproved HDS products and those with excessive claims being sold at community pharmacies in Bangkok. Therefore, it can be argued that the first step in promoting quality use of HDS is by ensuring that only quality products being stocked at the community pharmacies. Maintaining HDS product quality by pharmacists is supported by the FIP/WHO guideline for "Role of Pharmacist in Self-Care and Self-Medication" (50) and the Thai-FIP quality indicators for community pharmacies (172).

The findings from our study showed that many of our CP respondents endorsed a patient-centered care approach when dealing with HDS users. Many CPs mentioned that during encounters with customers requesting for HDS, they usually collect necessary information to understand customers' wants and needs, and assess the appropriateness of use of HDS. They consequently provide sufficient HDS information to assist the customers in making decision about using a HDS. Nevertheless, although the CPs always offer their opinions about what they think is

the best for the customers, the CPs normally provide the freedom for them to decide on whether or not to use a HDS, and to decide which products to use.

Thus, essentially the CPs use their professional skills to evaluate HDS use and transmitting HDS information while the customers direct and decide. This approach of providing PCare for HDS users has been preferred by HDS users in previous surveys (12, 15, 173). Nevertheless, the CPs will take a paternalistic approach in caring for their customers if they found out that the HDS that the customers requested are harmful (e.g., contraindicated, interacting with other drugs or diseases, etc.) (174). For such circumstances the CPs mentioned that they normally refuse to sell the HDS products.

#### **5.1.2. Behavioural beliefs**

In response to the second research question, the study showed that CPs were generally positive about providing PCare for HDS users. This finding was consistent with findings from several previous studies (81, 173, 175). In this regard, the CPs recognized the benefits of providing PCare for HDS users, and they readily associate this to a more rational and safer use of HDS among the users. In addition the CPs viewed PCare for HDS users as beneficial for their personal benefits (e.g., improves own knowledge, and makes them more trustworthy), and for their community pharmacies (e.g., promotes loyalty among customers, and attracts customers). Therefore, in efforts to encourage CPs to provide PCare for HDS users, these identified outcomes that deemed important to them can be highlighted.

#### **5.1.3. Normative beliefs**

For the third research question, the CPs identified several important entities such as the customers, their colleagues, and doctors that they believed can influence them to provide PCare for HDS users. Among the entities that motivated the CPs to provide PCare, the HDS users were the most frequently mentioned as having importance to them. In this regard, many CPs believed that the HDS users in general want the CPs to provide PCare for them. Only one CP mentioned a governmental organization (Thai FDA) and none cited any professional pharmacy associations. The majority of the

CPs however, mentioned that the provision of PCare for HDS users is generally self-initiated.

#### **5.1.4. Control beliefs**

In answering the fourth research question, the qualitative study identified various factors that CPs perceived as facilitators and barriers for the provision of PCare for HDS users. The most prominent influencing factor for the provision of PCare for HDS users was related to the HDS users themselves. In this study, although the HDS users were perceived as entities who motivate them to provide PCare, it was noted that there were occasions where the behaviors and attitudes of the HDS users can either facilitate or inhibit the CPs to provide PCare for them. Previous studies have shown that pharmacists are more likely to be reactive rather than proactive in providing advice related to public health (176) and lifestyle changes (177). Similarly, the CPs in the present study seemed to be motivated to provide PCare for HDS users who are proactive in asking questions or initiating a discussion with them. Additionally, the CPs tend to be more motivated to provide PCare for HDS users who were willing to spend time for the service, and for those who express trust in them.

On the contrary many CPs often in frustration mentioned that they also commonly encountered another group of HDS users who were more demanding, challenging and aggressive. Many CPs mentioned that this group of the HDS users often challenges their knowledge, and usually do not recognize their professional opinions. Several CPs mentioned that in many circumstances, their efforts to initiate PCare or to provide professional opinions to this group of customers were resentfully rejected. The emergence of this group of customers that have been described as “new consumers”, “assertive customers” or the “lay experts” has been reported in the pharmacy literature since the last two decades (173, 178-182). These customers have been reported to show a strong sense of self-perceived ability, and self-perceived confidence in deciding their own treatments (181). In previous studies, customers have been reported to decline CPs’ advice, even in regard to OTC medicines (180, 181). Furthermore, the CPs in the present study also often encountered HDS users who just come to the community pharmacies to “pick and pay” HDS products. In keeping with

previous studies (180, 181), these HDS users normally decline unsolicited advice from the CPs probably because they have been using a particular HDS product for a long time, and were committed to use the same. For these HDS users, the focus was more on purchasing HDS products rather than receiving care from CPs.

In a recent study carried out among CPs in Harbin, China, almost 40% (111/280) of the CP respondents agreed that the unwillingness of customers to accept PCare in respect to the OTC Traditional Chinese Medicine as a barrier to provide PCare (175). Similarly, HDS users who are assertive, and those who are in the “pick-and-pay” category can present a serious challenge for CPs to be more proactive in providing PCare for HDS users. The CPs may be reluctant to engage with these HDS users as they may fear that their unsolicited opinions may be rejected (176) or their interventions may have repercussions on their relationship with the customers (177).

However, without a mutual engagement between CPs and HDS users, it is impossible to guarantee whether the use of HDS among customers are appropriate, or are not causing any problems (23). Since HDS users normally obtained information from the Internet, family and friends which can be unreliable and misleading, self-selection of HDS by the users may potentially be inappropriate. In fact, many CPs in this present study have reported that many HDS users that they encountered were actually using HDS inappropriately. In this regard, the CPs had encountered HDS users who were using the products for the wrong indications, or at inappropriate dosages. Furthermore, the common sources of HDS information used by the public mainly focused on the benefits of self-treatment with HDS. Information regarding the risks associated with self-care such as misdiagnosis, potential HDS-interactions, and adverse effects are rarely included. Moreover, a previous study has found that community pharmacy customers who are described as the “lay experts” usually arrived at their own diagnosis and treatment after consultation with other “lay experts” (181). Although it can be argued that the HDS users themselves had experienced the outcomes of the products on their own health, this experience is hardly adequate for them to understand the complexities of HDS effects in human, especially when used together with modern medicines.

The reluctance of the HDS users to engage with CPs may be due the lack of understanding of the processes and the purposes of PCare. In addition, HDS users may perceive HDS as general items as those found at retail markets and shops. It may also be possible that HDS users may not have concerns about the risks of HDS as they may presumed that all items available in community pharmacies are safe (181). Therefore, although it is difficult to deal with customers who are unwilling to engage with CPs, it is imperative for CPs to attempt engaging with those customers by listening attentively to them even if they are adamant with their pre-existing knowledge and beliefs (51). It is important for CPs to understand the HDS users' perspectives including their desire and beliefs for using HDS for treatment of diseases or for maintenance of health. At minimum, CPs should at least ask new users the reasons for using HDS, and ask the existing users if they are experiencing any problems at the point of selling. CPs should also highlight if the HDS may potentially interact with modern medicines (173). In cases where self-selection of HDS by the customers are inappropriate, the customers should be asked about their source of information in a non-judgmental manner. CPs should explain the reason behind their professional judgment or opinions. There is also a need to find new ways of communication with HDS users especially for those who decline unsolicited CPs' advice. Perhaps it is viable to promote HDS users to present themselves to CPs if they feel that they are vulnerable for HDS-related issues. A campaign can target HDS users who are using conventional medicines, having chronic diseases, being pregnant, or elderly to talk to CPs about their HDS use. It is also important to prepare educational materials about HDS use at the community pharmacies since patients have been shown to favor support mechanism for them to care themselves (178).

The characteristics of HDS users may also influence CPs to provide PCare for them. This was a novel finding obtained from the present qualitative study. In this regard, several CPs categorized their HDS customers as easy and difficult to be provided with PCare according to their age, educational status, socio-economic status and occupations. CPs who had less experience in community pharmacy practice were noted to pay more attention on certain group of HDS users who they think are easier to be provided with PCare. This stereotyping behavior among CPs may have been



shaped by CPs' own experience dealing with HDS users, and can be seen as a strategy to only engage with "pleasant" HDS users and to avoid those who they perceived as more challenging or demanding. Arguably, the inclination of CPs to engage with HDS users that they perceived as easy to be provided with PCare may facilitate the continuity of the provision of PCare for HDS users in community pharmacies. However, there is a concern that those customers who were negatively stereotyped may in fact need PCare. It is also possible that HDS users who have been neglected due to CPs' stereotyping may have mistrust or misconceptions to CPs and avoid PCare altogether.

Many previous studies cited low self-perceived knowledge about HDS among CPs as a main barrier to provide PCare for HDS users. On the contrary, only a minority of informants in the present study had the belief that they had low knowledge in HDS. Instead, in the present study, half of the CPs (50%, 11/22) regarded themselves as "experts" in caring for HDS users. This is a good sign as self-efficacy is a key predictor for a performance of a behavior (183). Our findings showed that CPs who are less than 30 years old and having community pharmacy experience of less than 5 years, were more confident in providing PCare for HDS users. In a study in Australia, younger pharmacists were also found to be more likely to ask patients about CAM use (68). Our findings may suggest that younger CPs may be more receptive to the "pharmaceutical care provider" role of pharmacists. In addition, the younger CPs may be more cognizant of the current trend of HDS use among the public, and were more aware of the emergence of various HDS products in the market. Nevertheless, it should be noted that although many of the CPs regarded themselves as experts in caring for HDS users, many still perceived that continuing professional development (CPD) training in caring for HDS users as an important facilitator for them to provide PCare. In this regard, the CPs may feel that they have to keep updating themselves with knowledge of new HDS products that keep increasing in the market. Therefore community pharmacy owners or managers should be encouraged to provide such training for their staff on a frequent basis. Additionally, pharmacy-related governmental and non-governmental organizations in Thailand should regularly

organize CPD related to HDS to provide a means for CPs to update themselves with HDS knowledge.

In the present study many CPs agreed that the availability of printed materials such as leaflets, posters, and booklets about HDS are useful to support PCare for HDS users. It is worth noting however that most of these materials that CPs often referred to were supplied by the HDS manufacturers. It can be likely that the materials are promotional in nature. A survey carried out in the United Kingdom, has found out that many leaflets of herbal medicine products did not contain key safety information such as precautions and side effects (184). CPs should therefore be vigilant of printed materials that may be misleading and incomplete. Additionally many CPs also cited access to Internet as a facilitator for them to provide PCare for HDS users. Although the Internet may provide a means for obtaining immediate information especially within the context of busy pharmacy settings, CPs should be made aware that some information from the Internet may not be reliable. There is also a need to train CPs to appraise information obtained from the Internet.

#### **5.1.5. Professional normative beliefs**

Finally for the final research question for the qualitative study, the study affirmed that professional norm was an important factor for the provision of PCare for HDS users. In this regard, CPs generally believed that providing PCare for HDS users is in the job scope of a pharmacist. The CPs also highlighted that they are healthcare professionals and they should provide PCare for HDS users at standards higher than other retailers. This finding is consistent with results from previous studies that showed many pharmacists were positive about their role in ensuring the safe use of HDS (81, 173, 175).

Although the professional norm is not part of the TPB model, the inclusion of the construct may assist in the explanation CPs' provision of PCare for HDS users. In fact, in a systematic review of studies predicting healthcare professionals' behaviours, professional norm has been shown to be a significant determinant in almost 60% of the studies (17). Therefore, in an effort to encourage CPs to be more proactive in

providing PCare for HDS users, it may be important to emphasize that the responsibility of CPs does not only include the provision of PCare for conventional medicine users, but also for HDS users.

#### **5.1.6. Recommendation from qualitative study**

In order to promote CPs to become more proactive in providing PCare for HDS users, the benefits of the service can be conveyed to them. Community pharmacy owners or managers should strive to supply printed materials about HDS at the community pharmacies. Additionally, pharmaceutical or HDS manufacturer companies should ensure the content of HDS product leaflets or brochures to be reliable and evidence-based since these materials are often referred to by CPs and frequently distributed to customers. CPs may also benefit from CPD training related to PCare for HDS users to enhance their confidence or self-efficacy to provide such care. CPs should also be encouraged to ask simple but important questions to customers requesting HDS at their community pharmacy. In addition, CPs must be prepared for dealing with the “new consumers” who can be challenging and demanding. Pharmacy education and training should also include health psychology to help CPs engage with HDS users with different attitudes and behaviors. There is also a pressing need to educate the public in general, and the HDS users in particular, about the role of CPs in ensuring quality and safe use of HDS.

#### **5.1.7. Strengths and limitations**

This qualitative study was conducted only among CPs working in Bangkok for ease of data collection. Their practices of PCare for HDS users and the underlying beliefs and factors for its provision may be different from pharmacists in the other regions of the country. Additionally, the small sample size of the study while is appropriate for a qualitative study provide a limitation in generalizing the identified practices and beliefs to the broader CP population. However, CPs with various demographic and employment characteristics, and the type of community pharmacy were included in the study, resulted in a collection of a variety of accounts of CPs’ experiences. These data although are not statistically generalizable are considered theoretically

transferable, and can provide useful insights about the topic. In addition, CPs who have personal interests in HDS or are more positive towards CPs' roles in caring for HDS users, may be more motivated to participate in the study.

In addition, all interviews were conducted in English, and therefore there might be a risk of miscommunication between the interviewer and the informants. However, due to quality referrals, all of the informants were fluent in English, and did not require the aid of an interpreter. Additionally, since CPs were interviewed about their engagement in PCare activities, their responses may be subjected to social desirability bias. In effort to reduce social desirability bias, CPs were offered anonymity and confidentiality. It should be noted however, that the total sample of CPs also included those who admitted that they were not proactive in providing PCare for HDS users, providing an evidence that social desirability bias is somewhat reduced. Furthermore, although this study explored and identified the salient behavioral, normative, control and professional normative beliefs underlying the provision of PCare for HDS users among CPs, it could not determine the extent to which these beliefs are correlated with CPs' intentions to provide PCare for HDS users.

Despite the limitations mentioned, the salient beliefs underlying the provision of PCare for HDS users among CPs that have been identified in the present study were useful to guide the development of survey instruments to measure the determinant of PCare for HDS users. Similarly the practices of PCare for HDS users identified in the study assisted in the development of a scale to quantitatively measure the practice. The findings of the qualitative study formed the basis of item pools or draft scales in our Phase 2 study. These draft scales were then tested for their psychometric properties in our Phase 3 study.

## 5.2. Phase 2: Development of scales

The present study followed the recommendation by DeVellis to develop the Direct TPB, Indirect TPB and PCare-HDS scales (123). This approach enabled the development of the scales in a systematic manner. Additionally, the recommendation for constructing TPB scales was also observed (87). However, it should be noted that although the authors of the TPB suggested researchers to use the expected-value products (EVP) to measure beliefs, this method was not adapted in the present study (89). The EVP posit that a belief is the product of likelihood judgments (expectancy) and evaluation (value) judgments. For example, for the following behavioural belief item, *“If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions”* (with responses choices of: *strongly disagree* to *strongly agree*), the belief score should be multiplied with the evaluation score of a relevant item e.g., *“Ensuring the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions is...”* (with response choices of: *extremely undesirable* to *extremely desirable*).

The researchers of the present study decided to omit the evaluation judgment item for the Indirect TPB scale for two main reasons. First, it can be argued that the inclusion of the evaluation judgment item will increase the length of the scale and therefore may increase respondents' burden when answering the survey. Secondly there have been concerns regarding the method of measuring beliefs using EVP model as the calculation for the product of likelihood judgments and evaluation judgments are not standardized. Inappropriate scoring of the two items may misleadingly affect the predictive value of the Indirect TPB scale (185).

Additionally, findings from our qualitative study were found to be useful in informing the item pools for the Indirect TPB and PCare-HDS scales. The use of the findings from the qualitative study and the mixed-method item generation approach resulted in survey items that were constructed based on the voice of participants. Review by experts in the content validity study reduced items with low relevancy. In addition, participants of the face validity study assisted in providing feedback about the clarity and comprehensibility of the scales. These processes resulted in the development of

survey items for the three scales that are relevant and comprehensible to the target population.

### **5.3. Phase 3: Quantitative study**

Essentially the quantitative study was aimed to explore the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales, and to refine and validate the scales. To achieve these goals the study was divided into three stages. Stage 1: exploratory analysis and refinement of scales, Stage 2: validation of scales, and Stage 3: additional analysis to provide further evidence of validity of the scales. The discussion of study findings from the quantitative study is organized according to the research questions.

#### **5.3.1. Respondents characteristics and response rate**

Overall 703 CPs responded to our survey. Most of the key demographic characteristics of CPs in our study e.g., female (66.7%), holding a PharmD (13.1%), and holding a Bachelor degree (80.1%) were higher than those obtained in the study by Kangwol and Anantachoti (186): female (54.2%), holding a PharmD (6%), and holding a Bachelor degree (66.7%). Additionally 70.1% of the total sample of our CP respondents involved those who were working alone at the community pharmacy, whereas in Kangwol and Anantachoti study, 83.3% were working alone. The differences in the characteristics of CP respondents between the two studies may be due to the difference in methods and period of data collection.

In the present study, we used multiple methods for data collection. The decision to incorporate various methods for the data collection was due to low response rates among Thai pharmacists reported in previous studies. Based on these previous studies, response rates of approximately 30 - 50% have been observed among Thai pharmacists (187-189). In the survey by Kangwol and Anantachoti, the response rate reported was 5.5% (186). In our study, the useable response rates were 6.2% for the mail survey, 15.1% for the online survey, 22.5% for the survey during pharmacy seminars, and 69.6% for the store-to-store survey.

The use of the different type of data collection methods and the differences in response rate in each method may limit the generalization of our study findings. However, the primary aims of the present study were to develop measurement scales based on previous theoretical frameworks. As mentioned by Hulland *et al.*, if the study aims to test the veracity of proposed theoretical effects, the use of convenience sample is appropriate (190). Therefore, the sampling methods used in the present study were acceptable.

At the outset, the items used in the survey were practical evidenced by the low percentage of missing values and responses for N/A option. In this study, we did not collect data on the time taken for respondents to answer the survey. However, during the face validity study among a small sample of CPs and pharmacy students, the survey took 30 – 45 minutes to complete. It is estimated that each scale may take 10 – 15 minutes to complete. Further studies can explore the time taken for each scale to further investigate the practicality of the scales.

### **5.3.2. Stage 1: Exploratory analysis and refinement of scales**

Two research questions were addressed in Stage 1 of the quantitative study:

**RQ6.** What are the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales?

**RQ7.** Do the Direct TPB, Indirect TPB and PCare-HDS constructs have internal consistency reliability?

To answer RQ6, the factor structures of the three scales were examined using the EFA. Overall, the data cohered in a manner consistent with the theoretical specifications of the scales thus providing evidence for construct validity. The EFA supported a 5-factor structure for the Direct TPB scale. The factors for the Direct TPB scale include: (1) attitude, (2) subjective norm, (3) perceived behavioural control, (4) professional norm, and (4) intention. This is consistent to the m-TPB framework that was used to develop the scale. For the Indirect TPB scale, although it was hypothesized to have 3 factors, the EFA identified a 4-factor structure for the scale. In

this regard, the control belief domain was branched into two: facilitators related for pharmacists (CB1, CB3, CB4, CB7 and CB8), and facilitators related to customers (CB5 and CB6). The latter two items was placed in a separate factor called “Control Belief: Facilitators Related to Customers (CBC)” whereas the original control belief domain was renamed as “Control Belief: Facilitators Related to Pharmacists (CBP)”. The 4-factor Indirect TPB scale includes the following domains: (1) behavioural belief, (2) normative belief, (3) control belief: facilitators related to pharmacists, and (4) control belief: facilitators related to customer. For the PCare-HDS scale, an 8-factor structure was identified as hypothesized from findings of our Phase 1 study. The domains for the PCare-HDS scale include: (1) fostering relationship, (2) gathering information, (3) assessing HDS use, (4) assisting informed decision, (5) making professional decisions or suggestions about HDS use, (6) providing advice or information about HDS use, (7) seeking HDS information, and (8) maintaining HDS product quality.

In this study both the EFA and CFA were used to guide the refinement of the three scales. Data analysis from both the EFA and CFA were used in a complementary manner in which each analysis supported the decision to refine the scales. First, the EFA was used to identify items that were problematic based on factor loadings and presence of cross-loadings. Secondly, the scales were analyzed using the CFA to provide additional evidence for problematic items from the three scales based on model fit indices, factor loadings, and standardized residual covariances. In this study, the CFA supported the identification of problematic items as identified in the EFA. These items were subsequently removed from the datasets. At the outset, 3 items were deleted from each the Indirect TPB and PCare-HDS scales, respectively. No item was deleted from the Direct TPB scale.

For the Indirect TPB scale, the following items were deleted: item CB2 (*I think I can manage my time so that I can provide care for the HDS users*), item BB1 (*If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions*), and item CB7 (*In my opinion I have access to information about the HDS including the scientific evidences at my drugstore*). These items were noted to be sources of misfit to the model as indicated by the CFA. Upon inspection



of each item, it was observed that the items had some theoretical problems. For example, item BB1 can be considered to have a double-barreled meaning. In this regard the item carries two aspects of ensuring safety: avoiding side effects and avoiding disease- or drug-HDS interactions. Item CB2 was written to capture the ability of CPs to manage their time in their busy work schedule to provide PCare for HDS users. This item was included in the item pool since findings from the qualitative study showed that busyness hinder CPs to provide PCare for HDS users. This issue however, was not a major one identified in our qualitative study. Similar to item BB1, item CB7 appeared to have a double-barreled meaning. In this regard, the item carries two similar points – information about HDS and scientific evidences. Furthermore, the meaning of the item is quite similar to that of item CB8. These theoretical reasons further supported the deletion of the three items from the Indirect TPB scale.

For the PCare-HDS scale, the following items were deleted: item PAI8 (*I provide the HDS users with relevant HDS informational materials*), item MPD6 (*I report to the authority if the HDS users experience adverse events from HDS use*), and item SI1 (*I use reliable sources of information when providing information to the HDS users*). All three items showed low factor loadings in both the EFA and CFA. Interestingly both items (PAI8 and SI1) had high mean scores of  $3.742 \pm 0.958$  and  $3.607 \pm 1.088$ , respectively. However, inspection of the Cronbach's alpha value if the items were deleted showed that the removal of the items may increase the internal consistency reliability of their respective domain. This means that these items may not represent their domain effectively. Furthermore, the activity represented by item MPD6, may not be a common practice among our CPs. It was noted that the mean score of the item was the lowest in the PCare-HDS scale ( $3.106 \pm 1.132$ ). It should be noted that the number of items removed from the two scales did not exceed 20% and therefore the theoretical structures of the scales were maintained (146).

To answer RQ7, the factors for each scale were assessed for their internal consistency reliabilities by inspecting the Cronbach's alpha values. Overall, the internal consistency reliability of each subscale of the Direct TPB, Indirect TPB and PCare-HDS scales were good with all of them having a Cronbach's alpha value exceeding

0.80. The exploratory phase of the study provided an initial evidence of the construct validity, and internal consistency reliability of the scales. The number of items for the Direct TPB, Indirect TPB and PCare-HDS scales after refinement was 12, 13 and 30, respectively. The refined scales were then analyzed by using the CFA in Stage 2 of data analysis to validate the factor structures of the scales that were identified in this phase. The next section discusses findings from the validation phase.

### 5.3.3. Stage 2: Validation of scales

The second stage of data analysis was aimed to answer the following research questions:

**RQ8.** Are the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales identified in Stage 1 data analysis confirmed by the CFA?

**RQ9.** Do the Direct TPB, Indirect TPB and PCare-HDS scales have convergent and discriminant validity, and construct reliability?

**RQ10.** Do the Direct TPB, Indirect TPB and PCare-HDS constructs of the final models have internal consistency reliability?

In answering RQ8, the second half of the total samples for each scale were used to cross-validate the factor structures of the Direct TPB, Indirect TPB and PCare-HDS scales using the CFA. Overall, the data for each scale fit the model well. As evidenced from the goodness-of-fit indices, the CFA confirmed that the 5-factor Direct TPB, 4-factor Indirect TPB, and 8-factor PCare-HDS scales were acceptable as measurement models and are having construct validity. This means that the scales were measuring what they had been intended to measure (191).

RQ9 were answered by computing the factor loadings and CR for each item for the three scales. The factor loading and CR for each item of the scales exceeded 0.6 and 0.7, respectively, indicating that all constructs of the three scales had convergent validity (155). In other words, the items of the constructs that had been hypothesized to be related were in fact related. Additionally, the correlations between constructs of the scales were shown to be lower than the square root of AVE. Based on these

results, the scales were considered to have discriminant validity. This means that constructs of the scales that were supposed to be unrelated were in fact unrelated (155).

Analysis of the internal consistency reliability of each construct of the scales was performed to answer RQ10. The results from the analysis showed that all constructs had internal consistency reliability with a Cronbach's alpha value of more than 0.8. The results of the internal consistency reliability analysis were similar to that obtained in the exploratory phase of the study. The findings from the internal consistency reliability tests demonstrated that each subscale of the Direct TPB, Indirect TPB and PCare-HDS scales was consistent and each construct is measuring the same latent variable (130). In summary, findings from the validation study showed that the scales performed well as measurement models with construct, convergent and discriminant validity. The constructs for each scale also demonstrated good to excellent internal consistency reliability.

#### **5.2.4. Stage 3: Additional analyses**

Further analyses were carried out on the total sample obtained in the study to provide additional evidences for the validity of the three scales. The next three research questions were answered using Rasch analysis:

**RQ11:** Do the subscales of the Direct TPB, Indirect TPB and PCare-HDS scales map on to a common underlying construct based on the Rasch model?

**RQ12.** Do the structure of rating scales of the Direct TPB, Indirect TPB and PCare-HDS scales appropriate based on the Rasch model?

**RQ13.** Do items of the Direct TPB, Indirect TPB and PCare-HDS scales contain Differential Item Functioning (DIF) in terms of gender according to the Rasch model?

### Rasch analysis

Rasch analysis provided further means to assess the dimensionality of the Direct, Indirect and PCare-HDS subscales. Additionally the analysis provided useful item-level information regarding the psychometric properties of the scales. The findings supported that all items in the final version of the three scales fit to the Rasch model. This means that each item was measuring in a manner that is consistent with the underlying theory. Additionally, the 5-point Likert-type rating scales that were used in the scales were also found to be acceptable, as evidenced from ordered step calibrations (161).

In general, items of the Direct TPB, Indirect TPB and PCare-HDS scales were invariant across gender. In this regard, all items of the Direct TPB and PCare-HDS scales had no item with DIF. The majority of items in the Indirect TPB scale also had no substantial DIF. However, it was noted that two items (CB4 and CB8) from the Indirect TPB scale were DIF for gender with DIF contrasts of 0.52 and 0.55, respectively. This means that male and female CPs appeared to have different interpretations on what it means with the two items (CB4: *“I think my knowledge about the HDS is good”*, and CB8: *“I think I have enough informational materials about the HDS at my drugstore”*). Since the DIF of both items was not large, the items were retained. However, this issue should be further tested in future studies.

### Criterion validity

Further analyses were done to assess the criterion validity of the scales. The following research questions underpinned the examination of criterion validity in this study:

**RQ14.** Do the Direct TPB constructs i.e., attitude, subjective norm, perceived behavioural control, and professional norm correlate with intention?

**RQ15:** Do the Indirect TPB constructs i.e., behavioural belief, normative belief, and control belief correlate with their respective Direct TPB constructs i.e., attitude, subjective norm, and perceived behavioural control?

**RQ16.** Does the total mean score of the PCare-HDS scale correlate with the total mean score of the Direct TPB scale?

**RQ17.** Does the total mean score of the PCare-HDS scale correlate with the total mean score of the Indirect TPB scale?

**RQ18.** Are attitude, subjective norm, perceived behavioural control and professional norm a positive and significant predictor of intention to provide PCare?

**RQ19.** Are attitude, subjective norm, perceived behavioural control, professional norm, and intention a positive and significant predictor of self-reported provision of PCare for HDS users?

**RQ20.** Are attitude, subjective norm, perceived behavioural control, professional norm, and intention a positive and significant predictor for each construct of the PCare-HDS scale?

Results from the study showed that all factors of the Direct TPB scale had positive and significant correlation with the intention score, providing an evidence of concurrent validity of the scale. Concurrent validity was also established for the Indirect TPB scale as our results showed that each factor in the scale correlated positively and significantly with each of its respected Direct TPB factor. These findings showed that our study has identified “correct” factors that formed the attitude, subjective norm and perceived behavioural control for CPs to provide PCare for HDS users.

Each factor of the Direct TPB scale was also a significant predictor for the intention to provide PCare for HDS users based on our MRA results. However, only intention and perceived behavioural control were found to be the significant predictors for self-reported provision of PCare for HDS users, with intention as the strongest predictor. Since the intention was the strongest predictor for self-reported provision of PCare for HDS users, factors that may form their intention to provide such service should be strengthened.

Priority should be given to enhance subjective norm and perceived behavioural control since the intention score was correlated the highest with these two factors (subjective norm and intention:  $r = 0.544$ ,  $P < 0.001$ ; and perceived behavioural control:  $r = 0.516$ ,  $P < 0.001$ ). Additionally based on our MRA results, subjective norm and perceived behavioural control were the strongest predictors for the intention to provide PCare for HDS users. Perceived behavioural control was also a significant predictor to self-reported provision of PCare for HDS users, foster relationship, gather information, and seeking HDS information.

Our study showed that professional norm was a significant predictor for intention and self-reported provision of PCare for HDS users. However, the inclusion of professional norm to the TPB constructs although increased the proportion of variance in both intention and self-reported provision of PCare for HDS users in the models, the effects were small. This means that although CPs believe that providing PCare for HDS users is part of their professional responsibilities, their intention to provide the service are determined by their attitude, subjective norm and perceived behavioural control.

Results from the correlation test between the total mean score of PCare-HDS scale and Direct TPB scale showed that the scores of the two scales had positive and significant but small relationship ( $r = 0.284$ ,  $P < 0.001$ ). This means that CPs who had higher score for the Direct TPB scale would be expected to perform more PCare activities as in the PCare HDS scale. It should be noted that although the correlation between the mean scores of the two scales was small, it was close to being a practically significant relationship (168). In addition, the total mean score of PCare-HDS scale had a positive and significant but weak correlation with the total mean score of the Indirect TPB scale ( $r = 0.254$ ,  $P < 0.001$ ). This weak correlation although significant can be explained by the fact that the beliefs (Indirect TPB scale) were mediated through the direct measures (Direct TPB scale).

### 5.3.5. Recommendation from quantitative study

Based on our findings, extra efforts to provide support and encouragement for CPs to provide PCare for HDS users from the society (e.g., customers, colleagues, and relevant governmental or non-governmental bodies) may promote them to provide the service. In this regard, the public should be encouraged to recognize CPs' responsibilities in ensuring quality and safe use of HDS. Additionally, customers who are using or planning to use HDS should be encouraged to discuss with CPs. Furthermore social encouragement from colleagues, supervisors, managers and the governmental or non-governmental bodies (e.g., Thai FDA and CPA) should be given to CPs through means of word-of-mouth, bulletins or official endorsement.

In addition, measures to enhance confidence of CPs to provide PCare for HDS users should also be warranted. In the present study CPs had shown a moderate score for both perceived behavioural items: PBC1 (*I am confident that I can provide care for the HDS users*) with a mean score of  $3.174 \pm 1.080$  and PBC2 (*Providing care for the HDS users is easy*) with a mean score of  $2.891 \pm 1.163$ . In previous studies, pharmacists have been shown to have inadequate confidence in counseling (60, 68, 69), discussing (1, 79) and providing information (44, 73, 80) about HDS to patients. Our study has identified several factors that may enhance CPs' confidence in providing PCare for HDS users through the compilation of control beliefs about the behaviour. These factors include the perceived adequateness of previous education in HDS, perceived knowledge in HDS, belief about having enough training in PCare for HDS users, and the belief that there are sufficient informational materials at community pharmacy. Our results can informed several strategies to enhance confidence of CPs in providing PCare for HDS users.

First, pharmacy schools in Thailand should strive to include more content of HDS, and the aspects of caring for HDS users in the curriculum. A previous systematic review has indicated that in general pharmacy students believed that knowledge in HDS is crucial for them and the pharmacists. Additionally, HDS was perceived as an area that should be aggressively pursued and they welcomed topics of HDS to be included in the pharmacy curriculum (192). Seeing that a sufficient education in HDS

could enhance CPs' confidence in providing PCare for HDS users, and the topic is welcomed by many students, its inclusion in the pharmacy curriculum should be warranted.

Secondly, knowledge about the HDS among CPs should be enhanced. CPs in the present study perceived their knowledge in HDS as moderate with a mean score of  $2.687 \pm 0.946$  (item CB4: *I think my knowledge about the HDS is good*). In previous studies, many pharmacists perceived their knowledge in HDS as insufficient (65, 72, 81). In several studies, in which the actual knowledge of pharmacists in HDS was evaluated, the level of pharmacists' knowledge in HDS was found to be poor (55, 68, 193) or moderate (53, 194, 195). Therefore, attempts to increase knowledge of CPs in HDS should be warranted. This could be achieved by providing CPs with CPD education in HDS in a regular basis. This is important since our results showed that training in HDS was also an important factor that influences CPs' confidence in providing PCare for HDS users. However CPs in our study moderately agreed that they have received enough training to provide PCare for HDS users with a mean score of  $2.888 \pm 1.088$  for item CB1 (*I think I have received enough training to provide care for the HDS users*), supporting the recommendation to provide more training in HDS to CPs.

One interesting finding from the study was that many CPs in our qualitative study indicated that they are the experts in HDS, and should be the ones who provide PCare for HDS users. Whereas findings from the quantitative study showed that CPs rated their confidence and knowledge as moderate. This issue should be investigated further to explore the relationship between the two. It is possible that perceived expertise may not correlate with confidence and knowledge in providing PCare for HDS users.

Finally, it is recommended for community pharmacies to equip their stores with adequate informational materials such as leaflets, posters and booklets. These materials appeared to provide supports for CPs thereby enhancing their confidence in providing PCare for HDS users. However, efforts should be taken to ensure such materials are reliable and having adequate information to support the service.



### 5.3.6. Strengths and limitations of study

The present study was limited to the low response rate of CPs especially for the mail and online survey. In our study, the store-to-store survey resulted in a higher response rate compared to the other methods. Future researchers, who aim to carry out survey among this population in Bangkok, may consider using this method for data collection. However, such method may disrupt the privacy of CPs. Furthermore CPs who were approached using this method may responded to the survey due to courtesy. To minimize these problems, the research assistants were briefed to inform the CPs that the survey is voluntary and anonymous.

Other than that, it is possible that CPs who had personal interests in HDS or having favourable attitudes towards CPs' roles in caring for HDS users, may be more willing to respond to the survey. Additionally as the survey was written in the English language, those who were fluent in the language may be more likely to complete the survey. Moreover, the use of the English language in our survey may in part be a reason to the low response rate. However measures have been taken during the development of the survey to ensure that the scales were comprehensible even among pharmacy students by avoiding difficult sentences and terminologies. Our face validity study has shown that the scales were clear and understandable.

The low response rate and non-probability sampling used in the study may limit the generalization of our study results. However as discussed previously, since the primary aims of the present study were to test the veracity of proposed theoretical effects, our method of data collection is appropriate. Additionally, the sample used in the study came from one population, i.e., CPs in Bangkok, Thailand. The practices and beliefs of CPs in this region can be highly influenced by local cultures. Future studies may try to examine the invariance of the scales across cultures, by administering the scales in samples with different socio-cultural characteristics, such as in the North or South of Thailand, and perhaps in other regions in Southeast Asia.

Despite the limitations mentioned, the present study has recognized the significance of investigating PCare for HDS users. The development of the Direct TPB, Indirect

TPB and PCare-HDS scales provides a useful means for measuring various determinant and practices of PCare for HDS users among CPs in Bangkok. The information provided by these instruments can contribute to a better understanding about the provision of PCare for HDS users.

#### **5.4. Chapter summary**

This chapter provided discussion of the findings obtained in this study. The various activities that CPs described as PCare for HDS users were discussed. Additionally, the discussion about the salient beliefs about the provision of PCare for HDS users was also provided. Measures to improve CPs' engagement in PCare for HDS users activities were recommended. Additionally the chapter discussed the development of the scale and justified the approach used in the study. Finally, the chapter discussed results obtained from the study regarding the scales' validity and reliability. Strengths and limitations of each phase of the study were also discussed. Additionally, the chapter provided recommendation for future studies.

## CHAPTER 6: CONCLUSION

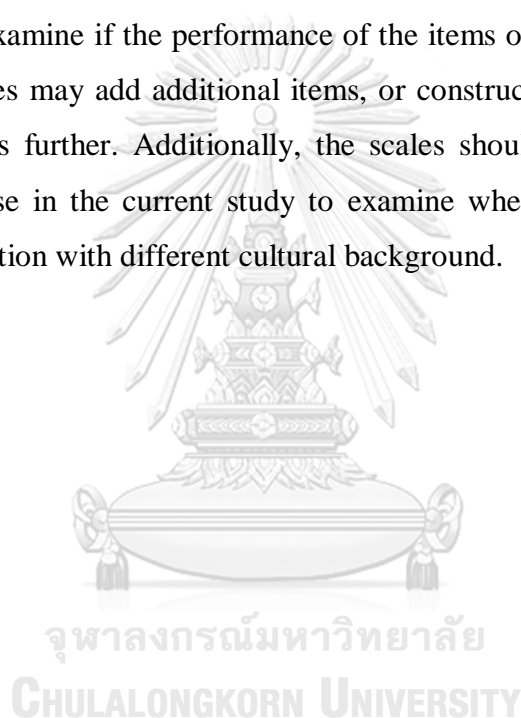
The present study has achieved its aims to develop survey instruments to measure the determinants and PCare for HDS users. A modified TPB framework formed the foundation for the development of the Direct and Indirect TPB scales. Additionally, the Indirect TPB and PCare-HDS scales were developed based on findings from our qualitative study. The scales were found to be valid and reliable. In this regard, the scales were shown to have content, construct, convergent, discriminant, and concurrent validity. The subscale of each scale was also shown to have good to excellent internal consistency reliability. The Rasch analysis further supported the validity of the scales.

This study has several implications for pharmacy practice, education and research within the context of PCare for HDS users. This study can potentially assist researchers and relevant bodies to understand the provision of PCare for HDS users among CPs in Bangkok. CPs' decision to provide PCare for HDS users as demonstrated in the present study can be the results of complex beliefs that they hold. The development of the theory-based survey instruments i.e., Direct TPB, Indirect TPB and PCare-HDS scales that are valid, reliable and relevant to CPs in Bangkok, can inform several strategies to promote CPs to become more proactive in providing PCare for HDS users.

The Direct and Indirect TPB scales may be of interest to researchers who aim to understand PCare for HDS users or those who are exploring ways to enhance CPs to provide PCare for HDS users. In this regard, the Direct TPB and Indirect TPB scales can be used to identify which aspect of CPs' beliefs that need improvement. Relevant governmental and non-governmental bodies and other relevant stakeholders can use the results to promote CPs to provide PCare for HDS users. For example, a campaign targeted among CPs to highlight their roles in ensuring quality and safe use of HDS may improve their attitudes towards the behaviour. A program that promotes the public to communicate with CPs about HDS use and the encouragement by relevant governmental and non-governmental bodies for CPs to provide PCare for HDS users may correspond to an increased social pressure to perform the behaviour (subjective

norm). Education and training in HDS may enhance their knowledge and skills thereby enhancing their self-efficacy and self-confidence in providing PCare for HDS users (perceived behavioural control). Additionally, the recognition that PCare for HDS users is part of CPs' responsibilities would enhance their professional normative beliefs. Additionally, it is also possible to use the PCare-HDS scale as a means of self-assessment by pharmacists, or as a measure for quality improvement.

Nevertheless, as with other measurement instruments, the Direct TPB, Indirect TPB and PCare-HDS scales should be tested further. A test-retest reliability assessment can be performed to examine if the performance of the items of the scales are stable over time. Future studies may add additional items, or constructs to the existing scales to improve the scales further. Additionally, the scales should be tested in population different than those in the current study to examine whether similar findings were obtained in population with different cultural background.



## APPENDIX

### Appendix A: Survey Tool Used in Qualitative Study

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#### Development of the Determinant Scale of Pharmacist's Care for Herbal and Dietary Supplement Users

*Please fill in the blanks or check ✓ for the appropriate answers for the following questions.*

#### **GENERAL QUESTIONS:**

1. How old are you? \_\_\_\_\_ years old.
2. Gender:
 

☐ Male
 ☐ Female
3. Number of years of licensure. \_\_\_\_\_ years.
4. How long have you been working as a community pharmacist? \_\_\_\_\_ years.

#### **QUESTIONS ABOUT YOUR WORKING PLACE:**

*If you are currently working at more than one community pharmacies, please provide answer for the community pharmacy that you spend the most time most months.*

5. Please state the name of the district in Bangkok where your workplace is located.  
\_\_\_\_\_
6. Type of community pharmacy:
 

☐ Independent
 ☐ Chain / Franchise
7. What is the status of your employment at the community pharmacy?
 

☐ Full-time
 ☐ Part-time

## Appendix B: Participant Information Sheet for Qualitative Study

<b>Title of research project:</b>	Development of a Determinant Scale of Pharmacist's Care for Herbal and Dietary Supplement Users
<b>Principle researcher's name:</b>	Mohd Shahezwan Abd Wahab
<b>Position:</b>	Principal investigator
<b>Office address:</b>	Faculty of Pharmaceutical Sciences, Chulalongkorn University, 254 Phayathai Road, Wangmai Patumwan Bangkok, 10330, Thailand
<b>Home address:</b>	509 SK Mansion Phetchburi 5, Tung Payathai, Bangkok, 10400, Thailand
<b>Cell phone:</b>	0943317264
<b>E-mail:</b>	<a href="mailto:ewan.pharmcare@gmail.com">ewan.pharmcare@gmail.com</a>

You are being invited to take part in a research project to investigate Thai community pharmacists' perceptions and beliefs about pharmacist's care for the herbal and dietary supplement users. Before you decide to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and do not hesitate to ask if anything is unclear or if you would like to have more information about the study.

**Purposes.** A team of researchers from the Faculty of Pharmaceutical Sciences, Chulalongkorn University are carrying out a study to develop a "Determinant Scale of Pharmacist's Care for Herbal and Dietary Supplement Users". The first part of the scale development is an exploratory study to investigate the perceptions and beliefs of the Thai community pharmacists about pharmacist's care for the herbal and dietary supplement users.

**Procedures.** In this study you will be interviewed about your understanding of "pharmacist's care for herbal and dietary supplement users"; your overall evaluations (advantages and disadvantages) of the behavior; important people who approve or disapprove the behavior; and the factors that may facilitate or inhibit you to provide care for the herbal and dietary supplement users. Please note that there is no right and wrong answer. Your perspectives can make a valuable contribution to this study.

You can participate in the study if you are:

1. a fully registered community pharmacist.
2. working in a community pharmacy as a full or part-time pharmacist.
3. working in an environment that allows direct contact with patients or customers.
4. working in a community pharmacy located in Bangkok.
5. able to communicate in the English language.
6. willing to participate in the study

You cannot participate in the study if:

1. your job scope is confined to administrative work or drug procurement only, even if you are working in a community pharmacy

The principal investigator will contact you if you are referred to us by your peers or other study informants, or if you had e-mailed or called us back to volunteer yourself to participate in the study. During the initial contact, the principal investigator will ask you a few questions to assess whether you are eligible for the study. An appointment for a meeting will be made

with you if you meet the inclusion criteria. You can decide where this interview will take place. If you do not satisfy the inclusion criteria you will be excluded from the study. In case where you were referred to us, and do not wish participate in the study, you may do so without any further questions asked.

For this study, you will be interviewed only once and each interview will take 45 – 60 minutes. The interview will be performed one-to-one in the English language by the principal investigator. At the beginning of the meeting for the interview, you will be firstly briefed about the study by the interviewer. You will be briefed about purposes and procedures of the study and your rights as a study participant. You will be provided with a consent form to sign to indicate your confirmation to participate in the study. You will receive a copy of the consent form. The procedure will be audio recorded. The recording of the interview will be transcribed and analyzed. Please note that your personal details will be deleted from all transcripts and only pseudonym will be used to prevent you from being identified. The recordings and transcriptions of all interviews in this study will be destroyed after the study is completed.

**Risks.** There are no physical risks associated with this study. However, discussion about your practices in pharmacy and issues regarding pharmacist's skills or confidence may cause discomfort to some community pharmacists. As a participant in this study, you have the right to refuse answering any questions asked by the interviewer. In addition, you may decline to talk about any topics that cause you uneasiness.

**Benefits.** As a participant in this study, you would not receive any personal benefits. However, findings from this study may be useful to the researchers in better understanding the perceptions and beliefs of the Thai community pharmacists about pharmacist's care for the herbal and dietary supplement users. The results of this study will also help us to develop a survey instrument that can further explore the issues, uncover new findings about community pharmacy practice and may help in assisting the professional development strategies for Thai community pharmacists.

**Voluntary participation and withdrawal.** Your participation in this study is entirely voluntary. You have the right to refuse from participating in this study. You are also able to withdraw from the study at any time even after providing your consent of participation. Your withdrawal from the study will not be questioned.

**Confidentiality.** As researchers, ethical and legal practice to manage all information will be followed. All information obtained from this study will remain confidential and kept in private, in a locked cabinet. All participants will be issued a pseudonym (code), and therefore your real name will not be used. Funder of this project (Chulalongkorn University) may review project files and documents to examine if we have followed correct study procedures. However, any information that may lead to your identification will be removed. Moreover, your identity and personal details will not be appearing in any publications or presentations of the study findings. The recordings and notes taken of the interviews will be erased and destroyed respectively after data transcriptions and analysis.

**Compensation.** Your participation in this project will not incur you any financial implications. You will be given THB 200 as a token of appreciation for taking your time participating in the study. If you would like to have the interview at the Faculty of Pharmaceutical Sciences, Chulalongkorn University, you will be provided with THB 400 to cover your travel expenses.

**Contact person.** If you have any question or would like to obtain more information, the principal investigator of the study can be reached at all time (Mohd Shahezwan Abd Wahab, phone number: 0943317264; e-mail: [ewan.pharmcare@gmail.com](mailto:ewan.pharmcare@gmail.com)). If the researchers have new information regarding the benefits and risk of the study, you will be informed as soon as possible. If you require more information about the rights of research participants or would like to report if the researchers in this study does not behave towards the participants as indicated in the information, you may contact the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (RECCU), Jamjuree 1 Bldg., 2<sup>nd</sup> Fl., 254 Phyathai Rd., Patumwan district, Bangkok 10330, Thailand, Tel./Fax. 0-2218-3202, e-mail: [eccu@chula.ac.th](mailto:eccu@chula.ac.th).





## Appendix C: Informed Consent Form

Address .....

Date .....

Code number of participant .....

I who have signed here below agree to participate in this research project

**Title:** Development of a Determinant Scale of Pharmacist's Care for Herbal and Dietary Supplement (HDS) Users

**Principle researcher's name :** Mohd Shahezwan Abd Wahab

**Contact address:** Faculty of Pharmaceutical Sciences, Chulalongkorn University, 254 Phayathai Road, Wangmai Patumwan Bangkok, 10330, Thailand

**Telephone:** 0943317264

I have **read or been informed** about rationale and objective(s) of the project, what I will be engaged with in details, risk/harm and benefit of this project. The researcher has explained to me and I **clearly understand with satisfaction.**

I willingly **agree** to participate in this project and consent the researcher to interview me only once, for a duration of approximately 45 – 60 minutes. I understand that the procedure will be audio recorded. The recordings and notes of the interviews will be erased and destroyed respectively after data transcriptions and analysis.

I have **the right** to withdraw from this research project at any time as I wish without the need to **provide any reason.** My withdrawal from the study **will not have any negative impact upon me.**

The researcher has guaranteed that procedure(s) acted upon me would be exactly the same as indicated in the information. Any of my personal information will be **kept confidential.** Results of the study will be reported as total picture. Any of personal information which could be able to identify me will not appear in the report.

**If I am not treated as indicated in the information sheet,** I can report to the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (RECCU), Jamjuree 1 Bldg., 2<sup>nd</sup> Fl., 254 Phayathai Rd., Patumwan district, Bangkok 10330, Thailand, Tel./Fax. 0-2218-3202 E-mail: [eccu@chula.ac.th](mailto:eccu@chula.ac.th).

I also have received a copy of information sheet and informed consent form

Sign .....  
(.....)  
Researcher

Sign .....  
(.....)  
Participant

Sign .....  
(.....)  
Witness

### Appendix D: Contact Summary Form

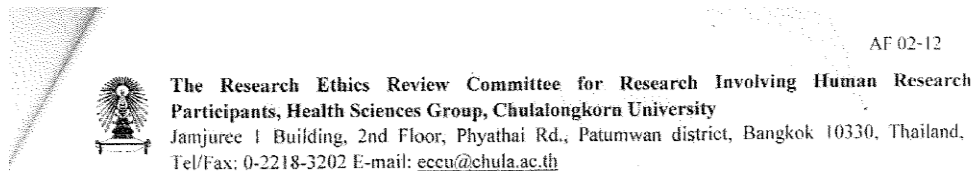
Location : Contact Date :  
Time : Duration :

1. What were the main issues or themes that struck you in this contact?
2. Summary of information obtained or failed to be obtained during the interview:

Question	Information
PCare for HDS users	
Behavioral belief	
Normative belief	
Control belief	
Professional normative belief	
Others	

3. Anything else that struck you as salient, interesting or important in this contact?
4. What can be improved in the next informant interview (e.g. questions, equipment, location, documents, etc.)?

## Appendix E: Ethical Approval for Qualitative Study: COA No. 189/2016



AF 02-12

COA No. 189/2016



### Certificate of Approval

Study Title No. 147.1/59 : DEVELOPMENT OF A DETERMINANT SCALE OF PHARMACIST'S CARE FOR HERBAL AND DIETARY SUPPLEMENT (HDS) USERS

Principal Investigator : MR. MOHD SHAHEZWAN ABD WAHAB


Place of Proposed Study/Institution : Faculty of Pharmaceutical Sciences,  
Chulalongkorn University

The Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University, Thailand, has approved constituted in accordance with the International Conference on Harmonization – Good Clinical Practice (ICH-GCP).

Signature:  Signature:   
 (Associate Professor Prida Tasanapradit, M.D.) (Assistant Professor Nuntaree Chaichanawongsaroj, Ph.D.)  
 Chairman Secretary

Date of Approval : 2 November 2016 Approval Expire date : 1 November 2017

#### The approval documents including

- 1) Research proposal
- 2) Patient/Participant Information Sheet and Informed Consent Form
- 3) Researcher  Protocol No. 147.1/59  
Date of Approval: 2 NOV 2016
- 4) Questionnaire Approval Expire Date: 1 NOV 2017

The approved investigator must comply with the following conditions:

1. The research/project activities must end on the approval expired date of the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (RECCU). In case the research/project is unable to complete within that date, the project extension can be applied one month prior to the RECCU approval expired date.
2. Strictly conduct the research/project activities as written in the proposal.
3. Using only the documents that bearing the RECCU's seal of approval with the subjects/volunteers (including subject information sheet, consent form, invitation letter for project/research participation (if available)).
4. Report to the RECCU for any serious adverse events within 5 working days
5. Report to the RECCU for any change of the research/project activities prior to conduct the activities.
6. Final report (AF 03-12) and abstract is required for a one year (or less) research/project and report within 30 days after the completion of the research/project. For thesis, abstract is required and report within 30 days after the completion of the research/project.
7. Annual progress report is needed for a two-year (or more) research/project and submit the progress report before the expire date of certificate. After the completion of the research/project processes as No. 6.

### Appendix F: Initial Item Pool, Item CVI and Comments from Reviewers

No.	Initial item	CVI	Remarks	Revised item
<b>Draft items for Direct TPB scale</b>				
<b>Attitude</b>				
1.	I think pharmacist care for the HDS users can bring many benefits to the customers, pharmacists and the drugstores.	1	-	-
2.	I enjoy providing care for the HDS users.	1	-	-
3.	I feel satisfied if I provide care for the HDS users.	1	Need minor revision.	If I provide care for the HDS users, I feel satisfied.
<b>Subjective norm</b>				
4.	The public expect me to provide care for the HDS users.	1	Need minor revision.	The public wants me to provide care for the HDS users.
5.	I need to provide care for the HDS users because this is what the society wants me to do.	1	Need minor revision.	I have to provide care for the HDS users because this is what the society wants me to do.
6.	People who are important to me want me to provide care for the HDS users.	0.75	Deleted	-
<b>Perceived behavioural control</b>				
7.	I am confident that I can provide care for the HDS users.	1	-	-
8.	For me to provide care for the HDS users is easy.	1	Need minor revision.	Providing care for the HDS users is easy.
9.	I can provide care for the HDS users if I want to.	0.75	Deleted	-
10.	Whether I provide care for the HDS users or not, is depends on me.	0.50	Deleted	-
11.	I believe that pharmacist care for the HDS users is a good thing to do.	1	-	-
12.	It is my professional responsibility as a community pharmacist to provide care for the HDS users.	1	-	-
<b>Intention</b>				
13.	I am always ready to provide care for the HDS users at my drugstore.	1	Need minor revision. Suggested to put time context.	I am ready to provide care for the HDS users on a regular basis during the next two weeks.
14.	I would like to provide care for the HDS users who come to my drugstore.	1	Need minor revision. Suggested to put time context.	I will try to provide care for the HDS users on a regular basis during the next two weeks.
15.	I have intention to provide care for the HDS users who	1	Need minor revision. Suggested to put time	I have intention to provide care for the HDS users on a

	come to my drugstore.		context.	regular basis during the next two weeks.
<b>Draft items for Indirect TPB scale</b>				
<b>Behavioural belief</b>				
1.	If I provide care, I can ensure the safety of the HDS users by considering side effects and disease- or drug-HDS interactions.	1	Change “considering” to “avoiding”.	If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions.
2.	If I provide care, I can ensure the HDS users are using the most suitable products.	1	-	-
3.	If I provide care, I can ensure the customers know the pros and cons of the HDS before deciding to use the products.	0.75	Deleted	-
4.	If I provide care for the HDS users, I can improve my knowledge about the HDS.	1	Need minor revision.	If I provide care for the HDS users, my knowledge about the HDS will be improved.
5.	If I provide care for the HDS users, I will be trustworthy.	1	Some CPs were not familiar with the word “trustworthy”. Therefore two synonyms were added.	If I provide care for the HDS users, I will be trustworthy (ethical / honest).
6.	If I provide care for the HDS users, they will come back to my drugstore in order to consult me.	1	-	-
7.	If I provide care for the HDS users, they will come back to my drugstore to make more purchasing.	1	Similar to item 6. Choose one.	-
8.	If I provide care for the HDS users, I can enhance the image of my drugstore.	0.75	-	-
9.	Providing care for the HDS users is time consuming.	0.75	-	-
<b>Normative belief</b>				
10.	My customers think that I should provide care for the HDS users.	1	Suggested to be more specific.	The HDS users want me to provide care for them.
11.	My colleagues (such as drugstore owner, other pharmacists, drugstore assistants, healthcare consultants, etc.) think that I should provide care for the HDS users.	1	Some CPs were not familiar with the word “colleagues”. Therefore the sentence was revised slightly.	Those who work with me (e.g., other pharmacists, drugstore assistants, healthcare consultants, etc.) think that I should provide care for the HDS users.
12.	The doctors think that I should provide care for the HDS users.	1	-	-
13.	The pharmaceutical companies encourage me to provide care for the HDS	0.75	Deleted	-

	users.			
14.	The Thai FDA encourage me to provide care for the HDS users.	0.75	Deleted	-
15.	The “Community Pharmacy Association” encourage me provide care for the HDS users.	0.50	Deleted	-
<b>Control belief</b>				
16.	I have received enough training about the HDS.	1	Suggested to revise the statement into a “belief” statement, “I believe”, “I think”, etc.	I think I have received enough training to provide care for the HDS.
17.	I am busy dealing with customers at the drugstore most of the times.	0.75	Deleted	-
18.	I have received sufficient education about the HDS in my previous undergraduate studies.	1	Suggested to revise the statement into a “belief” statement, “I believe”, “I think”, etc.	I believe I have received sufficient education about the HDS in my previous undergraduate studies.
19.	I think my knowledge about the HDS is good.	1	-	-
20.	The HDS users always start a conversation with me about their HDS use.	0.75	Deleted	-
21.	The HDS users are always open to my advice and suggestions.	0.75	Deleted	-
22.	The HDS users are always willing to spend time consulting me about their HDS use.	0.75	Deleted	-
23.	The HDS users are usually able to provide me with important details (such as medical, medication, and allergy histories).	0.75	Deleted	-
24.	My drugstore has a good source of information about the HDS.	1	Suggested to revise the statement into a “belief” statement, “I believe”, “I think”, etc.	In my opinion I have access to information sources including the scientific evidences for the HDS at my drugstore.
25.	I have easy access to the scientific evidences for the HDS.	1	Similar to item 24. Can be combined.	
26.	I always received assistance from my colleagues and assistants when I provide care for the HDS users.	0.50	Deleted	-
27.	The layout of my drugstore makes it easier for me to provide care for the HDS users.	0.75	Deleted	-
28.	Printed materials (such as the leaflets, posters, booklets, etc.) about the	1	Suggested to revise the statement into a “belief” statement, “I believe”, “I	I think I have enough informational materials (e.g., leaflets, posters,

	HDS make it easier for me to provide care for the HDS users.		think”, etc.	booklets, etc.) about the HDS at my drugstore.
<b>Draft items for PCare-HDS scale</b>				
<b>Foster relationship</b>				
1.	I listen carefully to the customers’ inquiries or requests for the HDS.	1	-	-
2.	I show open and neutral attitude when receiving inquiries or requests for the HDS from the customers.	0.75	Deleted	-
3.	I develop a good relationship with the HDS users.	1		-
4.	I am ready to receive questions and provide consultation about the HDS.	0.75	Deleted	-
5.	I respect the customers’ intentions to use the HDS to treat diseases, or to maintain their health.	1	Need minor revision.	I respect the customers’ intentions to use the HDS for treating diseases, or maintaining their health.
<b>Gather relevant information</b>				
6.	I ask the reasons why the customers would want to use the HDS.	1	-	-
7.	I ask the HDS users if they are using any medicines.	1	-	-
8.	I ask the HDS users if they have any illnesses or medical conditions (pregnancy, allergies, etc.).	1	-	-
<b>Assess HDS use</b>				
9.	I assess whether the HDS has any indication for the customers.	1	-	-
10.	I identify any adverse effects or other HDS-related problems associated with the use of the HDS.	1	-	-
11.	I assess whether the customers require further physical or laboratory examinations (e.g., blood glucose test, or blood pressure test) before using the HDS	1	Suggested to change “assess” to “recommend”.	I recommend the customers to have physical or laboratory examinations (e.g., blood glucose test or blood pressure test) before using the HDS.
12.	I identify disease– or drug–HDS interactions if the HDS users have medical illnesses or are using medicines.	1	-	-
<b>Assist informed decision</b>				
13.	To help the customers decide on whether or not to	1	Need minor revision.	I provide unbiased information about the HDS

	use the HDS, I provide unbiased information about the HDS.			to help the customers decide on whether or not to use the HDS.
14.	To help the customers decide on whether or not to use the HDS I explain the limitations and risks of the products.	1	-	-
15.	To help the customers decide on whether or not to use the HDS I explain the potential benefits of the products.	1	Similar to item 14. Can be combined.	-
16.	I tell the customers if there is no scientific evidence for the HDS use.	1	-	-
<b>Make professional decision</b>				
17.	If there is no contraindication to HDS use, I attempt to provide suggestion for the most appropriate HDS to the customers.	1	Suggested to briefly describe “appropriate HDS”.	If there is no contraindication to HDS use, I recommend HDS that is appropriate to the customer’s needs, in a suitable dose, for an adequate period of time, and at a suitable cost.
18.	If I need to suggest an HDS, I provide suggestions without conflict of interests.	0.75	Deleted	-
19.	I provide several appropriate choices of HDS for the customers to choose.	0.75	Deleted	-
20.	If the use of the HDS is not appropriate (not indicated, not appropriate, or contraindicated), I advise the customers not to use the HDS.	1	-	-
21.	I suggest using conventional medicine if it is more appropriate than using the HDS.	1	Change “conventional medicine” to “Western (modern) medicine”.	I suggest using Western (modern) medicine if it is more appropriate than using the HDS.
22.	I refer the customers to the physicians if I found out that they actually need medical treatment.	1	-	-
23.	If HDS users experience adverse events from HDS use I will report this to the authority.	1	-	-
<b>Provide advice or information</b>				
24.	When dispensing HDS, I tell the HDS users about what they can expect from the use of the HDS.	1	Suggested to briefly describe “what they can expect”.	When dispensing HDS, I tell the HDS users about what they can expect from the HDS (positive effects



				and side effects).
25.	When dispensing HDS, I advise how to use the HDS including the directions for use, and the maximum dose per day.	1	-	-
26.	When dispensing HDS, I provide counseling on the possible adverse effects of the HDS.	1	Similar to item 23. Can be combined.	-
27.	When dispensing HDS, I advise to avoid other non-prescription medications, and HDS that can cause interactions.	1	Need minor revision.	When dispensing HDS, I advise the HDS users to avoid other OTC medications, and HDS that can cause interactions.
28.	When dispensing HDS, I advise them to monitor their symptoms (improvement or worsening of health).	1	Change “them” to “the HDS users”.	When dispensing HDS, I advise the HDS users to monitor their symptoms (e.g., improvement or worsening of health).
29.	When dispensing HDS, I advise the HDS users to seek medical attention if their symptoms worsened.	1	-	-
30.	When dispensing HDS, I tell them the importance of adherence with the prescribed medicines, if they are using prescribed medicine,	1	Change “them” to “the HDS users”.	When dispensing HDS, I tell the HDS users the importance of adherence with the prescribed medicines, if they are using prescribed medicine.
31.	When dispensing HDS, I advise the HDS users to inform their physicians about their HDS use.	1	-	-
32.	I provide the HDS users with printed HDS information (brochures / pamphlets, or booklets, etc.).	1	Need minor revision.	I provide the HDS users with relevant HDS informational materials (e.g., brochures / pamphlets, or booklets, etc.).
33.	I make available brochures / pamphlets, booklets or other educational materials (posters, displays, etc.) about the HDS in my drugstore.	0.75	Deleted	-
34.	I show the educational materials (posters, displays, etc.) about the HDS that are available at the drugstore to the customers.	0.75	Deleted	-
35.	I use reliable sources of information when providing information to the HDS users.	1	-	-
36.	I make sure promotional	0.75	Deleted	-

	and reference materials in my drugstore are not misleading.			
37.	I follow up with the HDS users to find out if they experience good effects from the HDS use.	0.75	Deleted	-
38.	I follow up with the HDS users to find out if they experience negative effects from the HDS use.	0.75	Deleted	-
<b>Seeking HDS information</b>				
39.	I participate in awareness program to promote safe use of HDS.	0.50	Deleted	-
40.	I attempt to attend continuing education about the HDS.	0.75	Deleted	-
41.	I perform self-study about the HDS.	0.75	Deleted	-
42.	I read original research or review articles about the HDS.	0.75	Deleted	-
43.	I make sure that I know how to evaluate information about the HDS from various sources of information.	0.75	Deleted	-
44.	I request information about the HDS from the manufacturers.	0.75	Deleted	-
45.	I make sure that I am familiar with the common use of HDS.	1	Need minor revision. Suggested to change "common use" to "indications".	I make sure I know the indications of common HDS.
46.	I make sure that I am familiar with the pharmacology and pharmacokinetics of common HDS.	0.75	Deleted	-
47.	I make sure that I know some proven and potential interactions between common HDS and conventional (modern) medications.	1	Need minor revision.	I make sure I know some proven and potential disease- and drug-HDS interactions.
48.	I make sure that I know the signs and symptoms of potential adverse events and toxicities of common HDS.	1	Need minor revision.	I make sure I know the signs and symptoms of potential adverse effects of common HDS.
49.	I make sure that I know the effects of diseases and medical conditions (e.g., impaired renal / hepatic functions, pregnancy, etc.)	0.75	Deleted	-

	on the absorption, distribution, and elimination of HDS.			
<b>Maintain HDS product quality</b>				
50.	I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice (GMP).	1	-	-
51.	I only stock HDS that are of good quality.	0.75	Deleted	-
52.	I avoid keeping HDS that have excessive and illogical claims.	1	Suggested to briefly describe “illogical claims”.	I avoid keeping HDS that come with non-logical claims (e.g., curing cancer, whitening skin in few days, etc.).
53.	I avoid keeping HDS that are only endorsed by testimonials.	0.75	Deleted	-
54.	I ensure proper storage of HDS products in my drugstore.	1	Need minor revision.	I ensure good storage of HDS products in my drugstore.

## Appendix G: Survey Instrument Used in Quantitative Study

### Pharmacist Care for Herbal and Dietary Supplement Users Survey

#### Definitions:

##### **Herbal and dietary supplement (HDS):**

HDS in this survey refer to HDS products in the form of pills, capsules, tablets, powder or liquids that are taken by mouth (orally), and are used for treatment of disease or for maintaining health. Examples of HDS include ginkgo biloba, turmeric, *Fah Talai Jone*, garlic, vitamins (e.g. A, B, C, D, E, K, or multivitamins), and minerals (e.g. calcium, zinc, magnesium).

##### **Pharmacists care:**

Professional activities carried out by a community pharmacist when dealing with HDS users (e.g. gathering medical and medication histories, discussing about appropriate HDS selection, and providing counseling, etc.).

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#### **Section 1: Opinion on pharmacist care for the HDS users**

Please read each of the following statement, and please circle a number from 1 to 5 depending on your level of agreement. You may feel that some survey statements are repetitive. However, it is very important for you to provide a response to all of them. Please note that there is no correct or wrong answer.

**1 = STRONGLY DISAGREE; 2 = DISAGREE; 3 = NEUTRAL;  
4 = AGREE; 5 = STRONGLY AGREE; N/A = NON-APPLICABLE**

1.	I think pharmacist care for the HDS users can bring many benefits to the customers, pharmacists and the drugstores.	1	2	3	4	5	N/A
2.	I enjoy providing care for the HDS users.	1	2	3	4	5	N/A
3.	If I provide care for the HDS users, I feel satisfied.	1	2	3	4	5	N/A
4.	The public wants me to provide care for the HDS users.	1	2	3	4	5	N/A
5.	I have to provide care for the HDS users because this is what the society wants me to do.	1	2	3	4	5	N/A
6.	I am confident that I can provide care for the HDS users.	1	2	3	4	5	N/A
7.	Providing care for the HDS users is easy.	1	2	3	4	5	N/A
8.	If I provide care, I can ensure the safety of the HDS users by avoiding side effects, and disease- or drug-HDS interactions.	1	2	3	4	5	N/A
9.	If I provide care, I can ensure the HDS users are using the most suitable products.	1	2	3	4	5	N/A
10.	If I provide care for the HDS users, my knowledge about the HDS will be improved.	1	2	3	4	5	N/A

11. If I provide care for the HDS users, I will be trustworthy (ethical / honest).	1	2	3	4	5	N/A
12. If I provide care for the HDS users, they will come back to my drugstore in order to consult me.	1	2	3	4	5	N/A
13. The HDS users want me to provide care for them.	1	2	3	4	5	N/A
14. Those who work with me (e.g. other pharmacists, drugstore assistants, healthcare consultants, etc.) think that I should provide care for the HDS users.	1	2	3	4	5	N/A
15. The doctors think that I should provide care for the HDS users.	1	2	3	4	5	N/A
16. I think I have received enough training to provide care for the HDS users.	1	2	3	4	5	N/A
17. I think I can manage my time so that I can provide care for the HDS users.	1	2	3	4	5	N/A
18. I believe I have received sufficient education about the HDS in my previous undergraduate studies.	1	2	3	4	5	N/A
19. I think my knowledge about the HDS is good.	1	2	3	4	5	N/A
20. I think the HDS users are happy to talk with me about their HDS use	1	2	3	4	5	N/A
21. I think the HDS users would like to receive advice and suggestions about the HDS from me.	1	2	3	4	5	N/A
22. In my opinion I have access to information about the HDS including the scientific evidences at my drugstore.	1	2	3	4	5	N/A
23. I think I have enough informational materials (e.g. leaflets, posters, booklets, etc.) about the HDS at my drugstore.	1	2	3	4	5	N/A
24. As a community pharmacist, I believe that providing care for the HDS users is something I should do.	1	2	3	4	5	N/A
25. It is my professional responsibility as a community pharmacist to provide care for the HDS users.	1	2	3	4	5	N/A
26. I am ready to provide care for the HDS users on a regular basis during the next two weeks.	1	2	3	4	5	N/A
27. I will try to provide care for the HDS users on a regular basis during the next two weeks.	1	2	3	4	5	N/A
28. I have intention to provide care for the HDS users on a regular basis during the next two weeks.	1	2	3	4	5	N/A

**1 = NEVER; 2 = SELDOM; 3 = SOMETIMES; 4 = OFTEN; 5 = ALWAYS;**  
**N/A = NON-APPLICABLE**

29. For the past two weeks, how often have you provided care for the HDS users?	1	2	3	4	5	N/A
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## **Section 2: Specific pharmacist care activities**

In general, how often do you perform each of the following pharmacist care activity? Please circle a number from 1 to 5 depending on your level of engagement with the activity. You may feel that some survey statements are repetitive. However, it is very important for you to provide a response to all of them. Please note that there is no correct or wrong answer.

**1 = NEVER; 2 = SELDOM; 3 = SOMETIMES; 4 = OFTEN; 5 = ALWAYS**

30. I listen carefully to the customers' inquiries or requests for the HDS.	1	2	3	4	5
31. I develop a good relationship with the HDS users.	1	2	3	4	5
32. I respect the customers' intentions to use the HDS for treating diseases, or maintaining their health.	1	2	3	4	5
33. I ask the reasons why the customers want to use the HDS.	1	2	3	4	5
34. I ask the HDS users if they are using any medicines.	1	2	3	4	5
35. I ask the HDS users if they have any other illnesses or medical conditions (e.g. pregnancy, allergies, etc.).	1	2	3	4	5
36. I assess whether the HDS has any indication for the customers.	1	2	3	4	5
37. I identify any HDS-related problems associated with the use of the HDS.	1	2	3	4	5
38. I recommend the customers to have physical or laboratory examinations (e.g. blood glucose test or blood pressure test) before using the HDS.	1	2	3	4	5
39. I identify disease- or drug-HDS interactions if the HDS users have medical illnesses or are using medicines.	1	2	3	4	5
40. I provide unbiased information about the HDS to help the customers decide on whether or not to use the HDS.	1	2	3	4	5
41. To help the customers decide on whether or not to use the HDS, I explain both the potential benefits and limitations of the products.	1	2	3	4	5
42. I tell the customers if there is no scientific evidence for the HDS use.	1	2	3	4	5
43. If there is no contraindication to HDS use, I recommend HDS that is appropriate to the customer's needs, in a suitable dose, for an adequate period of time, and at a suitable cost.	1	2	3	4	5
44. If the use of the HDS is not appropriate (e.g. not indicated, not appropriate, or contraindicated), I advise the customers not to use the HDS.	1	2	3	4	5
45. I suggest using Western (modern) medicine if it is more appropriate than using the HDS.	1	2	3	4	5
46. I refer the customers to the physicians if I found out that they actually need medical treatment.	1	2	3	4	5
47. When dispensing HDS, I tell the HDS users about what they can expect from the HDS (positive effects and side effects).	1	2	3	4	5
48. When dispensing HDS, I advise how to use the HDS (e.g. directions for use and dose per day).	1	2	3	4	5
49. When dispensing HDS, I advise the HDS users to avoid other OTC medications, and HDS that can cause interactions.	1	2	3	4	5
50. When dispensing HDS, I advise the HDS users to monitor their symptoms (e.g. improvement or worsening of health).	1	2	3	4	5
51. When dispensing HDS, I advise the HDS users to seek medical attention if their symptoms worsened.	1	2	3	4	5
52. When dispensing HDS, I tell the HDS users the importance of adherence with the prescribed medicines, if they are using prescribed medicine.	1	2	3	4	5
53. When dispensing HDS, I advise the HDS users to tell their physicians about their HDS use.	1	2	3	4	5
54. I provide the HDS users with relevant HDS informational	1	2	3	4	5

materials (e.g. brochures, pamphlets, or booklets, etc.).					
55. I use reliable sources of information when providing information to the HDS users.	1	2	3	4	5
56. I report to the authority if the HDS users experience adverse events from HDS use.	1	2	3	4	5
57. I seek information about the indications of common HDS.	1	2	3	4	5
58. I seek information about disease– and drug–HDS interactions.	1	2	3	4	5
59. I seek information about signs and symptoms of adverse effects of common HDS.	1	2	3	4	5
60. I make sure that the HDS in my drugstore are produced by companies that practice good manufacturing practice.	1	2	3	4	5
61. I make sure that the HDS in my drugstore do not have non-logical claims (e.g. curing cancer, whitening skin in few days, etc.).	1	2	3	4	5
62. I make sure that the HDS in my drugstore are stored properly.	1	2	3	4	5

### **Section 3: Personal information**

Please check the box next to your answer or fill in the blank with your responses.

Gender	<input type="checkbox"/> Male	<input type="checkbox"/> Female
Which pharmacy undergraduate program have you completed?	<input type="checkbox"/> Bachelor of Pharmacy (BPharm) <input type="checkbox"/> Bachelor of Science in Pharmacy (BSciPharm) <input type="checkbox"/> Doctor of Pharmacy (PharmD) <input type="checkbox"/> Other _____	
In what year were you registered as a pharmacist in Thailand?	_____ (e.g. 2000 or 2543)	
Have you received further education in pharmacy? If yes please tick the appropriate answer ( <i>You can tick more than one box</i> ).	<input type="checkbox"/> No <input type="checkbox"/> Master's degree (e.g. MClPharm) <input type="checkbox"/> Doctor of Philosophy (PhD) <input type="checkbox"/> Other _____	
Have you attended any continuing education program about the HDS in the past six months? (e.g. conference, workshop, seminar, etc.)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Have you used the HDS in the past six (6) months?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Please answer the following questions about your work as a community pharmacist. If you are working at more than one drugstore, please provide answer with regard to the drugstore that you spend the most time.

What is your position as a community pharmacist in your drugstore ( <i>You can tick more than one box</i> )	<input type="checkbox"/> Full time staff <input type="checkbox"/> Manager <input type="checkbox"/> Other _____	<input type="checkbox"/> Part time staff <input type="checkbox"/> Owner
What is the type of your drugstore?	<input type="checkbox"/> Chain / franchise <input type="checkbox"/> University-affiliated <input type="checkbox"/> Other _____	
How long have you been working in the drugstore?	_____ year(s) _____ month(s)	

What is the postcode of the location of your drugstore?	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
How many hours do you normally work in the drugstore per week?	_____ Hours/week				
Approximately how many customers do you received per day?	_____ # customers per day				
Approximately how many customers buy the HDS at your drugstore per day?	_____ # customers per day				
How many other staff members are working together with you in the drugstore?	_____ # pharmacists _____ # pharmacy assistants _____ # pharmacy students (interns) _____ # other				
<p><i>“By completing and returning the survey, you will have a chance to win a book voucher worth THB 1000. Please state your e-mail address so that we can contact you if you are the lucky winner!”</i></p> <p><b>Your e-mail address:</b></p>					

**THANK YOU FOR YOUR COOPERATION**

**Please return the questionnaire to us in the stamped-envelope provided.**

จุฬาลงกรณ์มหาวิทยาลัย  
CHULALONGKORN UNIVERSITY



## Appendix H: Ethical Approval for Quantitative Study: COA No. 224/2017



The Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University  
Jamjuree 1 Building, 2nd Floor, Phyathai Rd., Patumwan district, Bangkok 10330, Thailand  
Tel/Fax: 0-2218-3202 E-mail: [eccu@chula.ac.th](mailto:eccu@chula.ac.th)

AF 02-12

COA No. 224/2017

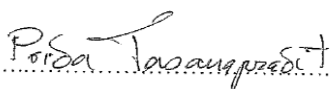
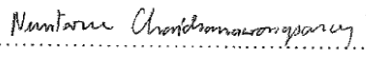
### Certificate of Approval

Study Title No. 147.1/59 : DEVELOPMENT OF A DETERMINANT SCALE OF PHARMACIST'S CARE FOR HERBAL AND DIETARY SUPPLEMENT (HDS) USERS

Principal Investigator : MR. MOHD SHAHEZWAN ABD WAHAB

Place of Proposed Study/Institution : Faculty of Pharmaceutical Sciences,  
Chulalongkorn University

The Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University, Thailand, has approved constituted in accordance with the International Conference on Harmonization – Good Clinical Practice (ICH-GCP) of phase 2-3 of research project.

Signature:  Signature:   
(Associate Professor Prida Tasanapradit, M.D.) (Assistant Professor Nuntaree Chaichanawongsaroj, Ph.D.)  
Chairman Secretary

Date of Approval : 22 November 2017 Approval Expire date : 21 November 2018

#### The approval documents including

- 1) Research proposal
- 2) Patient/Participant Information Sheet and Informed Consent Form
- 3) Researcher
- 4) Questionnaire



Protocol No. 147.1/59  
Date of Approval 22 NOV 2017  
Approval Expire Date 21 NOV 2018

#### The approved investigator must comply with the following conditions:

1. The research/project activities must end on the approval expired date of the Research Ethics Review Committee for Research Involving Human Research Participants, Health Sciences Group, Chulalongkorn University (RECCU). In case the research/project is unable to complete within that date, the project extension can be applied one month prior to the RECCU approval expired date.
2. Strictly conduct the research/project activities as written in the proposal.
3. Using only the documents that bearing the RECCU's seal of approval with the subjects/volunteers (including subject information sheet, consent form, invitation letter for project/research participation (if available)).
4. Report to the RECCU for any serious adverse events within 5 working days
5. Report to the RECCU for any change of the research/project activities prior to conduct the activities.
6. Final report (AF 03-12) and abstract is required for a one year (or less) research/project and report within 30 days after the completion of the research/project. For thesis, abstract is required and report within 30 days after the completion of the research/project.
7. Annual progress report is needed for a two- year (or more) research/project and submit the progress report before the expire date of certificate. After the completion of the research/project processes as No. 6.

### Appendix I: Percentage of Missing Value for Each Item of the Scales

Items	Number of missing values	Percentage of missing value n (%)
<b>Direct TPB</b>		
ATT1	4	0.6
ATT2	2	0.3
ATT3	2	0.3
SN1	2	0.3
SN2	5	0.7
PBC1	6	0.9
PBC2	2	0.3
PN1	6	0.9
PN2	8	1.1
INT1	10	1.4
INT2	14	2.0
INT3	12	1.7
<b>Indirect TPB</b>		
BB1	4	0.6
BB2	2	0.3
BB3	1	0.1
BB4	3	0.4
BB5	5	0.7
NB1	5	0.7
NB2	6	0.9
NB3	7	1.0
CB1	5	0.7
CB2	4	0.6
CB3	5	0.7
CB4	4	0.6
CB5	4	0.6
CB6	4	0.6
CB7	13	1.8
CB8	11	1.6
<b>PCare-HDS</b>		
FR1	20	2.8
FR2	20	2.8
FR3	20	2.8
GI1	20	2.8
GI2	20	2.8
GI3	20	2.8
AU1	20	2.8
AU2	20	2.8
AU3	20	2.8
AID1	19	2.7
AID2	19	2.7
AID3	19	2.7
MPD1	19	2.7
MPD2	20	2.8
MPD3	20	2.8
MPD4	20	2.8

MPD5	21	3.0
MPD6	19	2.7
PAI1	19	2.7
PAI2	19	2.7
PAI3	19	2.7
PAI4	19	2.7
PAI5	19	2.7
PAI6	19	2.7
PAI7	19	2.7
PAI8	19	2.7
SI1	19	2.7
SI2	19	2.7
SI3	19	2.7
SI4	19	2.7
MPQ1	19	2.7
MPQ2	19	2.7
MPQ3	19	2.7

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ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention; BB = behavioural belief; NB = normative belief; CB = control belief; FR = foster relationship; GI = gather information; AU = assess HDS use; AID = assist informed decision; MPD = make professional decision; PAI = provide advice or information; SI = seek HDS information; MPQ = maintain HDS product quality

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# **Appendix J: Socio-Demographic Characteristics of Completer and Non-Completer Respondents (N = 703)**

Demographics	Completer (n = 661)	Non-completer (n = 42)	P value <sup>a</sup>
n (%)			
Gender			
Male	221 (33.4)	13 (31)	0.741
Female	440 (66.6)	29 (69)	
Previous undergraduate education			
PharmD	83 (12.6)	9 (21.4)	0.247
BPharm / BSciPharm	533 (80.6)	30 (71.4)	
Others	45 (6.8)	3 (7.1)	
Having a postgraduate qualification			
Yes	93 (14.1)	2 (4.8)	0.087
No	568 (85.9)	40 (95.2)	
Number of years as a registered pharmacist			
≤ 10	230 (34.8)	17 (40.5)	0.474
11 – 20	280 (42.4)	19 (45.2)	
21 – 30	126 (19.1)	6 (14.3)	
> 30	25 (3.8)	0 (0)	
Type of community pharmacy			
Chain / franchise	222 (33.6)	12 (28.6)	0.771
Independent	420 (63.5)	29 (69)	
Others	19 (2.9)	1 (2.4)	
Number of years working in community pharmacy			
≤ 5	333 (50.4)	20 (47.5)	0.911
6 – 10	215 (32.5)	15 (35.7)	
> 10	113 (17.1)	7 (16.7)	
Position at community pharmacy			
Full-time	492 (74.4)	34 (81)	0.345
Part-time	169 (25.6)	8 (19)	
Number of hours working in a week			
≤ 20	118 (17.9)	4 (9.5)	0.369
21 – 40	125 (18.9)	8 (19)	
> 40	418 (63.2)	30 (71.4)	
HDS users <sup>b</sup>			
Yes	460 (69.6)	24 (57.1)	0.091
No	201 (30.4)	18 (42.9)	
Have attended HDS-related training <sup>b</sup>			
Yes	281 (42.5)	16 (38.1)	0.574
No	380 (57.5)	26 (61.9)	
Holding a managerial post at community pharmacy			
Yes	43 (6.5)	2 (4.8)	1.000 <sup>c</sup>
No	618 (93.5)	40 (95.2)	
Owner of community pharmacy			

Yes	202 (30.6)	14 (33.3)	0.706
No	459 (69.4)	28 (66.7)	
Number of pharmacist coworkers			
None	461 (69.7)	35 (83.3)	0.292
1	165 (25)	6 (14.3)	
2	25 (3.8)	1 (2.4)	
> 2	10 (1.5)	0 (0)	
Number of co-workers including pharmacists			
None	380 (57.5)	29 (69)	0.521
1	160 (24.2)	8 (19)	
2	75 (11.3)	3 (7.1)	
> 2	46 (7)	2 (4.8)	
Number of customers daily			
≤ 50	297 (44.9)	18 (42.9)	0.551
51 – 100	286 (43.3)	21 (50)	
> 100	78 (11.8)	3 (7.1)	
Number of HDS customers daily			
≤ 5	211 (31.9)	18 (42.9)	0.087
6 – 10	170 (25.7)	8 (19)	
11 – 15	150 (22.7)	13 (31)	
> 15	130 (19.7)	3 (7.1)	

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<sup>a</sup> Chi-squared test used unless specified otherwise

<sup>b</sup> In the past 6 months

<sup>c</sup> Fisher's exact test used

HDS, herbal and dietary supplements

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**Appendix K: Socio-Demographic Characteristics of the Early and Late Responders for Mail Survey (N = 254)**

Demographics	Early responders (n = 166)	Late responders (n = 88)	P value <sup>a</sup>
n (%)			
Gender			
Male	46 (27.7)	24 (27.3)	0.941
Female	120 (72.3)	64 (72.7)	
Previous undergraduate education			
PharmD	16 (9.6)	7 (8)	0.115
BPharm / BSciPharm	147 (88.6)	75 (85.2)	
Others	3 (1.8)	6 (6.8)	
Having a postgraduate qualification			
Yes	22 (13.3)	14 (15.9)	0.564
No	144 (86.7)	74 (84.1)	
Number of years as a registered pharmacist			
≤ 10	56 (33.7)	23 (26.1)	0.091
11 – 20	68 (41)	50 (56.8)	
21 – 30	26 (15.7)	11 (12.5)	
> 30	16 (9.6)	4 (4.5)	
Type of community pharmacy			
Chain / franchise	71 (42.8)	27 (30.7)	0.100
Independent	92 (55.4)	57 (64.8)	
Others	3 (1.8)	4 (4.5)	
Number of years working in community pharmacy			
≤ 5	95 (57.2)	44 (50)	0.538
6 – 10	36 (21.7)	23 (26.1)	
> 10	35 (21.1)	21 (23.9)	
Position at community pharmacy			
Full-time	135 (81.3)	72 (81.8)	0.923
Part-time	31 (18.7)	16 (18.2)	
Number of hours working in a week			
≤ 20	22 (13.3)	14 (15.9)	0.828
21 – 40	23 (13.9)	11 (12.5)	
> 40	121 (72.9)	63 (71.6)	
HDS users <sup>b</sup>			
Yes	116 (69.9)	51 (58)	0.057
No	50 (30.1)	37 (42)	
Have attended HDS-related training <sup>b</sup>			
Yes	76 (45.8)	40 (45.5)	0.960
No	90 (54.2)	48 (54.5)	
Holding a managerial post at community pharmacy			
Yes	16 (9.6)	4 (4.5)	0.152
No	150 (90.4)	84 (95.5)	

Owner of community pharmacy			
Yes	57 (34.3)	26 (29.5)	0.438
No	109 (65.7)	62 (70.5)	
Number of pharmacist coworkers			
None	123 (74.1)	65 (73.9)	0.696
1	36 (21.7)	19 (21.6)	
2	5 (3)	4 (4.5)	
> 2	2 (1.2)	0 (0)	
Number of co-workers including pharmacists			
None	97 (58.4)	58 (65.9)	0.236
1	30 (18.1)	15 (17)	
2	30 (18.1)	8 (9.1)	
> 2	9 (5.4)	7 (8)	
Number of customers daily			
≤ 50	54 (32.5)	34 (38.6)	0.282
51 – 100	96 (57.8)	42 (47.7)	
> 100	16 (9.6)	12 (136)	
Number of HDS customers daily			
≤ 5	37 (22.3)	21 (23.9)	0.989
6 – 10	38 (22.9)	19 (21.6)	
11 – 15	52 (31.3)	28 (31.8)	
> 15	39 (23.5)	20 (22.7)	
<sup>a</sup> Chi-squared test used			
<sup>b</sup> In the past 6 months			
HDS, herbal and dietary supplements			

**Appendix L: Socio-Demographic Characteristics of the Early and Late Responders for the Online Survey (N = 96)**

Demographics	Early responders (n = 57)	Late responders (n = 39)	P value <sup>a</sup>
n (%)			
Gender			
Male	26 (45.6)	16 (41)	0.656
Female	31 (54.4)	23 (59)	
Previous undergraduate education			
PharmD	13 (22.8)	8 (20.5)	0.935
BPharm / BSciPharm	43 (75.4)	30 (76.9)	
Others	1 (1.8)	1 (2.6)	
Having a postgraduate qualification			
Yes	13 (22.8)	7 (17.9)	0.565
No	44 (77.2)	32 (82.1)	
Number of years as a registered pharmacist			
≤ 10	24 (42.1)	20 (51.3)	0.443
11 – 20	24 (42.1)	12 (30.8)	
21 – 30	9 (15.8)	6 (15.4)	
> 30	0 (0)	1 (2.6)	
Type of community pharmacy			
Chain / franchise	24 (42.1)	12 (30.8)	0.133
Independent	32 (56.1)	23 (59)	
Others	1 (1.8)	4 (10.3)	
Number of years working in community pharmacy			
≤ 5	24 (42.1)	21 (53.8)	0.526
6 – 10	24 (42.1)	13 (33.3)	
> 10	9 (15.8)	5 (12.8)	
Position at community pharmacy			
Full-time	39 (68.4)	19 (48.7)	0.053
Part-time	18 (31.6)	20 (51.3)	
Number of hours working in a week			
≤ 20	13 (22.8)	15 (38.5)	0.237
21 – 40	11 (19.3)	7 (17.9)	
> 40	33 (57.9)	17 (43.6)	
HDS users <sup>b</sup>			
Yes	47 (82.5)	33 (84.6)	0.780
No	10 (17.5)	8 (15.4)	
Have attended HDS-related training <sup>b</sup>			
Yes	28 (49.1)	16 (41)	0.434
No	29 (50.9)	23 (59)	
Holding a managerial post at community pharmacy			
Yes	3 (5.3)	5 (12.8)	0.264 <sup>c</sup>
No	54 (94.7)	34 (87.2)	



Owner of community pharmacy			
Yes	19 (33.3)	11 (28.2)	0.594
No	38 (66.7)	28 (71.8)	
Number of pharmacist coworkers			
None	40 (70.2)	21 (53.8)	0.292
1	8 (14)	9 (23.1)	
2	7 (12.3)	5 (12.8)	
> 2	2 (3.5)	4 (10.3)	
Number of co-workers including pharmacists			
None	20 (35.1)	10 (25.6)	0.802
1	16 (28.1)	12 (30.8)	
2	12 (21.1)	10 (25.6)	
> 2	9 (15.8)	7 (17.9)	
Number of customers daily			
≤ 50	25 (43.9)	23 (59)	0.205
51 – 100	19 (33.3)	12 (30.8)	
> 100	13 (22.8)	4 (10.3)	
Number of HDS customers daily			
≤ 5	24 (42.1)	18 (46.2)	0.956
6 – 10	11 (19.3)	6 (15.4)	
11 – 15	8 (14)	5 (12.8)	
> 15	14 (24.6)	10 (25.6)	

<sup>a</sup> Chi-squared test used unless specified otherwise

<sup>b</sup> In the past 6 months

<sup>c</sup> Fisher's exact test used

**Appendix M: Socio-Demographic Characteristics of the Samples for Stage 1 And 2 Data Analysis of the Direct and Indirect TPB Scales (N = 678)**

Demographics	Stage 1 sample (n = 339)	Stage 2 sample (n = 339)	<i>P</i> value <sup>a</sup>	Total (n = 678)
Gender				
Male	126 (37.2)	101 (29.8)	0.051	227 (33.5)
Female	213 (62.8)	238 (70.2)		451 (66.5)
Previous undergraduate education				
PharmD	41 (12.1)	46 (13.6)	0.664	87 (12.8)
BPharm / BSciPharm	272 (80.2)	272 (80.2)		544 (80.2)
Others	26 (7.7)	21 (6.2)		47 (6.9)
Having a postgraduate qualification				
Yes	46 (13.6)	47 (13.9)	1.000	93 (13.7)
No	293 (86.4)	292 (86.1)		585 (86.3)
Number of years as a registered pharmacist				
≤ 10	119 (35.1)	117 (34.5)	0.950	236 (34.8)
11 – 20	141 (41.6)	148 (43.7)		289 (42.6)
21 – 30	66 (19.5)	62 (18.3)		128 (18.9)
> 30	13 (3.8)	12 (3.5)		25 (3.7)
Type of community pharmacy				
Chain / franchise	118 (34.8)	108 (31.9)	0.598	226 (33.3)
Independent	213 (62.8)	220 (64.9)		433 (63.9)
Others	8 (2.4)	11 (3.2)		19 (2.8)
Number of years working in community pharmacy				
≤ 5	167 (49.3)	173 (51)	0.202	340 (50.1)
6 – 10	121 (35.7)	102 (30.1)		223 (32.9)
> 10	51 (15)	64 (18.9)		115 (17)
Position at community pharmacy				
Full-time	255 (75.2)	252 (74.8)	0.791	507 (74.8)
Part-time	84 (24.8)	87 (25.7)		171 (25.2)
Number of hours working in a week				
≤ 20	56 (16.5)	62 (18.3)	0.831	118 (17.4)
21 – 40	64 (18.9)	63 (18.6)		127 (18.7)
> 40	219 (64.6)	214 (63.1)		433 (63.9)
HDS users <sup>b</sup>				
Yes	236 (69.6)	233 (68.7)	0.803	469 (69.2)
No	103 (30.4)	106 (31.3)		209 (30.8)
Have attended HDS-related training <sup>b</sup>				
Yes	144 (42.5)	144 (42.5)	1.000	288 (42.5)
No	195 (57.5)	195 (57.5)		390 (57.5)
Holding a managerial post at community pharmacy				
Yes	24 (7.1)	19 (5.6)	0.529	43 (6.3)
No	315 (92.9)	320 (94.4)		635 (93.7)
Owner of community pharmacy				
Yes	107 (31.6)	99 (29.2)	0.559	206 (30.4)
No	232 (68.4)	240 (70.8)		472 (69.6)

Number of pharmacist coworkers				
None	241 (71.1)	237 (69.9)	0.494	478 (70.5)
1	83 (24.5)	82 (24.2)		165 (24.3)
2	9 (2.7)	16 (4.7)		25 (3.7)
> 2	6 (1.8)	4 (1.2)		10 (1.5)
Number of co-workers including pharmacists				
None	191 (56.3)	200 (59)	0.241	391 (57.7)
1	91 (26.8)	74 (21.8)		165 (24.3)
2	32 (9.4)	44 (13)		76 (11.2)
> 2	25 (7.4)	21 (6.2)		46 (6.8)
Number of customers daily				
≤ 50	164 (48.4)	140 (41.3)	0.123	304 (44.8)
51 – 100	141 (41.6)	153 (45.1)		294 (43.4)
> 100	34 (10)	46 (13.6)		80 (11.8)
Number of HDS customers daily				
≤ 5	115 (33.9)	105 (31)	0.064	220 (32.4)
6 – 10	96 (28.3)	77 (22.7)		173 (25.5)
11 – 15	64 (18.9)	91 (26.8)		155 (22.9)
> 15	64 (18.9)	66 (19.5)		130 (19.2)
<sup>a</sup> Chi-squared test used				
<sup>b</sup> In the past 6 months				
HDS, herbal and dietary supplements				

**Appendix N: Socio-Demographic Characteristics of the Samples for Stage 1 and 2 Data Analysis of the PCare-HDS Scale (N = 682)**

Demographics	Stage 1 sample (n = 343)	Stage 2 sample (n = 339)	P value <sup>a</sup>	Total (n = 682)
Gender				
Male	122 (35.6)	104 (30.7)	0.175	226 (33.1)
Female	221 (64.4)	235 (69.3)		456 (66.9)
Previous undergraduate education				
PharmD	40 (11.7)	46 (13.6)	0.408	86 (12.6)
BPharm / BSciPharm	276 (80.5)	274 (80.8)		550 (80.6)
Others	27 (7.9)	19 (5.6)		46 (6.7)
Having a postgraduate qualification				
Yes	52 (15.2)	42 (12.4)	0.294	94 (13.8)
No	291 (84.8)	297 (87.6)		588 (86.2)
Number of years as a registered pharmacist				
≤ 10	112 (32.7)	126 (37.2)	0.276	238 (34.9)
11 – 20	144 (42)	145 (42.8)		289 (42.4)
21 – 30	71 (20.7)	59 (17.4)		130 (19.1)
> 30	16 (4.7)	9 (2.7)		25 (3.7)
Type of community pharmacy				
Chain / franchise	108 (31.5)	119 (35.1)	0.503	227 (33.3)
Independent	226 (65.9)	209 (61.7)		435 (63.8)
Others	9 (2.6)	11 (3.2)		20 (2.9)
Number of years working in community pharmacy				
≤ 5	168 (49)	174 (51.3)	0.299	342 (50.1)
6 – 10	108 (31.5)	114 (33.6)		222 (32.6)
> 10	67 (19.5)	51 (15)		118 (17.3)
Position at community pharmacy				
Full-time	259 (75.5)	250 (73.7)	0.597	509 (74.6)
Part-time	84 (24.5)	89 (26.3)		173 (25.4)
Number of hours working in a week				
≤ 20	53 (15.5)	67 (19.8)	0.266	120 (17.6)
21 – 40	71 (20.7)	60 (17.7)		131 (19.2)
> 40	219 (63.8)	212 (62.5)		431 (63.2)
HDS users <sup>b</sup>				
Yes	236 (68.8)	235 (69.3)	0.884	471 (69.1)
No	107 (31.2)	104 (30.7)		211 (30.9)
Have attended HDS-related training <sup>b</sup>				
Yes	143 (41.7)	146 (43.1)	0.716	289 (42.4)
No				393 (57.6)
Holding a managerial post at community pharmacy				
Yes	25 (7.3)	19 (5.6)	0.371	44 (6.5)
No	318 (92.7)	320 (94.4)		638 (93.5)
Owner of community pharmacy				
Yes	106 (30.9)	104 (30.7)	0.949	210 (30.8)
No	237 (69.1)	235 (69.3)		472 (69.2)

Number of pharmacist coworkers				
None	246 (71.7)	231 (68.1)	0.110	477 (69.9)
1	86 (25.1)	84 (24.8)		170 (24.9)
2	9 (2.6)	16 (4.7)		25 (3.7)
> 2	2 (0.6)	8 (2.4)		10 (1.5)
Number of co-workers including pharmacists				
None	205 (59.8)	190 (56)	0.553	395 (57.9)
1	82 (23.9)	81 (23.9)		163 (23.9)
2	36 (10.5)	40 (11.8)		76 (11.1)
> 2	20 (5.8)	28 (8.3)		48 (7)
Number of customers daily				
≤ 50	147 (42.9)	161 (47.5)	0.384	308 (45.2)
51 – 100	152 (44.3)	143 (42.2)		295 (43.3)
> 100	44 (12.8)	35 (10.3)		79 (11.6)
Number of HDS customers daily				
≤ 5	108 (31.5)	110 (32.4)	0.534	218 (32)
6 – 10	82 (23.9)	92 (27.1)		174 (25.5)
11 – 15	87 (25.4)	71 (20.9)		158 (23.2)
> 15	66 (19.2)	66 (19.5)		132 (19.4)
<sup>a</sup> Chi-squared test used				
<sup>b</sup> In the past 6 months				
HDS, herbal and dietary supplements				

**Appendix O: Comparison of Means of Direct TPB Subscales Based on Socio-Demographic Characteristics (N = 678)**

Scale / Subscale	IV	Levels of IV	Mean	SD	n	t	df	P value <sup>a</sup>
ATT	Gender	Male	3.468	1.07	227	-3.02	396	0.003 <sup>b</sup>
		Female	3.720	0.92	451			
SN		Male	3.064	1.10	227	-1.99	676	0.047
		Female	3.234	1.02	451			
PBC		Male	2.958	1.03	227	-1.34	676	0.182
		Female	3.070	1.03	451			
PN		Male	3.685	1.01	227	-0.25	676	0.806
		Female	3.705	1.00	451			
INT		Male	3.304	1.08	227	-0.41	676	0.681
		Female	3.338	0.97	451			
BEH		Male	3.080	0.86	227	0.43	676	0.664
		Female	3.060	0.77	451			
ATT	Undergraduate education	PharmD	3.667	0.85	87	0.36	123	0.722 <sup>b</sup>
		Non-PharmD	3.631	1.00	591			
SN		PharmD	3.115	0.99	87	-0.59	676	0.557
		Non-PharmD	3.186	1.06	591			
PBC		PharmD	3.011	0.99	87	-0.20	676	0.839
		Non-PharmD	3.036	1.03	591			
PN		PharmD	3.678	0.98	87	-0.20	676	0.840
		Non-PharmD	3.701	1.00	591			
INT		PharmD	3.421	1.00	87	0.94	676	0.347
		Non-PharmD	3.312	1.01	591			
BEH		PharmD	3.140	0.84	87	0.91	676	0.362
		Non-PharmD	3.050	0.79	591			
ATT	Having a postgraduate qualification	Yes	3.498	0.96	93	-1.46	676	0.145
		No	3.658	0.98	585			
SN		Yes	3.108	1.10	93	-0.68	676	0.494
		No	3.188	1.05	585			
PBC		Yes	2.720	1.06	93	-3.17	676	0.002
		No	3.082	1.01	585			
PN		Yes	3.683	0.96	93	-0.16	676	0.872
		No	3.701	1.01	585			
INT		Yes	3.423	1.08	93	0.99	676	0.321
		No	3.311	1.00	585			
BEH		Yes	3.060	0.86	93	-0.01	676	0.996
		No	3.060	0.79	585			
ATT	Years as registered pharmacists	≤ 10 years	3.702	0.90	236	1.34	535	0.181 <sup>b</sup>
		> 10 years	3.600	1.02	442			
SN		≤ 10 years	3.248	1.00	236	1.28	676	0.201
		> 10 years	3.139	1.08	442			
PBC		≤ 10 years	3.064	0.97	236	0.59	519	0.554 <sup>b</sup>
		> 10 years	3.016	1.06	442			
PN		≤ 10 years	3.701	1.01	236	0.56	676	0.956
		> 10 years	3.697	1.00	442			
INT		≤ 10 years	3.417	0.90	236	1.79	549	0.074 <sup>b</sup>
		> 10 years	3.278	1.06	442			
BEH		≤ 10 years	3.161	0.77	236	2.29	676	0.022
		> 10 years	3.014	0.81	442			
ATT	Years working in community pharmacy	≤ 5 years	3.820	0.89	340	5.00	662	<0.001 <sup>b</sup>
		> 5 years	3.451	1.03	338			
SN		≤ 5 years	3.363	0.99	340	4.69	676	<0.001

PBC		> 5 years	2.990	1.08	338			
		≤ 5 years	3.188	0.95	340	4.00	662	<0.001 <sup>b</sup>
PN		> 5 years	2.876	1.08	338			
		≤ 5 years	3.747	0.98	340	1.27	675	0.204 <sup>b</sup>
INT		> 5 years	3.649	1.02	338			
		≤ 5 years	3.443	0.86	340	3.04	629	0.002 <sup>b</sup>
BEH		> 5 years	3.209	1.13	338			
		≤ 5 years	3.153	0.77	340	2.89	676	0.004
		> 5 years	2.976	0.82	338			
ATT	Type of community pharmacy <sup>c</sup>	Chain /	3.839	0.89	226	4.08	505	<0.001 <sup>b</sup>
		Franchise	3.527	1.00	433			
		Independent						
SN		Chain /	3.283	1.07	226	2.11	657	0.035
		Franchise	3.102	1.03	433			
		Independent						
PBC		Chain /	3.146	0.98	226	2.12	657	0.034
		Franchise	2.969	1.04	433			
		Independent						
PN		Chain /	3.761	1.01	226	1.13	657	0.257
		Franchise	3.669	0.99	433			
		Independent						
INT		Chain /	3.459	0.90	226	2.78	518	0.006 <sup>b</sup>
		Franchise	3.242	1.04	433			
		Independent						
BEH		Chain /	3.106	0.74	226	1.03	657	0.304
		Franchise	3.039	0.82	433			
		Independent						
ATT	Position	Full-time	3.698	0.96	507	2.88	676	0.004
		Part-time	3.450	1.02	171			
SN		Full-time	3.282	1.04	507	4.53	676	<0.001
		Part-time	2.865	1.04	171			
PBC		Full-time	3.125	1.03	507	4.09	676	<0.001
		Part-time	2.757	0.98	171			
PN		Full-time	3.729	1.01	507	1.36	676	0.173
		Part-time	3.608	0.96	171			
INT		Full-time	3.388	0.99	507	2.75	676	0.006
		Part-time	3.144	1.04	171			
BEH		Full-time	3.112	0.81	507	2.68	676	0.008
		Part-time	2.924	0.77	171			
ATT	Being a manager	Yes	3.434	1.14	43	-1.40	676	0.163
		No	3.649	0.97	635			
SN		Yes	3.012	1.25	43	-1.06	676	0.288
		No	3.188	1.04	635			
PBC		Yes	2.895	1.17	43	-0.90	676	0.367
		No	3.042	1.02	635			
PN		Yes	3.430	1.18	43	-1.82	676	0.070
		No	3.717	0.99	635			
INT		Yes	3.054	1.21	43	-1.54	46	0.131 <sup>b</sup>
		No	3.345	0.99	635			
BEH		Yes	2.907	1.00	43	-1.09	46	0.282 <sup>b</sup>
		No	3.076	0.78	635			
ATT	Being an owner	Yes	3.516	1.04	206	-2.11	676	0.035
		No	3.688	0.95	472			
SN		Yes	3.078	1.07	206	-1.62	676	0.105
		No	3.220	1.04	472			
PBC		Yes	2.857	1.09	206	-2.96	676	0.003
		No	3.109	0.99	472			

PN		Yes	3.636	1.04	206	-1.07	676	0.284
		No	3.726	0.99	472			
INT		Yes	3.160	1.10	206	-2.70	345	0.007 <sup>b</sup>
		No	3.399	0.96	472			
BEH		Yes	3.053	0.88	206	-0.25	676	0.805
		No	3.070	0.76	472			
ATT	Have attended HDS-related training <sup>d</sup>	Yes	3.697	1.00	288	1.40	676	0.163
		No	3.591	0.96	390			
SN		Yes	3.271	1.11	288	1.97	584	0.049 <sup>b</sup>
		No	3.108	1.01	390			
PBC		Yes	3.082	1.08	288	1.05	582	0.292 <sup>b</sup>
		No	2.996	0.98	390			
PN		Yes	3.726	1.07	288	0.60	576	0.549 <sup>b</sup>
		No	3.678	0.95	390			
INT		Yes	3.426	1.00	288	2.21	676	0.027
		No	3.253	1.01	390			
BEH		Yes	3.073	0.78	288	0.22	676	0.823
		No	3.059	0.81	390			
ATT	Have used HDS <sup>d</sup>	Yes	3.581	0.97	469	-2.17	676	0.030
		No	3.758	0.99	209			
SN		Yes	3.118	1.06	469	-2.18	676	0.030
		No	3.309	1.02	209			
PBC		Yes	2.979	1.03	469	-2.04	676	0.041
		No	3.153	1.01	209			
PN		Yes	3.649	1.01	469	-1.92	676	0.056
		No	3.809	0.98	209			
INT		Yes	3.283	1.01	469	-1.69	676	0.092
		No	3.424	1.00	209			
BEH		Yes	3.058	0.82	469	-0.36	676	0.721
		No	3.081	0.75	209			

<sup>a</sup> Independent samples t-test used unless stated otherwise

<sup>b</sup> Welch's *t*-test used

<sup>c</sup> Comparison was only made for "Chain / Franchise" and "Independent" community pharmacies since the number of community pharmacies in the "Others" category was too small (*n* = 19)

<sup>d</sup> In the past 6 months

ATT = attitude; SN = subjective norm; PBC = perceived behavioural control; PN = professional norm; INT = intention; BEH = self-reported provision of PCare for HDS users



**Appendix P: Comparison of Means of PCare-HDS Subscales Based on Socio-Demographic Characteristics (N = 661)**

Scale / Subscale	IV	Levels of IV	Mean	SD	n	<i>t</i>	<i>df</i>	<i>P</i> value <sup>a</sup>
FR	Gender	Male	3.694	1.06	221	0.87	659	0.382
		Female	3.620	1.01	440			
GI		Male	3.499	1.05	221	-0.94	659	0.345
		Female	3.578	0.99	440			
AU		Male	3.468	0.95	221	-1.58	659	0.115
		Female	3.580	0.82	440			
AID		Male	3.481	1.01	221	0.19	659	0.847
		Female	3.465	1.00	440			
MPD		Male	3.677	0.86	221	1.21	659	0.225
		Female	3.590	0.87	440			
PAI	Undergraduate education	Male	3.569	0.86	221	-0.05	659	0.960
		Female	3.572	0.86	440			
SI		Male	3.327	0.86	221	-1.07	659	0.287
		Female	3.403	0.86	440			
MPQ		Male	3.677	1.00	221	-0.35	659	0.729
		Female	3.704	0.90	440			
FR		PharmD	3.827	0.95	83	1.74	659	0.083
		Non-PharmD	3.618	1.04	578			
GI		PharmD	3.723	0.96	83	1.65	659	0.099
		Non-PharmD	3.527	1.02	578			
AU		PharmD	3.466	0.88	83	-0.86	659	0.390
		Non-PharmD	3.554	0.87	578			
AID		PharmD	3.353	1.04	83	-1.14	659	0.255
		Non-PharmD	3.487	1.00	578			
MPD		PharmD	3.648	0.91	83	0.33	659	0.744
		Non-PharmD	3.615	0.86	578			
PAI		PharmD	3.577	0.84	83	0.06	659	0.951
		Non-PharmD	3.570	0.86	578			
SI		PharmD	3.514	0.86	83	1.54	659	0.123
		Non-PharmD	3.358	0.86	578			
MPQ	Having a postgraduate qualification	PharmD	3.631	0.93	83	-0.67	659	0.500
		Non-PharmD	3.704	0.93	578			
FR		Yes	3.484	1.15	93	-1.48	116	0.141 <sup>b</sup>
		No	3.671	1.01	568			
GI		Yes	3.452	1.13	93	-0.94	116	0.352 <sup>b</sup>
		No	3.568	0.99	568			
AU		Yes	3.538	0.96	93	-0.06	659	0.953
		No	3.543	0.85	568			
AID		Yes	3.584	1.04	93	1.18	659	0.238
		No	3.452	0.99	568			
MPD	Years as registered	Yes	3.508	0.94	93	-1.34	659	0.182
		No	3.637	0.86	568			
PAI		Yes	3.499	0.91	93	-0.87	659	0.384
		No	3.583	0.85	568			
SI		Yes	3.376	0.94	93	-0.02	659	0.987
		No	3.378	0.85	568			
MPQ		Yes	3.781	1.00	93	0.97	659	0.334
		No	3.681	0.92	568			
FR		≤ 10 years	3.751	0.97	230	2.00	504	0.046 <sup>b</sup>
		> 10 years	3.588	1.06	431			

GI	pharmacists	≤ 10 years	3.603	0.99	230	0.95	659	0.342
		> 10 years	3.524	1.02	431			
AU		≤ 10 years	3.529	0.82	230	-0.29	659	0.768
		> 10 years	3.550	0.89	431			
AID		≤ 10 years	3.510	0.95	230	0.74	659	0.457
		> 10 years	3.449	1.03	431			
MPD		≤ 10 years	3.626	0.87	230	0.15	659	0.879
		> 10 years	3.615	0.87	431			
PAI	Years working in community pharmacy	≤ 10 years	3.642	0.83	230	1.54	659	0.124
		> 10 years	3.534	0.87	431			
SI		≤ 10 years	3.417	0.83	230	0.86	659	0.388
		> 10 years	3.357	0.88	431			
MPQ		≤ 10 years	3.693	0.91	230	-0.04	659	0.965
		> 10 years	3.696	0.94	431			
FR		≤ 5 years	3.739	0.94	333	2.38	640	0.018 <sup>b</sup>
		> 5 years	3.549	1.10	328			
GI	Type of community pharmacy <sup>c</sup>	≤ 5 years	3.659	0.95	333	2.75	648	0.006 <sup>b</sup>
		> 5 years	3.443	1.06	328			
AU		≤ 5 years	3.552	0.80	333	0.27	642	0.790 <sup>b</sup>
		> 5 years	3.534	0.93	328			
AID		≤ 5 years	3.512	0.96	333	1.06	652	0.289 <sup>b</sup>
		> 5 years	3.429	1.04	328			
MPD		≤ 5 years	3.635	0.81	333	0.47	646	0.639 <sup>b</sup>
		> 5 years	3.603	0.92	328			
PAI	Position	≤ 5 years	3.642	0.83	333	2.15	659	0.032
		> 5 years	3.499	0.88	328			
SI		≤ 5 years	3.453	0.79	333	2.28	642	0.023 <sup>b</sup>
		> 5 years	3.301	0.92	328			
MPQ		≤ 5 years	3.687	0.92	333	-0.23	659	0.819
		> 5 years	3.703	0.95	328			
FR		Chain /	3.650	1.02	222	0.07	640	0.947
		Franchise	3.644	1.03	420			
GI	Independent	Chain /	3.682	0.94	222	2.37	488	0.018 <sup>b</sup>
		Franchise	3.490	1.03	420			
AU		Chain /	3.590	0.80	222	0.98	500	0.328 <sup>b</sup>
		Franchise	3.522	0.90	420			
AID		Chain /	3.587	0.98	222	2.12	640	0.034
		Franchise	3.411	1.01	420			
MPD		Chain /	3.712	0.78	222	1.93	505	0.054 <sup>b</sup>
		Franchise	3.580	0.89	420			
PAI	Independent	Chain /	3.645	0.78	222	1.59	504	0.112 <sup>b</sup>
		Franchise	3.537	0.89	420			
SI		Chain /	3.450	0.81	222	1.47	640	0.143
		Franchise	3.346	0.88	420			
MPQ		Chain /	3.734	0.99	222	0.73	640	0.465
		Franchise	3.678	0.90	420			
FR		Full-time	3.671	1.00	492	1.10	271	0.271 <sup>b</sup>
		Part-time	3.566	1.09	169			

GI		Full-time	3.581	0.99	492	1.23	272	0.219 <sup>b</sup>
		Part-time	3.465	1.07	169			
AU		Full-time	3.566	0.85	492	1.20	659	0.230
		Part-time	3.473	0.92	169			
AID		Full-time	3.524	0.95	492	2.16	255	0.032 <sup>b</sup>
		Part-time	3.316	1.12	169			
MPD		Full-time	3.635	0.87	492	0.80	659	0.423
		Part-time	3.573	0.87	169			
PAI	Being a manager	Full-time	3.613	0.83	492	2.15	659	0.032
		Part-time	3.449	0.93	169			
SI		Full-time	3.437	0.83	492	3.04	659	0.002
		Part-time	3.205	0.92	169			
MPQ		Full-time	3.707	0.90	492	0.55	262	0.584 <sup>b</sup>
		Part-time	3.707	1.02	169			
FR		Yes	3.364	1.08	43	-1.85	659	0.065
		No	3.664	1.02	618			
GI		Yes	3.488	1.10	43	-0.42	659	0.672
		No	3.556	1.01	618			
AU		Yes	3.473	0.86	43	-0.54	659	0.586
		No	3.547	0.87	618			
AID		Yes	3.481	1.01	43	0.07	659	0.945
		No	3.470	1.00	618			
MPD		Yes	3.595	0.88	43	-0.18	659	0.853
		No	3.621	0.87	618			
PAI	Being an owner	Yes	3.505	0.90	43	-0.52	659	0.602
		No	3.576	0.86	618			
SI		Yes	3.163	1.09	43	-1.69	659	0.091
		No	3.393	0.84	618			
MPQ		Yes	3.783	1.06	43	0.64	659	0.521
		No	3.689	0.92	618			
FR		Yes	3.602	1.07	202	-0.70	659	0.485
		No	3.663	1.01	459			
GI		Yes	3.530	0.98	202	-0.37	659	0.711
		No	3.561	1.03	459			
AU		Yes	3.530	0.90	202	-0.25	659	0.800
		No	3.548	0.86	459			
AID		Yes	3.480	1.04	202	0.17	659	0.869
		No	3.466	0.99	459			
MPD		Yes	3.644	0.82	202	0.48	659	0.631
		No	3.608	0.89	459			
PAI	Have attended HDS-related training <sup>d</sup>	Yes	3.576	0.80	202	0.09	659	0.930
		No	3.569	0.89	459			
SI		Yes	3.406	0.89	202	0.56	659	0.577
		No	3.365	0.85	459			
MPQ		Yes	3.761	0.90	202	1.21	659	0.228
		No	3.666	0.94	459			
FR		Yes	3.601	1.02	281	-0.93	659	0.355
		No	3.676	1.03	380			
GI		Yes	3.493	1.02	281	-1.27	659	0.203
		No	3.595	1.00	380			
AU		Yes	3.581	0.89	281	0.98	659	0.326
		No	3.514	0.85	380			
AID		Yes	3.440	1.06	281	-0.66	566	0.509 <sup>b</sup>
		No	3.493	0.96	380			
MPD		Yes	3.677	0.84	281	1.47	659	0.142
		No	3.576	0.89	380			

PAI	Have used HDS <sup>d</sup>	Yes	3.560	0.86	281	-0.28	659	0.778
		No	3.579	0.86	380			
SI		Yes	3.361	0.91	281	-0.43	570	0.666 <sup>b</sup>
		No	3.390	0.83	380			
MPQ		Yes	3.766	0.91	281	1.70	659	0.090
		No	3.642	0.94	380			
FR		Yes	3.609	1.05	460	-1.35	659	0.176
		No	3.726	0.98	201			
GI		Yes	3.545	1.02	460	-0.26	659	0.795
		No	3.567	1.00	201			
AU		Yes	3.519	0.88	460	-1.06	659	0.287
		No	3.597	0.84	201			
AID		Yes	3.454	1.01	460	-0.66	659	0.512
		No	3.509	0.99	201			
MPD		Yes	3.602	0.89	460	-0.78	659	0.439
		No	3.659	0.83	201			
PAI		Yes	3.520	0.88	460	-2.45	425	0.015 <sup>b</sup>
		No	3.689	0.79	201			
SI		Yes	3.348	0.89	460	-1.35	659	0.178
		No	3.446	0.80	201			
MPQ		Yes	3.660	0.95	460	-1.51	416	0.132 <sup>b</sup>
		No	3.774	0.87	201			

<sup>a</sup> Independent samples t-test used unless stated otherwise

<sup>b</sup> Welch's *t*-test used

<sup>c</sup> Comparison was only made for "Chain / Franchise" and "Independent" community pharmacies since the number of community pharmacies in the "Others" category was too small (*n* = 19)

<sup>d</sup> In the past 6 months

FR = Foster relationship; GI = Gather information; AU = Assess HDS use; AID = Assist informed decision; MPD = Make professional decision; PAI = Provide advice or information; SI = Seek HDS information; MPQ = Maintain HDS product quality



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