

Limitations and potential facilitators and benefits of
managing chronic conditions in community
pharmacy settings

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Summary

Pressure on GPs is increasing due to an aging population with an increased burden of chronic diseases. Community pharmacists (CPs) can potentially help provide healthcare for people with chronic conditions, thereby reducing the burden on GPs. Asthma was chosen as an example of a chronic condition to assess how well it is managed in the current type of practice. A mixed-method approach was used to investigate how well asthma patients were managed and to identify the opportunity for involving community pharmacies more generally in Managing Chronic Conditions (MCCs). The research shows that most asthma patients were not well managed (60.9%), did not adequately adhere to their medicines (76.8%), and were not using their inhalers properly (67%). To understand the potential involvement of CPs in MCCs, two qualitative studies and one postal questionnaire project were conducted. Semi-structured interviews were undertaken with CPs and stakeholders of community pharmacy services in Wales. Sixteen individual interviews were conducted: eleven face-to-face and five telephone interviews. Using inductive thematic analysis, strengths of community pharmacy settings, exploiting opportunities to provide a community-based chronic condition management service, barriers, and facilitators to MCCs in community pharmacies were identified. The themes were not only related to community pharmacists/pharmacies but also involve other stakeholders (e.g. patients and healthcare providers) and healthcare system (e.g. policy and regulation). To generalize the qualitative findings to a larger population, a postal questionnaire was designed based on the identified themes, and then disseminated to all community pharmacies in Wales (n=715, response rate=32.8%). The questionnaire survey showed a relatively high level of agreement among respondents to the identified themes. Of the 19 questions, 16 had a percentage agreement of almost 60% or more. Of those, 11 questions had a percentage agreement of 75% or more. In conclusion, although the potential benefit of managing chronic conditions in community pharmacies was recognised, there were several limitations that need to be addressed prior to moving forward.

List of Abbreviations

ACT	Asthma Control Test
ACTs	Accredited Checking Technician
AIM	Aerosol Inhalation Monitor
AOR	Adjusted Odds Ratio
BGMA	British Guideline on the Management of Asthma
BMI	Body Mass Index
BOS	Bristol Online Survey
BP	Blood Pressure
BTS	British Thoracic Society
CCM	Chronic Condition Management
CDC	Centre for Disease Control and Prevention
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
COVID19	Corona Virus Disease 2019
CP	Community Pharmacist
CPW	Community Pharmacy Wales
DMR	Discharge Medicines Review
DPI	Dry Powder Inhaler
ED	Erectile Dysfunction
EPP	Expert Patient Programme
FeNO	Fractional Exhaled Nitric Oxide
FEV1	Forced Expiratory Volume-one Second
FVC	Forced Vital Capacity
GCSE	General Certificate of Secondary Education
GMS	General Medical Services
GP	General Practitioner
GPhC	General Pharmaceutical Council
GPwSI	GP with Special Interest
HB	Health Board
HEIW	Health Education and Improvement Wales

HF	Heart Failure
HTN	Hypertension
ICS	Inhaled Corticosteroids
IgE	Immunoglobulin E
INR	International Normalized Ratio
IP	Independent Prescriber
IPC	Independent Prescribing Course
LABA	Long Acting Beta Agonists
LAMA	Long Acting Muscarinic Antagonist
LHB	Local Health Board
LTCs	Long Term Conditions
LTRA	Leukotriene Receptor Antagonists.
MART	Maintenance and Reliever Therapy
MCCs	Managing Chronic Conditions
MLR	Multinomial Logistic Regression
MRC	Medical Research Council
MUR	Medicines Use Reviews
NCDs	Non-Communicable Diseases
NHS	National Health Service
NVivo	Qualitative Data Analysis Computer Software Package
OR	Odds Ratio
Pharm.D	Doctor of Pharmacy Degree
PhD	Doctor of Philosophy Degree
PDE	Phosphodiesterase
PDIF	Participant Demographic Information Form
pMDI	Pressurized Metered Dose Inhaler
QUAL	Qualitative Approach
QUAN	Quantitative Approach
RPSW	Royal Pharmaceutical Society Wales
SLAs	Service Level Agreement
SPSS	Statistical Package for Social Sciences
TAI	Test of Adherence to Inhalers

UK	United Kingdom
US	United States
UTI	Urinary Tract Infection
WCPPE	Wales Centre for Pharmacy Professional Education
WHO	World Health Organisation
WPC	Welsh Pharmaceutical Committee
YRS	Years

Table of Contents

Acknowledgements	ii
Summary	iii
List of Abbreviations	iv
Table of Contents	vii
List of Tables	xix
List of Figures	xx
Chapter 1 – General introduction	1
1.1 Definition of chronic conditions	2
1.2 Burden of chronic conditions.....	2
1.3 Economic burden of chronic conditions	3
1.4 Risk factors of chronic conditions	4
1.5 Management and prevention of chronic conditions.....	5
1.6 The Welsh model of management of chronic conditions	7
1.6.1 Level 1: Primary prevention and health promotion	8
1.6.2 Level 2: Population management: ‘Practice-based’ CCM programme.....	8
1.6.3 Level 3: High risk management: ‘Network-based’ CCM services	8
1.6.4 Level 4: Case managed services	8
1.7 Structure of the NHS in Wales	9
1.8 Primary care clusters	10
1.9 Evolution in pharmacists’ role in managing chronic conditions.....	11
1.10 Asthma as an example of a chronic condition.....	13
1.10.1 History of asthma	13
1.10.2 Asthma – definition and symptoms	14
1.10.3 Asthma epidemiology	14

1.10.3.1 Asthma incidence and prevalence rates	14
1.10.3.2 Asthma mortality	16
1.10.3.3 Asthma morbidity and economic burden	16
1.10.4 Asthma diagnosis	17
1.10.5 Treatment of asthma	20
1.10.5.1 Milestones in the pharmacological treatment of asthma	20
1.10.5.1.1 Anti-Cholinergic treatment	20
1.10.5.1.2 Non- Anti-Cholinergic treatment	21
1.10.5.1.2.1 Methyl Xanthines	21
1.10.5.1.3 Direct adrenergic bronchodilators	21
1.10.5.1.4 Corticosteroid therapy	22
1.10.6 Asthma management	22
1.10.6.1 Non-pharmacological asthma management	22
1.10.6.2 Pharmacological management and treatment strategies of asthma	23
1.10.7 Impact of adherence on asthma control	26
1.10.8 Asthma dilemma	29
1.11 Research rationale	29
1.12 Research aims and objectives	31
Chapter 2 – General methodology	33
2.1 Introduction	34
2.2 The philosophy of science and theoretical framework	34
2.2.1 Paradigms	34
2.2.1.1 Postpositivist paradigm	35
2.2.1.2 Interpretivist/constructivist paradigm	35
2.2.1.3 Transformative paradigm	35

2.2.1.4 Pragmatist paradigm	35
2.2.2 The UK Medical Research Council’s framework	36
2.3 Mixed methods approach	37
2.3.1 Advantages of the mixed methods approach	37
2.3.2 Mixed methods design	38
2.3.3 Points of integration	39
2.4 Qualitative research.....	39
2.4.1 Qualitative interviewing.....	40
2.4.1.1 Focus groups, group interviews and individual interviews.....	40
2.4.1.2 Face-to-face, telephone, and internet video-based interviews	41
2.5 Quantitative research	42
2.5.1 Questionnaires	42
2.5.2 Cross-sectional studies.....	43
2.6 Differences between quantitative and qualitative research.....	44
2.7 A case of a mixed methods study in community pharmacy setting.....	45
2.8 Reflexivity in qualitative research.....	48
2.8.1 The researcher’s personal experience	49
2.9 Summary	51
Chapter 3 – Assessing inhaler techniques of asthma patients using Aerosol Inhalation Monitors (AIM): A cross-sectional study	52
3.1 INTRODUCTION.....	53
3.1.1 Aims and objectives	56
3.2 METHODS.....	57
3.2.1 Study design	57
3.2.2 Ethical approval.....	57
3.2.3 Sampling and recruitment	57

3.2.4 Data collection	57
3.2.5 Data handling	58
3.2.6 Data analysis	59
3.3 RESULTS	61
3.3.1 Sample characteristics	61
3.3.2 Evaluation of inhaler technique	62
3.3.3 The impact of demographic variables and smoking status on inhaler technique	62
3.4 DISCUSSION.....	65
3.4.1 Study strengths and limitations	68
3.5 CONCLUSION.....	70
Chapter 4 - Is asthma well managed? The impact of inhaler technique and adherence to inhaler on asthma control	72
4.1 INTRODUCTION.....	73
4.1.1 Asthma Control Test (ACT).....	75
4.1.2 Test of Adherence to Inhalers (TAI)	75
4.1.3 Aerosol Inhalation Monitor (AIM).....	76
4.1.4 The rationale, aim, and objectives of the study	76
4.2 METHODS.....	76
4.2.1 Study design	77
4.2.2 Ethical approval.....	77
4.2.3 Sampling and recruitment	77
4.2.4 Data collection	77
4.2.5 Data handling	78
4.2.6 Data analysis	78
4.3 RESULTS	80

4.3.1 Characteristics of the participants	80
4.3.2 Impact of demographic characteristics and smoking status on asthma control and adherence	81
4.3.3 Asthma control, adherence to inhalers and inhaler technique	81
4.4 DISCUSSION.....	83
4.4.1 Strengths and limitations	86
4.5 CONCLUSION.....	88
Chapter 5 - Community pharmacists' views about managing chronic conditions in their pharmacies.....	89
5.1 INTRODUCTION.....	90
5.1.1 The aim of the study	93
5.2 METHODS.....	94
5.2.1 Ethical Approval	94
5.2.2 Sampling.....	94
5.2.3 Recruitment	94
5.2.4 Selection.....	95
5.2.5 Topic guide design.....	95
5.2.6 Reviewing the topic guide.....	96
5.2.7 Study setting	96
5.2.8 Data collection	97
5.2.9 Incentive.....	98
5.2.10 Data analysis	99
5.3 RESULTS	100
5.3.1 Participants	100
5.3.2 Themes and subthemes	101
5.3.2.1 Regulations and policy	102

5.3.2.1.1 Health care professional boundaries and accountabilities.....	102
5.3.2.1.2 Heterogeneity and consistency in community pharmacy	104
5.3.2.1.3 Identifying eligible patients for services and referring.....	106
5.3.2.1.4 Reallocation of responsibilities in community pharmacy.....	107
5.3.2.1.5 Accessing and sharing patients' medical information	108
5.3.2.1.6 Funding and remuneration	110
5.3.2.1.7 Training and education	113
5.3.2.2 Awareness raising and guidance.....	114
5.3.2.3 Accessibility of community pharmacy	116
5.3.2.4 Facilities and equipment in community pharmacy.....	116
5.3.2.5 Workload and staffing in community pharmacy	118
5.3.2.6 Healthcare professionals' collaboration and relationship with community pharmacists.....	121
5.3.2.7 Patients' interactions and relationships with community pharmacists	123
5.3.2.8 Confidence and willingness of community pharmacists to manage chronic conditions	125
5.4 DISCUSSION.....	127
5.4.1 Themes at healthcare system level.....	128
5.4.2 Themes at community pharmacy level.....	134
5.4.3 Themes at healthcare provider and patient level.....	135
5.4.4. Strengths and limitations	137
5.5 CONCLUSION.....	138
Chapter 6 - Community pharmacists' views about managing chronic conditions in their pharmacies: A cross-sectional quantitative study	140
6.1 INTRODUCTION.....	141
6.1.1 The aim of the study	141

6.2 METHODS.....	141
6.2.1 Study design	141
6.2.2 Questionnaire design	142
6.2.3 Piloting questionnaire	144
6.2.4 Reliability and validity	144
6.2.5 Ethical Approval	146
6.2.6 Sampling and selection	146
6.2.7 Recruitment and dissemination.....	147
6.2.8 Data collection	148
6.2.9 Data handling	148
6.2.10 Data analysis	149
6.2.10.1 Quantitative analysis.....	150
6.2.10.2 Qualitative analysis	150
6.3 RESULTS	151
6.3.1 Response rate.....	151
6.3.2 Characteristics of the participants	151
6.3.3 Distribution of participants across the Local Health Boards (LHBs)	152
6.3.4 Distribution of participants across community pharmacies.....	153
6.3.5 Chronic health condition management in community pharmacy	154
6.3.6 Community-based chronic condition management (barriers and facilitators)	155
6.3.7 Qualitative comments provided by participants	158
6.3.7.1 Regulations and policy	158
6.3.7.1.1 Health care professional boundaries and accountabilities.....	158
6.3.7.1.2 Heterogeneity and consistency in community pharmacy	158
6.3.7.1.3 Reallocation of responsibilities in community pharmacy.....	159

6.3.7.1.4 Accessing and sharing patients' medical information	159
6.3.7.1.5 Funding and remuneration	160
6.3.7.1.6 Training and education	160
6.3.7.2 Awareness raising and guidance.....	161
6.3.7.3 Accessibility in community pharmacy.....	162
6.3.7.4 Facilities and equipment in community pharmacy.....	162
6.3.7.5 Workload and staffing in community pharmacy	162
6.3.7.6 Healthcare professionals' collaboration and relationship with community pharmacists.....	163
6.3.7.7 Patients' interactions and relationships with community pharmacists	164
6.3.7.8 Confidence and willingness of community pharmacists to manage chronic conditions	164
6.4 DISCUSSION.....	165
6.4.1 Strengths and limitations	169
6.5 CONCLUSION.....	173
Chapter 7 - Stakeholders' views about the management of chronic conditions in community pharmacies.....	174
7.1 INTRODUCTION.....	175
7.1.1 The aim of the study	176
7.2 METHODS.....	176
7.2.1 Ethical Approval	176
7.2.2 Sampling.....	176
7.2.3 Recruitment	177
7.2.4 Selection.....	177
7.2.5 Topic guide design.....	178
7.2.6 Reviewing the topic guide.....	178

7.2.7 Study setting	178
7.2.8 Data collection	179
7.2.9 Data analysis	180
7.3 RESULTS	181
7.3.1 Participants	181
7.3.2 Themes and subthemes	181
7.3.2.1 Strengths of community pharmacy settings	183
7.3.2.1.1 Accessibility and convenience	183
7.3.2.1.2 Consistency of healthcare providers and engagement with patients	185
7.3.2.1.3 Expertise in medicines and reducing expenditures	186
7.3.2.1.4 Welsh Government support for community pharmacy	188
7.3.2.2 Exploiting opportunities to provide a community-based chronic condition management service.....	189
7.3.2.2.1 Unmet public needs and shortage of GPs.....	190
7.3.2.2.2 Getting the most out of community pharmacy’s workforce and technology.....	191
7.3.2.3 Limitations to managing chronic conditions in community pharmacy settings	193
7.3.2.3.1 Inconsistency and bureaucracy in commissioning pharmacy services	193
7.3.2.3.2 Availability of funding and resources.....	196
7.3.2.3.3 Disagreement and uncertainty about contribution in the community pharmacy sector.....	199
7.3.2.3.4 Continuity of patient medical information and fragmented care .	202
7.3.2.3.5 Capacity and facility in community pharmacy	203
7.3.2.3.6 Pharmacy education and clinical expertise	206

7.3.2.3.7 Patient acceptability	207
7.4 DISCUSSION.....	208
7.4.1 Strengths and limitations	218
7.5 CONCLUSION.....	219
Chapter 8 – General discussion	220
8.1 Introduction	221
8.2 Implications for the design and implementation of a community-based chronic condition management service	221
8.2.1 Potential benefits of managing chronic conditions in community pharmacy settings	224
8.2.2 Limitations and potential facilitators of managing chronic conditions in community pharmacy settings.....	225
8.3 Recommendation for the design and implementation of a community-based chronic condition management service	231
8.4 Strengths and limitations.....	232
8.5 Future research.....	234
8.6 Conclusion.....	235
8.7 Personal reflections	235
8.7.1 Personal reflections on managing chronic conditions in community pharmacy.....	235
8.7.2 Personal reflections on the engagement of participants in research	236
8.7.3 Personal reflections on conducting and dealing with qualitative project/data	237
8.7.4 Personal reflections on disseminating postal questionnaires	238
8.8 Summary of key findings from the thesis	239
Bibliography	240
Appendices	263

Appendix 3.1 - Research poster	264
Appendix 3.2 - Ethical approval	265
Appendix 3.3 - Participant information sheet	266
Appendix 3.4 - Consent form	271
Appendix 3.5 - Data collection tool (standardised form)	272
Appendix 4.1 - Ethical approval	273
Appendix 4.2 - Participant information sheet	274
Appendix 4.3 - Consent form	281
Appendix 4.4 - Data collection tool (standardised form)	282
Appendix 4.5 - ACT questionnaire	283
Appendix 4.6 - TAI questionnaire	284
Appendix 5.1 - Research poster	285
Appendix 5.2 - Ethical approval	286
Appendix 5.3 - Invitation emails sent to gatekeepers and community pharmacists	287
Appendix 5.4 - Reminder emails sent to gatekeepers and community pharmacists	289
Appendix 5.5 - Participant information sheet	290
Appendix 5.6 - Participant demographic information form	296
Appendix 5.7 - Consent form	297
Appendix 5.8 - Community pharmacists topic guide.....	298
Appendix 5.9 – Qualitative data analysis.....	301
Appendix 6.1 - Ethical approval	302
Appendix 6.2 - Ethical approval	303
Appendix 6.3 - Community pharmacists questionnaire cover letter	304
Appendix 6.4 - Participant information sheet	306

Appendix 6.5 - Community pharmacists questionnaire	308
Appendix 6.6 - Community pharmacists reminder letter.....	313
Appendix 7.1 - Research poster	314
Appendix 7.2 - Ethical approval	315
Appendix 7.3 - Invitation email sent to stakeholders of pharmacy services.....	316
Appendix 7.4 - Reminder email sent to stakeholders of pharmacy services	317
Appendix 7.5 - Participant information sheet	318
Appendix 7.6 - Stakeholders of pharmacy services topic guide.....	323
Appendix 7.7 - Consent form	325

List of Tables

Table 1.1: A list of diagnostic tests that are used to diagnose and monitor people with asthma.....	Pg. 18
Table 3.1: Participant demographic information and smoking status (n=212)	Pg. 61
Table 3.2: Inhaler device * AIM result cross-tabulation (295 AIM assessments)	Pg. 62
Table 3.3: Relationship between AIM pMDI simulators and demographic variables (n=174)	Pg. 63
Table 3.4: Relationship between AIM pMDI+spacer simulators and demographic variables (n=49).....	Pg. 64
Table 3.5: Relationship between AIM DPI simulators and demographic variables (n=72).....	Pg. 64
Table 3.6: Adjusted and unadjusted odds ratios table and corresponding confidence intervals.....	Pg. 65
Table 4.1: Demographic and smoking status information (n=69).....	Pg. 80
Table 4.2: The impact of demographic information and smoking status on asthma control and adherence to inhalers (n=69).....	Pg. 81
Table 4.3: Cross-tabulation table of asthma control, adherence, and inhaler technique (n=69).....	Pg. 82
Table 5.1: Emergent themes and subthemes	Pg. 102
Table 6.1: The distribution of participants across LHBs and frequency/percentage of participants from the total number of community pharmacies in each LHB (n=229)	Pg. 153
Table 6.2: The percentage of agreement and disagreement of participants on the questionnaire's items (n=229)	Pg. 157
Table 7.1: Emergent themes and subthemes.....	Pg. 182

List of Figures

Figure 1.1: The Welsh Chronic Conditions Model. Adapted from Welsh Government (2007): “Designed to Improve Health and the Management of Chronic Conditions in Wales: An integrated model and framework”	Pg. 9
Figure 1.2: Stepwise approach to asthma management in adults. Retrieved from (BGMA). ICS=inhaled corticosteroids; LABA=long-acting beta agonists; MART=maintenance and reliever therapy; LTRA=leukotriene receptor antagonists.....	Pg. 24
Figure 2.1: A mixed methods approach.....	Pg. 47
Figure 3.1: Components of AIM device. Retrieved from Vitalograph Website.....	Pg. 55
Figure 3.2: Components of AIM device. Retrieved from Vitalograph Website.....	Pg. 55
Figure 3.3: Result lights. Retrieved from Vitalograph Website.....	Pg. 56
Figure 3.4: Summary of where drug deposits in patient’s respiratory system. Retrieved from Vitalograph Website.....	Pg. 56
Figure 6.1: The position of participants in community pharmacy (n=229)...	Pg. 152
Figure 6.2: The types of pharmacy services provided by participants (n=229).....	Pg. 152
Figure 6.3: The distribution of participants across different locations of community pharmacy (n=229)	Pg. 154
Figure 6.4: The frequency of chronic conditions that participants felt confident to manage in pharmacy (n=229)	Pg. 155

Chapter 1 – General introduction

1.1 Definition of chronic conditions

There is no specific definition of chronic conditions in the academic literature (Bernell and Howard 2016). The terminology of chronic disease is interchangeably used with other terminologies, such as non-communicable diseases (NCDs), long term conditions (LTCs), and lifestyle-related diseases. Chronic disease has been described in the literature and reliable information sources, such as the National Health Service (NHS) and the Centre for Disease Control and Prevention (CDC), as a condition that persists for more than one year, impacts people's daily life, requires the provision of medical care, is incurable, and finally can be controlled with pharmacological and/or non-pharmacological therapies (Bernell and Howard 2016; Centre for Disease Control and Prevention 2019; NHS 2019b). The World Health Organization (WHO) (2019a) has defined chronic diseases as conditions that last for a long period of time and are attributed to a combination of several factors: genetic, physiological, environmental, and behavioural. There are many types of chronic disease around the world. The leading cause of death from chronic conditions worldwide is cardiovascular disease, followed by chronic respiratory diseases, cancer, and diabetes (Riley and Cowan 2014). These common diseases are mainly attributed to common risk factors such as smoking, high alcohol consumption, unhealthy diet, and an inactive lifestyle. The presence of a risk factor or several risk factors together may lead to the development of a chronic condition (Riley and Cowan 2014). For example, a family history of diabetes, aging, inactive lifestyle, obesity, abnormal cholesterol levels, or hypertension can increase the risk of type 2 diabetes (American Heart Association 2015).

1.2 Burden of chronic conditions

Chronic diseases are considered to be the leading cause of mortality and morbidity worldwide (Yach et al. 2004; Suhrcke et al. 2006). In 2002, around 29 million deaths were attributed to the most frequent chronic diseases: cardiovascular disease, cancer, chronic respiratory disease, and diabetes (Yach et al. 2004). In 2005, the WHO projected that the number of deaths from chronic conditions would be double the number of those who died due to infectious diseases (World Health Organization 2005). The alarming thing about chronic diseases is the increase in their prevalence. Globally, it is estimated

that one in three adults live with more than one chronic condition (Hajat and Stein 2018). It has been projected that the prevalence of chronic diseases will continue to increase in the future. By 2020, studies have estimated that 75% of deaths worldwide will be attributed to chronic diseases (World Health Organization 2019b).

In the United Kingdom, dealing with chronic diseases is a huge challenge for the National Health Services (NHS). It has been estimated that around 17.5 million adults might live with a chronic disease (Department of Health 2019). Seventy-five percent of people over 75 years have a long-term condition (Department of Health 2019). It has also been projected that the incidence of chronic diseases in those over 65 years will continue to increase (Department of Health 2019), and will more than double by the year 2030. Forty-five percent of patients with non-communicable diseases have more than one chronic disease (Department of Health 2019). The estimated number of total deaths due to chronic diseases is 557,000, which represents around 89% of all deaths (Riley and Cowan 2014). In Wales, between 2004 and 2015, the percentage of people living with at least one chronic disease increased by 30%. On the other hand, the percentage of those who live with multiple chronic diseases increased by 56% during the same period of time (The Health Foundation 2016). It has been estimated that there will be a notable increase in people with diabetes (from 186,365 to 220,376), heart diseases (from 253,406 to 321,986), and stroke (from 69,656 to 90,214) between 2017 and 2035 (Graham et al. 2018).

1.3 Economic burden of chronic conditions

The health care services provided for people with chronic conditions have an economic burden on societies. This includes patients, their families, and health systems (World Health Organization 2005). Chronic diseases can affect a country's economy both directly and indirectly (Department of Health 2019), starting from reducing or losing labour productivity, and ending with huge costs to health care services, such as the cost of treatment and hospitalization. This is a real challenge for governments, especially in respect of health and social care resources (Department of Health 2019). Since chronic diseases include conditions that are incurable, they involve visiting physicians more

frequently. People with chronic conditions account for around 50% of consultations provided by GPs (Pharmaceutical Services Negotiating Committee 2020a). They are also more likely to be hospitalized and have a longer length of stay in comparison to those who are free from chronic diseases. More than 60% of hospital bed days are attributed to patients with chronic conditions or complications related to a chronic illness (Department of Health 2019). More than 66% of people admitted to emergency rooms are admitted because of chronic diseases or have a chronic condition (Department of Health 2019).

Wales has the highest rates of chronic conditions among the UK's four nations (Welsh Government 2007). Within the adult population, 800,000 people are reported to have at least one chronic condition (National Public Health Service for Wales and National Assembly for Wales 2006). Two-thirds of Welsh people aged 65 years and older have at least one chronic disease. The other third reported that they had two or more chronic conditions (National Public Health Service for Wales and National Assembly for Wales 2006). Knowing that chronic diseases are associated with aging, and that the number of people aged 65 years and older is expected to increase by 32% by 2026, this would add an additional burden on the national economy (Wales Audit Office 2014). People with chronic conditions account for 58% of hospitalization expenditure (Watt and Roberts 2016).

1.4 Risk factors of chronic conditions

Although unmodifiable risk factors such as aging and genetic factors play an important role in developing chronic conditions, there are several other risk factors for chronic conditions (Guralnik 1996; Klein et al. 2004; Department of Health 2012). The most common modifiable risk factors that contribute to chronic conditions are tobacco smoking, harmful use of alcohol, physical inactivity, unhealthy weight (defined as a body mass index (BMI) equal to or greater than 25), and unhealthy diet (Guralnik 1996; Fine et al. 2004). In the United States, the first four risk factors (i.e. tobacco smoking, harmful use of alcohol, physical inactivity, and unhealthy weight) accounted for 36.8% of deaths that occurred in 2000 (Mokdad et al. 2004).

Chronic conditions are more common in the elderly in comparison to other age groups (Guralnik 1996; National Public Health Service for Wales and National Assembly for Wales 2006). This might be attributed to two main factors. First, chronic diseases take a long time to develop. Unlike acute conditions, chronic diseases might take many years to develop. Second, human organs and systems function less well as people get older. All body systems and parts will undergo certain physiological changes with aging. The process of deterioration with age would end by developing chronic diseases (Boss and Seegmiller 1981), not to mention poor behaviour habits/lifestyle factors that would accelerate the development of chronic conditions.

Socioeconomic status could also affect people's wellbeing across different age groups and lead to the development of chronic conditions (Marmot 2005; Haan et al. 1989). It was reported that the mortality and morbidity rates of populations varied based on socioeconomic status (Marmot et al. 1984; Haan et al. 1989; Marmot 2005). There are several social determinants of health (Marmot and Wilkinson 2003). These include, but are not limited to, support in early life, poverty, stress in the workplace, unemployment, transportation, friendship, and social support (Marmot and Wilkinson 2003). The association between socioeconomic status and the development of chronic diseases has been widely addressed. An association has been found between low socioeconomic status and the development of several chronic diseases, such as hypertension and diabetes (Medalie et al. 1978; Gottdiener et al. 2000; Department of Health 2012). This might be because people who are at the bottom of the socioeconomic hierarchy are more exposed to physical, psychological, social, and economic challenges compared to those who are at the top of the hierarchal structure.

1.5 Management and prevention of chronic conditions

Chronic diseases cannot be cured but could be prevented (Jamison et al. 2006). Therefore, the effective approach to deal with chronic conditions is to prevent them from developing. Knowing that there are shared risk factors among the most common chronic conditions would make this issue easier to tackle. The risk factors most

commonly associated with chronic conditions are excessive consumption of alcohol, cigarette smoking, sedentary lifestyle, and being overweight (Fine et al. 2004). It has been estimated that premature mortality (defined as dying because of a chronic condition at any age from 30 to 70 years without competing causes) from the main chronic conditions – cardiovascular diseases, diabetes, cancer, and chronic respiratory diseases – would be reduced by around 20% if people were to follow a healthier lifestyle (Kontis et al. 2014). Furthermore, better control of chronic conditions' risk factors would delay or prevent around 58 million deaths in people between the ages of 30 years and 70 years globally for the period between 2010 and 2025 (Kontis et al. 2014). The prevention of chronic diseases mainly focuses on introducing preventive interventions that are designed to target risk factors. This requires cooperation between the public and private sectors in order to raise individuals' awareness about a healthy lifestyle. Cecchini and colleagues (2010) argued that an active lifestyle, eating a healthy diet, health promotion, establishing a policy for food advertised to children, and food pricing intervention (increasing the prices of unhealthy foods and reducing the prices of healthy foods) could lead to substantial improvements in people's wellbeing.

Management of chronic diseases is varied, based on the nature of each chronic disease. However, patients with chronic conditions may improve their disease outcomes by following a healthier lifestyle (Cecchini et al. 2010). Given the huge burden on the health services from patients with chronic diseases, people are now more involved in managing their own illnesses. Patients have evolved from passive recipients to active participants in managing their chronic conditions (i.e. self-management) (Barlow et al. 2002). There is no single definition of self-management, but the NHS (2019a) has defined self-management as any action taken by individuals to deal with any issue relating to their health. This could be done on their own or in cooperation with other health care providers. Knowing that there are different approaches to manage chronic diseases, the self-assessment approach is the most frequently used in primary care settings and is linked to attaining better health outcomes (Reynolds et al. 2018).

1.6 The Welsh model of management of chronic conditions

The pattern of diseases has changed over time, from communicable to non-communicable diseases, and from diseases that affect young people to those that develop with aging (Dargie 2000). There are also drivers to change the way in which chronic diseases are managed. These drivers include but are not limited to long waits, fragmented health services, and low involvement of patients in their treatment plan. To accommodate this, health commissioners in Wales have introduced an integrated model and framework to deliver better health care services for patients with chronic conditions. This aims mainly to prevent or delay the development of chronic conditions (Welsh Government 2007). Moreover, it also aims to provide integrated health services for those living with chronic conditions with more service user involvement (Welsh Government 2007). As a result, the Welsh Chronic Conditions Management Model (CCM, Figure 1.1) was published in 2007 by the Welsh Government. The model was built on several crucial factors in managing people with chronic conditions, as follows:

- Self-monitoring and using telecommunication technology such as telecare.
- Self-management education
- Targeting people at high risk
- Patient involvement
- Sharing knowledge and skills
- Broad managed care programmes

The model addresses the need to distribute health services provided to patients on a whole system basis and to empower patients and carers to manage their conditions in their homes or local communities. In this model, four levels of care are introduced based on the complexity of an individual's condition. The level of care that a patient may have will differ according to each individual case at a given time. That means patients might be stepped up or down the model based on the severity of their cases (Welsh Government 2007).

1.6.1 Level 1: Primary prevention and health promotion

This level is designed to promote a healthy lifestyle for people within their communities, such as smoking cessation, healthy food, weight management, and exercise (Welsh Government 2007). Thus, chronic conditions can be prevented or delayed.

1.6.2 Level 2: Population management: 'Practice-based' CCM programme

This level is designed to detect chronic diseases at early stages, delay disease progression, prevent complications, and empower patients to effectively manage their conditions. Services are provided at a GP practice level. Patients are advised to get support from self-management programs, such as the expert patient programme (EPP) (Welsh Government 2007).

1.6.3 Level 3: High risk management: 'Network-based' CCM services

At this level, services are provided at the "network" practice level. They could be provided in community facilities, hospitals, clinics, or even by GPs on behalf of the network. Information is shared electronically, such as electronic records, to make sure patients get the best level of care from health providers in the network. Patients whose conditions are complicated or those who have been hospitalised because of their diseases are targeted at this level. Patients are empowered by specialists, such as physiotherapists and GPs with special interest (GPwSI), to manage their conditions effectively at home (Welsh Government 2007).

1.6.4 Level 4: Case managed services

This level is designed for people who have been admitted frequently for one or more highly complex chronic diseases. Patients at this level are assessed holistically by care coordinators to identify and effectively manage complex cases (Welsh Government 2007).

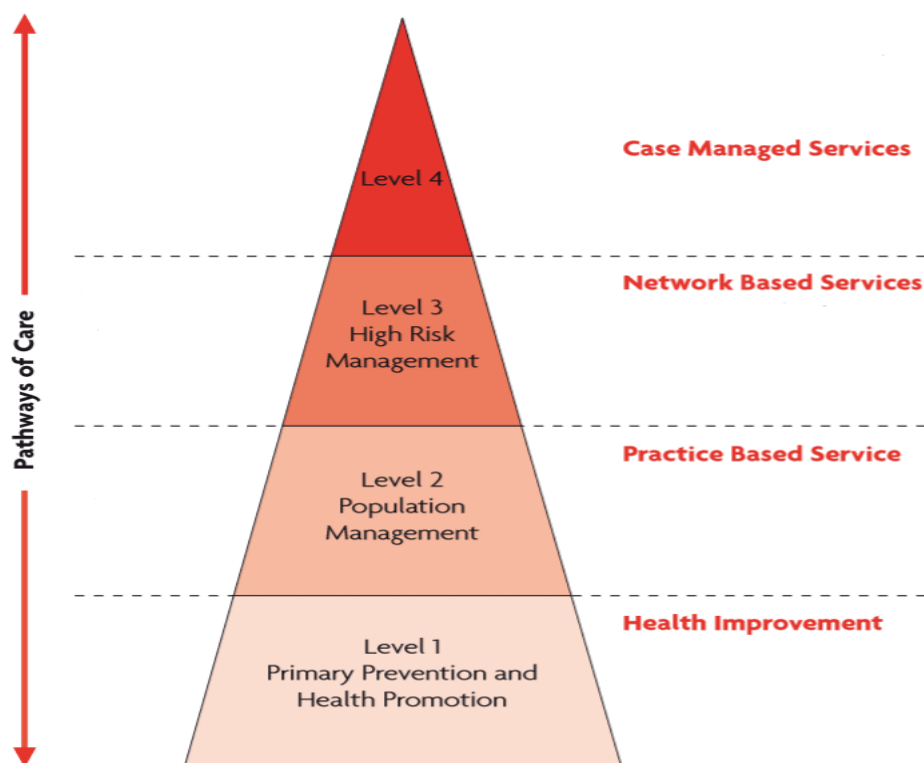


Figure 1.1: The Welsh Chronic Conditions Model. Adapted from Welsh Government (2007): “Designed to Improve Health and the Management of Chronic Conditions in Wales: An integrated model and framework”.

1.7 Structure of the NHS in Wales

In order to implement the new model of chronic disease management effectively and to improve health outcomes, taking into account the increase in the older population, chronic conditions, and the provision of timely and effective services in rural areas, the structure of the NHS in Wales had to be reformed. In 2009, the NHS in Wales underwent major reform in which the 22 local Health Boards (LHBs) and seven NHS trusts were replaced by only seven local health boards. In addition, a new unified system was established to include three NHS trusts: the Welsh Ambulance Services for emergency services, Velindre NHS Trust, which provides specialist services for people with cancer, and Public Health Wales. In October 2018, a new body – Health Education and Improvement Wales (HEIW) – was established, aiming to enhance health care providers’ skills, which would support the provision of high-quality health care services (<https://heiw.nhs.wales/>). The new system of integrated local health boards would reduce bureaucracy and simplify the process of delivering effective healthcare services

to people in need. The reform would change the responsibility of local health boards from confrontation to collaboration, from commissioning to planning, focusing on the whole system, not hospitals, wellness not sickness, and working with partners. Thus, local health boards will be responsible for all healthcare services provided to the population of Wales (NHS Wales 2009).

1.8 Primary care clusters

Primary care services include several healthcare services that are provided for patients by different health care professionals (NHS Wales 2014). The General Practitioner (GP) is considered the main core of primary care services. In addition, primary care services comprise other elements, such as optometry, pharmacy, and dentistry. It was reported that more than 90% of patients in Wales contact primary care services as the first point of treatment (NHS Wales 2014). The primary care services also help members of the community to have better and healthier lives. They provide the community with a variety of services given by staff with different expertise, such as health visitors, mental health care assistants, social services, and midwives (NHS Wales 2014).

At the end of 2014, the Welsh Government announced that they were going to implement a new plan for primary care services (NHS Wales 2015c). According to the Planned Primary Care Workforce for Wales, there are certain factors and motives that drove this change, as follows:

- Disease prevention is a core element of a healthy life
- Cooperation between health care providers such as specialists and other supported organizations in the community will help in preventing people from getting ill and promote their health.
- Active engagement of patients, family members, and carers, in health care decision-making is recommended.
- Designing services that aim to serve around 25,000-100,000 people per community.
- Principles of prudent healthcare.

There was a need to have a place of care where ill people in different geographic areas can be treated in an efficient manner (National Assembly for Wales 2017). Therefore, the decision-makers took action to redesign the primary care services to primary care clusters. In this new concept of patient care, health care services are provided based on population needs (NHS Wales 2015c). The new reform aims to group GPs located near each other into a cluster where the patients can be provided with a variety of health and social services (National Assembly for Wales 2017).

The primary care cluster brings together a variety of health care services that are provided in a local area in which the number of health care professionals would work cooperatively to fulfil people's needs (NHS Wales 2015c, 2019a). There are 64 primary care clusters distributed across Wales. Each cluster serves a geographical area with a population ranging from 25,000 to 100,000 patients. The number of clusters is determined by NHS Wales Local Health Boards (LHBs, NHS Wales 2019b). There will be 64 clusters across Wales, which are supported and monitored by the LHBs to meet community needs (NHS Wales 2019b). Thus, it will be more convenient for people to access different healthcare services in their local communities.

...As well as planning and delivering more primary care services to meet local needs, primary care clusters will play a significant role in planning the transfer of services and resources out of hospitals and into their local communities for the benefit of their local populations... (National Assembly for Wales 2017).

1.9 Evolution in pharmacists' role in managing chronic conditions

Due to the high demand for medical services provided by the NHS in Wales, combined with a shortage in numbers of physicians and nurses, there is a need to involve other health practitioners, such as pharmacists. Therefore, pharmacists have been assigned additional roles in order to maximise their skills and to use NHS resources more efficiently. This will lead to an expansion of services provided by pharmacists and other healthcare professionals. Ultimately, this would help NHS in Wales to provide patients with high-quality care in a timely and cost-effective manner (NHS Wales 2015a, b).

Primary care clusters were established to achieve a high degree of integration and cooperation between pharmacists and other health care practitioners and to provide patients with efficient and effective health services. In this multidisciplinary primary care system, pharmacists will be involved in several health and medicine models. This will increase access to pharmacists and improve health services provided to patients (NHS Wales 2015a, b). These models are as follows:

- 1- Individualised Medicines Optimisation: by working with other health care providers, and utilising their skills as experts in medications to provide patients with safe and effective treatment plans
- 2- Service developments through Community Pharmacy Network: make the most of the community pharmacy network to provide patients with advanced and enhanced services.
- 3- Screening and Signposting: pharmacists' skills and expertise can be used to prevent and detect diseases at early stages and refer patients to GPs if necessary.
- 4- Training and Education: pharmacists' knowledge and expertise can be used to deliver training courses and education programs for other healthcare providers and also for patients.
- 5- Medicines Management and local medicines formulary: As experts in medicines, pharmacists can effectively contribute to choosing cost-effective medications.

Under the community pharmacy contractual framework, the role of the community pharmacist focuses on three main domains as follows:

- Essential services: these services mainly include dispensing medication, disposing of unwanted medications, signposting, health promotion, and self-care support. Services falling under this category must be provided by all community pharmacists (NHS Wales 2015b; Welsh Government 2019c).
- Advanced services: in this category, community pharmacists are required to meet certain criteria in order to be qualified to provide patients with more advanced clinical services such as Discharge Medicines Reviews (DMR), Medicine

Use Reviews (MUR), and Appliance User Reviews (AUR) (NHS Wales 2015b; Welsh Government 2019c).

- Enhanced services: services are commissioned by local health boards based on the need of local populations. Under this category, community pharmacists must be qualified to provide enhanced services, such as providing flu vaccines, smoking cessation, emergency contraception, and common ailments services (NHS Wales 2015b; Welsh Government 2019c).

1.10 Asthma as an example of a chronic condition

1.10.1 History of asthma

The word 'Asthma' is derived from a Greek word meaning 'opening the mouth while breathing' (Marketos and Ballas 1982; Holgate 2010). This condition may be as old as man himself. People in ancient civilizations suffered from asthma, such as the Ancient Egyptians, Chinese, and Greeks (Cserháti 2004). From that time onward, many theories have been proposed regarding the aetiology of asthma and how it can be treated. The Chinese used the Ephedra plant as a bronchodilator more than 5000 years ago (Cserháti 2004). Ephedrine, the active ingredient in the ephedra, helps in relieving shortness of breath (Cserháti 2004). The ancient Egyptians were treating asthma thousands of years ago. It was mentioned in their Ebers Papyrus, which contains medical information and herbal prescriptions for diseases at that time, including asthma (Cserháti 2004; New World Encyclopedia 2020). The father of medicine, Hippocrates (460-377 BC), described the word 'panting' with the word 'asthma', making him the first scientist to use the word 'asthma' as a medical term (Marketos and Ballas 1982). Scientific research on asthma continued during the middle ages. In this period, knowledge about the nature of this disease was developed, leading to extensive writings expounding theories about the triggers and treatment of asthma (Floyer 1698; Cserháti 2004).

1.10.2 Asthma – definition and symptoms

Asthma is considered one of the most common respiratory diseases nowadays (Ferkol and Schraufnagel 2014). People of all ages can be affected by this disease (National Heart, Lung, and Blood Institute (NHLBI, 2020). The main characteristics of this disease are difficulty in breathing, wheezing, chest tightness, and coughing (Zahran et al. 2011). These symptoms can be experienced at different levels according to the genetic variations among people with asthma and patient lifestyles (Zahran et al. 2011; Asthma UK 2019a). Asthma develops as a result of inflammation in the small airways in the respiratory system (Busse et al. 1993). When this happens, these airways become hyper-sensitive and narrow, making it difficult to breathe (Busse et al. 1993). Asthma is considered to be an incurable disease (Levy et al. 2012). Fortunately, asthma symptoms can be controlled and managed adequately using anti-inflammatory (i.e. preventer) and bronchodilator (i.e. reliever) inhalers (Giraud and Roche 2002). These inhalers are effective if used properly, allowing patients to maximize the benefit obtained from their medicine. On the other hand, poor technique and adherence to inhalers will significantly reduce the effectiveness of medicine and place an economic burden on the healthcare system (Blaise et al. 1998; Giraud and Roche 2002; Bahadori et al. 2009).

1.10.3 Asthma epidemiology

1.10.3.1 Asthma incidence and prevalence rates

Asthma is considered a serious chronic disease that affects people's quality of life and might lead to death. It is widely spread over the world. The prevalence and incidence rates of asthma are increasing in many countries (Nunes et al. 2017). This increase is not only attributed to genetic factors, but also to environmental factors in the modern era, leading to an increase in the economic burden of asthma (Nunes et al. 2017). The epidemiology of asthma varies among and within countries due to several factors, such as age, sex, and geographic areas (Nunes et al. 2017; American Thoracic Society 2020).

In the United Kingdom (UK), statistics have shown that eight million people have been diagnosed with asthma, representing 12% of the total population. This means that asthma has the highest prevalence of any lung disease. Since asthma symptoms might disappear with time, especially in people below the age of puberty, children may grow out of asthma. As a result, around 5.4 million people out of the eight million diagnosed with asthma in the UK are currently treated with asthma medicines (British Lung Foundation 2020). The incidence of asthma is considered the highest among lung diseases. Approximately, 160,000 people per year are diagnosed with asthma in the UK. However, this number decreased by 10% in the period between 2008 and 2012. This might be related to the misdiagnosis of asthma, and especially its confusion with Chronic Obstructive Pulmonary Disease (COPD), or asthma might be becoming less common (British Lung Foundation 2020).

The incidence and prevalence rates of asthma vary according to the places where people live. People who live in Wales and Scotland develop asthma more than those who live in other parts of the country. The prevalence rate of asthma also varies among different regions in the UK. People who live in the East Midlands, the East of England, the North West and the South West have a higher chance to develop asthma in comparison to people living in other areas of the UK (British Lung Foundation 2020).

Gender has a slight effect on asthma incidence and prevalence rates in the UK. In 2012, the numbers of females and males who were newly diagnosed with asthma were 284 and 261 per 100,000, respectively. The prevalence rate of asthma is also higher in females compared to males. In 2012, the total number of females with asthma was 12,565 per 100,000, compared to 12,033 per 100,000 for males (British Lung Foundation 2020).

People in different age groups can develop asthma. However, statistically, children are more likely to have asthma in comparison to other age groups. In the period between 2004 and 2012, the occurrence of asthma in children decreased, while the opposite was seen in adults. The same pattern is also observed regarding the incidence rate for

asthma. It is higher in people below the age of 16 than in adults (British Lung Foundation 2020).

1.10.3.2 Asthma mortality

According to the most recent statistics, more than 1,400 people died from asthma in Wales and England in 2018, which was considered the highest number in the last decade (Asthma UK 2019b). It seems that there is a relationship between when deaths occur and the season. More people die during the cold winter months than in warmer months (Office for National Statistics 2015). The death rate due to asthma varies around the UK. Although the prevalence of asthma in the West Midlands and the South East is not the highest in the UK, these regions had the highest death rates from asthma in the period between 2008 and 2012 (British Lung Foundation 2020). Conversely, the South West had the lowest asthma death rate despite having the highest asthma prevalence (British Lung Foundation 2020). Although the mortality rate of asthma disease seems low in comparison to other lung diseases (British Lung Foundation 2020), it can be reduced by providing patients with better care. That is because several studies have shown that asthma can be improved and better managed (Blaise et al. 1998; Giraud and Roche 2002). In a study that aimed to estimate the number of preventable asthma deaths, Levy et al. (2014) found that 67% of the deaths that occurred were considered 'preventable'. Most of those who died of asthma did not see an asthma specialist in the last year of their lives (Levy et al. 2014).

1.10.3.3 Asthma morbidity and economic burden

Uncontrolled asthma can lead patients to be hospitalized. The number of hospital admissions due to asthma across the UK is relatively low compared to other lung diseases, such as pneumonia and COPD. However, it is considered high based on the nature of the disease, which is one that should be easily managed. Every year, there are around 60,000 hospital admissions across the UK due to asthma. It accounts for 200,000 bed days annually. More importantly, large numbers of asthma patients visiting the emergency department are actually not in a serious condition that requires a hospital admission. This also adds extra avoidable pressure on health professionals and health

services, and correspondingly increases the economic burden of the disease (British Lung Foundation 2020).

The NHS spends around 1.1 billion pounds on asthma every year (Asthma UK Centre for Applied Research 2016). This includes the costs of GP visits, prescriptions, hospital care, and disability claims. Spending on asthma prescriptions is considered the highest, as this alone costs around 666 million pounds annually (Asthma UK Centre for Applied Research 2016). The cost of asthma varies from one country to another. In Europe, it is estimated that on average, every asthma patient costs around €1,583 per year. Globally, the total cost of asthma was more than spending on tuberculosis and HIV/AIDS combined in 2004 (Nunes et al. 2017).

1.10.4 Asthma diagnosis

Asthma diagnosis may not be clearly identified. There is no gold standard test to diagnose asthma, and physicians mainly depend on patient history. Studies have shown that asthma diagnoses are not always accurate. Around 30% of people who have been diagnosed with asthma might not actually have this disease. On the other hand, other studies report that the total number of people with asthma might be underestimated (National Institute for Health Care Excellence 2017).

The first step in asthma diagnosis involves asking suspected asthma patients about asthma symptoms. Clinicians should ask patients about coughing, wheezing, chest problems, and breathing difficulties. Moreover, they should check whether the patients or their relatives have asthma or any kind of allergy or have had allergies in the past. That is because there are several factors that are associated with asthma, such as genetic and environmental factors. In addition to taking patient and family history, there are several tests that can be done to help clinicians to diagnose and monitor asthma. However, they should not be used in isolation to diagnose asthma. The results of tests should be always combined with clinical assessment and taking a patient and family history (National Institute for Health Care Excellence 2017; British Thoracic Society 2019).

These diagnostic tests focus mainly on two things: airflow obstruction and airway inflammation (British Thoracic Society 2019). They are designed to examine whether the airway is inflamed or narrowed and to see how a patient's lungs respond to asthma therapy (British Thoracic Society 2019). Table 1.1 shows a list of diagnostic tests that are used to diagnose and monitor people with asthma.

Strategy	Description
Spirometry	A lung function test that measures lung capacity and ability to exhale. Patients are requested to take a deep breath and then to breathe out completely as fast and long as they can (Asthma UK 2018a). This test measures lung sizes via measuring FVC (Forced Vital Capacity) (Worker Health 2020). The idea behind this test is to measure the amount of air breathed out in litres after a deep exhalation (Worker Health 2020). The test also measures another parameter, namely the Forced Expiratory Volume-one second (FEV1) (Worker Health 2020). This test aims to calculate the amount of air that a patient can exhale in one second after taking a deep inhalation (Worker Health 2020). The FEV1/FVC ratio is used to measure the percentage of lung size (FVC) that is exhaled in one second. It helps clinicians to classify respiratory disease as obstructive or restrictive. In restrictive lung disease, the lung's ability to expand is limited due to lung stiffness, which makes it hard to fully fill the lungs with air (Pathway Medicine 2020a), whereas obstructive lung disease is characterized by the presence of airflow resistance, which makes it hard to breathe. The source of airflow resistance varies among lung diseases, but in asthma, narrowing of the airways is most likely to cause airflow resistance (Pathway Medicine 2020b).

Bronchodilator reversibility test	The idea behind this test is to perform a spirometry test before and after taking β_2 agonist bronchodilators (Richter et al. 2008; National Asthma Council 2020). Knowing the baseline reading and the reading after administering medicine helps clinicians to distinguish between asthma and COPD.
Challenge test	This test aims to see how patients' lungs respond to asthma triggers, such as histamine and methacholine (Calvin 1983; Asthma UK 2018a). Asthma patients are hyper-responsive to these agents. Non-atopic people (people without allergic responses) do not respond to the low level of doses given. Asthma patients will have bronchoconstriction.
Peak flow	This is a lung function test that measures the peak flow rate.
FeNO test	The Fractional Exhaled Nitric Oxide (FeNO) test measures the amount of nitric oxide in the exhaled air. Having a high level of nitric oxide indicates the presence of inflammation in the lungs (Asthma UK 2018a).
Blood eosinophils test	Eosinophils are a type of white blood cell that are increased when there is asthma-induced pulmonary inflammation (Casciano et al. 2016).
IgE test	IgE levels are elevated in patients with asthma. This is not specific to asthma, as IgE levels will be elevated for anything a patient is allergic to but do not necessarily cause asthma (Sandeep et al. 2010).
Skin prick test	In this test, patients' skin is pricked with a small amount of allergen that patients are most likely to be allergic to (Asthma UK 2018a).

Table 1.1: A list of diagnostic tests that are used to diagnose and monitor people with asthma.

Diagnosing people with asthma is not a straightforward procedure. That is because asthma, as a disease, might vary among people. For instance, not all people with asthma

have the same symptoms. Also, the diagnosis of asthma in adults is different in comparison to children (British Thoracic Society 2019). More importantly, asthma intensity varies over time for the same patient, so this might affect the results of diagnostic tests that are done at a single point in time (National Institute for Health Care Excellence 2017; British Thoracic Society 2019). Finally, the result of diagnostics tests might also differ based on gender, age and height (Asthma UK 2018a). All these factors make it difficult to diagnose asthma accurately.

1.10.5 Treatment of asthma

1.10.5.1 Milestones in the pharmacological treatment of asthma

Since the most obvious symptom of asthma is difficulty in breathing, asthma is treated mainly by taking medicines that cause bronchodilation (Cserhádi 2004). People have used bronchodilators, such as ephedrine, since the ancient times. In the last century, people with asthma were treated using four types of medication: anticholinergic medicines, non-anti-cholinergic bronchodilator stimulation, corticosteroids, and targeted asthma treatments (Chu and Drazen 2005).

1.10.5.1.1 Anti-Cholinergic treatment

According to the Twentieth Century Practice (1985), Stewart and Gibson, in their medical daily practice, advised asthma patients to use belladonna alkaloids. Patients smoked cigarettes containing these belladonna alkaloids, which were called asthma cigarettes. Alkaloids of belladonna are the active ingredients of *Datura stramonium*, also known as the thorn-apple. Alkaloids of belladonna inhibit cholinergic neurotransmission, thus helping in asthma control. At the beginning of the twentieth century, Osler claimed that injecting pilocarpine could help in treating patients with asthma. In 1914, inhaled and injectable anticholinergic treatments were the drugs of choice in asthma therapy. This continued until 1975, when Howell claimed that belladonna alkaloids were effective therapies in treating asthma. In the 1980s, the treatment of asthma changed. Physicians started to prescribe ipratropium bromide as a rescue medication to control asthma. This anti-cholinergic bronchodilator treatment

was introduced to avoid the common side effects of the adrenergic bronchodilator (Chu and Drazen 2005).

1.10.5.1.2 Non- Anti-Cholinergic treatment

1.10.5.1.2.1 Methyl Xanthines

In the fifth edition of Cecil's Textbook of Medicine (1940), methyl xanthines were introduced as a bronchodilator for the treatment of asthma patients. They improve asthma outcomes via several mechanisms, but the most important one is via the inhibition of phosphodiesterase (PDE), which leads to bronchodilation. Aminophylline was dissolved in water and given as an intravenous injection. People also used the other form of methyl xanthine, theophylline, to treat asthma. Although theophylline has a narrow therapeutic window, it was considered an effective therapy in asthma treatment. For this reason, physicians were advised to monitor patients' blood plasma. At a later time, new medications were preferred over theophylline due to safety and effectiveness issues (Chu and Drazen 2005).

1.10.5.1.3 Direct adrenergic bronchodilators

The Chinese were using ephedrine to treat people with asthma thousands of years ago (Cserhádi 2004), whereas the first use of adrenergic treatment in people with asthma in western countries was at the beginning of the 20th century (Chu and Drazen 2005). Melland (1910) discussed the effectiveness of giving adrenalin injections to people with asthma. Several years after this, Thomas (1926, cited in Chu and Drazen 2005) conducted a study of using ephedrine in people with asthma and found that some patients' symptoms were partially relieved.

Toward the middle of the 20th century, Rackemann (1947, cited in Chu and Drazen 2005), recommended that ephedrine could be given by inhalation to asthma patients. As a result, metered dose inhalers were developed to deliver ephedrine or isoproterenol (a selective β -adrenergic agonist). Later, between the 1960s and the 1970s, the first β_2 -adrenergic agonists, such as albuterol, metaproterenol, isoetherine, and terbutaline,

were developed. Since these inhaled medicines have a rapid onset of action and fewer side effects, they became the drugs of choice for people with asthma (Chu and Drazen 2005).

1.10.5.1.4 Corticosteroid therapy

Corticosteroids were first used as a medicine in the middle of the twentieth century. In the 1950s, scientists found that the use of corticosteroids and adrenal corticotropic hormone was effective in managing asthma (McCombs 1952, cited in Chu and Drazen 2005). Corticosteroids are effective in treating asthma, as they inhibit airway inflammation (Barnes et al. 1998). In the 1970s, physicians started to use systematic corticosteroids to treat severe asthma attacks and to prevent its exacerbations (Chu and Drazen 2005). Patients experiencing severe asthma were prescribed corticosteroid tablets to be taken every day or every other day. This was considered a major problem for those with intermittent or mild asthma because of the medications' side effects (Chu and Drazen 2005). Brown et al. (1972) innovated a new route of administration to deliver corticosteroids, which is by inhalation.

1.10.6 Asthma management

A national clinical guideline, 'The British Guideline on the Management of Asthma' (BGMA), is published by the British Thoracic Society (BTS) and the Scottish Intercollegiate Guidelines Network. It was first published in 2003 and the latest version of this guidance was updated in July 2019. This guideline discusses aspects of asthma management in detail. The management of asthma is divided into two important parts, namely non-pharmacological and pharmacological management (British Thoracic Society 2019).

1.10.6.1 Non-pharmacological asthma management

It is well known that there are many factors that make asthma worse. These factors are called asthma triggers. They could be environmental factors, dietary factors, or any other trigger that could irritate the respiratory system. For this reason, avoiding asthma

triggers will reduce the frequency of asthma episodes and will reduce the need to take relievers. According to the BGMA, there are several recommendations regarding dealing with the most common asthma triggers. These recommendations fall into two categories: primary prevention and secondary prevention. Primary prevention means trying to prevent disease occurrence, which will lead to a reduced incidence of the disease, whereas secondary prevention deals with interventions that aim to reduce the impact of the disease after it develops.

1.10.6.2 Pharmacological management and treatment strategies of asthma

The management of asthma focuses mainly on controlling its signs and symptoms. Asthma is considered to be completely controlled when the following criteria are met:

1. Not having daytime and night-time symptoms, such as coughing, shortness of breath, wheezing, or awakening because of asthma.
2. Not using rescue inhalers.
3. Free of asthma attacks.
4. Practising daily activities without limitations of any kind due to asthma.
5. Normal lung function.
6. Few adverse drug events from medications.

According to the British Guideline on the Management of Asthma (BGMA), people with asthma are treated based on stepwise management. In this approach patients are stepped up or down based on disease control (see Figure 1.2). All people with asthma should be prescribed a short-acting β_2 agonist as a reliever. They should use the inhaler as required. If the patient is prescribed more than one short acting bronchodilator pre-month, they should be assessed. As a rule of thumb, patient adherence and inhaler technique should be checked prior to adding a new therapy.

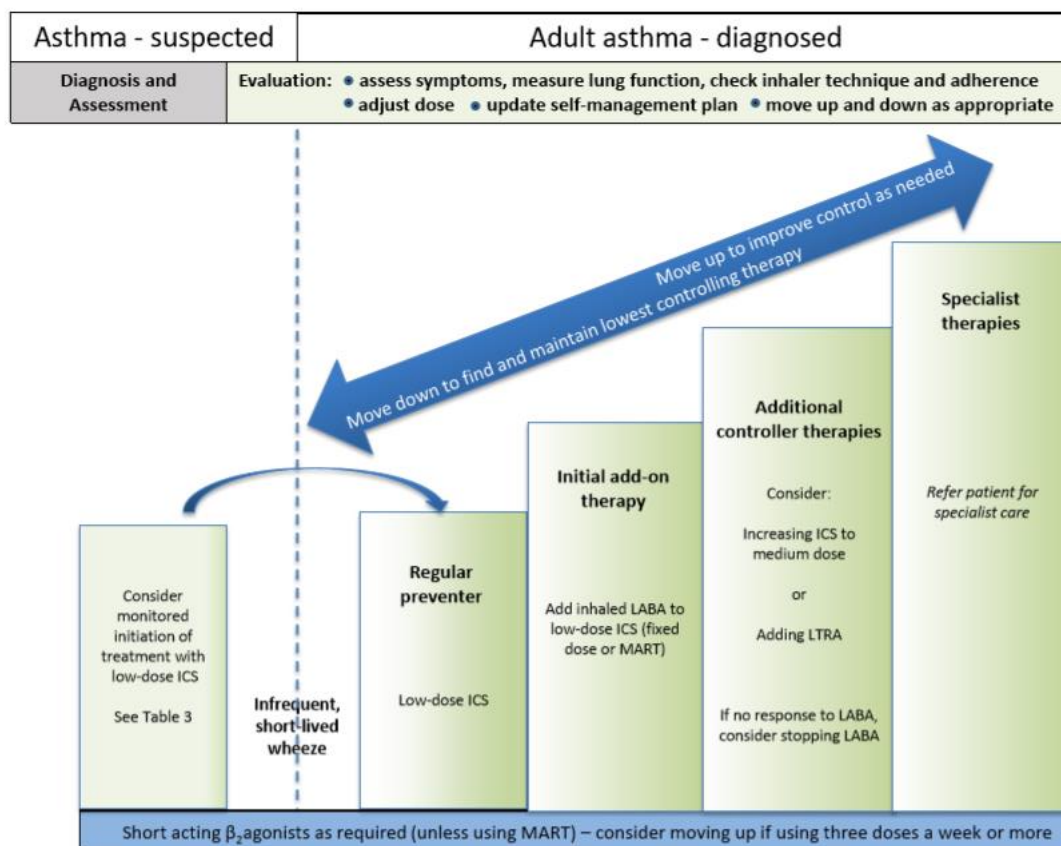


Figure 1.2: Stepwise approach to asthma management in adults. Retrieved from (BGMA). ICS=inhaled corticosteroids; LABA=long-acting beta agonists; MART=maintenance and reliever therapy; LTRA=leukotriene receptor antagonists.

Health care providers should consider adding inhaled corticosteroids (ICS) if a patient has had an asthma attack and been prescribed oral corticosteroids in the last two years, or if a patient is using β_2 agonists at least three times a week, or experiences asthma symptoms at least three times a week, or is waking up due to asthma at least once a week. Physicians should start ICS at doses that match the severity of the disease. Whenever possible, using ICS twice a day is slightly more effective than once a day. ICS might be used once a day in well-controlled asthma. Health care providers should consider titrating ICS doses to the minimum level that achieves adequate asthma control. ICS are considered the drug of choice as a preventer therapy for adults and children.

In cases of uncontrolled asthma, patients should be stepped up once inhaler technique and adherence have been checked and found to be adequate. The drug class of choice that needs to be considered after initiating ICS is a long-acting β_2 agonist. There is no

specific ICS dose at which a long-acting β_2 agonist should be used. Adding a long-acting β_2 agonist to ICS is considered the treatment of choice in those with uncontrolled asthma despite using ICS. Physicians should consider adding a long-acting β_2 agonist prior to increasing the ICS dose. A long-acting β_2 agonist should always be accompanied with an ICS. In practice, it is highly recommended to prescribe a combination inhaler of corticosteroids and a long-acting β_2 agonist to improve adherence and to avoid taking long-acting β_2 agonists without ICS (British Thoracic Society 2019).

If the asthma symptoms remain uncontrolled and there is limited response to a long-acting β_2 agonist, health care providers should increase the dose of ICS. If there is no response to the long-acting β_2 agonist, the medication should be stopped, and the ICS dose should be increased. In addition, adding a new medication, such as a Leukotriene Receptor Antagonist (LTRA) or theophylline, is recommended (British Thoracic Society 2019).

If asthma symptoms are not controlled after increasing the dose of ICS plus using long-acting β_2 agonist, the health care provider should consider increasing the ICS dose and adding another therapy such as an LTRA (if not already added), theophylline, or tiotropium, which is a long-acting muscarinic antagonist (LAMA). The side effects that might occur as a result of adding these medications are very common. No controlled trial has been done to prioritize one option over another, but the possibility of side effects occurring is greater with theophylline (British Thoracic Society 2019).

In the case of asthma that is not controlled, despite increasing the ICS dose and adding a new medication, health professionals should consider reducing ICS dose and stopping the add-on treatment. Health care providers might consider starting low-dose oral steroids in patients with uncontrolled asthma. Long-term usage of oral steroids puts people at risk of developing serious side effects, so they should be closely monitored. Finally, if people with asthma show no improvement after all pharmacological treatments have been tried, health care providers might consider bronchial thermoplasty. This is a medical procedure designed to improve breathing by applying

heat to the inner part of the airways. It improves airway conductance by decreasing the thickness of the smooth muscle tissue in the airways (British Thoracic Society 2019).

Reviewing patients' medications and stepping them down the therapeutic ladder is essential for managing patients whose asthma is under control (British Thoracic Society 2019). Health care providers should consider reducing the doses and number of medicines for people with asthma every three months once their asthma is well controlled (Hawkins et al. 2003). When thinking about which medication should be decreased or stopped first, health care providers should consider several factors, such as medications' safety profile, the benefit achieved, the time spent taking medications, and finally, patients' preferences. Keeping patients on a very low dose of ICS is highly recommended. Health prescribers should consider decreasing the ICS dose by 25%-50% every three months for those whose conditions are under control. Even though there is a clear asthma guideline, not all health professionals follow it. This might lead improper management of the disease (Sharon et al. 2007).

1.10.7 Impact of adherence on asthma control

One of the factors that may determine asthma control is adherence to inhalers. It is not easy to measure and determine patient adherence (Sulaiman et al. 2018). However, clinicians have used several ways to determine adequate adherence, namely patient self-reports, dose counts, pharmacy records, and electronic monitoring (Lareau and Yawn 2010). Patient self-reports and counting remaining doses are not reliable bases upon which to make a medical decision (Lareau and Yawn 2010). This is because of the high probability of social desirability bias. In this type of bias, patients try to make their health care providers happy with their answers. Therefore, they will give answers that make them look good. Moreover, in a study that assessed patient adherence, scientists found that patients tend to empty their inhaled medications prior to primary care visits (Rand et al. 1992). Thus, dose counts might not give valid results. However, patient self-report and dose counts are considered to be easy and non-expensive ways to assess patient adherence (Lareau and Yawn 2010).

The other two ways that can be used to track patient adherence are monitoring pharmacy data and using electronic devices. While pharmacy data can show accurately how many medications and doses are prescribed for each patient, it does not guarantee that patients have taken them (Lareau and Yawn 2010). Therefore, using this method to assess patient adherence is considered inaccurate. On the other hand, using electronic devices can give more accurate data, but it is expensive, susceptible to malfunction, and finally, does not guarantee that a patient actually took the dose (Lareau and Yawn 2010; Milgrom et al. 1996).

Adherence to inhalers can be affected by two factors. The first is 'temporal adherence', which is defined as intentionally taking medication at the exact time and intervals. The second, 'technique adherence', means using the right inhaler technique to administer medications (Moran et al. 2017). Both types of adherence are important in ensuring that patients benefit from prescribed medicine to control their asthma.

Adherence to ICS is linked to better asthma outcomes (Blaise et al. 1998). It plays a crucial role in keeping asthma under control. For this reason, people who are experiencing asthma symptoms are advised to use an inhaled corticosteroid regularly. It had been proven that using ICS corresponds with a decrease in airway inflammation (Blaise et al. 1998). Children who were >80% adherent with ICS had better asthma control in comparison to those who were less adherent (Klok et al. 2014). Moreover, studies have shown that ICS are effective in treating all levels of asthma (Kerrebijn et al. 1987; Haahtela et al. 1991). Therefore, using ICS to treat people with asthma has become an essential step to control asthma in most cases (British Thoracic Society 2019). Being adherent to medicines is a key factor in disease management (Osterberg and Blaschke 2005). Thus, it is likely that asthma will get worse in non-adherent patients. Since ICS reduce pulmonary inflammation, they reduce the frequency and severity of asthma attacks. Studies using ICS in people with asthma have found that patients using ICS have less frequent disease symptoms, morbidity, and mortality (Barnes et al. 1998;

Suissa et al. 2000, 2002). Clinical trial evidence proves that ICS help to control all types of asthma in all age groups (Barnes and Busse 1998).

There are particular causes that might affect patients' adherence to ICS. Many people have concerns about using ICS, especially because of their potential to cause systemic side effects (Barnes 1995; Dahl 2006). Another reason is the relatively long time needed for a desirable effect to occur. Some people might stop using ICS because they have not noticed a positive effect straight away after taking the dose compared to relievers (Rau 2005). These causes might explain why some people tend to stop using ICS or not take the medicines as prescribed. Given that ICS is considered to be the cornerstone of asthma treatment, health care providers should play an important role in clarifying any doubts patients may have regarding using ICS. This would maximize the odds of using prescribed preventers as directed, and consequently would improve asthma control.

ICS are delivered directly to the lung, so systemic penetration is minimal at the relatively low doses used to treat most asthma patients (Barnes 1995; Pedersen and Byrne 1997). Also, patients with mild asthma attacks are advised to use spacers as they administer inhalers and to wash their mouth after each use (Asthma UK 2018b; British Thoracic Society 2019) to reduce adverse drug events that might occur through the use of ICS (Asthma UK 2019c). More importantly, people with asthma should consider the advantages and disadvantages of using ICS. In most cases, the advantages outweigh the disadvantages. Therefore, if patients agree to use ICS, they should take their medicines as directed until the end of the treatment course. That is because preventers are not like rescue medications in term of onset of action. They need weeks to start working and to reduce airway inflammation (Barnes and Busse 1998). Finally, practitioners should follow the asthma stepwise management approach. In this type of management, every patient will be stepped up or down, as needed, based on their response to the treatment plan. That means that even if a patient has been on a high dose of ICS, they should be stepped down once their asthma symptoms improve (British Thoracic Society 2019).

1.10.8 Asthma dilemma

Several studies have shown that asthma is poorly controlled in many patients (Giraud and Roche 2002; Molimard 2003; Press et al. 2012, Price et al. 2014). The reason for having uncontrolled asthma might be attributed to several factors, namely disease-related factors (e.g. treatment-resistant asthma, triggers), patient-related factors (e.g. adherence, perception, and knowledge about the disease), inhaler device-related factors (drug formulation and device features) and healthcare provider-related factors (e.g. guidelines implementations, and the lack of understanding of proper inhaler technique, Braido 2013; De Tratto et al. 2014; Scichilone 2015). However, several studies have shown that the two main aspects that greatly impact asthma control are patient adherence and inhaler technique (Giraud and Roche 2002; Molimard 2003; Williams et al. 2004; Fink 2005; Chrystyn et al. 2017). Thus, health care providers should carefully check whether people with asthma are adherent and using inhalers properly (Sulaiman et al. 2018). Therefore, there is a need to assess how asthma is managed in the Welsh population and to assess the impact of adherence and inhaler technique on asthma control using validated and objective assessment tools.

1.11 Research rationale

In the United Kingdom, dealing with chronic diseases is a huge challenge for the National Health Services (NHS). It has been estimated that around 17.5 million adults might live with a chronic disease (Department of Health 2019). It has also been projected that the incidence of chronic diseases in those over 65 years will continue to increase (Department of Health 2019) and will more than double by the year 2030. In Wales, between 2004 and 2015, the percentage of people living with at least one chronic disease increased by 30%. On the other hand, the percentage of those who live with multiple chronic diseases increased by 56% during the same period of time (The Health Foundation 2016). People with chronic conditions account for around 50% of consultations provided by GPs (Pharmaceutical Services Negotiating Committee 2020a). Pressure on GPs is increasing due to an aging population with an increased burden of chronic diseases. This may affect how chronic conditions are managed in a primary care setting. Knowing that chronic diseases are associated with aging, and that the number of people

aged 65 years and older is expected to increase by 32% by 2026, this would add an additional burden on the national economy (Wales Audit Office 2014). People with chronic conditions account for 58% of hospitalization expenditure (Watt and Roberts 2016). In this thesis, the researcher is going to take asthma as an example of a chronic disease and investigate how well it is managed in the current type of practice via using validated and objective assessment tools. Then, the researcher will qualitatively and quantitatively explore the potential of community pharmacists' involvement in managing chronic conditions.

Asthma was selected as a good exemplar of a chronic condition that might be managed by pharmacists for several reasons. The first is that there are clear guidelines for the management of asthma patients. The second is that the majority of asthma is managed in primary care. The third is that the current management of asthma is not optimal (based on mortality and number of preventable asthma deaths, see section 1.10.3). The fourth is that the most frequent contact asthma patients have is with their pharmacist when they collect repeat prescriptions.

As a potential solution to help with this problem, community pharmacists can be utilized more effectively in respect of managing people with long-term conditions. As highly educated health professionals, community pharmacists have expertise and skills that would help to improve healthcare services and to reduce the burden on services provided by other health care providers. They are also more accessible than GPs, so patients can more easily see a community pharmacist compared to a GP. The integration of community pharmacy in the NHS multidisciplinary model would utilise the NHS resources efficiently and provide patients with timely and convenient health services. Therefore, to investigate this topic exhaustively, there was a need to conduct projects to gather the opinions of community pharmacists and stakeholders of pharmacy services in Wales regarding expanding the role of the community pharmacy profession.

1.12 Research aims and objectives

The general aim of the work presented in this thesis is to understand how well asthma is managed in the primary care setting and how community pharmacies could be more involved in managing chronic conditions. A mixed-methods approach across five studies was conducted to better explore and investigate the topic (Johnson et al. 2007). The aims of each project are as follows:

- I. Project one (quantitative study): to investigate the prevalence of improper inhaler technique in asthma patients.
- II. Project two (quantitative study): to assess how well asthma is managed by assessing inhaler technique, adherence to inhalers, and asthma control.
- III. Project three (qualitative study): to explore community pharmacists' views regarding managing chronic conditions in a community pharmacy setting.
- IV. Project four (quantitative study): to determine if the views expressed by the sample of community pharmacists in project three were representative of the wider population of community pharmacists practising in Wales.
- V. Project five (qualitative study): to elicit the views of community pharmacy service stakeholders in Wales about expanding the role of community pharmacists in managing people with chronic conditions.

Chapter 2 – General methodology

2.1 Introduction

Choosing a proper research methodology is an important step in conducting any research. Buckley and Chiang (1976) defined research methodology as a strategy in which an approach is mapped out to solve a problem. Research should not be led by methodological approaches: that is, choosing an appropriate methodology should involve something beyond the practicalities (Holden and Lynch 2004). A proper methodology should be selected based on two factors: the nature of the research question being investigated and the philosophical stance of the researchers (Holden and Lynch 2004). There are three main research approaches – qualitative, quantitative, and mixed methods (Creswell 2014) – and each has its own strengths and limitations. This chapter will discuss the theoretical assumptions, research philosophy, paradigms and methodological approaches undertaken to investigate how well asthma is managed and to examine factors influencing the involvement of community pharmacy in managing chronic conditions. It will discuss the methodological considerations for the thesis. Each individual project will contain a methods section discussing the distinct methodology for that study in more detail.

2.2 The philosophy of science and theoretical framework

The selection of an appropriate method of investigation is mainly based on the investigator's assumption about society (Bowling 2009). An investigator may start with developing a theory and testable hypothesis which can be tested by data (deduction), or by gathering data and information, so that the hypothesis can be generated and tested (induction, Bowling 2009). Deductive reasoning is primarily used with quantitative methods, whereas inductive reasoning is mainly associated with qualitative methods (Winit-Watjana 2016).

2.2.1 Paradigms

Investigators' opinions and assumptions might affect how they look at a research topic. According to Kuhn (1970), what people see is dependent on what they look at and on their previous experience. The philosophical framework that determines the

investigator's position on research is called in philosophy a "paradigm". A research paradigm is a set of beliefs that guides investigators in research (Guba 1990). Creswell and Plano Clark (2018) described the four main types of theoretical paradigm that are used in mixed methods research as follows:

2.2.1.1 Postpositivist paradigm

A postpositivist paradigm is mainly aligned with quantitative methods in which researchers seek knowledge via cause-and-effect relationships, reductionism by selecting certain variables to study, empirical observation and measuring variables, and theory verification (Creswell and Plano Clark 2018).

2.2.1.2 Interpretivist/constructivist paradigm

This paradigm is mainly aligned with qualitative approaches. It focuses on understanding phenomena through studying participants' perspectives on the research topic in which their perspective is also formed as a result of their interaction with others (Creswell and Plano Clark 2018).

2.2.1.3 Transformative paradigm

In this paradigm, researchers are focusing on achieving justice and pursuing human rights. It is focussed on social justice, which is concerned with improving society by enabling a better life for specific groups of people, such as those with disabilities, or racial and ethnic groups (Creswell and Plano Clark 2018).

2.2.1.4 Pragmatist paradigm

This paradigm is commonly used in the mixed methods approach (Creswell and Plano Clark 2018). It focuses on dealing with problems in real-world practice (Creswell and Plano Clark 2018). Deductive and inductive research are used to provide pragmatic solutions (Winit-Watjana 2016). Multiple methods can be used to investigate the research topic. Thus, scientists who favour pragmatism appreciate its flexibility in

respect of not being restricted to a specific methodology or philosophical framework. Creswell (2003) claimed that the pragmatic paradigm provides an investigator conducting a mixed methods study with an opportunity to use multiple methods, different philosophical frameworks, multiple data collection tools and different analyses.

2.2.2 The UK Medical Research Council's framework

Developing a complex health care intervention may have several interacting components making it difficult to develop, document, and reproduce (Campbell et al. 2000). The UK Medical Research Council (MRC) developed a framework for the design and evaluation of complex interventions. The framework comprises of five phases, namely, the preclinical or theoretical phase; defining components of the intervention (phase 1); defining trial and intervention design (phase 2); methodological issues for the main trial (phase 3); and promoting effective implementation (phase 4, Campbell et al. 2000). The framework is used to describe and guide the process of translating the research into practice. It was mainly used in developing the research questions that helped to better understand the research topic in respect to barriers/facilitators to managing people with chronic conditions in community settings. The researchers in the preclinical phase identify the needs for an improved approach to address existing health needs (Campbell et al. 2000). Also, this phase should discuss the potential benefits of such an intervention (Campbell et al. 2000). After suggesting that community pharmacists might be able to manage people with chronic conditions in a community setting, phase one started. In phase one, a mixed-methods approach was conducted with the stakeholders of community pharmacy to better understand the barriers and facilitators to provide community-based chronic condition management services (Campbell et al. 2000). Conducting a mixed-methods approach guided by the MRC framework may provide a thorough understanding of the topic. Identifying the interacting components and practicalities of the intervention is essential in developing a complex intervention (O'Cathain et al. 2019). Therefore, several stakeholders (community pharmacists, the Welsh Government, the Royal Pharmaceutical Society,

local health boards, and Community Pharmacy Wales) were individually interviewed to achieve a thorough understanding of the topic.

2.3 Mixed methods approach

A mixed methods approach is seen as a useful alternative approach to either qualitative or quantitative methodology. Hesse-Biber and Johnson (2015) claimed that mixed methods should contain at least one qualitative and one quantitative approach conducted in the same study or across several related projects. After reviewing several definitions of mixed methods, Creswell and Plano Clark (2018) mentioned several characteristics of the mixed methods approach. They claimed that any researcher conducting a mixed methods study should:

- Gather qualitative and quantitative data and analyse them in respect to the research question;
- Combine the two forms of data;
- Organize data and conduct procedures in a logical manner, showing the purpose of using mixed methods;
- Provide a theoretical and philosophical explanation for their mixing of methods.

2.3.1 Advantages of the mixed methods approach

Many scientists consider mixed methods as an approach that provides useful and complete information allowing the whole picture of the issue to be seen (Johnson et al. 2007). Thus, researchers who use a mixed methods approach could investigate phenomenon in the social world using more than one research approach (i.e. quantitative and qualitative approaches). Creswell and Plano Clark (2018), in their book, *Designing and Conducting Mixed Methods Research*, mentioned several advantages of using a mixed methods approach. They claimed that conducting both quantitative and qualitative projects would minimize the weaknesses of conducting each approach on its own. For example, conducting a survey study based on qualitative project findings could help to solve the issue of generalizability for the qualitative approach. Another advantage is that a mixed methods approach gives researchers more freedom to

investigate the problem both quantitatively and qualitatively, and more importantly to answer research questions that could not be answered well using one approach. Finally, it would allow the use of multiple paradigms instead of using one paradigm associated with each study approach (i.e. qualitative and quantitative).

2.3.2 Mixed methods design

In order to conduct a well-designed mixed methods study, a researcher should pay attention to the mixed methods design. Several approaches to the design of mixed methods studies have been debated in the literature (Creswell and Plano Clark 2018). Teddlie and Tashakkori (2009) argued that due to the nature of mixed methods designs, it is difficult to have a complete typology of mixed methods approaches. However, according to Tariq and Woodman (2010), there are five main mixed methods designs: the convergent design (quantitative and qualitative studies conducted at the same time and then mixed at discussion); the explanatory sequential design (a qualitative study is conducted after a quantitative study to justify and explain the quantitative study's findings); the exploratory sequential design (a quantitative approach follows a qualitative method to quantify its findings); the embedded design (a small qualitative part is embedded in a larger quantitative study or vice versa); and the mixed methods systematic review design (a systematic review containing the two data types). Creswell and Plano Clark (2018) came up with the same typology, but replaced the "mixed methods systematic review" design with the "multiphase design". A few years later, Creswell and Plano Clark changed their typology of mixed methods designs to include only three core designs: explanatory sequential, exploratory sequential, and convergent (2018).

There are many reasons why researchers combine quantitative and qualitative studies together. Greene et al. (1989) argued that there are five main purposes of combining both quantitative and qualitative approaches, namely triangulation, complementarity, development, initiation, and expansion. It is possible for a mixed methods study to have more than one of the five purposes mentioned above.

2.3.3 Points of integration

The point at which qualitative and quantitative data are brought together is called the “point of integration” (Schoonenboom and Johnson 2017). Each mixed methods study should have at least one point of integration (Schoonenboom and Johnson 2017). An integration point has been defined as any point of the study in which a researcher is combining or connecting two or more research components together (i.e. qualitative and quantitative, Guest 2012; Schoonenboom and Johnson 2017). Feters and colleagues (2013) reported that integration in mixed methods research occurs at three levels. First, integration can occur at the study design level (the conceptualization of the study) in which the initial component findings for a project are used to design or to drive changes in the data collection for the other project, such as “instrument development”. Second, integration can occur at the methods and analysis level via linking the methods of data collection and analysis. This can happen in several ways: connecting (interviewing participants who already completed a survey), building (using the results of one study to inform the data collection approach of the other), merging (bringing the two data sets together, analysing them, and then merging) and embedding (integration occurs if the analysis and data collection are linked at several points). Third, integration can occur at the interpretation level, when the researcher describes the qualitative and quantitative findings in reports; it can also occur via data transformation and via joint display (drawing out new insights, which cannot be obtained by conducting separate analysis in which the two data sets are brought together using a visual means, such as figures).

2.4 Qualitative research

Qualitative research is a type of social research that is designed to deal with non-numerical data. The aim of this type of research is to study and understand people’s opinions in their natural social setting (Bowling 2009). The focus of qualitative research is on words rather than numbers, through observation, interviews, and analysis of records and documents (Bowling 2009), as discussed further in section 2.6.

2.4.1 Qualitative interviewing

The qualitative interview is considered the most common data collection tool used in qualitative research (Jamshed 2014). It depends on an interaction between an interviewer and a respondent in which certain questions are prepared in advance to be asked (Babbie 2014). The interviewer uses a topic guide which contains the prepared questions, which may or may not be required to be asked using a specific order or wording (Ryan et al. 2009; Babbie 2014). There are three main types of interview: structured, semi-structured, and in-depth (unstructured) interviews (Britten 1995). However, structured interviews are not used in conducting qualitative research (Bolderston 2012). These types vary in respect of the nature and number of prepared questions to be asked (Britten 1995). In a structured interview, the researcher uses a topic guide that contains specific questions associated with certain responses from which participants should choose (Ryan et al. 2009). Unlike structured interviews, in-depth interviews may only cover one or two main questions (Gilbert 2001). This type of interview is used when the researchers are unfamiliar with the topic of interest or have little knowledge about it (Ryan et al. 2009). A semi-structured interview is more flexible than a structured interview, as the researcher can ask open-ended questions and does not have to follow a specific sequence of questions or wording (Tod 2006). Also, interviewers can adapt the topic guide, ask probing questions and investigate emerging issues (Gilbert 2001; Tod 2006).

2.4.1.1 Focus groups, group interviews and individual interviews

There are three main ways for conducting an interview in qualitative research: focus groups, group interviews, and individual interviews. In focus groups and group interviews, a researcher gathers a group of people to collect their opinions regarding a topic of interest (Arthur et al. 2012). Focus groups have been defined by Morgan as a research technique that aims to gather data generated via discussion and interaction between several participants on a certain topic determined by the researcher (1997), whereas in group interviews, the discussion occurs mainly between the interviewer and each participant in the group (Arthur et al. 2012). The main distinction between focus groups and group interviews is the interaction within the group: that is, between

participants (Arthur et al. 2012). Unlike group interviews, the group opinion is important in focus groups, and discussion can proceed without high involvement from the researcher (Arthur et al. 2012). In an individual interview, a one-to-one discussion is conducted with a single participant to collect data about that participant's attitudes, behaviour, perspectives, beliefs and knowledge on a topic of interest (Lambert and Loiselle 2008). An individual interview can be conducted in person (face-to-face) or using technology (telephone and internet-based method such as Skype) (Holt 2010; Lo Iacono et al. 2016). Internet-based methods will be discussed in more detail in section 2.4.1.2.

Morgan (1997), in his book *Focus Groups as a Qualitative Research*, claimed that the most advantageous feature of focus groups over individual interviews is that they allow participants to interact with each other and to have more control over the discussion. This would enhance the dynamics of the interviews by allowing the free-flowing discussion to occur. This might be also considered a disadvantage in conducting interviews that require more control from the moderator, such as structured interviews. Also, focus groups are much harder to control, especially with a large group and participants who are highly involved with the topic. Morgan goes on to argue that the amount of information obtained from participants varies based on the type of interview: whether they are focus groups or individual interviews. Individual interviews allow the collection of more information from participants, since each participant would have enough time to express their opinions. However, if participants are not familiar with the topic, focus groups will generate a much greater depth of information. The same thing applies when the investigators are not familiar with the topic of interest: focus groups would produce better data. However, focus groups might be inappropriate for discussing sensitive topics.

2.4.1.2 Face-to-face, telephone, and internet video-based interviews

Face-to-face and online video-based interviews enable researchers to capture participants' nonverbal communication, which is not possible with telephone interviews (Holt 2010; Lo Iacono et al. 2016). In comparison to face-to-face interviews, a telephone interview is more convenient in terms of the availability of potential participants (Holt

2010). Face-to-face interviews require the physical presence of the researcher and participant, whereas that is not required in online video-based and telephone interviews. Therefore, it is considered less expensive and more convenient to conduct interviews via technology (Lo Iacono et al. 2016). Ethical considerations in online video-based interviews are the same as in face-to-face interviews (Janghorban et al. 2014). Consent could be received online, via email, or by posting the consent forms to all participants. Furthermore, online interviews could be recorded using software that supports this feature, allowing researcher to revisit the interviews when needed (Janghorban et al. 2014). However, interviews conducted using the internet would perhaps need additional arrangements, such as software, access to the internet, and digital literacy (Janghorban et al. 2014; Lo Iacono et al. 2016).

2.5 Quantitative research

Quantitative methods are commonly used due to their ability to measure outcomes in the form of numbers (Lakshman et al. 2000). In such research, causal relationships between independent variables and dependent variables (outcome of interest) can be investigated using true experiments or by studying associations through statistical analysis (Lakshman et al. 2000), as discussed further in section 2.6.

2.5.1 Questionnaires

Questionnaires are widely used by researchers to predict an outcome or to study people's attitudes, values and behaviour in a way that can be expressed numerically (Gilbert 2001; Creswell 2014). This approach enables researchers to investigate a certain topic by collecting information from a specific target population using face-to-face, telephone, electronic, or postal questionnaires (Gilbert 2001; Jones et al. 2013). One of the crucial features of using a quantitative questionnaire study is the ability to generalize the findings. Since it is difficult to study the whole population, the result of studying a sample of a specified population could be generalized to the whole of this population (Creswell 2014). Jones and colleagues (2013) discussed the advantages and disadvantages of each survey method. Although face-to-face and telephone

questionnaires allow clarification, they are more strongly associated with bias introduced by the researcher. They also consume a lot of time and resources in comparison to the other two methods (i.e. postal and online questionnaires). Postal and electronic questionnaires could be distributed to a larger population compared to the other two methods; however, they usually have low response rates (Gilbert 2001; Jones et al. 2013). Conversely, Hardigan et al. (2016) claimed that the postal questionnaire generated the highest response rate in comparison to other data collection means. Furthermore, postal and electronic surveys are more closely associated with response bias. Visual aids could be used in face-to-face, electronic and postal questionnaires, but not in a telephone survey. One of the advantages of electronic surveys over all other methods is time for data compilation. In an electronic survey, responses could be submitted and loaded into statistical software very quickly (McDonald and Adam 2003; Jones et al. 2013).

Postal questionnaire surveys have been commonly conducted to investigate the views of large populations (Gilbert 2001). This is an inexpensive data gathering tool that can provide researchers with information at participants' convenience (Gilbert 2001). A postal questionnaire is also considered the option of choice when it is difficult to conduct individual interviews (Dillman 1978).

2.5.2 Cross-sectional studies

Cross-sectional studies are defined as observation of participants or phenomena at a certain point in time (Babbie 2014). The purpose of conducting a cross-sectional study is usually to estimate the prevalence of a desirable outcome (Levin 2006). It has been widely used in exploratory and descriptive studies in which information is collected about participants, such as demographic information, and about outcomes of interest (Babbie 2014). Thus, it gives a snapshot of the outcome of interest considering associated independent variables at a given point in time (Levin 2006).

2.6 Differences between quantitative and qualitative research

Quantitative and qualitative research methods are widely used in social research. They differ significantly in terms of conceptualisation and methodology (Minichiello 1990). Qualitative research focuses on understanding participants' experience and behaviour, whereas in quantitative research, the focus is on collecting facts (in the form of numbers) on participants' behaviour (Minichiello 1990; Bogdan et al. 1998). In qualitative research, themes are usually used as a result of data analysis, whilst in quantitative research data are commonly analysed numerically and using statistical inference (Minichiello 1990). Researchers who conduct qualitative research usually use an inductive approach in which they depend on observation of the field to develop a hypothesis (Krathwohl 1998). Conversely, those who conduct quantitative research usually follow a deductive approach in which they test a hypothesis generated by reviewing the literature (Castellan 2010). Researchers in qualitative research are trying to understand the meanings of participants' responses (Shulman 1986), whereas quantitative research mainly attempts to determine causality (Palinkas 2014). Qualitative research could provide more in-depth understanding of the phenomenon by asking narrative questions (e.g. why and how) which might be difficult to handle in quantitative research (VanderStoep and Johnson 2009). Further, the sample size in qualitative research is usually small and participants are usually chosen purposefully (Luborsky and Rubinstein 1995; Sandelowsk 1996), while samples are often larger and randomly selected in quantitative research (Jurs 1998). Finally, the trustworthiness of qualitative research could be established by assessing credibility (instead of internal validity), transferability (instead of external validity), dependability (instead of reliability), and confirmability (instead of objectivity, Guba 1986). Further discussion on approaches used to establish trustworthiness will be provided within each project.

The characteristics of quantitative and qualitative methodology and their appropriateness in conducting social research are controversial (Bryman 1984). This is mainly attributed to the difference in the epistemology of each methodology. The positivist paradigm, which is sometimes called "scientific research" is more strongly associated with quantitative research, while an interpretivist/constructivist paradigm is

more likely to be aligned with qualitative research (Mackenzie and Knipe 2006). These paradigms were discussed in more detail in section 2.2. Choosing a specific epistemological framework would lead researchers to prefer one method over another (Bryman 1984). Thus, looking at the issue from a certain epistemological framework would impact how issues are investigated and analysed in social science. More importantly, it has been argued that qualitative and quantitative approaches have incompatible paradigms (Dures et al. 2010), and that therefore, it might be difficult to mix the two approaches together. However, a mixed methods approach is used in social science and was the preferred methodology in answering the research question in the present thesis.

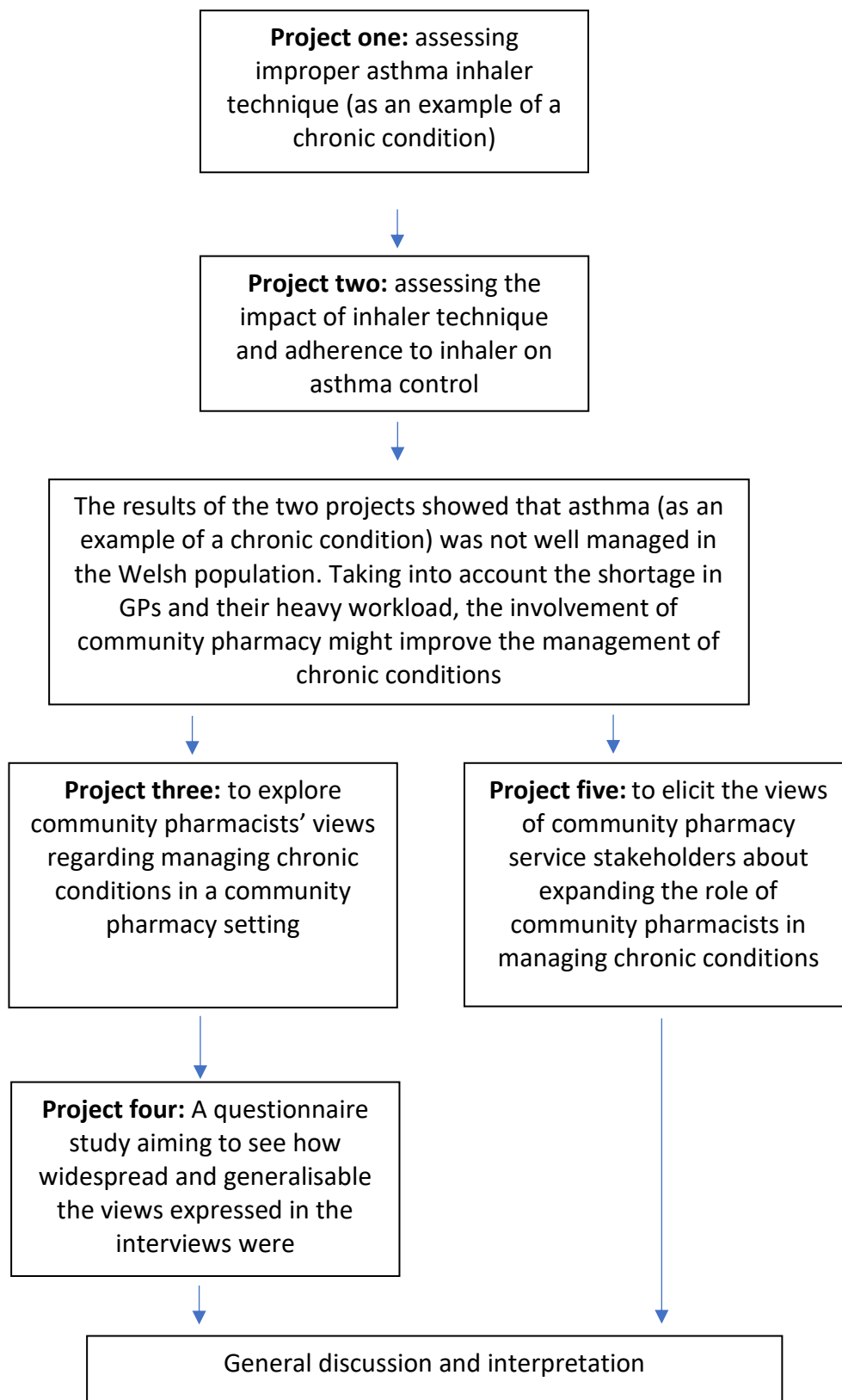
2.7 A case of a mixed methods study in community pharmacy setting

Considering the advantages of using the mixed methods approach, it was the most appropriate methodology to answer the thesis question. Since the thesis presented here is focusing on the management of asthma and factors influencing the involvement of community pharmacists in such management, it was of fundamental importance to use more than one methodology to properly answer the research question. That was because there was a need to study how effective asthma control is, to generalize the findings of a qualitative project (e.g. a questionnaire following a qualitative component) and finally to better understand the topic by conducting qualitative projects. Therefore, applying a mixed methods approach would allow the use of different research methods, data collection tools and forms of analysis.

Throughout the thesis, three quantitative and two qualitative projects have been conducted. The first set out to investigate the prevalence of improper inhaler technique (as an example of chronic conditions management): see Chapter 3. The second project was a quantitative study to investigate how well asthma was managed by assessing asthma control, adherence to inhalers and inhaler technique: see Chapter 4. The nature of the first two projects helped in assessing how well asthma was managed in current practice. The third project was a qualitative study which aimed to explore community pharmacists' views regarding managing chronic conditions in a community pharmacy

setting: see Chapter 5. The fourth was a questionnaire that aimed to generalize findings generated from the previous qualitative project (i.e. project 3): see Chapter 6 for more detail. The last study was a qualitative study aiming to understand the future of community pharmacy in managing chronic conditions from the perspective of the stakeholders of Welsh community pharmacy services: see Chapter 7. The two qualitative projects helped in providing in-depth understanding of how community pharmacy could be more involved in managing chronic conditions.

A mixed methods approach was chosen because neither qualitative nor quantitative methods alone can adequately answer the research question. When it was identified that asthma as was not well managed in the Welsh population (via conducting two quantitative studies), it became necessary to understand how community pharmacy could be more involved in managing people with chronic conditions. To better understand how community pharmacies could be more engaged in managing chronic conditions, qualitative interviews were conducted with community pharmacists and stakeholders of community pharmacy services in Wales. Since the findings of a qualitative study are usually not representative of the whole population, it was necessary to test these findings on a large scale among community pharmacists via conducting a postal questionnaire study distributed to all community pharmacies in Wales: see Flowchart 2.1.



Flowchart 2.1: A mixed methods approach.

The work presented in this thesis is taken from a pragmatic point of view in which the researcher could pursue objective and subjective information (facts and perspectives). Deductive and inductive reasoning were used to generate and test hypotheses. A multiphase mixed methods design was used, since more than one mixed methods design was conducted (Schoonenboom and Johnson 2017). The integration between the qualitative and quantitative approaches occurred at multiple points across three different levels (study design, methods and analysis, interpretation levels). Different data collection tools were applied to gather quantitative and qualitative data as follows:

Project 1 (quantitative study): a questionnaire was used to collect patient information and the results of inhaler technique.

Project 2 (quantitative study): three questionnaires were used to collect patient information and the results of inhaler technique, asthma control, and adherence to inhalers.

Project 3 (qualitative study): individual face-to-face interviews were conducted to gather qualitative data.

Project 4 (quantitative study): a questionnaire was designed based on the findings of project three. It was sequentially dependent, where the data investigated in this project were mainly dependent on project three (QUAL \longrightarrow quan, Schoonenboom and Johnson 2017). The questionnaire was primarily designed to collect quantitative data; however, one qualitative question was embedded.

Project 5 (qualitative study): individual face-to-face and telephone interviews were conducted to collect qualitative data.

2.8 Reflexivity in qualitative research

Reflexivity was commonly used interchangeably with other concepts, such as reflectivity and critical reflection (Berger 2013). It was viewed as:

...turning of the researcher lens back onto oneself to recognize and take responsibility for one's own situatedness within the research and the effect that it may have on the setting and people being studied, questions being asked, data being collected and its interpretation. (Berger 2013)

Reflexivity has a very important impact on qualitative research (Berger 2013). It has been recognised as a crucial strategy in conducting qualitative research (Ahmed et al. 2010). It can be affected by the researcher's level of knowledge and involvement in the researched topic (Berger 2013).

2.8.1 The researcher's personal experience

It is important to talk about my previous experience in the area of research and how that might influence the work presented. I graduated from a clinical pharmacy college in Saudi Arabia, and then got a master's degree in pharmacy administration from an American pharmacy school. My previous work experience was as a faculty member in a Saudi pharmacy school. I have not worked as a community pharmacist before, but I am familiar with the community pharmacy setting in Saudi Arabia, since I completed a training course during my Pharm.D. degree. As an international student doing a PhD in the UK, I was not familiar with the UK health system and community pharmacy setting prior to starting my PhD. However, the Saudi community pharmacy setting has some similarities to the Welsh setting. Both have a limited role in managing chronic conditions and both focus on dispensing. During the first project, which aimed to assess patient inhaler technique, I met several community pharmacists across Wales and discussed various issues about community pharmacy. I had the opportunity to see how pharmacists performed their daily tasks in a community setting. I was exposed to the environment of community pharmacy and the staff involved. I have been in a variety of consultation rooms and sometimes in kitchens because there was no place to sit. I dealt with the pharmacy system in order to recruit participants for my first project. As a result, my understanding of the Welsh health system and the community pharmacy setting was greatly increased.

Prior to conducting the qualitative projects, I enrolled in several workshops about using qualitative approaches, conducting interviews, and analyses. I also enrolled in an NVivo workshop to enhance my skills in handling and analysing qualitative data using NVivo software. In addition, I read relevant primary and secondary sources to expand my understanding of the qualitative approach and the topic of research. Continuous discussion with my supervisory team also had a great impact in keeping me on the right track and in giving me advice on what should I do or avoid when conducting a qualitative project, especially in terms of constructing the topic guides, conducting interviews, and performing the analysis. During the study design phase of the qualitative project, the stakeholders were also involved in designing the topic guide. Their feedback allowed me to design a more valid and reliable guide. Since the subjectivity of the researcher is intimately involved in qualitative studies, themes and interviews were reviewed by the supervisory team to make sure that the emergent themes truly reflected what participants had said. The emergent themes of the qualitative project were also discussed with an experienced community pharmacist who took part in the study to ensure that all relevant themes were identified. The discussion between the researcher and the experienced pharmacists took place after analysing all interviews and generating the themes. The reason for doing this was to make sure that all themes related to the topic were ideally identified and defined.

Although I tried my best to be as objective as I could when conducting the qualitative projects, the research presented in this thesis will undoubtedly have been impacted by my previous experience, perceptions, and beliefs on the community pharmacy setting. This may influence the studies in respect to asking probing questions and identifying themes within the qualitative data sets. For example, when I was conducting the asthma project in community pharmacies, I started to compare the Welsh and Saudi community pharmacy settings. Even though the community pharmacists in Saudi Arabia have a heavy workload, community pharmacists in Wales are involved in providing more healthcare services for patients. Moreover, my personal experience with the community pharmacy setting might also impact the interpretation of the qualitative data sets (for more details on my personal experience, see section 8.7.1).

Personal reflection on managing chronic conditions, conducting and dealing with qualitative research, participants, and questionnaire dissemination will be discussed thoroughly in section 8.7.

2.9 Summary

In order to have a deep understanding of managing chronic conditions in community pharmacy settings, a mixed methods approach was conducted to better conceptualize the topic of interest. The flexibility of the mixed methods approach allows the application of multiple paradigms, methodologies, data collection tools and analysis. Therefore, it provides more comprehensive information, allowing the whole picture of the topic to be seen, which could not be achieved by applying either a qualitative or a quantitative approach in isolation.

Chapter 3 – Assessing inhaler techniques of asthma patients using Aerosol Inhalation Monitors (AIM): A cross-sectional study

3.1 INTRODUCTION

This chapter presents the findings of a quantitative study to assess the prevalence of improper inhaler technique and potential factors affecting inhaler technique. This study was accepted and published as a poster titled 'Assessing Inhaler Techniques of Asthma Patients Using Aerosol Inhalation Monitors (AIM): A Cross-Sectional Study' presented to the Health Services Research and Pharmacy Practice Conference in 2019. A copy of the poster is provided in Appendix 3.1.

Several studies have demonstrated the importance of inhaler technique and patient adherence in improving asthma outcomes (Blaise et al. 1998; Giraud and Roche 2002). Health care providers should check patients' inhaler technique and adherence prior to prescribing add-on therapies (British Thoracic Society 2019). Previous studies have reported that a high percentage of people with asthma are not well controlled (Giraud and Roche 2002; Molimard 2003; Press et al. 2012; Price et al. 2014). Part of this problem is because patients are not fully aware of the appropriate use of asthma medications (Giraud and Roche 2002; Molimard 2003). Moreover, around 90% of physicians dealing with asthma claimed that participation in studies to assess the handling of inhalers helped them to identify errors in inhaler technique (Molimard 2003). Approximately 28% to 68% of patients who use metered-dose inhalers (pMDI) or dry powder inhalers (DPI) are using their inhalers incorrectly (Fink and Rubin 2005). Poor inhaler technique means that patients may not be receiving a therapeutic dose, adversely affecting their quality of life and increasing the risk of morbidity and mortality (Giraud and Roche 2002; Fink and Rubin 2005). From this perspective, paying more attention to educating patients about the best way to take asthma medications may lead to a substantial improvement in terms of patient wellbeing and reduced NHS expenditure (Fink and Rubin 2005).

Asthma control might be affected by a number of factors. These are factors related to patients (e.g. not being adherent to an inhaler), factors related to healthcare providers (e.g. not showing patients the proper inhaler technique), and factors related to inhaler devices (e.g. intrinsic resistance and inspiratory flow rate needed). One of the factors

that could greatly affect asthma control is inhaler technique. Studies have shown that the majority of asthma patients were not using their inhaler devices properly (Giraud and Roche 2002; Molimard 2003; Fink and Rubin 2005; Chrystyn et al. 2017). The findings of these studies were widely varied in terms of improper inhaler technique across inhaler devices. That might be attributed to subjectivity of inhaler technique assessments and lack of objective measurements. Thus, use of an objective quantitative assessment tool would allow a more accurate assessment of the quality of patients' inhaler technique across three types of inhaler device: pMDI, pMDI+spacer, and DPI. The pMDI delivers a certain amount of medicine from a pressurized canister and requires coordination between the start of inhalation and actuation of the device (Richter 2004). Whereas DPI does not need coordination since it delivers the medicine in a powder form (Richter 2004). Creating an optimal fine particle fraction resulting from producing adequate inspiratory flow rate is important for successful DPI use (Richter 2004). Spacers are used with pMDI providing better drug deposition into the lung and reducing side effects (Prokopovich 2013). Other factors that are related to the patient and impact the level of asthma control include smoking and age. Studies have shown that smoking and being older negatively affect the respiratory system and asthma outcomes (Flodin et al. 1995; Hanania et al. 2011). Furthermore, the ability to learn proper inhaler techniques has been found to be affected by age. Older people are found to be unable to learn the correct inhaler technique despite having normal abbreviated mental test scores (a test that assesses cognitive status of elderly patients, Allen and Ragab 2002).

The Aerosol Inhalation Monitor (AIM, Vitalograph, UK) is one such device. It is an interactive tool that enables healthcare providers to objectively assess patient inhaler technique. The AIM can classify patient inhaler technique across all three inhaler device types mentioned above into three categories (good, suboptimal, and poor) based on specific parameters. Components of the AIM device are described in Figures 3.1 and 3.2. It measures four essential components of good inhaler technique, which are: correct canister activation, inspiratory flow rate, breath hold time, and inhalation time (Carpenter et al. 2017). When patients use the AIM device, they will be shown an estimation of where the drug is deposited in their lungs (Figure 3.3). The quality of the technique is assessed as predicted pulmonary drug deposition based on the aspects of

good inhaler technique mentioned above (Figure 3.4). The categories of good, suboptimal, and poor are defined as drug deposition in the small airways, large airways or oropharyngeal area, respectively (Vitalograph 2018).

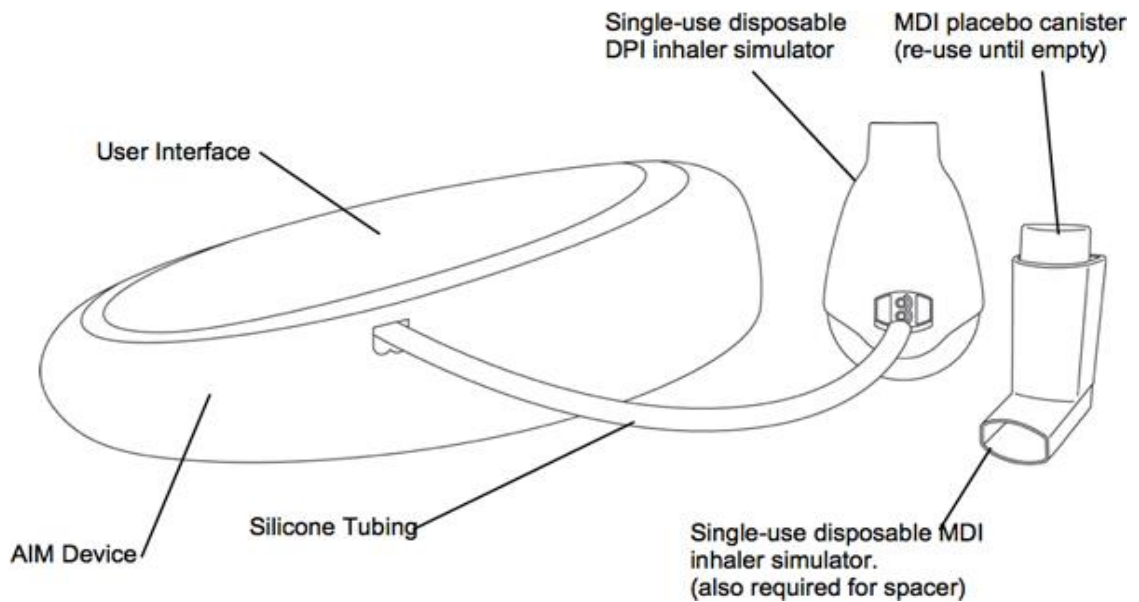


Figure 3.1: Components of AIM device. Retrieved from Vitalograph Website.

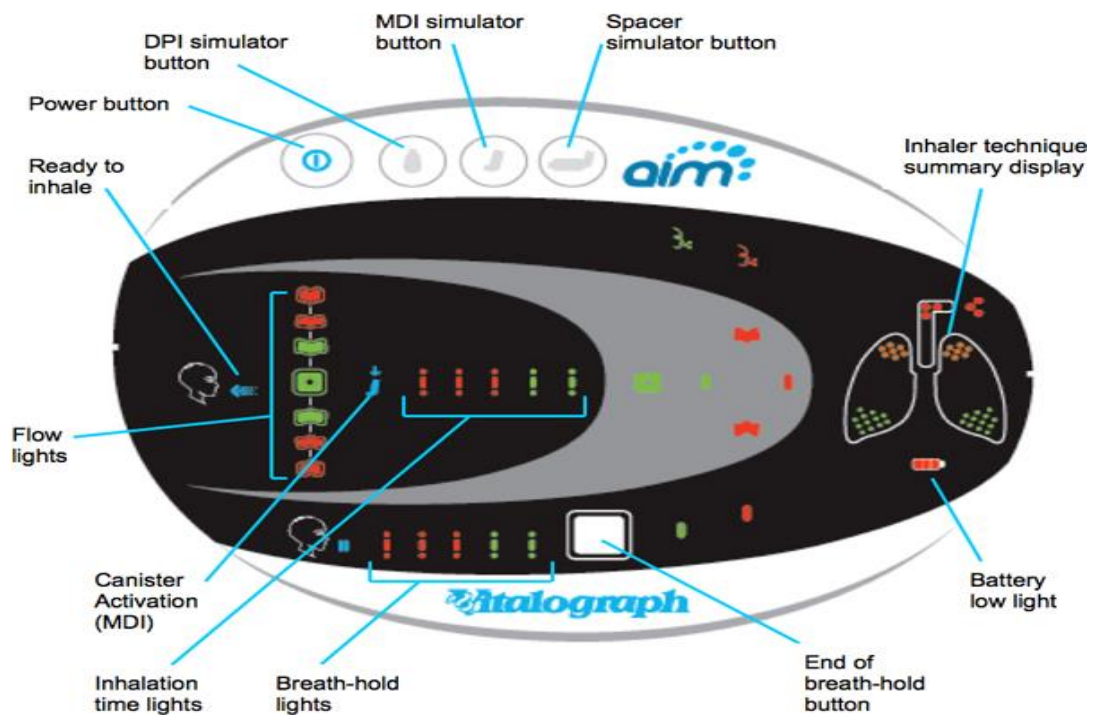


Figure 3.2: Components of AIM device. Retrieved from Vitalograph Website.

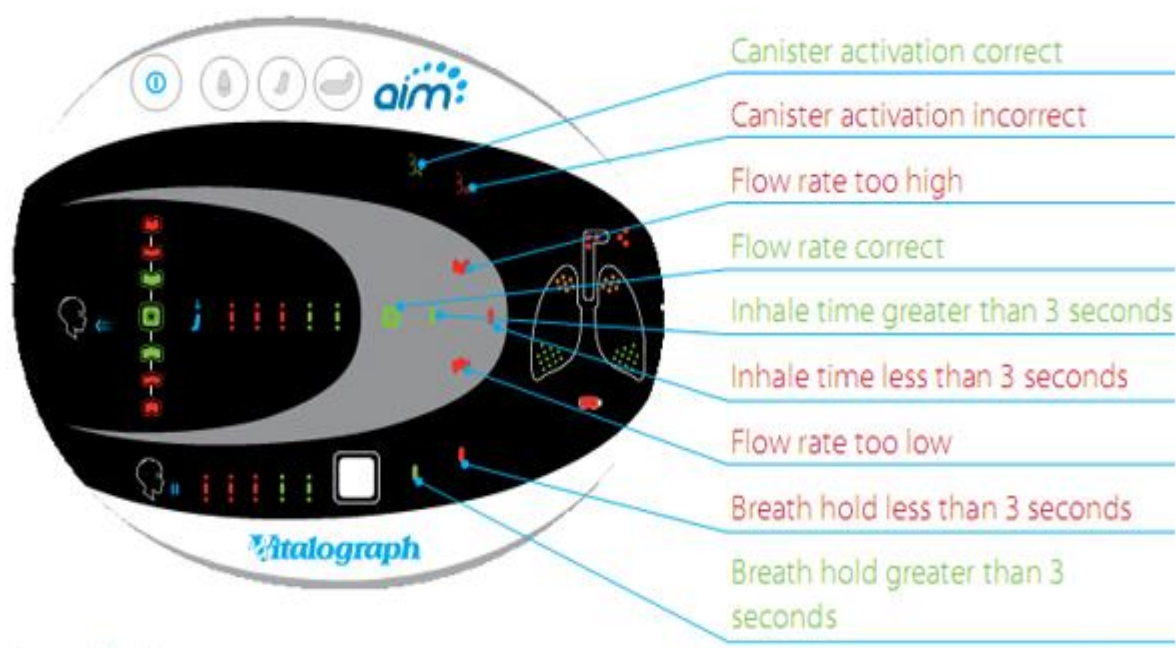


Figure 3.3: Result lights. Retrieved from Vitalograph Website

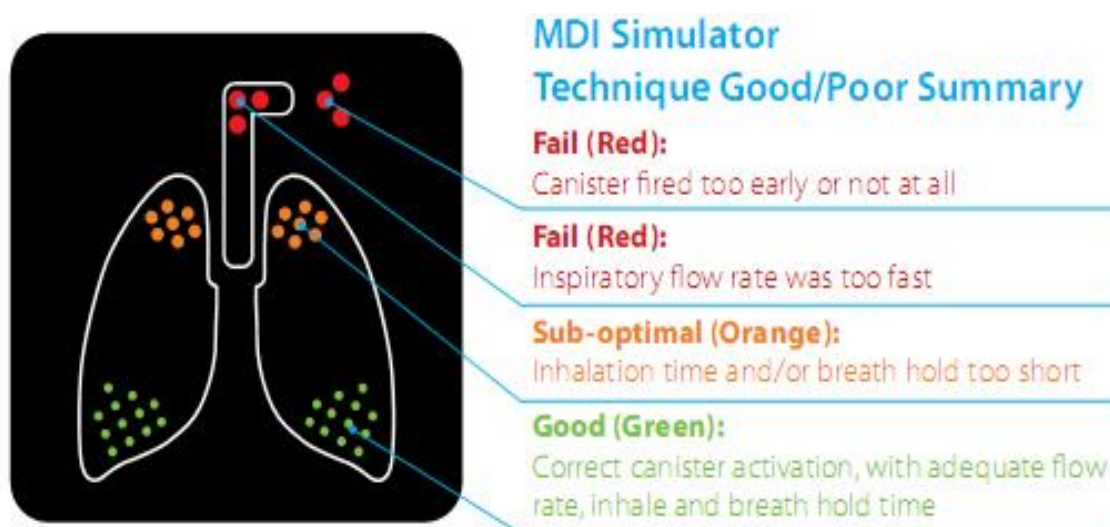


Figure 3.4: Summary of where drug deposits in patient's respiratory system. Retrieved from Vitalograph Website.

3.1.1 Aims and objectives

The aim of this study was to assess the prevalence of poor inhaler technique in an asthma patient population. The research had two objectives: first, to investigate how asthma patients handled inhalers across three different inhaler devices; and second, to assess the impact of various demographic parameters and smoking status on technique quality to try to identify any factors that might be associated with poor inhaler technique.

3.2 METHODS

3.2.1 Study design

Details on the design of this cross-sectional study were reported in Chapter 2 (section 2.5).

3.2.2 Ethical approval

This project was part of a large project that was approved by the Research Ethics Committee in Cardiff School of Pharmacy and Pharmaceutical Sciences. Ethical approval was granted for the study (see Appendix 3.2).

3.2.3 Sampling and recruitment

Eight community pharmacies in South Wales were chosen to recruit patients. The selected pharmacies were located in different geographic areas and differed in the socioeconomic status of the areas they served. Pharmacies were selected to try and ensure that the patient sample was as broad as possible. The selected pharmacies were located in Penarth, Newport (two pharmacies), Pontypool, Trevechin, Caerphilly, Cathays, and Blackwood. Any asthma patient older than 12 years could participate in the study. Convenience sampling was used to recruit patients (Etikan et al. 2016). This is a type of non-probability sampling in which participants are recruited based on availability and convenience (Etikan et al. 2016). Patients were invited to participate in the study in two ways. Firstly, they were invited at the time of dispensing of asthma medications in the pharmacies. Secondly, patients were identified from pharmacy databases and then contacted by phone. They were given a participant information sheet and asked to consent prior to taking part in the study (see Appendix 3.3 and 3.4).

3.2.4 Data collection

Data were collected in the selected community pharmacies by six students plus me. All students had attended training sessions conducted by the principal researcher and practised using the device prior to recruiting people with asthma. The AIM device

objectively assesses patient inhaler technique, and therefore it would not be impacted by the subjectivity of the assessors. I was actively involved in collecting data from five community pharmacies (the ones in Blackwood, Pontypool, Caerphilly, Penarth, and Newport). Data collection took place in the period from October 2016 to July 2018. The data collection was not active at all times within this period but was dependent on the availability of undergraduate students. Most data were collected in the period from October to December of 2016 and 2017. That was because undergraduate students were available to work on this project during this period. However, I was involved in data collection from the start of my PhD (i.e. in October 2017) until March 2018. Patients were interviewed in a quiet room (i.e. consultation room). After receiving the consent form, patient demographic/clinical information and inhaler technique results were collected using a standardised form (see Appendix 3.5). The form had three main sections: participant demographic information, clinical information (e.g. information about asthma and medications) and AIM result. Once the first two sections were completed by assessors, patients were asked to demonstrate their inhaler technique using the AIM device. Each participant was given a unique identification number based on the location of the community pharmacy.

3.2.5 Data handling

Data were collected using a standardized Excel spreadsheet. In order to maintain the security of patient identity, each participant's data was associated with a unique identification number. A separate secure database was maintained where the identification number was associated with the patient's name, address, and NHS number. All Excel files were stored securely in the database and protected by a password. All the students including myself had access to the database, so data could be uploaded/revisited. Excel spreadsheets (i.e. data from each community pharmacy) were combined in one Excel file by the researcher (MM). Entries in the combined file were checked for missing information and were checked and compared with the original files for accuracy. A standardized coding system was used to code all data. Age was collected as a continuous variable and then converted into a nominal variable, so that people in different age categories could be compared. Using several age categories led

to having small numbers of participants under many variables. For this reason, a cut-off point for age was used to overcome this problem. Therefore, participants were grouped into two categories (below 65 years, and 65 years and older). The age of 65 years was used as a cut-off point because the elderly population is defined as being 65 years or older (Orimo et al. 2006). The same procedure was applied for smoking status. Patients were grouped into two categories (smokers and non-smokers). Participants who were previously smokers were treated as non-smokers. Excel functions were used to organize data prior to exporting them into SPSS. When data were exported into SPSS, all entries were re-checked with the combined Excel file to assure accuracy.

3.2.6 Data analysis

Data analysis was carried out using IBM SPSS Statistics 25 software. Frequencies and descriptive statistics were calculated to get a general view on patient' demographic variables, smoking status, and AIM assessments across inhaler devices. All variables were treated as nominal variables except for the dependent variable (i.e. AIM assessments), which was treated as ordinal. Asthma patients were divided into three groups based on different types of inhaler (1=pMDI 2=pMDI+spacer, 3=DPI). Some patients used more than one type of inhaler device, so this analysis was performed based on the total number of AIM assessments that were carried out across inhaler devices. To be clearer, the AIM assessments were used as a unit of analysis. The outcome of each inhaler's technique assessment using the AIM device was coded into three categories (1=poor, 2=suboptimal, 3=good). A Chi-square statistical test was used to assess the association between inhaler devices and the quality of inhaler technique. It was also used to evaluate the association between independent variables and AIM assessments. Fisher's exact test was used instead of the Chi-square test when more than 20% of cells had expected values of less than five (Kim 2017).

As the Chi-square test did not identify which variable was statistically significant, a post hoc test was conducted to find statistical differences within the variables (Beasley and Schumacker 1995). The adjusted standardized residual value (i.e. Z score) associated with an alpha value of 0.05 is 1.96 (Hazra 2017). The Z scores were calculated using

contingency table analysis (Beasley and Schumacker 1995). A Z score of less than -1.96 or greater than 1.96 would be significantly different (Beasley and Schumacker 1995). However, the adjusted standardized residual values needed to be corrected, as there were nine cells being tested within the Chi-square test (i.e. three inhaler devices multiplied by the number of outcome levels, Beasley and Schumacker 1995). This would help to avoid making a Type 1 error (i.e. finding a significant difference when there is no actual significant difference, Beasley and Schumacker 1995; Lieberman and Cunningham 2009). To achieve this, the adjusted alpha was calculated using the equation provided by Beasley and Schumacker (1995). The new adjusted alpha was 0.0057. Any p-value less than this value would be considered to indicate a significant difference (Beasley and Schumacker 1995). As the adjusted standardized residual values were not associated with p-values, the p-values were computed via transforming the Z scores into chi-square values, and then the exact p-values were calculated (via the significance function) (Beasley and Schumacker 1995). Exact p-values less than the adjusted p-value (i.e. 0.0057) were considered to indicate a significant difference.

To assess the association between demographic variables and the quality of inhaler technique on the AIM device, the data were analysed using Multinomial Logistic Regression (MLR). Three MLR models were performed to obtain the odds ratios and associated p-values. The inhaler devices were stratified into three groups (pMDI, pMDI+spacer, DPI). Then, a univariate multinomial logistic regression was performed for each device. According to Hosmer and Lemeshow (2000), independent variables with a p-value of less than 0.25 should be considered in the multivariate model, in addition to those that are known to have a clinical impact on outcome factors. After considering the clinical impact of independent variables on the outcome factor and the results of the univariate MLR models (Table 3.6), all independent variables were included in the final model (multivariate MLR). A separate multivariate MLR model was applied for each different inhaler device (pMDI, pMDI+spacer, DPI) independently. This would not violate the assumption of the independency of observations, which was essential in order to have valid results after running the model. The other assumptions of MLR analysis were checked and there were no violations. By running a separate multivariate MLR model, it would be possible to study the association between independent variables (age, gender,

and smoking status) and the outcome (poor, suboptimal, and good) for all AIM assessment results. The adjusted odds ratios with a 95% confidence interval (95% CI) for independent variables were obtained to assess the relationship between independent and dependent variables. For all statistical tests, a p-value of 0.05 was considered to be statistically significant, and all statistical tests were two-tailed.

3.3 RESULTS

3.3.1 Sample characteristics

Two-hundred and twelve patients participated in the study between October 2016 and July 2018 (Table 3.1). Their ages ranged from 16 to 91 years ($m = 57.1$, $SD \pm 19.1$). Of those who participated in the study, 113 (53%) participants were female. The majority of participants were younger than 65 years ($n = 124$, 59%). Most of the participants were non-smokers ($n = 180$, 85%). The total number of inhaler technique assessments was 295. That is because 75 participants (35%) were using more than one type of inhaler device. In total, 174, 49, and 72 AIM assessments were carried out for pMDI, pMDI+spacer, and DPI, respectively (Table 3.2).

Participant demographic info. (n=212)		Frequency	Percent
Gender	Male	99	46.7
	Female	113	53.3
	Total	212	100.0
Age	Less than 65 years	124	58.5
	65 years and older	88	41.5
	Total	212	100.0
Smoking status	Non-smoker	180	84.9
	Smoker	32	15.1
	Total	212	100.0

Table 3.1: Participant demographic information and smoking status (n=212).

3.3.2 Evaluation of inhaler technique

There were significant differences in the quality of inhaler technique across the three inhaler types ($p < 0.05$, Chi-squared test). The best inhaler technique was associated with DPI simulators, for which 42 AIM assessments (58%) out of 72 were good, compared with pMDI simulators, for which 32 AIM assessments (18%) out of 174 were good, and pMDI+spacer simulators, for which 23 AIM assessments (47%) out of 49 were good (Table 3.2). The worst inhaler technique was associated with pMDI simulators, for which 102 AIM assessments (58%) out of 174 were poor, in comparison to pMDI+spacers, for which 12 AIM assessments (24%) out of 49 were poor, and DPI simulators, for which 7 AIM assessments (10%) out of 72 were poor (Table 3.2). Suboptimal inhaler technique was more frequently observed with DPI simulators, for which 23 AIM assessments (32%) were suboptimal, compared to 14 (28%) and 40 (23%) for AIM pMDI+spacer and AIM pMDI simulators, respectively (Table 3.2). The results of the post hoc test showed that four groups were statistically different. Good inhaler technique was more strongly associated with DPI simulators, which also had fewer poor results ($p < 0.0057$). Conversely, pMDI simulators were more strongly associated with poor inhaler technique and had fewer good results ($p < 0.0057$). No statistical differences were associated with using pMDI+spacers nor with suboptimal outcomes.

295 AIM assessments		AIM Result			Total
		Poor	Sub-Optimal	Good	
Inhaler Device	pMDI	102(58.6%)	40(23%)	32(18.4%)	174
	pMDI+spacer	12(24.5%)	14(28.5)	23 (47%)	49
	DPI	7(9.7%)	23(32%)	42(58.3%)	72
Total		121	77	97	295

Table 3.2: Inhaler device * AIM result cross tabulation (295 AIM assessments). P-value is < 0.05

3.3.3 The impact of demographic variables and smoking status on inhaler technique

There was a potential association between gender and quality of pMDI technique ($p < 0.08$, Chi-squared test). No other associations were found between gender and other inhaler devices. Age was significantly associated with the quality of technique for

patients using pMDI+spacer ($p < 0.02$, Fisher's exact test). The relationship between age and quality of inhaler technique will be described later using the MLR analysis. For the other devices (DPI and pMDI), no relationship was found between age and quality of inhaler technique (Tables 3.3, 3.4 and 3.5). The probability of having good, suboptimal, or poor inhaler technique significantly varied based on independent variables, as determined by the adjusted odds ratios (AOR). For pMDI simulators, men were 2.6 times more likely to have good technique compared to women (AOR 2.6, 95% CI: 1.121-6.111; $p < 0.05$: see Table 3.6). For pMDI+spacer simulators, participants younger than 65 years were less likely to have suboptimal results (AOR 0.024, 95% CI: 0.002-0.331; $p < 0.05$: see Table 3.6). Men were also less likely to have a suboptimal technique with pMDI+spacer devices in comparison to women (AOR 0.097, 95% CI: 0.011-0.870; $p < 0.05$: see Table 3.6). There was no potential association between smoking status and quality of inhaler technique. For DPI simulators, no relationship was found between performance on AIM device and independent variables (Table 3.6).

N=174 AIM assessments					
Variable		pMDI Inhaler Device			P-value
		Poor (Freq/%)	Suboptimal (Freq/%)	Good (Freq/%)	
Age	Less than 65 years	65 (37.4%)	20 (11.5%)	22 (12.6%)	0.206
	65 years and older	37 (21.3%)	20 (11.5%)	10 (5.7%)	
Gender	Male	45 (25.9%)	17 (9.8%)	21 (12.1%)	0.079
	Female	57 (32.8)	23 (13.2%)	11 (6.3%)	
Smoking	Non-smoker	90 (51.7%)	32 (18.4%)	25 (14.4%)	0.260
	Smoker	12 (6.9%)	8 (4.6%)	7 (4%)	

Table 3.3: Relationship between AIM pMDI simulators and demographic variables (n=174).

N=49 AIM assessments					
Variable		pMDI+spacer Inhaler Device			P-value
		Poor (Freq/%)	Suboptimal (Freq/%)	Good (Freq/%)	
Age	Less than 65 years	10 (20.4%)	4 (8.2%)	13 (26.5%)	0.019*
	65 years and older	2 (4.1%)	10 (20.4%)	10 (20.4%)	
Gender	Male	6 (12.2%)	4 (8.2%)	14 (28.6%)	0.199
	Female	6 (12.2%)	10 (20.4%)	9 (18.4%)	
Smoking	Non-smoker	8 (16.3%)	12 (24.5%)	20 (40.8%)	0.313
	Smoker	4 (8.2%)	2 (4.1%)	3 (6.1%)	

Table 3.4: Relationship between AIM pMDI+spacer simulators and demographic variables (n=49)

N=72 AIM assessments					
Variable		DPI Inhaler Device			P-value
		Poor (Freq/%)	Suboptimal (Freq/%)	Good (Freq/%)	
Age	Less than 65 years	3 (4.2%)	9 (12.5%)	18 (25%)	0.938
	65 years and older	4 (5.6%)	14 (19.4%)	24 (33.3%)	
Gender	Male	3 (4.2%)	10 (13.9%)	21 (29.2%)	0.939
	Female	4 (5.6%)	13 (18.1%)	21 (29.2%)	
Smoking	Non-smoker	6 (8.3%)	22 (30.6%)	35 (48.6%)	0.354
	Smoker	1 (1.4%)	1 (1.4%)	7 (9.7%)	

Table 3.5: Relationship between AIM DPI simulators and demographic variables (n=72).

AIM assessment	Variable	Unadjusted OR [95%CI]	Adjusted OR [95%CI]
pMDI (suboptimal)	Sex (ref=women) Men	0.93 [0.44-1.96]	0.84 [0.39-1.80]
	Age (ref=65 years and older) Less than 65 years	0.56 [0.27-1.19]**	0.48 [0.22-1.06]
	Smoking Status (ref=smoker) Non-smoker	0.53 [0.20-1.42]**	0.43 [0.15-1.20]
pMDI (good)	Sex (ref=women) Men	2.41 [1.05-5.53]**	2.61 [1.12-6.11]*
	Age (ref=65 years and older) Less than 65 years	1.25 [0.53-2.92]	1.33 [0.55-3.24]
	Smoking Status (ref=smoker) Non-smoker	0.47 [0.17-1.33]**	0.46 [0.16-1.34]
pMDI+spacer (suboptimal)	Sex (ref=women) Men	0.40 [0.07-2.02]	0.09 [0.01-0.87]*
	Age (ref=65 years and older) Less than 65 years	0.08 [0.01-0.54]**	0.02 [0.002-0.331]*
	Smoking Status (ref=smoker) Non-smoker	3.00 [0.44-20.43]	0.68 [0.06- 7.71]
pMDI+spacer (good)	Sex (ref=women) Men	1.55 [0.38-6.35]	0.95 [0.19- 4.58]
	Age (ref=65 years and older) Less than 65 years	0.26 [0.04-1.46]**	0.32 [0.04- 2.28]
	Smoking Status (ref=smoker) Non-smoker	3.33 [0.60-18.37]**	2.22 [0.36- 13.55]
DPI (suboptimal)	Sex (ref=women) Men	1.02 [0.18-5.66]	1.01 [0.17-5.91]
	Age (ref=65 years and older) Less than 65 years	0.85 [0.15-4.76]	1.02 [0.16-6.50]
	Smoking Status (ref=smoker) Non-smoker	3.66 [0.19-67.65]	3.71 [0.18- 76.00]
DPI (good)	Sex (ref=women) Men	1.33 [0.26-6.70]	1.35 [0.25-7.14]
	Age (ref=65 years and older) Less than 65 years	1.00 [0.19-5.03]	1.03 [0.17- 5.98]
	Smoking Status (ref=smoker) Non-smoker	0.83 [0.08-8.04]	0.83 [0.07-9.08]

Table 3.6: Adjusted and unadjusted odds ratios table and corresponding confidence intervals.

*P-value<0.05, **p-value< 0.25

3.4 DISCUSSION

Studies have shown that the majority of asthma patients are not using their inhaler devices properly (Giraud and Roche 2002; Molimard 2003; Fink and Rubin 2005; Chrystyn et al. 2017). In these studies, there was a wide variation in the percentage of patients who had improper inhaler technique. Inhaler technique was generally assessed

by observation rather than empirical measurement in those studies and thus it is hard to estimate inspiratory flow rates and timing of activation by simple observation. Thus, there was a need to assess patients' inhaler techniques via an objective quantitative assessment tool. Therefore, an AIM device was used to assess the prevalence of improper inhaler technique in people with asthma. To the best of my knowledge, this study is the first to assess patients' inhaler technique and the impacts of demographic variables across all types of inhaler device using an objective quantitative assessment tool.

After assessing patients' inhaler technique, it seemed that the majority of asthma patients were not using their inhalers appropriately. Sixty-seven percent of participants in the cohort had poor or suboptimal inhaler technique as assessed by an AIM device across the three inhaler devices. This is really an alarming percentage, since the inhaler technique is essential in getting the most out of inhaled medications (Giraud and Roche 2002; Fink and Rubin 2005). Participants were more likely to use the DPI device appropriately in comparison to the pMDI+spacer and pMDI devices. The same finding was also observed elsewhere (Molimard et al. 2003). Although the best inhaler technique was associated with DPI devices, there are some circumstances in which using DPI is not advisable, such as in patients who are unable to produce sufficient inspiratory flow, such as children or some elderly people (Haughney et al. 2010). Furthermore, some adult asthma patients face difficulty in using DPI devices during an asthma attack. That is because DPI devices need a fast inhalation rate compared to the other two device types (Fink and Rubin 2005). Therefore, using DPI as the only inhaler device for managing all groups of asthma patients cannot be recommended. Prescribers may consider checking patients' inhaler techniques prior to dispensing inhalers and also considering patients' preferences. By doing that, it would be more likely that the dispensed inhaler would fit the patient's ability to generate adequate inspiratory flow. This could be done by using training devices (e.g. AIM and In-Check Dial devices) to assure that patients could use their inhalers properly.

This study showed that the probability of using pMDI properly was greater in men in comparison to women. Chorão and colleagues (2014), in their cross-sectional

observational study, also found that females were more likely than males to incorrectly use a specific type of pMDI inhaler device. Even though the relationship between gender and pMDI usage in the present study was not significantly different ($p = 0.079$), it might be significant with a larger sample size. That was because participants were classified into different categories and this led to having a relatively few participants in each group making extrapolation of the statistical analysis quite difficult. However, when all independent variables were included in the multivariate MLR model for the pMDI device, gender was found to significantly affect the quality of the inhaler technique. Men were 2.6 times more likely to have a proper inhaler technique in comparison to women ($p < 0.05$).

Several electronic devices could be used to assess patients' inhaler technique; however, the AIM device was the only one that could be used to assess patients' inhaler technique across three different inhalers. Carpenter et al. (2017) conducted a recent study aimed to review multiple electronic devices available on the market that assess patients' inhaler technique and provide feedback. The results they provided indicated that the AIM device was the only device that could be used across the three types of inhaler (i.e. pMDI, pMDI with spacer, and DPI). The latest version of the In-check DIAL (i.e. G16 In-check DIAL) could be used to evaluate the handling of 16 inhalers on the market via assessing patients' inspiratory effort (Sanders 2017). The device is built to resemble the resistance of the 16 inhaler devices (i.e. gentle inspiratory effort for pMDIs and fast for DPIs) (Sanders 2017). Although this device might be more accurate in assessing the inspiratory effort needed, as the intrinsic resistance of an inhaler device changes in comparison to the AIM, it does not assess the other essential factors required for a proper inhaler technique (i.e. correct canister activation, inhalation times, and breath-hold times: Carpenter et al. 2017; Sanders 2017).

Health care providers should pay attention to patients' inhaler technique. However, even though asthma management guidelines stress the importance of checking the inhaler technique, it seemed that most of the asthma patients were not using their inhaler devices properly. Health care providers should pay more attention to pMDI users in particular. This is because pMDI devices are associated with the worst inhaler device

technique (Molimard et al. 2003; Levy et al. 2013). They should also take into consideration the variation in the pMDI technique among people with different genders. Further, prescribing one type of inhaler that matches patients' ability to produce an adequate inspiratory flow rate might improve asthma control. That is because having more than one type of inhaler device would increase the probability of improper inhaler device usage (Chrystyn et al. 2017). On the other hand, although the probability of having suboptimal results on the pMDI+spacer device was statistically significant in respect of age and gender, it is probably not clinically significant. As proper inhaler technique is essential in asthma control, the British Thoracic Society (2019) stresses the importance of demonstrating optimal inhaler techniques, not suboptimal ones. Further, several studies have shown that poor inhaler technique was associated with poor asthma control (Giraud and Roche 2002; Fink and Rubin 2005).

3.4.1 Study strengths and limitations

Assessing patients' inhaler technique using a checklist may vary due to variation of assessment amongst assessors. Assessors might not be able to accurately assess some essential components of the proper inhaler technique, such as inspiratory flow rate and timing of canister activation. This study assessed patients' inhaler technique using an objective quantitative device that was approved to check technique (Carpenter et al. 2017). Using an objective tool yields more accurate and consistent results. However, convenience sampling was used to recruit participants: the sample was collected from several community pharmacies in Wales to try and ensure good representation of the patient population. It was not possible to use probability sampling, as the total population of people with asthma in Wales is huge, at around 314,000 patients (Asthma UK 2020a), and the researcher did not have access to all patient information. More importantly, even if the researcher had access to all people with asthma, it would be difficult to recruit patients from the whole country, taking into consideration the limited resources available. That being said, the cohort sample was recruited from different geographic areas (areas with different socioeconomic status) and included female and male patients of different ages. Therefore, the sample was more likely to be representative of the whole population. Although an AIM device, which has the

advantage of being a quantitative tool to check the quality of technique, was used to assess patients' inhaler technique, it had only one resistance level for all DPI devices (Haidl et al. 2016). Actual DPI inhaler devices currently on the market have widely varying airflow resistances and inspiratory flow rates (Fink and Rubin 2005; Dal Negro 2015). They are classified based on intrinsic resistance into three categories: low, moderate, and high resistance DPIs (Dal Negro 2015). Thus, adequate drug deposition in people using DPIs depends not only on inspiratory flows generated by patients' inspiratory effort but also on DPIs' internal resistance (Clark and Hollingworth 1993; Broeders and Molema 2003). Patients need to generate adequate inspiratory effort based on the degree of intrinsic resistance in order to achieve optimal drug deposition (Dal Negro 2015). This would lead to desegregating powder particles into very fine ones that can be inhaled and deposited adequately in the lungs. A higher degree of inhaler internal resistance needs a deeper, stronger inspiratory effort (Sanders 2017). Therefore, people who cannot generate a high inspiratory flow rate are advised to use DPI devices that have low intrinsic resistance (Janssens et al. 2008).

Knowing that the DPI simulator uses one level of resistance, which is moderate (Haidl et al. 2016), this may lead to underestimation of the quality of technique for low resistance DPI devices and overestimation for high resistance DPI devices. That being said, there is a minimum required inspiratory flow rate, which is called "acceptable inhalation rate", for each type of DPI device (Haidl et al. 2016). In a study that aimed to determine the inspiratory flow rate limits of inhaler requirements, most of the DPI devices on the market were found to have an acceptable inspiratory flow rate ranging from 30-35 L/min (moderate resistance: Haidl et al. 2016). As the increase of intrinsic resistance would need a fast-inspiratory flow rate (Sanders 2017), DPIs with moderate intrinsic resistance may not require a very fast flow rate. Therefore, knowing that the AIM DPI simulator has only a moderate level of resistance (i.e. the same level that was associated with the acceptable inspiratory flow rate) might indicate that the AIM could be used to assess the quality of the inhaler technique for a wide range of DPI devices. Another important point related to the AIM device is the validation of the AIM device. Although the AIM device has had been approved by the FDA, there were no published studies about the validation of the device. This may affect the accuracy of the data collected.

The dependent variable (i.e. the quality of inhaler technique) was treated as a nominal variable instead of an ordinal one in the MLR model. All statistical tests that were performed (e.g. Chi-square and MLR) could be conducted on both variables (i.e. nominal or ordinal). It has been claimed that the MLR could be run for an ordinal variable without violating any assumptions as long as the researcher is able to answer the research question (Flom 2010; Martin 2020). The appropriateness of using MLR analysis with an ordinal variable might be impacted as the number of independent variables increases or as the categories of the dependent variable increase (Campbell and Donner 1989). Given that there were only a few independent variables and categories, an MLR analysis was conducted. Further, it would be preferable to use multilevel multinomial logistic regression and consider the patient as the unit of analysis, especially when it comes to examining the impact of the number of inhaler devices used per patient on the quality of inhaler technique. This analysis was not performed because it would end up with a very low number of patients in many subgroups. Thus, the researcher decided to use the MLR analysis and considered AIM assessment as a unit of analysis to overcome the issue of having very few participants in several subgroups.

3.5 CONCLUSION

The majority of asthma patients were not using their inhaler devices appropriately across all types of inhaler and more frequently for pMDI users. Females were more likely to improperly use pMDI than males. Health care providers should make sure that people with asthma demonstrate proper inhaler technique on a regular basis and more importantly prior to stepping patients up to higher levels of treatment. They might consider prescribing one type of inhaler device, taking into account patients' preferences and ability to produce an adequate inspiratory flow rate. Pharmaceutical companies should also be involved in optimising inhaler technique. This could be done by working on the most frequent errors that are made by asthma patients while using inhalers (e.g. errors related to correct canister activation, intrinsic resistance, and inhalation effort needed). Further studies are needed to examine the relationship

between having a proper inhaler technique, good adherence, and asthma control via quantitative objective assessment.

**Chapter 4 - Is asthma well managed? The impact of
inhaler technique and adherence to inhaler on asthma
control**

4.1 INTRODUCTION

Asthma in the patient population is generally not well controlled (Giraud and Roche 2002; Molimard 2003; Press et al. 2012; Price et al. 2014). This might be attributable to several factors related to patients, health care providers, and inhaler devices. One crucial patient-related factor that could greatly affect asthma control is inhaler technique. Studies have shown that the majority of asthma patients do not use their inhaler devices properly (Giraud and Roche 2002; Molimard 2003; Fink 2005; Chrystyn et al. 2017). Another important factor is the level of adherence to asthma medication. In a retrospective study to assess the impact of adherence to corticosteroid treatment on asthma outcomes, researchers found that the overall inhaled corticosteroid adherence was 50% (Williams et al. 2004). More importantly, there was a negative correlation between being adherent to ICS and emergency visits. Further, previous studies have identified a strong relationship between having a proper inhaler technique and being adherent to inhalers, leading to better asthma outcomes (Blaise et al. 1998; Giraud and Roche 2002).

Medication adherence is a crucial factor in disease management. It is an agreement between a health care provider and a patient in respect of administering medications and following clinicians' recommendations (National Institute for Health Care and Excellence 2009). Medication adherence is defined as the extent to which patients take their medications as directed by prescribers, such as medication dose, route of administration, and course of treatment (Ho et al. 2009). When a patient is not adherent to a therapeutic plan, this should not be considered to be the fault of the patient alone. Instead, health care providers should look for the reasons that led to this result. That is because it is very important to understand the patient's perspective regarding how they use their medications. For example, why do they not take their medicines as prescribed? Around 33% to 50% of all prescribed medicines for chronic diseases are not taken as directed (National Institute for Health Care and Excellence 2009). This can have a huge impact on patient wellbeing, society, and the health care system.

Non-adherence is caused by several different factors. These factors can be classified as belonging to one of two main groups: intentional non-adherence and unintentional non-adherence. Intentional non-adherence is defined as not taking medications as recommended intentionally (National Institute for Health Care and Excellence 2009). That happens when patients themselves decide not to follow prescribers' recommendations, such as not taking a steroid. It is highly influenced by patients' beliefs and perceptions. Thus, health care providers should understand and discuss patient concerns in order to achieve good adherence. Unintentional non-adherence, in contrast, occurs when a patient is unintentionally not following prescribers' recommendations. It occurs when patients are willing to be adherent to the prescribers' directions, but this does not happen due to factors beyond their control. For example, patients might be non-adherent because of difficulty in paying for medication, poor inhaler technique, not understanding prescribers' recommendations or forgetting to take medications (National Institute for Health Care and Excellence 2009).

More than 1,400 people died from asthma in Wales and England in 2017 (Asthma UK 2019b). More importantly, 67% of asthma deaths could be prevented (Levy et al. 2014). This may indicate that asthma may not be well managed in the patient population. As discussed earlier in Chapter 1, the three aspects that might impact asthma outcomes are as follows: effectiveness of asthma medications and treatment strategies, patients' adherence, and inhaler technique. Asthma medications have been tested and validated for their efficacy and safety (Adams et al. 2001; Eccles et al. 2001; Carlsen et al. 2005). Therefore, the two other factors that would lead to proper asthma outcomes would be good patient adherence and proper inhaler technique. Health care providers are advised to carefully check patient inhaler technique and adherence to inhaler use (British Thoracic Society 2019). Therefore, to assess patient asthma control, inhaler technique, and adherence to an inhaler, an objective assessment tool and validated instruments were used in this study, as discussed in detail below.

4.1.1 Asthma Control Test (ACT)

The main outcome measure was asthma control, as assessed using the ACT. This is a self-assessment tool that can be administered to people with asthma to determine whether their asthma is controlled or uncontrolled (Nathan et al. 2004). Patients answer five questions assessing the extent of asthma symptoms experienced over the last four weeks (Nathan et al. 2004). These questions ask about 1) number of dyspnoea episodes, 2) night-time asthma symptoms, 3) using rescue medications, 4) the impact of asthma on patient daily activities, and 5) the overall patient self-assessment of asthma control. Each question is assessed using a five-point scale (Nathan et al. 2004) ranging from zero, which indicates no control, to five, which indicates complete control (Nathan et al. 2004). The results of these items are summed together to produce the final ACT score. A high overall score indicates that asthma is well controlled, whereas a low score indicates that it is poorly controlled (Nathan et al. 2004). Patients with an ACT score of more than 19 are considered to be well controlled (Nathan et al. 2004). The ACT has been validated by comparing the score derived using the test with relevant clinical measures of asthma control, such as Forced Expiratory Volume values (FEV₁), specialists' rating of control and treatment recommendations (Nathan et al. 2004).

4.1.2 Test of Adherence to Inhalers (TAI)

The TAI is a tool that can be used by health care providers to assess adherence in people with asthma and COPD. Using this tool, health care professionals can identify patients' levels of adherence, which are classified as poor, intermediate, or good. It can also help health care providers to identify the pattern of patients' non-compliance, making it easier to address. It has been validated to assess inhaler adherence in patients with asthma and COPD (Plaza et al. 2016). There are two versions of the TAI that can be used together or separately. The first one (the 10-item TAI) determines the level of adherence, whereas the second (the 12-item TAI) identifies the pattern of patients' non-compliance. The second version assesses patient compliance by asking healthcare providers two additional questions about their patients. The two questions are meant to collect information about whether patients remember the regimen (dose and frequency) that they were prescribed and the quality of their inhaler technique. In this

study, the 10-item questionnaire is used to identify the level of patient adherence (i.e. good, intermediate, and poor). The 10-item TAI contains 10 questions that need to be completed by asthma or COPD patients. The score for each question ranges from 1 to 5. Low scores are associated with factors that are linked to poor adherence. The overall score of this instrument ranges from 10 to 50. A total score of 50 points indicates good adherence, while a score of 46-49 indicates intermediate adherence, and a score of less than 46 indicates poor adherence.

4.1.3 Aerosol Inhalation Monitor (AIM)

The AIM device was discussed in detail in Chapter 3 (for further details, see section 3.1.2).

4.1.4 The rationale, aim, and objectives of the study

The findings of previous studies reporting on the quality of patient inhaler technique were very varied, which might be due to subjectivity in how inhaler technique was assessed and lack of objective measurements (Giraud and Roche 2002; Molimard 2003; Fink and Rubin 2005; Chrystyn et al. 2017). Therefore, there was a need to use an objective tool (i.e. the AIM device) and validated instruments (i.e. ACT and TAI) to assess inhaler technique, asthma control and adherence more accurately. This study aimed to assess how asthma was controlled in the Welsh population using a validated questionnaire, namely the ACT. There were two objectives for this research: first, to assess the potential association between inhaler technique, adherence, and asthma control; and second, to assess the impact of demographic characteristics and smoking status on asthma control and adherence.

4.2 METHODS

4.2.1 Study design

This was a cross-sectional quantitative study. For more information on the study design, see section 2.5.

4.2.2 Ethical approval

The project was approved by the Research Ethics Committee in Cardiff School of Pharmacy and Pharmaceutical Sciences. The ethical approval letter was granted before starting the study (see Appendix 4.1). Permission to use the TAI questionnaire was received by email prior to establishing the study.

4.2.3 Sampling and recruitment

The method for choosing community pharmacies and recruiting patients was the same as previously described (see section 3.2.3 for more information). Patients were recruited from nine community pharmacies across South Wales. These included community pharmacies located in Penarth, Cathays, Caerphilly, Crumlin, Newport, Pontypool, Sketty, Langdon, and Kingsway. Participants were recruited by final year undergraduate pharmacy students. To be included in the study, patients had to meet the following criteria: asthma patients who were older than 18 (to be qualified for taking the TAI questionnaire: Nathan et al. 2004), diagnosed at least one month before the study (to accurately answer the two questionnaires, since they ask about the last four weeks: Nathan et al. 2004; Plaza et al. 2016), and using preventers (to adequately answer the TAI questionnaire, since it asks about preventers: Nathan et al. 2004). Participants were given a participant information sheet and consent was received prior to taking part in the study (see Appendix 4.2 and 4.3).

4.2.4 Data collection

Data were collected over two periods: from October to December 2018 and from October to December 2019. The PhD student (MM) worked as coordinator and facilitator to make sure that the required data were collected appropriately in a

standardized way. After receiving the consent form, students used a short questionnaire to collect general information (e.g. demographic information, asthma medications: see Appendix 4.4 for further information). Participants were then asked to complete the ACT and TAI questionnaires (see Appendix 4.5 and 4.6). Once they were completed, participants were asked to demonstrate their inhaler technique using an AIM device according to the types of inhalers they were using. Results of the ACT, TAI, and AIM were recorded in a standardized way (i.e. on the questionnaire).

4.2.5 Data handling

Patient data for each community pharmacy were entered separately into a password-protected, encrypted Excel spreadsheet and uploaded to an online server. A standardized spreadsheet and coding system were used to eliminate any source of misunderstanding (for more information on how data were recorded and kept, see section 3.2.5). Entries were searched for missing information, and there were no missing values. The researcher (MM) combined the data together in one Excel spreadsheet file. To validate data input, ten percent of the sample was randomly checked with the original files, and no errors were found (Kupzyk and Cohen 2014). Variables were coded in a way that could be read by SPSS (i.e. not using letters). Using Excel functions, some variables were combined/organized prior to transferring data into SPSS (e.g. creating a new variable for having at least one poor inhaler technique while administering the AIM device for those who were using more than one inhaler device (e.g. DPI and MDI). Creating this variable would help in investigating which variable (i.e. inhaler technique or adherence) would affect asthma control the most. The values of the newly created variables were manually double-checked across all original variables for accuracy, and no error was found. Values were exported into SPSS software, and 10% of the sample was checked randomly (Kupzyk and Cohen 2014).

4.2.6 Data analysis

Data were analysed using SPSS software, version 25. Frequencies were calculated to obtain a general view of the cohort sample. Means were calculated for the continuous

variables (i.e. age, ACT, and TAI scores). Since the scores for two variables (i.e. ACT and TAI) were based on ordinal scales and patient opinion (e.g. always, almost always, never), data should be considered as being non-parametric (i.e. not normally distributed, Allen and Seaman 2007; Mu et al. 2012). For the variables, education level was treated as an ordinal variable, smoking was treated as a nominal variable, and gender and previous inhaler technique training were treated as dichotomous variables. Appropriate statistical tests were determined based on the research question, data type, and number of groups (Nayak and Hazra 2011). In this study, the non-parametric statistical tests that were performed include the Chi-square, Mann-Whitney U, Kruskal-Wallis H, and Spearman rank-order correlation coefficient tests. The assumptions for each statistical test were checked prior to application. For example, when more than 20% of cells had expected values less than 5 (i.e. an assumption of Chi-square test was violated), Fisher's exact test was reported (Kim 2017). The monotonic relationship between variables was checked prior to conducting the Spearman correlation test by creating a scatterplot. Since the ACT and TAI scores contain cut-off points, and to increase the confidence in the findings, a combination of statistical tests was used when appropriate (Thurmond 2001). For example, ACT and TAI were treated at first as continuous variables, and then as categorical ones (e.g. grouping scores into categories such as good adherence, intermediate adherence, poor adherence based on the cut-off points). Thus, the Chi-square test was used to increase the confidence of the findings of the non-parametric tests conducted (i.e. Mann-Whitney U and Kruskal-Wallis H tests). When the Kruskal Wallis H test indicated a significant difference between categories, a post hoc Kruskal-Wallis test was conducted to identify which groups were significantly different (Dunn 1964; Dinno 2015). The required sample size was calculated after conducting the project. That was because the researcher aimed to recruit as many participants as possible in a specific period. The effect size that was used to calculate the proper sample size was based on the value of the Z score, the standardized value for the U-value (Tomczak and Tomczak 2014). After computing the effect size, G*Power software was used to calculate the required sample size, which was 1800 participants. The statistical significance was set at $p < 0.05$, and all tests were two-tailed.

4.3 RESULTS

4.3.1 Characteristics of the participants

During the two periods of data collection, 83 participants were recruited. Of those, 69 asthma patients met the inclusion criteria for this present study. Ten participants were not included because they were not using preventers (i.e. inhalers containing corticosteroids), so the TAI questionnaire could not be completed accurately. Three patients had only been diagnosed with asthma within the last month, so they were not included in the study. One patient was younger than 18 years. Of the remaining 69 patients, 41 (59.4%) participants were female. The age of participants ranged from 18 to 91 years (mean = 49.5, SD \pm 19.2). More than half of the sample had A-levels or university level of education (n=37, 53.6%). Eighteen participants (26.1%) had a GCSE or equivalent qualification, whereas 14 patients (20.3%) had no educational qualifications. Most of the sample (40 patients: 58%) were not currently smokers, with 18 (26.1%) and 11 (15.9%) reporting that they were smokers or ex-smokers, respectively. See Table 4.1 for demographic and smoking status information.

N= 69 participants		
Variable	Frequency	Percentage
Gender:		
<i>male</i>	28	40.6
<i>female</i>	41	59.4
Educational attainments:		
<i>university</i>	28	40.6
<i>A-levels</i>	9	13
<i>GCSE or eq.</i>	18	26.1
<i>none of these</i>	14	20.3
Smoking status:		
<i>non-smoker</i>	40	58
<i>ex-smoker</i>	11	15.9
<i>smoker</i>	18	26.1

Table 4.1: Demographic and smoking status information (n=69).

4.3.2 Impact of demographic characteristics and smoking status on asthma control and adherence

This study showed that there was no significant difference between gender and asthma control as determined by the ACT ($U = 568.5, p > 0.05$). However, there was a trend toward significance when assessing the impact of gender on adherence. Adherence to inhaler medicines tended to be higher in females than in males, although this difference was not statistically significant ($U = 433.5, p = 0.08$). The level of education had no significant impact on asthma control or preventer adherence ($H = 1.4, p > 0.05$; $H = 3.4, p > 0.05$, respectively). Similarly, smoking status had no significant effect on asthma control or preventer adherence ($H = 2.3, p > 0.05$; $H = 2.5, p > 0.05$, respectively). Analysis of the correlation between age and asthma control yielded no monotonic significant correlation between the two variables ($r_s = -0.001, p > 0.05$). However, a statistically significant positive monotonic correlation was identified between age and adherence to preventers ($r_s = 0.41, p < 0.05$: see Table 4.2).

N= 69 participants		
Variable	Asthma control	Adherence to inhaler
Gender	$p = 0.94$	$p = 0.08$
Age	$p = 0.99$	$p = 0.0004^*$
Educational attainments	$p = 0.69$	$p = 0.32$
Smoking status	$p = 0.30$	$p = 0.27$

Table 4.2: The impact of demographic information and smoking status on asthma control and adherence to inhalers (n=69). The exact p-values are reported.

4.3.3 Asthma control, adherence to inhalers and inhaler technique

It seemed that the vast majority of the participants had uncontrolled asthma. Of the patient cohort, 42 out of 69 (60.9%) had an ACT score below 20. ACT scores ranged from 5 to 25 (mean = 17.4, SD \pm 4.9). Furthermore 27 out of 69 (39.1%) participants had poor adherence to preventer use, whereas 16 out of 69 (23.3%) and 26 out of 69 (37.7%) individuals had good and intermediate adherence, respectively. The mean TAI score for the sample was 44.8, SD \pm 5.7 and ranged between 29 and 50. As mentioned earlier, a score of 50 points indicates good adherence, 46-49 indicates intermediate adherence,

and a score of less than 46 indicates poor adherence. Almost all participants, 68 out of 69 (98.6%) had been shown inhaler technique by healthcare professionals. Of the total sample, 51 out of 69 individuals (73.9%) had been asked by a healthcare professional to practically demonstrate how to use inhaler devices. When inhaler technique was assessed via the AIM device, it was obvious that most patients were not using their inhalers properly. Of the patient cohort, 46 out of 69 (66.7%) had at least one poor inhaler technique, as some patients were using more than one inhaler device (e.g. using both pMDI and DPI), while only 23 of the 69 (33.3%) participants had good or suboptimal inhaler technique (see Table 4.3).

Asthma control	Inhaler technique	Adherence			Total Freq (%)
		Good Freq (%)	Intermediate Freq (%)	Poor Freq (%)	
<i>Good asthma control</i>	At least one poor inhaler technique	3 (16.7)	7 (38.9)	8 (44.4)	18 (100)
	Good or suboptimal inhaler technique	3 (33.3)	3 (33.3)	3 (33.3)	9 (100)
Total		6 (22.2)	10 (37)	11 (40.7)	27 (100)
<i>Poor asthma control</i>	At least one poor inhaler technique	6 (21.4)	10 (35.7)	12 (42.9)	28 (100)
	Good or suboptimal inhaler technique	4 (28.6)	6 (42.9)	4 (28.6)	14 (100)
Total		10 (23.8)	16 (38.1)	16 (38.1)	42 (100)

Table 4.3: Cross-tabulation table of asthma control, adherence, and inhaler technique (n=69).

Asthma control had no statistically significant impact on adherence to preventer inhalers (the dependent variable was adherence, $U = 536$, $p = 0.70$, $X^2 = 0.05$, $p = 0.97$). A Chi-square test was performed to increase confidence in the first finding (for more information, see section 4.2.6). When the level of adherence (good, intermediate, poor) was compared to ACT scores (i.e. the dependent variable was asthma control), no statistical significance was observed ($H = 0.65$, $p = 0.72$). When the correlation between ACT and TAI scores was investigated, the results showed no significant negative correlation between the two variables ($r_s = -0.14$, $p = 0.26$). There was also no significant difference between inhaler technique and asthma control ($U = 495$, $p = 0.66$, and $X^2 = < 0.01$, $p = 1.00$), nor with adherence ($U = 449$, $p = 0.30$, and $X^2 = 1.4$, $p = 0.48$). The quality of inhaler technique for those who had inhaler technique demonstrated to them in the

past was not significantly different from the quality of technique of those who had not ($X^2 = 0.33, p = 0.56$).

A Kruskal-Wallis test indicated there was a significant difference ($H = 9.8, p = < 0.05$) between the time elapsed since patients were last seen at an asthma clinic and asthma control (i.e. at least one pair of groups was statistically different). When Dunn's pairwise tests were conducted for the ten pairs of groups and the p -values were adjusted for multiple tests, there was no significant difference. The same was observed when testing the impact of time elapsed since patients were last seen at an asthma clinic and adherence. A Kruskal-Wallis test indicated that there was a significant difference between the mean ranks of at least one pair of groups ($H = 9.7, p = < 0.05$). After carrying out Dunn's pairwise tests and adjusting p -values for multiple tests, no significant difference was seen among pairs of groups. In respect of the inhaler technique, no effect was observed for the time elapsed on inhaler technique ($X^2 = 2.6, p = 0.64$).

4.4 DISCUSSION

Following on from the previous study investigating the prevalence of improper inhaler technique in the Welsh community (see Chapter 3 for more details), there was a need to assess how well asthma was controlled in the patient population. Asthma control is not only affected by the quality of inhaler technique, as adherence to asthma medications plays an important role in asthma management (Williams et al. 2004). As 67% of asthma deaths could be prevented (Levy et al. 2014), this may show that the UK could do better in managing asthma patients. Uncontrolled asthma might be mainly attributable to improper adherence, poor inhaler technique, and resistance to corticosteroids (Blaise et al. 1998; Giraud and Roche 2002; Barnes 2013). As asthma medication has been shown to be effective and only a small number of asthma patients are completely resistant to corticosteroids (Adams et al. 2001; Eccles et al. 2001; Carlsen et al. 2005; Barnes 2013), this might mean that the main factors affecting asthma control are adherence and inhaler technique. For this reason, assessing asthma control, inhaler technique and adherence to inhalers together should give a clear picture of how well asthma is being managed in the patient population.

The results of this study indicate that asthma is not well controlled in the Welsh patient population. The most important aspects of having controlled asthma were not adequately met (i.e. most patients in this study had poor inhaler technique, and were non-adherent to their preventer medication). These findings are concordant with those of other published studies conducted in other countries around the world (Molimard 2003; Williams et al. 2004; Fink 2005; Chrystyn et al. 2017). Improper inhaler technique and adherence to preventers may lead to poor asthma control, which in turn may affect patients' quality of life and may lead to premature deaths. It might also increase burden on NHS services, as uncontrolled asthma patients might need to be hospitalized, which would lead to an increase in healthcare expenditure. In 2016/2017, more than 77,000 patients were admitted to hospitals because of asthma exacerbation in the UK (Asthma UK 2020b). More than 1,400 individuals living in the UK lost their lives in 2017 due to asthma (Asthma UK 2020b). These mortality and morbidity rates might be minimized if better care were provided for people with asthma (Levy et al. 2014). Although published in 2014, there are clear recommendations about the causes and steps needed to reduce asthma deaths and hospitalisation. It was reported that the NHS spends around 1.1 billion pounds on asthma every year (Asthma UK Centre for Applied Research 2016). That includes costs of GP visits, prescriptions, hospitalization, and disability claims. Therefore, the economic burden of asthma, patients' quality of life, and mortality and morbidity rates might be improved if better care were provided.

The way in which asthma patients are monitored may need to be evaluated. The present study showed that more than 25% of the sample were never asked to demonstrate inhaler technique prior to being prescribed medications or in their usual review visits. This issue needs to be carefully looked at because patients will not get the full benefit from their medications if they are not using inhalers properly. It might be helpful to employ technology in assessing patient inhaler technique (e.g. AIM and In-Check devices). This would greatly help in three main aspects. First, it would allow practitioners to assess important inhaler technique aspects that cannot be checked through observation, such as inspiratory flow rate. Therefore, assessing patient inhaler technique would not be impacted by the subjectivity of health care providers. Second,

assessment would be based on an objective tool that might eliminate the lack of understanding of adequate inhaler technique by health professionals (De Tratto et al. 2014). Third, it would identify the best inhaler type to use in each patient group (such as elderly and newly diagnosed patients). Thus, patients' ability to properly use the prescribed medications could be checked prior to prescribing, as inhaler devices vary widely in respect of internal resistance and inspiratory flow rates needed (Dal Negro 2015; Haidl et al. 2016; for more information about inhaler devices, internal resistance and respiratory flow rate, see section 3.4). Moreover, active engagement of asthma patients in their management plan might lead to better outcomes. Even though the asthma action plan is designed to help people look after their asthma (e.g. by informing them which medicines to take and what to do if the condition gets worse; Asthma UK 2020c), the results of this study suggest that this may not be properly implemented. Asthma action plans might be more enforced so that every patient is asked to complete and bring their plan when visiting their healthcare providers. Understanding when the condition is well managed (e.g. by knowing the number of rescue medication doses used, and asthma symptoms per week) might enable patients to understand their condition better. More engagement of patients in their treatment plan would not only improve their condition, but might also decrease the economic burden on the NHS by avoiding preventable hospital admissions.

The current study showed that the demographic information of participants and smoking status had no impact on asthma control or adherence. However, it was reported by other researchers that asthma outcomes are impacted by demographic data and smoking (Althuis et al., 1999; Bacon et al. 2009). Althuis and colleagues (1999) reported that smoking affected the severity of asthma and its symptoms. Bacon et al. (2009) found that people with asthma who had less than 12 years of education were 55% more likely to be admitted to hospitals. Although this present study showed that females might have better adherence compared to males (a trend towards a significant difference: $p = 0.09$), Almqvist et al. (2007), in a systematic review, found that asthma tended to be more severe in females than in males. Regarding the impact of age on asthma outcome, there was no difference observed in the cohort sample. However, Talreja and Baptist (2011) found that the elderly had poor asthma outcomes in the short

term (symptoms last month) as well as the long term (activity limitations last year). The only exception was the moderate positive correlation between age and the level of adherence. Adherence increased as people got older. This might be attributed to variations in lifestyle. Young people tend to spend more time outside the home, so they may have limited access to inhalers. Volerman et al. (2019) claimed that one of the barriers to inhaler self-carrying in young people resulted from forgetting or losing their inhalers.

4.4.1 Strengths and limitations

Demonstrating a proper inhaler technique and being adherent to inhaler medications is considered essential in managing people with asthma (British Thoracic Society 2019). Thus, assessing patient inhaler technique and adherence using validated and objective tools would increase the robustness of a study. To the best of the researcher's knowledge, this was the first study to assess the impact of inhaler technique (via a quantitative objective tool), and adherence (using a validated instrument) on asthma control. This approach minimizes the issue of the assessor's subjectivity when they assess patient inhaler technique. For further discussion on using the AIM device, see section 3.4. Moreover, involving patients from several cities and towns in Wales may make the study sample more representative of the whole population. Triangulation of data analysis techniques was used to better understand the phenomena and to increase the reliability of the findings (Thurmond 2001; Lauri 2011). For example, when cut-off points (e.g. patients with an ACT score of more than 19 are considered to be well controlled) were essential in determining the outcomes, another statistical test was conducted to increase the confidence in the results (for more information, see section 4.2.6).

Although having good adherence and proper inhaler technique is essential in asthma management (Giraud and Roche 2002; Fink and Rubin 2005), it was surprising to see no association between asthma control, adherence, and inhaler technique. Clinical trials and asthma management guidelines have shown the importance of inhaler technique and adherence to inhalers in controlling asthma (Blaise et al. 1998; Giraud and Roche

2002; Osterberg and Blaschke 2005; British Thoracic Society 2019). Not observing a significant difference among participants in respect of asthma control might be attributed to the small sample size. The participants were classified into different categories (e.g. poor, intermediate, and good adherence vs. good and poor asthma control). This led to having a relatively few participants with good technique/adherence compared to other groups making extrapolation of the statistical analysis (e.g. observing a significant difference between groups) quite difficult (Salkind 2010). When the required sample size was calculated based on a Mann-Whitney U test, it was found that 1800 individuals were needed to observe a significant difference between groups. This would not be feasible for a Ph.D. student due to time constraints and the effort required. Another potential factor that might contribute to the unpredictable findings was the use of questionnaires to assess adherence and asthma control. Although the two instruments had been validated (Nathan et al. 2004; Plaza et al. 2016), they might be impacted by information bias. It might be difficult to answer questions about things that happened four weeks ago, plus participants might answer questions in a way that makes them look good to others (Althubaiti 2016). Using other parameters to assess patients' adherence might increase confidence in the current findings (e.g. using an electronic device to assess adherence). Another limitation of this study was regarding using of the AIM device in assessing different inhaler devices. The AIM device is designed to assess the patient inhaler technique across three inhaler devices (DPI, pMDI, pMDI with spacer). DPI devices vary in terms of intrinsic resistance (Dal Negro 2015). The AIM DPI simulators only have one level of resistance and therefore might yield inaccurate results (this point was discussed in detail in section 3.4.1). Further, selection bias might be introduced in the study, as some patients were less or more likely to take part in the study (Simundić 2013). The actual extent of uncontrolled asthma, poor inhaler technique, and non-adherence might be much higher than what was observed in this study. Non-adherent patients may be less likely to visit a pharmacy and participate in the study. That would mean that the cohort sample would involve a higher proportion of adherent patients when compared to the total number of asthma patients. Further, most of the data were collected on weekdays. Working age adults might find it difficult to attend pharmacies during the week. There was some limited data collection carried out at the weekends, but this did not represent a large proportion of the total sample.

4.5 CONCLUSION

It is clear that asthma in the patient population is not well controlled. Neither inhaler technique nor adherence was optimal for a large proportion of people with asthma. People could be more actively involved in managing their conditions for example by knowing the indicators of asthma control (e.g. frequency of asthma symptoms and usage of rescue medication). This would not only improve their condition, but might also reduce avoidable hospitalizations.

Chapter 5 - Community pharmacists' views about managing chronic conditions in their pharmacies

5.1 INTRODUCTION

This chapter presents the findings of a qualitative study exploring community pharmacists' perspective about managing people with chronic conditions in pharmacy. A preliminary report of this data was presented as a poster titled "Community pharmacist views about the management of chronic conditions in their pharmacies: barriers and potential ways forward" in the Health Services Research and Pharmacy Practice Conference 2020 (see Appendix 5.1).

It has been reported that chronic conditions are the leading cause of mortality and morbidity around the world (Yach et al. 2004; Suhrcke et al. 2006). Cardiovascular diseases, chronic respiratory diseases, cancer, and diabetes are the most frequent contributors to death globally (Riley and Cowan 2014). More importantly, the prevalence rate of chronic conditions is expected to increase. It was estimated that three-quarters of all deaths would be attributed to chronic conditions by 2020 (World Health Organization 2019b). In Wales, the percentage of people who live with one or more chronic conditions increased significantly by 86% between 2004 and 2015 (The Health Foundation 2016). The expected increase in people who are 65 years and older in the next two decades, aligned with a shortage of GPs, would put current clinical systems for the management of people with chronic conditions under immense pressure (Wales Audit Office 2014).

As discussed in Chapter 1, the demand for medical services from the Welsh NHS is increasing (NHS Wales 2015b). This, combined with a shortage in numbers of GPs, makes involving other health care providers in delivering care for patients a sensible alternative solution (NHS Wales 2015b). As a result, the role of the pharmacist is evolving to include the provision of more clinical services for patients (Welsh Government 2019c) by utilising the relatively untapped skills of pharmacists as health care providers. In addition, the expansion of primary care services provided by pharmacists would allow delivery of more convenient and cost-effective health services to patients (NHS Wales 2015a; NHS Wales 2015b). However, community pharmacists are currently not significantly involved in the clinical management of patients with chronic conditions (i.e. monitoring conditions, identifying disease progression, interpreting lab results,

recommending or implementing a change in therapy, and prescribing; for further discussion, see section 1.8). Offering more clinical services in community pharmacies may increase the number of health professionals available to provide these services, which may reduce the burden on GPs and decrease patients' waiting times.

The community pharmacy sector is an important part of the primary care setting. When it comes to the workforce, community pharmacists are estimated to be the third largest healthcare professional group worldwide (Habeeb Ibrahim et al. 2012). More than 74 million prescriptions were dispensed in Wales during 2018-2019 (Welsh Government 2019c), indicating a massive opportunity for patient interaction in community pharmacies. Community pharmacies have several advantages, making them competitive places to offer health services. They are distributed almost everywhere. Almost every community, even in the most deprived areas, is serviced by a local community pharmacy (Pharmaceutical Services Negotiating Committee 2020b). In England, community pharmacies are visited by around 1.6 million people every day (Pharmaceutical Services Negotiating Committee 2020b). Ninety-eight percent of people in England can access a community pharmacy within a 20-minute walk (Pharmaceutical Services Negotiating Committee 2020b). In the Community Pharmacy Services in Wales 2018-19 report, which was published by the Welsh Government (2019c), patients identified four main reasons to access health services at a community pharmacy. They are as follows, from most to least frequent: no need for an appointment, more convenient in terms of location, visiting the pharmacy for another health service, and business/shop opening hours.

Community pharmacy resources could be better utilized (NHS Wales 2015a). Given the professional education and training that pharmacists have, they could be involved in providing more clinical services rather than focusing on dispensing. In order to empower community pharmacists and assign them more patient-facing roles, the Welsh Government started to involve community pharmacists in providing enhanced and advanced pharmacy services. Within these services, the pharmacists use their skills and expertise to deal with various issues, such as common ailments, Medicine Use Reviews (MUR), and Discharge Medicine Reviews (DMR: NHS Wales. 2015b; Welsh Government

2019c). Further, providing more clinical services would allow community pharmacists to apply their skills and use their expertise (Welsh Government 2015).

Community pharmacists could play additional roles in delivering health services rather than being mainly focused on dispensing. Several studies have shown that the interventions conducted by pharmacists improved outcomes in several chronic conditions, such as diabetes, hypertension, and cardiovascular diseases (Machado et al. 2007; Santschi et al. 2014; Omboni and Caserini 2018). George and colleagues (2010) conducted a literature review to investigate the evolving role of community pharmacists in managing chronic conditions globally. They included 45 articles in their systematic review, of which 32% were based in the UK. They found that community pharmacists were involved in managing multiple chronic conditions, such as asthma, diabetes, hypertension, and heart diseases. They concluded that the role of community pharmacists in primary care had evolved. More importantly, the interventions made by community pharmacists in managing hyperlipidaemia, diabetes, hypertension, and preventive services (osteoporosis, flu vaccinations, and obesity) were effective. In a large meta-analysis of randomized control trials that included 14,224 hypertensive patients, Santschi and colleagues (2014) assessed the interventions made by pharmacists in managing hypertension. Three main interventions were identified: patient education and information about medication adherence; feedback to physicians regarding drug-related problems and medication change; and, finally, medication management which involves therapy monitoring with adjustment or change in therapy. The meta-analysis showed that interventions conducted by pharmacists led to good improvement in disease outcomes (systolic BP and diastolic BP) compared with the usual current practice.

Even though the expansion of the community pharmacy profession to include managing chronic conditions seems effective, several limitations might hinder its involvement. Several studies have explored the limitations of managing certain chronic conditions in a community setting globally (Alzubaidi et al. 2018; Donald et al. 2017; McMillan et al. 2013). However, no study has explored community pharmacists' perspective on managing multiple chronic conditions (i.e. more than a single specific chronic condition)

in the UK. Katangwe et al. (2019) conducted a study exploring the views of English community pharmacists on the provision of diabetes preventive services in pharmacy. Although the study did not directly investigate the management of chronic conditions in a community setting, it shed light on aspects that might limit the engagement of community pharmacy in providing clinical care for potential patients with chronic conditions. The authors identified five main themes that hindered the provision of preventive services in a community setting. These were challenges of managing pre-diabetic patients; barriers related to the community pharmacy setting, such as space issues; the level of awareness regarding services provided in community pharmacy; relationships and communication; and barriers related to the delivery of pharmacy services (i.e. the practical aspects). In another study aiming to explore reforms and strategies to expand community pharmacists' roles in developed countries, including the UK, Mossialos et al. (2015) identified several limitations to expanding the role of community pharmacists. They claimed that collaboration and support from other healthcare providers, funding and mechanisms for reimbursement, access to medical records, and competition between health professionals were all considered limitations to the expansion of clinical roles for community pharmacists (Mossialos et al. 2015).

Given that the policy and legislation that regulate the community pharmacy profession are varied around the globe, plus the willingness of NHS Wales to fully utilize community pharmacists' expertise and skills in offering more patient-centred services (NHS Wales 2015a), there was a need to investigate the potential involvement of community pharmacists in managing chronic conditions. This was investigated from the perspective of community pharmacists working in the Welsh community.

5.1.1 The aim of the study

This study was designed to explore the views of community pharmacists around the management of chronic health conditions in community pharmacies. The research objectives were to identify factors influencing the management of chronic conditions and potential facilitators. Further, the research would identify/explore chronic conditions that could be managed in a community setting.

5.2 METHODS

To explore the perspectives of community pharmacists about the management of chronic health conditions in community pharmacies, a face-to-face qualitative interview approach was used (for more detail, see section 2.4.1). The intention was to conduct focus groups, but that did not prove to be feasible (see section 8.7.2).

5.2.1 Ethical Approval

Ethical approval for this study was granted by the Research Ethics Committee in Cardiff School of Pharmacy and Pharmaceutical Sciences (see Appendix 5.2).

5.2.2 Sampling

Since community pharmacists have varied backgrounds and qualifications (e.g. Independent Prescribers (IPs), locums) and work in different types of community pharmacies (e.g. independent and chain pharmacies), purposive sampling was used to recruit participants in the study (Tongco 2007). Selecting a purposive sample would allow a more comprehensive understanding of the topic of interest (Palinkas et al. 2013) and ensure that a wide variety of opinion was captured. Creswell and Plano Clark (2018) advised that researchers planning to conduct an exploratory sequential study, as is the case in this study, should choose participants purposefully. Therefore, the rationale for this approach was to comprehensively understand the topic by recruiting as diverse a sample as possible in a reasonably short amount of time (Etikan et al. 2016). To widen the range of selection, participants were also asked to invite others whom they thought would be interested in the topic (i.e. snowball sampling). In snowball sampling, participants are recruited from a given finite population in which every participant invites other potential individuals to take part in the study (Institute of Mathematical Statistics 1961).

5.2.3 Recruitment

An invitation email was sent to three groups of recipients: The Royal Pharmaceutical Society of Wales (RPSW), gatekeepers (three teaching practitioners and a pharmacy

programme administrator at Cardiff Pharmacy School) and publicly available community pharmacist/pharmacy contact information (see Appendix 5.3). The invitation to participate was also advertised on the Pharmacy Forum, UK. The RPSW also advertised the project via their Facebook account. Reminder emails were sent when no response had been received after 10-14 days from when the original communication was sent out (see Appendix 5.4). The gatekeepers were asked to forward the invitation email to potential participants. An incentive of a £10 voucher was offered for participation (for more details on incentives, see section 5.2.9). A participant information sheet was attached with all invitation emails sent (i.e. emails sent to participants by gatekeepers and the researcher: see Appendix 5.5). Those who agreed to participate in the study were emailed a Participant Demographic Information Form (PDIF: see Appendix 5.6), a consent form (see Appendix 5.7), and a participant information sheet. The PDIF is designed to collect some general information about participants (e.g. position in the pharmacy, years of experience) and about the community pharmacies (e.g. type and location of the pharmacy) where they work. It was designed to support the recruitment of a diverse sample for the study.

5.2.4 Selection

The inclusion criteria were that all participants must be community pharmacists working in Welsh pharmacies. No exclusion criteria were required. The selection process operated on a 'first come, first served' basis, taking into account the need for sample diversity. The information provided in the PDIF was used to inform the selection of a diverse sample. After completing the forms, a face-to-face interview was scheduled based on the participant's preference (i.e. date/time and location). Those who could not be recruited (i.e. those who did not meet the inclusion criteria or because the saturation point was reached) received a thank-you email.

5.2.5 Topic guide design

Topic guides can help interviewers conducting interviews and ensure that the topic of interest is ideally covered across all interviews (Turner 2010: for more details, see section 2.4.1). The topic guide was developed based on a review of literature (Morrison

2013; Mossialos et al. 2015) and then discussed with two members of the supervisory team (WF, LH) and an expert in the field (KH). The topic guide started with a general introduction and focused on three main domains: the current practice in community pharmacy, community pharmacy's involvement in managing chronic conditions, limitations of managing chronic conditions and how these could be overcome. The three main domains were supported by prompt questions which could be used to initiate further discussions and gain a better understanding of the researched topic (Holloway and Galvin 2017: see Appendix 5.8). The topic guide started with a general question about the current practice in community pharmacy, providing participants with a topic to which they could easily respond to open the discussion (Doody and Noonan 2013). Then, conversations were gradually moved to the main topics of interest, such as managing chronic conditions in pharmacy.

5.2.6 Reviewing the topic guide

After the initial topic guide had been designed, it was discussed with at least one of the supervisory team and several changes were made in respect of wording, adding prompt questions, and the general structure. These changes included adding general prompt questions, reducing the amount of information in the introduction section, proofreading and wording. After that, a face-to-face meeting was held with two community pharmacists to ensure that the topic was properly covered and questions were clearly constructed. The comments and proposed amendments were discussed with at least one member of the supervisory team and then implemented when appropriate. The amendments included adding some probing questions regarding limitations to managing chronic conditions in pharmacy. The topic guide was reviewed by two community pharmacists to enhance its validity prior to the interviews.

5.2.7 Study setting

Semi-structured face-to-face interviews were conducted at a place and time of each participant's convenience (for more information about semi-structured interviews, see section 2.4.1). All interviews were conducted in a quiet room, either in the Cardiff School of Pharmacy and Pharmaceutical Sciences or in consultation rooms where the

pharmacists were located. This served to protect participants' confidentiality and also to minimise the possibility of being distracted (Doody and Noonan 2013).

5.2.8 Data collection

Following the ethical approval, initial contact was made with potential participants to establish a place and time for an interview, as previously reported. Data collection ran from early August 2019 until December 2019. The participants were asked to provide consent before interviews were conducted, and any questions they had were answered before starting the interviews. The interviewer informed participants that there was no right or wrong answer (Doody and Noonan 2013); instead, the purpose of the interview was to hear about participants' experiences and opinions in respect of the research topic. The semi-structured interview format allowed the researcher to ask questions to prompt exploration of the topic guide rather than following a specific interview structure (Gilbert 2001; Tod 2006; Babbie 2014). The interview started with an introduction to the study and an overview of the aim of the interview. The entire interview was designed to last no longer than an hour due to the busy nature of community pharmacies. Questions being asked were influenced by the responses received from the interviewees and the emergent themes (Gilbert 2001; Tod 2006). The researcher asked open-ended questions to explore topics, supported by prompt questions when needed (Holloway and Galvin 2017). Leading questions were avoided, to avoid influencing the responses received (Babbie 2014). During discussions, the researcher kept eye contact with the interviewees, tried to be neutral, and avoided showing strong reactions to respondents' answers (Doody and Noonan 2013). Non-verbal communications were noted separately and added to the analysis of transcripts.

The interviews were audio-recorded using two digital voice recorders (Olympus/VN-732PC). Audacity (www.audacityteam.org) was used to play back the audio files, so transcripts could be generated. All audio records were transcribed verbatim by the researcher. To ensure the accuracy of the generated transcripts, two accuracy checks were carried out (Hagens et al. 2009). First, the researcher checked the generated transcripts by listening to the audio recording while reading through the transcript. Second, transcripts were sent out to the participants once generated and participants

were asked to check their accuracy (Hagens et al. 2009). Participants were informed that they had the option to make changes or even withdraw from the study at this point. Only a few amendments were made to three transcripts (this included clarifying some words that were not clear). Six participants approved the generated transcript. One participant did not respond to the transcript review email, so the transcript was included in the analysis after sending two follow-up emails within two weeks of initially sending out the transcript. Once the transcript had been approved by the participants, it was analysed to identify themes. The topic guide was adapted when needed to ensure that it covered any themes that emerged in earlier interviews. At the end of each interview, the participants were asked if they had anything to add about the topic to make sure that nothing was left undiscussed. Once saturation had been reached, when no new themes emerged (Fusch and Ness 2015), no more interviews were conducted. To be more specific, the saturation point was reached on the fifth interview, but the researcher decided to conduct one more interview to double check that saturation had been reached. When the sixth interview was conducted, a new theme emerged. After conducting the seventh interview, no new themes emerged. At that point, a decision was made to stop conducting additional interviews, as sufficient information had been collected to construct the questionnaire (i.e. the second component of the exploratory sequential study: see Chapter 6. More details on data saturation will be provided in sections 5.4.1 and 8.4). Interviews lasted between 24 and 54 minutes: the average length was 35 minutes.

5.2.9 Incentive

As a small token of recompense for their time, participants were given a gift card with the value of £10 once they had attended the interviews and transcripts had been viewed. Offering a financial incentive is helpful in enhancing recruitment for research (Dunn and Gordon 2005). The recompense was available irrespective of whether participants decided to remain part of the study after viewing the transcripts.

5.2.10 Data analysis

Transcripts were analysed using thematic analysis in NVivo (version 11, Braun and Clarke 2006). Thematic analysis is a method that can be used in qualitative studies to identify themes by careful reading and re-reading of a set of data (Rice and Ezzy 1999; Braun and Clarke 2006). The initial analysis (by listening to the audio recording more than once or reading the transcript, if generated) of each interview was carried out prior to conducting the next, allowing the identification of new themes. The second main analysis (after receiving the revised transcripts) was based on a six-phase framework (Braun and Clarke 2006, see Appendix 5.9). In this framework, six stages were considered and implemented while doing thematic analysis, as follows: familiarizing the researcher with the data, generating codes, creating, reviewing, refining, and defining themes, and producing the report. Familiarization with the data was achieved by transcribing the interview and reading the generated transcripts more than once. During data transcription, the researcher had to listen to the audio recordings many times, and this helped in being able to engage with the data set and understand the meanings and patterns within the interview. In addition, the researcher used notes that were taken during interviews to best understand participants' opinions. After generating the transcript, it was exported into NVivo software, where data were coded. The initial phase (familiarization) helped in forming ideas about the content of each interview and was very useful in data coding. By collecting relevant codes together, potential themes and subthemes were created. NVivo software allowed notes to be made while analysing data using the memo feature. This feature helped in connecting thoughts together, and thus led to better understanding of qualitative data. After that, the initial themes were checked by reviewing codes and corresponding quotes to ensure the accuracy of generated themes. The themes were identified via inductive analysis (i.e. emergent themes from the interviews (Braun and Clarke 2006)). A thematic map was generated and discussed with the whole research team. A narrative of the themes was written based on the identified quotes as evidence to illustrate the findings (Braun and Clarke 2006).

To ensure the trustworthiness of the present study, several approaches were taken, as discussed earlier. These included being familiar with the field and the setting (Shenton

2004; for more information, see section 2.8.1), frequent discussion with experts on the topic and with the supervisory team (Shenton 2004), and review of the topic guide by community pharmacists. Participants had the right to check the transcripts and even to withdraw from the study (Shenton 2004). Each transcript was re-analysed a few days after the first analysis. When a new theme was identified, the researcher revisited the previously generated transcripts to double check for the same theme (Noble and Smith 2015). Also, at least two members of the supervisory team reviewed the transcripts and the generated themes (Noble and Smith 2015). A meeting was held with the supervisory team to discuss the findings and consensus was reached. Finally, one participant was invited to check that the generated themes accurately reflected the topic of interest (Shenton 2004; Noble and Smith 2015).

5.3 RESULTS

5.3.1 Participants

Eleven participants were willing to participate in the study. Of those, two were not included in the study because they did not meet the inclusion criteria: one was working in an English community pharmacy, and one was not practicing. A locum pharmacist was not included in the study because the sample had a balanced number of locums (in comparison to other participants included in the study) and saturation point had been reached. As mentioned earlier, no new themes emerged from the fifth and seventh interviews; plus, since the sample already included two locums, a decision was made to stop recruitment and start work on the second phase of the research (i.e. designing the questionnaire). Another participant could not find enough time to be interviewed, so decided not to continue in the study. Seven participants were included in the study (four males and three females). Four participants were recruited via direct contact, two via the gatekeepers, and one was referred by a participant. Although more than one strategy was used to recruit participants, participants were purposefully sampled based on individual characteristics, such as position in the pharmacy, years of experience and the characteristics of their workplaces, to enable the study sample to capture as wide a variety of perceptions as possible. The mean age of the cohort was 31.7 years, ranging

from 26 to 42 years. The years of experience as a community pharmacist ranged from 3 to 19 years ($m = 8.4$ years). The sample involved two pharmacy managers, two locum pharmacists, one regular pharmacist, one superintendent pharmacist, and one independent prescribing pharmacist. They were working in three different LHBs: Cardiff and Vale University, Cwm Taf University, and Aneurin Bevan University. Five participants worked for a company that had more than 20 branches, one was employed by a company that had from two to five branches and one participant worked for a company that had only one branch. The characteristics of the community pharmacies where they worked were as follows: supermarket, independent, multiple, large, and small chain community pharmacies.

5.3.2 Themes and subthemes

The thematic analysis produced several themes and subthemes (see Table 5.1). The themes presented below are supported by quotes aligned to participant codes. To distinguish the participants' quotes in the results section, quotes are italicised. Each participant was given a unique code consisting of three parts. For example, ManagerCP2(6yrs) means the second community pharmacist interviewed, who was a manager of a pharmacy and had been working in community pharmacy for six years.

Theme	Subtheme
1. Regulations and policy	<ul style="list-style-type: none"> • Health care professional boundaries and accountabilities • Heterogeneity and consistency in community pharmacy • Identifying eligible patients for services and referring • Reallocation of responsibilities in community pharmacy • Accessing and sharing patients' medical information • Funding and remuneration • Training and education
2. Awareness raising and guidance	
3. Accessibility in community pharmacy	
4. Facilities and equipment in community pharmacy	
5. Workload and staffing in community pharmacy	
6. Healthcare professionals' collaboration and relationship with community pharmacists	
7. Patients' interactions and relationships with community pharmacists	
8. Confidence and willingness of community pharmacists to manage chronic conditions	

Table 5.1: Emergent themes and subthemes

5.3.2.1 Regulations and policy

5.3.2.1.1 Health care professional boundaries and accountabilities

This theme was identified in several interviews. The lack of clarity around healthcare professionals' boundaries and accountabilities was seen as a barrier to delivering clinical services to patients. Crossing or breaking boundaries among professions would not only confuse healthcare providers, but also potentially confuse patients, as more than one health profession would be delivering the same service. Furthermore, it might lead to a waste of resources, as patients might receive the health service more than once. It could also increase the burden on healthcare providers and might waste their time. Therefore,

working in a multidisciplinary team, in which each member is positioned based on their own expertise, and being informed about everyone's responsibilities may help in providing better healthcare for patients.

...I guess everyone's just a bit confused about who has the responsibility to deliver what service... ManagerCP4(3yrs).

...you need to completely delineate what is the role of the community pharmacist in this aspect because if you've got the blurring of the roles, you've got the issue that community pharmacist that just becoming many GPs and those roles are stepping on each other's toes... LocumCP2(3yrs).

Uncertainty about who should provide a certain service for patients might lead to patients not receiving the healthcare service at all. Several participants argued that because of the lack of clarity over the boundaries between professions, it might be assumed that a patient was seen/monitored by other healthcare providers. This could put the health of patients at risk, as they may fall through the gaps where healthcare providers were not sure who should take responsibility. This suggests that this issue goes beyond the community pharmacy and so a fundamental change needs to be considered in order to clearly define the boundaries between health professions.

...I guess always that assumption that somebody else is going to do the action that you are thinking about taking and somebody else is monitoring these people... ManagerCP4(3yrs).

The involvement of community pharmacists in delivering clinical services might be limited due to the lack of clarity about their role as healthcare providers. The expansion of the Community Pharmacy Contractual Framework to include provision for more clinical services might still not be well understood by community pharmacists. One participant claimed that the lack of clarity over services other than dispensing led community pharmacists to stick to their primary role as dispensers. This might be because dispensing is approved as an essential service, so all contractors must provide

this service. The lack of clarity around the role of community pharmacists may impact the provision of services provided in a pharmacy and may also impact the public's understanding of the contributions of community pharmacists.

...part of the reason I think that pharmacist is clinging to dispensing is that the alternative roles are not clear at all... LocumCP2(3yrs).

To overcome the issue about the lack of clarity around health care professionals' responsibilities in delivering clinical services, participants claimed that the provision of clinical services needed to be clearly defined in community pharmacy. This would include three main elements, namely who should provide the service, how the service should be delivered, and who is accountable for patient outcomes. It was indicated that the definition had to go beyond the community pharmacy contract and should involve other health professions. This would enable the professional boundaries to be clearly drawn amongst all health care providers involved in an individual patient's care. More clarity was needed about the point at which the community pharmacist's responsibility stopped and another healthcare professional's role began (and vice versa). For the management of chronic conditions, where crossing boundaries between professions might be more likely, a specific service level agreement between all health professions involved was considered to be a potential facilitator by several participants.

...if you're creating services, all these services have to be extremely specific. Okay, you know, a service level agreement has to be written on how that service is to be carried out and provided within the pharmacy... RegularCP3(14yrs).

5.3.2.1.2 Heterogeneity and consistency in community pharmacy

The way services are commissioned was identified as a barrier to managing patients with chronic conditions in community pharmacies. Some participants argued that the variation among LHBs in commissioning pharmacy services might affect the provision of services. Services might be provided in a certain location but not in others. As such, there may be geographical differences in care, which may result in health inequalities due to differences in the service provision for patients. To illustrate this issue, a

pharmacist gave an example on variations seen in providing the sore throat test-and-treat service across Wales.

...so you could go to someone in North Wales currently and get the sore throat test-and-treat service and get given antibiotics for a bacterial throat infection. Go to where you are in Wales and you can't..... you can't receive that same service... LocumCP2(3yrs).

Even though heterogeneity in the services provided across community pharmacies might confuse patients, one participant argued that patients should not expect that all services should be provided in one place.

...I don't think a patient should expect every pharmacy to deliver every single service... ManagerCP4(3yrs).

The issue of heterogeneity within the community pharmacy sector not only appeared in services provided but also in pharmacy software applications. Two participants (both locum pharmacists) reported that using different software programmes in different pharmacy companies was time consuming. Software may vary in terms of functionality and level of ease. This comment was only made by locum pharmacists who worked at different locations.

...you need to get used to a system.....because then that way you know how to identify patients... LocumCP1(3yrs).

Most participants agreed that the quality of clinical services provided for patients was not consistent. This might be attributable to several factors, such as workload, competency of community pharmacists, and the different service requirements that each LHB required prior to providing a new service. Each LHB has its own criteria and requirements that have to be met prior to providing a certain service. The variation in requirements for providing any given pharmacy service among LHBs may impact the quality and consistency of the service provided. If a chronic condition management

service was not approved as a national service (i.e. the service requirements would be the same across all LHBs), patients might experience inconsistent care.

...I'm not sure how, like, you know, the consistency in which this service is provided whether all pharmacists actually cover the same things in each consultation as I do... LocumCP1(3yrs).

5.3.2.1.3 Identifying eligible patients for services and referring

It seemed that there was an issue with identifying patients eligible for professional pharmacy services. Several participants reported that patients eligible for clinical services in pharmacy could not be easily identified. There was no mechanism in place to identify patients who needed to be seen by community pharmacists. It was up to pharmacists to decide for whom and when a service should be provided. Therefore, the lack of an effective formal route for identifying patients who might benefit from a given service would severely impact the ability of pharmacists to take care of patients and might also impact the equity of care for patients across Wales. Pharmacists might be selective in providing certain services that would benefit them most (e.g. services that generate more profits). This might lead to not providing pharmacy services for people who really need them.

...there's not really a mechanism as to how we filter these patients. It's like up to the pharmacist to decide.....who's like.....who's appropriate for this given service... LocumCP1(3yrs).

Most of the services provided in community pharmacies were described as “opportunistic” by two participants. This required participants to spend more time trying to form a clear picture about patients’ health. They had to rely only on information provided by patients to evaluate patients’ health issues. Information provided by patients might not be enough in determining the required health care intervention. This is because patients might not have the required clinical knowledge to determine which service they should receive. Therefore, establishing an effective formal route for

identifying patients who might benefit from a service would be a necessity prior to moving forward with managing chronic conditions in pharmacy.

...most of our services are opportunistic or client led... Independent prescriberCP6(12yrs)

...a lot of the care that's beneficial in community pharmacy is through chance encounters currently. So if a pharmacist has the thought of just asking 'how is your asthma?' to a patient.....Every now and then.....then they may find out that they're struggling and they have not used their Ventolin more often, but there's currently no structure in place that forces people to do that... LocumCP2(3yrs).

In addition to the points mentioned above, some participants indicated that there was an issue with referring patients between primary care settings (e.g. between GPs and community pharmacies). The lack of clear criteria for referring led patients to be referred to community pharmacies when this was not appropriate. This would not only inconvenience patients, but also would add unnecessary workload onto community pharmacies. Given that chronic conditions are varied in terms of nature and complexity, implementing clear referral criteria among primary care settings would ensure the provision of seamless health care services.

...patient will walk into a GP surgerysee the receptionisttell them what's wrong with them and the receptionist will say that's something your pharmacy can do.....and when they come into the pharmacy, we find actually they've got a number of symptoms that exclude them from the service, so they do need to see their GP... RegularCP3(14yrs).

5.3.2.1.4 Reallocation of responsibilities in community pharmacy

Participants argued that community pharmacists were not utilised effectively. Most participants claimed that community pharmacists could be more involved in tasks that better utilised their expertise. Being involved in responsibilities that did not necessarily

require the skills and knowledge of community pharmacists increased their workload and squandered the available resources (e.g. human and financial resources). They felt that they could be involved in providing more patient-centred services, but this should be done after delegating other services that did not utilize their skills.

...I feel that (checking prescriptions) can be delegated to like trained staff whilst the pharmacist is delivering like a service that actually needs the skills of the pharmacist to deliver... LocumCP1(3yrs).

In addition to freeing up community pharmacists' time to deliver more services that utilise their expertise, two participants believed that other pharmacy staff (e.g. ACTs) could be much better than community pharmacists in delivering some services (e.g. accuracy checks). This might be attributed to the wide number of responsibilities community pharmacists had. They were involved in several clinical and non-clinical services. Thus, reallocation of community pharmacy services (ones that do not necessary need the expertise of community pharmacists) not only would enable community pharmacists to provide chronic condition management services, but also might improve the quality of other provided services.

...we clinically check them but a lot of the accuracy check and then is done by the technicians. I see them as probably more accurate than the pharmacists we've had, including myself, because they have one role there, that's it... Independent prescriberCP6(12yrs).

5.3.2.1.5 Accessing and sharing patients' medical information

All participants raised concerns about the importance of having access to patient medical records in order to get the whole picture of their health situation and provide better health services. Under the current practice, community pharmacists have limited access to patient records, which reduces the level of care they can provide. The current sources of information about a patient's medical history would be the patients themselves or reviewing prescription and dispensing records. The amount of information provided in MURs was not considered to be helpful in providing community

pharmacists with the information needed to clinically manage patients with chronic conditions properly. This was not only limited to patient medical history, but also to other important information, such as lab tests and practitioner notes.

...I think it'd (community pharmacy involvement in managing chronic conditions) be very limited because you don't know blood results... ManagerCP5(19yrs).

...It's (MURs) just checking that they're taking the medication as prescribed... LocumCP2(3yrs).

Most participants seemed to be blinded about what happened to patients beyond the pharmacy doors. The fragmented care would significantly impact the ability of community pharmacists to provide good healthcare services for patients. As healthcare providers, they should be empowered not only to access patient medical records but also to contribute to these records. By having read and write access to patient medical records, community pharmacists would be more involved in providing multidisciplinary care. That is because managing chronic conditions would need all healthcare providers involved in the care of a patient to work in an integrated manner. This would ensure that community pharmacists would not be solely dependent on information provided by patients but would also have access to practitioner comments and lab results. More importantly, their contribution to patient health could be accessed by other practitioners. Thus, the quality of care provided to the patient would be enhanced, as well as saving time and effort (e.g. patients may not be asked to check inhaler technique if another health care provider had just checked their technique).

...if the asthma nurse has decided on a certain treatment plan, if we could get copied into it and then agree to check up on the patient's adherence and how they're getting on, it might just be more beneficial than sporadic asthma appointments... ManagerCP4(3yrs).

Interestingly, one participant argued that patients assumed community pharmacists could access patient medical records. Community pharmacists are part of the healthcare

team, so it would be sensible to empower them to access medical records. If patient confidentiality is the issue, patients should be informed that the quality of healthcare services provided to them (i.e. managing chronic condition services) would be greatly impacted by not allowing community pharmacists to access their essential medical information.

...patients really are shocked that the community pharmacy doesn't have any access to medical information and medical records... LocumCP2(3yrs).

5.3.2.1.6 Funding and remuneration

Almost all participants raised their concerns about how the service of managing chronic conditions in community pharmacies would be funded. Their financial concerns involved several aspects which might increase the economic burden on community pharmacy in direct or indirect ways. This included, but was not limited to, hiring additional staff to cope with managing chronic conditions in pharmacy (for more information, see section 5.3.2.5), buying equipment (for more information, see section 5.3.2.4) and training costs (for more information, see section 5.3.2.1.7), as well as the cost of cover staff while the main pharmacist undertook the required training.

...if a pharmacy is going to do that (managing chronic conditions), you know, they can't keep being out of pocket... SuperintendentCP7(5yrs).

...I supposed the remuneration needs to match up to being able to hire another pharmacist or another ACT to be able to help out with the actual day-to-day role of pharmacists... Independent prescriberCP6(12yrs).

Participants claimed that the way a community pharmacy is reimbursed needed to be changed if chronic conditions are going to be managed by them. The current remuneration model was criticized for being a quantity-driven model. The quality of care provided was not as important as the quantity in reimbursing community pharmacy. More focus needed to be given to assessing the quality of services provided. Further,

considering quality indicators in reimbursing a community pharmacy may ensure the provision of good quality care and therefore may improve patient outcomes. Moving away from a quantity-driven model to a quality-driven model might be a necessity when providing direct patient care. As some community pharmacies might not be willing to provide clinical services and might instead be more focused on dispensing, the new remuneration model should take this fact into consideration. Therefore, community pharmacies which are not involved in managing chronic conditions should be able to survive and promote the sustainability of their businesses. That means that the reimbursement model for community pharmacy should guarantee producing profits for pharmacies that would continue doing what they are currently doing.

...for an MUR we get paid 28 pounds. Is that enough? Sometimes I see some pharmacists sit down for less than five minutes, have a quick chat and it's done. Sometimes I see pharmacists for a half an hour with a patient... RegularCP3(14yrs)

...and there's no reimbursement model for giving a quality of care... LocumCP2(3yrs).

Since the current remuneration model is mainly quantity-driven, one participant argued that community pharmacists and management of community pharmacies were selective in providing services that generated more profits. Community pharmacists tended to choose simple tasks to increase their income rather than choosing those that benefited patients the most. Part of the problem might also be attributed to the lack of a formal route in identifying eligible patients for pharmacy services, which was discussed previously in section 5.3.2.1.3.

...I feel that community pharmacists probably feel quite restricted in the standard of care that they can provide because they have a lot of pressure from management to hit the dispensing targets ... you've got to make sure that the contracts is fulfilled, which involves dispensing the prescriptions, then you kind of keep the company that you're working for happy... LocumCP2(3yrs).

The Welsh Government is trying to encourage community pharmacies to provide more clinical services by reallocating funds given to community pharmacy (i.e. shifting part of the funds allocated for dispensing towards other clinical services provided in pharmacy). This decision was not welcomed by one community pharmacist. As discussed above, the sustainability of the community pharmacy business should be carefully considered when designing a new remuneration model.

...so that means more remunerations, rather than it being cut cut cut all the time... ManagerCP5(19yrs).

...for the pharmacies to do it, there has to be an incentive for the pharmacies to do it as well... SuperintendentCP7(5yrs).

Another point that needs to be considered while designing a new remuneration model is reimbursing all practitioners involved in managing patients with chronic conditions. It was argued by participants that the current remuneration model did not support multidisciplinary collaborative work. There were no criteria for reimbursing a multidisciplinary team for achieving patients' desirable care outcomes that need collaboration between different professions. This might create financial disputes among community pharmacy and primary care providers, and therefore may impact their relationship. Therefore, since managing chronic conditions might require healthcare providers to work together as a team for the best interest of the patients, designing a remuneration model that supports collaborative work would be an enabler.

...we both (GPs and community pharmacy) make a bit of money off of the flu vaccinations and it does create a bit tension sometimes so we work really hard to work with the surgeries, but I feel like if we pushed our flu vaccination service, it would, it would harm our relationship with surgeries... Independent prescriberCP6(12yrs).

Several participants came up with ideas that might help in designing a new remuneration model that might fit the management of chronic conditions in pharmacy. This included shifting from the quantity-driven model towards a quality-driven model, allocating some funds from the community pharmacy contract, and assigning a fixed cost for each particular chronic condition (further discussion will be presented in the discussion section).

5.3.2.1.7 Training and education

All participants agreed that training and education would be essential prior to managing chronic conditions in a community setting. Managing chronic conditions might require skills and knowledge that are not part of pharmacists' education and training. This includes not only theoretical information that helps in identifying disease progression and determining the proper treatment plan, but also technical and clinical skills that might be necessary in managing chronic conditions, such as taking patient history and interpreting lab results. This might be more important for the more experienced pharmacists, since their pharmacy education was not as clinically oriented as the current pharmacy programs.

...if we're doing monitoring things like blood results and things like that, then most community pharmacists don't use that information very often, so they don't have that familiarity to be able to kind of process information... RegularCP3(14yrs).

Since managing chronic conditions may require further professional qualifications, most participants believed that being an independent prescriber would be a necessity. Being a pharmacist independent prescriber not only would enable pharmacists to prescribe medications, but also might increase their expertise in certain diseases and advance their clinical skills. The availability of training courses is an area that needs to be improved. Although general online training courses were found to be helpful and accessible by some participants, enrolling in independent prescribing courses was found to be difficult. This might be attributable to high demand for these courses, as the Welsh Government wants to increase the number of Independent Prescribers (IPs) in

community pharmacy. If managing people with chronic conditions would require enrolling in IP courses, the availability of these courses should be significantly increased.

...some colleagues were doing a diabetes modules part of that IP and let's say they are a lot more qualified to follow up people with diabetes... Independent prescriberCP6(12yrs).

...I've been looking at for a while (independent prescribing course), but I haven't been able to get so... SuperintendentCP7(5yrs).

5.3.2.2 Awareness raising and guidance

Most participants argued that there was a need to raise the public's awareness of community pharmacy as a profession (i.e. the role of community pharmacy staff) and services provided in that setting. Patients needed to be aware of services provided in pharmacy, so that they could benefit most from community pharmacies. This might be attributable to the massive change in the community pharmacy profession. The community pharmacy sector has evolved significantly in the last two decades, increasing the provision of more patient-facing services. The uncertainty about services provided in a pharmacy was not just an issue for the public, but also among other healthcare professionals. This might mean that the role of community pharmacy should be advertised at a higher level (i.e. advertising to healthcare providers as well). Another identified issue was that the public could not distinguish between the roles of community pharmacists and other pharmacy staff, such as pharmacy technicians. People tended to ask community pharmacists questions that did not need the expertise of a pharmacist to answer.

...I think the extra services that community pharmacist provides in general have not been sold very well to the public... LocumCP2(3yrs).

...we have a lot of people visiting this pharmacy from healthcare backgrounds and government backers, and they're always surprised as well (about services provided in pharmacy) ... Independent prescriberCP6(12yrs).

...sometimes they (patients) ask to see the pharmacist and it's something that might... technician could have dealt with... RegularCP3(14yrs).

Participants claimed that public awareness of community pharmacy could be improved by creating outreach campaigns and media activities. Making the most of technology in advertising the role of community pharmacy in providing healthcare services could be helpful. Community pharmacists could also play an important role in marketing themselves by offering services that benefit patients most. Other healthcare providers could also help in this regard by referring patients in need to receive professional pharmacy services.

...more media campaigns more services... ManagerCP5(19yrs)

...so, I think advertising what we're doing and whether that be to the public or to other healthcare professionals... Independent prescriberCP6(12yrs).

Two participants argued that community pharmacy needed better guidance. Having more than one body involved in regulating/advising on community pharmacy issues (e.g. LHBs, Community Pharmacy Wales, Welsh Pharmaceutical Committee) might confuse beneficiaries. There should be a clear formal route through which advice could be obtained when needed. One participant suggested that there might be inequity in supporting community pharmacists. Pharmacists who were not engaged with regulatory bodies might not receive as much support as engaged pharmacists.

...I think there are a lot of pharmacists are keen (talking about independent prescribing courses), but they don't know in what direction to go... SuperintendentCP7(5yrs).

...but whether that voice is reaching some of the maybe the quieter pharmacies and people that aren't that engage with the regulatory bodies I'm not sure... Independent prescriberCP6(12yrs).

5.3.2.3 Accessibility of community pharmacy

Community pharmacists are well known for being highly accessible in comparison to other healthcare providers. Several participants reported that community pharmacies were widely distributed and easily accessible. However, one participant mentioned that sometimes they might not be physically accessible, especially when they are not located on the ground floor, and no lift or escalator is in place. Patients with disabilities or those who use mobility scooters might find it difficult to access a pharmacy on an upper floor when there are no lifts.

...the patients going to have better access to those care pathways than they would if they were in the hands of the GP... LocumCP2(3yrs).

...it could be the pharmacies in a shopping centre which have to get some steps to get into or something like that... RegularCP3(14yrs).

In addition to their wide distribution, participants thought that the accessibility of community pharmacies was good due to their working hours. It was reported that community pharmacy open hours were an advantage, as they are open for longer hours than GPs and even during weekends. This is likely to be more important for carers who might be restricted in accompanying an older relative during their normal working hours.

...some GP surgeries only do it (vaccinations) on a weekday and that doesn't suit people if they're still working, for example, so they might choose to come to the pharmacy on Sunday to get it done... RegularCP3(14yrs).

5.3.2.4 Facilities and equipment in community pharmacy

Almost all community pharmacists agreed that facilities and equipment in community pharmacies would require further improvement prior to managing chronic conditions. The extent of the development/improvement needed would be based on how much a community pharmacy would be involved in dealing with chronic conditions: for example,

whether they are going to take blood samples or not. Such limitation in facilities and equipment was expected, since the current scope of community pharmacy does not require the same tools as general practice.

...it depends what we're going to do: whether you need an area for the patient to be able to lie down or just to sit down... RegularCP3(14yrs).

...so when you talk about diabetes, maybe you have HBA1C machine..... something that we could actually help them and show them markers of what their condition is improving or not... Independent prescriberCP6(12yrs).

Since managing people with chronic conditions would mean that community pharmacists will use consultation rooms more frequently, the number of consultation rooms in each community pharmacy might be an issue. Several participants indicated that one consultation room might not be enough if they were to manage chronic conditions. Pharmacists are not the only community pharmacy staff who use the consultation rooms. Other pharmacy staff also use these rooms to provide certain services. Moreover, managing several chronic conditions in a pharmacy may increase footfall significantly in a way that could be difficult to manage. Therefore, this would not only affect the capacity of community pharmacy but also might negatively impact the patients' experience. Patients might have to wait longer to access consultation rooms and see a community pharmacist, which would lead them to experience the same issues they encounter when they see their GPs.

...I don't have a lot of space really because the consultation room is quite often used by other members of staff... ManagerCP4(3yrs).

One pharmacist criticized consultation rooms as being less professional than they should be for both patients and pharmacists. The consultation rooms should look tidy and professional so patients would feel comfortable while they are visiting the community pharmacy. The image of consultation rooms would have a great impact on a patient's respect for community pharmacy and community pharmacists. Patients would perhaps

expect to be in a consultation room that is comparable to what they see in general practice.

...It's (consultation room) not a comfortable environment for patients to be in. It's not a comfortable environment for pharmacists to be in... LocumCP2(3yrs).

The size of consultation rooms was an issue raised by two participants. The consultation rooms were claimed to be too small: barely able to accommodate two persons. This would be a crucial issue with some wheelchair patients accompanied with a carer. The tiny consultation rooms might lead to safety and security issues. Patients and their carers might leave their belongings outside the consultation rooms, at risk of being stolen. Also, gathering more than two people in a small room might put people's safety at risk, especially when dealing with hazardous objects.

...I don't have room for them to bring their mobility scooter into the consultation room, which means I would have to ask them to leave it in the middle of the shop and often has big shopping baskets or things like that... RegularCP3(14yrs).

...if then we're talking about using sharps, so we are doing blood testing or vaccinations or something like that, you then got added risk assessment to do if you've got another person in the room alongside them... RegularCP3(14yrs).

5.3.2.5 Workload and staffing in community pharmacy

All participants indicated that the current workload of community pharmacists was considered a major barrier to providing more clinical services for patients. Furthermore, expanding the role of community pharmacists without considering the heavy workload they have might decrease their job satisfaction and threaten patients' safety. Community pharmacists might find it difficult to cope with performing many different tasks ranging from filling in forms to making treatment and care decisions on patients' health. The quality of service provided would perhaps be impacted, as community pharmacists need to tackle high demands on professional pharmacy services. This might also impact the experience of patients, as they would receive a low-quality service,

which would reflect negatively on the image of community pharmacy and lead patients to prefer to see other healthcare providers if they have the option to do so.

...I don't think the community pharmacist would have enough time to (manage chronic conditions). And I think that's....that might be too much pressure on the community pharmacist... ManagerCP5(19yrs).

...like I said, not all pharmacists do that, pretty sure not all pharmacist ask (how to use inhalers) because it takes too much time... LocumCP1(3yrs).

The issue with heavy workloads was not just a problem for the community pharmacists themselves but also impacted other members of the community pharmacy workforce. The work environment of the setting was claimed to be very busy. This makes utilising technology to reduce workload a necessity in community pharmacy. As the dispensing function represents a huge part of the pharmacist's daily duties in community pharmacy, employing technology such as hub-and-spoke and robots might free up pharmacists' time. This would allow community pharmacists to focus on tasks that effectively utilise their clinical expertise and skills.

...they (pharmacy technicians) have the same constraints as the pharmacist in terms of time and.....and especially in community, it's not just about your services, it's about everything else in running a store which I think difficult... ManagerCP5(19yrs).

Almost all participants agreed that for chronic conditions to be managed properly in a community setting, there would be a need to employ a second community pharmacist. Managing people with chronic conditions would mean spending more time in consultation rooms. To make sure that other pharmacy services (i.e. services that need a pharmacist to deliver) are provided smoothly, another pharmacist should be available behind the counter at all times.

...so if the pharmacist is in the consultation room for let's say 30 minutes, all the prescriptions that arrived in that pharmacy within 30 minutes cannot be processed properly until the pharmacist has looked at them specifically, so that would have an impact if there's a single pharmacist... RegularCP3(14yrs).

Not having enough staff, or not having sufficient qualified staff to provide a certain service, was claimed by several participants to impact the provision of pharmacy services. Pharmacists might be reluctant to provide further services because of staffing issues. More importantly, not being able to employ qualified staff would greatly impact the continuity of service provided, as some pharmacy services would require additional qualifications. When patients visit a GP for a certain issue, they might be more certain that they would receive the service. This might not be the case when they visit a community pharmacy, as the continuity of the service is a common issue in this sector. This issue might be more frequently observed when chronic conditions are managed in pharmacy, as it is more likely that staff would require further qualifications.

...I know a lot of my colleagues with smaller pharmacies find it difficult to move away from the dispensing because there just isn't the staff to help out with that... SuperintendentCP7(5yrs).

...for example, the sore throat test and treat, we have two pharmacists but only one of us is trained up..... so there are gaps where we are not able to provide that sore throat service until we've trained up our other pharmacist provider” Independent prescriberCP6(12yrs).

Participants suggested several solutions to improve the workforce and the community pharmacy environment prior to moving forward with managing chronic conditions. Increasing staff members, employing technology, establishing appointment systems, and decreasing workload for community pharmacists by taking away some tasks were all suggested as ways to facilitate the introduction of chronic disease management. Even though establishing appointment systems might help in managing workloads, other participants believed that this would be against the essence of community pharmacy in

terms of accessibility. Seeing patients by appointment would make community pharmacy more like GPs, so patients might experience long waiting times. Moreover, having more than one community pharmacist on duty was not only seen as helpful in coping with a heavy workload, but also would be supportive in other ways. Community pharmacy can be an isolated environment for pharmacists in terms of the lack of colleagues and peer support. Having two pharmacists on duty would allow for scientific conversations and mutual exchange to occur, which would ultimately benefit both pharmacists and patients.

...I'm not sure whether this (establishing appointment systems) would be suitable for patients. Like they may feel like that you're restricting them to access these services at a particular time... LocumCP1(3yrs).

...so we'll talk about clinical conversations about some prescriptions and why some interventions that maybe I wouldn't have noticed or my colleague would have noticed that one of us does and then we had to educate each other as well... Independent prescriberCP6(12yrs).

5.3.2.6 Healthcare professionals' collaboration and relationship with community pharmacists

Most participants indicated that the level of collaboration and interaction with other healthcare providers, especially GPs, needed to improve in order to provide a good level of care for patients. Providing healthcare services should not be the responsibility of one healthcare sector. Healthcare services should be delivered in a more integrated way, allowing for the multidisciplinary team to work collaboratively in patients' best interests. Managing chronic conditions properly would require the expertise of different healthcare professionals (i.e. people from different professions). For example, combining the expertise of physicians in diseases and diagnosis and the knowledge of community pharmacists in medicines aspects may improve patients' care outcomes. The healthcare system should support collaborative work among practitioners, instead of leaving it to practitioners to decide whether they want to collaborate or not.

...I think a lot of GPs benefit from pharmacy collaboration, but I think there's still a bit to go... ManagerCP5(19yrs)

Several participants claimed that the relationship between GPs and community pharmacists was not ideal. Not having a good relationship might affect the amount of collaboration between the two professions. Several participants argued that the relationship between the two sectors needed to be improved in the interest of patients. It seemed that the relationship between GPs and community pharmacy was impacted by several factors, namely previous experience they had, GPs' perceptions about community pharmacy, and the amount of face-to-face interaction. GPs who had good experiences with certain community pharmacists might be more likely to have good relationships with those pharmacists. The negative perceptions some GPs have about community pharmacists might reduce their interaction and impact their relationship with community pharmacists. GPs might be reluctant to deal with community pharmacists because they were not seen as "healthcare providers". The historical stereotype about community pharmacists being "dispensers" may adversely affect the relationship and the amount of collaboration.

...GPs who have had positive experience of community pharmacists will hold community pharmacist in a high regard... LocumCP2(3yrs).

...any time that you try and chat to a GP, sort of met with a bit of resistance, and a bit of suspicion about why you're looking for this information (information about patient's condition)... ManagerCP4(3yrs).

Participants came up with several ideas that could help in improving the interaction and collaboration between healthcare professionals. They claimed that interprofessional education, shared educational courses, and having more face-to-face interaction would all make people from different healthcare professions much closer. Pharmacists who worked at community pharmacies attached to GPs claimed to have a better relationship in comparison to those working in other places. This might be attributed to the opportunity for more face-to-face interactions/meetings with each other. It was also

argued by one participant that the new way in which the quality payments system works encouraged community pharmacists to have more face-to-face meetings with GPs and therefore would improve the relationship.

...I think there needs to be more education probably in medical degrees of integrated care and how best to utilize resources available in NHS... LocumCP2(3yrs).

...I think the way that we have the quality payments now encouraging collaboration visits between pharmacies and GPs really helps because we do, you know, it encourages you to make the time to go and visit them and have those face-to-face interactions and I've had good experience of that actually solving issues that have been underlying before ... RegularCP3(14yrs).

5.3.2.7 Patients' interactions and relationships with community pharmacists

It appeared that the relationship and interaction between community pharmacists and patients varied from one person to other. Several factors were identified as impacting the relationship and interaction between patients and community pharmacists. Two participants claimed that the place where the pharmacist works may impact the relationship with patients. Pharmacists who work in a pharmacy in or attached to a supermarket might receive less appreciation from patients. Patients might think that these pharmacists are more concerned about generating profits, so they might not adhere to their health recommendations despite the fact that they are for their best interests. Conversely, community pharmacists working at a pharmacy attached to a GP surgery might receive more appreciation. Having said that, several participants working at different places indicated that patients might have a specific stereotypical view about community pharmacy that could be a barrier to managing chronic conditions in pharmacy. The historical stereotype about community pharmacists as "chemists" might limit their involvement in providing more clinical services. Thus, patients might prefer to see a GP for their chronic illness rather than seeing a community pharmacist. Other factors impacting the relationship/interaction between patients and community pharmacists were previous experience and difficulty seeing GPs. Patients might decide

to see a community pharmacist because they could not access a GP (more detail was provided in section 5.3.2.3). On the other hand, the personality of community pharmacists might play an important role in initiating and developing good relationship with patients.

...so I think in supermarkets a lot of patients very sceptical of anything extra.....these.....the pharmacist has to offer even if it would benefit them... LocumCP2(3yrs).

...because they (people) might not believe the pharmacist is equipped enough (talking about managing chronic conditions) ... ManagerCP5(19yrs).

...it's not as easy to pull people into a room and people are quite resistant to having chats with the pharmacist... ManagerCP4(3yrs).

Patients' willingness to see a community pharmacist to manage their illness might be greatly impacted by the medical hierarchy. Patients may believe that GPs are the best people to see regarding their illness. One participant claimed that patients saw community pharmacists as "discount GPs". The excellent accessibility of community pharmacy might lead patients to be less appreciative of community pharmacists. Community pharmacists are the only healthcare providers who can be accessed without making an appointment.

...I still think that they (patients) have quite a strong belief in medical hierarchy in that doctors are still the best person to see and that seemed a community pharmacist is purely cost-cutting: that they're getting basically a discount GP which they can see without having to make an appointment... LocumCP2(3yrs).

It was also claimed by two participants that some patients were reluctant to share their medical information. This would be a major barrier to managing chronic conditions in pharmacy. Community pharmacists would not be able to manage chronic conditions without knowing relevant information about patient health conditions. Patient trust in

community pharmacists would be essential in developing a good relationship. This trust could be built by raising the public's awareness about the role of community pharmacists and their contribution to people's health. Provision of excellent patient care would also improve the image of community pharmacists in the eyes of the public.

...they're not comfortable with sharing information with me, especially because I don't have any access to the information... ManagerCP4(3yrs).

Conversely, some participants indicated that patients would like to talk with pharmacists regarding their health issues, as they had a more friendly relationship with them in comparison to the GP in addition to being more accessible. As mentioned in section 5.3.2.3, the accessibility of community pharmacy may be advantageous in creating more points of contact with patients. As patients with chronic conditions would need to access a community pharmacy more frequently to pick up their medications, this would increase the opportunity for interaction with community pharmacists. Continuing interaction with patients may play an important role in developing a good relationship. Having a good relationship with patients and knowing them better may improve the patient care outcomes.

...a lot of the time when people are diagnosed with stuff, that first consultation with the consultant or GP can be a bit overwhelming, so then they come to us for a bit more advice on what they can do on a practical level or what they've just been told we can re-explain it to me, we dumb it down a bit more for them... Independent prescriberCP6(12yrs).

5.3.2.8 Confidence and willingness of community pharmacists to manage chronic conditions

It seemed that most community pharmacists expressed their willingness to expand their role in managing chronic conditions, if all related issues were addressed (e.g. workload, remuneration model, staffing). However, some participants claimed that some experienced community pharmacists might not be interested in managing people with chronic conditions. This might be attributed to the fact that the old pharmacy

educational programs were not as clinically oriented as the current ones (for more information, see section 5.3.2.1.7). All community pharmacists indicated that their competency in managing chronic conditions varied based on the types of chronic conditions and personal knowledge. That was not a surprising finding, as chronic conditions are widely varied in terms of their nature, complexity, and treatment. Community pharmacists' confidence in managing chronic conditions could be increased by completing training courses related to managing chronic conditions (for further information about training, see section 5.3.2.1.7).

...it just depends on our own personal knowledge of that condition in terms of how much more information you can give them... ManagerCP5(19yrs).

...I think I'd need a little bit more training whether that be a couple of days in university or some modules from WCPPE... Independent prescriberCP6(12yrs).

It seems that some participants did not feel comfortable with having the responsibility of managing people with chronic conditions. They would prefer to work collaboratively in a multidisciplinary team, so patients could be managed properly. This was expected, as community pharmacists may not be as well trained as GPs in some respects, such as differential diagnosis. Community pharmacists may be best placed in dealing with aspects of medication, such as therapeutic management, drug-drug interaction, drug-disease interaction, and medication side effects. Therefore, their involvement in managing chronic conditions should be based on an integrated healthcare model in which all health care providers work collaboratively for the best interests of the patients. Not addressing pharmacists' needs (e.g. through providing specialized training courses) or not involving them in a multidisciplinary team might impact the quality and safety of the service provided.

...speak with a pharmacist who is an independent prescriber who can monitor your...your health condition, make alterations to the prescription, and then if absolutely necessary and things have changed, then they can refer them back to their GP if it's outside of their clinical expertise... LocumCP2(3yrs).

When participants were asked to mention five chronic conditions that they could manage properly, most of them could not do so. They took a long time thinking of an answer in comparison to other questions, and their non-verbal communication (e.g. looking around, scratching their heads, taking a deep breath) indicated that they were struggling to answer this question (although the researcher is not specialised in body language, the broad non-verbal communications were captured and interpreted). The most frequent chronic conditions mentioned by participants were asthma, diabetes, hypertension, heart failure, and COPD. There were several reasons why participants chose these chronic health conditions. These were that the diseases had a well-defined therapeutic management plan, the intervention was medical in nature, patients could be hugely involved in managing their conditions (i.e. self-management), they had a high prevalence rate, not complex chronic conditions (i.e. it was easy to monitor them in the pharmacy and assess the patient care outcomes), and it was possible to provide educational interventions for patients. This might mean that not all chronic conditions could be managed in community pharmacy. Therefore, starting with chronic conditions that have all or most of the characteristics mentioned above may help in implementing a successful chronic condition management model.

...I would find it very difficult to pinpoint five... RegularCP3(14yrs).

...there's a lot of education needed around those, Ventolin and preventers are all these... Independent prescriberCP6(12yrs).

5.4 DISCUSSION

Given that the scope of pharmacy practice has evolved over time and is expected to expand, as discussed in the introduction section, the potential involvement of community pharmacists in managing chronic conditions should be investigated. Understanding the community pharmacist's perspective about being more involved in chronic conditions management may help to shape a new model of community-based chronic condition management. The aim of this study was to explore the perceptions of community pharmacists regarding managing chronic clinical conditions in a community setting. In general, community pharmacists expressed several factors that might

influence their ability to manage chronic conditions. Although the competency of community pharmacists was an important element in managing chronic conditions, many other influencing factors were beyond the control of community pharmacists, such as policy and regulations. Themes identified during this study were associated with all tiers of the community pharmacy sector ranging from governance and pharmacy operation to the individual (pharmacist, other healthcare providers such as GPs and potential patients). These tiers are used to group related themes together and will each be discussed in turn.

5.4.1 Themes at healthcare system level

Community pharmacists in this study believed that they could be more involved in managing chronic conditions, but that several regulatory changes needed to be considered. As the management of chronic conditions would need several different health professions to work together, it will be necessary to move towards an integrated healthcare system in which practitioners from different sectors are empowered by the system to work collaboratively in a multidisciplinary team. This could ensure that patients receive high quality and seamless care. To tackle the lack of clarity about the boundaries of different healthcare professionals, a service level agreement should be written to clearly indicate how the service would be provided and who would be involved. This would eliminate duplication of roles (i.e. providing the same service for the same patient by different health professionals) and minimize the wasting of time and resources, as patients would not be seen twice for the same service. It would also help in having a more successful integrated healthcare system, as everyone involved would know when one person's role starts and ends. The opinion expressed by participants about the lack of clarity between health profession' boundaries were in agreement with the findings of Donald et al (2017). The authors of that study reported that there was a "lack of clarity" regarding responsibilities about patient outcomes among healthcare professionals. Moving away from the fragmented health care system to an integrated one may also encourage health professionals to work collaboratively for the patients' best interests. This might be enhanced by utilizing technology efficiently in terms of communication and sharing data (NHS Wales 2018). Under one primary care electronic system, health professionals involved in patient care could actively interact

and communicate with each other. They could contribute and share patient medical information, which might help to improve patient health and wellbeing. A unified electronic medical record would contain the opinions and input of different healthcare professionals which would lead to better decision making to the benefit of patient health and wellbeing. This would enable community pharmacists to make healthcare decisions based on reliable and enough information instead of being solely dependent on what patients disclose and the limited amount of information available to community pharmacy. According to a recent report published by the Welsh Pharmaceutical Committee (2019), the community pharmacy team will be integrated with other healthcare professionals to work collaboratively in primary care clusters. Further, in a recent legislative change, all general medical contractors will be required by the core contract to be part of a cluster (Welsh Government 2019b, for more information about clusters see section 1.7). This will change the ways in which services are provided for patients and might help to improve their experience, especially in a service where inputs from different health professions are crucial (e.g. managing chronic conditions). However, involving community pharmacy in a multidisciplinary team to provide patient care might be threatened by patients' confidentiality. Participants expressed that patients might not be willing to provide community pharmacies with access to their medical information. It has previously been argued that a community pharmacy is a public place where patients are called by their names and receive health advice in the presence of others, which might threaten their privacy (Hattingh et al. 2014). Also, it was identified that some patients were not happy with multiple pharmacy staff knowing about their medical conditions as several staff members were involved in the conversation and dispensing process (Hattingh et al. 2014). That being said, community pharmacies are equipped with consultation rooms, so all interaction between pharmacists and patients regarding their illness should occur in a private place. Further, in a large British study that included more than 7,000 participants, patients were happy with community pharmacists gaining access to their GPs' records (Mahmood et al. 2015, cited in Royal Pharmaceutical Society 2016, p.15). The Welsh Government (2020a), in a recent statement, said that community pharmacists providing clinical services would be given access to GPs' records. This would be a huge move towards enabling community pharmacies to provide better patient clinical care.

An integrated healthcare system may also help to solve the issue expressed by participants regarding identifying eligible patients for professional pharmacy services. How community pharmacy provides services for patients was criticized for the lack of a formal route to identify eligible patients for pharmacy services. Participants argued that not being able to identify eligible patients would impact the provision of health services for patients in need. Therefore, they might end with a deterioration of their health and incur additional costs on the NHS, as they might require hospitalization. The lack of this mechanism, in terms of patients with chronic conditions, may also impact the equality of service provided to patients, as not all patients would have the same opportunity to get the service (i.e. providing a service may depend on the subjectivity of the providers). Moreover, patients do not have the required expertise and knowledge in leading their medical management (Fitzpatrick 2005), so they might be unable to identify their need to be seen by a healthcare provider. Therefore, having a mixed approach that combines the advantages of both approaches (patient-led services and healthcare professional-led services) would ensure that patients could get the service they need and at the same time would help patients who are not fully aware of their health condition/problem to be seen by a health care professional. This might help in reducing health inequalities, which were a priority for the Welsh Government in their planning framework (Welsh Government 2018). Furthermore, establishing clear criteria for referring patients between primary care settings (e.g. GPs and community pharmacies) and managing them in a community setting would ensure that all patients would have the same opportunity and also might prevent them from falling through the gaps. A huge legislative change is expected to be implemented in the future such that all patients with stable chronic conditions will be monitored in community pharmacy (Welsh Pharmaceutical Committee 2019). This will make it much simpler to identify eligible patients. Patients with stable chronic conditions could be easily referred by their GPs to their local community pharmacy which provides the service needed. If patients' conditions deteriorate, they can be smoothly referred to the GPs, as they may need a more complex intervention. This might necessitate a referral pathway in which patients could be smoothly moved amongst health sectors. This would go in line with the new

Welsh plan for health and social life in respect to working collaboratively to deliver seamless care for the Welsh population (Welsh Government 2019a).

The way in which LHBs were commissioning community pharmacy services was described in this study as being varied, and was a source of confusion for beneficiaries (i.e. community pharmacy and patients). Services that were approved to be provided in one place might not be approved in another, leading to a reduction in the provision of that service and consequently decreasing its accessibility. The most widespread chronic conditions (e.g. asthma, diabetes, and hypertension) are common across all parts of Wales. Therefore, approving a chronic condition management service as a national service (i.e. LHBs should not be able to change or add additional requirements) would ensure the equality of service provided. This would also provide contractors with the same opportunity to serve their community, as the requirements to provide the service would be the same across Wales. Moreover, multiple community pharmacies are located across Wales (i.e. in different LHBs), so it may be more convenient and practical for them to apply the same requirements. Conversely, if a community pharmacist is qualified to provide a service in one of the LHBs, this pharmacist might not be able to provide the same service in another LHB and the continuity of the service might be affected. This makes having a standardized service requirement an essential step towards having a successful model of community-based chronic conditions management. Opponents to this idea might say that each LHB would need to implement specific requirements to ensure the safety of its population. First, the service would be approved at the national level, so the safety of the population would be kept as a priority. Second, any safety concern could be discussed at the national level, so an agreement would be reached. Third, it is less likely that variations will be found between chronic conditions and patients with these conditions among different LHBs. Chronic conditions have the same characteristics regardless of the location of the LHB.

The current community pharmacy funding and remuneration model was considered inappropriate for the management of chronic conditions in pharmacy. Participants argued that managing chronic conditions in pharmacies would incur additional costs and may require additional reimbursement for pharmacists. The same finding was identified

in other studies (McMillan et al. 2013; Puspitasari et al. 2015). Although the funding available for community pharmacies to provide clinical services has more than doubled in the last three years (Welsh Government 2020a), it does not cover the management of chronic conditions. As the clinical role of community pharmacists continues to grow, the Welsh Government (2020a) stated that further funding will be allocated to train the community pharmacy workforce, integrate community pharmacy with other primary care clusters, and fund technology use in community pharmacy. Community pharmacy would need additional funds to cover potential expenditure on the facilities and equipment needed to manage chronic conditions. The costs of training and the cost of hiring staff to cover for pharmacy members while they are attending training courses would also need to be considered. Participants suggested that the source of this additional funding may be allocated from the general practice fund, as community pharmacy would free up GPs' time. This could be funded by cutting some funds allocated to other services, such as dispensing. This, however, might impact the quality of service provided, as there is an association between the quality of service and being incentivised (Campbell et al. 2009). Further, employing technology (e.g. robots) to provide some pharmacy services (e.g. dispensing) might help in reducing spending, so the saved money could be allocated to other services.

Participants claimed that the way the remuneration model was built seemed to be more focused on quantity rather than quality. Even though the Welsh Government introduced the quality and safety scheme in the community pharmacy contract (Community Pharmacy Wales 2019a), it would need to go further to assure patients with chronic conditions that they would receive high-quality care. Conversely, having a quantity-driven model raised several issues within community pharmacy and with other primary care settings. Participants maintained that community pharmacists might be selective in providing certain services for patients, as they might choose services that are profitable and easy to deliver, rather than choosing them based on their impact on patient health (part of that might be attributed to the lack of a formal route to identify patients, as discussed earlier). Furthermore, having a remuneration model that does not support collaborative working between different professions may cause financial disputes and impact collaboration. There might be a need to design a remuneration model that takes

into consideration three main aspects: the quality of service provided, reimbursement based on collaboration via achieving shared patient care outcomes, and the sustainability of the community pharmacy business. The quality of the service provided could be achieved by determining specific indicators for each service. Quality could then be assessed by measuring these indicators. It was argued that one of the barriers to managing chronic conditions in pharmacy was related to how quality indicators are used in the remuneration model (i.e. giving a monetary value for interventions provided by pharmacists: Mossialos et al. 2015). After identifying the quality indicators of the service, the reward should go to all practitioners who are involved in achieving these outcomes based on their engagement in managing patients. To elaborate further on this issue, when talking about chronic conditions, the essential outcomes of each disease should be identified for each patient. Each patient would have certain desirable outcomes based on several factors, such as the progression of the disease, complications, age, and so on. The desirable outcomes for each patient can be determined by a health care provider (e.g. GP, specialist) and then shared with a community pharmacy, so patients could be managed in the pharmacy. When patients meet the desirable outcomes, all those who are involved in patient care should be rewarded. This would eliminate the possibility of having financial conflicts among health care providers, as in the case of flu vaccination, which was raised by several participants. Implementing a remuneration model based on quality indicators and shared outcomes would motivate community pharmacists to provide more clinical services, as they would be rewarded for providing clinical services. Also, it would encourage all health professionals to work collaboratively to meet the desired outcomes for patients, so that they are rewarded. Thus, it would be more likely to improve patient health. Finally, the remuneration model should take into consideration community pharmacies that are not willing to expand their role in managing chronic conditions. Community pharmacy businesses focusing on dispensing should be able to survive and make reasonable profits. This could be achieved by gradually shifting community pharmacy contracts towards providing more clinical services. Further, minimising the funds allocated for dispensing to a certain limit (a limit that discourages pharmacists from being solely dispensers and at the same time would maintain their profitability if they continued to do so) might be helpful. With time, the culture of the community pharmacy sector may

change, especially with employing young pharmacists, so they would perhaps be more interested in providing direct patient care.

Participants believed that accessing training courses might be a barrier to the management of chronic conditions in pharmacy. They argued that they faced difficulties accessing these courses. According to the Welsh Pharmaceutical Committee, all community pharmacies across Wales will have at least one pharmacist independent prescriber by 2030 (Welsh Pharmaceutical Committee 2019). This may help in implementing the chronic condition management model in pharmacy. As the demand for IP courses is likely to increase, the capacity would need to be increased to accommodate an increase in demand. To overcome this issue, pharmacy schools could be more involved by embedding IP courses within their current pharmacy programs. The graduates of these programs would be better prepared to be IPs. The same principle could be applied to any academic course that would help in managing chronic conditions in pharmacy. For example, students could enrol in elective courses to specialize in certain chronic conditions after finishing pharmacy programs. This would increase the number of qualified community pharmacists who can provide the service (i.e. managing chronic conditions) and reduce demand on training courses.

5.4.2 Themes at community pharmacy level

One of the main concerns expressed by participants in this study was the heavy workload in community pharmacy. The same findings have been reported in many other studies in the UK and around the globe (Hassell et al. 2011; Puspitasari et al. 2015; Alzubaidi et al. 2018). Community pharmacists' current workload might hinder the expansion of professional pharmacy services. Hassell et al. (2011) reported that community pharmacists' workload has increased in the UK after implementing the contractual frameworks for community pharmacy. Although their study was conducted nine years ago, and several things have changed, it appears that community pharmacists are still facing the same issue. Hassell et al. (2011) also claimed that due to the amount of workload, community pharmacists felt stressed. Being stressed might be associated with having lower job satisfaction and may increase the likelihood of quitting their roles. Tweddell and Wright (2000) found that 39% of community pharmacists who decided to

quit their jobs wanted to have more clinical roles. In a large UK study, Seston et al. (2009) found that community pharmacists were less satisfied than pharmacists working in other sectors. Thus, recruitment in community pharmacy might be negatively impacted, as contractors might find it more difficult to recruit community pharmacists, who would move to other sectors to improve their job satisfaction. However, delivering tasks that utilise the expertise of community pharmacists (e.g. clinical tasks) has been found to be helpful in improving job satisfaction (Welsh Government 2015). Therefore, tasks that do not need the expertise of community pharmacists to deliver may be replaced by others that effectively utilize their knowledge and skills (e.g. managing chronic conditions). This would not only effectively utilize pharmacy staff but also create headroom for community pharmacists to contribute more to patient care. In a recent report, the Welsh Pharmaceutical Committee (2019) mentioned that community pharmacists will no longer be responsible for dispensing. Automated systems and pharmacy technicians will be dispensing and providing advice on medications and adherence (Welsh Pharmaceutical Committee 2019). Further, using technology may also improve service accessibility. Seeing patients via video chat software (e.g. Skype) would increase accessibility to community pharmacists, especially for those who have physical limitations. In a study that aimed to identify what innovations people wanted from their community pharmacies, McMillan and colleagues (2014) found that people wanted virtual pharmacy consultations. Employing technology in providing health services would be important in the technology era and would meet people's expectations.

5.4.3 Themes at healthcare provider and patient level

Generally, the opinion expressed by community pharmacists is that they were willing to expand their role. However, this would be greatly affected by their competency in managing certain illnesses. Participants claimed that one of the main enablers to managing chronic conditions in pharmacy was upskilling community pharmacists. The results of this study showed that participants considered training and education of community pharmacists would be essential before they could manage chronic conditions in a community setting. This finding was concordant with a study that aimed to propose key steps to integrate community pharmacists into patient care pathway. Molen et al. (2017) claimed that training of community pharmacists needed to be

consider prior to providing clinical services. The training may include courses that improve practical skills needed to assess patients (e.g. taking blood pressure readings, taking patient history, interpreting lab tests) or courses that expand their knowledge in certain aspects (e.g. clinical information about certain chronic conditions, prescribing). It appeared that taking an independent prescribing (IP) course was considered to be an enabler in managing chronic conditions.

The way community pharmacists are perceived may impact the type of relationship/interaction they have with other stakeholders (patients and other healthcare providers). The historical stereotypes about community pharmacists as being “chemists” and “dispensers” might still impact how they are seen by the public and by health professionals. McMillan et al. (2013) found that some consumers were not sure about what services community pharmacists could deliver beyond dispensing. As a result, community pharmacists’ contribution to patient care might be limited, as they were not seen as “healthcare providers”. Moreover, community pharmacists are almost the only health care providers who are involved in selling items. Participants claimed that patients might be reluctant or sceptical when they are offered certain services. In a Scottish study, Gidman et al. (2012) claimed that there was a lack of trust from the public side in services provided by pharmacists. Their trust in GPs was greater than in community pharmacists in delivering primary healthcare services (Gidman et al. 2012). The mistrust in community pharmacists was attributed to the commercial setting of community pharmacy (i.e. patients’ interests might not be above pharmacists’ interests), competency of community pharmacists (e.g. training they had), and patients’ confidentiality (e.g. discussing patients information in front of other patients, Gidman et al. 2012). Another reason that might negatively impact public perceptions of community pharmacists might be related to the fact that they are more accessible than other healthcare providers (i.e. they are more readily available due to longer opening hours). Community pharmacists might be the only healthcare providers that patients could see without the need to book an appointment. Although this is the essence of community pharmacy, this result in patients undervaluing community pharmacists in comparison to other healthcare professionals where they have to book appointments prior to being seen. Further, it was claimed that the public were not fully aware of

services provided in community pharmacy (Katangwe et al. 2019, 2020). To improve the public awareness regarding services provided in pharmacy, participants suggested that the role of community pharmacists needs to be better advertised to the public and also to health professionals. The Welsh Government (2019) recently identified this need and planned to raise public awareness about the change in the nature of community pharmacy services. In addition, participants thought that community pharmacists should also promote their skills to patients by offering more services, which ultimately would raise patient awareness about services provided in pharmacy. If GPs were to refer patients to community pharmacies and inform them that their pharmacists are best placed to provide certain services, this might also improve perceptions about community pharmacists. An increase in interactions with patients and provision of high-quality healthcare services could improve not only perceptions but also trust (Gidman et al. 2012).

5.4.4. Strengths and limitations

As the Welsh Government is willing to expand the clinical role of community pharmacists in managing chronic conditions by 2030, this study is considered the first to explore the perspective of Welsh community pharmacists on the management of multiple chronic conditions in pharmacy. It has revealed the view of community pharmacists regarding factors that might hinder the management of chronic conditions in community pharmacies. Thus, it may help to shape a new model of chronic conditions management in a community-based setting. In addition, the study uncovered the main features of chronic conditions that could be managed in a community setting from the perspective of community pharmacists. The data were collected using in-depth face-to-face interviews, which allowed for a deep understanding of the topic (more discussion about the intention to use focus groups is provided in sections 2.4.1.1 and 8.7.2). The two accuracy checkpoints of generated transcripts, the data analysis process (using the six-phase framework and NVivo software) and the internal validity of analysis (designing and reviewing topic guide by experts and two community pharmacists, revisiting interviews when new themes emerged, analysing data twice, and the revision of transcripts and generated themes by two other researchers) all maximize the quality and robustness of the study findings.

As the aim of the study was only to get opinions of community pharmacists in Wales, community pharmacists working in Welsh pharmacies were recruited. The study could therefore be considered to be targeted appropriately. However, there are several differences among community pharmacy settings across the UK. For example, there are seven LHBs commissioning community pharmacies in Wales which are not necessarily available in the other countries (England, Scotland, Northern Ireland). Also, people in England do not get free prescriptions in comparison to people in the other three countries (Robinson 2017). These variations might restrict the generalization of the results to the whole population of community pharmacists across the UK. Another potential limitation of this study was that only seven participants were recruited in this research. However, the study sample included a wide variety of participants from different positions (e.g. independent prescriber, locum, regular pharmacist, manager, superintendent) working at different types of pharmacy (supermarket, large and small chains pharmacy), located in several LHBs. Therefore, the study captured opinions from a wide diversity of community pharmacists in Wales. Further, the saturation point was reached on the fifth interview, but the researcher decided to conduct one more interview to double check that saturation had been reached. When the sixth interview was conducted, a new theme emerged. After conducting the seventh interview, no new themes emerged. At that point, a decision was made to stop conducting additional interviews, as sufficient information was collected to design a questionnaire. The quantitative study was planned to be conducted based on these results and distributed to a larger population. It would allow participants to provide further information, using a free text box, so that the topic would be more likely to be well covered (further discussion will be provided in section 8.4).

5.5 CONCLUSION

Community pharmacists believed that patients with chronic conditions can be managed in community pharmacy; however, several barriers needed to be considered prior to moving forward. These barriers are not only related to community pharmacists/pharmacies but also extend to other stakeholders (i.e. patients and healthcare providers) and regulatory bodies. Moreover, this study provided more

understanding about chronic conditions that could be managed in community pharmacy and why they were selected. The most frequent conditions included asthma, COPD, diabetes, hypertension, and heart failure.

**Chapter 6 - Community pharmacists' views about
managing chronic conditions in their pharmacies: A
cross-sectional quantitative study**

6.1 INTRODUCTION

This study is part of a mixed method project investigating the views of community pharmacists about managing chronic conditions in a community setting. The first part of this project was discussed in detail in Chapter 5. After interviewing community pharmacists and identifying themes in relation to the topic of interest, there was a need to understand whether the opinions that made up the themes were a reasonable generalisation of the wider community pharmacist population across Wales. This chapter presents the findings of a quantitative study exploring the views of community pharmacists about managing chronic conditions in pharmacy. The investigating tool (i.e. the questionnaire) was constructed based on emergent themes from the qualitative project. The questionnaire is designed to assess how widespread the views identified in the interview stage of the study were across the community pharmacist population of Wales.

6.1.1 The aim of the study

The aim of this study was to determine if the views expressed on the sample of community pharmacists used in the qualitative project were a good representation of the wider population of community pharmacists practising in Wales. The objectives of this study were to determine the level of agreement among community pharmacists on the identified themes and to identify new themes related to the topic.

6.2 METHODS

6.2.1 Study design

This was a cross-sectional postal questionnaire study (for more detail on the postal questionnaire, see section 2.5.1).

6.2.2 Questionnaire design

The questionnaire was designed on the basis on the themes identified in Chapter 5. To collect the views of a larger population and maximize the response rate, it was necessary to make the questionnaire as short as possible. Short questionnaires are more likely to be associated with a high response rate (Sahlqvist et al. 2011). Even though designing a short questionnaire might impact the amount of information being tested, the purpose of this study was not to investigate each dimension in depth (i.e. asking several questions for each identified theme). Therefore, a decision was made to design a short questionnaire but still met the aim of the study.

The questionnaire was divided into three main sections. Section A gathered general information about the participant and the community pharmacy. Section B examined the management of clinical chronic conditions and section C was the qualitative section, requesting additional information/comments.

Section A requested demographic information about participants and the community pharmacies where they worked most, such as their position in the pharmacy (locum pharmacist, regular pharmacist, etc.), years of experience, type of services provided (enhanced services, advanced services, essential services only), and the location of the pharmacy. The demographic data would be used to determine how diverse the cohort sample was, which would use to determine if there were any specific characteristics associated with responders. This would help to detect potential responder bias. This section was constructed from six closed-ended questions. Closed questions were considered easier to complete and more likely to be answered in comparison to open-ended questions (Ferligoj and Mrvar 2003; Connor Desai and Reimers 2018). When applicable, participants had the opportunity to write an answer (i.e. to provide more details in the free text box if the provided answer was not applicable). This would help in collecting more accurate data.

Section B was based on emergent themes from the previous qualitative project. Since the number of identified themes was relatively large (15 themes and subthemes), the research team made the decision to not ask about issues that were well identified in

literature and had a large degree of consensus from the previous study (e.g. findings about time and workload in pharmacy). At least one question was constructed to address each emergent theme, making a total of 20 questions. The structure of this section and the types of questions asked, such as whether to use open or closed-ended questions, and questions with or without ordered answers, were discussed with the research team. A decision was made to use closed questions with unordered answers (i.e. agree or disagree) for two main reasons. Firstly, as the purpose of this project was to see how widely distributed the views identified in the interviews were in the Welsh community pharmacist population, it was not necessary to measure the intensity of an opinion with a Likert scale. Every effort was made to construct the questions in such a way that each participant practising in a community pharmacy would have an opinion about topic. Therefore, the questionnaire was designed to see whether participants agreed or disagreed with the findings identified from the previous study. This would serve the purpose of this study in respect of assessing how well the previous findings were generalized across a larger sample of participants. Only one question (question number 1, section b, a question that assesses participants' confidence in managing chronic conditions) out of 20 asked participants to select more than one answer. A free text box was also provided for this question in case participants wanted to include answers that were not already supplied. The question assessed participants' confidence in managing chronic conditions. The participants had to choose from five chronic conditions, which were identified from the previous project. They had the chance to provide other chronic conditions that they felt confident to manage in the free text box. Secondly, the questionnaire was intended to be short whilst collecting relevant information. It was thus necessary to make the questionnaire as simple as possible so that it could be completed easily and quickly, due to the busy nature of community pharmacy. This would also maximise the response rate and help meet the research objective to assess whether the findings in Chapter 5 are a general reflection of views held by Welsh community pharmacists.

Section C was mainly designed to collect qualitative data. In this section, participants would have the chance to add further information about the topic of interest. The section was provided to encourage participants to add any comment they might have

about the topic in the provided free text box. This would ensure that the topic was appropriately covered and understood (Johnson et al. 2007; Tariq and Woodman 2010, for more information, please see section 2.5). After developing the questionnaire, the questions were revised by the research team for common errors, such as typographical errors, or vague, leading, and double-barrelled questions.

6.2.3 Piloting questionnaire

First, the questionnaire was reviewed by the research team to assess its appropriateness in meeting the research objective. The comments provided were addressed, and questions were amended/rephrased where appropriate. Then, the questionnaire was piloted by four community pharmacists to check the clarity of the wording and to determine how much time would be needed to complete it. Two sets of feedback were given face-to-face and two via email. There were minor amendments following the piloting stage in terms of question wording. Furthermore, the intention was to pilot the questionnaire on a larger scale among English community pharmacies (i.e. 10% of the target sample), so that internal consistency could be checked. The reason for choosing English community pharmacies for the pilot was because there are no fundamental differences in community pharmacy setting between Wales and England. This would enable the researcher to send the questionnaire to all community pharmacies in Wales. The Research Ethics Committee in Cardiff School of Pharmacy and Pharmaceutical Sciences did not consider including the pilot sample appropriate as they were not asked for feedback or informed that it would be a pilot study, especially as piloting has already been done with another group of community pharmacists. Due to the time constraints of the researcher's scholarship and the additional time it might take to negotiate this issue with the Ethics Committee, a decision was made to continue without piloting the questionnaire among English community pharmacists.

6.2.4 Reliability and validity

Validity and reliability are two important factors that need to be considered when designing an instrument (Williams 2003). Validity means that the instrument really measures what it is intended to measure (Bolarinwa 2015), whereas reliability is the

ability of the instrument to produce replicable results (Bolarinwa 2015). In the present study, the intention was to construct a short questionnaire that could explore the views of community pharmacists based on the emergent themes identified from a previous qualitative project (for more details, see Chapter 5). Before designing the questionnaire, face-to-face meetings were held with the research team members and another meeting was held with a community pharmacist to get their opinion regarding how to construct the questionnaire and what themes should be included. A decision was made to build the questionnaire on the findings from a previous qualitative study that was designed to investigate the same purpose (i.e. barriers and facilitators to managing chronic health conditions in community pharmacy). Since the identified themes were multidimensional (e.g. themes related to community pharmacists, regulators, other health care providers, and patients), it would not be possible to design a short questionnaire without sacrificing content under each dimension (i.e. investigating each dimension in depth). Given that the objective of this study was mainly to validate the themes identified in interviews with a relatively small sample across a larger sample taken from community pharmacists practising in Wales, a short questionnaire that addressed all important findings was designed. After designing the questionnaire, it was piloted by four community pharmacists to check its acceptability and validity (Williams 2003). It was planned to pilot the questionnaire on a larger sample of participants, but that was not possible, as mentioned in section 6.2.5.

Reliability of a questionnaire can be tested via three main ways: test-retest reliability (i.e. administering the questionnaire twice to the same participants at two different points in time, and then comparing the two results), alternate-form reliability (i.e. measuring the amount of agreement between more than one questionnaires that are designed to measure the same research construct and administered at almost the same time), and internal consistency reliability (the extent to which items on a questionnaire or research construct are measuring the same thing, mainly tested by using the coefficient alpha index, Bolarinwa 2015). Given that there was no instrument available to measure the same research construct, it would not be possible to test the reliability via alternate-form reliability. Three out of four community pharmacists who piloted the questionnaires had completed the questionnaires again. The test-retest reliability

indicated that the questionnaire had good reliability (0.77). To check the reliability of the questionnaire on a larger population, the internal consistency reliability needed to be calculated. Internal consistency is typically assessed using Cronbach's alpha test if the items have more than two possible answers, such as 'agree', 'disagree', and 'strongly disagree' (Bolarinwa 2015). Alternatively, reliability of items that have only two possible answers (i.e. dichotomous data) can be tested via the Kuder–Richardson 20 (KR-20) test (Bolarinwa 2015). The values of both tests usually range from 0 to 1 (Tavakol and Dennick 2011; Bolarinwa 2015) and indicate the extent to which items included in the questionnaire measure the same construct: in other words, they assess the inter-relatedness of the items within the instrument or construct (Tavakol and Dennick 2011). As a general rule, the reliability of the instrument increases as the value increases (Bolarinwa 2015). Nunnally and Bernstein (1994) suggested using 0.7 as a cut-off point, meaning that values that are equal to or greater than 0.7 would be acceptable (i.e. considered reliable). When the Kuder–Richardson 20 index was calculated in the present study, it yielded a low value. That was not surprising, since the questionnaire was multidimensional and had a small number of questions (19 dichotomous questions, more discussion will be provided in section 6.4.1).

6.2.5 Ethical Approval

This study is a part of a mixed method project that has been approved by the Research Ethics Committee in the Cardiff School of Pharmacy and Pharmaceutical Sciences on 13/05/2019, application number (1819-12) (see Appendix 6.1). An amendment form was completed, so that the questionnaire could be used as a data collection tool to investigate the topic, and then submitted to the Research Ethics Committee. The ethical approval letter was granted before starting the study (see Appendix 6.2).

6.2.6 Sampling and selection

It was not feasible to contact all community pharmacists working in Wales due to difficulties in finding all community pharmacists' contact information. Therefore, the postal questionnaire was sent out to all community pharmacies across Wales. To be included in the study, a participant had to be a qualified community pharmacist and be

working in a Welsh community pharmacy. There were no exclusion criteria. All participants who returned the pre-paid envelopes were included in the study. Since reaching all community pharmacists working in Wales would not be possible via postal questionnaires alone (e.g. some community pharmacies had more than one pharmacist and there was only one questionnaire copy in each envelope), participants were advised to share the QR code for the online questionnaire, provided in the cover letter, with other community pharmacists (i.e. snowball sampling). More information on snowball sampling is provided in section 5.2.2.

6.2.7 Recruitment and dissemination

The postal addresses of all Welsh community pharmacies were obtained from the Community Pharmacy Wales website (<http://www.cpwales.org.uk/>). The website contained the addresses of 715 community pharmacies distributed across the seven LHBs as of February 2020 (this was the total number of community pharmacies in Wales). The questionnaires were posted to all community pharmacies across Wales using first class post. Each envelope contained four items: a cover letter, participant information sheet, questionnaire, and a free-return envelope (see Appendices 6.3, 6.4, 6.5). The participant information sheet was also attached as a link in the online questionnaire version, so any pharmacist who completed the online questionnaire would be able to access information about the study. Consent for participation was implied by completing and returning the questionnaire.

The questionnaire was built using the Bristol Online Survey (BOS) tool. BOS allows researchers to design paper or electronic questionnaires. The main method that was used to collect data was via postal mail questionnaire. However, the cover letter included a QR code in case participants preferred to complete an electronic version. The QR code was generated via a website that provided this service for free. The mass mailing function in Microsoft Word was used to generate address labels for the community pharmacies. These labels were printed on A4 self-adhesive labels. Pre-paid, pre-addressed envelopes were provided for participants to return the questionnaires. The return address was also provided at the end of the questionnaire, in case participants lost the free return envelope. Every attention was paid while designing and

distributing the questionnaire to maximise the response rate (Dillman 1978). This included using unique envelopes and coloured printing papers, mailing via first class postage, professional appearance of the questionnaire, providing a cover letter, building trust with respondents, eliminating any sources of direct and indirect costs, avoiding sensitive questions and sending reminders (for more elaboration on these points, see the discussion section).

6.2.8 Data collection

After gaining ethical approval, the questionnaires were mailed out on 24th February 2020. The first and second reminders were sent out to all community pharmacies in Wales on 4th, 16th March, respectively. Reminders were sent to all community pharmacies as the returned questionnaires were anonymous. All mail posting services were via first-class postage. First class post was used to reduce the time needed to send and receive envelopes. That was why a short period of time (9-12 days) was allowed between each contact. The variation in the period between each reminder was arranged to avoid the delivery of envelopes at the weekend. At this stage (i.e. first and second reminders), each community pharmacy received a reminder letter (see Appendix 6.6), another copy of the questionnaire, and a pre-paid envelope. At all stages (i.e. initial contact, first reminder and second reminder stages) participants had the opportunity to complete either an enclosed paper questionnaire or an online one by scanning the QR code printed on the cover/reminder letters. April 1st was set as the cut-off date for both the online and the paper questionnaire. However, due to the COVID-19 pandemic, the deadline for the paper questionnaire was shortened. The researcher faced difficulty in accessing the school and collecting envelopes due to school closure. The last day when envelopes could be collected was on 19 March. After this day, the school was closed, so it was no longer possible to collect any further returned envelopes. The impact that COVID-19 might have on this project is discussed thoroughly in section 6.4.1.

6.2.9 Data handling

Each questionnaire returned was given a serial number so that it could be identified and referred to when analysing the data. All completed questionnaires were manually

transcribed to an Excel file and linked to the serial number of each participant. Responses were coded starting from one to the highest number of possible answers (e.g. for the LHBs question, the responses were coded from one to eight). Continuous data (i.e. years of experience) was exported without any manipulations. Since Q1 in section B asked respondents to choose more than one answer, if applicable, it was coded in two ways. First, the total number of chronic conditions that participants felt confident to manage was considered as a variable. In this case, the coding started from zero in cases where participants did not feel confident to manage any chronic disease. Second, every possible option (i.e. every predetermined answer: asthma, COPD, etc.) was considered as a separate variable. To ensure data accuracy, every case entered in the Excel spreadsheet was double-checked once it had been coded. Unclear data (i.e. choosing more than one answer or missing information) was given the code "99". However, although they were clearly instructed to select one answer, some participants in section A, Q1 (about the position in the pharmacy) selected more than one answer (e.g. manager and regular pharmacist or owner and regular pharmacist). In this case, the highest position in the hierarchy was considered as the participant's position. After that, data were exported into SPSS software for statistical analysis. Ten percent of data exported into SPSS were randomly checked against the original data (Kupzyk and Cohen 2014). This was done by selecting a random sample of the paper/online questionnaires and comparing responses to data entries on SPSS. No errors were identified. Qualitative data that were provided by participants in the free-text boxes (i.e. input in "other" options and further information provided in section C) were transcribed verbatim into a Microsoft Word file associated with participants' unique number, position, and years of experience.

6.2.10 Data analysis

Given that the collected data included quantitative and qualitative data, inputs were analysed based on the type of data collected (more information about each data type are provided in the next two sections). Missing data were checked for the whole sample (i.e. the percentage of missing data in all returned questionnaires), for every case (i.e. the percentage of missing data in each individual questionnaire), and for every variable (the percentage of missing data in each individual question). It is recommended that

cases and variables that have more than 15% of the data missing be dropped entirely from the analysis (George and Mallery 2012). Missing values might be replaced by the mean or mode for continuous and categorical data, respectively (George and Mallery 2012; Hardt et al. 2013). Replacing a small number of values, such as less than 15%, would have little influence on the analysis and outcomes (George and Mallery 2012).

6.2.10.1 Quantitative analysis

Data were analysed using SPSS software, version 25. Missing data were calculated for every case and variable and for the whole sample. Cases that had more than 15% of the values missing were removed from the sample. The total number of missing values after deleting cases that had more than 15% of data missing was 56 out of a total of 5954 possible values (0.94%). At a variable level, the highest percentage of missing values per categorical variable was 4.8%, whereas the highest percentage of missing values per continuous variable was 5.7%. Given that the data set had a very low number of missing values compared to the total, and per variable, means and modes were used to replace missing information. Since the aim of this project was to confirm that previously gathered data was representative of a larger cohort, descriptive analysis and frequency were used to meet the aim of this study.

6.2.10.2 Qualitative analysis

Participant comments in section C (i.e. the free-text input where participants could provide further comment on the topic) were transcribed into a Microsoft Word file and subjected to a thematic analysis. Since this study followed a qualitative project exploring the same topic, data were analysed mainly using the deductive thematic approach (i.e. a theory-driven approach, Nowell et al. 2017). Data were also analysed inductively to identify new themes (i.e. a data-driven approach, Nowell et al. 2017). Responses provided in addition as a participant-entered option to fixed response questions were also entered into Microsoft Word and quantified. Data were coded in a Microsoft Word file using the 'highlight' function. Each theme had a unique colour. That was because the comments provided per participant were relatively short in comparison to an interview

transcript, so they could be easily managed without using qualitative data analysis software (e.g. NVivo).

6.3 RESULTS

6.3.1 Response rate

The questionnaire was sent out to 715 community pharmacies across Wales. Of those, 222 participants returned the questionnaires, and 13 participants completed the online questionnaire version, providing a total of 235 questionnaires received from the three mailings (initial contact, first and second reminders). The response rate for all returned questionnaires was 32.8%. Although the cut-off date was originally set as April 1st 2020, it was not possible to adhere to this date, as the COVID-19 pandemic negatively impacted the data collection phase. Therefore, the last date of data collection for paper questionnaires was 19th March 2020. Conversely, the online questionnaire remained open until the pre-determined cut-off date. The last online questionnaire was submitted on 18th March 2020.

6.3.2 Characteristics of the participants

Of the 235 returned questionnaires, two were entirely blank and four were missing more than 15% of data (i.e. four or more values were missed out of 26). These cases were removed from the sample (George and Mallery 2012), leaving a total of 229 participants. The majority of the sample were working as managers (n=92; 40%) or regular pharmacists, (n=69, 30%), respectively (see Figure 6.1). Twenty-seven respondents owned their pharmacies, representing 12% of the cohort sample. A small number of participants were working as locum and relief pharmacists, representing 8% of the sample for each category. Five participants (2%) provided entries that were not listed on the questionnaire, which included four superintendent pharmacists and one training manager. Years of experience as community pharmacists ranged from 0.25 to 45 years (mean=16.69, SD \pm 12.84). The vast majority of participants (n=206; 90%) provided enhanced and advanced pharmacy services (see Figure 6.2). Participants providing

essential services plus enhanced or advanced services numbered 18 (8%) and 1 (0.5%), respectively. Four respondents (2%) only provided essential services. Only 21 participants (9%) were qualified as independent prescribers.

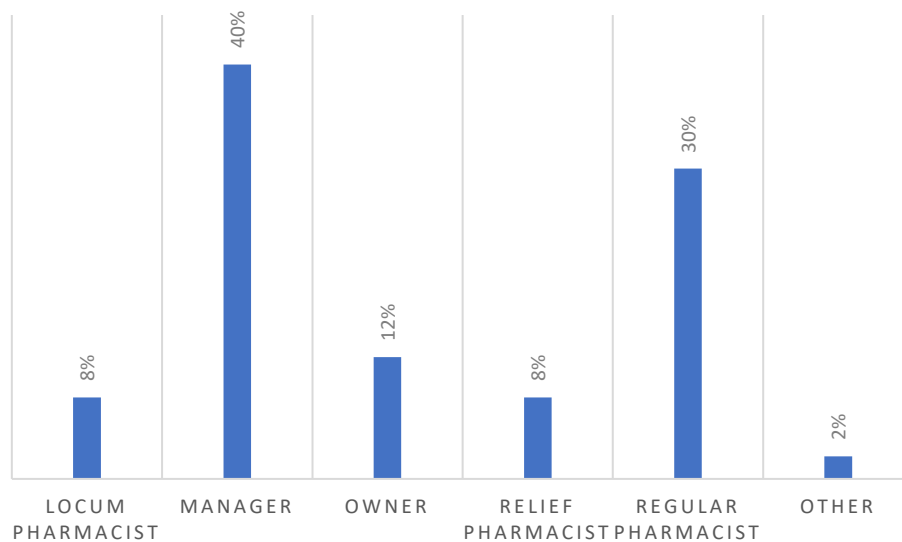


Figure 6.1: The position of participants in community pharmacy (n=229).

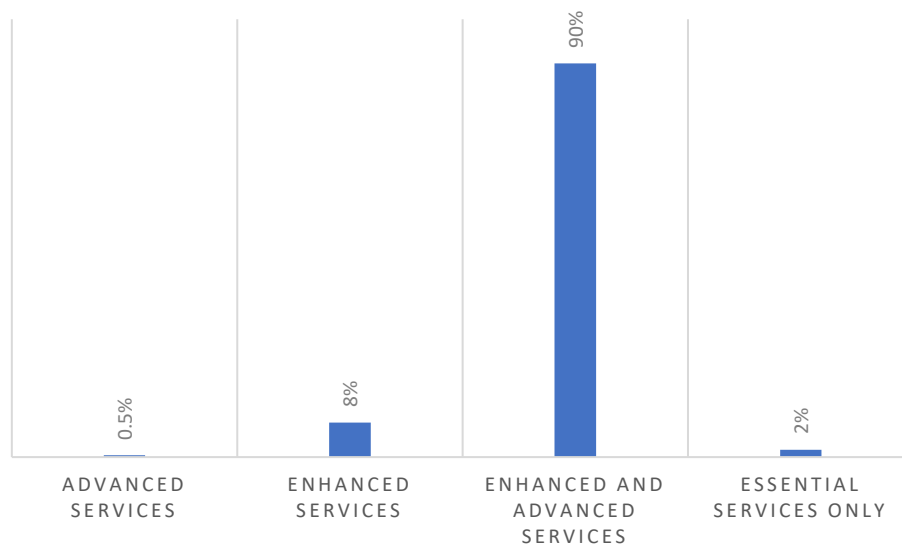


Figure 6.2: The types of pharmacy services provided by participants (n=229).

6.3.3 Distribution of participants across the Local Health Boards (LHBs)

The community pharmacies where all participants worked were distributed across all seven LHBS (see Table 6.1). Forty-six community pharmacies (20%) were located in Betsi

Cadwaladr University HB, 41 (18%) in Aneurin Bevan University HB, 38 (17%) in Cardiff and Vale University HB, 33 (14%) in both Hywel Dda University HB and Swansea Bay University HB, 31 (13.5%) in Cwm Taf Morgannwg University HB, and finally 6 (3%) in Powys Teaching HB. One participant selected the “other” option, indicating that they worked as a locum in all seven LHBs. Even though the number of respondents was varied across the seven LHBs (ranging from 6 to 46), the representation of the different LHBs in the sample was more consistent (ranging from 26% to 36%, Table 6.1). That was because the numbers of community pharmacies in each LHB varied significantly, ranging from 23 to 152 community pharmacies in each LHB.

Local Health Board	Respondents (n=229)	Percentage of total (%)	Number of community pharmacy in each LHB	Percentage of respondents in each LHB
Aneurin Bevan University HB	41	17.9	132	31%
Betsi Cadwaladr University HB	46	19.2	152	30.2%
Cardiff & Vale University HB	38	16.6	107	35.5%
Cwm Taf Morgannwg University HB	31	13.5	110	28.1%
Hywel Dda University HB	33	14.4	99	33.3%
Powys Teaching HB	6	2.6	23	26%
Swansea Bay University HB	33	14.4	92	35.8%
Other	1	0.4	NA	NA

Table 6.1: The distribution of participants across LHBs and frequency/percentage of participants from the total number of community pharmacies in each LHB (n=229).

6.3.4 Distribution of participants across community pharmacies

Around one-third of the cohort sample (35%; n=80) were working in community pharmacies located in city/town high streets (see Figure 6.3), whereas 57 (25%) participants were working in a city/town but not on a high street. Thirty-eight (17%) respondents worked in a pharmacy that was in or attached to a GP surgery. Twenty-eight (12%) of respondent pharmacies were in a rural area. Only four participants (2%) indicated that they were working in a pharmacy that was in or attached to a supermarket. Twenty-two participants, representing 10% of the cohort sample, provided other answers in the free text box. The answers were transcribed verbatim as

follows: Village (n=4), Adjacent to GP surgery (n=3), Retail parks (n=3), opposite to GP surgery (n=2), village high street (n=1), small shopping precinct in small town (n=1), village (next door to GP surgery) (n=1), shopping park (n=1), on the edge of a town (n=1), rural area-village high street (n=1), large village (n=1), close to a GP (n=1), in a housing estate (n=1), all the above (n=1).

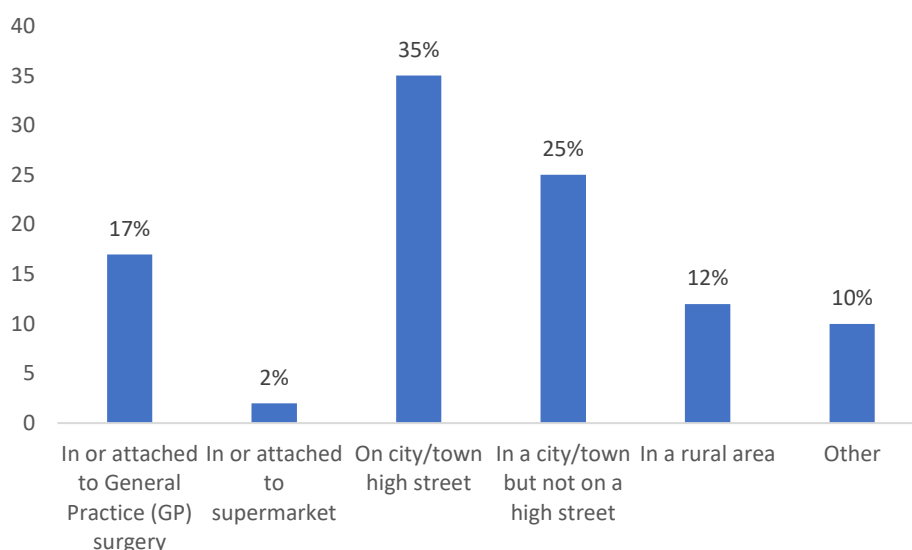


Figure 6.3: The distribution of participants across different locations of community pharmacies (n=229)

6.3.5 Chronic health condition management in community pharmacy

Of the 229 participants, 194 (84.7%) indicated that they could manage at least one chronic condition, while 35 participants (15.3%) did not feel confident managing chronic conditions. The number of chronic conditions that participants felt confident to manage in pharmacy ranged from 0 to 8 conditions (mode=3). The most frequent conditions were asthma (n=182, 79.5%), hypertension (n=159, 69%), COPD (n=123, 54%), diabetes (n=101, 44%), and heart failure (n=41, 18%, Figure 6.4). Only eight participants (3.5%) mentioned that they could manage other chronic conditions that were not listed on the questionnaire. Even though some of the provided conditions are not “chronic conditions”, all provided data were transcribed verbatim as follows: rheumatoid arthritis, polymyalgia rheumatica, Parkinson’s disease, mental health, pain management, UTI, anticoagulant, ED, eczema, IBS, acne, INR (Warfarin).

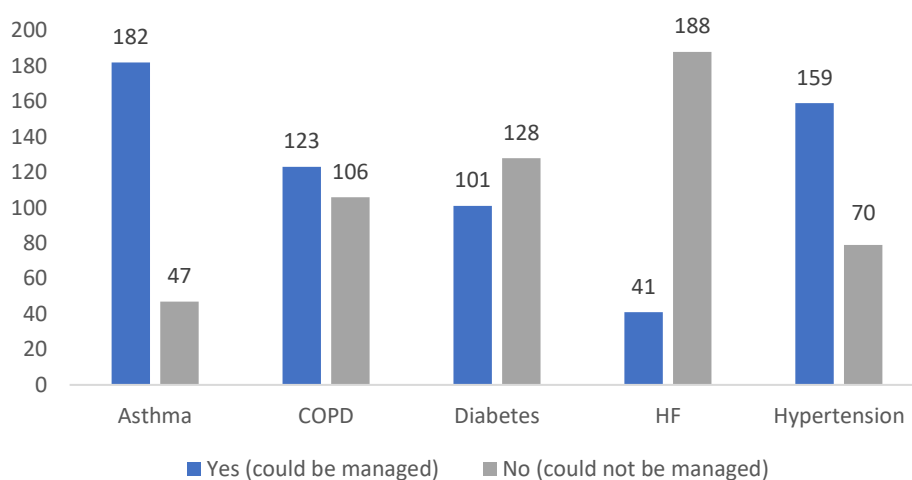


Figure 6.4: The frequency of chronic conditions that participants felt confident to manage in pharmacy (n=229).

6.3.6 Community-based chronic condition management (barriers and facilitators)

More than the half of the sample (n=129, 56%) believed that professional pharmacy services provided to the public by community pharmacists were not advertised adequately. The vast majority (n=220, 96%) agreed that formal guidance for community pharmacists and other health care providers regarding expectations from each profession in respect of managing chronic conditions would be helpful. Around 67% of the sample (n=153) indicated that community pharmacists were reluctant to give up dispensing because the alternative roles for community pharmacists were not yet sufficiently clear. The majority of the sample (n=154, 67%) believed that the quality of services delivered by community pharmacists was not consistent. Meanwhile, 84% of participants (n=192) agreed that dispensing services could be delegated to other pharmacy trained staff whilst the pharmacist is delivering a service that needs their skills. A large percentage of respondents (n=209, 91%) indicated that community pharmacy should have a system in which patients who are eligible for professional pharmacy services could be identified. Two-hundred and fourteen participants (93%) agreed that the provision of pharmacy services was impacted by the type of pharmacist (e.g. regular pharmacist, locum pharmacists). Almost all of the sample (n=224, 98%) believed that it was important for community pharmacists to access patient medical records so that they could manage chronic conditions in pharmacy. The vast majority of

the responses 205 (89.5%) indicated that community pharmacists needed to be financially incentivised to manage chronic conditions in pharmacy. Around 86% of the participants (n=196) thought that there was a need for community pharmacists to be upskilled prior to managing chronic conditions. One hundred and forty-three participants (62%) indicated that they could not access training courses that they needed. Around three-quarters of participants (n=173, 75.5%) agreed that community pharmacists were restricted in the standard of care that they could provide because they had a lot of pressure from their management to hit dispensing targets. Around half of the respondents (n=115, 50%) indicated that the space in the consultation rooms where they worked was not appropriate to provide care for patients with chronic conditions. Almost 76% of the sample (n=174) indicated that the consultation rooms where they worked were easily accessible to all patients. More than the half of the sample (n=136, 59%) believed that patients would prefer to see a GP rather than a community pharmacist to manage their conditions. Around half of the participants (n=129, 56%) indicated that community pharmacists were familiar with the range of services they could provide for patients. Many participants (n=164, 72%) indicated that being an IP was essential in managing chronic conditions. Almost all participants (n=224, 98%) agreed that collaboration between community pharmacies and general practices should be improved so that chronic conditions could be well managed in pharmacies. A large number of respondents (n=182, 79.5%) believed that moving away from dispensing to more clinically facing roles would be faced with some resistance from many community pharmacists who were comfortable with their primary role as dispensers (for a summary of all responses, Table 6.2).

Items	Agree (%)	Disagree (%)
In general, professional pharmacy services provided by community pharmacists have generally been advertised well to the public.	44	56
Formal guidance for community pharmacists and other healthcare providers about what is expected from each other will be helpful in clinical chronic conditions management in pharmacy.	96	4
Part of the reason that community pharmacists are reluctant to give up dispensing is that alternative roles for community pharmacists are not yet clear enough.	67	33
The quality of professional pharmacy services delivered by community pharmacists is consistent.	33	67
Dispensing services could be delegated to other pharmacy trained staff whilst the pharmacist is delivering a service that needs the skills of the pharmacist to deliver.	84	16
There needs to be a system for identifying patients who are candidates for professional pharmacy services.	91	9
The provision of pharmacy services is impacted by the type of pharmacist (locum, regular, manager, relief, owner).	93	7
It is important for community pharmacists to be able to access patients' medical records if they are going to clinically manage chronic conditions.	98	2
Community pharmacists need to be financially incentivised to clinically manage chronic conditions in pharmacy.	89.5	10.5
In general, community pharmacists need to be upskilled to clinically manage chronic conditions in pharmacy.	86	14
I can easily access all pharmacy training courses that I need.	38	62
Community pharmacists are restricted in the standard of care that they can provide because they have a lot of pressure from management to hit dispensing targets.	75.5	24.5
The consultation room where I work is too small to offer chronic conditions clinical management services.	50	50
The consultation room where I work is easily accessible to all patients.	76	24
A lot of patients with chronic conditions would prefer to see a community pharmacist rather than a General Practitioner (GP) to clinically manage their condition.	41	59
A lot of community pharmacists are unfamiliar with the range of services they can provide for patients.	44	56
It would be difficult for a community pharmacist to clinically manage chronic conditions without being an independent prescriber.	72	28
Better collaboration between GP practices and community pharmacies is needed for chronic conditions to be well managed in pharmacies.	98	2
There may be resistance to a change away from dispensing to more clinically facing roles from many community pharmacists who are comfortable with their primary role being dispensers.	79.5	20.5

Table 6.2: The percentage of agreement and disagreement of participants on the questionnaire's items (n=229).

6.3.7 Qualitative comments provided by participants

The questionnaire allowed participants to comment if they had something to add about the topics in the questionnaire. Of 229 completed questionnaires, 86 participants provided additional comments in section C. Codes were linked to the themes identified in the previous qualitative component (for more information on identified themes, see Chapter 5, section 5.3). No new theme was identified. Themes presented below were supported with quotes associated with participants' unique codes, which comprised three elements: 1) community pharmacist's title (e.g. manager, locum) 2) participant number (e.g. CP2), and 3) years of experience as a community pharmacist (e.g. 6). Quotes are italicised, so that they can be easily identified.

6.3.7.1 Regulations and policy

6.3.7.1.1 Health care professional boundaries and accountabilities

The responsibility of healthcare providers was not clear enough.

*...there would need to be clarity on professional responsibilities with patients...
ManagerCP2 (20yrs).*

The service level agreement needed to be clearer, so that community pharmacists could deliver pharmacy services adequately. Also, it would indicate the expected contributions for every healthcare provider involved.

...SLAs (service level agreements) services need to be more clearer and less long winded... ReliefCP109 (3)

6.3.7.1.2 Heterogeneity and consistency in community pharmacy

How community pharmacies are commissioned across Wales (i.e. involving LHBs) might be an obstacle in managing chronic conditions.

...Welsh government is all for developing pharmacy in the community, but the health boards are reluctant to play ball. Welsh government needs to direct the Health Boards better or pull it all in centrally... OwnerCP78 (34yrs).

Having a national framework was seen as an enabler to managing chronic conditions. Having different service requirements across the LHBs might not be helpful in managing chronic conditions.

...national framework required... LocumCP54 (42yrs).

6.3.7.1.3 Reallocation of responsibilities in community pharmacy

It was claimed that some pharmacy services should be delegated to other pharmacy staff.

...this will need legislative changes to supply laws or changes to services provision allowing techs to deliver the services and pharmacists oversee and interpret results... OwnerCP102 (30yrs).

Others argued that some community pharmacists' responsibilities could be delegated to some extent. This may show the importance of ensuring patients' safety when delegating tasks.

...it is okay to utilise pharmacy technician, assistant, ACTs to carry out general dispensing procedure but this can only be done to a point... ManagerCP197 (20yrs).

6.3.7.1.4 Accessing and sharing patients' medical information

Access to patients' medical records would be essential in managing chronic conditions, so chronic conditions could be managed properly and safely.

...access to GP notes is the key. There is no way you can safely manage chronic conditions without access to bloods... RegularCP30 (1yr).

A participant indicated the need to share patients' medical information within a multidisciplinary team.

...patients should have their own record and they choose who sees it. No GP dictating who can... SuperintendentCP31 (11yrs).

6.3.7.1.5 Funding and remuneration

No matter what the position of the participant was (i.e. locum, manager etc.), they indicated that they needed to be remunerated/ incentivized to provide clinical services.

...proper remuneration for the work is key. Pharmacists do not live on water alone! LocumCP146 (30yrs).

Under the current situation, moving away from dispensing would threaten the sustainability of pharmacy businesses. Dispensing was a huge revenue generator for pharmacies.

...I want to move my businesses away from dispensing but the reduction in income prevents me from investing in the resources... OwnerCP93 (30yrs).

...I think resistance would not be because we prefer dispensing just that. There is not a viable escape from it yet. 90% of income is from dispensing services, so this needs to be maintained... ManagerCP104 (13yrs).

6.3.7.1.6 Training and education

Several participants indicated that training courses were not easily accessible.

...more training needed and more easily accessible resources needed... ReliefCP109 (3yrs).

Finding a mentor to get onto IP courses was the main issue for some participants.

...it is difficult to get onto independent prescriber course as need a GP who is willing and able to be a mentor. They can be reluctant to commit and if there is a student doctor then there is no chance... ManagerCP188 (20yrs).

...would like to become an IP, but after approaching 10-15 surgeries to find a GP mentor without even one response, cannot agree that I can find all the training I desire... RegularCP167 (32yrs).

6.3.7.2 Awareness raising and guidance

Increasing awareness among the public and healthcare providers about services provided in community pharmacy was seen important.

...the public and GP's need to be aware of how to access services we are providing... LocumCP171 (32yrs).

...better understanding of pharmacy roles by patients is needed... ManagerCP37 (0.25yr).

It was argued that community pharmacists needed more guidance and support from regulators.

...I do not think community pharmacists get enough support and training from Health Boards and their employers... RegularCP193 (4yrs).

6.3.7.3 Accessibility in community pharmacy

Being able to see a pharmacist at any time was seen as an advantage of the community pharmacy setting.

...availability of pharmacists may make it (managing chronic conditions) more accessible and convenient... ManagerCP104 (13yrs).

6.3.7.4 Facilities and equipment in community pharmacy

Participants argued that managing chronic conditions would require having adequate equipment and facilities as well.

...the issue with managing chronic conditions is blood test, spirometry, etc.... OwnerCP59 (38yrs).

...two consultation rooms should be available to manage either technician or pharmacist services... ManagerCP198 (24yrs).

6.3.7.5 Workload and staffing in community pharmacy

Workload/time was considered the biggest restrictions by many participants.

...finding the time in a busy pharmacy for extra services is the biggest restriction... ManagerCP105 (12yrs).

Staffing should be carefully considered when managing chronic conditions in pharmacy, indicating that organizational barriers might hinder the management of chronic conditions by pharmacists.

...if companies want us to do more, then they need to put another pharmacist in store to help checking or adopt system like Europe... ReliefCP22 (1.5yrs).

There was an association between continuity of the service and staffing issues.

...services offered change entirely when a locum pharmacist is working (sometimes no services offered) ... Regular121 (1.5yrs).

Participants suggested that employing technology would help to release capacity.

...new technology is important to help free up time... OwnerCP89 (10yrs).

6.3.7.6 Healthcare professionals' collaboration and relationship with community pharmacists

Several participants argued that other healthcare providers did not regard community pharmacists as healthcare providers. This might hinder collaborative work in managing chronic conditions.

...we are unfortunately seen as "not clinical" enough by other health care professionals... RegularCP196 (22yrs).

...there is no appreciation for community pharmacists from other sectors of the pharmacy professionals and are "looked down" upon, stating that that's all we do is dispense... ManagerCP173 (18yrs).

GPs were accused of not being collaborative as well.

...we also need to be better included by GPs rather than being left out of the loop... RegularCP13 (8yrs).

...GPs are not always supportive of this new enhanced role for pharmacists... LocumCP146 (30yrs).

6.3.7.7 Patients' interactions and relationships with community pharmacists

Some participants argued that patients regarded community pharmacists as non-health-care providers. Patients gave them "no respect".

...as they (patients) literally see us as putting tablets in bottles... ManagerCP37 (0.25yr).

...the public treat us with little or no respect... RegularCP196 (22yrs).

Therefore, patients might prefer to see a GP rather than a community pharmacist if they had the choice to do so in managing chronic conditions.

...patient would probably prefer to see GP if they had the choice... ManagerCP104 (13yrs).

6.3.7.8 Confidence and willingness of community pharmacists to manage chronic conditions

Community pharmacists' confidence in managing chronic conditions was somewhat of a mixed bag. Some pharmacists were confident, while others were not.

...we train to recognize drugs, signs and symptoms, so why not utilise this training... OwnerCP99 (35yrs).

...often, I am disappointed in patients' awareness of chronic conditions, particularly diabetes, and I definitely feel there is room for pharmacists to tackle this. ManagerCP170 (8yrs).

Some participants thought that community pharmacists would not be able to manage chronic conditions safely and properly.

...I do not believe every pharmacist should offer this service, some pharmacies do not have the skill mix... ManagerCP76 (15yrs).

...many pharmacists do not recognise their limitations but are perhaps foolishly willing to take the responsibility. This may not be in the patient's best interests... ManagerCP74 (16.6yrs).

6.4 DISCUSSION

The scope of community pharmacy as a profession has expanded in the last two decades to include more direct patient care, such as enhanced and advanced services (Pharmacy Practice Research Trust 2008). The evolution in the role of community pharmacists will go on to include managing conditions in a community setting (Welsh Pharmaceutical Committee 2019). Following a qualitative study that aimed to explore the views of community pharmacists regarding the potential of managing chronic conditions in pharmacies, there was a need to assess how widespread the themes that emerged from the relatively small sample of pharmacists interviewed were across the community pharmacist population of Wales. Thus, a questionnaire was designed to assess several dimensions related to managing chronic conditions in pharmacy. It was mainly focused on barriers and facilitators in the management of people with long-term diseases. Questionnaires would allow access to a wider population, so that the study's aim could be met.

As this chapter was completely dependent on the previous qualitative component, and to avoid repetition, the findings (i.e. barriers and facilitators) will not be discussed in detail again. Instead, the focus will be on discussing the agreement of the quantitative findings from the survey with the themes identified from the previous interview-based study (Chapter 5). The discussion will also examine interesting findings that were identified in this chapter (e.g. interesting quotes). Further, the results of all projects conducted (Chapters 3 to 7) will be presented and interpreted in an integrated way in the final general discussion (Chapter 8).

The results of this questionnaire showed a relatively high level of agreement among respondents with the provided statements. Of the 19 agree/disagree questions, 16 had a percentage agreement/disagreement of 60% or more, and 11 of these questions had an agreement/disagreement percentage of 75% or more. This indicated that there was an overall agreement amongst community pharmacists on barriers and facilitators in respect of managing chronic conditions in pharmacy. The three questions that received less agreement were about public awareness of services provided in pharmacy, the adequacy of consultation room space to manage chronic conditions, and finally understanding of the role and responsibility of a community pharmacist in a community setting.

Although there was no major consensus about the issue identified in the previous qualitative component regarding public awareness of services provided by pharmacists (around 57% of participants disagreed that the pharmacy services were well advertised to the public), this percentage was nonetheless quite high. It might be understood from this finding that the public need to be more aware of the types of service provided in pharmacy. How can services be delivered to the public if they are not aware of them? The same finding was observed by McMillan and colleagues (2013). In their study, they found that patients were not fully aware of services provided by community pharmacists. For more discussion on this issue and how it may be overcome, please see section 5.4.

Another aspect about which the cohort sample had almost equal opinions was the adequacy of consultation room space. Although half of the respondents believed that the space they had would be enough to manage chronic conditions, the other half did not. This would be a real challenge, as half of community pharmacists indicated that they would not have enough space to monitor patients. As discussed in Chapter 5, patients with chronic conditions may visit the pharmacy with carers or using mobility scooters, and therefore might not be accommodated well. In a British study that aimed to see how pharmacy spaces were aligned to good professional practice, Rapport et al. (2009) reported that pharmacists claimed that their consultation rooms lacked space and were not sufficiently professional in appearance. A professional-looking

consultation room may enhance pharmacists' professional self-identity and patients' perceptions about community pharmacy. Further, having enough space is important not only to accommodate patients, but also to improve communication. Sundstrom (1975) found that limited space might reduce communication, as it may impact people's feelings. This may impact the amount of information given by patients and also by pharmacists, and therefore might not be in the patients' best interest.

After conducting the previous qualitative project, it was surprising to find that participants claimed that some community pharmacists were unsure of services they could provide for patients. According to the current results, around half of the community pharmacists (48%) were unfamiliar with services they could provide. How can the public be aware of pharmacy services if pharmacists themselves are not aware? The lack of clarity regarding pharmacists' contribution to people's health might impact the provision of pharmacy service. Pharmacists might not be able to provide healthcare services if they are unfamiliar or unsure about their role. The uncertainty about community pharmacists' contribution to patient's health might be attributed to several factors. The evolution in the community pharmacy setting in respect to moving towards providing more clinical services associated with inappropriate guidance from LHBs might lead this issue. As raised in Chapter five, pharmacists who were not engaged with regulatory bodies might not receive as much support as engaged pharmacists. The uncertainty might also be attributed to community pharmacists as individuals. Some pharmacists might be happy with their primary role as being dispensers, so they are not willing to contribute more to patient's health. Looking at this issue from a larger perspective (i.e. the role of pharmacists within a multidisciplinary team) might impact the patients' health, as pharmacists are uncertain about their responsibilities in patient care. Donald et al. (2017) reported that pharmacists and physicians were unclear regarding who is responsible for patient outcomes. The responsibility and accountability of each practitioner involved in patient care need to be addressed prior to expanding the scope of community pharmacy practice. This would be of great importance when providing clinical services that require a high level of cooperation among health care providers from different primary care settings (e.g. GPs, community pharmacy). Prior to providing a new service, health care providers should be fully aware of how services will

be provided and who is going to be involved, to eliminate any source of confusion. This could be implemented in an integrated way in which the responsibilities of each health care provider are clearly defined (more discussion of this topic can be found in section 5.4).

The current remuneration model was described in general as a quantity-driven model. Community pharmacies were paid according to how many services/items they provided/prescribed (Community Pharmacy Wales 2019b; Welsh Government 2020). Since community pharmacies are run by contractors, one of their main goals is to maximise profit. They might be focused on tasks that generate more profits, and therefore the community pharmacy has been described as a commercial setting (Gidman et al. 2012). As the results of this study showed, most of the respondents (75.5%) felt that community pharmacists were restricted in the standard of care that they provided because they were under a lot of pressure from their management to hit dispensing targets. Having a quantity-driven remuneration model might lead community pharmacists to prioritize revenue generator services (e.g. dispensing) over other health care services. For more information on funding and remuneration models, see sections 5.4 and 7.4.

Upskilling of community pharmacists enables them to manage chronic conditions in a pharmacy. Participants believed that they would need to be enrolled in courses that enhance their clinical knowledge and skills, so that they could be more confident in managing chronic conditions. It has been claimed that most community pharmacists would need additional training prior to providing more direct patient care (Molen et al. 2017). Courses that are designed to improve clinical skills, such as IP courses, might be helpful in managing chronic conditions. The Welsh Government (2020) is planning to provide further funds to enable community pharmacists to qualify as IPs. The real challenge facing community pharmacists was the ability to access these courses. To be an IP, community pharmacists are required to be trained and supervised by a medical practitioner (General Pharmaceutical Council 2020). This might have been acceptable when these courses were first offered, but once there are qualified pharmacist IPs who have enough experience (e.g. being IPs for several years), they could be involved in

supervising their colleagues. This would increase the number of mentors and consequently the total number of qualified IPs. For more information, see section 5.4.

Despite all barriers that might stop community pharmacists from managing chronic conditions, this study showed that most participants (around 85%) were able to manage at least one chronic condition. This was a really good indicator, showing the ability of community pharmacy to manage people with chronic conditions. Therefore, if pharmacists are allowed to manage chronic conditions, they might decrease the burden on GPs. Given that large percentage of appointments made with GPs are attributed to chronic conditions (Pharmaceutical Services Negotiating Committee 2020a), this would free up GPs to take care of more serious cases, not to mention the other potential advantages, such as cost savings, as pharmacists might reduce spending on medications and the difference in wages between the two professionals (Roberts et al. 2001; Primary Care Pharmacy Association 2020). For more information on the advantages of managing chronic conditions in pharmacy, see section 7.4.

6.4.1 Strengths and limitations

As the Welsh Government had a plan to involve community pharmacists in managing chronic conditions (Welsh Pharmaceutical Committee 2019), there was a need to assess barriers and facilitators of this new orientation. Further, identifying chronic conditions that could be managed by community pharmacists might help in designing the new model of care. The current study tested the findings of the previous qualitative component on a large scale among the community pharmacist population across Wales. The study sample was representative of the Welsh community pharmacy setting. The present study included an embedded qualitative part which received relatively high input in that 86 participants provided additional qualitative comments. That might indicate that community pharmacists were interested in managing chronic conditions, so that they provided more details. However, no new theme was identified, meaning that the themes identified in Chapter five likely represent the sum total of themes and a saturation point was reached.

Given the workload faced by community pharmacists, designing a short questionnaire might encourage them to complete it, and therefore maximize the return (Dillman 1978). This would help in achieving the aim of this study, which was to confirm themes identified on a larger population. As the short questionnaire was designed based on several themes, the research instrument was impacted by multidimensionality. Designing a multidimensional questionnaire that covers each dimension thoroughly would require the construction of a long questionnaire. Although the content validity of the questionnaire might be questionable, the questionnaire measured what it intended to measure. There was a high level of agreement between the questionnaire findings and themes identified in Chapter five and other literatures. The questionnaire was built on robust findings and was checked and piloted by the research team and community pharmacists, respectively. All these would enhance and ensure its validity (Del Greco et al. 1987; Bolarinwa 2015). Moreover, the intention of designing the quantitative part was to confirm identified themes and not to explore a new research.

The retest reliability showed that the questionnaire had an acceptable reliability. Although the intention was to measure reliability on a larger scale (as mentioned in section 6.2.3), only three people completed the questionnaire twice. When the internal consistency reliability was assessed on the total sample using the Kuder–Richardson 20 index (the equivalent of the Cronbach’s alpha test for dichotomous data, Bolarinwa 2015), it yielded a very low value. This outcome should be expected when items are multidimensional and questionnaires contain relatively few questions. According to Tavakol and Dennick (2011), unidimensionality (i.e. homogeneity) is an assumption of the reliability concept; if this cannot be met, reliability will be significantly underestimated. They argued that it would be pointless to assess or report reliability in this case (i.e. with multidimensional items). The reliability score would also be impacted by the number of items under each construct. In this questionnaire, almost every question was constructed on a separate theme/subtheme. Reliability increases as the number of questions that measure the same construct increases (Bolarinwa 2015). Finally, Streiner (2003) argued that the length of the questionnaire impacted its reliability. Instruments that had 20 questions or more would have acceptable reliability values (Streiner 2003). Therefore, knowing that the items constructed in this

questionnaire were based on several heterogenic themes (15 themes and subthemes), might contribute to a major underestimation of the internal consistency of the questionnaire. However, having two different reliability scores were expected in this questionnaire. As mentioned earlier Kuder–Richardson 20 is concerned about the extent to which items on the questionnaire are measuring the same thing (Bolarinwa 2015). Whereas the retest reliability is concerned about the test consistency over a period of time (Del Greco et al. 1987). In this study, participants were asked agree/disagree questions about their views regarding barriers and facilitators to managing chronic conditions in a community setting. It would be more likely to have similar answers as the questions were not on a Likert scale in which several answers are listed.

Another potential limitation of this study was the relatively low response rate achieved (32.8%). Although achieving a response rate of 60% or above is desirable for most research (Kishore 2016), Visser and colleagues (1996) argued, that some studies with low response rates might produce more accurate data compared to studies with higher response rates (i.e. 60% and higher). The response rate of this study was close to and sometimes higher than other reported response rates in questionnaire studies conducted in British community pharmacy settings, which were 34.3%, 35.3% and 23.1% (Barry et al. 2013; Millar et al. 2016; Cameron 2019). The representative sample might indicate that responder bias was less likely to be a significant factor.

Although the aim of this study was not to conduct advanced statistical tests that might require a high sample size, every attention was paid while designing and disseminating the questionnaire to maximize the response rate. The following steps were implemented to ensure a high response rate: using unique envelopes (professional ones but rectangular in shape) and official/coloured printing paper were used so that the questionnaire looked different from other commercial letters (Dillman 1978). This might maximize the likelihood that participants would open the envelope and complete the questionnaire (Dillman 1978). A cover letter was enclosed to encourage participants to take part in the study (King et al. 2001). The cover letter included all essential information that participants might need, such as the purpose of the study, information about the research team, how to participate, time needed to complete the

questionnaire, the deadline, and an assurance of participants' confidentiality (Dillman 1978; King et al. 2001). The cover letter appreciated participants' involvement in the research and included a QR code and an online link to the electronic questionnaire (for more information about the cover letter, see Appendix 6.3). Designing an online version might help in reaching a wider population, as not all community pharmacists could be reached and some might prefer online questionnaires (Wright 2006). Although this might affect the accuracy of the response rate, the response rate was less important than getting a large sample size. Further, only 13 of the 235 respondents completed the questionnaire online. This showed that the online questionnaire had no or a little impact on the reported response rate. The researcher made sure that the questionnaire and other enclosed documents appeared professional and interesting (Dillman 1978; King et al. 2001). Trust was built by providing the researcher's contact information and giving respondents the opportunity to gain access to the results after conducting the study (Dillman 1978; King et al. 2001). The questionnaire did not ask sensitive or objectionable questions, such as addresses, names, or other contact information (Dillman 1978; King et al. 2001). However, the researcher included a statement at the end of the questionnaire informing participants that they could access the results by emailing the researcher and showing their interest (Dillman 1978). The researcher eliminated any source of direct or indirect costs to respondents by providing prepaid envelopes, and by making the questionnaire short and easy, so that it would not take up a lot of their time and effort (Dillman 1978; King et al. 2001). Each community pharmacy received the questionnaire three times (i.e. two reminders were sent, King et al. 2001). Questionnaires were disseminated during weekdays (i.e. the researcher avoid sending questionnaires on weekends and holidays). First class postage was used for all outgoing and incoming envelopes (i.e. envelopes sent by the researcher and return envelopes) as the type of stamp used may impact the response rate (King et al. 2001).

Despite implementing all steps mentioned above to maximize the response rate, it might have been impacted by the COVID-19 pandemic. The data collection phase had to cease 11 days prior to the planned cut-off date, resulting in only six questionnaires being returned after sending the second reminder. That was because the school where the envelopes were delivered to was inaccessible during that period. Moreover, it might

have been more challenging for community pharmacists to complete the questionnaire during the pandemic period. The workload in community pharmacy was increased by around 60% in comparison to the usual workload (BBC South Today 2020). The number of prescriptions increased significantly, accompanied by a shortage in community pharmacists due to self-isolation (Smith 2020), not to mention the closure of some community pharmacies and the government advice to avoid unnecessary travel, meaning that pharmacists might be reluctant to drop off the envelopes (Smith 2020; Wickware 2020). In addition to the COVID-19 pandemic, the response rate might also be impacted by receiving several research questionnaires during the same period. After starting the first phase of this study, the researcher was told by someone involved in research with the school and the NHS that several other questionnaire studies were being conducted in community pharmacies at that time. It seems that a lot of research is initiated in community pharmacy at the end of February each year, as pharmacists are more likely to be available (i.e. after the end of the New Year and school holidays).

6.5 CONCLUSION

The opinions identified from interviews of a small sample of pharmacists in Chapter five seemed to be largely representative of the wide population in Wales. Most community pharmacists expressed that they could manage chronic conditions in a community setting. They were interested in managing several chronic conditions, which would reduce burden on primary care services provided by GPs and might also decrease spending on healthcare.

**Chapter 7 - Stakeholders' views about the management
of chronic conditions in community pharmacies**

7.1 INTRODUCTION

The findings of a qualitative study which aimed to explore the perspective of pharmacy service stakeholders will be presented in this chapter. A poster titled “Commissioners of pharmacy services views about the management of chronic disease in community pharmacies” was presented in the Health Services Research UK Conference 2020 (see Appendix 7.1).

Considering all the issues that have been addressed in Chapters 1 and 5 regarding the burden of chronic health conditions and the pressure they place on NHS services, especially GPs, the Welsh Government started to fundamentally change how health care would be provided for patients. To shine some light on this matter, the Welsh Government recently launched a new vision and objectives toward 2030 in respect of having a healthier population (Welsh Government 2019a; Welsh Pharmaceutical Committee 2019). The Welsh plan for health and social care is aimed at providing longer healthier lives for the Welsh population by maintaining people active and independent in their homes, away from medical centres (Welsh Government 2019a). This would be achieved by improving people’s health and wellbeing, promoting health and disease prevention, and enhancing home-based care and self-management. In respect of how chronic conditions are clinically managed, the intention is to make patients much more involved in their own clinical care (Welsh Government 2019a). To help achieve this vision, community pharmacies will focus more on wellbeing and disease prevention. They will be integrated with other health care providers, so that health services can be provided seamlessly. The way in which care is delivered will also change, allowing for more collaboration between pharmacies and other healthcare professionals. The focus of community pharmacists will be on optimisation of therapeutic outcomes and prescribing. Therefore, every community pharmacy will have at least one IP pharmacist. More importantly, all people who have stable chronic conditions will be managed in community pharmacies (Welsh Pharmaceutical Committee 2019). This may decrease demands on other NHS sectors such as GPs and may also improve patient accessibility to healthcare services. To better understand the future involvement of community pharmacies in clinically managing chronic conditions, there was a need to capture opinions from the stakeholders of pharmacy services in Wales.

7.1.1 The aim of the study

The aim of this study was to elicit the views of community pharmacy service stakeholders, such as the Welsh Government, Local Health Boards (LHBS), Community Pharmacy Wales (CPW) and the Royal Pharmaceutical Society Wales (RPSW), on the future of community pharmacy in clinically managing chronic conditions. The research objectives were to understand the potential of providing additional patient-centred care for patients with chronic conditions in community pharmacies and identify potential limitations of this approach.

7.2 METHODS

Semi-structured face-to-face or telephone interviews were conducted with individual community pharmacy stakeholders to explore their views about the potential of clinically managing chronic conditions in community pharmacies (for more information about qualitative interviewing, see section 2.4.1).

7.2.1 Ethical Approval

Ethical approval was provided by the Research Ethics Committee in the Cardiff School of Pharmacy and Pharmaceutical Sciences before starting the study (see Appendix 7.2).

7.2.2 Sampling

This project was designed to capture the views of community pharmacy stakeholders in Wales, who work for the government, LHBS, and community pharmacy organizations (e.g. CPW, WPC and RPSW). Purposive sampling was used to recruit eligible participants (Palinkas et al. 2013). This is because some stakeholders (for example, in RPSW) were involved in hospital pharmacy, and therefore were not invited. Snowball sampling was also used by one participant (for more information on purposive and snowball sampling, see section 5.2.2).

7.2.3 Recruitment

Community pharmacy stakeholders were identified via generally available online information. The list of people/entities involved was obtained via two sources: the researcher's previous knowledge and discussions with experts in the community pharmacy setting. The list included people who worked for the Welsh Government, NHS Wales, chairs of the LHBs, and members of CPW and the RPSW. After identifying potential participants (those who worked in/with the community pharmacy sector from the list above), invitation emails were sent out to all identified individuals (see Appendix 7.3). Nine invitation emails were sent to identified individuals at the national level (Welsh Government, LHBs, and NHS). Another seven emails were sent to all research and development offices within the LHBs to help in recruiting participants. A few of them responded that this would need additional approval (more discussion on this issue will be provided in sections 7.4.1 and 8.7.2). For those who were members of CPW and RPSW, eight and four invitations were sent, respectively. Another general invitation email was also sent to the general email address for the WPC. That was because there was no information posted online indicating members of this committee and their contact information. One participant forwarded the general invitation email to other potential participants (five individuals from different LHBs). Of the five, one agreed to take part in the study. However, after sending more than one email to schedule a meeting, the researcher did not receive any response. Two reminder emails were sent to all other identified potential participants 10 days after the initial contact/first reminder (see Appendix 7.4). A Participant Information Sheet was attached to all invitations and reminding emails (see Appendix 7.5). Participants had the option to choose from different interview types (i.e. face-to-face, telephone, and Skype interviews). Each interview was scheduled according to the participant's preference (i.e. interview type, date/time, and location).

7.2.4 Selection

There were no selection criteria: all accessible individuals (i.e. all those who could be identified) who were involved in commissioning/advising on community pharmacy services and agreed to take part were recruited in the study.

7.2.5 Topic guide design

The topic guide was developed to explore the future of community pharmacy's involvement in managing chronic conditions (see Appendix 7.6). The discussions with the supervisory team and individuals working within community pharmacy helped in designing the topic guide (Rowley 2012). After its design, the topic guide was discussed with the supervisory team (Babbie 2014). It started with a general introduction (Babbie 2014) and focused on three areas: the current practice of community pharmacy, the future of community pharmacies' involvement in managing chronic conditions, and the advantages and disadvantages of managing chronic conditions in a community setting. Since the aim was exploratory, broad questions were used to encourage participants to take the lead on the narrative, so that probing questions could be asked (Ritchie and Lewis 2003). Prompt questions were provided under each main question so that further discussion could be initiated, allowing for better understanding (Holloway and Galvin 2017). A general question about the current practice was asked first (Babbie 2014). This would make participants more comfortable and engaged in the discussion (Doody and Noonan 2013). The topic guide then moved gradually to the important section, which was the future of managing chronic conditions in pharmacy and potential limitations.

7.2.6 Reviewing the topic guide

Due to the nature of the topic, the type of participants, and the very small population, it was difficult to pilot the topic guide. However, since the first participant withdrew from the study after reviewing the transcript, that helped in reviewing the topic guide and adding probing questions before conducting the second interview.

7.2.7 Study setting

Semi-structured face-to-face and telephone interviews were conducted based on the preference of each participant. All participants were interviewed in a suitable place (e.g. in a meeting room in Cardiff School of Pharmacy and Pharmaceutical Sciences, in a hotel meeting lounge, or in meeting rooms at participants' work premises). This enhanced the confidentiality for participants and reduced the risk of distraction (Doody and Noonan

2013). The telephone interviews were conducted in a quiet room using the researcher's phone number (MA).

7.2.8 Data collection

The data collection phase was planned to last from September 2019 until January 2020. Consent was received from participants prior to interviewing (see Appendix 7.7). This was done electronically via email if a participant chose a telephone interview or in person before conducting a face-to-face interview. Participants were encouraged to ask questions prior to conducting the interviews, so that any doubts could be clarified. They were informed that there were no right or wrong answers (Doody and Noonan 2013), and that the researcher was interested in exploring the future of community pharmacy in Wales. The researcher started the interview by introducing the topic and the purpose of the study. Due to the nature of the participants (i.e. they were likely to be busy) the interview was designed to take no longer than half an hour.

Following the general question about current pharmacy practice, the researcher used open-ended questions to explore the topic, and asked probing questions to clarify stated information or to initiate further discussion (Holloway and Galvin 2017). The researcher avoided asking leading questions, so that the generated data were more likely to express participants' viewpoints (i.e. to minimize researcher bias) (Rowley 2012). During discussions, the researcher maintained good non-verbal communication with participants and tried to be neutral by not showing any reactions that might impact participants' answers (Doody and Noonan 2013). The researcher took notes when necessary (e.g. to write a key word for a probing question).

The interviews were audio-recorded via two digital voice recorders (Olympus/VN-732PC). This would allow the researcher to revisit interviews when needed and to be an active listener while conducting the interviews (Doody and Noonan 2013). Interviews were transcribed verbatim by a third-party company (only the first interview was transcribed by the researcher: for more information about the process undertaken, see section 5.2.8). To ensure the accuracy of the transcripts produced by the third-party company, more than one accuracy check was done (Hagens et al. 2009). First, the

researcher checked the transcripts word-by-word by listening to each audio recording while reading through the transcript. As a result of this process, several corrections were made. Second, each participant received a transcript, so that it could be reviewed and approved (Hagens et al. 2009). They had one month to review the transcript and approve it. If no response was received within a month, it was assumed that the participant was happy with the transcript. Participants were also informed that they could make changes to the transcripts or even withdraw from the study at any point in time prior to approving the transcript. No amendments were made to any of the transcripts. To cover the topic properly, the participants had a chance to add any comments they had at the end of each interview. Once saturation point was reached (i.e. no new themes emerged), no more interviews were conducted (Fusch and Ness 2015). The interviews lasted between 20 and 71 minutes, with an average length of 38.5 minutes.

7.2.9 Data analysis

The qualitative data set was analysed via thematic analysis using NVivo (version 11) software (Braun and Clarke 2006). More information on thematic analysis was provided in section 5.2.10. The initial analysis was conducted immediately after generating each transcript, and therefore emergent themes could be identified and included in the topic guide. When a transcript was generated, a six-phase framework was used to analyse the data (Braun and Clarke 2006). This framework focuses on six stages that researchers should carefully consider while analysing data thematically, which were discussed in detail in section 5.2.10. To apply these stages in the current study, the following actions were taken: Familiarization with the data was achieved by listening to the audio recordings more than once. After the transcripts had been generated by a third-party company, the researcher checked the produced transcripts word-by-word while listening to the audio recordings. Further, reading the transcripts several times enhanced the researcher's engagement with the data set. Using notes that were written down at the time of each interview was also helpful. Once the researcher was familiar with the data set, the generated transcripts were exported into NVivo software, in which data coding started. Once the data coding stage had finished, similar codes were grouped together, so that themes and subthemes could be generated. After that, the

generated themes were checked by reviewing codes and corresponding quotes in the transcripts. Finally, similar themes/subthemes were merged, and a narrative of the themes was written. The themes were identified via inductive thematic analysis (Braun and Clarke 2006). For more information about the reasoning approach and methods used to increase study credibility, see section 5.2.10.

7.3 RESULTS

7.3.1 Participants

Ten participants agreed to take part in the study. Of the ten, one participant did not respond to further communications. Nine interviews were conducted (four face-to-face and five telephone interviews). Another participant withdrew from the study after reviewing the generated transcript. This made a total of eight participants who took part in the study. No quotes were used from the interview conducted with the withdrawn participant. However, the topic guide was adapted following this interview, as it was the first interview in the series. The cohort sample was as follows:

- Two participants representing the government and LHBs.
- Five participants representing the CPW.
- One participant representing the RPSW.

7.3.2 Themes and subthemes

Three main themes were identified from the data set. These were strengths of community pharmacy settings, exploiting opportunities to provide a community-based chronic condition management service, and limitations to managing chronic conditions in community pharmacy settings. Several subthemes were found under each emergent theme (see Table 7.1). In the results section, identified themes were supported with quotes associated with participants' codes, which were given to differentiate the different participants within the cohort. The quotes and participants' codes are italicised to distinguish them from the other parts of the results section. Participants who worked for the Welsh Government or for LHBs are classified as stakeholders A, whereas those who were members of CPW or RPSW are classified as stakeholders B. This would help

with exploring a variety of viewpoints of participants who work for different entities. At the same time, it would protect participant confidentiality as the study sample had only one participant from the government, LHBs and RPSW. Each participant was given a participant number (e.g. 3), so they could be distinguished from others.

Themes	Subthemes
1. Strengths of community pharmacy settings	1.1 Accessibility and convenience 1.2 Consistency of healthcare providers and engagement with patients 1.3 Expertise in medicines and reducing expenditures 1.4 Welsh Government support for community pharmacy
2. Exploiting opportunities to provide a community-based chronic condition management service	2.1 Unmet public needs and shortage in GP numbers 2.2 Getting the most out of community pharmacy's workforce and technology
3. Limitations to managing chronic conditions in community pharmacy settings	3.1 Inconsistency and bureaucracy in commissioning pharmacy services 3.2 Availability of funding and resources 3.3 Disagreement and uncertainty about contribution in community pharmacy sector 3.4 Continuity of patient medical information and fragmented care 3.5 Capacity and community pharmacy facilities 3.6 Pharmacy education and clinical expertise 3.7 Patient acceptability

Table 7.1: Emergent themes and subthemes.

7.3.2.1 Strengths of community pharmacy settings

This theme involved points of strength that made community pharmacy a desirable place for managing chronic conditions. It included things that were unique for the community pharmacy sector that gave community pharmacy an advantage over other sectors with respect to managing people with chronic conditions. This theme identified the strengths of community pharmacy in several aspects: workforce, workplace, and support from the government (more discussion will be provided under each subtheme). Under this theme, four subthemes were identified.

7.3.2.1.1 Accessibility and convenience

There was a general agreement amongst participants that community pharmacy had excellent accessibility. This accessibility of community pharmacy was not only related to being available everywhere and within short distances from where people live, but also being accessible for longer hours and on days when no other primary care settings are open. Given that chronic conditions are more frequent in elderly people, offering a chronic condition management service in their local pharmacy might be more convenient for them. Further, this would allow them to be managed and receive their medications at a single place, which might improve their experience and may have a good impact on the environment. Undertaking less travel (e.g. patients being managed in a local pharmacy close to their homes and receiving their medications at the same place where they are managed) may improve the ecosystem and make the environment more friendly.

...most people are within a very short journey of their pharmacy... Stakeholder B3.

...because they are often open longer hours for the retail offer, which then means that there's better access... Stakeholder A6.

One participant had a different concept about accessibility in community pharmacy. Stakeholder A4 claimed that accessibility did not mean being open for longer hours,

although it did mean being able to provide the service for patients when needed. This would shed light on an important issue seen in community pharmacy regarding the continuity of service provided. Although community pharmacy may offer several services, these services may not necessarily be available when patients want them. Not being able to provide services for patients when needed might impact patients' experience and convenience. To tackle this problem, several participants thought that skilling up all pharmacists and accrediting them to offer all services would be the solution. However, Stakeholder A6 argued that asking everyone to do everything would really affect the quality of service provided. Therefore, the consistency of service provided within each community pharmacy might vary. Although this might be true, setting up quality indicators for each service provided might help in reducing inconsistency. It might be difficult to eliminate inconsistency in service provided even at an individual level (i.e. the quality of service provided by one practitioner might vary on different occasions). As long as community pharmacists are qualified and accredited to provide the service, there should be no reason to prevent them from caring for their community and improving the service's accessibility.

...the community pharmacy sector likes to promote the idea of its accessibility as being its real strength. Well, accessibility is a product of not only being open at times when people want to access pharmacies but having the services available at those times when people want to access them... Stakeholder A4.

...what we can risk doing is saying, 'Everybody should do everything,' and we end up with everybody doing everything to a mediocre standard... Stakeholder A6.

It appeared that community pharmacy was an essential part of every community across Wales. Patients in certain communities may have not access to healthcare providers other than community pharmacy. Community pharmacies are located in almost all types of community, in the least deprived communities and in the most deprived ones as well. This would allow community pharmacists to better understand the community's needs, as they are part of that community. Moreover, community pharmacies, especially in small towns, are owned by local employers who may employ local pharmacy staff.

Therefore, they would play an important role in their foundational economies and in making the community pharmacies more stable as businesses.

...the things that underpin high-streets in small towns like Aberdare or Neath or wherever you might be, pharmacies are absolutely part of that, they're local employers, they employ skilled technical staff, so create many of whom will come from the local community... Stakeholder A4.

...there's a lot of people who own their own pharmacies so there's a lot more stability there... Stakeholder B2.

7.3.2.1.2 Consistency of healthcare providers and engagement with patients

One of the advantageous features of community pharmacy over other primary care settings was the consistency in seeing a healthcare provider. Unlike the GPs nowadays, patients usually see the same pharmacist every time they visit a community pharmacy, thus allowing pharmacists to have frequent contact with the same patients. Being managed by the same healthcare provider may improve patients' care outcomes and also their experiences. Practitioners would be more familiar with patients' cases, as they see them frequently, and patients may not be required to describe their illness each time they visit a practitioner. It may also minimize unnecessary changes in treatment plans, as every practitioner may have different opinions about the patients' conditions and plans. Several participants claimed that the consistency of healthcare providers in community pharmacy may improve engagement with patients. Patients see their local pharmacists more often, allowing the creation of good rapport.

...a lot of the people see their pharmacist regularly... Stakeholder B3.

...you know, of that community pharmacy as being in that community for 10, 20, 30, 40, 50 years sometimes... Stakeholder B2.

...I think that's a breakdown we've had in general practice over the years, that we no longer see the same GP when we go to our GP. I think that's, that's led to worse outcomes for patients, poorer relationships with their general practitioner, and generally a more hesitant consultation... Stakeholder A6.

As a result of seeing patients frequently, participants claimed that community pharmacists tended to know their patients very well. They would know their names, illnesses, and what medications they are taking. This indicates how community pharmacy is medically and socially involved in patients' lives. The nature of community pharmacy (i.e. as a part of the community) and opportunities to be engaged in patients' health and wellbeing may lead to better health outcomes in respect of chronic condition management. Patients might feel more open to discuss health issues they have with their pharmacists informally. This would allow community pharmacists to address and deal with patients' needs or refer them to other practitioners when necessary.

...I come across a number of cases where it's a member of staff in the pharmacy who's noticed that somebody hasn't come to collect their medicines, or they haven't been in for something, or they've not seen them, and that's when they're found, they've had a fall, or there's some problem at home... Stakeholder A6.

...but community pharmacies, perhaps in particular because of the nature of them, because of this more social aspect they have, because of the informality that you can get in a community pharmacy, lends itself to an engagement with individual patients... Stakeholder A4.

7.3.2.1.3 Expertise in medicines and reducing expenditures

Community pharmacists' education and training make them the foremost experts in the aspect of medicines in comparison to other professionals. Several participants argued that community pharmacists were very knowledgeable about medicines and were the best suited to deal with these elements. They were described as being the best health care providers to deal with issues such as medicine use, medication safety, drug-drug interaction, drug-disease interaction, and medication adherence. The deep knowledge

held by community pharmacists about medications could be effectively utilised in managing chronic conditions. Further, some people might have more than one chronic condition. Therefore, allowing community pharmacists to manage people with stable chronic conditions might improve patients' outcomes and reduce drug-drug interaction and drug-disease interaction.

...I actually think that pharmacists are probably the best-placed profession to really understand the disease-drug and the drug-drug interactions. I also think pharmacists tend to be much more aware of the risks around medicines than any other healthcare profession... Stakeholder A6.

... I think we're better placed in that way that we can more frequently contact the person, we could look at the duration of repeat prescription dispensing to look at compliance. So, I think we're well-placed to do it in that way... Stakeholder B3.

Although community pharmacists are currently able to use their expertise in medicines to provide care for patients, their involvement is limited to some extent. They have to seek the GPs'/specialists' approval to enact changes into patient clinical management plans. Therefore, they could be more engaged in providing interventions that are therapeutic in nature (e.g. stepping asthma patients up or down, increasing the therapeutic dose for a hypertensive patient). In addition to the expected health benefits to patients, greater engagement of community pharmacists in managing chronic conditions might reduce health expenditure. Their expertise in medicines could be used to minimise direct spending on medications, such as in patients who use unnecessary medications (e.g. therapeutic duplication). The contribution of community pharmacists might also prevent serious side effects, leading to a cost saving for the NHS. Furthermore, their frequent contact with patients might result in addressing issues earlier, so it would help to achieve better outcomes and not worsen the patient's condition. The reduction in cost would not only be observed within the healthcare system, as patients may also save money due to reduced travel costs.

...it's (managing chronic conditions in pharmacy) probably cost-effective for the NHS... Stakeholder B5.

...given the scale of medicines expenditure and what we expect medicines to achieve, pharmacists are perhaps more critical to that than some other professions... Stakeholder A4.

7.3.2.1.4 Welsh Government support for community pharmacy

Several participants argued that the Welsh Government was supportive of community pharmacy, no matter what their job titles were (i.e. LHBS, government, CPW, RPSW). In general, they indicated that the Welsh Government and politicians in Wales were really concerned about community health. As community pharmacy could play an important role in improving people's health and wellbeing, it was empowered by the government to provide more clinical services to patients. The empowerment of community pharmacy is expected to increase, as the new vision for community pharmacy includes providing more clinical services for patients (Welsh Government 2019a, Welsh Pharmaceutical Committee 2019). This would increase the focus of community pharmacy on the population's health as a health and wellbeing hub rather than the current primary role as a place for picking up prescriptions.

...so, there's a real desire (from the Welsh Government) to see community pharmacies being strong in communities... Stakeholder A4.

...I think we're really lucky in Wales that Welsh Government is committed to supporting the, the...official role for community pharmacy... Stakeholder B8.

The Welsh Government's willingness to support community pharmacy in providing more clinical services was accompanied by legislative changes in the community pharmacy contract to encourage pharmacies to engage more in delivering more clinical services to patients. The shift in the contract towards providing more clinically based services may encourage community pharmacists to do so. Welsh Government support for community

pharmacy was not limited to changing the contract to reflect the new direction of travel, but also included providing necessary training to provide the new clinical services. All of these steps mean that it is likely to be only a matter of time before chronic conditions can be managed in community pharmacy.

...and the direction of the pharmaceutical contract is meaning that we have to do more services which are clinically based... Stakeholder B7.

...we can do lots of things around supporting those individuals (community pharmacy), so we can help them understand the value of those services. We can give them the training around the clinical skills... Stakeholder A4.

As community pharmacy is expected to have a greater role in managing patients with chronic conditions, this may mean working collaboratively with different health professions in providing an integrated health service. Therefore, support for community pharmacy in increasing their role should also include help and guidance for pharmacists to work collaboratively in a multidisciplinary team.

7.3.2.2 Exploiting opportunities to provide a community-based chronic condition management service

This theme included opportunities that were available to community pharmacy with respect to managing chronic conditions. These opportunities were not effectively utilised in community pharmacy. Being able to make the most of these opportunities might increase the potential of community pharmacy success in managing people with chronic conditions. This included aspects that are related to other community pharmacy staff than community pharmacists and technology (more discussion will be provided under each subtheme). This theme also discussed opportunities that arose outside the community pharmacy setting in respect to managing chronic conditions. For example, the shortage in GPs and a general increase in the elderly population. Two subthemes were identified under the theme of opportunities.

7.3.2.2.1 Unmet public needs and shortage of GPs

It appeared to participants that there were unmet public needs that could be met by community pharmacy. These needs are being exacerbated due to the fact that the number of GPs practising in Wales is declining and a general increase in the elderly population with an associated increase in healthcare requirements. Several participants indicated that the Welsh population is living longer, and this is associated with an increase in comorbidities. Given that people are currently facing difficulties seeing their GPs, the situation is likely to worsen as the number of people living with chronic conditions increases and the number of GPs decreases. Not being able to monitor people with chronic conditions regularly might lead to inability to manage their illness properly. Their conditions might progress, and they might end up being hospitalised. This may lead to increased burden on health, mortality, and morbidity rates as well.

*...the population continues to live longer with more comorbidity in Wales...
Stakeholder A4.*

Furthermore, there might be an issue with health inequality. As a number of GPs' surgeries are closing in some parts of Wales, people would find it more difficult to address their basic health needs. Failing to satisfy people's health needs may lead to a deterioration in their health and wellbeing. Therefore, involving community pharmacy in managing chronic conditions could help maintain equity of access to healthcare across Wales. Furthermore, the involvement of community pharmacists in the clinical management of chronic diseases would help to reduce the increasing burden on GPs. This should free up GPs' time and may make it generally easier for patients to access GPs. Therefore, GPs would have more headroom, allowing them to focus on serious conditions, leading to a potential decrease in the demands on secondary care settings.

...lots of GP practices are closing... Stakeholder B3.

7.3.2.2.2 Getting the most out of community pharmacy's workforce and technology

Most participants argued that community pharmacists could be more effectively utilised in providing care for patients. Community pharmacists represent a large group of the healthcare professionals in Wales. Their current contributions to patient care might go beyond their current role. Tasks that could be performed by other pharmacy staff (e.g. pharmacy technicians) should not be assigned to the community pharmacist. Community pharmacists should be assigned tasks in which they could add value. Further, community pharmacists could be engaged in visiting patients at home and delivering healthcare services. This would enhance access to healthcare services and ensure that people in need are seen by a healthcare provider.

...we have professionals (community pharmacists) who we don't utilise as effectively as we could. So, it's important for us to maximise the value we get from the sector... Stakeholder A4.

...I don't think we've got as much of a role (in managing chronic conditions) as we could have... Stakeholder B3.

...we have got an untapped resource in terms of the skills and the rapport and the trust that sits in a community pharmacy. We're not using it very effectively. We're - we've got a big sports car and we're driving it round at 20 mile an hour everywhere... Stakeholder A6.

Effective utilisation of community pharmacists' skills and expertise may not only improve patient care outcomes and decrease the burden on other parts of the healthcare system, but also boost the job satisfaction of community pharmacists. Doing tasks that do not necessarily require the expertise of a pharmacist is likely to increase workload and contribute to the number of pharmacists who leave the profession. Therefore, to improve job satisfaction and decrease pharmacists' workload, some tasks may be delegated to other trained pharmacy staff. Patient safety is the first priority, so delegated tasks may only be limited to specific activities (e.g. clinical checks for people with common ailments, or low-risk medications).

...the arguments around clinical checks - yes, community pharmacists do pick up issues, but I would argue that in most of those cases a technician would have picked up the same issue, because usually it's when it's outside of a normal range, it's a weird drug... Stakeholder A6.

Another opportunity that might be better utilised in providing care for patients was technology. Several participants claimed that technology was not well utilised in community pharmacy. Technology could be used to deliver digital consultations to patients. Patients who could not access a primary care setting for whatever reason could simply have a video chat with a community pharmacist. Using technology could also increase capacity (e.g. using robots in dispensing), so that pharmacists would have the capacity to deal with chronic conditions. Further, patients will perhaps expect to use technology in all aspects of their lives in the future. Therefore, technology should be efficiently utilised in community pharmacy to meet patients' expectations, improve capacity and broaden the provision of pharmacy services. More importantly, using technology might decrease medication errors. Medication errors happen often in community pharmacy settings. Employing technology might reduce the probability of such errors. Technology may better be utilised in several aspects, such as dispensing, identifying drug-drug interaction and drug-disease interaction, and detecting abnormal therapeutic doses.

...you might speak to a pharmacist through Skype or through WhatsApp, or whatever other means of technology you want to engage... Stakeholder A4.

...you could follow up with telephone or, you know, in the future it could be IT-based, digital consultations... Stakeholder B3.

...supply function is a process; a robot can probably do it better than me... Stakeholder B9.

However, extreme dependence on technology in providing services to patients might negatively impact footfall and relationships with pharmacists. Reducing footfall in

community pharmacy might affect profits generated from other services (e.g. selling cosmetics). This might affect the sustainability of the pharmacy business. Moreover, there is perhaps a need for face-to-face interaction between patients and healthcare providers, so that rapport can be initiated and continued. Having a good and continuous relationship with healthcare providers might be important in managing chronic conditions, as discussed previously in section 7.3.2.1.2.

7.3.2.3 Limitations to managing chronic conditions in community pharmacy settings

Under this theme, several obstacles might hinder the implementation of the model for the management of chronic conditions in community pharmacy. These limitations could be seen as weaknesses of the community pharmacy setting. Managing people with chronic conditions would require addressing and dealing with these deficiencies. Not being able to consider these limitations might impact the success of the community-based chronic condition management model. The identified limitations were related to several aspects linked to the community pharmacy sector. That included commissioning community pharmacy services, limitations to provide the services, limitations to the community pharmacy setting (more discussion will be provided under each subtheme). Seven subthemes related to limitations were identified.

7.3.2.3.1 Inconsistency and bureaucracy in commissioning pharmacy services

Most participants were disappointed with how LHBs were commissioning community pharmacy. It appeared that the current way of commissioning pharmacy services across Wales varied, which caused a lot of tension and disparities within the community pharmacy sector. The lack of consistency in commissioning amongst LHBs was a major issue not only for members of CPW and RPSW but also for those who worked for the government or LHBs. The results showed that community pharmacies were willing to provide more services that they thought would be beneficial for their community but were told that there was no need to do so. Further, each LHB had its own requirements and policy to approve and commission pharmacy services. More importantly, pharmacy services provided in one LHB may not be available for all community pharmacies in that LHB or even other LHBs. This may lead to unequal opportunities amongst community

pharmacies in respect of serving their communities and generating profits. It may also lead to health inequalities among patients, as some of them might not be able to access services that they need.

...health boards is a completely different board game, so it depends on the health board. So, you have to understand we come from completely different angles on this (offering pharmacy services) ... Stakeholder B2.

...I think we're in a situation currently where pharmacists are looking for more services to do, but health boards in some areas aren't commissioning them, but in others they are... Stakeholder B9.

...I understand there's inconsistency because sometimes health boards take on the role of assurance in a way that conflicts with other bodies who are already giving assurance; I think that is an area that needs to be worked on... Stakeholder A4.

Stakeholder A4 argued that pharmacy services were offered by LHBs based on the community's needs. However, Stakeholder A6 had a completely different opinion, arguing that services were not offered based on the needs of the population but based on the willingness of community pharmacies to provide these services. The variations in the concept of offering pharmacy services between the direct regulators may reflect the amount of inconsistency in commissioning pharmacy services. There might be a need for a standardized procedure for commissioning community pharmacy, making the situation much clearer for beneficiaries and regulators as well.

...there is variation between health boards in which service they commission from pharmacies. That reflects... I hope reflects the needs of the population, so it isn't the case that all pharmacies should do all things... Stakeholder A4.

...there are issues with the way in which we commission, that we don't always have services offered where we need them. We have them where there's a pharmacy wanting to provide them... Stakeholder A6.

The inconsistency in commissioning pharmacy services was observed even if a service was agreed at the National Enhanced Services Board. The advantage of approving services at the national level might be in having a national service specification, so that services could be provided widely without extra requirements. Each LHB could add additional requirements, which might be unhelpful for the purpose of having a national service. These variations in commissioning community pharmacy services might hinder the achievement of the new vision of community pharmacy. This is because each LHB may use different policies and regulations, which would adversely affect the aim of achieving a new enhanced role for community pharmacy in serving the local community as a health and wellbeing hubs. Further, the lack of formal mechanism in commissioning and solving problems within the LHBs may result in unhelpful decisions.

...we have cases of health boards not liking the answers for what's agreed at a national level and therefore, not implementing it even though it may be implemented in the other six health boards... Stakeholder B5.

...we've got the seven health boards, but there's also others in the, in the group; we've got everybody's agenda. Everybody has a different perspective on how to solve the problem and what the problems are, and I think sometimes what we end up with is something that ticks the boxes for everybody's agenda... Stakeholder A6.

...we have more challenges around service commissioning. And I think sometimes it's not so much the board, it might be individuals working within the teams that are actually commissioning... Stakeholder B8.

Most participants claimed that the process of commissioning pharmacy services was bureaucratic. It involved multiple layers, causing delay in approving services and huge

amounts of administrative work. This would not only cause delays in providing care to patients but also would add additional burdens on community pharmacy. Having more people involved in commissioning community pharmacy might make the process much more complex and unhelpful. This might discourage the provision of new services for patients and might kill creativity and development.

...I think in the main, there are delays, the process is very unwieldy for commissioning. There are many, many, many people involved... Stakeholder A6.

...cause the amount of paperwork that we have to keep for all these services when they haven't gone electronic is ridiculous... Stakeholder B9.

It appears that bureaucracy is everywhere in the community pharmacy sector. Participants argued that monitoring visits could be minimized, as the inspections performed usually involved the same things. Monitoring bodies could create one checklist, so that all aspects could be checked in one overarching inspection. Using an automated system would help in saving documents and allow different entities to access them when needed. Having one overarching inspection would not be only helpful for community pharmacy but also for other regulatory bodies, as they would then have more capacity.

...every year we do an information governance and clinical governance toolkit; then the health board come and do a monitoring visit and check the same things, and then the GPHC come and do an inspection and check the same things... Stakeholder B3.

7.3.2.3.2 Availability of funding and resources

Providing a community-based chronic condition management service might not be feasible without additional funding and a change in the remuneration model to reflect the new direction of travel. Almost all participants claimed that managing chronic conditions in pharmacy would require change in how community pharmacy was funded

or reimbursed. The additional funding might be spent on hiring new staff, training, purchasing tools and equipment, and incentivising pharmacy staff. The current community pharmacy funding model focuses on dispensing. It is a quantity-driven model, which might be inappropriately used to generate profits regardless of the meaningfulness of the intervention. Therefore, to manage chronic conditions properly, the remuneration model should focus more on quality. That is because pharmacists may need to pay more attention to patients' conditions, as they might be elderly with comorbidities and taking several medications. This could be achieved by setting shared quality indicators for each patient case (for more information on this, please see sections 5.3.2.1.6 and 5.4).

...the remuneration model for dispensing is to chase as many items as you can possibly do, dispense them as quickly as you possibly can and give them out as quickly as you possibly can [laughs]. There's no...no focus on quality, it's on volume... Stakeholder B3.

... so MURs, it's all about volume, it's not about quality. It doesn't matter if you spot a problem or not, doesn't matter if they're on two medicines or 20, doesn't matter if they're frail, elderly or, or 50-year-old. You're gonna do the simple patients on the minimum medicines, because that is the revenue generator... Stakeholder A6.

However, as the Welsh Government continues to gradually reduce funding allocated for dispensing, the participants expressed the opinion that some community pharmacies might not like it. Cutting funds for dispensing while the number of dispensing items continued to increase every year might be disappointing for some community pharmacies. It might be the right decision to take, but more importantly, community pharmacies should have equal opportunities to cover the loss in their incomes as the funds allocated for dispensing are decreased. As mentioned in section 7.3.2.3.1, the way in which LHBs commission pharmacy services may prevent some pharmacies from providing certain services. This consequently would impact their opportunity to generate more profits in comparison to others. Another point to consider is that cutting

funds on a service might impact the quality at which that service is provided. Therefore, setting a quality indicator for every clinical service provided may enhance patient care outcomes.

...by this year 19/20, the amount of money that's available for dispensing has reduced to around 120 million. So on top of that, there have been volume increases, so people are working harder, but if you're only doing the same things you were doing in 16/17, you are now effectively getting 14 million pounds less a year to do that... Stakeholder A4.

...there are pharmacies providing independent prescribing services at the moment that are, that are being funded out of the global sum. That is not accessible by every contractor in Wales... Stakeholder B7.

In the opinion of participants, engaging community pharmacies in managing chronic conditions might make community pharmacy businesses more sustainable. This would be due to the huge number of people living with chronic conditions, as well as the impact that reducing funds on dispensing would have on pharmacy businesses. Therefore, community pharmacy might find managing chronic conditions profitable, which would keep them economically viable. Moreover, the dispensing function might be replaced in the future by robots and central mail-order delivery models. This may require community pharmacy to find another revenue generator. In addition, offering clinical services in pharmacy might attract new pharmacists to work in the sector. All of these aspects would help making community pharmacy businesses more sustainable.

Participants identified that the management of chronic conditions in pharmacy would require consideration of other resources as well as financial ones. Considering the variety in chronic conditions and the number of people living with these illnesses, it would be challenging to provide/allocate sufficient training courses, trainers, time and spaces to train. Thus, gradual engagement in managing chronic conditions might be helpful (i.e. starting with a limited number of chronic conditions across Wales). Another issue raised was regarding workforce. Hiring additional staff was claimed to be

challenging. This might threaten the management of chronic conditions in pharmacy, as there might be a need to recruit more staff.

...the barrier that comes hot on the tail of that is how do you create enough time and space and resource to train the workforce to do that... Stakeholder A4.

...I think we are embarking on a period of shortage within the pharmacy, community phar-, community pharmacy is struggling to recruit in many areas. I think we're probably bordering on a, a bit of a workforce crisis... Stakeholder B8.

Participants identified several ways to fund the chronic conditions management model. These included shifting the resources available within the current contractual framework, reallocating the resources that exist within the NHS (e.g. General Medical Services GMS funding), delegating some pharmacists' tasks to other pharmacy staff or employing technology, so that the overall cost of the service could be reduced, and finally empowering patients to take ownership of their health by purchasing medicines (e.g. patients with common ailments) or at least introducing a small fixed amount of money per prescription (more discussion on this was provided in sections 5.3.2.1.6 and 5.4).

7.3.2.3.3 Disagreement and uncertainty about contribution in the community pharmacy sector

Participants felt that a proportion of contractors and community pharmacists might have different perspectives than the Welsh Government about the contributions of community pharmacy to people's health. They might not be in favour of moving away from dispensing towards providing more clinical services. How community pharmacy is reimbursed might be one of the reasons (as discussed earlier in section 7.3.2.3.2), but there might be other factors too. Experienced pharmacists would perhaps be less interested in providing clinical services. They might be more comfortable doing what they are currently doing. Moreover, providing more clinical services may place an additional burden on the business, such as training, or further spending. As community pharmacies are run by contractors, the Welsh Government might face difficulties in

achieving their vision regarding the community pharmacy sector. It would be difficult for the Welsh Government to implement their plan without collaboration with pharmacy contractors. The change in the contractual community pharmacy framework might not be enough to encourage or discourage certain behaviours/practices. Community pharmacy as a sector should fully understand its new orientation and why it is moving in that direction. This may help in conceiving the importance of the potential change in how community pharmacy contributes to people's health and wellbeing.

...the pharmaceutical bodies and the, the government and other people, in my opinion, do not fully value the dispensing process, and they see it as a commodity-based service... Stakeholder B7.

...I think the final challenge is a need for a change in the mindset of the sector, so individual pharmacists get this, some pharmacy contractors get it, but equally, some pharmacists and some pharmacy contractors don't: they're quite happy to put their fingers in their ears and say actually, I want to keep doing what I've always done and I don't want to expand what I do. And even if we make the incentives right and make the disincentives right, there will still be people who don't want to do it ... Stakeholder A4.

Although the Welsh Government was found to be supportive of community pharmacy and willing to expand their contribution to the population's health, it appeared that better communication was needed between community pharmacy and regulators (e.g. LHBs). A few participants indicated that the messages being sent between regulators and community pharmacy were not being appropriately delivered. The direction of travel and the future contribution of community pharmacy to people's health might not be fully understood by community pharmacy. The community pharmacy sector is currently in a transition stage, a stage where a significant change in its vision and contributions is planned to occur in the future.

...the comments of Welsh Government talk about a changing role, you know... replacing supply with clinical services, but we haven't replaced it, we've added it on. At the moment, nothing has gone... Stakeholder B3.

...I think really importantly, for the sector, it needs to change what it does, so I make a big point of trying to explain to community pharmacists that it's not... a drive to move away from dispensing, is not... the government isn't necessarily forcing that to happen, consumer behaviour is the thing that will drive that... Stakeholder A4.

While the Stakeholder A4 argued that consumer behaviour would drive the change in community pharmacy, Stakeholder B2 claimed that the expectations of NHS Wales about services delivered by community pharmacy were not the same as patients' expectations. NHS Wales would expect community pharmacy to be more engaged in providing more clinical services, but this was not the expectation of the patients. The patients' expectations in community pharmacy might not be as high as those of the NHS. This example illustrates the gap between regulators and the community pharmacy setting in understanding the current situation and barriers that might hinder the provision of clinical services in pharmacy. More discussion on patient acceptability is provided in section 7.3.2.3.7.

...I think what NHS Wales wants from us is probably different to what the patients want from us... Stakeholder B2.

Another issue raised by one participant was about the lack of government endorsement of the new vision of community pharmacy. It was argued that even if the vision and direction of travel were clear, this was not officially endorsed by the government. This might cause doubts in the community pharmacy sector about its future. Being certain and clear about the vision and expected contributions would allow community pharmacy to plan ahead of time and be ready for the future. Lack of clarity, or doubts about the direction of travel would not only adversely affect community pharmacy, but could also potentially lead to a failure to revamp the overall healthcare system, which

ultimately might impact the whole primary care setting, and more importantly, patient health and wellbeing.

...I think we have a good document there (Pharmacy: Delivering a Healthier Wales) but I'm also aware that that's not been officially endorsed by the NHS in Wales or the Welsh Government. So while it's a sort of professional direction of travel, and I am not believing that the Welsh Government and NHS are totally behind it, because it's not formally endorsed, it does leave some questions about whether that really is the direction of travel... Stakeholder B5.

7.3.2.3.4 Continuity of patient medical information and fragmented care

Most of the participants identified a critical issue in the primary care setting in respect of continuity of information among different healthcare settings and the lack of cooperation. Community pharmacy was not well connected with other primary healthcare settings. When patients move from one primary setting to another, not only should they move seamlessly, but also all relevant information should move as well. The places where primary care services are provided should be joined up, allowing for a continuation of care when patients move from one place to another. Having one medical record for each patient that could be accessed by different practitioners across different healthcare settings may help in enhancing the care provided. That is because managing chronic conditions may need continuous inputs from different healthcare professionals. Thus, practitioners should be enabled to work together effectively in the best interest of their patients. For instance, community pharmacists may access patients' medical records to look at lab tests that were performed by phlebotomists at GPs' surgeries and read their notes. This would not only allow practitioners to work collaboratively for the best interest of patients but also potentially save considerable time and resources. More discussion about integrated healthcare was provided in sections 5.3.2.1.5 and 5.4.

...so even though we've got fabulous services over here, the poor services over here are what people talk about. They don't talk about where services are working, 'cos often the GPs don't even know that their patients are accessing a

service (a service which was provided in a community pharmacy), because that's working... Stakeholder A6.

...every pharmacist will need access to patient records, really. Without full access to patient notes, that position (managing chronic conditions) becomes extremely difficult... Stakeholder B9.

Even if the healthcare system becomes more integrated and primary care settings are well joined up, practitioners from different professions might not be willing to work with each other. Therefore, using the contractual framework contract for each profession to encourage collaborative working might be helpful. Setting up shared patient care outcomes for each patient with a chronic condition between healthcare providers involved in patient care may eliminate the concept of “ownership of patients”. Reimbursement based on achieving these outcomes may encourage practitioners to work together. For more discussion on collaborative working and reimbursement, see section 5.4.

...a little questioning about whether GPs actually want us to do that role and how easy they may make it for us... Stakeholder B5.

7.3.2.3.5 Capacity and facility in community pharmacy

Almost all participants agreed that it would be difficult to manage chronic conditions in a community pharmacy with the current type of practice. Community pharmacists had heavy workloads, making it unfeasible to expand their role in managing chronic conditions in the absence of other changes. Managing chronic conditions properly would require community pharmacists to spend more time looking at patient medical records and counselling patients. All of this would add to their workload and might hinder their ability to complete other tasks assigned to them. The quality of service provided might be affected and the opportunity for medication errors to occur might increase as the workload increases. To increase capacity and allow community

pharmacists to focus on tasks that only they can conduct, other community pharmacy staff and technology would need to be more effectively utilised.

... if we don't release some capacity to make some headroom for community pharmacists to evolve that role, there's just not the space there to do at the moment... Stakeholder B8.

...I don't think it's feasible (managing chronic conditions in pharmacy) with current models of work. We're - I think 75 million prescription items are supplied through community pharmacy in Wales each year... Stakeholder A6.

Several participants also argued that the current policy of period of treatment (i.e. using 28-day prescribing) caused additional administrative workload in community pharmacy. Even though having a short period of treatment might increase footfall in community pharmacy and may generate more profits, expanding the period of treatment would create more capacity. The period of treatment could be extended based on the type of treatment/condition and clinical need of the patient. There is no reason why the period of treatment could not be extended if the patient is stable and will be on their medications permanently. If medication wastage and consequent money loss is the reason (i.e. if the dose is changed), then the period of treatment could be extended for low-cost medications. The cost of time that community pharmacists and other practitioners spend in seeing patients and checking and dispensing medications might be more than the loss incurred through wastage of low-cost medicine. Further, if the prescribed medications need continuous monitoring (i.e. high-risk medications), the period of treatment might be kept the same. Therefore, community pharmacists as experts in medicines could be more empowered with greater control in determining the optimal period of treatment for each patient. They could determine the proper period of treatment for the patients they are managing based on patient condition and stability, and the risk and cost of medications. This would not only boost capacity, but also potentially improve patient satisfaction, as it would reduce unnecessary visits.

...whether we could move some of those treatments to 56- or 84-day treatment periods, to reduce the actual volume of prescriptions, to release capacity... Stakeholder B3.

...I think we should be seriously considering why we're using 28-day prescribing. It is a huge administrative burden in the pharmacy, and in the general practice, and for the patient... Stakeholder A6.

Most participants raised the issue of community pharmacy facilities. They argued that the equipment in community pharmacy might not be adequate to manage people with chronic conditions. This was an expected finding, as community pharmacy is not designed to manage chronic conditions (i.e. people with chronic conditions are mainly seen and managed by their GPs). The high involvement of community pharmacy in managing chronic conditions might need further development of the workplace. That might include fitting consultation rooms with the tools and equipment needed for managing chronic conditions or building additional consultation rooms. This is likely to be a challenge for small community pharmacies that do not have enough space. Further, the role of community pharmacists in managing chronic conditions should be limited to their area of expertise, so that they could avoid additional workload and medication/medical errors. For instance, community pharmacy is not the best place to provide a phlebotomy service. If they were to provide this service, it would add additional workload, need further equipment, and more importantly patients might be harmed, as pharmacies are not the best place to conduct this service.

...if you've got a technician doing your supervised consumption and smoking cessation service, you need a second consultation room, maybe a third. Many community pharmacy premises are not fit for purpose... Stakeholder A6.

...go back to the scenario about having high blood pressure, well if we've got healthcare support workers in general practice doing it (measuring blood pressure), whatever grade a healthcare support worker would be doing it, why

do we suddenly need to leap to a highly qualified pharmacist making those sort of interventions... Stakeholder A4.

7.3.2.3.6 Pharmacy education and clinical expertise

While almost all participants were in favour of expanding the role of community pharmacists in managing chronic conditions, they were concerned about the clinical expertise of pharmacists. Managing chronic conditions is not about being an expert in all aspects of medicines. Community pharmacists would need to use advanced clinical skills that would enable them to manage patients properly (e.g. identifying disease progression, interpreting lab tests). The current pharmacy education and pre-foundation programs might not be primarily focused on the clinical side. To be able to manage chronic conditions properly, community pharmacists would need to expand their knowledge and enhance their clinical skills. Not to mention that most practising community pharmacists qualified many years ago (i.e. their pharmacy education programs might not include as much clinical information as the current ones). That does not mean that pharmacy education/training should be more like medical education. However, community pharmacists should gain clinical skills and knowledge to help them in managing chronic conditions. Improving their clinical skills should be part of their core (undergraduate) training. More importantly, their pharmacy education and training should be changed to reflect the new direction of travel (further discussion on pharmacy education and training is provided in sections 5.3.2.1.7 and 5.4).

...the bulk of our workforce in community pharmacy are 10, 15, 20, 25 years qualified. They qualified from an MPharm degree or a BSc degree, BPharm degree, that didn't include a lot of clinical information, or nothing like it is now... Stakeholder A6.

...I think there's a couple of areas that we would need to improve on, and partly that's to do with record writing, and partly that's to do with some of the more examinational skills... Stakeholder B5.

As current community pharmacists' clinical knowledge and expertise in managing chronic conditions might be insufficient, patient health might be affected. They might make inappropriate medical decisions that put patient lives at risk. Therefore, every step should be taken with care, to ensure that patients receiving care in pharmacies would not be harmed. The LHBs, employers and community pharmacists should all be clear about where liability falls if patients are harmed. LHBs should ensure that the services are provided by competent community pharmacists. Employers should not allow unqualified pharmacists to provide services that need further training/qualifications. Community pharmacists should only provide services that are within their professional competence and that they are legally qualified to provide.

*...somebody will get hurt, yeah, from a consultation, there will be a fatality, there'll be sepsis missed. That has already happened with a paramedic...
Stakeholder B2.*

7.3.2.3.7 Patient acceptability

Patients would be the beneficiaries of chronic condition management services. Their willingness to have their chronic condition managed by a community pharmacist is an important enabler to having a successful model. Several participants indicated that patients might be reluctant to see community pharmacists for their illness. This might be attributed to the historical stereotype about community pharmacists being dispensers. Patient perceptions about community pharmacy need to reflect the new direction of travel. They should see community pharmacists as "healthcare providers", not as "dispensers", and community pharmacies as "health and wellbeing hubs", not as "places to pick up prescriptions". Failing to achieve this change might result in having a less successful model, especially if patients have the option about whom to see (i.e. if they could see either GPs or community pharmacists for their illnesses). Patients might prefer to see GPs over community pharmacists, as they might have strong beliefs in medical hierarchy (further discussion on this theme was provided in sections 5.3.2.7 and 5.4).

...so, I think patients' perceptions about where they get these services (managing chronic conditions) done needs to change, and that could risk our ability to do that... Stakeholder B5.

...some patients wouldn't want to change, so... and this is coming back to my point of trying to be a mix of services, so those patients who actually value being seen by their consultant or seen by their GP, we don't want to remove those options from people, we want to increase choice and accessibility, not change choice and accessibility... Stakeholder A4.

7.4 DISCUSSION

There are huge demands on general practice, which have led to difficulties in accessing GPs and had a negative effect on public satisfaction (Baird and Holmes 2019). These huge demands might be attributed to an increase in the proportion of elderly patients within the population, plus a shortage in the number of GPs across the country (Royal College of General Practitioners 2019). Thus, the NHS has to change to avoid collapse (NHS Wales 2015a). In response to this crisis, as indicated by the Welsh Government, community pharmacists will be more involved in managing chronic conditions (Welsh Pharmaceutical Committee 2019). To better understand the future involvement of community pharmacies in managing chronic conditions, there was a need to understand the perceptions of the stakeholders of community pharmacy services in Wales. Interviewing those who were involved in community pharmacy sector would lead to a better understanding of the topic and might help in designing a community-based chronic condition management model.

The results of the present study indicated that there were three main themes, strengths of community pharmacy settings, exploiting opportunities to provide a community-based chronic condition management service, and limitations to managing chronic conditions in community pharmacy settings. Sub-themes under "strengths" would make the community pharmacy setting a desirable place for managing chronic conditions. Conversely, sub-themes under "limitations" might hinder the expansion of community pharmacy's role in managing chronic conditions. Moreover, the identified sub-themes

under “opportunities” might be better utilised to increase the contributions of community pharmacy in people's health. Further consideration would be needed prior to enacting the plan to increase the involvement of community pharmacists in the clinical management of chronic conditions. This will be discussed in detail below.

The findings from this study showed that participants believe that community pharmacists are not currently being effectively utilized. Given that pharmacists are experts in medicines, they argued that community pharmacists could contribute more to people's health and wellbeing. Several studies have shown that interventions conducted by community pharmacists improved patient care outcomes in multiple chronic conditions, such as diabetes, hypertension, and cardiovascular diseases (Machado et al. 2007; Santschi et al. 2014; Omboni and Caserini 2018). More importantly, randomised clinical trials have shown that interventions conducted by pharmacists reduced inappropriate prescribing, side effects, medication use, and spending on medicines (Hanlon et al. 1996; Roberts et al. 2001). However, the current involvement of community pharmacists in dealing with chronic conditions is limited to a few services, such as MUR and DMR. Even though these services might have some benefits for patients, they may restrict the contributions of community pharmacists to patient health. It was argued that the way in which the MUR service was constructed (i.e. focused mainly on medicine itself rather than on the patients' illness) may not really improve patient care outcomes (Latif et al. 2011, 2013). Therefore, managing chronic conditions would need further empowerment, so that community pharmacists could use their knowledge and clinical expertise in providing direct patient care. Weiss et al. (2014) explored the relationship between different prescribers (GPs, nurses, and pharmacists) and patient outcomes. They found that patients were more engaged in making decisions about their treatment plans in the prescribing pharmacists' group (Weiss et al. 2014). This might be attributed to the pharmacists' expertise in medicines, enabling them to offer patients more than one treatment option. Although the clinical expertise of community pharmacists in managing chronic conditions might not be as good as their expertise in medicines, they might be upskilled and involved in managing patients with stable chronic conditions. Enrolling pharmacists in training courses that

aim to enhance their clinical knowledge and skills in certain aspects (e.g. IP courses) might improve their competencies and advance their confidence.

It might be difficult to manage all patients with chronic conditions in community pharmacy. That is because chronic illnesses are varied in nature and complexity. According to the Welsh Pharmaceutical Committee (2019), all patients with stable chronic conditions will be managed in community pharmacy. This would be more realistic, especially when the scope of chronic conditions only includes the most frequent chronic conditions whose management depends mainly on therapeutic interventions and lifestyle modifications. This would allow community pharmacists to use their non-pharmacological and pharmacological knowledge to manage their patients.

Stakeholders of community pharmacy services reported that involving community pharmacists in managing chronic conditions would potentially have several advantages at multiple levels (i.e. individual, community pharmacy, and healthcare structure). It may improve job satisfaction and reduce the number of pharmacists leaving the sector. Community pharmacists have a lower job satisfaction in comparison to hospital pharmacists, which might lead to more leaving the profession (McCann et al. 2009; Seston et al. 2009). Further, involving community pharmacies in managing chronic conditions would make pharmacy businesses more sustainable and profitable. This would make it difficult to replace community pharmacy with technology (e.g. using robots in dispensing), as the focus would be shifted from dispensing to providing direct patient care. Further, it would improve health inequality, as patients would be able to access healthcare services in places where there is no GP. Increasing access to healthcare services would consequently improve patient satisfaction (Papastergiou et al. 2014). Involving pharmacists in managing chronic conditions might also reduce spending on health, as detecting health issues earlier and providing better care might contribute to less morbidity (Hawksworth et al. 2001; Tsuyuki et al. 2002). It would also reduce the burden on GPs freeing up capacity, so that they could focus on serious conditions. All of these factors could improve patient care, accessibility to health

services, job satisfaction, and business sustainability, and decrease the burden on the NHS and GP services.

Participants indicated that one of the issues facing the current healthcare system was the lack of consistency in seeing healthcare professionals. Patients might see different practitioners every time they visit the primary care centres. This might impact on the outcomes for patients and affect their relationship with care providers. In a large-scale British study, Levene and colleagues (2018) found that the continuity of the relationship between patients and GPs has decreased by 27% over the period 2012-2017. Further, Barker et al. (2017) found that being seen by the same general practitioner was associated with fewer hospital admissions. Unlike general practice, patients could see the same community pharmacists every time they visit their local pharmacies. This would help in building better relationships with patients and forming informal relationships. This would be important in managing chronic conditions, as patients might be more open to discuss their concerns and, more importantly, to adhere to a healthcare provider's advice. All of these aspects may contribute to better patient care outcomes.

One of the unique characteristics of community pharmacy expressed by participants was related to its accessibility and convenience to patients. Patients could easily access a community pharmacy within a few minute's walk from where they live (Pharmaceutical Services Negotiating Committee 2020b). Although community pharmacy has good accessibility, this is meaningless if patients cannot access an advertised service when visiting a pharmacy. The continuity of the service is as important as its accessibility. In the recent changes to the Community Pharmacy Contractual Framework 2019/20 (2019), the Welsh Government financially incentivised community pharmacies that offer certain services on at least 60% of the workdays per month. This legislative has been designed to encourage community pharmacies to provide the services more frequently and should improve their accessibility. Since chronic conditions need further training and accreditation, the continuity of service might be impacted. Therefore, establishing the model with a defined limited list of chronic conditions that could be managed by pharmacists in the first instance may help in providing the time needed to upskill more pharmacists. Further, having at least two qualified pharmacists in each community

pharmacy that has more than one pharmacist would assure continuity of service. This would increase demands on training. That is why involving pharmacy schools in providing embedded pharmacy programmes might help in this regard (for more discussion on this, see section 5.4).

The community pharmacy sector has been through a range of fundamental changes towards providing more direct patient care, such as flu vaccinations and respiratory services, which has helped in freeing up GPs' time and providing convenient health services for patients (Welsh Government 2019d, 2020; Community Pharmacy Wales 2020b). Several legislative changes have occurred and will occur in the future to convert community pharmacies into health and wellbeing hubs (Welsh Government 2019a.b; Welsh Pharmaceutical Committee 2019). Community pharmacists will have more roles in disease prevention and monitoring (Welsh Pharmaceutical Committee 2019). As articulated in this study, the huge planned transformation in community pharmacy might not yet be fully understood by people involved in community pharmacy settings (e.g. pharmacists and contractors). It is fundamental that community pharmacies understand the importance of changes and the direction of travel (i.e. moving towards providing more clinical services in pharmacy). Disagreements about the role played by community pharmacy in people's health (i.e. moving away from dispensing) between regulators and community pharmacy might damage the evolution of the sector as well as patient care. Participants argued that some experienced community pharmacists may not be willing to accept new clinical roles, such as managing chronic conditions. This might be attributed to the fact that the ability to take on risk decreases as people get older (Deakin et al. 2004). Although changing the contractual framework might help in encouraging some practices, getting people involved in community pharmacy and supportive of the changes may assure that they deliver the service for its own sake. Therefore, achieving the goals set for the community pharmacy sector would require collaboration from all people involved. Effective communication with contractors, explaining the need for changes to avoid the decline of the NHS, may help to conceptualize the problem. Providing equal opportunities for all contractors to generate revenue from other pharmacy services rather than dispensing may be helpful.

Participants argued that the vision of community pharmacy and how it could be achieved should be clear for all stakeholders and endorsed by the Welsh Government. While the Welsh Pharmaceutical Committee is the statutory advisory committee that advises the Welsh Government on the pharmacy and pharmaceutical profession (Welsh Government 2020b), it is not a legislative authority. Thus, it was claimed that this might not be sufficiently clear for the contractors and pharmacists as to whether the Welsh Government agrees with the new direction of travel. More importantly, achieving this vision would require huge change within community pharmacy (e.g. employing technology, upskilling staff). There would need to be time and a lot of planning from the contractor's side as well as from community pharmacists. The lack of governmental endorsement of the vision for community pharmacy may negatively impact its success. It has been claimed that sharing the same values (e.g. the vision and mission of an organization) is important in making organizations successful (Singh 2013). Conversely, not sharing the same values would lead individuals to follow their own personal goals (Singh 2013). Therefore, endorsement of the vision by the Welsh Government may encourage community pharmacies to work towards achieving their goals.

One of the biggest issues expressed by participants that threaten the goal of managing chronic conditions in community pharmacy is the way in which LHBs commission pharmacy services. There are seven LHBs regulating community pharmacies in Wales (UK Government 2013; NHS Wales 2020a). Each LHB determines pharmacy services that could be provided in each community pharmacy within that LHB based on the community's needs (NHS Wales 2020a). However, this study has indicated that there appears to be a willingness on the part of community pharmacies to provide more services, but they could not get their LHBs' approval. Approving a service to be provided in any pharmacy willing to provide it may improve patients' access to healthcare. If a community pharmacy is willing to provide a specific service, it might mean that there would be demand for that service. In other words, the community needs that service, and consequently, patients would benefit accessing these services. When no one accesses that service in a community pharmacy, LHBs will not have to pay for a service that is not provided. More importantly, improving access to healthcare services (e.g. by allowing accredited pharmacists to provide a variety of services) would assure health

equality among populations, especially in some communities that have limited access to primary care centres. Even when a service has been approved at the national level (i.e. National Enhanced Services Board), participants claimed that LHBs may change or add additional requirements. This may make approving a service at the national level less helpful. Opponents of this opinion might say that LHBs should be able to ensure patients' safety by asking for additional requirements. Although ensuring patients' safety is important, the National Enhanced Service Board would not approve a service without considering the safety of the population. Further, it would reduce health inequality (as discussed earlier) and offer equal opportunities for contractors to improve their communities and make profits. Currently, the main revenue generator for community pharmacy is dispensing (Chisadza 2018). All community pharmacies are required to provide this service (Pharmaceutical Services Negotiating Committee 2020c). Therefore, the opportunity to dispense medications is equal for all contractors because it has been approved as an essential service. This provides community pharmacies with an equal opportunity to generate profits, and in the meantime prevents variations in service commissioning (e.g. service requirements). More importantly, it ensures that the large proportion of the community pharmacy fund is distributed fairly among community pharmacies. Moreover, the available funds allocated for dispensing have been reduced and more funds have been allocated to provide more clinical pharmacy services (Welsh Government 2017, 2020). This might mean that the profits that a community pharmacy could make would be hugely impacted by the LHB's decision regarding the provision of a service (i.e. LHBs decide who should provide a specific clinical service and who should not). There should be an equal opportunity for all contractors to serve their community and also to generate profits. Therefore, the community-based chronic condition management service should be approved at a national level without allowing LHBs to add extra requirements, which might be unhelpful for the purpose of having a national service and may negatively impact the ability of contractors to provide health care services and generate profits. This will mean any qualified community pharmacist willing to provide the service and meets the standardized service requirements can provide it.

The bureaucracy in the commissioning of community pharmacy was another major issue identified by participants. Bureaucracy in community pharmacy might be a significant

barrier to expanding the role of community pharmacists in providing direct patient care. This finding is concordant with the results of another study conducted by Scahill et al. in 2010. The way in which regulatory bodies (e.g. LHBs, General Pharmaceutical Council GPHS) regulate community pharmacies was found to be time-wasting and involves a huge administrative load. Participants argued that having several entities/people involved in commissioning may add an unnecessary burden on community pharmacy. Even though the process of approving and accrediting pharmacy services was significantly changed in 2018 to simplify requirements and reduce duplication (Community Pharmacy Wales 2020a), it still did not meet stakeholder expectations as expressed in this study. Participants believed that approving services at the national level, conducting one overarching inspection, and employing technology in commissioning pharmacy may reduce duplication and improve efficiency. Aspects that could be monitored remotely could be uploaded to a system, so that they could be checked by different regulators. All of these steps would significantly decrease the burden on community pharmacy by removing unnecessary monitoring visits or at least minimising the time and effort required. This is a very important consideration because of the heavy workload experienced by community pharmacies. Therefore, the burden of administrative work should be reduced to a lower level.

Stakeholders of community pharmacy services claimed that managing chronic conditions in community pharmacies would require additional funds. That is because providing good quality care may require spending more time with patients. Weiss et al. (2014) found that there was a positive association between time spent with patients and improving patients' satisfaction and adherence to medicines. The current remuneration model might not be appropriate to use and was criticised for being a quantity-driven model. The management of chronic conditions may require more focus on the quality of care provided rather than on how many patients a pharmacy sees within a given period. That is because pharmacists would need to look carefully at patients' medical records, medication history, lab tests, disease progression, side effects, interactions, and contraindications. Therefore, the remuneration model should take into consideration the quality of service provided based on achieving shared patient outcomes with other healthcare providers. Section 5.4 discussed in detail how this could be done. The big

question that would need to be answered is how much each practitioner involved in managing a patient should get. The logical answer would be that every practitioner would be reimbursed based on their contribution in achieving the desired outcomes. That means community pharmacies and GPs might get paid based on their involvement in providing healthcare for patients with stable long-term conditions. General practitioners might be paid a fixed amount of money for every stable patient referred to community pharmacy. This might ensure that GPs are incentivised to make use of pharmacy services. If patients with stable conditions are well managed in community pharmacies without the need to see GPs or being hospitalized, that will improve disease outcomes and consequently save a huge amount of money in the long run. Part of the saved money (e.g. fixed amount of money for every well-managed patient) might go to GPs on an annual basis as they are also involved in keeping patients away from hospitals. This would ensure that they continue to make a profit for all patients who are well managed in pharmacy. Moreover, when a community pharmacy refers patients to GPs for a serious condition, they might receive additional compensation. All of these steps might encourage GPs to refer stable patients to community pharmacy, improve collaborative working between professions, and more importantly may improve patient care outcomes.

Participants suggested that the additional funds needed to manage chronic conditions in pharmacy could be obtained in several ways: shifting the resources available within the current contractual framework, allocating resources that exist within the NHS, imposing a fixed amount of money per prescription (e.g. co-payment) and finally increasing the budget assigned to community pharmacy from the government. One of the direct sources of generating funds is imposing a fixed amount of money per prescription. Paying a flat fee per prescription is not a new practice in Wales. Until April 2007, the Welsh population paid £3 as a flat rate for every prescription dispensed (NHS Wales 2010). The flat charge was not only a fund generator but also reduced government spending on medications (Soumerai et al. 1987). Cohen et al. (2010) found that there was a modest increase in the number of dispensed medications when compared to the period before the abolition of this fee in April 2007. The increase in the number of dispensed medications might not just be attributed to the abolition, as other

causes might impact dispensing, such as aging and comorbidities. The co-payment could be imposed on all prescriptions, or only on prescriptions that include medication for a chronic illness. That is because the economic burden of chronic conditions is very high (Watt and Roberts 2016) and might be prevented by following a healthy lifestyle (Jamison et al. 2006; Kontis et al. 2014). Thus, empowering patients to take ownership of their health by paying for their medications might encourage them to take care of their health. However, this is not the only potential outcome. In a systematic review, it was found that increasing the cost to patients was significantly associated with a decrease in adherence (Eaddy et al. 2012). Patients might not be able to buy medications or might reduce their medication consumption (e.g. skipping doses, Steinman et al. 2001). Therefore, the cost paid by patients should be at a level that does not cause a burden to them but at the same time helps the NHS to provide better patient care. As an incentive to adherent patients, those who meet the desired outcomes set by healthcare providers could be exempted from paying the charges. This would hopefully improve the health of the population and would reduce the economic burden on secondary care in the long term due to a decrease in the number of hospitalized patients. Those who do not meet the desired outcomes for their chronic health conditions may continue to pay the charge, as they may consume more resources in comparison to other controlled patients. For other sources of funds, see section 5.4.

Participants believed that healthcare services are not appropriately joined up. The fragmented care and lack of continuity of information across different healthcare providers might undermine the feasibility of managing chronic conditions in the community pharmacy sector. Participants argued that community pharmacists would need to be integrated into a multidisciplinary team, so that they could manage chronic conditions properly. Employing technology would be necessary to improve patient outcomes and collaborative work among professions. This would also improve pharmacists' access to relevant information, instead of them being mainly dependent on what patients tell them and on prescription records. Further, the transfer of patient information using envelopes to be handed to other care providers by patients, as is currently the case in some services (e.g. DMR, Pharmaceutical Services Negotiating Committee 2014), should not be necessary in the technology era. However, while the date of the reference seems old, the use of envelopes to transfer discharge information

still exists. Patients simply might not bring the envelopes to the community pharmacy, which could affect the continuity of care. In order to move towards more integrated health services, the Welsh Government (2020a) addressed the need to integrate community pharmacists with other healthcare providers and provide them with access to GPs' records. More discussion on integrated care and multidisciplinary teams working was provided in section 5.4.

7.4.1 Strengths and limitations

Community pharmacies have undergone significant evolution in the last two decades. The direction of travel for community pharmacy is changing towards providing more clinical services. Considerable work has been done in this regard, such as providing enhanced and advanced services. With a shifting compass towards managing chronic conditions on a community basis, there was a need to understand this orientation from the perceptions of the stakeholders of community pharmacy services. The present study was the first to explore the views of community pharmacy stakeholders in Wales. It involved participants who were involved in community pharmacy sector from government, LHBs, CPW, and RPSW. Some participants were also members of other pharmaceutical groups/boards (for participants' confidentiality, names are not disclosed) related to community pharmacy sector. This allowed exploration of the research topic from different perspectives and backgrounds. Using in-depth interviews allowed for a deep understanding of the topic. The two accuracy checks that were applied to the produced transcripts, use of the six-phase framework for analysis, analysing data twice, revisiting transcripts to identify themes, and the revision of transcripts and generated themes by at least one member of the supervisory team all enhanced the quality and robustness of the study findings, and thus the credibility of the study (Hagens et al. 2009; Noble and Smith 2015). Nevertheless, there were a few limitations to the present study. Due to difficulties in conducting face-to-face interviews, as some participants were located very far away and sometimes outside Wales, some interviews were conducted via phone. It was thus not possible to observe non-verbal communication. Also, due to technical errors, the quality of the calls was sometimes affected. For instance, the phone calls were sometimes cut off and or reception cut out. This partially impacted the quality of the generated transcripts. However, the researcher

ensured that the collected information was accurate by repeating questions and asking for clarification during the interviews. Furthermore, the participants had the chance to review and approve the transcripts, which should improve the quality of the collected information. The study might also be impacted by social desirability bias. Some participants might provide answers that do not necessarily reflect reality. However, the researcher reminded participants about the confidentiality and anonymity of participants and informed them that there were no wrong or right answers. Moreover, several limitations to managing chronic conditions in a community setting were identified indicating that social desirability bias was less likely to be a significant factor. Another point pertains to how representative the sample was of community pharmacy stakeholders. Although participants were recruited purposefully, the study had a very small number of people representing LHBs. Recruiting more people from the LHBs might lead to more comprehensive coverage of the topic. The inability to recruit more participants from the LHBs was due to difficulties in securing ethical approval from each LHB (more discussion will be provided in the final chapter: see section 8.7.2)

7.5 CONCLUSION

It was clear that the potential benefit of managing chronic diseases in community pharmacies was recognised. The community pharmacy setting has several strengths and opportunities, which might make it a desirable place to manage people with chronic conditions. This may improve the care provided for patients, business sustainability, pharmacists' job satisfaction, accessibility to health services, and reduce spending on patients' care. However, several limitations expressed by stakeholders of pharmacy services need to be considered prior to moving forward. These limitations are not only related to community pharmacists and community pharmacy settings (e.g. clinical expertise, capacity). The fragmented healthcare services and the way in which community pharmacy is commissioned and funded may all hinder the management of chronic conditions in pharmacy.

Chapter 8 – General discussion

8.1 Introduction

The purpose of this chapter is to give the reader a summary of the findings. The findings of the projects will be presented in an integrated manner to meet the overall aim of the thesis. The chapter will also cover the implications and recommendations for the design and implementation of a community-based chronic condition management service. Finally, the strengths and limitations of the thesis, future research, conclusion, and personal reflections will also be discussed.

8.2 Implications for the design and implementation of a community-based chronic condition management service

Pressure on GPs' services is increasing as the Welsh population grows older, with an increased burden of chronic conditions (Wales Audit Office 2014; Baird et al. 2016). Around 50% of GPs appointments are for people with chronic conditions (Pharmaceutical Services Negotiating Committee 2020a). As the demand for GPs' care increases, there is a need to involve other practitioners to provide direct patient care (NHS Wales 2015a,b). Therefore, to investigate how well asthma was managed in Wales and the potential involvement of community pharmacy in managing chronic conditions, five studies were conducted. The first two quantitative studies clearly indicated that people with asthma were not well managed. A high percentage of the cohort sample had inadequate inhaler technique, inappropriate adherence to inhalers, and poor asthma control. The same findings were reported in other studies (Giraud and Roche 2002; Molimard 2003; Williams et al. 2004; Fink and Rubin 2005). This provides evidence that the issue is not unique to Wales and can be generalised across a much wider patient population. It would indicate that the management of asthma in Wales was not disproportionately worse than elsewhere. Further, demonstrating a proper inhaler technique and good adherence to inhalers are essential in managing asthma. Several studies showed the importance of having proper adherence and inhaler technique on asthma control (Blaise et al. 1998; Giraud and Roche 2002; Williams et al. 2004). However, the two projects conducted on asthma patients in this thesis could not identify a significant association between proper inhaler technique, good adherence, and good

asthma control. This might be attributed to the small sample size and information bias (for more discussion, see section 4.4.1).

It could be assumed from the above findings (i.e. the high percentage of poor asthma control, inappropriate inhaler techniques, and adherence) that patients under the current practice were not getting adequate care/attention from their healthcare providers, especially when most of the cohort sample experienced the same issues in respect of asthma control, adherence, and inhaler technique. A considerable proportion of the patients could not administer inhalers properly. They failed to meet several essential criteria of the proper inhaler technique (e.g. correct canister activation (for pMDIs), proper inspiratory flow rate, adequate inhalation time, and breath-hold time) across all the three inhaler devices (i.e. DPI, pMDI, pMDI+spacer). Gruffydd-Jones et al. (1999) found that 62% of asthma patients had not attended the asthma clinic in the last 12 months. However, while the date of the reference seems old, not getting adequate attention from healthcare providers might still exist as the patients with asthma had high percentage of poor asthma control, inhaler technique and adherence. Incorrect use of inhalers has been found to be associated with poor asthma outcomes (Giraud and Roche 2002). Errors while administering inhalers could be identified at the review visit or when a new inhaler is prescribed. Simulator inhalers (e.g. AIM and In-Check DIAL G16) could be used to coach patients prior to prescribing, so that the most appropriate inhaler device could be determined. More importantly, using such devices would allow practitioners to assess essential inhaler technique aspects that cannot be checked through observation, such as inspiratory flow rate. Furthermore, the results of this thesis showed that around 26% of the study sample was never asked by healthcare providers to demonstrate their use of inhalers, and therefore this may impact their ability to have a proper inhaler technique (see Chapter 4 for more detail). Those who had never been asked to demonstrate inhaler technique might represent a huge number, given that there are 314,000 asthma patients in Wales (Asthma UK 2020a).

This failure to ask patients to demonstrate inhaler technique might be attributed to several factors that were identified in the two qualitative projects conducted in this thesis. The shortage in health care professionals, workload, unfamiliarity with the

proper inhaler technique, and fragmented care and the lack of information continuity among healthcare providers all might lead to that result. The shortage in healthcare providers and workload they have might impact the quality of healthcare provided. Providing clinical services take longer to deliver in comparison to dispensing. Thus, healthcare providers might be inconsistent in providing such services. Further, even though health care providers, who were responsible for dealing with asthma patients, were supposed to be well informed about using inhalers, researchers have reported that there is a lack of understanding about proper inhaler handling among health care professionals (De Tratto et al. 2014). This illustrates the importance of providing training courses for practitioners dealing with asthma patients. Healthcare providers could be trained by using devices that simulate the intrinsic resistance and preferably assess the other essential steps of a proper inhaler technique (e.g. AIM and In-Check DIAL G16, Carpenter et al. 2017; Sanders 2017). Finally, primary care provision is not properly joined up. Every healthcare provider involved in providing care for patients must know who should provide the service, how the service should be delivered, and who is accountable for patient outcomes. This would enable the professional boundaries to be clearly drawn amongst all health care providers involved in an individual patient's care. For example, pharmacists might assume that the patient's inhaler technique has been checked by another health care provider (e.g. asthma nurse, GP), so patients might receive their inhalers without coaching.

Patients with chronic conditions should be empowered, to some extent, to take care of themselves and to avoid serious exacerbations that can result in hospitalisation or death. When applicable, providing patients with chronic conditions with action plans for their illnesses and making them mandatory in review visits might help in improving care and consequently may reduce healthcare spending. In a Cochrane review of 36 randomised controlled trials, Gibson et al. (2003) found that completing an asthma action plan combined with regular clinical review significantly improved patient quality of life and healthcare utilization. Information provided in the action plans may include information about their medicines (e.g. how to use them, serious side effects to watch out for, precautions), conditions (e.g. indications of good and bad control and symptoms to watch), how to monitor their condition (e.g. checking blood glucose levels), and what

to do if the condition gets worse. As discussed earlier, chronic conditions might not be well controlled if patients are not seeing their healthcare providers regularly. Therefore, even if patients have written action plans, healthcare providers might not be able to monitor patients if they are not attending the review visits. Thus, developing an electronic action plan that is linked to patients' medical records and could be accessed by the patients and their care providers anywhere and at any time may improve the reporting and accuracy of data provided. It might be more convenient for patients in the technology era to report issues experienced instantly from their phones. The electronic action plan could be applied to all chronic conditions where self-monitoring makes a massive difference. Assuming that patients would keep their electronic action plans up to date and accurate, community pharmacists could easily monitor a large proportion of chronic patients remotely. They could access their medical records, read the action plans and other relevant information, evaluate the cases, and provide recommendations directly to the patients. This would perhaps not be feasible for all types of chronic conditions and patients, but it would be applicable for others.

8.2.1 Potential benefits of managing chronic conditions in community pharmacy settings

The opinions of participants in the studies presented in this thesis indicates that there is room for improvement in how patients with chronic conditions are managed in primary care settings. Community pharmacists could play additional roles in managing people with chronic conditions. The findings of this programme of research showed that most community pharmacists would like to be more involved in managing chronic conditions. Their confidence in managing chronic conditions varied; however, most of the participants were able to manage at least one chronic condition. On average, each participant could manage approximately 3 chronic conditions. The willingness of community pharmacists to manage certain chronic health conditions was determined based on several factors, such as the nature of the chronic conditions (i.e. how to monitor and assess the disease outcomes), the standardized therapeutic management plan (e.g. having a stepwise management plan), personal knowledge and interest, patients' involvement in managing their conditions (i.e. how much the case has to do with self-management), whether the potential intervention is medicinal in nature (i.e.

depends on therapeutic interventions), the prevalence of the condition, and the ability to provide educational intervention (i.e. it involves providing training sessions such as how to use inhalers). The five most frequently mentioned conditions that could be managed in community pharmacy were as follows: asthma, hypertension, COPD, diabetes, and heart failure. The potential benefits of involving community pharmacies in managing chronic conditions may have positive impacts on NHS, community pharmacy setting and workforce, and patients as well. It would decrease burden on GPs and offer cost-effective services for patients. For example, being able to manage the five diseases mentioned above in community settings may significantly improve GPs' capacity, as they are very prevalent. The accessibility of community pharmacy would help in meeting unmet public needs as people are struggling to access GPs. This would allow community pharmacists to address and deal with patients' needs, which ultimately might improve patient experience and may prevent deterioration of their health. More importantly, it would improve health inequality, as patients would be able to access healthcare services in places where there is no GP. The consistency of healthcare providers and engagement with patients might be better in community pharmacy setting in comparison to other healthcare sectors. Unlike general practice, patients could see the same community pharmacists every time they visit their local pharmacies. This would help in building better relationships with patients, so they might be more open to discuss their concerns and, more importantly, to adhere to a healthcare provider's recommendations. Further, providing a community-based chronic management service would make pharmacy businesses more sustainable and profitable, especially as the available funds allocated for dispensing have been reduced. Finally, the effective utilisation of community pharmacists' skills and expertise may improve their job satisfaction and reduce the number of pharmacists leaving the sector (for more discussion, see sections 5.4, 6.4 and 7.4).

8.2.2 Limitations and potential facilitators of managing chronic conditions in community pharmacy settings

Pharmacists and community pharmacy stakeholders identified several considerations that needed to be addressed prior to moving forward with managing chronic conditions in pharmacy. These considerations (i.e. barriers and facilitators to managing chronic

conditions) were not only related to community pharmacists. There were other limitations that were attributed to the current policy and regulation (i.e. related to the government and LHBs), community pharmacy setting (e.g. staffing), and other stakeholders (e.g. patients, other health care providers). This will be discussed in an integrated manner below.

The opinions expressed by participants in the studies described in this thesis support the importance of integration of community pharmacists in a multidisciplinary team, so that they could manage chronic conditions properly. The healthcare system may need to move away from fragmented care towards an integrated model, so that patients can move seamlessly among healthcare settings. The results of asthma projects show that around 26% of the study sample was never asked by healthcare providers to demonstrate their use of inhalers. This may indicate how fragmented care might impact care provided for patients. Asthma patients usually see more than one healthcare provider for their illnesses (e.g. a nurse, GP, pharmacist for collecting prescriptions). When patients move from one primary setting to another, not only should they move seamlessly, but also all relevant information should move as well. Katangwe et al. (2019) claimed that there was a need for community pharmacy to be integrated with other primary care settings so that patient care could be provided efficiently. Further, the need for integrated healthcare was addressed by the Welsh Government. The community pharmacists and GPs would be integrated into clusters to work together collaboratively (Welsh Government 2019a; Welsh Government 2019b; Welsh Government 2020a). This would ensure that all practitioners from different specialties work together to provide seamless care in the patients' best interests. Further, the boundaries between professions should be clearly determined, so that everyone would know when each person's role starts and ends. The lack of clarity about healthcare professionals' responsibilities and accountability was found to be a barrier to expanding the community pharmacists' role in direct patient care (Donald et al. 2017). Setting up clear responsibilities for each health professional involved in managing chronic conditions may minimize the risk of patients falling through the gaps such that they cannot receive a healthcare service. Moreover, the lack of a formal route to identify patients who needed to be seen by community pharmacists was considered a limitation

of the current practice. As patients would be more likely to follow their GPs' recommendations (Twigg et al. 2013), employing an electronic system that starts with GPs referring eligible patients to community pharmacists might improve the practicality of the model.

Variations among LHBs (e.g. in services provided and service requirements) was claimed by participants to be one of the obstacles that might hinder the management of chronic conditions in pharmacy. The disparities among LHBs might increase health inequality and impact the opportunity of contractors to provide the service. To ensure that chronic condition management services are equally available to all pharmacy contractors, it should be approved as a national service without allowing the LHBs to amend service requirements. This will ensure that all qualified community pharmacists will be able to provide the service regardless of their locations. Therefore, all community pharmacies would have an equal opportunity to generate revenue, which would be extremely important as the funds allocated to dispensing will gradually decrease (Department of Health and Social Care 2019). Moreover, it might improve access to healthcare, as more community pharmacies would be able to provide the service for their communities. The most frequent chronic conditions (e.g. asthma, diabetes, and hypertension) are widely distributed and frequent in the patient population (NHS Wales 2020b). Thus, all community pharmacies, regardless of their locations, should be empowered to provide the service based on standardized service requirements. The discrepancies among LHBs may create an additional burden on community pharmacy, lead to bureaucracy, and cause delays in meeting patients' needs.

Community pharmacy sector indicated they needed better guidance from commissioners of pharmacy services in respect of the direction of travel and contributions of community pharmacy in patient care. The new vision of community pharmacy and the potential contributions in patient care (Welsh Government 2019a) should be clear and endorsed by the Welsh Government. As community pharmacies will be the site for monitoring people with stable chronic conditions (Welsh Pharmaceutical Committee 2019), they should be supported and better guided to achieve this goal. One of the main steps that are essential in guiding community pharmacy towards achieving

its new vision is changing the mindset of people involved in community pharmacy (e.g. pharmacists, contractors). The huge transformation in the community pharmacy setting that has been occurring to increase these pharmacies' contributions to healthcare may help in introducing community pharmacy to a bigger role (i.e. managing chronic conditions). Community pharmacists and contractors who prefer dispensing over other services might start to see the benefits of providing direct patient care and therefore be encouraged to provide services to manage chronic conditions. This could be achieved by making the provision of such clinical services at least as profitable as dispensing. The contractors and community pharmacists would be more likely to follow services that generate more profits. Moreover, ensuring that contractors have equal opportunities to provide the service (i.e. not allowing the LHBs to add additional requirements or prevent some contractors from providing certain services) may help with acceptance of the new direction of travel. On the other hand, the current and the potential involvement of community pharmacists in providing clinical services may help in changing public perceptions about community pharmacy. Thus, when chronic conditions are managed in pharmacy, more people might trust community pharmacists and accept seeing pharmacists for their chronic illnesses.

One of the biggest issues identified by participants was funding and the community pharmacy reimbursement model. Managing chronic conditions would need a huge investment in community pharmacy. As the initial stage of implementing the model would need direct funds, the model might be able to generate indirect funds as time goes on. Community pharmacists' expertise in medicines can lead to reduced spending on health, improve patients' outcomes, and decrease hospitalization, and therefore the saved costs could be allocated to fund the model (Hawksworth et al. 2001; Tsuyuki et al 2002, for more information, see section 7.4). The current community pharmacy reimbursement model was found to be quantity-driven, which might not be appropriate for managing chronic conditions. The remuneration model should consider several aspects. The first is the quality of the service provided. Most of the participants claimed that the pharmacy services provided for patients were inconsistent. Ensuring the quality level of chronic condition management by reimbursing pharmacists based on achieving the quality indicators for each patient and illness might be essential (e.g. maintaining a

good glucose blood level for a diabetic patient). The second aspect pertains to encouraging collaborative work among different health professionals by working on achieving patients' outcomes. The third is the sustainability and profitability of community pharmacies. The new remuneration model should be a revenue generator for community pharmacy, and at the same time pharmacies that are not engaged in managing chronic conditions should be able to survive. For more information about potential ways to allocate funds, and how the remuneration model for chronic conditions may work, see sections 5.4 and 7.4.

Even though community pharmacies are well known for having good accessibility (Pharmaceutical Services Negotiating Committee, 2020b), the results of the studies presented here showed that pharmacists and stakeholders believed that it is continuity of service that really matters. It does not really matter how accessible a community pharmacy is if it does not provide services that patients need. The continuity of the service will be a real challenge facing the management of chronic conditions in pharmacy, as additional qualifications will be required. It should be ensured that patients can access the service they need when they visit the pharmacy. This might be done by implementing an appointment system; however, this would run counter to the essence of community pharmacy. The continuity of the service could be improved by ensuring that more than one pharmacy member is qualified to provide the service (for more information, see sections 5.4 and 7.4). The capacity of community pharmacists to provide more clinical services could be increased by the delegation of tasks that do not necessarily utilize the pharmacists' expertise to other pharmacy staff, increasing the period of treatment, and employing robots and technology. The capacity might worsen, as the current findings indicated that community pharmacists are facing difficulties with recruiting staff, especially in some areas of Wales. Managing chronic conditions might need additional staffing, and this might threaten the capacity of community pharmacy and the continuity of the service.

Factors related to individuals (e.g. healthcare providers, patients) would perhaps impact the expansion of the provision of clinical services in community pharmacy. In general, more collaboration between community pharmacists and other health care providers,

especially GPs, was identified as being necessary. The level of collaboration between community pharmacy and other professions was assumed to be affected by the location of community pharmacy (i.e. community pharmacy next to a GP surgery may have better collaboration than a supermarket community pharmacy), face-to-face interaction, meetings, and previous experience. Community pharmacists expressed that some healthcare providers might see them as “failed doctors” or “dispensers” rather than “health service providers”. This was attributed to having almost isolated entities (e.g. pharmacy students go to pharmacy schools, medical students go to medical schools, and there are few or no shared courses). Participants suggested that increasing the interaction between health professions through, for example, inter-disciplinary education, meetings, and educational events, may improve relationships/collaboration. It was identified that the lack of collaboration and support from other healthcare providers may negatively impact the expansion of clinical roles for community pharmacists (Mossialos et al. 2015). Further, the relationship between patients and community pharmacists had an impact on the provision of more services in pharmacy as well. Patients’ perceptions, previous experience with a community pharmacist, and the location of the community pharmacy (e.g. next to a GP, in a supermarket) were all found to affect the relationship with community pharmacists. It was argued that patients had inappropriate stereotypes about community pharmacists. They thought of community pharmacists as “chemists”, “extension of the shop”, or “discounted GPs” who were not sufficiently qualified to provide clinical services. The locations of community pharmacies were claimed to affect patients’ relationships with the community pharmacists. Community pharmacists working in supermarket pharmacies may receive less respect than others. Patients tended to be “sceptical” of any service offered by a community pharmacist working in a supermarket. Therefore, patient acceptability to be managed for a chronic condition in community pharmacy might hinder expanding the role of community pharmacy in managing chronic conditions. This might be more clearly observed when patients have the choice of whether to see a GP or a community pharmacist. The results showed that community pharmacists believed that most patients would prefer to see a GP for their illness rather than being seen by a community pharmacist. A model that encourages GPs to refer patients to community

pharmacy to be managed is highly recommended (see sections 5.4 and 7.4 for more discussion).

8.3 Recommendation for the design and implementation of a community-based chronic condition management service

After conducting the projects presented in this thesis, several suggestions were presented and discussed previously (see the discussion sections for each project). In addition, a series of recommendations were developed from the opinions that were expressed which might help in designing and implementing a community-based management service for chronic conditions. They were as follows:

- Community pharmacists are underutilised as healthcare professionals. They could be more effectively utilised in managing chronic conditions. However, it is appropriate to be cautious about expanding the scope of community pharmacists without ensuring patient safety and considering the current responsibilities for community pharmacists. They are best placed in dealing with aspects related to medications. Medical tasks that are beyond the essence of the community pharmacy should not be assigned to them (e.g. taking blood samples or measurements). Their involvement in managing chronic conditions should be limited to patients with stable conditions (who are referred from GPs).

- Chronic conditions vary in complexity and prevalence. The new model of chronic condition management may start with chronic conditions that are of high prevalence (this would free up GPs' time) and easy to manage (a lot of pharmacists would participate). Starting with few chronic conditions may help in qualifying more pharmacists and ensuring that the service is widely available. As things go well, other chronic conditions could be added to the scheme. Chronic conditions should be introduced gradually for four main reasons: to cope with the possible potential demands on training courses, to give community pharmacy the chance to manage the potential increase in footfall, to allow people enough time to adapt to the new model of care, and finally to ensure that management of a certain chronic condition is widely available in the community (i.e. that there are a lot of pharmacists managing the condition).

- To guarantee effective implementation of the community-based chronic condition management model, pharmacists will need to be more involved in a multidisciplinary team as “health care providers”. A collaborative chronic condition management plan should be established between a GP and a community pharmacy that are in the same area (i.e. the same neighbourhood or cluster). This plan should be established for each patient and for each chronic condition. The plan should clearly indicate the desirable disease outcomes determined by patients and their health care providers (e.g. GP, specialist) and how these outcomes could be achieved. The community pharmacists’ role should start after referral of patients by their GPs to the nearest pharmacy providing that service or based on patients’ preferences. Then, community pharmacists would work with patients with stable chronic conditions to achieve their health-related goals. As pharmacies have limited capacity, there should be a limit on the number of patients who could be managed in each pharmacy (i.e. referred from a GP to a pharmacy). This number might be determined based on several criteria, such as the prevalence of chronic conditions, the number of qualified pharmacists in the pharmacy who can provide the service, the number of consultation rooms, and the number of patients with chronic conditions who are managed in that pharmacy.

- Chronic condition management services should be agreed at the National Enhanced Service Board without allowing for changing service specifications at a local level (i.e. LHBs). LHBs could discuss any concerns they have at the national level so that an agreement would be reached. That is because changing service specifications would increase disparities among LHBs, may create bureaucracy, and more importantly, may increase health inequality. Moreover, service provision should be available equally for all contractors. Given that it would be the new revenue generator for community pharmacy, all contractors should be able to provide the service for their communities when they meet the standardized service specifications.

8.4 Strengths and limitations

The work presented here has several strengths and limitations. All identified strengths and limitations were discussed separately in each project. This section discusses the strengths and limitations of the study design chosen (i.e. mixed methods design). One

of the major strengths of the work presented here was its use of a mixed-methods approach. Using this approach allowed the researcher to investigate and understand the topic comprehensively. Thus, it resulted in a deep understanding of the phenomenon (for further discussion, see section 2.3.1). There were also several other strengths related to the three main levels of research, namely the study design level (the conceptualization of the study), the methods and analysis level, and the interpretation level. One of the main strengths of the study design level was designing a questionnaire based on qualitative findings. The themes identified from the qualitative component helped in constructing the questionnaire. In respect of the methods and analysis level, using an embedded qualitative part within a questionnaire to ensure the coverage of themes identified in the qualitative component was a crucial strength. As no new themes were identified after analysing the embedded qualitative part, this indicated the robustness of the first qualitative project (i.e. Chapter 5). Using more than one study (different data tools, study designs, and statistical tests) to investigate the topic yielded a better understanding. There were also more specific strengths that were discussed earlier in detail under the discussion section for each study. These included using an objective tool to assess inhaler technique, triangulation of the findings, representative samples, conducting face-to-face semi-structured interviews, the two accuracy checks for generated transcripts, and the trustworthiness of the collected data. For more detail, see sections 3.4.1, 4.4.1, 5.4.4, 6.4.1, and 7.4.1.

However, while the presented work had several strengths, a series of limitations were identified. It has been argued that quantitative and qualitative studies cannot be combined due to the different procedures and paradigms (Tariq and Woodman 2010). Further, both would need specific skills and require different experiences (Tariq and Woodman 2010). That being said, a mixed methods design was the best approach to answer the research question (for more discussion, see section 2.3.2). The researcher enrolled in different training courses to enhance his knowledge and advanced his research skills in the two approaches (i.e. quantitative and qualitative, see section 2.8.1 for more information). That is why doing a PhD using a mixed methods approach may significantly improve students' skills in research. Another limitation of this thesis was that the researcher did not seek the opinions of other stakeholders about the potential

introduction of expanded services in community pharmacies. A better understanding of the topic would require interviewing patients and GPs as their views are important in designing a community-based chronic management service. Given that the number of projects conducted and time constraints of the researcher's scholarship, it was difficult to interview other stakeholders. The other limitations that were identified in this thesis were as follows (all the following limitations were discussed thoroughly in the previous chapters). There are limitations in using the AIM device and sampling. The sample size in Chapter four was relatively low. A relatively small number of interviews with community pharmacists were conducted; however, saturation point was reached, and themes were replicated in each interview. Further, no new themes were identified when the questionnaire was disseminated to a larger population. Another reason might be because one of the participants was very familiar with the topic and had a research background. The input of that interview was helpful. Another limitation was that the response rate of the returned questionnaires was relatively low; however, no differences were seen between respondents and non-respondents. Finally, conducting phone interviews when participants could not be interviewed in person might be a limitation. All of these limitations were discussed thoroughly in sections 3.4.1, 4.4.1, 5.4.4, 6.4.1, and 7.4.1.

8.5 Future research

As the presented work might help in designing and implementing a community-based chronic condition management service/model, it would be useful to conduct further research to understand the perspectives of other involved stakeholders, such as GPs/specialists, other pharmacy staff and patients. Chronic condition management services are not only related to community pharmacy. A deep understanding of barriers and facilitators to managing chronic conditions in pharmacy from the perspectives of patients and other practitioners would yield a better understanding of the topic. Potential research areas might include patients' acceptance of being managed by community pharmacists and GPs' perceptions about involving pharmacists in managing chronic conditions. Moreover, qualitative research could be conducted to understand the perceptions of GPs and community pharmacists regarding the suitable reimbursement model. It might be helpful to know how the best model is going to work

for the two professions and how they should be reimbursed for providing multidisciplinary care. Finally, a health economic study of the potential cost/benefits of the new model (i.e. managing chronic conditions in a community setting) might be needed.

8.6 Conclusion

Patients with chronic conditions might not be properly managed in the primary care setting. As community pharmacists are underutilized and willing to expand their clinical role, their potential involvement may help in providing better care and reduce the burden on GPs. This issue seems increasingly important as the prevalence of chronic conditions increases, combined with a fall in GP numbers across Wales. Although community pharmacists are able to manage several chronic conditions, there are several limitations that need to be addressed prior to expanding their role.

8.7 Personal reflections

As I conducted the five projects and have been living in Wales, I have observed and experienced several situations related to the research presented here. I am going to share my personal reflection on managing chronic conditions in community pharmacy, engagement of participants in research, and finally conducting and dealing with qualitative and quantitative project/data.

8.7.1 Personal reflections on managing chronic conditions in community pharmacy

While conducting my research, I have been in several consultation rooms. I could say that a considerable proportion of them may not be appropriate to manage chronic conditions due to space, physical accessibility, and lack of professional appearance. The tiny space would make it difficult to accommodate a mobility scooter or wheelchair for disabled patients. One of the consultation room was located on the first floor with no lift/escalator equipment on the premises. This may make it inaccessible for a large proportion of people with chronic conditions. The appearance of the consultation room

is important as well. They should look as professional as GPs' rooms, so that both patients and pharmacists feel comfortable.

One of the situations related to the space of consultation rooms that I experienced in my personal life was when I visited a pharmacy with my three-year child for a minor ailment service. It was very difficult and awkward to accommodate the stroller in the consultation room. The pharmacist and I had to squeeze so that the door could be shut. It was neither a professional nor a comfortable place to receive a health care service. Another personal experience I had was related to asthma inhalers. When my child was suspected to have asthma, he was prescribed a rescue inhaler, so that asthma could be ruled out. When I went to pick up the inhaler, no one showed me how to use it. I was not even asked if I knew how to use it, despite the fact that he was being prescribed Ventolin for the first time. Not showing patients the proper inhaler technique would impact their ability to administer inhalers properly.

While I was conducting interviews with community pharmacists, I felt that they were enthusiastic about having more involvement in managing chronic conditions. Also, when the questionnaires were returned, a relatively high number of participants (compared to other studies) had completed the optional qualitative part. This might indicate that the participants were interested in the topic, and thus spent additional time expressing their views in writing.

8.7.2 Personal reflections on the engagement of participants in research

Given that all of the five projects conducted were primary research (i.e. I was actively involved in collecting data), it was really challenging to engage participants in the research. These difficulties occurred at two main stages: first, difficulties in gaining the required ethical approval to recruit participants; and second, difficulties in data collection and recruitment. For one of the conducted projects (Chapter 7), it transpired that I had to get ethical approval from all seven LHBs across Wales to recruit participants from each LHB. This would mean applying seven times to gain separate approval from each LHB. An integrated application system in which an application is submitted once would save considerable time and effort for applicants and processors.

Recruiting patients in my projects was challenging. I had to change/modify my thesis objectives for this reason. The percentage of participants who agreed to take part was low. Even when they were contacted by phone more than once at different times and received invitation letters, only a very small number of patients agreed to take part. That was why I decided not to continue in conducting a project that aimed to assess the impact of educational intervention on inhaler technique (i.e. I needed to see the same patients more than once). Another annoying point was about “no-show” patients. It was disappointing when I travelled for two hours in bad weather to meet a patient and no one showed up.

Finally, recruiting community pharmacists was also difficult. In the beginning, I was willing to run several focus groups across Wales. Despite offering a reasonable incentive for participation (£50) and reducing travel costs to a minimum by arranging meetings near participants’ locations, this approach was not feasible, with only two participants being willing to participate. Thus, I decided to amend the ethical approval so that I could conduct individual interviews instead. Even after getting approval to conduct individual interviews, community pharmacists were very difficult to recruit. I contacted the Royal Pharmaceutical Society Wales (RPSW) and Community Pharmacy Wales to help me with recruiting participants. After several emails and phone calls, the RPSW agreed to publicize the project via their Facebook page. Even recruiting via other gatekeepers did not yield a good number of potential participants. I think meeting community pharmacists at a scientific conference relevant to them might be a good option.

8.7.3 Personal reflections on conducting and dealing with qualitative project/data

Throughout my career before starting my PhD, I was not exposed to qualitative research. However, one of my personal goals related to doing the PhD was to expand my knowledge and skills in research. I wanted to gain as many research skills as I could by conducting a variety of study designs, which would help me not only during my PhD but also beyond. I worked on constructing topic guides, conducting interviews, transcribing and analysing data, identifying themes, and writing qualitative project chapters. All of these stages enhanced my skills and advanced my knowledge in conducting research

and dealing with participants. However, despite trying my best to be prepared for my first qualitative interview (by rehearsing, memorizing the main questions, practising techniques to move from one dimension to another prior conducting the interview), I was a bit nervous when I conducted this first interview. I faced difficulties in moderating the first interview, especially when the interviewee discussed several things together (i.e. answering questions that I had not yet asked). I believed that my performance was much better after the first interview. I felt more confident as I conducted more interviews. I started to use probing questions much more effectively to clarify things and generate more information. This helped a lot with some participants who tended not to provide detailed answers. I experienced another challenge with participants who gave too much detail on every question asked. Given that the interview length was limited, I had to manage this issue by trying to step in by responding to something that they mentioned, and then moving the participants' attention to an area that had not yet been covered. Finally, conducting qualitative research that was not in my native language was relatively difficult. That was because some participants used new idioms, unfamiliar vocabulary and informal language, or talked very fast, which in a few instances impacted the quality of the message delivered. I tried to overcome this issue by asking for clarifications and making sure that I understood what they meant. Moreover, data transcription was a really tough job. It was one of the most difficult tasks I have performed during my PhD journey. On average, it took me around 20 hours to transcribe a 30-minute interview. Although I had obtained ethical approval for transcription of the interviews by a third-party company and had sufficient funds to do so, I decided to transcribe all the interviews for Chapter 5 myself. I wanted to gain new skills and to immerse myself more in the data. This was very helpful in analysing the qualitative data set.

8.7.4 Personal reflections on disseminating postal questionnaires

Although I had the option to disseminate the questionnaire online by contacting gatekeepers who were involved with community pharmacists (such as some participants I interviewed in my second qualitative project), I decided to use a postal questionnaire. It might be more convenient to conduct an online questionnaire than a postal one. However, the postal questionnaire would reach a larger sample of participants.

Disseminating questionnaires to 715 community pharmacies across Wales (a total of 2145 for the three rounds) was a real challenge. I spent a lot of time doing administrative work, such as photocopying, enclosing several documents in each envelope, labelling, transferring responses to an Excel spreadsheet, and reading and transferring participants' handwritten responses to a Microsoft Word file. The consequences of engaging in a large postal questionnaire study should be carefully considered by PhD students prior to moving forward.

8.8 Summary of key findings from the thesis

- There is room for improvement in how patients with chronic conditions are managed in the Welsh patient population.
- Community pharmacies could play additional roles in managing people with chronic conditions. This may decrease burden on NHS, enhance sustainability of pharmacy business, and improve patient experience and job satisfaction of community pharmacists.
- Several limitations at multiple levels need to be considered prior to moving forward with managing chronic conditions in a community setting. These limitations are not only related to community pharmacists/pharmacies but also extend to other stakeholders (e.g. patients, other healthcare providers).

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Appendices

Appendix 3.1 - Research poster

Dear Colleague,

Thank you very much for submitting revised abstract, **Assessing inhaler techniques of asthma patients using aerosol inhalation monitors (AIM): A cross-sectional study**, to HSRPP 2019.

I, on the behalf of the HSRPP 2019 Scientific Committee, am pleased to inform you that your abstract has been accepted for a **POSTER** presentation for Health Services Development Showcase (HSDS). The date and time of your 'Poster Walk' session will be communicated later, once the programme has been finalised.

Please remember to purchase your conference ticket from <https://www.birmingham.ac.uk/facilities/mds-cpd/conferences/hsrpp-2019/registration.aspx> . The Early Bird Deadline is 15th February 2019. Please note that the abstract will be dropped from the final programme if none of the authors register for the conference.

Please note that the poster formatting requirements will be emailed to you at a later date.

Appendix 3.2 - Ethical approval

SPPS Amendment Approval Notification (AAN)

11/10/14 v1

Cardiff School of Pharmacy and Pharmaceutical Sciences, Research Ethics Approval

AMENDMENT APPROVAL

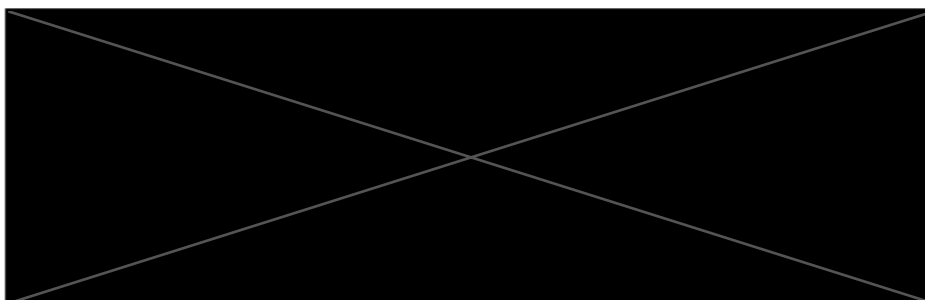
This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for amendment(s) to the following study:

Project ref and title:	1617-01 Evaluation of a community pharmacy based asthma care plan
------------------------	---

Name of researcher: (PG/Staff projects only)	Will Ford
Name of supervisor(s):	

The amendment(s) dated 10 Oct 2018 have been reviewed and approved.

Any further amendments will require approval.





Cardiff School of Pharmacy & Pharmaceutical Sciences

Participant Information Sheet

Title of study: Evaluation of a community pharmacy-based asthma care plan

Do you have asthma?

If you have asthma, we would like you to participate in this study so please read on. If you do not suffer from asthma then this study is not suitable for you, but thank you for taking the time to consider it.

If you have asthma, we would like to invite you to take part in our study. Before you decide, we would like you to understand why the study is being carried out and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

Please feel free to talk about the study with anyone you want and ask us if there is anything that is not clear to you.

What is the purpose of the study?

Millions of people in the UK have asthma. Previous research has indicated that patients are not getting the full benefit from the medicines that are available to treat asthma. As asthma is a potentially life-threatening condition, we are running this study to see if we can help patients manage their condition better to improve their quality of life and reduce the risk of their asthma becoming a more serious problem.

Why have I been invited to take part?

You have been invited to participate as we think you might have been told you have asthma. If this is not the case, the study is not suitable for you and please let us know so we do not take up any more of your time needlessly.

Do I have to take part?

No. It is up to you to decide whether you want to take part. We will describe the evaluation and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to help us fill in two short questionnaires about you, your asthma and how you use your asthma medicines. You will then be asked to demonstrate how you use an inhaler, using an inhaler attached to a machine that measures how good your technique is. The test inhaler is the same type of inhaler that you normally use, but it does not contain any drug (medicine).

Once we have completed the questionnaires and tests, we will provide you with advice about how to improve the benefit you get from medicines prescribed for you to treat your asthma. We may recommend other services that are available from your pharmacy or GP clinic that may help you and your asthma. We estimate that the whole appointment should take between 20-30 minutes.

We will be running this study every year and will ask if we can write to you next year to invite you back for another appointment. This should be around September/October next year or possibly earlier. We will not contact you unless you have said it is OK for us to do so. Your contact details will be kept confidential and not shared with anyone other than study investigators.

What are the possible disadvantages and risks of taking part?

There are no expected risks in taking part in this study.

What are the possible benefits of taking part?

We hope that participation will improve the benefit you get from your asthma medicine and give you a better understanding of how to manage your asthma.

Will my taking part be kept confidential?

Yes, it will not be possible to identify you as a participant from any of the data we publish in student dissertations, scientific conferences or journal articles. Although we will be collecting your NHS number that can be used to identify you, it will be kept separately from your study information. This means that it is not possible to identify you from your study data without reference to the separate database. We will only use your NHS number to help us contact you to invite you to an annual follow-up appointment, to match you to your records on follow-up appointments, or if information is requested by your GP. The lead pharmacist and chief investigator will be the only members of the study team who can access to the database with your NHS number.

How is the project being funded?

The Cardiff School of Pharmacy and Pharmaceutical Sciences of Cardiff University are funding the project.

What will happen to the results of the service evaluation?

The results of the study will be used by the investigators to write dissertations as part of their degree in pharmacy, and may be presented in scientific conferences and journals. A summary of the results will be provided to the Aneurin Bevan University Health Board.

It will not be possible for anyone to identify you from the information in the reports, dissertations or publications.

What should I do next?

If you have decided that you would like to participate in the study, the please call your Mayberry pharmacy to make an appointment with one of our researchers. You can choose which of the pharmacies is most convenient for you from list at the end of this email. If you do not wish to participate there is no need to do anything further.

Who should I contact for further information?

If you have any questions or require more information about this service evaluation, please contact the chief investigator:

Dr Will Ford

Cardiff School of Pharmacy & Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

CF10 3NB

Telephone: 02920 874781

What if there is a problem?

If you have a concern about any aspect of this service evaluation, you should speak to the chief investigator, Dr Will Ford (details above). If you remain unhappy and wish to complain formally, you can contact Cardiff University for further advice and information at University Governance and Complaints Division, Cardiff University, 4th Floor, McKenzie House, 30-36 Newport Road, Cardiff CF24 0DE.

Thank you for reading this information sheet and for considering taking part in this research. Please keep this leaflet for future reference.

Mayberry Pharmacy Ltd:



Blackwood, 175 High Street, NP12 1AA

Telephone: 014 9522 4875

Trevethin, 6 Church Avenue, NP4 8DH

Telephone: 014 9576 3431

Newport, 103 Durham Road, SP19 7DP

Telephone: 016 3324 4026

Pontypool, 21 Crane Street, NP4 6LY

Telephone: 014 95750095

Appendix 3.4 - Consent form



Patient Consent Form

Evaluation of a community pharmacy-based asthma care plan

	Please initial
I confirm that I have read the information sheet dated 17/10/17 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without my medical care or legal rights being affected.	
I understand that the information collected about me will be used to support other research in the future by sharing with other researchers or publishing journal articles. This data will be anonymous and it will not be possible to identify you as a participant.	
I agree to take part in the above study.	
I agree to be contacted for follow-up	

Name of participant Signature Date

Name of person taking consent Signature Date

Appendix 4.1 - Ethical approval

SPPS Amendment Approval Notification (AAN)

11/10/14 v1

Cardiff School of Pharmacy and Pharmaceutical Sciences, Research Ethics Approval

AMENDMENT APPROVAL

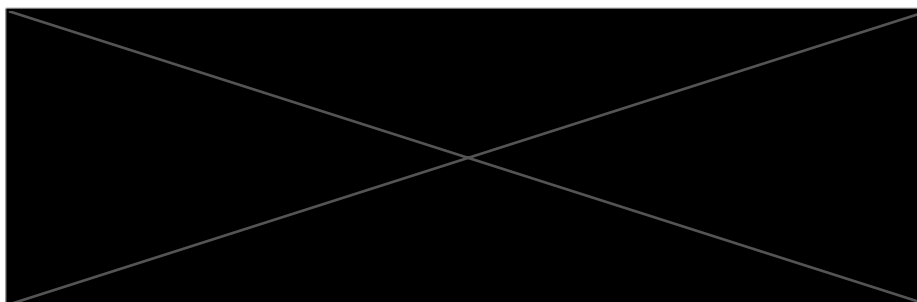
This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for amendment(s) to the following study:

Project ref and title:	1617-01 Evaluation of a community pharmacy based asthma care plan
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Name of researcher: (PG/Staff projects only)	Will Ford
Name of supervisor(s):	

The amendment(s) dated 10 Oct 2018 have been reviewed and approved.

Any further amendments will require approval.





Cardiff School of Pharmacy & Pharmaceutical Sciences

Participant Information Sheet

Title of study: Evaluation of a community pharmacy-based asthma care plan

Do you have asthma?

If you have asthma, we would like you to participate in this study so please read on. If you do not suffer from asthma then this study is not suitable for you, but thank you for taking the time to consider it.

If you have asthma, we would like to invite you to take part in our study. Before you decide, we would like you to understand why the study is being carried out and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

Please feel free to talk about the study with anyone you want and ask us if there is anything that is not clear to you.

What is the purpose of the study?

Millions of people in the UK have asthma. Previous research has indicated that patients are not getting the full benefit from the medicines that are available to treat asthma. As asthma is a potentially life-threatening condition, we are running this study to see if we can help patients manage their condition better to improve their quality of life and reduce the risk of their asthma becoming a more serious problem.

Why have I been invited to take part?

You have been invited to participate as we think you might have been told you have asthma. If this is not the case, the study is not suitable for you and please let us know so we do not take up any more of your time needlessly.

Do I have to take part?

No. It is up to you to decide whether you want to take part. We will describe the evaluation and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

You will be asked to help us fill in two short questionnaires about you, your asthma and how you use your asthma medicines. You will then be asked to demonstrate how you use inhalers, using an inhaler attached to a machine that measures how good your technique is. The test inhaler is the same type of inhaler that you normally use, but it does not contain any drug (medicine).

Once we have completed the questionnaires and tests, we will provide you with advice about how to improve the benefit you get from medicines prescribed for you to treat your asthma. We may recommend other services that are available from your pharmacy or GP clinic that may help you and your asthma. We estimate that the whole appointment should take between 20-30 minutes.

We will be running this study every year and will ask if we can write to you next year to invite you back for another appointment. This should be around September/October next year or possibly earlier. We will not contact you unless you have said it is OK for us to do so. Your contact details will be kept confidential and not shared with anyone other than study investigators.

What are the possible disadvantages and risks of taking part?

There are no expected risks in taking part in this study.

What are the possible benefits of taking part?

We hope that participation will improve the benefit you get from your asthma medicine and give you a better understanding of how to manage your asthma.

Will my taking part be kept confidential?

Yes, it will not be possible to identify you as a participant from any of the data we publish in student dissertations, scientific conferences or journal articles. Although we will be collecting your NHS number that can be used to identify you, it will be kept separately from your study information. This means that it is not possible to identify you from your study data without reference to the separate database. We will only use your NHS number to help us contact you to invite you to an annual follow-up appointment, to match you to your records on follow-up appointments, or if information is requested by your GP. The lead pharmacist and chief investigator will be the only members of the study team who can access to the database with your NHS number. This data will be retained over the 5 year period of the study and will then be destroyed. After this time, it will not be possible to identify you from data that we retain.

Data protection

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. The University has a Data Protection Officer who can be contacted at inforequest@cardiff.ac.uk . Further information about Data Protection, including your rights and details about how to contact the Information Commissioner's Office should you wish to complain, can be found at the following: <https://www.cardiff.ac.uk/publicinformation/policies-and-procedures/data-protection>

Under data protection law we have to specify the legal basis that we are relying on to process your personal data. In providing your personal data for this research we will process it on the basis that doing so is necessary for our public task for scientific and historical research purposes in accordance with the necessary safeguards, and is in the public interest. The University is a public research institution established by royal charter to advance knowledge and education through its teaching and research activities. Our charter can be found on the Cardiff University website.

You have a number of rights under data protection law and can find out more about these on our website. Note that your rights to access, change or move your personal data are limited, as we need to manage your personal information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

How is the project being funded?

The Cardiff School of Pharmacy and Pharmaceutical Sciences of Cardiff University are funding the project.

What will happen to the results of the service evaluation?

The results of the study will be used by the investigators to write dissertations as part of their degree in pharmacy, and may be presented in scientific conferences and journals. A summary of the results will be provided to the Aneurin Bevan University Health Board.

It will not be possible for anyone to identify you from the information in the reports, dissertations or publications.

What should I do next?

If you have decided that you would like to participate in the study, the please call your Mayberry pharmacy to make an appointment with one of our researchers. You can choose which of the pharmacies is most convenient for you from list at the end of this email. If you do not wish to participate there is no need to do anything further.

Who should I contact for further information?

If you have any questions or require more information about this service evaluation, please contact the chief investigator:

Dr Will Ford

Cardiff School of Pharmacy & Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

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Telephone: 02920 874781

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If you have a concern about any aspect of this service evaluation, you should speak to the chief investigator, Dr Will Ford (details above). If you remain unhappy and wish to complain formally, you can contact Cardiff University for further advice and information at University Governance and Complaints Division, Cardiff University, 4th Floor, McKenzie House, 30-36 Newport Road, Cardiff CF24 0DE.

Thank you for reading this information sheet and for considering taking part in this research. Please keep this leaflet for future reference.

Mayberry Pharmacy Ltd:



Blackwood, 175 High Street, NP12 1AA

Telephone: 014 9522 4875

Caerphilly, 40 Cardiff Road, CF83 1JP

Telephone: 016 3324 4026

Crumlin, 15 Main Street, NP11 4PT

Telephone: 014 9524 4617

Newport, 103 Durham Road, NP19 7DP

Telephone: 016 3324 4026

Pontypool, 21 Crane Street, NP4 6LY

Telephone: 014 9575 0095

Penarth, 3 Royal Buildings, Stanwell Road,

CF64 3EB

Telephone: 029 2070 8313

Trevethin, 6 Church Avenue, NP4 8DH

Telephone: 014 9576 3431

Appendix 4.4 - Data collection tool (standardised form)

NHS number:				Study visit num	
Gender:				Date:	
Age:				Study ID	
Smoking status:	<input type="checkbox"/> non-smoker		<input type="checkbox"/> smoker		<input type="checkbox"/> ex-smoker
Educational Attainment:			Pks/day		
University	A-levels	CSE or equivalent			
none of these qualifications					
List current asthma medication:					Dose
Roughly when were you diagnosed with asthma?					
within a month		within 6 months			
within a year		within the last 5 years		> 5 years	
When did you last see someone about your asthma?					
within a month		within 3 months		within 6 months	
within a year		> one year			
Have you been shown how to use your inhaler/s?					
				Y	N
Have you been asked to demonstrate how you use your inhaler					
				Y	N
Who showed you?					
Nurse		GP		Pharmacist	
Other:					
Have you ever been prescribed oral steroids (prednisolone) or been admitted to hospital because of your respiratory condition?					
Yes		No			
If yes, how long ago?					
Inhaler test:					
Device shaken	<input type="checkbox"/> Yes		<input type="checkbox"/> No		
Breath hold	<input type="checkbox"/> Yes		<input type="checkbox"/> No		
DPI	<input type="checkbox"/> Fail		<input type="checkbox"/> Sub-optimal		<input type="checkbox"/> Good
MDI	<input type="checkbox"/> Fail (canister)		<input type="checkbox"/> Fail (flow)		<input type="checkbox"/> Sub-optimal
	<input type="checkbox"/> Good				
Spacer	<input type="checkbox"/> Fail (canister)		<input type="checkbox"/> Fail (flow)		<input type="checkbox"/> Sub-optimal
	<input type="checkbox"/> Good				
ACT score		Adherence (Q1-		Incheck	
		Adherence (Q6-		Pass	
		Adherence total		Fail	

Appendix 4.5 - ACT questionnaire

Participant i.d.:

Date:



Asthma Control Test™

The Asthma Control Test™ provides a numerical score to help you and your healthcare provider determine if your asthma symptoms are well controlled.

Take this test if you are 12 years or older. Share the score with your healthcare provider.

Step 1: Write the number of each answer in the score box provided.

Step 2: Add up each score box for the total.

Step 3: Take the completed test to your healthcare provider to talk about your score.

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what the score, bring this test to your healthcare provider to talk about the results.

1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home? SCORE

All of the time [1]	Most of the time [2]	Some of the time [3]	A little of the time [4]	None of the time [5]	<input type="text"/>
---------------------	----------------------	----------------------	--------------------------	----------------------	----------------------

2. During the past 4 weeks, how often have you had shortness of breath?

More than once a day [1]	Once a day [2]	3 to 6 times a week [3]	Once or twice a week [4]	Not at all [5]	<input type="text"/>
--------------------------	----------------	-------------------------	--------------------------	----------------	----------------------

3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?

3 or more times per day [1]	1 or 2 times per day [2]	2 or 3 times per week [3]	Once a week or less [4]	Not at all [5]	<input type="text"/>
-----------------------------	--------------------------	---------------------------	-------------------------	----------------	----------------------

4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as Ventolin)?

3 or more times per day [1]	1 or 2 times per day [2]	2 or 3 times per week [3]	Once a week or less [4]	Not at all [5]	<input type="text"/>
-----------------------------	--------------------------	---------------------------	-------------------------	----------------	----------------------

5. How would you rate your asthma control during the past 4 weeks?

Not controlled [1]	Poorly controlled [2]	Somewhat controlled [3]	Well controlled [4]	Completely controlled [5]	<input type="text"/>
--------------------	-----------------------	-------------------------	---------------------	---------------------------	----------------------


TOTAL

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what your score is, share the results with your healthcare provider.

Appendix 4.6 - TAI questionnaire

Questionnaire about how you use your inhalers

Please read through the following questions about how you use medicine you take regularly for your asthma. You will normally be asked to take this kind of medicine every day rather than to help you breathe when you are having an asthma attack.

 If you are unsure what medicine this is, please ask your researcher to explain.

1. How often did you forget to take your regular inhalers in the last 7 days?

1. Always 2. More than half 3. About half 4. Less than half 5. None

2. You forget to take your inhalers:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

3. When you are feeling well, you stop taking your inhalers:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

4. At the weekend or when you go on holiday, you stop taking your inhalers:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

5. When you are anxious or sad, you stop taking your inhalers:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

6. You stop taking your inhalers out of fear of potential side effects:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

7. You stop taking your inhalers because you believe that they are of little help in treating your condition:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

8. You take fewer inhalations than prescribed by your doctor:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

9. You stop taking your inhalers because you believe that they interfere with your day-to-day or work life:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

10. You stop taking your inhalers because you have trouble paying for them:

1. Always 2. Almost always 3. Sometimes 4. Almost never 5. Never

Appendix 5.1 - Research poster



↩ Reply ↶ Reply all → Forward 📁 Archive 🗑 Delete ⋮

Abstract Acceptance for HSDS Poster Session



HSRPP 2020 <no-reply@oxfordabstracts.com>



07/01/2020 11:45 AM

To: Mansour Alotaibi

Dear Mr Mansour Alotaibi

We are pleased to inform you that your abstract 68 has been accepted as a poster to the Health Services Development Spotlight session of the Health Services Research & Pharmacy Practice Conference 2020: Transforming Healthcare: Keeping the Patient at the Centre. to be held on April 16th and 17th 2020 at Cardiff University. We would now like to provide you with some important poster information.

Poster presentation guidance

All posters should be prepared in **PORTRAIT** format and be **A0** size. Lettering should be legible at two metres. Oversized posters will not be accepted for display.

- Fixings for posters will be provided
- Presenters are responsible for printing their own poster
- All posters will be displayed throughout the two days of the conference.

Poster presenters are advised to look at the RPS advice on ["Preparing a research poster for a conference"](#) which is available online from the Pharmaceutical Journal.

All accepted posters have been given a number. Please look at the attached document to find your poster title and make a note of this number. You will need this number to communicate with the HSRPP team (see below). This will also identify which numbered poster board you should attach your poster to when you arrive at the conference.

There will be a prize for the best poster presentation at the conference. There will also be a prize for the best oral presentation and best oral presentation or poster by a PhD student.

Appendix 5.2 - Ethical approval

SPPS Amendment Approval Notification (AAN)

11/10/14 v1

Cardiff School of Pharmacy and Pharmaceutical Sciences, Research Ethics Approval

AMENDMENT APPROVAL

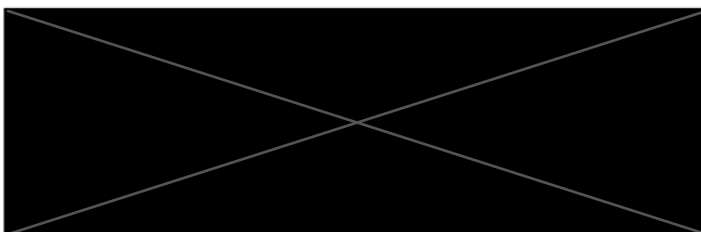
This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for amendment(s) to the following study:

Project ref and title:	1819-12: Community pharmacist views about the management of chronic disease in their pharmacies
------------------------	---

Name of researcher: (PG/Staff projects only)	<u>Mansour Alotaibi</u>
Name of supervisor(s):	<u>Will Ford</u>

The amendment(s) dated 01 Aug 2019 have been reviewed and approved.

Any further amendments will require approval.



Appendix 5.3 - Invitation emails sent to gatekeepers and community pharmacists

Subject heading: Community pharmacist views about the management of chronic disease in their pharmacies

Gatekeepers invitation email

Dear Sir/madam,

A research team from the Pharmacy and Pharmaceutical Sciences School, Cardiff University, is inviting community pharmacists to take a part in a study titled **Community pharmacist views about the management of chronic disease in their pharmacies**. The potential participants are expected to discuss management of chronic disease in their pharmacies in face to face, phone or Skype interview at a place of their convenience. They would like to hear from you specifically about your current role in managing chronic diseases and how this could be improved. They hope that participation in this study would give you an opportunity to share your perspectives, and views in managing people with chronic diseases. This research may help inform the development of new primary care models with enhanced roles for pharmacists. Participants who are selected and take part in the study will be given a gift card with the value of £10 from a top retailer as a token recompense for their time. There are no specific inclusion or exclusion criteria except being a community pharmacist. Participants will be chosen for inclusion in a face to face, Skype or telephone interview on a first come first served basis, taking into account diversity in the sample. The data collection phase is planned to be conducted any time between August and end of October.

For further information, please check the attached file of **Participant Information Sheet (PIS)**. If you would like to take part in the study, please let the research team know by responding to this email (AlotaibiM8@cardiff.ac.uk). If you are not willing to participate and know someone who might be interested in the study, kindly forward this email to him/her.

Please, feel free to contact the research team via this email address (AlotaibiM8@cardiff.ac.uk). If you have any questions about the study, they will be very happy to answer your inquiries.

Thank you very much for reading this email,

Yours faithfully,

Subject heading: Community pharmacist views about the management of chronic disease in their pharmacies

Public Invitation Email

Dear (name),

Hope this email finds you well. This is Mansour Alotaibi, a PhD student at the School of Pharmacy and Pharmaceutical Sciences, Cardiff University. I am working on a project titled **Community pharmacist views about the management of chronic disease in their pharmacies**. The aim of this project is to get community pharmacists' opinions, perspectives on the current and prospective community pharmacist role in managing chronic diseases. The potential participants are expected to discuss management of chronic diseases at community pharmacies in face to face, Skype or telephone interview at a time and place of your convenience. We would like to hear from you specifically about your current role in managing chronic diseases and how this could be improved. We hope that participation in this study would give you an opportunity to share your perspectives and views in managing people with chronic diseases. This research may help inform the development of new primary care models with enhanced roles for pharmacists. Participants who are selected and take part in the study will be given a gift card with the value of £10 from a top retailer as a token recompense for their time. There are no specific inclusion or exclusion criteria except being a community pharmacist. Participants will be chosen on a first come first served basis, taking into account diversity in the research sample. The data collection phase is planning to be conducted any time between August and end of October.

For further information, please check the attached file of **Participant Information Sheet (PIS)**. If you would like to take part in the study, please let me know by responding to this email (AlotaibiM8@cardiff.ac.uk). If you are not willing to participate and know someone who might be interested in my study, kindly forward this email to him/her.

Please, feel free to contact me via this email address (AlotaibiM8@cardiff.ac.uk). If you have any questions about the study, I will be very happy to answer your inquiries.

Thank you very much for reading this email,

Yours faithfully,

Appendix 5.4 - Reminder emails sent to gatekeepers and community pharmacists

Dear (...),

We recently contacted you by email (date) to invite you to participate in a project titled "Community pharmacist views about the management of chronic disease in their pharmacies". As we had not yet heard from you, we just wanted to send you a reminder as we would be very interested to hear what you have to say on the subject.

The aim of this project is to get community pharmacists' opinions, perspectives on the current and prospective community pharmacist role in managing chronic diseases. The potential participants are expected to discuss management of chronic diseases at community pharmacies in face to face, Skype, or telephone interviews at a time and place of your convenience. Participants who are selected and take part in the study will be given a gift card with a value of £10 from a top retailer as a token recompense for their time. Let me know if you are interested

Best wishes,

Mansour,



Cardiff School of Pharmacy & Pharmaceutical Sciences

Participant Information Sheet

Title of study: Community pharmacist views about the management of chronic disease in their pharmacies

What is the purpose of the study?

The aim of our research is to get your perspectives on the current role and potential future roles played by community pharmacists in managing chronic diseases. We would like to explore what potential barriers may exist that could limit the ability of community pharmacists in taking on roles managing chronic disease and what could be done to overcome these.

Why have I been invited to take part?

You have been invited to participate as you are a community pharmacist. If this is not the case, the study is not suitable for you and please let us know so we do not take up any more of your time needlessly.

Do I have to take part?

No. It is up to you to decide whether you want to take part. If you agree to take part, we will then ask you to sign a consent form and complete participant demographic information form.

What will happen to me if I take part?

If you agree to take part, you will be sent three documents to read and complete; a participant information sheet, a consent form and a demographic information form. Upon receipt of completed forms, an interview will be arranged at a time and location convenient for you. If it is not possible to arrange a face-to-face interview, a Skype or phone interview will be arranged. The interview will last no more than one hour. The discussion will be audio recorded to allow the researcher to generate anonymous transcripts for analysis. Identifying remarks will be redacted and you will be asked to check the transcript for your interview for accuracy and whether there is any information that might identify you. You are also welcome to publicise the study to other community pharmacists via sending them the invitation email that you have received.

What are the possible disadvantages and risks of taking part?

There are no expected risks in taking part in this study.

What are the possible benefits of taking part?

We hope that participation in this study would give you an opportunity to share your perspectives, and views about the role of community pharmacists in managing chronic diseases. This research may help inform the development of new primary care models with enhanced roles for pharmacists. As a small token of recompense for your time, you will be also given a gift card, with the value of £10, once you have attended the interview and transcripts have been viewed.

This will be available irrespective of whether you decide to remain part of the study after viewing the transcript.

Will my taking part be kept confidential?

Yes, it will not be possible to identify you as a participant from any of the data we publish in student dissertations, scientific conferences or journal articles. You will be given an opportunity to check for any identifying remarks when you approve the transcript from the interview.

Data protection

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. The University has a Data Protection Officer who can be contacted at inforequest@cardiff.ac.uk. Further information about Data Protection, including your rights and details about how to contact the Information Commissioner's Office should you wish to complain, can be found at the following: <https://www.cardiff.ac.uk/publicinformation/policies-and-procedures/data-protection>. Under data protection law we have to specify the legal basis that we are relying on to process your personal data. In providing your personal data for this research we will process it on the basis that doing so is necessary for our public task for scientific and historical research purposes in accordance with the necessary safeguards, and is in the public interest. The University is a public research institution established by royal charter to advance knowledge and education through its teaching and research activities. Our charter can be found on the Cardiff University website. Cardiff University will need to share audio records with [<http://www.transcribe-this.com/>] for transcription services. Audio records will be converted to anonymised transcripts straight away after each interview. Your personal data will be anonymised, meaning we will remove any identifiers that can identify you from the data you have provided. This anonymous information may be kept indefinitely or published in support of the research. Other personal data we may have collected, such as your consent to participate in the study will be kept for

five years in accordance with the University Records Retention Schedules. You have a number of rights under data protection law and can find out more about these on our website.

Can I withdraw from the study?

Yes. You are free to withdraw from the study at any time up to when you have approved the anonymised transcript. Once the data has been anonymised, it will not be possible to identify your contribution and so will not be possible to withdraw. If you decide not to remain part of the study, we will destroy all of your personal data that we hold.

How is the project being funded?

The Cardiff School of Pharmacy and Pharmaceutical Sciences of Cardiff University are funding the project.

What will happen to the results of the study?

The results of the study will be used by the investigators to write a thesis as part of a PhD degree, and may be presented in scientific conferences and journals.

What should I do next?

If you have decided that you would like to participate in the study, please let us know so we can send you consent and participant demographic information forms. Upon completion, the researcher will work with you to arrange for an interview that fits your schedules most. If you do not wish to participate there is no need to do anything further.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the research investigators:

Dr Will Ford

Cardiff School of Pharmacy & Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

CF10 3NB

Telephone: 02920 874781

Mansour Alotaibi

Cardiff School of Pharmacy & Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

CF10 3NB

Telephone: 07402591290

What if there is a problem?

If you have any concerns or complaints during the course of this research project, please contact [William Ford, FordWR@cardiff.ac.uk] who will address the issue. If you remain unhappy and wish to complain formally, you can do this

by contacting the Director of Research, Cardiff School of Pharmacy and
Pharmaceutical Sciences, Redwood Building, King Edward VII Avenue, Cardiff
CF10 3NB, phrmyresoffice@cardiff.ac.uk)

**Thank you for reading this information sheet and for considering taking
part in this research. Please keep this leaflet for future reference.**

Appendix 5.6 - Participant demographic information form

Participants' Demographic Information Sheet, V6

07/08/2019



Cardiff School of Pharmacy & Pharmaceutical Sciences

Community pharmacist views about the management of chronic disease in their pharmacies

A) Participant information:

Name	
Job title (e.g. locum, independent prescriber, etc.)	
Age	
Years of experience (as a community pharmacist)	
E-mail	

B) Workplace information: Please, tick the most appropriate option:

1- In which health board is your main workplace located?

- Abertawe Bro Morgannwg University Aneurin Bevan University Betsi Cadwaladr University
 Cardiff & Vale University Cwm Taf University Hywel Dda University
 Powys Teaching

2- Is your workplace located in:

- In or attached to GP surgery In a supermarket A regular pharmacy shop Other, please specify

3- How many branches does your pharmacy company have?

- 1 2-5 6-10 11-20 >20

Appendix 5.7 - Consent form



Cardiff School of Pharmacy & Pharmaceutical Sciences

Community pharmacist views about the management of chronic disease in their pharmacies

Participant Consent Form

For ethical reasons, a Participant Consent Form is needed for all participants of our study. Please read the Participant Consent Form below, initial each statement where indicated, and finally sign and date at the bottom of the form.



Statement	Please initial
I was given a clear explanation of the nature and purpose of the research study and all my questions have been answered adequately.	
I was provided with contact information for the researchers.	
I understand that my participation is voluntary and that I may withdraw myself or my data from the study at any time up to when I have approved the anonymised transcript.	
I understand that the discussion will be audio recorded, transcribed by a third party, and used anonymously by the researcher in his thesis or any other research publications.	
I agree to the use of my comments as illustrative quotations in publications with any identifying information redacted.	
I confirm that I have read the participant information sheet dated 07/08/2019 version 6, for the above study.	
I agree to take part in the above study.	



Name of participant Signature Date

Name of person receiving consent Signature Date



Cardiff School of Pharmacy & Pharmaceutical Sciences

Community pharmacist views about the management of chronic disease in their pharmacies

Interview Schedule and Script

Introduction:

- Greeting and welcoming
- Introduce my self
- Aim of the project
- Reminder that the interview is recorded

1. Do you have any questions?

Let's get started!

Current practice: 1- Rather than dispensing medications, what do you do currently with patients as a community pharmacist? *Prompt: consultation, medication reviews, health promotion.*

2- How do you feel about type of care that you provide for patients with long term diseases in community pharmacy? *Prompt: Clinical review services, smoking cessation, weight management. Satisfied or not? If not, link to next section?*

3- How do you feel about type of care that you provide for asthma patients in community pharmacy? *Prompt: Inhaler technique checking, medication review, satisfied or not, If not link to next section?*

Assuming that chronic diseases management need improving (based on participants' answer in q2 and q3) "someone said he feels he is not able to.....!"

Proposed plan (managing chronic diseases): 4- In your opinion, what is the best model of care in terms of managing people with chronic diseases in community pharmacy? *Prompt: involvement of community pharmacy in managing patients with chronic diseases.*

5- What things need to be done to establish this model? *Prompt: clear responsibilities for community pharmacists and GPs, reward scheme, facilities, and training, access to medical records, requesting lab tests, changing in your role to fit the new model such as prescribing medication, cooperation and working with other medical staff*

6- How could asthma management be improved in community pharmacy? *Prompt: training courses, facilities/resources e.g. lab tests, medical devices to assess inhaler technique, do you have enough time.*

7- Could you mention 5 common chronic diseases that you think you could manage appropriately? Why did you choose them?

Limitations: 8- What are the limitations of managing patient with chronic diseases in community pharmacy?

9- Are there any additional barriers that might stop you from managing people with chronic diseases? *Prompt: organizational, personal (confidence, capability), patients, health system, related barriers, dispensing (workload), time, incentive, facility, training, knowledge, cooperation with other professional staff.*

10- If they said "yes there are barriers.....do you have any solutions or suggestions to overcome this? What could help you do this?"

11- If they did not mention dispensing (workload) as a limitation..... Taking into account daily workload the community pharmacist has, how could you balance between your daily tasks and managing people with chronic diseases? *Prompt: any suggestions to overcome this issue?*

Closing:

That is all what we have, thank you again for your participation in this conversation, do you want to add anything to our discussion?

A list of general prompt questions that might help during the discussion:

Could you give me another example?

Can you explain a bit more about that?

Could you elaborate a bit on?

What are the pluses and minuses of.....

Appendix 5.9 – Qualitative data analysis

Nodes							
Name	Sources	References	Created On	Created By	Modified On	Modified By	
Believes		0	05/09/2019 2:36	M	05/09/2019 2:36	M	
CP		1	11/09/2019 2:54	M	11/09/2019 2:54	M	
GPs		3	05/09/2019 2:37	M	13/09/2019 3:28	M	
Patients		5	05/09/2019 2:36	M	07/11/2019 1:56	M	
Collaboration between health professionals		7	14/30/08/2019 1:37	M	15/11/2019 12:58	M	
Communication		2	13/09/2019 2:49	M	18/09/2019 3:12	M	
Consistency of the services		2	16/09/2019 11:29	M	18/09/2019 2:33	M	
Dependency		2	13/09/2019 3:14	M	18/09/2019 3:35	M	
Employee satisfaction		4	13/09/2019 3:52	M	16/09/2019 1:20	M	
Facility barriers		7	29/08/2019 12:09	M	07/11/2019 1:05	M	
Financial barriers		1	29/08/2019 12:10	M	16/09/2019 11:18	M	
Financial Contension		3	13/09/2019 4:08	M	07/11/2019 2:17	M	
funding		2	07/11/2019 1:32	M	15/11/2019 1:27	M	
incentive to provid the service		4	12/09/2019 2:27	M	15/11/2019 1:08	M	
Quick earning		1	05/09/2019 1:50	M	16/09/2019 12:48	M	
Reward system		3	05/09/2019 6:08	M	15/11/2019 1:09	M	
Training cost		3	05/09/2019 6:15	M	07/11/2019 1:31	M	

Appendix 6.1 - Ethical approval

SPPS Amendment Approval Notification (AAN)

11/10/14 v1

**Cardiff School of Pharmacy and Pharmaceutical Sciences,
Research Ethics Approval**

AMENDMENT APPROVAL

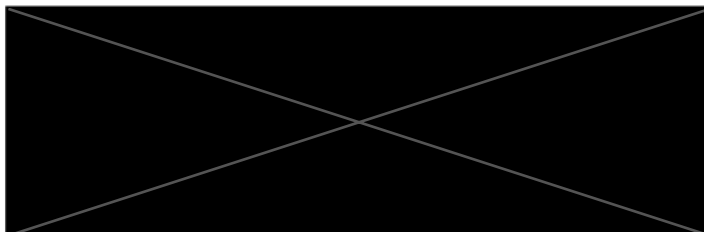
This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for amendment(s) to the following study:

Project ref and title:	1819-12: Community pharmacist views about the management of chronic disease in their pharmacies
------------------------	---

Name of researcher: (PG/Staff projects only)	<u>Mansour Alotaibi</u>
Name of supervisor(s):	<u>Will Ford</u>

The amendment(s) dated 01 Aug 2019 have been reviewed and approved.

Any further amendments will require approval.



Appendix 6.2 - Ethical approval

SPPS Amendment Approval Notification (AAN)

11/10/14 v1

Cardiff School of Pharmacy and Pharmaceutical Sciences, Research Ethics Approval

AMENDMENT APPROVAL

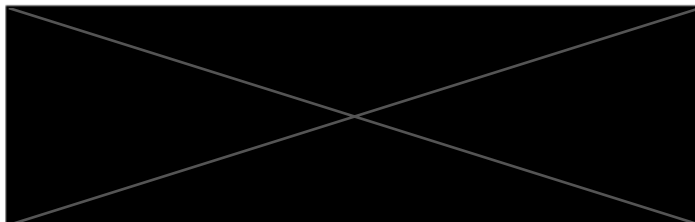
This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for amendment(s) to the following study:

Project ref and title:	1819-12: Community pharmacists views about management of chronic condition in their pharmacies
------------------------	--

Name of researcher: (PG/Staff projects only)	Mansour Alotaibi
Name of supervisor(s):	Will Ford, Louise Hughes and Jenna Bowen

The amendment(s) dated 13 Jan 2020 have been reviewed and approved.

Any further amendments will require approval.



Appendix 6.3 - Community pharmacists questionnaire cover letter

Community pharmacists views about management of chronic condition in their pharmacies

Dear Community Pharmacist,

My name is Mansour Alotaibi, a PhD student from the Cardiff School of Pharmacy and Pharmaceutical Sciences. Part of my PhD is focused on obtaining the views of community pharmacists on the management of chronic conditions in their pharmacies. To date, I have conducted several interviews with community pharmacists exploring this topic.

As a community pharmacist working in Wales, I would like to invite you to participate in the next stage of the study. An invitation letter is being sent to all community pharmacies across Wales. Your participation is entirely voluntary; however, I would really appreciate it if you could **complete and return the questionnaire**. The questionnaire should take **no longer than 5 minutes** to complete. You can either complete a paper questionnaire and return it via the **provided pre-paid envelope**, or complete **an online questionnaire** that can be accessed by scanning the QR code, or typing the link provided at the bottom of this letter in your browser. I would like to receive your responses by 15th March 2020 to allow time to analyse the results. Please feel free to forward the online questionnaire link to other community pharmacists working in Wales that you think might be interested in taking part. Your inputs are **valuable, confidential** and will be **completely anonymous**, so no one will be able to identify your responses including the researchers.

This questionnaire should only be completed by a **registered community pharmacist working in Welsh community pharmacies**. If you do not meet these requirements, please do not complete the questionnaire but you can hand it to a pharmacist in the pharmacy. Instructions on how to complete the questionnaire are provided within each section of the questionnaire.

Your responses will be of great importance in providing perspective for my PhD thesis and will hopefully help shape a new model of community based chronic diseases management. By returning the provided pre-paid envelope, you consent to your answers being included in the study analysis. It will not be possible to withdraw. If you would like further information about the study, you could read the enclosed Participant Information Sheet (PIS), or alternatively contact the researcher via this email address (alotaibim8@cardiff.ac.uk).

I look forward to receiving your completed questionnaire. Thank you very much for your time and cooperation.

Yours sincerely,

Mansour Alotaibi
Researcher/PhD Student



<https://cardiff.onlinesurveys.ac.uk/community-pharmacist-views-about-the-management-of-chronic>

Research team contact details:

Mansour Alotaibi
Cardiff School of Pharmacy and Pharmaceutical Sciences
Redwood Building
King Edward VII Avenue
Cardiff
CF10 3NB
Email: alotaibim8@cardiff.ac.uk

Dr Will Ford
Cardiff School of Pharmacy and Pharmaceutical Sciences
Email: FordWR@cardiff.ac.uk
Telephone: +44 (0)29 2087 4781

Dr Jenna Bowen
Cardiff School of Pharmacy and Pharmaceutical Sciences
Email: bowenj12@cardiff.ac.uk
Telephone: +44 (0)29 22510106

Dr Louise Hughes
Cardiff School of Pharmacy and Pharmaceutical Sciences
Email: hughesml@cardiff.ac.uk
Telephone: +44 (0)29 2087 6432



Community pharmacists views about management of chronic condition in their pharmacies

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

1. What is the purpose of this research project?

Chronic conditions are not managed appropriately in the primary care setting. Part of the reason is because due to shortage in the number of General Practitioners (GPs) accompanied by an increasing number of people with chronic conditions. Community pharmacy is an important sector of the primary care setting that have expertise and skills to provide clinical services for people with chronic conditions. Therefore, this project is designed to obtain the views of community pharmacists on the management of chronic conditions in their pharmacies.

2. Why have I been invited to take part?

You have been invited to take part in this research as you are a practicing community pharmacist working in Wales. All qualified community pharmacists working in Wales are eligible to participate in this study. Whatever your position in the pharmacy is, whether it is a locum, manager, relief pharmacist etc, as long as you are a qualified community pharmacist working in Wales, you are qualified to take part in this project.

3. Do I have to take part?

No, your participation in this research project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. If you choose to take part, please answer all questions in the questionnaire as best you can and as honestly as possible. By starting and submitting the questionnaire you consent to the data collected being used as outlined in 'What will happen to the results of the research project?' (below)

4. What will taking part involve?

Involvement from the participant will include the completion of either a paper questionnaire, returned via the **provided pre-paid envelope** or completion of **an online questionnaire** that can be accessed by scanning the QR code, or by typing the link provided in your browser. The questionnaire consists of questions in two main sections. The first section is about you as a community pharmacist and the pharmacy where you work the most. Information you provide in this section will help us in contextualising your responses. The second section is about managing chronic conditions in community setting. Once the questionnaire has been returned no further activity from the participant is required. The questionnaire should take no more than 5 minutes to complete.

5. What are the possible benefits of taking part?

Your contribution is vital and will be of great importance in providing perspective for my PhD thesis and will hopefully help shape a new model of community based chronic diseases management.

6. Will my taking part in this research project be kept confidential?

All information collected from you during the research project will be kept confidential. No personal information will be collected during the course of the questionnaire and all responses will be anonymised. Please see ‘What will happen to my Personal Data?’ (below) for further information.

7. What will happen to my Personal Data?

Your responses, including any free text answers you provide, will be accessed only by the project team (myself, my academic supervisory team (Dr Will Ford, Dr Jenna Bowen, and Dr Louis Hughes). All questionnaire responses are collected over encrypted SSL (TLS) connections and data will be stored on the secure server of the online questionnaire platform. Your responses will remain confidential and no identifiable, personal information will be collected. Questionnaire responses will be kept for no more than 1 year.

8. What will happen to the results of the research project?

The results/responses from the questionnaire will be used by the investigators to write dissertations/thesis as part of a PhD degree, and may be presented in scientific conferences and journals or shared with people who are interested in this topic.

9. What if there is a problem?

If you have any concerns or complaints during the course of this research project please contact the academic supervisor, Dr Will Ford (FordWR@cardiff.ac.uk), who will address the issue. If you remain unhappy and wish to complain formally, you can do this by contacting the Director of Research via email at phrmyresoffice@cardiff.ac.uk or in writing: Cardiff School of Pharmacy and Pharmaceutical Sciences, Redwood Building, King Edward VII Avenue, Cardiff CF10 3NB.

10. Who is organising and funding this research project?

The Cardiff School of Pharmacy and Pharmaceutical Sciences of Cardiff University are funding the project.

11. Who has reviewed this research project?

This research project has been reviewed and given a favourable opinion by the Cardiff school of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

12. Further information and contact details

Should you have any questions relating to this research project, you may contact the project team during normal working hours:

Mansour Alotaibi, researcher/ PhD Student
AlotaibiM8@cardiff.ac.uk

Many thanks for considering participating in this research project, your time and responses are very much appreciated.

Appendix 6.5 - Community pharmacists questionnaire



Community pharmacists views about management of chronic condition in their pharmacies

Section A: Participant and community pharmacy information: This section is about you as a community pharmacist and the pharmacy where you work the most. Information you provide in this section will help me determine whether the sample we obtain is representative of Welsh community pharmacies. Kindly, select only one answer for each question:

Q1 Your position in the pharmacy:

Locum pharmacist Manager Owner Relief pharmacist
Regular pharmacist Other, please specify

Q2 How long have you been qualified as a community pharmacist?
..... (in years)

Q3 Which of the following types of service do you offer?

Enhanced services Advanced services Enhanced and advanced services
Essential services only

Q4 Are you qualified as an independent prescriber?

Yes No

Q5 With regard to the pharmacy where you work most, in which Local Health Board (LHB) is this pharmacy located?

Aneurin Bevan University HB Betsi Cadwaladr University HB Cardiff & Vale University HB
Cwm Taf Morgannwg University HB Hywel Dda University HB
Powys Teaching HB Swansea Bay University HB

Other, please specify

Q6 How would you describe the location of this pharmacy?

In or attached to General Practice (GP) surgery In or attached to supermarket
On city/town high street In a city/town but not on a high street
In a rural area

Other, please specify

Section B: Clinical chronic conditions management: In this section, please read each statement carefully and select only one answer unless otherwise indicated. Kindly, notice whenever you see the terms (clinical management/clinically manage/clinically managing) it means to monitor conditions, identify disease progression, recommend or implement a change in therapy, prescribe or refer patients to other health care providers, if necessary. The scope of chronic conditions in this project includes common conditions including but not limited to hypertension, diabetes, asthma, Chronic Obstructive Pulmonary Disease (COPD).

Q1 From the list of the chronic conditions below, select conditions that you feel confident to manage: (select all conditions that apply)

Asthma Chronic Obstructive Pulmonary Disease (COPD) Diabetes
Heart failure Hypertension None

Other, please specify

.....

	Agree	Disagree
Q2 In general, professional pharmacy services provided by community pharmacists have generally been advertised well to the public.		
Q3 Formal guidance for community pharmacists and other healthcare providers about what is expected from each other will be helpful in clinical chronic conditions management in pharmacy.		
Q4 Part of the reason that community pharmacists are reluctant to give up dispensing is that alternative roles for community pharmacists are not yet clear enough.		
Q5 The quality of professional pharmacy services delivered by community pharmacists are consistent.		
Q6 Dispensing services could be delegated to other pharmacy trained staff whilst the pharmacist is delivering a service that needs the skills of the pharmacist to deliver.		
Q7 There needs to be a system for identifying patients who are candidates for professional pharmacy services.		
Q8 The provision of pharmacy services is impacted by the type of pharmacist (locum, regular, manager, relief, owner).		
Q9 It is important for community pharmacists to be able to access patients' medical records if they are going to clinically manage chronic conditions.		
Q10 Community pharmacists need to be financially incentivised to clinically manage chronic conditions in pharmacy.		
Q11 In general, community pharmacists need to be upskilled to clinically manage chronic conditions in pharmacy.		
Q 12 I can easily access all pharmacy training courses that I need.		
Q 13 Community pharmacists are restricted in the standard of care that they can provide because they have a lot of pressure from management to hit dispensing targets.		
Q14 The consultation room where I work is too small to offer chronic conditions clinical management services.		
Q 15 The consultation room where I work is easily accessible to all patients.		
Q16 A lot of patients with chronic conditions would prefer to see a community pharmacist rather than a General Practitioner (GP) to clinically manage their condition.		
Q17 A lot of community pharmacists are unfamiliar with the range of services they can provide for patients.		
Q18 It would be difficult for a community pharmacist to clinically manage chronic conditions without being an independent prescriber.		
Q19 Better collaboration between GP practices and community pharmacies is needed for chronic conditions to be well managed in pharmacies.		
Q20 There may be resistance to a change away from dispensing to more clinically facing roles from many community pharmacists who are comfortable with their primary role being dispensers.		

Section C: Additional information/comments:

If you would like to add any other comments you may have about managing chronic conditions in community pharmacy, please, use the free text box below.

Thank you for completing the questionnaire, we really appreciate your time and the effort you put in. If you would like to receive a summary of key findings or to contact the research team regarding this study, please feel free to contact them via this email alotaibim8@cardiff.ac.uk, we will be very happy to answer your inquiries.

Research team contact details:

Mansour Alotaibi

Cardiff School of Pharmacy and Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

CF10 3NB

Email: alotaibim8@cardiff.ac.uk

Dr Will Ford

Cardiff School of Pharmacy and Pharmaceutical Sciences

Email: FordWR@cardiff.ac.uk

Telephone: +44 (0)29 2087 4781

Dr Jenna Bowen

Cardiff School of Pharmacy and Pharmaceutical Sciences

Email: bowenjl2@cardiff.ac.uk

Telephone: +44 (0)29 22510106

Dr Louise Hughes

Cardiff School of Pharmacy and Pharmaceutical Sciences

Email: hughesml@cardiff.ac.uk

Telephone: +44 (0)29 2087 6432

**kindly return the completed questionnaire using the provided pre-paid envelope.
Please submit your completed questionnaire to Mansour Alotaibi at:**

Cardiff School of Pharmacy and Pharmaceutical Sciences, Redwood Building, King
Edward VII Avenue, Cardiff, CF10 3NB

Appendix 6.6 - Community pharmacists reminder letter

Community pharmacists views about management of chronic condition in their pharmacies

Dear Community Pharmacist,

As a community pharmacist practicing in Wales, you have been invited recently via post mail to participate in a project conducted by the Cardiff School of Pharmacy and Pharmaceutical Sciences that aims to obtain the views of community pharmacists on the management of chronic conditions in their pharmacies. Your responses will be of great importance in providing perspective for my PhD thesis and will hopefully help shape a new model of community based chronic diseases management.

If you have completed this questionnaire before, we would like to thank you and ask if you could pass it on to another pharmacist in your pharmacy, if there are any. If you have not had the chance yet, it would be appreciated if you could complete the attached short questionnaire. The questionnaire should take **no longer than 5 minutes** to complete. You can complete either a paper questionnaire and return it via the **provided pre-paid envelope**, or complete **an online questionnaire** that can be accessed by scanning the QR code, or typing the link provided at the bottom of this letter in your browser.

If you would like further information about the project, kindly contact me via this email (alotaibim8@cardiff.ac.uk)



<https://cardiff.onlinesurveys.ac.uk/community-pharmacist-views-about-the-management-of-chronic>

I look forward to receiving your completed questionnaire. Thank you very much for your time and cooperation

Yours sincerely,

Mansour Alotaibi
Researcher/ PhD Student
Cardiff School of Pharmacy and Pharmaceutical Sciences

Appendix 7.1 - Research poster

— □ ×

↶ Reply ↷ Reply all → Forward 📁 Archive 🗑 Delete ⋮

HSR UK Conference, 1-3 July 2020: Abstract Submission Update



hsrukconference@eventage.co.uk <hsrukconference@eventage.co.uk>

31/01/2020 11:17 AM



To: Mansour Alotaibi



Dear Mansour

HSR UK CONFERENCE 2020 - POSTER PRESENTATION OFFER

Thank you for submitting your abstract **Commissioners of pharmacy services views about the management of chronic disease in community pharmacies** to the **HSR UK 2020 Conference on 1-3 July 2020 in Manchester**. We are pleased to inform you that your abstract has been selected by the Conference Organising Committee for poster presentation. We had over 160 abstract submissions for the conference this year, and the standard of submissions was very high.

We know that some poster presenters would welcome the opportunity to present their work in an oral session as well, and so following the success of last year's 'Rapid Fire Poster Presentation Sessions', we are once again allocating some parallel sessions for brief oral

Appendix 7.2 - Ethical approval

SPPS Ethics Approval Notification (EAN)

8/9/14 v12

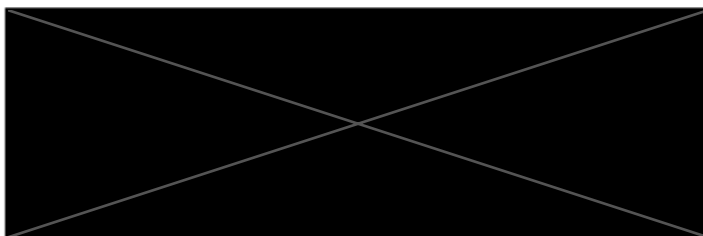
Cardiff School of Pharmacy and Pharmaceutical Sciences, Research Ethics Approval

This form has been signed by the School Research Ethics Officer as evidence that approval has been granted by the Cardiff School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee for the following study:

Project title:	1819-26: Commissioners of pharmacy services views about the management of chronic disease in community pharmacies
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This is a/an:	Undergraduate project	
	ERASMUS project	
	Postgraduate project	X
	Staff project	

Name of researcher: (PG/Staff projects only)	Mansour Alotaibi
Name of supervisor(s):	Will Ford



Appendix 7.3 - Invitation email sent to stakeholders of pharmacy services



Cardiff School of Pharmacy & Pharmaceutical Sciences

Invitation Email

Subject: The views of pharmacy service commissioners on the future of community pharmacies.

Dear [name],

This is Mansour Alotaibi, a PhD student at the School of Pharmacy and Pharmaceutical Sciences, Cardiff University. I am working on a project with the title of “**The views of pharmacy service commissioners on the future of community pharmacies**”. The aim of the project is to obtain the views of commissioners of pharmacy services on the future of community pharmacies in Wales. As a [generic job title], you are invited to participate in an individual interview (face to face, Skype, or phone interview) that lasts around 30 minutes to discuss the topic. This research would help provide perspective for my PhD thesis and overall study about the future of community pharmacies. Therefore, your participation would be highly valued.

For further information, please see the attached file of **Participant Information Sheet**. If you would like to take part or have any other questions about the study, please let me know by responding to this email (AlotaibiM8@cardiff.ac.uk).

Thank you very much for reading this email,

Yours faithfully,

Appendix 7.4 - Reminder email sent to stakeholders of pharmacy services



Cardiff School of Pharmacy & Pharmaceutical Sciences

Follow up Email

Subject: The views of pharmacy service commissioners on the future of community pharmacies.

Dear (name),

We recently contacted you by email [DATE] to invite you to participate in a project titled **“The views of pharmacy service commissioners on the future of community pharmacies”**. As we had not yet heard from you, we just wanted to send you a reminder as we would be very interested to hear what you have to say on the subject.

The aim of this project is to get commissioners of pharmacy services opinions, perspectives on the future of community pharmacies in Wales. As a [generic job title], you are invited to participate in an interview (face to face, Skype, or phone) that lasts around 30 minutes to discuss the topic. This research would help provide perspective for my PhD thesis and overall study about the future of community pharmacies. Therefore, your participation would be highly valued.

For further information, please see the attached file of **Participant Information Sheet**. If you would like to take part or have any other questions about the study, please let me know by responding to this email (AlotaibiM8@cardiff.ac.uk).

Thank you very much for reading this email,

Yours faithfully,



Cardiff School of Pharmacy & Pharmaceutical Sciences

Participant Information Sheet

Title of study: The views of pharmacy service commissioners on the future of community pharmacies

What is the purpose of the study?

The role of community pharmacists is going through a period of evolution with additional services being made available to augment patient-centred care. The aim of our research is to get the perspectives of pharmacy service commissioners about this evolution and where it might lead.

Why have I been invited to take part?

You have been invited to participate as you are a commissioner of pharmacy services. If this is not the case, the study is not suitable for you and please let us know so we do not take up any more of your time needlessly.

Do I have to take part?

No. It is up to you to decide whether you want to take part. If you agree to take part, we will ask you to sign a consent form and arrange a time for the interview.

What will happen to me if I take part?

If you agree to take part, we will arrange an interview that fits in with your schedule the best. The location of the interview will be at your convenience. Ideally, the interview would be face-to-face but, if it is not possible, a Skype or phone interview will be arranged. The interview should last around 30 minutes. The discussion will be audio recorded to allow the researcher to generate anonymous transcripts for analysis. You will be asked to check the transcripts of your interview to ensure that it accurately reflects your views and does not contain identifying information. Participants will be asked to sign a consent form prior to conducting the interview. This could be done via a physical copy of the consent form before a face-to-face interview or by mail (a self-addressed stamped envelope will be provided) or email (if they can sign electronically).

What are the possible disadvantages and risks of taking part?

There are no expected risks in taking part in this study.

What are the possible benefits of taking part?

We hope that participation in this study would let you share your perspectives, and views about the evolution of community pharmacy services in Wales. This research may help inform the development of new primary care models with enhanced roles for pharmacists.

Will my taking part be kept confidential?

Yes, your name will not be disclosed in student dissertations, scientific conferences or journal articles. You will be given an opportunity to check for any identifying remarks when you approve the transcript from the interview. Any that are identified will be removed prior to use in any publication or thesis.

Data protection:

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. The University has a Data Protection Officer who can be contacted at inforequest@cardiff.ac.uk. Further information about Data Protection, including your rights and details about how to contact the Information Commissioner's Office should you wish to complain, can be found at the following: <https://www.cardiff.ac.uk/publicinformation/policies-and-procedures/data-protection>. Under data protection law we have to specify the legal basis that we are relying on to process your personal data. In providing your personal data for this research we will process it on the basis that doing so is necessary for our public task for scientific and historical research purposes in accordance with the necessary safeguards, and is in the public interest. The University is a public research institution established by royal charter to advance knowledge and education through its teaching and research activities. Our charter can be found on the Cardiff University website. Cardiff University will need to share audio records with [<http://www.transcribe-this.com/>] for transcription services. Audio records will be converted to anonymised transcripts straight away after each interview. Your personal data will be anonymised meaning we will remove any identifiers that can identify you from the data you have provided. This anonymous information may be kept indefinitely or published in support of the research. Other personal data we may have collected, such as your consent to participate in the study will be kept for five years in accordance with the University Records Retention Schedules. You have a number of rights under data protection law and can find out more about these on our website. If you decide not to remain part of the study, we will destroy all your personal data.

Can I withdraw from the study?

Yes. You are free to withdraw from the study at any time up until the transcript has been reviewed and approved by you. Once the data has been anonymised, it might not be possible to identify your contribution and so it will not be possible to withdraw after that point. If you decide not to remain part of the study, we will destroy all your personal data

How is the project being funded?

The Cardiff School of Pharmacy and Pharmaceutical Sciences of Cardiff University are funding the project.

What will happen to the results of the study?

The results of the study will be used by the investigators to write dissertations/thesis as part of a PhD degree, and may be presented in scientific conferences and journals.

What should I do next?

If you have decided that you would like to participate in the study, the researcher will work with you to arrange for an interview that fits in with your schedule the best. If you do not wish to participate there is no need to do anything further, although we may remind you about the opportunity to participate in the study on one further occasion.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact the research investigators:

Mansour Alotaibi

Cardiff School of Pharmacy & Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

CF10 3NB

Telephone: 07402591290

Dr Will Ford

Cardiff School of Pharmacy & Pharmaceutical Sciences

Redwood Building

King Edward VII Avenue

Cardiff

CF10 3NB

Telephone: 02920 874781

What if there is a problem?

If you have any concerns or complaints during the course of this research project, please contact [William Ford, FordWR@cardiff.ac.uk] who will address the issue. If you remain unhappy and wish to complain formally, you can do this by contacting the Director of Research, Cardiff School of Pharmacy and Pharmaceutical Sciences, Redwood Building, King Edward VII Avenue, Cardiff CF10 3NB, phrmyresoffice@cardiff.ac.uk)

Thank you for reading this information sheet and for considering taking part in this research. Please keep this leaflet for future reference.



Cardiff School of Pharmacy & Pharmaceutical Sciences

Commissioners of pharmacy services views about the management of chronic disease in community pharmacies

Interview Schedule and Script

Introduction:

Hello,

- Greeting and welcoming
 - Introduce my self
 - Aim of the project
 - Reminder that the interview is recorded
2. Do you have any questions?

Let's get started!

Current practice: 1- What do you think of contributions of community pharmacists to the current mission of NHS? *Prompt: their tasks as a community pharmacist on a daily basis, services provided to the patients*

Prompt1: you mentioned community pharmacists providing to the patients, How do you feel about type of care provided for patients in community pharmacy?
Prompt: Such as, clinical review services, smoking cessation, weight management.

Prompt2: What do you think needs to be changed in the future? If they mentioned somethingWhat are the drivers of these changes? Number of GPs, waiting time, access to health services.

Transition: (based on participants' answered) "you said community pharmacy should be involved (effectively utilized) in clinical services provided to the patients.....! (link to the next section)

Proposed plan (managing chronic diseases): 2- What is the future of community pharmacy involvement in managing chronic diseases?

Prompt1: How do you see feasibility of community pharmacists being managing people with chronic diseases in terms of capacity, capability and funding.

Pros and cons: 3- What are the pros and cons of managing people with chronic diseases in community pharmacy? Prompt: Impact on patient care, health system (GPs), other health professionals, money allocation, number and distribution of community pharmacies/pharmacists

Prompt1: you mentioned that might hinder expanding of pharmacy services, what are other limitations of expanding the role of community pharmacists in managing patients with chronic diseases? Prompt: personal, organizational, policy, funding.

Prompt2: How could these barriers be overcome?

Closing:

That's all what we have, thank you again for your participation in this conversation. Do you want to add anything to our discussion?

A list of general prompt questions that might help during the discussion:

Could you please clarify.....?

Can you explain a bit more about that?

You slightly covered this point could you elaborate a bit on

Appendix 7.7 - Consent form



Cardiff School of Pharmacy & Pharmaceutical Sciences

Participant Consent Form

For ethical reasons, a Participant Consent Form is needed for all participants of our study. Please read the Participant Consent Form below, initial each statement where indicated, and finally sign and date at the bottom of the form.

Statement	Please initial
I was given a clear explanation of the nature and purpose of the research study and my questions have been answered adequately.	
I was provided with contact information for the researchers.	
I understand that my participation is voluntary and that I may withdraw myself or my data from the study at any time up to when I have approved the anonymised transcript.	
I understand that the discussion will be audio recorded, transcribed by a third party, and used by the researcher in his thesis or any other research publications.	
I understand that identifying remarks will be redacted from transcripts and I will be asked to check the transcript of my interview to ensure it accurately reflects my views and does not contain identifying information.	
I agree to the use of my comments as illustrative quotations in publications with any identifying information redacted.	
I confirm that I have read the participant information sheet dated 2/09/2019 version 3, for the above study.	
I agree to take part in the above study.	

Name of participant Signature Date

Name of person receiving consent Signature Date