

School of Pharmacy

**Early Detection of Bowel Disease in Symptomatic Patients
Attending Community Pharmacies**

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**This thesis is presented for the Degree of
Doctor of Philosophy
of
Curtin University**

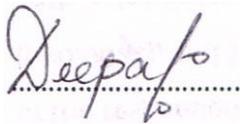
May 2016

Declaration

To the best of my knowledge and belief, this thesis contains no material previously published by any other person, except where due acknowledgement has been made.

This thesis contains no material that has been accepted for the award of any other degree or diploma in any university.

Signature

A handwritten signature in black ink, appearing to read "Deepa", written over a horizontal dotted line. The signature is cursive and includes a small flourish at the end.

Date

26.11.2015

Table of Contents

Declaration.....	i
Table of Contents.....	ii
List of Tables	vi
List of Figures	vii
List of Abbreviations	viii
Conferences and Published Abstracts	ix
List of Peer Reviewed Articles Related To This Thesis	x
Acknowledgement	xi
Dedication	xii
Abstract.....	xiii
1. Introduction	1
1.1. Background	1
1.2. Research Questions	3
1.3. Theoretical Framework Guiding the Project.....	5
1.4. Significance	7
2. Literature Review	9
2.1. Primary Health Care.....	9
2.1.1. Philosophy of Primary Health Care	9
2.1.2. Primary Health Care Delivery.....	10
2.2. Primary Health Care and Community Pharmacy	12
2.2.1. Staffing in Pharmacies.....	14
2.2.2. Roles of Pharmacists and Pharmacy Assistants	19
2.2.3. Value of Pharmacy Advice.....	21
2.3. Effective Primary Health Care.....	22
2.3.1. Inter-Professional Care	23
2.3.2. Referral from Pharmacy to General Practice.....	23
2.4. Practice Change in Community Pharmacy.....	26
2.5. Behaviour Change in Community Pharmacy Practice.....	27
2.5.1. Theory of Planned Behaviour.....	28
2.5.2. Predicting Behaviour using the Theory of Planned Behaviour	30
2.5.3. Willingness to Pay for Community Pharmacy-Delivered Cognitive Services .	32
2.6. Bowel Disease	34
2.6.1. Diverticular Disease	34

2.6.2.	Inflammatory Bowel Disease	36
2.6.3.	Irritable Bowel Syndrome	38
2.6.4.	Colorectal Cancer	39
2.7.	Help-Seeking Behaviour	41
2.7.1.	Bowel Disease and Help-Seeking Behaviour	42
2.7.2.	Role of Pharmacies in the Management of Bowel Symptoms.....	44
2.7.3.	Literature Search.....	45
2.7.4.	Questionnaires for Screening of Bowel Symptoms	48
2.8.	Conclusion and Recommendations.....	55
3.	Development and Validation of a Bowel Symptom Consultation Guide	56
3.1.	Introduction	56
3.2.	Aim and Objectives	58
3.3.	Method	58
3.3.1.	Questionnaire Development.....	58
3.3.2.	Validation	60
3.4.	Results.....	62
3.4.1.	Questionnaire Construction.....	62
3.4.2.	Readability	62
3.4.3.	Validation	62
3.5.	Discussion.....	64
3.6.	Limitations.....	66
3.7.	Conclusion and Recommendations.....	67
4.	Trial of the Jodi Lee Test (JLT)	68
4.1.	Background	68
4.2.	JLT Trial.....	68
4.2.1.	Introduction	68
4.2.2.	Materials and Methods.....	70
4.2.3.	Results.....	74
4.2.4.	Discussion.....	77
4.2.5.	Conclusion.....	80
4.3.	Additional Information.....	80
4.3.1.	Perceived Roles of Pharmacy Staff and Pharmacists	80
4.3.2.	Actor-Simulation study	82
4.3.3.	Additional Discussion	86
4.4.	Conclusion and Recommendation	87
5.	Intention of Pharmacy Staff to Change Behaviour	89

5.1.	Introduction	89
5.2.	Aims and Objectives.....	90
5.3.	Methods.....	91
5.3.1.	Study Design.....	91
5.3.2.	Study Participants	91
5.3.3.	TPB-Based Questionnaire	91
5.3.4.	Statistical Analysis.....	94
5.4.	Results.....	95
5.4.1.	TPB Questionnaire	95
5.4.2.	Statistical Analysis.....	99
5.5.	Discussion.....	106
5.5.1.	Limitations.....	110
5.6.	Conclusion.....	110
6.	Willingness to Pay for a Quality-Enhanced Service in Community pharmacies	112
6.1.	Introduction	112
6.2.	Willingness to Pay	113
6.2.1.	Introduction	113
6.2.2.	Methods.....	114
6.2.3.	Results.....	117
6.2.4.	Discussion.....	119
6.2.5.	Conclusion.....	120
6.2.6.	Additional Limitations from the WTP Study	120
6.2.7.	Updates to the published article.....	121
7.	Discussion.....	122
7.1.	Overview	122
7.2.	Discussion based on Research Questions	123
7.3.	Limitations.....	132
7.4.	Implementation of the JLT	134
8.	Conclusion and Recommendations.....	137
8.1.	Conclusion.....	137
8.2.	Recommendations	139
8.2.1.	Recommendation 1: Standardised Consultations.....	139
8.2.2.	Recommendation 2: Staff Training	140
8.2.3.	Recommendation 3: Uptake Enhanced Services	140
8.2.4.	Recommendation 4: Client satisfaction	140
8.2.5.	Recommendation 5: Reducing administration	141

8.2.6.	Recommendation 6: JLT should be used routinely	141
8.2.7.	Recommendation 7: Pharmacy involvement in health care.....	141
Reference		143
Appendices.....		168
Appendix 3.1: Author Permission License		168
Appendix 3.2: Nominal Group technique for JLT Item Generation		170
Appendix 3.3: Aspects of Delphi Technique- Suggestions Following Each Round of Iteration		171
Appendix 3.4: Jodi Lee Test.....		172
Appendix 4.1: Flyer		174
Appendix 4.2: Instructions to Pharmacy Staff for Usual Practice		176
Appendix 4.3: Instructions to Pharmacy Staff for JLT Phase		177
Appendix 4.4: Baseline Booklet		179
Appendix 4.5: Control Group Booklet.....		190
Appendix 4.6: JLT Booklet		196
Appendix 4.7: Bowel Symptom Scenarios		204
Appendix 4.8: Bowel Symptom Scenarios Checklist		212
Appendix 5.1: Scoring sheet - TPB		220
Appendix 5.2: TPB-Questionnaire.....		222
Appendix 6.1: Author permission License		224
Appendix 6.2: Script for Usual Practice Video		226
Appendix 6.3: Screenshot of Usual Practice Video		228
Appendix 6.4: Script for Quality-Enhanced Video		229
Appendix 6.5: Screenshot of Quality-Enhanced Service Video.....		231
Appendix 6.6: Willingness to Pay–Information Sheet and Consent form		232
Appendix 6.7: Willingness to Pay Questionnaire		235
Appendix 7.1: JLT Letter-pad		238

List of Tables

Table 1.1: Overview of Thesis Chapters Based on MRC Framework	6
Table 2.1: Health Care System - Primary Healthcare Services	11
Table 2.2: Levels of Pharmacy Staff Training in Australia	18
Table 2.3: Facilitators (Factors) and Items Forming (facilitating) that Factor.....	27
Table 2.4: Prevalence and Help-Seeking Rate for Rectal Bleeding	43
Table 2.5: Literature Search Strategy and Results	46
Table 2.6: Colorectal Cancer risk and PCQ score	53
Table 3.1: Sensitivity and Specificity of the Jodi Lee Test Compared to the PCQ Threshold Score (n=118)	63
Table 4.1: Impact Evaluation: Usual-Practice Phase <i>versus</i> Intervention Phase	76
Table 4.2: Frequency of Data Code elicited from Responses of Pharmacy Staff on Their Role in Bowel Symptom Management.....	81
Table 4.3: Actors' Documentation of Questions and Management of their Bowel Symptom Scenario by Pharmacy Staff	85
Table 5.1: TPB Questions to Examine Intention to Change Practice and provide cognitive services among Pharmacy Staff.....	97
Table 5.2: Demographic Characteristics of the Pharmacy Staff.....	99
Table 5.3: Intention to Provide Cognitive Services (Q13) and to Change Practice (Q14) (n=182)	100
Table 5.4: Univariate Analysis using Perceived Behavioural Control, Subjective Norm and Attitude to Predict Intention to Provide Cognitive Services	101
Table 5.5: Multivariate Logistic Regression for Intention to provide Cognitive Services	103
Table 5.6: Multivariate Logistic Regression for Intention to Change Practice.....	103
Table 5.7: Responses of Participants at post-JLT (n=47) for Intention to Provide Cognitive Services (Q13) and to Change Practice (Q14)	104
Table 5.8: Intention of Participants Who Completed Baseline and Post TPB Survey (n=23)	105
Table 6.1: Demographic Characteristics of Willingness to Pay Survey participants	118
(N=175)	118
Table 6.2: Willingness to Pay for the Standard Service Vs the Quality-Enhanced service	119

List of Figures

Figure 2.1: Pharmacists – Percentage Distribution across Australian States.....	15
Figure 2.2: Pharmacists – Percentage by Gender across Australia in 2014	16
Figure 2.3: Consumer Satisfaction with Pharmacy Services (N=1201).....	22
Figure 2.4: Theory of Planned Behaviour	29
Figure 2.5: Theory of Reasoned Action	29
Figure 2.6: Natural History of Diverticulosis.....	35
Figure 2.7: Diagnostic Criteria of Ulcerative Colitis and Crohn’s Disease	37
Figure 2.8: Flow diagram of the Results of a Literature Search of Risk Factors of Bowel Disease.....	48
Table 3.2: The Relationship between the Jodi Lee Test (JLT) Recommendation and PCQ Threshold Score of 30.....	63
Figure 3.1: Receiver Operator Curve (ROC) - JLT Sensitivity <i>versus</i> JLT Specificity	64
Figure 6.1: Willingness to Pay Survey.....	116
Figure 8.1: Thesis based on Medical Research Council Framework.....	138

List of Abbreviations

UK	United Kingdom
US	United States
GP	General Practitioner
WA	Western Australia
JLT	Jodi Lee Test
MRC	Medical Research Council
TPB	Theory of Planned Behaviour
PBC	Perceived Behavioural Control
SN	Subjective Norm
WTP	Willingness To Pay
AUD	Australian Dollar
CRC	Colorectal Cancer
IBD	Inflammatory Bowel Disease
IBS	Irritable Bowel Syndrome
FOBT	Faecal Occult Blood Test
QoL	Quality of Health
PCQ	Patient Consultation Questionnaire
AUC	Area Under the Curve
UP	Usual Practice

Conferences and Published Abstracts

Sriram D, Jiwa M, **McManus A**, Emmerton L, Parsons R. Streamlining Care: A Model for Effective Assessment and Referral of Pharmacy Clients with Bowel Symptoms. *International Forum of Quality and Safety in Healthcare: Asia*. Hong Kong Convention and Exhibition Centre, Hong Kong. 28-30 September 2015

Sriram D, Jiwa M, **McManus A**, Emmerton L, Parsons R. Development and Validation of a Clinical Decision-Making Aid for Screening Bowel Symptoms in Community Pharmacies. *Primary Health Care Research Annual Conference*, Canberra 23-25 July 2014

Sriram D, Jiwa M, **McManus A**, Emmerton L, Parsons R. Development and validation of a clinical decision-making aid for screening bowel symptoms in community pharmacies. *7th Annual Meeting of the Cancer and Primary Care Research International Network (Ca-PRI)* 10-13 June 2014 Winnipeg Manitoba, Canada. (Abstract published *European Journal of Cancer Care* 2014; 23:18)

Media Coverage of Jodi Lee Test trial: ScienceNetwork, Western Australia October 2014, Bowel Disease Questionnaire Developed for Pharmacies

Media Coverage for Willingness to Pay study: Australian Doctor, National February 6 2015, Pharmacists consults worth \$15

List of Peer Reviewed Articles Related To This Thesis

Title	Year	Journal	Thesis Chapter
Development and Validation of a Clinical Decision-Making Aid for Screening bowel Symptoms in Community pharmacies	2014	<i>Journal of Evaluation in Clinical Practice; 20:260-266</i>	Chapter 2 (Literature Review) Chapter 3 (Development and validation of Jodi Lee Test)
Will Australians Pay for Health Care Advice from a Community pharmacist? A Video Vignette Study	2015	<i>Research in Social and Administrative Pharmacy; 11(4): 579-583</i>	Chapter 6 (Willingness to Pay study)
A Model for Effective Assessment and Referral of Clients with Bowel Symptoms in Community Pharmacies	2016	<i>Current Medical Research and Opinion; 32(4): 661-667</i>	Chapter 4 (Trial of Jodi Lee Test)

Acknowledgement

I would like to thank and acknowledge all the people who have assisted in the completion of this thesis.

Firstly, I would like to thank all my supervisors, Professor Moyez Jiwa, Professor Alexandra McManus, Associate Professor Lynne Emmerton and Professor Jeff Hughes. Thank you Prof. Jiwa, Prof. McManus and A/Prof. Emmerton for your on-going support, encouragement, motivation and supervision. I would like to thank you all for encouraging my research and for allowing me to grow as a researcher. Moyez, a big thanks for understanding my limitations and strengths and being there as a friend, finding time to listen to me and guiding me during difficult days. Alex, special thanks to you for taking on the main-supervisor role during my last (most difficult) year of PhD journey, the writing phase! Lynne, your thorough review and feedback have been priceless. I would like to express my special appreciation and thanks to Dr. Richard Parsons for his statistical advice. I sincerely thank Dr. Rima Caccetta, the thesis chairperson for your support.

I would like to express my sincere gratitude to Gia Cecchele, John Cooke and Nick Ng, owners/pharmacists of pharmacy banner groups, for their valuable input and support throughout the study. I would like to thank all the pharmacists and pharmacy assistants of the participating pharmacies for helping me carry out different phases of the study.

I am extremely thankful to my colleagues and friends, Irene and Devesh, who helped, encouraged and supported me throughout my PhD journey. I thank all my friends in Perth and Gladstone for their encouragement and emotional support.

Finally, a special thanks to my family. Words cannot express how grateful I am to my husband, Sriram and children, Dhruv and Diya for their support, love, patience and most of all, for being there for me.

Dedication

I would like to dedicate this thesis in the honour of my brother-in-law, Ramesh for being the first one to sow the seed of PhD in my mind and my cousin, Vijay for all the initial encouragement. I am sure both are smiling from up there.

Abstract

Effective delivery of primary health care is arguably the best way to improve health outcomes. A more integrated primary health care system should lead to higher quality service to clients. Community pharmacy is well placed to play a constructive and dynamic support role in the provision of effective primary health care. In addition to being one of the first port of call for health advice for the general population, referral to other health services is emerging as an important strength of community pharmacy.

Bowel symptoms such as diarrhoea, constipation and rectal bleeding are common, and a number of bowel diseases share common clinical presentations. Certain symptoms significantly raise the probability of serious underlying conditions such as cancer, colitis, or large adenomatous polyps. Seeking medical advice and initiation of treatment in the early stage of a disease improves the prognosis and quality of life. To reduce delayed diagnosis of bowel pathologies, there must be increased efforts to identify people with high-risk symptoms and refer them to appropriate care. Self-administered questionnaire can be an effective tool in supporting primary health care professionals to triage cases that warrant further investigation for indicators of possible colorectal conditions.

This thesis explores the use of pharmacy setting to triage clients for investigation of symptoms that may indicate colorectal pathology. The purpose of this thesis was to develop and test a simple screening tool with high sensitivity for bowel disease (Jodi Lee Test; JLT) that could be used by pharmacy staff to identify and encourage individuals to seek medical help. Furthermore, this thesis examines the intention of the pharmacists and pharmacy assistants to change practice when consulting clients with bowel symptoms. The thesis also measures the willingness to pay for the deployment of a tool such as the JLT when used in the pharmacy during consultation with a client.

The design of this project was guided by the Medical Research Council framework, which outlines the appropriate steps in designing complex interventions. The behavioural study was based on the Theory of Planned Behaviour. Data were collected using various techniques: on-site in pharmacies, online using video vignettes and telephone follow-up. The tools used to collect data were self-administered questionnaires: JLT, a questionnaire based on Theory of Planned Behaviour, a post-evaluation questionnaire, video vignettes based willingness to pay questionnaire and notes from pharmacists.

The major outcomes from the thesis are:

- **Study 1:** The JLT, a short, self-administered questionnaire was developed and validated against an existing validated screening tool, the Patient Consultation Questionnaire (PCQ), to assess the sensitivity and specificity of JLT. The JLT contains eight questions. It has a Flesh-Kincaid reading score of 79.5. Different score thresholds on the gold standard, the PCQ, were considered, and a receiver-operator characteristic (ROC) curve was calculated to assess effectiveness of the JLT. From a sample of 118 subjects, the area under the ROC curve was 0.94. At a threshold score of 30 on the PCQ, the sensitivity was 100% for identifying the clients with high risk of bowel disease. The specificity was 65%.
- **Study 2:** The JLT was trialled using a prospective pre-post design to examine the feasibility and effectiveness of use of the JLT as a screening tool in pharmacies for easy identification of bowel symptoms that would benefit from further medical investigations. Studies were conducted in 21 community pharmacies in Western Australia. Data were collected to describe usual practice of pharmacy staff when consulting clients with bowel symptoms. This was followed by data collection for consultation in the pharmacies using the JLT as the intervention tool. The value of the JLT was assessed between the two phases of the study by comparing the referrals to, and subsequent contact with, the clients' general practitioner (GP) for those considered to

have signs of potentially-serious disease. Eighty-four participants were recruited for usual-practice phase and 80 for the JLT (Intervention) phase. The quantitative impact measures comparing 'usual practice' and 'the JLT intervention' indicated a significantly-higher referral rate in the Intervention group (38%) compared to the usual-practice group (20%). The p-value (chi-square) for comparison of the proportions of clients who were recommended to consult a GP was $p=0.029$. The participants' acceptance rate of GP referral was also higher for the Intervention group (40% vs 6%), with the p-value (Fisher's exact test) being $p=0.017$. Forty-seven pharmacy staff completed the feedback questionnaire. Thirty (64%) of the pharmacy staff agreed that the JLT could be incorporated in the pharmacy, and 33 (70%) indicated they would use the JLT in future when managing clients with bowel symptoms.

- **Study 3:** A cross-sectional design was used to assess the intention of the pharmacy staff to change practice and to use a screening tool such as the JLT when consulting clients with bowel symptoms. A pre-JLT-intervention survey and post-JLT-intervention survey was conducted to compare the factors that influence the intention to change practice before and after the intervention (the JLT). A questionnaire was developed based on the Theory of Planned Behaviour (TPB), and assessment of internal consistency and scoring were completed based on recommendations by Francis *et al.*[1] For purposeful selection of variables, univariate analysis was performed and the chi-square statistic was then used to assess the association between each of the questions and the intention to provide the cognitive service inclusive of the JLT. Logistic regression analysis was performed to identify independent variables contributing significantly to the prediction of intention. One hundred and ninety-three pharmacy staff completed the TPB questionnaire at baseline (Pre-JLT-intervention) from 21 participating pharmacies. The perceived behavioural control (Confidence) questions ($p=0.002$), and subjective norm ($p=0.002$) were independently associated with the intention to provide cognitive services. Perceived behavioural control (Confidence) questions ($p=0.046$) and subjective norm ($p=0.022$) showed independent

association with intention to change practice. Social or subjective norm, and self-efficacy of the pharmacy staff to identify 'red-flag' symptoms and to give recommendations for such clients, were the most influencing factors of the intention of staff to change practice and deploy JLT as screening tool for pharmacy clients presenting with bowel symptoms. Forty-seven participants completed the post-JLT-intervention TPB questionnaire. The pattern of the response appeared to be similar to the baseline survey.

- **Study 4:** A willingness to pay (WTP) study was conducted as a survey-based method to determine monetary valuations of a standard pharmacy consultation *versus* cognitive service, a quality-enhanced service where the pharmacists offer advice and written referral to the GP, with reference to response to a self-administered questionnaire about the presenting symptoms completed by the client. A video-vignette based WTP survey was adopted. Participants viewed two videos online – one depicting standard client-consultation practice, and the other depicting a quality-enhanced consultation based on a screening tool with greater privacy – and then completed a brief WTP questionnaire online. Descriptive statistics were used to report the study sample and identify the proportion of the consumers who were willing to pay. Logistic regression was used to explore the influence of demographic data on their responses. A total of 175 participants completed the WTP survey. Almost one-third (49/175, 28%) indicated WTP for service offered in Video 2 (quality-enhanced practice), indicating a median payment of AUD15.

Overall, this thesis found that guided communication by appropriately-trained pharmacy personnel around symptoms is effective in alerting health professionals and clients to the need for clinical consultation. This early intervention, at a point where clients may be seeking symptomatic relief through a pharmacy, has the potential to be extended to other symptom complexes for which clients might benefit from discussion with a general practitioner.

1. Introduction

1.1. Background

Bowel symptoms – such as diarrhoea, constipation and rectal bleeding – are common, with around one in four people experiencing these symptoms each year in developed countries.[2-4] In the majority of cases, these symptoms are benign, however some may cause considerable distress or may be due to a serious underlying disease. A number of bowel diseases such as cancer, inflammatory bowel disease, irritable bowel disease, large adenomatous polyps and diverticular disease, share common clinical presentation.[5-7]

Early detection and treatment of these diseases may improve prognosis and quality of life. Failure to seek help in the early stages of disease, thus delaying diagnosis, may result in a poor prognosis.[8, 9] There is robust evidence to suggest many people with bowel disease present late with symptoms, even when they have been persistent.[3, 10-12] Definitive diagnosis of persistent symptoms requires medical consultation.[13] Recognition of the significance of symptoms by the general public is a key factor in motivating people to seek medical help. However, in studies conducted with people with bowel symptoms in Australia, the United States (US) and the United Kingdom (UK), the rates of medical practitioner consultation varied from 14% to 41%.[14-16]

In Australia, it has been estimated that there are over 250 million occasions each year during which pharmacists could provide professional advice and service to their clients.[17-19] An Australia-wide survey by Mott[20] reported that one in three of the 2,005 respondents used a pharmacy as a prelude to making an appointment with a general practitioner (GP). Published data suggest that some people consult a pharmacist for advice on their lower bowel symptoms.[21-23] For example, in 16 pharmacies recruited to a study in Western Australia (WA), it was estimated that at least three clients per pharmacy present every week seeking treatment for bowel symptoms.[21] Interactions between pharmacists and their symptomatic clients offer

an ideal opportunity to explore how pharmacy staff can identify clients with possible risk factors for bowel disease and encourage them to consult their GP.

However, in another WA-based survey of pharmacists, it was demonstrated that high-risk bowel symptoms were not recognised in a significant proportion of cases.[13] When compared to an expert panel's opinion, 30% of pharmacists of the 167 registered pharmacists surveyed did not agree that rectal bleeding for four weeks duration warrants a GP referral. Over 60% of pharmacists did not consider persistent diarrhoea in a 65-year-old client as a likely symptom of significant bowel pathology, which was in contrast to cancer guidelines.[13, 24]

Discussing embarrassing symptoms has been reported as a barrier to seeking help, a challenge encountered by pharmacists when trying to obtain an accurate history and symptom details from their clients.[25]

Screening tools for identification and triage of people at higher risk of bowel disease affords effective continuity of care in the primary health care system.[26-28] Research supports the use of short, self-administered questionnaires to help pharmacists identify clients whose symptoms may warrant further investigation for bowel pathology in a more efficient and private manner.[29-31] Despite this, there is a lack of literature around the availability of valid and reliable tools to help pharmacists identify clients with symptoms that would require further investigations for possible irritable bowel syndrome, diverticulosis, haemorrhoids, polyps, inflammatory bowel disease and cancer.

In light of the above, a self-administered decision-aid tool (i.e. the Jodi Lee Test; JLT) was developed which could be offered to pharmacy clients presenting with bowel symptoms. Clients' responses on the JLT guided pharmacy staff in identifying those who might benefit from medical review. Furthermore, this study evaluated clients' willingness to pay for such a service through pharmacies. The feasibility of implementing the JLT was also considered including factors that might influence change of pharmacy practice.

Through its component studies, this research provided an understanding of the process of development, validation and trial of a pharmacy-led decision-making tool (the JLT) that identifies clients who might benefit from medical intervention for bowel symptoms and encourages them to seek timely help.

1.2. Research Questions

As evident in the literature, many adults do not seek timely help for their bowel symptoms. [32-36] Furthermore, a significant proportion of people identified pharmacies as a good source of advice for their bowel symptoms.[21] This led to the opportunity to investigate if early identification of pharmacy clients presenting with significant bowel symptoms would encourage them to seek medical help.

Nine research questions formed the framework of this thesis:

1: Can community pharmacy help to identify clients who might be at high risk of bowel disease?

2: Do pharmacy staff know which clients should be encouraged to consult their general practitioner (GP) based on symptoms?

After confirming that pharmacies were suitable locations for early identification of bowel symptoms, it was essential to search the literature for any existing screening, triage procedures and/or decision-making tools available for early detection of bowel disease.

3: What are the available screening and triage tools for bowel symptoms?

The next step was to develop a simple tool for use by pharmacy staff to guide their consultation with symptomatic clients.

4: Can a simple, easy-to-use, self-administered questionnaire (i.e. the JLT) be developed to identify pharmacy clients who might be at risk of bowel disease?

5: Is the JLT a valid tool for assisting pharmacy staff to identify clients at risk of bowel disease in a pharmacy and to encourage them to consult a GP?

It was then essential to test the JLT in community pharmacies to examine the effectiveness of this decision aid to guide pharmacy staff in identification and referral of at-risk clients for further investigation.

6: Is the JLT an effective assessment tool for pharmacy clients presenting with bowel symptoms, assisting pharmacy staff to identify at-risk clients and provide a referral to consult their GP?

7: Can use of the JLT and referral from pharmacies encourage clients to consult their GP?

Implementation of new behaviour or any change in behaviour requires understanding of specific factors that influence the behaviour.[37] As a result, it became important to identify factors that might influence the pharmacy staff to change practice.

8: Do attitudes, perceived barriers and social pressure affect the intention of pharmacy staff to perform an activity?

Lack of reimbursement for clinical services is one of the most common reasons cited by pharmacists regarding their failure to provide extended services.[38-41] This led to the determination of clients' willingness to pay (WTP) if a screening service, where a self-administered questionnaire (the JLT) guides the pharmacist-client consultation and results in a referral to the GP if the response to the questionnaire warrants one, were offered in the pharmacy.

9: Will Australians pay for healthcare screening and triage service from a community pharmacy?

1.3. Theoretical Framework Guiding the Project

Complex interventions are often used to investigate or address health issues in fields such as health services, public health practice and areas of social policy making.[5] An intervention is considered complex when it has a number of elements:[42] several interacting components, a study of behaviours of those delivering or receiving the intervention, a number of groups or organisations involved in the intervention, variability of the outcomes and a degree of flexibility permitted.[43]

This study was considered a complex intervention because of the following:

- there was no single primary outcome in this study - a range of outcomes were examined
- the intention of the pharmacy staff (who delivered the intervention) to change behaviour was examined
- several dyads were examined, including the client-pharmacist, client-researcher and client-GP
- there were three groups of subjects in this study:
 - pharmacy clients with bowel symptoms, recruited when they visited the pharmacy for management of their symptoms
 - pharmacy staff, in terms of their intention to change practice and behaviour relating to the intervention
 - the general population, sampled in the WTP for screening services, such as the screening using the JLT, if offered in pharmacies.

The design of this study was guided by the Medical Research Council (MRC) framework.[43] The MRC framework was introduced in 2000 (and extended in 2006) to assist researchers to identify and adopt appropriate steps when designing a complex intervention.[42, 43] More attention to the initial development of the intervention, and a less linear and more flexible approach, were included in the extended version.[43] The extended version of MRC framework recognised that an

intervention may require adaptation to local settings, and that there may be difficulties in fully evaluating experimental designs in practice.[43]

The MRC framework states the phases of a complex intervention are:[42, 43]

- **Preclinical or theoretical phase:** identifying the evidence available for the research questions
- **Modelling/development phase:** defining the components of the intervention based on existing evidence
- **Assessing feasibility:** testing the feasibility of the intervention
- **Evaluation phase:** trialing the intervention to assess its effectiveness, measuring outcomes and understanding the change process
- **Implementation phase:** examining the possibility of implementation of the intervention into practice.

Table 1.1 shows how the MRC framework [43] guided this thesis.

Table 1.1: Overview of Thesis Chapters Based on MRC Framework

Thesis Chapters	MRC Framework
1. Introduction	
2. Literature Review	Preclinical phase Assessing feasibility
3. Development and Validation of a Bowel Symptom Consultation Guide	Modelling/development phase
4. Jodi Lee Test - Prospective Observational study	Evaluation phase – assessing effectiveness and measuring outcomes
5. Intention to Change Practice in Community Pharmacy	Evaluation phase – understanding change
6. Willingness to Pay for Quality-Enhanced Service in Community Pharmacy	Evaluation phase – examining willingness to pay for tool such as the JLT
7. Discussion	
8. Conclusion and Recommendations	Implementation phase

1.4. Significance

Evidence documents that the prevalence of bowel symptoms in the community is high. Over a one-year period, almost one in four people in most developed countries experience lower gastrointestinal symptoms, such as rectal bleeding and diarrhoea.[2, 3] Many people attempt to manage their symptoms through over-the-counter pharmacy preparations rather than present to their GP, with rate of doctor consultation among these patients varying from 14% to 41%.[2-4, 20] A definitive diagnosis for persistent bowel symptoms requires a medical consultation.[13] There is evidence to suggest that many symptomatic people with bowel disease present late and only a minority of them seek timely medical advice.[3, 10-12] Delayed diagnosis of serious colorectal pathology occurs mainly due to delay in the presentation to a GP, delayed referral to a specialist, and delay in diagnosis.[44]

Pharmacy staff are well placed to help identify symptomatic clients and encourage them to consult a GP. Pharmacies are readily accessible to the general community, and many of their clients with bowel symptoms visit a pharmacy for non-prescription medicine purchases. Early intervention at a point where clients may simply be seeking symptomatic relief from a pharmacy is possible. Pharmacies could potentially screen clients who might benefit from medical advice especially when symptoms described suggest significant risk of colorectal disease and encourage them to consult their GP by providing them a formal, written referral letter to the GP.

There is evidence that a self-administered questionnaire can be an effective tool in supporting pharmacists triage cases that need further investigation for bowel pathology.[30] Challenges, however, relate to conducting a private consultation with clients in a pharmacy setting who may have embarrassing signs or symptoms, and require referral for further investigation. Another obstacle that often precludes delivery of pharmacy-led primary prevention initiatives is a heavy workload.[38-40]

There is a need for a simple, brief decision-making aid that can be used by pharmacy staff to identify clients with bowel symptoms that require medical consultation, and

thus may potentially improve prognoses for these clients through more timely diagnosis of serious conditions such as bowel cancer.

This research makes a contribution to identifying how community pharmacy staff can be proactively involved in the continuum of health care of their clients by:

- examining the effectiveness of the JLT, a decision-making aid tool, as a guide to pharmacy staff to identify and refer clients with bowel symptoms
- determining factors that influence the intention of the pharmacy staff to change practice, and
- estimating the proportion of the general population who are willing to pay for pharmacists' quality-enhanced services, such as screening for bowel disease and referring to a GP for further medical investigation.

2. Literature Review

2.1. Primary Health Care

2.1.1. Philosophy of Primary Health Care

The *World Health Report 2008* noted robust primary healthcare systems are the most effective way to “produce better health outcomes, improve health equity and respond to social expectations.”[45-47] According to the Australian Primary Health Care Research Institute,[48] primary health care is defined as a “socially-appropriate, universally-accessible, scientifically-sound first-level care provided by a suitably-trained workforce supported by integrated referral systems in a way that gives priority to those most in need, maximises community and individual self-reliance and participation, and involves collaboration with other sectors.”[28, 48] The Australian Medical Association also endorses this definition,[28] stating the need for balance between curative services and promotion, prevention and rehabilitation.[28]

The philosophy behind primary health care is based upon understanding health and wellbeing and recognising determinants of health, such as gender, housing, education, planning, social and other services. Involvement of communities and individuals in planning, accessibility, acceptance and affordability of services to people in need remains a focus of primary health care. As such, the importance of health promotion and disease prevention in eliminating causes of ill health is recognised.[45]

The Alma-Ata Declaration,[49] convened by the World Health Organization and United Nations Children’s Fund, made primary health care a core policy.[46] The Declaration was signed in 1978 by 134 health ministries during the International Conference on Primary Health Care, urging all participating governments to formulate policies to effectively implement primary health care.[50] The Declaration defined primary health care as “incorporating curative treatment given by the first contact provider along with promotional, preventive and rehabilitative services

provided by multi-disciplinary teams of healthcare professionals working collaboratively.”[28] This definition is reflected in the Australian Primary Health Care Research Institute definition of primary health care. This development was significant in entrenching the idea of health care as a human right and recognising the importance of primary health care in achieving this.[51]

Primary health care includes health promotion, illness prevention, care of the sick, advocacy and community development.[28, 48] Health promotion is one of the key principles of primary health care. Health promotion, according to the Ottawa Charter, is “the process of enabling people to increase control over, and to improve, their health.”[52] The Ottawa Charter was the first International Conference on Health Promotion, held in 1986, and built on the progress from the Declaration on Primary Health Care at Alma-Ata.[52] According to the Charter, health promotion demands coordinated action by all concerned: individuals, community groups, health professionals, health service institutions and governments. It is about reorienting health services, which would lead to change of attitudes and organisation of health services to refocus on the needs of the individual.[52]

2.1.2. Primary Health Care Delivery

The philosophy of delivery of efficient health care is based on social, biomedical and health services research.[45] The National Primary Health Care Strategic Framework takes a broad and comprehensive view of primary health care,[53] recognising that the concept of primary health care extends beyond the traditional ‘general practice’ focus of care.[53]

Primary health care is delivered in the community outside of hospitals. Community-based providers are diverse (Table 2.1), and include GPs, practice nurses, psychologists, physiotherapists, community health workers and community pharmacists.[54]

Table 2.1: Health Care System - Primary Healthcare Services

Services Promoting Health	Primary Healthcare Services	Secondary Healthcare Services	Tertiary Healthcare Services
Sectors that have relationships between health and wellbeing	Usually the first point of contact for patients; generally do not require referral to access the service	Usually do not have first contact with the patient; require referral to access services or services provided in a hospital setting	Specialist referral services
<ul style="list-style-type: none"> • Housing and community services • Economy and employment • Security and justice • Education and early life • Infrastructure, planning and transport • Environmental sustainability 	<ul style="list-style-type: none"> • General practice • After-hours medical locum service • Residential and community aged care • Allied health • Ambulance services • Aboriginal Medical Services • Community Pharmacy • Community health services • Child and Family Health Centres • Non-Government Organisations and peak bodies which provide health services • Private community based services • Nurse-led clinics • School nurses • Self-help organisations • Consumer organisations • Dental services • Health-direct Australia • Government services outside Health Directorate and Community Services 	<ul style="list-style-type: none"> • Pathology • Radiology • Specialists • Hospital inpatient services • Emergency Departments • Hospital-based allied health services • Ambulatory care clinics 	<ul style="list-style-type: none"> • Specialist care such as intensive or coronary care, neurosurgery

Adapted with permission from the ACT Health Government[45]

In accordance with the aforementioned definitions (Section 2.1.1), for a primary healthcare system to be effective, it should help patients better self-manage their health conditions and prevent disease. It is crucial that individuals receive the health care they need, when and where they need it.[54] An effective way to deliver primary care is through primary care teams comprising GPs and other skilled healthcare professionals, such as pharmacists, physiotherapists or dietitians.[28] This is discussed in later sections of this chapter, in the context of pharmacy-GP coordinated care. In general terms, the primary health care team affords patients continuity of care through access to a comprehensive range of professional expertise.[28]

2.2. Primary Health Care and Community Pharmacy

The vast majority of Australians consult a GP or another primary care health professional at least once per year.[48] Traditionally, the primary role of pharmacies is to provide medication; however, pharmacists are providing an increasingly wider range of healthcare services in the community.[55] Community pharmacy is well placed to play a constructive and dynamic support role in the provision of effective primary health care.[55] Pharmacies have become the most accessible points of contact for individuals within the healthcare system, regardless of location; indeed, consumers can expect to receive professional attention almost immediately and without an appointment.[55]

The Pharmacy Guild of Australia[56] and Pharmaceutical Society of Australia[57] have released papers explaining the broader role of community pharmacy in primary health care.[54] In general terms, the role includes assisting consumers with chronic disease, in their adherence with medication and other management, and with the consumer's lifestyle and preventative health issues. Community pharmacies also play an important role in assisting other health professionals' clinical decisions based on individuals' medication profiles, and serve as a focal point for health screening programs and a referral point for government health campaigns.[54]

In Australia, community pharmacists represent a large professional body of individuals who are tertiary trained.[55] Pharmacists are registered by the Pharmacy Board of Australia.[58] They practise according to Australian Government and state and territory government legislation and regulations, and interact extensively with other health professionals, especially the medical profession.[55, 59] As such, community pharmacists should be fully integrated members of the healthcare system, as they play a role in primary health care and health education, and are often the first point of contact within the healthcare system for the general public.[60] It is recognised that community pharmacists balance the delivery of wide range of healthcare services with the supply of medicinal products.[55]

In the *Consumer Experience, Needs and Expectation of Community Pharmacy* project, undertaken as part of the Third Community Pharmacy Agreement in Australia, 30% of the respondents reported using a community pharmacy to decide whether to consult a doctor.[54] That study also identified that whilst people over 65 years make up approximately 14% of the Australian population they contribute to 80% of the prescription volume in pharmacies.[54] This supports the view that older people are extensive users of community pharmacies.[61] People over 65 years of age were reported to be more likely to patronise a particular pharmacy because the pharmacist appeared to take a keen interest in them and gave good advice.[61] Together, these reports suggest loyalty plays a significant role in developing trust and continuity of care for people with greater needs for primary care.

Despite Australia having among the lowest population density in the world, the extensive network of community pharmacies provides Australians with convenient, reliable and high-quality access to health services.[19] There are approximately 5,500 community pharmacies across Australia, where the population exceeds 23 million.[19, 55, 60, 62] On average, Australians visit a community pharmacy 14 times each year.[63] Other data suggest there are over 250 million occasions each year during which pharmacists may provide professional advice and service.[18, 19, 64] Ninety-four percent of Australian adults use a pharmacy each year, and 3.9 million

Australians ask a pharmacist for health advice each year, with 79% reporting the advice met their needs completely.[65]

2.2.1. Staffing in Pharmacies

Key features of the staffing functions and operational responsibility in Australian community pharmacies are:[66]

- A pharmacy manager/owner is in a position of responsibility and leadership.
- There will always be a qualified pharmacist on duty.
- Dispensary assistants' work concentrates on dispensing activities, but may include some front-of-shop activities.
- Pharmacy assistants' duties may include non-dispensing activities and limited elements of dispensing (e.g. collection of prescriptions).
- Pharmacy assistants may also be involved in back-of-shop tasks (e.g. ordering).
- There may be a range of other staff in a pharmacy, including nurses, dietitians and storeperson.

A number of these features are described below in the context of provision of pharmacy services.

2.2.1.1. Pharmacists in Australia

In 2014, there were over 28,000 registered pharmacists in Australia (Figure 2.1).[67] The available data do not indicate the proportion of these in active community practice; however, 2006 Australian Bureau of Statistics data cited in a national workforce report[68] indicate two-thirds of registered pharmacists were active in pharmacy workforce, and approximately 85% of pharmacists were employed in the community sector.

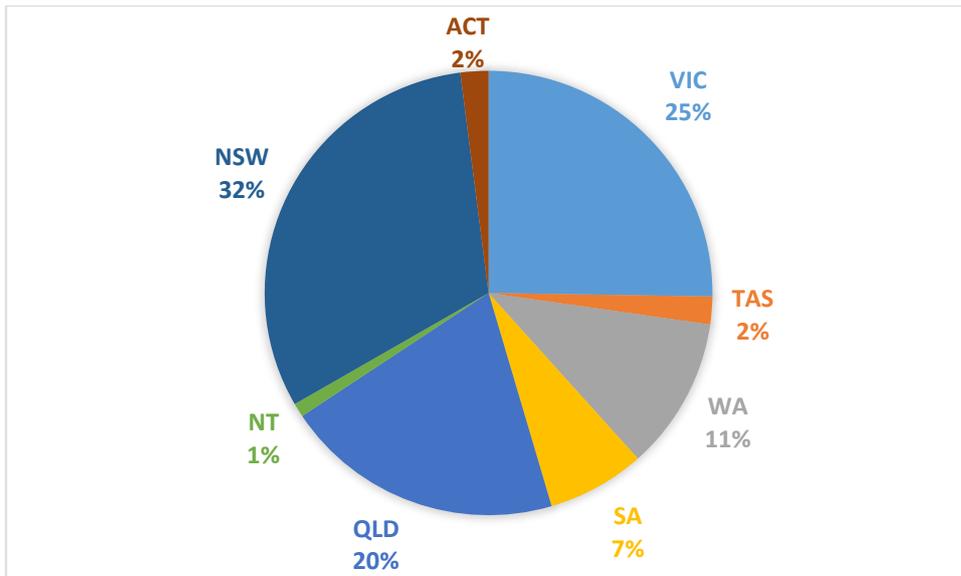


Figure 2.1: Pharmacists – Percentage Distribution across Australian States (N=28,883)

Adapted with permission from Pharmacy Board of Australia[67]

Of the 28,883 pharmacists registered in Australia,[67] approximately 11,000 are aged 25-34 years, followed by about 5,800 in the age range of 35-44 years.[67] Analysis by gender shows more female (n≤17,400; ~60%) than male (n≤11,400; ~40%) pharmacists.[67] Over half of employed pharmacists are women.[69] The percentage of male and female pharmacists across Australia based on 2014 Pharmacy registrant data[67] are illustrated in Figure 2.2. These demographic data are not available specifically for pharmacists practising in community settings.

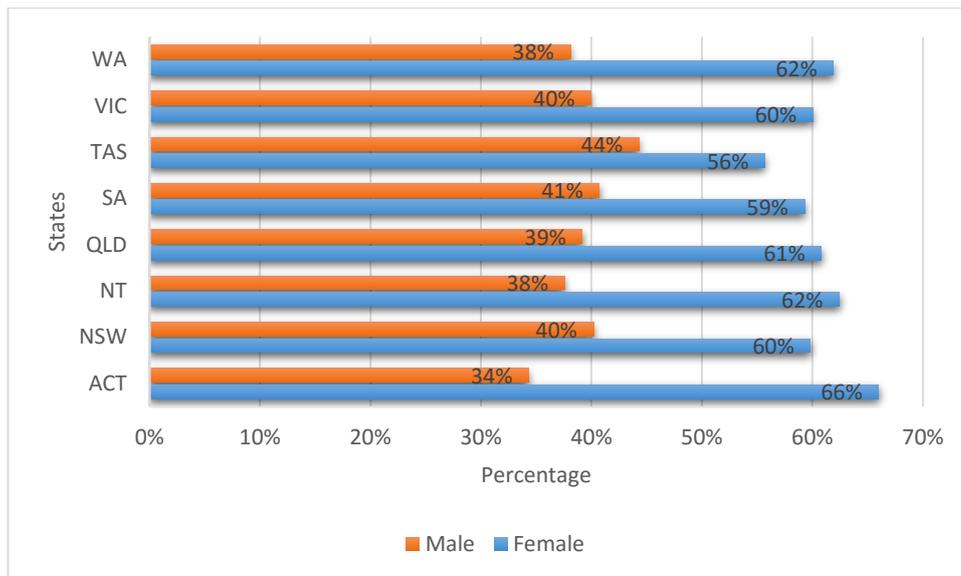


Figure 2.2: Pharmacists – Percentage by Gender across Australia in 2014
Adapted with permission from Pharmacy Board of Australia[67]

In Australia, pharmacists complete either a four-year Bachelor degree or a two-year Graduate Entry Master degree, followed by a one-year internship.[70] The subtypes for registration of pharmacists, according to data from the Australian Health Practitioner Regulation National Boards,[58] are ‘general’, ‘provisional’, ‘limited’ and ‘non-practising’. Pharmacy interns are granted provisional registration, and must obtain general registration before they are eligible to work unsupervised. The transition from provisional registration to general registration entails completion of intern training, oral and written examinations and 1,824 hours of approved supervised practice.[58]

Limited registration is generally awarded to overseas-qualified pharmacists who do not qualify for general registration until they undertake a period of supervised practice in Australia. The supervised practice required is less than the full internship period of 1,824 hours required for conversion of provisional to general registration.[71]

2.2.1.2. Pharmacy Assistants in Australia

There are over 43,300 pharmacy assistants employed across Australia.[70] Pharmacy employees are predominantly females (nearly 88%), with a mix of full-time, part-time and a small number of casual employees.[70] Relatively few are employed full-time.[60]

A pharmacy technician is a person who assists pharmacists in the dispensary, and undertakes customer service and sales.[66, 72] The primary distinguishing feature between a pharmacy technician and pharmacy assistant is the more significant involvement of the technician in dispensing area.[68] The role of pharmacy assistants can vary according to the legislation applicable in the relevant state and/or workplace setting.[72] Due to indistinct role classifications, the term 'pharmacy assistant' has been used in this thesis to collectively refer to pharmacy assistants and pharmacy technicians.

Pharmacy assistants must have successfully completed, or be in the process of completing, a course recognised by the registering authority of the state in which the pharmacy is located. They also receive ongoing training in line with State Government requirements and in the area of involvement in the pharmacy.[72] The training for pharmacy assistants is undertaken at the vocational education and training sector level,[66] by State/Territory-registered training organisations. There are around 80 competency units in the training package included in Certificate levels I to IV.[66] The training for supervised provision of Pharmacy (Schedule 2) Medicines and management of requests for Pharmacist Only (Schedule 3) Medicines forms a critical component of Certificate II, III and IV.[60]

An overview of the Certificates is as follows:[66]

- **Certificate I:** designed for an employee who is new to the industry, covering tasks such as customer relationships, sales skills and stock handling.

- **Certificate II:** requires a greater understanding of medications and more product-specific knowledge. The pharmacy assistant is expected to develop skills to enable recommendation of non-prescription medicines to customers, and to learn how to ‘filter’ information for referral to the pharmacist for Pharmacist Only (Schedule 3) Medicines.
- **Certificate III:** designed for more experienced employees who do not require supervision and who may begin specialising in a particular area of pharmacy practice, e.g. dispensary assistant roles or front-of-shop coordination. Emphasis is also placed on skills for ‘filtering’ information for referral to the pharmacist.
- **Certificate IV:** more management focused, covering tasks such as staff management and training, pharmacy management, and stock control. Training also includes advice and information about medicines and medicinal products to clients under the supervision of the pharmacist.

A nationwide survey[66] of pharmacies to examine workflow processes and gain insight into the use of pharmacists and pharmacy assistants produced responses from 80 of 400 pharmacies, with 39 pharmacists and 248 pharmacy assistants providing data.[66] Most commonly, pharmacy support staff had not completed formal training (Table 2.2), and there were none who had successfully completed Certificate IV at the time of the survey.[66]

Table 2.2: Levels of Pharmacy Staff Training in Australia

Current level of training	% (N=248)
Secondary schooling less than Year 12	31.9%
Secondary schooling to Year 12	42.3%
On the job training	56.9%
Formal pharmacy training	22.2%
Certificate I	13.3%
Certificate II	27.0%
Certificate III	15.3%
Pharmacy Guild of Australia Industry Grade 3	3.2%
Pharmacy Guild of Australia dispensary training	12.1%

Adapted with permission from The Pharmacy Guild of Australia[66]

Twenty-eight percent of the respondents were either front-of-pharmacy managers, salespersons or in an administrative support role. Fifty-three percent were pharmacy assistants and 19% were dispensary technicians. Nearly 50% of the pharmacy assistants reported they were interested in pursuing further training in community pharmacy, and 89% of the pharmacy manager/owners indicated their pharmacy encourage advanced training of assistants.[66] Furthermore, the survey reported pharmacy owners/managers and salaried pharmacists envisaged a greater role for assistants in the dispensary area and in providing advice on medicine and other health care.[66]

2.2.2. Roles of Pharmacists and Pharmacy Assistants

Pharmacists are recognised by the Australian public as providing valued advice on a range of health issues.[54] In addition, pharmacists rated second in the 2014 Gallup Poll among the most trusted professionals,[73] and second for honesty and ethical standards according to the 2015 Roy Morgan survey.[74] The Australian public's trust and confidence in pharmacists has increased vastly over the years.[75] In the recently published report by the Pharmacy Guild of Australia[76] on the survey of 3000 consumers as a part of the Fifth Community Pharmacy Agreement Research and Development Program, 90% of participants reported being satisfied with the interaction they had with the pharmacists.

Pharmacists are accountable for the advice and service provided in their pharmacies.[19] They are well positioned to identify clients who may benefit from information and advice on effective health care, and can provide them with valuable advice about medications, products and services. Pharmacists can also refer clients to other local health services when appropriate. Pharmacists have become increasingly involved in client-orientated services involving development of client profiles, client monitoring and client counselling.[61, 77]

The services offered by pharmacists differs from pharmacy to pharmacy in response to local needs. The most common preventative and chronic management services offered[63] are:

- Asthma management support
- Blood pressure monitoring
- Bone density testing
- Diabetes risk assessment and self-management support (including Diabetes MedsCheck) and National Diabetes Services Scheme (NDSS) Access Point
- Cholesterol testing
- Weight loss, sleep apnoea and smoking cessation programs
- Product recalls and safety alert information and co-ordination
- Continence support
- Community health education/promotion (structured).

The pharmacist in charge of the pharmacy business is responsible for ensuring pharmacy assistants' functions are limited to those not requiring them to exercise professional judgement.[78] Pharmacy assistants perform various duties in the pharmacy independently or under the supervision of a qualified pharmacist.[66]

Pharmacy assistants can provide general product knowledge and advice to the client and refer clients with symptoms or medical conditions or queries about the medications to the pharmacist. The duties of assistant in the dispensing area might include stock management, preparing and attaching dispensing and cautionary and advisory labels, gathering non-clinical information from clients and collating prescriptions.

It has been suggested that working with suitably-qualified pharmacy assistants to perform routine technical tasks should reduce the burden of the pharmacist, thus increasing the time for professional contact with clients.[72]

2.2.3. Value of Pharmacy Advice

In addition to dispensing, pharmacies have become important providers of various client-centred healthcare services.[55, 77] Several of these activities present pharmacists with opportunities to identify and address health-related issues in their clients.[77] Pharmacists may provide various preventive interventions, such as lipid and osteoporosis testing. [79] As established in Section 2.2.2, pharmacists are a valuable member of the primary health care team.[79]

Consumers' satisfaction with pharmacy services has always been high. Convenience of location and health advice by the pharmacists have been rated highly, and reported as the primary reason for patronising a specific pharmacy.[73] In the US National Pharmacy Consumer survey, consumers (N=1201) who reported having filled at least one prescription in the past six months were asked about their satisfaction relating to a range of consumer experiences.[80] The top six response options (of 12) indicate communication was highly valued (Figure 2.3).[80]

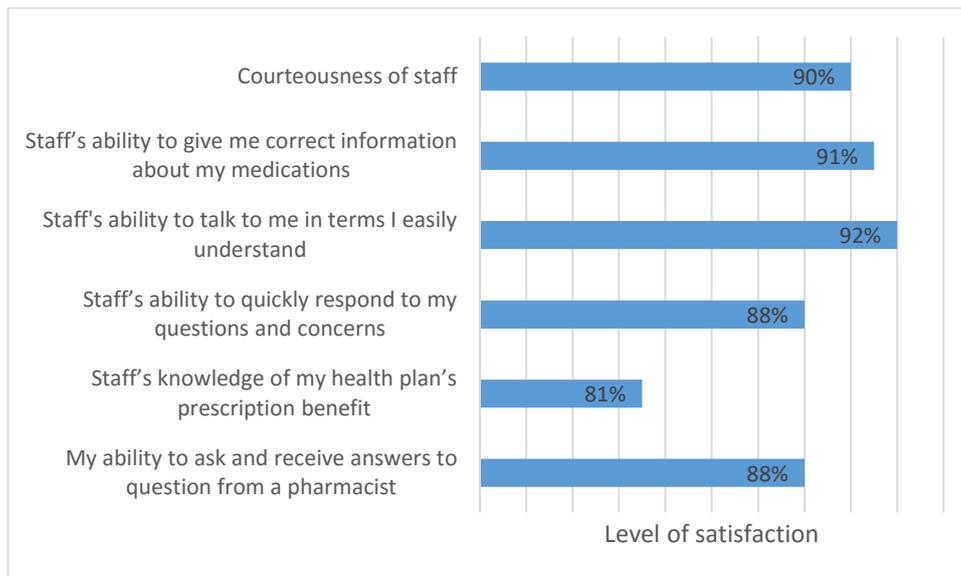


Figure 2.3: Consumer Satisfaction with Pharmacy Services (N=1201)
Adapted with permission from Stergachis *et al.*[80]

An Australia-wide pharmacy survey by Hamilton and Tee (2010) investigated the forward-looking and value-adding services in pharmacies that could determine their potential effects on client service and client satisfaction.[81] The most positive factors were personalised services such as immunisation, risk reports and advice, and efforts made to meet each client's requirement. Additionally, the ability of clients to access additional health information and thorough, but not excessive, consultation with supporting explanation by the pharmacists was claimed to add to the value of the pharmacies.[81]

2.3. Effective Primary Health Care

Health stakeholders, including government services, private health services and non-government organisations, along with individual health professionals and consumers, play a major role in delivering effective primary health care.[45] The primary health care system should encourage coordination between consumers and their carers to provide health care that is safe and of high quality.[45] Trust and established relationships between stakeholders, including consumers, are important to work towards the common goals of delivering effective primary health care.[45]

2.3.1. **Inter-Professional Care**

Inter-professional care is grounded in professional communication skills, mutual respect of the expertise of other health professionals, and referral networks.[45] Primary health care is facilitated by inter-sectoral cooperation and coordination at all levels, developing a balance between health promotion, preventive care and illness treatment, and developing multi-disciplinary teams drawn from a variety of disciplines, including medical, nursing, pharmacy, allied health, community aid, population health, and health promotion and education.[45]

While pharmacy consultation and a GP consultation differ in their scope and intent, pharmacy offers a convenient encounter with the health system for many purposes. Pharmacies are positioned to become, and be recognised, as the most commonly accessed health service provider, with the capacity to promote symptom awareness and to offer support and/or referral to individuals with symptoms who have not sought diagnosis, advice or treatment.[82]

2.3.2. **Referral from Pharmacy to General Practice**

In addition to being recognised as one of the first ports of call for health advice, referral to other health services is increasingly mentioned as an important strength of community pharmacy.[83] A number of studies evaluating the impact of collaboration of pharmacists and GPs resulting in positive client outcomes have been reported.

Hassel *et al.*[83] explored the advice-giving behaviour of staff in community pharmacies. The researchers used an ethnographic style research strategy, combining pharmacists and client interviews with non-participant observation of medicines- and health-related interaction between pharmacy users and staff. From the observational data, several criteria were identified as important in pharmacists' decisions to refer cases to general practice or other services. A pharmacist participating in the study said, "It depends on the symptoms you are treating, if it is

straightforward self-limiting ailment, then that's actually quite straightforward to deal with. If there are other things that provide question marks in your mind, you refer." [83] Furthermore, for some clients, the pharmacy was viewed as a 'filter' to the GP, someone to use before going to the GP, or someone who could advise a visit to the GP if one was thought necessary. [83] Findings from the study suggest that pharmacists often identify potentially serious symptoms that may be overlooked or ignored by clients. This study did not report if the clients consulted their GP after being advised by the pharmacist, and if so, whether further investigations were recommended or if a diagnosis was made.

Bereznicki *et al.* [84] assessed the impact of an intervention initiated by community pharmacists that involved the provision of educational material and GP referral. The impact on asthma knowledge and self-reported asthma control and asthma-related quality of life was recorded in clients whose asthma was not managed well. The intervention pack included: a personalised letter from the pharmacist, referring the client to his/her GP; an asthma knowledge, asthma control and asthma-related quality of life questionnaire; and the dispensing details of the client to give to the GP. The researchers claimed their study provided evidence that community pharmacists could effectively identify clients who may have suboptimal management and refer such clients to their GP for review, and community pharmacists and GPs could effectively work together to improve client-reported outcomes in asthma. [84]

Although there was no mention in that study of the proportion of participants who sought a review with their GP, it is assumed that the improvement in the asthma control in the intervention group was based on better medical management. As such, the study also provided evidence that community pharmacists were well placed to identify clients with suboptimal management and control of their asthma because of their access to computerised dispensing records and their frequent contact with the client. This facilitated easy referral of the clients to their GP for review. [84]

In Australia, the Pharmacy Diabetes Care Program investigated the capacity of community pharmacies to identify, and refer to the GP, people in the community at

risk of Type 2 diabetes.[85] The study compared two screening methods managed in the pharmacy: risk assessment alone, and risk assessment followed by a finger-prick random or fasting glucose test. The GP referral form included the participant's details and consent form, results from the glucose test (if applicable), and a request for further tests to be conducted by the GP.[85] GP referral from pharmacists and the uptake of referral was higher for the glucose-tested group, suggesting the addition of a clinical test provided results more meaningful to both pharmacists and clients. The findings from the study showed the pharmacy screening service had potential to identify a substantial number of people in the community who have undiagnosed type 2 diabetes.[85]

A pilot study by Jiwa *et al.*[31] validated a cough questionnaire used to triage clients presenting in community pharmacies. The Pharmacy Cough Assessment Tool identifies clients with cough who may benefit from referral to a GP. Clients whose symptom profile warranted a referral were provided with a printed template referral letter along with the completed questionnaire to take to the GP. Of the 37 clients who were advised to consult their GP, seven attended their doctor. Although the referral uptake was not significant, of the clients who made an appointment to consult the GP, most were offered further investigation.[31] All 37 who were referred scored poorly on the quality of life questionnaire, indicating that people identified using this assessment tool could have benefited from GP consultation.

Another proof-of-concept study by Jiwa's team[23] explored the identification of pharmacy clients with high-risk bowel symptoms. This study tested the deployment of a self-administered questionnaire as an aid to advising pharmacy customers with bowel symptoms. The initiative involved a template referral letter issued when GP consultation was deemed appropriate. Of the eight patients with scores of concern on the intervention tool (the Patient Consultation Questionnaire, described in Section 2.7.4.1), five visited their GP when referred by the pharmacists.[23] There was no control group to compare the referral rate and the GP visit rate.

2.4. Practice Change in Community Pharmacy

Cognitive pharmacy services are “professional services provided by pharmacists, using their skills and knowledge to take an active role in contributing to client health through effective interaction with both clients and other health professionals”.^[86] Community pharmacy in Australia has been at the forefront of this international trend toward the delivery of cognitive pharmacy services.^[87] However, there is some evidence that actual practice often differs from the recommended delivery of services,^[88] and there are substantial gaps between best evidence and the management clients receive.^[89-91] Implementation of a particular behaviour requires an understanding of specific factors that influence the behaviour.^[37]

For successful implementation of any evidence-based practice, the barriers – which could be at the individual, organisational or/and national level – should be recognised and addressed.^[88] A systematic review by Cabana *et al.* proposed the barriers affecting the change in practice as knowledge, attitude, resources and other external factors:^[92]

- Knowledge
 - Lack of awareness and familiarity or disagreement with the change
 - Lack of skills to implement a change
- Attitude
 - Difficulty in changing ingrained practices
 - Feeling that new practice would not bring positive outcomes
- Resources
 - Lack of staff
 - Lack of resources
 - Lack of managerial leadership
- External barriers
 - Attitudes of clients who may resist a new practice
 - Environmental factors such as lack of time, organisational constraints
 - Structure of reimbursement mechanisms.

Research was conducted by Roberts *et al.* to identify the key components needed for the development of a practice change model for Australian community pharmacies.[87] The study developed and validated an instrument to allow the identification and quantification of facilitators of practice change, drawing on the experiences of those involved with existing community pharmacy services and programs.[87] Roberts *et al.*'s study identified a range of facilitators for change of practice in community pharmacies and items forming each factor (Table 2.3).

Table 2.3: Facilitators (Factors) and Items Forming (facilitating) that Factor

Factor	Items
Relationship with GP	Communication with GP Good working relationship with GP Cooperation with GP on key elements of change
Remuneration	Payment is necessary Incentive payments for pharmacies Profitable for pharmacies Key concern in deciding to implement change
Pharmacy layout	Right pharmacy layout is necessary for implementation of change in practice Designated pharmacy area for delivering service
Patient Expectation	Motivated because customers expect it Demand for services
Staffing	Sufficient number of staff as a key factor in implementation of change in practice
Communication and teamwork	Communication with staff member of proposed change Importance of working as a team
External support/assistance	External support for pharmacies to implement practice change

Adapted with permission from Roberts *et al.*[87]

Adherence to a change in practice may be hindered by a variety of barriers. A theoretical approach can help explain these barriers and help target interventions to address specific barriers.

2.5. Behaviour Change in Community Pharmacy Practice

Change in pharmacy practice, particularly to facilitate new primary healthcare services, requires consideration of behaviour change theory. Change is more likely to

be accepted and implemented if strategies are developed after identifying the barriers.[93] Numerous approaches that contribute to the understanding of the process of change have been reported:[88]

- *Learning theories* suggest particular behaviours will be repeated if they are rewarded with incentives, and stopped if they are penalised
- *Social cognition models* propose beliefs and attitudes as key to the way people behave
- *Organisational models of change* examine stages that organisations go through in the process of change.

The Theory of Planned Behaviour (TPB) is a Social Cognition model and is considered the direct determinant of behaviour. As such, it constitutes a theoretical framework for the explanation and prediction of social behaviour.[94]

2.5.1. **Theory of Planned Behaviour**

Concepts referring to behavioural dispositions, such as attitudes, beliefs and social influence, have played an important role in understanding and predicting human behaviour. The TPB (Figure 2.4) is one of the most tested and robust social psychological models, designed to predict and explain human behaviour in specific context.[95, 96] The TPB is an extension of the Theory of Reasoned Action (Figure 2.5).[95] According to the Theory of Reasoned Action, “a person's intention to perform a specific behaviour is a function of two factors: attitude (positive or negative) toward the behaviour and the influence of the social environment (general subjective norms) on the behaviour.”[97] As in the Theory of Reasoned Action, a central factor in the TPB is the individual’s intention to perform a given behaviour. The TPB incorporates perceived behavioural control as a third factor that influences behavioural intention.[97]

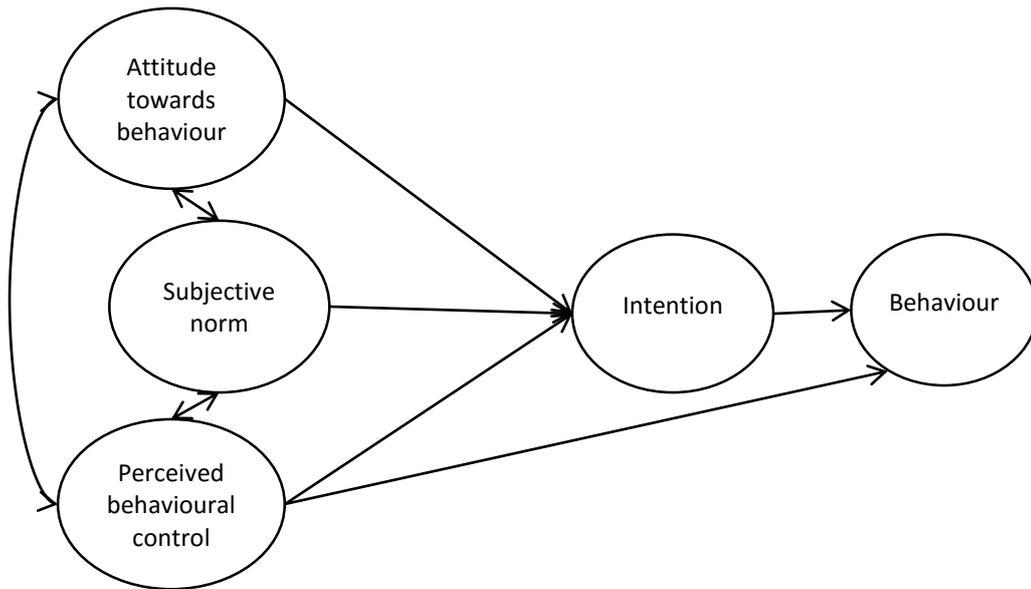


Figure 2.4: Theory of Planned Behaviour
Adapted with permission from Ajzen’s Theory of Planned Behaviour[95, 97]

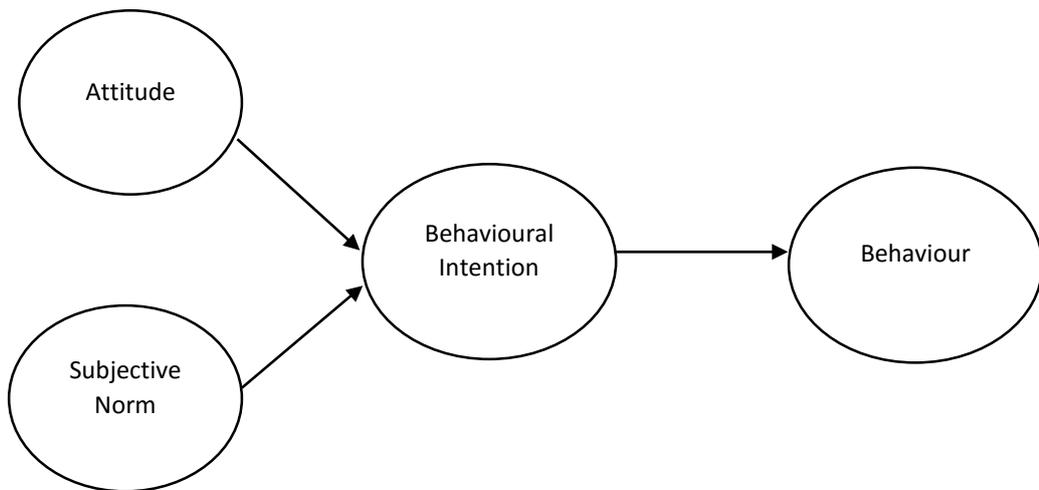


Figure 2.5: Theory of Reasoned Action
Adapted with permission from Madden *et al.*[97]

2.5.1.1. Intention

The TPB proposes ‘intention’ is the immediate determinant of behaviour, because it reflects the person’s level of motivation and desire to exert effort.[98] The intention of a person to perform the behaviour depends on the person’s willingness to try and

the effort required to perform that behaviour. The stronger the intention, the more likely the behaviour would be performed.

2.5.1.2. Attitude

The attitude toward the behaviour is determined by the person's belief that a given outcome will occur if he/she performs the behaviour, and by an evaluation of the outcome.[97] Attitude refers to the degree to which a person has a favourable or unfavourable evaluation or appraisal of the behaviour in question.[95]

2.5.1.3. Subjective Norm

The social or the subjective norm is the level of influence of what others think he/she should do, has on a person to perform a behaviour.[97, 99] In other words, subjective norm is the perceived social pressure to perform or not to perform the behaviour.[94]

2.5.1.4. Perceived Behavioural Control

Perceived behavioural control plays an important part in the TPB. In TPB, the perceived behavioural control, attitude and subjective norm hold the same level of influence on the behavioural intention, which in turn influences the behaviour. (Figure 2.5).[94] Perceived behavioural control reflects the ease or difficulty associated with performance, and the person's confidence in performing that action. Preparation to perform an activity and effort expended during performance can be influenced by self-efficacy beliefs.[100]

The perceived behavioural control also has a direct influence on the behaviour. The effort expended to successfully perform a behaviour is directly proportional to the perceived behavioural control.[95]

2.5.2. Predicting Behaviour using the Theory of Planned Behaviour

The TPB has been widely used to understand health professionals' attitude, perceived barriers, beliefs and the influence of external factors in achieving best practice. The ability of the TPB to predict behaviour has been corroborated by numerous studies:

meta-analytic reviews across a range of behaviours,[101] health behaviours in general,[102-104] adherence to exercise,[98, 105] and prediction of participation in cancer screening.[106, 107] There are number of studies conducted in pharmacies to predict behaviour using this theory, as described below.

Farris *et al.* studied the relationship between intention to change behaviour and provision of pharmaceutical care.[108] Pharmaceutical care is defined as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a client’s quality of life”.[109] These researchers also quantified intention and behaviour to provide pharmaceutical care, and studied the relationship between intention and behaviour. The reported findings supported previous work that indicated that behavioural control has additional power in predicting goal-oriented behaviours.[95, 110] The authors argued pharmaceutical care implementation programs considering perceived behavioural control in providing pharmaceutical care, rather than addressing individual factors, could be key in the success of the implementation program.[108] The behavioural measure employed was self-reported, and the causal model reported in this study requires further validation, given the changing nature of pharmacy practice.

A pharmacy smoking cessation study conducted in the US[111] evaluated the knowledge and attitude of pharmacy technicians after they attended an education program. Community pharmacy staff are ideally situated to promote smoking cessation to clients, but barriers were identified for not providing this service in the pharmacy. Knowledge and attitudes of the pharmacy assistants were evaluated before and after a continuing education program. Both significantly improved after the program.[111] This is in line with the TPB stating that confidence, a factor of perceived behavioural control, influences the action of a person. Self-efficacy beliefs influence choice of activities and effort expended during performance.[95]

Odedina *et al.*[37] developed a theoretical framework that explained pharmacists’ behaviour relative to the provision of pharmaceutical care. The implementation of pharmaceutical care in pharmacies involves change in the functions of pharmacists,

and change in the relationship of pharmacists with clients and other health care providers.[109] Odedina's study confirmed the TPB, in that perceived behavioural control significantly predicted behavioural intention, and attitude and subjective norm also directly influenced behavioural intention. According to these authors, if pharmacists' attitudes towards the behaviour are identified, and perceived behavioural control and influencing social norms are addressed, this will facilitate enhanced delivery of pharmaceutical care.[37]

A study by Grimshaw *et al.* applied the TPB to community pharmacy behaviour, identifying the barriers to/facilitators of evidence-based practice, and examined the relationship between beliefs and intention to change behaviour relating to the treatment of vaginal candidiasis with non-prescription medicines.[112] The researchers developed a questionnaire based on the TPB, completed by community pharmacists. The pharmacists showed positive attitude towards supply of antifungals to symptomatic women. This study showed that the pharmacist's attitude was the best predictor of behavioural intention. The pharmacy setting, pharmacist's knowledge and customer characteristics (e.g. elderly, pregnant) also played an important role in decision-making.[112]

2.5.3. Willingness to Pay for Community Pharmacy-Delivered Cognitive Services

Cognitive pharmacy services provided within pharmacies require effective use of skills and knowledgeable staff. This is achieved by active and adequate interaction with the client and other health professionals. Despite attempts to more broadly increase the community pharmacist's role in health care, obstacles often preclude delivery of such quality-enhanced pharmacy services.[113] Along with heavy workloads, lack of reimbursement for clinical services is one of the most common reasons cited by pharmacists regarding their failure to provide such services.[38-41] Economic viability through public and private funding would be key in the long-term sustainability of such services in the pharmacies, especially in a budget-constrained health system.[114]

Health-related advice in Australian pharmacies is provided at no cost to clients, and without financial support from government or private health insurance.[114] This financial barrier is one of the most common reasons for pharmacists' reluctance to provide more comprehensive cognitive services, the common perception being clients are not willing to pay for such services.[115] Contrary to that belief, there is evidence that more clients are willing to pay for pharmacists' services today than 15-20 years ago.[116] Few studies have attempted to investigate WTP for pharmacy services in Australia.

A study evaluating client's WTP for personalised asthma management trialled – at no cost to participants – in Australian pharmacies reported the participants valued the pharmacists' services and were willing to pay.[114] In further analysis, the same researchers identified clients were willing to pay a median of AUD18.00 for consultation in a private area, and AUD22.80 for provision of comprehensive advice on asthma and related medication.[117]

A recent study of 80 participants recruited from eight pharmacies in WA[118] determined WTP and cost-effectiveness pertaining to a pharmacy-based smoking cessation program that used digital ageing of the client's image as a motivational intervention. The program was cost-effective, with an incremental cost-effectiveness ratio of AUD46 per additional quitter.[118] On average, participants indicated they were willing to pay AUD20.25 for the service.[118]

Hanna *et al.*[115] determined the WTP of clients (n=130) and its relation to demographic variables for diabetes management in 14 community pharmacies across Sydney, Australia. WTP was assessed by asking how much the clients were willing to pay for initial and follow-up consultation, ranging from AUD0-80 in \$10 increments, per 30 minutes of consultation.[115] The four scenarios assessed were 50 and 100% improvement in diabetes control after a 30-minute initial and 30-minute follow-up consultation. For 50% improvement following a 30-minute initial consultation, clients were willing to pay a median of AUD30, while for 100% improvement, they were

willing to pay AUD40. The WTP for a 30-minute follow-up consultation was AUD20 for 50% improvement, and AUD30 for 100% improvement.[115]

2.6. Bowel Disease

This section explores the clinical presentation of bowel conditions, as a foundation for the clinical intervention reported in this thesis. The role of pharmacies in management of bowel symptoms in the community is then evaluated with reference to published research.

Bowel symptoms, such as diarrhoea, constipation and rectal bleeding, are common.[4] Over a one-year period, almost one in four people in most developed countries experience lower gastrointestinal symptoms, such as rectal bleeding and diarrhoea.[2, 3] Similarly, it has been reported one or more gastro-intestinal symptoms are prevalent in 47% of women and 27% of men.[119] A number of bowel (colorectal) diseases share common clinical presentations, and certain symptom profiles significantly increase the risk of serious underlying conditions such as cancer, inflammatory bowel disease (IBD), large adenomatous polyps,[5] diverticular disease and irritable bowel syndrome (IBS).[6, 120] Other benign bowel diseases include haemorrhoids, anal fistula and anal fissure, all of which need to be managed conscientiously.[121] The symptoms of benign bowel disease often mimic those of malignant conditions, complicating diagnosis. Symptoms of particular concern, and that have been associated with colorectal cancer (CRC) are rectal bleeding, abdominal pain and abnormal bowel habits. CRC is also a major public health concern.

2.6.1. Diverticular Disease

Colonic diverticulosis refers to bulging pockets of tissue (sacs) that push out “colonic lumen due to mucosal herniation through the colonic wall at sites of vascular perforation.” In diverticulitis, the diverticulum ruptures and becomes infected. Diverticular disease and its complications are responsible for nearly 40% of hospital emergency admissions for bowel pathology. The prevalence of colonic diverticulosis

increases with age, and the condition is more prevalent in developed countries.[122-124] Diverticular disease affects more than 65% of people over the age of 80, whereas less than 10% of people younger than 40 will develop the disease.[123, 124]

Non-symptomatic diverticular disease is frequently an incidental finding during an assessment for a different purpose using stool testing or colonoscopy.[122] While majority of patients with diverticulosis are asymptomatic, 20-30% will develop symptoms.[6] Patients with symptomatic diverticular disease present with abdominal pain, bloating and constipation.[6, 7, 122, 123, 125] Since the incidence of this disease increases with age, those presenting with symptoms are mostly the elderly.[6] [6, 122] Another complication is haemorrhage, affecting 5-15%.[6] Inflammatory bowel disease, Crohn’s disease and ulcerative colitis, may have similar presentation to diverticulitis.[6] Figure 2.6 shows the diagrammatical representation of the natural history of diverticulitis, adapted to highlight the associated symptoms.[6]

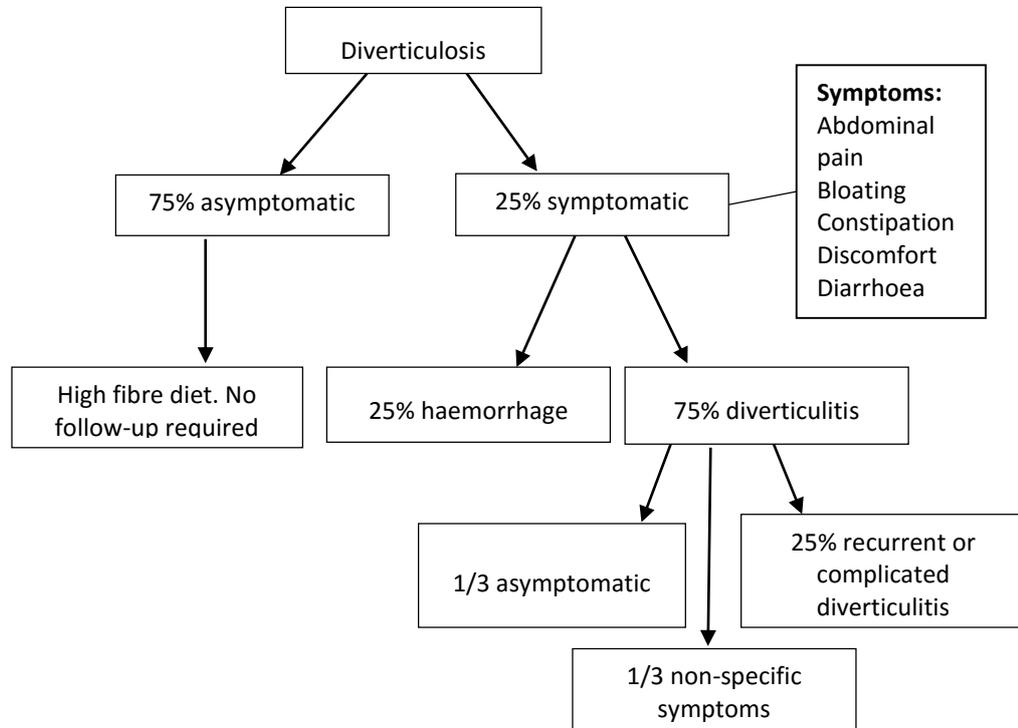


Figure 2.6: Natural History of Diverticulosis

Produced using data from Fearnhead *et al.*[6]

Diverticular haemorrhage, which is more common in the older age group, is not tolerated well by these individuals, leading to significantly high morbidity and mortality rates.[6] Diverticulitis ranges from uncomplicated diverticulitis, which is more common, to complicated diverticulitis, which requires surgical intervention.[6] The majority of patients with diverticulitis present with short duration of symptoms and may have recurrent attacks.[124]

Diverticulitis impacts the health-related quality of life of patients. Studies show evidence of poor scores on SF-36 quality of life (QoL) questionnaire by patients with this disease.[126, 127] Specifically, diverticulitis was reported to have a negative impact on QoL scores relating to physical, psychological and social functioning.[126-128] These manifest as compromised work productivity, sleep interruption, sexual dysfunction, depression, lack of motivation, anger and anxiety.[128]

The severity of diverticulitis is often graded via Hinchey's classification: the risk of death is less than 5% for most patients with Stage 1 or 2 diverticulitis, approximately 13% for those with Stage 3, and 43% for those with Stage 4.[124]

2.6.2. Inflammatory Bowel Disease

IBD is not a single entity, rather a collection of inflammatory disorders of the bowel, which include Crohn's disease and ulcerative colitis.[129-132] These diseases are characterised by relapses and remissions.[133] The aetiologies of these diseases are at this time unknown.[133] They represent a collection of diseases where the lining of digestive tract becomes inflamed and damaged.[132] The incidence and prevalence of IBD has increased significantly in the past decade.[129] The prevalence of IBD is highest in developed countries, e.g. North America and Europe. However, IBD cases are emerging in developing countries like China, South Korea and India, possibly related to industrialisation of these countries.[134] The prevalence of ulcerative colitis worldwide ranges from 37 to 246 cases per 100,000.[129] The prevalence of Crohn's disease worldwide ranges from 26 to 199 cases per 100,000.[129]

Common symptoms in ulcerative colitis and Crohn's disease are rectal bleeding, diarrhoea, abdominal pain and weight loss (Figure 2.7).[130, 132] The disorders share other points of similarity: features of genetic susceptibility, epidemiologic, immunologic, and other pathogenetic features. However, ulcerative colitis involves the colon (large intestine) only, whereas any part of the gastrointestinal tract may be affected in Crohn's disease.[135] For most people with IBD, there will be periods of remission interspersed with flare-ups. The flare-ups are the active stage of the disease.[136] Although there is no cure for IBD, it can often be effectively managed with medication.

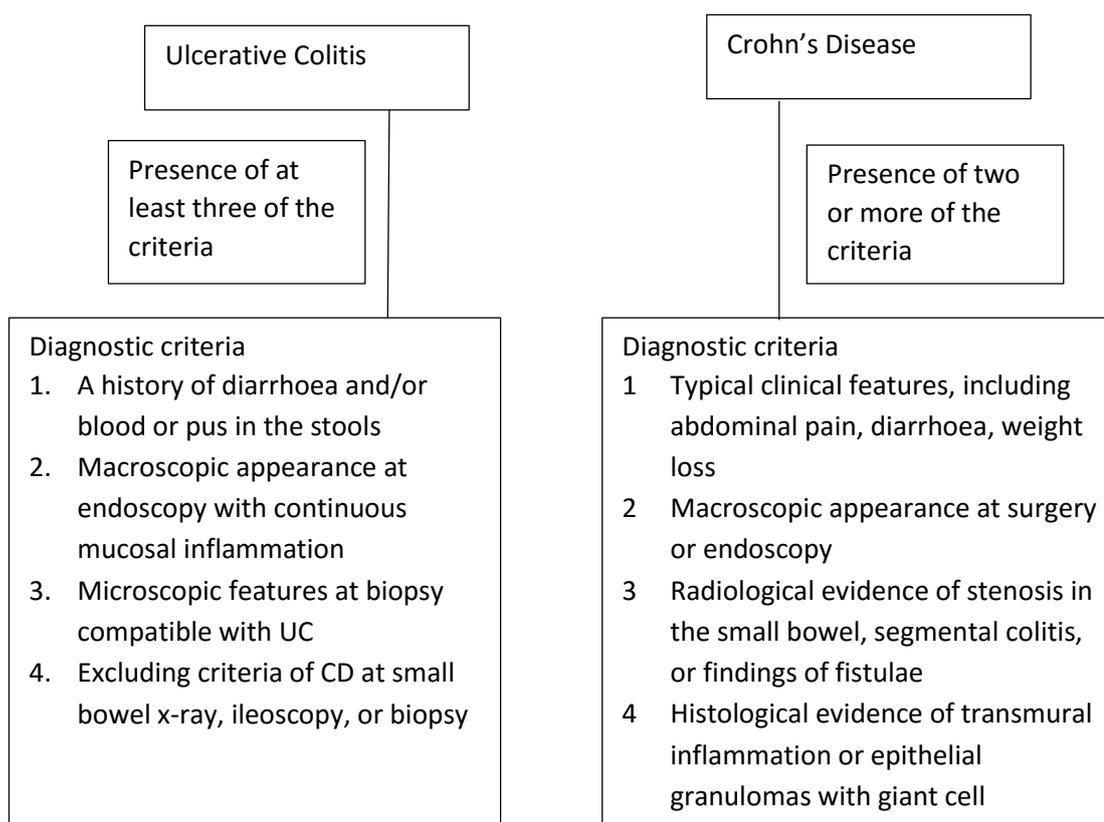


Figure 2.7: Diagnostic Criteria of Ulcerative Colitis and Crohn's Disease
Produced using data from Bernklev *et al.*[135]

IBD is chronic and debilitating, with a significant impact on health status,[137] activity limitation and restriction in participation.[138] A disease-specific symptom scale, the Inflammatory Bowel Disease Questionnaire, has been developed to assess quality of life of patients with IBD, and comprises four domains: assessing the bowel symptoms, systemic symptoms, emotional functions and social functions.[131, 137, 139]

Using the Inflammatory Bowel Disease Questionnaire, researchers have identified a negative correlation between quality of life in IBD patients and variables such as unemployment and sick leave.[135] Indeed, work absenteeism and requirement for financial support add to the mounting cost of these diseases.[140, 141]

Patients with IBD are at increased risk of developing CRC. Although IBD-associated cancer only constitutes 1-2% of all colorectal carcinomas, CRC is a common cause of death in IBD patients.[142, 143]

2.6.3. Irritable Bowel Syndrome

IBS is characterised by chronic abdominal pain or discomfort associated with a change in bowel habit that cannot be explained by any organic or biochemical abnormality.[120] It is defined as a “group of functional bowel disorders in which abdominal discomfort or pain is associated with defecation or a change in bowel habit, and with features of disordered defecation.”[120, 144-146] The Rome III classification system characterises IBS in terms of multiple physiological determinants contributing to a common set of symptoms, rather than a single disease entity. Diagnosis is based on identifying positive symptoms and excluding “alarm features” such as weight loss, refractory diarrhoea, and family history of colon cancer.[120]

Symptoms that cumulatively support the diagnosis of IBS are:[120]

- abnormal stool frequency
- abnormal stool form (lumpy/hard or loose/watery stool)
- abnormal stool passage (straining, urgency, or feeling of incomplete evacuation)
- passage of mucus
- bloating or feeling of abdominal distension.

Population-based studies estimate prevalence of this condition at 7-22%, higher in women, and initial presentation commonly at 15-40 years of age.[7, 147-150]

Patients with IBS exhibit similar degrees of impairment of QoL to those reported by those with IBD.[147] The natural history of IBS is one of relapsing symptoms.[147] The presence of co-morbid medical conditions and the extent to which their IBS symptoms affect their physical and mental wellbeing determine patients' help-seeking behaviour.[16]

2.6.4. **Colorectal Cancer**

Bowel cancer, which includes cancers of the bowel or large intestine and cancers of the rectum and anus, is sometimes referred to as CRC.[151] It is the second-most-common cancer diagnosed in males (after prostate cancer) and in females (after breast cancer) in Australia. The incidence of bowel cancer has been increasing each year since 1982, with 15,151 new cases diagnosed in 2011. In 2011, the age-standardised incidence rate was 62 cases per 100,000 persons.[152] It is also second only to lung cancer as the most common cause of cancer death in Australia.[151] There is currently a one-in-10 lifetime risk for males of being diagnosed with CRC by the age of 85 years, and a one-in-15 risk for females.[153]

Lower bowel symptoms may be indicative of CRC, especially when persisting for at least four weeks in individuals aged ≥ 60 years, and for at least six weeks in those aged ≥ 40 years, respectively.[154] Almost 40% of people aged 50 years and older harbour

adenomatous polyps; 2% of such adenomas will progress to cancer.[155] Prognosis is better if CRC is detected at an early stage. The progression from identifiable precancerous phase to CRC takes approximately 5-10 years. So there is opportunity for screening programs. When CRC is diagnosed at an early, localised stage, the five-year survival rate is 91%, decreasing to just 9% for diagnosis involving distant metastases.[156, 157] In Australia, bowel cancer is not diagnosed at an early stage in the majority of cases.[156]

Symptoms such as rectal bleeding, anaemia, change in bowel habit and abdominal pain are predictors of CRC and advanced adenomas.[158-162] Retrospective data suggest about 40% of patients with CRC have rectal bleeding, but the risk of CRC for a patient with rectal bleeding is thought to be relatively low.[163] Rectal bleeding has a positive predictive value of 3-7% for CRC and 4% for colonic adenomas.[163] The National Institute for Health and Clinical Excellence, UK, recommends urgent referral of clients aged over 40 years with six weeks of rectal bleeding accompanied by diarrhoea, and referral of clients aged 60 years or more with rectal bleeding for six weeks without anal symptoms or diarrhoea.[154] An estimated 28-41% of people experiencing rectal bleeding consult their GP.[3, 164]

Clients with more severe chronic constipation are associated with a significantly greater risk of developing CRC and benign colorectal neoplasm over time, compared to chronic constipation-free patients.[165]

The prognosis for CRC detected at early stage is good. Hamilton *et al.* reported in their recent study that colon cancer was one of the cancers for which the symptomatic patients would benefit in expediting the diagnosis.[166] Adenomatous polyps, generally accepted as non-obligate precursor lesions, are common in adults over age 50 years, but the majority of polyps will not develop into adenocarcinoma; histology and size determine their clinical importance.[167-169]

The testing options for early detection of CRC and adenomatous polyps for adults aged 50 years and older are:[169]

- flexible sigmoidoscopy every 5 years, or
- colonoscopy every 10 years, or
- double-contrast barium enema every 5 years, or
- computed tomographic colonography every 5 years.
- Annual guaiac-based faecal occult blood test (FOBT).

2.6.4.1. Faecal Occult Blood Test

One screening test that is accessible and key to early detection of CRC is the FOBT, which can detect small amounts of blood in the bowel motion. This involves testing two or three motion samples. Samples are collected in the privacy of the patient's home, deposited at an agency, and forwarded to a pathology laboratory for analysis. The results are sent to the patient and his/her GP. If the results are positive, further investigations are recommended.[170]

Although this test is the most researched for bowel cancer, there are limitations in its availability via the National Bowel Cancer Screening Program in Australia. Since the program is limited to people aged 50, 55, 60, 65 and 74 years, it excludes a proportion of people at risk of CRC. The average age of a patient with CRC is 68 years.[171] Participation in the program is reportedly poor,[172] with barriers such as "inconvenience of the testing process, aversion to manipulating faeces, lack of perceived benefit of screening, fear of a diagnosis of cancer, cost, views about personal invulnerability, and cultural beliefs and attitudes."[173]

2.7. Help-Seeking Behaviour

Seeking medical advice and initiation of treatment in the early stage of a disease improves the prognosis and QoL. It follows that late presentation or failure to seek medical help may delay the diagnosis and worsen the prognosis.

Help seeking is a complex phenomenon that may be influenced by a multitude of factors including age, socioeconomic status, marital status, education, employment

status, level of health insurance, ethnicity, lack of perception of the seriousness of the disease, an assumption that the condition would clear up by itself or embarrassment.[8, 174-179] Several studies have shown delay in seeking medical consultation is common.[32-36] Along with the clients' recognition and awareness of the symptoms, the understanding of the potential seriousness of the symptoms is also very important.

2.7.1. Bowel Disease and Help-Seeking Behaviour

There is robust evidence to suggest many patients with colorectal disease present late with symptoms, and only a minority of patients seek timely medical advice for their symptoms, the rate of doctor consultation among these patients varying from 14% to 41%.[3, 10-12] Of the 7-10 months' median delay between onset of symptoms and diagnosis of CRC, at least three months is due to delay by the patient in seeking medical help; the rest is due to a delay in diagnosis.[159]

A population-based telephone survey (n=1019) of people's knowledge about CRC-associated symptoms in the UK revealed delays in medical investigation due to ignorance of bowel cancer symptoms (50% of respondents), lack of appreciation of the significance of the symptoms (40%) and attributing bowel habit change to diet alterations (15%).[159]

A number of community-based studies have reported the prevalence of rectal bleeding and the consultation rate of people who had rectal bleeding in the past 12 months or during their lifetime (Table 2.4). A notable trend in the studies indicates that less than 45% of participants with rectal bleeding sought timely help.

Table 2.4: Prevalence and Help-Seeking Rate for Rectal Bleeding

Study	Country	Age range (years)	Sample Size	Prevalence	% Seeking Medical Help
Talley et al.[11]	United States	20-64	1643	15.5% Past 12 months	13.9%
Crosland et al.[3]	United Kingdom	20-80	1200	19% Past 12 months	41%
Byles et al.[178]	Australia	>40	2619	20% Lifelong	30%
Eslick et al.[14]	Australia	>18	338	18% Past 12 months	31%

Produced using data from Eslick *et al.*[14]

In a British study of 3,264 patients with IBD-related faecal incontinence, the researchers claimed 74% of the sample reported faecal incontinence, but only 38% sought medical help for this symptom.[15] The reasons for not seeking help were perceived lack of interest and sympathy from healthcare professionals, embarrassment and unawareness of available help.[15]

In a population-based study in the US to determine the factors associated with healthcare seeking behaviour of patients with IBS, William *et al.* reported only 49% sought medical care for abdominal symptoms associated with IBS in the past 12 months.[16] The researchers noted patients whose work and social functioning was affected by the symptoms, thus scoring low on IBS-specific QoL scale, were more likely to have sought medical help for their symptoms.[16]

Delayed diagnosis of serious colorectal pathology occurs due to delay in the client's presentation to a doctor, delayed referral to a specialist, and finally, the delay in diagnosis.[44] A systematic review by Mitchell *et al.*[44] of the influences of pre-hospital delay in the diagnosis of CRC points to the influences of social network and support as a potentially important factors in reducing delay.[44] Symptom awareness and clients' interpretation of symptoms was a common theme across the studies

identified in the systematic review. Lack of knowledge about colorectal diseases and/or the availability of screening were major contributors to increased delay.[44] Furthermore, the authors observed an increased delay was also found in clients who self-diagnosed or self-medicated before presenting to a GP.[8, 44] They suggested people associate the symptoms to benign disease, and embarrassment of symptoms would deter reporting.[44]

2.7.2. Role of Pharmacies in the Management of Bowel Symptoms

Published data suggest one in 15 people identify the pharmacist as a source of advice about bowel symptoms.[21] In Australia, three or more clients present per pharmacy every week seeking symptomatic treatment for bowel symptoms.[21] A study by Phillip *et al.* stated at the onset of diarrhoea, 16% would consult a pharmacist and only 8% would consult a GP.[180] Similarly, while rectal bleeding is common in the general population, only one-third of those with rectal bleeding in an Australian population consulted a GP about their condition, as has been noted in other populations.[14, 181, 182]

Definitive diagnosis of persistent symptoms requires medical consultation.[13] Given that bowel symptoms such as diarrhoea, rectal bleeding and altered bowel habit can be attributed to self-limiting or benign illness, GPs differentiate between patients with benign symptoms and those with symptoms that could be due to a serious bowel condition.

Pharmacists are well placed to help identify symptomatic clients in community pharmacies who should be encouraged to consult a medical practitioner. Despite this, in a survey of 167 registered pharmacists in WA, it was demonstrated that bowel symptoms indicative of serious disease were not recognised in a significant proportion of cases.[13, 24] A self-administered questionnaire with vignettes constructed around six clinical variables: age, gender, duration of symptom, rectal bleeding, change in bowel habits and weight loss, were completed by the pharmacists. They described their referral pathway for each of the nine vignettes

posted to them.[13, 24] When compared to the expert panel's opinion, 63% of pharmacists disagreed on weight loss due to bowel symptoms as warranting a GP referral and 30% did not agree that rectal bleeding for four weeks duration merits a referral. Over 60% of pharmacists did not consider persistent diarrhoea in a 65-year-old client as a likely symptom of significant bowel pathology which was in contrast to cancer guidelines.[13, 24]

Discussing embarrassing symptoms has been reported as a barrier to seeking help.[183] For example, when pharmacists were probed on their views and beliefs about benefits of treating women with symptoms suggestive of vaginal thrush, the popular perception was around client embarrassment, influenced by lack of privacy.[25] The major challenge encountered by pharmacists in this situation is to obtain an accurate history and symptom details from the client.[25]

Similar issues are expected to arise in consultations relating to bowel symptoms. Despite this, there appears to be a role for community pharmacy staff in the management/triage of clients with bowel symptoms. Pharmacies are accessible, and clients present for non-prescription medicine purchases. There is some evidence that a self-administered questionnaire can be an effective tool in supporting primary health care professionals to triage cases that warrant further investigation for colorectal pathology.[30] In order to explore the strength of evidence in this field, a comprehensive literature search was undertaken, as reported below.

2.7.3. Literature Search

A comprehensive literature review was conducted to identify the risk factors for bowel disease. Studies reporting trials of published instruments were also reviewed to determine the effectiveness of questionnaires in identifying symptoms indicating risk of bowel disease. A search strategy was developed to source peer-reviewed English-language papers using CINAHL, Medline (Ovid) and Scopus databases. The search spanned January 1990 to October 2012. The search method is shown in Table 2.5.

This literature search was reported in the following paper:

Sriram D, Jiwa M, McManus A, Emmerton L, Parsons R. Development and validation of a clinical decision-making aid for screening bowel symptoms in community pharmacies. *Journal of Evaluation in Clinical Practice* 2014; 20: 260-6.

Table 2.5: Literature Search Strategy and Results

Database Searched	Search Terms	Results
CINAHL	(Questionnaire OR Survey OR Advice OR "Cognitive Service" OR Referral) AND (Bowel OR "Bowel Symptoms")	574
	("Bowel Symptoms" OR Bowel) AND "Primary Health Care"	16
	("Bowel Symptoms" OR Bowel) AND (Pharmacy OR Chemist OR "Drug store")	6
	("Bowel symptoms" OR Bowel) AND ("Bowel disease" OR "Bowel pathology")	317
Medline (Ovid)	(Questionnaire OR Survey OR Advice OR "Cognitive Service" OR Referral) AND (Bowel OR "Bowel Symptoms")	36
	("Bowel Symptoms" OR Bowel) AND "Primary Health Care"	6
	("Bowel Symptoms" OR Bowel) AND (Pharmacy OR Chemist OR "Drug store")	1
	("Bowel symptoms" OR Bowel) AND ("Bowel disease" OR "Bowel pathology")	414
Scopus	(Questionnaire OR Survey OR Advice OR "Cognitive Service" OR Referral) AND (Bowel OR "Bowel Symptoms")	499
	("Bowel Symptoms" OR Bowel) AND "Primary Health Care"	94
	("Bowel Symptoms" OR Bowel) AND (Pharmacy OR Chemist OR "Drug store")	17
	("Bowel symptoms" OR Bowel) AND ("Bowel disease" OR "Bowel pathology")	388

Limiters: Adult, Human, English language, Peer reviewed

The researcher (DS) and two co-investigators (MJ and AM) reviewed the titles and abstracts of the articles and reached a consensus on articles that met the inclusion criteria of:

- Publication in English
- Peer-reviewed research article (rather than letter or commentary)
- Primary focus on bowel symptoms, duration of symptoms
- Focus on primary health care
- Reporting pharmacy as the setting for health advice
- Reporting a screening questionnaire for bowel disease.

The search produced 2,368 reports. Deletion of duplicates reduced the total to 1,243. Title and abstract review further reduced the search results to 110 articles. The literature search results are shown in Figure 3.1. Of the 110 identified reports, 14 focussing on bowel symptoms were identified, and the significance, duration and associated risks of these symptoms were noted.[4, 119-121, 148-150, 154, 155, 161, 162, 165, 180, 184]

Review of the literature suggested the following symptoms indicate significant risk for chronic bowel disease and warrant consideration in a screening questionnaire: rectal bleeding, change in bowel habit, increased frequency in bowel motions, abdominal pain, abdominal discomfort, and incomplete defecation.[30, 148, 154, 165, 185] The duration and frequency of the symptom(s), pain, loss of weight, anaemia and history of gastrointestinal disease were also considered key factors for diagnosis of bowel disease.[29, 162, 185]

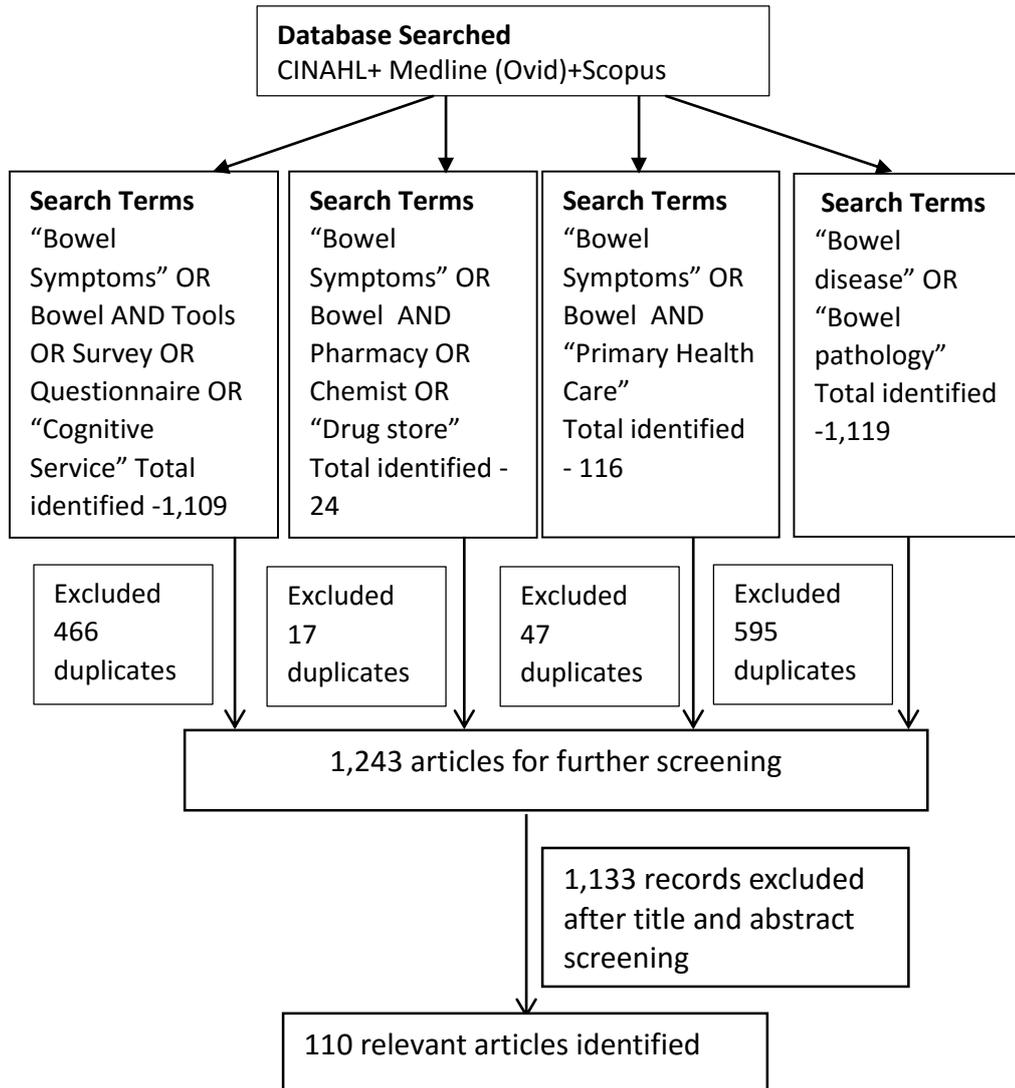


Figure 2.8: Flow diagram of the Results of a Literature Search of Risk Factors of Bowel Disease

2.7.4. Questionnaires for Screening of Bowel Symptoms

The Rome III Diagnostic Questionnaire for Functional Gastro-Intestinal Disorders was developed by the Rome Foundation, Inc. (US), based on Rome III diagnostic criteria.[144] The rationale behind the development of symptom-based diagnostic classification was the presence of symptom clusters that remain consistent across different gastrointestinal tract. These criteria can be used for reliable diagnosis and specific treatment.[144] The questionnaire applies a coding system and takes 15-20 minutes to complete. This questionnaire is designed for clinical use, with a

psychosocial module and response format including Yes/No, five-point ordinal scales for conditional questions and seven-point ordinal scales for frequency questions. The questionnaire is subdivided into question and coding modules for oesophageal, gastro-duodenal, gall bladder/sphincter of Oddi, bowel, chronic abdominal pain and anorectal disorders.[144]

Kolosky *et al.*[186] used the Rome III diagnosis questionnaire for functional constipation and IBS symptoms, the Hospital Anxiety and Depression Scale for assessing psychological distress, and the SF-12 to measure QoL, in a population-based study to differentiate IBS-constipation from functional constipation. A postal survey of 3,260 randomly selected Australians using this self-report instrument reported that abdominal pain associated with IBS-constipation resulted in more people seeking health care than patients with functional constipation. Lifestyle factors and psychological distress remained similar in both sub-types of constipation. This study also argued that the symptom cluster as classified in the Rome III questionnaire was somewhat superficial, except for the frequency of abdominal pain, and suggested differentiation based on symptom severity rather than cluster.

Talley *et al.*[187, 188] developed and validated a Bowel Symptom Questionnaire to identify patients with functional gastrointestinal disease, IBS and functional dyspepsia. The questionnaire covers 46 gastrointestinal symptoms and questions exploring past and present health, a Psychosomatic Symptom checklist, health habit questions and socio-demographic items.[189] This instrument is 15 pages long and comprises 83 items. The instrument was completed by 467 patients before their clinical evaluation to determine the diagnostic value of an *a priori* symptom score.[187] The researchers developed a symptom score to identify and classify patients with functional gastrointestinal disease; however, further validation has not been reported.[187]

The Elderly Bowel Symptom Questionnaire,[190] based on the Bowel Symptom Questionnaire, was developed for elderly patients aged 65 to 95 years of age, and has value in community and out-patient settings for identifying persons with chronic

gastrointestinal symptoms, including IBS. It takes approximately 20 minutes to complete.

The Bowel Symptom Checker[191] (<https://www.nhs.uk/symptom-checker/>) developed by the National Health Service, UK, is a web-based screening instrument. This website prompts the individual to answer questions about his/her symptom(s), and based on the reply, consequent questions are prompted. The symptom checker then provides management advice, including referral to the GP, depending on the symptom pattern.[191] There is no available evidence regarding scientific validation of the symptom assessment questions.

The CRISP (Colonoscopy Research into Symptom Prediction) Study [29, 161] developed and validated a bowel symptom questionnaire to be deployed before a patient's specialist consultation. The CRISP study aimed to develop and assess the reliability of a bowel symptom self-administered questionnaire potentially relating to CRC. In a trial in Australia, this questionnaire was administered to 263 patients who were likely to have a colonoscopy, before they consulted a gastroenterologist or a colorectal surgeon. The researchers reported it as reliable in assessing bowel symptoms, and acceptable by patients to complete in the waiting room. It took approximately 15 minutes to complete. The patients from this study reported, on average, one extra symptom than elicited by the specialist,[192] which is consistent with other research.[193]

Hippisley-Cox and Coupland[162] derived and validated a risk-prediction algorithm to quantify the absolute risk of CRC in patients. This prospective cohort study was carried out on primary care patients obtained using the QResearch database (version 30) from practices in England and Wales. Over 2 million (n = 2,351,052) patients were included for development of the algorithm and 1,236,601 patients for validation of the algorithm. Patients included were free at baseline from CRC and without any symptoms of rectal bleeding, abdominal pain or weight loss in the last 12 years. The primary outcome was incident diagnosis of CRC in the next 2 years after study entry. The algorithm was based on a combination of risk factors: age, family history of

gastrointestinal cancer, anaemia, rectal bleeding, abdominal pain, appetite loss and weight loss in females. Similar risk factors were used for males, with inclusion of alcohol use and change in bowel habits. The authors claimed that while the algorithm is likely to be most applicable in that setting, it could be used elsewhere, e.g. by patients using a web calculator, provided caution is applied in the interpretation of clinical symptoms by non-health professionals. Since the diagnosis and analysis is algorithm based, the limitation of this method is inaccurate or missing data. Since the information for validation was obtained from the same clinical computer system as used for development of the algorithm, external validation is required.

Hamilton's review[194] of the CAPER (Cancer Prediction in Exeter) study reported the quantification of risk of cancer symptoms and primary care investigations. CRC was one of the six cancers investigated in that study. Bowel symptom plus threshold haemoglobin values contributed highly to the CAPER score, thus facilitating easy identification and a cue to GPs for further investigation. Khan[195] tested the feasibility of a paper-based assessment tool incorporating the CAPER score in patients presenting for GP consultation. The study protocol of the assessment tool included the GP calculating the CAPER score, a score of 35 or over prompting a referral, which might include FOBT, haemoglobin test and rectal examination. The assessment tool compliance rate was low. Recommendations from the assessment tool were not routinely followed by the GP. In many cases, test results, such as haemoglobin level, were not recorded in the assessment tool. This study identified barriers in effective implementation at practice level, similarly to a study by Khammarina *et al.*[196] There were also barriers relating to the healthcare professionals' action, which is in line with Cabana *et al's* systematic review, which identified individuals' knowledge, attitudes and behaviour as barriers to adoption of a change in practice[92].

Khan's study on implementation of assessment tool thus a change in practice, brings into focus the design and the delivery of assessment tools in the primary care. This reiterates the importance of identifying barriers for a change to be accepted and implemented.[93]

The findings from the CRISP study[192] and Fromme *et al.*[193] further establish the importance of a self-administered questionnaire for eliciting symptoms, especially if the patient is embarrassed or hesitant to discuss symptoms.

Most of the above studies were developed with high sensitivity for CRC, and were tested in the GPs' or colorectal specialists' waiting rooms.[187, 192, 195] Another commonality is that most of the questionnaires took approximately 15-20 minutes to complete. There were no reported studies that reported the use of these questionnaires in a community pharmacy setting.

One additional questionnaire was developed with high sensitivity for CRC and for use within general practice: the Patient Consultation Questionnaire (PCQ). This instrument is critiqued below.

2.7.4.1. Patient Consultation Questionnaire

Within general practice, the PCQ has been demonstrated as an efficient and objective self-administered instrument that prioritises colorectal referral, and has high sensitivity for serious colorectal pathologies.[5, 197] Prospective studies from the UK have validated the PCQ for prediction of CRC and prioritisation of CRC referrals.[5, 30, 197, 198] The PCQ is a 60-domain questionnaire of bowel symptoms and symptom complexes, its duration, progression, medical and family history. The value of this questionnaire, compared to others, is that it offers a numeric score for the risk of colorectal pathologies. Each symptom has a score which depends on the patient's age, type of bleeding, frequency and duration of symptoms. The PCQ data had to be entered into a computer software program to get a score ranging from zero to one hundred.[197]

Rai *et al.* conducted a prospective study to validate the PCQ against the 'two-week wait' system introduced by the UK Government for the prioritisation of CRC referral.[197] The study was conducted on 3,128 patients, including those referred

by their GP for specialist consultation and those on the two-week wait referral list. The completed PCQs from 1,422 patients indicated the most common presenting symptom as rectal bleeding and change in bowel habits.[197] There were 83 confirmed diagnoses amongst the 1,422 patients. Table 2.6 shows the risk of cancer with increasing PCQ score. A score of 70 and over equates to a risk ratio of 1:5 for CRC.[197]

Table 2.6: Colorectal Cancer risk and PCQ score

PCQ Weighted Numerical Score	No. of cancers (%)	Risk ratio for CRC
<40	4 (0.8)	1 in 123
40-49	3 (1.4)	1 in 74
50-59	12 (5.4)	1 in 19
60-69	11 (5.4)	1 in 18
≥ 70	53 (18.7)	1 in 5

Adapted with permission from Rai *et al.*[197]

In a prospective study by Ballal *et al.* in a district hospital in Wales,[5] 3,457 bowel symptomatic patients who were referred by their medical practitioners to consult colorectal specialists completed the PCQ. This study was conducted to further validate the scores for prioritising referral of CRC. Patients underwent colorectal investigations, and sensitivity, specificity and accuracy of CRC detection (as determined by the score) were established. This study reported similar results to those of Rai *et al.*[197] with regard to the risk ratio for CRC. Scores in the range of 50-59 corresponded to a risk ratio of 1:19, and 70 and over, a risk ratio of 1:8.[5] This led to the conclusion that the relative risk for CRC with a PCQ score in the range 50-59 is 1:19, rising to a risk between 1:5 to 1:8 for patients with a score at or above 70.[5, 197]

Jiwa and colleagues used the PCQ in community pharmacy setting in a feasibility study for triage of clients who might be at high risk of CRC.[23] Twenty-one WA community pharmacies used the PCQ to identify clients at risk of CRC. Pharmacy

clients with bowel symptoms completed the PCQ, and the completed questionnaire was posted to the researcher to determine the score using a programmed algorithm. A score of 50 was considered the threshold, above which the participants were referred to their GP. Referral advice was sent to the participants approximately one week after their pharmacy visit. The low PCQ scores were consistent with the profile of clients who seek over-the-counter treatment.[23, 199] Only eight patients were recommended to consult their GP, five of whom followed this advice.

The researchers noted three main problems with implementing the PCQ in pharmacies:

- The PCQ is a 60-domain questionnaire and takes approximately 10 minutes to complete. Therefore, it is expected to be impractical and burdensome for completion in a busy pharmacy setting.
- PCQ scoring required input into a computerised scoring system. The algorithm was not available in a mobile platform at the time of the study, nor were pharmacists granted access to the algorithm, requiring data input by the researcher. This limited the application of the PCQ in the pharmacy, as the results and the referral could not be provided to the client immediately during consultation with the pharmacists.
- The PCQ was developed to prioritise CRC referral. In practice, clients may present with multiple conditions, which although identified as benign and self-limiting using the PCQ, may benefit from the advice of a GP (e.g. severe haemorrhoids, persistent diarrhoea and recurrent constipation).[154, 155]

With reference to the published literature on the PCQ and other instruments for bowel symptom screening, it is evident a simpler screening tool is needed, retaining high sensitivity for bowel disease, to triage clients presenting with bowel symptoms at pharmacies. A self-administered questionnaire would be ideal for a client presenting with embarrassing symptoms in a busy pharmacy. A simple decision-aid tool can help in standardising and streamlining the consultation process for bowel symptoms in the pharmacy. There is an opportunity to test the value of a simple

triage tool to help pharmacists and pharmacy staffs identify symptomatic patients who should be referred to a medical practitioner.

2.8. Conclusion and Recommendations

This review of published literature has established the value of community pharmacy in primary health care. Bowel symptoms are prevalent in the community, and a number of bowel diseases share common clinical presentations. Furthermore, certain symptom profiles significantly raise the probability of serious underlying conditions such as cancer, colitis, or large adenomatous polyps. Research has also established many people with colorectal disease present late with such symptoms, yet the public identifies pharmacies as good source of advice for their bowel symptoms.

To improve the outcomes of symptomatic clients who might be at risk of bowel disease, they should be encouraged to consult the GP for a definitive diagnosis. There is evidence a self-administered questionnaire can be an effective tool in supporting the pharmacist to triage cases for further investigation for colorectal pathology. The available questionnaires for bowel symptoms have been developed for use in a different setting to pharmacy. For symptomatic clients who present in community pharmacies, it would be helpful to design and test validated tools that can be used by pharmacy staff to identify and encourage individuals to seek medical help.

The following two chapters explore the development and application of a self-administered questionnaire that facilitates identification of clients who might benefit from GP consultation, and encourages at-risk clients to seek medical review.

3. Development and Validation of a Bowel Symptom Consultation Guide

3.1. Introduction

It is evident from the review of published literature (Chapter 2) that community pharmacies are well placed to play a constructive and dynamic role in the provision of effective primary health care. Pharmacies have become important providers of various client-centred healthcare services, which present pharmacists with opportunities to identify and address health-related issues. Pharmacists also have the capacity to offer support and/or referral to symptomatic clients who would benefit from medical advice from a GP. Indeed, a number of studies have reported positive impact from the collaboration of pharmacists and GPs in patient management.[23, 31, 83-85]

Chapter 2 presents evidence around the common occurrence of bowel symptoms and their association with serious underlying conditions such as CRC, large adenomatous polyps, diverticular disease, IBS and IBD. Published data suggest that the majority of people identify pharmacists as a source of advice about bowel symptoms.[21] Pharmacies are accessible, and clients present for both prescription and non-prescription medicine purchases. Challenges, however, relate to conducting a private consultation with clients who are embarrassed about their signs/symptoms, and providing appropriate management of referrals for further investigation.

There is evidence that a self-administered questionnaire can be an effective tool in supporting the primary health care professionals to triage cases that warrant further investigation for colorectal pathology.[30] Almost all bowel symptom questionnaires reported in Chapter 2 (Section 2.7.4) have been developed for use in other settings. Most have multiple domains and pages, and take approximately 15-20 minutes to complete. There are no reported studies that have used these questionnaires in a pharmacy setting other than the PCQ feasibility study, which is reported in detail in Section 2.7.4.1. The researchers found the 60-domain questionnaire (the PCQ), and its requirement of computerised algorithm for scoring, to be burdensome to deploy

in a busy pharmacy setting. Moreover, the PCQ was developed with high sensitivity for CRC and to prioritise CRC referral. To improve the outcome of symptomatic clients who present in the pharmacy with bowel symptoms, there is a need for a simpler screening tool that retains high sensitivity for bowel disease, to identify who might be at risk and encourage them to consult their GP for a definitive diagnosis.

This chapter outlines the steps involved in developing and validating a self-administered clinical decision-making aid for use in pharmacies to help pharmacists and pharmacy staff to identify symptomatic clients who should be referred to a GP. The questionnaire was named the 'Jodi Lee Test' (JLT) to acknowledge the Foundation sponsoring this research.

The Jodi Lee Foundation (www.jodileefoundation.org.au) was formed in Australia in honour of Jodi Lee, who died of bowel cancer at the age of 41 years. The Foundation's mission is to "prevent bowel cancer by motivating people to take screening tests regularly, act quickly on symptoms and lead healthy and active lifestyles." [200] Initiatives include awareness campaigns to educate Australians about the importance of early detection of bowel cancer, and a program for corporate business to screen employees for bowel cancer. In this drive for bowel cancer prevention, the Foundation offered a research fellowship to promote medical consultation by people presenting at pharmacies with bowel symptoms.

A paper describing the study in this chapter has been published in the *Journal of Evaluation in Clinical Practice*, paraphrased and expanded upon in this chapter. Limited content from the published paper has been reproduced with the publisher's permission (Appendix 3.1)

Sriram D, Jiwa M, McManus A, Emmerton L, Parsons R. Development and validation of a clinical decision-making aid for screening bowel symptoms in community pharmacies. *Journal of Evaluation in Clinical Practice* 2014; 20: 260-6.

3.2. Aim and Objectives

The aim of this research stage was to develop and validate a questionnaire for use with pharmacy clients presenting with bowel symptoms. Specific objectives were to:

- identify signs and symptoms that can be considered ‘red flags’ for bowel disease
- construct a decision-aid tool for pharmacy staff to identify who would benefit from further medical consultation and
- validate the identified signs and symptoms, and evaluate the tool’s sensitivity and specificity for symptomatic clients at risk of bowel disease.

3.3. Method

3.3.1. Questionnaire Development

The self-administered questionnaire was developed in three stages: application of evidence from the comprehensive literature search (Section 2.7.3), questionnaire construction, and statistical validation against an existing validated screening tool, the PCQ (Section 2.7.4.1).

Given the limitations of the PCQ in pharmacy settings (noted in Section 2.7.4.1), the JLT was designed with the following features in mind:

- The instrument had to be usable by all pharmacy staff that interacts with clients with bowel symptoms who present in the pharmacy for advice: pharmacy assistants to determine if the client requires consultation with a pharmacist, and pharmacists to determine if referral to the GP is warranted.
- The instrument had to be simple, short, easy-to understand and self-completed by clients, especially if when embarrassed to discuss their symptoms in a busy pharmacy. The questionnaire was designed to be completed by the client using a paper copy, as this was considered appropriate for review and interpretation by the pharmacy staff.

- The instrument was intended to act as a *guide* to clinical decision making. This would facilitate easy interpretation of the responses and thus encourage pharmacists to give appropriate advice and referral during their consultation with the client.
- A 'checklist' approach without score-calculation was determined to be more appropriate in a pharmacy setting rather than to compute a risk score.

All symptoms and questions considered for inclusion in the questionnaire were reviewed by an expert panel, comprising a GP with special interest in bowel disease, a community pharmacy researcher, a public health practitioner and two practising community pharmacists, to enhance the face and content validity of the instrument. For the item-generation phase, a nominal group technique[201] was used. During the initial discussion, each member of the expert panel and the researcher presented their points in a round-robin fashion. The researcher recorded each item on a whiteboard in full view to each member. Free discussion ensued, during which time, opinions and clarifications were expressed and new items were added to the list. At the end of the discussion, all items generated for the questionnaire were recorded by the researcher (Appendix 3.2) Once the questionnaire was prepared, aspects of the Delphi process[202] were applied to identify essential components. The panellists had previously rated (and ranked) the items as part of their involvement in the initial item-generation discussion. Several rounds of iteration to reassess initial judgement of items took place. A revised version of the questionnaire was circulated, taking account of the comments and suggestions from the panel. This was conducted with a view to retaining the minimum number of relevant questions in the instrument that could elicit a decision about referral in a community pharmacy setting. Eliminating ambiguity in the wording and instructions was also considered. Appendix 3.3 illustrates the suggestions resulting from each round of iteration. The process continued until consensus was reached on all parameters.

3.3.1.1. Questionnaire Construction

Clarity, comprehensiveness and representativeness of each item were improved after several rounds of consultation between members of the expert panel. The panellists identified the questions (relating to high-risk symptoms) that would warrant referral to a GP, and an appropriate order for the questions. A decision was made to include constipation as a single symptom, due to evidence from literature that chronic constipation is associated with significantly higher prevalence and incidence of CRC and benign colorectal neoplasm.[165] The other symptoms included in the questionnaire were diarrhoea, rectal bleeding, alternating diarrhoea and constipation, and discomfort in the back passage, due to their strong association with bowel diseases in the literature.

Changes to the draft version included removal of indicators unable to be determined in a pharmacy, such as 'anaemia'. For clients with multiple bowel symptoms, 'Tick all that apply' was included in the question about symptoms. 'Is this symptom(s) associated with any pain?' determined associated pain without localising the pain. A question concerning prior consultation regarding the presenting symptom(s) was retained to provide background information for the pharmacist and GP.

Referral to the GP was indicated if one or more of the five symptoms (diarrhoea, rectal bleeding, alternating diarrhoea and constipation, discomfort in the back passage, constipation) were present for at least one week.

3.3.2. Validation

Readability was considered, as the JLT was designed to be self-completed by the client; however, it was intended that pharmacy staff would assist those who required help to complete the JLT. The Flesh-Kincaid assessment system was used to check the readability of the questionnaire. The score is based on a 100-point scale: the higher the score, the easier it is to comprehend.[203] A score between 70 and 100 was the target.

The PCQ was used as a proxy independent measure of the endpoint, GP consultation. Approval was obtained to use an existing database of 120 PCQ responses from a previous feasibility study.[21, 23] This validation process involved the researcher (DS) completing a JLT from each client record in the PCQ database.[21, 23] In cases where the PCQ data or a corresponding answer in the JLT was unclear, two other researchers (MJ, AM) assigned the JLT responses. One hundred and eighteen PCQ records were translated into responses using the JLT. Two records from the original PCQ dataset were excluded due to the volume of missing information.

The PCQ produces an integer score between 0 and 100 for the risk of bowel disease.[30] In the aforementioned pilot study of the PCQ,[23] a score of 50 was identified as the threshold score, above which, individuals were issued a referral for further investigation. The JLT, by comparison, was designed as a guide for the pharmacy staff member in decision making about client symptom management. The JLT assisted the clinical decisions by highlighting symptoms that persisted for at least one week, thus warranting clinical investigation.

The two instruments (PCQ and JLT) were compared to identify clients who might be at risk of bowel disease and would benefit from referral to a GP. This was achieved by cross-tabulating their corresponding data. Thresholds for referral were identified, and the sensitivity and specificity of the JLT in suggesting referral were calculated. *Sensitivity* refers to the percentage of cases with a PCQ score above the threshold who also returned a positive JLT recommendation (i.e. cases recommended to consult a GP).[204] *Specificity* indicates the percentage of those with a low PCQ score (below the threshold) who also returned a negative JLT recommendation (i.e. cases who would not be recommended to consult a GP).[204] The ideal characteristics of the JLT are high sensitivity (to refer clients who have a high PCQ score and therefore require follow-up) and relatively modest specificity (to not refer those who are likely not to require follow-up). Threshold PCQ scores ranging from 5 to 65 were used for this exercise, to encompass the threshold score of 50 used in the published pilot study. [23] Thirty was used here as the threshold PCQ score to capture a range of

bowel diseases, while a score of 50 in the PCQ pilot study [23] was chosen to focus on CRC.[184]

A receiver operator characteristic (ROC) curve was generated from sensitivity and specificity calculations to ascertain the relationship between the two tests. The ROC curve displays the trade-off between the sensitivity and specificity (false positive) across a series of cut-off points.[205] This curve is useful in evaluating the discriminatory ability of the JLT to correctly identify subjects who require referral and those who do not. It also suggests an optimal cut-off point for minimal misclassification of subjects in the referral and non-referral groups.[206] The area under the curve (AUC) is an overall measure of the diagnostic accuracy of an instrument.[205] The maximum AUC=1 means the instrument accurately differentiates between 'true' positive and 'true' negative. The AUC of this curve was calculated using the non-parametric Mann-Whitney U statistic.[205] Each black dot on the graph corresponds to an observation: the 'true' positive rate (sensitivity) and 'false' positive rate (1-specificity).

3.4. Results

3.4.1. Questionnaire Construction

The final version of the JLT comprised eight questions, took approximately three minutes to complete, and mostly required tick-box responses from clients (Appendix 3.4).

3.4.2. Readability

Readability of the JLT, measured by Flesh-Kincaid grade level, was 4 (i.e. an average grade 4 student should be able to read the instrument). The Flesh-Kincaid reading ease assessment resulted in a score of 79.5, the reading level of a child nine years of age.[207, 208]

3.4.3. Validation

Table 3.1 illustrates the sensitivity and specificity of the JLT for each PCQ cut-off score. At the threshold score of 30, the sensitivity of the JLT was 100% and specificity was 65%.

Table 3.1: Sensitivity and Specificity of the Jodi Lee Test Compared to the PCQ Threshold Score (n=118)

PCQ Threshold Score	JLT- Sensitivity (%)	JLT- Specificity (%)
5	68.8	100.0
10	75.6	96.9
15	81.9	84.8
20	84.8	80.8
25	88.5	69.7
30	100.0	65.0
35	100.0	61.2
40	100.0	57.8
45	100.0	54.7
50	100.0	51.5
55	100.0	49.1
60	100.0	46.8
65	100.0	46.0

Table 3.2: The Relationship between the Jodi Lee Test (JLT) Recommendation and PCQ Threshold Score of 30

PCQ Threshold Score	JLT Recommendation				Total
	Referral Not Warranted		Referral Warranted		
	N	%	n	%	
≤30	52	65	28	35	80
31 +	0	0	38	100	38
Total	52		66		118

n - number

52 - 'true' negative, 0 - 'false' negative, 28 - 'false' positive, 38 - 'true' positive

The cross-tabulation at the threshold score of 30 (Table 3.2) illustrates the 'true' positive (TP) and 'true' negative (TN) GP referral rates of the 118 subjects, where all 38 cases with a high PCQ score (>30) would be referred, and 52 of the 80 subjects

with a low PCQ score (≤ 30) would not be referred, if using the JLT. The remaining 28 cases with a low score would also be referred to their GP, according to the JLT.

Figure 3.1 shows the ROC curve plotting sensitivity (y-axis) *versus* 1-specificity (x-axis). The area under the ROC curve was 0.94.

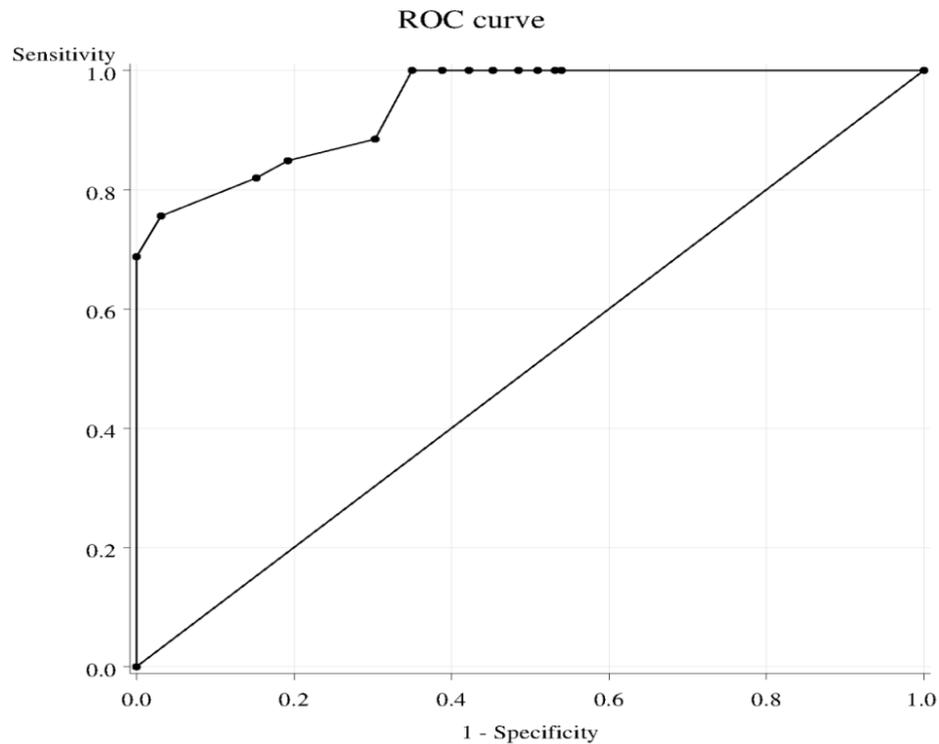


Figure 3.1: Receiver Operator Curve (ROC) - JLT Sensitivity *versus* JLT Specificity

3.5. Discussion

This study reported the development of the JLT, a self-administered questionnaire to aid consultations of pharmacy staff (pharmacists and pharmacy assistants) with clients presenting with bowel symptoms that would benefit from medical referral. The literature review (Chapter 2) emphasised the importance of community pharmacy as a major, easily accessible source of health advice. The literature suggested the need to develop a simple, valid screening tool that could be used

within the pharmacy setting to assist with coordinated, cooperative health care between community pharmacists and GPs.

The JLT requires minimal time commitment by the client and pharmacy staff, and was developed to be easily assimilated into everyday pharmacy practice. It was designed for self-completion by the client, with readability equivalent to school grade four (age around nine years). This should offer confidence to clients in conveying details about their bowel symptom(s), especially if they are embarrassed and/or have limited health literacy.

Brevity in the questionnaire was essential to retain the JLT as a simple guide for use in a busy pharmacy setting, but it had to be highly sensitivity for bowel disease. Review of the literature indicates symptoms and their duration play an important role in determining risk of more serious bowel disease.[29, 162] History of gastrointestinal diseases, and loss of weight, were also considered key factors for diagnosis of bowel disease,[29, 162, 185] and were referred to in Questions 5 and 7, respectively, in the JLT. While other decision-making tools incorporate scoring systems, as was evident from the literature review (Section 2.7.4) and the PCQ, the JLT acknowledges the importance of *clinical judgement* by pharmacists and pharmacy staff in client consultations. As such, pharmacists and pharmacy staff may consider responses to the JLT questions collectively, with the client's verbalised complaints or responses, in deciding if the client requires referral.

In the validation exercise, the PCQ was used as a proxy independent measure of the endpoint, GP consultation. While the PCQ has been validated for serious bowel disease at high cut-off score, a lower cut-off may indicate emerging disease or other bowel conditions that require GP intervention, and are appropriately identified in a community pharmacy setting.[197] The JLT is more sensitive to less severe bowel symptoms than the PCQ. Fifty-seven percent of symptomatic people attending a pharmacy who completed a PCQ scored in excess of 30, demonstrating early signs of colorectal disease that might benefit from GP intervention.[154, 155, 184]

In this validation exercise, the JLT demonstrated high sensitivity of 100% and modest specificity of 65%. The high sensitivity may help in identifying clients at high risk of disease, while the relatively modest specificity may also identify clients who are unlikely to have serious bowel disease, but nevertheless would benefit from a GP consultation when reporting non-life-threatening pathologies. The JLT is not likely to suggest consultation for clients with short-lived self-limiting conditions that are appropriately managed with over-the-counter treatments.

This ROC curve displays the full picture of trade-off between the sensitivity and 1-specificity (false positive) across a series of cut-off points, each represented as a black dot (Figure 3.1). The larger the AUC, better is the performance of the instrument in question to correctly pick the 'true' positive and 'true' negative.[205] The large AUC of 0.94 indicates the favourable overall performance of the JLT to identify clients at risk of serious bowel pathology.

3.6. Limitations

In this study, the JLT was tested against the PCQ. In ideal research practice, clients would complete both the PCQ and the JLT, and criterion validity would be established by demonstrating similar outcomes from the application of both tests. In this study, the key questions in the JLT match some of the questions in the PCQ. Therefore, the scores of the PCQ were used to determine the sensitivity and specificity of the JLT.

The other limitation of the developed questionnaire is that as many as 35% of cases identified by the JLT as warranting referral have a PCQ score of less than 30, suggesting these subjects are at low risk of serious bowel disease. As pharmacists are in a position to apply clinical judgement when using the JLT, they can override the referral recommendation if they deem the symptoms may be due to factors other than underlying (or developing) disease. This is particularly the case when considering answers to Question 6 (prior consultation GP regarding the presenting bowel symptom) and Question 7 (medication).

A modified nominal group technique and Delphi technique were used to generate items for the JLT questionnaire and to reach consensus among the members of the expert panel. Conventional methods of scoring and ranking the items were completed during the developmental phase of the questionnaire rather than during the Delphi Technique as it was essential to include all key clinical markers of possible bowel disease.

Pharmacy staff were involved in the development of the JLT. There was however, no direct involvement of the clients in the design of the JLT. This was because the intervention was aimed at, and managed by, pharmacy staff. The readability of JLT was measured by Flesh-Kincaid grade 4 level, indicating that an average grade 4 student (aged 10-11 years) should be able to read the instrument.

3.7. Conclusion and Recommendations

Any new screening test should demonstrate the ability to clearly delineate cases that require medical advice. The JLT exhibited high sensitivity for identification and triage of symptoms of bowel disease. In the current drive for health promotion initiatives within community pharmacy, an easy, user-friendly, valid triage instrument such as the JLT has the potential to improve pharmacy practice.

The next step is a prospective evaluation of the JLT against the referral of clients who may be at risk of bowel disease to further confirm the validity of the JLT in practice. The issues listed in the limitations can be studied in detail during a prospective study to test the use of the JLT in community pharmacies.

4. Trial of the Jodi Lee Test (JLT)

4.1. Background

Building on the results and conclusions of Chapter 3 (describing development and validation of the JLT), a prospective observational study was proposed and conducted to trial the JLT. The key findings of this study are reported in a journal article prepared for submission in *Current Medical Research and Opinion* entitled *A Model for Effective Assessment and Referral of Clients with Bowel Symptoms in Community Pharmacies*, authored by Deepa Sriram, Alexandra McManus, Lynne Emmerton, Richard W Parsons and Moyez Jiwa. All authors were involved in the study design. DS conducted the study and RP provided statistical guidance.

This article is reproduced in Section 4.2. Spelling and styles used for citations, headings and tables are aligned with the thesis. Supplementary information (considered beyond the length and scope of a scientific journal article) is included in Section 4.3.

4.2. JLT Trial

4.2.1. Introduction

Help seeking is considered to be the recognition of a health concern followed by a range of actions, one of which may be health service utilisation.[209] Interviews with people experiencing symptoms of bowel disease have shown that a significant proportion try to manage their own symptoms,[210] rather than consult a doctor, even when symptoms are persistent and subsequently found to be due to a life-limiting condition.[176, 211]

A number of bowel diseases share clinical presentations, and certain symptom profiles that are associated with serious underlying conditions such as cancer, inflammatory bowel disease or degenerative bowel conditions.[5] To improve outcomes, clients need to recognise the significance of their symptoms, and GPs need to accurately diagnose and manage bowel diseases.[27, 44]

Faecal occult blood test screening (FOBT), available via the National Bowel Cancer Screening Program in Australia, is limited to people turning 50, 55, 60, 65 and 74 years (the average age of a patient with colorectal cancer is 68 years).[171] Biennial screening for those aged 50-74 began in 2015 and is due to be completed in 2020. [170] Detection of blood in bowel motions (from the FOBT) prompts recommendations for further investigations such as colonoscopy.[170] At more than 30 times the price of FOBT, colonoscopy is too expensive for a population-based screening tool. [170] Although FOBT is a valid test for bowel cancer, participation in the program is reportedly poor[172], with barriers such as: “inconvenience of the testing process; aversion to manipulating faeces; cost; views about personal invulnerability; and cultural beliefs and attitudes”. [173]

Community pharmacies are a recognised and used as common source of health advice by many Australians.[212] Results from a survey of patients attending general practice in Australia show that pharmacists were identified as the most likely health professionals, other than GPs, who might advise about bowel symptoms.[21] Three or more clients per week, on average, seek symptomatic treatment for bowel symptoms[21] in each of Australia’s 5450 pharmacies.[19] Interactions between pharmacists and their symptomatic clients therefore offer an ideal opportunity to explore how pharmacy staff can identify patients with possible emerging serious illness.

However, a survey of pharmacists in Australia[13] demonstrated a lack of awareness of high-risk bowel symptoms. This finding recognises the requirement for better education to understand when to refer for further medical investigation.

Research supports the use of self-administered questionnaires to help primary health care professionals identify cases that warrant further investigation for colorectal pathology.[30, 31, 192] The Jodi Lee Test (JLT) is a simple, short, client-completed questionnaire developed to aid consultation between pharmacy staff and clients with bowel symptoms.[213] The data provided can be reviewed by any pharmacy staff

who interact with clients: pharmacy assistants to determine when the client should be referred to the pharmacist, and pharmacists to determine when referral to a GP is required.[213] The key items in the JLT indicating the need for referral for GP assessment are the client's symptom(s), symptom duration and history of gastrointestinal disease.[213] The JLT demonstrates high sensitivity (100%) and modest specificity (65%) for identification and triage of symptoms of bowel disease when compared to a validated tool, the Patient Consultation Questionnaire (PCQ).[213] By comparison, the PCQ assists GPs in prioritising referrals for colorectal conditions, and has high sensitivity for serious colorectal pathologies.[5, 197]

The purpose of this study was to examine the feasibility and effectiveness of use of the JLT as a guide to pharmacy staff to identify clients with bowel symptoms warranting GP assessment ('referral').

4.2.2. Materials and Methods

Ethical approval was granted by the Curtin University, Human Research Ethics Committee (HR19_2013). This study used a prospective pre-post design in community pharmacies in WA, and was conducted from May 2013 to March 2014. Prior to the commencement of the intervention, data were collected concerning the usual practice (UP) of pharmacy staff dealing with clients seeking assistance for bowel symptoms. Following the UP phase, the JLT was introduced to guide the pharmacy staff in their interaction with the client (the intervention: JLT phase). These phases are described below. The value of the JLT was assessed between the two phases of the study by comparing the referrals to, and subsequent contact by the client with, the clients' GP for those considered to have signs of potentially serious disease.

4.2.2.1. Sample Size

The development and validation of the JLT (Chapter 3) study reported that 55% of clients who were screened using the JLT required GP referral.[213] For the purposes of this study, it was conservatively assumed the referral rate would reduce to approximately 35% after the pharmacist reviewed the completed questionnaire,

communicated with the client, and applied his/her clinical judgment, in line with the protocol for use of the JLT. In the JLT validation study, approximately 10% of eligible clients were referred to their GP when the pharmacist was not using a decision support aid.[21] In order to detect a difference of this magnitude in the proportion of clients referred for further investigation 'using' versus 'not using' the decision-support aid (35% vs. 10%) with power=90% and $\alpha=0.05$, 65 participants would be required in each arm of the trial. Allowing for an estimated 20% loss to follow-up, this number was adjusted to n=82 in each arm. Conservatively assuming that each pharmacy would recruit at least one participant each week, i.e. a one-in-three recruitment rate,[13] it was estimated that 20 pharmacies would be required to complete the study within the proposed timeframe.

A convenience sample of 21 pharmacies in WA was recruited to take part in the study: 17 in the Perth metropolitan area and four from regional towns. The locations of the pharmacies were selected to represent a range of socioeconomic areas. Data collection commenced with the UP phase; however, these data were not collected from two pharmacies, as they joined the study just prior to the commencement of the intervention. During the recruitment process, the pharmacies were provided with promotional flyers for the study which included the timeline and study protocol (Appendix 4.1). Written consent was gained from all staff members of the pharmacies, including pharmacy assistants, pharmacists, pharmacists-in-training (pre-registered pharmacists) and locums, prior to commencement of the study (Appendices 4.2 to 4.4). Prior to commencement of each phase, the researcher conducted a training session on the research protocol for the staff of each pharmacy. Instructions were given on recruitment of clients and study documentation. A written instruction sheet was left with each pharmacy for further reference, and staff members were invited to report any queries or feedback (Appendix 4.5 and 4.6). A feature of the JLT is that the pharmacist applies his/her interpretation of the questionnaire responses; as such, there was no training in clinical management of individual clients

4.2.2.2. Baseline

The staff members of the 21 pharmacies completed a baseline survey comprising, among other questions, an open-ended question concerning their role in management of clients with bowel symptoms. Data were coded using key words elicited from the responses, and the roles of pharmacy assistants and pharmacists were determined collectively across the pharmacies.

4.2.2.3. Usual-Practice Phase

Pharmacy staff recruited consecutive clients seeking advice for bowel symptoms or seeking medicines normally used to treat diarrhoea, constipation or haemorrhoids. Participating clients were to be aged at least 18 years and able to give written informed consent to take part in the study, which included contact by the researcher for follow-up after their pharmacy visit.

The pharmacy staff continued their usual service in managing clients' bowel symptoms. Consultations with consenting clients were documented by the pharmacists, recording the clients' reported symptom(s), medication purchased, verbal referrals for further investigation, and reasons for referrals. The pharmacies aimed to recruit and follow-up a total of 82 participants for this phase over a period of 12 weeks.

Follow-up of the recruited clients took place four weeks following their pharmacy visit. The researcher contacted clients by telephone to determine if their symptom(s) persisted, whether referrals were acted upon, and if so, investigations undertaken by the GP. Verbal consent for a second follow-up at a negotiated time was obtained from those with pending investigations to determine their ultimate diagnosis. Participants who were not contactable for follow-up after three attempts were deemed lost to follow-up.

4.2.2.4. Intervention (JLT) Phase

Recruitment started four weeks after the completion of the UP Phase. The same eligibility criteria, client recruitment and follow-up processes were used for the Intervention Phase as for the UP Phase of the study.

In this phase, the pharmacy staff, following client consent, deployed the JLT to guide decision making in their consultation. The JLT, a paper-based questionnaire comprising eight questions, was self-completed by clients in a private or semi-private area in the pharmacy (if available), with the assistance of the staff member if required. On reviewing the completed JLT, the attending pharmacy assistant decided whether or not to refer the client to the pharmacist; likewise, the pharmacist applied his/her clinical judgement regarding referral to the client's GP. For cases warranting GP investigation, the pharmacist completed details on a standard referral letter, issued to the client with the completed JLT and verbal recommendations. Verbal recommendations included sale of medicines, instructions for use of these medicines, and relevant warnings. A carbon copy of the completed JLT was posted to the researcher in a reply-paid envelope following recruitment of each participant. The researcher contacted pharmacies twice weekly by telephone and email to monitor and discuss their progress. The recruitment and follow-up period for this phase was extended to 20 weeks to account for increased pharmacy workload during December 2013 and January 2014.

Similarly to the UP Phase, clients who were referred for consultation with a GP were contacted by the researcher four weeks after their pharmacy visit to determine if they had visited their GP, if any further investigation had taken place, and if a diagnosis had been made.

4.2.2.5. Evaluation by Staff

Within two weeks of the completion of the intervention phase, staff of the participating pharmacies was asked to complete a post-trial feedback questionnaire to assess the utility of the JLT. The questions included the usability of JLT, reasons

why the JLT had or had not been used during the consultation, intentions to continue using the JLT, if they would recommend it to their colleagues, and which (if any) other symptoms would benefit from a questionnaire such as the JLT. A copy of the JLT was attached to the post evaluation survey for the respondents to refer to especially if they had not used JLT for consultation

4.2.2.6. Analysis

The effectiveness of the JLT intervention was determined by:

1. The proportion of clients who were referred to their GP following use of the JLT compared to UP
2. Comparison of GP attendance rates for clients referred to the GP following use of the JLT compared to UP
3. Diagnoses of colorectal pathologies in clients following the use of JLT compared to UP
4. Feedback from pharmacy staff on the utility of the JLT.

Demographic details of the study participants and baseline practice were summarised using standard descriptive statistics. Differences in referral rates and GP consultations were assessed using the chi-square and Fisher's exact test. The SPSS® version 22 statistical software was used for all analyses. A p-value<0.05 was indicated a statistically significant association.

4.2.3. Results

4.2.3.1. Baseline

One hundred and ninety-one pharmacy staff, comprising 122 pharmacy assistants, 62 pharmacists and seven pre-registered pharmacists, completed the baseline survey. The mean age for pharmacy assistants was 28 years (range: 15-62 years), and 32 years (range: 22-56 years) for pharmacists. The pharmacists had around 10 years' work experience in pharmacy, while the pharmacy assistants recorded approximately

six years. Twenty-one percent of the pharmacy assistants were tertiary educated, and 44% had completed only up to year 12 or equivalent. Self-reported data from the participating pharmacies revealed pharmacy assistants typically gathered information about clients' symptoms, history and lifestyle. The pharmacists offered advice on managing symptoms and lifestyle, and provided further information about the symptoms, medication and referral to a GP.

4.2.3.2. Assessment of the JLT Intervention

Eighty-four clients were recruited and followed up over 12 weeks in the UP Phase (Table 1); these comprised 60 (71%) females and 24 (29%) males. Twenty-one were lost to follow-up, and seven were excluded on the basis of age. Staff of 19 of the 21 selected pharmacies recruited clients for this phase.

Eighty clients were recruited and followed up over 20 weeks in the Intervention Phase, comprising 54 (68%) females and 26 (33%) males. Fourteen were lost to follow-up. Fifty of the 80 clients (63%) were initially identified on self-completion of the JLT as meriting referral to a GP. However, during the ensuing consultation between client and pharmacist, only 30 (38%) were confirmed by pharmacists as warranting referral. Common reasons why the pharmacists did not refer cases indicated as concerning by the JLT were that the client's GP was aware of the symptoms for which he/she was seeking advice, or that the presenting symptom was an obvious side effect of a prescription medication the client was taking.

The intervention was associated with a significantly higher referral rate compared to the UP Phase: 38% vs 20% (Table 1). The acceptance of the recommendation to consult a GP (i.e. attendance rate for GP consultation) was also higher during the Intervention Phase: 40% vs 6%. Three clients from each of the UP and the Intervention Phases who were referred to consult the GP were lost to follow-up. The p-value (Fisher's Exact test) for comparison of the proportions of clients who were recommended to consult a GP (1/14 and 12/27, excluding those lost to follow-up), was $p=0.031$. More diagnoses were made for clients who consulted a GP following

the pharmacist’s referral using the JLT, while there was no definitive diagnosis for the one client from the UP group who consulted a GP.

Table 4.1: Impact Evaluation: Usual-Practice Phase *versus* Intervention Phase

Variable	Usual Practice	Intervention
Recruited	84	80
Referred to General Practitioner	17 (20%)	30 (38%)*
Consulted General Practitioner	1/17 (6%)	12/30 (40%)**
Details of General Practitioner Consultation	#55: No follow-up for diagnosis	#05: Monitored by General Practitioner #07: Ultrasound → diverticulitis #13: Blood tests → monitored by General Practitioner #26: No further action #41: No further action #51: Dairy allergy #55: Monitored by General Practitioner #58: No follow-up for diagnosis #74: Blood and stool test → all clear #76: Stool test → all clear #80: Colonoscopy → monitored by General Practitioner #83: Colonoscopy → monitored by General Practitioner

p=0.029 (chi-square)
** p=0.017 (Fisher’s Exact)

4.2.3.3. Pharmacy Evaluation

Forty-seven pharmacy staff completed the feedback questionnaire. In this evaluation, each of the 19 participating pharmacies was represented by at least one full-time pharmacist and one pharmacy assistant. The respondents comprised 19 pharmacists and 27 pharmacy assistants. Though only 21 (45%) reported using the JLT when consulting clients with bowel symptoms, 30 (64%) of the pharmacy staff agreed that the JLT could be incorporated in the pharmacy after reviewing the

attached JLT. Thirty three (70%) indicated they would use the JLT in future when managing clients with bowel symptoms.

The effectiveness of JLT is illustrated by the following quotations from pharmacy staff:

“Effective way to establishing client needs and current bowel symptoms”
(pharmacy assistant).

“Confirming ‘red flags’ for early detection of bowel signs and symptoms that warranted referral for medical advice” (pharmacist).

“Establishing consistent practice in the pharmacy” (pharmacist).

“Providing timely, effective professional advice and information to clients, including advice about consulting a GP” (pharmacist).

“Helpful in reinforcing the case of referral when the client was initially hesitant to see the GP” (pharmacist).

Additional feedback related to the JLT being simple and quick to use, easy to understand by the client, non-invasive, easier for clients who feel embarrassed to discuss their bowel symptoms, and a good checklist approach for quick response in a busy pharmacy. In critiquing the tool, some stated the study protocol booklet format was time consuming and a deterrent to the recruitment process. Reasons given by staff for not using the JLT were largely logistical, including workflow, and few clients perceived as eligible. Other conditions for which the pharmacy staff would accept a JLT-like questionnaire were urinary tract infections, asthma, vaginal candidiasis, cough, chronic pain, kidney problems, headaches, and upper gastro-intestinal symptoms.

4.2.4. Discussion

This prospective study supports the use of the JLT, a brief self-administered questionnaire, as a clinical decision tool for pharmacy staff to identify symptoms that might require medical investigation, and serves as a written referral to the GP. The

staff in the pharmacy were made aware of clients who were presenting with symptoms that may require medical assessment. The client and the pharmacist were afforded the opportunity to discuss these in detail, and in some cases, referral was considered unnecessary. A reasonable assumption was made by the pharmacists that if a client had recently consulted a GP, the GP was almost certainly aware of the symptom(s) and was managing the client appropriately. Other clinical situations may have also led a pharmacist not to refer a client.

In those cases where referral was warranted, the participants were advised on the need for a medical consultation and given a referral letter to take to the GP. Use of the JLT resulted in 38% of clients being referred to their GP, compared to 20% during UP. This result is in line with studies reporting that health questionnaires completed by patients frequently captured more positive symptoms than elicited during consultation.[193, 214] Our empirical evidence also indicates a greater proportion of the clients accepted the pharmacist's referral, consistent with other studies that reported increased GP consultation after being encouraged by a pharmacist.[21, 215]

The concept of applying a decision-support tool in pharmacy practice was novel to our participating pharmacy staff, and although it may not be applicable to all practice settings or situations, the JLT shows promise in guiding management of bowel symptoms. In particular, the documentation produced for cases warranting referral appears to hold value for clients, evidenced by their uptake of recommendations to consult their GP. Alternatively, for situations able to be managed in the pharmacy, the JLT highlights to the pharmacy staff member the presenting symptoms and their significance.

As established in the baseline phase, the first point of contact for the client was commonly the pharmacy assistant. As such, prompting pharmacy assistants' use of a simple, structured assessment tool can benefit the pharmacy workflow, in triaging clients to be referred to the pharmacist and supporting the provision of non-prescription medicines; these are recognised roles for pharmacy assistants in Australia.[78]

Most of the pharmacy staff found the JLT to be a simple and effective assessment guide for management of bowel symptoms, and reported that clients managed to complete the questions unassisted. As such, its deployment did not burden pharmacy staff. The majority of burden related to client recruitment and consent for research purposes (follow-up).

A randomised controlled trial is the ideal design to test pharmacy-led interventions; however, it was not feasible in this case for several reasons. Firstly, one of the objectives of the study was to identify if a change in referral practices of pharmacists could be achieved by introducing to them a structured questionnaire approach (the JLT) for these clients. Once the JLT is used for a particular client in a pharmacy, it would not be practical to revert to UP for a subsequent client. A cluster design where pharmacies applied only UP or the JLT would have avoided the issue of randomising clients, but differences between practices in terms of staffing and demographic profile may have confounded the analysis. For these reasons, a pre-post design was considered the most appropriate.

The study protocol was not consistently applied in some pharmacies, highlighting the challenges of research in a naturalistic setting. Although the researcher closely monitored the study progress, adherence to the study protocol by individual staff was not able to be controlled. Ideally, this trial would have also included client feedback on the JLT to supplement developmental research in its design,^[213] and validation of client outcomes using general practice data. Further research on the acceptability of the JLT directly from the client's perspective is required to determine their expectations of pharmacy services when presenting with bowel symptoms. Though a practising GP was involved in the design and validation stage of JLT,^[213] no GPs to whom the clients were referred to, were asked to give feedback on the written referral that was given to clients whose symptoms warranted further medical consultation. Loss to follow-up is also recognised as a limitation in outcomes-focused research.

Our findings suggest potential for wider application of the JLT as an optional practice-enhancing guide to over-the-counter consultations in the community pharmacy setting. There is potential for the documentation to be adapted to guide management of other complex symptoms potentially warranting GP investigation and potentially associated with early-stage cancer. There is potential for future research on development and trial of a JLT-like questionnaire for screening of pharmacy clients presenting with symptoms indicative of conditions such as urinary tract infection, vaginal candidiasis and kidney problems.

4.2.5. Conclusion

The JLT was found to be an acceptable assessment tool for the triage of bowel symptoms in the community pharmacy setting. Its effectiveness was demonstrated by prompting a higher rate of referrals in those who would benefit from a GP investigation, a higher rate of uptake of recommendations for referral and more clinical diagnoses compared to the usual model of consultation. As such, the JLT shows promise as an effective decision-making aid in the pharmacy to triage clients at higher risk of bowel cancer.

4.3. Additional Information

4.3.1. Perceived Roles of Pharmacy Staff and Pharmacists

Of the 191 questionnaires completed by pharmacy staff of the recruited pharmacies (Section 4.2.3.1), 25 had missing responses to the open-ended question exploring the role of pharmacy staff in the management of bowel symptoms. Table 4.3 represents the frequency of the 166 coded valid responses to the open-ended question described in Section 4.2.3.1. Pharmacy assistants perceived their role as eliciting as much information as possible from the client about his/her symptom(s), while pharmacists perceived their role in management of the symptom(s).

Table 4.2: Frequency of Data Code elicited from Responses of Pharmacy Staff on Their Role in Bowel Symptom Management

Characteristics	Pharmacists N=53 (%)	Pharmacy assistants N=113 (%)
To gather as much information from the client about his/her symptom(s)	27 (50.9)	79 (69.9)
To elicit information about the duration of symptom(s)	12 (22.6)	40 (35.4)
To elicit information about presenting symptom(s)	15 (28.3)	45 (39.8)
To obtain information about pain or discomfort in the back passage	0 (0)	2 (1.8)
To obtain information about bleeding	1 (1.9)	8 (7.1)
To obtain information about the client's lifestyle	2 (3.8)	2 (1.8)
To obtain information about the client's diet	0 (0)	7 (6.2)
To ask about prior consultation with a doctor regarding this symptom(s)	0 (0)	2 (1.8)
To gather information about medication having or tried for the presenting symptom(s)	6 (11.3)	22 (19.5)
To gather information about the client's medical history	9 (17)	13 (11.5)
To gather information about the client's family medical history	1 (1.9)	2 (1.8)
To gather information about the client's other regular medication	9 (17.0)	25 (22.1)
To give product advice	20 (37.7)	14 (12.4)
To give lifestyle advice	16 (30.2)	8 (7.1)
To give diet advice	5 (9.4)	4 (3.5)
To give prevention advice	2 (3.8)	3 (2.7)
To give general advice about the client's symptom(s)	41 (77.4)	48 (42.5)
To either refer or get assistance from (another) pharmacist	2 (3.8)	84 (74.3)
To sell medication or offer treatment	36 (67.9)	55 (48.7)
To offer bowel scanning kit	2 (3.8)	3 (2.7)
To refer to doctor	34 (64.2)	29 (25.7)
To take to a private spot for consultation	0 (0)	1 (0.9)

Seventy-five percent of the pharmacy assistants (n=84) reported that they would refer the client to the pharmacist if they think the symptom warrants a pharmacist's intervention. Sixty-four percent of the pharmacists (n=34) consider they would give verbal advice to consult a GP. Very few pharmacists (3.8%) and pharmacy assistants

(2.7%) reported that they would normally offer a faecal specimen-collection kit to the client.

4.3.2. Actor-Simulation study

The perceived roles of the pharmacy staff on the management of bowel symptoms in their pharmacy is reported in the previous section (4.3.1), however there can be inconsistencies between real and reported behaviour.[216] Information given in surveys and questionnaires may not be in accordance with the actual (usual) behaviour in a natural setting.[216]

Participant observation can elicit information to help verify information that is gathered from a survey.[216] Standardised patients are increasingly used to assess primary care practice.[217-221] An actor-simulation study was conducted at the baseline phase to ascertain the accuracy of the baseline survey conducted for the pharmacy staff. This aspect of the study was conducted to glean the normal procedures for managing patients presenting with bowel symptoms.

4.3.2.1. Method

Four scenarios relating to diarrhoea, constipation, rectal bleeding and alternating constipation and diarrhoea were prepared for this study (Appendix 4.7). These are common bowel symptoms, and there is evidence showing that one in 15 people identify the pharmacist as a source of advice for these symptoms.[21]

A checklist approach completed soon after the actor-pharmacy staff interaction was taken for collection of data in this actor-simulation study. Electronic device malfunction was reported as the cause of data loss in few studies using recording instruments for collecting data. [217, 221] A checklist was developed for each of the four scenarios. It captured the consultation provided, history taking and management by the pharmacy staff during the actor visit (Appendix 4.8).

Ethical approval was granted by the Curtin University, Human Research Ethics Committee (HR19_2013). As indicated in Section 4.2.2, the pharmacy staff gave written consent before the commencement of the baseline phase of the JLT trial; this included consent for the actor-simulation study. This kind of consent is called the 'principle' consent where the participant gives prior consent without knowing the exact day or time of the simulated-client's visit.[222]

Of the 21 pharmacies recruited for the prospective study, seven pharmacies were chosen randomly to represent the pharmacies from Perth metropolitan area and different pharmacy locations (shopping centre, medical centre, city/suburb stand-alone). Four actors (2 males and 2 females, aged approximately 30-45 years), were selected from a number of ethnic groups (Caucasian, African and Indian) and trained for one of the symptom scenarios. The scenario included the detail about the symptom, duration, medical history and medication taken for the presenting symptom. Each scenario also depicted who to talk to, how to sound when conveying the symptom, and what to say. Three training sessions were held for the actors by the researcher. They were trained on how to act as a pharmacy client with the bowel symptom and to observe and recall pharmacy staff's action during the visit. Information on how to respond for different management suggestions by the pharmacy staff was also given to each actor. Training was followed by two practice sessions with an academic pharmacist and GP.

Each pharmacy received one visit (one scenario) by all four actors at randomly assigned times over a period of 30 days. The pharmacy staff were not aware when an actor would present with his/her scenario. The interaction with the pharmacy staff was documented by the actor based on the checklist of questions soon after the consultation with the pharmacy staff. No audio-recording took place, in line with the ethical approval for this study.

4.3.2.2. Results

There were 28 actor-pharmacy staff interactions. All actors were first offered assistance by the pharmacy assistant. All seven of the 'alternating diarrhoea and constipation' cases were referred to the pharmacists by the assistants, compared to six of the seven 'rectal bleeding' cases. Two cases each from the 'constipation' and 'diarrhoea' cases were referred to pharmacists. In all but three 'rectal bleeding' scenarios, a medication was sold to the actor. Table 4.2 illustrates the responses documented by the actor for each symptom, and how the pharmacy staff questioned and managed each symptom.

Six 'constipation' cases were managed by the pharmacy assistant without involving the pharmacist, while all seven cases of 'alternating constipation and diarrhoea' were managed by the pharmacist. In six 'rectal bleeding' scenarios, actors were referred to pharmacists; of these, three actors were advised to consult a GP at their earliest convenience. One pharmacist offered to book a GP appointment for the actor with the 'rectal bleeding' case scenario.

Surprisingly, none of the staff asked the actors if they had discomfort (pain or a lump) in the back passage except for three cases with rectal bleeding scenario. None of the actors reported as being asked about weight loss by the pharmacy assistants or pharmacists.

Table 4.3: Actors' Documentation of Questions and Management of their Bowel Symptom Scenario by Pharmacy Staff

	Potential to be overheard by other clients (%)		Offered private space to discuss symptoms (%)		Asked about duration of symptom(s) (%)		Medication history taken (%)		Medical history taken (%)		Asked about discomfort in the back passage (%)		Prior GP consultation notes taken (%)		Asked about weight loss (%)		Asked about tiredness (%)		Advised to consult GP (%)	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Constipation	6 (85.7)	1 (14.3)	1 (14.3)	6 (85.7)	6 (85.7)	1 (14.3)	2 (28.6)	5 (71.4)	1 (14.3)	6 (85.7)	0 (0)	7 (100)	0 (0)	7 (100)	N/A	N/A	N/A	N/A	0 (0)	7 (100)
Diarrhoea	2 (28.6)	5 (71.4)	3 (42.9)	4 (57.1)	6 (85.7)	1 (14.3)	3 (42.9)	4 (57.1)	2 (28.6)	5 (71.4)	0 (0)	7 (100)	0 (0)	7 (100)	0 (0)	7 (100)	0 (0)	7 (100)	4 (57.1)	3 (42.9)
Alternating Diarrhoea and Constipation	3 (42.9)	4 (57.1)	1 (14.3)	6 (85.7)	7 (100)	0 (0)	7 (100)	0 (0)	4 (57.1)	3 (42.9)	0 (0)	7 (100)	3 (42.9)	4 (57.1)	0 (0)	7 (100)	0 (0)	7 (100)	5 (71.4)	2 (28.6)
Rectal Bleeding	4 (57.1)	3 (42.9)	2 (28.6)	5 (71.4)	4 (57.1)	3 (42.9)	2 (28.6)	5 (71.4)	3 (42.9)	4 (57.1)	3 (42.9)	4 (57.1)	1 (14.3)	6 (85.7)	0 (0)	7 (100)	0 (0)	7 (100)	6 (85.7)	1 (14.3)
Total	28		28		28		28		28		28		28		28		28		28	

4.3.3. Additional Discussion

Two additional sets of data have been presented in this section: self-perceived roles of pharmacy staff and pharmacists in managing bowel symptoms; and an actor-simulation study to verify the normal procedures for managing patients presenting with bowel symptoms.

Statements in surveys and interviews may not be in accordance with the factual behaviour.[216] In natural settings, the actual staff response is brought to light without being influenced by the awareness that the behaviour is being monitored.[222] Standardised patients' assessments are a valid measure of quality of care given in primary care setting.[217, 223] The baseline survey reported in brief in Section 4.2.3.1 and in detail in Section 4.3.1 is the self-reported role of bowel symptom management perceived by the respondents: pharmacy assistants and pharmacists. The actor-simulation study is the standardised clients' assessments to verify the perceived role to the actual behaviour in the natural setting.

In the actor-simulation study, pharmacy assistants were confident in managing constipation and diarrhoea symptoms, but referred the actors for pharmacist consultation when symptoms involved alternating diarrhoea and constipation or rectal bleeding. This study verified the role of pharmacy assistant as usually the first point of contact for clients presenting in a community pharmacy. Ethnically-diverse actors were assigned to a single case and all pharmacies in the actor-simulation study received all cases. The risk of detection of simulated consultation by the pharmacy staff would be higher in rural setting where a 'new face' would be detected in the close-knit community.[223] The participating pharmacies for this study were from the metropolitan area and there was no reported detection of the simulated clients by the pharmacy staff.

One of the limitation is that there was no covert recording during the consultation and therefore no validation of the documentation made by the actors. Systematic review by Rethans *et al.*[220] on actor-simulation studies in real practice reported

that studies that used electronic devices to record the consultation had the scope for failing due to technical failure of the device. As reported in the systematic reviews by Watson *et al.*[224] and Xu *et al.*[222] a checklist method was the most common method of documentation of the simulated-client's visit. Nevertheless, there is potential for error in data due to memory and recall time.[222] The documentation on the checklist for this study was made by the actors as soon as they came out of the pharmacies, so as to minimise recall bias. It is recommended that in future studies, consideration could be given to a combination of checklist documentation and audio-recording for validation of data.

The open-ended descriptions from pharmacy assistants and pharmacists regarding their perceived role in management of clients presenting with bowel symptoms should be interpreted with caution. Self-report is one way of collecting data for health research, but the response is influenced by the cognitive and technical factors in understanding and responding to the questions.[225] An open-ended question was used to reduce the bias that might be introduced by prompting response from pharmacy staff on management of bowel symptoms.

4.4. Conclusion and Recommendation

Findings from this JLT prospective study suggest there is potential for implementation of a questionnaire such as the JLT in pharmacies for screening and management of complex symptoms that might benefit from a medical consultation to initiate treatment at an earlier stage of a potentially serious pathology.

Implementation of behaviour, such as quality-enhanced services in community pharmacy, requires understanding of specific factors that influence the behaviour.[37] Provision of services in pharmacies where the pharmacy staff identify and refer clients requiring further medical investigations based on their responses to questionnaire such as the JLT, requires understanding of the intention, and the factors that influence the intention, of pharmacy staff. Intention, which directly influences the behaviour, reflects the person's motivation and desire to perform that

behaviour.[98] Factors influencing intention are the person's perceived barriers, perceived social behaviour and attitudes about the outcome of the behaviour.[95] A study to examine the attitudes, beliefs and intention of the pharmacy staff towards changing practice to implement quality-enhanced services in the community pharmacy setting was proposed and conducted, and is described in the Chapter 5.

5. Intention of Pharmacy Staff to Change Behaviour

5.1. Introduction

It is evident from the review of the literature (Section 2.4) that for successful implementation of any evidence-based practice, understanding of the factors that influence behaviour (change of practice) is required. Multiple barriers may exist that hinder the successful application of knowledge into practice.[112]

Designing strategies based on the TPB can assist adoption of a behaviour of interest, such as a change in practice among pharmacy staff.[1] According to this theory (Section 2.5.1), the intention that directly influences a behaviour reflects a person's motivation and desire to perform an action.[98] The factors that influence this intention are:

- PBC: ease or difficulty associated with the performance and confidence in performing an action; PBC also has direct influence on behaviour
- Subjective Norm: perceived social pressure to perform or not to perform an action, and
- Attitude: degree of evaluation or appraisal of the behaviour.[94, 95, 97-100]

The TPB has been widely used to understand health professionals' attitudes, perceived barriers, beliefs and the influence of external factors in achieving best practice. Numerous studies have used this theory for meta-analytic reviews across a range of behaviours, to predict general health behaviour, participation in cancer screening, and adherence to exercise.[98, 101, 103-107, 226] Section 2.5.2 presented evidence around use of the TPB to understand the relationship between influencing factors and the intention to change behaviour in pharmacies. Farris *et al.*[108] studied the relationship between intention to change behaviour and provision of pharmaceutical care, defined as "the responsible provision of drug therapy to improve the patient's quality of life." [109] Odedina *et al.*[37] developed a theoretical framework that explained pharmacists' behaviour relative to the provision of pharmaceutical care. A pharmacy smoking cessation study evaluated the knowledge

and attitude of pharmacy assistants after they attended an education program.[111] Furthermore, Grimshaw *et al.* applied the TPB to examine the relationship between beliefs and intention to change pharmacists' behaviour relating to the treatment of vaginal candidiasis with non-prescription medicines.[112]

The development and implementation of the JLT (Chapter 4 - JLT trial) is an example of a quality-enhanced service in pharmacy that involved reviewing client responses to a symptom-based questionnaire that facilitates identification and triage of symptoms that might indicate the respondent is at risk of potential serious pathology. This value adds to (enhances) the usual service that pharmacy staff undertake when managing symptomatic clients. To facilitate successful implementation of a quality-enhanced service using instruments such as the JLT, it is essential to examine the factors that influence the intention to change usual practice to quality-enhanced service.

This component of the thesis provides understanding of how perceived barriers, confidence, positive or negative evaluation of a behaviour, and social pressure might influence the intention of pharmacy staff to change practice around the management of clients presenting with bowel symptoms. This chapter presents a study examining the intention of pharmacy staff, both pharmacists and pharmacy assistants, to change practice and provide quality-enhanced service. The quality-enhanced service in this study refers to the service where symptom complexes indicating serious underlying bowel pathology are identified and clients referred for further medical investigations based on a screening tool such as the JLT.

5.2. Aims and Objectives

The aim of this study was to assess the factors that influence pharmacy staff (pharmacists and pharmacy assistants) in their decision to provide a quality-enhanced service for bowel symptom management.

The specific objectives were to:

- evaluate the domains (Attitude, PBC and Subjective Norm) of the TPB framework that influence the intention of pharmacy staff to change practice and
- compare their intention to change practice before and after the JLT trial (Chapter 4).

5.3. Methods

5.3.1. Study Design

A cross-sectional survey (administered both pre and post intervention) was used to predict the intention of pharmacy staff to change practice when managing clients presenting with bowel symptoms.

5.3.2. Study Participants

The staff of pharmacies recruited for the JLT trial (Chapter 4) consented to this study when they provided written consent to the JLT trial (refer to Appendix 4.1 for the information sheet and consent form). The participants were invited to complete a questionnaire based on the TPB at the baseline of the JLT trial, as described in Chapter 4. Construction of the questionnaire is described in Section 5.3.3.

Pharmacy staff were invited to complete the questionnaire again as part of the post-evaluation measures (Section 4.2.3.3), approximately 30 weeks following completion of the baseline questionnaire. All staff who completed the post-JLT-intervention TPB survey were aware of how their consultation was intended to change when using the JLT as a decision-aid tool.

5.3.3. TPB-Based Questionnaire

Questionnaire construction followed recommendations by Francis *et al.*[1] specific to the TPB. Items were generated to assess all domains specified in the TPB, with reference to the literature, with a five-point response scale. Demographic questions

were added to record the respondent's age, gender, education, employment status in the pharmacy and years of experience in pharmacy. Pharmacists responded to additional questions relating to the location of the pharmacy and clientele. The questionnaire was pilot tested by four pharmacy staff, two pharmacists and two pharmacy assistants to assess readability and comprehension. These participants were from one of the recruited pharmacies. They repeated the exercise with the other respondents in the actual survey.

Quality-enhanced service was termed 'cognitive service' in the questionnaire, as this is more common in the professional literature. Cognitive service was defined as "professional services provided by pharmacists, who use their skills and knowledge to take an active role in patient health, through effective interaction with both patients and other health professionals." [86] The definition was provided in the TPB questionnaire for the benefit of pharmacy assistants. The pharmacy clients were referred to as 'customers' in the questionnaire for relevance to pharmacy assistants

5.3.3.1. Intention

Two questions – the intention to provide cognitive services to clients with lower bowel symptoms at some time in the future, and intention to change usual/current practice in the future – were included in the Intention domain. The construct for this domain was taken from Francis *et al.* [1] Recommendations from Conner and Sparks were considered when wording the questions. [227] These questions were coded using a five-point Likert scale ranging from "Strongly Disagree" to "Strongly Agree". Other studies have used similar Intention questions, with "over the next 10 weeks" for an adherence to exercise study [98] and "likelihood of visiting a GP in the next six months" in a follow-up study on colorectal cancer care, [228] instead of "in the future", as used in this study on pharmacy staff. Both questions measuring the different end-points were treated as individual questions in the analysis.

5.3.3.2. Perceived Behavioural Control (PBC)

PBC factors were measured using five items in the method of Francis *et al.*[1] Staff members completed questions related to their ease of communication, knowledge and confidence and perceived barriers and burden with regard to managing clients presenting with embarrassing bowel symptoms. Ease of engaging with the client was determined using two questions about providing privacy and ability to elicit symptom information for embarrassing symptoms, and were coded on a five-point Likert-type scale ranging from “Extremely Difficult” to “Extremely Easy”. The two questions about respondents’ confidence in recognising warning signs and making recommendations were coded on a five-point Likert scale ranging from “Strongly Disagree” to “Strongly Agree”. “Providing cognitive services to customers with lower bowel symptoms would be a burden on pharmacy staff” was included as the fifth PBC question, following the definition of cognitive service. This was coded on a five-point Likert scale ranging from “Strongly Disagree” to “Strongly Agree”.

5.3.3.3. Subjective Norm

The subjective norm construct was measured by three items reported by Francis *et al.*[1] This domain determined the level of the influence of the client, other pharmacies and the owner/manager of the participant’s pharmacy on his/her intention to change practice. All three questions were coded on a five-point Likert scale ranging from “Strongly Disagree” to “Strongly Agree”. The owner/manager was instructed to omit the question about the owner/manager’s influence.

5.3.3.4. Attitude

Four questions assessed the staff member’s attitude towards providing cognitive services and giving recommendations for bowel symptoms. This too was derived from Francis *et al.*[1] One statement – “Pharmacists providing recommendation to customers regarding their lower bowel symptoms is consistent with good professional practice” – measured attitudes towards providing appropriate recommendations. The other three items were attitudinal questions about providing cognitive services to clients with bowel symptoms: “enhancing customer service”,

“providing even higher level of care” and “ensuring appropriate care”. The questions were coded on a five-point Likert scale ranging from “Strongly Disagree” to “Strongly Agree”.

5.3.4. Statistical Analysis

Data were analysed using the SAS® version 9.2 statistical software (SAS Institute Inc, Cary, NC, USA, 2008).

The negatively-worded question for PBC, “Providing cognitive services (*please refer to the definition given above*) to customers with bowel symptoms would be a burden on pharmacy staff” was reverse-coded so the lowest score represented “no burden”. Mean scores were calculated for each domain, as the mean and median for each domain were close. Scoring details are provided in Appendix 5.1, and followed the methods of Francis *et al.*[1] Cronbach’s alpha was calculated to assess the internal consistency of questions within each domain. A Cronbach’s alpha coefficient of 0.7 or above was considered acceptable.[229, 230] The two questions for Intention were not tested for internal consistency, as they measured intention for two different variables namely the intention to change behaviour in future, and the intention to provide cognitive services in future. These intention questions were reclassified as binary variables (agree or strongly agree to the intention *versus* disagree or undecided) on account of the distribution of responses.

For purposeful selection of variables for regression analysis, univariate analysis was firstly performed.[231] Chi-square analysis was then used to assess the association between each of the questions and intention to provide the cognitive service. Some questions in the PBC domain were treated individually, while others were grouped. For the pair of questions relating to the ease of engaging with a client with embarrassing symptoms, the Cronbach’s alpha was 0.576, indicating both questions should be retained individually for analysis. Questions 3 and 4 were grouped as PBC_Confidence for the analysis. Question 5 of the PBC domain, the perceived

barriers in providing cognitive services, was also treated as an individual question for this univariate analysis.

For both the grouped and individual variables in all domains, the responses were treated numerically (1-5, with 5 representing “strong agreement”). Where a domain was represented by more than one question, the average of the relevant questions was calculated to represent the level of agreement with the domain. The scores for each domain were classified similarly to the intention questions, as 4 or more *versus* less than 4. In this way, a score of at least 4 showed that there was at least general agreement with the domain.

Multivariate logistic regression was used to identify which of the domains were independently associated with intention. The logistic regression model was developed using backward elimination to identify independent variables contributing significantly to the prediction of intention. Backward elimination is preferable to obtain the best subset of retained independent variables.[232, 233] However, in this analysis, both backward elimination and forward stepwise inclusion of variables[232] would give similar results due to the absence of missing values. The pairwise interactions between final variables that remained in the model were checked for statistical significance. Following convention, a p-value <0.05 was taken to indicate a statistically-significant association in all tests.

5.4. Results

5.4.1. TPB Questionnaire

The pharmacy staff who took part in the pilot test suggested changes in the order and some wording of the questions. The final TPB questionnaire comprised 14 questions and took approximately 10 minutes to complete (Appendix 5.2).

Table 5.1 presents the questions for each of the three domains of the TPB and the questions to assess the intention to change practice and provide cognitive services, along with Cronbach's alpha coefficients to assess internal consistency.

Table 5.1: TPB Questions to Examine Intention to Change Practice and provide cognitive services among Pharmacy Staff

Theory of Planned Behaviour Domains	Questions	Cronbach's Alpha
Intention	1. In the future, I will provide cognitive services to customers with lower bowel symptoms 2. In the future, I will change my usual/current practice for customers with lower bowel symptoms Likert scale ranging from "Strongly Disagree" to "Strongly Agree"	N/A
Attitude	1. Pharmacists providing recommendation to customers regarding their lower bowel symptoms is consistent with good professional practice 2. Providing cognitive services to customers with lower bowel symptoms will allow pharmacists to provide an even higher level of care to patients 3. Providing cognitive services to customers with lower bowel symptoms will enhance customer satisfaction even more 4. Providing cognitive services to customers with lower bowel symptoms will make it even more likely that pharmacists will ensure people with lower bowel symptoms get appropriate care Likert scale ranging from "Strongly Disagree" to "Strongly Agree"	0.884
Subjective Norm	1. I would like to provide cognitive services to customers with lower bowel symptoms because customers expect it 2. I would like to provide cognitive services to customers with lower bowel symptoms because other pharmacies are doing it 3. I would like to provide cognitive services to customers with lower bowel symptoms because the pharmacy owner/manager expects me to do it Likert scale ranging from "Strongly Disagree" to "Strongly Agree"	0.734

Perceived Behavioural Control	<p>Ease of engaging with customer presenting with embarrassing symptoms</p> <ol style="list-style-type: none"> 1. For me to take a customer to a private space to speak about his/her embarrassing symptoms is 2. For me to obtain the reason for the patient's visit to the pharmacy with embarrassing symptoms is generally - <p>Likert-type scale ranging from "Very Difficult" to "Very Easy"</p>	0.576
	<p>Confidence in recognising and making recommendations for bowel symptoms</p> <ol style="list-style-type: none"> 1. I am confident in making recommendations to customers regarding their lower bowel symptoms 2. I am confident in recognising signs, symptoms and risk factors (warning signs) of bowel disease that may require consultation with the general practitioner (GP) <p>Likert scale ranging from "Strongly Disagree" to "Strongly Agree"</p>	0.759
	<p>Perceived barrier</p> <p>Providing cognitive services to customers with lower bowel symptoms would be a burden on pharmacy staff</p> <p>Likert scale ranging from "Strongly Disagree" to "Strongly Agree"</p>	N/A

5.4.2. Statistical Analysis

One hundred and ninety-three pharmacy staff from 21 participating pharmacies completed the TPB questionnaire at baseline (pre-TPB). Their average age was 29.1 (SD 10.3) years, with 16.1% male and 83.9% female (Table 5.2).

Table 5.2: Demographic Characteristics of the Pharmacy Staff

Demographic Characteristics		Response (N=193)	
		Number	%
Gender	Male	31	16.1
	Female	161	83.5
Age (15-62)	Mean (SD) years		29.1
Education Level	Less than Year 10	3	1.6
	Year 10 or equivalent	27	14.3
	Year 12 or equivalent	54	28.6
	Diploma or equivalent	11	5.7
	Tertiary education	94	49.7
Employment Status in the Pharmacy	Pharmacist	62	32.5
	Pre-registrant	7	3.6
	Pharmacy assistant	122	63.2
Location of Pharmacy	Medical centre	134	72.4
	≤25 shops shopping centre	23	12.4
	> 25 shops major shopping centre	7	3.8
	City, suburban shopping strip	18	9.7
	Other	3	1.6

The concept of 'intention' (Questions 13 and 14) represented the respondents' level of agreement that they would provide cognitive services (Q13) and change practice (Q14) for customers with lower bowel symptoms in the future. Of the 193 respondents, 11 did not give a response to these intention questions. Those who strongly agreed showed a clear intention to either provide cognitive services (Q13) or change practice (Q14) (Table 5.3).

Table 5.3: Intention to Provide Cognitive Services (Q13) and to Change Practice (Q14) (n=182)

Response	Intention to Provide Cognitive Service Number (%)	Intention to Change Practice Number (%)
Strongly Disagree	3 (1.6)	10 (5.6)
Disagree	4 (2.1)	16 (8.9)
Neutral	27 (14.0)	60 (33.5)
Agree	69 (35.8)	56 (31.3)
Strongly Agree	79 (40.9)	37 (20.7)

Univariate associations between the questions and the 'intention' questions (provide cognitive services and change practice), demonstrate a number of significant associations (Table 5.4).

Table 5.4: Univariate Analysis using Perceived Behavioural Control, Subjective Norm and Attitude to Predict Intention to Provide Cognitive Services

Variable	Intention to provide cognitive services n/N (%)	p-value	Intention to change practice	p-value
PBC Q1 and Q2		0.0851		0.8446
Q1 (For me to take a customer to a private space to speak about his/her embarrassing symptoms is)				
Extremely Difficult, Difficult or Neutral (1-3.9)	8/28 (28.6)		5/26 (19.2)	
Easy or Extremely Easy (4-5)	71/154 (46.1)		32/153 (20.9)	
Q2 (For me to obtain the reason for the patient's visit to the pharmacy with embarrassing symptoms is generally)		0.0250		0.2021
Extremely Difficult, Difficult or Neutral (1-3.9)	9/34 (26.5)		4/32 (12.5)	
Easy or Extremely Easy (4-5)	70/147 (47.6)		33/146 (22.6)	
PBC_Confidence (average Q3 and Q4)		0.0015		0.0555
1-3.9	34/102 (33.3)		15/97 (15.5)	
4-5	45/79 (57.0)		22/81 (27.2)	
PBC Q5 (Providing cognitive services to customers with lower bowel symptoms would be a burden on pharmacy staff)		0.7811		0.7145
Strongly Disagree, Disagree, Neutral (1-3.9)	73/167 (43.7)		34/167 (20.4)	
Agree or strongly agree (4-5)	6/15 (40.0)		3/12 (25.0)	
Subjective Norm (average Q6, Q7 and Q8)		<0.0001		0.0082

1-3.9	40/120 (33.3)		18/110 (15.1)	
4-5	39/60 (65.0)		19/59 (32.2)	
Attitude (average Q9 to Q12)		0.0006		0.0449
<4	0/15 (0.0)		0/15 (0)	
4-5	72/158 (45.6)		33/155 (21.3)	

Q3- I am confident in making recommendations to customers regarding their lower bowel symptoms

Q4- I am confident in recognising signs, symptoms and risk factors (warning signs) of bowel disease that may require consultation with the (GP)

Q6- I would like to provide cognitive services to customers with lower bowel symptoms because customers expect it

Q7- I would like to provide cognitive services to customers with lower bowel symptoms because other pharmacies are doing it

Q8- I would like to provide cognitive services to customers with lower bowel symptoms because the pharmacy owner/manager expects me to do it

Q9- Pharmacists providing recommendation to customers regarding their lower bowel symptoms is consistent with good professional practice

Q10- Providing cognitive services to customers with lower bowel symptoms will allow pharmacists to provide an even higher level of care to patients

Q11- Providing cognitive services to customers with lower bowel symptoms will enhance customer satisfaction even more

Q12- Providing cognitive services to customers with lower bowel symptoms will make it even more likely that pharmacists will ensure people with lower bowel symptoms get appropriate care

Questions 1 and 2 in the TPB questionnaire about perceived barrier in consulting clients with embarrassing symptoms and providing cognitive services as perceived burden (Q5) did not influence the intention of the staff to provide cognitive services and change practice. Tables 5.5 and 5.6 show the results of logistic regression analysis for the outcome variables ‘the intention to provide cognitive services’ and ‘the intention to change practice’, respectively. The PBC questions about confidence in identifying and making recommendations of ‘red-flag’ symptoms (average of Q3 and Q4) and subjective norm were independently associated with the intention to change practice by providing quality-enhanced service when dealing with people with bowel symptoms.

Table 5.5: Multivariate Logistic Regression for Intention to provide Cognitive Services

Variable	Odds Ratio	95% Confidence Interval	p-value
PBC_Confidence*			
<4	1 (reference)		
4-5	2.79	1.45 – 5.37	0.0022
Subjective Norm			
<4	1 (reference)		
4-5	4.07	2.00 – 8.29	0.0001

* PBC_confidence: Average of Q3 and Q4

Q3- I am confident in making recommendations to customers regarding their lower bowel symptoms

Q4- I am confident in recognising signs, symptoms and risk factors (warning signs) of bowel disease that may require consultation with the (GP)

Table 5.6: Multivariate Logistic Regression for Intention to Change Practice

Variable	Odds Ratio	95% Confidence Interval	p-value
PBC_Confidence*			
<4	1 (reference)		
4-5	2.15	1.01 – 4.57	0.0458
Subjective Norm			
<4	1 (reference)		
4-5	2.40	1.32 – 6.02	0.0073

* PBC_confidence: Average of Q3 and Q4

Q3- I am confident in making recommendations to customers regarding their lower bowel symptoms

Q4- I am confident in recognising signs, symptoms and risk factors (warning signs) of bowel disease that may require consultation with the (GP)

Demographic variables and the location of pharmacy were not significantly associated with intention to either provide quality-enhanced cognitive services or change practice.

Forty-seven participants completed the post-intervention TPB questionnaire, 23 (10 pharmacists and 13 pharmacy assistants) of whom had also completed the baseline questionnaire. This participation rate was not representative of the original cohort, limiting the pre/post analysis. The proportion of “Strongly Agree” (46.8%) and “Neutral” (21%) responses increased slightly in the post-intervention for the intention to provide cognitive services (Q13) when compared to pre-JLT-intervention data (Table 5.7). However, the pattern of responses for the intention to change practice (Q14) was almost similar to the pre-JLT-intervention response, where “strongly agree” was 23.4% and “neutral” 36.2%.

Table 5.7: Responses of Participants at post-JLT (n=47) for Intention to Provide Cognitive Services (Q13) and to Change Practice (Q14)

Response	Intention to Change Practice Number (%)	Intention to Change PracticeNumber (%)
Strongly disagree	1 (2.1)	0
Disagree	2 (4.3)	6 (12.8)
Neutral	10 (21.3)	17 (36.2)
Agree	12 (25.5)	13 (27.7)
Strongly agree	22 (46.8)	11 (23.4)

Table 5.8: Intention of Participants Who Completed Baseline and Post-TPB Survey (n=23)

Intention	Pre (% agree + strongly agree)	Post (% agree + strongly agree)
Q13 (In the future, I will provide cognitive services to customers with lower bowel symptoms)	91.3%	74%
Q14 (the future, I will change my usual/current practice for customers with lower bowel symptoms)	43.4%	56.5%

Cross-tabulation of response of the 23 participants showed that six respondents who had agreed to provide cognitive services (Q13) in the baseline survey, changed to either neutral (unsure) or disagreed to provide cognitive services in the post-JLT-intervention TPB questionnaire, while two of them agreed to provide the service in the post survey when they were unsure in the baseline survey. The rest remained the same, agreeing to provide cognitive services in pre and post measures. Four of the respondents who were unsure or had disagreed to change practice (Q14) in the baseline survey agreed to change practice in the future during the post-JLT survey. Five respondents remained neutral in both baseline and post-JLT survey, and the rest of the respondents agreed to change practice in both baseline and post-intervention measures.

While 10 respondents were confident in making recommendations (Q3) for clients with at-risk symptoms both in pre and post JLT-intervention survey, seven who were not confident in making recommendations in the pre-JLT intervention survey reported that they were confident in making recommendations in the post-JLT-intervention survey. Five respondents remained neutral while just one reported he/she was not confident in making recommendations in the baseline and post survey. Nine pharmacy participants who were not confident in recognising 'warning' signs (Q4) in the baseline TPB survey reported that they were confident in recognising these signs in the post-JLT-intervention survey. One participant who was neutral in

the baseline reported that he/she was not confident in recognising the 'red flag' signs for bowel disease in the post survey.

Seven participants of the 23 participants who completed both baseline and post-JLT-intervention survey, did not think that they would provide cognitive service if the client preferred it (Q6). This was different from their baseline TPB survey where they had agreed to provide cognitive services because the "customers wanted it". Other subjective norm questions about perceived social pressure: 'because other pharmacies were providing it' (Q7) and 'because the owners of the pharmacies wanted it' (Q8), was very similar to the baseline survey.

Attitudinal rate towards providing cognitive services and changing practice among the respondents, was high in the post-JLT-intervention survey as was in the baseline survey.

5.5. Discussion

This study provides an understanding of how perceived barriers, confidence, attitude and social pressure influence the intention of pharmacy staff to provide quality-enhanced services (cognitive services) and have potential to change their usual management of clients presenting with bowel symptoms.

The Cronbach's alpha coefficient provided an understanding of all possible combination of items within each domain. For the pair of questions relating to the ease of engaging with a client with embarrassing symptoms, the Cronbach's alpha was 0.576, indicating both questions should be retained individually for analysis. Although 'embarrassing symptoms' was the common factor in both the questions, each measured a different parameter: ease of taking the client to a 'private space' and ease of 'obtaining the reason of visit'.

The PBC questions assessing the confidence of the respondents (Q3 and Q4) that measured the perceived self-efficacy of the respondents in identifying 'red-flag'

symptoms and making recommendations ($p=0.002$), and subjective norm (Q6 to Q8) about the perceived social pressures ($p=0.002$), were both independently associated with intention to provide cognitive services. Similarly, the PBC confidence, Q3 and Q4 ($p=0.046$) and subjective norm ($p=0.022$) showed independent association with intention to change practice. These findings are discussed below.

PBC, particularly the self-efficacy questions about respondents' confidence in recognising high-risk symptoms and making recommendations, had a significant influence on their intention to provide cognitive services. Even if their attitude towards delivering a service that is beneficial to the client was positive, lack of confidence might have a negative impact on their intention to perform it.[108] Greater self-efficacy will most likely lead to increased intention to deliver a cognitive service.[87, 108, 234] A questionnaire such as the JLT[213] that would assist in identification of 'red-flag' symptoms of the pharmacy client has potential to increase the confidence of the pharmacy staff. The post-JLT-intervention survey indicates an increase in confidence in the participants who completed both baseline and post-JLT-intervention survey.

Perceived burden of providing quality-enhanced services and the set-up of the pharmacy to facilitate private consultation with the client were not a significant influencing factor on the intention. This was reflected in the feedback from the pharmacy staff during the post-evaluation phase of the JLT trial (Chapter 4, Section 4.2.3.3), where they reported that JLT deployment was not a burden and they would accept a JLT-like questionnaire for screening of urinary tract infections, asthma, vaginal candidiasis, cough, chronic pain, kidney problems, headaches, and upper gastro-intestinal symptoms.

Similar to other studies that examined intention of pharmacy staff,[87, 235, 236] subjective norm emerged as the major influence on intention to provide quality-enhanced service and change practice. Most of the pharmacy staff appeared to be willing to change practice and provide quality-enhanced services if clients (Q6 in the TPB questionnaire) preferred it or if other pharmacies were providing it (Q7 in the

TPB questionnaire). Pharmacists may feel more pressure to perform a behaviour that is beneficial to their clients and satisfy regulatory pressure.[237] Persuasion of peers can accelerate the diffusion of the service.[238, 239] In the present study, adoption and implementation of JLT may be influenced by the opinions of others within their professional network. Once a service, in this case the deployment of JLT for screening of bowel disease, is adopted by some individuals, it becomes increasingly likely that other members of that social/professional network will also adopt it.[240] Preference of the owner (Q8 in the TPB questionnaire) of the pharmacy also played a significant role in the intention of the staff. This again is reflected in this thesis where the owner of the pharmacy was the driving force in the deployment of JLT for screening clients presenting with bowel symptoms. In the post-JLT-intervention TPB survey, the results showed trends similar to the baseline survey with regards to peer pressure and owner's preference.

The high attitudinal rating of pharmacy staff about outcomes when providing cognitive services suggests an appreciation of staff of the benefits of this type of practice. Although the attitudinal questions were associated with intention in the univariate analyses, they were not included in the multivariate analysis due to the generally positive responses. This high attitudinal rating is consistent with a pharmacy-based TPB study in the US by Farris and Schopflocher on community pharmacists' assessment of pharmaceutical care[108] and the Herbert *et al.* study in Canada on pharmacists' intention to provide medication therapy management service for Medicare beneficiaries.[241] Farris and Schopflocher acknowledged the small sample size and potential self-reported bias in their survey, while Herbert *et al.* considered possible sampling bias. Behavioural decision-making models such as the Theory of Reasoned Action and TPB mostly rely on self-report.[101] While Gavaza *et al.* reported considerable variation between self-reported behaviour and actual behaviour,[242] Armitage and Connor[243] showed few effects of social-desirability when self-reporting the TPB components. Future studies aimed at measuring the actual behaviour and validating the attitude[244] should be conducted. In the present study, the high attitudinal rate was reflected in the JLT-intervention study (Chapter 4) with increase in the referral rate and a greater proportion of clients accepting the

pharmacist's referral and consulting a GP, when the pharmacy staff based their consultation of bowel symptomatic client on the client's response to the JLT.

At the pre-JLT-intervention survey (n=193), pharmacy staff were generally positive about their intention to provide quality-enhanced service and to change practice. The post-JLT-intervention survey response from the participants who completed both baseline and post survey (n=23) indicated a decrease in the percentage of positive response for providing cognitive services in the future. Although the respondents did not think that providing cognitive services was a burden (Q5) in the baseline TPB survey (n=193), the recruitment for JLT intervention (Chapter 4, Section 4.2.4) and adherence to study protocol (Chapter 4) was considered as an issue. This could have been due to the paperwork involved for ethical purposes: consent form, information sheet, and for research purposes: the notes page. The responses of pharmacy staff to the post-JLT-intervention TPB survey could have been largely influenced by the study protocol they had to follow when recruiting clients for the JLT trial (Chapter 4), which they thought was cumbersome. Nevertheless, the 23 respondents were more positive about changing practice, which was reflected in the pharmacy evaluation study of the JLT (Chapter 4, Section 4.2.3.3), where the pharmacy staff reported that using the JLT when consulting with clients with bowel symptoms established a "consistent practice".

The two 'intention' questions measured intention for two different variables namely the intention to change behaviour in future, and the intention to provide cognitive services in the future. Recommendations by Conner and Sparks[227] for developing multiple intention measures, was considered when wording the questions. The word intend which was the term recommended by Francis *et al.*[1] was replaced by "in the future, I will".

The demographic characteristics and the location of the pharmacy did not significantly influence future intention to change practice or provide quality-enhanced services. This was in line with a study conducted by Herbert *et al.*[241] on predicting intention of pharmacy staff to provide medication therapy management

service for Medicare beneficiaries. The study reported that the location of pharmacy and education level were not significant predictors for intention to provide service. Past experience was reported as significantly influencing the attitude, subjective norm and PBC. In the present study, the participants were not asked about their past experience in providing cognitive services.

5.5.1. Limitations

The results of this study should be interpreted with caution for the following reasons: behavioural intention measures were self-reported. Behavioural decision-making models such as the TPB often rely on self-report.[101] As discussed above, evidence suggests that individuals may provide socially-desirable answers in terms of attitude and intention.[101] Additional research to further validate the observed behavioural change is required.

The post-JLT-intervention survey of respondents' intention to provide cognitive services and change practice was conducted to examine the change in intention and the influencing factors of their intention from the pre-JLT-intervention responses. The other purpose was to examine the longer-term behavioural change, beyond the study period. The response rate for the post-intervention survey was lower than expected, and limited the comparison of pre- and post- responses. This low response rate could have been due to change in pharmacy staff over the period of the study, research fatigue, and/or staff not using the JLT during the intervention declining to complete the post-intervention survey, despite the researcher's encouragement. Providing incentives could improve the participation rate and motivate participants to sustain interest throughout the study.[245]

5.6. Conclusion

This study examined if the constructs of the TPB influenced the intention of pharmacy staff to provide quality-enhanced (cognitive) services and change from their practice. The pre-JLT-intervention survey results suggest the pharmacy staff had a positive attitude towards providing cognitive service. Lack of confidence in making a clinical

assessment was considered a barrier in providing cognitive services, whereas greater adoption of the enhanced cognitive services by other pharmacists and the client's preference were perceived as driving adoption of these services.

This is valuable information for efficient implementation of interventions in community pharmacies. Screening tools such as the JLT, when used in pharmacies, are intended to facilitate identification of complex symptoms that could be associated with serious underlying pathology. This may increase the confidence of pharmacy staff to provide screening services in their pharmacies. As established in previous chapters, early intervention for identification and triage of clients who might benefit from further medical investigation should enable treatment to be initiated at an earlier stage, thus improving prognosis.

Adherence to change in practice may be hindered by economic reasons. Lack of reimbursement for clinical services is one of the most common reasons cited by pharmacists regarding their failure to provide cognitive services.[38-41] A study to determine the monetary value for a quality-enhanced service, where pharmacy staff use a questionnaire such as the JLT to identify and triage clients who might be at risk of a serious underlying condition, was proposed, keeping the prospects of implementation of JLT in mind. The next chapter (Chapter 6) describes the WTP study conducted for a quality-enhanced service in community pharmacy.

6. Willingness to Pay for a Quality-Enhanced Service in Community pharmacies

6.1. Introduction

It is evident from the review of published literature (Chapter 2) that community pharmacies are important providers of client-centred, value-added healthcare services, which present pharmacists with opportunities to identify and address health-related issues and offer support and/or referral to symptomatic clients who have not sought medical advice. A number of studies have reported positive impact from the collaboration of pharmacists and GPs in patient management.[23, 31, 83-85]

Economic viability through public and private funding would be key in the long-term sustainability of cognitive services in the pharmacies, especially in a budget-constrained health system.[114] Chapter 2 presented evidence that studies attempting to investigate WTP in Australian pharmacies, showed clients were willing to pay for quality-enhanced services offered in pharmacies. WTP is defined as the (maximum) sum of money an individual is willing to contribute for a specified health gain.[246]

This chapter outlines a WTP study for a quality-enhanced service such as the JLT (described in Chapters 3 and 4), whereby pharmacists offer advice and, if warranted, provide written referral to the GP, following consideration of a client's responses to a self-administered questionnaire about the presenting symptom(s).

The WTP study is presented in Section 6.2 of this chapter as a published Research Brief, reproduced with the publisher's permission (Appendix 6.1):

Sriram D, McManus A, Emmerton L, Jiwa M. Will Australians pay for health care advice from a community pharmacist? A video vignette study. *Research in Social and Administrative Pharmacy* 2015; 11(4): 579-83.

No changes have been made to the content of the published paper, including tense. The formatting and numbering of the headings, tables and reference have been changed to sync with the thesis requirements. The authors acknowledge statistical advice from Dr Richard Parsons, School of Pharmacy, Curtin University. There was no competing interest declared by the authors.

6.2. Willingness to Pay

6.2.1. Introduction

People living in Australia who are concerned about symptoms are able to consult a community pharmacist without making an appointment and at no charge. Alternatively, if they choose to consult a general practitioner (GP), they may also do so without incurring a fee-for-service at some practices in Australia.[247] However, in the 2014 federal budget, the Australian Government proposes to introduce a AUD7 co-payment levy for GP consultations.[248] Experts are concerned that:

Vulnerable groups, including children, Indigenous people, older people and the financially disadvantaged, may delay seeking treatment for serious illness — or even serious worry — with consequent health compromise.[248]

While consumer co-payments introduced in other countries have demonstrated minimal impact on consumer behaviour,[248] the impact of similar charges in the Australian healthcare system is unclear. Furthermore, it is possible that payment to other healthcare providers could also come under consideration.[249] This raises an interesting question about consumers' perceived value of health-related consultations. In the case of community pharmacists, the first hypothesis was that most people would continue to expect consultation at no cost. However, the researchers wished to explore willingness to pay (WTP) for an advanced model of pharmacy consultation that would better determine the need for, and coordinate with, GP consultation. The second hypothesis, therefore, was that Australians are

more willing to pay for a service that includes systematic assessment of symptoms and formal referral to a medical practitioner if necessary.

The aim of this study was to deploy a survey-based method to determine monetary valuations of a standard pharmacy consultation *versus* quality-enhanced service (QES). Few studies that have attempted to investigate WTP show that 13-57% of people are willing to pay for services in pharmacies, depending on the type of pharmacy service provided.[250]

6.2.2. Methods

The project was approved by the Curtin University Human Research Ethics Committee (HR19_2013). The researchers selected assessment of bowel symptoms as the basis to test the hypotheses, following evidence that pharmacies are well utilised for purchase of medicines for diarrhoea, constipation and rectal bleeding.[21] A recently-published decision-aid tool to manage customers presenting with bowel symptoms to a community pharmacy [213] was the inspiration for the QES.

6.2.2.1. Vignettes

A video-vignette based Willingness to pay (WTP) survey was adopted. Vignettes are often used to elicit information about values, beliefs and perceived societal norms from participants. The use of video clips to deliver information to research participants makes vignettes more realistic, helps to engage the interest of research participants, and makes any variations in the vignettes more obvious.[251] A major advantage of this methodology is allowing comparison of different respondents' behaviour over the same set of scenarios and estimating the independent effects of specific information on a person's judgements.[13]

The two video vignettes depicted a pharmacy customer supposedly with lower bowel symptoms being consulted by the pharmacists

1. Video 1: standard (current) practice, using verbal approach to get symptom information and for giving advice/referral; duration 50 seconds (Appendix 6.3)
2. Video 2: quality-enhanced service (QES), depicting greater privacy, systematic assessment of symptoms based on the decision-aid tool, and referral to a GP if necessary; duration 75 seconds. (Appendix 6.5)

The script for each video is included in Appendix 6.2 and 6.4. Adult English-speaking consumers whose age and gender profile closely matched recent census data were recruited for this study from across WA[252] using the services of Qualtrics, an online survey organisation. Participants viewed both videos online, and then completed a brief WTP questionnaire online. Consent form for participants is attached as Appendix 6.6.

6.2.2.2. WTP Questionnaire

The Contingent Valuation Method (CVM), which is a survey-based, hypothetical, direct method to determine monetary valuations of effects of health technologies or interventions, was applied.[253] WTP elicited by the Contingent Valuation Method directly refers to the expense or cost that equals the valuation of the presented health outcome.[254] The WTP questionnaire comprised questions about the participants' understanding of the scenarios depicted in the two video vignettes, their perception of the service provided in each video, and their WTP for each service, including the sum they would consider paying for the QES depicted in Video 2. (Figure 6.1) Content and face validity were confirmed by a panel comprising a general practitioner, a community pharmacy researcher and a public health practitioner (authors MJ, LE and AM), and then by pilot testing with 10 volunteers. Refinements to the questionnaire were made following each validation phase. Self-reported demographic data were age, gender, marital status, education level, employment status, annual household income, and postcode of residency.

1. Did you notice a difference in the way the man was dealt with in Video 1 compared to Video 2?
2. Which consultation do you think was longer?
3. In which video was the man offered more privacy?
4. Assuming that the man had the same problem in both the videos, which consultation do you think was more helpful in providing advice?
5. If you were the man in the video, which type of service/consultation would you prefer?
6. If you were the man in **Video 1**, would you be willing to pay for the service you received in the pharmacy? If yes, how much would you be willing to pay?
7. If you were the man in **Video 2**, would you be willing to pay for the service you received in the pharmacy? If yes, how much would you be willing to pay?

Figure 6.1: Willingness to Pay Survey

6.2.2.3. Data Analysis

A sample size of approximately $n=110$ is adequate for regression analysis to detect an independent variable exhibiting an effect size of $r=0.3-0.5$. [255, 256] Descriptive statistics were used to report the study sample and identify the proportion of the consumers who were willing to pay. Logistic regression was used to explore the influence of demographic data on their responses. For all statistical testing, a significance level of $p<0.05$ was adopted. Analyses were conducted using SPSS® V22.

6.2.3. Results

The target number of 175 participants completed the WTP survey. The WTP questionnaire is attached as Appendix 6.7. The sample was representative of the WA population regarding their age and gender profile.

Seventy-nine percent of participants (n=139) perceived a difference in the service offered in the two videos, and 82% (n=144) acknowledged that the consultation length in Video 2 was longer than Video 1. Forty-one percent of participants (n=72) were not willing to pay for either service. Twenty-eight percent (n=49) of participants were willing to pay for the QES (Table 6.2), indicating a median payment of AUD15 (range \$1-\$75). In comparison, 11% (n=19) of participants were willing to pay for the standard service, indicating a median payment of AUD10 (range \$1-\$50). Eighty-two percent of the people who were willing to pay (n=40) preferred the service/consultation depicted in Video 2 (QES) and 88% of the participants thought that the consultation offered in video-2 (QES) was more helpful in providing advice.

Education status was the only demographic variable that significantly influenced a positive attitude to WTP for the QES. Holders of a trade certificate or diploma were less willing to pay compared to the high school education level or tertiary education level (odds ratio 0.265).

Table 6.1: Demographic Characteristics of Willingness to Pay Survey participants
(N=175)

Demographic variable	Frequency (n)	Percent (%)
Gender		
Male	84	48.0
Female	91	52.0
Total	175	100
Employment status		
Unemployed	33	18.9
Employed full time	56	32.0
Employed part time	29	16.6
Student	10	5.7
Pensioner	32	18.3
Other	15	8.6
Total	175	100
Education level		
Year 12 and less	72	41.1
Trade certificate/ TAFE/ diploma	54	30.9
Tertiary	49	28
Total	175	100
Age Range (years)		
18-29	31	17.7
30-59	99	56.6
60+	44	25.1
Total	175	100
Annual Income (AUD)		
Less than \$40,000	36	20.6
\$41,000-\$80,000	60	34.3
\$81,000 - \$120,000	30	17.1
\$120,000 - \$160,000	20	11.4
More than \$1,60,000	8	4.6
I prefer not to answer this question	21	12.0
Total	175	100
Marital Status		
Single	36	20.6
Married	108	61.7
Separated	5	2.9
Divorced	14	8.0
Widowed	4	2.3
Never Married	8	4.6
Total	175	100.0

In the regression analysis, the 19 participants who were willing to pay for the standard service were excluded, as the majority of these indicated they were also willing to pay for the QES. Of particular interest was the profile of the participants

who were not willing to pay for the standard service and were willing to pay for QES or were unsure about paying for QES (n=58, i.e. 9+24+25), compared with those who were not willing to pay for the QES (n=79). Binary logistic regression revealed no significant association between the socio-demographic variables and a change in the decision towards a positive response for the QES model.

Table 6.2: Willingness to Pay for the Standard Service Vs the Quality-Enhanced service

		Video 2 (Quality-Enhanced Service): Willing to pay?			Total
		Yes	No	Not sure	
Video 1 (Standard Service): Willing to pay?	Yes	Count 16 % of Total 9.1%	Count 2 % of Total 1.1%	Count 1 % of Total 0.6%	Count 19 % of Total 10.9%
	No	Count 24 % of Total 13.7%	Count 72 % of Total 41.1%	Count 25 % of Total 14.3%	Count 121 % of Total 69.1%
	Not Sure	Count 9 % of Total 5.1%	Count 5 % of Total 2.9%	Count 21 % of Total 12.0%	Count 35 % of Total 20.0%
Total		Count 49 % of Total 28.0%	Count 79 % of Total 45.1%	Count 47 % of Total 26.9%	Count 175 % of Total 100.0%

McNemar Test $p < 0.001$

6.2.4. Discussion

These data offer some support for the primary hypothesis, insofar as most (121/175, 69%) of this representative sample of Western Australians were not willing to pay for the standard service. There was also some support for the second hypothesis, as almost one-third (49/175, 28%) indicated WTP for a QES. An equally large proportion was ambivalent about their WTP for the QES (47/175, 27%). This is consistent with previous reports from pharmacies about the services for which consumers are willing to pay.[21, 116]

An unexpected finding was that income was not a significant factor in determining a person's WTP. This may reflect economic circumstances in WA, where tradespeople have comparatively high incomes.[257] Interestingly, the participants were also willing to pay more than the proposed AUD7 GP co-payment. It is hypothesised that this may be related to the convenience of attending a community pharmacy, where there is no need to make an appointment. Therefore, it is speculated that WTP may reflect the value placed on convenience as much as on the perceived expertise of the community pharmacist.

The key limitation to the study is the measurement of WTP, an inherently subjective concept. Experience of the service, face-to-face, by a consumer experiencing symptoms of concern, may elicit a perceived value of the service that differs from that indicated in a theoretical exercise.[116] Despite this, theoretical WTP studies are a cornerstone of exploratory research in the development of new services or products, and the findings suggest significant consumer acceptance of a user-pays pharmacist-led service in triage of symptoms. A prospective study of the feasibility and clinical value of the QES described in this paper is underway. Further research is warranted to develop suitable decision support tools that could support a QES for the majority of customers who might seek health advice at a community pharmacy.

6.2.5. Conclusion

The majority of Western Australians may be willing to pay for a consultation service at a community pharmacy that offers enhanced privacy and a time-intensive experience, with documented GP referral where required.

6.2.6. Additional Limitations from the WTP Study

The participants who completed the survey were representative of the English-speaking Western Australian population in terms of age and gender. Other demographic characteristics such as the educational status or socio-economic status,

were not taken into account during recruitment. This could limit generalisability of the results.

The same male actor was used in two scenarios used to measure respondent reactions (due to funding constraints). This was not considered an issue, as the scenarios focussed on showcasing different pharmacy services rather than gender or age of the client. Results should therefore be read with caution as it is possible an observer effect could have influenced respondent views.

Based on the limitation of sample size and unknown characteristics of the subjective nature of the WTP study, further research should be conducted to confirm the findings

6.2.7. Updates to the published article

At the time of writing the article, the Australian government's proposal of the co-payment towards GP consultation levy was being considered however, it has been abolished due to changes in federal policy. The results reported in this study about the WTP by Australian public for quality-enhanced service, are not affected by this decision.

The next chapter discusses the results of the literature review and the key findings reported in Chapters 3-6, and how they address the research questions.

7. Discussion

7.1. Overview

This chapter draws together the extant literature and key findings reported in Chapters 3-6. This body of research was conducted with the intention of early detection of bowel disease in community pharmacies. A comprehensive literature search reported in Chapter 2 set the stage for the thesis, with evidence supporting a need for early detection of bowel disease.

Chapter 3 described the development and validation of a screening tool (the JLT) that would facilitate the easy identification and triage of pharmacy clients who might be at risk of bowel disease. Building on the results and conclusion of the Development and Validation of JLT reported in Chapter 3, a prospective observational study (Chapter 4) was conducted to examine the feasibility and effectiveness of the JLT as a guide to pharmacy staff to identify clients with bowel symptoms warranting referral to a GP. Data were collected concerning the 'usual practice' of pharmacy staff when consulting clients presenting with bowel symptoms. The JLT was then introduced to guide the consultation of clients with bowel symptoms after the UP phase. Data regarding advice and management of clients based on their response to the JLT questions were collected in this 'intervention phase'. The value of the JLT was assessed between the two phases of the study by comparing the referrals to, and subsequent consultation with GP, recommendations made by the GPs, and evaluation of the JLT by the pharmacy staff.

Chapter 5 provided an insight into how perceived barriers, confidence, attitude and social pressure influence the intention of pharmacy staff to provide quality-enhanced service (cognitive services) and have potential to change their usual management of clients presenting with bowel symptoms. This study explored the factors that might influence the intention of pharmacy staff to provide a service using a screening tool such as the JLT as a guide to the consultation with their pharmacy clients. The questionnaire developed to be completed by the pharmacy staff was based on the

TPB. According to the TPB, intention, which is determined by attitude, perceived social pressure, perceived barrier and self-efficacy, is the direct determinant of the behaviour.[95] Intention reflects the level of motivation of the person to perform the behaviour. Attitude is the degree of evaluation of the behaviour: perceived advantages or disadvantages in performing the behavior while the subjective norm, is the perceived social pressure to perform the behaviour and PBC is the perceived barriers, level of ease and confidence in performing the behaviour.[95] Data were collected from the pharmacy staff who participated in the JLT trial described in Chapter 4. This study helped determine the factors that influenced the intention of the pharmacy staff to provide quality-enhanced service for clients presenting with bowel symptoms.

Chapter 6 was a study of the WTP for a quality-enhanced service in community pharmacy. This study was conducted to determine monetary valuations of a standard pharmacy consultation *versus* quality-enhanced service where the pharmacists offer advice and written referral to the GP, with reference to response to a self-administered questionnaire completed by the client regarding the presenting symptom. This study used video vignettes to demonstrate these two services to the participants. The two video vignettes depicted a pharmacy customer being consulted by the pharmacists using standard practice and quality-enhanced service. Members of the public recruited for this study viewed both videos online, and then completed a brief WTP questionnaire online.

7.2. Discussion based on Research Questions

Nine research questions formed the basis of the thesis. Reflections on these research questions are presented below.

1: Could community pharmacy help to identify clients who might be at high risk of bowel disease?

The literature review (Chapter 2) provided evidence around the initial research questions that community pharmacy could be an ideal primary care setting for testing interventions for early detection of bowel disease and triage of high-risk clients to appropriate care.

Pharmacies have become the most accessible points of contact for individuals within the Australian healthcare system due to their wide distribution in urban, regional and rural areas. They are well placed to play a constructive and dynamic support role in the provision of effective primary health care.[55] The primary health care reform aims at creating a more integrated primary health care system, ensuring that consumers receive high quality and equitable care.[48] This increases the opportunity for community pharmacies to play an increased role in achieving this.

Certain common bowel symptom profiles significantly raise the probability of serious underlying conditions such as cancer, colitis, or large adenomatous polyps. Research has established many patients with colorectal disease present late with such symptoms, yet the public identifies pharmacies as good source of advice for their bowel symptoms.[3, 10-12]

2: Do pharmacy staff know which clients should be encouraged to consult their GP based on symptoms?

Pharmacists are accountable for the advice and service provided in their pharmacies.[19] Pharmacists have become increasingly involved in client-orientated services including development of client profiling, monitoring and counselling.[61, 77] The pharmacist in charge of the pharmacy business is responsible for ensuring pharmacy assistants work within their levels of skill and knowledge.[78] Pharmacy assistants can provide general product knowledge and advice to clients but must refer clients with symptoms, medical conditions or queries about the medications to the pharmacist.[66]

Despite pharmacists being well placed to help identify symptomatic clients presenting to community pharmacies who would benefit for consultation with a medical practitioner, in a survey of pharmacists in Australia, it was demonstrated that bowel symptoms indicative of serious disease were not recognised in a significant proportion of cases.[13, 24] One of the major challenges that pharmacists face in discussing client symptoms that could be considered personal and/or embarrassing, is being able to obtain an accurate history and symptom details from their clients within a 'traditional' pharmacy setting.[25] Evidence supported the need for an effective and evidence-based screening tool to support pharmacy staff to triage cases that warrant further investigation for colorectal pathology.

3: What are the available screening and triage tools for bowel symptoms?

A number of studies reported the development and use of bowel symptom questionnaires, such as the Rome III Diagnostic Questionnaire for Functional Gastro-Intestinal Disorders,[144] Bowel Symptom Questionnaire to identify patients with functional gastrointestinal disease, IBS and functional dyspepsia developed by Talley *et al.*[187, 188], bowel symptom questionnaire developed during the CRISP study,[29, 161] and a risk-prediction algorithm developed by Hippisley-Cox and Coupland.[162] There were few that reported the development of questionnaires with high sensitivity to CRC and testing for use by a GP or a colorectal specialist; examples are the PCQ and the CRISP study.[187, 192, 195] Jiwa and his colleagues studied the feasibility of using PCQ for screening pharmacy clients[21, 23] which is also reported in a recent systematic review by Lindsey *et al.*[258] There were no reported studies that developed bowel symptom questionnaires with high sensitivity for bowel disease for use in a community pharmacy setting. The literature suggested the need to develop a simple, valid screening tool that could be used within the pharmacy setting as part of the continuity of care health care model.

4: Could a simple, easy-to-use, self-administered questionnaire (the JLT) be developed to identify pharmacy clients who might be at risk of bowel disease?

Based on the evidence presented in Chapter 2, there was a need for a screening tool for use in a pharmacy for management of clients presenting with bowel symptoms, with the following characteristics:

- Self-administration, to reduce the workload of pharmacy staff in gathering appropriate information for effective management of symptoms
- Facilitation of accurate information gathering, especially when the client is embarrassed to discuss his/her symptoms
- High sensitivity for bowel disease
- Facilitation of decision making without a need for computerised scoring calculations
- Ability to present 'an assessment' to the client at the time of consultation
- Easy and efficient identification of clients requiring further medical assessment
- Effective referral of identified clients to appropriate medical care.

Chapter 3 reported the development of a self-administered, decision-aid screening tool for use in the community pharmacies was developed to help pharmacists and pharmacy assistants identify clients presenting with bowel symptoms who should be referred to a GP. The questionnaire, named the JLT to acknowledge the foundation sponsoring this research, the Jodi Lee Foundation, was developed to be simple and requiring no score calculation, and to assist identification and referral process. The final questionnaire comprised eight questions and was developed to be easily assimilated into everyday practice without adding burden with regard to time and process.

5: Could the JLT be a valid tool in identifying clients at risk of bowel disease in a pharmacy and be encouraged to consult a GP?

Statistical validation of the JLT was undertaken against a validated screening tool, the PCQ to assess its sensitivity and specificity. The large area under the curve of 0.94 indicates the favourable overall performance of the JLT to identify patients at risk of bowel pathology.

Few studies[25, 192] have reported symptom history taking and getting symptom details especially when clients are embarrassed to talk about their symptoms, as one of the major barriers the pharmacy staff face during a consultation. A triage tool such as the JLT would facilitate easy and accurate information gathering about the presenting symptoms and history taking. This would alert the pharmacists to 'red flag symptoms' which would benefit from further medical consultation.

The advantage of the JLT is that it can be completed very quickly and facilitates decision making for GP referral by the pharmacist simply, without the need for complex calculations, which was the case with the scoring system in the PCQ.[197] The design of the tool incorporates the views of pharmacists and GPs. The JLT has high sensitivity and low specificity; the high sensitivity may help in identifying clients at high risk of disease, while the low specificity may also identify clients with lesser, non-life-threatening pathologies and unlikely to have bowel disease, but nevertheless would benefit from a GP consultation. The JLT may also standardise the consultation process of pharmacy staff with clients presenting with bowel symptoms.

Following the development and validation of a bowel questionnaire with high sensitivity for bowel disease exclusively for pharmacy setting, the next step was to trial the questionnaire in community pharmacies.

6: Could the JLT be an effective assessment tool for pharmacy clients presenting with bowel symptoms, assisting the pharmacy staff to identify at-risk clients and provide a referral to consult their GP?

This prospective study, reported in Chapter 4, supports the use of the JLT to identify symptomatic pharmacy clients who might require further medical investigation, and refer them to appropriate care. The present empirical evidence indicated a higher rate of referral in the intervention group. These findings are in line with studies that indicated structured symptom checklist and screening tools are an effective method to elicit symptoms that would benefit from medical consultation.[193, 214, 259, 260]

Although the deployment of the JLT was not considered onerous by pharmacy staff, the majority of burden to the pharmacy staff was related to client recruitment for research purposes. One of the main reasons given by the staff for the slow recruitment during the intervention phase was the size of the booklet, which consisted of the information sheet, consent form and other paperwork to be completed by the staff. Even though the JLT was a short questionnaire, requiring less than three minutes to complete, the information sheet and consent form for ethical purposes, and notes pages to be completed by the pharmacy staff for research purposes, added to the bulkiness of the booklet and was reportedly a deterrent to recruitment. A similar challenge with engagement by research pharmacists was reported in a study by Emmerton *et al.*[261] about the experiences of community pharmacists involved in the delivery of a specialist asthma service in Australia, in which bulky research documentation deterred the potential participants from taking part in the study.[261]

The concept of applying a decision-support tool in pharmacy practice was accepted by most of the pharmacy staff. They found the JLT to be a simple and effective assessment guide for management of bowel symptoms. The deployment of the JLT as a standalone intervention tool did not burden the staff, as most of the clients completed the JLT unassisted. The pharmacy assistants benefitted from the use of the JLT, as it structured the workflow and guided them to refer appropriate clients to the pharmacists. The JLT intervention was associated with a significantly higher referral rate compared to the UP Phase: 38% vs 20%. These clients were then clinically managed by the pharmacists.

7: Could use of the JLT and referral from pharmacies encourage clients to consult their GP?

The present study reported that greater proportion of referred client consulted their GP for further investigations. The acceptance of the recommendation to consult a GP (i.e. attendance rate for GP consultation) was also higher during the intervention phase than the UP phase: 40% vs 6%. The study reported more diagnoses being made for clients who consulted a GP following the pharmacist's referral using the JLT.

The JLT was found to be an acceptable assessment tool for the triage of bowel symptoms in the community pharmacy setting. Findings from this JLT prospective study suggest there is potential for implementation of questionnaire such as the JLT in pharmacies for screening and management of complex symptoms. There is potential for the documentation to be adapted to guide management of other complex symptoms potentially warranting GP investigation and potentially associated with early-stage cancer, such as pain or urinary tract infections.

This brings the focus on the knowledge, confidence, attitude, perceived barriers and social pressure in influencing the intention to comply with a change in practice.

8: Do attitude, perceived barriers and influence of other people affect the intention of pharmacy staff to perform an activity?

Identifying the perceived barriers, the most influencing social norms and attitude of pharmacy staff for providing quality-enhanced services, and addressing these concepts, would enhance the implementation of such services.[37] The relationship of intention with individual domains of attitude, subjective norm and PBC was studied using univariate analysis. Providing quality-enhanced service was not perceived as a burden by pharmacy staff. The pharmacy staff did not relate the pharmacy layout as a barrier to providing quality-enhanced service. In other words, keeping implementation of the JLT in mind, pharmacy staff did not consider the use of questionnaires such as the JLT burdensome in their day-to-day functioning of the

pharmacy. Furthermore, they should not have to make any major structural changes to the pharmacy to deploy the JLT to clients presenting with bowel symptoms. The post-JLT-intervention survey response from the participants who completed both the baseline and post-JLT-intervention surveys (n=23) indicated a slight decrease in the percentage of positive responses for intention to provide a cognitive service. As discussed in response to research question 6, although the respondents did not think that providing a cognitive service was a burden, recruitment for the JLT intervention and adherence to the study protocol were considered an issue. Responses by participating pharmacy staff to the post-JLT-intervention TPB survey on intention to provide cognitive services could have been influenced by the study protocol they had to follow when recruiting clients for the JLT trial, although they were positive in their response for changing practice to a more “consistent practice”, as established in the pharmacy evaluation study (Section 4.2.3.3).

Interestingly, perceived confidence level in identifying and giving appropriate recommendations played an important part in the intention of the pharmacy staff in providing quality-enhanced services and change their usual practice. This brings into focus a questionnaire such as the JLT that would facilitate in easy identification of ‘red-flag’ symptoms of pharmacy clients. Feedback on the JLT by the pharmacy staff post-intervention (Section 4.2.3.3) pointed out that they accepted the JLT as a simple, easy-to-use questionnaire that “confirmed the ‘red-flag’ for early detection of bowel signs and symptoms that warranted referral for medical advice” and “helped reinforce the cases for referral”. The JLT has potential to increase confidence of the pharmacy staff in accurate identification of clients who would benefit from further medical consultation. The post-JLT-intervention survey also indicated an increase in confidence in the participants who completed both the baseline and post-JLT intervention surveys. Greater self-efficacy would most likely lead to increased intention to deliver a quality-enhanced service.[108, 234]

All three social norm factors – pharmacy clients, other pharmacies and owner of the pharmacy – positively influenced the intention of pharmacy staff to provide quality-enhanced service. In the hope of facilitating implementation of JLT, these findings of

the influence of social norms on intention of pharmacy staff play a vital role. Similar to other studies that measured the intention of pharmacy staff by applying the TPB,[235, 262] social norm was a strong influence on their intention. The pharmacy staff felt under pressure to provide quality-enhanced service and thus change their usual practice, if it was beneficial to the client. The influence of the owner and peer pressure also played an important role on their intention to provide quality enhanced service and change in practice. Persuasion of peers can accelerate the diffusion of the service.[238, 239] Implementation of the JLT with a focus on increasing client expectations and convincing owners to adapt quality-enhanced service is more likely to be successful than without. Adoption and implementation of the JLT may also be influenced by the opinions of others within their professional network. Once a service, in this case, the deployment of JLT for screening of bowel disease, is adopted by some individuals, it becomes increasingly likely that other members of that social/professional network will also adopt it.[240]

Pharmacy staff in this study showed a positive attitude towards provision of quality enhanced service. However, intention to provide quality enhanced service and change practice was very high in this study, leaving very little potential for change in attitude. This was reflected in the post-JLT-intervention TPB study, which again showed positive attitudes towards providing a cognitive service and changing practice. This finding is consistent with a pharmacy-based TPB study in the US by Farris and Schopflocher on community pharmacists' assessment of pharmaceutical care[108] and the Herbert *et al.* study in Canada on pharmacists' intention to provide a Medicare medication therapy management service.[241] In the present study, the high attitudinal rate was reflected in the JLT trial (Chapter 4), with increase in the referral rate and a greater proportion of clients accepting the pharmacist's referral and consulting a GP, when the pharmacy staff based their consultation of bowel symptomatic client on the client's response to the JLT.

Economic viability through public and private funding could be key in the long-term sustainability of such services in the pharmacies.[114]

9: Will Australians pay for healthcare screening and triage service from a community pharmacy?

One-third of the 175 participants were willing to pay a median amount of AUD5 for a quality-enhanced service where the consultation between pharmacists and client was based on the client's response to a symptom screening tool. An equally-large proportion was ambivalent in their WTP for quality-enhanced service. This suggests a realistic fee is appropriate for quality-enhanced service in community pharmacies. This is consistent with other studies that have attempted to investigate the WTP for pharmacies services in Australia.[114, 117, 118] Interestingly, the participants acknowledged the longer consultation time in quality enhanced service and majority found the advice given in the video depicting the enhanced service in pharmacy, more helpful.

The findings in this theoretical WTP study suggested significant consumer acceptance of a user-pays pharmacist-led service in triage of symptoms. This could be an economically-viable option for pharmacy staff if they provide JLT-based quality-enhanced service, even if it is not government funded.

7.3. Limitations

A randomised controlled trial is the ideal design to test pharmacy-led interventions, but in this case, the objective of the JLT-intervention study was to identify if a change in practice of pharmacists could be achieved by introducing to them a structured questionnaire consultation approach for their clients. The practicality of alternating between JLT-led consultation and UP in a busy pharmacy with multiple staff consulting the clients was one reason for not conducting a randomised controlled trial. Clustered randomisation instead of client randomisation was not applied, due to differences in practice in terms of staffing and demographic profile, which would confound the analysis. A pre-post prospective study was considered appropriate for this study.

Recruitment to health research in primary care remains a hurdle.[263] There are published systematic reviews of factors that have an impact on recruitment process for health research.[245, 263-265] Strategies to boost recruitment should be one of the priorities when developing a study. An unfortunate side-effect of ethical committees, which play a hugely valuable role in protecting the participant and the study, is the paperwork that comes with it, which could be burdensome to the client and the pharmacy staff.[263] A less daunting and more acceptable format for carrying out this quality-enhanced service in the pharmacy could be the JLT presented in a letter-pad format. Following the post-evaluation phase of the JLT-intervention study (Chapter 4), the JLT was formatted into a letter-pad style questionnaire (Appendix 7.1) and distributed to the participating pharmacies for future use. No data were collected about the use of the JLT in the letter-pad format, as it was outside the scope of the study.

The other reason for slow recruitment during the intervention phase of the JLT trial study (Chapter 4) was the added burden to the pharmacies of seasonal changes. This study was conducted from May 2013 to March 2014. Recruitment for the intervention phase, which coincided with the Christmas holiday season, was considerably slow due to the shift in focus of the pharmacies. Since it is highly unlikely to avoid long periods with no added burdens such as audits, seasons with other priorities such as festivities in this retail business,[266] it becomes important to maintain flexibility and acknowledge the other commitments of participating pharmacies.

The study protocol was not consistently applied in some pharmacies, highlighting the challenges of research in a naturalistic setting. Although the staff of the participating pharmacies were trained in the protocol and significance of a screening tool such as the JLT in early detection of bowel disease, non-compliance with the protocol could not be controlled in some pharmacies, even when the researcher closely monitored the study progress. Low compliance with the assessment tool was also reported in the CAPER study,[195] where the recommendations made by the assessment tool were not routinely followed by the participating practitioner.

There was no direct involvement of the clients in the design and evaluation of JLT. This was on the account of the intervention being managed by the pharmacy staff. The readability of JLT was measured by Flesh-Kincaid grade level, indicating that an average grade 4 student should be able to read the instrument. Although feedback from pharmacy staff about the JLT was positive in terms of standardising the consultation for clients presenting with bowel symptoms, no direct feedback to assess the client's acceptability was obtained. The pharmacy staff reported that the JLT was easy to complete and clients managed the form unassisted. Further research on the acceptability of JLT directly from the client is required to determine their expectations towards pharmacy when presenting with bowel symptoms.

Behavioural decision-making models such as the TPB (Chapter 5) often rely on self-report.[101] Evidence suggests that individuals may provide socially-desirable answers in terms of attitude and intention.[101] Additional research to further validate the observed behavioural change is required.

The response rate for the post-JLT-intervention behavioural survey (Chapter 5) was lower than expected, and limited the comparison of pre- and post- responses of the intention to change behaviour and provide cognitive service. The majority of pharmacists and pharmacy staff involved in this study participated enthusiastically, which is reflected in their 'attitudinal responses' to surveys, but a few could not sustain that motivation.

Providing incentives could improve the participation rate and motivate participants to sustain interest throughout the study.[245]

7.4. Implementation of the JLT

The process of introducing a new service could be daunting. To achieve successful implementation of the JLT in community pharmacies, effective engagement of pharmacy staff, resources, policy makers and researchers is required.[87] Roberts *et*

al. identified seven key facilitators of practice change in Australian community pharmacies[87] that were addressed in the present study:

- **Inter-professional communication:** The JLT facilitated identification of symptomatic clients and triggered a referral process for the client to consult a GP. This early intervention, at a point where clients may be seeking symptomatic relief from a pharmacy medicine, has potential to initiate early treatment and thus improve prognosis. A less daunting and more acceptable format for carrying out this cognitive service in the pharmacy could be the JLT presented in the aforementioned letter-pad format. Though the JLT based consultation provided a written referral to engage the client without any direct communication between pharmacists and the GP, the JLT trial reported in Chapter 4 indicates that the acceptance to this kind of referral by the client resulted in increased rate of consultation with the GP which again resulted in increased diagnosis after GP consultation
- **Remuneration:** Findings from the WTP study suggest that people might be willing to pay for a service in the pharmacy, whereby a screening tool such as the JLT is used for triage of clients at high risk of bowel disease. A full cost-benefit analysis would be ideal to assess the economic-viability of providing quality-enhanced service where JLT is used for screening of bowel disease in community pharmacies
- **Pharmacy layout:** Although the study by Roberts *et al.* identified the presence of a private consultation area as a key facilitator,[87] the TPB study (Chapter 5, section 5.5) indicated that providing privacy during consultation with clients with embarrassing symptoms was not considered difficult by the pharmacy staff.
- **Client expectation:** Subjective norm was identified as a significant influencing factor for the intention to provide quality-enhanced service in the TPB-based study (Chapter 5, section 5.5). Pharmacy staff value the clients' expectations and needs.[267] This act of working towards fulfilling expectations and needs of the clients is a facilitator in implementation of the service. Studies determining clients' feedback about the JLT would be ideal to obtain information about their expectations.

- **Staff:** Skills and knowledge of the staff was a key facilitator for implementation of a service, as identified by Roberts *et al.*[87] This was reflected in this present study by the self-efficacy of staff in identifying high-risk symptoms, and their confidence in making recommendations, both significant influences on their intention to provide quality-enhanced service as well as change practice. The staff reported in their feedback of the JLT that they found it to be a simple-to-use questionnaire that confirmed the 'red-flag' symptoms that warranted GP consultation. The JLT can potentially increase confidence in identification and triage of high-risk bowel symptoms.
- **Communication and teamwork:** Roberts *et al.*'s study identified a leadership role by the owner and pharmacists and engaging the entire pharmacy by active communication as key facilitators for implementation of a service. The TPB study in this thesis reflects on owners influencing the intention of staff to provide quality-enhanced service and to change practice. Implementation strategies for the JLT should consider the importance of owners and managers being aware of the need to include the entire pharmacy team towards the common goal of successful implementation.

Overall, findings from this thesis suggests the validated assessment tool, JLT is an acceptable tool for triage of bowel symptoms in the community pharmacy. It has high potential in standardising the consultation of pharmacy clients presenting with bowel symptoms. In the current drive for health promotion initiatives within community pharmacy, an easy, user-friendly, valid triage instrument such as the JLT has the potential to improve pharmacy practice.

Potential future research is discussed in the following chapter.

8. Conclusion and Recommendations

8.1. Conclusion

The complex intervention, as described in this thesis, clearly reflects the steps of the MRC framework (Figure 8.1). The review of published literature in Chapter 2 established the value of community pharmacy in primary health care. It also established the gap in research on early identification of bowel symptomatic clients in community pharmacies. To improve the outcome of clients presenting at pharmacies for management of their bowel symptoms, they should be encouraged to consult the GP for definitive diagnosis. The PCQ study reported in Section 2.7.4.1 assessed the feasibility of a bowel symptom management intervention in community pharmacy. For symptomatic clients who present in community pharmacies, there was a need to design and test validated tools that can be used in the pharmacies to identify and encourage them to seek medical help.

The development and validation of the JLT, outlined in Chapter 3, fills the gap in the literature with a self-administered questionnaire that successfully identifies pharmacy clients who may well be suffering from bowel conditions that would benefit from medical advice instead of self-management. The reports of prospective observational study of the JLT, described in Chapter 4, shows that pharmacy staff found the JLT to be a simple and effective assessment tool for management and triage of bowel symptoms. The findings highlight that guided communication around symptoms is effective in alerting health professionals and clients to the need for clinical consultation. With evidence stating that a substantial number of individuals in the community manage symptoms without seeking medical help,[268] a pharmacy service with symptom management based on a decision-making tool such as the JLT should demonstrate value in triage of clients with underlying health conditions.

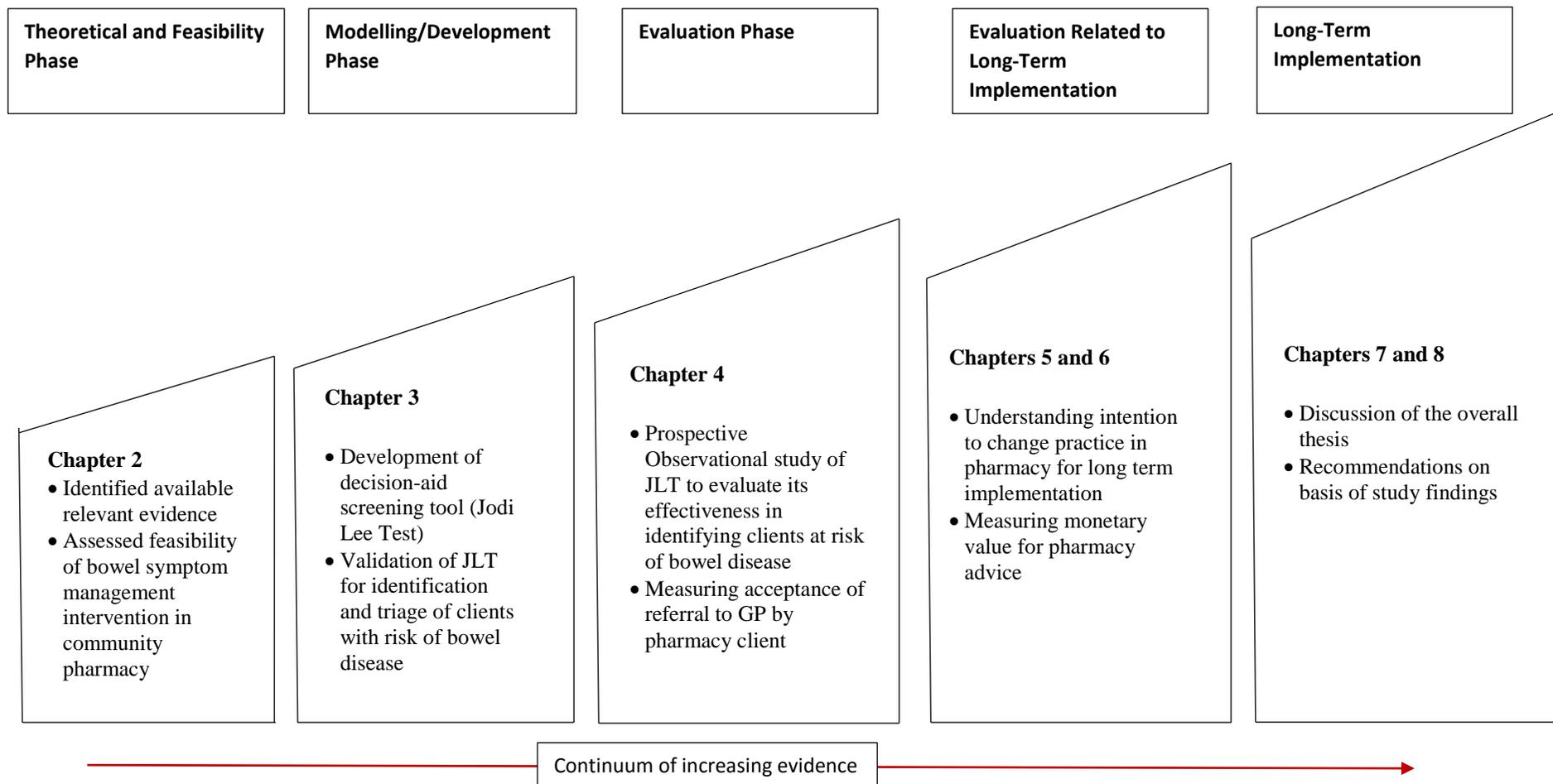


Figure 8.1: Thesis based on Medical Research Council Framework

Intention of pharmacy staff to change practice, outlined in Chapter 5, found the confidence level of pharmacy staff, and social pressure from client, peer group and the owner, strongly influenced their intention to provide quality-enhanced service such as the JLT screening service, in their pharmacies. The WTP study, reported in Chapter 6, showed that clients may be willing to pay for a service where a questionnaire such as the JLT is used to identify 'red-flag' symptoms which require further medical investigation.

Overall, this thesis has demonstrated the development, validation and a prospective observational study of a self-administered bowel questionnaire, JLT for use in community pharmacies for triage of clients who might be at risk of bowel disease.

8.2. Recommendations

The findings of this study may inform intervention efforts for early detection and referral of symptomatic clients who present to community pharmacies. Community pharmacy staff are well placed to play a dynamic support role in effective primary health care as they are the most accessible points of contact within the healthcare system.[55] This makes them the key focal point for interventions aiming at screening and referral to appropriate care. Pharmacy clients value pharmacists' advice and consider positively suggestions to seek GP referral.[21, 215, 269]

Early intervention in pharmacies where clients may simply be seeking symptomatic relief from a pharmacy medicine, has the potential to be extended to other symptom complexes associated with early-stage of serious pathology.

8.2.1. Recommendation 1: Standardised Consultations

During the post-evaluation phase of the JLT trial (Section 4.2.3.3), the pharmacy staff reported that they would accept a JLT-like questionnaire in the pharmacy for conditions such as urinary tract infection, vaginal candidiasis, kidney problems and headaches.

There is potential for development of JLT-like questionnaires and testing of these self-administered screening tools in community pharmacies. This would expand the role of pharmacy staff in identifying and referring clients who would benefit most in further medical consultation. Standardised consultation in pharmacies would benefit the clients and guide them to appropriate care.

8.2.2. **Recommendation 2: Staff Training**

Findings from Chapter 5 provided an insight into the intention, attitude and perceived barriers and social pressures in delivery of quality-enhanced services and changes to usual practice. The results suggest the participating pharmacy staff had a positive attitude towards providing cognitive services. Lack of confidence in making a clinical assessment was considered a barrier in providing cognitive services. Future intervention studies could concentrate on addressing the self-efficacy of pharmacy staff in identification and triage of symptoms indicative of serious underlying pathology, via training, a study package, information materials and screening tools such as the JLT.

8.2.3. **Recommendation 3: Uptake Enhanced Services**

Findings from Chapter 5 also suggested that greater adoption of the enhanced cognitive services by other pharmacists and endorsement by the owner of the pharmacy could be the driving force in successful implementation of cognitive services. Effective engagement of pharmacy owners and staff has the potential to achieve successful implementation of evidence-based pharmacy research.

8.2.4. **Recommendation 4: Client satisfaction**

Client satisfaction was another influencing factor for the intention of pharmacy staff to provide cognitive service. It would be worthwhile to find the client's feedback about the JLT to elicit information about their expectations. Consideration should

also be given to creating public awareness about symptoms and continuity of care for various conditions.

8.2.5. **Recommendation 5:** Reducing administration

Research-related burden is only an issue during the evaluation of a new intervention. Studies using standardised pharmacy clients might be a way to reduce administration burdens that usually hinder recruitment process. Ongoing implementation would require considerably reduced burden from paperwork and contact with researchers.

8.2.6. **Recommendation 6:** JLT should be used routinely

There is scope to trial the JLT in the letter-pad format developed during the evaluation process of the JLT. Should that prove effective, JLT could be adopted as routine part of care for clients presenting with bowel symptoms.

To avoid adding an administrative burden on participants, studies can be conducted on the feasibility of deploying the JLT in an electronic version.

8.2.7. **Recommendation 7:** Pharmacy involvement in health care

The research identified scope for facilitating greater involvement of pharmacy assistants in pharmacy operations outside the dispensary. This would require additional training pharmacy assistants in appropriate protocols for administration of tools such as the JLT. It should also be noted that all involved should be clear about their role in the assessment and referral processes (e.g. definitive diagnosis is not feasible within a pharmacy; the pharmacist contributes to the continuity of care across the health care system, in this case, using a valid screening tool).

Overall, this thesis has demonstrated that a screening tool such as the JLT is a viable method to support pharmacy staff in triage of clients at risk of bowel disease. This instrument, and the findings regarding validation and evaluation, are offered to the

academic community with a view to further research into the contribution of community pharmacy to primary health care and effective continuity of care.

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Appendices

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License Number	3758701308263
License date	Nov 30, 2015
Licensed Content Publisher	John Wiley and Sons
Licensed Content Publication	Journal of Evaluation in Clinical Practice
Licensed Content Title	Development and validation of a clinical decision-making aid for screening bowel symptoms in community pharmacies
Licensed Content Author	Deepa Sriram,Alexandra McManus,Lynne Emmerton,Richard Parsons,Moyez Jiwa
Licensed Content Date	Mar 14, 2014
Pages	7
Type of use	Dissertation/Thesis
Requestor type	Author of this Wiley article
Format	Print and electronic
Portion	Full article
Will you be translating?	No
Title of your thesis / dissertation	Early Detection of Bowel Disease in Symptomatic Patients Attending Community Pharmacies
Expected completion date	Feb 2016
Expected size (number of pages)	230
Requestor Location	Deepa Sriram Curtin University Perth, Australia 6102 Attn: Deepa Sriram

Appendix 3.2: Nominal Group technique for JLT Item Generation

Ten ideas were generated at the conclusion of the discussion.

1. Symptoms to be included:
 - a. Rectal bleeding
 - b. Alternating diarrhoea and constipation
 - c. Diarrhoea
2. Duration of symptoms
3. Importance of GP consultation for the presenting symptom
4. Name of the questionnaire – to be clarified
5. Inclusion of weight loss in the questionnaire
6. Medical history
7. Inclusion of pain 'meter'
8. Medication taken by the client
9. The key questions that would aid the pharmacists and their staff to make a better informed decision about referring to GP
10. Tick-type format for questionnaire with simple wording

Appendix 3.3: Aspects of Delphi Technique- Suggestions Following Each Round of Iteration

Suggestions Recorded After Round 1 of Iteration

1. Change wording of 'pain' question and order to question 5.
2. All symptoms to be present as one question.
3. Name of the questionnaire to acknowledge the foundation sponsoring the researcher.
4. Add bowel-related issues to question 8 as a prompt to help the client.
5. Change the wording of weight loss question so as not to indicate the presenting symptom as illness.
6. Symptom questions should be followed by the duration.
7. Duration should be followed by the 'GP consultation' question.

Suggestions Recorded After Round 2 of Iteration

1. Avoid sub-division for symptoms - make it simple.
2. Have 'discomfort (soreness, itch, lump)' as a separate symptom question.
3. Move 'GP consultation' question to question number 6. It is to be used as additional information for the pharmacists, and should not be a major deciding factor for referral to GP unless the client was buying medication prescribed by the GP.
4. Change the wording for 'usual bowel habit' question for simplicity.

Suggestions Recorded After Round 3 of Iteration

1. Change wording of the 'GP consultation' question and prompt as a following question when the client had last seen the doctor. 'Last seen' to be included to give the pharmacists information about the recurring symptom.
2. Remove the word 'tummy' from the 'pain meter' question to make it a general pain meter for the presenting symptom.
3. Change the order of questions to include symptoms first followed by duration, 'usual bowel habit', 'pain meter', 'weight loss', 'GP consultation', medical history, medication taken.

Suggestions Recorded After Round 4 of Iteration

1. Changes to wording for 'medical history' and 'medication' questions.

There were formatting improvements that included colour, font size and highlighters to indicate the key questions for alerting the pharmacists and their staff.

Appendix 3.4: Jodi Lee Test

Q1. Are you experiencing any of the following symptoms? (tick **ALL** that apply)

Diarrhoea (loose, watery and frequent bowel motions)

Constipation

Alternating constipation and diarrhoea

Bleeding from the back passage

Discomfort at your back passage (soreness, itch, lump)

Q2. How long have you had these symptoms?

Less than 1 week

1 week or more

Q3. Is this unusual for you?

Yes

No

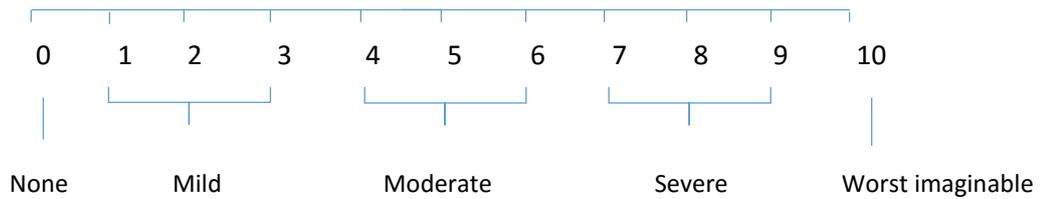
Q3a. If yes, in what way is it unusual?

Q4. Is this symptom(s) associated with any pain?

Yes

No

Q4a. If yes, what is the pain like? (*circle the number that describes the pain*)



Q5. Have you lost weight unexpectedly in the past 4 weeks?

Yes

No

Q5a. If yes, approximately how much weight have you lost? ___kg

Q6. Have you talked to a doctor about this symptom(s)?

Yes

No

Q6a. If yes, when was the last time you talked to the doctor about this symptom(s)?

Q7. Have you had any bowel problems in the past 12 months?

Haemorrhoids (Piles)

Colitis

Polyps

Cancer

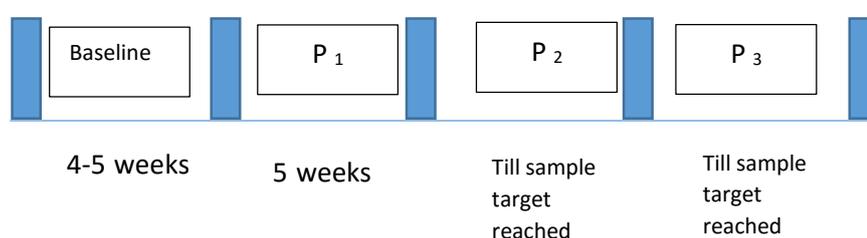
Other _____

Q8. Please list any medication that you are currently taking (including medicines bought without a prescription, and natural products).

Appendix 4.1: Flyer



Early detection of Bowel Disease in Community Pharmacies



Key:

P₁- Simulated actor consultation in pharmacy and usual practice documented

P₂- Implementation of JLT in pharmacy

P₃- Post intervention 'usual practice'

Timeline for Pharmacies participating in Early Detection of Bowel Disease in Symptomatic Patients

- **Establish Baseline of Current Pharmacy Practice**
 - Recruit pharmacies into study. Need a minimum of 25 pharmacies.
 - **Fill out team surveys to show current practice** of detection of bowel disease in pharmacy. Participants include **all pharmacists, pre-registration pharmacists and all team members that are accredited to work in the S2/S3 area.**

- **Recruit Patients into Name collection/control phase**
 - **Mystery shop** of 5 to 10 random pharmacies to see their **current practice**.
 - Recruit **2-3 participants/week** into study. **Participants are asked to participate in phone survey (follow-up call)** regarding their symptoms. Participants will be **given \$5 off** the cost of their purchased item as incentive to participate in phone survey. Follow up by Deepa Sriram of Curtin Innovation Health Research Institute within 4 weeks of patient consent.

- **Recruit patients to Jodi Lee Test Intervention phase**
 - Participating pharmacies asked to **trial** the intervention tool designed to ascertain Early Detection of Bowel Disease in Symptomatic Patients (**Jodie Lee Test Intervention Tool**) in general Community Pharmacy practice. The Pharmacists will be asked **to advise the participants based on their response to JLT**. Participating pharmacies asked to **2-3 participants/week** into study
 - The consented participants who complete the JLT will be followed up by Deepa Sriram of Curtin Innovation Health Research institute within 4 weeks of patient consent. Participants will be given **\$5 off the cost** of their purchased item as incentive to participate in this phase.

Thank You for your time

Appendix 4.2: Instructions to Pharmacy Staff for Usual Practice

PHASE 2- Control Phase/Name Collection Phase

Instruction for Staff members

You have to recruit customers with lower bowel symptoms like diarrhoea, constipation rectal bleeding, for this phase of the study.

Eligible participants are

- Customers 18 and over who can give informed consent.
- Who present in the pharmacy for advice or medication for lower bowel symptoms (Diarrhoea, Constipation, Rectal Bleeding)- preferably not prescription medication for their presenting symptoms.

What you would be asked to do

- When a customer presents with the above mentioned symptoms, **tell him/her about the study** and if willing, give them the booklet with information sheet and consent form to complete.
- The **participant has to just give his/her name and best contact details** for this bit of the study and I would follow them up after 4 weeks. They can have the main copy of the consent form - **tear the consent form off and give to the customer.**
- **They get \$5 off their purchase** if they sign the consent form
- The **Staff** who deals with that particular customer should complete **the notes page** in the booklet.
- **Carry on with your usual management of the symptom.**
- **Booklet should be posted** back to Deepa Sriram.

For further information please contact

Deepa Sriram

Email- d.sriram@curtin.edu.au

Tel No- 94565473, 0431890299

Curtin University

Thank you for your participation

Appendix 4.3: Instructions to Pharmacy Staff for JLT Phase

JLT Phase - Intervention Phase

Instruction for Staff members

You have to recruit customers with lower bowel symptoms like diarrhoea, constipation rectal bleeding, for this phase of the study.

Eligible participants are

- Customers 18 and over who can give informed consent
- Who present in the pharmacy for advice or medication for lower bowel symptoms (Diarrhoea, Constipation, Rectal Bleeding)- preferably not prescription medication for their presenting symptoms.

What you would be asked to do

- When a customer presents with the above mentioned symptoms, **tell him/her about the study** and if willing, give them the booklet with information sheet and consent form to complete.
- The **participant has to complete the consent form and the Jodi Lee test (JLT)** for this bit of the study and I would follow them up after 4 weeks. They can have the main copy of the consent form and the JLT- **tear the main copy consent form and JLT –pages 3, 4 and 5 off and give to the customer.**
- **Check the completed JLT** and if there is a **tick in the highlighted boxes**, the client will get **a referral. Sign page 7** and tear and **give the main copy to the client.**
- Even if the completed JLT warrants a referral, **you can decide by clinical judgement if the client requires a referral from further questioning or from the responses to Jodi Lee test (JLT), eg, Q6 and Q8.**
- **They get \$5 off their purchase** if they sign the consent form.
- The **Staff** who deals with that particular client **should complete page 6** in the booklet.

- **Carry on with your usual management of the symptom.**
- **Booklet should be posted** back to Deepa Sriram.

For further information please contact

Deepa Sriram

Email- d.sriram@curtin.edu.au

Tel No- 94565473, 0431890299

Curtin University

Thank you for your participation

Appendix 4.4: Baseline Booklet

Booklet Cover page



Early Detection of Bowel Disease In Community Pharmacy



Booklet Back page



THANK YOU FOR YOUR PARTICIPATION IN THIS RESEARCH PROJECT

For further information, please contact

Deepa Sriram

Email : d.sriram@curtin.edu.au

Tel: 08-92669581

Curtin Health Innovation Research Institute (CHIRI)

Curtin University

GPO Box U1987

WA 6845



Baseline Booklet

Information Sheet

Early detection of Bowel Disease in symptomatic patients attending community pharmacy

This pharmacy is currently participating in the research study conducted by a PhD candidate from Curtin University. We are asking for your help in trialling an assessment tool (Jodi Lee Test - JLT) to support pharmacy staff to advice customers who present with lower bowel symptoms.

What will I be asked to do?

- Complete four short questionnaires. This will be at baseline and after each of the 3 short phases of the study. Each questionnaire would take 5-10 minutes to complete.
- Provide your usual service for a mystery shopper. About five actors will present at the pharmacy with specific problems. You are invited to consult them as per your normal practice. The actor will document the consultation once he/she is out of the pharmacy and relay it to the researcher. The data will be used by the researcher to determine the current practice by offering a case scenario. Though you will not be aware of the exact date or time when the actors would present themselves, once the consultation is finished, you will be informed by the researcher of the 'actor consultation'.
- Recruit eligible customers to the study those who are over 18 years of age and able to provide informed consent, who attend a participating community pharmacy to seek advice and/or request to buy a product to manage a current symptom of bowel disease that includes diarrhoea, constipation and/or rectal bleeding. You will also be invited to document your interaction with those customers.

What will happen

During my first visit to your pharmacy I will explain

- The study and the intervention tool (JLT)
- How to recruit participants
- How to record interaction with participants

How will my privacy be protected?

We believe it is extremely important to keep your personal information confidential. The researchers will need to collect personal data about you, which may be sensitive. Examples of such data include your name, contact details, date of birth and other relevant information. However, personal information will be kept private and confidential. It will be stored securely

and only authorised persons, who understand the confidential nature of the information, will have access to it.

Any data that is required for data analysis will be securely exported to Curtin University and given a number so that your identity will not be apparent.

The results of the research will be made available to other health professionals through medical journal, meetings or conferences, but you will not be identifiable in any of these communications.

Can I decline to take part or withdraw if I change my mind?

Participation in this study is purely voluntary. You may decline to take part or withdraw from this study at any time.

All pharmacy customers will receive the same quality of service that is available in pharmacies regardless of participation in this project. Where you deem that a client should consult a General Practitioner for any reason, they will be urged to do so notwithstanding the focus of this project.

The JLT offered will not replace clinical expertise. It is designed to guide your discussion with the patient.

Are there any risk or benefits?

There are no risks involved in this study.

The questionnaire that you complete at every study end point will help the researcher evaluate change in pharmacy practice. We anticipate that having your practice observed may have an impact on your current practice. At each stage of this study, we offer a different intervention. In order to identify the impact on your practice, we are inviting you to complete a short questionnaire to help identify which intervention was most helpful. This will help researchers understand how patients are advised about their lower bowel symptoms in this setting and what might help staff to advise them most appropriately. You may find this observation a little challenging, however, all the information you offer will be de-identified in any reports or publications or presentations from this study.

For more information about the study please contact
Ms Deepa Sriram
Curtin Health Innovation Research Institute/Curtin University
Phone: 92669581
Email address: d.sriram@curtin.edu.au

The study has been approved by the Curtin University Human Research Ethics Committee (Approval Number-HR 19/2013). The committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained by either writing to the Curtin University Human Research Ethics Committee on telephone number, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

Consent Form

Early detection of Bowel Disease in symptomatic patients attending community pharmacy

This pharmacy is currently participating in the research study conducted by a PhD candidate from Curtin University. We are asking for your help in trialling an assessment tool (Jodi Lee Test - JLT) to support pharmacy staff to advice customers who present with lower bowel symptoms.

By completing the consent form below, you certify that you:

1. Have read and understood the information provided regarding the above mentioned study and have had an opportunity to ask questions.
2. Are willing to participate by completing four questionnaires, actor consultation and recruiting eligible participants for the study.

Name _____

Pharmacy Name _____

Pharmacy Address

Signature _____

Date _____

About you

1. What is your age as of your last birthday?

2. What is your gender

Female

Male

3. Highest level of Education...

Less than Year 10

Year 10 or equivalent

Year 12 or equivalent

Diploma or equivalent

Tertiary education

What are your formal qualifications?

4. Employment status in the pharmacy:

Pharmacist

Full-time

Owner

Part Time/ Locum/Casual

Pre-Registrant Pharmacists

Pharmacy assistant

5. How long have you worked in a community pharmacy setting (years)?

6. What is your role in managing customers with lower bowel symptoms (eg., constipation, diarrhoea, rectal bleeding) ?

Please provide as much details as possible

Pharmacy Assistant please go to page 8 and complete Page 8 and 9

Please answer the following question if you are a pharmacist

7. When you are at work, how many other pharmacists also are present at your practice at the same time?

- None, I am the sole pharmacist
- One other pharmacist
- 2-4 other pharmacists
- 5 or more other pharmacists

8. The location of this pharmacy

- Medical Centre
- Local shopping centre (<25 shops)
- Major shopping centre (>25 shops)
- City, suburb or Town-centre strip
- Other (please specify)

9. The majority of your customers are :

- Seniors
- Young families
- Working adults
- Young people

10. Approximately how many customers attend the pharmacy with symptoms before they consult their GP per day?

Pharmacy Questionnaire

Please do not consult any member of the team when filling in this questionnaire

3. For me to take a customer to a private space to speak about his/her embarrassing symptoms is
Extremely difficult 1 2 3 4 5 Extremely easy
4. For me to obtain the reason for the customer's visit to the pharmacy with embarrassing symptom is generally
Extremely difficult 1 2 3 4 5 Extremely easy
5. I am confident in making recommendations to customers regarding their lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree
6. I am confident in recognising warning signs of bowel disease that may require consultation with the general practitioner (GP)
Strongly disagree 1 2 3 4 5 Strongly agree

Cognitive pharmaceutical services can be defined as professional services provided by pharmacists, who use their skills and knowledge to take an active role in patient health, through effective interaction with both patients and other health professionals.

7. Providing cognitive services (**Please refer to the definition given above**) to customer with lower bowel symptoms would be a burden on pharmacy staff
Strongly disagree 1 2 3 4 5 Strongly agree
8. I would like to provide cognitive services to customers with Lower bowel symptoms because customers expect it
Strongly disagree 1 2 3 4 5 Strongly agree
9. I would like to provide cognitive services to customers with Lower bowel symptoms because other pharmacies are doing it
Strongly disagree 1 2 3 4 5 Strongly agree
- 10. If you are the owner/manager of this pharmacy please move to question 9**

I would like to provide cognitive services to customers with Lower bowel symptoms because the pharmacy owner/manager expects me to do it
Strongly disagree 1 2 3 4 5 Strongly agree

11. Pharmacists providing recommendation to customers regarding their lower bowel symptoms is consistent with good professional practice
Strongly disagree 1 2 3 4 5 Strongly agree
12. Providing cognitive services to customers with lower bowel symptoms will allow pharmacists to provide an even higher level of care to patients
Strongly disagree 1 2 3 4 5 Strongly agree
13. Providing cognitive services to customers with lower bowel symptoms will enhance customer satisfaction even more
Strongly disagree 1 2 3 4 5 Strongly agree
14. Providing cognitive services to customer with lower bowel symptoms will make it even more likely that pharmacists will ensure that people with lower bowel symptoms get appropriate care
Strongly disagree 1 2 3 4 5 Strongly agree
15. In the future I will provide cognitive services to customers with Lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree
16. In the future I will change my usual/current practice for customers with lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree

Appendix 4.5: Control Group Booklet

Participant Information Sheet

We are interested in the best way to provide advice people who come into a Pharmacy with lower bowel symptoms. We are very interested in your opinion.

Who can participate?

You are eligible to participate if you are over 18 years of age and able to provide informed consent.

What will you be asked to do?

1. You will be asked to provide your name, address and a contact telephone number. This information will ONLY be used for study. It will not be used for any other purpose and will be destroyed at the end of this research.
2. A researcher named Deepa Sriram, will telephone you in the next 4 weeks to ask you a few brief questions about whether you have sought any more advice about your symptoms. This will take approximately five (5) minutes.
3. As a token of appreciation for your time in participating in the telephone survey, you will receive a \$5 discount from your purchase in this pharmacy.

How will my privacy be protected?

We believe it is extremely important to keep your personal information confidential. As noted before, the information you provide to us will *only be used for this research*. After the research project is finished, it will be destroyed. You will not be named in any publication and any results will be summarised as percentages or proportions of the total number of participants in this study.

Can I decline to take part in this study or withdraw if I change my mind?

Participation in this study is voluntary. You may decline to take part or withdraw from this study at any time.

Are there any risk or benefits?

There are no risks involved in this study. You will continue to receive the usual service from this pharmacy. Your answers will help researchers to find better ways to help patients with bowel symptoms.

What if I have questions once I have completed the study?

If you would like a copy of this questionnaire for your own information or would like further information on the study, please contact:

Ms Deepa Sriram

Curtin Health Innovation Research Institute (CHIRI)

Curtin University

Building 609

GPO Box U 1987

Phone: 92669581

Email id: d.sriram@curtin.edu.au

The study has been approved by the Curtin University Human Research Ethics Committee Approval Number HR19/2013. The committee is comprised of members of the public, academics, lawyers, doctors and pastoral cares. Its main role is to protect participants. If needed, verification of approval can be obtained by either writing to the Curtin University Human Research Ethics Committee on telephone number, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

All study participants will be provided with a copy of the Information Sheet and Consent

Participant Consent Sheet

This pharmacy is currently participating in a study conducted by the Curtin Health Innovation Research Institute. The study seeks to identify people who present at a pharmacy with lower bowel symptoms. Your participation is voluntary.

By completing the consent form below you certify that you:

1. Are over the age of 18 years.
2. Have read and understood 'participant information sheet'.
3. Have had any questions answered about this study to your satisfaction.
4. Are willing for a member of the research team to telephone you in the next 4 weeks.

Please note: It is *important we are able to contact you by phone and by mail* so we would appreciate you making sure your details are complete and correct.

First Name			
Surname			
Mailing Address			
Suburb	Post Code		
Telephone number/s	Date of Birth	_/_ /_	
Best time to call	You will be called by Deepa		

Your signature: _____

Date: _____

Name of Pharmacy _____

Signature of Pharmacist: _____

The study has been approved by the Curtin University Human Research Ethics Committee Approval Number HR19/2013. The committee is comprised of members of the public, academics, lawyers, doctors and pastoral cares. Its main role is to protect participants. If needed, verification of approval can be obtained by either writing to the Curtin University Human Research Ethics Committee on telephone number, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au. All study participants will be provided with a copy of the Information Sheet and Consent

For Pharmacy Staff - Please document the consultation with the customer

Date ____/____/____

Name of the Patient _____

1. What symptoms were reported by the patient?

2. What questions did you ask?

3. Was any medication sold? Yes No

If yes, what were the medication sold?

4. Did you refer the patient to consult their GP? Yes No

If yes, Why?

5. How long did this consultation take (time in mins)? _____ mins

6. Did you give any other advice to the patient? Please comment.

Thank You for your support

Name: _____

Pharmacy: _____

Appendix 4.6: JLT Booklet

Participant Information Sheet

You have been asked to volunteer in this study because you were seeking treatment for a particular bowel symptom or condition. This study seeks to explore the best way to advice people who present with bowel symptoms.

Who can participate?

- You are eligible to participate if you are 18 years of age
- Over able to provide informed consent.

What will you be asked to do?

1. You will be asked to provide your name, address, a contact telephone number and the name of your general practitioner. This information will allow us to do follow up calls ONLY for the purpose of this study.
2. You will be asked to answer a brief questionnaire about your lower bowel symptoms. This will take you approximately 3 minutes to complete.
3. Approximately 4 weeks after you complete this survey, we will telephone to ask you a few brief questions about what you have decided to do about your symptoms. This will take approximately 5 minutes.
4. You will receive \$5 voucher for use in this pharmacy to cover your time today and when we call you next month for follow-up.
5. When we call you next month, if you have been to see a GP on the pharmacist's advice, we will call your GP for information about your bowel symptoms.

How will my privacy be protected?

We believe it is extremely important to keep your personal information confidential. As noted before, the information you provide to us will *only be used for this research*. After the research project is finished, it will be destroyed. You will not be named in any publication and any results will be summarised as percentages or proportions of the total number of participants in this study.

Can you decline to take part or withdraw if you change my mind?

Participation in this study is purely voluntary. You may decline to take part or withdraw from this study at any time.

Are there any risk or benefits?

The completed questionnaire will show if you would benefit from talking to a doctor.

There are no risks involved in this study. However, you may feel a little anxious if the pharmacist suggests that you make an appointment with your doctor. If that happens or you have any concerns please do not hesitate to discuss with the pharmacist.

What if you have questions once you have completed the study?

If you would like a summary of the result of this project, please contact:

Ms Deepa Sriram

Curtin Health Innovation Research Institute (CHIRI)

Curtin University

Building 609

GPO Box U 1987

Phone: 9266 9581

Email id: d.sriram@curtin.edu.au

The study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR19/2013). The committee is comprised of members of the public, academics, lawyers, doctors and pastoral cares. Its main role is to protect participants. If needed, verification of approval can be obtained by either writing to the Curtin University Human Research Ethics Committee on telephone number, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

Participant Consent Sheet

This pharmacy is currently participating in a study conducted by the Curtin Health Innovation Research Institute. The study seeks to identify people who present with lower bowel symptoms and participation is purely voluntary.

By completing the consent form below you certify that you:

1. Are 18 years and over
2. Have read and understood the participant information sheet.
3. Have had any questions answered about this study to your satisfaction.
4. Are willing for a member of the research team to telephone you in the next 4 weeks.
5. Are willing for us to contact your GP if your pharmacist refers you to them about your bowel symptoms.

Please note: It is important we are able to contact you both by phone and by mail so please ensure these details are both complete and correct.

Personal Details

First Name _____

Surname _____

Address _____

Suburb _____ Post Code _____

Gender Male Female

Telephone _____

Date of Birth __/__/____

Best Time to call _____

(you will be called by Deepa Sriram)

GP details

Name of GP _____

Name of Medical Centre _____

Name of Pharmacy _____

Signature: _____ Date: _____

The study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR19/2013). The committee is comprised of members of the public, academics, lawyers, doctors and pastoral cares. Its main role is to protect participants. If needed, verification of approval can be obtained by either writing to the Curtin University Human Research Ethics Committee on telephone number, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

Jodi Lee Test (JLT)

Q1. Are you experiencing any of the following symptoms? (tick **ALL** that apply)

Diarrhoea (loose, watery and frequent bowel motions)

Constipation

Alternating constipation and diarrhoea

Bleeding from the back passage

Discomfort at your back passage (soreness, itch, lump)

Q2. How long have you had these symptoms?

Less than 1 week

1 week or more

Q3. Is this unusual for you?

Yes

No

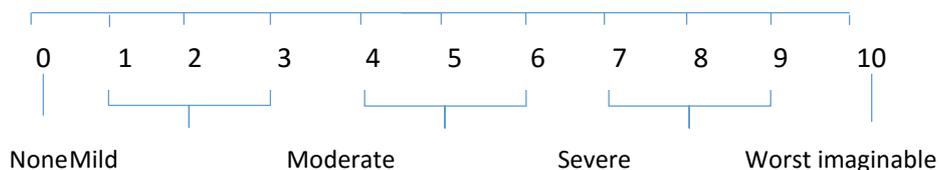
Q3a. If yes, in what way is it unusual?

Q4. Is this symptom(s) associated with any pain?

Yes

No

Q4a. If yes, what is the pain like? (**circle** the number that describes the pain)



Q5. Have you lost weight unexpectedly in the past 4 weeks?

Yes

No

Q5a. If yes, approximately how much weight have you lost? _____ kg

Q6. Have you talked to a doctor about this symptom(s)?

Yes

No

Q6a. If yes, when was the last time you talked to the doctor about this symptom(s)?

Q7. Have you had any bowel problems in the past 12 months?

Haemorrhoids (Piles)

Colitis

Polyps

Cancer

Other _____

Q8. Please list any medication that you are currently taking (including medicines bought without a prescription, and natural products).

For Pharmacy Staff

Date ____/____/____

Name of the Patient

1. Did the JLT indicate this person should be referred to a GP?

Yes

No

2. Did you refer this person to a GP?

Yes

No

Document your reasons

3. Did you give the JLT referral letter to the person?

Yes

No

Referral Letter

Dear Doctor

This patient attended this pharmacy today. Based on the symptom reported they have been advised to consult you for further investigation. See attached questionnaire.

With kind regards

Pharmacy-

Appendix 4.7: Bowel Symptom Scenarios

Scenario: Constipation

Setting the scene- talk to the first person and ask for assistance for constipation, please check the name plate to see if you are being served by a Pharmacy assistant or pharmacist or student or any other staff member....

What you say

1. I have been having constipation for about 3 days
2. Got slight discomfort and slight tummy pain (just below your chest)
3. What can I do.....is there anything I can take

Pharmacy assistant might refer you to pharmacists or student-pharmacists

Whoever serves you might ask these following questions. **The reply for them are in maroon font**

- For how long have you been constipated? **For about 3 days**
- Are u not going to the toilet at all? **Going to the toilet everyday but not fully cleared, not emptied satisfactorily.**
- Bloating? **Yes, slightly**
- Eating ok? **yes**
- Drinking water? **Yes**
- Any change in diet lately? **No**
- Any family history? **No**
- Do you have any pain or lump or any kind of discomfort when passing motion? **No**
- Are you using any other medication – **using ventolin (about once a month.....whenever have to take)**
- Are you taking any medication for this problem? **No**
- Have you had this kind before – **sometimes, and on few occasions have had laxatives**
- Have you seen a GP regarding this issue?- **No**

We now have these choices:

1. medication suggested : buy the pdt (pharmacist might say things like this: Anal fissure or Haemorrhoid. This might be just to ease the bleeding)
2. Recommendation to consult a GP- If not resolved in 3-4 days, see GP
3. Both - same reply as stated above
4. No recommendations
5. Other recommendations

Scenario: Diarrhoea

Setting the scene- talk to the first person and ask for assistance for diarrhoea, please check the name plate to see if you are being served by a Pharmacy assistant or pharmacist or student or any other staff member....

You are embarrassed to discuss this...talk in a quiet voice when discussing

What is your condition (u just say Diarrhoea, and wait till they ask other questions)

4. I have had diarrhoea for 2 days now
5. Been drinking water...
6. There is no vomiting
7. I go to the toilet 4-5 times a day and it is watery
8. What can I do.....is there anything I can take

Pharmacy assistant might refer you to pharmacists or student-pharmacists

Whoever serves you might ask these following questions. **The reply for them are in maroon font**

- When did it start? **I have had it for about 2 days**
- Is it getting worse? **No**
- Any other symptoms? **No**
- Is there any blood- **No**
- Any mucous? **No**
- Does it continue after you finish going to the toilet? Or is there any leakage - **No**
- Do you think it could be because of any food you ate)- **No, but I had gone out for dinner 2-3 days back**
- Anyone in the family having it? **No**
- Any travel? **No**
- How often do you go to the toilet? **About 4-5 times /day**
- Do you have any pain or lump or any kind of discomfort when passing motion? – **No**
- Are you using any other medication –Multivit. Have been having for a while...had no issues
- On antibiotic? **No**
- Any significant weight loss over the past 4 weeks? – **No**
- Have you felt excessively tired?- **not particularly**
- Have you been diagnosed with (haemorrhoids it is also called piles) or polyps or any other bowel disease?- **No**

We now have these choices:

6. medication suggested : **buy the pdt**
7. Recommendation to consult a GP- **oh, is it serious?! Can I wait since I have to go away for a week regd work or Oh, how soon do you think I should see a doc, can it wait till after I come back from a work trip next week?**
8. Both - **same reply as stated above**
9. If pharmacist says "I can get the appt for you now so that you can go before your trip"- **just say that you would do it yourself**
10. No recommendations
11. Other recommendations

Scenario: Alternating Constipation and Diarrhoea

Setting the scene- Setting the scene- talk to the first person and ask for assistance, please check the name plate to see if you are being served by a Pharmacy assistant or pharmacist or student or any other staff member....

You are embarrassed to discuss this... talk in a quiet voice when discussing

What you say

9. I have constipation and diarrhoea...on and off...pattern is completely different...
10. Been having it for a while now...hmmm...say about 3-4 weeks..
11. I will be constipated for 2-3 days then for the next few days will be frequent motions. It would settle down for some time then the same pattern would happen....

Pharmacy assistant might refer you to pharmacists or student-pharmacists

Whoever serves you might ask these following questions. **The reply for them are in maroon font**

- How long have you been having it? **It has been there for a whilesay...3-4 weeks**
- Any bloating? **No**
- Loss of appetite? **No**
- Is this been your normal pattern for bowel motions? **No, regular bowel movement**
- Do you have any pain or lump or any kind of discomfort when passing motion? – **No**
- Are you using any other medication – **using ventolin (about once a month....whenever have to take)**
- Have you taken any medication? **No, I thought it would settle down**
- Have you seen a doc or got advice anywhere else for this? **No, thought it would settle down....now this is becoming a consistent pattern...that is why I came here to get something for this.**
- Are you taking any medication for this problem? **No**
- How often do you go to the toilet? **When I have diarrhoea, I go about 4-6 times**
- Any significant weight loss over the past 4 weeks? – **No**
- Have you felt excessively tired?- **not particularly**
- Have you been diagnosed with (haemorrhoids it is also called piles) or polyps or any other bowel disease?- **No**

We now have these choices:

12. medication suggested : buy the pdt (diagnosis could be IBS)
13. Recommendation to consult a GP- oh, is it serious?! Can I wait since I have to go away for a week regd work or Oh, how soon do you think I should see a doc, can it wait till after I come back from a work trip next week?
14. Both - same reply as stated above
15. If pharmacist says "I can get the appt for you now so that you can go before your trip"- just say that you would do it yourself
16. No recommendations
17. Other recommendations

Scenario: Rectal Bleeding

Setting the scene- talk to the first person and ask for assistance for rectal bleeding, please check the name plate to see if you are being served by a Pharmacy assistant or pharmacist or student or any other staff member....You are embarrassed to discuss this...talk in a quiet voice when discussing

What you say

13. I have noticed blood in the toilet paper the last few days
14. I have been noticing it for a week now.
15. Could you please help me?

Pharmacy assistant might refer you to pharmacists or student-pharmacists

Whoever serves you might ask these following questions. **The reply for them are in maroon font**

- When did it start? **I started noticing it for about a week**
- What kind of blood, fresh or not? **Hmm...not able to say....not sure**
- Large amount of blood or not? **Less in the toilet paper**
- What colour was the blood- **normal..... red..... I guess**
- Does it continue after you finish going to the toilet? - **No**
- Have you had a change in bowel habit like constipated or having loose motion (Diarrhoea)- **No, everything's pretty normal. I'm pretty regular**
- How often do you go to the toilet? **Most days About 1-2 times /day**
- Do you have any pain or lump or itchiness or any kind of discomfort when passing motion? – **No**
- Are you using any other medication – **using ventolin (about once a month....whenever have to take)**
- Any significant weight loss over the past 4 weeks? – **No**
- Have you felt excessively tired?- **not particularly**
- Have you been diagnosed with (haemorrhoids it is also called piles) or polyps or any other bowel disease?- **No**
- Have you seen a GP regarding this issue?- **No**
- Are you taking any medication for this problem? **No**

We now have these choices:

18. medication suggested : buy the pdt (pharmacist might say things like this: Anal fissure or Haemorroid. This might be just to ease the bleeding)
19. Recommendation to consult a GP- oh, is it serious?! Can I wait since I have to go away for a week regd work or Oh, how soon do you think I should see a doc, can it wait till after I come back from a work trip next week?
20. Both - same reply as stated above
21. If pharmacists says "I can get the appt for you now so that you can go before your trip"- just say that you would do it yourself
22. No recommendations
23. Other recommendations

Appendix 4.8: Bowel Symptom Scenarios Checklist

CONSTIPATION CHECKLIST

Name of Pharmacy-

1. Did the Pharmacy assistant refer you to a pharmacist or any other person after hearing your symptoms Yes No
2. how long did you have to wait to see the pharmacists? Approx _____ mins
3. Did you feel that you would be overheard by other customers at any stage in the pharmacy Yes No
4. Did the staff offer to take you to a private space to speak? Yes No
5. Did the staff ask you the following questions
 - the duration of the symptom Yes No
 - about any medications that you were taking? Yes No
 - other medical condition that you may have? Yes No
 - how frequently you went to the toilet? Yes No
 - about any discomfort in back passage like soreness, lump, itchiness Yes No
 - if you had seen the GP regarding this particular issue? Yes No
 - if you had this problem often? Yes No
 - If you had any change in bowel habit Yes No
 - Did he ask if you thought it could be any food that you must have had Yes No
6. What other questions did he/she ask?

7. Was there any medication sold? Yes No

If yes, please specify

8. Was there any recommendation to consult a doctor? Yes No

9. Who was it who finally dealt with your issue?

Student

Pharmacy assistant

Pharmacist

Trainee

Other _____

10. How confident was the staff in making recommendations? (for e.g. I think you should see the doc....after a while or after u ask some questions like stated in the 'choices' box, he/she changing advice to just use this medication for 2-3 days and then see a doc if necessary...)

Very confident 1 2 3 4 5 Not confident

DIARRHOEA CHECKLIST

Name of Pharmacy-

1. Did the Pharmacy assistant refer you to a pharmacist or any other person after hearing your symptoms Yes No
2. how long did you have to wait to see the pharmacists? approx _____ mins
3. How many people did you speak to till you were finally offered an advice and/or product? _____
4. Did you feel that you would be overheard by other customers at any stage in the pharmacy Yes No
5. Did the staff ask you the following questions
 - the duration of the symptom Yes No
 - about any medications that you were taking? Yes No
 - other medical condition that you may have? Yes No
 - how frequently you went to the toilet? Yes No
 - about any discomfort in back passage like soreness, lump, itchiness Yes No
 - if you had seen the GP regarding this particular issue? Yes No
 - if you had this problem often? Yes No
 - If you had any change in bowel habit Yes No
 - If there was any weight loss Yes No
 - If you were feeling tired Yes No
 - Did he ask if you thought it could be any food that you must have had? Yes No
6. What other questions did he/she ask?

7. Was there any medication sold? Yes No

If yes, please specify

8. Was there any recommendation to consult a doctor? Yes No

9. Who was it who finally dealt with your issue?

Student

Pharmacy assistant

Pharmacist

Trainee

Other _____

10. How confident was the staff in making recommendations? (for eg, I think you shud see the doc....after a while or after u ask some questions like stated in the 'choices' box, he/she changing advice to just use this medication for 2-3 days and then see a doc if necessary...

Very confident 1 2 3 4 5 Not confident

ALTERNATING CONSTIPATION AND DIARRHOEA CHECKLIST

Name of Pharmacy-

1. Did the Pharmacy assistant refer you to a pharmacist or any other person after hearing your symptoms Yes No
2. how long did you have to wait to see the pharmacists? approx _____ mins
3. Did you feel that you would be overheard by other customers at any stage in the pharmacy Yes No
4. Did the staff offer to take you to a private space to speak? Yes No
5. Did the staff ask you the following questions
 - the duration of the symptom Yes No
 - about any medications that you were taking? Yes No
 - other medical condition that you may have? Yes No
 - how frequently you went to the toilet? Yes No
 - about any discomfort in back passage like soreness, lump, itchiness Yes No
 - if you had seen the GP regarding this particular issue? Yes No
 - if you had this problem often? Yes No
 - If you had any change in bowel habit Yes No
 - If there was any weight loss Yes No
 - If you were feeling tired Yes No
6. What other questions did he/she ask?

7. Was there any medication sold? Yes No

If yes, please specify

8. Was there any recommendation to consult a doctor? Yes No

9. Who was it who finally dealt with your issue?

Student

Pharmacy assistant

Pharmacist

Trainee

Other _____

10. How confident was the staff in making recommendations? (for eg, I think you shud see the doc....after a while or after u ask some questions like stated in the 'choices' box, he/she changing advice to just use this medication for 2-3 days and then see a doc if necessary...

Very confident 1 2 3 4 5 Not confident

RECTAL BLEEDING CHECKLIST

Name of Pharmacy-

1. Did the Pharmacy assistant refer you to a pharmacist or any other person after hearing your symptoms Yes No

2. how long did you have to wait to see the pharmacists? approx _____ mins

3. Did you feel that you would be overheard by other customers at any stage in the pharmacy Yes No

4. Did the staff offer to take you to a private space to speak? Yes No

5. Did the staff ask you the following questions
 - the duration of the symptom Yes No
 - about any medications that you were taking? Yes No
 - other medical condition that you may have? Yes No
 - how frequently you went to the toilet? Yes No
 - about any discomfort in back passage like soreness, lump, itchiness Yes No
 - if you had seen the GP regarding this particular issue? Yes No
 - if you had this problem often? Yes No
 - If you had any change in bowel habit Yes No
 - If there was any weight loss Yes No
 - If you were feeling tired Yes No

6. What other questions did he/she ask?

7. Was there any medication sold? Yes No

If yes, please specify

8. Was there any recommendation to consult a doctor? Yes No

9. Who was it who finally dealt with your issue?

Student

Pharmacy assistant

Pharmacist

Trainee

Other _____

10. How confident was the staff in making recommendations? (for eg, I think you shud see the doc....after a while or after u ask some questions like stated in the 'choices' box, he/she changing advice to just use this medication for 2-3 days and then see a doc if necessary...

Very confident 1 2 3 4 5 Not confident

Appendix 5.1: Scoring sheet - TPB

Questions measuring Perceived Behavioural Control of pharmacy staff for management of embarrassing bowel symptoms

1. For me to take a customer to a private space to speak about his/her embarrassing symptoms is
Extremely difficult 1 2 3 4 5 Extremely easy
2. For me to obtain the reason for the patient's visit to the pharmacy with embarrassing symptoms is generally
Extremely difficult 1 2 3 4 5 Extremely easy
3. I am confident in making recommendations to customers regarding their lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree
4. I am confident in recognising signs, symptoms and risk factors (or just- warning signs) of bowel disease that may require consultation with the general practitioner (GP)
Strongly disagree 1 2 3 4 5 Strongly agree
5. Providing cognitive services to customer with lower bowel symptoms would be a burden on pharmacy staff
Strongly disagree 1 2 3 4 5 Strongly agree

Recode Question 5 which has negative endpoint. Mean of item score gives overall PBC score.

Questions measuring subjective norms of pharmacy staff when providing cognitive service to clients presenting with bowel symptoms.

1. I would like to provide cognitive services to customers with lower bowel symptoms because customers expect it
Strongly disagree 1 2 3 4 5 Strongly agree
2. I would like to provide cognitive services to customers with lower bowel symptoms because other pharmacies are doing it
Strongly disagree 1 2 3 4 5 Strongly agree
3. I would like to provide cognitive services to customers with lower bowel symptoms because the pharmacy owner/manager expects me to do it

Strongly disagree 1 2 3 4 5 Strongly agree

Mean of item score gives an overall subjective norm score.

Questions measuring attitude of pharmacy staff when providing cognitive service to clients presenting with bowel symptoms.

1. Pharmacists providing recommendation to customers regarding their lower bowel symptoms is consistent with good professional practice
Strongly disagree 1 2 3 4 5 Strongly agree

2. Providing cognitive services to customers with lower bowel symptoms will allow pharmacists to provide an even higher level of care to patients
Strongly disagree 1 2 3 4 5 Strongly agree

3. Providing cognitive services to customers with lower bowel symptoms will enhance customer satisfaction even more
Strongly disagree 1 2 3 4 5 Strongly agree

4. Providing cognitive services to customer with lower bowel symptoms will make it even more likely that pharmacists will ensure that people with lower bowel symptoms get appropriate care
Strongly disagree 1 2 3 4 5 Strongly agree

Mean of item score gives an overall Attitude score.

Questions measuring intention of pharmacy staff when providing cognitive service to clients presenting with bowel symptoms.

1. In the future I will provide cognitive services to customers with lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree

2. In the future I will change my usual/current practice for customers with lower bowel symptoms

Mean of item score gives an overall Attitude score.

Appendix 5.2: TPB-Questionnaire

Please do not consult any member of the team when filling in this questionnaire

1. For me to take a customer to a private space to speak about his/her embarrassing symptoms is
Extremely difficult 1 2 3 4 5 Extremely easy

2. For me to obtain the reason for the patient's visit to the pharmacy with embarrassing symptoms is generally
Extremely difficult 1 2 3 4 5 Extremely easy

3. I am confident in making recommendations to customers regarding their lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree

4. I am confident in recognising signs, symptoms and risk factors (or just- warning signs) of bowel disease that may require consultation with the general practitioner (GP)
Strongly disagree 1 2 3 4 5 Strongly agree

Cognitive pharmaceutical services can be defined as professional services provided by pharmacists, who use their skills and knowledge to take an active role in patient health, through effective interaction with both patients and other health professionals.

5. Providing cognitive services (**Please refer to the definition given above**) to customer with lower bowel symptoms would be a burden on pharmacy staff
Strongly disagree 1 2 3 4 5 Strongly agree

6. I would like to provide cognitive services to customers with lower bowel symptoms because customers expect it
Strongly disagree 1 2 3 4 5 Strongly agree

7. I would like to provide cognitive services to customers with lower bowel symptoms because other pharmacies are doing it
Strongly disagree 1 2 3 4 5 Strongly agree

8. **If you are the owner/manager of this pharmacy please move to question 9**

I would like to provide cognitive services to customers with lower bowel symptoms because the pharmacy owner/manager expects me to do it
Strongly disagree 1 2 3 4 5 Strongly agree

9. Pharmacists providing recommendation to customers regarding their lower bowel symptoms is consistent with good professional practice
Strongly disagree 1 2 3 4 5 Strongly agree
10. Providing cognitive services to customers with lower bowel symptoms will allow pharmacists to provide an even higher level of care to patients
Strongly disagree 1 2 3 4 5 Strongly agree
11. Providing cognitive services to customers with lower bowel symptoms will enhance customer satisfaction even more
Strongly disagree 1 2 3 4 5 Strongly agree
12. Providing cognitive services to customer with lower bowel symptoms will make it even more likely that pharmacists will ensure that people with lower bowel symptoms get appropriate care
Strongly disagree 1 2 3 4 5 Strongly agree
13. In the future I will provide cognitive services to customers with lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree
14. In the future I will change my usual/current practice for customers with lower bowel symptoms
Strongly disagree 1 2 3 4 5 Strongly agree

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Licensed content date	July–August 2015
Licensed content volume number	11
Licensed content issue number	4
Number of pages	5
Start Page	579
End Page	583
Type of Use	reuse in a thesis/dissertation
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Format	both print and electronic
Are you the author of this Elsevier article?	Yes
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Expected completion date	Feb 2016
Estimated size (number of pages)	230

Appendix 6.2: Script for Usual Practice Video

Scenario: Query asked of Pharmacy Assistant and Pharmacist only.

About client: Frank James: 55 year-old male who has a cough that has been bothering you for about two months. You are frustrated and concerned.

Client sounds like: A typically worried customer asking for help at a Pharmacy (Chemist).

What the pharmacy assistant will say:

- Hello, how can I help you today?

What **client** says: I've got this problem ...

PAUSE. Screen fades out then up again

What **client** says:

- It's been hanging around for a while and nothing I've tried seems to work.
- Can you give me some advice
- I'm looking for something stronger.

What the pharmacy assistant will say:

1. Let me get the Pharmacist for you.

PAUSE. Screen fades out then up again.

What the Pharmacist says:

- Hello, my assistant tells me you have a problem which has been bothering you for sometime.
- What have you tried for it?

What **client** says:

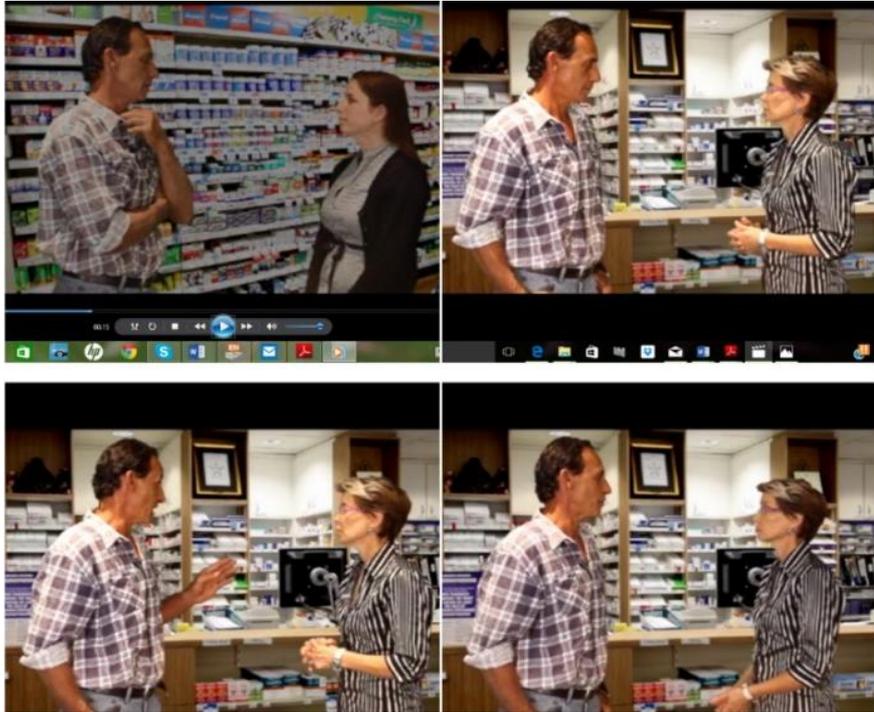
1. I've tried most of the things over there (you point to the medication in the aisle)...but nothing seems to work. Have you got something stronger?

PAUSE. Screen fades out then up again.

What **client** says to the pharmacist:

1. Thanks for that thorough advice.

Appendix 6.3: Screenshot of Usual Practice Video



Appendix 6.4: Script for Quality-Enhanced Video

Scenario: Query asked of Pharmacy Assistant/Pharmacist and to GP Reception

About client: Frank James: 55 year-old male who has a cough that has been bothering client for about two months. Client are frustrated and concerned.

Client sound like: A typically worried customer asking for help at a Pharmacy (Chemist).

What the pharmacy assistant will say:

- Hello, how can I help you today?

What **client** say: I've got this problem ...

PAUSE. Screen fades out then up again

What **client** says:

- It's been hanging around for a while and nothing I've tried seems to work.
- Can you give me some advice
- I'm looking for something stronger.

What the pharmacy assistant will says:

- Let me get the Pharmacist for you.

What the Pharmacist says:

- Hi, Mr James, my assistant says you have a problem let's move to a quieter place, so I can help you.

PAUSE: Screen fades out then up again

What the Pharmacist says:

- My assistant tells me this problem has been bothering you for some time.
- What have you tried for it?

What **client** says:

- I've tried most of the things over there (you point to the medication in the aisle)...but nothing seems to work. Have you got something stronger?

What the Pharmacist says:

- In order for me to help you, could you please answer a few questions in this questionnaire? It would take a couple of minutes.

PAUSE. Screen fades out then as it returns, the pharmacist gives a paper to the customer. and the customer leaves the pharmacy with a paper in his hand.

What **client** says:

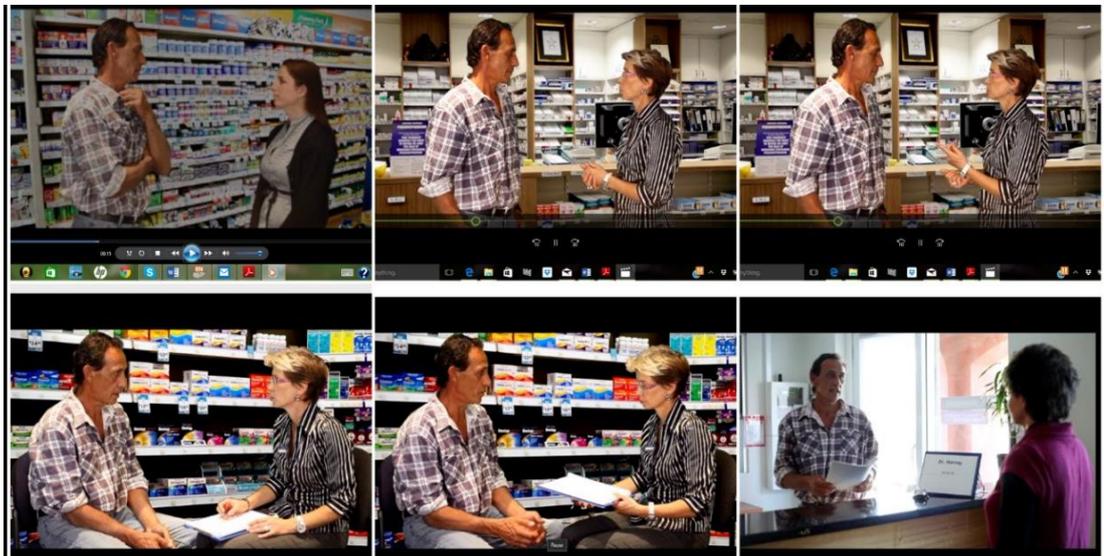
- Thank you for the thorough advice I will make an appointment to see the Doctor and take this report with me.

PAUSE: Screen fades out and starts again with customer giving the paper to the receptionist in the medical clinic

What **you** say:

- I've got an appointment to see Dr Harvey, and I have this report from the Pharmacist for Dr Harvey to see. (Handing over the piece of paper to the Receptionist).

Appendix 6.5: Screenshot of Quality-Enhanced Service Video



Appendix 6.6: Willingness to Pay–Information Sheet and Consent form

Participant Information Sheet

This study seeks to evaluate the value of pharmacist’s advice and how much people are willing to pay for service where pharmacy staffs use a tool which would guide them to identify symptomatic patients who should be advised to consult a medical practitioner.

Who can participate?

You are eligible to participate if you are over 18 years of age and able to provide informed consent.

What will I be asked to do?

You will be asked to provide some information about yourself including your contact details. This information will be used ONLY for the purpose of this study. You will be asked to watch a video clipping You will be asked to answer a brief questionnaire. This will take you approximately five (5) minutes to complete.

How will my privacy be protected?

We believe it is extremely important to keep your personal information confidential. The information provided will be used for the purpose of this project ONLY and results will be reported in groups.

Can I decline to take part or withdraw if I change my mind?

Participation in this study is purely voluntary. You may decline to take part or withdraw from this study at any time.

Are there any risk or benefits?

There are no risks involved in this study. This study will help in evaluation the monetary value you would ascribe for a pharmacists’ advice.

Study Team Contact Details

If you would like a copy of this questionnaire for your own information or would like further information on the study, please contact:

Deepa Sriram

Curtin Health Innovation Research Institute (CHIRI)

Curtin University

GPO Box U1987, PERTH WA 6845

Phone: 9266 9581, Fax: 9266 9801

Email: d.sriram@curtin.edu.au

This study has been approved by the Curtin University Human Research Ethics Committee - approval number - HR19/2013

Consent Form

You have been asked to volunteer for this study that seeks to evaluate the value of pharmacist's advice and how much people are willing to pay for service where pharmacy staffs use a tool which would guide them to identify symptomatic patients who should be advised to consult a medical practitioner.

Please note: It is important we are able to contact you by email. So please ensure these details are both complete and correct

By completing the consent form below you certify that you:

- You are over the age of 18.
- Have read the "Participant Information Sheet" and have had any questions answered to your satisfaction by the researcher.
- Have been informed of the benefits and risks associated with this research study.
- Understand that you are free to withdraw from the study at any time, for any reason, and without prejudice.
- Agree to take part in this research study and for the data obtained to be published, provided your name or other identifying information is not used.

-

If you are unclear about anything you have read in the Participant Information Sheet or this Consent Form, please speak to the researcher before signing this Consent Form.

- Yes, I agree with the above points and consent to participate in this study

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR - 19/2013). The committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, the verification of approval can be obtained either by writing to the Curtin University Human Ethics Committee, c/- office of research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning (08) 9266 2784 or by emailing hrec@curtin.edu.au

Appendix 6.7: Willingness to Pay Questionnaire

About yourself

1. What is your age in years on your last birthday? _____

2. What is your gender
 - Female
 - Male

3. What is your present marital status?
 - Never Married, single
 - Widowed
 - Married or domestic partnership
 - Separated
 - Divorced

4. Highest level of Education...
 - Completed primary school
 - Less than Year 10
 - Year 10 or equivalent
 - Year 12 or equivalent
 - Trade certificate/TAFE
 - Diploma or equivalent
 - Tertiary education

5. What is your current employment status?
 - Unemployed/homemaker
 - Employed full time
 - Employed part time
 - Student
 - Pensioner or on social security
 - Other (Please specify)

6. What is your annual household income?
 - Less than \$40,000
 - \$41,000-\$80,000
 - \$81,000 - \$120,000
 - \$120,000 -\$160,000
 - More than \$1,60,000
 - I prefer not to answer this question

7. What is the post code of your place of residence

8. In which state do you reside?

About the videos/consultation

1. Did you notice a difference in the way the man was dealt with in Video 1 compared to

Video 2?

Yes

No

Not sure

2. Which consultation do you think was longer?

Video 1

Video 2

Not sure

3. In which video was the man offered more privacy?

Video 1

Video 2

Not sure

4. Assuming that the man had the same problem in both the videos, which consultation do you think was more helpful in providing advice?

Video 1

Video 2

Neither

Not sure

5. If you were the man in the video, which type of service/consultation would you prefer?

Video 1

Video 2

Neither

Both

6. If you were the man in **Video 1**, would you be willing to pay for the service you received in the pharmacy?

Yes

No

Not sure

If yes, how much would you be willing to pay? \$ _____

7. If you were the man in **Video 2**, would you be willing to pay for the service you received in the pharmacy?

Yes

No

Not sure

If yes, how much would you be willing to pay? \$ _____

Appendix 7.1: JLT Letter-pad

Jodi Lee Test for Bowel Symptoms

Name of customer _____

Date _____

Symptom	Present	Present for more than 1 week*
Diarrhoea	<input type="checkbox"/>	<input type="checkbox"/>
Constipation	<input type="checkbox"/>	<input type="checkbox"/>
Alternating diarrhoea and constipation	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding from back passage	<input type="checkbox"/>	<input type="checkbox"/>
Discomfort at your back passage (soreness, itch, lump)	<input type="checkbox"/>	<input type="checkbox"/>
		*Refer to pharmacist if any box above ticked

Have you had any bowel problems in the past 12 months?

Haemorrhoids (piles)

Colitis

Polyps

About the presenting symptom	Yes	No
Have you talked to a doctor about this symptom(s)?	<input type="checkbox"/>	<input type="checkbox"/>
Have you lost weight unexpectedly in the past 4 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
Symptom associated with pain?	<input type="checkbox"/>	<input type="checkbox"/>
How much pain do you have? (circle the most relevant number in this scale)		
0 1 2 3 4 5 6 7 8 9 10 None Mild Moderate Severe worst imaginable		

Cancer

Other (please specify) _____

List any medication that you are currently taking (including medicines bought without a prescription, and natural products):

Recommendation

See your GP

Other _____